Preference for voltage or current stimulation pulse trains is not consistent in patients undergoing spinal cord stimulation (SCS) trial - #161

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BACKGROUND

Commercially available SCS devices control the energy delivered to neural tissue through constant voltage (CV) or constant current (CC) stimulation (Figure 1). Both activate neural tissue, causing the sensation of paresthesia. Anecdotal information has suggested that patients can perceive a difference between current-controlled and voltage-controlled stimulation. However, no studies have assessed whether patients can consistently detect pulse-type differences or whether they consistently prefer one pulse type over the other.

We recently reported an investigation1 which determined that preference for CC or CV is not clear cut. Many patients performed poorly in correctly identifying two pulse train pairs as same and different.

Here we report that 5/14 patients indicated an initial preference for a pulse type (CC or CV), but did not retain this preference through the blinded portion of the study.

Figure 1

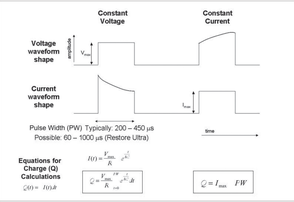


Figure 1. Voltage and current waveforms are depicted on the left. Charge delivered per pulse was calculated for current and voltage modes based on the equations below, where Q = charge; I = current amplitude; V = voltage amplitude; RC = time constant.

METHODS

In this IRB-approved multicenter feasibility study, patients (n = 14; 5 male, 9 female) undergoing SCS trial participated in a single in-clinic study. An external neurostimulator (ENS), Model 37021 NP with firmware modified from the commercially available Model 37021 SCS screener was used to deliver stimulation to the externalized trial leads. The screener was controlled via software on a laptop computer, called the NP Programmer. The computer was powered by its own internal battery when used with subjects.

At the onset of the study, patients were either presented with CC or CV stimulation (randomized) and paresthesia thresholds were obtained. Stimulation was then alternated (toggled) between CV and CC to establish similar intensity paresthesia. At this point patients were asked if they preferred one type of stimulation over the other. Subsequently, each patient received a total of 20 pairs of 15-second pulse trains (Figure 2). Patients identified whether the two pulse trains were the same or different, and if different, if they preferred the first or second train (Figure 3). Patients and the experimenter asking for patient response were blinded to the type of stimulation presented. Pulse train pairs were randomly presented as:

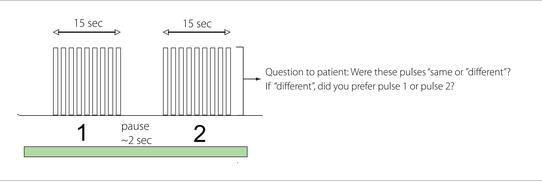
Figure 2

CC-CV CV-CC CV-CV CC-CC

1	2	3	4
5	6	7	8
9	10	11	12
13	14	15	16
17	18	19	20

Example randomization scheme for delivering 20 trials. The colors represent two types of pulses presented (green: CC-CV; yellow CV-CC; blue CV-CV, and red CC-CC). Numbers represent the order in which the trials were presented.

Figure 3



RESULTS

1 We previously reported that few patients (n=3) are able to beat the group average and distinguish same and different pulses.

different \ same	Below 56% correct (Incorrectly identifying same)	Above 56% correct (Correctly identifying same)	Total patients
Below 67% correct (Incorrectly identifying different)	3	4	7
Above 67% (Correctly identifying different)	4	3	7
Total patients	7	7	14

Unable to correctly identify pulse pairs
Identified pairs as "same"
Identified pairs as "different"
Able to correctly identify pulse pairs

1 preferred CC
2 preferred CV

Patients were categorized based on their performance in the blinded pulse-pair task. One group performed poorly (below the group average) in identifying pulse types (red). A second group performed well in identifying pulses as "same", but also thought different pulses felt the "same". In this study, these patients indicated that CV and CC pulses feel same (dark yellow). A third group could not consistently identify "same" pulses (light yellow). Therefore, caution should be taken in interpreting their indicated preference. The most credibility in pulse preference belongs to a fourth group which performed above the group average in correctly identifying both same and different pulse pair trains (green).

2 Charge per pulse did not differ when similar paresthesia intensity was obtained in voltage- & current-controlled modes.

	Amplitude: Voltage mode (V)	Calculated current amplitude (mA)	Amplitude: Current mode (mA)	Calculated voltage amplitude (V)	Charge per pulse Voltage mode (µCoulomb)	Charge per pulse Current mode (µCoulomb)
Similar Intensity Stimulation	4.9 ± 2.7	9.1 ± 4.5	8.6 ± 5.1	4.8 ± 3.0	3.7 ± 1.8	3.7 ± 2.2

n.s. n.s. n.s.

Once "strong but tolerable" levels were obtained, stimulation was toggled between current and voltage to ensure similar intensities. Using Ohm's law (V = IR), the corresponding current and voltage amplitudes were calculated based on the resistance measurement obtained while in voltage mode. Arrows compare current to "calculated current" and voltage to "calculated voltage." n.s. = not significant (paired T-test).

