

Improved Selectivity in Eliciting Evoked Electromyography Responses With High-Resolution Spinal Cord Stimulation

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Received, October 02, 2023; **Accepted,** December 29, 2023; **Published Online,** February 20, 2024.

Neurosurgery 00:1–8, 2024

<https://doi.org/10.1227/neu.0000000000002878>

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BACKGROUND AND OBJECTIVES: As spinal cord stimulation (SCS) offers a therapy for increasing numbers of patients with chronic pain and spinal cord injury, it becomes increasingly important to better understand its somatotopy. In this prospective study, we investigate whether high-resolution SCS (HR-SCS) offers improved selectivity assessed through elicitation of evoked electromyography (EMG) responses as compared with commercial paddle leads.

METHODS: Vertical tripole configurations were used to elicit EMG responses in both types of paddles placed for standard-of-care indications between T6 and 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 was calculated at a group level. Heat maps were generated to identify responders for each muscle group. Responders were considered patients who had a >50% change in root mean square over baseline.

RESULTS: We demonstrated significantly greater motor responses across medial and lateral contacts and greater responder rates consistently at the T6 and T9 levels with HR-SCS as compared with commercial paddles in 18 patients. Distal muscle groups (gastrocnemius and tibialis anterior) and proximal muscle groups (biceps femoris and quadriceps) were selectively activated at both levels.

CONCLUSION: We demonstrate that HR-SCS has greater selectivity in eliciting evoked EMG responses in an intra-operative setting. HR-SCS offers recruitment of muscle groups at lateral contacts concurrently with medial contacts. We provide data that HR-SCS may provide higher spatial resolution, which has the potential to allow for personalization of care and treatment of pain syndromes/symptoms which to date have not been effectively treated.

KEY WORDS: Chronic pain, Evoked EMG, High-resolution spinal cord stimulation, Lower extremity muscles, Mediolateral selectivity

Spinal cord stimulation (SCS) has been shown to be effective for the treatment of failed back surgery syndrome, neuropathic pain, and complex regional pain syndrome.¹⁻⁴

While SCS can treat pain in most of the implanted patients, sometimes certain regions have suboptimal pain relief.^{5,6} Furthermore, over time, new areas of pain may develop, and often, it is difficult with the existing placement of the device to treat these symptoms. Generally, the placement of SCS focuses on covering the dorsal columns based on the gate theory of pain and new theories involving wide dynamic range neurons.^{7,8} Stimulation of the lateral aspects of the spinal column might also have benefit as shown through the literature on dorsal root ganglion (DRG) stimulation.⁹⁻¹³ Placement of DRG stimulation tends, however, to be more technically challenging and does not allow for coverage of the medial structures.¹³⁻¹⁶

ABBREVIATIONS: AH, adductor hallucis; BF, bicep femoris; DRG, dorsal root ganglion; EMG, electromyography; HR-SCS, high-resolution spinal cord stimulation; IONM, intraoperative neurophysiological monitoring; MG, medial gastrocnemius; RMS, root mean square; SCS, spinal cord stimulation; TA, tibialis anterior.

Supplemental digital content is available for this article at neurosurgery-online.com.

To overcome the constraints of current devices, a high-resolution spinal cord stimulation (HR-SCS) paddle was developed. The device is wider and 60% thinner on the edges, which allows it to be more malleable to the curvature of the thecal sac.¹⁷ In this article, using intraoperative neurophysiological monitoring (IONM), we examine the selectivity of this paddle in eliciting evoked motor responses in the lower extremities and compare these data with those obtained with commercial SCS paddles.

METHODS

Patients with chronic leg and back pain who underwent a successful trial of SCS—defined as >50% response on the numerical rating scale, a psychological assessment that confirmed candidacy, and preoperative imaging—were offered participation in this Investigational Device Exemption study (FDA IDE number: G210346). The local Institutional Review Board approved the protocol through Institutional Review Board #5151 and #6426. It was listed through ClinicalTrials.gov (Identifier: NCT05459324). All patients provided written informed consent before enrollment.

