

## Constant Current vs. Constant Voltage Systems for Temporal Spinal Cord Stimulation for Intractable Pain

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Although spinal cord stimulation (SCS) is a useful treatment for chronic intractable pain, the optimal method of stimulation has not yet been established. In this prospective, crossover study, we compared the efficacy of using a constant current (CC) system with that of a constant voltage (CV) system for temporal SCS. Twenty patients were enrolled and divided into two groups. For 10 patients, a CV system was applied on Days 1-5, followed by the use of a CC system on Days 6-10. For the other 10 patients, a CC system was applied for the first five days, followed by a CV system for the subsequent five days. We evaluated the alteration of pain intensity using a visual analogue scale (VAS), the area of stimulation, the stability of effect, and patient satisfaction regarding treatment. The pain scores decreased significantly after the start of the SCS. There was no significant difference in the change in VAS between the two systems. The stimulation method used for temporal SCS did not affect the reduction of pain intensity. Patients felt a wider stimulation area by the CC system compared to the CV system.

**Key words:** spinal cord stimulation, constant current system, constant voltage system, chronic intractable pain, pain score

Since Shealy *et al.* [1] reported a successful case of dorsal column stimulation (currently known as spinal cord stimulation or SCS) for the treatment of cancer pain in 1967, the effectiveness of SCS for chronic intractable pain has been investigated [2,3]. The more recent development of SCS has depended largely on improvements of the stimulation devices' components such as electrodes and generators. Two different types of electrical stimulators are currently available: constant current (CC) systems and constant voltage (CV) systems. The first successful case of SCS was performed using a CV system in 1967 [1], and a CC system was first used in 1997. Subsequently, several

studies have shown the efficacy of both CV systems and CC systems [4,5].

For effective pain relief, it is necessary to provide sufficient coverage of the affected area with the paresthesia induced by SCS [6-8]. Since the method of stimulation differs between CC and CV systems, the range of paresthesia induced by the 2 methods is thought to differ even when the electrode is placed at the same position. A CV system supplies fixed (*i.e.*, constant) voltage by varying the amount of current, depending on changes in the resistance. Conversely, a CC system supplies a constant current by adjusting the voltage in response to resistance. Therefore, if the resistance increases during SCS, a CC system provides constant

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current, whereas in a CV system the current decreases as the resistance increases. As a CV system delivers the maximum current at the start of stimulation, its efficacy may decrease as the resistance increases. Although differing efficacies of CC and CV systems have been reported [9, 10], these results have been controversial.

In this prospective, crossover study, we investigated whether a CC system and a CV system in SCS used to treat intractable pain differed with regard to analgesic efficacy and patient preference.

### Methods

This study was approved by the institutional ethics committee of Kobe University (Approval No. 1227). Written, informed consent was obtained from all patients, and the study was performed in accordance with the principles outlined in the Declaration of Helsinki.

**Patients.** Patients with chronic intractable pain participated in this prospective crossover study. They were recruited by several physicians at Kobe University Hospital. All patients had been diagnosed with neuropathic pain resistant to both pharmacological treatment (including anti-inflammatory drugs, opioids, antidepressants, and anticonvulsants) and nerve block therapy. Only patients who had pain with a spinal nerve distribution were selected; patients with head, neck, and/or facial pain were excluded. Patients with blood coagulation abnormalities and psychiatric disorders were also excluded.

We divided the patients into 2 groups, according to the method of SCS employed. Patients were randomly assigned to the groups according to a computer-generated sequence contained in sealed, opaque envelopes.

**Spinal cord stimulation.** Percutaneous SCS was performed on all patients. Stimulation was applied through a lead inserted percutaneously via X-ray guidance with the patient in the prone position (Fig. 1). The lead had quadripolar electrodes, and stimulation was produced by an extracorporeal device. For the CV system, an extracorporeal device manufactured by Medtronic (Screening Stimulator, Minneapolis, MN, USA) was used, and for the CC system, an extracorporeal device manufactured by St. Jude Medical (Multiprogram Trial Stimulator, St. Paul, MN, USA) was used. The lead was placed at the appropriate site to provide 80% coverage of the affected area (Fig. 2).

Patients were asked to draw their pain distributions, and these diagrams were referenced to achieve precise coverage of the affected area by carefully adjusting stimulator parameters.

