Pain Medicine, 22(1), 2021, 34–40
doi: 10.1093/pm/pnaa215
Advance Access Publication Date: 4 August 2020
Original Research Article

Reoperation Rates of Percutaneous and Paddle Leads in Spinal Cord Stimulator Systems: A Single-Center Retrospective Analysis

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Funding sources: Supported in part by the South Carolina Clinical & Translational Research Institute (NIH/NCATS UL1TR001450).

Disclaimer: The contents are solely the responsibility of the authors and do not necessarily represent the official views of the National Institutes of Health, National Center for Advancing Translational Sciences, National Institute of General Medical Sciences, or National Institute of Arthritis and Musculoskeletal and Skin Diseases.

Conflicts of interests: D.A., no conflict. W.G., no conflict. A.R., no conflict. B.J.W., no conflict. R.N., no conflict. M.S., no conflict. M.H., no conflict.

Abstract

Objective. We hypothesize that reoperation rates of spinal cord stimulation (SCS) systems utilizing percutaneous leads are comparable to those utilizing paddle leads. We attempt here to characterize causes for those reoperations and identify any related patient characteristics. **Design and Subjects.** This study is a single-center retrospective chart review of 291 subjects (410 operations) who underwent at least one permanent SCS implantation utilizing percutaneous or paddle leads over a 10-year period at the Medical University of South Carolina. **Methods**. Charts were reviewed for height, weight, body mass index, gender, race, age, stimulator type, type of reoperation, diabetes status, history and type of prior back surgery, top lead location, and number of leads placed. Comparisons of patient and procedural characteristics were conducted using a two-sample *t* test (continuous variables), chi-square, or Fisher exact approach (categorical variables). Univariate and multivariate Cox regression models were developed, identifying associations between patient characteristics, SCS characteristics, reoperation rates, and time to reoperation. **Results.** Thirty point five eight percent of subjects (89/291), required at least one reoperation. The reoperation rate was 27.84% for percutaneous systems (N = 54/194) and 27.78% for paddle systems (N = 60/216). Time to reoperation also did not differ between the two systems (hazard ratio [HR] = 1.06, 95% CI = 0.70–1.60). Of all factors examined, younger age at time of placement was the only factor associated with risk of reoperation (HR = 0.73, 95% CI = 0.62–0.87, $P < 0.001$). **Conclusions.** Our data suggest that reoperation rates and time to reoperation between percutaneous and paddle leads are clinically similar; therefore, rates of reoperation should have no bearing on which system to choose.

Key Words: Spinal Cord Stimulation; Paddle Leads; Percutaneous Leads; Lead Revisions; Spinal Cord Stimulator Complications; Spinal Cord Stimulator Revisions

Introduction

Since the initial clinical use of neuromodulation in the early 1970s, spinal cord stimulation (SCS) has become a mainstay in the modern management of chronic pain syndromes. While these systems have proven to be highly effective and safe, practitioners continue to refine knowledge regarding which type of system (i.e., paddle lead vs percutaneous lead) to use to optimize long-term patient outcomes. It is important to consider the appropriateness of lead selection as it pertains to failure and revision rates between the two system types in order to minimize health care costs and patient complications.

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Currently, data comparing patient outcomes of percutaneous vs paddle leads, with regard to migration, revision, and explantation rates, are lacking. As such, the aim of this study was to contribute data comparing the rates of reoperation of SCS systems placed percutaneously with paddle leads placed via laminectomy.

To date, there is no consensus in the literature that favors one lead type over another. Some clinicians recommend using percutaneous electrodes for the trial, as well as for permanent implantations whenever possible because it is a less invasive, technically easier, and less costly procedure [1]. Kumar et al. (2007) further state, "The percutaneous technique has several obvious advantages, although there is little objective evidence indicating which of the two electrode placement systems (percutaneous electrodes or laminectomy electrodes) produces better long-term results." On the other hand, others have noted that insulated paddle electrodes reduce unwanted current spread and provide more coverage of the low back, while reducing power consumption [2, 3].

