Outcomes Using an SCS Device Capable of Delivering Combination Therapy (Simultaneous or Sequential) and Advanced Waveforms/Field Shapes

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BACKGROUND

In recent years, spinal cord stimulation (SCS) technology has undergone a surge in advances and techniques that all aim to improve the induction of pain relief in patients with chronic pain. These developments include use of different frequencies[1-3], field shapes[4], and neural anatomical targets[5]. Given the diversity of options now available to patients, developing "all-in-one" SCS systems that possess the capability and flexibility for multiple types of neurostimulation paradigms will likely empower patients to identify the best treatment approach suitable for their own particular needs. In this report, we present patient outcomes using a new SCS System designed to offer patients the capability to personalize SCS by offering combination therapy (simultaneous or sequential) and waveform automation.

METHODS

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Study Design	Multicenter, Consecutive, Observational, Case-Series
Study Device	Multiple Waveform SCS system (Spectra WaveWriter, Boston Scientific) with the following capabilities: • Combination Therapy (sequentially or simultaneously) • Multiple waveforms and advanced field shapes • Waveform automation
Sample Size	79 patients diagnosed with chronic pain
Key Inclusion	Real-World cohort, implanted on-label.

RESULTS

Baseline Demographics (N=79)

Gender - Females (%)	53% (41/78)
Age [Mean (SD)]	60.2 (14.5) yrs. n = 79
Pain Location (%)	Low Back Pain (76%)
	Low Back and Legs (81%)
Baseline NRS [Mean (SD)]	7.7 (1.7) n = 79
Follow-up duration [Mean (SD)]	32 (34.3) days n = 75

Change in Overall Pain Scores (NRS) at Last Follow-up (n = 79)
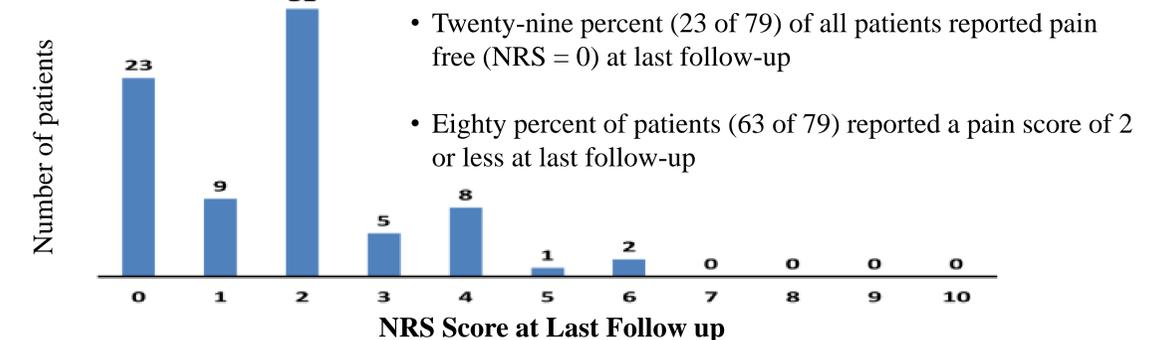

Δ = 6.0 (p < 0.0001)
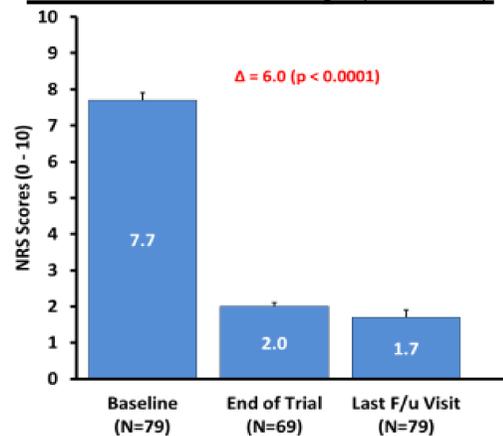
Distribution of Percent Pain Relief at Last Follow-up (N=76*)

Fifty-seven percent (43 of 76) of all patients reported 81 – 100% improvement in overall targeted pain at their last follow-up.

*3 patients data missing
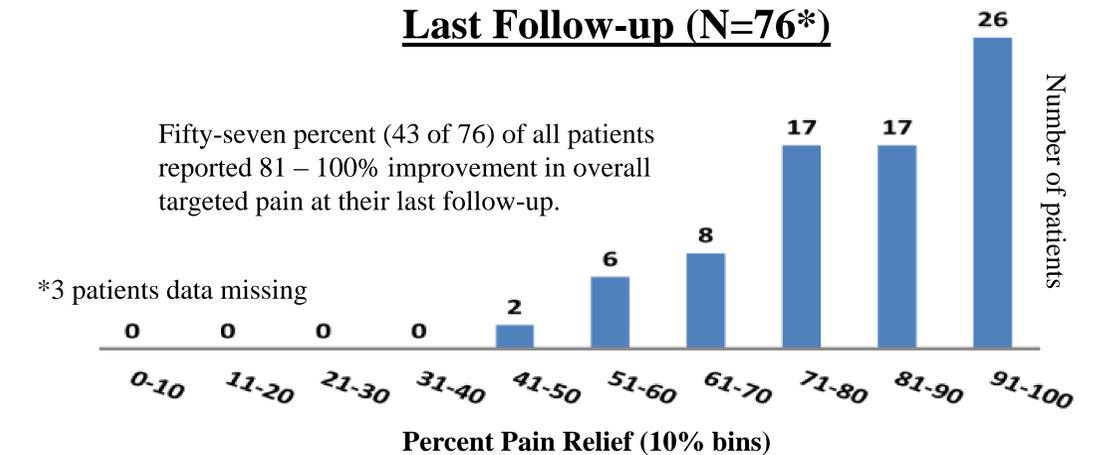
Distribution of Pain Scores (NRS) at Last Follow-up (n = 79)

• Twenty-nine percent (23 of 79) of all patients reported pain free (NRS = 0) at last follow-up

• Eighty percent of patients (63 of 79) reported a pain score of 2 or less at last follow-up

CONCLUSIONS

• This multi-center, real-world, observational study provides initial insights into the use of a newly introduced SCS system capable of offering combination therapy and waveform automation.
• In a large cohort of 79 subjects implanted with recently introduced SCS System, a statistically significant improvement in overall targeted pain scores at last follow-up was reported (7.7→1.7).
• Eighty percent (63 of 79) of all patients reported a pain score of 2 or less at their last follow-up.
• Further studies investigating long term follow-up and maintenance of pain improvement are needed.

REFERENCES

1. Al-Kaisy A., et al. Pain Med. 2014 Mar;15:347-54.
2. North JM, Hong KJ, Cho PY. Neuromodulation. 2016 Oct;19(7):731-737.
3. De Ridder D., et al. World Neurosurg. 2013 Nov;80(5):642-649.
4. Veizi E., et al. Pain Med. 2017 Aug 1;18(8):1534-1548.
5. Deer TR., et al. Pain. 2017 Apr;158(4):669-681.