

Long-term Outcomes of Fast-acting Sub-perception SCS: Multinational, Real-world Analysis across Europe and the United States

Simon Bayer^{1,2}, Jose Paz-Solis³, Georgios Kyriakopoulos⁴, Ashish Gulve⁵, Philippe Rigoard⁶, Jose E. Llopis Calatayud⁷, Georgios Matis⁸, Jan Vesper⁹, Sarah Love-Jones¹⁰, Adam Williams¹⁰, Jan Willem Kallewaard¹¹, M. Angeles Canos-Verdecho¹², Sylvie Raoul¹³, Clark Metzger¹⁴, Blake Hammond¹⁵, Richard Ferro¹⁶, James North¹⁷, Stephen Pyles¹⁸, Andy Kranenburg¹⁹, and Edward Goldberg²⁰

1. Inter Neuro, Berlin, Germany 2. Charité -Universitätsmedizin, Berlin, Germany 3. University Hospital La Paz, Madrid, Spain 4. Johanniter-Kliniken, Hamm Germany 5. The James Cook University Hospital, Middlesbrough, UK 6. Poitiers Hospital University, Poitiers, France 7. Hospital de la Ribera, Valencia, Spain 8. University Hospital Cologne, Cologne, Germany 9. Heinrich Heine University, Düsseldorf, Germany 10. Southmead Hospital, Bristol, UK 11. Rijnstate Hospital, Arnhem, Netherlands 12. University and Polytechnic Hospital La Fe, Valencia, Spain 13. Nantes University Hospital, Nantes, France 14. HCA Florida West Orthopedic Specialists, Pensacola, Florida, USA 15. Multidisciplinary Pain Management Services, Okemos, Michigan, USA 16. The Center for Clinical Research, LLC, Winston-Salem, North Carolina, USA 17. Florida Pain Clinic, Ocala, Florida, USA 18. Southern Oregon Orthopedics, Medford, Oregon, USA 19. Michigan Pain Specialists, Ann Arbor, Michigan, USA 20. Boston Scientific Neuromodulation, Valencia, CA, USA

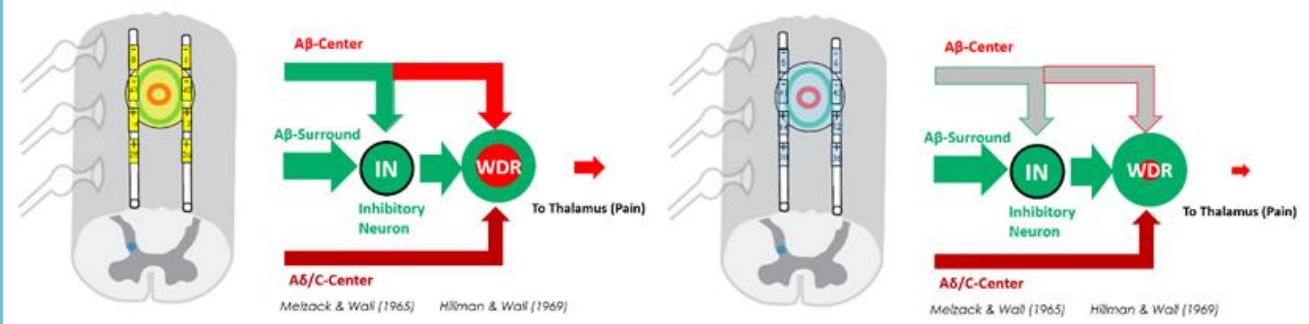
BACKGROUND

Fast-Acting Sub-Perception Therapy (FAST), as a paresthesia-free Spinal Cord Stimulation (SCS) approach, can elicit pain relief within seconds to minutes following neurostimulative activation.¹ Alternatively, traditional paresthesia-free SCS using high frequencies exhibits a slow “wash in” (i.e., the duration until maximum pain relief is achieved after device activation). FAST-SCS induced analgesia is mediated by mechanisms controlled by Surround Inhibition (SI).^{2,3} SI is a physiological mechanism that regulates transmission of perception signals to focus and control sensory signaling to the central nervous system. FAST-based neurostimulation is thought to re-engage SI-driven mechanisms thought to have become disrupted in chronic pain disorders.⁴⁻⁶ FAST-SCS requires precise parameters and targeting to effectively engage SI-based mechanisms. Parameters required for FAST-SCS as a treatment for chronic pain were discovered empirically and validated pre-clinically.¹⁻³ Here, we describe our experience using FAST-SCS and examine analgesic outcomes in Persistent Spinal Pain Syndrome (PSPS) patients who preferentially used FAST-SCS.

