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)

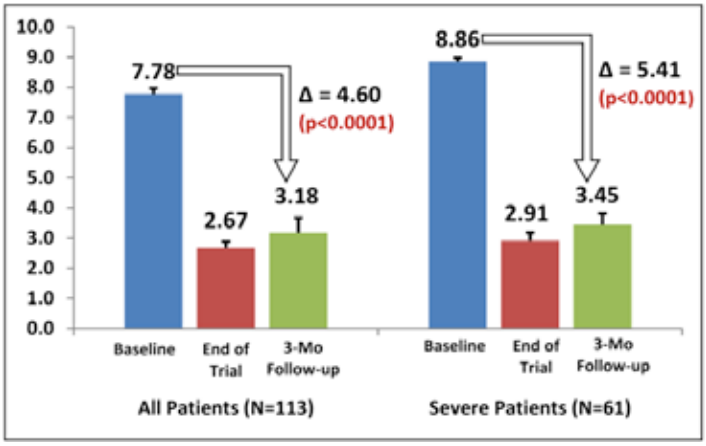

Figure 1

- 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.

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.

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