Transverse Tripolar Spinal Cord Stimulation: Results of an International Multicenter Study

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■ Abstract

Experienced neurosurgeons at eight spinal cord stimulation centers in the United States, Canada, and Europe participated in a study from 1997 to 2000 investigating the safety, performance, and efficacy of a Transverse Tripolar Stimulation (TTS) system invented at the University of Twente, the Netherlands. This device was proposed to improve the ability of spinal cord stimulation to adequately overlap paresthesia to perceived areas of pain. Fifty-six patients with chronic, intractable neuropathic pain of the trunk and/or limbs more than three months' duration (average 105 months) were enrolled with follow-up periods at 4, 12, 26, and 52 weeks. All patients had a new paddle-type lead implanted with four electrodes, three of them aligned in a row perpendicular to the cord. Fifteen of these patients did not undergo permanent implantation. Of the 41 patients internalized, 20 patients chose conventional programming using an implanted pulse generator to drive four electrodes, while 21 patients chose a tripole stimulation system, which used radiofrequency power and signal transmission and an implanted dual-channel receiver to drive three electrodes using simultaneous pulses of independently variable amplitude. On average, the visual analog scale scores dropped more for patients with TTS systems (32%) than for conventional polarity systems (16%). Conventional polarity systems were using higher frequencies on average, while usage range was similar. Most impressive was the well-controlled "steering" of the paresthesias according to the dermatomal topography of the dorsal columns when using the TTS-balanced pulse driver. The most common complication was lead migration. While the transverse

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stimulation system produced acceptable outcomes for overall pain relief, an analysis of individual pain patterns suggests that it behaves like spinal cord stimulation in general with the best control of extremity neuropathic pain. This transverse tripole lead and driving system introduced the concept of electrical field steering by selective recruitment of axonal nerve fiber tracts in the dorsal columns. ■

KEY WORDS: spinal cord stimulation, SCS transverse tripole, neuromodulation, FBS, neuropathic pain, failed back syndrome

INTRODUCTION

A necessary condition for the success of spinal cord stimulation (SCS) is adequate paresthesia overlap of the painful area (1). It may be difficult to achieve proper electrode positioning producing optimal paresthesia overlap during an initial implant procedure. Paresthesia location is determined by those fibers within the spinal cord that are nearest to the stimulating cathode. The following issues are impacted by or impact the implant procedure and production of appropriate paresthesia location: prolonged intraoperative time necessary to find the appropriate electrode position; concomitant fluoroscopy exposure; 15–25% of patients do not pass screening; the benefits of optimal positioning may be lost by lead migration; programming the best polarities may take a long time; and long-term efficacy still appears to be in the 50–70% range (2). Up to 16 contacts are now being utilized to produce adequate programming capabilities to ensure adequate overlap of paresthesias, often with related high power requirements. The typical implanted lead used today contains a linear array of contacts with 4–12 mm edge to edge spacing (3). Utilizing such arrays, the neural target must reside underneath the cathode. This often results in uncomfortable stimulation of nonpainful areas or recruitment of undesirable structures such as the intercostal nerve roots. This paper presents the results of a multicenter study conducted in the United States, Canada, and Europe from 1997 to 2000 investigating the safety, performance, and efficacy of a Transverse Tripolar Stimulation (TTS®) system, which has U.S. patents 5501,703 and 5643,330 invented at the University of Twente in the Netherlands (4). The system represents a departure from standard SCS systems in having a paddle-type lead with three electrodes oriented across the spinal axis, allowing programming of anodes over the dorsal roots to shield them. An innovative new driver was developed that delivered two simultaneous pulses of independently variable amplitude from two anodes toward a central common cathode. Utilizing this new system, paresthesias could be carefully steered to desired parts of the dorsal spinal cord. Preliminary results have been published (5–10).

MATERIALS AND METHODS

Eight experienced SCS implant centers participated in the study. All patients signed an institutional review board (IRB) or ethical committee-approved informed consent prior to participating in the study. The 41 patients outside the United States had leads and radiofrequency receivers that were investigational, and their participation was in compliance with each country's respective laws for use of investigational devices. In the United States, 15 patients had device components implanted that were not investigational, since they had been approved for commercial distribution by the FDA (Food and Drug Administration) by the 510(k) process. The study started on March 5, 1997, and ended on April 25, 2000.

Inclusion criteria included chronic, intractable neuropathic pain of the trunk or limbs, pain greater than three months' duration, and known etiology. Exclusion criteria were off-label indication for SCS, inability to understand or use the device properly, inability to comply with study protocol, less than 21 years of age, pregnant, having a demand pacemaker, likely to require magnetic resonance imaging (MRI), life expectancy less than 1 year, presence of concomitant diseases or conditions that could interfere with the therapy or study compliance, or the patient had a prior paddle-type lead at the epidural site anticipated for this study's lead.

