

# Clinical outcomes of running with FAST and contour stimulation in the spinal cord stimulation therapy trial only in Japan

## Abstract

**Purpose:** Using Fast-Acting Sub-Perception (FAST) and Contour Therapy, new stimulation settings for spinal cord stimulation therapy, we investigated whether patients with low back and leg pain were able to run after surgery in Japan.

**Method:** Spinal cord stimulation trial was conducted from 2023 to 2024 and a prospective study was conducted. Fifteen patients (6 male, 9 female) were evaluated on whether they could run after spinal cord stimulation therapy using the average walking time (seconds) when walking 210 cm and the Numerical Rating Scale (NRS) for pain assessment. Patient satisfaction was rated on a 5-point scale, with 5 being very satisfied, 4 somewhat satisfied, 3 normal, 2 somewhat dissatisfied, and 1 very dissatisfied. Sleep quality was rated on a 10-point scale. Statistical t-test was used and  $P < 0.01$  was considered a significant difference.

**Results:** The NRS showed improvement from 10 to 2.72. The average walking time was 3.48 seconds faster. Regarding patient satisfaction, 11 patients were very satisfied, 2 somewhat satisfied, 1 normal, and 1 somewhat dissatisfied. Sleep quality (good 10 to poor 0) improved from an average of 4.8 to 7.3. Twelve patients were able to run. Significant differences were found.

**Discussion:** FAST and Contour stimulation, new stimulation settings in spinal cord stimulation therapy, improved not only low back and leg pain, but also walking ability and sleep quality. We believe that patients feel more motivated and ultimately patients are able to run and patient satisfaction increase. As a new evaluation of spinal cord stimulation therapy, whether patients will be able to run should also be considered in the future.

**Keyword:** spinal cord stimulation, FAST, contour therapy, wave writer alpha boston scientific

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**Abbreviations:** FAST, fast acting sub-perception; NRS, numerical rating scale; SCS, spinal cord stimulation therapy; CPS, central points of stimulation

## Presentation of actual cases

85-year-old woman, Chief complaint: Low back pain, lower limb pain, Current medical history: She was diagnosed with lumbar spinal canal stenosis by an orthopedic surgeon at a nearby clinic and was treated with oral medication Figure 1. She had low back and leg pain, and intermittent claudication with bilateral low back pain and heaviness in the lower extremities after walking 50 m and unable to walk without rest. A spinal cord stimulation therapy trial (Boston Scientific) was performed at our hospital. In this trial, Fast-Acting Sub-Perception (FAST) stimulation was performed postoperatively, and she was able to walk more than 200 m the day after surgery with FAST stimulation alone, and the Numerical Rating Scale (NRS) improved from 10 to 2, and it was 0 after the trial at an outpatient visit one month later. The average walking time (in seconds) when walking 210 cm improved from 4.98 to 3.13 seconds. Satisfaction was rated on a 5-point scale, she was 5, very satisfied. Sleep quality (on a scale of 10) improved from 6 to 9. Back bending improved from 27 to 54 degrees. She was able to run after the trial. Three months have passed since the trial and her progress is good.

## Purpose

Newer stimulation methods in spinal cord stimulation therapy include Contour Therapy and Fast-Acting Sub-Perception Therapy

(FAST). Both of these treatments can be performed with paresthesia-free. Contour Therapy selectively stimulates the dorsal horn of the spinal cord and directly suppresses neuronal activity in the dorsal horn. FAST exerts surround inhibition of targeted areas in the posterior column of the spinal cord, selectively excites inhibitory interneurons, and suppresses input from A-delta and C fibers to WDR neurons. As a new treatment for low back and leg pain, we evaluated whether this treatment could not only suppress pain but also enable patients to run, as well as sleep quality, patient satisfaction, and walking time. Background of spinal cord stimulation therapy treatment in Japan will be presented.

## Methods

Fifteen patients (6 male, 9 female), mean age 79.8 years, who had undergone Contour Therapy and Fast-Acting Sub-Perception Therapy (FAST) by Boston Scientific, were evaluated on whether they could run after spinal cord stimulation therapy using the average walking time (seconds) when walking 210 cm, and pain was assessed using the Numerical Rating Scale (NRS). Patient satisfaction was rated on a 5-point scale, with 5 being very satisfied, 4 somewhat satisfied, 3 normal, 2 somewhat dissatisfied, and 1 very dissatisfied. Sleep quality was rated on a 10-point scale (bad 1 to good 10).

