Patient-Perceived Differences Between Constant Current and Constant Voltage Spinal Cord Stimulation Systems

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**INTRODUCTION**

An estimated 100 million Americans, which represents approximately 30% of the population, currently suffer from chronic pain (1). Although a number of treatment options are available to these patients, many have exhausted all first- and second-line options and have reached the end of the treatment continuum where spinal cord stimulation (SCS) lies. Pain considered to be of neuropathic origin is considered to be the best type of pain treated with SCS; however, pain of somatic origin may respond also. Examples of successfully treated chronic pain conditions include diabetic neuropathy (2), failed back surgery syndrome (3,4), complex regional pain syndrome (5), ischemic limb pain (6,7), postherpetic neuralgia and acute herpes zoster pain (8), refractory angina (9), and, recently, abdominal pain resulting from chronic pancreatitis (10).

Electrical stimulation can be supplied to the spinal cord using an implantable pulse generator (IPG) that utilizes either a constant current (CC) or a constant voltage (CV) power source. A CC source supplies current to the tissue by adjusting the voltage in response to impedance resulting from lead positioning, presence of fibrous encapsulation, and scar tissue (11). A CV source adjusts current in response to impedance, thereby maintaining the voltage constant (Fig. 1). Therefore, variations in impedance can impact stimulation strength during the intrastimulus pulse (12), as well as the efficacy of stimulation over the long term (13–15). Both systems produce paresthesia and both systems have been shown to effectively treat abdominal pain resulting from chronic pancreatitis (10).

**Materials and Methods:** This Institutional Review Board-approved, randomized, double-blinded crossover study compared patient preference for the stimulation sensation elicited by a CC or CV neurostimulation system. Thirty patients completed a baseline evaluation prior to implantation of a percutaneous trial system and returned one-day postimplant for randomization and initiation of SCS. Three days later, patients were evaluated and crossed over into the alternate treatment group. Final evaluation of patient well-being, pain relief, satisfaction, quality of life, preference, and stimulation sensation occurred on Day 6. Patient preference was assessed using a one-sample Z-test. Treatment and group differences were explored using paired t-test for continuous and ordinal variables and chi-square of Fisher’s exact test for categorical variables.

**Results:** More patients (70%) preferred CC stimulation over CV stimulation (30%), and CC stimulation produced a significantly larger decrease in pain scores than CV stimulation. Interestingly, patients initially exposed to CC stimulation were less likely to be satisfied with CV stimulation.

**Conclusions:** The results from this study indicate that patients preferred and experienced greater satisfaction and pain relief with the CC system during an SCS trial period. Differences between the two systems following long-term use has yet to be compared. However, the benefits of the CC system seen with short-term use should be considered when selecting an SCS system.

**Keywords:** Chronic pain, constant current, constant voltage, neurostimulation, spinal cord stimulation

**Conflict of Interest:** Stephanie Washburn is an employee of St. Jude Medical and owns stock. Bernard Canlas has previously been a paid consultant of St. Jude Medical.

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chronic pain. However, recent evidence suggests that patients prefer CC over CV systems (16). For example, in a recent study, patients previously implanted with a CV SCS system for chronic pain of the trunk and/or limbs were switched to a CC system and patient preference was assessed. All patients preferred CC stimulation, rating it as more comfortable and providing better pain relief. They also described it as soothing or pleasant while CV was described as comfortable or massaging. While interesting, these results should be interpreted with caution as the study only evaluated a relatively small number of patients, and programming during CC and CV stimulation was not kept constant. In addition, the switch from the CV system to the CC system occurred due to device issues in most cases and could have biased patient preference. The present study was designed to address these issues and adequately assess patient preference for the stimulation sensation elicited by CC and CV systems. Differences in pain relief, patient satisfaction, and quality of life between these two systems were also compared.

