Original Article

Five-year radiological outcomes between decompression alone and decompression with an interlaminar device for lumbar spinal stenosis

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Background: There is limited literature regarding radiological outcomes in the use of interlaminar devices as an adjunct to decompression compared to decompression alone (DA) for symptomatic lumbar spinal stenosis (LSS). This study aims to assess and compare 5-year radiological outcomes following spinal decompression and decompression with ILD (D + ILD).

Methods: We conducted a retrospective review of prospectively collected data of 94 patients who underwent spinal decompression with or without ILD insertion between 2007–2015. Patients with symptomatic LSS who met the study criteria were offered spinal decompression with or without ILD insertion. Those patients who accepted ILD insertion were placed in the D + ILD group (n=39); while those opting for DA, were placed in the DA group (n=55). Radiological indices were assessed preoperatively, immediate post-operative, 2 years and 5 years postoperatively.

Results: There were a total of 94 patients with 55 in the DA group and 39 in the D + ILD group. In both groups, there was no significant change post-operatively in the sagittal balance parameters namely, the mean pelvic incidence, pelvic tilt, sacral slope and pelvic incidence minus lumbar lordosis (PI – LL) during the 5-year follow-up. Comparing between the groups, there was no significant difference in sagittal balance parameters. Comparing between DA versus D + ILD, there was no significant difference in overall lordosis, but the D + ILD had a significant reduction in sagittal angle (at the index level) of 2.3° compared to the DA group (P=0.01). In the control group, there was no significant difference in the anterior disc, posterior disc and foraminal height post-operatively. In the D + ILD group, there was a significant mean increase of 1.3 mm in anterior disc height, 1.8 mm in posterior disc height and 4.7 mm in foraminal height compared to the control group. In both groups, there was significant improvement in all clinical outcomes namely 36-item short form survey physical component summary (SF36 PCS), 36-item short form survey mental component summary (SF36 MCS) and visual analogue scale (VAS). Comparing the groups, there was significant improvement in the D + ILD group in SF36 MCS (P=0.01) but no difference in SF36 PCS or VAS. Reoperation rates were equivalent.

Conclusions: Our study found that in the management of lumbar stenosis, the use of an ILD as an adjunct device compared to DA had significant improvement in anterior disc, posterior disc and foraminal height with expected focal kyphosis at the level of intervention without change in the lumbar lordosis and sagittal balance at 5 years.

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Keywords: Lumbar spinal stenosis (LSS); lumbar decompression; interlaminar device (ILD); interspinous device

Submitted Mar 13, 2024. Accepted for publication Jun 27, 2024. Published online Sep 09, 2024.
doi: 10.21037/jss-24-33
View this article at: https://dx.doi.org/10.21037/jss-24-33

Introduction

Lumbar spinal stenosis (LSS) remains to be one of the more common degenerative spine conditions encountered in patients 50 to 70 years of age, with a large impact on the elderly population (1). Patients suffering from LSS typically adapts a stooped forward posture as it increases the cross-sectional area of the spinal canal, thereby alleviating their symptoms. In doing so, this introduces a positive sagittal balance and this abnormal balance results in increased back pain and fatigue. This compensatory posture may cause a cascade of abnormal alignment including retroversion of the pelvis, extension of the hips, reduction in lumbar lordosis, forward bending with increased sagittal vertical axis (SVA), and bending of the knees (1-6).

In recent years, there has been an increased focus on restoring spinal alignment in adult spinal deformity surgery. Multiple studies on spinal deformity surgery have found a strong association between restoration of the SVA and pelvic tilt and positive patient reported outcomes (7-9). There has been limited literature regarding the effect of spinal decompression on spinal alignment. Several short-term studies on decompression alone (DA) found that sagittal alignment improves and can correct to normal alignment with improvement in patient outcomes (4,10). However, it can potentially disrupt the stability of the index lumbar segment, with loss of radiological correction and relapse of symptoms (11).