In this study, we hypothesize that SCS leads placed via a percutaneous approach have revision rates similar to those of paddle leads placed via a laminectomy. Our research is intended to discover the historical revision surgery rates at our center and to identify any predictive patient factors associated with revision rates for the guidance of clinical decision-making. In addition, our hope is that future prospective interventional studies might be able to use our results for computing an adequate sample size for more highly powered studies.

Methods

Institutional review board approval was obtained. The population of interest was studied by retrospective chart review of patients who were implanted with either a percutaneous or paddle lead system at the Medical University of South Carolina (MUSC) over a 10-year period (2009–2018). Criteria for inclusion in the study included having the initial permanent SCS system placed at our center. Patients who only underwent an SCS trial, who had their initial permanent SCS system placed outside of the MUSC, or who underwent a battery replacement for an end-of-life pulse generator were excluded from the study. We used current procedural terminology (CPT) codes for SCS implantation, revision, and removal and the aforementioned criteria to identify the 291 patients who were included in our analysis. The chart review was performed by our research team, and each reoperation event and its data were verified by the lead investigator.

Charts were reviewed for the following data parameters: patient height, weight, body mass index (BMI), gender, race, age at time of surgery, stimulator type (percutaneous vs paddle leads), type of reoperation (revision/removal), diabetes status (yes/no), history of prior back surgery (yes/no), type of back surgery if they had a prior surgery (laminectomy vs laminectomy + fusion), location of top lead placement (cervical or thoracic), and number of leads placed. Device manufacturer data were not collected. The focus of this study was to compare lead types and to identify all causes for reoperation. Stimulator parameters and waveforms were also not collected, as these are not consistently and routinely documented in clinical notes, and SCS devices changed significantly over the 10-year inclusion period. As such, our study would not have been powered to detect effects related to specific devices or waveforms.

Descriptive statistics for all patient and procedural characteristics were determined across all patients and by stimulator type. Comparisons of patient and procedural characteristics by initial stimulator type were conducted using a two-sample t test approach for continuous variables and using a chi-square or Fisher exact approach when appropriate for categorical variables. The main outcomes of interest were rates of reoperation and time to reoperation, where for the purposes of our study the definition of "reoperation" used was revision or explantation of a permanent SCS system due to any reason other than routine battery replacement. Univariate associations between time to reoperation and patient and procedural characteristics were examined using a Cox regression approach. As patients could have more than one occurrence of reoperation, the Cox models included a random frailty effect to account for occurrence of multiple reoperation events within an individual. A multiple Cox regression model of time to reoperation considering all variables with a univariate significance of $P < 0.20$ and a random frailty effect was also developed. Backwards selection was used to select the final model, retaining all variables with $P < 0.10$. The proportional hazards assumption was examined using the Grambsch-Therneau test, and transformations of fixed effects were considered if needed. Median survival time and 95% confidence intervals based on the log-log estimate of standard error were also estimated for the two stimulator types. The rate of reoperation by stimulator type was evaluated using a generalized linear mixed model including a random subject effect to account for repeated reoperations on a subject. All analyses were conducted in SAS, version 9.4 (SAS Institute, Cary, NC, USA).

Results

A total of 291 participants undergoing permanent spinal cord stimulator implantation were included in our analysis. Of those, 31.58% (N = 89/291) eventually required at least one revision, 6.87% (N = 20/291) required two or more revisions, and 1.72% (N = 5/291) required three revisions. Among the 89 subjects requiring at least one revision, percutaneous systems were initially placed in 49.44% (44/89) of participants, and paddle systems were initially placed in 50.56% (45/89) of participants. Among subjects with an initial percutaneous system that

Table 1. Patient and procedural characteristics by type of simulator initially placed