MATERIALS AND METHODS

All study sites received Institutional Review Board approval prior to study initiation. All patients provided written informed consent prior to the performance of any study procedures. After the patient signed the informed consent, they underwent a baseline evaluation. All patients were trialed using two Octrode™ trial leads (St. Jude Medical, Plano, TX, USA). Following placement of the trial leads, patients were randomized in a 1:1 ratio into two treatment groups (Fig. 2): Treatment group A (CV stimulation followed by CC stimulation) or Treatment group B (CC stimulation followed by CV stimulation). Both treatment groups received trial stimulation from both the TR-16 CV trial system (St. Jude Medical) and the Multiprogram Trial Stimulator System (MTS™; St. Jude Medical) which uses a CC power source. Both systems consisted of an external stimulator, two trial cables, and single or multiple percutaneous leads. Trial cables were used to connect an externalized lead to a test stimulator for intraoperative testing and/or for an extended trial procedure.

Patients returned to the clinic one day following trial lead placement for “initial” programming, which was used for the duration of the study. The same trial programs including electrode configuration, pulse width, and frequency were used by the patient throughout the study. Patients could adjust amplitude as needed throughout the study. Patients were only permitted to have two programs available for use during the study. The patient’s programming parameters could not be changed during the study. If a patient’s programming was altered during the study, the patient was immediately exited from the study. In order to ensure the same programming configuration, the patient was programmed by the same person throughout the study. Patients were allowed to switch between the two programs to maximize coverage and pain relief within each treatment session. Frequency (Hz), pulse width (μsec), and amplitude (mA or V) were recorded for each stimulation set and program. Patients were allowed to use either program during the course of the study. However, only parameters for the most used program were recorded after each three-day treatment period. For purposes of analysis, pulse width values were averaged across the two stimulation sets in cases where more than one set was utilized. Due to the nature of the device, frequency stayed consistent between programs. Comparison of amplitude during the two treatment periods was not possible because impedance values were not recorded. Impedance values are needed to adequately convert milliamps to volts or vice versa, which would allow for a direct comparison of the amplitudes produced by the two modalities.

Patients returned to clinic three (± one) days following initial programming for evaluation. Following evaluation, all patients were crossed over to the alternative treatment regimen. Patients returned to the clinic three (± one) days after crossover to the alternative treatment regimen for evaluation, removal of the trial leads, and exit from the study. The following parameters were evaluated during the study: stimulation sensation, numerical rating scale (NRS) scores for pain intensity, patient satisfaction and quality of life rating, stimulation preference, paresthesia coverage, and trial success. Both investigators and patients were blinded to treatment.

Baseline Pain Evaluation

Patients were asked to rate their overall pain at the time of the baseline assessment (Pain Now) as well as overall pain on a typical day (Pain Average) using an 11-point NRS in which 0 = “no pain” and 10 = “pain as bad as you can imagine”. Pain location was also assessed using an anatomical chart divided into four subdivisions within the back, buttocks, left leg, and right leg. This initial pain location assessment was used to determine paresthesia coverage of painful areas at the subsequent follow-up visits.

Stimulation Coverage

The same anatomical chart that was used to assess pain areas at the baseline visit was used to assess areas of paresthesia after each treatment period. Percent of paresthesia overlap (stimulation coverage) was calculated by dividing the number of painful areas covered by stimulation after each three-day treatment period by the total number of pain areas captured at the baseline visit.

Treatment Evaluation

Patient-Reported Pain Relief

Patients were asked to rate the percent of overall pain relief after three days of CC stimulation and after three days of CV stimulation. The percentage of patients reporting 50% or greater pain relief was also calculated.

NRS

Patients were asked to rate their pain relief at the time of assessment (Pain Now) and their average pain during the preceding three days (Pain Average) using an 11-point NRS.

Patient Satisfaction and Quality of Life

Patients rated treatment satisfaction and quality of life using a global impression item at the end of each treatment session. For
satisfaction, patients were asked to indicate if they were very satisfied, satisfied, unsatisfied, very unsatisfied, or neither satisfied or unsatisfied. For quality of life, patients were asked if they were greatly improved, improved, deteriorated, greatly deteriorated, or neither improved or deteriorated.

Stimulation Sensation
Patients were asked if they experienced the following sensations during stimulation: massaging, throbbing, warm, cold, soothing, aching, stinging, tingling, jolting, or constant. In addition, patients could identify up to three other sensations that were not listed. If the patient experienced the sensation, they were asked if they liked it, disliked it, or were unsure how they felt.

Patient Preference
At the end of the study, patients were asked which treatment they preferred and the reason for their preference. Patients could indicate up to three reasons that included more complete coverage of painful area, preference for the stimulation sensation, and "other", which included a blank for a write-in answer.

