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A novel workflow with mid-trial X-rays for spinal cord stimulator trials

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Dear Editor

The clinical implementation of spinal cord stimulation (SCS) has rapidly grown in the past decade, with an estimated 50,000 devices implanted annually [1]. Although the need for SCS trials has been recently debated [2], most insurers require a trial phase. Furthermore, a trial can be helpful for optimizing stimulation location and parameters and deciding which patients should proceed to permanent implant. Lead migration during the trial period can be associated with numerous unwanted outcomes, including suboptimal programming, truncated trial period, or false-negative results [3,4]. Furthermore, large lead migrations may necessitate a re-trial, increasing healthcare costs and the likelihood of a false negative trial.

Migration is especially problematic for paresthesia-free stimulation paradigms, such as passive charge balance burst stimulation and high-frequency stimulation, where lead movements are only clinically detected if the patient fails to obtain pain relief [5,6]. As such, there has been significant interest in identifying the ideal lead fixation techniques, as it is the only anchoring point to prevent migration throughout the trial period. Proposed approaches include suturing the lead to the skin, tunneling, adhesive bandages, such as adhesive skin strips and others (e.g., StayFIX®), and recently, a new device designed specifically for trial lead fixation [7].

Here, we present a single-center retrospective analysis of patients at an academic hospital comparing lead migration for sutures alone versus Steri-Strips alone during spinal cord stimulation trials. Data of patients who underwent a spinal cord stimulator trial were reviewed by two clinicians between January 1, 2016, and December 31, 2020.

One hundred and one patients, ages 18–80 years, who had undergone a spinal cord stimulator trial were identified (Fig. 1). To be included in the study, the patient must have completed an X-ray during their mid-trial follow-up visit, which was 2–4 days post-lead insertion procedure, to assess the lead placement and optimize programming. Exclusion criteria included revision of leads during the trial period, a trial period of fewer than 24 hours, morbid obesity (BMI$>$ 40), or poor imaging quality of X-rays that prevented accurately measuring the distance of migration.

At this academic medical center, we modified our spinal cord stimulator trial workflow to include a mid-trial X-ray to address the increased utilization of paresthesia-free programs. The X-ray was obtained immediately before the standard mid-trial office visit, and the workflow change was implemented in 2019. As these X-rays were done before pain relief was assessed at the office visit, they were done irrespective of patient reports of efficacy.

The clinical rationale for this workflow was that patients programmed with paresthesia-free parameters may not appreciate the clinical benefits of the device until a few days after the start of the trial, referred to as the "wash-in" period [8]. If a macro lead migration occurred soon after lead placement, the patient was at higher risk of a false negative trial because they may not experience nor report a loss of efficacy. Instead, the patient and clinical team would erroneously conclude that the device was not helpful for their pain from the outset and that the patient is not a responder.

Eighteen patients met the inclusion criteria; one was excluded due to poor imaging quality, and three excluded due to morbid obesity. Fourteen patients were included in the study, and each had two leads placed during the trial. Seven patients had leads affixed with sutures, and seven with adhesive skin strips, for fourteen percutaneous leads in each group. There were no significant differences in patient ages, BMI, and gender between the groups (Table 1).

Consistent with prior studies [3,9], we observed only *caudal* migrations at the 2–4 days follow-up visit. The average migration distances for the adhesive skin strips and suture groups were 26.7 $\pm$ 5.1 mm and 24.4 $\pm$ 5.2 mm per lead (Table 1). There was no statistically significant difference between the two groups. The 95 % confidence intervals were [13.2, 35.63] and [15.6, 37.83] for strip and suture groups, respectively, which implies non-zero migration distances for both.

The total lead migration was summed per patient and compared with the two securing techniques, and no significant difference was observed. Significant statistical differences were not observed between the two leads and either securing strategy via ANOVA ($F(3,24) = 0.22$, $p = 0.88$). While there was a trend for more substantial lead migration in patients with larger BMIs, correlation analysis was not significant. (Pearson correlation coefficient, $r = 0.34$, $p = 0.23$). Similarly, there was no correlation between lead migration and mid-trial pain scores recorded at the time when the X-ray was obtained (Pearson correlation

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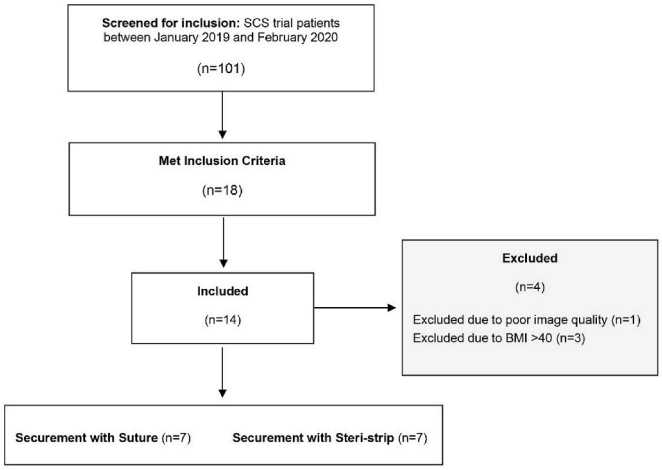

Fig. 1. Patient study flow diagram.

