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# Assessment of Patient Preference for Constant Voltage and Constant Current Spinal Cord Stimulation

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**Objectives:** Spinal cord stimulation devices control energy by generating either constant voltage (CV) pulses or constant current (CC) pulses. This study aimed to investigate: 1) whether patients feel differences between CV and CC stimulation; 2) if patients prefer CV or CC stimulation.

**Methods:** Fourteen patients blinded to the type of pulse generation received 20 randomized pairs of 15-sec pulse trains (CC-CV, CV-CC, CV-CV, or CC-CC). Patients identified whether the pairs were the same or different, and if they preferred the first or second train.

**Results:** There was no difference in charge-per-pulse input between CV and CC modes. Patients performed at chance level in identifying identical pairs ( $55.7 \pm 24.1\%$  correct, 10 trials), and slightly better in identifying different pairs ( $67.1 \pm 25.2\%$  correct, 10 trials). No patients correctly identified all pairs. Patients were categorized based on their performance in this task. Only three patients fell into a category where preference could be established with some confidence with respect to the group averages. Two of these patients preferred CV, while one patient preferred CC.

**Conclusion:** The lack of patient ability to discriminate in this preliminary investigation suggests that patient preference for a stimulation type should not be the key determining factor in choosing a spinal cord stimulation system.

**Keywords:** Back pain, current, paresthesia, spinal cord stimulation, voltage

**Conflict of Interest:** Authors Johanek and King are Medtronic employees. Authors Schade, Schultz, and Sasaki have been on Advisory Panels for Medtronic, and they have conducted consulting, education, and training for Medtronic.

## INTRODUCTION

Spinal cord stimulation (SCS) is a treatment for chronic pain that delivers electrical pulses to spinal neural tissue generating the sensation of paresthesia. The generally accepted belief is that the paresthesia sensation must be present and overlap with the region of pain in order to provide effective pain relief (1–3).

Spinal cord stimulation devices control the energy being delivered to neural tissue by generating either constant voltage (CV) or constant current (CC) pulse trains. The first commercially available SCS devices were voltage-controlled and numerous studies have reported the efficacy of these devices (4–8). More recently, current-controlled devices have become commercially available. The energy output from both CV and CC devices are able to activate similar populations of neurons as evidenced by the resulting paresthesia, and both systems are effective in clinical trials (9–11).

Although both CV and CC devices supply energy to tissue, there are differences in how this is accomplished (12,13). CV devices supply a fixed (constant) voltage by varying the amount of current as dependent on changes in impedance. In contrast, CC devices supply a fixed (constant) amount of current by adjusting the amount of voltage dependent on impedance. Thus, if impedance increases over the course of a pulse, CC devices will supply CC by increasing the voltage. In contrast, CV devices will decrease the current with increasing impedance to maintain a CV. Furthermore,

impedance increases as scar tissue slowly forms around the SCS lead, causing CC devices to increase the power output while CV devices will decrease the power output. These distinct features have been anecdotally reported to result in differences in sensation and subsequent pain relief.

Arguments can be made that there should be no physiologic difference between CC and CV stimulation or that the differences are irrelevant. 1) Although the shape of the microsecond current pulse may differ between CC and CV, the energy actually penetrating into the cord is minimal, whereby about 90% of the power delivered is dissipated in the cerebral spinal fluid and less than 10%

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enters the spinal cord (14). Additionally, the pulse shape that reaches the cord will be different than the shape at the electrode because of attenuation and filtering because of capacitive effects across the tissue. 2) Per the traditional strength-duration curve, it is the charge (pulse width  $\times$  amplitude) being delivered that will be the main determining factor whether neurons are activated. 3) CC increases the power delivered secondary to increasing impedance during fibrosis. However, the slow changes in impedance during fibrosis are less concerning than the required amplitude adjustments patients must make on a daily basis. Patients using both systems must still adjust stimulation levels during changes in posture, and therapy impedance is stable with body position (15,16). Neither CC nor CV systems adjust stimulation levels in response to the changes as the spinal cord moves farther from or nearer to the lead. Patients must manually adjust their stimulation level because of the changes in paresthesia threshold and intensity (17). 4) The patient's perceived stimulation preferences are often secondary to pain levels that change frequently in response to multiple factors such as medication ingestion, weather, activity, and disease state (18,19). 5) No large-scale studies have assessed whether there are any long-term differences in pain relief or quality of life between CV and CC devices. Clinical investigations of SCS efficacy either use only one type of neurostimulator or include both types of devices into the study. A small study comparing SCS therapy outcomes by technologies found negligible differences and cautioned on drawing conclusions from the small number of patients surveyed (20). 6) With both types of stimulation devices, there will be some patients who experience limited pain relief. For example, a recent publication reported on patients with less than 50% pain relief after SCS trial using a current-controlled device (21). Interestingly, these patients who "failed" their trial and still received permanent implants later experienced an increase in pain relief with their stimulation systems. This indicates that pain relief at trial is not necessarily indicative of long-term outcome.