Primary Statistical Analysis
The primary statistical hypothesis was based on the assumption that more than 50% of patients would prefer CC over CV. A randomized, cross-over design was employed to allow patients to experience both systems while controlling for differences over time during the trial. Statistical analysis was performed using a one-sample Z-test with a significance level (α) of 0.05.

Secondary Analyses
Trial success rate was calculated based on the proportion of patients who achieved a 50% reduction in pain and continued to permanent implant. Secondary variables were tabulated and descriptive statistics were calculated. These included means (or medians) and standard deviations (or interquartile ranges) for continuous or ordinal variables and proportions for categorical variables. Treatment and group differences were explored using paired t-test for continuous and ordinal variables, and chi-square of Fisher's exact test for categorical variables.

In addition, an analysis was conducted to verify randomization success. This was done to confirm the treatment groups were equal in all known factors. The following factors were evaluated by t-tests: age, height, weight, baseline NRS scores, and number of painful areas on the anatomical chart at baseline. In addition, the following factors were evaluated by chi-square tests: gender, ethnicity, primary diagnosis, each area of pain on the anatomical chart, and location of lead tips at implant. No significant difference between the treatment groups was found in these analyses (p > 0.05).

RESULTS
Demographics
A total of 44 patients were enrolled. Of these, 30 patients completed the study, 5 were screen failures, 3 patients did not complete the study because the equipment was not available at crossover, and 6 were dropped due to reprogramming. Data were collected from four investigational sites from September 2007 to December 2008.

Patient demographics and histories were collected during the baseline study visit. Table 1 contains details on patient demographics and patient histories. Of the 30 patients included in the study, 15 (50.0%) were male and 15 (50.0%) were female. The age of enrolled patients ranged from 32 to 81 years of age, with a mean (±SD) of 52.9 (±10.4) years. All patients, except one, indicated that their race was Caucasian. Failed back surgery syndrome was the
most prevalent primary diagnosis with 23 patients (76.7%), followed by radiculopathies and complex regional pain syndrome type I with two patients in each diagnosis (6.7%). One patient was diagnosed with traumatic crush injury, another was diagnosed with degenerative disc disease, and the remaining patient was diagnosed with peripheral neuropathy. As noted previously, no statistical difference between the two treatment groups was noted for any of these variables.

**Baseline Pain Evaluation**

The mean (±SD) pain rating for Pain Now was 6.2 (±2.0) in patients randomized to initially receive CC stimulation (Group B) and 6.3 (±2.5) in patients randomized to receive CV stimulation first (Group A). The mean (±SD) pain rating for Pain Average was 6.8 (±1.8) in Group B and 6.9 (±1.8) in Group A. No statistical differences were noted for either Pain Now or Pain Average between the two groups. The majority of patients (66.7%) indicated that they experienced pain in the back, buttocks, and leg(s) at the baseline visit. Again, there was no statistical difference between the two groups for pain pattern.

**Programming Parameters**

Pulse width was averaged within (as described in the Methods section) and across patients. Frequency was averaged across patients. The mean (±SD) frequency during CC stimulation was 77.5 (±70.8) Hz and the range was 20 Hz to 325 Hz. The mean (±SD) frequency during CV stimulation was 79.7 (±69.4) Hz and the range was 30 Hz to 325 Hz. No group differences were observed for this parameter, paired t(29) = 0.6, p = 0.537. The mean (±SD) pulse width during CC stimulation was 303.7 (±89.8) μsec, and the range was 100 μsec to 500 μsec. A significant group difference was found for this parameter, paired t(29) = 2.23, p = 0.03.

The percentage of patients that changed programs when switching treatments was also analyzed to determine whether more patients switched programs when they crossed over from CV stimulation to CC or vice versa. It was determined that 40% of patients in Group A changed programs when switching to CC stimulation and 20% of patients in Group B changed programs when switching to CV stimulation. This difference was not significant, Fisher’s exact test, two sided, p = 0.427.

**Stimulation Coverage**

Stimulation coverage was calculated for each patient during CC and CV stimulation. During CC stimulation, patients averaged 72.3 (±31.9)% coverage, and during CV stimulation they averaged 73.6 (±27.0)% coverage. No group differences were found, paired t(27) = -0.407, p = 0.69.