The interlaminar device (ILD) was first introduced as an adjunct to decompression surgery to serve as the middle ground between DA and spinal fusion (12). It provides the benefit of surgical decompression with symptoms resolution and less soft tissue morbidity (13,14). It would also allow for dynamic stabilisation at the index segment with the intent to preserve the natural lordosis and reduce complications of fusion such as adjacent segment disease (13,14). There are limited long term studies evaluating the radiological correction and sagittal alignment in patients who undergo decompression with ILD (D + ILD).

We hereby present a 5-year review of radiological parameters and sagittal alignment in patients with symptomatic LSS (up to grade I spondylolisthesis) who underwent DA or decompression with the insertion of an ILD. We present this article in accordance with the TREND reporting checklist (available at https://jss.amegroups.com/article/view/10.21037/jss-24-33/rc).

Highlight box

Key findings

- The use of the interlaminar device (ILD) (namely Coflex) device in the management of lumbar stenosis had a significant improvement in anterior, posterior disc height and foraminal height that was maintained at 5 years compared to decompression surgery alone.

What is known and what is new?

- The insertion of the ILD (namely Coflex) device does introduce focal kyphosis at immediate post-operative. However, this reverts back to baseline at the 2-year mark.
- The introduced focal kyphosis does not affect the overall lordosis or sagittal balance.

What is the implication, and what should change now?

- The use of the ILD (namely Coflex) device a beneficial adjunct to decompression surgery in patients with lumbar spinal stenosis with at most grade 1 spondylolisthesis.

Methods

This study is a retrospective review of prospectively collected data of 94 patients under a single surgeon in a tertiary hospital. All patients underwent either single level spinal decompression or single level spinal decompression with an ILD (Coflex) insertion between 2007–2015. All patients included in this cohort were suitable for either type of surgery. During the informed consent process, patients were first educated on lumbar decompression surgery and the role of an adjunct ILD based on current available literature. Patients were given a choice—those who chose to undergo DA were placed in the control group (n=55), and those who chose to undergo decompression with the insertion of the ILD were placed in the intervention group (D + ILD) (n=39). The preoperative and postoperative radiographs as illustrated in *Figure 1*. The inclusion criteria are patients age 21 years and above, patients