Paresthesia is produced by activation of large-diameter sensory axons in the dorsal columns and/or dorsal roots. Modeling studies predict that large, myelinated axons would be activated at much lower amplitudes than small, unmyelinated axons, particularly at microsecond pulse widths (14). Thus, at the same settings (electrode configuration, pulse width, frequency, and amplitude) similar populations of large-diameter axons should be activated by CC and CV devices. From a neurophysiologic perspective, it is unclear as to why SCS patients might perceive a "better" paresthesia sensation with either a CC or CV device when stimulating under the same parameters.

In lieu of finding a physiologic explanation for a CV or CC "preference," perhaps product attributes and outside factors influencing human preference should be considered. If patients are asked to choose between two systems (CV or CC), there may be numerous factors influencing patient choice, such as aesthetics, function, experiences, and experimental bias. Furthermore, if two systems have been programmed independently, possible confounding variables include differences in programmable parameters and differences in the time spent optimizing parameters. Therefore, any study purely assessing the sensation of CV vs. CC sensation should control for these other variables.

Because of anecdotal reports that patients do perceive a difference between CC and CV, this prospective, randomized, blinded study was designed to provide preliminary insight into this phenomenon (12,13). This study aimed to investigate: 1) whether patients could correctly identify identical and different CV- or CC-generated pulse trains; 2) if patients prefer CV or CC stimulation.

Patients participating in this study were undergoing their SCS therapy trial.

## METHODS

### Subjects

Patients participated in this IRB-approved multicenter study after giving written informed consent. Fourteen patients were recruited from investigators' practices at three pain management clinics in the USA (The Center for Pain Control, TX, USA, center 1; Medical Advanced Pain Specialists [MAPS], MN, USA, center 2; John Sasaki, M.D., Inc., CA, USA, center 3). Because the scope of the study was to obtain preliminary information, the study was not powered and no sample size calculations were performed.

Because the patient's own SCS therapy was not a part of this protocol, there was no requirement or controls placed on lead number, configuration, or implant technique. Ultimately, the CC vs. CV comparison was made within subject.

### Study devices and programming

An external neurostimulator (ENS) with firmware modified from the commercially available Medtronic Model 37021 ENS was used to deliver stimulation to the externalized trial leads. The screener was controlled via software on a laptop computer. The computer was powered by its own internal battery when used with subjects.

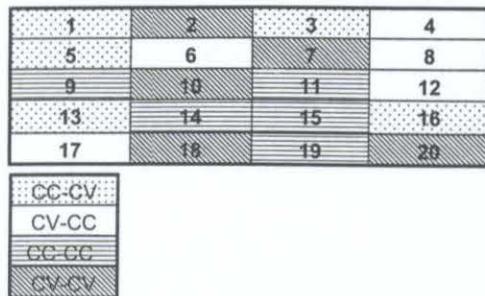
Before the study began, an impedance check was performed. Electrodes with impedance above 3500  $\Omega$  were not used. Programming of anodes and cathodes was typically based on the patient's trial programming to optimize paresthesia coverage over the patient's pain area, and therefore varied from patient to patient.

### Study design

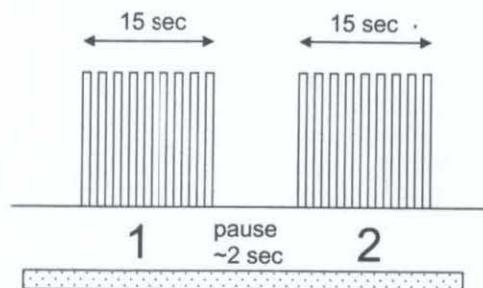
After the settings were established, patients were randomized to experience either CV or CC stimulation. Stimulation amplitude was slowly increased by the investigator until the patient first reported a sense of paresthesia (threshold). The amplitude was further increased by the investigator, and patients were instructed to indicate when the paresthesia felt "strong, but tolerable enough to leave on for 30 min." The threshold and strong-but-tolerable amplitudes were recorded for each patient in both CV and CC modes. A therapy impedance measurement was taken after stimulation in the voltage mode.

Once the strong-but-tolerable amplitude was established in both stimulation modes, stimulation was alternated (toggled) between CV and CC to establish similar paresthesia intensity. Because the "sensation" of paresthesia might be different between CV and CC, it was important to exclude intensity as a potential variable. Once similar paresthesia intensity was established, patients were not told which type of stimulation they were receiving, but were asked if they had a preference for stimulation "A" or stimulation "B." Patient preference (if any) and amplitudes in both modes were recorded.

Patients next received a total of 20 randomly presented pairs of 15-sec pulse trains (Fig. 1). This allowed patients to experience pairs of pulses that were the same (CC-CC and CV-CV) and different (CV-CC and CC-CV). Patients were asked for verbal feedback by the investigator whether they felt the two pulse trains were the same or different, and if different, if they preferred the first or second train (Fig. 2). Patients and the experimenter asking for patient response were blinded to the type of stimulation presented.



