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Comparison analysis of safety outcomes and the rate of subsequent spinal procedures between interspinous spacer without decompression versus minimally invasive lumbar decompression

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ABSTRACT

Introduction Treatment for degenerative lumbar spinal stenosis (LSS) typically begins with conservative care and progresses to minimally invasive procedures, including interspinous spacer without decompression or fusion (ISD) or minimally invasive lumbar decompression (MILD). This study examined safety outcomes and the rate of subsequent spinal procedures among LSS patients receiving an ISD versus MILD as the first surgical intervention.

Methods 100% Medicare Standard Analytical Files were used to identify patients with an ISD or MILD (first procedure=index date) from 2017 to 2021. ISD and MILD patients were matched 1:1 using propensity score matching based on demographics and clinical characteristics. Safety outcomes and subsequent spinal procedures were captured from index date until end of follow-up. Cox models were used to analyze rates of subsequent surgical interventions, LSS-related interventions, open decompression, fusion, ISD, and MILD. Cox models were used to assess postoperative complications during follow-up and logistic regression to analyze life-threatening complications within 30 days of index procedure.

Results A total of 3682 ISD and 5499 MILD patients were identified. After matching, 3614 from each group were included in the analysis (mean age=74 years, mean follow-up=20.0 months). The risk of undergoing any intervention, LSS-related intervention, open decompression, and MILD were 21%, 28%, 21%, and 81% lower among ISD compared with MILD patients. Multivariate analyses showed no significant differences in the risk of undergoing fusion or ISD, experiencing postoperative complications, or life-threatening complications (all p≥0.241) between the cohorts.

Conclusions These results showed ISD and MILD procedures have an equivalent safety profile. However, ISDs demonstrated lower rates of open decompression and MILD.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Multiple surgical interventions are available to treat lumbar spinal stenosis (LSS), including minimally invasive procedures scuh as minimally invasive lumbar decompression (MILD) and interspinous spacer without decompression (ISD).

WHAT THIS STUDY ADDS

⇒ This study examines longitudinal rates of safety outcomes and the rate of subsequent spinal procedures in a matched cohort of ISD and MILD.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study may inform clinical decisions regarding minimally invasive procedures to treat LSS.

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INTRODUCTION

Lumbar spinal stenosis (LSS) represents a narrowing of the spinal canal to the point where the neurovascular structures of the spine are compressed.[1 2] A degenerative form of LSS often occurs with aging when arthritic changes in the intervertebral discs, ligamentum flavum, and facet joints cause narrowing of the spaces around the neurovascular structures of the spine. Neurogenic intermittent claudication is a common clinical presentation of LSS, manifesting as pain, discomfort, and/or weakness in the back and legs, often resulting in difficulty walking.[2]

Prevalence estimates vary considerably based on population and methodology.[2] However, LSS is estimated to affect 11% of the general population, 39% of those in primary and secondary care, and up to 47% of those older than 60 years.[3 4] LSS can be either congenital or acquired; the prevalence of the latter increases with age.[2 4] In addition to decrements to patient functioning and walking, the economic cost to treat LSS is substantial, both for surgical treatment[5] and medical therapy.[6]

Initial treatment for LSS typically consists of physical therapy, epidural injections, and/or pain medications,[2] but these interventions often have only a minimal effect on pain and functioning.[7] While opioids are commonly prescribed for low back pain,[8] they may fail to provide clinically important relief.[9] Surgical treatment intended to alleviate symptoms and improve functioning may include open lumbar decompression, which can be effective in reducing symptoms but can have significant postoperative complications.[2]

Minimally invasive procedures may be appropriate for some patients. During a minimally invasive lumbar decompression (MILD) procedure,

small amounts of lamina and hypertrophic ligamentum flavum are removed to achieve decompression in order to improve functioning and reduce pain.[10] Interspinous spacers without decompression or fusion (ISD) have been developed to relieve symptoms by preventing the repetitive compression of neurovascular elements during back extension. These spacers are inserted posteriorly via a minimally invasive procedure without the need for concomitant surgical decompressive laminectomy. This reduces procedure time and associated risks,[2] and the spacers have been shown to reduce pain, improve functioning, reduce the use of pain medications, and positively impact patients' health-related quality of life.[11–14]

Minimally invasive procedures can be a good option for patients for whom conservative care has failed to relieve symptoms but who are contraindicated for surgery because of comorbidity burden or risk from general anesthesia.[15] However, few data currently exist directly comparing the safety outcomes and subsequent interventions following minimally invasive procedures. Therefore, this study sought to examine the rates of postoperative complications and subsequent interventions between patients who received ISD versus MILD as their first surgical intervention.

