Low Back Pain Relief with a New 32-Contact Surgical Lead and Neural Targeting Algorithm

Julie G. Pilitsis MD, PhD; Giancarlo Barolat MD; Joshua M. Rosenow MD FAANS FACS; James J. Brennan MD; Alexander S Bailey MD; Jeffrey M. Epstein MD; Blake Hammond P.A.; Clark Metzger M.D.; Dat Huynh Ph.D.; Kristen Lechleiter M.S.; Nitzan Mekel-Bobrov PhD

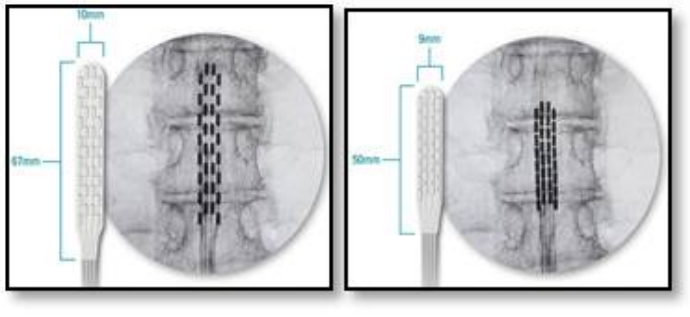
Albany Medical College, Albany NY; Barolat Neuroscience, Denver CO; Northwestern University, Chicago IL; Florence Neurosurgery and Spine, Florence SC; Precision Spine and Orthopedic, Overland Park, KS; St. Catherine of Siena Medical Center, Smithtown, NY; West Florida Pain Group, Pensacola, FL; Boston Scientific Corporation, Valencia, CA

Introduction

Spinal cord stimulation (SCS) is standard in treating lumbosacral radiculopathy. Historically, however, SCS has been challenging for low-back pain, attributed to less representation of the back within dorsal columns. It is postulated that advances in surgical leads and programming capabilities would result in increasingly effective low-back pain relief (1). The recent introduction of a 32-contact surgical lead, coupled with multiple independent current control (MICC) and anatomically-based targeting algorithms, represents such an advance by allowing for specific programming optimization previously not possible. Clinical experience out to 1 year post-implant with this advanced surgical lead in subjects with low back pain as part of the LUMINA observational study is presented here.

Methods

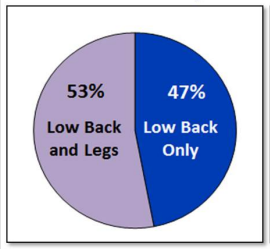
Study Design	Multi-center, **consecutive** observational study
Study Device	32 contact surgical lead using anatomically guided neural targeting advanced SCS
Sample Size	100 implanted subjects
Number of Sites	Up to 10 sites
Follow-up Duration	24 months (currently at 12 months post-implant)
Key Inclusion Criteria	Real-world cohort – only on label treatment with the study device 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 (NRS), Activities of Daily Living, Medication intake



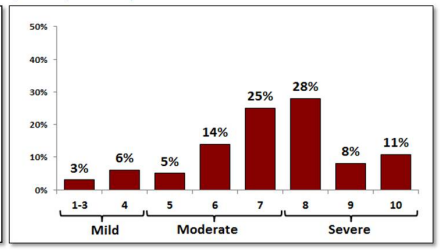
Results

Baseline Iinformation

- **Age** Mean[SD]): 61 [33.0]
- **Gender:** 51% F, 49% M
- **Mean Baseline Pain (0-10 NRS):** 7.2 (SD 1.84)

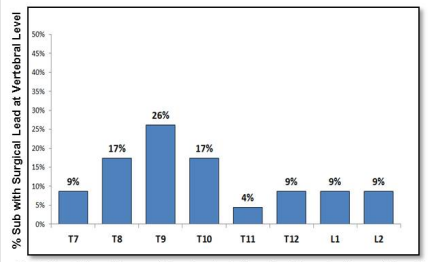


Pain Locations



Baseline Distribution of Pain Intensity (NRS)

Procedural Information

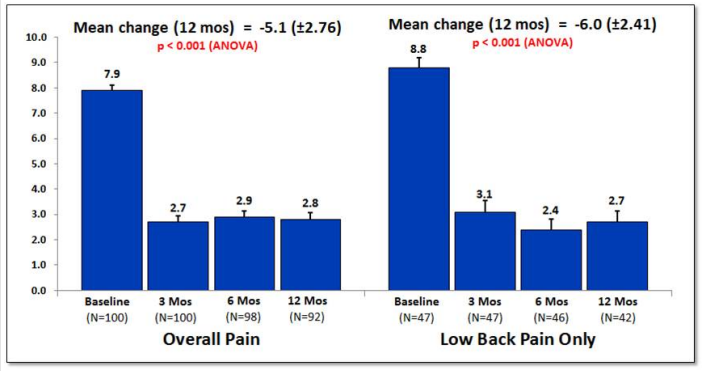


Vertebral Positions of Implanted Surgical Leads (top of lead)

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

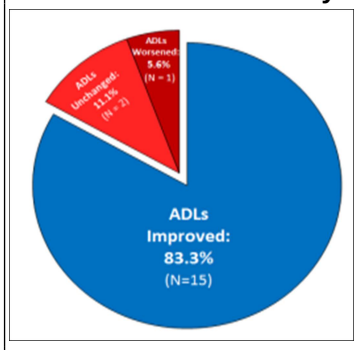
IPG Programming Parameters

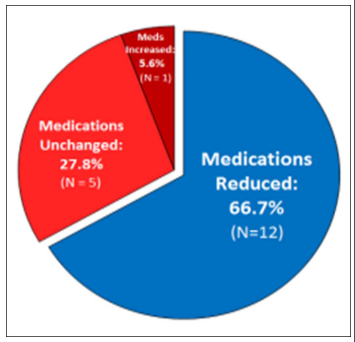
Overall and Low Back Pain Outcomes



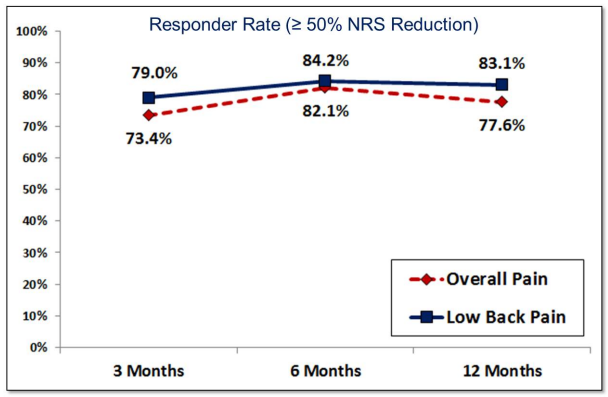
Patients in this cohort showed both highly significant overall and low back pain relief

Secondary Assessments





Change in ADLs (patient reported change) & Pain Medications (based on total prescriptions) in patients at 12 months post-implant (N=18)



Conclusions

In a multicenter cohort of 100 patients implanted with the 32-contact paddle and neural targeting SCS, we found at 12 months post-implant:

- 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 observed

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

References

1. Kinfe TM., et al.. *Neuromodulation*. 2012. 15(4):402-7.