**Figure 1.** Example randomization scheme for delivering 20 trials. The shading of the boxes represents the types of pulse pairs presented. Numbers represent the order in which the trials were presented. CC, constant current; CV, constant voltage.



**Figure 2.** Two pulse trains were presented to the patient in succession (pulse pairs). Following the second pulse train, the patient was asked whether these pulse trains were the "same" or "different." If the patient reported that the two pulse trains were different, they were asked whether the first or second pulse train was preferred.

### Calculations and analysis

Ohm's law ( $V = IR$ ) was used to calculate the corresponding stimulation amplitude, where  $R$  equaled the therapy impedance determined in voltage mode. An estimate of charge per pulse ( $Q$ ) was obtained by the following equation:  $Q(t) = I(t)dt$ . In current mode, this was a simple  $Q = I_{\max} \times (PW)$ , where  $I$  is the current amplitude, and PW is the pulse width. The calculation of charge in voltage mode considered the change in impedance over the duration of a single pulse with the equation:

$$I(t) = \frac{V_{\max}}{R} \times e^{\frac{-t}{RC}}$$

then,

$$Q = \frac{V_{\max}}{R} \int_{t=0}^{PW} e^{\frac{-t}{RC}} dt$$

where  $V$  is the voltage amplitude and  $RC$  is the time constant of decay.

Paired  $t$ -tests were used to compare the amplitudes and charge obtained in CC and CV modes. All significance levels were set at  $p < 0.05$ .

## RESULTS

### Subjects

Fourteen patients were enrolled (5 male, 9 female) between the three centers (center 1, 5 patients; center 2, 5 patients; center 3, 4

patients). Thirteen patients were diagnosed with failed back/low back syndrome and/or radicular pain syndrome, while one patient was diagnosed with complex regional pain syndrome. The average age was 50.3 years (range: 38.3–76.4 years). The average duration of pain at the time of enrollment was 8.3 years (range: 2–20 years), and average pain over the week prior to enrollment was  $7.6 \pm 1.8$  on a 0–10 numeric rating scale. All patients were determined to be candidates for SCS therapy. Patients participated in this out-patient clinic study during their SCS trial. While four adverse events were reported, none of these were unanticipated. One patient experienced the two adverse events of nausea and ongoing paresthesia after the conclusion of the study; no interventional activities were taken. A second patient experienced two adverse events consisting of skin irritation from the bandage materials and lead migration. Although the lead migrated during the trial, programming still allowed for paresthesia coverage more than approximately 50% of the pain area and the patient continued participation in the study without any interventional activity taken.

### Programming

Patients had epidural percutaneous SCS leads implanted as part of their normal pain management and SCS therapy trial. No restriction was placed on lead type, number of leads, or level of implantation. Leads included a single octad, dual octads, a midline octad flanked by quads, and a midline quad flanked by two quads. Electrode configurations included bipolar, longitudinal tripole, transverse tripole, and other variations. Frequency and pulse width were programmed based on the patient's trial programming (average:  $66 \pm 19$  Hz and  $439 \pm 40$   $\mu$ sec). These parameters remained consistent in both CV and CC modes. The average therapy impedance was  $576 \pm 275 \Omega$ .

### Paresthesia amplitudes

The intensity of the stimulation was slowly increased until the patient reported the sensation of paresthesia ("threshold" in Table 1). The intensity of the stimulation was further increased to a "strong-but-tolerable" level. Using the therapy impedance, Ohm's Law was used to calculate the corresponding current and voltage. This allowed for comparison between modes. When thresholds were determined independently in CV and CC modes, the maximum amplitude in the voltage mode was slightly higher ( $p < 0.05$ ). However, the charge delivered in the two different modes (current- and voltage-controlled) was not significantly different. Thus, when asked to report threshold and "strong-but-tolerable" paresthesia in voltage and current mode independently, patients in this study reported paresthesia intensity with similar charge input.

After determining strong-but-tolerable levels in each mode, a toggling feature in the programming software was used. Amplitudes were adjusted accordingly until the patient felt that both stimulation modes were approximately of equal intensity (Table 1). The overall charge calculated was not significantly different between current- and voltage-controlled modes (Table 1).

### Initial patient preference

After toggling, many patients felt that both modes were equal in intensity and reported no preference for either mode (9/14). However, five patients did report a preference for a particular stimulation mode (Table 2). Four patients reported a preference for CC stimulation, while one patient reported a preference for CV stimulation in the uncontrolled portion of the study.