METHODS

Study design and data source

This study was a retrospective claims analysis of patients receiving ISD or MILD as their first surgical intervention for LSS. The data source was 100% Medicare Standard Analytical Files (SAFs). These files include enrollment and demographic information for Medicare beneficiaries as well as billing data for health encounters that occur in both the inpatient (eg, hospital, skilled nursing facility) and outpatient (eg, clinic, emergency department, physician office) settings. The encounter files are constructed from billing claims where diagnoses and procedures are documented using International Classification of Diseases, 9th/10th Revision, Clinical Modification (ICD-9/10-CM) or Procedure Coding System (ICD-9/10-PC) codes, Current Procedural Terminology 4th edition (CPT) codes, and Healthcare Common Procedure Coding System codes. The data reflect information from patients with either Medicare part A or part B coverage. Those covered by Part C (ie, Medicare Advantage) are not included. Further, SAFs do not include pharmacy data, even for beneficiaries with Part D coverage. Sample selection and creation of analytic variables were performed using the Instant Health Data software (Panalgo, Boston, Massachusetts, USA). Statistical analyses were generated by using StataCorp. 2021.

These data are available to any entity who can meet Centers for Medicare and Medicaid Services' (CMS) criteria regarding the study purpose and the ability to house and manage the fully deidentified data.

For this study, patients receiving either ISD or MILD between January 1, 2017 and September 30, 2021 were identified, with the index date as the first date of a claim for either procedure during that time. Patients were followed from the index date until the end of study period, the end of Medicare coverage, or death, whichever was first. A baseline period of 12 months prior to index was also defined, during which demographics and clinical characteristics were measured.

Study population and outcome measures

In addition to the presence of at least one claim for an ISD or MILD procedure (ISD: CPT 22869, 22870, and ICD-10-PC 0SH00BZ for ISD; MILD: CPT 0275T and ICD-10-PC 00NY3ZZ) during the study period, eligible patients were those aged at least 50 years as of the index date with at least 12 months of continuous enrolment with medical coverage during the baseline period. Patients with prior lumbar spine surgeries during the baseline period were excluded.

The subsequent spine interventions included subsequent ISD and/or MILD procedures, open decompression (with or without fusion), fusion (without decompression), and placement of an interspinous spacer with open decompression. A subsequent ISD procedure within the ISD cohort represented a repeat procedure (similarly a subsequent MILD for the MILD cohort), although we did not separate out repeat procedures from the other types of procedures. Other subsequent lumbar surgical interventions included the removal of the implant, spinal cord stimulation, a disc procedure, a drug delivery implant, endoscopic decompression, repair of a dural or cerebrospinal fluid leak, vertebral excision, discectomy, vertebroplasty, or kyphoplasty. Reoperation rate defined as having an open decompression, fusion, or device removal[16] during the 2-year follow-up was reported among ISD patients.

Safety events included postoperative complications and life-threatening events. Complications included mechanical complications due to displace of device, mechanical complications due to breakdown or unspecified complication of device, an allergic reaction to device implant, an infection or inflammation to device implant, a lumbosacral spine injury, cerebrospinal fluid leaks, a nerve root injury, wound infections, dehiscence, or hematomas, thrombophlebitis, and a closed (collapsed) lumbar vertebra fracture including spinous process fracture. Life-threatening events relevant to surgical operations[17–20] within 30 days of index procedure included sepsis, pneumonia, acute myocardial infarction, cardiac arrest, pulmonary embolism, deep venous thrombosis, or stroke. Diagnosis and procedure codes used to identify patient comorbidity and outcomes are presented in online supplemental table 8.

