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

1.Albany Medical Center, Albany, NY 2. Barolat Neuroscience, Denver, CO 3. Northwestern University School of Medicine, Chicago, IL 4.Florence Neurosurgery and Spine, Florence, SC. 5. Precision Spine and Orthopedic Specialists, Overland Park, KS 6. St. Catherine of Siena Medical Center, Smithtown, NY 7. West Florida Pain Group, Pensacola, FL, 8. Boston Scientific

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Introduction

Spinal cord stimulation (SCS) has become standard in treating lumbosacral radiculopathy, with reports of up to 70% leg-pain relief (1). 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 (3). 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 3D neural targeting algorithms, this lead allows for patient-specific programming optimization previously not possible. We present here a multi-center, consecutive, observational study of experience with the new 32-contact surgical lead when using 3D Neural Targeting SCS. We examine data from 100 implanted patients, including baseline medical history, procedural information, pain reduction and response rate.

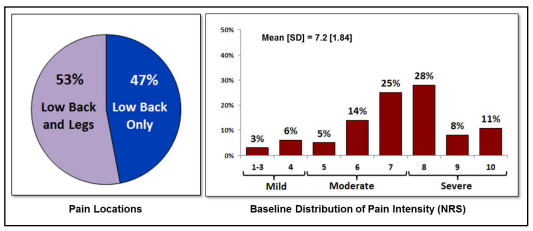
Methods

Study Design	Multicenter, consecutive, observational
Study Device	Precision Spectra with 32-contact surgical lead using anatomically-guided 3D Neural Targeting
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

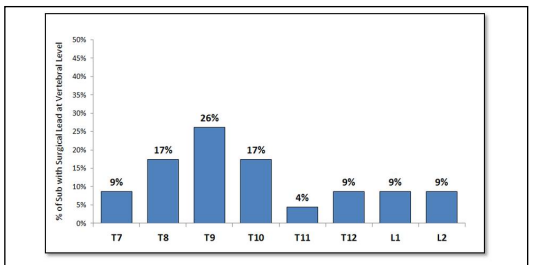
Baseline Information

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



Procedural Information

- Placement of surgical leads was distributed between T7 and L2, with the peak at T9 (26%) and tail-end of the distribution in the lumbar region (18%).

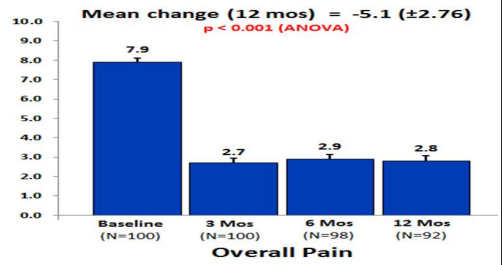


Vertebral Positions of Implanted Surgical Leads (top of lead)

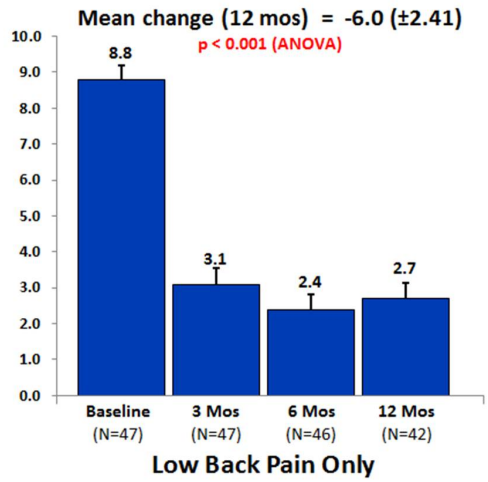
IPG Programming Parameters

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

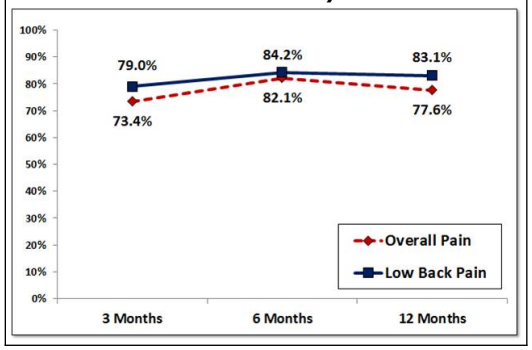
Clinical Outcomes (Overall Pain Patients)



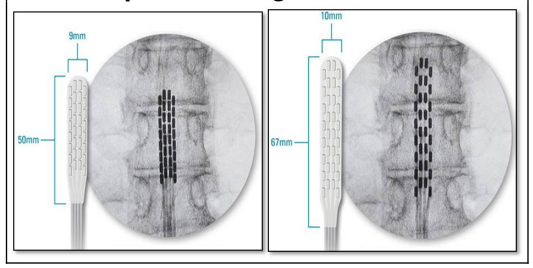
Clinical Outcomes (Low Back Pain Patients)



Clinical Outcomes (Responder Rate - 50% or More Pain Reduction)



Implanted Surgical Paddles



Conclusions

This multicenter cohort of 100 patients implanted with a 32-contact paddle and using 3D 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

References

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