

Patient Experience with a Flexible Closed Loop Spinal Cord Stimulation System: 18-Month Outcomes

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Background

- Success of spinal cord stimulation (SCS) therapy is typically measured by change in pain intensity, which insufficiently describes the patient experience.¹
- Composite outcomes have been developed to capture the interplay between physical pain on quality of life, disability, and sleep status among other factors.²
- Here we report a composite outcome³ associated with various closed-loop (CL) waveforms in patients with chronic low back and/or limb pain.
- CL-SCS systems automatically adjust stimulation amplitude in response to sensed physiological signals to maintain consistent therapy delivery.
- The CL feature is flexible in that in can be applied to tonic or multiplexed waveforms

Methods

- Prospective study being conducted at 7 sites in Australia (NCT05177354). The study has 2 parts: a) in-clinic, randomized, cross-over, single blind, testing for Primary Endpoint at 1-month and b) long-term, single-arm follow-up for pain outcomes at 3-, 6-, 12-, 18- and 24-months post Device Activation. Primary outcome has been previously described.⁴
- Additional objective of the study is characterizing a multidimensional composite outcome³ at 18-months

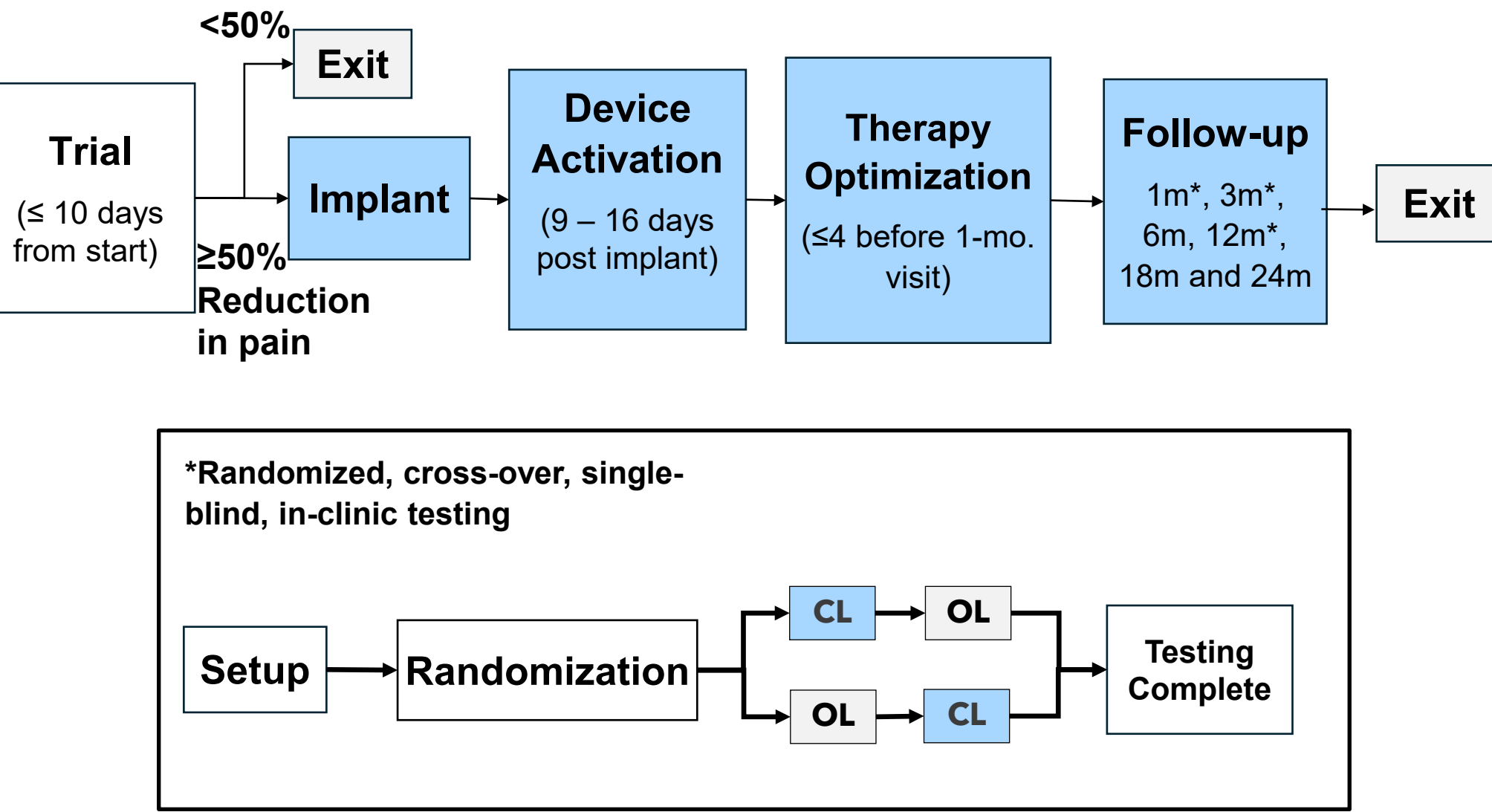


