Clinical Outcomes in Patients Using a Spinal Cord Stimulation System with Multiple Neurostimulative Modalities For Chronic Pain: Initial Real-World Experience From Europe

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BACKGROUND

Spinal cord stimulation (SCS) systems equipped with several available modalities of neurostimulation such as multiple waveforms, advanced/customizable field shape programming, and combination therapy are designed to provide for robust customization of treatment for chronic pain. This capability is particularly relevant given the dynamic nature of chronic pain. Recent reports of real-world observational data demonstrated a mean 5.1-point NRS pain score reduction in a cohort of 420 subjects at last follow-up (mean 3-months) utilizing an SCS system with such capabilities (Metzger, C. et al. INS 2019). Here, we now report our initial experience in Europe with a recently launched SCS system capable of delivering multiple waveforms and advanced modalities including combination therapy and customizable field shapes.

METHODS

Study Design	Multicenter, Consecutive, Observational, Case-Series (all data collected by site personnel)
Study Device	Spectra WaveWriter SCS System (Boston Scientific) with the following capabilities: <ul style="list-style-type: none">Combination therapyMultiple waveforms and advanced field shapesWaveform automation
Subjects	75 patients diagnosed with chronic pain
Key Inclusion	Real-World cohort, implanted on-label.

Baseline Characteristics (n = 75)

Gender - Females (%)	53.3% (40/75)
Age [Mean (SD)]	59.5 (12.4) years n = 74
Key Diagnosis (note: patients may have multiple diagnoses)	<ul style="list-style-type: none">Failed Back Surgery Syndrome (65%)Myelopathy (15%)Lumbosacral Radiculopathy (12%)
Pain Location (n%)	Low Back and legs (86.7%)
Baseline NRS [Mean (SD)]	7.9 (1.9) n = 75
Follow-up Duration [Mean (SD)]	82 (58) days n = 74

RESULTS

Overall Pain, Low Back and Leg Pain Scores at 3 months*

Distribution of Low Back Pain Scores at 3 months (n = 38)*

*Not all patients reached their 3 month follow up. Data collection is ongoing

CONCLUSIONS

- In this multicenter, real-world cohort (EU sites only) of 75 patients implanted with a recently launched SCS System, a statistically significant improvement in low back pain ($p < 0.0001$) reported at 3 months was observed ($8.1 \rightarrow 2.3$, $\Delta = 5.4$):
 - A 5.1 point improvement ($8.0 \rightarrow 2.4$) was noted in leg pain scores and a similar improvement in overall pain was reported
 - Fifty-eight percent of patients reported a low back pain score of 2 or less at 3 mos.
- These results are consistent with the outcomes of a recent observational study reporting use of this system in the U.S.A. in a cohort of over 400 patients (Metzger C. et. al., INS 2019).