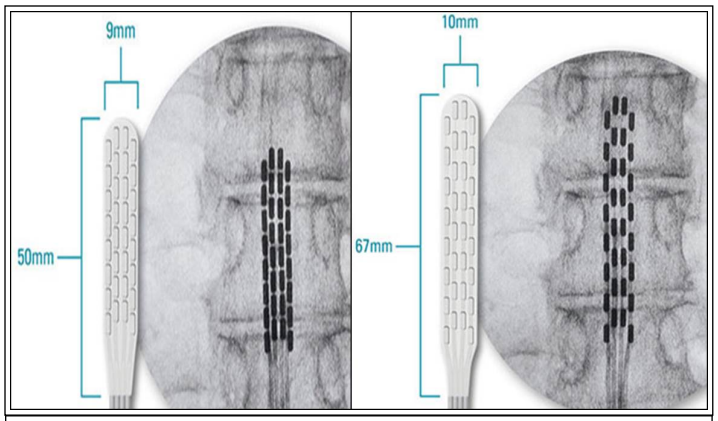
Characteristics of Subjects with a Complaint of Low Back Pain Using a Novel 32-Contact Surgical Lead

J. Pilitsis; G. Barolat; J. Rosenow; A.Bailey; J. Brennan; B. Hammond; C. Metzger; M. Bucci; C. Mina; E. Loudermilk; T. M. Crooks; K. Lechleiter; R. Jain; D. Huynh; N. Mekel-Bobrov

1.Albany Medical College, Albany NY; 2. Barolat Neuroscience, Denver CO; 3. Northwestern University, Chicago IL; 4. Precision Spine and Orthopedic, Overland Park, KS; 5. Florence Neurosurgery and Spine, Florence SC; 6. West Florida Pain Group, Pensacola, FL; 7. Piedmont Spine/Neurosurgical Group, Anderson SC; 8. Arrowhead Health Centers, Glendale AZ; 9. Boston Scientific Corporation, Valencia CA

Introduction

Spinal cord stimulation (SCS) is standard in treating lumbosacral radiculopathy (1). Historically, however, SCS has been challenging for low-back pain, attributed to less representation of the back within dorsal columns (2). It is postulated that advances in surgical leads and programming capabilities would result in increasingly effective low-back pain relief (3). 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. Early clinical experience with this advanced surgical lead in subjects with low back pain as part of the LUMINA observational study is presented here.



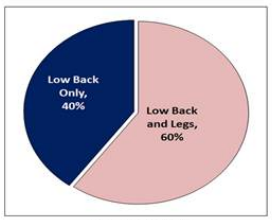
Methods

Study Design	Multi-center, **consecutive**, observational study (all patients meeting inclusion criteria were included without bias)
Study Device	32 contact surgical lead using anatomically guided neural targeting advanced SCS
Sample Size	Up to 100 implanted subjects (currently at 25)
Number of Sites	Up to 10 sites
Follow-up	24 months (currently 6 months post-implant)
Key Inclusion Criteria	Real-world cohort – only requirement is 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 Activities of Daily Living -Medication intake

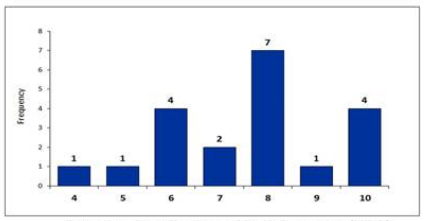
Results

Baseline Information

- Age (mean [SD]): 55.7 [13.91]
- Gender: 44% (11) F, 56% (14) M
- The baseline distribution of pain intensities was skewed towards the severe category with **median of 8.0** points.
- Placement of the surgical lead in this cohort was distributed between T7 and L2, with the peak at T9 (26%) and elongated tail-end of the distribution in the lumbar region (18%).