SCS was carried out for 10 days in all patients. We divided the patients randomly into 2 groups of 10 each for a crossover study. One group patients had a CV system applied from Day 1 to Day 5; this was changed to a CC system from Day 6 to Day 10 (the CV-CC group). The other group had the CC system applied for the first 5 days, and then the CV system was applied for the next 5 days (the CC-CV group) (Fig. 3).



Fig. 1 The spinal cord stimulation (SCS) lead insertion procedure.

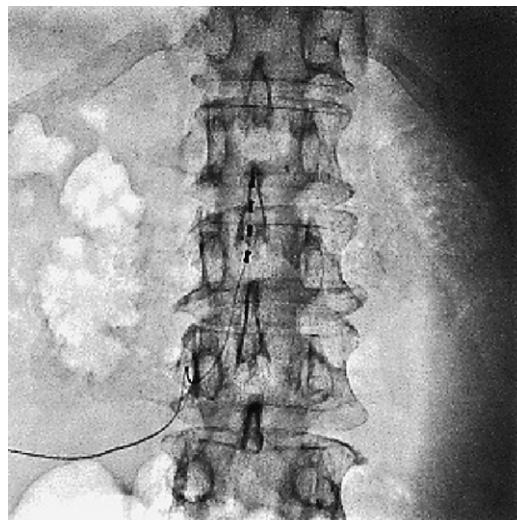
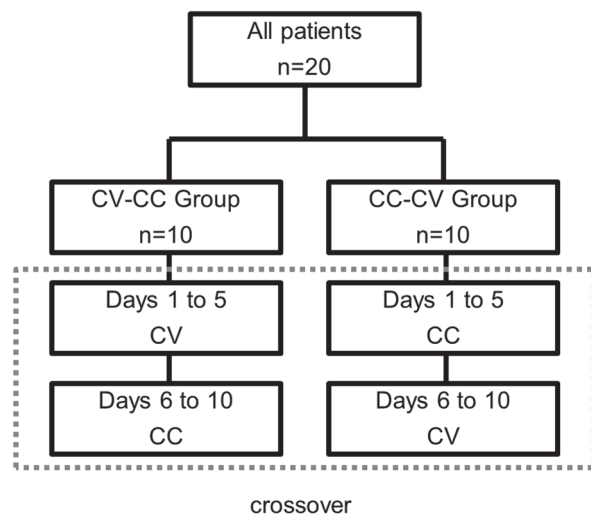


Fig. 2 Example of staggered lead placement in SCS.



**Fig. 3** Patients were randomized into 2 groups ( $n=10$  each). The CV-CC group received 5 consecutive days of stimulation by the constant voltage (CV) system followed by 5 consecutive days of stimulation by the constant current (CC) system. The CC-CV group received 5 consecutive days of stimulation by the CC system followed by 5 consecutive days of stimulation by the CV system.

The stimulation parameters (intensity, frequency, and pulse-width) were set on the first day of SCS lead insertion, and this was not changed during the study period.

**Pain evaluation.** We evaluated the change in the patients' pain intensity with the use of a visual analogue scale (VAS); the patients' scoring on the VAS was used as the primary outcome. We also recorded the area of stimulation, the stability of the effect, and patient satisfaction regarding SCS treatment as secondary outcomes.

**VAS.** The attending physician at our pain clinic recorded the VAS for each patient at the patient's initial examination. A 100-mm scale plate was used to assess the patients' VAS score, where 0 mm indicated no pain, and 100 mm indicated maximal pain. During the study, the daily average VAS of each patient was recorded before he or she went to bed.

**Area of stimulation.** For effective analgesia, the area of stimulation must cover the affected region precisely. However, the area where stimulation is obtained varies according to the patient's posture and/or activities of daily living. We therefore asked the patients which system provided the most appropriate cover on the last day of their SCS (the tenth day from inception of SCS).

**Stability of effect.** Because patients with chronic, intractable pain have been suffering for a long time, it is crucial to determine whether or not the effect of SCS is stable. Patients were thus asked on the last day of SCS which stimulation method had provided the most stable effect on their pain.

**Patient satisfaction.** We also asked the patients which system provided the most satisfactory pain relief.

**Statistical analysis.** Data are expressed as means (95% confidence interval, 95%CI) or  $n$  (%). The comparisons of the 2 groups' data was done using the  $t$ -test and Fisher's exact test. To compare the change in VAS values between the 2 groups, we performed a two-way, repeated analysis of variance (ANOVA) test. A  $p$ -value  $< 0.05$  was considered significant. Statistical analyses were performed using SPSS software, ver. 20.0.

