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Int J Spine Surg published online 12 February 2021
https://www.ijssurgery.com/content/early/2021/02/10/8020

The International Journal of Spine Surgery
2397 Waterbury Circle, Suite 1,
Aurora, IL 60504, Phone: +1-630-375-1432

International Journal of Spine Surgery, Vol. 00, No. 00, 0000, pp. 000–000
https://doi.org/10.14444/8020

Comparison of Adverse Outcomes Following Placement of Superion Interspinous Spacer Device Versus Laminectomy and Laminotomy

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ABSTRACT

Background: Current evidence suggests placement of the Superion interspinous spacer (SISS) device compared with laminectomy or laminotomy surgery offers an effective, less invasive treatment option for patients with symptomatic lumbar spinal stenosis. Both SISS placement and laminectomy or laminotomy have risks of complications and a direct comparison of complications between the 2 procedures has not been previously studied. The purpose of this study is to compare the short-term complications of the SISS with laminectomy or laminotomy and highlight device-specific long-term outcomes with SISS.

Methods: Via retrospective review, 189 patients who received lumbar level SISSs were compared with 378 matched controls who underwent primary lumbar spine laminectomy or laminotomy; data were collected from the American College of Surgeons National Surgical Quality Improvement Program database. Complications analyzed included rates of wound infection, pulmonary embolism, deep venous thrombosis, urinary tract infection, sepsis, septic shock, cardiac arrest, death, and reoperation within 30 days of index surgery. Differences between groups were analyzed using the χ^2test. Device-specific complication (DSC) rates included device malfunction or misplacement (DM), device explantation (DE), spinous process fracture (SPF), and subsequent spinal surgery (SSS).

Results: No differences in demographics or comorbidities existed between groups. There was no significant difference in rates of complications between groups. A total of 44.4% of patients in the SISS group experienced DSCs with 11.1% of patients experiencing DM, 21.1% experiencing an SPF, 20.1% requiring DE, and 24.3% requiring SSS. Having at least 1 DSC significantly increased odds of SSS, odds ratio >120, $P < .0001$.

Conclusion: Rates of 30-day complications in the SISS group were not significantly different from patients undergoing laminectomy or laminotomy. Rates of 2-year DSC within SISS and cumulative risk associated with these complications should be considered further as they likely represent need for additional procedures for patients and substantial cost to the healthcare system.

Level of Evidence: 4.

Clinical Relevance: Having no differences in adverse events between laminectomies or laminotomies and SISS plus evidence of substantial device-specific long-term adverse outcomes and reoperation should be given consideration when deciding on surgical intervention of 1-2 level lumbar spinal stenosis.

New Technology

Keywords: laminectomy, laminotomy, interspinous spacer

INTRODUCTION

Laminectomies and laminotomies (LLs) are common surgical interventions for spinal stenosis when conservative measures have been exhausted. There is known potential for significant morbidity and mortality associated with LL.[1–3] Current literature suggests that placement of an interspinous spacer (ISS) is a less invasive and potentially equally effective treatment option when compared to LL[4–7]; however, systematic reviews of primary research have demonstrated that use of ISS devices is associated with higher costs and reoperation rates.[8–10] Still, the causes of the higher reoperation rate were not identified. Since the advent of the ISS, there has been a growing range of ISS devices available for use in surgical practice. Many studies have examined a variety of these devices, and it is

known that both ISS placement and LL have risks of complications. To our knowledge, a direct comparison of complications between one widely used device, the Superion ISS (SISS) (Vertiflex, Inc, Carlsbad, California) and LL has not been studied.