Figure 1. Study visits through the 24-month follow-up. The randomized in-clinic testing at 1-, 3- and 12-month visits is shown as an inset.

Table 1. Baseline Characteristics for Complete Case Set Subjects	
Baseline Characteristics	18 Months (N= 43)
Age, Mean (SD) years	58.6 (13.2)
Female, n (%)	20 (46.5%)
Primary Location of Pain, n (%)	
Low Back/Leg	41 (95.3)
Upper Limb	2 (4.7%)
Years Since Pain Onset, Mean (SD)	9.8 (9.6)
Baseline Opioid Use, n (%)	32 (74.4%)
Baseline Overall VAS, Mean (SD)	77.7 (9.64)
Severe Disability/Crippled ODI, n/N (%)	35/41 (85.4%)

Subject Disposition to 18M follow-up:

- 94 subjects were enrolled, 75 trialed and 60 were implanted with the CL-SCS device.
- 4/75 subjects that completed the Trial had <50% relief and were not eligible for implant. 11/75 were exited for other reasons - per PI/subject (8), deviation (2) and adverse event (AE; 1).
- 17 subjects exited between implant and the 18M visit due to lead revision (n=1), non-compliance with study (n=4), lost to follow-up (n=2), confounding or new pain condition (n = 7), IPG pocket dehiscence and infection secondary to shingles (n=1), anxiety (n=1), and spine surgery (n=1).

CL is effective across a variety of programming types

Preferred Programming Types at 18-Months

79% Were using closed-loop therapy as their most used program (n=43)