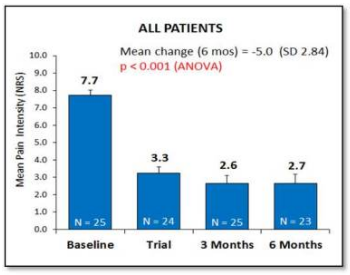


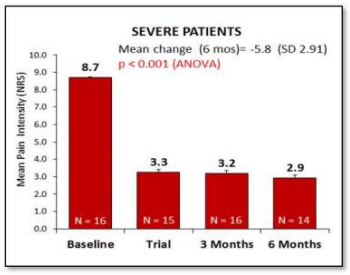
Pain Locations



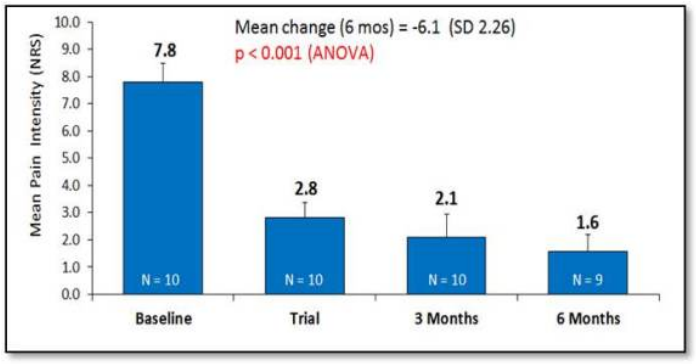
Baseline Distribution of Pain Intensity (NRS)

Overall Pain Outcomes

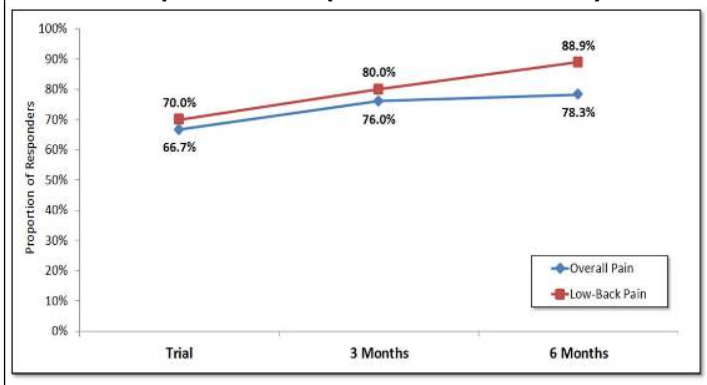




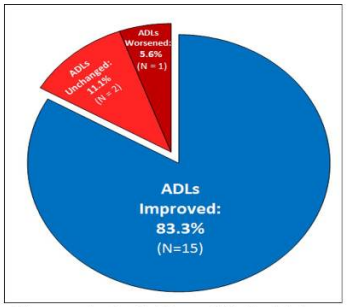
Low Back Outcomes



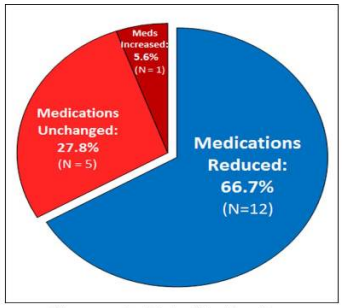
Responder Rate (50% NRS Reduction)



Secondary Assessments



Change in Activities of Daily Living
(based on patient reported change)



Change in Pain Medications
(based on total prescriptions)

Conclusions

The multicenter LUMINA Study cohort of 25 patients implanted with 32-contact paddle and neural targeting SCS at 6 months post-implant demonstrated :

- Significant back pain reduction
- Response rate of 89% with back pain alone
- Improvement in activities of daily living and reduction in pain medications.

Further study is underway in both a randomized controlled trial (RCT) and a large-scale outcomes registry.

References

1. Stidd DA., *et al. J. Pain Res*. 2014. 12;7465-70.
2. Oakley JC. *et. al. Neuromodulation*. 2006. 9(3):192-203.
3. Kinfe TM., *et al.. Neuromodulation.* 2012. 15(4):402-7.