Baseline data included the recording of: patient initials, sex, and birth date; durations of the neuropathic pain to be treated; etiology; prior procedures or therapies; hours per day of pain; 10 cm visual analog scale (VAS) for low back, leg, or buttock, or other pain labeled from no pain, to worst

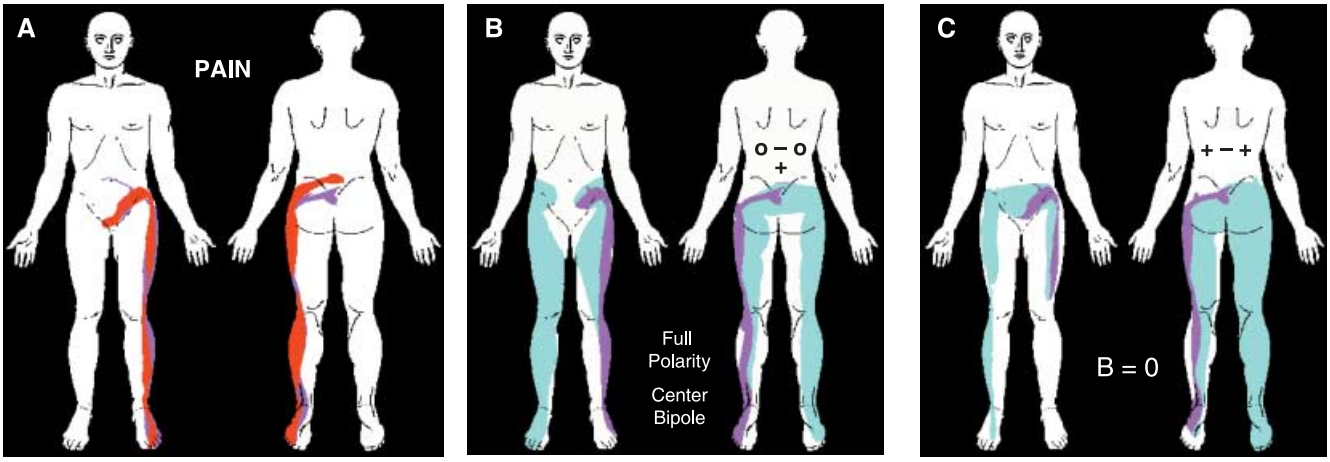

Figure 1. Examples of patient pain mapping (A), and paresthesia overlapping (B and C). In A, the patient circled or colored areas on the homunculus representing painful regions; one map for worst pain (purple), another for all pain (red), sometimes with some variation. In B, the areas of paresthesia perception were later superimposed by computer on the areas of worst pain circled or colored. The paresthesia map was drawn during conventional strong, but tolerable stimulation from a bipole at mid-T9. In C, the superimposition is shown for strong transverse tripolar stimulation, with equal pulses going toward the left and right electrodes, balance = 0.

possible pain; number of days per week using narcotics, analgesic medications. The patient encircled all areas of body pain and areas of worst body pain on separate maps, each with a frontal and rear depiction of a human body (Fig. 1A). All operating room details of the screening lead of the subsequent internalized system or revisions were recorded.

The Transverse Tripole Lead (TTL®, Model 3991A, Medtronic Inc., Minneapolis, MN, USA) is a paddle-type epidural stimulation lead, 10 mm wide and 40 mm long, requiring laminectomy to insert (Fig. 2). It contains four electrodes clustered together: 1) two outer cylindrical electrodes (E0, left; E3, right if the lead is inserted in a rostral direction), each 1 mm diameter × 10.0 mm exposed for one-half of their circumference on the edge of the paddle; 2) a central electrode (E1), 1.5 mm tall and 4.5 mm wide, on the midline between E0 and E3; and 3) a second midline electrode (E2) like E1, only 3 mm more caudal. The centers of the first three electrodes formed a line, which was transverse to the axis of the spinal cord, hence, the therapy of using them constituted TTS. There also were two radiopaque markers more rostral for alignment purposes, and the rostral part with the markers could be trimmed in the operating room, as required for insertion.

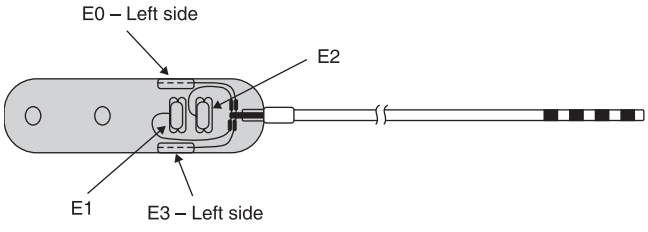

Figure 2. Transverse Tripole Lead, Medtronic Model 3991A.

This lead was inserted in the epidural space at the estimated optimal level by laminectomy at the next lower space. Outside the United States, nearly all leads were inserted under general anesthesia, aligning the midline electrodes and markers to the vertebral bone midline using fluoroscopy. In the United States, the 15 patients underwent lead implantation under local anesthesia with anesthesiologist monitoring, or awakened during lead implantation to test for paresthesia reports.

A disposable percutaneous harness connected the lead to four screening wires through the skin. The screeners available were either the conventional Medtronic Models 3625 or 3628, or a new screener, Model 3669 used with a Mattrix Model 3273 radiofrequency transmitter, which produces two simultaneous pulses between the common central cathode (E1) and the lateral anodes (E0 and E3), thus enabling different voltages between the cathode and each anode. In contrast, conventional screeners apply the same voltage to any cathode and to any anode, respectively. Prior to discharge from the hospital, a study nurse worked with each patient to determine optimal polarities

and parameters for stimulation. Also, many maps of paresthesia location at amplitudes between threshold and discomfort levels were systematically tested and recorded using two modes of 10 conventional polarities or 12 balances of TTS steering for documentation, and to find the best polarities for matching the paresthesia to the areas of worst pain. The patient circled areas on the anterior and posterior body maps indicating where paresthesia was felt with each level of stimulation. These maps were subsequently retraced into a computerized system (Fig. 1B,C), and calculations were made of overlap with the initial pain maps using bit-by-bit comparisons.