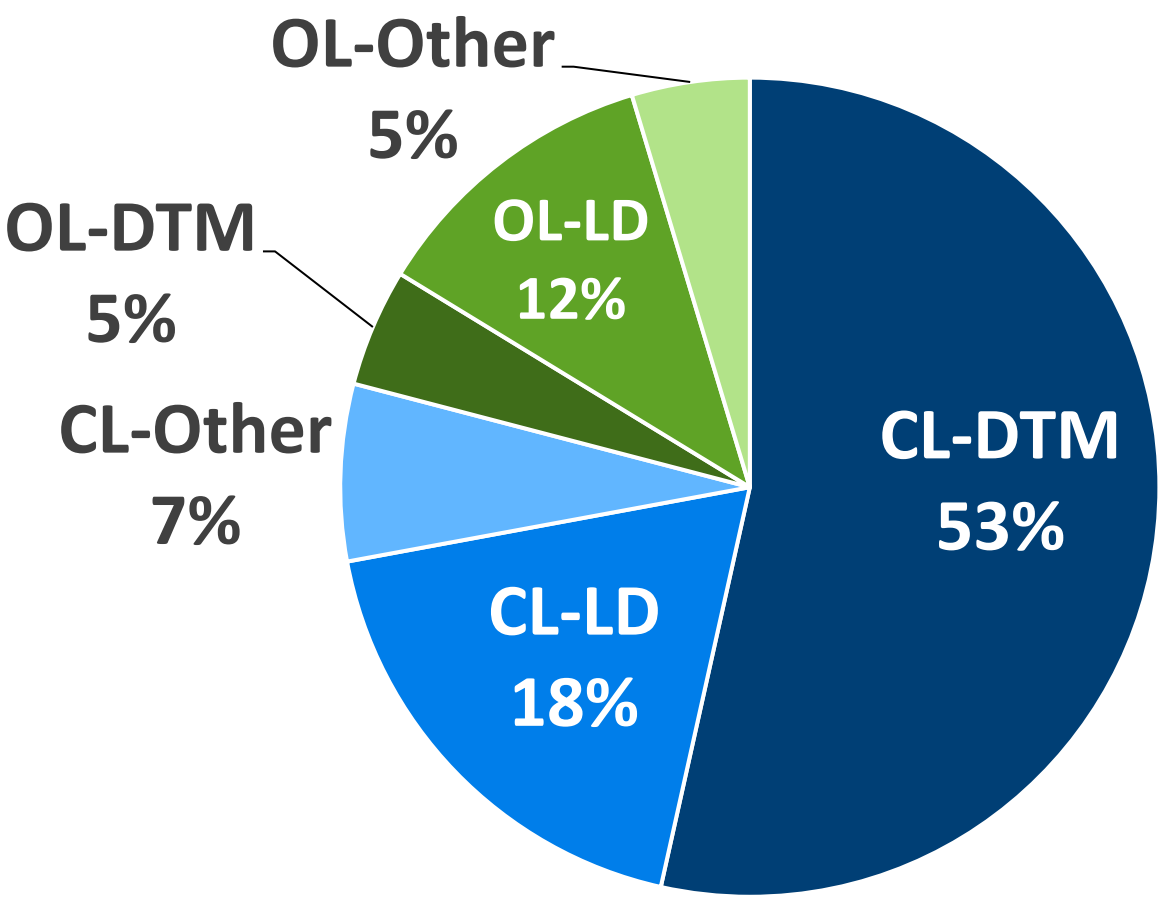


Figure 2. Preferred programming groups of the 18M complete case set based on device data (n=43).

Results and Discussion

Sustained and significant improvements in low-back pain and composite outcomes were seen through the 18M visit

