Early Clinical Experience with a New Spinal Cord Stimulation Lead for Multi-Site Pain

Romanth Waghmarae¹, Edward Washabaugh², Stephen Pyles³, Melinda Lawrence⁴,
Yu Pei⁵, Kristen Lechleiter⁵, Roshini Jain⁵

1. Advanced Pain and Wellness Institute, Williamsville, NY USA 2. Forest Health Medical Center, Ypsilanti, MI USA
3. Pain Treatment Centers, Ocala, FL USA 4. University Hospitals of Cleveland – Case Western Reserve Medical Center, Cleveland, OH USA
5. Boston Scientific, Valencia, CA USA

BACKGROUND

Chronic pain patients often report experiencing pain derived from multiple anatomical locations or dermatomes. Recent developments in Spinal Cord Stimulation (SCS) such as new neural targeting technologies and advancements in lead designs may be used to better treat patients with multi-site pain.

In this report, we present early clinical outcomes/experience using a newly available lead with a longer span covering over 3 vertebral levels and minimal spacing between electrodes (versus other traditional linear designs) used as part of an SCS system for treating chronic pain.

METHODS

Study Design	Multicenter, Consecutive, Observational, Case-series (n = 29)
Study Device	Multiple Waveform SCS system (Precision and Precision Spectra, Boston Scientific) with following capabilities: 16-contact lead with 1 mm spacing between electrodes (Infinion CX, Boston Scientific) - Multiple Independent Current Control (MICC) - Anatomically-Guided (3D) Neural Targeting (Precision Spectra) - Multiple available waveforms and/or field shapes
Follow-up Duration	45.4 (41.7) days post-implant [Mean (SD)]
Key Inclusion	Real-World Chronic Pain Patient Cohort

RESULTS

Baseline Demographics (n = 29)

Gender - Females (%)	44.4% (12/27)
Age [Mean (SD)]	56.4 (12.0) yrs. n = 28
Pain Location (n = 29)	Back and Leg(s) – 51.7%
	Lower Limb(s) – 20.7%
Baseline NRS [Mean (SD)]	8.6 (1.5) n = 29
Follow-up duration [Mean (SD)]	45.4 (41.7) days n = 27

Distribution of Percent Pain Relief at Last Follow-up (n = 25*)

- Sixty percent (15 of 25) of patients reported 71 – 100% improvement in overall targeted pain at their last follow-up.
- Ninety six percent (24 of 25) of patients reported greater than 50% improvement at their last follow-up

Change in Overall Pain Scores (NRS) at Last Follow up (n = 29)

A statistically significant improvement in overall pain (8.6→2.7) was reported at a mean last follow-up duration of 45 days post-implant.

Distribution of Overall Pain Scores at Last Follow-up (n = 29)

CONCLUSIONS

- A 16-electrode lead with minimal contact spacing and longer vertebral span offers the possibility to improve patient outcomes, target multiple sites of pain, and mitigate the loss of analgesia or need for revision due to lead migration.
- In this small, multicenter, real-world cohort of 29 patients with chronic pain, a statistically significant improvement in overall pain (p < 0.0001) was reported at their last follow-up (mean = 45 days post-implant).
- Over 96% of patients reported >50% improvement at last follow-up.