## Results

**Patient characteristics.** Twenty patients with chronic intractable pain participated; their characteristics are summarized in Table 1. We randomly divided the patients into a CV-CC group and a CC-CV group of 10 patients each. The patients' ages ranged from 44 to 81 years, with a mean (95%CI) of 67.8 (62.0, 73.5) years. There was no significant difference in age between the 2 groups. Six were male (30%), 14 were female (70%) and there were also no significant differences in sex between the 2 groups.

Post-herpetic neuralgia (PHN) was the most prevalent diagnosis, occurring in 8 patients (40%), followed by spinal canal stenosis in 5 patients (25%). Of the latter, 4 patients had lumbar stenosis and one had cervical stenosis. Patients with cervical and lumbar spinal canal stenosis were diagnosed as having neuropathic pain with unilateral or focal radiculopathy. Three patients (15%) were diagnosed with complex regional pain syndrome, and 3 others (15%) were diagnosed with failed back surgery syndrome. One patient was diagnosed with peripheral neuropathy (5%). There was no significant difference between the 2 groups regarding diagnosis.

Regarding the affected regions, 12 patients (60%) had a lumbar spinal nerve distribution of pain, followed by 4 patients with a cervical distribution and another 4 with a thoracic distribution. There was no significant difference between the 2 groups regarding the distribution of pain. The mean (95%CI) duration of onset of disease to the commencement of SCS in the

CV-CC group was 12.5 (4.9, 20.1) months. In the CC-CV group this was 11.4 (1.3, 21.5) months. The difference in duration between the 2 groups was not significant.

**Analgesic effect (Change in VAS).** The mean (95%CI) VAS of all patients at their initial consultations at our hospital was 85.3 (74.5, 96.0) and did not differ significantly between the 2 groups: The mean (95%CI) in the CV-CC group was 89.5 (78.9, 100.1), whereas in the CC-CV group this was 81.0 (63.6, 98.4). After the first visit, the VAS of all patients decreased gradually after treatment with medication and/or neural blockade. The VAS immediately prior to the present study commencement was 57.5 (42.1, 72.9) in the CV-CC group and 58.0 (45.2, 70.8) in the CC-CV group, with no significant difference between the 2 groups (Table 1).

During the 10-day study period, the VAS scores decreased significantly after the start of SCS in both groups ( $p < 0.001$ ) (Fig. 4). However, there was no significant difference in the change in VAS during the study period between the 2 groups ( $p = 0.57$ ) (Fig. 4). We

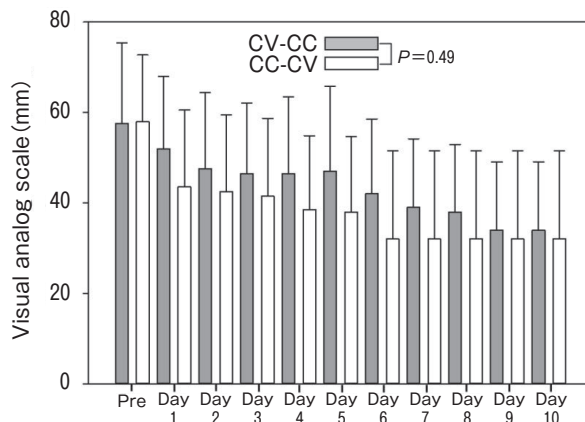


Fig. 4 Time course of analgesic effect. Gray bar: The sequential changes in the visual analog scale (VAS) during SCS in the CV-CC group. White bar: The change in VAS during SCS in the CC-CV group. There was a significant change in VAS during the time course ( $p = 0.016$ ). However, there was no significant difference between the 2 groups ( $p = 0.49$ ).

Table 1 Patient characteristics

	CV-CC group (n = 10)	CC-CV group (n = 10)	p-value
Age (years)	65.4 (58.1, 72.7)	70.1 (62, 78.2)	0.41
Males: females	4:6	2:8	0.63
Diagnosis			
PHN	3 (30%)	5 (50%)	0.79
LSCS	2 (20%)	2 (20%)	
CRPS	2 (20%)	1 (10%)	
Others	3 (30%)	2 (20%)	
Pain location			
Cervical	1 (10%)	3 (30%)	0.51
Thoracic	2 (20%)	2 (20%)	
Lumber	7 (70%)	5 (50%)	
VAS at initial consultation	89.5 (78.9, 100.1)	81 (63.6, 98.4)	0.42
VAS before SCS placement	57.5 (42.1, 72.9)	58 (45.2, 70.8)	0.96
Duration from onset to study	12.5 (4.9, 20.1)	11.4 (1.3, 21.5)	0.87
Duration from onset to study	12.5 (4.9, 20.1)	11.4 (1.3, 21.5)	0.87

Data are presented as n (%) or mean (95%CI), as appropriate. CV, constant voltage; CC, constant current; PHN, post-herpetic neuralgia; LSCS, lumbar spinal canal stenosis; CRPS, complex regional pain syndrome; VAS, visual analogue scale; SCS, spinal cord stimulation.