METHODS

Study Design	Multicenter, Consecutive, Observational, Case-Series. Data collected by site personnel. ClinicalTrials.gov identifier NCT01550575
Study Device	WaveWriter Alpha and Spectra WaveWriter Spinal Cord Stimulation System (Boston Scientific) capable to deliver SCS with: <ul style="list-style-type: none"> FAST (Fast-Acting Sub-Perception Therapy) Paresthesia-based SCS with MICC (multiple independent current control) and 3D neural targeting algorithm Dorsal horn modulation sub-perception therapy with Contour algorithm Combination therapy
Cohort	PSPS consecutive patients who preferentially used FAST-SCS

FAST-SCS mechanism of action and programming



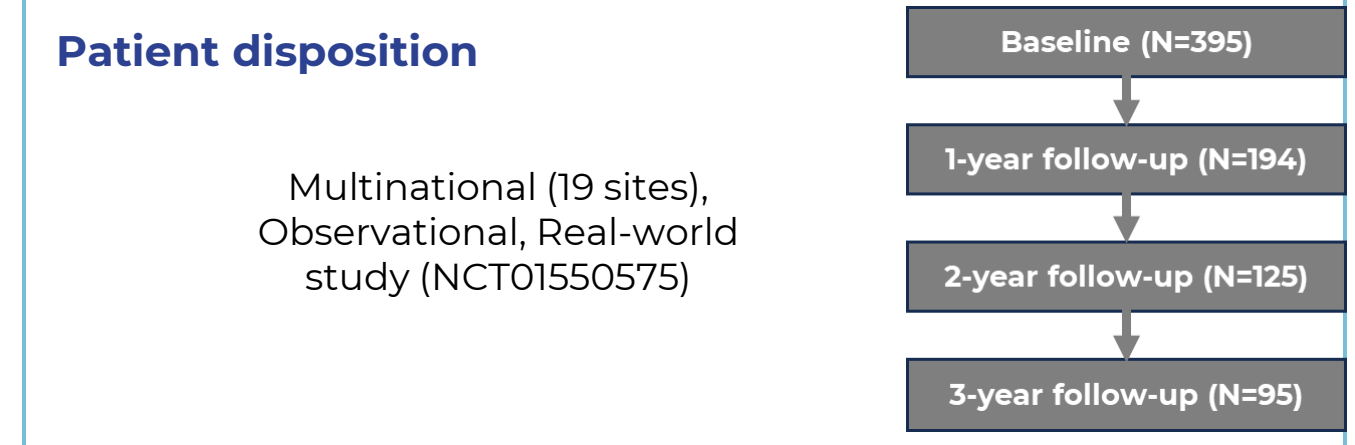
Mixed effects of paresthesia-based spinal cord stimulation (SCS) (supra-perception intensity) with the gate control theory mechanism

Inhibitory effects of Fast-Acting Sub-perception Therapy (FAST)-SCS (sub-perception intensity) with the surround inhibition mechanism

- FAST-SCS**
- Paresthesia-guided targeting
 - Active recharge waveforms (90 Hz, 210µs)
 - 30% to 40% perception threshold