Statistical analysis

To address confounding by indication potentially arising in comparative effectiveness research due to a lack of randomization in treatment assignment, ISD patients were matched 1:1 to MILD patients using propensity score matching. A caliper of 0.02 on the probability scale was used for matching without replacement.[21] The standardized mean difference (SMD) was used to determine the balance of covariate distribution between matched cohorts, with an SMD of <10 indicating an acceptable (negligible) imbalance between the two groups. Matching factors included age, gender, geographical region, race, index year, and Charlson Comorbidity Score.

Categorical variables are presented as the count and percent of patients in each category, while continuous variables as mean and SD. In addition to calculating the per cent of patients experiencing outcomes, incidence rates of outcomes per 10,000 person-years between the ISD and MILD cohorts were calculated and compared using Kaplan-Meier log-rank tests. Cox proportional hazards regression was used to examine the time to several events, including subsequent lumbar spine intervention, LSS surgical intervention, open decompression, and any adverse event. In these Cox model analyses, patients were followed until the outcome of interest, or until death, end of eligibility, or end of follow-up (September 30, 2021), whichever occurred first. Logistic regression was used to examine the likelihood of a life-threatening event within 30 days of the index procedure. All models were adjusted using patient demographic and clinical

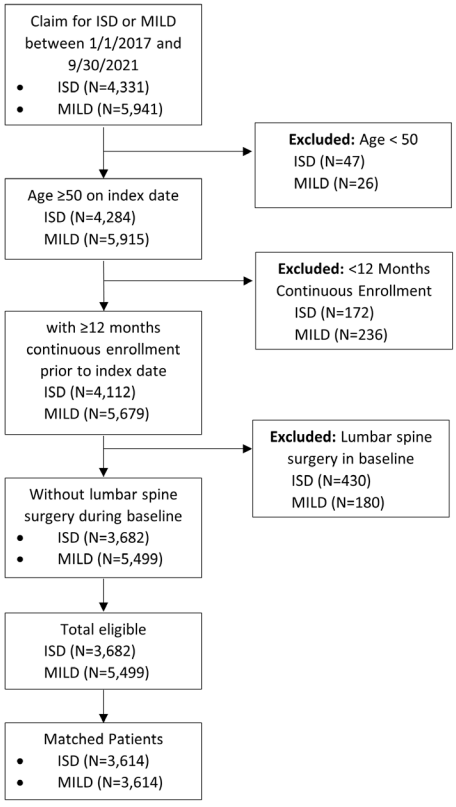

Figure 1 Flow chart of patient selection for minimally invasive lumbar decompression (MILD) and interspinous spacer implantation without decompression or fusion (ISD) cohorts.

characteristics; a full list of variables and their output parameters can be found in online supplemental tables 3 and 4, and a list of codes used can be found in online supplemental table 8. An alpha of 0.05 was used to signal statistical significance. Multiple comparison adjustment to control for the false discovery rate using Benjamini-Hochberg procedure[22] was performed. The p values of the main findings remain significant after the adjustment. Details of the adjustment can be found in online supplemental table 9.

RESULTS

Study population

When inclusion and exclusion criteria were applied, 3682 ISD and 5499 MILD patients were identified (figure 1). Of these, 3614 ISD patients were matched 1:1 to MILD patients; after matching, all SMDs of demographic variables were <10, and both cohorts had a mean follow-up length of 20.0 months (table 1).

The mean age of matched cohorts was 74 years; slightly more than half were female (55%). The cohorts were predominantly Caucasian (92% for ISD, 93% for MILD), with 4% of Black race and 4% of other races. Most patients lived in the South region of the USA (46% of ISD and 47% of MILD), followed by the Midwest (30% for both), West (14% for ISD, 13% for MILD), and Northeast (11% for both, table 1).

The most prevalent comorbidities among both cohorts included hypertension (an average of 62%), osteoarthritis (35%), diabetes (27%), obesity (16%), and lumbar spondylolisthesis (11%, table 1).

