LOW BACK PAIN RELIEF WITH A NEW 32-CONTACT SURGICAL LEAD AND NEURAL TARGETING ALGORITHM

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BACKGROUND

Spinal cord stimulation (SCS) has become standard in treating lumbosacral radiculopathy, with reports of up to 70% leg-pain relief1. Historically, however, SCS has been more challenging for low-back pain, attributed to less representation of the back within dorsal columns, resulting in less availability to superficial stimulation.2 It has been postulated that advances in surgical leads and programming capabilities would result in increasingly effective low-back pain relief.2 The best example of this is a recently introduced 32-contact surgical lead. Coupled with 32-contact multiple independent current control (MICC) and anatomically-based stimulation targeting algorithms, this lead allows for patient-specific programming, optimizing previously not possible. We present here a multi-center, consecutive, observational study of experience with the new 32-contact surgical lead when using advanced Neural Targeting SCS. We examine data from 100 implanted patients, including baseline medical history, procedural information, pain reduction and response rate.

METHODS

Study Design Multi-center, consecutive, observational

Study Device 32 contact surgical lead using anatomically guided neural targeting advanced SCS

Sample Size 100 implanted subjects

Number of Sites Up to 10 sites

Follow-up Duration 24 months (currently at 12 months post-implant)

Key Inclusion Criteria Real-world cohort – on-label treatment for back with or without leg pain.

Study Assessments

Baseline information: demographics, diagnosis, pain location

Procedural information: lead configuration, programming parameters

Clinical outcomes: - Pain intensity (0-10 numerical rating scale - NRS)  - Activities of Daily Living  - Medication Intake

RESULTS

Clinical Outcomes (Overall Pain and Low Back Patients)

Procedural Information

Baseline Information

- Age (mean[SD]): 61 (33.0)
- Gender: 51% Female, 49% Male
- Mean baseline pain (0-10 NRS): 7.2 (SD 1.84)

Pain Locations

baseline distribution of pain intensity (NRS)

Vertebral Positions of Implanted Leads (top of lead)

IPG Programming Parameters

- # of active contacts: 15 (4.4)
- # of anodes: 7 (2.7)
- # of cathodes: 5 (1.6)
- Frequency (Hz): 59 (19.9)

Implanted Surgical Lead Paddles

CONCLUSIONS

This multicenter cohort of 100 patients implanted with a 32-contact paddle and using Neural Targeting SCS out to 12 months post-implant demonstrated:

- Significant back pain reduction, equivalent to overall pain reduction (p < 0.001)
- Response Rate of 83.1% for low back pain alone
- Improvements in activities of daily living and reduction in pain medications have been observed

Further study is ongoing in a large-scale outcomes registry.

REFERENCES