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ORIGINAL ARTICLE

Lead migration and fracture rate in dorsal root ganglion stimulation using anchoring and non-anchoring techniques: A multicenter pooled data analysis

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Abstract

Introduction: Dorsal root ganglion stimulation (DRG-S) is a neuromodulation technique introduced in the last decade with evolving implant methods. Initial prospective research found low incidences of lead migration and lead fracture with DRG-S. However, several recent studies have highlighted high lead migration and lead fracture rates with DRG-S. We investigated the influence of lead anchoring on migrations and fractures.

Methods: We performed a retrospective review between 2016 and 2020 of individuals implanted with DRG-S leads by 4 experienced implanters. The implanters independently changed their standard practice regarding lead anchoring over time, with opposing trends (no anchoring > anchoring, anchoring > no anchoring). We compared lead migration and lead fracture rates between anchored and unanchored DRG-S leads in the entire study cohort. Cox regression was performed on lead migration and fracture distributions.

Results: We included 756 leads (n = 565 anchored and n = 191 unanchored) from 249 patients. In unanchored leads, migration occurred in 16 leads (8.4%) from 13 patients (21.0%). In anchored leads, migration occurred in 8 leads (1.4%) from 5 patients (2.7%). Fracture in unanchored leads occurred in 6 leads (3.1%) from 6 patients (9.7%). Fractures in anchored leads occurred in 11 leads (1.9%) from 9 patients (4.8%). The migration survival distributions for the anchored and unanchored leads were statistically significantly different ($p < 0.01$) with decreased survival for unanchored leads (hazard ratio = 5.8, 95% confidence interval [CI] = 2.2–15.5).

Discussion: We found that anchoring DRG-S leads significantly reduces lead migration when compared to leads placed without an anchor. There was no significant difference in fracture rate between anchored and unanchored leads.

KEYWORDS
anchoring, dorsal root ganglion stimulation, fracture, migration, pain management

INTRODUCTION

Since its introduction in 1967, spinal cord stimulation (SCS) has been the mainstay of neurostimulation therapy for complex regional pain syndrome (CRPS), failed back surgery syndrome (FBSS), ischemic limb pain, and intractable angina.[1] SCS uses electrical energy to modulate dorsal column fibers to achieve pain relief in the corresponding dermatomal regions.

SCS leads are prone to migration and fracture.[2,3] A systematic review showed SCS lead migration and fracture rates of 13.2% and 9.1%, respectively.[1] To reduce these complications, device manufacturers developed various lead anchors and adhesives for the initial implantation procedure. Lead stabilization techniques became the standard of care, and significant reductions in migration rates followed.[4,5] A study combining computer modeling, laboratory testing, and in vivo animal testing identified best practices to reduce SCS lead migrations through anchor use. However, it was somewhat paradoxically noted that the use of anchors could be associated with lead breakage, by creating a rigid point for flexion and possible stress fatigue.[6] Improvements in SCS electrode configurations, lead integrity, and programmability, combined with improvements in anchor structure have improved fracture rates seen in recent studies.[7–9]

Originally developed as a modification of SCS, dorsal root ganglion stimulation (DRG-S) has demonstrated superiority to SCS for CRPS and shows promise for low back pain and other pain syndromes.[10–13] DRG-S implantation differs from SCS in several ways: (1) the leads are thinner and more flexible; (2) leads have 4 contacts; (3) a guidewire and introducer are used to maneuver the lead through the intraforaminal ligaments; and (4) an S-shaped tension loop is created within the epidural space after placing the contacts, for lead stabilization.[14,15] A commonly practiced method of implantation uses the epidural S-loop, followed by either a superficial incision and the tunneling device, or a tunneled epidural catheter technique with a Tuohy needle to drive the lead to the pocket site.[16]

Because DRG-S is a relatively new modality, surgical methods have evolved since its market release. Initially, it was believed that there was a negligible risk for intraforaminal lead migration, due to the limited cerebrospinal fluid layer, presence of multiple intraforaminal ligaments, and reliable location of the DRG within the bony, immobile foramen.[14] Unfortunately, recent studies found higher than expected DRG-S lead migration and fracture incidences.[17,18] Lead migration can have significant consequences. The small size of the target DRG, combined with only 4 contacts per lead, means that even slight migration can result in loss of efficacy. Studies on lead anchoring to prevent migration have been encouraged,[17] but are lacking to date.

Contrary to SCS, lead anchoring is not standard practice in DRG-S; consensus guidelines leave lead anchor placement to the discretion of the provider.[19] Three recent publications[11,12,20] using DRG-S for low back pain demonstrated a total of 9 lead migrations in 41 implants (none of which used lead anchors). This is a 22% rate of migration per implant, which is significantly higher than previously published data.[10] This inequity led implanters from multiple centers to investigate the incidence of DRG-S lead migrations and fractures in both anchored and unanchored leads.