Characteristic	Paddle (N = 143)	Percutaneous (N = 148)	*P*
Gender (male)	70 (49.0)	63 (42.6)	0.275
Age, y	56.2 (13.4)	54.9 (12.5)	0.378
Race*			0.164
White	113 (81.3)	95 (74.2)	
AA†	26 (18.7)	33 (25.8)	
BMI, kg/m^2	31.0 (7.12)	30.4 (6.88)	0.501
Diabetes (yes)*	32 (21.7)	33 (22.5)	0.988
Prior back surgery (yes)*	107 (74.8)	90 (61.2)	0.013
If yes, type of surgery			0.078
Laminectomy	19 (20.9)	20 (33.9)	
Laminectomy + fusion	72 (79.1)	39 (66.1)	
No. of leads*			<0.001
1	142 (99.3)	27 (18.4)	
>1	1 (0.70)	120 (81.6)	
Lead location*			0.073
Cervical	8 (5.59)	17 (11.5)	
Thoracic	135 (94.4)	131 (88.5)	

Continuous variables are reported as mean (SD) and categorical variables as No. (%).
BMI = body mass index.
*Nine subjects were missing race; all other categories flagged with an asterisk were missing one observation.
†There was one Asian subject who was grouped with African Americans.

had a revision, 22.73% (10/44) were replaced with paddle systems compared with 2.22% (1/45) of patients with initial paddle placements switching to percutaneous systems. Of the 20 subjects who required two or more revisions, 45.0% (nine of 20) initially had paddle systems and 55.0% (11/20) had percutaneous systems. Of the nine subjects with more than one revision and initial paddle system placement, 11.11% (one of nine) converted to a percutaneous system, and of the 11 subjects requiring more than one revision and an initial percutaneous system, 54.55% (six of 11) converted to paddle systems. Reasons for requiring a reoperation were not consistent within patients (e.g., a patient that had more than one reoperation did not necessarily have the same reason for requiring a reoperation each time). These are reported in Table 3. Demographic data are reported in Table 1. In our study population, 50.86% (N = 148/291) of the subjects underwent initial percutaneous lead placement and 49.14% (N = 143/291) of subjects underwent initial paddle lead placement. Females represented 54.3% (N = 158/291) of study subjects. A majority of patients were of white/Caucasian ethnicity (71.48%, N = 208/291). The average age at the time of first implant was 55.5 years (Table 1). Diabetes was present in 22.34% of subjects (N = 65/291). Most patients had a history of back surgery (67.7%, N = 197/291).

A total of 410 systems were placed, accounting for both initial placement and revisions, of which 194 were percutaneous systems and 216 were paddle systems. The majority of subjects with paddle systems underwent implantation of a single lead (97.69%, N = 211/216), while most patients with percutaneous systems underwent implantation of more than one lead (79.38%, N = 154/194). Leads were mostly implanted in the thoracic region (90.49%, N = 371/410), while only 9.51% were implanted in the cervical region. The reoperation rate was 27.84% (N = 54/194) for percutaneous systems and 27.78% (N = 60/216) for paddle systems. Time to reoperation was evaluated for associations with type of stimulator (percutaneous vs paddle), age at time of initial placement (10-year increase), BMI (five-unit increase), sex, race, presence of diabetes, history of previous back surgery, lead location (cervical vs thoracic), and number of leads. The time to reoperation was not significantly different when comparing the two groups (hazard ratio [HR] = 1.06, 95% CI = 0.70–1.60). Out of all the factors presented above, age at time of placement was the only factor associated with increased risk of reoperation (10-year increase HR = 0.73, 95% CI = 0.62–0.87, $P < 0.001$). Specifically, in both univariate and multivariate Cox models, a 10-year increase in age was associated with a 27% decrease in the risk of revision (Table 2). The median time to reoperation in patients with paddle systems was 1.75 years (95% CI = 1.36–3.12 years), and in patients with the percutaneous system it was 2.13 years (95% CI = 1.30–5.21 years). Kaplan-Meier survival curves for patients with percutaneous and paddle systems are shown in Figure 1. Notably, sex, obesity, previous back surgery, number of leads, and lead location were found not to be associated with rates of revision.