Table 1 Demographic and baseline clinical characteristics of matched cohorts

Demographics used in propensity score matching	ISD	MILD	Absolute SMD
Sample size, n	N=3614	N=3614	
Age at index, mean (SD) in years	74.1 (7.9)	74.2 (7.6)	1.014
Sex, n (%)			0.612
Female	1984 (54.9)	1995 (55.2)	
Male	1630 (45.1)	1619 (44.8)	
Region, n (%)			0.973
Midwest	1066 (29.5)	1066 (29.5)	
Northeast	392 (10.8)	392 (10.9)	
South	1651 (45.7)	1682 (46.5)	
West	505 (14.0)	471 (13.0)	
Race, n (%)			3.470
Caucasian	3318 (91.8)	3359 (92.9)	
Black	160 (4.4)	130 (3.6)	
Other/unknown	136 (3.8)	125 (3.5)	
Year of index procedure, n (%)			0.359
2017	186 (5.1)	168 (4.6)	
2018	459 (12.7)	457 (12.6)	
2019	1042 (28.8)	1091 (30.2)	
2020	1266 (35.0)	1232 (34.1)	
2021 (up to September 30, 2021)	661 (18.3)	666 (18.4)	
Selected comorbidities, n (%)			
Hypertension	2339 (64.7)	2148 (59.4)	
Osteoarthritis	1294 (35.8)	1217 (33.7)	
Diabetes	987 (27.3)	951 (26.3)	
Obesity	550 (15.2)	589 (16.3)	
Lumbar spondylolisthesis	428 (11.8)	374 (10.3)	
Charlson Comorbidity Index, mean (SD)	1.1 (1.5)	1.1 (1.6)	2.55

ISD, interspinous spacer without decompression; MILD, minimally invasive lumbar decompression; SMD, standardised mean difference.

Subsequent spinal procedures

The ISD cohort showed lower rates of any subsequent surgical intervention (13.9% vs 17.2%) and LSS surgical intervention (11.0% vs 14.8%, table 2). Specifically, the ISD cohort had lower rates of MILD (0.4% vs 2.0%), open decompression (5.4% vs 6.8%), and open decompression alone (3.4% vs 4.5%, table 2). Incidence rates showed similar differences (online supplemental table 1). Adjusted Cox regression confirmed these results, demonstrating a 21% reduction in risk of a subsequent surgical intervention (hazard ratio (HR) 0.79, 95% CI 0.70 to 0.89, figure 2), a 28% reduction in risk of a second LSS surgical intervention (HR 0.72, 95% CI 0.64 to 0.83, figure 2), a 21% reduction the risk of a subsequent open decompression (HR 0.79, 95% CI 0.65 to 0.96, figure 2), and a 81% reduction in risk of a subsequent MILD (HR 0.19, 95% CI 0.11 to 0.33), compared with MILD. There were no significant differences in the risk of undergoing a fusion surgery (HR 0.92, 95% CI 0.67 to 1.27) or ISD (HR 0.87, 95% CI 0.69 to 1.10) between the two cohorts.

The ISD cohort had higher rates of other lumbar spine interventions (4.1% vs 2.9%, table 2). After adjustment, Cox regression revealed a significantly higher risk of other subsequent surgical interventions (HR 1.38, 95% CI 1.07 to 1.78, figure 2) but no difference in the risk of a spinal cord stimulation (HR 1.44, 95% CI 1.00 to 2.07). Among ISD patients with 2 years

Table 2 Subsequent interventions between matched ISD and MILD patients during follow-up (incidence rates of these outcomes are available in online supplemental material)