The SISS, a US Food and Drug Administration–approved and commercially available medical device commonly used in the outpatient surgical setting for the treatment of symptomatic spinal stenosis, is placed in a minimally invasive fashion using a percutaneous approach which only brings minor change to the local spinal anatomy. The SISS was selected for comparison given evidence suggesting that it is efficacious in the treatment of moderate lumbar spinal stenosis with neurogenic claudication symptoms and may pose lower risks inherent to LL and other spinal decompression procedures.[11,12] Nunley et al[13,14] showed that SISS provided measurable relief at 4 and 5 years postimplantation for patients with intermittent neurogenic claudication symptoms secondary to moderate lumbar spinal stenosis. Given these potentially promising outcomes, the rates of complications with the SISS compared to LL must be clearly defined. Moreover, analysis of device-specific complications (DSCs) should be considered as previous ISS devices have demonstrated concerning rates of DSC and reoperation rates.[15] To address this, our study specifically examines the comparison of complications between indirect decompression using the SISS and direct decompression via LL while also assessing rates of DSC in the SISS group.

The purpose of this study was to compare the short-term complications of the SISS with LL as well as highlight device-specific outcomes and causes of secondary surgical intervention after SISS implantation at long-term, defined as 2 years, postoperative follow-up.

MATERIALS AND METHODS

Using the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) database and the Vertiflex-provided database, this study compares the rate of complications in patients that underwent LL to those who received the SISS. The ACS-NSQIP database was retrospectively evaluated to identify patients who had undergone LL between 2014 and 2016. The ACS-NSQIP database is a nationally validated, risk-adjusted, and outcomes-based program that tracks surgical outcomes for 30 days postoperatively and is used for quality improvement in surgical care.[16,17] The ACS-NSQIP data collection process is utilized by institutions nationwide and requires specific training along with a certification that must be repeated annually. Furthermore, there is the addition of site auditing to ensure data collection processes remain acceptable and consistent.[17] SISS data was provided by Vertiflex, Inc, and included patients who underwent SISS placement between 2008 and 2011 in different medical facilities. Vertiflex, Inc, had no role in the study design, data collection, analysis, or writing of this manuscript.

Patients were selected from the ACS-NSQIP database that underwent 1–2-level lumbar LL procedures including partial excision of a posterior vertebral component for intrinsic bony lesion, laminectomy, facetectomy, and/or foraminotomy as identified by the following primary current procedural terminology (CPT) codes: 22012, 63047, and 63048.

Exclusion criteria included patients that were under 45 years old, had nonelective procedures, had secondary CPT codes that occurred on the same day of primary laminectomy procedure, including any LL procedure done for indications that were not stenosis, fusion, tumor resection, infection removal, revision procedure, or procedure extending to the thoracic, cervical, sacral, or pelvic region. Additionally, patients in the SISS data set who lacked enough data for statistical comparison were excluded.

The refined ACS-NSQIP cohort comprised our control group. Controls were matched based on sex, race or ethnicity, age (stratified as 45–49, 50–54, 55–59, 60–64, 65–69, 70–74, 75–79, 80–84, 85–89, and 90+), body mass index (BMI) class (underweight BMI <18.5, normal 18.5–24.9, overweight 25–29.9, class I obesity 30–34.9, class II obesity 35–39.9, class III obesity 40.0+) and known comorbidities of diabetes with and without insulin, hypertension requiring medication, and smoking status at the time of surgery. Pairs were randomly selected from the matched control list to be assigned to each appropriately matched SISS patient resulting in 2 ACS-NSQIP patients matched to 1 SISS counterpart. In 4 of the SISS cases where controls could not be matched with these criteria, we extended our matching inclusion to a wider range of numeric BMIs and/or age ranges with 5 more years. These discrepancies between the exact 2:1 ratio of controls to SISS BMIs are reflected in Table 1. These

Table 1. Obesity classification.[a]

Classification	BMI	Control (LL), n (%)	SISS, n (%)
Underweight	<18.5	2 (0.5)	1 (0.5)
Normal	18.5–24.9	61 (16.1)	31 (16.4)
Overweight	25–29.9	153 (40.5)	76 (40.2)
Class I obesity	30–34.9	111 (29.4)	55 (29.1)
Class II obesity	35–39.9	49 (12.9)	25 (13.2)
Class III obesity	40.0+	2 (0.5)	1 (0.5)

Abbreviations: BMI, body mass index; LL, laminectomy or laminotomy; SISS, Superion interspinous spacer.
[a]Discrepancies between exact 2:1 ratio of controls:cases are due to inability to match some SISS patients to controls by BMI class alone and therefore attempts to match within a close range to the numerical value of BMI were used.

modifications did not impact statistical differences between groups.