Reasons for reoperation are presented in Table 3. Each category is not mutually exclusive, and thus multiple reasons are often present to account for each reoperation event. Patient complaints regarding the SCS system were the most common, with 93 of 114 reoperations having an associated complaint. These complaints included "IPG [implanted pulse generator] site pain," "other pain," "explant requested (NOS)," "loss of

Table 2. Hazard ratios for reoperation for all univariate and multivariate Cox regression models

Variable	Univariate HR (96% CI)	*P*	Multivariate HR (96% CI)	*P*
Stimulator type (paddle vs percutaneous)	1.06 (0.70–1.60)	0.779	1.03 (0.72–1.60)	0.710
Age (10-y increase)	0.73 (0.62–0.87)	<0.001	0.43 (0.62–0.87)	<0.001
BMI (5-unit increase)	1.03 (0.89–1.19)	0.681		
Sex (female vs male)	1.20 (0.79–1.81)	0.387		
Race (white vs other)	1.17 (0.73–1.86)	0.515		
Diabetes (yes vs no)	0.70 (0.41–1.20)	0.197		
Prior back surgery (yes vs no)	1.14 (0.88–0.74)	0.558		
Lead location (cervical vs thoracic)	1.13 (0.56–2.28)	0.726		
No. of leads (increase by 1)	0.97 (0.66–1.42)	0.875		

P values reported in the table are based on the Wald test.
BMI = body mass index; HR = hazard ratio.

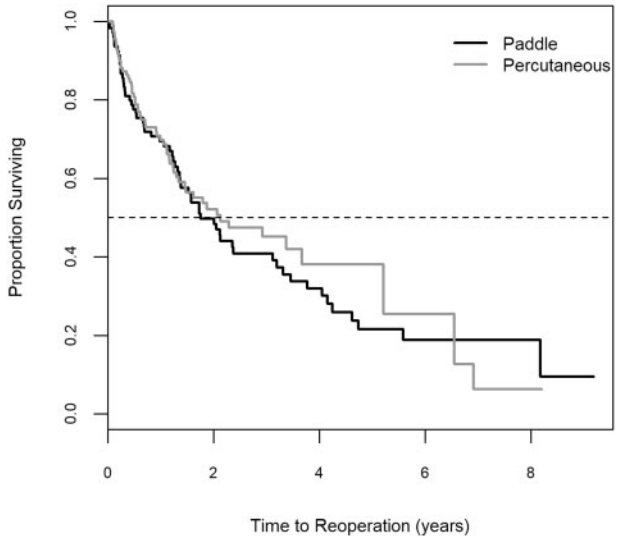

Figure 1. Kaplan-Meier survival curves for time to reoperation by stimulator type. The dashed line represents the median survival.

effectiveness," and "difficulty charging." Other reasons for reoperation were due to device issues (39.47%, N = 45/114) or were procedure related (6.14%, N = 7/114). Device-related issues included hardware malfunction, lead damage, lead migration, unspecified, erosion of lead or IPG, and lead connection failure. Procedure-related issues included dural tear, infection, neurologic deficit, hematoma, and wound dehiscence.

Discussion

We calculated an overall reoperation rate of 31.58% (N = 89/291), which is comparable to other published data on revision rates of spinal cord stimulators [4]. However, it is important to note that revision rate data are rather limited in the literature. There are a few reports that compare clinical outcomes between implanted lead types. Villavicencio et al. (2000) followed a small number of patients (N = 41) over 34 months to compare outcomes after implantation of spinal cord stimulator systems [5]. The study discovered significantly better long-term pain scores with paddle leads; however, failure and revision rates were not reported. North et al. (2005) report on 24 patients randomized to either a percutaneous 1 × 4 lead or a 1 × 4 paddle lead. The authors reported removal of SCS systems in 20% of all patients due to clinical failure but did not distinguish the lead type associated with the failure [6]. De Carolis et al. (2012) presented an abstract at the 2012 North American Neuromodulation Society conference that compared clinical outcomes between surgical and percutaneous SCS leads. They did not report failure or revision rates [7]. Matias et al. (2014) reported that in patients with failed percutaneous SCS leads and no previous revisions, subsequent revision with paddle leads led to a three-point pain reduction and an overall satisfaction with therapy in >50% of patients [8]. Again, there was no comparison of failure or revision rates between the two systems. Still, other studies have reported comparisons of lead types, but none has mentioned reoperation rates specifically [9–12].

