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


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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)

• 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.
**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.

**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 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.