**Table 1.** Comparison of Amplitudes and Charge Delivered in Current and Voltage-Controlled Modes.

Paresthesia	Amplitude voltage mode (V)	Calculated current amplitude (mA)	Amplitude current mode (mA)	Calculated voltage amplitude (V)	CV charge per pulse ( $\mu$ C)	CC charge per pulse ( $\mu$ C)
Threshold	3.6 $\pm$ 2.2	6.8 $\pm$ 4.2*	5.1 $\pm$ 3.6	3.0 $\pm$ 2.3†	2.7 $\pm$ 1.7	2.3 $\pm$ 1.7 <sup>NS</sup>
Strong-but-tolerable	5.3 $\pm$ 2.9	9.6 $\pm$ 4.6*	8.8 $\pm$ 4.9	4.9 $\pm$ 3.1†	3.9 $\pm$ 1.9	3.8 $\pm$ 2.1 <sup>NS</sup>
Similar intensity stimulation	4.9 $\pm$ 2.7	9.1 $\pm$ 4.5 <sup>NS</sup>	8.6 $\pm$ 5.1	4.8 $\pm$ 3.0 <sup>NS</sup>	3.7 $\pm$ 1.8	3.7 $\pm$ 2.2 <sup>NS</sup>

As stimulation amplitude increased, patients were asked to indicate when they first detected paresthesia (paresthesia threshold). Amplitude was increased until a "strong-but-tolerable" level was achieved (a strong paresthesia sensation that could be left on for at least 30 min). Patients were randomized as to whether they first experienced current or voltage-controlled stimulation. Using Ohm's law ( $V = IR$ ), the corresponding current and voltage amplitudes were calculated based on the therapy resistance measurement obtained while in voltage mode. Once "strong-but-tolerable" levels were obtained, stimulation was toggled between current and voltage to ensure similar intensities.

\* $p < 0.05$  from current mode amplitude (paired *t*-test).

† $p < 0.05$  from voltage mode amplitude (paired *t*-test).

NS, not significant ( $p > 0.05$ ) from corresponding stimulation mode (paired *t*-test).

CC, constant current; CV, constant voltage.

**Table 2.** Patient Preference After Alternating Between CV and CC Stimulation.

Patient	Preference	Frequency (Hz)	Pulse width ( $\mu$ sec)	Preference after blinded study
1	No preference	60	450	—
2	No preference	90	450	—
3	No preference	90	450	—
4*	No preference	90	440	CV
5	CC	90	450	—
6	No preference	50	450	—
7	No preference	50	450	—
8	No preference	50	300	—
9	CC	50	450	—
10	CV	40	450	—
11	CC	90	450	—
12*	CC	60	450	CC
13	No preference	60	450	—
14*	No preference	60	450	CV

Once "strong but tolerable" levels were obtained, stimulation was toggled between current and voltage to ensure similar intensities. Patients were not told which type of stimulation they were experiencing, but were asked by the experimenter if they preferred "Pulse A" or "Pulse B." Nine (9/14) patients did not indicate a preference, while five (5/14) patients claimed to prefer one type of stimulation. There is no obvious association between frequency and preference and pulse width was typically set at 450  $\mu$ sec.

\*Three patients who fell into category A when compared with group averages. The preference after the blinded, randomized, controlled portion of the study also is shown.

CC, constant current; CV, constant voltage.

**Table 3.** Group Performance in Identifying "Same" and "Different" Pulses.

Same pulses (CC vs. CC or CV vs. CV)		Different pulses (CC vs. CV or CV vs. CC)	
Different	Same	Different	Same
44.3%	55.7%	67.1%	32.6%

CC, constant current; CV, constant voltage.

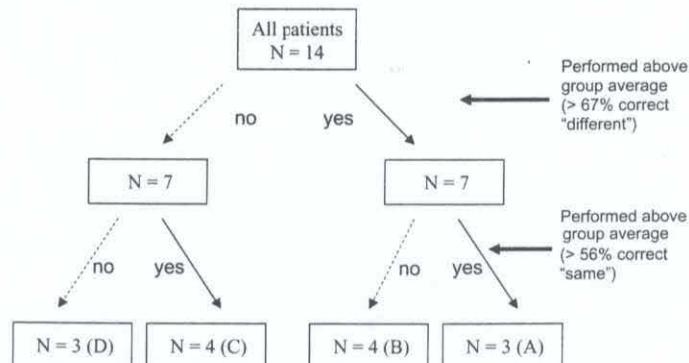
### Blinded pulse pairs

Patients were next presented with the randomized, blinded pulse train pairs. No patients were able to correctly identify all pulse comparisons as "same" or "different." Patients correctly identified "same" pulse pairs as "same" only 55.7% of the time (Table 3). Patients correctly identified "different" pulse pairs as "different" 67.1% of the time. An incorrect randomization scheme was inadvertently used for the first two patients who received 10 CV-CC trials and no CC-CV trials.

### Classification 1\*

Because patients could not consistently identify same and different pulse pair trains, the preference for voltage- or current-controlled stimulation was not clearly demonstrated. Therefore, criteria were needed to assess how much meaning to place on patient preference. First, it was assumed that for patient preference to have meaning, the patient should have correctly identified "different" pulse pairs as "different." To compare patients relative to each other, the group averages were used as cut-off points. Thus, using the group average (67.1%) as the cut-off criteria, seven patients fell below and seven patients fell above the group average. Of the seven patients above the group average, four had a stronger preference for CC, while three had a stronger preference for CV.