Surgical Workflow

After consent was obtained, patients underwent a standard-of-care laminectomy, which was performed with the previously published IONM procedure.¹⁸ As part of the surgical routine at our institution, somatosensory evoked potentials, compound motor action potentials, and evoked EMGs were recorded to ensure patient safety. Nine muscle groups were tested including the upper and lower rectus abdominis (upper abdominals; lower abdominals), quadriceps, adductor magnus, tibialis anterior (TA), adductor hallucis (AH), gluteus maximus, biceps femoris (BF), and medial gastrocnemius (MG). Once the laminectomy was completed, an investigational HR-SCS paddle (**Supplemental Digital Content 1, Figure 1**, <http://links.lww.com/NEU/E135>) was placed (Micro-Leads Inc.). The HR-SCS paddle was centered over the individualized “sweet spot” based on trial data (Figure 1). C-arm fluoroscopy (GE HealthCare) confirmed placement.

Two configurations consisting of a longitudinal tripole (+/−/+) at both the top and bottom of the HR-SCS and commercial paddles were tested in 9 participants. Only the bottom tripole was tested in the first 9 participants. Stimulation at 60 Hz/300 μs was delivered through a handheld programmer designed/developed during the course of the grant. The HR-SCS pulse generator is a current-based, charge-balanced biphasic system that delivers programmed current amplitudes to the paddle electrodes. Amplitudes gradually increased by a 0.5 mA step size until significant electromyography (EMG) activity seen on IONM was reached or a maximum stimulation amplitude of 10 mA was reached. A Cascade PRO IONM system (Cadwell Inc.) was used for monitoring and recording of the EMG data. After completion of the study portion, the commercial paddle was placed over the clinically indicated “sweet spot” and the same stimulation algorithm was followed. To limit the risk of placing and removing paddles, HR-SCS was always performed first. Because of this concern, we measured biospectral index in our first few patients and ensured that it was the same for both groups. Furthermore, often, light anesthesia is evident in EMG changes that occur spontaneously. There was no evidence of this occurring in any patient at the time of the study.

During offline analysis, fluoroscopic imaging was used to determine the anatomic midline position for both paddles to allow for normalization

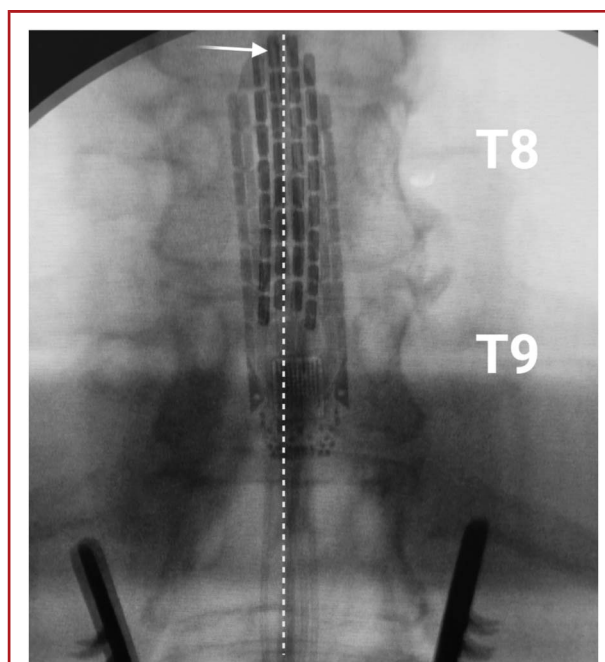


FIGURE 1. Images taken of the commercial and HR-SCS have been overlaid on an intraoperative fluoroscopic image. The dashed white line indicates the anatomic midline. We see that the orientation of both paddles differs in relation to midline at T8 and T9. The white arrow shows that column 2 (from left) in the commercial paddle overlaps with column 4 (from left) on the HR-SCS paddle. This normalization and alignment of contacts were essential for data comparison. HR-SCS, high-resolution spinal cord stimulation.

and alignment (Figure 1). Specifically, a column positioned at the anatomic midline was labeled “0” along with “−1 and +1,” which were considered as medial contacts with the left-sided columns labeled negative (−4, −3, −2) and right-sided columns labeled positive (+2, +3, +4). We did not perform comparisons at ±4 columns because of limited commercial paddle data.

