

Results from a Prospective, Multi-Center Clinical Study Testing a Novel, Pulsed Spinal Cord Stimulation Pattern

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Introduction

- High frequency and burst SCS patterns have shown superior results over low frequency tonic in treating low back pain
- Each pattern evokes potentially different neural mechanisms that impact analgesia
- We tested Nalu Stim, a novel, pulsed stimulation pattern (PSP) in patients with predominant low back pain

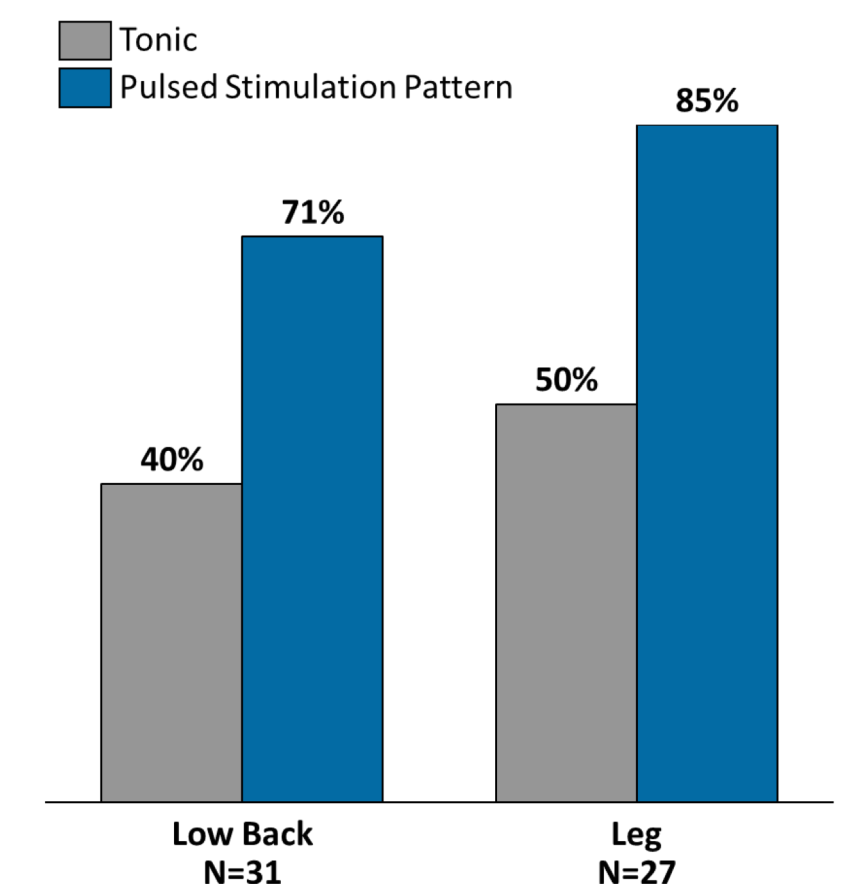
Methods

- All experimental procedures were approved by local ethics committees subjects were consented
- Subjects had primarily LBP (baseline NRS>5)
- Subject were randomized to receive anatomic or physiologic lead placement/utilization
- Pain scores were collected at baseline as well as following use of either low-frequency, tonic SCS (LF-SCS) or a novel, pulsed stimulation pattern (PSP)
- Subjects were allowed to use either stimulation pattern for up to 12-days
- N=37 total subjects

Results

- Responder rates ($\geq 50\%$ pain relief) were statistically greater with PSP compared to LF-SCS ($p < 0.05$)
- Overall, subjects reported greater pain relief when utilizing the PSP versus LF-SCS ($p < 0.0001$)
- Subjects also demonstrated better pain relief when leads were positioned anatomically versus physiologically
- Patients reported no paresthesias when using the PSP in contrast to LF-SCS that generated tingling sensations