Key Points

- DRG-S lead anchoring reduces lead migration rates
- DRG-S lead anchoring does not increase lead fracture rates

METHODS

Institutional review board (IRB) approval or waiver from each participating institution was obtained before commencing the retrospective chart review. The data were collected from patients implanted with DRG-S leads (Axium and Proclaim systems, Abbott) from April 1, 2016, to September 30, 2020, from 4 centers in the United States; 3 interventional pain physicians and a neurosurgeon were the implanters. All were experienced with SCS implantations, as defined by implanting more than 25 systems per year,[21] and had undergone additional training for DRG-S system implantation. The 4 implanters used the contemporary implant technique for lead placement.[15,22] This approach starts with needle puncture at the lateral aspect of the pedicle two levels below the target foramen using a contralateral approach. Epidural strain relief loops are placed in an "S" configuration with multiple loops in the inferior and superior aspects of the "S." The implantable pulse generator (IPG) is placed in the gluteal region. Across the 4 centers, there was varied lead management outside of the epidural space, which provided the opportunity to study the implantation method's influence on migration and fracture. Implanters 1 and 2 did not anchor leads initially, and independently modified their surgical technique to include lead fixation after noting a higher than expected number of lead migrations. Implanter 1 used the silastic anchor and implanter 2 used a purse string suture. Implanter 3 *initially* anchored leads with a suture tie and then discontinued anchoring due to the concern that anchor placement increased lead fracture risk. Implanter 4 anchored all cases, either with a suture tie or a silastic anchor. He utilized the silastic anchor if he determined the final "S" loop configuration was suboptimal or in the presence of friable tissue to allow suture tie fixation (see Table 1; for categorization purposes, suture ties were considered the initial technique and silastic anchors the modified technique).

The inclusion criteria for this study were: all DRG-S leads permanently implanted in all consecutive adult patients between 2016 and 2020. We included leads from patients implanted for any indication. DRG-S is currently US Food and Drug Administration (FDA) approved for the treatment of chronic nerve pain associated with CRPS and/or peripheral causalgia,[23] but is clinically applied in a broader patient population and we wanted the present analysis to be reflective of the real-world migration and fracture complications of DRG-S. Patients with lead migration presented with loss of therapy coverage and any therapy interruption was confirmed either radiologically or with the clinician programmer to identify lead shift or structural compromise. The time between patients experiencing loss of coverage to being clinically evaluated ranged from several days to 1 month after contacting their physician. If confirmation imaging was required, it was ordered at the visit that migration or fracture was suspected. The date of lead migration or lead fracture was defined as the date it was clinically confirmed. Clinical primary diagnoses were grouped into categories (complex regional pain syndrome, failed back surgery syndrome, non-surgical low back pain, peripheral neuropathy, joint pain, dermatomal neuropathic pain, radiculopathy, peripheral vascular disease, abdominal/pelvic pain, and sacroiliac joint pain) to allow for concise data presentation. Dermatomal pain was used to categorize pain syndromes limited to a dermatome which were not secondary to causalgia. These syndromes included ilioinguinal neuropathy, intercostal neuralgia, and post herpetic neuralgia. Joint pain was used to describe pain stemming from a joint which did not meet the criteria for causalgia. This included primarily nociceptive shoulder, hip, knee, and ankle conditions. Patient demographics, diagnoses, lead location, and occurrences of migration and fracture were stratified by the use of anchored versus unanchored leads. Comparisons between anchored and unanchored leads were made on an individual lead level since patients are often implanted with multiple leads. To assess characteristics potentially associated with events, we compared characteristics of migrated versus non-migrated leads and fractured versus non-fractured leads using Fisher exact tests (with Freeman–Halton extension for > 2 categories), unpaired *t*-tests, and Mann–Whitney *U* tests. Normality of data was assessed using the Shapiro–Wilk test. Fracture or migration survival in anchored and unanchored leads was the primary outcome of this study and was graphed using reverse (failure) Kaplan–Meier curves and compared using Cox regression that adjusted for clustering of leads within patients. Hazard ratios with a 95% confidence interval (CI) were generated to compare migration and fracture rates between the anchored and unanchored

TABLE 1 Techniques used for dorsal root ganglion stimulation lead implantation

Initial technique				
	Implanter 1	**Implanter 2**	**Implanter 3**	**Implanter 4**
Implants sample size, *n*	24	11	29	44
Leads sample size, *n*	89	31	80	108
"S" loop placement	Yes	Yes	Yes	Yes
Anchor?	No	No	Yes	Yes
Anchor method	None	None	Suture tie	Suture tie
Lead site incision depth	Subcutaneous tissue[a]	Deep fascia	Deep fascia	Deep fascia
Tension loops	No	No	Yes	Yes
Reason for modification	Migrations	Migrations	Concern Fractures	If felt "S" loop needed reinforcement
Modified technique				
	Implanter 1	**Implanter 2**	**Implanter 3**	**Implanter 4**
Implants sample size, *n*	78	23	27	13
Leads sample size, *n*	296	53	71	28
"S" loop placement	Yes	Yes	Yes	Yes
Anchor?	Yes	Yes	No	Yes
Anchor method	Silastic anchor	Purse string suture	None	Silastic anchor
Lead site incision depth	Deep fascia	Deep fascia	Fascia	Deep fascia
Tension loops	Yes	Yes	Yes (unanchored)	Yes

[a]Tunneled epidural catheter technique for lead pass to pocket.

leads. Survival was censored at the end of the observation period, when patients withdrew from the care of the center where they were implanted, or at fracture/explant and migration/explant for the lead migration and lead fracture analyses, respectively. We performed additional sensitivity analyses restricted to 1.5 years observation of follow-up to exclude influence from any events that only occurred at long-term follow-up and an imbalance in long-term follow-up between anchored and unanchored leads. Statistical analyses were performed using R version 3.6.2. A 2-sided $p < 0.05$ was considered statistically significant.

