Clinical Highlights

The BOLD Clinical Trial

BurstDR™ Microdosing Stimulation in De-Novo Patients

Deer T. Efficacy of Burst Spinal Cord Stimulation Microdosing in a De-Novo Patient.
Poster presented at: NAPA Pain 2019.

OVERVIEW

BurstDR™ stimulation is a therapy that has been shown to provide superior relief from pain and suffering† when compared to traditional tonic stimulation.[1] Dosing is the intermittent delivery of BurstDR stimulation. The BOLD study evaluated the therapeutic efficacy of different dosed BurstDR stimulation programs in patients with chronic intractable pain. A low-energy, recharge-free system allows the patient to focus less on the maintenance of their device.

STUDY SUMMARY

The study was a prospective, open-label, multicenter feasibility trial with follow-up periods at 1, 3 and 6 months. At the start of the trial phase, patients were given a baseline dosing stimulation program. At the end of the trial, all subjects with at least 50% pain relief were implanted. Following implant, patients were programmed using an electronic dosing protocol, aiming to provide therapeutic relief at the lowest possible dose. Patients were initially programmed at a low dose and their dosage was only increased if they received less relief than the trial period.

RESULTS

- 46% of patients utilized the program with the lowest dose setting (Figure 1)
- 76% pain reduction in trial responders
- Dosing with BurstDR stimulation effectively relieved pain for 6 months
- Visual Analog Scale (VAS) pain scores (overall, back and leg) were significantly reduced from baseline at all time points (Figures 3A-C)
- Attention to pain (Pain Catastrophizing Scale (PCS)) (Figure 2), quality of life (EQ-5D) and disability (Oswestry Disability Index) improved throughout follow-up
- All patients used therapy for 6 hours or less per day
- 6-month data endpoint
- Dosed BurstDR stimulation can significantly increase battery longevity[2]

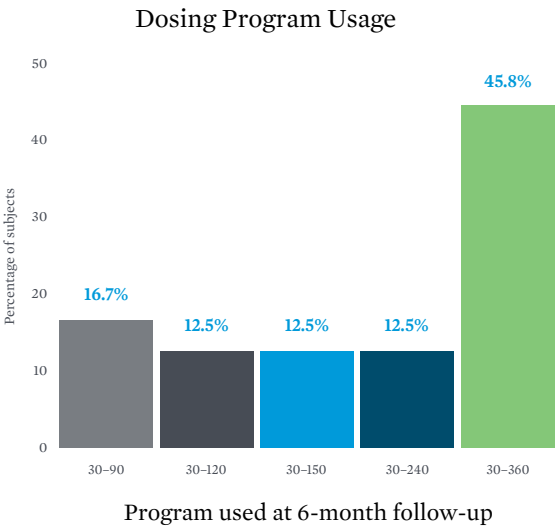

Figure 1: Dosing program usage at the 6-month follow-up visit.

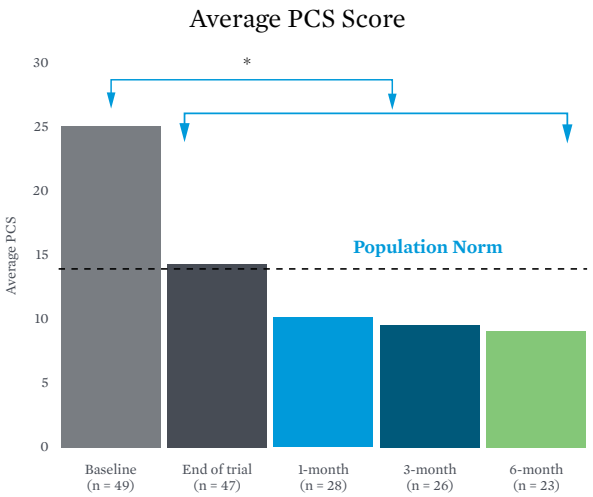

Figure 2: Average PCS score (*p < 0.001); dashed line represents non-pain population norm (13.9).[3]

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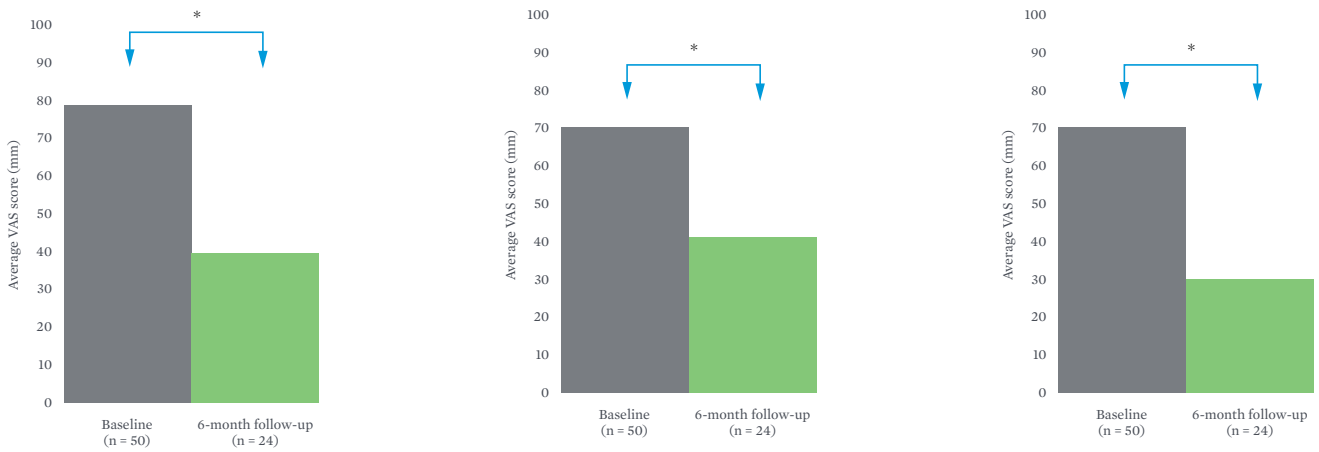

Figure 3: Effect of dosing BurstDR™ stimulation on pain. Average overall (A), back (B) and leg (C) pain at baseline and at 6-month follow-up visit (*p < 0.001).

CONCLUSIONS

- Dosing results in patients receiving minimal stimulation while maintaining therapeutic effect
- These findings present intriguing implications for the optimal dose of electricity in BurstDR™ stimulation and may offer many advantages such as:
  - Potentially mitigating therapy habituation or tolerance
  - Significantly reducing pain catastrophizing and disability
  - Significantly improving quality of life
  - Extending battery life

†Pain and suffering as measured by VAS.
*Indicates a statistically significant difference.

1. Deer T. Efficacy of Burst Spinal Cord Stimulation Microdosing in a De-Novo Patient. Poster presented at: NAPA Pain 2019.
2. Abbott. St. Jude Medical Proclaim™ Neurostimulation System Clinican's Manual. Plano, TX. 2018.
3. Osman A, Barrios FX, Gutierrez PM, Kopper BA, Merrifield T, Grittmann L. The Pain Catastrophizing Scale: further psychometric evaluation with adult samples. *J Behav Med.* 2000;23(4):351-365.

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