Responder Rates



LBP Responder Analysis

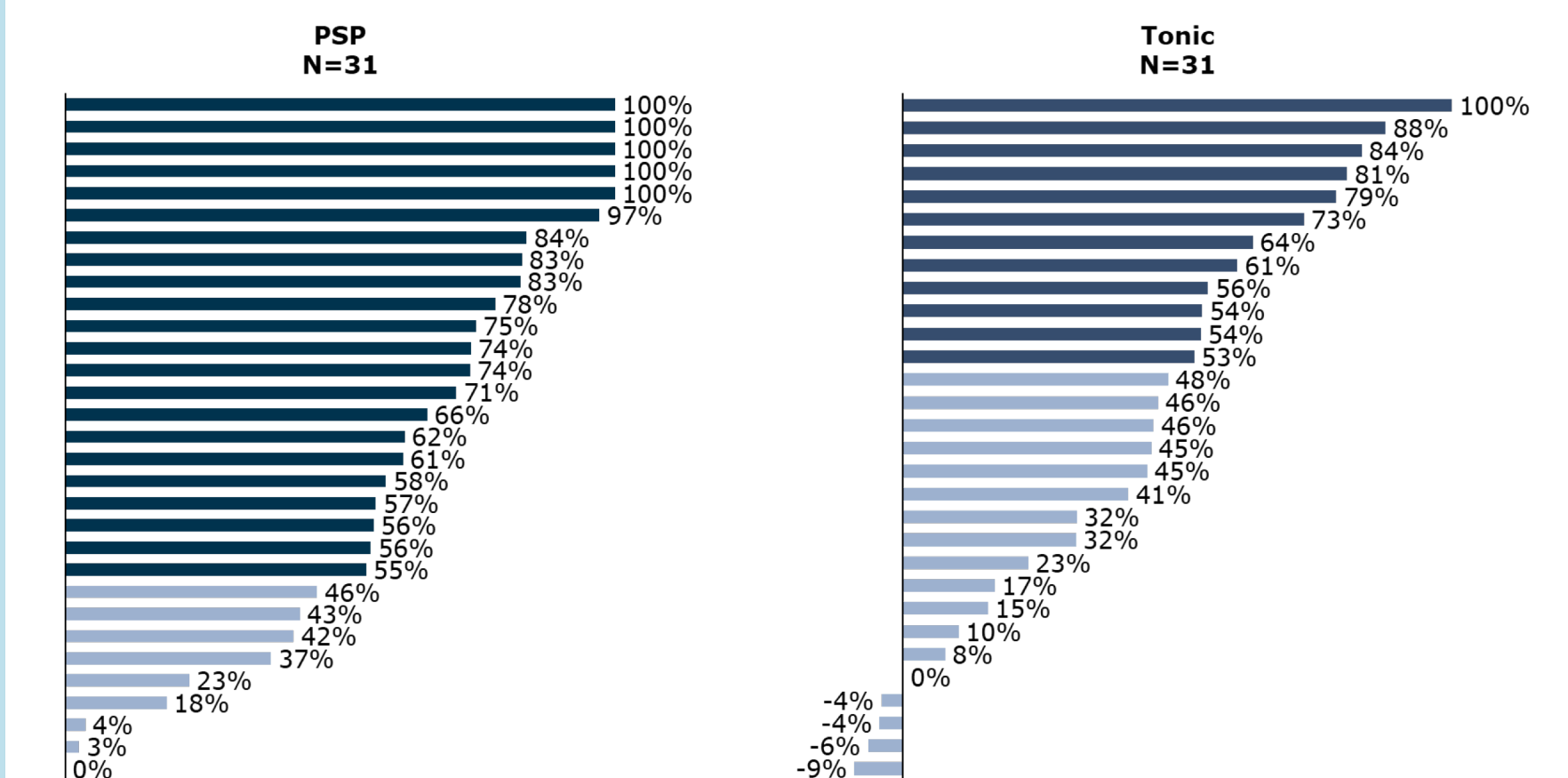
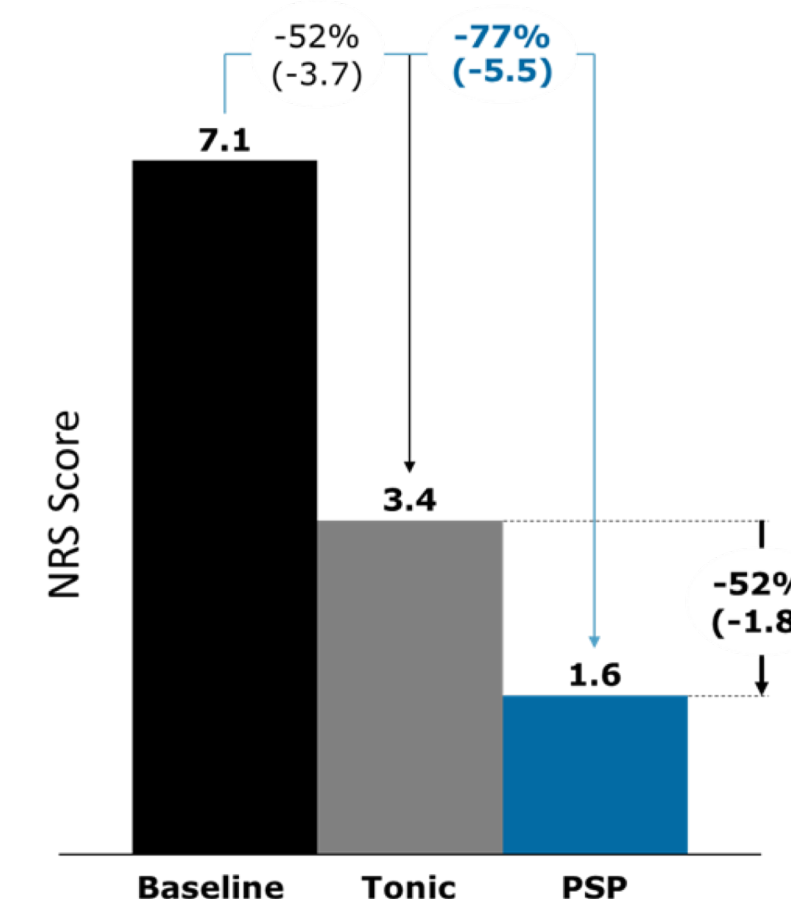