Complications were tracked by both databases. The ACS-NSQIP database is standardized to track complications for 30 days following procedures, and therefore limited all comparison of complications to those in the SISS group which occurred within a 30-day timeframe. This included: wound infection, pulmonary embolism, deep venous thrombosis, urinary tract infection, sepsis, septic shock, cardiac arrest, death, and reoperation. DSCs were assessed in the SISS group, tracked for 2 years, and categorized as follows: device misplacement/malfunction (DM), device explant (DE), spinous process fracture (SPF), and subsequent spine surgery (SSS). Any procedure that followed the initial placement of the device that included return to the operating room for any reason, including wound debridement or reoperation for DSCs, were included in the comparison of 30-day reoperation. Any DSCs within the SISS group that occurred at any time point following the index procedure were tracked for 2 years.

Statistical Methods

To define the comparability of the studied groups, differences concerning demographic and general clinical characteristics were analyzed using a 2-tailed t test for continuous variables and a χ^2 test for categorical variables. Statistical significance of differences in the rate of complications was assessed using a 2-tailed Fischer exact test. The data set was then evaluated for any associations between revealed postoperative complications and SSS in the SISS (case) group. The risk of complications and secondary surgical interventions were defined using percentage with 95% confidence limits (95% CL) for long term follow-up. To evaluate an association between SSS and the postoperative complications, an odds ratio (OR) with 95% CL was used and the P value was defined by the 2-tailed Fischer exact test. The influence of potential confounders such as demographic characteristics and comorbidities on the risk of SSS was studied using the same methods. Statistical significance was considered if $P \leq .05$. The time between the index operation and secondary surgical intervention was defined in days. The distribution of this index was presented as a histogram, the mean and standard deviation were defined.

Digital software JMP® Pro 15.0.0 (2019 SAS Institute, Cary, North Carolina) was used for the statistical analysis.

RESULTS

Initially, the SISS data set included 191 patients. Application of exclusion criteria resulted in only 2 of the 191 SISS patients being removed before statistical analysis. In total, 378 ACS- NSQIP LL controls were matched with 189 SISS patients. The average age of the SISS group was 66.9 ± 9.5 (mean ± SD) years, while the control group was 66.9 ± 9.8 years. There were 80 (42.4%) females and 109 (57.7%) males in the SISS group and 160 (42.3%) females and 218 (57.7%) males in the control group. The average BMI for the SISS group was 29.5 ± 4.6 kg/m^2 and 29.4 ± 4.9 kg/m^2 in the control cohort. Distribution of obesity classifications for the SISS group and control group are included in Table 1.

Patients who were current smokers at the time of surgery represented 12.7% (n = 24 and 48 in the SISS group and control group, respectively). Patients with diabetes represented 11.1% (n = 21 and 42); hypertension included 57.7% (n = 109 and 218) of patients. Overall, there were no significant differences in demographics or medical comorbidities between the study groups; however, more than 95% of patients in both groups were white/Caucasian.

Comparison of short-term complications between the groups (Table 2) showed no significant difference in rates of wound infection (SISS: 2.1% versus LL: 1.6%; $P = .65$), pulmonary embolism (0.53% versus 0%; $P = .13$), deep venous thrombosis (0% versus 0.53%; $P = .20$), urinary tract infection (0.5% versus 2.1%; $P = .09$), sepsis (0% versus 0.53%; $P = .11$), septic shock (0% versus 0%), cardiac arrest (0% versus 0.3%; $P = .36$), death (0.50% versus 0.25%; $P = .62$), or occurrence of any of the listed complications (5.3% versus 3.9%, $P = .61$). Reoperation within 30 days of index surgery did not show

Table 2. Comparison of complications between control laminectomy or laminotomy (N = 378) and Superion interspinous spacer device (N = 189).