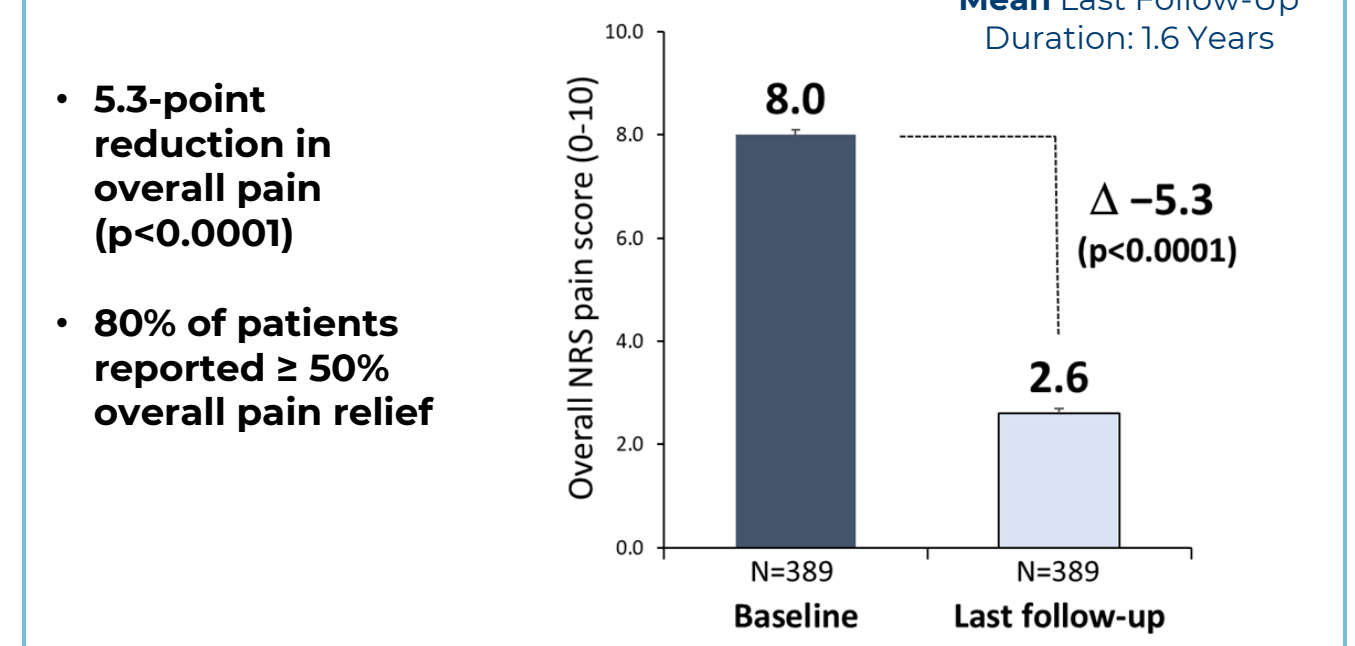
RESULTS

Baseline characteristics (N=395)	
Age – Mean (SD) n	61.7 years (13.4) 380
Gender (Female) - % (n/N)	58.7% (232/395)
Pain location (%)	Low back and/or legs (100%)
Percutaneous perm leads	68% (262/385)
Surgical perm leads	32% (123/385)
Overall Pain (NRS)- Mean (SD) n	8.0 (1.4) 389
Oswestry Disability Index (ODI)- Mean (SD) n	58.7 (15.0) 62
EQ5D5D-VAS- Mean (SD) n	27.0 (16.7) 82
Follow-up Duration (years) – Mean (SD) n	1.6 years (1.5) 389