For the next two to eight days, the patients were asked to use two types of stimulation at home for pain relief. Patients used two devices during their trial period: one device for stimulating standard polarity (Medtronic model 3625 or 3628) or conventional stimulation, and a second device that allowed steering stimulation (Medtronic model 3669). Neither patients nor investigators were blinded in the use of the devices. All stimulation involved square-wave, voltage-controlled pulses with charge balance. Pulse width was usually not changed, but patients freely adjusted frequency and amplitude. Two types of stimulation were applied:

1. Polarity conventional stimulation, or "PC stimulation," used the same voltage on any electrodes that was a cathode and on any electrode that was an anode. This is the usual stimulation since multielectrode SCS systems were introduced worldwide, where each electrode is a cathode, an anode, or disconnected. If the patient chose to use the electrodes E0, E1, and E3 in a (+,−,+) polarity, a transverse tripole (transverse guarded cathode) is created.
2. Steering stimulation, "TTS," used only the three electrodes in the line transverse to the spinal cord. It had the ability to assign each of the two outer electrodes a different positive (anodal) voltage with respect to the central electrode, which was always a cathode (0 volt). Hence, it produced two simultaneous pulses of independently selectable positive voltage at each anode. These anodal voltages may vary between a maximum (100%) and the cathodal voltage (0%). By adjusting the eight throw switches on the back of the Mattrix transmitter, 31 steps were available in the proportion of the two anodal voltages (Table 1). This had the effect to move the center of the cathodal field in the spinal cord in 31 equal steps from left to right. At a balance of B = 0, that is, with full cathodal stimulation in the midline and the lateral contacts as full anodes, there was the equivalence to a PC stimulation transverse tripole (+,−,+) with identical anodal voltages. At this balance the center of the cathodal field corresponded with the mediolateral position of the central cathode. At a balance of B+15, the voltage of the right-side anode (0%) equals the voltage of the central cathode and this anode is converted into a "full" cathode (from left to right: +,−,−).

Table 1. Voltages, Expressed as Percentage Anodal, on Outer Electrodes (E0 = left, E3 = right) With a Transverse Tripole Simulation System, Assuming the Transverse Tripole Lead, Model 3991A, was Inserted in a Rostral Direction Through a Laminectomy. One Hundred Percent (100%) Means the Outer Electrode Is a "full" Anode, 0% Means It Is a "full" Cathode (Negative). The Center Electrode (E1) Is Always a Cathode

Balance	E0	E3
B = 15 (right)	100%	0%
B = 14	100%	7%
B = 13	100%	13%
B = 12	100%	20%
B = 11	100%	27%
B = 10	100%	33%
B = 9	100%	40%
B = 8	100%	47%
B = 7	100%	53%
B = 6	100%	60%
B = 5	100%	67%
B = 4	100%	73%
B = 3	100%	80%
B = 2	100%	87%
B = 1	100%	93%
B = 0 (center)	100%	100%
B = –1	93%	100%
B = –2	87%	100%
B = –3	80%	100%
B = –4	73%	100%
B = –5	67%	100%
B = –6	60%	100%
B = –7	53%	100%
B = –8	47%	100%
B = –9	40%	100%
B = –10	33%	100%
B = –11	27%	100%
B = –12	20%	100%
B = –13	13%	100%
B = –14	7%	100%
B = –15 (left)	0%	100%

Now the center of the cathodal field, created by E1 plus E3, is displaced maximally to the right side of the dorsal columns. When the voltage of either the left- or the right-side anode is changed from 100% to 0%, it converts smoothly from a "full" anode into a "full" cathode, thus displacing the cathodal field transversely across the dorsal columns of the spinal cord.

When patients returned to the clinic, they were asked to describe the stimulation and the degree of pain relief from each type of stimulation. For both the types PC stimulation and TTS, they reported: 1) hours of pain each day; 2) VAS pain degree at each of three sites; 3) days per week using narcotics; 4) overall percentage pain relief (i.e., pain levels with stimulation compared to pain levels without stimulation); 5) if greater than 50% pain relief during the trial, which system they wanted to have permanently internalized; 6) comfort; 7) degree of match of paresthesia to pain location; and 8) ease of use. Paresthesia maps were again systematically drawn during 22 tests of the two modes of stimulation. Then the implanter and the patient met to determine if there was sufficient pain relief to justify internalization, and to determine which type of stimulation power source to permanently use (i.e., implantable pulse generator for PC stimulation or radiofrequency receiver for TTS). If they preferred PC stimulation, an Itrel 3 pulse generator (Model 7425) or a radiofrequency Xtrel receiver (Model 3470 using transmitter Model 3425) was internalized. If they preferred TTS, a special radiofrequency receiver ("Tripole Stimulation System," TTS® Model 3273) was internalized and used a Mattrix radiofrequency transmitted (Model 3210).

Patients were asked to return at 4, 12, 26, and 52 weeks for recording of outcomes, and systematic mapping of paresthesia with 10 or 12 available patterns of electrodes combinations and balance, depending on the internalized system. Adverse events were recorded and tracked whenever they occurred. A rating of "excellent" outcome represented an estimated 75%+ pain relief; a "good" outcome rating represented some incident pain with occasional medication use, and an estimated 50–74% pain relief. A "fair" outcome rating represented a definite, appreciated improvement in pain but at 25–49% pain relief, and a "poor" outcome being less than 25% pain relief with no change in medication and activity.