RESULTS

A total of 249 patients were included. Demographic and clinical data on a patient level is presented in Table 2. The mean patient age was 55 ± 15 years. The most common primary diagnoses were complex regional pain syndrome ($n = 106$, 43%), failed back surgery syndrome ($n = 64$, 26%), and non-surgical low back pain ($n = 23$, 9%). Across all patients, the median duration of follow-up was 790 days. Follow-up duration was censored for patients withdrawing from care at the center where they were implanted in 12 cases (5%). Patients with anchored

TABLE 2 Demographic and clinical characteristics of patients implanted with anchored and unanchored dorsal root ganglion stimulation leads

	Patients with anchored leads	Patients with unanchored leads	*p*-Value[b,c]
Sample size, *n*	187	62	N/A
Age at implantation in years, mean ± *SD*	56 ± 16	50 ± 13	<0.01
Sex in female/male, *n*/*n* (%/%)	110/77 (59/41)	43/19 (69/31)	<0.001
Body mass index in kg/m^2, mean ± *SD*	31 ± 5	30 ± 5	0.17
Primary diagnosis, *n* (%)			0.35
Complex regional pain syndrome	81 (43)	25 (40)	
Failed back surgery syndrome	49 (26)	15 (24)	
Non-surgical low back pain	19 (10)	4 (6)	
Peripheral neuropathy	9 (5)	3 (5)	
Joint pain	8 (4)	2 (3)	
Dermatomal neuropathic pain	6 (3)	6 (10)	
Radiculopathy	9 (5)	0 (0)	
Peripheral vascular disease	1 (1)	1 (2)	
Abdominal/pelvic pain	5 (3)	5 (8)	
Sacroiliac joint pain	0 (0)	1 (2)	
Vertebral level of leads placed, *n* of patients (%)[a]			
C4–C8	4 (2)	5 (8)	0.05
T1–T2	2 (1)	2 (3)	0.26
T7	1 (0.5)	0 (0)	1.00
T9–T11	2 (1)	3 (5)	0.10
T12	85 (45)	25 (40)	0.56
L1	15 (8)	11 (18)	0.05
L2	19 (10)	3 (5)	0.30
L3	24 (13)	11 (18)	0.40
L4	40 (21)	23 (37)	0.02
L5	37 (20)	21 (34)	0.04
S1	128 (68)	24 (39)	<0.001
S2	6 (3)	3 (5)	0.69
S3	2 (1)	0 (0)	1.00
Time to last follow-up in days, median (IQR)	620 (384, 956)	1076 (922, 1201)	<0.001

[a] *n* and % across all levels is greater than total number of patients because leads can be located at multiple levels within the same patient.
[b] *p*-Value compares patients with anchored leads vs. patients with unanchored leads.
[c] *t*-test used to compare means, Mann–Whitney *U*-test used to compare medians, Fisher exact test used to compare proportions.

leads versus unanchored leads were older and a larger proportion was male; see Table 2. Within the group of patients with anchored leads a larger percentage of patients had S1 leads when compared to the percentage of patients with S1 leads within the group of patients with unanchored leads. Conversely, within the group of patients with unanchored leads a larger percentage had L4 leads when compared to the percentage of patients with L4 leads within the group of patients with anchored leads.

A total of 756 implanted DRG-S leads were included from the 249 patients. One hundred ninety-one leads from 62 patients were unanchored and 565 leads from 187 patients were anchored either with a silastic anchor ($n = 324$) or with a suture tie ($n = 241$).

Lead migration

In unanchored leads, migration occurred in 16 leads (8.4%) from 13 patients (21.0%). In anchored leads, migration occurred in 8 leads (1.4%) from 5 patients (2.7%). Among anchored leads, migrations occurred in 2 leads (0.6%) with a silastic anchor and in 6 leads (2.5%) anchored with a suture tie. The migration survival distributions for the anchored and unanchored leads were statistically significantly different ($p < 0.001$; Figure 1A) with decreased survival for unanchored leads (hazard ratio = 5.8, 95% CI = 2.2–15.5). The sensitivity analysis on 1.5 year follow-up data yielded a similar result (hazard ratio = 5.6, 95% CI = 2.1–15.1; $p < 0.01$; Figure 1B).

Table 3 describes characteristics of migrated and non-migrated leads in anchored and unanchored leads. Demographic and clinical characteristics were similar across migrated and non-migrated leads for both anchored and unanchored leads.

Patients with migrated leads presented with loss of treatment efficacy and after failed attempts at reprogramming, all migrations were confirmed radiographically. Most migrations (18 of 24, 75%) were precipitated by an identifiable event that patients reported such as exercise, motor vehicle accidents, sudden forceful movements, and sexual activity.