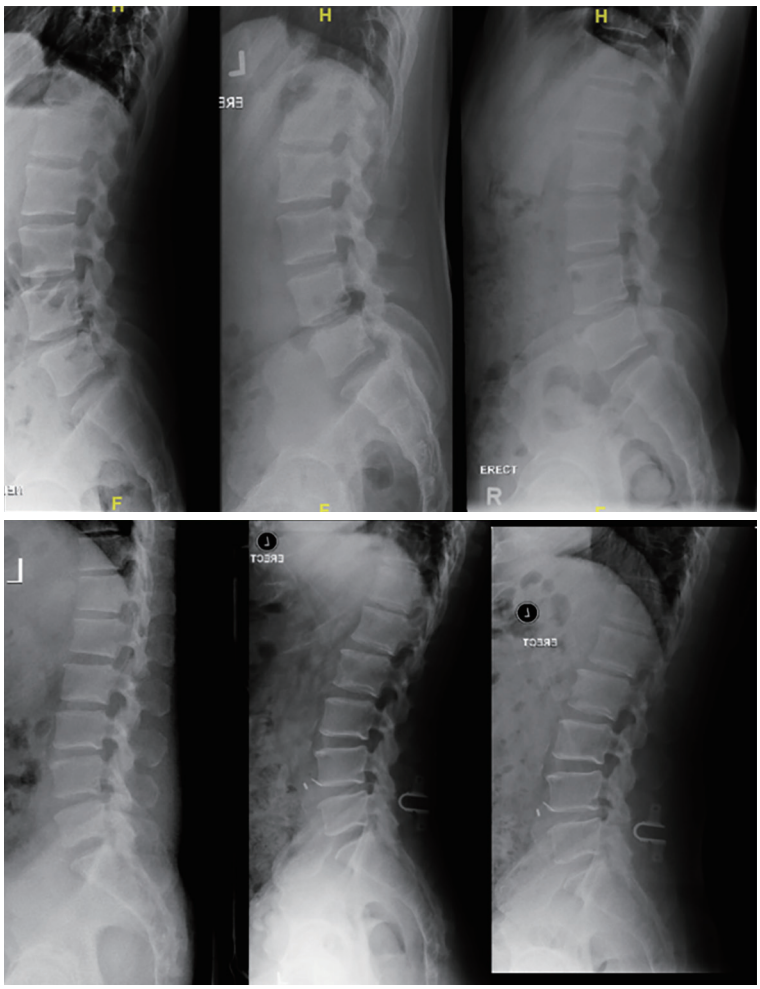

Figure 1 Lumbar spine lateral radiographs of a patient who underwent decompression surgery alone at preoperative, immediate postoperative and at 5 years (top left, top middle and top right). Lumbar spine lateral radiographs, taken while standing erect, of a patient who underwent decompression surgery with insertion of ILD at preoperative, immediate postoperative and at 5 years (bottom left, bottom middle and bottom right). ILD, interlaminar device.

diagnosed with single level spinal stenosis with either no spondylolisthesis or up to grade 1 spondylolisthesis. Patients were excluded if they were younger than 21 years old, had presence of spondylolisthesis grade 2 or higher, LSS of multiple levels, spondylolysis, had previous lumbar surgery or a diagnosis of malignancy as shown in *Table 1*.

All patients were followed up for 5 years postoperatively with 16 patients lost to follow-up and 1 patient who deceased. We allowed data points to be collected if they were within 6 months of their due follow-up. Prior to surgery, all patients included had anterior-posterior, lateral erect, lateral flexion and extension radiographs of the lumbar spine to assess for dynamic instability. After surgery, all patients had yearly anterior-posterior and lateral radiographs of the lumbar spine.

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the institutional ethical committee (DSRB reference 2020/00995) and informed consent was taken from all the patients.

Surgical technique

All patients underwent general anaesthesia and were positioned prone. The surgical approach was standard posterior midline. The interlaminar decompression was done using microscope assistance. Unilateral and/or bilateral

Table 1 Study inclusion and exclusion criteria

Inclusion criteria
Age ≥21 years
Single level spinal stenosis
No or up to grade I spondylolisthesis
No spondylolysis or dynamic instability
Exclusion criteria
Age <21 years
Multiple level lumbar spinal stenosis
Spondylolisthesis grade II or above
Spondylolysis
Primary or secondary metastasis to the spine
Previous lumbar spinal surgery
Previous history of spinal infection

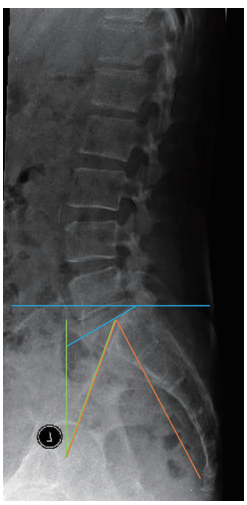

Figure 2 Lumbar spine lateral radiograph measuring pelvic tilt (green line), pelvic incidence (orange line) and sacral slope (blue line).

laminotomy with bilateral decompression was carried out with preservation of midline structures. In the D + ILD group, the insertion of the Coflex implant was carried out through the same surgical incision. The supraspinous ligament was first dissected subperiosteally, elevated and hinged on the superior spinous process. The interspinous ligaments were excised. After successful interlaminar decompression, a trial sizer was used to determine the size of the ILD to be implanted. The size was the one that provided the best interference fit without introducing segmental kyphosis intraoperatively. The implant was inserted between the adjacent spinous processes and laminar to reach the spinolaminar line and the flanges were crimped and seated snugly. The placement of the implant was confirmed under image intensifier guidance. The surgical technique has remained consistent as described above during the study period.

Postoperative care

After surgery, both group of patients had the same rehabilitation protocol and were allowed to ambulate as tolerated from immediate postoperative and early return to activities were encouraged.

Clinical outcomes assessment

The clinical outcome scores measured during specified timepoints were visual analogue scale (VAS), and short form-36 (SF-36). The standardised questionnaires were administered trained professionals and appropriate scores calculated.