Table 1
Patient Characteristics and lead migration distances.

	Steri-Strips (N = 7)	Suture (N = 7)	Overall (N = 14)
Demographics			
Age			
Mean (SD)	50.7 (16.7)	64.0 (12.9)	57.4 (15.9)
Median [Min, Max]	53 [21, 71]	62 [43,78]	58.5 [21, 78]
Body mass index			
Mean (SD)	29.9 (4.3)	28.9 (4.9)	29.4 (4.5)
Median [Min, Max]	29.9 [24.4, 35.6]	27.4 [23.7, 36.6]	28.7 [23.7, 36.6]
Gender			
Female, n (%)	5 (71.4)	3 (42.9)	8 (57.1)
Male, n (%)	2 (28.6)	4 (57.1)	6 (42.9)
Pain scores (NRS)			
Baseline (pre)			
Mean (SD)	5.7 (2.2)	6.9 (1.9)	6.3 (2.1)
Median [Min, Max]	6 [2, 8]	8 [4, 9]	6.5 [2, 9]
Mid-trial			
Mean (SD)	5.1 (1.3)	5.9 (2.3)	5.5 (1.9)
Median [Min, Max]	5 [3, 7]	6 [3, 9]	5.5 [3, 9]
Individual lead movement			
Lead 1			
Mean (SD)	24.6 (20.0)	21 (14.8)	22.8 (17.0)
Median [Min, Max]	25 [2, 61]	16 [6, 47]	20.5 [2, 61]
Lead 2			
Mean (SD)	28.9 (19.8)	27.9 (23.9)	28.4 (21.1)
Median [Min, Max]	21 [7, 65]	21 [9,78]	21 [7, 78]
Lead movement per patient			
Mean (SD)	53.4 (37.1)	48.9 (23.5)	51.1 (30.0)
Median [Min, Max]	53 [14, 126]	53 [15, 89]	53 [14, 126]
Combined lead movement			
	N = 14	**N = 14**	**N = 28**
Mean (SD)	26.7 (19.2)	24.4 (19.4)	22.8 (17.0)
Median [Min, Max]	23 [2, 65]	18.5 [6, 78]	20.5 [2,61]

Abbreviations: Max, maximum; Min, minimum; NRS, Numerical Rating Scale; SD, standard deviation. Lead movements are reported in millimeters.

coefficient, r = 0.11, p = 0.71).

We conclude that substantial caudal lead migrations are widespread during trials and implantations [3,10], regardless of percutaneous or surgical fixation technique. Our findings are consistent with a recent retrospective study by Dombovy-Johnson et al., that found that 88.5 % of leads migrated post-implantation [10].

Recent trends in SCS implementation, with an increase in paresthesia-free SCS programming, make our findings especially relevant to the neuromodulation community. While patients who have paresthesia programming may be more likely to notice and report the immediate clinical loss of paresthesia or efficacy, this may not be the case with paresthesia-free paradigms. Presently, paresthesia-free SCS paradigms are preferred by patients and have proven superior to traditional paresthesia-based waveforms [11–13]. Thus, as their popularity continues to grow, physicians should consider adapting workflows to ensure that patients do not experience false-negative trials due to undetected lead migration. This is particularly critical for anatomically based stimulation strategies, such as those that target the T9/10 intervertebral level [14–16].

Overall, the main limitation of our study is a small sample size. However, our findings, combined with the results of other studies [3, 10], may suggest that percutaneous trial leads should be placed approximately one vertebral body more cephalad than the intended target. Mid-trial thoracolumbar X-rays should be considered in all patients, to confirm lead location regardless of pain scores, and guide reprogramming. Pain scores were not correlated with the lead migration distances, so these subjective pain scores should not be solely relied upon for prompting reprogramming.

Declaration of competing interest

Sandy Christiansen reports a relationship with Pacific Spine and Pain Society and the American Society of Regional Anesthesia and Pain Medicine that includes: board membership and travel reimbursement. Sandy Christiansen reports a relationship with The North American Neuromodulation Society, PainWEEK and Modern Wound that includes: travel reimbursement and honorarium. Sandy Christiansen reports a relationship with Avanos Medical Inc and Sorrento Therapeutics Inc that includes: institutional funding grants. Sandy Christiansen reports a relationship with Gerson Lehrman Group that includes: consulting. Andrei Sdrulla reports a relationship with The North American Neuromodulation Society that includes: travel reimbursement. Janice Yates reports no conflicts of interest.

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