Complication	Control (LL), n (%)	SISS, n (%)	*P* value
Wound infection	6 (1.6)	4 (2.1)	0.65
PE	0 (0)	1 (0.53)	0.13
DVT	2 (0.53)	0 (0)	0.20
UTI	2 (0.5)	4 (2.1)	0.09
Sepsis	3 (0.53)	0 (0)	0.11
Septic shock	0 (0)	0 (0)	N/A
Cardiac arrest	1 (0.3)	0 (0)	0.36
Death	1 (0.3)	1 (0.5)	0.62
Any of the listed complications	15 (3.9)	10 (5.3)	0.61
Reoperation within 30 POD	11 (2.5)	3 (1.6)	0.32

Abbreviation: DVT, deep venous thrombosis; LL, laminectomy or laminotomy; PE, pulmonary embolism; POD, postoperative days; SISS, Superion interspinous spacer; UTI, urinary tract infection.

a difference between groups, (1.6% versus 2.5%; $P = .32$).

When looking at the distribution of the number of days from the index operation to SSS in the SISS group, taking into consideration long-term follow-up shown in the Figure, approximately 50% of reoperations occurred during the first postoperative year while the other 50% occurred during next 2.8 years (418.1 ± 339.4 days). Of note, only 3(6.6%) of all 45 reoperations observed in the case group occurred during the first 30 postoperative days. No significant differences between studied complications by the reoperation time were revealed; however, reoperations due to the device misplacement tended to occur earlier, mainly during the first postoperative year, while other complications caused reoperations mainly later but had a very wide range of the time variability (Table 5). Because ACS-NSQIP data only track complications and reoperations for 30 days, we could not compare or assess reoperation rates past the first 30 days with the control group.

Of note, evaluation of complications specific to the SISS group taking into consideration long-term postoperative follow-up (Table 3) showed that 11.1% of patients experienced DM, 21.1% experienced a SPF, 20.6% required DE and 24.3% required SSS. A total of 84 (44.4%) of the 189 SISS patients experienced 1 or a few complications: 39 (20.6%) had 1 complication, 45 (23.8%) had 2–4 complications, and 59 (31.2%) had 1–4 DSCs other than SPF, including 14 (7.4%) with 1 such complication, 32 (16.9%) with 2, 11 (5.8%) with 3, and 2(2%) with 4.

When assessing for an association of complications with previously mentioned SSS (Table 4), the occurrence of any DSC was found to be significantly associated with SSS: odds ratio (OR) > 120, $P < .0001$, 46(54.8%) of 84 cases with any DSC required SSS, while none of 105 cases without DSC required SSS. In particular, the following complications had strong association with SSS: DE, OR = 289 (95% CL 60–1399, $P < .0001$), 37(94.9%) of 39 cases; ≥2 DSC in 1 patient, OR = 564(95% CL 67–4741, $P < .001$), 38(84.4%) of 45 cases; and any of DSC(s) excluding SPF, 46(77.9%) of 59 cases, OR > 410, $P < .0001$. The following complications did not have significant association with SSS: DM, 8 (38.1%) of