Lead fracture

Fracture in unanchored leads occurred in 6 leads (3.1%) from 6 patients (9.7%). Fractures in anchored leads occurred in 11 leads (1.9%) from 9 patients (4.8%). Among anchored leads, fractures occurred in 7 leads (2.2%) with a silastic anchor and in 4 leads (1.7%) anchored with a suture tie. The lead fracture survival distributions for the anchored and unanchored leads were not statistically significantly different; see Figures 2A, 2B. Compared to lead migration, lead fracture occurred later after implantation; for migrated leads the median time to migration was 128 days (interquartile range [IQR] = 19, 320) and for fractured leads the median time to fracture was 257 days (IQR = 141, 455), $p = 0.03$.

Table 4 describes the characteristics of fractured and non-fractured leads in anchored and unanchored leads. Demographic and clinical characteristics were similar between non-fractured leads and fractured leads, except for the vertebral level of DRG-S lead implantation in anchored leads ($p = 0.04$). The distance from the IPG to the target DRG level appeared to affect fracture rates for anchored leads, as fractured leads were more commonly placed at spinal levels with a long subcutaneously tunneled distance to the implantation pocket than leads that did not fracture. For example, 45% of the total leads that fractured were placed at T12, whereas 27% of the total leads in the unfractured group were placed at T12. Similarly, 18% of leads that fractured were placed at L1, where 3% of leads that did not fracture were.

Patients with lead fracture presented with loss of treatment efficacy and 7 fractures (41%) were visible radiographically in addition to being detected upon interrogating the DRG-S device. In 6 out of those 7 cases, the lead fracture occurred superficially near the lead entry site at the skin. In the seventh case, the fracture was visible where the lead entered the IPG pocket. Precipitating events were reported in only 3 cases (18%). All fractured leads were removed and replaced in the standard fashion, except for one case where an S1 lead separated in the deep musculature and could not be removed. In this case, considering the anterior sacral foraminal size, it was decided to place a second lead in the foramen adjacent to the retained lead fragment.

DISCUSSION

Lead migration and fracture are the most frequently reported complication of DRG-S[17] that result in significant treatment disruption, exposing patients to the risks of reoperation along with added healthcare costs. Revision of DRG-S leads can be challenging when adhesions are present from the initial surgery, further increasing patients' risk of treatment complications.

Since the introduction of DRG-S therapy, the "S" tension loop has been the standard in the placement of leads to safeguard the final lead position permanency. Reliance on the "S" loop may have led practitioners to abandon the securing of leads to the deep fascia as the practice of anchor fixation is not widely adopted. Although the manufacturer clinician manual and early published implantation techniques advocate surgical fixation to reduce DRG-S leads migration,[14,15,22,24] recent DRG-S guidelines, on the contrary, do not recommend anchoring and instead leave it to the discretion of the implanter.[19] Such discrepancy is due to conflicting evidence. A literature review of anchoring techniques has demonstrated satisfactory results without anchor