"Same" pulse trains were intended to be a control condition; however, as a group, patients performed at chance in correctly identifying these pulse pairs. For an individual patient, interpretation of their stimulation preference should consider the number of correct "same" responses. It was assumed that for a reliable preference,



**Figure 3.** Tree diagram depicting categorization of patients based on performance relative to the group average. Patients meeting the established criteria are indicated by the solid arrows. Patients failing to meet the criteria are indicated by the dashed arrows. Patients in group A beat the group average in both instances. Patients in group B failed the second criteria and performed below the group average in identifying the control "same" pulse comparisons. Group C patients, in contrast, identified "same" pulse comparisons above the group average, but failed the criteria requiring a certain number of "different" pulse trains to be correctly identified. Patients in group D failed both criteria and fell below the group average in identifying any pulse train comparisons correctly.

**Table 4.** CV vs. CC Preference for Patients Falling into Group A

Patient	Total pairs correctly identified as "different"	CV	Co.
4	8	8	0
12	7	0	7
14	10	8	2

CC, constant current; CV, constant voltage

patients must correctly identify same pairs, and the group average (56% correct) was chosen as the cut-off. Three of the seven patients passing the first criterion also met this second criterion (Fig. 3).

The classification scheme in Figure 3 groups patients into four categories. Patients in group A beat the group average in both instances. The blinded study indicated that these patients did have a preference, and because the patients correctly identified the control pulses, this preference appears to be valid. One patient preferred CC, while two patients preferred CV (Table 4).

Patients in group B failed the second criteria and performed below the group average in identifying the control "same" pulses. In general, these patients tended to identify control pulses as "different." Group C patients, in contrast, correctly identified "same" pulses (above the group average), but failed the criteria requiring a number of "different" pulses to be correctly identified. These patients would tend to identify different pulses as "same." Finally, patients in group D failed both criteria and fell below the group average in identifying any pulses correctly.

## Classification 2

As a secondary analysis, classification was also performed using 50% correct as the cut-off, meaning that patients must have at least 5/10 correct responses in both the "same" and "different" trials (Fig. 4). Using these classification parameters, only one more patient fell into group A (patient #2). Of the four patients in group A, two patients preferred CV and two preferred CC. Classifying patients in this manner placed seven patients in group B. These patients correctly identified at least 5/10 "different" pulses, but correctly identified less than 5/10 "same" pulses. Thus, a majority of pulse pairs were described as "different" by group B patients.

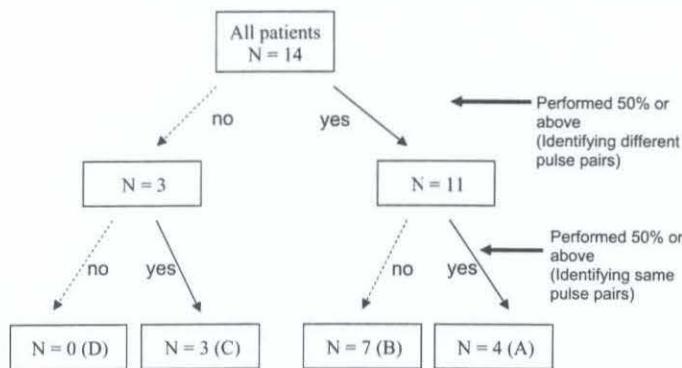
### Initial vs. blinded preference

Finally, we looked back at those patients who initially indicated a preference for one type of stimulation after toggling between the two modes (Table 2). If the patient initially sensed a distinct difference between voltage- and current-controlled stimulation, it was expected that the patient would be able to pick out this preferred pulse type in the blinded study. However, this was not the case (Tables 2 and 5). One patient initially indicating a preference for voltage-controlled stimulation entirely switched preference to current-controlled stimulation (patient 10). Furthermore, this patient had difficulty correctly identifying "same" pulses and was classified into group B. Two patients with initial preferences for CC (patients 9 and 11) performed below the group average in identifying pulse pairs (group D). A fourth patient initially preferring CC actually chose more CV pulses (patient 5), but overall claimed that a majority of pulses felt "same" (group C). Only one patient with an initial preference for CC was able to consistently pick out CC as their preferred pulse type (patient 12).

## DISCUSSION

This study began a preliminary investigation into the idea that the paresthesia generated by CV and CC stimulation may "feel" different to SCS patients, and therefore, patients may prefer one stimulation mode over the other. While the study was not powered to determine statistical preference, the general performance failure on control pulses and the inability to pick out a preferred pulse questions the existence of stimulation mode preference and suggests that differences in the control of energy during CV or CC stimulation play a minor role in the adoption of SCS therapy.