In one study, Kim et al. (2011) compared lead migration complications between percutaneous and surgical paddle leads, but the authors did not report revision rates [13]. In yet another, Pahapill (2015) examined the outcomes of 126 patients who initially received paddle leads and found that no revisions were required for lead fracture, migration, or infection. This study had an average follow-up period of 20 months, with a 65% clinical success rate at 29 months [14]. Rosenow et al. (2006) evaluated SCS failure in 289 patients who were followed for a median of 490 days. Approximately a quarter of these patients (N = 65, 22% of entire cohort) required more than one revision surgery. Moreover, the same data also showed that paddle leads were associated with higher rates of lead breakage, migration, and infection than percutaneous leads [15].

Perhaps most pertinent to our study, Babu et al. (2013) compared complications and costs of surgical vs percutaneous implanted SCS leads [16]. They utilized the Reuter's MarketScan database to perform a retrospective, cross-sectional, population-based study and

Table 3. Reasons for reoperation

Stimulator in Place Before Revision	Paddle			Percutaneous			Total
Revision Number	1st Revision (N = 45)	2nd Revision (N = 12)	3rd Revision (N = 3)	1st Revision (N = 44)	2nd Revision (N = 8)	3rd Revision (N = 2)	All Revisions (N = 114)
Complaint types							
Device	12 (26.67)	6 (50.0)	1 (50.00)	20 (45.45)	6 (75.00)	0 (0.00)	45 (39.5)
Procedure	3 (6.67)	1 (8.33)	0 (0.00)	2 (4.55)	1 (12.50)	0 (0.00)	7 (6.14)
Patient	36 (80.00)	10 (83.33)	2 (100.0)	34 (77.27)	8 (100.0)	3 (100.0)	93 (81.6)
Combinations of complaints							
Device only	2 (4.44)	2 (16.67)	1 (50.00)	6 (13.64)	0 (0.00)	0 (0.00)	11 (9.65)
Procedure only	3 (6.67)	0 (0.00)	0 (0.00)	2 (4.55)	0 (0.00)	0 (0.00)	5 (4.39)
Patient only	26 (57.78)	6 (50.00)	1 (50.00)	20 (45.45)	2 (25.00)	3 (100.0)	58 (50.88)
Device + procedure	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Device + patient	10 (22.22)	3 (25.00)	0 (0.00)	14 (31.82)	5 (62.50)	0 (0.00)	32 (28.07)
All 3	0 (0.00)	1 (8.33)	0 (0.00)	0 (0.00)	1 (12.50)	0 (0.00)	2 (1.75)
Device reason							
Hardware malfunction	2 (4.44)	1 (8.33)	0 (0.00)	7 (15.91)	1 (12.50)	0 (0.00)	11 (0.65)
Lead damage	1 (2.22)	1 (8.33)	0 (0.00)	1 (2.27)	0 (0.00)	0 (0.00)	3 (2.63)
Lead migration	7 (15.56)	3 (25.00)	1 (50.00)	12 (27.27)	5 (62.50)	0 (0.00)	28 (24.56)
Unspecified	2 (4.44)	1 (8.33)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	3 (2.63)
Erosion of lead or IPG	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Lead connection failure	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Procedural reasons							
Dural tear	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	1 (12.50)	0 (0.00)	1 (0.88)
Infection	2 (4.44)	1 (8.33)	0 (0.00)	2 (4.55)	0 (0.00)	0 (0.00)	5 (4.39)
Neurologic deficit	1 (2.22)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	1 (0.88)
Hematoma	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Wound dehiscence	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Patient reasons							
IPG site pain	15 (33.33)	4 (33.33)	0 (0.00)	15 (34.09)	2 (25.00)	3 (100.0)	39 (34.22)
Other pain	1 (2.22)	3 (25.00)	1 (50.00)	2 (4.55)	1 (12.50)	0 (0.00)	8 (7.02)
No longer want	6 (13.33)	4 (33.33)	1 (50.00)	6 (13.64)	2 (25.00)	0 (0.00)	19 (16.67)
Loss of effectiveness	23 (51.11)	5 (41.67)	0 (0.00)	19 (43.18)	5 (62.50)	0 (0.00)	52 (45.61)
Difficulty charging	2 (4.44)	1 (8.33)	0 (0.00)	5 (11.36)	0 (0.00)	0 (0.00)	8 (7.02)