	Matched ISD	Matched MILD	P value*
Sample size, n	N=3614	N=3614	
Subsequent lumbar spine surgical intervention, n (%)	503 (13.9)	623 (17.2)	<0.001
LSS surgical intervention, n (%)	397 (11.0)	535 (14.8)	<0.001
ISD	132 (3.7)	150 (4.2)	0.286
MILD	15 (0.4)	73 (2.0)	<0.001
Open decompression	196 (5.4)	245 (6.8)	0.009
Open decompression alone	123 (3.4)	162 (4.5)	0.016
Open decompression with fusion	74 (2.0)	88 (2.4)	0.253
Fusion alone	72 (2.0)	80 (2.2)	0.511
Spacer with open decompression	N/A‡	13 (0.4)	N/A
Other lumbar surgical intervention, n (%)	147 (4.1)	105 (2.9)	0.007
Spinal cord stimulation	72 (2.0)	49 (1.4)	0.036
Procedural removal of an implant in the spine region†	35 (1.0)	N/A	N/A
Disc procedure	N/A‡	N/A‡	N/A
Drug delivery implant	22 (0.6)	15 (0.4)	0.246
Endoscopic decompression	N/A‡	N/A‡	N/A
Repair of dura or cerebrospinal fluid leak	N/A‡	N/A‡	N/A
Vertebral excision/ corpectomy	N/A‡	N/A‡	N/A
Other lumbar spine surgeries (eg, discectomy, vertebroplasty, kyphoplasty)	12 (0.3)	20 (0.6)	N/A
Time to a subsequent surgical intervention (months), mean (SD)	9.6 (8.0)	9.6 (7.9)	0.866

*P value compares ISD versus MILD using a log-rank test.
†In claims data outcomes determined by ICD-10-PC or CPT codes are limited to a procedure rather than a device. These numbers reflect procedural removal of an implant in the spine region and are not device specific (and therefore even though some MILD patients may have had this procedure it would not be specifically related to the MILD procedure). They are stand-alone interventions that do not accompany open decompression and/or fusion, which may signify a complication rather than passive removal during open spine surgery.
‡Reflects cell counts less than 11 individuals which cannot be displayed per the data use agreement with the Centers for Medicare and Medicaid Services.
CPT, current procedural terminology; ICD-10-PC, International Classification of Diseases, 10th Revision, Procedure Coding System; ISD, interspinous spacer without decompression; LSS, lumbar spinal stenosis; MILD, minimally invasive lumbar decompression; N/A, not available.

of follow-up, the reoperation rate was 9.8%. Among MILD patients, the reoperation rate was 12.7%.

Safety outcomes

There were no significant differences between the ISD and MILD cohorts in rates of complications (4.3% vs 4.1%, p=0.711). Among those that occurred in at least 11 patients, there were no significant differences in: allergic reaction to device (1.2% vs 0.9%), hematomas (0.5% vs 0.4%), thrombophlebitis (0.3% vs 0.4%), or closed lumbar vertebra fracture (1.5% vs 1.9% table 3). Incidence rates showed similar trends

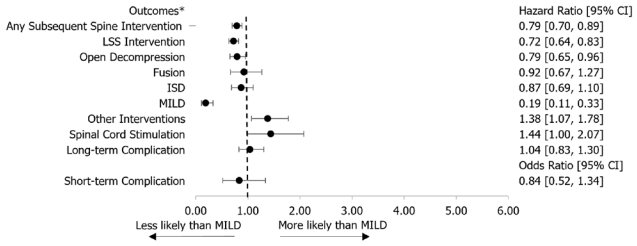

Figure 2 Adjusted Cox proportional hazards model and logistic regression on key outcomes. *Cox hazard model and logistic regression conducted on these outcomes adjusted for age, sex, race, region, index year, Charlson Comorbidity Index score, diagnosis of asthma, back syndrome, chronic obstructive pulmonary disease, diabetes, diabetic neuropathy, intervertebral disc disorders, heart failure, hypertension, obesity, osteoarthritis, osteoporosis, closed lumbar, vertebral, or hip fracture, lumbar spondylolisthesis, spondylolisthesis in other regions, and vascular claudication. ISD, interspinous spacer without decompression; LSS, lumbar spinal stenosis; MILD, minimally invasive lumbar decompression.