Only a few patients in this study (5/14), before being presented with blinded pulse choices, reported a preference. One patient preferred CV stimulation, while four patients chose CC. If patients truly felt a difference in sensation, it was expected that they could determine in a blinded test which pulses felt different and which they preferred. However, three of the four patients who initially preferred CC stimulation performed below the group average in distinguishing which pulse pairs were different. They could not consistently pick out the CC stimulation they reported to prefer. This suggests



**Figure 4.** Tree diagram depicting categorization of patients based on performance relative to chance. Patients meeting the criteria are indicated by the solid arrows. Patients failing to meet the criteria are indicated by the dashed arrows. Patients in group A performed at 50% correct or above in correctly identifying both "same" and "different" pulse comparisons. Patients in group B failed the second criteria and performed below 50% in identifying the control "same" pulse comparisons. Group C patients, in contrast, identified "same" pulse trains above 50% correct, but failed the criteria requiring a certain number of "different" pulse trains to be correctly identified. Under this classification scheme, no patients fell into group D.

**Table 5.** Patient Preference is not Reliable Based on Blinded Testing.

Patient	Initial preference	Total pairs correctly identified as "different"	CV preference	CC preference	Group
5	CC	4	3	1	C
9	CC	6	2	4	D
10	CV	9	0	9	B
11	CC	5	2	3	D
12	CC	9	0	9	A

Of the five patients that initially indicated a preference for either current or voltage, only one patient could consistently identify the pulse they indicated an initial preference for.

CC, constant current; CV, constant voltage.

that even if patients do perceive a difference between CV and CC stimulation, this difference is not robust enough for consistent identification in a blinded test.

The blinded pulse comparisons tested the patient's ability to correctly determine when pulse pairs were the same (CC-CC and CV-CV), and when pulse pairs were different (CV-CC and CC-CV). The "same" comparisons were incorporated as a control. If patients claimed that these felt different, then it decreased their ranking when stating a preference for a "different" pulse. Overall, patients performed poorly, correctly identifying only 56% of "same" pulse pairs. Similarly, if CC and CV truly did feel different, then patients were expected to pick out the "different" pairs. Furthermore, if the patient truly did have a preference, then patients were expected to pick out their preferred pulse type. However, some patients picked few total pulses that felt "different." Other patients, when identifying pulses as different, chose a mix of CV and CC. Finally, some performed so poorly on the "control" pulses that it was impossible to interpret any preference during the different pulses.

Two classification schemes were used to organize and assess patient preference. One was based on performance relative to the group average (Fig. 3); the other was based on performance relative to chance (Fig. 4). In both classification schemes, only a small number of patients (3/14 and 4/14, respectively) appear to have a reliable preference for a stimulation mode. To highlight those patients performing above the group average, the discussion is based upon the classification scheme used in Figure 3.

Although this study cannot be generalized to the entire SCS population, it does challenge reports stating that most patients will show a preference for CC stimulation (22,23). First, when given iden-

tical pulse sequences in a blinded manner, patients in this study identified these pulses as "different" 44.3% of the time. Because patients have problems identifying back-to-back identical pulse pairs, it questions whether patients who experience CC and CV with any significant time delay between the two will be able to accurately compare the sensation delivered by each mode. Second, there were patients in this study who either did not detect a difference between CC and CV or who appeared to be guessing whether pulse sequences were identical or different. Finally, we only found a small number of patients (3/14) who could consistently identify identical and different pulse pairs. These patients scored above the group averages in both categories and, thus, were given the most credibility in terms of their preference. Their choices did not appear to be a random pick between CV and CC, but consistent choosing of a preferred pulse type. They could also, with some consistency, identify "same" and "different" pulse pairs. Interestingly, two preferred more CV pulses, while one preferred more CC pulses.

Studies that attempt to assess a difference in sensation between current- and voltage-controlled stimulation must control for the intensity of the stimulus being delivered. However, stimulation amplitude is often not reported (24). In this study, amplitude was not pre-chosen; rather, the patients themselves provided feedback to indicate paresthesia intensity. When patients independently experienced voltage-controlled or current-controlled stimulation, the calculated charge per pulse at these levels was not different. Furthermore, when current and voltage was toggled and patients could directly compare the sensation, nearly identical amplitudes and subsequent charge were chosen. Thus, regardless of how stimulation was controlled, patients in this study could tell how

much energy input they needed to achieve a certain level of paresthesia.

The ability to deliver the voltage-controlled and current-controlled pulses through the same equipment, without having to exchange devices, was important for two reasons. First, this eliminated any potential influence induced by differences in appearance or usability. Even small differences in an object's color, weight, and features have the potential to influence human preference. In this study, patients were not influenced by differences in the physical machinery delivering the stimulation. Second, voltage- and current-controlled stimulation were being delivered by a modified commercially available ENS. Comparisons were not being made against an "older" stimulator model that may function differently relative to more advanced versions. Parameters were held as constant as possible to allow focus on the sensation generated from two different stimulation modes.

The study is not without its caveats. No constraints were placed on lead number, placement, or electrode configuration therefore these parameters varied between patients. However, this is of minimal concern as all parameters were held constant within the patient as they experienced blinded CV and CC pulses. Other study designs requiring large numbers of participants could better address a true difference in perception between CV and CC. For example, a "duo-trio" test would present one pulse type first and require the participant to next determine which in a subsequent pair was identical to the first. This type of design would entail a fairly quick comparison between the two samples being tested (i.e. a toggling feature), require a sizable number of patients, and only test whether a difference is detectable (not preference).

