Real-World Outcomes Using Spinal Cord Stimulation for Treatment of Chronic Back Pain with No Prior Back Surgery

Richard Rauck[1], VB Study Group, Lilly Chen[2], Edward Goldberg[2]

1. Carolinas Pain Institute, Winston-Salem, NC USA 2. Boston Scientific, Division of Neuromodulation, Valencia, CA USA

BACKGROUND

Chronic intractable low back pain (i.e., back pain persisting for at least 6-months) refractory to treatment is complex and dynamic. A recent meta-analysis of 96 randomized trials involving over 26,000 subjects with chronic pain demonstrated that use of opioid drugs was not associated with significant improvements in pain and physical function, nor associated with outcomes that were significantly better than that achieved using conventional treatments (i.e., antidepressants, nonsteroidal anti-inflammatory drugs, anticonvulsants, cannabinoids, or usual care).[1] Hence, an approach that includes non-opioid therapies such as neuromodulation for the management of pain has been recommended (HHS 2019 Best Practices report and 2022 CDC guidelines).[2, 3]

Previously published studies support the use of Spinal Cord Stimulation (SCS), a reversible treatment option, prior to back surgery.[4-6] However, these studies have not yet evaluated SCS systems that can provide multiple neurostimulative approaches that can be selectively used per patient.

Here, we report outcomes in real-world patients with no prior back surgery who used various SCS systems capable of customizable neuromodulatory approaches.

METHODS

Real-world data with use of a commercially-available Boston Scientific SCS systems in the treatment of pain was collected among patients with no prior back surgery

1. RELIEF Prospective, multicenter registry (NCT01719055)
2. Retrospective, observational case-series (NCT01550575)

RESULTS

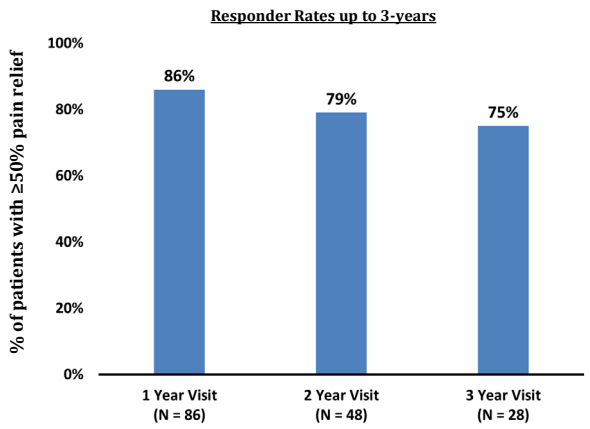
A total of 262 real-world participants were identified:

- Prospective, multicenter registry: 108
- Retrospective, observational case series: 154

Baseline Characteristics (n = 262)

	Prospective Registry (n = 108)	Observational Case-Series (n = 154)
Gender - Females (%)	63% (68/108)	61% (90/148)
Age [Mean (SD)] n	60.4 (13.4) yrs. n = 108	59.5 (14.4) n = 137
Baseline NRS [Mean (SD)] n	7.2 (1.8) n = 60	7.4 (1.9) n = 154
Follow-up duration [Mean (SD)] n	Ongoing up to 3-years	375.6 days (507.4) n = 154

Prospective Multicenter Registry (n=108)



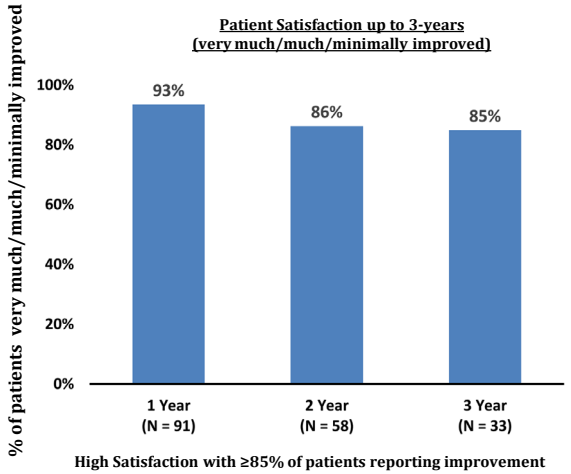
≥75% responder rate (% of patients with 50% or more pain relief) reported up to 3-year follow-up

Observational Case Series (n=154)

At last follow-up (mean = 375.6 days)

- **47% of patients reported a pain score of 3 or less**
- **A mean 3.4-point improvement (7.4 → 4.1, p<0.0001) was noted among all patients (n = 154)**

Prospective Multicenter Registry (n=108)



High Satisfaction with ≥85% of patients reporting improvement (very much/much/minimally) up to 3-year follow-up

CONCLUSIONS

- Results from two ongoing, real-world, multicenter, studies (consecutive patients) demonstrate a durable and significant improvement in pain and satisfaction suggesting that SCS may be an option for chronic pain in patients with no history of prior back surgery.
- High responder rates (≥75%) and high satisfaction (≥85% of patients reporting improvement) were reported up to 3-years indicated sustained efficacy.
- Additional studies of chronic pain patients with no history of prior back surgery who are implanted with SCS systems equipped with advanced, technological capabilities are now needed.

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DISCLOSURES

Study sponsored by Boston Scientific. Dr. Richard Rauck has a consulting agreement with Boston Scientific. Lilly Chen and Edward Goldberg are employees of Boston Scientific. VB Study group includes study investigators who contributed to the analysis from the two studies. Full list on file.

INDICATIONS FOR USE

View Boston Scientific Spinal Cord Stimulator System Indications, Safety, and Warnings at bostonscientific.com/scs-indications

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

Subperception stimulation has been demonstrated to be safe and effective in patients who have been treated successfully with conventional, paresthesia-inducing stimulation for at least six months. Full stimulation parameter ranges and options for both paresthesia-based and subperception therapy are available for clinician's use throughout the patient's experience and treatment with SCS.

OUS Indications for USE: CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device or at www.IFU-BSCI.com. Products shown for INFORMATION purposes only and may not be approved or for sale in certain

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