**Pain Evaluation**

Patient-Reported Pain Relief

Patients were asked to rate the percent of overall pain relief at the time of assessment. These values are depicted in Figure 3a. During CC stimulation, patients reported 53.7 (±30.5)% pain relief, and during CV stimulation they reported 50.5 (±29.8)% pain relief. These values were not statistically different, paired t(29) = 0.553, p = 0.58. The percentage of patients that reported 50% or greater pain relief was also calculated and is shown in Figure 3b. During CC stimulation 63.3% reported 50% or greater pain relief, whereas 60.0% reported 50% or greater during CV stimulation. This difference was not significant, chi-square = 0.07, df = 1, p = 0.79.

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**Figure 3.** Mean patient-reported percent pain relief for all patients during constant current and constant voltage stimulation (a). Percentage of patients reporting 50% or greater pain relief during constant current and constant voltage stimulation (b). Mean NRS scores for Pain Now and Pain Average for all patients during constant current and constant voltage stimulation (c). Mean percent change from baseline for NRS scores for Pain Now and Pain Average for all patients during constant current and constant voltage stimulation (d).
NRS

Figure 3c depicts NRS results. During CC stimulation, patients reported an average Pain Now score of 3.6 (±2.2) and an average Pain Average score of 3.9 (±1.8). During CV stimulation they reported an average Pain Now score of 4.2 (±2.3) and an average Pain Average score of 4.7 (±1.9). Pain Average scores were significantly different between treatment with CC and CV, paired t(29) = −2.408, p = 0.02.

Percent change from baseline was also calculated for both Pain Now and Pain Average NRS scores and is shown in Figure 3. Patients experienced a 35.1% decrease in Pain Now scores during CC stimulation and a 22.5% decrease during CV stimulation. For Pain Average scores, patients reported a 40.5% decrease during CC stimulation and a 27.9% decrease during CV stimulation. A significant treatment difference was found for percent change from baseline for both Pain Now scores, paired t(29) = 2.03, p = 0.05, and Pain Average scores, paired t(29) = 2.79, p = 0.01.

NRS scores for Pain Now and Pain Average were also assessed at Day 3 and Day 6 for both groups separately and together. For all patients, mean Pain Now score was 3.8 at Day 3 and 4.0 at Day 6. This difference was not significant, paired t(29) = −0.626, p = 0.54. For all patients, mean Pain Average score was 4.4 at Day 3 and 4.2 at Day 6. This difference was not significant, paired t(29) = 0.620, p = 0.54. Patients who received CV stimulation initially (Group A) showed a decrease in both Pain Now and Pain Average NRS scores when they switched from CV stimulation (Day 3) to CC stimulation (Day 6). The mean Pain Now score at Day 3 was 4.2, and this dropped to 3.8 at Day 6. This drop was not statistically significant, paired t(14) = −0.627, p = 0.54. The mean Pain Average score at Day 3 was 4.7, and this dropped to 3.7 at Day 6. This was found to be a statistically significant drop, paired t(14) = 2.48, p = 0.03. Patients who received CC stimulation initially (Group B) showed the opposite trend for both Pain Now and Pain Average NRS scores. These patients experienced an increase in pain when switched to CV stimulation. Their Pain Now score during CC stimulation (Day 3) was 3.3, and this increased to 4.3 during CV stimulation (Day 6). Their Pain Average score at Day 3 was 4.1, and this increased to 4.7 at Day 6. However, these differences were not significant. Figure 4 shows these results.

Patient Satisfaction and Quality of Life

Figure 5 displays patient satisfaction and quality of life results. During CV stimulation, 56.7% of patients indicated they were satisfied or very satisfied whereas 73.3% of patients indicated they were satisfied or very satisfied during CC stimulation. This trend was also observed for quality of life in which 46.7% of patients indicated that they were improved or greatly improved during CV stimulation and 63.3% indicated that they were improved or greatly improved during CC stimulation. In addition, patients initially exposed to CC stimulation were less likely to be satisfied during CV stimulation (Fig. 6). Of patients that experienced CC stimulation first (Group A), 73.3% of patients that were satisfied or very satisfied during the CV treatment session and 66.7% of patients were satisfied or very satisfied during the CC treatment period. Of patients that experienced CC stimulation first (Group B), 80.0% were satisfied or very satisfied during the CC treatment period but only 40.0% were satisfied or very satisfied during CV stimulation. This difference was found to be statistically significant, chi-square = 5.0, df = 1, p = 0.03.

