Automated Sub-perception Neural Dosing to Provide Sustained Spinal Cord Stimulation Therapy

Richard Ferro[1], James North[2], Andy Kranenburg[3], Stephen Pyles[4], Clay Dorenkamp[5], Jason Poston[6], John Schneider[7], Kacey Auten[8], Yu Pei[8], Edward Goldberg[8]

1. Multidisciplinary Pain Management Services, Okemos, MI USA 2. Carolinas Pain Institute and Center for Clinical Research, Winston-Salem, NC USA , 3. Southern Oregon Orthopedics, Medford, OR USA 4. Florida Pain Clinic, Ocala, FL USA 5. Michigan Orthopedic Center, Lansing, MI USA 6. Pain and Spine Specialists of Idaho, Idaho Falls, ID USA 7. Comprehensive Pain and Neurology Center, Murfreesboro, TN USA 8. Boston Scientific Neuromodulation, Valencia, CA USA

BACKGROUND

Treatment of chronic pain using contemporary Spinal Cord Stimulation (SCS) devices now routinely involves the personalized delivery of therapy via application of highly customized stimulation settings and approaches per the specific preference and clinical response of each patient. As such, there is a large compendium of published studies that report positive clinical outcomes in patients with access to multiple SCS-based chronic pain treatment options within a single device.[1-5] Individualized automation of SCS programming (i.e., automatic modulation of stimulation programming according to one's schedule/activities/other) is yet another, more recently-introduced, customizable feature provided on commercially-available SCS-systems that some patients use.

Here, we present outcomes as part of a multicenter observational case series. To be included, all patients must have employed Fast-Acting Sub-perception Therapy (FAST) biphasic-symmetric waveform to treat chronic pain using an automated programming schedule (FAST AutoDose). Following initial device implantation, patients were provided with an automated program regimen consisting of different sub-perception neural doses, thereby requiring reduced patient interaction with the remote control. Pain scores and other clinical measures (per standard of care) were collected and analyzed from the cohort.

METHODS

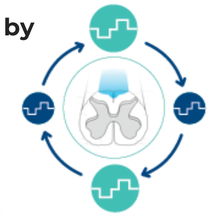
Study Design	Multicenter, Consecutive, Observational, Case-Series. Data collected by site personnel only.
Study Device	Spinal Cord Stimulation (SCS) System (WaveWriter Alpha, Spectra WaveWriter, Boston Scientific): • Engage multiple mechanisms of action • Paresthesia-Guided Stimulation Field Targeting, Fast-Acting Sub-Perception Therapy (FAST) • Customized Field Shape Programming (Contour) • 3D Neural Targeting Algorithm with Multiple Independent Current Control (MICC)
Cohort	73 patients diagnosed with chronic pain

RESULTS

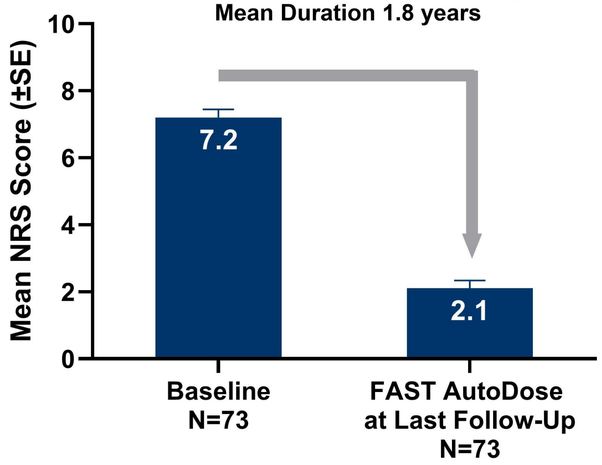
Baseline Characteristics (n = 73)

Gender - Males (%)	48% (35/73)
Age [Mean (SD)]	66.8 (13.5) years n = 73
Pain Location (%)	Low Back Pain (86%)
Baseline NRS [Mean (SD)]	7.2 (2.1) n = 73

FAST AutoDose automates personalized neural dosing by delivering a proactive stimulation bolus within specified intervals to help reduce habituation and provide significant and sustained pain relief.

