EVOLVE WORKFLOW OUTCOMES

Evolve℠ workflow Retrospective Multicenter Study Highlights

Medtronic
Further, Together

STUDY

A Large Retrospective, Multi-Center Cohort Study Evaluating a Novel SCS Workflow for Failed Back Surgery Syndrome (FBSS) Back and Leg Pain: Final Analysis with 3+ Month Outcomes[1]

Results Presented at AAPM 2018

TRIAL RESPONSE (N = 114)

83%
Percentage of responders (≥ 50% change in pain)

75%
% improvement in responder group

STUDY TYPE

Retrospective, multicenter study (seven U.S. sites)

THERAPY DESCRIPTION

- Medtronic RestoreSensor™ Spinal Cord Stimulation (SCS)
- High-dose (HD) stimulation before low-dose (LD) stimulation
- Pre-defined high-dose stimulation with 1,000 Hz, 90 µs
- Stimulation delivered with a bi-pole electrode configuration at the T9-T10 interspace
- Minimum 48 to 72 hours to respond to therapy

PATIENTS

Key Inclusion Criteria

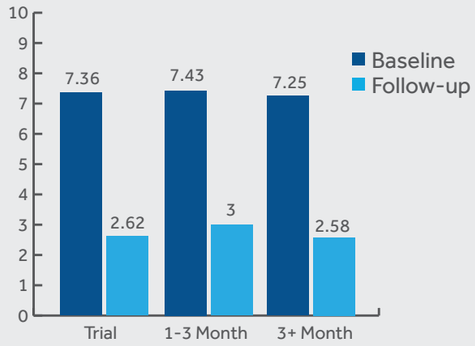
- ICD 10 indicating post laminectomy or chronic postoperative pain
- Patients diagnosed with low back and/or chronic leg pain
- Documented SCS trial that began with HD stimulation at or around the T9-10 interspace
- Minimum 48-hour exposure to therapy during the SCS trial per the workflow

PATIENT COHORTS

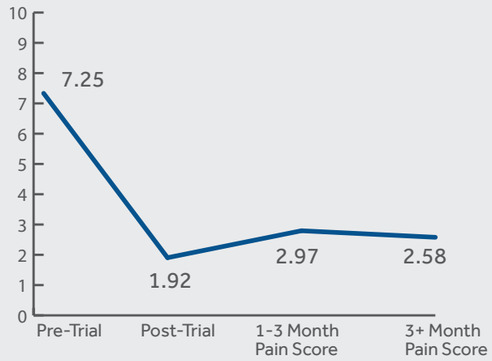
- 114 SCS screening trials
- 57 patients had evaluations 1–3 months post operatively
- 39 patients had an additional evaluation at 3+ months post operatively

REAL-WORLD CLINICAL EFFECTIVENESS

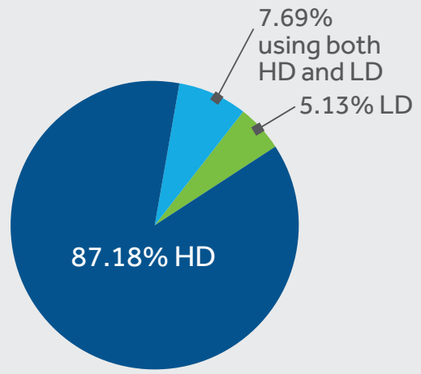
PAIN RELIEF FOR EACH FOLLOW-UP COHORT



PAIN RELIEF FROM BASELINE FOR 3+ MONTH COHORT



HIGH DOSE VS. LOW DOSE AT 3+ MONTHS



EVOLVE WORKFLOW

1 **IF** lead placement spans the T9/T10 space after mapping,

THEN consider the Evolve℠ workflow deliberate dose strategy, using both HD and LD.

2 Use the suggested dose sequence, beginning with predefined HD settings.

HD → **LD**

3 **CONDUCT DILIGENT PATIENT FOLLOW-UP** TO ASSESS FOR OPTIMAL PROGRAMMING

The Evolve℠ workflow is guidance only.

Physicians should use their medical judgement and product labeling to optimize therapy for individual patients.

CONCLUSIONS

1. 83% of patients achieved an average of 75% pain relief during the screening trial.
2. 87% (N=39) of patients were using HD at the 3+ months follow-up visit.
3. 85% (33 of 39) of patients who completed a 3+ month follow-up visit had significant and sustained pain relief.

Note: This is one part of the Evolve℠ evidence strategy, which includes building a higher level of evidence for the Evolve℠ workflow.

SCHEDULE AN EVOLVE TRIAL TODAY

Contact your Medtronic representative

REFERENCE

1. Verdolin M, Hatheway J, Roy L. A Large Retrospective, Multi-Center Cohort Study Evaluating a Novel SCS Workflow for Failed Back Surgery Syndrome (FBSS) Back and Leg Pain: Final Analysis with 3+ Month Outcomes. Abstract LB004, AAPM 2018

NEUROSTIMULATION SYSTEMS FOR PAIN THERAPY

See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. If using an MRI SureScan device, see the MRI SureScan® technical manual before performing an MRI. For further Consult instructions for use at this website. Manuals can be viewed using a current version of any major Internet browser. For best results, use Adobe Acrobat Reader® with the browser.

www.medtronic.com/manuals

Consult instructions for use at this website. Manuals can be viewed using a current version of any major Internet browser. For best results, use Adobe Acrobat Reader® with the browser.

Medtronic

Medtronic International
Trading Sàrl.
Route du Molliau 31
Case postale
1131 Tolochenaz
Switzerland
Tel: +41 (0)21 802 70 00
Fax: +41 (0)21 802 79 00

medtronic.eu

Medtronic Limited
Building 9
Croxley Park
Hatters Lane
Watford
Hertfordshire
WD18 8WW
Tel: +44 (0)1923 212213
Fax: +44 (0)1923 241004

medtronic.co.uk

Medtronic Ireland Limited
Block G, First Floor
Cherrywood Business Park
Loughlinstown
Dublin 18
Tel: +353(0)1 511 1400
Fax: +353(0)1 807 7220

medtronic.ie