\*Others: 3 patients had Failed Back Surgery Syndrome, 1 patient had cervical spinal stenosis, and 1 patient had peripheral neuropathy.



compared the VAS scores between the 2 groups during the CV system usage and that of the CC system (Fig. 5). No significant difference in the VAS scores was revealed between the uses of CV and CC ( $p=0.8$ ).

**Area of stimulation.** Regarding the area of stimulation, each patient was asked on the last day of the study whether they reported better coverage of the affected area during the first 5 days or the last 5 days. Eight patients (40%) reported that the CC system was superior to the CV system in this regard. No patient reported that the CV system was superior. Twelve patients reported that there was no difference between the 2 systems (60%). The CC system was significantly better than the CV system regarding the area of stimulation provided ( $p=0.005$ ) (Table 2). The voltage in the CV system ranged from 1.5 to 6.0 V, and the electric current in the CC system ranged from 1.5 to 4.0 mA.

**Stability of effect.** Nine patients reported that the CC system provided greater stability of effect than the CV system (45%). Four patients reported that CV system was more stable than the CC system (20%). Seven

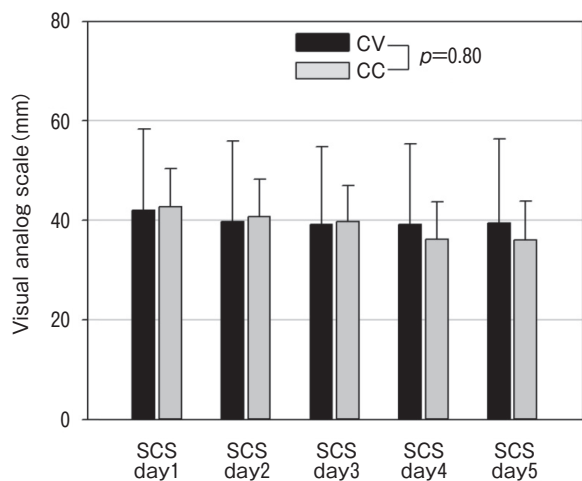
patients reported no difference between the CC and CV systems (35%). There was no significant difference in the stability of effect between the CV and CC systems ( $p=0.17$ ) (Table 2).

**Patient satisfaction regarding SCS treatment.** Four patients preferred the CV system (20%) whereas 9 preferred the CC system (45%). Seven patients reported no difference between the CC and CV systems. There was no significant difference in patient satisfaction between the CV and CC systems ( $p=0.17$ ) (Table 2).

### Discussion

We compared the efficacy of a CC system and a CV system for providing temporal SCS for intractable pain. Both systems provided significant decreases in reported pain scores after the commencement of SCS. However, there was no significant difference between the 2 systems regarding the change in VAS. While patient satisfaction and effect stability did not differ between the systems, the area of stimulation provided by the CC system was larger than that provided by the CV system.

The mechanism of analgesic efficacy in SCS is based on Melzack's gate control theory [11]. SCS may modulate pain signal inputs by covering the painful area with impulses traveling in the opposite direction to pain signals originating from the dorsal column [2, 12, 13]. For effective treatment, it is very important that the dorsal column is precisely stimulated. Schade *et al.* used 15 sec of constant current or constant voltage stimulation to evaluate whether patients could detect a difference in the paresthesia induced by SCS [9]. In the present study, we examined patients for 2 periods of 5 days each, during which they received treatment with either the CV or CC system followed by a crossover. We then compared the efficacy of pain reduction, the stability of stimulation, the area of stimulation, and patient satisfaction. There was no significant difference between the 2 systems in analgesic efficacy as measured by the VAS. This suggests that the type of SCS system employed has no impact on analgesic efficacy when the



**Fig. 5** Summary of the analgesic effects. The black bar indicates sequential changes in VAS during SCS by the CV system. Gray bar: The change in VAS during SCS by the CC system. There was no significant difference between the analgesic effect provided by the CV and CC systems ( $p=0.80$ ).