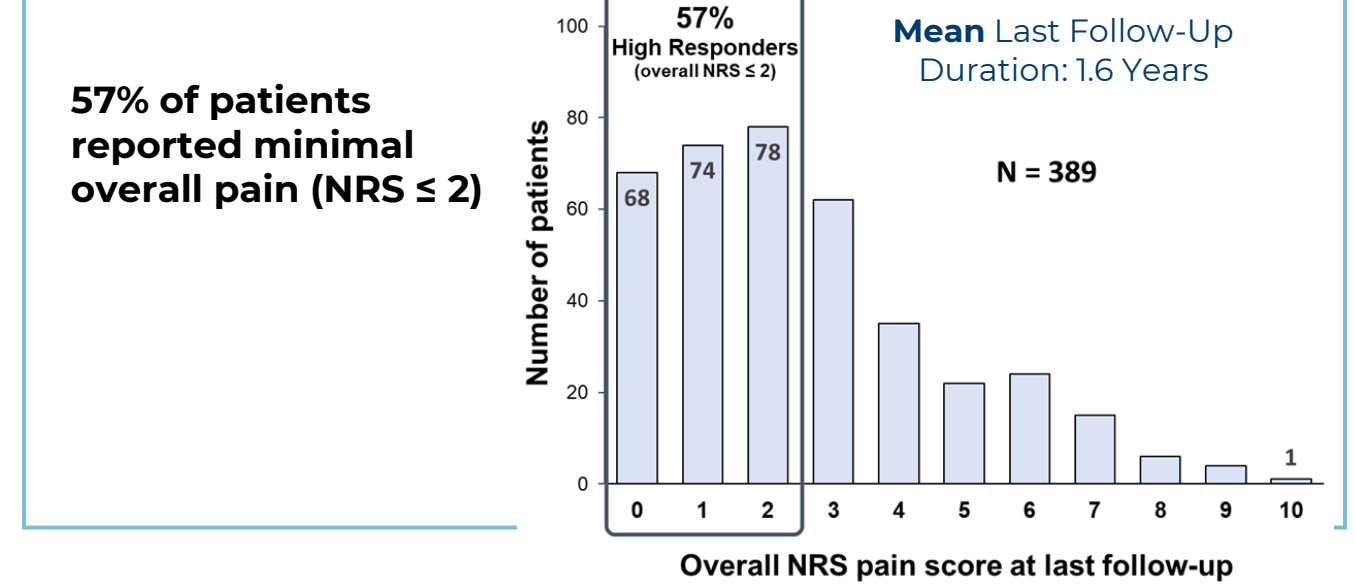


PAIN RELIEF AT LAST FOLLOW-UP

Overall NRS pain score



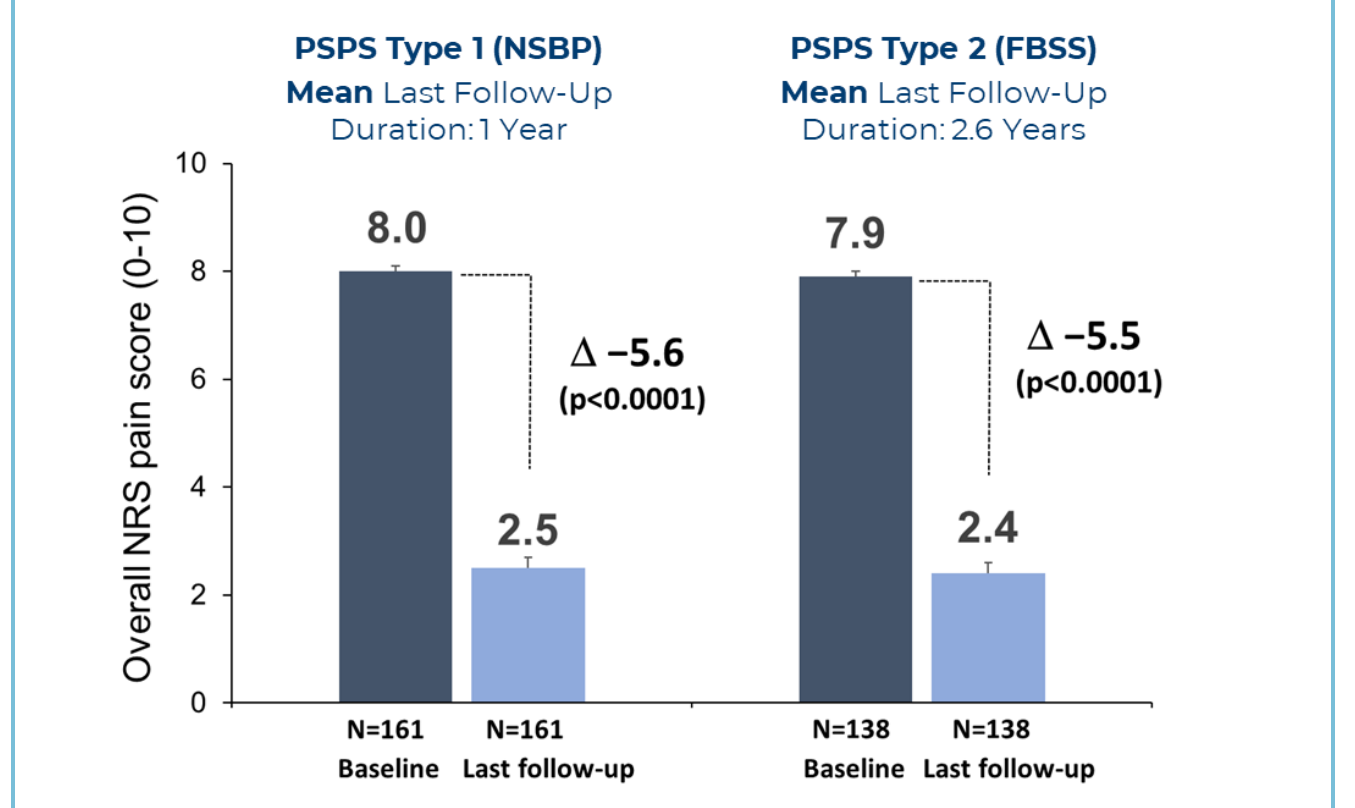
High responders



PSPS TYPE 1 (NSBP) AND TYPE 2 (FBSS)