Table 2. Etiology of Pain

Failed back syndrome—37
Complex regional pain syndrome type I—4
Extremity pain persisting post-trauma—4
Phantom limb—2
Diabetic neuropathy—1
Strumple disease—1 (Pelvic girdle pain)
Other—4

A *t*-test was used to test for significant difference in VAS scores and a chi-square test was used to test for a significant difference in patient outcomes. A p value of < 0.05 was considered statistically significant. Continuous data are presented as the mean ± standard deviation of mean (range).

RESULTS

Fifty-six patients were included in the study. The average age at the start of the study was 47.8 years (range: 22–82 years). The average number of months in pain was 105 (range: 9–336 months). All patients' pain distribution included the back and/or at least one lower extremity. One patient with four limb complex regional pain syndrome (CRPS) underwent implantation of the transverse tripole lead at the C_{4-5} level. All other patients underwent implantation in the low thoracic spine. Table 2 shows the distribution of presumed etiologies for the pain.

Fifty-six patients were enrolled, and two of them did not perform trials, one due to hematoma and one due to noncooperation. Of the 54 patients trialed, 13 (24%) had insufficient pain relief and were not internalized; 35 (65%) had 50% or more pain relief and were internalized; 6 (11%) had < 50% pain relief and were still internalized. Pain relief for the six patients with trial results < 50% pain relief did not improve except for one patient who had 60% relief at one year. These six patients will not be discussed further in this paper. During trial stimulation, six patients (11%) had their lead surgically repositioned to place the wide central contact closer to the physiologic midline or to try to achieve better low back pain relief.

Outcomes are reported at one year follow-up or at last follow-up prior to system removal for "poor" relief, or were indeterminate, due to various

factors discussed below, at 12 months or sooner. Seventeen of the 35 patients (49%) passing trial stimulation chose conventional polarity power (PC stimulation) to drive their system. Two of the 17 patients had indeterminate outcomes, although at last follow-up, their pain relief was "excellent." Outcomes were 29% "excellent," 24% "good," 6% "fair," and 29% "poor," with 12% indeterminate. Only four of these 17 patients chose polarities that did not use the lower central electrode E2; hence, only 24% used the true tripolar configuration. Some of the patients chose internalization to PC stimulation by necessity to avoid having the central electrode E1 being a cathode, which was always the case for this particular TTS system, or by choice to avoid using a radiofrequency system in general.

Eighteen of the 35 patients (51%) chose a TTS system, using only the three collinear tripole contacts with steering of fields from two simultaneous, but varied-amplitude pulses. Outcomes were "excellent" 33%, "good" 28%, "fair" 0%, "poor" 17%, and 22% indeterminate. At last follow-up, two of the four patients with indeterminate outcomes were having "excellent" results, one had a "good" result, and one had a "poor" result. These patients, and even some getting PC stimulation, usually reported that TTS felt more pleasant than PC stimulation. They also perceived finer changes in paresthesia as amplitude was increased with any given set of polarities of balances.

On average, although not statistically significant ($p = 0.21$), VAS scores dropped more for patients with TTS systems (32%; from 72 ± 14 to 48 ± 26) than for those with PC systems (16%; from 65 ± 12 to 56 ± 26). This study had 80% power to detect a difference of 27 points in VAS score changes between groups. Patients with PC systems used higher frequencies on average (82 vs. 64 Hz, $p = 0.48$). Usage range (ratio of maximum tolerated voltage to threshold) was similar on the average (1.82 TTS vs. 1.77 PC), and may have been primarily expanded by having three longitudinal electrode arranges, with the possibility of anodes over the dorsal roots.

Depending on the degree of right/left steering of fields, patients drew maps showing paresthesia in a "W" pattern on the body, as shown in the data in Figures 3 and 4 from an illustrative patient who chose a TTS system after screening. The patient was male, age 44 years, and had 13 years of chronic neuropathic pain initiated by severe trauma causing a ruptured disk at L4/5. He was helped by chymopapain injections, but 5 years later his pain returned and an L2/3 disc herniation was found. Laminectomy and discectomy were done. Eight years after the first injury, another trauma led to L3/4 herniation and postsurgery this got infected. He was treated by several rhizotomies, and had numbness in the posterior thigh and calf regions of both legs. At trial start, he had pain 16 hours each day in varying locations throughout both legs (Fig. 3A), with the worst pain being described as feeling like a "spear of pain" passing through his body, from the right iliac crest to the right inguinal region.

The TTL paddle was placed under general anesthesia with the transverse three electrodes at mid-T9 vertebral level. After a week of trial screening, his VAS dropped from 70 to 45 with conventional PC stimulation and pain relief was 30%, while with TTS the VAS dropped to 17 and pain relief was judged to be 75%. He chose a permanent TTS system.

Figure 3 shows drawings of his pain pattern (A) and paresthesia patterns (B–F) using PC stimulation of five of the 10 possible polarity combinations systematically recorded, data being recorded at the end of his trial SCS. Paresthesia maps were done in each case using amplitudes that produced strong but tolerable paresthesia. The polarities of the four electrodes are depicted on the back figures in each case. Only the PC polarity toward the right with two cathodes (+,–,–) pattern gave paresthesia into the worst pain area (Fig. 3D).