(online supplemental table 2). All other complications occurred in less than 11 (0.3%) patients in each cohort. Adjusted Cox regression confirmed that there was no significant difference in the likelihood of a complication (HR 1.04, 95% CI 0.83 to 1.30, figure 2). Rates of life-threatening events within 30 days occurred in 0.9% of ISD patients and 1.1% of MILD patients (p=0.636, table 3). The adjusted odds ratio (OR) of experiencing a life-threatening complication between ISD and MILD cohorts was non-significant (adjusted OR 0.84, 95% CI 0.52 to 1.34).

DISCUSSION

When matched with patients receiving MILD to treat LSS, those receiving ISD as a first surgical intervention experienced a similar rate of safety events while achieving lower rates of subsequent surgical interventions and LSS surgical interventions (including open decompression, MILD or ISD). Specifically, 4.3% of ISD patients experienced a safety event and 0.9% a life-threatening event within 30 days, similar to the 4.1% and 1.1%, respectively, of the MILD cohort. Further, the rates of safety outcomes observed in either cohort was less than has been reported in studies of other surgical interventions. Recent studies of open decompression have reported complications in 7.5%–12.15%[23 24] of patients. In fusion surgeries, a claims analysis reported the complication rate at 2 years to be 24.9%,[25] while an RCT reported complications in 23% of patients after receiving fusion surgery.[26] The reduced rate of adverse postoperative outcomes conferred by these minimally invasive procedures could have significant implications to the clinical burden of LSS.

The 13.5% of ISD patients who received any subsequent spine intervention and the 11.0% with LSS surgical intervention were both significantly less than observed in MILD patients (17.0% and 14.8%). Rates of subsequent spine surgery vary in previous studies. For example, Welton *et al* identified a subsequent spine surgery in 24.3% of patients receiving ISD over a 2-year follow-up,[27] while Hagerdone *et al* report that 5.3% of MILD patients and 0.8% ISD patients underwent subsequent lumbar spine surgery (p=0.093), representing either fusion or laminectomy.[28]

In the current data, reoperation occurred in 9.8% of the ISD cohort, which is less than half of that reported in the Superion

Table 3 The per cent with safety outcomes between matched ISD and MILD patients during follow-up (incidence rates of these outcomes are available in online supplemental material)

	Matched ISD	Matched MILD	P value*
	N=3614	N=3614	
Postoperative complication, n (%)	154 (4.3)	149 (4.1)	0.711
Mechanical complications due to displacement of device†	N/A‡	N/A‡	N/A
Mechanical complications due to breakdown or unspecified complication of device†	N/A‡	N/A‡	N/A
Allergic reaction to device implant†	45 (1.2)	32 (0.9)	N/A
Infection or inflammation to device implant†	N/A‡	N/A‡	N/A
Lumbosacral spine injury	N/A‡	N/A‡	N/A
Nerve root injury	N/A‡	N/A‡	N/A
Cerebrospinal fluid leaks	N/A‡	N/A‡	N/A
Wound infections	N/A‡	N/A‡	N/A
Wound dehiscence	17 (0.5)	N/A‡	N/A
Hematomas	19 (0.5)	14 (0.4)	N/A
Thrombophlebitis	12 (0.3)	15 (0.4)	N/A
Closed (collapsed) lumbar vertebra fracture including spinous process fracture	53 (1.5)	69 (1.9)	N/A
Time to the first fracture including spinous process fracture (month), mean (SD)§	8.4 (8.6)	12.4 (12.2)	N/A
Life-threatening events within 30 days of index procedure, n (%)	34 (0.9)	38 (1.1)	0.636
Pneumonia	N/A‡	N/A‡	N/A
Acute myocardial infarction	N/A‡	N/A‡	N/A
Cardiac arrest	N/A‡	N/A‡	N/A
Pulmonary embolism	N/A‡	11 (0.3)	N/A
Deep venous thrombosis	N/A‡	N/A‡	N/A
Ischemic stroke	N/A‡	N/A‡	N/A
Sepsis	N/A‡	N/A‡	N/A

*P value compares ISD versus MILD using a log-rank test.
†In claims data, outcomes determined by ICD-10-PC or CPT codes are limited to a procedure rather than a device. These numbers reflect any implant that results in mechanical complications, allergic reactions or infection/inflammation and are not device specific.
‡Reflects cell counts less than 11 individuals.
§Spinous process fractures occurring several months after the index procedure may be unrelated to the index procedure.
.CPT, current procedural terminology; ICD-10-PC, International Classification of Diseases, 10th Revision, Procedure Coding System; ISD, interspinous spacer without decompression; MILD, minimally invasive lumbar decompression; N/A, not available.