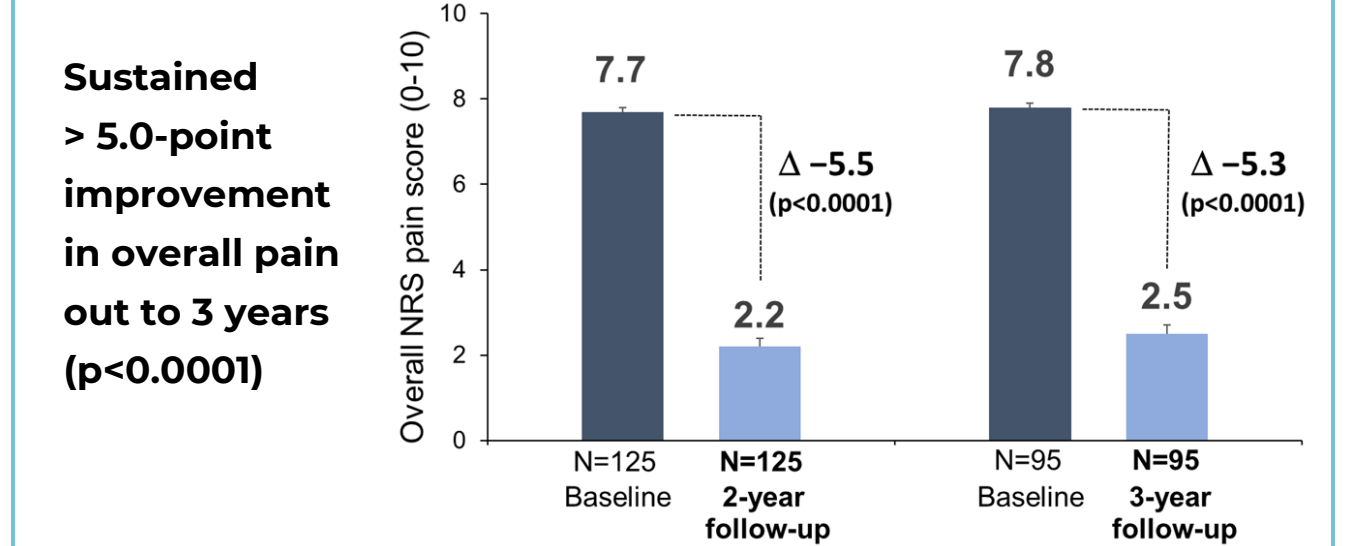
Overall NRS Pain Score at last follow-up

- > 5.5-point reduction in overall pain compared to baseline
- 80% patients reported ≥ 50% pain relief