Figure 4 shows drawings of his pain pattern and paresthesia patterns using TTS with amplitudes producing strong but tolerable paresthesia. As balance, B, moves from +15 to −15, the paresthesia shifted from just the upper right leg and side, to the center, and then to the upper left leg. The most symmetric paresthesia pattern was B = 0, although for some other patients the balance for this might be different, due to lead location and tilt.

This patient described his pain relief consistently at 50% up to last follow-up of 16 months. He used 50 Hz, and used stimulation at three balances: B = +13 to +15 at 6.8 V, 110 μsec pulse width, which gave paresthesia feeling like a pleasant path through that right iliac/inguinal zone; B = −13 to −15 at 7.0 V, 110 μsec for left side leg

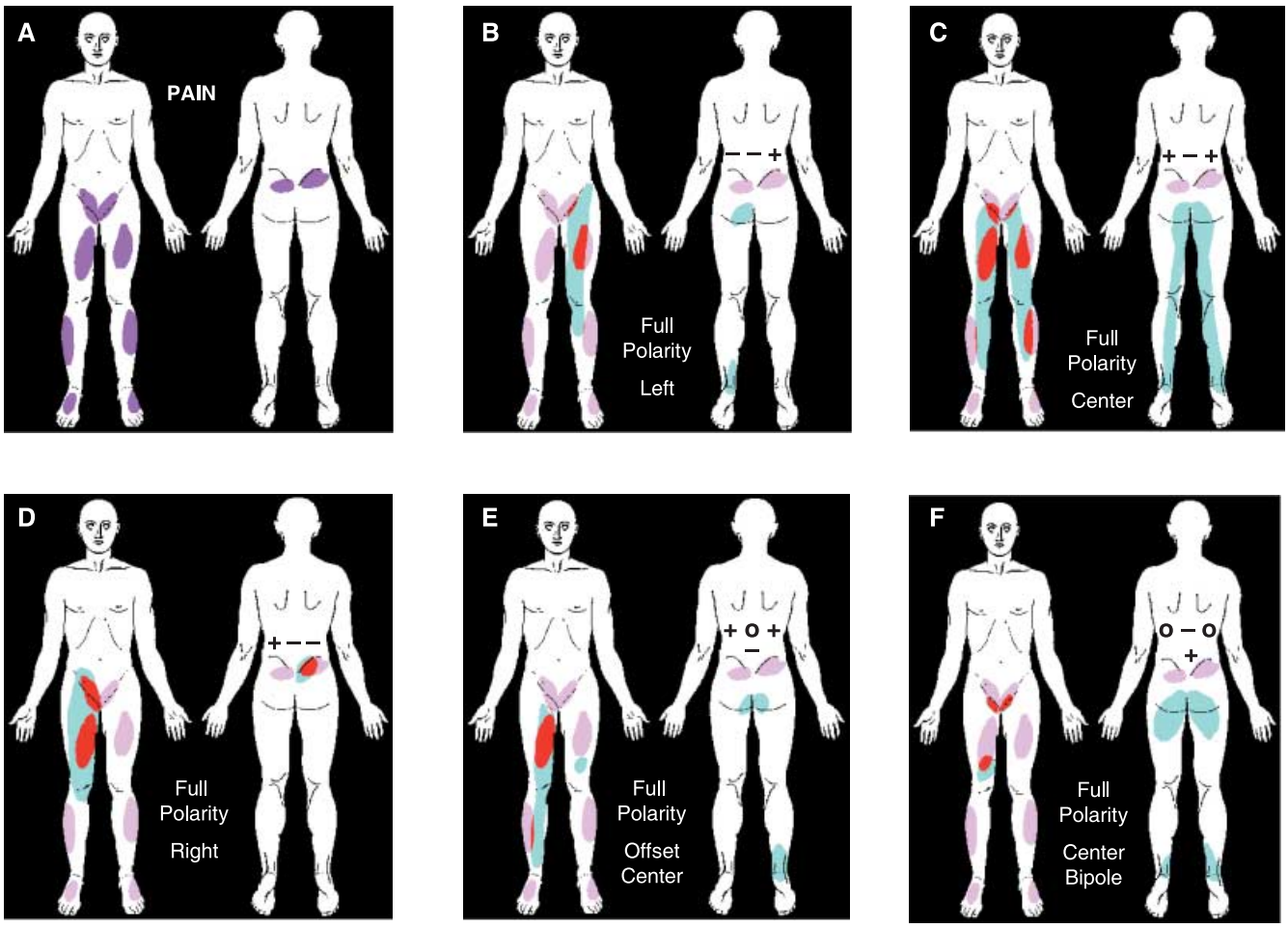

Figure 3. One patient with bilateral pain sites and paresthesia from conventional PC stimulation. In A, all chronic pain zones are shown, and the worst pain felt like a spear passing from the right iliac crest to the right inguinal area. In B–F, paresthesia zones drawn by the patient were later superimposed on the original pain map by computer. Blue signifies paresthesia, pink the zones of pain not covered by paresthesia, red the zones of pain covered by paresthesia. Each inset was from a different combination of polarity of electrodes, and the pattern is shown on the backside of the patient figure.

and inguinal pain; and B = 0 at 4.8 V, 90 microseconds for bilateral inguinal, leg and foot pain.