## Results

Twelve patients (80%) were able to run Figure 2, 3. The NRS showed improvement from 10 to 2.72 Figure 4. The average walking time was 3.48 seconds faster. Regarding patient satisfaction, 11

patients were very satisfied, 2 somewhat satisfied, 1 normal, and 1 somewhat dissatisfied Figure 5. Sleep quality (good 10 to poor 0) improved from an average of 4.8 to 7.3 Figure 6.

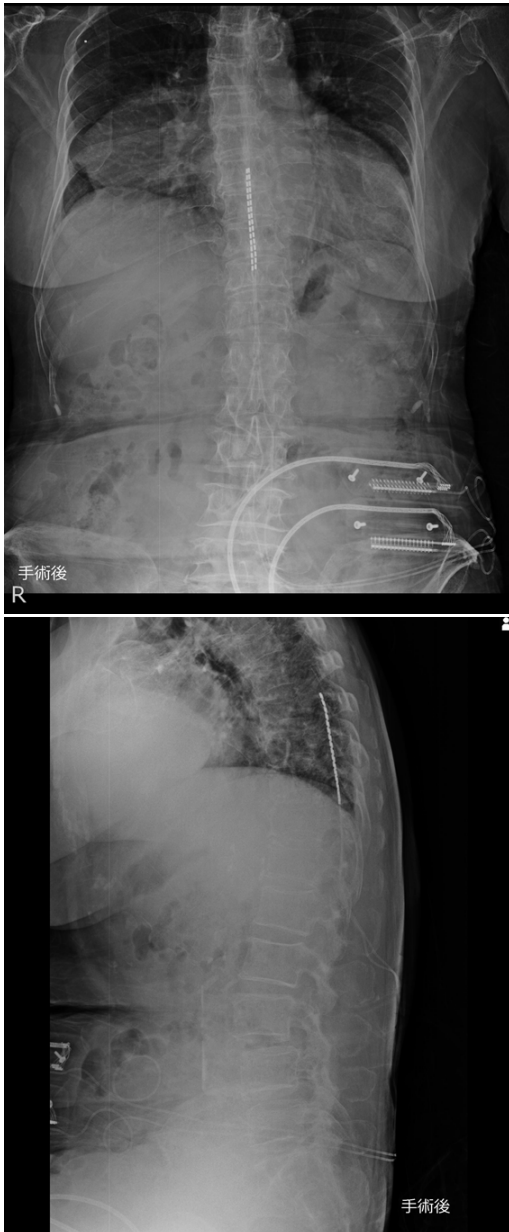


Figure 1 X-ray frontal and lateral views after spinal cord stimulation therapy trial.

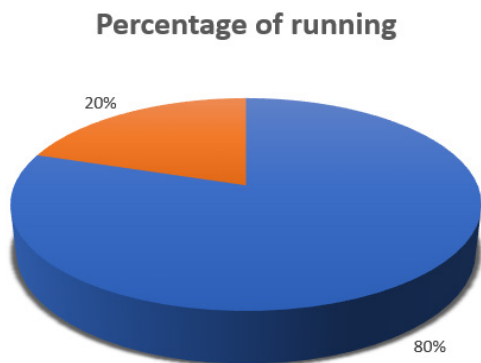


Figure 2 Percentage of patients who could run.



Figure 3 Patient able to run after spinal cord stimulation trial.

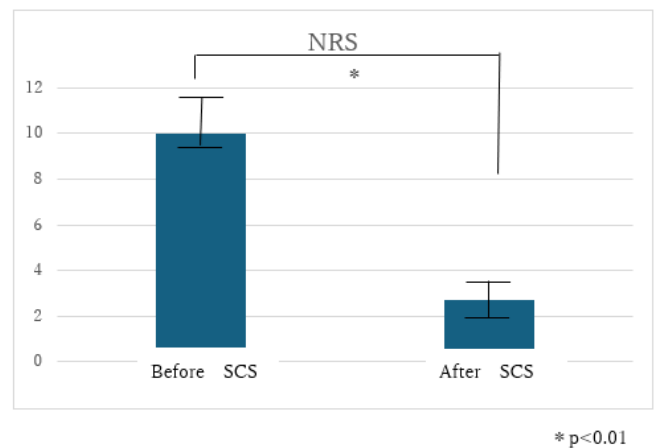


Figure 4 NRS before and after spinal cord stimulation trial.