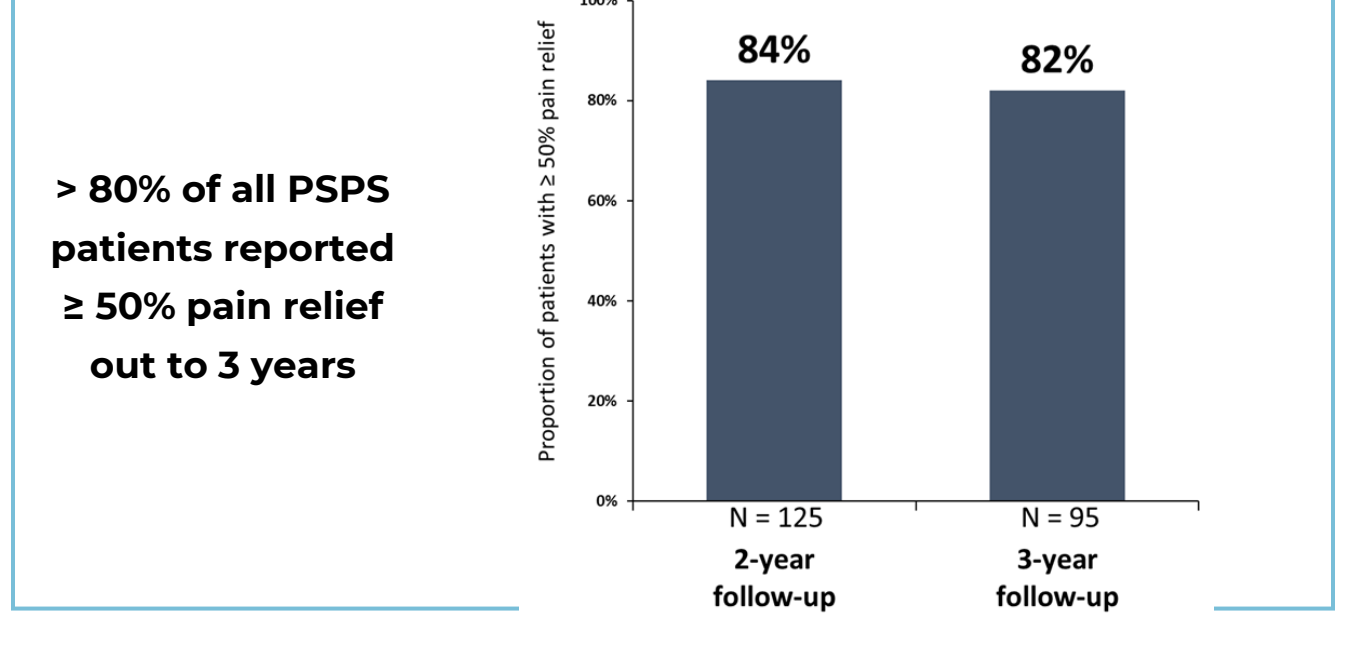


3-YEAR OUTCOMES

Overall NRS Pain Score (0-10)



Responder rate out to 3 years



CONCLUSION

These real-world multinational findings demonstrate that **FAST-SCS therapy provided significant long-term improvements** in patients with **Persistent Spinal Pain Syndrome (Type 1_NSBP and Type 2_FBSS)**.

At last follow-up (N=389)

- 5.3-point reduction in overall pain
- 80% responder rate (310/389)
- 57% patients report minimal pain (NRS ≤ 2)
- Both indications (PSPS Type 1 and 2) experienced similar improvements

At 2-year (N=125) and 3-year follow-up (N=95)

- Sustained >5.0-point reduction in overall pain
- Sustained >80% responder rate (≥50% pain relief)

Our results are consistent with previously published 2-year reports.⁷⁻⁹ Study is ongoing.

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DISCLOSURES

Study Sponsored by Boston Scientific (NCT01550575)
Edward Goldberg is an employee of Boston Scientific



INDICATIONS FOR USE



View Boston Scientific Spinal Cord Stimulator System Indications, Safety, and Warnings at [bostonscientific.com/scs-indications](https://www.bostonscientific.com/scs-indications)

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 countries. This material not intended for use in France.

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.

Warning: Stimulation modes. Only paresthesia-based stimulation mode has been evaluated for effectiveness in the diabetic peripheral neuropathy (DPN) population

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NM-2428204-AA



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