An interesting effect of the TTS field steering as shown by the paresthesia maps in Figure 4 is a conversion of bilateral three-dimensional paresthesia locations to a two-dimensional shifting of paresthesia following a "W" pattern as shown in Figure 5. Paresthesia started from the upper thigh and right hip and wrapped around to the outer back (4A, balance B = +15), then extending down that leg to the foot (4B and 4C, B = +12 to +9), rising up the back of that leg to the tailbone (4D and 4E, B = +5 and B = 0), down the back of the other leg (4F, B = −5), and then up the front of that leg to the opposite hip and outer back (4G and 4H, B = −12 and −15). These findings mimic the dermatomal topography of the dorsal columns, that is, the order that dorsal roots enter the dorsal columns laterally and demonstrate that TTS can selectively activate dorsal columns fibers at various medial-to-lateral locations.

Generally, the paresthesia "W" had a finite vertical extent: with the tripole at vertebral level T8 or T9, it extended from the lower ribs to the knees; at T10 it extended from the mid-buttocks to the ankles; and at T11 it extended from the tailbone to all parts of the feet. Near the physiologic midline (usually B = 0), there often was paresthesia on the front of the legs, but most of it was usually on the back, especially the sacral region, for example, with the patient data depicted in Figure 1C. If the central electrode is not shielded laterally by

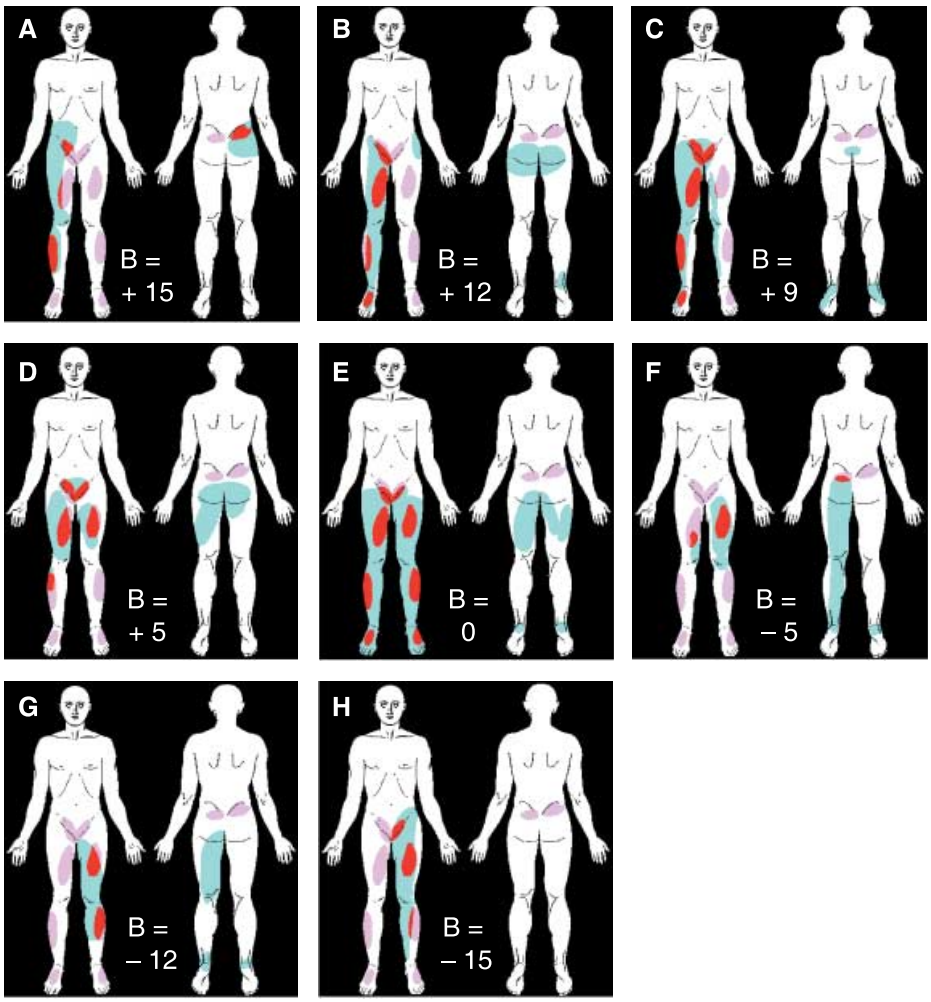

Figure 4. The same patient as in Figure 3, only paresthesia is shown from Transverse Tripole Stimulation (TTS) from eight different balances of steering. Three of these balances use full cathode potentials, like PC, in insets A, E, and H. Blue signifies paresthesia, pink the zones of pain not covered by paresthesia, red the zones of pain covered by paresthesia.

anodes (a bipole, –,+, along the midline), there is usually substantially more activation on the front on the legs with PC stimulation (Fig. 1B) than when TTS is used (Fig. 1C), B = 0 or (+,–,+). Perhaps the symptom of numbness on the posterior areas of the legs with the patient in Figures 3 and 4 led to less paresthesia in these areas in general, even with a balance B = 0 (Fig. 4E).

The indeterminate outcomes were seen in six patients, two in the PC group and four in the TTS group. In one case at 5 weeks and another at 1 week following implant, two patients developed receiver pocket infections and the systems were removed. A wheelchair athlete, seeking optimal performance, had a lead repositioned surgically, then at 5 weeks turned off his SCS and tried an implanted drug administration system, but returned to SCS alone eventually with a "good" result. One patient was lost to follow-up. One patient developed intermittent stimulation at 30 weeks but did not have the system checked until after the 12-month follow-up. In one patient the battery expired and the insurance carrier would not authorize a new battery during the study. Of these patients, five of the six reported "good" to "excellent" outcomes at last report. If these indeterminate patients are excluded from the analysis, 79% of the remaining TTS population received "good" to "excellent" outcomes, compared with 60% of those in the remaining PC population.

