A Prospective Evaluation of Selectivity in a High-resolution Spinal Cord Stimulation Paddle

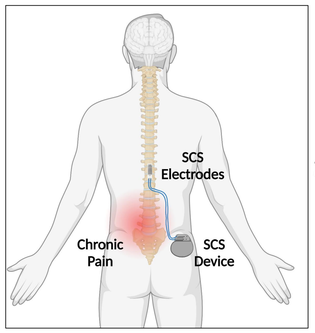
Deepak Berwal[1], Alejandra Quintero[1], Ilknur Telkes[2], Marisa DiMarzio[1], Tessa Harland[3], Steven Paniccioli[4], John Dalfino[3], Yohannes Iyassu[5], Bryan McLaughlin[5#], Julie G Pilitsis[1$]*

[1]Department of Clinical Neurosciences, Florida Atlantic University, Boca Raton, FL, [2]Department of Biomedical Sciences, Florida Atlantic University, Boca Raton, FL, [3]Department of Neurosurgery, Albany Medical College, Albany, NY, [4]NuVasive Clinical Services, San Diego, CA, [5]Micro-Leads Inc., Somerville, MA

Correspondence: *dberwal@health.fau.edu, #bryan@micoleads.com, $jpilitsis@health.fau.edu

Introduction

- Spinal cord stimulation (SCS) has been shown to be effective for the treatment of patients with chronic pain and with spinal cord injury.
- SCS delivers electrical pulses with adjustable amplitude, width, and frequency to an electrode array placed in the epidural space in spinal cord and induces pain relief.
- In this prospective study, we investigate whether high-resolution spinal cord stimulation (HR-SCS) offers improved selectivity assessed through elicitation of evoked electromyography (EMG) responses as compared to commercial leads.



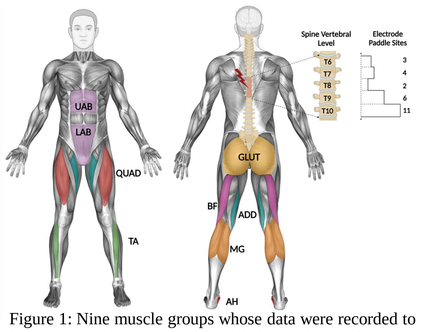


Figure 1: Nine muscle groups whose data were recorded to investigate their responses at applied stimulation. Spine vertebral levels where SCS paddles were placed to investigate muscle responses.

Methodology

- Vertical tripole configurations (60Hz/300µs) were used to elicit EMG responses in both types of paddles in 18 patients placed for standard of care indications between T6-T10.
- In HR-SCS, evoked EMG responses in lower extremity/abdominal muscle groups were monitored at 6 to 8 mediolateral sites. All commercial paddle columns were tested.
- Percentage change in the maximum root mean square value (RMS_{max}) was calculated at a group level.
- Heat maps were generated to identify responders for each muscle group. Responders were considered patients that had a > 50% change in RMS over baseline.

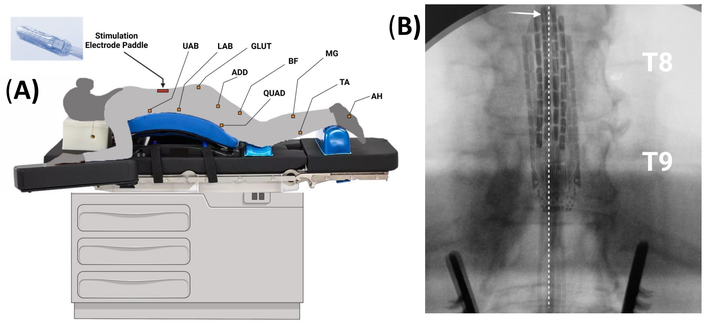


Figure 2: (A) Patients position on bed during IONM procedure to acquire SCS-induced responses. (B) Images taken of the commercial and HR-SCS have been overlaid on an intraoperative fluoroscopic image. The dashed white line indicates the anatomic midline.