Investigational Device Exemption (IDE) trial (20.0%).[29] This may reflect physician experience or adjustments in the surgical technique in real world settings since the clinical trial. The observed rate in this analysis may reflect a reoperation on the same level or an operation on a different level due to limitations of claims data, which means that true reoperation rate on the same level is at most 9.8% and may be lower if some of the reoperations included those on a different level. Rates of removal of implant observed in this study (1.0%) were much lower than in previously published work reporting on device removal (20.1%)[27] or revision (3.6%).[30]

While the current study did not examine changes in symptoms, functionality, or pain, previous studies have reported these outcomes for both ISD and MILD. In a prospective clinical trial (MiDAS ENCORE), 143 MILD patients experienced a 47% improvement in pain scores over a 2-year period, as well as 28% and 29% improvements in Zurich Claudication Questionnaire (ZCQ) scores for symptoms and functioning, respectively.[10] By comparison, 2-year outcomes of a prospective IDE trial revealed a 64% reduction in axial pain and a 79% reduction in extremity pain, as well as a 36% improvement in ZCQ symptom and functioning scores.[31] If generalizable, these data would suggest ISD confers more improvement in pain relief, symptoms, and functioning than MILD.

The strengths of this study include the large, geographically diverse sample (largest sample size of ISD and MILD patients), and the lengthy follow-up. Additionally, matching ISD and MILD cohorts should mitigate potential confounding factors. The limitations of this study include those inherent in any retrospective claims analysis, namely that the data rely on administrative claims for clinical details. These data are subject to data coding limitations and data entry error. For example, diagnosis codes may lack detail and activities not needed to justify payment may be omitted. Claims also do not capture imaging data or patient-reported outcomes that are relevant to assess the efficacy of the index procedure, namely visual or numeric pain scores and ZCQ responses. Additionally, it is not possible to capture the severity of LSS (or the severity of complications) from claims, so the severity of LSS at the time of index procedure could not be determined, nor could outcomes be examined by LSS severity. And, as a result, we were not able to adjust for these factors in the Cox or logistic regression models. It should also be noted that patients were not randomized to treatment groups in this retrospective study and that MILD and ISD do not have identical clinical indications (for MILD, stenosis must occur with hypertrophied ligamentum flavum), which could lead to implicit bias in patient selection. Further, the primary results in this study are limited to individuals with Medicare coverage, and consequently, results of this analysis may not be generalizable to patients with other insurance or without health insurance coverage. However, due to the high prevalence of LSS in adults aged 65 and older who have Medicare insurance coverage, this analysis does represent a large proportion of eligible patients.

CONCLUSIONS

This analysis demonstrated that ISD and MILD procedures have an equivalent safety profile with similar short-term and long-term complication rates. However, compared with MILDs, ISDs demonstrated somewhat lower rates of any subsequent spine intervention, LSS surgical intervention, open decompression, and subsequent MILD. Further, there were meaningful reductions in reoperation rates observed in this real-world setting compared with the original Superion IDE trial.

Correction notice This article has been corrected since it published Online First. The second affiliation and the correspondence address has been updated.

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Competing interests OT is a full-time employee of Boston Scientific.

Patient consent for publication Not applicable.

Ethics approval Since this study does not involve human participants, neither institutional review board (IRB) approval nor participant consent was obtained. The

data for this study were provided through a specific data use agreement with CMS, and included only deidentified information, therefore, no IRB review was required.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement No data are available. This study used administrative claims data from CMS. Due to data use agreements signed with CMS, the data cannot be provided externally. Other researchers can purchase the same dataset to carry out similar analyses.

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