Signal Processing

All signals were processed offline in MATLAB R2022b (MathWorks). The EMG signals were denoised using an algorithm developed previously by setting a 10% threshold and removing values exceeding it.¹⁹ The root mean square (RMS) of signals was computed at each amplitude (stimulation ON) for all patients and normalized for baseline (stimulation OFF).

$$\text{Normalized RMS (\% change)} = \frac{\text{RMS}_{\text{ON}_i} - \text{RMS}_{\text{OFF}}}{\text{RMS}_{\text{OFF}}} \times 100.$$

Both at the individual and group level, maximum percentage change in RMS (maxRMS) was determined for amplitudes ≤6 and ≤10 mA. The lower range was examined because motor responses in the HR-SCS paddle were visualized at or approximately 6 mA when responses from the commercial paddle often necessitated amplitudes up to 10 mA (**Supplemental Digital Content 2, Table**, <http://links.lww.com/NEU/>

E136). For further assessment, contacts ± 1 and 0 were grouped as medial contacts and ± 4 , ± 3 , and ± 2 were grouped as lateral contacts.

Motor heatmaps were created in GraphPad Prism-10 (GraphPad Software, Inc.) for all 9 muscle groups at each spine level first on the patient level and then at the group level. Based on maxRMS, subjects were divided into responders (values $\geq 50\%$ RMS change for baseline) and nonresponders (values $< 50\%$ RMS change for 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.

Statistical Analysis

Statistical analyses were performed in MATLAB R2022b (MathWorks). To compare the HR-SCS and commercial paddle motor responses, the Pearson χ^2 test of independence and the Kruskal–Wallis test were performed. Bonferroni correction was used for multiple comparisons. For cases in which the Pearson χ^2 test of independence was unable to be performed, Fischer's exact t -test was conducted as a corrective measure. A linear mixed-effects model was also applied to see the effect of the spine level, muscles, and contact alignment. The impact of demographics and other variables on RMS values was assessed through correlation analysis and analysis of variance with the post hoc Tukey test.

RESULTS

A total of 21 participants were included in this trial. Both HR-SCS and commercial data were available in 18 patients—12 female and 6 male patients. Of the 18, 9 were diagnosed with neuropathic pain, 7 with failed back surgery syndrome, and 2 with complex regional pain syndrome. The number of tripoles tested varied across thoracic levels. Specifically, 3 tripoles were assessed at T6, 4 at T7, 2 at T8, 6 at T9, and 11 at T10. The specific number of data points at each level is described in Table 1.

At a group level, we first examined the average maxRMS change for the baseline for HR-SCS and commercial paddles at 6 mA (Figure 2). At T9, HR-SCS elicited responses in the most lateral contacts ± 4 . The maxRMS values were significantly greater in the HR-SCS group in most of the overlapping contacts ($P < .01$) at T6 and T9 (Table 2). When we examined responses up to 10 mA, results were similar (**Supplemental Digital Content 3, Figure 2**, <http://links.lww.com/NEU/E137>). Sex and age did not correlate with differences in RMS. We examined the mean RMS from all muscle groups broken down by patient diagnosis and number of columns on paddles. Five different paddles with 2–5 columns from 3 different manufacturers were used for this study. When we examined the RMS data from the commercial paddles, there was no difference based on the paddle used. Diagnosis only had an effect on AH RMS in the HR-SCS only. Specifically, patients with neuropathic pain had a higher RMS in AH than those with failed back surgery syndrome ($P = .011$). Dorsal cerebrospinal fluid thickness did not affect maxRMS, but did affect maximal stimulation amplitude needed to obtain a response (data not shown).

Lateral contacts from HR-SCS paddles produced significantly higher muscle responses for both distal and proximal muscles at T6 ($P < .001$), T7 ($P < .05$), and T9 ($P < .05$), and medial contacts evoked similar responses at T6 (Figure 3, top left) and T9 (Figure 3, top right). Of note, the commercial paddle had more robust results at T10 in AH and MG ($P < .01$). Regarding the mediolaterality, responses obtained up to 10 mA were similar at T7 and T9 (Figure 3). Only the right-sided lateral contacts showed a significant difference at the T7 and T8 levels. The commercial paddle did not show robust results at any level. Lateral contacts at T7 and medial contacts at T9, for both distal and proximal lower extremities, showed similar significant differences at 10 mA and 6 mA (Figure 3).

TABLE 1. The Number of Contacts Tested at T6–T10 Spinal Levels for HR-SCS and Commercial Paddles

Spine level	Contact	−4	−3	−2	−1	0	1	2	3	4
		Number of recordings								
T6	Investigational	1	3	2	1	3	2	1	3	2
	Commercial	ND	1	1	2	3	1	2	2	ND
T7	Investigational	2	4	2	2	4	2	2	4	2
	Commercial	ND	1	2	3	4	1	3	2	ND
T8	Investigational	2	2	ND	2	2	ND	2	2	ND
	Commercial	ND	1	1	2	1	2	1	ND	ND
T9	Investigational	5	6	2	6	6	2	6	6	1
	Commercial	ND	1	ND	4	2	5	2	5	1
T10	Investigational	8	11	7	10	11	7	11	10	2
	Commercial	ND	ND	3	6	6	8	3	2	ND

HR-SCS, high-resolution spinal cord stimulation; ND, no data.