Stimulation Sensation

When stimulation sensations were analyzed between the two treatments (CC vs. CV), no one stimulation sensation was used to describe CC stimulation over CV stimulation. However, when analys-
constant voltage or constant current stimulation. Stimulation (Group A) or constant current stimulation (Group B) that preferred isfied for very satisfied during constant current and constant voltage stimulation. Patients that received CV stimulation first (Group A), 66.7% preferred CC stimulation and 33.3% preferred CV stimulation whereas only 67% of patients (6/9) that choose CV stimulation said they did so because they preferred the stimulation sensation. Interestingly, no single stimulation sensation descriptor was used more often to describe one stimulation modality over the other, indicating that patients were unable to articulate the reason they preferred the sensation elicited by CC stimulation. Additional studies are warranted to explore this issue.

The secondary objective of this study was to evaluate patient pain relief, trial success rate, paresthesia coverage of pain areas, patient satisfaction, and quality of life. Pain relief was assessed in two ways. The first was patient-reported percent of pain relief. Patients reported comparable percentages of pain relief during both CC stimulation and CV stimulation. The second was by the NRS in which raw scores were evaluated and percent change from baseline was calculated. For the most part, no significant differences were found when raw NRS scores were analyzed. However, percent change from baseline calculations revealed that patients experienced a greater significant decrease in pain during CC stimulation.

Overall, patients were equally satisfied and experienced an improvement in quality of life during CC and CV stimulation. Additionally, patients who initially received CC stimulation were less likely to be satisfied during CV stimulation and patients who initially received CV stimulation were less likely to be satisfied during CC stimulation (initial treatment paradigm effect). However, this effect was more profound in patients who received CC stimulation followed by CV stimulation.

This study was not without limitations. The first was the inability to compare amplitudes across the two systems. It is imperative in future studies to record impedance values so that amplitudes can be directly compared. The second can...
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be argued as a necessary component of patient care that must be incorporated into the study design. The patient’s ability to change stimulation programs when they switched treatments is fundamental to optimizing stimulation during each treatment period and providing adequate patient care. However, it can also be argued as problematic for treatment comparison because patients potentially did not have the same program during both treatments. Future studies should address this concern by evaluating two groups of patients, where programming stays consistent throughout the study in one group and programming is optimized during each treatment session in the other as optimization of CV stimulation may result in abolition of differences between stimulation types.

A third concern is performing the testing during a trial period when patients are adjusting to the stimulation sensation. A different pattern of results could emerge in patients that have had experience with the stimulation sensation. The final limitation of this study was the lack of assessment of adequacy of patient blinding. Patients were not asked to indicate which stimulation type they thought they were assigned to at the conclusion of each stimulation period, rendering it impossible to determine whether patients were truly blinded to stimulation type and whether this biased the study results.

The results from the current study provide supporting evidence for patient preference for the stimulation sensation generated by CC systems over that generated by CV systems. In another study evaluating patient preference for CC or CV SCS systems, 14 patients were asked to identify whether the two 15-sec pulse trains generated by either a CC or CV system were the same or different, and if different, which do they prefer (17,18). They found that the majority of patients could not differentiate between the two pulse trains. However, pulse trains generated with the CC system were preferred more often than those generated by a CV system among pulse trains rated as different. The authors concluded that the preference for voltage- or current-driven stimulation is elusive because of the patient’s inability to consistently identify same and different pulse pair trains. They propose that the interpretation of patient preference should consider the number of correct responses and that correct identification of a certain number of same and different pairs (above the group mean) is required for reliable preference. This was a well-designed study complete with randomization and equalization of charge per pulse between the two groups to ensure relevant unbiased comparison. However, the authors’ assumption that a reliable preference is contingent upon the patient’s ability to distinguish between the two stimulation modes is refuted by an extensive body of literature that suggests that preference is not reliant upon perceptual and cognitive processes (19–22). Zajonc (22) asserts that “a number of experimental results on preferences, attitudes, impression formation, and decision making, as well as come clinical phenomena, suggest that affective judgments may be fairly independent of, and precede in time, the sorts of perceptual and cognitive operations commonly assumed to be the basis of these affective judgments.” The study actually lends further credence to this claim as there was a trend for patients to prefer CC stimulation over CV stimulation although they were unable to detect a difference between the two stimulation types. A larger patient population is warranted to statistically resolve this issue.