**Table 2** Outcome assessment

	CV > CC	CV = CC	CV < CC	p-value
Stability of stimulation	4/20 (20%)	7/20 (35%)	9/20 (45%)	0.17
Area of stimulation	0/20 (0%)	12/20 (60%)	8/20 (40%)	0.005
Patient satisfaction	4/20 (20%)	7/20 (35%)	9/20 (45%)	0.17

same stimulation parameters (site of electrode, pulse-width, frequency, and amplitude) are set.

Most previous clinical studies investigating the effectiveness of SCS have looked at either a CC system or a CV system. There are few reports comparing the efficacy of both systems. Some recent studies evaluated the differences between a CC system and a CV system. Washburn *et al.* treated 30 patients with SCS using either a CC system or a CV system for 3 days each, and they reported that many patients preferred the CC system over the CV system, and that CC system reduced pain scores to a greater degree compared to the CV system [10]. Other reports have indicated that many patients did not experience any difference between the 2 systems [9], with only a few differences in efficacy reported [12]. How the type of stimulation system modulates analgesic effects remains a matter of controversy.

During the use of a CV system, the electrical current varies depending on tissue resistance, while the voltage remains constant. Conversely, a CC system provides a constant current flow by regulating the voltage according to the tissue resistance. This may be the reason why a CC system can achieve greater stability than a CV system, as well as why a CC system may provide superior analgesia. In our study, however, there was no significant difference in pain scores VAS or the stability of stimulation achieved. We speculate that there may be 2 reasons for this result.

First, although the pulse shape in 1 msec in response to resistance differs electrically between a CC system and a CV system, there is no physiologic difference between the 2 systems because the amount of energy that spreads due to stimulation is small, and the electric current that reaches the spinal cord is < 10% of the total current [14]. Second, the primary factor determining whether or not neurons are stimulated is the amount of charge (pulse width  $\times$  amplitude), not the type of stimulation system used. It is our opinion that the primary outcome that we measured VAS was influenced by these 2 factors.

In this study, we evaluated 3 additional parameters as secondary outcomes (the area of stimulation, the stability of stimulation, and patient satisfaction) to compare the differences between the CC and CV systems in detail. The only significant difference revealed was that the CC system provided a wider area of stimulation than the CV system. A CC system produces a rectangular-shaped voltage pulse because the voltage,

rather than the current, changes in response to the resistance. A CV system, in contrast, delivers a spike-shaped pulse (which results from a steep rise at the beginning of the pulse) and a slow decay of the resultant current, in response to resistance.

Several studies suggested that different pulse shapes can selectively activate nerve fibers of varying diameters under specific conditions [15-18]. The spiked pulses of a CV system may not be ideal for activating the A $\beta$  fibers associated with touch sensation within the dorsal columns, and these pulses may be painful, especially at the beginning of the pulse. With a CC system, increased stimulation may result in a greater area of analgesic cover. These factors may explain the wider coverage achieved when the CC system was used in the present study.

Regarding patient satisfaction, our patients' reports showed no significant difference between the CC and CV systems. Patient satisfaction is influenced by factors such as the patient's backgrounds, previous treatment, and the severity and intensity of pain. We suspect that the main reason why patient satisfaction did not differ between the 2 groups was that the 2 systems provided equivalent analgesic efficacy.

There are several limitations to this study. First, this was a single-center study, with a small number ( $n=20$ ) of eligible participants, *i.e.*, patients with intractable pain resistant to multiple treatment modalities. However, this is a greater number of patients compared to previous reports. Second, we evaluated patients with a chronic condition for a limited period (10 days), but SCS for a chronic pain is applied over a period of months or years. When resistance to SCS therapy develops during a longer period, a CC system may be favorable as it can provide constant current. Further studies examining subjects over a longer period are required. Third, although we evaluated the differences between 2 systems by looking at 4 factors, many other variables should be considered to comprehensively evaluate pain profiles. Finally, we were unable to compare amplitude and resistance values and changes between the 2 systems. Different results may have been recorded if we had altered stimulation settings.

In conclusion, the type of stimulation method employed did not affect analgesic efficacy. There were no significant differences between the CC system and the CV system regarding patient satisfaction and the stability of stimulation. A CC system might provide a

greater area of coverage compared to CV systems.

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