Effects of streamlined high dose and high frequency stimulation in SCS to determine optimal settings

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DISCLOSURES

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INTRO

- Spinal cord stimulation (SCS) has been shown to be an effective intervention for chronic pain.
- Changing positions has long been known to alter how patients feel SCS, especially when patients lie supine.\(^1\)
- Termed “Shuffle”, adaptive SCS has been shown to be preferred by patients and to improve certain outcomes.\(^2\)
- Here we streamline programming to determine whether “Shuffle” can be widely disseminated and used.


In this 10-week cross-over study, patients are randomized to receive either high dose (HD) stimulation or Shuffle for a 4-week study period, then are switched to the other stimulation (HD or Shuffle) for the second study period (Figure 1). HD was delivered at a consistent setting, whereas Shuffle used integrated accelerometry to alter stimulation depending on whether the patient was sitting or standing.

Subjects completed the Numeric Ratings Scale (NRS), Oswestry Disability Index (ODI), Beck Depression Inventory (BDI), Pain Catastrophizing Scales (PCS), McGill Pain Questionnaire (MPQ), Insomnia Severity Index (ISI), Epworth Sleepiness Scale (ESS), and several Activity (AT) scales (sleeping, bathing, standing, dressing, eating, walking, driving, lifting and sitting) pre-operatively and after each study period.

Raw scores for the 6 patients who have completed the study thus far were compared between treatments via repeated measures ANOVAs.

**Figure 1: Study Design**
RESULTS

- Both the MPQ-Sensory and the MPQ-Total demonstrated that scores with HD programming were significantly improved as compared to baseline scores ($p=0.03$ & $p=0.05$, Figure 1).

- No significant difference between on any other outcomes (MPQ-affective, ODI, BDI, PCS, NRS, ESS, ISI, $p>0.05$ for all).

Figure 1: Baseline, HD, and Shuffle scores for the MPQ-Sensory (left, $p=0.03$ for Baseline vs HD) and the MPQ-Total (right, $p=0.05$ for Baseline vs HD).
RESULTS

- Comparing scores via T-test, both the NRS-Pain under stimulation and NRS-Pain right now demonstrated lower scores (indicating less pain) in patients receiving Shuffle ($p=0.025$ & $p=0.049$, Figure 2).

- No significant differences on other scores ($p>0.05$ for MPQ, ODI, BDI, PCS-total, ESS, and ISI).

Figure 2: Scores following HD versus Shuffle T-test results for the NRS-Pain under stimulation scale (left, $p=0.025$) and the NRS-Pain right now (right, $p=0.049$)
RESULTS

- The AT-Bathing, AT-Driving, and AT-Sitting scales all demonstrate trending towards improvement with Shuffle as compared to baseline via rmANOVA (Figure 3).

- No significant or trending improvements on AT-sleeping, AT-standing, AT-dressing, AT-eating, AT-walking, or AT-lifting.

Figure 3: Trending differences for three activities. 
LEFT: AT-Bathing: Baseline vs. Shuffle scores, \( p=0.06 \). Baseline vs HD, \( p=0.56 \). 
MIDDLE: AT-Driving, Baseline vs HD, \( p=0.07 \). Baseline vs Shuffle, \( p=0.09 \). 
RIGHT: AT-Sitting, Baseline vs Shuffle, \( p=0.07 \). Baseline vs HD, \( p=0.17 \).
Independent of their outcomes, 67% (4/6) of patients reported that they preferred the Shuffle algorithm.
DISCUSSION

- Largely positive outcomes were noted with both HD and Shuffle stimulation.

- Shuffle may provide superior improvement in functionality with regards to bathing, sitting, and driving activities.

- Following interim analysis, programming parameters have been revised going forward. We look forward to confirming these findings in a larger cohort with our updated parameters.