

Highly Significant Pain Reduction with the Precision Spectra™ Spinal Cord Stimulation (SCS) System

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Presented at the 2013 North American Neuromodulation Society (NANS) Annual Meeting

Purpose

- Presenting outcome data from a retrospective, multi-center study of the Precision Spectra SCS System.

Methods

- Retrospective, consecutive case-series of 213 patients who underwent Precision Spectra trials at 13 sites. Among them, 113 patients proceeded to permanent implant at the time of this analysis.
- Clinical outcomes were analyzed in terms of baseline and 3 month post-implant pain intensity, percent pain relief, sleep improvement, medication reduction, and the activities of daily living. The outcomes were also analyzed for a subgroup of severe patients (NRS 8 – 10).
- The number, type and location of leads used during the permanent implant were also reported.

Patient Cohort

Among the 213 patients who underwent SCS trials,

- 41% of patients reported low back and leg pain, 36% of patients reported low back pain only, 23% of patients reported leg pain only
- Baseline pain intensity has a median of 7.4 points

Results

- Ninety-six percent (96%) of patients achieved greater than 50% perceived pain relief (PPR) at end of the trial period
- At three month post implant, patients (n=113) showed a highly statistically significant reduction in pain

intensity ($p < 0.0001$) with a mean change of 4.60 points (± 2.81) from a baseline numeric rating scale (NRS) of 7.78 (Figure 1)

- Severe patients (n=61) demonstrated an even greater improvement with a mean change of 5.41 points (± 2.64) from a baseline NRS of 8.86. (Figure 1)

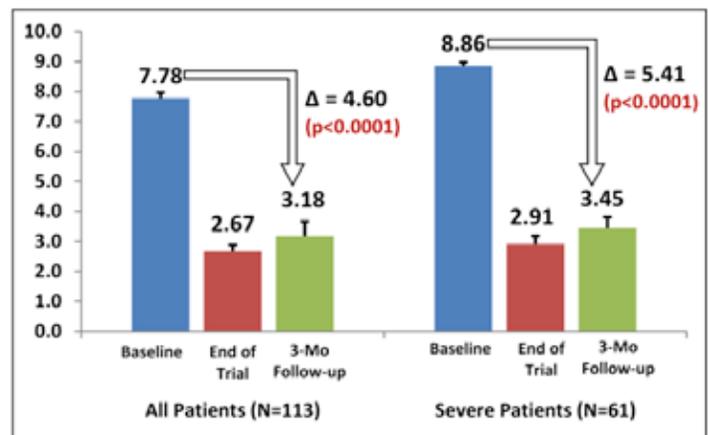


Figure 1

- Other clinical improvements reported by these patients included improvement in activities of daily living, sleep, physical function, and medication reduction.
- Leads were placed primarily between T6 and T8 with the Spectra system allowing for a wide range of lead configurations (Figure 2). The predominant mode of implant for Spectra was two 1x16 Infinion leads (40% of patients). Seventy percent of patients were treated with configurations using 24 – 32 contacts.

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Clinical Summary

Clinical Outcomes with Spectra Treatment

Lead Configurations	
One 1x8 lead (8 contacts)	1%
Two 1X8 leads (16 contacts)	26%
One 1X16 Infinion lead (16 contacts)	1%
One 2x8 paddle (16 contacts)	2%
Three 1X8 leads (24 contacts)	16%
One 2x8 paddle + One 1x8 (24 contacts)	1%
Four 1X8 leads (32 contacts)	12%
Two 1X16 Infinion (32 contacts)	40%
One 1x16 Infinion + Two 1X8 (32 contacts)	1%

Figure 2

Author Conclusions

- In our early real-world, multi-center, consecutive patient experience with the Precision Spectra system in a diverse cohort of 213 patients across 13 different clinical sites, we found very a high trial success rate (94%) and sustained pain relief through 3 months post-implant.
- The Precision Spectra System is being implanted with a broad range of lead configurations, with 9 different configurations used, and 70% of patients treated with lead configurations with more than 16 contacts.
- A limitation of this study is its retrospective nature. Consecutive enrollment was mandated to minimize bias. These patients will continue to be followed long term.

Discussion Points

- What kind of pain reduction do you routinely see in severe patients 3 months post implant?

In this study, severe patients reported statistically significant mean NRS change of 5.41 points from baseline NRS of 8.86 ($p < 0.0001$).

- Do you see the need of using a variety of lead configurations to treat different pain patterns?

In this study, 9 different configurations were used with Precision Spectra, and 70% of patients were treated with more than 16 contacts.

Indications for Use. Boston Scientific's Spinal Cord Stimulator systems (SCS) are indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with failed back surgery syndrome, intractable low back pain and leg pain. **Contraindications.** The Spinal Cord Stimulator systems are not for patients who are unable to operate the system, have failed trial stimulation by failing to receive effective pain relief, are poor surgical risks, or are pregnant. **Warnings.** Patients implanted with a Spinal Cord Stimulator system should not be exposed to Magnetic Resonance Imaging (MRI). Exposure to MRI may result in dislodgement of the stimulator or leads, heating of the stimulator, severe damage to the stimulator electronics and an uncomfortable or jolting sensation. As a Spinal Cord Stimulation patient, you should not have diathermy as either a treatment for a medical condition or as part of a surgical procedure. Strong electromagnetic fields, such as power generators or theft detection systems, can potentially turn the stimulator off, or cause uncomfortable jolting stimulation. The system should not be charged while sleeping. The Spinal Cord Stimulator system may interfere with the operation of implanted sensing stimulators such as pacemakers or implanted cardiac defibrillators. Advise your physician that you have a Spinal Cord Stimulator before going through with other implantable device therapies so that medical decisions can be made and appropriate safety measures taken. Patients should not operate motorized vehicles or potentially dangerous machinery with therapeutic stimulation switched "on." Your doctor may be able to provide additional information on the Boston Scientific Spinal Cord Stimulator systems. For a copy of the Boston Scientific Spinal Cord Stimulator Systems Patient Handbook, including the indications for use, contraindications, warnings, precautions, and side effects, call 866.360.4747 or visit ControlYourPain.com.

Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician. Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

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