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

Julie Pilitsis[1], Giancarlo Barolat[2], Joshua Rosenow[3], James Brennan[4], Alexander Bailey[5], Jeffrey Epstein[6], Blake Hammond[7], Clark Metzger[7], Dat Huynh[8], Kristen Lechleiter[8], Nitzan Mekel-Bobrov[8]

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

## BACKGROUND

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 stimulation 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 advanced Neural Targeting SCS. We examine data from 100 implanted patients, including baseline medical history, procedural information, pain reduction and response rate.
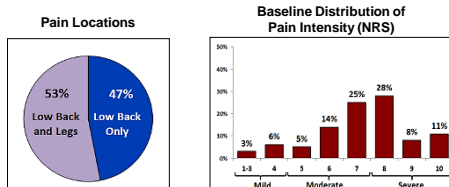
## METHODS

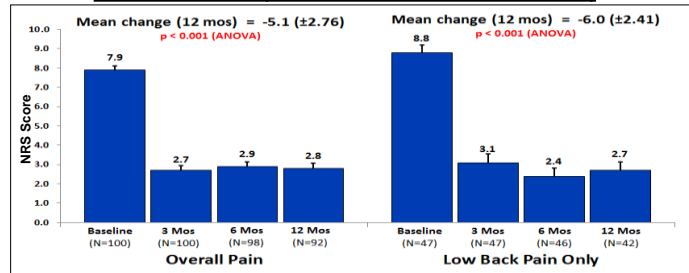| Study Design | Multi-center, consecutive, observational |
|---|---|
| Study Device | 32 contact surgical lead using anatomically guided neural targeting advanced SCS |
| Sample Size | 100 implanted subjects |
| Number of Sites | Up to 10 sites |
| Follow-up Duration | 24 months (currently at 12 months 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<br>**Procedural information:** lead configuration, programming parameters<br>**Clinical outcomes:**<br>- Pain intensity (0-10 numerical rating scale - NRS)<br>- Activities of Daily Living<br>- 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)

**Pain Locations**



53% Low Back and Legs
47% Low Back Only

**Baseline Distribution of Pain Intensity (NRS)**



3%, 6%, 5%, 14%, 25%, 28%, 8%, 11%
Mild — Moderate — Severe

### 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%).
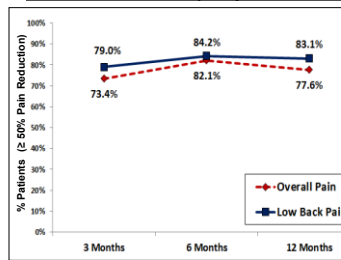
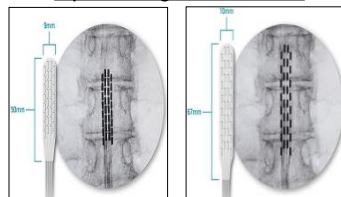**Vertebral Positions of Implanted Leads (top of lead)**



9% T7, 17% T8, 26% T9, 17% T10, 4% T11, 9% T12, 9% L1, 9% L2
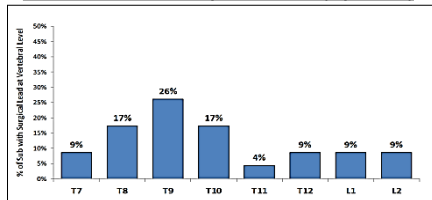
**IPG Programming Parameters**

| | 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 and Low Back Patients)



Mean change (12 mos) = -5.1 (±2.76) p < 0.001 (ANOVA)
Mean change (12 mos) = -6.0 (±2.41) p < 0.001 (ANOVA)

Overall Pain: Baseline (N=100) 7.9, 3 Mos (N=100) 2.7, 6 Mos (N=98) 2.9, 12 Mos (N=92) 2.8
Low Back Pain Only: Baseline (N=47) 8.8, 3 Mos (N=47) 3.1, 6 Mos (N=46) 2.4, 12 Mos (N=42) 2.7

### Clinical Outcomes (Responder Rate)



Overall Pain: 3 Months 73.4%, 6 Months 82.1%, 12 Months 77.6%
Low Back Pain: 3 Months 79.0%, 6 Months 84.2%, 12 Months 83.1%

**Implanted Surgical Lead Paddles**



## REFERENCES

1. Stidd DA., Rivero S., Weinand ME., "Spinal cord stimulation with implanted epidural paddle lead relieves chronic axial low back pain." *J. Pain Res.* 2014. 12;7465-70.

2. Oakley JC. Espinosa F., Bothe H., McKean J., Allen P., Burchiel K., Quartey G., Spincemaille G., Nuttin B., Gielen F., King G., Holsheimer J. "Transverse tripolar spinal cord stimulation: results of an international multicenter study." *Neuromodulation.* 2006. 9(3):192-203.

3. Kinfe TM., Schu S., Quack FJ., Wille C., Vesper J. "Percutaneous implanted paddle lead for spinal cord stimulation: technical considerations and long-term follow-up." *Neuromodulation.* 2012. 15(4):402-7.

## 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 on-going in a large-scale outcomes registry.**