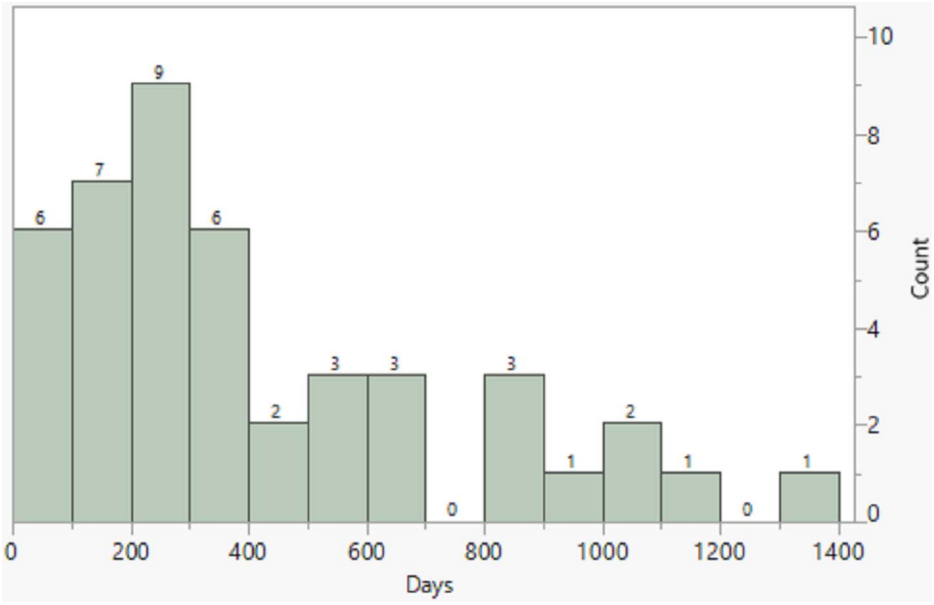

Figure. Distribution (histogram) of number of days between subsequent spine surgery and the index operation in Superion interspinous spacer group (418.1 ± 339.4 days, mean ± SD).

Table 3. Cumulative number and rate (%) of device-specific complications in Superion interspinous spacer group at long-term follow-up of 2 years, N = 189.

Complication	n	% (95% CL Min, Max)
Device misplacement/malfunction (DM)	21	11.1 (6.6,15.6)
Device explant (DE)	39	20.1 (14.4, 25.8)
Subsequent spine surgery (SSS)	46	24.3 (17.7, 29.9)
Spinous process fracture (SPF)	40	21.1 (15.3, 26.9)
Any of the listed device-specific complications (excluding SPF), 1–4 complications	59	31.2 (24.6, 37.8)
Any of the listed device-specific complications[a]	84	44.4 (37.3, 51.5)
Number of patients experiencing 1 complication	39	20.6 (14.8, 26.4)
Number of patients experiencing ≥2 complications	45	24.4 (18.3, 30.5)

[a]Counts number of patients with 1 or more of DM, DE, SSS, SPF.

21, OR = 2.2 (95% CL 0.8–5.6, $P = .11$), and SPF, 8 (17.8%) of 40, OR = 0.8 (95% Cl 0.3–1.9, $P = .67$). Of note, 2 cases that experienced a DSC did not have SSS and the reasons for these cases were not clearly stated by the records provided by the Vertiflex data set. One of the 2 cases had documented that with the attempted placement of the device, degenerative changes were found to be too severe to support adequate placement of the device.

Nonspecific variables such as sex, age, BMI, height, weight, and the studied 30-day complications did not show significant association with SSS in the SISS group during the whole period of postoperative observation.

DISCUSSION

In our study, the rates of complications of wound infection, pulmonary embolism, deep venous thrombosis, urinary tract infection, sepsis, septic shock, cardiac arrest, death, occurrence of any complication, and reoperation within 30 days of index surgery showed no difference between the SISS group and the LL group. Our study results are consistent with previous studies demonstrating that there are no significant differences in rates of perioperative complications between LL and ISS devices.[4,9] The review done by Wu et al[4] showed a complication rate of 11.3% (23/204 cases) in the ISS device groups and 8.3% (18/217 cases) ($P = .23$) in the traditional decompression surgery groups during 1–2 years of follow- up. Zhao et al[9] did not find a significant difference in rates of perioperative complications after ISS device use (6.5%) versus decompression alone (12.5%), $P = .20$. This is reassuring; however, the nature of complications documented in previous studies varies widely from device-related complications to general postoperative spinal surgery complications.[4,9,15,18,19] This makes comparing the complication rates across studies difficult and reflects a need for consistency in defining, tracking, and studying complications in these and related procedures.