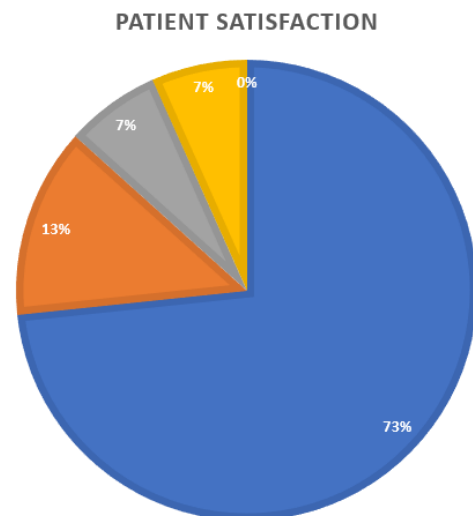
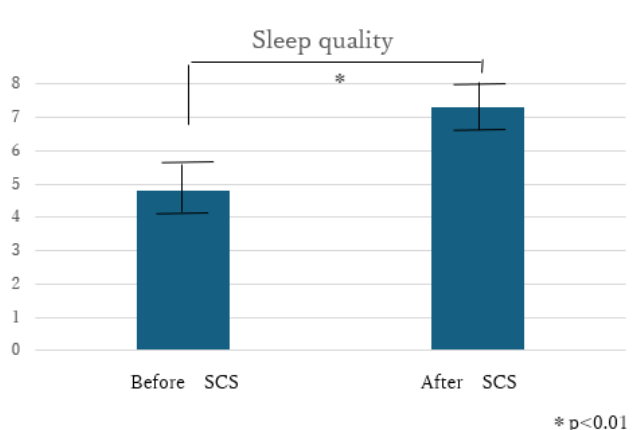


Figure 5 Patient satisfaction after Spinal Cord Stimulation.



**Figure 6** Sleep Quality before and after spinal cord stimulation trial.

## Discussion

Spinal cord stimulation therapy (SCS) is a treatment in which spinal cord stimulating electrodes called leads are inserted into the epidural space to deliver a weak electric current to the posterior column of the spinal cord, resulting in pain relief and improved blood flow. It is considered that spinal cord stimulation therapy requires consultation, examination, and appropriate diagnosis by an orthopedic surgeon, technique and knowledge by an anesthesiologist, and specialized evaluation and rehabilitation training by a rehabilitation doctor. Therefore, it is very important for multiple professions to work together. Although the procedure should take as little time as possible, it is necessary to spend time intraoperatively adjusting the stimulation after electrode insertion. The most important aspect of spinal cord stimulation therapy treatment is to ensure that the posterior cords are stimulated and that the electrodes are in the median. Although pain and daily living are often assessed as part of the evaluation of spinal cord stimulation therapy, some reports suggest that patient satisfaction should be assessed by performing multifaceted evaluations.<sup>1</sup> In fact, although the pain has not improved, there is symptomatic improvement in posture, walking time, and activities of daily living, as well as the ability to run. As for the surgical procedure, the procedure is performed in the supine position under local anesthesia, and electrical stimulation is adjusted from an external tablet device. The paresthesia is confirmed while talking with the patient, and a lead (electrode) is placed in the epidural.

FAST stimulation is a stimulation method that maximizes analgesic effects at an early stage by performing peripheral inhabitation of the central points of stimulation (CPS) in the posterior column of the spinal cord. Paresthesia can be identified during surgery to allow stimulation to reach the pain site. First, before stimulation, a uniform electric field is created in the plane, by calculating it using Boston Scientific's stimulation system, MICC (Multiple Independent Current Control) and a three-dimensional spinal cord model is constructed. Then, Illumina 3D, which makes it easy to program recommended electrode configurations by simply selecting the area to be stimulated (CPS) based on lead placement and a 3D spinal cord model, makes it possible to easily overlap paresthesia. Boston Scientific electrodes have up to 16 electrodes, allowing the use of leads with narrow electrode spacing to reliably stimulate the CPS. Active Recharge, a method of releasing the charge and then forcing it back, is now possible in the range of 2 to 1,200 Hz, allowing for more effective nerve activation at lower frequencies. For FAST stimulation, the output is set to 30% of the threshold of paresthesia, the frequency to