Values are reported as No. (%) for the system type at time of placement (paddle or percutaneous) by revision event number (first, second, or third revision). Note that reasons for reoperation are not mutually exclusive. Eighty-nine subjects had at least one revision, 20 of these 89 subjects had more than one revision, and five of the 89 subjects had three revisions. Of the 20 subjects who had a second revision, four were converted from percutaneous to paddle systems at the first revision, and one was converted from a paddle system to a percutaneous system. Of the five subjects that had a third revision, two were converted from percutaneous to paddle systems at the second revision.

IPG = impulse generator.

identified patients who received an SCS system with either a percutaneous or surgical lead between 2000 and 2009. They reported that overall reoperation rates were significantly higher for percutaneous leads compared with surgically placed paddle systems (10.65% vs 7.69%, $P < 0.0001$). Of those percutaneous systems undergoing revision, 70% were revised with repeat percutaneous lead systems. There are several differences between their study and ours. Although their data were entirely obtained via a database of reported patient claims, this may not be representative of the entire population of interest, as such; our study aims to evaluate *all* systems implanted at our center over a 10-year period. Another major difference is the time period during which the data were generated. We postulated that a one-decade difference in time should account for lesser rates of overall device-related complications and more sustainable therapy due to improvements in surgical technique and device technology; however, this was not seen.

Despite all of these previous findings, the review paper on general recommendations for SCS use by the Neuromodulation Appropriateness Consensus Committee states, "No prospective study to our knowledge, has compared the risks of these techniques [percutaneous vs paddle lead] adequately; the only RCT involved too small a sample to address these infrequent events" [17].

We also reviewed the Medtronic product performance registry of 2010, which compiles adverse events from 1,783 enrolled patients [18]. The registry reports on SCS lead migrations, but not on how many required revision surgeries. The Medtronic product performance registry of 2012 reported adverse events from 2,210 enrolled patients [19]. Again, no reports were made on revision surgery rates, nor was any distinction made between paddle and percutaneous SCS leads.

Patient demographics in our patient population were found to be similar to other groups described in previous studies. Our mean age at initial placement of 55.7 years was similar to Hoelzer at el., Babu et al., and Taylor et al. [4, 16, 20]. The presence of diabetes was also similar to these studies. A large number of studies cite "failed back surgery syndrome" as their primary diagnosis [8, 13, 16, 20]. Our study population is likely similar, as more than half of our patients underwent prior back surgery.

While no association was found between lead type and time to reoperation, a relationship was discovered between age and risk for reoperation. For every 10-year increase in age, there was a 27% decrease in risk of reoperation. We postulate this effect to be due to greater levels of physical activity and/or flexibility in younger patients, which may cause lead migration during flexion and extension movements, leading to therapy failure. Another possible explanation for this finding could be that younger patients develop a tolerance to SCS more quickly than older patients. A similar age-related "tolerance" effect to opioid therapy has been previously reported in the literature by Buntin-Mushok, et al. (2005), whereby younger patients developed tolerance and required increasing doses of opioids more rapidly than older patients [21]. It may be possible that a similar effect could be responsible for the age-related effect discovered in our data. Further investigation is needed in order to elucidate the exact cause of this association.

Interestingly, the most common sole reason for reoperation was patient complaint (i.e., "IPG site pain," "other pain," "explant requested [NOS]," "loss of effectiveness," and "difficulty charging"), rather than device issues (i.e., hardware malfunction, lead damage, lead migration, unspecified, erosion of lead or IPG, lead connection failure) or procedural complications (i.e., dural tear, infection, neurologic deficit, hematoma, and wound dehiscence). The main complaint was loss of effectiveness, followed by pain at the IPG site. IPG pocket pain was present in 9.51% (N = 39/410) of all implants analyzed, which is similar to several studies across the literature [1, 22].