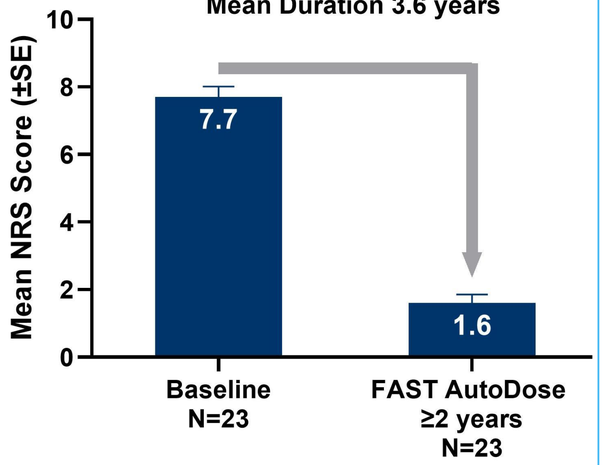


Pain Scores with FAST AutoDose



- **A mean 5.1-point improvement from Baseline was achieved with FAST AutoDose (p<0.0001)**
- **Mean duration from Initial Programming of FAST AutoDose to Last Follow-up Visit is 1.0 years (range: 15 to 816 days)**

2 Years or More



- **A mean 6.1-point improvement from Baseline was achieved with FAST AutoDose (p<0.0001)**
- **Mean duration from Implant to Last Follow-up Visit is 3.6 years (n=10 at 2 years, n=13 more than 3 years)**

CONCLUSIONS

- Clinical results from this real-world, multicenter observational case-series demonstrate that FAST AutoDose provides profound, long-term pain relief:
  - 5.1-point improvement in overall pain (7.2 → 2.1, n = 73) at **last follow-up**
  - 6.1-point improvement in overall pain (7.7 → 1.6, n = 23) at **2 years or more**
- FAST AutoDose delivers automated neural dosing personalized to each patient's perception threshold, for profound and sustained relief, without requiring manual therapy adjustments by the patient.

REFERENCES

1. Paz-Solis J, Thomson S, Jain R, Chen L, Huertas I, Doan Q. Exploration of High- and Low-Frequency Options for Subperception Spinal Cord Stimulation Using Neural Dosing Parameter Relationships: The HALO Study. Neuromodulation. 2022 Jan;25(1):94-102.
2. Wille F, Breel JS, Bakker EW, Hollmann MW. Altering Conventional to High Density Spinal Cord Stimulation: An Energy Dose-Response Relationship in Neuropathic Pain Therapy. Neuromodulation. 2017 Jan;20(1):71-80.
3. Duse G, Reverberi C, Dario A. Effects of Multiple Waveforms on Patient Preferences and Clinical Outcomes in Patients Treated with Spinal Cord Stimulation for Leg and/or Back Pain. Neuromodulation. 2019 Feb;22(2):200-207.
4. Kallewaard JW, Paz-Solis JF, De Negri P, et al. Real-World Outcomes Using a Spinal Cord Stimulation Device Capable of Combination Therapy for Chronic Pain: A European, Multicenter Experience. J Clin Med. 2021 Sep 10;10(18):4085.
5. Rigoard P, Ounajim A, Goudman L, et al. The Challenge of Converting "Failed Spinal Cord Stimulation Syndrome" Back to Clinical Success, Using SCS Reprogramming as Salvage Therapy, through Neurostimulation Adapters Combined with 3D-Computerized Pain Mapping Assessment: A Real Life Retrospective Study. J Clin Med. 2022 Jan 5;11(1):272.

DISCLOSURES

Study Sponsored by Boston Scientific. Kacey Auten, Yu Pei and Edward Goldberg are employees of Boston Scientific.

NANS2025 ANNUAL MEETING

INDICATIONS FOR USE

US Indications for Use: The Boston Scientific Spinal Cord Stimulator Systems are indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs including unilateral or bilateral pain associated with the following: failed back surgery syndrome, Complex Regional Pain Syndrome (CRPS) Types I and II, Diabetic Peripheral Neuropathy of the lower extremities, intractable low back pain and leg pain, radicular pain syndrome, radiculopathies resulting in pain secondary to failed back syndrome or herniated disc, epidural fibrosis, degenerative disc disease (herniated disc pain refractory to conservative and surgical interventions), arachnoiditis, multiple back surgeries. The Boston Scientific Spectra WaveWriter™, WaveWriter Alpha™ and WaveWriter Alpha™ Prime SCS Systems are also indicated as an aid in the management of chronic intractable unilateral or bilateral low back and leg pain without prior back surgery.
Contraindications, warnings, precautions, side effects. The SCS Systems are contraindicated for patients who: are unable to operate the SCS System, have failed trial stimulation by failing to receive effective pain relief, are poor surgical candidates, or are pregnant. Refer to the Instructions for Use provided with the SCS System or Pain.com for potential adverse effects, warnings, and precautions prior to using this product.

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

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

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.

NM-2115414-AA