AH- Abductor Hallucis, TA- Tibialis Anterior, MG- Medial Gastrocnemius, BF- Biceps Femoris, ADD- Adductor Magnus, QUAD- Quadriceps, GLUT- Gluteus, LAB- Lower Abdominis, UAB- Upper Abdominis

Results

Average maximum RMS change (%) with respect to baseline at 6mA or lower

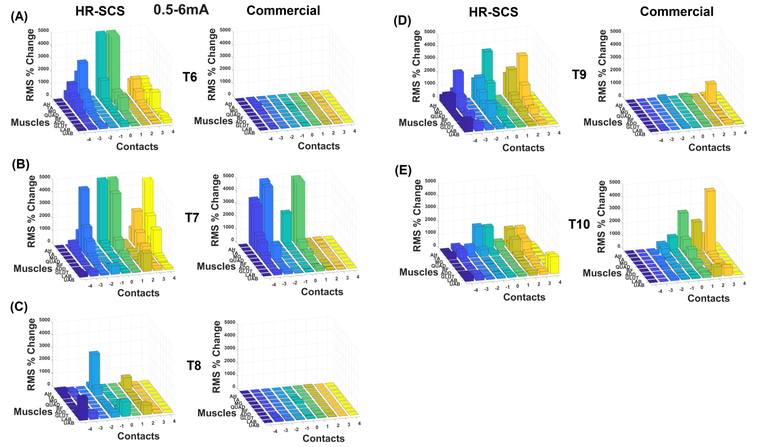
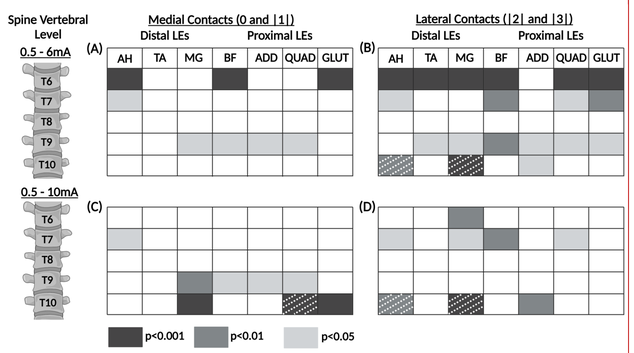


Figure 3: Average maximum RMS change (%) with respect to baseline at 6mA or lower. The data was then aligned with respect to the physiological midline (0 - Contact), where left-sided contacts have negative values and right sided – positive. The mean values from both left and right-sided muscles were used in contact 0 calculations. (A) Data from three patients were recorded at T6. (B) Data from four patients were recorded at the T7 spinal level. (C) Data from two patients were recorded at the T8 spinal level. (D) Data from six patients were recorded at the T9 spinal level. (E) Data from eleven patients were recorded at the T10 spinal level.

Comparison of HR-SCS and commercial paddles for all muscles at T6 to T10 spine levels

Figure 4: Comparison of HR-SCS and commercial paddles for all muscle groups at T6 to T10 spine levels. The contacts corresponding to anatomic midline column were labeled Contact 0. Contacts 0 and |1| were considered medial. |1| includes both –1 and 1 and a similar absolute value expression was used for all contacts. Contacts |2| and |3| were assumed to stimulate lateral structures. Recordings were taken from 18 patients. The number of recordings for each contact at each paddle varied from 0 to 11. RMS_{max} group averages of evoked EMG responses for medial and lateral contacts with stimulation at amplitudes of (A-B) 0.5-6mA and (C-D) 0.5-10mA were calculated. Significance was determined using a linear mixed-effects model. Commercial paddles had higher muscle responses (AH and MG) than HR-SCS paddle for 0.5-6mA amplitude and AH, MG and QUAD for 0.5-10mA amplitude at T10 level (indicated by dotted squares).