In our study, reoperations due to issues with the implanted device occurred in 35.59% of participants with paddle stimulators, compared with 47.17% of participants with percutaneous stimulators, with the most common device failure being lead migration. A few studies have compared lead migration between paddle and percutaneous systems and found them to be similar [13, 23]. New anchoring techniques have been, and will likely continue to be, an important development in order to decrease lead migration for both implant types. Less common device failures included other hardware complications involving the pulse generator, lead connections to the generator, and extensions and lead fractures. Lead damage incidence was much lower in our analysis when compared with Kumar et al. and Mekhail et al. [1, 24]. These are older studies, so the decreased incidence of lead damage could possibly be attributed to improvements in the hardware of the SCS system.

Procedural issues were the least common cause of reoperation, affecting only 11.86% of patients with paddle stimulators and 5.66% with percutaneous systems. The most common procedural complication was infection. Our overall infection rate of 1.95% (N = 8/410) is similar to other publications [1, 6, 20, 24]. Notably, paddle leads were associated with nearly three times the rate of infection (10.17%, N = 6/59) compared with percutaneous leads (3.77%, N = 2/53). Two complications pertaining to procedural issues included one dural tear and one neurological deficit leading to explantation of the device. The neurological complaint occurred in a patient who underwent T5-T10 fusion in an attempt to correct symptomatic kyphosis. This was done some time after placement of a paddle lead system. The patient developed dense paraplegia after their spinal surgery, and a subsequent myelogram demonstrated blockade to the flow of contrast dye at the level of the SCS paddle lead. The SCS

system was then removed. Notably, the patient's paraplegia did not resolve with removal of the SCS.

While we attempted to remain as objective and true to the nature of scientific research as possible, we recognize that our study is subject to all the limitations of retrospective research. These limitations include errors in charting of the original data under investigation, errors in gathering of such data upon chart review, and misinterpretation of data gathered. We attempted to minimize the risk of these errors occurring by utilizing multiple individuals independently collecting the same data and by having the most senior author involved cross-reference data with source material for collection errors after the data were collected. Nonetheless, taking into consideration the nature of retrospective research, readers should not extrapolate our results as definitive evidence.

Conclusions

Although there are many variables involved in the selection of one lead type over another, our retrospective data suggest that rates of reoperation are not statistically significant between the two SCS systems. Review of the literature also supports the position that neither lead type is necessarily the preferable choice for permanent implantation. Further prospective research in this area is needed to better answer the question of the superiority of either the paddle lead or the percutaneous lead system.