Attention should be drawn to the alarmingly high rates of SISS DSCs consistent with findings of other ISS. Even when we excluded patients who experienced SPF as a complication of the device, the rates of DSC were still experienced by almost one-third of patients over the next 2 years, 59/189 (31.2%), with the majority occurring within the first year. The literature shows that complication rates associated

Table 5. Distribution of number of days from day of surgery (DOS) to subsequent spine surgery (SSS) classified by the main device-specific complications, N = 84.

Device-specific complication	SSS Days From DOS, Mean ± SD	Median (Min, Max)
Device misplacement	222 ± 133	235 (14, 461)
Spinous process fracture	378 ± 328	285 (80, 951)
Device explant	439 ± 350	360 (0, 1367)
Any device-specific complication	418 ± 339	305 (0, 1367)

Table 4. Association of device-specific complications (DSC) with subsequent spine surgery (SSS) in the SISS (case)-group during postoperative follow-up period, N=189.

		SSS, n (%)			
Complication	Subgroups	Yes	No	OR (95% CL Min, Max)	*P*(F) value
Device misplacement	Yes	8 (38.1)	13 (61.9)	2.2 (0.8, 5.6)	.11
	No	37 (22)	131 (78)		
Device explant	Yes	37 (94.8)	2 (5.2)	289 (60, 1399)	<.0001
	No	9 (6)	141 (94)		
Spinous process fracture (SPF)	Yes	8 (17.8)	32 (82.2)	0.8 (0.3, 1.9)	.67
	No	37 (24.8)	112 (75.2)		
Any of the device-specific complications	Yes	46 (54.8)	38 (45.2)	>120	<.0001
	No	0 (0)	105 (100)		
Number of device-specific complications in 1 patient	2–4	38 (84.4)	7 (15.6)	≈564 (67, 4741)	<.0001
	1	7 (18)	32 (82)	≈22.5 (2.7, 191)	<.0001
	0	0 (0)	105 (100)	1	

with ISS devices as a whole are significant enough to raise concern for the practicality and efficacy of using these devices as an intervention for symptomatic spinal stenosis and our study further supports that conclusion.[15] The SISS device has been considered an improvement compared to earlier generations of ISS devices[5]; however, some prospective studies suggest otherwise, showing that SISS DSCs are similar to those of other ISS devices. Complications such as SPF, DM, and device migration are also documented in the literature, but rates of such complications are unclear.[18,19] Regarding SSS rates, one study showed 3.8% of patients underwent SISS DE and SSS.[18] Patel et al[19] found reoperation rates as high as 23.2% for the SISS device within the first 2 years, with Nunley et al[13] showing increases up to 25.2% at 5 years. Other ISS devices have been studied and show similar rates of reoperation. Wu et al[4] reported a reoperation rate of 19.3% (31/161 cases), Zhao et al[9] reported 28.8%, and Ravindra et al[20] reported a range of 6%–85%. Across both SISS and other ISS devices, patients who underwent device removal and/or SSS most commonly noted misplacement or malfunction of the device and lack of improvement or worsening symptoms as indications for reoperation.[18,19] Our results indicate similar findings and of note, there were no cases of SSS that were the result of complications related to wound infection during index procedures.