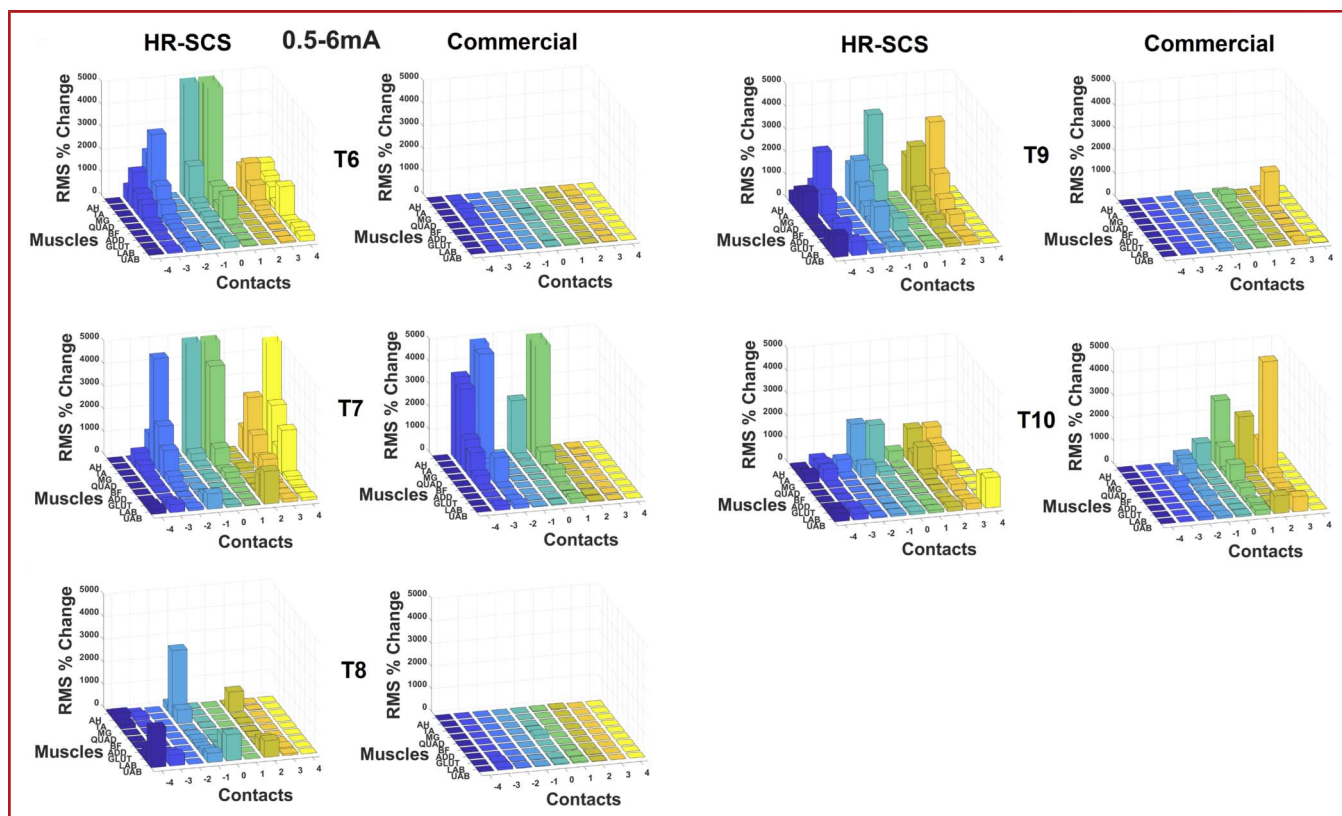


FIGURE 2. Average maximum RMS change (%) for baseline at 6 mA or lower. The data were then aligned for the physiological midline (0—Contact), where left-sided contacts have negative values and right-sided contacts have positive values. The mean values from both left- and right-sided muscles were used in contact 0 calculations. (Top Left) Data from 3 patients were recorded at T6. (Middle Left) Data from 4 patients were recorded at the T7 spinal level. (Bottom Left) Data from 2 patients were recorded at the T8 spinal level. (Top Right) Data from 6 patients were recorded at the T9 spinal level. (Middle Right) Data from 11 patients were recorded at the T10 spinal level. HR-SCS, high-resolution spinal cord stimulation; RMS, root mean square.