Figure 3. Upper Panels. Percentage low back pain relief in all subjects (left panel) and in subjects deemed responders (right panel; $\geq 50\%$ pain relief). Lower left. Responder rate to therapy. Lower right. All subject responses.

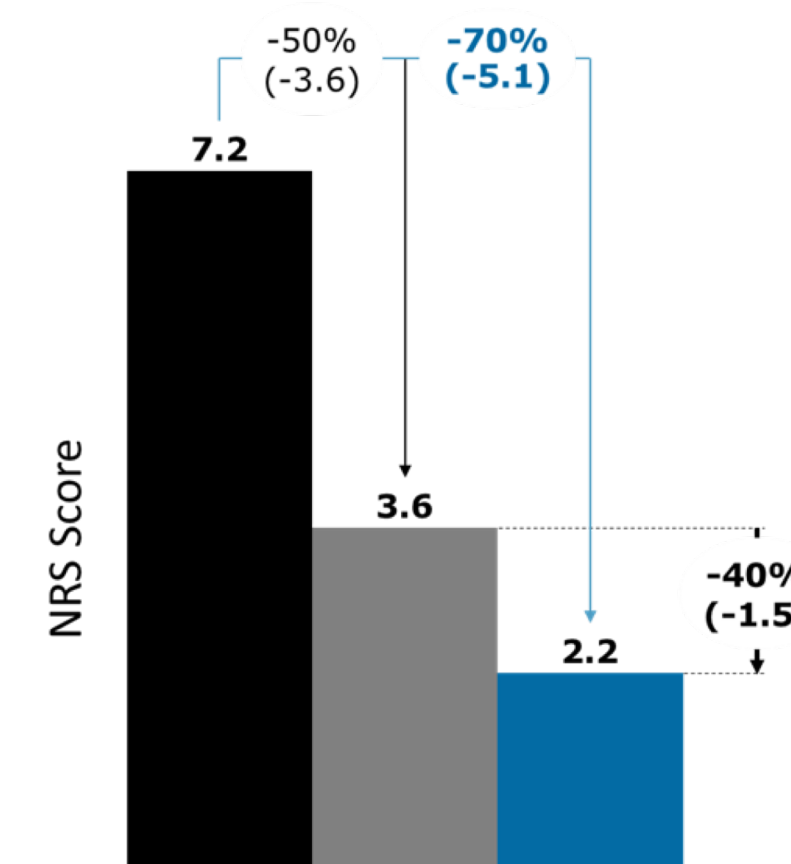
Leg Pain

N=22



Low Back Pain

N=22



Conclusions

In N=31 acute human study, novel, pulsed stimulation pattern (PSP) demonstrated:

- Significantly greater responder rate for Low Back Pain and