Motor recruitment heatmaps for Adductor Hallucis (AH) at amplitudes at T6 to T10

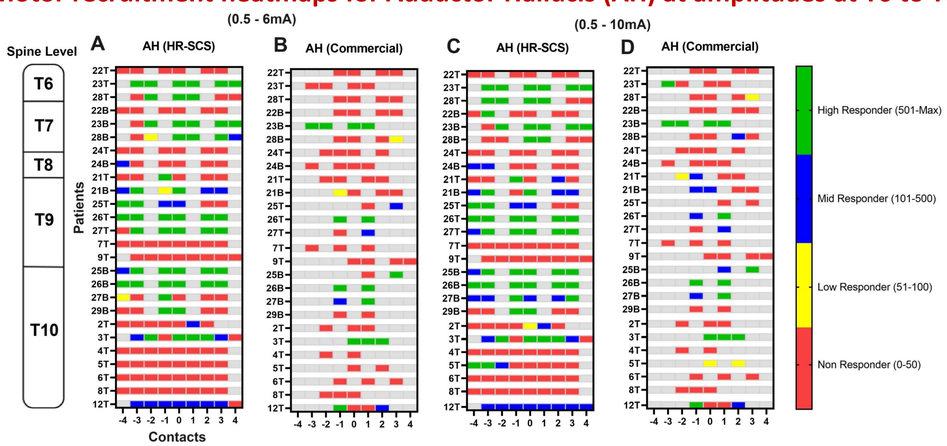


Figure 5: Motor recruitment heatmaps for Adductor Hallucis (AH) at amplitudes (A-B) 0.5-6mA (C-D) 0.5-10mA at T6 to T10. (A) and (C) depict HR-SCS results and (B) and (D) commercial paddles. Responders were determined based on values >50% RMS change with respect to baseline and non-responders were classified as values <50% RMS change with respect to baseline. The responder group was then separated into low (51-100 %RMS change), mid (101-500 %RMS change), and high (500-max %RMS change) responders. These values were decided based on the change in percentage threshold.

Acknowledgement: This study was sponsored by the NIH U44NS115111.

Responders of HR-SCS and commercial paddles at 6mA

Table 1: Comparison of responders of HR-SCS and commercial paddles for all muscle groups at T6 to T10 spine levels at 6mA. The percentage of responders for each muscle at each level for HR-SCS and commercial paddles were determined, and chi-square and Fisher's exact test used to determine significance. Bold values showed a significant difference between responders.

Muscles	T6	T7	T8	T9	T10
ADD	>0.9999	0.924	>0.9999	0.0982	0.7715
AH	>0.9999	**0.0391**	>0.9999	0.077	0.3045
BF	0.4529	0.0666	>0.9999	**0.0001**	0.3925
GLUT	>0.9999	>0.9999	>0.9999	**<0.0001**	0.3934
LABs	>0.9999	0.1589	**<0.0001**	0.0669	0.9567
MG	<0.0001	>0.9999	>0.9999	**0.0114**	0.881
QUAD	0.0632	**0.0244**	**0.0042**	0.9441	**0.0195**
TA	**<0.0001**	0.2299	>0.9999	**0.0114**	0.8376
UABs	**<0.0001**	0.1693	**0.0431**	0.6603	0.3989

Conclusion

- We demonstrate that HR-SCS has greater selectivity in eliciting evoked EMG responses in an intraoperative setting.
- We demonstrate that motor responses and responder rates both support this finding notably at T6 and T9.
- HR-SCS offers recruitment of muscle groups at lateral contacts concurrently with medial contacts.
- We provide data that in an intraoperative setting HR-SCS is able to stimulate a wider region of the dorsal structures of the spinal cord which allows for further advancing our understanding of spinal cord somatotopy and ideally for proving better symptom control.

Future Direction

- Treating pain by selectively targeting the involved dermatome is a crucial step toward personalized treatment for each patient with chronic pain.
- Our goal for future research is to test long-term permanent HR-SCS implants in patients and assess pain relief in the affected dermatomes, over a wide range of thoracic levels and lateralities.
- Our study had a limited sample size across various spinal levels, so in future we aim to increase our sample size for better interpretation of our conclusions.

References

1) Telkes I, Hadanny A, DiMarzio M, et al. High-Resolution Spinal Motor Mapping Using Thoracic Spinal Cord Stimulation in Patients With Chronic Pain. Neurosurgery. Sep 1, 2022; 91(3):459-469. doi:10.1227/neu.0000000000002054

2) Telkes I, Behal A, Hadanny A, et al. Rapid Visualization Tool for Intraoperative Dorsal Column Mapping Triggered by Spinal Cord Stimulation in Chronic Pain Patients. Annual International Conference of the IEEE Engineering in Medicine and Biology Society IEEE Engineering in Medicine and Biology Society Annual International Conference. Nov 2021;2021:5760-5763. doi:10.1109/embc46164.2021.9630459