Because the primary objective was to determine whether patients felt a difference between the two stimulation conditions, the testing performed in this study did not allow for assessment of pain relief. The design allowed the patient to feel paresthesia for enough time (15 sec) to make an assessment of sensation and compare with the second pulse in quick succession. A completely different study design would be needed to determine if one type of stimulation is better for long-term pain relief. No studies have assessed long-term outcomes (e.g. pain relief or quality of life) in commercially available CV devices compared with CC devices. For studies that have assessed short-term, day-long comparisons of CC and CV during the SCS trial period (22,23), arguments can be made that the patient report of pain relief is influenced by placebo effects and may not reflect long-term outcome. Patient expectation and placebo at trial may confound the results of studies assessing pain relief at trial. Because our study dealt only with the sensation of paresthesia generated by two different stimulation types, there is less concern that this data is influenced by placebo.

The order of fiber recruitment within the dorsal columns is predominantly related to fiber diameter and distance from the cathode (25). Modeling studies have demonstrated that it is unlikely that any structures apart from the dorsal roots and a thin outer layer of the dorsal columns are recruited with epidural stimulation (14). Thus, if both CV and CC activate large-diameter A $\beta$  fibers at paresthesia threshold and during comfortable paresthesia, it is unclear from a neuronal perspective why this activation should "feel" different. Even so, three patients in this study consistently picked out a preferred pulse type. This suggests that the patients are experiencing a specific unique sensation in CV vs. CC mode. It is unclear how this perceptual experience corresponds to unique neuronal activation and a subsequent difference in paresthesia sensation leading to a

preference for either CV or CC stimulation. It is still unknown at this time whether these perceptual differences influence long-term therapeutic outcome.

## CONCLUSIONS

After categorizing patient performance in a blinded pulse-comparison task, few patients (3/14) showed a detectable and reliable preference for a specific stimulation mode. However, analysis of this study is limited by the small sample size and thus prevents drawing concrete conclusions regarding patient preference.

It is of note that patients determined their own paresthesia intensity levels in each stimulation mode and that the charge per pulse generated from the resulting amplitudes was not different. Therefore, regardless of how stimulation was being controlled by the device, patients in this study could tell how much energy input they needed to achieve a certain level of paresthesia. This suggests that similar neuronal populations are being activated in both modes. At the same time, the finding that three patients had reliable preference suggests that stimulation mode is somehow a factor in how these patients perceive stimulation. Thus, the way stimulation is controlled may be a factor for some patients undergoing SCS therapy. Differences in stimulation are likely not detected by the remainder of patients, and caution should be used when patients claim to have a preference after a single trial of CV and CC. Furthermore, the general failure of patients to discriminate between pulse types suggests that differences in the control of energy during CV or CC stimulation play a minor role in the adaptation of SCS therapy.

## Authorship statements

Dr. King was instrumental in the design of the study, with input from Dr. Schade, Dr. Schultz, and Dr. Sasaki. These authors conducted the study, with the additional contributions from Dr. Tamayo including patient recruitment and data collection, and Dr. Johanek including data collection and data analysis. Dr. Johanek prepared the manuscript draft with critical intellectual input and revision from Dr. Schade and additional important intellectual contributions from Drs. King, Sasaki, and Schultz. All authors approved the final manuscript. Medtronic, Inc. provided funding for the study and assisted in analyzing the data with input from Dr. Schade, Dr. Schultz, and Dr. Sasaki.

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## REFERENCE

1. Barolat G, Massaro F, He J, Zeme S, Ketcik B. Mapping of sensory responses to epidural stimulation of the intraspinal neural structures in man. *J Neurosurg* 1993;78:233–239.
2. Barolat G, Zeme S, Ketcik B. Multifactorial analysis of epidural spinal cord stimulation. *Stereotact Funct Neurosurg* 1991;56:77–103.
3. North RB, Kidd DH, Zahurak M, James CS, Long DM. Spinal cord stimulation for chronic, intractable pain: experience over two decades. *Neurosurgery* 1993;32:384–394.
4. Kumar K, Taylor RS, Jacques L et al. The effects of spinal cord stimulation in neuropathic pain are sustained: a 24-month follow-up of the prospective randomized