Radiological assessment

All radiographers had at least 3 years of experience. Standardised, erect antero-posterior and lateral lumbar spine radiographs were assessed by two blinded observers, who did not participate in the surgery and measurements were taken using the Universal Viewer Zero Footprint. Pictorial charts demonstrating the standing posture were shown to the patient and standardized verbal instructions given by the radiographer to best standardise the radiographs taken.

Radiological indices were categorised into three groups. First, sagittal balance was accounted using standard measurements—pelvic incidence, pelvic tilt and sacral slope (15) as illustrated in *Figure 2*. Second, lumbar lordosis was measured by—overall lordosis (from lumbar one to sacral one) and sagittal angle (at the index segment). All three angles were measured by determining the angle subtended between the lines drawn parallel to the superior endplate of the cephalad vertebra and the inferior endplate of the caudad vertebra as illustrated in *Figure 3*. Third, intervertebral height was measured through—anterior disc height, posterior disc height and foraminal height. Anterior disc height was calculated as the distance between the anterior inferior corner of the upper vertebral body and the anterior superior corner of the lower vertebral body. Posterior disc height was calculated as the distance between

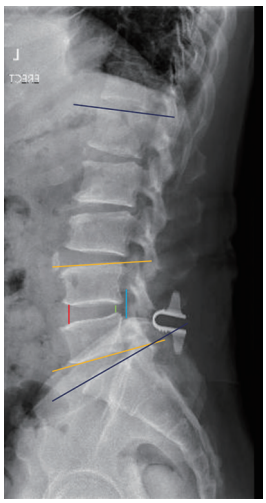

Figure 3 Lumbar spine lateral radiograph, taken while standing erect, of a patient who underwent decompression surgery and interlaminar device insertion at L4/5 measuring overall lumbar lordosis (dark blue line), sagittal angle (orange line), anterior disc height (red line), posterior disc height (green line) and foraminal height (blue line).

Table 2 Demographics of study population between DA and D + ILD

Demographics	DA (n=55)	D + ILD (n=39)
Age (years), mean (range)	59.5 (23–79)	58.5 (40–76)
Gender, n		
Males	39	19
Females	16	20
Level of surgery/instrumentation, n		
L2/L3	1	0
L3/L4	2	0
L4/L5	36	39
L5/S1	16	0
No spondylolisthesis, n	47	31
Spondylolisthesis grade 1, n	8	8
Dynamic instability, n	0	0

DA, decompression alone; D + ILD, decompression with ILD; ILD, interlaminar device.

the posterior inferior corner of the upper vertebral body and the posterior superior corner of the lower vertebral body. Foraminal height was measured as the maximum distance between the inferior margin of the pedicle of the superior vertebra and the superior margin of the pedicle of the inferior vertebra as illustrated in *Figure 3*. All radiological parameters were collected by experienced personnel with at least 3 years of training.

Statistical analysis

Statistical analysis was performed using the Statistical Package for Social Sciences (ver. 19, SPSS Inc., Chicago, IL, USA). For continuous variables, a paired *t*-test was performed to compare the immediate postoperative, 1 year, 2 years and 5 years radiological outcomes with the respective preoperative scores in both groups. Mixed model analysis was performed to compare the improvement in radiological parameters between the DA and D + ILD group. Unstructured variance-covariance was used and the baseline was included in the model for adjustment. The influence of duration of follow-up on the outcome parameters was also included in the analysis. A P value of <0.05 was considered as statistically significant.

Results

There were a total of 94 patients with 58 males and 36 females. In the control group, i.e., DA, there were 55 patients with a mean age of 59.5 (range, 23–79) years. All patients had follow-up at least to the 2-year mark with similar lost to follow-up rates between both groups. All patients who were lost to follow up had no significant difference in clinical and radiological parameters from the 1- to 2-year follow-up. There was no significant difference between those lost to follow up and those who completed it. The most common level for LSS who underwent DA was L4/L5 (65.5%) followed by L5/S1 (29.1%), L3/L4 (3.6%) and L2/L3 (1.8%). There were 8 patients (14.5%) with grade 1 spondylolisthesis and no patients with dynamic instability. In the study group, i.e., D + ILD group, there were 39 patients with a mean age of 58.5 (range, 40–76) years. All patients underwent D + ILD at L4/L5. There were 8 patients (20.5%) with grade 1 spondylolisthesis and no patients with dynamic instability (*Table 2*).