References

1. Kumar K, Buchser E, Linderoth B, Meglio M, Van Buyten J. Avoiding complications from spinal cord stimulation: Practical recommendations from an international panel of experts. Neuromodulation 2007;10(1):24–33.
2. North R, Kidd D, Olin J, et al. Spinal cord stimulation for axial low back pain: A prospective, controlled trial comparing dual with single percutaneous electrodes. Spine 2005;30(12):1412–8.
3. North R, Kidd D, Olin J, Sieracki J. Spinal cord stimulation electrode design: Prospective, randomized, controlled trial comparing percutaneous and laminectomy electrodes-part i: Technical outcomes. Neurosurgery 2002;51(2):381–90.
4. Hoelzer B, Bendel M, Deer T, et al. Spinal cord stimulator implant infection rates and risk factors: A multicenter retrospective study. Neuromodulation 2017;20(6):558–62. 2017;
5. Villavicencio A, Leveque J, Rubin L, Bulsara K, Gorecki J. Laminectomy versus percutaneous electrode placement for spinal cord stimulation. Neurosurgery 2000;46(2):399–406.
6. North R, Kidd D, Petrucci L, Dorsi M. Spinal cord stimulation electrode design: A prospective, randomized, controlled trial comparing percutaneous with laminectomy electrodes: Part ii-clinical outcomes. Neurosurgery 2005;57(5):990–6.
7. De carolis G, Paroli M, Tollapi L, et al. Pain relief and quality-of-life improvement after spinal cord stimulation for FBSS: A comparison between the paddle and cylindrical leads. Paper presented at: 16th Annual Meeting North American Neuromodulation Society; Las Vegas, NV; Dec 6–9, 2012.
8. Matias C, Amit A, Lempka S, et al. Long-term outcomes after replacement of percutaneous leads with paddle leads in a retrospective cohort or patients with spinal cord stimulation systems. Neurosurgery 2014;75(4):430–6.
9. Oakley J, Prager J. Spinal cord stimulation: Mechanisms of action. Spine 2002;27(22):2574–83.
10. Sankarasubramanian V, Buitenweg J, Holsheimer J, Veltink P. Triple leads programmed to perform as longitudinal guarded cathodes in spinal cord stimulation: A modeling study. Neuromodulation 2011;14(5):401–11.
11. Oakley JC, Espinosa F, Bothe H, et al. Transverse tripolar spinal cord stimulation: Results of an international multicenter study. Neuromodulation 2006;9(3):192–203.
12. North RB, McNamee JP, Wu L, Piantadosi S. Spinal cord stimulation with percutaneous and plate electrodes: Side effects and quantitative comparisons. Neurosurg Focus 1997;2(1):e3.
13. Kim D, Vakharyia R, Kroll H, Shuster A. Rates of lead migration and stimulation loss in spinal cord stimulation: A retrospective comparison of laminotomy versus percutaneous implantation. Pain Physician 2011;14(6):513–24.
14. Pahapill P. Incidence of revision surgery in a large cohort of patients with thoracic surgical three-column paddle leads: A retrospective case review. Neuromodulation 2015;18:367–75.
15. Rosenow J, Stanton-Hicks M, Rezai A, Henderson J. Failure modes of spinal cord stimulation hardware. J Neurosurg Spine 2006;5(3):183–90.
16. Babu R, Hazzard M, Huang K, et al. Outcomes of percutaneous versus paddle lead implantation for spinal cord stimulation: A comparative analysis of complications, reoperation rates and health-care costs. Neuromodulation 2013;16(5):418–26.
17. Deer TR, Mekhail N, Provenzano D, et al. The appropriate use of neurostimulation of the spinal cord and peripheral nervous system for the treatment of chronic pain and ischemic diseases: The Neuromodulation Appropriateness Consensus Committee. Neuromodulation 2014;17(6):515–50.
18. Medtronic. The implantable systems performance registry. 2010. Available at: https://www.medtronic.com/content/dam/medtronic-com/products/product-performance/ppr-reports/product-performance-report-2010.pdf (accessed October 2018).
19. Medtronic. The implantable systems performance registry. 2012. Available at: https://www.medtronic.com/content/dam/medtronic-com/products/product-performance/ppr-reports/product-performance-report-2012.pdf (accessed October 2018).
20. Taylor R, Van Buyten J, Buchser E. Spinal cord stimulation for chronic back and leg pain and failed back surgery syndrome: A systematic review and analysis of prognostic factors. Spine 2005;30(1):152–60.
21. Buntin-Mushock C, Phillip L, Moriyama K, Palmer P. Age-dependent opioid escalation in chronic pain patients. Anesth Analg 2005;100(6):1740–5.
22. Deer T, Stewart C. Complications of spinal cord stimulation: Identification, treatment, and prevention. Pain Med 2008;9(Suppl 1):S93–101.
23. Gazelka H, Freeman E, Hooten W, et al. Incidence of clinically significant percutaneous spinal cord stimulator lead migration. Neuromodulation 2015;18(2):123–5.
24. Mekhail N, Mathews M, Nageeb F, Guirguis M, Mekhail M, Cheng J. Retrospective review of 707 cases of spinal cord stimulation: Indications and complications. Pain Pract 2011;11(2):148–53.