The question of why patients prefer CC stimulation over CV stimulation remains unresolved. However, the properties, specifically the pulse shape generated by the different stimulation types in response to impedance, may provide some insight. CC sources produce a rectangular-shaped voltage pulse because voltage, rather than current, changes in response to impedance (see Fig. 1). CV systems, on the other hand, ultimately generate spiked shaped pulse which results from a steep rise at the beginning of the pulse and slow exponential decay of the current injected in response to impedance. While unlikely that CC and CV stimulation results in differential activation of individual neurons given the membrane time constant and that the average energy during the pulse is similar, research suggests that different pulse shapes can selectively activate nerve fibers of varying diameters under specific conditions (23–26). For example, spiked shaped pulses have been shown to selectively activate small myelinated α-fibers and unmyelinated C fibers without activation of the larger αβ fibers (23). SCS is thought to function by activating the αβ fibers within the dorsal columns to suppress pain (27,28). The spiked pulses that are generated in response to impedance in CV may not be ideal for achieving this activation and could result in painful stimulation, especially at the beginning of the pulse. However, as discussed previously, adjustment of CV stimulation parameters (optimization) could potentially resolve any uncomfortable stimulation.

Preclinical studies have begun to elucidate physiological differences between CC and CV stimulation. A recent study comparing the effects of SCS produced by a CC and CV system at various frequencies and intensities on nociception in a rat model of visceral pain showed that CC SCS reduced visceral motor responses evoked by colorectal distension significantly more than CV SCS. In addition, high-frequency SCS reduced intraspinal somatic nociceptive transmission more than low frequency SCS (29).

Patient preference is not the only observed advantage of current driven systems as a number of technical advantages have also been put forth (12,30). These advantages are tied to the differing physical properties of the two systems that is illustrated by Ohm’s law (V = IR; where V = voltage, I = current, and R = resistance [impedance]). In CC systems, the voltage changes in response to impedance in the system that, in the case of SCS, can result from fibrosis in the epidural space of the spinal column after lead implantation. In contrast, the current delivered to the system changes in response to impedance in a CV system. This may be relatively unimportant in situations in which impedance does not change; however, it is known that tissue impedance in the epidural space changes over time (13–15). Changes in impedance can dramatically impact SCS systems that utilize a CV source because the pulse amplitude can be reduced below the threshold required for nerve fiber activation. The changes in current that occur when using a CV IPC can negatively impact nerve activation. In addition, the tissue is maximally stimulated only at the beginning of the pulse and as current decreases, stimulation efficiency decreases throughout the pulse (12). Amplitude would need to be continuously adjusted in response to tissue impedance, which can take several months to stabilize, in order to maintain adequate stimulation (30).

In conclusion, CC and CV systems appear to provide comparable pain relief, patient satisfaction, and quality of life; however, more patients preferred the sensation produced by the CC stimulation system. In a systematic review of SCS, it was found that almost 50% of patients did not respond favorably to the therapy when trial failures were included in the analysis (31). Although not specifically stated, this unacceptably high failure rate may be partially attributed to patient’s dislike of the stimulation sensation as the majority of the studies included in this review were performed with CV systems. This highlights the importance of presenting the patients with the choice of a CC system as they may utilize the SCS device more if they enjoy the stimulation sensation.
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Authorship Statement

Drs. Caitlin, Bethel, and Canlas designed and conducted the study, including patient recruitment, data collection, and data analysis. Dr. Washburn prepared the manuscript draft with important intellectual input from Drs. Caitlin, Bethel, and Canlas. All authors approved the final manuscript. St. Jude Medical provided funding for the study, statistical support in analyzing the data with input from Dr. Washburn, and also funding for editorial support. Drs. Caitlin, Bethel, and Canlas had complete access to the study data. We would like to thank Roni Diaz and Tracy Cameron for editorial support during preparation of this manuscript.