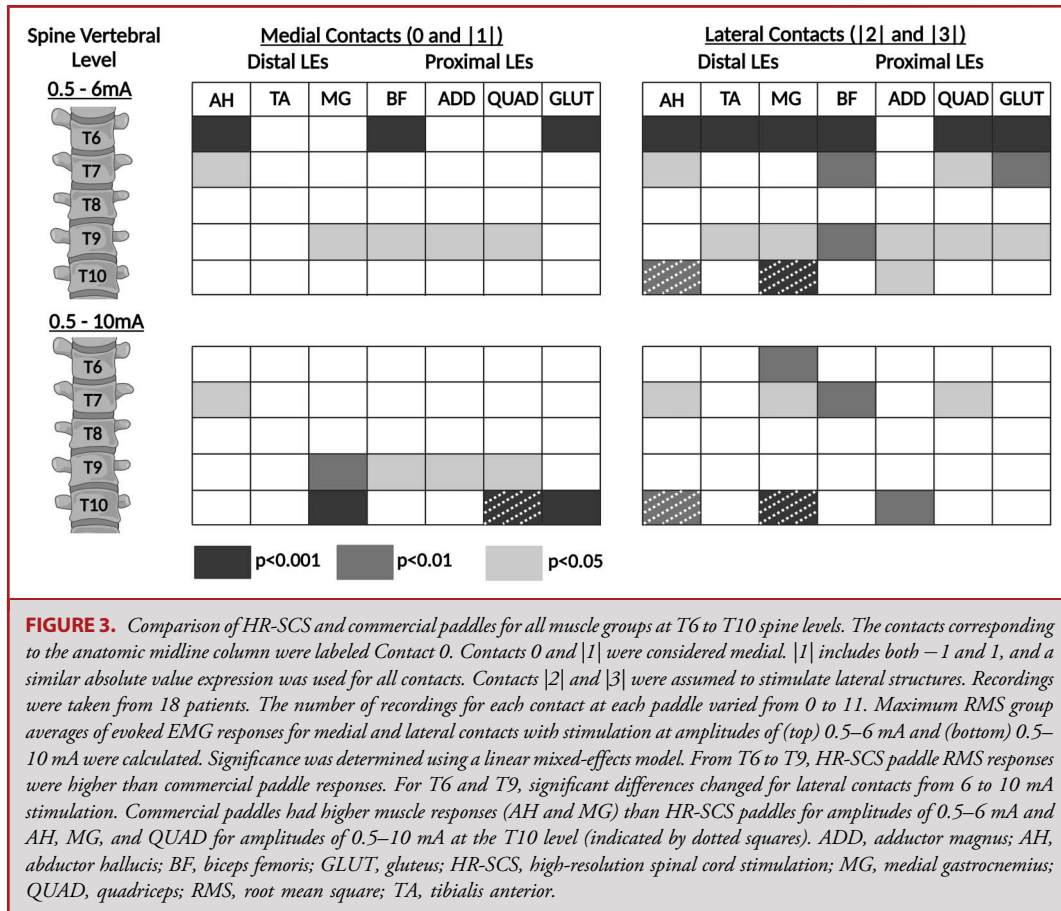
Then, we examined the responder rates based on maxRMS. Figure 4 displays the maxRMS changes (%) for the AH at the group level for both HR-SCS and commercial paddles at 6 mA (Figure 4, left side) and 10 mA (Figure 4, right side). Similarly, heatmaps were

created for each muscle group. As summarized in Table 3, there were significantly more responders in the HR-SCS group at T6 and T9 in stimulating TA and MG ($P < .05$; χ^2 , Fisher’s exact t -test) and in proximal muscles (BF and GLUTs) at T9 ($P < .001$).