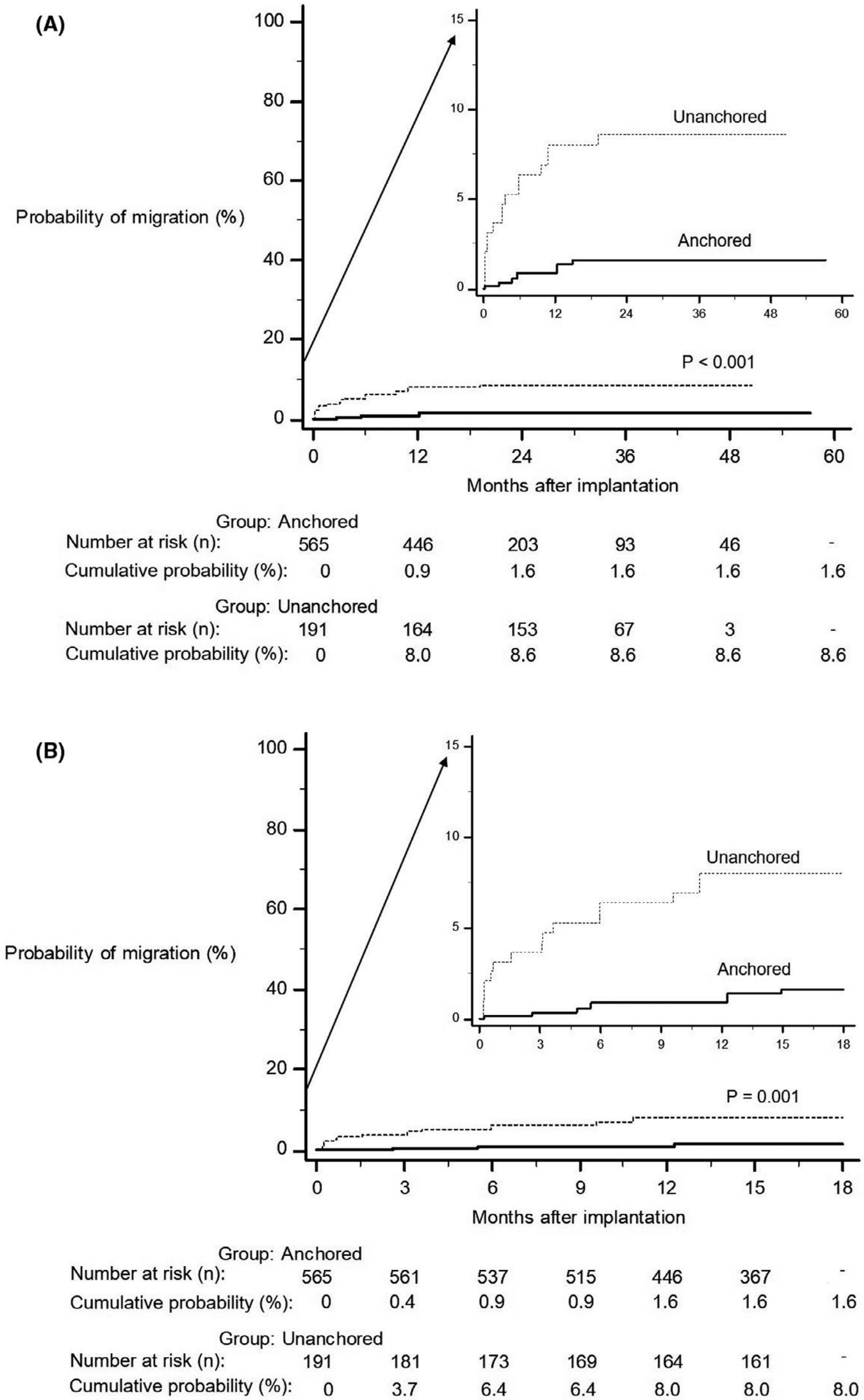

FIGURE 1 Reverse Kaplan–Meier curves of lead migration in anchored and unanchored dorsal root ganglion stimulation leads. Panel (a) depicts migration in all leads with all follow-up and panel (b) depicts a sensitivity analysis on migration limited to 1.5 year follow-up. Figure insets show axis magnifications

placement.[13,22] On the other hand, a review of 57 implanted DRG-S leads found nine lead migrations, even when anchors were placed.[25] Although the evidence on the benefit of lead anchoring is incongruous, our results underscore the importance of anchor placement in mitigating lead migration rate, without affecting fracture rate.

Migrations

When lead anchoring was employed for DRG-S, the migration rate was 1.4% per lead and 2.7% per implanted patient. The observed migration rates were 8.4% per lead and 21.0% per implant when leads were unanchored. A significant difference in the survival distribution of

TABLE 3 Characteristics of migrated and non-migrated leads in anchored and unanchored dorsal root ganglion stimulation leads

	Anchored leads (n = 565)			Unanchored leads (n = 191)		
	Migrated leads	Non-migrated leads	p-Value[a, b]	Migrated leads	Non-migrated leads	p-Value[a, b]
Sample size, n	8	557	N/A	16	175	N/A
Age at implantation in years, mean ± SD	51 ± 19	57 ± 15	0.32	50 ± 10	50 ± 12	0.89
Sex in female/male, n/n (%/%)	3/5 (37/63)	315/242 (57/43)	0.24	12/4 (75/25)	121/54 (69/31)	0.43
Body mass index in kg/m^2, mean ± SD	30 ± 8	31 ± 5	0.58	29 ± 6	30 ± 5	0.45
Primary diagnosis, n (%)			0.36			0.29
Complex regional pain syndrome	3 (37.5)	198 (36)		7 (44)	62 (35)	
Failed back surgery syndrome	2 (25)	175 (31)		4 (25)	47 (27)	
Non-surgical low back pain	1 (12.5)	66 (12)		0 (0)	13 (7)	
Peripheral neuropathy	0 (0)	30 (5)		2 (12.5)	9 (5)	
Joint pain	0 (0)	26 (5)		1 (6)	7 (4)	
Dermatomal neuropathic pain	0 (0)	18 (3)		1 (6)	16 (9)	
Radiculopathy	2 (25)	18 (3)		0 (0)	0 (0)	
Peripheral vascular disease	0 (0)	3 (0.5)		0 (0)	4 (2)	
Abdominal/pelvic pain	0 (0)	23 (4)		1 (6)	13 (7)	
Sacroiliac joint pain	0 (0)	0 (0)		0 (0)	4 (2)	
Vertebral level of implantation, n (%)			0.71			0.66
C4–C8	0 (0)	9 (2)		1 (6)	8 (5)	
T1–T2	0 (0)	2 (0.4)		0 (0)	2 (1)	
T7	0 (0)	1 (0.2)		0 (0)	0 (0)	
T9–T11	0 (0)	2 (0.4)		1 (6)	4 (2)	
T12	2 (25)	153 (27)		3 (19)	45 (26)	
L1	0 (0)	21 (4)		0 (0)	14 (8)	
L2	1 (12.5)	23 (4)		0 (0)	3 (2)	
L3	1 (12.5)	27 (5)		3 (19)	13 (7)	
L4	0 (0)	49 (9)		3 (19)	24 (14)	
L5	0 (0)	48 (9)		1 (6)	24 (14)	
S1	4 (50)	207 (37)		4 (25)	33 (19)	
S2	0 (0)	12 (2)		0 (0)	5 (3)	
S3	0 (0)	3 (0.5)		0 (0)	0 (0)	
Time to last follow-up in days, median (IQR)	168 (113, 372)	577 (381, 865)	<0.001	95 (13 – 236)	1020 (878, 1186)	<0.001

[a]p-Value compares migrated leads vs. non-migrated leads.