While the TTS produced acceptable outcomes for overall pain relief, an analysis of individual

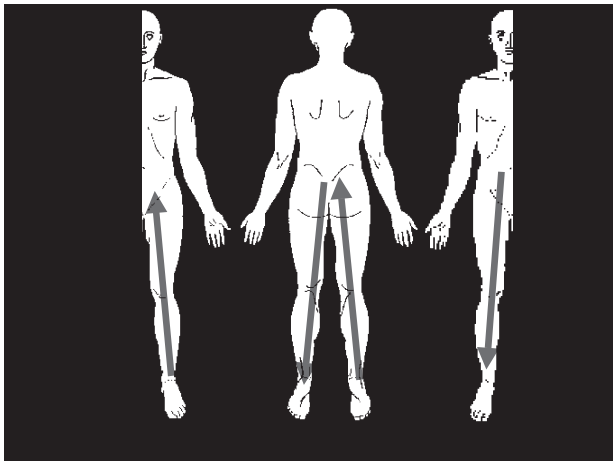

Figure 5. The "W" two-dimensional pattern of paresthesia movement as Transverse Tripole Stimulation (TTS) balance is changed from B = +15 (right hip and upper leg) to B = –15 (left hip and upper leg).

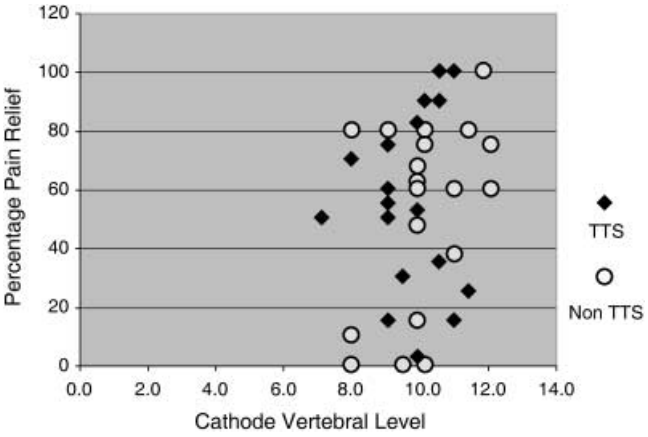

Figure 6. Lack of correlation between electrode position and pain relief. Ordinate: thoracic implant level; abscissa, percentage pain relief.

pain patterns suggests that it behaves as SCS in general, with the best control in cases of extremity neuropathic pain. No attempt was made in this pilot study to specifically target or analyze the production of paresthesia in the lower back. Likewise no specific study of the relief of lower back pain was attempted. In patients who were observed to perceive paresthesia in the lower back and who had pain in the lower back, relief of the pain was not generally seen. In one U.S. center, unsuccessful attempts were made to produce lower back parethesias, leading to repositioning prior to implant in three patients although the leg paresthesias were felt to be adequate (6).

There was no correlation between the site of lead implantation and the percentage of pain improvement. This was true for both TTS and PC patients. Figure 6 illustrates this finding.

The most common complication of transverse tripole lead implant was migration. There were 11 reoperations (20%) to reposition leads in the 56 patients. Three of these (5%) were not due to migration as noted above. In two cases (4%), one prior to internalization and one after, the lead required repositioning after trauma due to a fall. In two cases (4%), the lead shifted to one side after about 4 weeks, without trauma. In summary, outside the United States, in centers using general anesthesia for lead implantation, six out of 42 leads (14%) were repositioned, two as a result of a fall. In centers using local anesthesia (the United States), five of 15 patients (33%) required repositioning, two with spontaneous migration (13%), and three others (20%) at one center attempting to cover the lower back.

There were no statistically significant differences in outcomes using PC or TTS ($p = 0.63$). Sixty-one percent of TTS patients and 53% of PC patients had "good" to "excellent" outcomes at 1 year.

DISCUSSION

The development of transverse tripole stimulation introduced to SCS the concept of electrical field steering. The concept itself had been used in selectively recruiting nerve bundles in peripheral nerves (11–13). The TTS system achieves paresthesia steering by utilizing a paddle-style array with three transversely oriented contacts and two simultaneous electrical pulses of independently variable amplitudes (4,8). The system is successful in shifting the paresthesia to various anatomical locations by selectively stimulating segments of the spinal cord dorsal columns, as shown by the changes in paresthesia in lower dermatomes in Figure 4. The paddle lead requires a laminotomy insertion technique and the pattern of paresthesia produced is sensitive to the cephalo-caudal position of the transverse array. In order to produce paresthesia higher, for example, in the back area, the array is placed at a higher cephalo-caudal target. In doing so, the ability to select the distal

lower extremity may be compromised. A solution to this problem could be the production of a lead with two separated transverse electrode arrays. The system also was noted to be very sensitive to placing the midline cathode as close to the physiologic midline as possible. Outside the United States, the midline electrodes of the TTL lead were aligned to the vertebral bone midline, which may differ up to 2 mm from the spinal cord "physiological" midline (14). Since in the U.S. centers, leads were positioned using paresthesia feedback from the patients, it is likely that these leads were in a more optimal position giving a better "steering" performance. This confirmed more quantitative reports of the behavior of this electrode array by the Twente group (7,8,15). Note that the center electrode is 4.5 mm wide and if it is two or more millimeters off the physiologic midline, part of it is over a dorsal root. Some patients had to choose between surgical repositioning of the lead or using only PC (single channel) pulse generators that could allow the center electrode to not be a cathode. Future systems should allow both PC and TTS features for all electrodes and perhaps a narrower central electrode.

