# Long-Term Chronic Pain-Relief Outcomes Using an SCS System Capable of Combination Therapy

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## BACKGROUND

Single-modality Spinal Cord Stimulation (SCS) approaches are currently available to patients.[1-4] However, these approaches are typically only available via separate commercially-available SCS devices. Systems capable of providing multiple therapeutic neurostimulation modalities and adjustable programming options are now thought to be key for personalizing therapy to identify the best, patient-specific course of treatment and may help avoid surgical revision and/or explant.

In this report, we present outcomes from multiple centers using a new SCS system designed to provide patients with an enhanced capability for customizing SCS treatment by offering combination therapy (sequential or simultaneous delivery of neurostimulation) and waveform automation.

## METHODS

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|---|---|
| **Study Design** | Multicenter, Consecutive, Observational, Case-Series - All data collected by site personnel |
| **Study Device** | Multiple Waveform SCS system (Spectra WaveWriter, Boston Scientific) with following capabilities:<br>- Combination Therapy (sequential or simultaneous neurostimulation)<br>- Multiple waveforms and field shapes<br>- Waveform automation |
| **Cohort** | 420 patients diagnosed with chronic pain |
| **Key Inclusion Criteria** | Chronic Pain Patients implanted with SCS |

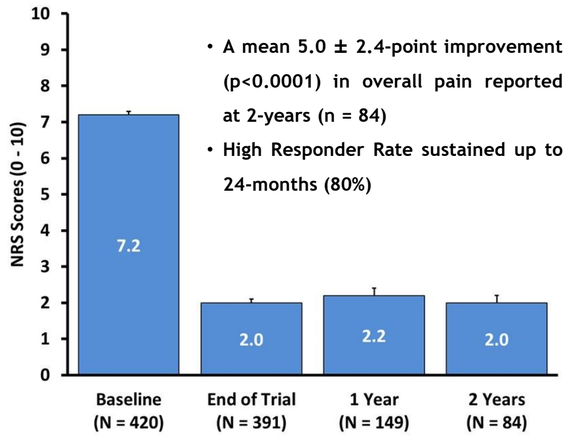
## RESULTS

**Baseline Characteristics (n = 420)**

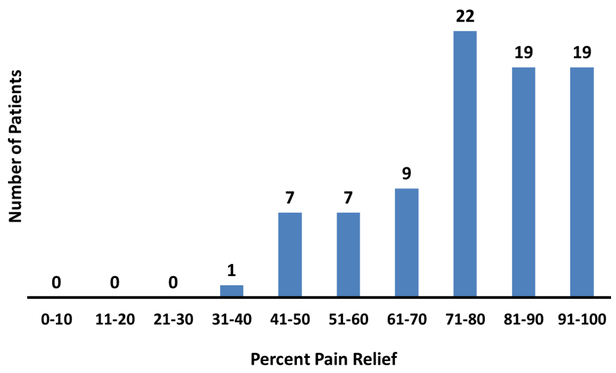
| | |
|---|---|
| **Gender - Females (%)** | 53.1% (217/409) |
| **Age [Mean (SD)]** | 66.2 (13.4) years n = 417 |
| **Pain Location (%)** | Low Back Pain (67.9%) |
| | Low Back and Legs (85.7%) |
| **Baseline NRS [Mean (SD)]** | 7.2 (1.8) n = 420 |
| **Follow-Up Duration [Mean (SD)]** | 371 (393) days n = 420 |

Responder Rate is the proportion of patients with 50% or more improvement in overall pain

**Overall Pain Scores at Baseline and up to 2-years**

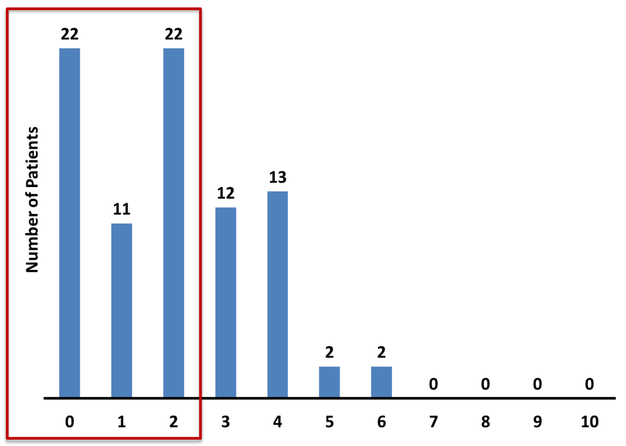



**Percent Pain Relief in Overall Pain at 2-year follow-up post-implant (n = 84)**




45% (38 of 84) of patients reported >80% pain relief at 2-year follow-up

**Overall Pain Scores at 2-year follow-up (n = 84)**




At 2-years:

- 65% (55 of 84) reported a pain score of 2 or less
- 26% (22 of 84) of patients reported being pain free (NRS = 0)

Data Collection Ongoing. Several patients have not completed follow up

## CONCLUSIONS

- **Results from this large, multicenter, real-world observational cohort demonstrated sustained significant improvement in overall pain with the use of an SCS system capable of providing combination therapy, and multiple waveforms/field shapes.**
- **This evidence aligns with that of previous studies indicating the practical value of providing various SCS-based programming options to patients[5-10]**
- **At 2-year follow-up:**
  - **65% (55 of 84) reported a pain score of two or less.**
  - **26% (22 of 84) of patients reported no pain (NRS = 0).**
  - **45% (38 of 84) of patients reported greater than 80% pain relief.**

## REFERENCES

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## DISCLOSURES

- Study sponsored by Boston Scientific
- Drs. Pyles, Waghmarae, Berg, and North have consulting agreements with Boston Scientific
- Yu Pei and Roshini Jain are employees of Boston Scientific

# Indications

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.

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, intractable low back pain and leg pain. Associated conditions and etiologies may be: 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. 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 risks, 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. Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

Outside of US 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. Information for use only in countries with applicable health authority registrations. 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.



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