[b]t-test used to compare means, Mann–Whitney U-test used to compare medians, Fisher exact test used to compare proportions.

anchored and unanchored leads was found; clearly, lead anchoring is strongly indicated. Our migration rate in unanchored leads was nearly identical to the cumulative results of three studies where leads were not anchored: 134 leads in 56 implanted patients had 12 migrations, a rate of migration 9.0% per lead and a 21.4% migration rate per implanted patient.[11,12,26] Two different types of anchors were used in our study cohort; our results showed a migration rate of 0.6% per lead using the silastic anchors compared to a 2.5% migration rate in suture

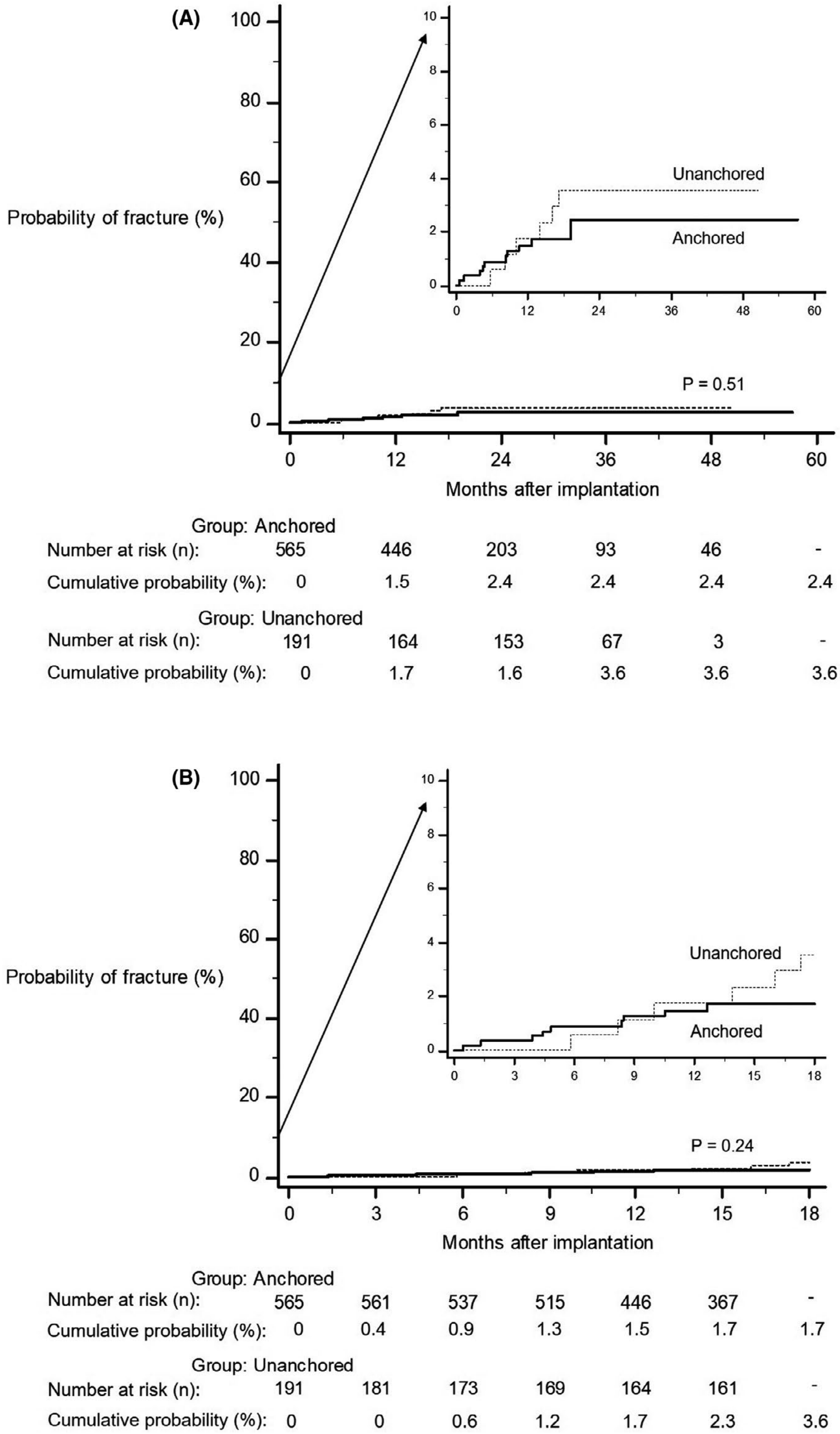

FIGURE 2 Reverse Kaplan–Meier curves of lead fracture in anchored and unanchored dorsal root ganglion stimulation leads. Panel (a) depicts fracture in all leads with all follow-up and panel (b) depicts a sensitivity analysis on fracture limited to 1.5 year follow-up. Figure insets show axis magnifications

tie fixated leads. Survival analysis on anchor types was not performed given the very low total number of failures in both groups.