TABLE 2. For Normalization, HR-SCS and Commercial Paddle Columns Were Aligned With Fluoroscopy

Spine level	Left lateral contacts			Medial contacts			Right lateral contacts		
	-4	-3	-2	-1	0	1	2	3	4
T6		0.015	<0.001	0.894	<0.001	0.003	0.627	0.001	
T7		0.17	0.79	0.96	0.12	0.45	0.62	<0.001	
T8		0.015		<0.001	0.353		0.002		
T9		<0.001		0.003	<0.001	0.005	<0.001	0.046	0.69
T10			0.96	0.89	0.5	0.015	0.2	0.5	

The contact corresponding to the paddle’s column at the anatomic midline was labeled Contact 0. Recordings were taken from 18 patients. The number of recordings for each contact at each paddle varied from 0 to 11. Maximum root-mean-square group averages of evoked EMG responses with stimulation at amplitudes of 0.5–6 mA were compared using the Kruskal–Wallis test with Bonferroni corrections. $P < .0056$ denotes where greater RMS values were seen in HR-SCS compared with commercial paddles.



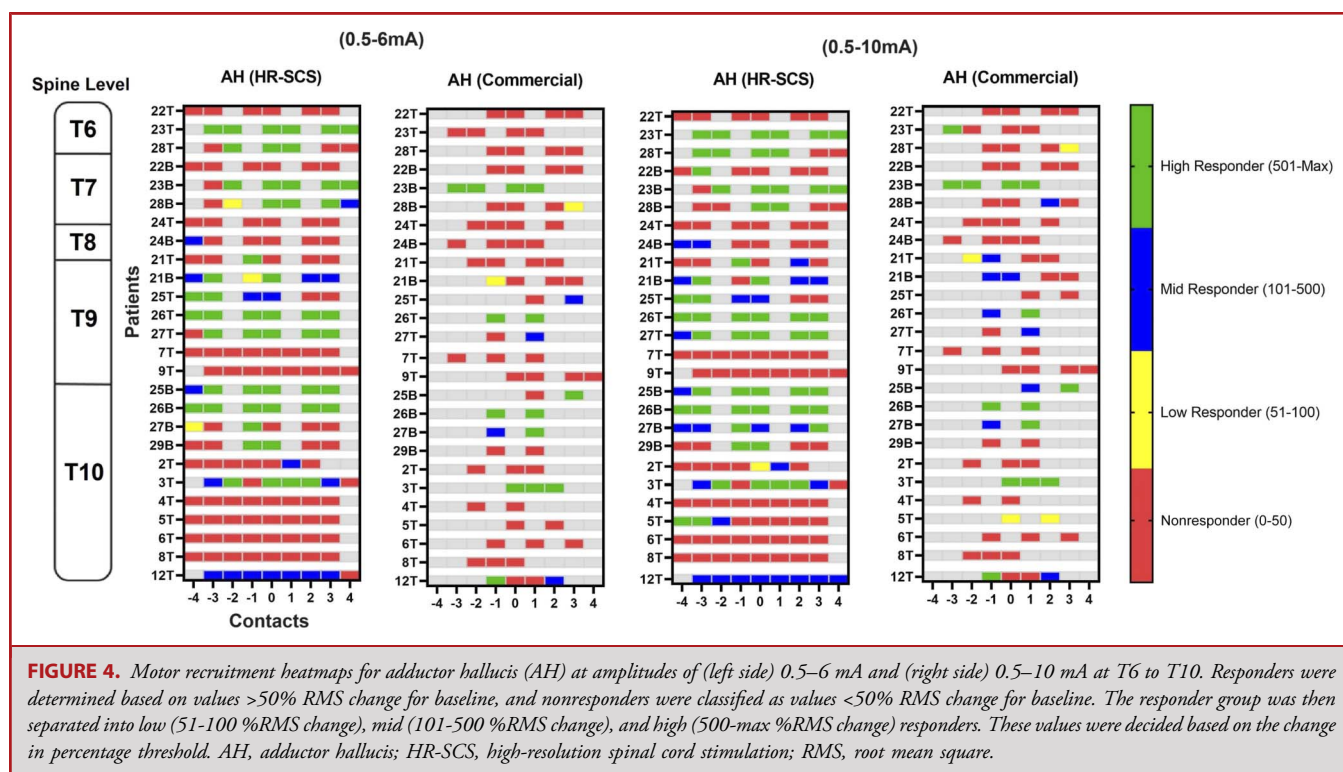
DISCUSSION

In this study, our goal was to determine whether an HR-SCS paddle had greater spatial resolution which enabled more selective activation of EMG responses than commercial paddles across thoracic levels during standard-of-care SCS implantation. We demonstrated greater motor responses across medial and lateral contacts and responder rates at T6 and T9 levels with HR-SCS as compared with commercial paddles. In lateral and medial contacts of the HR-SCS paddle, distal muscle groups (MG and TA) and proximal muscle groups (BF and quadriceps) were selectively activated at both spine levels (at ≤ 6 mA, Figures 2 and 3). In our initial work,¹⁷ we demonstrated that both HR-SCS medial and lateral contacts affected EMG response as proof of principle. In this article, we demonstrate that the greater spatial resolution of HR-SCS allows for finer motor mapping at thoracic levels in addition to mediolateral recruitment patterns. We hypothesize that this capability may mimic coverage seen in lateral recess percutaneous leads or DRG stimulation²⁰ while maintaining the midline coverage typically obtained by SCS paddles and percutaneous leads.