Although our study does not directly compare reoperation rates outside 30 days from index surgery between LL and the SISS group, the literature reports reoperation rates for LL ranging from 6.9% to 9.4%.[4,8,9] This suggests that the rate of reoperation after the SISS device is greater than after LL, and as previously mentioned, consistent with reoperation following other ISS devices. Lauryssen et al[7] acknowledge that the reoperation rate for SISS is higher but that indications for these surgeries are different, highlighting that laminectomy should be reserved for more severe stenosis and that placement of SISS can be an earlier, less invasive option in less severe cases. Still this does not address the concern of added cost for multiple procedures in the long term or how the SISS compares with laminotomy, a procedure with more comparable indications.[8,21] Our study's findings, as well as those found in the literature, highlight a lack of consistency in the reporting of complication and reoperation rates across ISS devices. This comparison should be further evaluated, but with caution in the use of prospective studies.

Another critical factor to consider in the outcomes and complications data associated with the SISS and other ISS devices is patient-specific contraindications for use of the device over LL. The main contraindications for ISS devices include spinal pathologies of isthmic spondylolisthesis, degenerative spondylolisthesis, and fracture of the target segment.[22] Other contraindications that are documented in the literature include osteoporosis, instability of the lumbar spine, lumbar spine scoliosis, previous surgery, obesity, facet joint hypertrophy, absolute lumbar spinal stenosis, kyphotic malalignment, <50 years old, sensory/motor deficits, and uncontained disc herniation.[20,22,23] The majority of these contraindications were part of the exclusion criteria for the SISS patients during initial data collection. However, complication and reoperation and/or explantation rates of both the SISS and other ISS devices suggest that unidentified contraindications may exist that are contributing to the high rate of negative outcomes. Better assessment of risk factors that could lead to reoperation, complications, or poor outcomes with ISS devices could potentially improve outcomes. Further studies should investigate other potential contraindications.

Our study was limited by its retrospective design and the comparison of 2 separate data sets that were both gathered before our investigation. Comparing 2 separate databases limited our ability to match patients. Each data set contained unique and limited variables that dictated what characteristics we were able to match the patients on, inherently introducing confounding variables in this process. The ACS-NSQIP data set was more extensive in documenting patient comorbidities and complication rates in comparison to the SISS device data, which was provided by the instrumentation company, except for ACS-NSQIP data only tracking postoperative complications and reoperations for 30 days. Variables and patient characteristics that were not clearly defined in the SISS data set were subsequently not used for matching purposes. This included important factors such as operating room time, length of stay, and cost of index surgery. Through this process we thoroughly analyzed, deemphasized, and appropriately weighted variables from the SISS data set that showed any signs of inconsistency in data gathering or recording in the attempt to limit inherent bias in the data collected

by the manufacturer of the device. The cost of index surgery as well as subsequent revisions was not documented in either data set and should be tracked and investigated in future studies. Cairns et al[6] suggest that cost of SISS is lower than that of LL at the time of index procedure but reoperation costs have not been evaluated for SISS.

This study was also limited by a small sample size. Future studies should look to match a larger cohort of patients with controls based on more extensive demographic, comorbidity factors, and spinal levels treated to achieve more reliable outcomes. Furthermore, the absence of patient-reported outcome scores limits the ability for assessment of patient function and satisfaction with each procedure. From previous studies, patient-reported outcomes and satisfaction from Nunley et al[13] and Patel at al[19] demonstrated improvement in neurogenic claudication symptoms; however, these studies did not report a comparison to LL procedure outcomes.

CONCLUSION

There were no differences in complications between the SISS patients and those undergoing laminectomy or laminotomy. SSS interventions after SISS implantation at long-term follow-up are mainly associated with DSCs requiring DE. This is linked with recurrent stenosis rather than posterior SPF. These complications should be studied further as they likely represent a substantial additional cost to the healthcare system that may not be justified by improved patient outcomes.

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Disclosures and COI: The authors have no relevant disclosures as it pertains to the content discussed in this study. Data regarding patients who received the Superion Interspinous Spacer were provided by Vertiflex, Inc (Carlsbad, California). However, the company had no hand in study design, data analysis, statistical review, or manuscript production.

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Published 0 Month 2021