Our results indicate that lead anchoring reduces lead migration in DRG-S without increasing fracture rates. These results are contrary to a report of 62 cases, where anchoring leads was discontinued mid-study due to concerns that fixation contributed to lead fracture, after which no migrations were noted in unanchored leads.[13] Surgical experience is correlated to complication rates,[27] and thus the accumulation of DRG-S cases may explain their results. In this report, our 4 experienced implanters

TABLE 4 Characteristics of fractured and non-fractured leads in anchored and unanchored dorsal root ganglion stimulation leads

	Anchored leads (n = 565)			Unanchored leads (n = 191)		
	Fractured leads	Non-fractured leads	p-Value[a,b]	Fractured leads	Non-fractured leads	p-Value[a,b]
Sample size, n	11	554	N/A	6	185	N/A
Age at implantation in years, mean ± SD	56 ± 13	57 ± 15	0.85	55 ± 11	50 ± 12	0.33
Sex in female/male, n/n (%/%)	7/4 (64/36)	311/243 (56/44)	0.43	3/3	130/55	0.26
Body mass index in kg/m^2, mean ± SD	32 ± 6	31 ± 5	0.65	32 ± 8	30 ± 5	0.95
Primary diagnosis, n (%)			0.13			0.39
Complex regional pain syndrome	4 (36)	197 (36)		1 (17)	68 (37)	
Failed back surgery syndrome	2 (18)	175 (32)		2 (33)	49 (26)	
Non-surgical low back pain	1 (9)	66 (12)		0 (0)	13 (7)	
Peripheral neuropathy	0 (0)	30 (5)		0 (0)	11 (6)	
Joint pain	1 (9)	25 (5)		1 (17)	7 (4)	
Dermatomal neuropathic pain	0 (0)	18 (3)		2 (33)	15 (8)	
Radiculopathy	0 (0)	20 (4)		0 (0)	0 (0)	
Peripheral vascular disease	0 (0)	3 (0.5)		0 (0)	4 (2)	
Abdominal/pelvic pain	3 (27)	20 (4)		0 (0)	14 (8)	
Sacroiliac joint pain	0 (0)	0 (0)		0 (0)	4 (2)	
Vertebral level of implantation, n (%)			0.04			0.36
C4–C8	0 (0)	9 (2)		1 (17)	8 (4)	
T1–T2	0 (0)	2 (0.4)		0 (0)	2 (1)	
T7	0 (0)	1 (0.2)		0 (0)	0 (0)	
T9–T11	0 (0)	2 (0.4)		0 (0)	5 (3)	
T12	5 (45)	150 (27)		3 (50)	45 (24)	
L1	2 (18)	19 (3)		1 (17)	13 (7)	
L2	0 (0)	24 (4)		0 (0)	3 (2)	
L3	1 (9)	27 (5)		1 (17)	15 (8)	
L4	1 (9)	48 (9)		0 (0)	27 (15)	
L5	1 (9)	47 (8)		0 (0)	25 (14)	
S1	0 (0)	211 (38)		0 (0)	37 (20)	
S2	1 (9)	11 (2)		0 (0)	5 (3)	
S3	0 (0)	3 (0.5)		0 (0)	0 (0)	
Time to last follow-up in days, median (IQR)	254 (126, 352)	577 (381, 865)	<0.001	363 (249, 487)	1013 (853, 1154)	<0.01

[a] p-Value compares fractured leads vs. non-fractured leads.
[b] t-test used to compare means, Mann–Whitney U test used to compare medians, Fisher exact test used to compare proportions.

offer a more dichotomous perspective, where 2 practitioners did not anchor in their initial 39 implants, another abandoned anchor placement after 29 implants and subsequently experienced increased migration rates, and the final used anchors intermittently.

Compared to fractures, lead migrations were observed relatively early after implantation (median of 4.2 months), and often with a precipitating physical event. A similar rapid appearance of migrations was observed in SCS and improved with anchor placement.[3,4]

DRG-S has been shown to significantly improve function,[11,12,28,29] and likely led to a restoration of activities and quality of life shortly after implantation.

Fractures

We observed that when lead anchoring is employed for DRG-S, the fracture rate is 1.9% per lead and 4.7% per implanted patient. Fracture rates in the unanchored group were 3.1% per lead and 9.7% per implanted patient. The fracture survival distributions between anchored and unanchored rates were not significantly different. These combined results suggest that anchoring does not increase the risk of lead fracture. In our study, fractures tended to occur later than migrations at a median of 8.4 months post-implantation. When compared to migrations, fractures were unlikely to be associated with an identifiable precipitating event. Distance from the IPG to the target foremen was observed to be a potential risk for fracture when comparing lead characteristics, however, we did not assess this in a formal survival analysis. In SCS, this has been identified as a risk for migration,[30] not fracture.