- controlled multicenter trial of the effectiveness of spinal cord stimulation. *Neurosurgery* 2008;63:762–770.
5. Manca A, Kumar K, Taylor RS et al. Quality of life, resource consumption and costs of spinal cord stimulation versus conventional medical management in neuropathic pain patients with failed back surgery syndrome (PROCESS trial). *Eur J Pain* 2008;12:1047–1058.
  6. Kumar K, Taylor RS, Jacques L et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomised controlled trial in patients with failed back surgery syndrome. *Pain* 2007;132:179–188.
  7. North RB, Kidd D, Shipley J, Taylor RS. Spinal cord stimulation versus reoperation for failed back surgery syndrome: a cost effectiveness and cost utility analysis based on a randomized, controlled trial. *Neurosurgery* 2007;61:361–368.
  8. Van Buyten JP, Van ZJ, Vughehs P, Vanduffel L. Efficacy of spinal cord stimulation: 10 years of experience in a pain centre in Belgium. *Eur J Pain* 2001;5:299–307.
  9. Cameron T. Safety and efficacy of spinal cord stimulation for the treatment of chronic pain: a 20-year literature review. *J Neurosurg* 2004;100 (Suppl. Spine):254–267.
  10. Alo KM. Spinal cord stimulation for complex pain: initial experience with a dual electrode, programmable, internal pulse generator. *Pain Pract* 2003;3:31–38.
  11. Abejon D, Reig E, del Pozo C, Contreras R, Insausti J. Dual spinal cord stimulation for complex pain: preliminary study. *Neuromodulation* 2005;8:105–111.
  12. Schade C, Sasaki J, Schultz D, Greenberg J, Johanek L, King G. Voltage versus current stimulation pulse trains in patients undergoing spinal cord stimulation (SCS) trial. North American Neuromodulation Society, 12th Annual Meeting, 2008.
  13. Sasaki J, Schade C, Schultz D, Greenberg J, Johanek L, King G. American Academy of Pain Medicine Annual Meeting Abstracts: preference for voltage or current stimulation pulse trains is not consistent in patients undergoing spinal cord stimulation (SCS) trial (#161). *Pain Med* 2009;10:228.
  14. Holsheimer J. Which neuronal elements are activated directly by spinal cord stimulation. *Neuromodulation* 2002;5:25–31.
  15. Abejon D, Feier CA. Is impedance a parameter to be taken into account in spinal cord stimulation? *Pain Physician* 2007;10:533–540.
  16. Schade CM, Schultz D, Tamayo N, Balasubramanian S, Panken E. Automatic Adaptation of Spinal Cord Stimulation (SCS) intensity in response to posture changes. North American Neuromodulation Society, 13th Annual Meeting, 2009.
  17. Cameron T, Alo KM. Effects of posture on stimulation parameters in spinal cord stimulation. *Neuromodulation* 1998;1:177–183.
  18. Vlaeyen JW, Linton SJ. Fear-avoidance and its consequences in chronic musculoskeletal pain: a state of the art. *Pain* 2000;85:317–332.
  19. Shutt MS, Jr, Cundiff G, DeGood DE. Pain complaint and the weather: weather sensitivity and symptom complaints in chronic pain patients. *Pain* 1992;49:199–204.
  20. Haddadan K, Krames ES. The effect of spinal cord stimulation, overall, and the effect of differing spinal cord stimulation technologies on pain, reduction in pain medication, sleep, and function. *Neuromodulation* 2007;10:156–163.
  21. Oakley JC, Krames ES, Stamatos J, Foster AM. Successful long-term outcomes of spinal cord stimulation despite limited pain relief during temporary trialing. *Neuromodulation* 2008;11:66–73.
  22. Diaz R, Catlin R. A prospective, randomized multi-centered crossover study to evaluate constant current versus constant voltage trial stimulation systems: patient perceived differences. North American Neuromodulation Society, 12th Annual Meeting, 2008.
  23. Diaz R. American Academy of Pain Medicine Annual Meeting Abstracts: a prospective, randomized multi-centered crossover study to evaluate constant current versus constant voltage trial stimulation systems: patient perceived differences (#165). *Pain Medicine* 2009;10:230.
  24. Catlin R, Washburn SN, Bethel K, Florete O, Shadid E. Constant current versus constant voltage in spinal cord stimulation: patient perceived differences. Program No. 266.1 2008 Neuroscience Meeting Planner. Washington, DC: Society for Neuroscience, 2008. Online.
  25. Holsheimer J. Principles of neurostimulation. In: Simpson BA, ed. *Electrical stimulation and the relief of pain*. Vol. 15. Amsterdam, Netherlands: Elsevier Science, 2003: 17–36.

## COMMENTS

The authors present an elegant interesting study. There are several factors that compromise the ability to draw meaningful conclusions from this work.

1. The authors point out that this study was performed on patients during spinal cord stimulation trials. One purported advantage of constant current (CC) is that it may better compensate for impedance changes that occur as a result of epidural fibrosis. Unfortunately, the trial is certainly not the time when the bulk of fibrosis occurs and this therefore limits one potential ability of CC to produce a patient preference.
2. The device used to produce CC is an adaptation of a constant voltage device and may not be programmed in the fashion that a true CC device is optimized.
3. As with many studies sponsored by medical device manufacturers that compare technologies among competitors, this study would be more convincing if performed by a variety of researchers with diverse primary corporate relationships.

It is useful not only to demonstrate a lack of perceived difference between CC and constant voltage but also to explore whether there was a difference in efficacy. If these data were collected, it certainly would be a contribution to our knowledge to compare CC and constant voltage in terms of efficacy, for example pain score changes or changes in quality of life.

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