3 After a comparable intensity, 9/14 patients had no preference, while 5/14 patients did indicate a preference.

Patient ID	Preference after toggling	Frequency (Hz)	Pulse Width (µsec)
16390101	No preference	60	450
16390102	No preference	90	450
16390103	No preference	90	450
16390104	No preference	90	440
16390105	CC	90	450
16390201	No preference	50	450
16390202	No preference	50	450
16390203	No preference	50	300
16390204	CC	50	450
16390205	CV	40	450
16390301	CC	90	450
16390302	CC	60	450
16390303	No preference	60	450
16390304	No preference	60	450

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 µsec.
Patients then entered the blinded portion of the study, where both patient and experimenter asking for patient response were blind to the stimulation given. Those patients highlighted in green represent the three from Table 1 who performed above the group average in identifying both same and different pulse pairs.
After the blinded portion of the study, two of these patients preferred CV, while one preferred CC.

4 Patient preference is not consistent.

Patient ID	Preference after toggling	Current/voltage preference in blinded portion of study	Category (See Panel 1)
16390105	CC	CC 1, CV 3	Preference switched to CV; however, few pulses felt "different" and most pulse pairs were identifies as "same"
16390204	CC	CC 4, CV 2	Patient chose more CC pulses; however, patient had difficulty identifying "same" pairs. Patient performed below the group average in identifying both types of pulse pairs.
16390205	CV	CC 9, CV 0	Patient preference switched completely to CC; however, patient had difficulty identifying "same" pairs. Thus, even same pulse pairs were identified as different.
16390301	CC	CC 3, CV 2	No strong preference for either pulse type. Patient also had difficulty identifying "same" pairs. Patient performed below the group average in identifying both types of pulse pairs.
16390302	CC	CC 7, CV 0	Patient displayed a consistent preference for CC

We previously reported that because patients could not consistently identify same and different pulse pair trains, the preference for voltage- or current-controlled stimulation is not clear cut.
The interpretation of patient preference should consider the number of correct responses. Patients were classified based on the following assumptions:
Assumption 1: For a reliable preference, patients must correctly identify a certain number of different pairs (criteria: above the group average: 67% correct or at least 7/10 correct trials).
Assumption 2: For a reliable preference, patients must correctly identify a certain number of same pairs (criteria: above the group average: 65% correct or at least 6/10 correct trials).
Of the five patients that initially indicated a preference for either current or voltage, only one patient could consistently identify the pulse for which they indicated a preference (highlighted in green). The colors correspond to the category the patient was placed into in Panel 1.

CONCLUSIONS

The charge per pulse did not differ when similar parasthesia intensity was obtained in voltage and current modes.

At similar paresthesia intensity, (9/14) patients did not indicate a preference for either CV or CC. When a preference was initially indicated (5/14), in only one (1/14) case did the blinded, randomized portion of the study support the patient's perceived stimulation preference.

As per our previous report, patients have a difficult time determining that two identical pulse pairs are the same, and/or that different pulse pairs are different. Only 3/14 patients performed well (above the group average) in identifying both same and different pulse pair trains. Two preferred CV and one preferred CC.

In this study a small number of patients (5/14) subjectively asserted a difference between CC and CV stimulation. However, the difference in sensation was not great enough for the patients to consistently pick out their initial preference during objective blinded pulse trials (1/14).

This study suggests that caution should be used when interpreting studies that assess patient preference after a single crossover trial of voltage- and current-controlled stimulation.

REFERENCES

1. Voltage versus current stimulation pulse trains in patients undergoing spinal cord stimulation (SCS) trial. North American Neuromodulation Society (NANS) 12th Annual Meeting Conference Poster.

ACKNOWLEDGEMENTS

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NEUROSTIMULATION SYSTEMS FOR PAIN THERAPY

Brief Summary: Product manuals must be reviewed prior to use for detailed disclosure.

Indications
Implantable neurostimulation systems - A Medtronic implantable neurostimulation system is indicated for spinal cord stimulation (SCS) system as an aid in the management of chronic, intractable pain of the trunk and/or limbs-including unilateral or bilateral pain associated with the following conditions:

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Contraindications
Diathermy - Do not use shortwave diathermy, microwave or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and cause tissue damage at the locations of the implanted electrodes, resulting in severe injury or death.

Warnings
Sources of strong electromagnetic interference (eg, defibrillation, diathermy, electrocautery, MRI, RF ablation, and therapeutic ultrasound) can interact with the neurostimulation system, resulting in serious patient injury or death. These and other sources of EMI can also result in system damage, operational changes to the neurostimulator or unexpected changes in stimulation. Rupture or piercing of the neurostimulator can result in severe burns. An implanted cardiac device (eg, pacemaker, defibrillator) may damage a neurostimulator, and the electrical pulses from the neurostimulator may result in an inappropriate response of the cardiac device.

Precautions
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