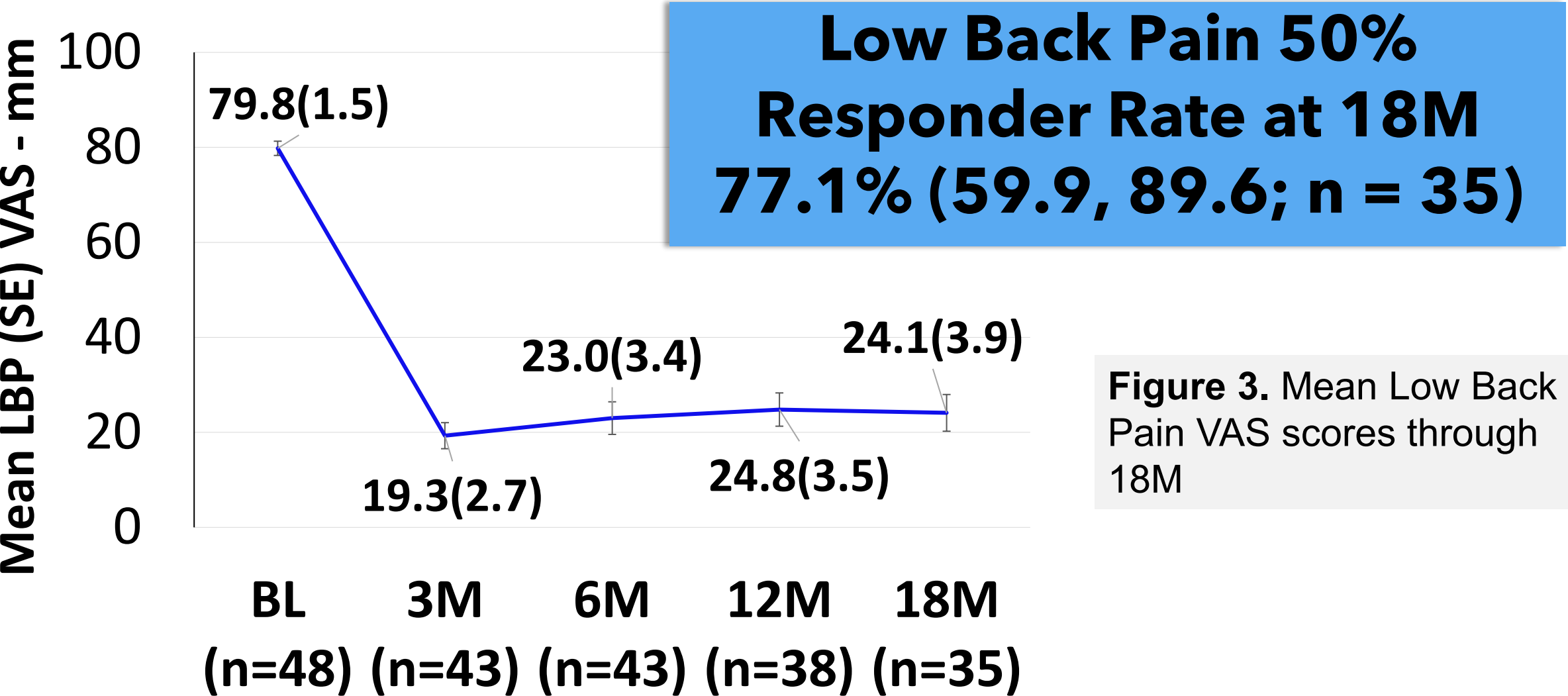


Figure 3. Mean Low Back Pain VAS scores through 18M

95%

Would definitely or probably recommend therapy to family or friends (n = 43)

98%

Expressed Satisfaction with therapy (n = 43)



81% improved in QoL (EQ-5D-5L ▲ by ≥0.074, n = 43)

Responder in ≥ 1 Domains (41/43) 95%



43% Improved in Mood (POMS ▼ ≥10, n = 42)

Responder in ≥ 2 Domains (38/43) 88%



73% improved Physical Function (Oswestry Disability Index ▼ ≥10, n = 41)

Responder in ≥ 3 Domains (33/43) 77%



63% improved in sleep quality (PSQI ▼ ≥3.0, n = 43)

Responder in ≥ 4 Domains (25/43) 58%

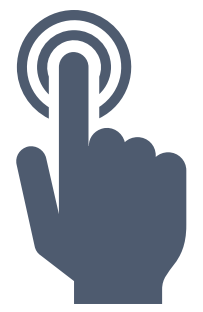


88% improved in Overall Pain (VAS ▼ ≥30%, n = 43)

Responder in all 5 Domains (11/40) 28%

Figure 4. Multimodal treatment responders at 18M. Responder is defined for each domain as improvements in VAS ≥ 30%, ODI ≥ 10, EQ-5D ≥ 0.074, PSQI ≥ 3, POMS ≥ 10

Low manual adjustment burden with CL-SCS during at-home use at the 12M follow-up



Subjects using CL-SCS adjusted the stimulation amplitude once (Median, IQR: 0-3) over 30 days (n=29)

50%

of survey participants made adjustments once per week to ≥1 per day with OL-SCS⁵

SUMMARY

- CL-SCS can successfully be programmed to a variety of waveforms and reduce the need for manual amplitude adjustments.
- Significant and sustained improvements were observed in Pain, Physical Function, and Quality of Life through 18-months.
- Final 24M outcomes are forthcoming to evaluate the long-term benefits of this flexible CL-SCS platform.

References:
1. Gewandter et al. Pain. 2021
2. Goudman et al. Neuromodulation. 2021
3. Levy et al. Neuromodulation. 2023
4. Mohabbati et al. Pain Med. 2025
5. Pritzlaff et al. Pain Phys. 2025

Disclosures:
MAR and VM have consulted for Medtronic. VM, MAR, RS, PG, and JY are participating investigators in this study.

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