The finding that lower stimulation amplitudes are needed for lateral structures has been previously demonstrated. Specifically,

IONM during DRG stimulation uses even lower amplitudes ($< 3.2 \mu\text{A}$) than HR-SCS presumably because of the more lateral lead placement.²¹ Higher amplitudes for medial structures have been documented in other studies.^{21,22} Our data indicate that HR-SCS can evoke responses at lower stimulation amplitudes (≤ 6 mA) at both medial and lateral contacts, which are approximately 1.5–2 mA lower on average than the commercial paddle readings at these contacts. Even at low stimulation, the number of responders at the T6 and T9 spine levels is higher, and a significant difference is observed in distal lower extremity muscles. This further highlights the fact that the spatial resolution of HR-SCS allows for greater fine tuning of response. Typically, when we use IONM in our experience, stimulation up to 10 mA is used to determine whether evoked EMG responses are present.^{17,23,24} In our early work¹⁷ and these data (**Supplemental Digital Content 2, Table**, <http://links.lww.com/NEU/E136>), we observed that responses with HR-SCS occurred at lower amplitudes. To quantify that observation, we examined responses both at or below 6 mA and those at or below 10 mA. Results were similar at both thresholds.

The finding that the greatest selectivity was seen at T6 and T9 was initially somewhat surprising. Generally, SCS leads placed for



standard of care are placed covering T9–T10.^{25,26} Programming then typically looks either at the level above or below based on patient symptoms and the type of device implanted. As we labeled our tripoles by vertebral body as opposed to disk space, we may be capturing anything between the T8–T9 and T9–T10 disk space in this group. More interesting was the selectivity evoked at T6. Because these are standard-of-care leads, one may ask why we even had data at this level. All these leads used a device from a single manufacturer, which, in many cases, works at higher thoracic levels.^{27,28} When we review their class paper by Professor Barolat, these findings may be less surprising. The group noted that a peak in low-back stimulation was observed when the contacts were positioned laterally at T6 and T7 although clinical benefit was limited because of paresthesias in abdominals.²⁸ The role of this level warrants further exploration now that subparesthesia programming has been used.

More recent work has explored the somatotopy of the spinal cord in a feline model.²⁹ These authors used this model to aid in determining the level of activation for SCS in spinal cord injury and found that L3–L5 provided the most benefit in generating stepping motions. In this study, they used monopolar stimulation at an amplitude between 10 and 200 μ A and a frequency between 1 and 100 Hz to define the most effective parameters for stepping initiation. Their work, like ours, used assessment of evoked EMG to determine levels of the spinal cord associated with different muscle groups. Understanding the somatotopy of the thecal sac at various levels becomes increasingly important because we ponder

new indications for SCS. Higher regions of the thoracic cord, eg, T6, have historically been used for the treatment of angina, and more lateral stimulation has been used at these levels for

TABLE 3. Comparison of HR-SCS and Commercial Paddles for all Muscle Groups at T6 to T10 Spine Levels at 6 mA

Muscle	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

ADD, adductor magnus; AH, abductor hallucis; BF, biceps femoris; GLUT, gluteus; HR-SCS, high-resolution spinal cord stimulation; LAB, lower abdominals; MG, medial gastrocnemius; QUAD, quadriceps; TA, tibialis anterior; UAB, upper abdominals. The percentage of responders for each muscle at each level for HR-SCS and commercial paddles was determined, and χ^2 and Fisher's exact tests were used to determine significance (bold values).

abdominal pain.³⁰⁻³³ Lower thoracic levels have been increasingly used for coverage of feet in diabetic peripheral neuropathy (T9-T11) and pelvic pain (T11-12).³⁴⁻³⁹ As we explore the role of SCS in spinal cord injury, our understanding of the somatotopy needs to increase. Theoretically, more precise targeting could improve lower-extremity motor function recovery^{40,41} and potentially even control of respiration or urination.⁴²

In the short term, improved mediolateral selectivity may offer further options for patients with chronic pain who have suboptimal stimulation defined as either the painful area not having coverage or the painful area having coverage but at the expense of high energy going through the entirety of the system. Unpleasant paresthesias that prevent daily function may occur when such a large amount of energy is used.^{7,43} In subparesthesia programming, high therapeutic doses may cause unwanted effects such as headaches and/or paradoxical pain generation.^{7,43,44} Further recharging intervals and battery depletion occur at higher stimulation rates.⁴⁵ 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.