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COMMENTS

This interesting paper attempts to confirm the long standing belief that constant current stimulation is preferred by SCS patients over constant voltage stimulation. The belief was held, at least in part, based on Ohm’s law which states that voltage is equal to the product of current and impedance (resistance). Given that patients sense current, a constant current should be superior to a constant voltage system as the latter would result in delivery of lower currents if and/or when impedance increases. To prove this concept, the authors set out to design an elegant double blind study and concluded that SCS patients preferred constant current over constant voltage stimulation. Nonetheless, this paper suffers from two flaws that cast a question over the drawn conclusions: 1) The investigators failed to check the internal validity of the blinding by not asking patients (or blinded programmers) to guess which stimulation mode was being delivered.
Hence, while the results of this study seem to indicate SCS patients preferred constant current over constant voltage, the conclusions are far from being beyond the shadow of a doubt.

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This well-fashioned, randomized, double-blinded, cross over study seeks to test and answer the ongoing question: is constant-current or constant-voltage best? While the study supports patient preference and patient satisfaction for constant current systems, there was no statistical difference between the percentage of patients reporting greater than 50% pain relief, nor in patient reported pain relief. Yet, in terms of reporting of pain with the NRS there were statistical differences in favor of constant current exposure. While well organized, the study is hampered by its small size and it focuses on the trial period, when decisions of great value are made, perhaps hastily. High-level science is hard to do. While it is clear that neuromodulation is a treatment of great value to our society, we still do not have conclusive evidence regarding these differences in electrical anesthesia. Future studies would do well to follow the implants prospectively in time and report differences in outcome. Competitive, controlled, prospective and longitudinal studies comparing constant current and constant voltage will likely be simply too expensive in the current medical construct. For now we must focus on good patient selection, excellent physician training, error-free implantation and low complications, new indications and better technological answers. Patients will win with this approach. Dollars spent may better serve our field, when comparing the efficacy of neuromodulation to other treatments, or to “relative lack of treatment” an approach our next medical paradigm will likely favor.

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The authors have made a reasonable attempt to study a difficult topic in the field of dorsal column stimulation—namely whether there is any difference in perception or outcome comparing devices which rely on constant current (CC) delivery or devices which rely on constant voltage (CV) delivery. This is difficult to study because it is potentially confounded by differences in optimized programming within and between patients and devices, and because of the ever-present nature of placebo-type effects which may be playing a role at each juncture of treatment. This work attempts to control for some of these problems (fixed programs, same programmer, crossover to avoid placebo effects), though the concern as to whether patients are programmed ‘optimally’ (and independent of sponsoring company personnel) is still at issue. The amount of time allowed to program patients optimally may not have been adequate to compare the stimulation systems (the study was performed during the trial period only and started after day 1). Finally, it is still not the case that adjustments in constant voltage systems were made to “compensate” for any perception differences—something that surely would be done in real programming situations. For example, a patient with a constant voltage system who had a less than ideal feeling with the stimulation would have adjustments in frequency, pulse width, and/or amplitude to make it more palatable without losing the benefit. Such adjustments were not able to be realized in this study. Using the measured impedances to convert current to voltage and vice-versa as was done, attempting to control the amplitudes appropriately, is also potentially problematic because the impedances are measures between contacts but not necessarily indicative of what reaches the cord in any given patient — though in the early trial period this may be only a minimal difference.

Finally, it is laudable that the authors discuss some aspects of mechanism with regard to this question. How a difference in pulse shape (which is ultimately the difference between the two) on the order of microseconds can have much of a perceptual effect clinically when the membrane time constants themselves of the stimulated axons are on the order of a millisecond has always eluded me. It is possible there is a small effect on which adjunctive smaller diameter fibers are brought to threshold in CV (which has a higher peak to its pulse shape) and this might explain some of the perception differences. How this might translate into more or less benefit in pain relief remains a question however.

Whether CC or CV systems have any differences has been bandied about in the field for years, and certainly the real question is whether either type of system can achieve a good outcome—to which the answer is certainly “yes”. However, it is important to better understand whether there is an overarching preference with patients, generally speaking, whereby one system is always more likely to have a good outcome or perception at least than the other, both for best practices and device design moving into the future. This paper makes a valiant attempt to begin that process.

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Comments not included in the Early View version of this paper.