Radiological outcomes

Sagittal balance

The mean values of the spinopelvic sagittal parameters at preoperative, immediate post-operative, 2 and 5 years are shown in *Table 3*. In both the DA and D + ILD group, there was no significant change post-operatively in the

Table 3 Radiological sagittal balance and lordosis parameters between DA and D + ILD

Groups	Radiological sagittal balance and lordosis parameters											
	PI (°)	P value†	PT (°)	P value‡	SS (°)	P value§	PI – LL (°)	P value¶	Overall LL (°)	P value#	SA (°)	P value^
DA												
Preop	52.4 (ref)		19.7 (ref)		31.8 (ref)		10.2 (ref)		41.4 (ref)		17.4 (ref)	
Immediate postop	52.7	0.29	20.1	0.10	31.5	0.39	10.3	0.94	42.4	0.51	17.3	0.87
2-year	52.8	0.10	20.1	0.10	31.6	0.61	10.4	0.91	42.5	0.47	17.2	0.84
5-year	53	0.34	20	0.18	31.9	0.46	9.7	0.80	43	0.79	18	0.86
D + ILD												
Preop	54.8 (ref)		21.2 (ref)		34.6 (ref)		9.4 (ref)		45.4 (ref)		18.2 (ref)	
Immediate postop	55	0.70	21.5	0.53	34.6	0.94	13.2	<0.01	41.8	<0.01	14.2	<0.01
2-year	55.7	0.35	22.1	0.34	34.5	0.63	9.4	0.58	45.9	0.77	17.4	0.31
5-year	54.7	0.99	20.4	0.63	34.7	0.21	9.5	0.18	44.6	0.38	14.9	0.10
P value	–	0.72	–	0.99	–	0.57	–	0.52	–	0.38	–	0.01

†, P value comparing the post-operative against the pre-operative PI; ‡, P value comparing the post-operative against the pre-operative PT; §, P value comparing the post-operative against the pre-operative SS; ¶, P value comparing the post-operative against the pre-operative PI – LL; #, P value comparing the post-operative against the pre-operative overall LL; ^, P value comparing the post-operative against the pre-operative SA. DA, decompression alone; D + ILD, decompression with ILD; ILD, interlaminar device; PI, pelvic incidence; PT, pelvic tilt; SS, sacral slope; PI – LL, pelvic incidence minus lumbar lordosis; LL, lumbar lordosis; SA, sagittal angle; ref, reference.

mean pelvic incidence, pelvic tilt, and sacral slope during the 5-year follow-up. Comparing between the DA and D + ILD group, there was no significant difference in pelvic incidence (P=0.72), pelvic tilt (P=0.99) and sacral slope (P=0.57) across the time points.

In the DA group, the preoperative mean pelvic incidence minus lumbar lordosis (PI – LL) was 10.2°. Postoperatively, the mean PI – LL was 10.3°, 10.4° and 9.7° with no significant difference across the 5-year follow-up. In the D + ILD group, the preoperative mean PI – LL was 9.4°. At immediate postoperative, there was an increase in PI – LL to 13.2° (P<0.01). Subsequently the mean PI – LL return back to baseline at 2- and 5-year follow-up. There was no significant difference in mean PI – LL between the groups (P=0.52).

Lordosis

In the DA group, the mean preoperative overall lumbar lordosis was 41.4°. Postoperatively, the mean overall lumbar lordosis was 42.4°, 42.5° and 43.0° with no significant difference across the 5-year follow-up. In the D + ILD group, the mean preoperative overall lumbar lordosis was 45.4°. At immediate post-operative, there was significant loss of lordosis at 41.8° (P<0.01). Subsequently, the mean overall lumbar lordosis is restored to preoperative of 45.9° and 44.6° at 2 and 5 years respectively with no significant difference. Comparing the groups, there was no significant difference in overall lumbar lordosis (P=0.38).