Limitations

We recognize a number of constraints in this clinical trial investigation. Our study had a limited sample size across various spinal levels. The study took place during an IONM procedure, restricted to a 25-minute monitoring session under general anesthesia. Finally, we used predetermined SCS programming settings during stimulation.

CONCLUSION

We demonstrate that HR-SCS has greater selectivity in eliciting evoked EMG responses in an intraoperative setting. We demonstrate that both motor responses and responder rates 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.

Funding

This study was sponsored by Microleads through NIH U44NS115111.

Disclosures

Julie G. Pilitsis receives grant support from Medtronic, Boston Scientific, Abbott, NIH 2R01CA166379, NIH R01EB030324, and NIH U44NS115111. Julie G. Pilitsis is the medical advisor for Aim Medical Robotics and has stock equity. Ilknur Telkes has grant support from NIH R00NS119672, NIHU44NS115111, and FAU COECS/I-SENSE.

Bryan McLaughlin has grant support from NIH U44NS115111 and is an employee of Micro-Leads, Inc. Yohannes Iyassu is an employee of Micro-Leads Inc. The other authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article. Steven Panicoioli is an employee of NuVasive Clinical Services.

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Acknowledgments

Author Contribution: M.D., T.H., S.P., J.D., Y.I., B.L.M., and J.G.P. performed experiments; D.B. and A.Q. analyzed data; I.T., D.B., and J.G.P. interpreted results of experiments; D.B. and A.Q. prepared figures; D.B. and A.Q. drafted manuscript; D.B., A.Q., I.T., and M.D. edited and revised manuscript; All authors reviewed final manuscript; B.L.M. and J.G.P. approved the final version of manuscript.

Supplemental digital content is available for this article at neurosurgery-online.com.

Supplemental Digital Content 1. Figure 1. HR-SCS paddle dimensions. (A) View of an 8-column HR-SCS paddle facing the dura. W: Paddle width. L: Paddle length (B) View of the paddle facing away from the dura. The thickness varies from 0.7 mm laterally to 2.3 mm medially. The top and bottom 3 rows (8 column only) for the second phase patients and bottom 3 rows for the first phase patients were used for longitudinal tripolar stimulation (guarded cathode). The rest of the electrodes were inactive and were not used for stimulation.

Supplemental Digital Content 2. Table 1. Average maximum current stimulation amplitude across patients at each contact for T6-T10 spinal levels from HR-SCS and commercial paddle.

Supplemental Digital Content 3. Figure 2. Average maximum RMS change (%) for baseline at 10 mA or lower. The data were then aligned for the physiological midline (0—Contact), where left-sided contacts have negative values and right-sided contacts have positive values. The mean values from both left- and right-sided muscles were used in contact 0 calculations. (A) Data from 3 patients were recorded at T6. (B) Data from 4 patients were recorded at the T7 spinal level. (C) Data from 2 patients were recorded at the T8 spinal level. (D) Data from 6 patients were recorded at the T9 spinal level. (E) Data from 11 patients were recorded at the T10 spinal level.

COMMENTS

The authors present further analysis of their high-resolution spinal cord stimulation (HR-SCS) paddle, which is an experimental 8-column paddle with tighter contact spacing compared with commercially available hardware. This is important work in the innovation of SCS, which has seen much in terms of waveform development, but little in terms of hardware advancement. The current article demonstrates that the HR-SCS can facilitate advanced motor mapping and mediolateral EMG recruitment due to its greater spatial resolution. Interestingly, this may have the potential to facilitate stimulation coverage patterns typically afforded by spinal nerve root stimulation or dorsal root ganglion stimulation, while simultaneously providing the more standard midline stimulation coverage. This has important implications for improving stimulation selectivity and coverage, potentially allowing for more personalized and customizable pain control.

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