Of lead fractures in the thoracolumbar region, in 7 instances (50%), the practitioner documented a visible lead fracture on imaging. In 6 out of 7 cases, the lead fracture occurred superficially near the lead entry at the skin. In the seventh case, the fracture was visible as it entered the IPG pocket. The presence of disruptive forces that are so strong that they fracture the lead's encased alloys rather than cause the lead to migrate suggests an entrapment of the lead between the epidural space and the fracture site.[6] Thus, implantation techniques may be a precipitating factor. This has been reviewed extensively for SCS.[6,31]

Some DRG-S implanters believe that anchor placement increases fracture rates[13] but our data contradict this notion. Absolute fracture percentages unadjusted for observation time were higher in the unanchored cohort, but the survival distributions did not significantly differ. In unanchored leads, it has previously been hypothesized that a lack of bypassing the superficial fascial plane during tunneling was a potential cause of lead fracture.[32] A tunneled epidural catheter or a superficial stab incision is commonly used to create a point to tunnel the lead and may decrease infection risk and operating room (OR) time.[16] However, not bypassing the superficial fascia may lead to entrapment of the lead in this plane. This point of lead fixation may lead to tension, friction, and potentially fracture. When anchoring is not performed, the smaller skin incision and the shallow angle used to tunnel the lead may thus increase the likelihood of ensnarement in the superficial fascial plane. This in contrast to a larger incision required to achieve adequate depth for anchoring.

Although the lead fracture rate in our study was low compared to other studies, practitioners utilizing 4 leads per implant would still have a fracture rate of 7.6% per patient. Practitioners have voiced their concern that a new, more durable lead is required to reduce rates further. In the context of SCS, improved lead design has been suggested to be helpful to reduce fractures.[33] However, a recent publication on multifidus stimulation noted that 44 out of 94 leads developed high impedance, a sign of fracture, during the year-long study.[34] Their approach for placement of the 1.2 mm diameter leads was in the oblique plane with the lead travelling medially through the iliocostalis and multifidus muscles, similar to DRG-S lead placement. Consistent with our previously cited hypothesis,[32] the authors hypothesized that transecting fascial planes played a role in fracture and they modified their technique to take a midline approach, which appeared to improve outcomes.[34] DRG-S leads have an ~ 30% thinner diameter than SCS leads and have been assumed to be less durable, although the test data that was submitted for FDA approval is not necessarily reflective of this.[23,35] Lead body flex fatigue testing through repetitive bending motions followed by an assessment of lead integrity for DRG-S was 3.5 million flexural cycles, 75 times more than the 47 thousand required for SCS, with lower acceptable changes in impedance. Given that even the thicker 1.2 mm multifidus leads[36] fractured at a high rate, we propose that the aforementioned anatomical path of DRG-S leads is more important in causing lead fractures. We suggest that future studies should investigate a more medial approach for DRG-S implant to avoid transecting large muscles and fascial plains that may impose significant strain on the leads with movement.

Limitations

There are several limitations that pertain to this study. First, as a retrospective multicenter study, DRG-S lead implant techniques were not standardized, including anchoring with a silastic anchor or a purse string. Second, there was relatively longer follow-up for the unanchored cohort compared to the anchored cohort. Additionally, more anchored leads were included in the analysis. We corrected for these differences by performing survival analyses that handle group and follow-up differences well and we conducted additional sensitivity analyses. Third, it is possible that evolving surgical techniques and implanter experience, as naturally occurred during this review period, may improve outcomes irrespective of anchor use. However, this factor was likely balanced by opposing trends in changing anchoring strategies between the different implanters.

CONCLUSIONS

DRG-S is an effective therapy to reduce the impacts of CRPS and has shown promising results in treating other pain syndromes. However, real-world experience has demonstrated a significant migration rate in unanchored leads that resulted in therapy interruption. In this study, we found that anchoring DRG-S leads reduces lead migration compared to leads placed without an anchor. Our findings suggest that the implantation technique that uses strain-relief loops without surgically securing the leads, which many pain physicians use, is insufficient. Anchoring leads was not associated with higher fracture rates. This retrospective review supports that anchoring DRG-S leads should be the surgical standard, either using a midline incision or incisions over the Tuohy needle puncture sites. Additional comparative and long-term clinical data regarding migration and fracture rates will hopefully further elucidate the benefits and risks of lead anchoring in DRG-S.

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CONFLICTS OF INTEREST

Jan Willem Kallewaard is on the advisory boards of Abbott, Saluda, Nevro, and Boston Scientific. Timothy Deer is a consultant for Abbott, Medtronic, Boston Scientific, Nevro, Nalu, and Saluda. He has equity in Saluda, SPR, Spinethera, Nalu, Cornerloc, Paintec, and Vertos. He has received research funding from Boston Scientific, Abbott, and Saluda. Alon Mogilner is a consultant for Abbott Medical and Medtronic, and has received fellowship funding from Abbott and Medtronic. Timothy Lubenow is a consultant for Abbott, Boston Scientific, Medtronic, Nevro, Avanos, and Flowonix. He has received research funding from Abbott, Boston Scientific, and Nevro. Kiran Patel is a consultant and speaker for Abbott Neuromodulation. Kenneth Chapman, Ajax Yang, Abhishek Yadav, and Noud van Helmond have nothing to disclose.

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