Three-Year Spinal Cord Stimulation Outcomes Across Chronic Pain Indications: Results from a Global Registry

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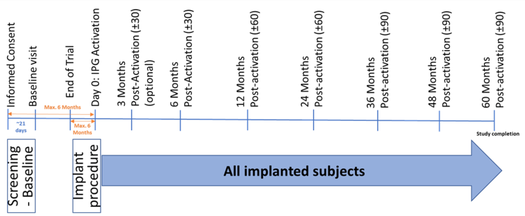
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BACKGROUND

Spinal cord stimulation (SCS) has been used for decades to treat chronic neuropathic pain with technological and clinical advancements supporting its safety and effectiveness across multiple pain etiologies.[1-7] In contrast, conservative medical management for chronic low back pain has been associated with modest average pain reductions, typically ranging from 4-14%, which often fall below commonly accepted thresholds for clinically meaningful improvement used in SCS studies including ≥50% pain relief, functional improvement, and patient reported global benefit.8 While randomized control trials have established the efficacy of SCS under controlled conditions, their limited duration and restrictive inclusion criteria may not fully reflect long-term, real-world outcomes across heterogeneous patient populations. To address this gap, a large, multi-center, global trial was conducted to evaluate the durability and clinical effectiveness of SCS across approved indications using meaningful patient-centered outcomes over extended follow-up.

METHODS

Study Design	Prospective, multicenter, single-arm study (NCT01719055)
Study Device	Boston Scientific SCS Systems
Primary Endpoint	Proportion of subjects with ≥50% reduction from Baseline Visit in average targeted pain intensity
Secondary endpoints	Secondary endpoints*: Pain intensity (VNRS), disability (ODI), health-related quality of life (EQ5D-5L) and patient satisfaction (PGIC)

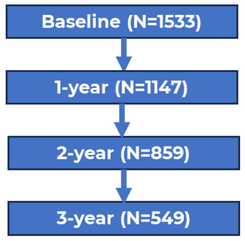


* VNRS: Verbal Numerical Rating Scale; ODI: Oswestry Disability Index; EQ5D-5L EuroQol 5 Dimension 5 Level; PGIC: Patient Global Impression of Change

RESULTS

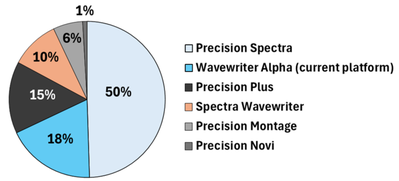
Demographic data	All patients	PSPS type 2 (FBSS)	PSPS type 1 (NSBP)	CRPS	DPN
Implanted subjects (N)	1,533	1,029	519	109	43
Age (years)	58 years	58 years	59 years	50 years	63 years
Gender (% female)	57%	55%	60%	65%	38%
Pain duration (median)	8 years	9 years	7 years	5 years	10 years

Study design and Schematic

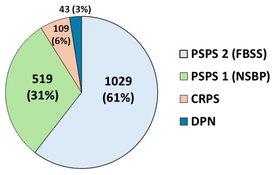


SCS system

>1,500 patients implanted with Boston Scientific SCS systems from 2012 to 2025

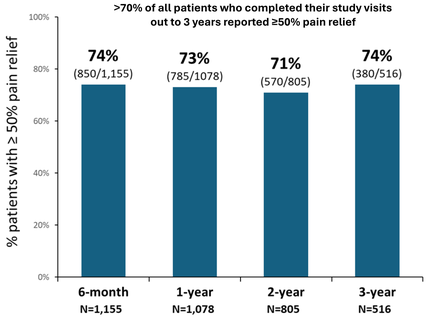


PSPS: Persistent Spinal Pain Syndrome
Type 1: NSBP (Non-Surgical Back Pain)
Type 2: FBSS (Failed Back Surgery Syndrome)
CRPS: Complex Regional Pain Syndrome
DPN: Diabetic Peripheral Neuropathy



RESPONDER RATE OUT TO 3 YEARS

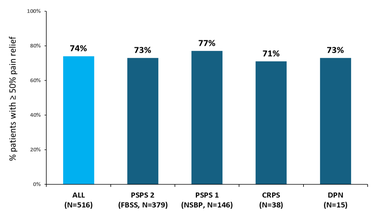
>70% of all patients who completed their study visits out to 3 years reported ≥50% pain relief



THREE-YEAR OUTCOMES BY INDICATION

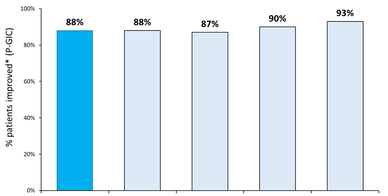
Responder rate at 3-year follow-up

>70% of patients reported ≥50% pain relief at 3-years across all indications



Patient satisfaction at 3-year follow-up

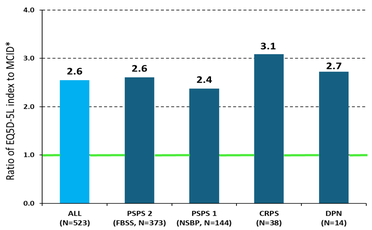
≈ 90% improved at 3-years across all indications



*minimally / much / very much improved

Quality of life at 3-year follow-up

EQ5D-5L index improved by 2 to 3 times the MCID (0.069)[9] across all indications (p<0.0001)



CONCLUSIONS

This global real-world prospective RELIEF ongoing registry demonstrates the efficacy and durability of SCS therapy across multiple indications.

Three-year results across various indications showed:

- Greater than 70% responder rate
- ~90% patients reported being improved
- Significant improvement in quality of life

This effectiveness report complements safety findings which had showed low annualized explant rate (all cause: 3.5%; loss of efficacy: 1.1%).[6] The present analysis focused on 3-year outcomes.

Extended follow-up is ongoing.

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DISCLOSURES

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