The overlapping of the painful area by stimulation produced paresthesia has been a fundamental principle in the application of SCS to relieve pain. This study affirms that principle and suggests that how a paresthesia is produced is less important than the overlapping of the painful area. Paresthesia overlap and the ability to produce this response in the painful area appeared subjectively to the various investigators to be enhanced over traditional electrodes and drivers by the transverse tripole electrode when used in conjunction with the TTS transmitter and receiver. This suggests that the system may be utilized as an effective screening tool to determine the most effective electrode configuration to be driven with PC. This could be particularly useful with a percutaneously available array. The patients felt that the paresthesias perceived when using the TTS were more comfortable or tolerable than those produced by PC and could discern finer changes in topologies of their paresthesia as amplitude increased. This may be related to the ability of TTS to recruit axons deeper in the dorsal columns (i.e., more recruited fibers per dermatome) than PC stimulation as shown by computer simulations, due to shielding of dorsal roots by the very lateral anodes of the TTS lead (16–18). Further study comparing the TTS with standard systems would need to be undertaken to prove this impression.

Most remarkable was the ability of the TTS system to convert three-dimensional paresthesias maps into a two-dimensional representation, based on the dermatomal topography of the axons in the dorsal columns. This manifested itself in the "W" configuration of paresthesias as the balance control is steered from one side to the other. This represents a direct correlate to the ability to recruit axons that are so layered in the dorsal columns as they ascend (18). This outcome is a confirmation of the predictions obtained by computer modeling (4,8,16), although its significant clinical utility was not fully anticipated prior to this trial.

The transverse tripole electrode offered an ability to penetrate deep into the dorsal columns of the spinal cord presumably due to the shielding effect of the lateral anodic electrodes. This effect could be seen even in the PC tripolar configuration using the transverse midline electrode as the conventional cathode (Figs. 1C, 3C). The usage range of about 1.8 of the two methods of stimulation appears to be higher than the more typical 1.40 usage range reported in other SCS trials (10,14). In finding the higher usage range with the transverse tripole electrode, we believe this indicates that dorsal root fibers have an increased threshold as compared to dorsal column fibers due to the lateral anodal fields (14). The usage range relates to the point above the perception of stimulation paresthesia that results in discomfort. A higher usage range implies that the recruited dorsal column areas will be deeper and their lateral extent will be broader than configurations that give a lower usage range. Some of the efficacy seen here is attributed to use of an optimally spaced electrode array with electrodes in a choice of three lateral positions (i.e., the TTL lead itself).

A major degree of the utility of transverse tripole electrodes to determine the most effective configuration of stimulation contacts is produced by its ability to produce a two-dimensional paresthesia path, the "W" pattern (Figs. 4, 5), as the stimulation balances are swept from one side to the other. Based on the paresthesia mapping observations, it is important to position the tripole at the proper cephalo-caudal level to allow the cathodal

stimulation to produce paresthesias as high (e.g., lower back) as desired. Experience with this electrode has shown that lower positions (e.g., T10–11) of the tripole effectively cover lower extremity areas from the feet to the sacral area. Higher positions can reach as high as costal margins but may then lose coverage of the distal extremity.

With proper longitudinal placement of the TTS electrode array, the ability to produce lower back paresthesias without painful thoracic intercostal stimulation might seem to be enhanced over standard implant arrays. However, in one center where this was analyzed, this did not appear to improve the relief of lower back pain (6). This may be a major observation of this study: the computer-designed TTL is able to recruit more dorsal column fibers because the threshold of dorsal root fibers is selectively increased by anodal shielding, thus increasing discomfort threshold as well. Yet, relief of back pain from this effect was not noticeably better. The optimal cathode position to stimulate the low back is centered at T9–T10, which excludes a role of the L2 dorsal roots in the relief of back pain by SCS (20). It is more likely that anatomical factors, such as the mediolateral position of the low back fibers in the dorsal columns and their caliber, and the generally large distance between the epidural lead and the dorsal columns at that level limit the stimulation of these fibers (10). The ability to steer fields has been shown to depend strongly on the relative electrodes spacing and distance from the spinal cord (19). Further studies are warranted.

When given the opportunity to choose between the TTS and PC systems for long-term stimulation, 17 of 35 patients optioned for the more traditional implant. The decision to use PC was sometimes biased by the ability to use a totally implanted pulse generator to drive the electrode as opposed to an external radiofrequency transmitter necessary to the tripole stimulation system. This would suggest that the more comfortable perception of paresthesia and the steering capability of transverse tripole stimulation did not always outweigh the more cosmetic advantages of a totally implantable devise, at least during a short one-week trial. Some bias could have entered into the device selection because of a lack of familiarity with TTS and an inability to fully inform the patient about advantages and disadvantages. However, it is likely that given other aspects of the TTL lead, such as root shielding, the target of stimulation could be adequately located for many patients using the conventional polarity stimulation, thereby making the need to drive the system with the TTS radiofrequency system unnecessary. While the study allowed trial with both PC and TTS, a better system would make both types of stimulation available after implant as well.

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