Three-Year Real-World Outcomes of Fast-Acting Sub-Perception SCS In a Multinational Persistent Spinal Pain Syndrome (PSPS) Cohort

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BACKGROUND

Fast-acting sub-perception therapy (FAST) is a paresthesia-free Spinal Cord Stimulation (SCS) approach, which can elicit pain relief within seconds to minutes following neurostimulative activation.[1] The analgesia induced by this SCS modality is mediated by mechanisms controlled by Surround Inhibition (SI).[2,3] Parameters required for fast-acting sub-perception therapy as a treatment for chronic pain were discovered empirically and validated pre-clinically.[1-3] Multiple publications from different countries have recently established the effectiveness of fast-acting sub-perception therapy out to 2-years in various cohorts of patients.[4-6] Here, we present the global long-term real-world outcomes of SCS in a consecutive pooled population of patients with Persistent Spinal Pain Syndromes (PSPS) from both Europe and the United States of America (USA) who preferentially used fast-acting sub-perception therapy at their last follow-up visit.

METHODS

Study Design	• Multicenter, Consecutive, Observational, Case-Series. • Retrospective chart review: all data collected by sites and documented per standard of care • ClinicalTrials.gov identifier NCT01550575
SCS Device	SCS Systems (Boston Scientific) with below capabilities: • Standard rate with MICC* technology • Fast-acting sub-perception therapy • Combination therapy • Dorsal horn modulation algorithm (i.e., Contour) • High-rate sub-perception options
Cohort	Consecutive PSPS patients who preferentially used FAST-SCS at their last follow-up visit

*MICC, Multiple Independent Current Control

RESULTS

Baseline characteristics (N=424)

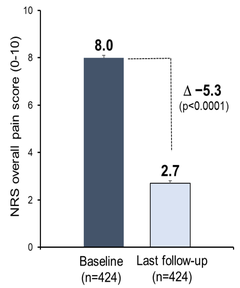
Age – Mean (SD) n	61.6 years (13.5) 415
Gender (Female) - % (n/N)	57% (241/424)
PSPS Type 1- % (n/N)	39% (166/424)
PSPS Type 2- %(n/N)	61% (258/424)
Percutaneous leads	70% (288/410)
Surgical leads	30% (122/410)
Overall Pain (NRS)- Mean (SD) n	8.0 (1.4) 424
Follow-up Duration (years) – Mean (SD) n	1.6 years (1.5) 424

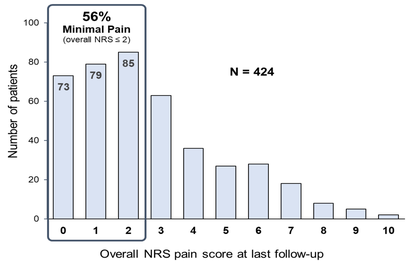
Patient disposition



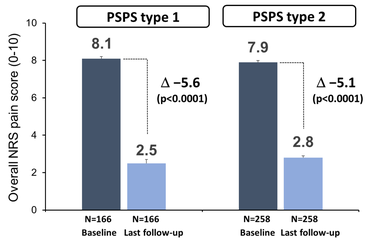
For each annual time point, the analysis included all patients that reached this follow-up within pre-defined windows. The remaining patients either had not yet reached the visit, lacked a visit recorded within the window per standard of care practices, or have been lost to follow-up.

Results at last follow-up (mean 1.6 years)

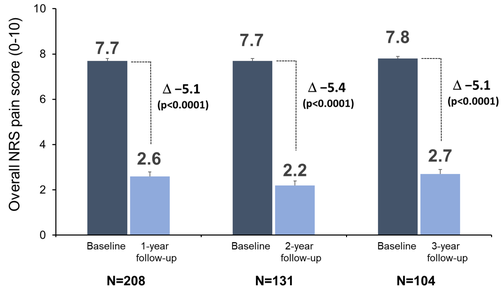


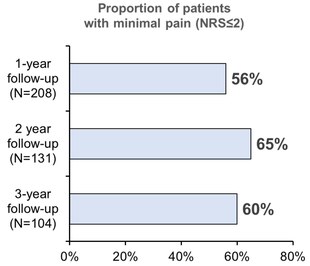


- Overall NRS pain scores reduced by **more than 5-points (p<0.0001)**
- **56%** of patients reported minimal pain (NRS ≤2)
- **62%** of patients who completed PPR reported ≥80% pain relief (180/292).



Outcomes out to 3-years





- Significant and durable reduction in the overall pain by **more than 5-points at all timepoints**
- At 3-year follow-up, **60%** of the patients reported **minimal pain (NRS ≤2)**

CONCLUSIONS

Our long-term clinical results provide real-world observational evidence demonstrating that fast-acting sub-perception therapy activating the surround inhibition mechanism is an effective and durable treatment for patients with persistent spinal pain syndrome (PSPS). Significant pain relief was observed out to 3-year follow-up in a large and global population including PSPS type 1 as well as PSPS type 2 patients.

At the last follow-up visit (1.6 years after implantation):
- Overall pain improved by more than 5-points (p<0.0001) for both PSPS Type 1 and PSPS Type 2 patients
- 56% of all patients reported minimal pain (NRS≤2)

At 3-year follow-up (N=104):
- 5.1-point reduction in overall pain (p<0.0001)
- 60% of patients reported minimal pain (NRS ≤2)

Our long-term results provide robust clinical evidence supporting the use of fast-acting sub-perception therapy (FAST) in PSPS patients.

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DISCLOSURES

Study Sponsored by Boston Scientific.
Edward Goldberg is employee of Boston Scientific

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