90 Hz, and the pulse width to 160-260  $\mu$ s. The average effect onset time is reported to be 11.2 minutes.<sup>2</sup>

Metzger et al.,<sup>2</sup> reported that FAST stimulation in 41 of 66 patients with lower back and lower extremity pain who went on to implantation resulted in 81.5% improvement in low back pain and 81.7% improvement in lower extremity pain, with analgesic effects maintained. Contour Therapy is a stimulation method that creates a uniform electric field in the plane, minimizes activation of the dorsal cords, selectively stimulates the dorsal horn of the spinal cord, and directly inhibits neurocyte activity in the dorsal horn. It stimulates a wide area, reliably captures the area to be stimulated, and elicits analgesic effects. For stimulation, the output is set to 50% of the threshold of paresthesia, the frequency to 200 Hz, and the pulse width to 200  $\mu$ s.

Paz et al.,<sup>3</sup> reported that contour stimulation reduced low back pain by 67% and leg pain by 72% in 30 patients with back and leg pain. It also states that the 200 Hz stimulus setting maintained the analgesic effect. Spinal cord stimulation therapy is indicated for the treatment of chronic intractable pain and has often been performed on patients with failed back surgery syndromes and peripheral vascular diseases until now. However, our institution actively uses its treatment to back pain and leg pain caused by orthopedic disorders such as compression fractures of the thoracolumbar spine or lumbar spinal stenosis. Compression fractures often result in residual and chronic low back pain, which interferes with daily life. Therefore, in the case of patients with chronic intractable pain that does not improve with drug treatment or nerve blocks after approximately two months or more, aggressive therapeutic intervention should be started early on. This often leads to not only pain relief, but also to faster gait initiation, improved posture, and easier turning over and getting up movements. It is also important to be active during hospitalization with rehabilitation. Our clinic also uses self-initiated exercises, such as patients walking in the corridor or doing bending exercises while holding on to the handrails by themselves.<sup>4</sup> With combined rehabilitation, muscle strength and balance ability may also improve after the trial, and the patient may be able to run.

AJ Awad et al.,<sup>5</sup> conducted a retrospective study from 2013 to 2020 and reported that spinal cord stimulation therapy for intermittent claudication in lumbar spinal canal stenosis during conservative treatment improved intermittent claudication and remained good conditions for at least 2 years, regardless of whether or not spinal surgery was performed. In recent years, spinal cord stimulation therapy has been positioned as a conservative treatment for orthopedic low back and leg pain. Considering the unique characteristics of spinal cord stimulation therapy, it may be a good indication to use spinal cord stimulation therapy as a conservative treatment rather than spinal surgery in order to increase patient satisfaction in patients who do not want to undergo surgery or who are inoperable due to the risk of surgery and who do not respond to pharmacologic therapy or nerve block therapy. The ability to perform treatment with puncture-trial is the greatest advantage of spinal cord stimulation therapy over other surgical treatments. In addition, since the procedure can be performed under local anesthesia, it is less invasive and relatively safe even in the presence of underlying diseases. The patients are hospitalized for one week for careful and multifaceted evaluation and consultation, and are trained by a rehabilitation specialist.

It has 16 electrodes available and incorporating them into spinal cord stimulation therapy treatment while taking advantage of a wide range of stimulation settings can help patients feel more positive, improve motivation, and ultimately enable them to run. Patients may

want to continue good condition after discharge from the hospital only for a trial and continue to do well in rehabilitation at home, or they may want to devote more time to their hobbies. In spinal cord stimulation therapy, it is important for the health care provider to evaluate the patient from multiple perspectives, find out what the patient can do, and praise he or her to do so. FAST and Contour stimulation in spinal cord stimulation therapy could be a new treatment option for patients with chronic intractable pain caused by compression fractures of the thoracolumbar spine and lumbar spinal canal stenosis, which are common orthopedic conditions in daily practice.

## Acknowledgments

None.

## Conflicts of interest

The author declares that there is no conflicts of interest.

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