In the DA group, the mean preoperative sagittal angle was 17.4°. Postoperatively, the mean sagittal angle was 17.3°, 17.2° and 18.0° with no significant difference across the 5-year follow-up. In the D + ILD group, the mean preoperative sagittal angle was 18.2°. Postoperatively, there was a significant reduction in mean sagittal angle at immediate postoperative of 14.2° (P<0.001) with resolution to baseline at 2 years at 17.4° (P=0.31) and 5 years at 14.9° (P=0.10). The D + ILD group had a significant mean sagittal angle at the index level of 2.3° compared to DA group (P=0.01) (*Table 3*).

Intervertebral height

In the DA group, the mean preoperative anterior disc height was 11.9 mm. Postoperatively, the mean anterior disc height was 11.4, 11.0 and 10.8 mm with no significant difference across the 5-year follow-up. In the D + ILD group, the mean preoperative anterior disc height was 11.4 mm. At post-operative, there was a significant increase at immediate post-operative at 12.4 mm (P<0.01). However, the increase in anterior disc height was not maintained at 2 and 5 years with 12.0 mm (P=0.11) and 11.1 mm (P=0.34) respectively.

Table 4 Radiological intervertebral height parameters between DA and D + ILD

Groups	Radiological intervertebral height parameters					
	ADH (mm)	P value[†]	PDH (mm)	P value[‡]	FH (mm)	P value[§]
DA						
Preop	11.9 (ref)		6.4 (ref)		15.5 (ref)	
Immediate postop	11.4	0.50	6.4	0.91	15.6	0.87
2-year	11.0	0.57	6.3	0.62	15.8	0.42
5-year	10.8	0.59	6.4	0.51	15.6	0.82
D + ILD						
Preop	11.4 (ref)		6.9 (ref)		17.0 (ref)	
Immediate postop	12.4	<0.01	9.4	<0.01	21.9	<0.01
2-year	12.0	0.11	7.8	0.01	20.3	<0.01
5-year	11.1	0.34	7.9	0.03	20.7	0.01
P value	–	0.01	–	<0.01	–	<0.01

[†], P value comparing the post-operative against the pre-operative ADH; [‡], P value comparing the post-operative against the pre-operative PDH; [§], P value comparing the post-operative against the pre-operative FH. DA, decompression alone; D + ILD, decompression with ILD; ILD, interlaminar device; ADH, anterior disc height; PDH, posterior disc height; FH, foraminal height; ref, reference.

Comparing the mean change in anterior disc height across time, the D + ILD group had a significant mean increase of 1.3 mm compared to control group (P=0.01)

In the DA group, the mean preoperative posterior disc height was 6.4 mm. Postoperatively, the mean posterior disc height was 6.4, 6.3 and 6.4 mm with no significant difference across the 5-year follow-up. In the D + ILD group, the mean pre-operatively posterior disc height was 6.9 mm. There was a significant difference at immediate post-operative at 9.4 mm (P<0.01). This increase in posterior disc height was maintained at 2 and 5 years with 7.8 mm (P=0.01) and 7.9 mm (P=0.03) respectively. Comparing the mean change in posterior disc height across time, the D + ILD group had a significant mean increase of 1.8 mm compared to DA group (P<0.01).

In the DA group, the mean preoperative foraminal height was 15.5 mm. Post-operatively, the mean foraminal height was 15.6, 15.8 and 15.6 mm with no significant difference across the 5-year follow-up. In the D + ILD group, the mean pre-operatively foraminal height were 17.0 mm. At post-operative, there was a significant difference at immediate post-operative at 21.9 mm (P<0.01). This increase in foraminal height was maintained at 2 and 5 years with 20.3 mm (P<0.01) and 20.7 mm (P=0.01) respectively.

Comparing the mean change in foraminal height across time, the D + ILD group had a significant mean increase of 4.7 mm compared to DA group (P<0.01) (*Table 4*).

SF-36

In the DA group, the mean pre-operatively 36-item short form survey physical component summary (SF36 PCS) were 36.3. At post-operative the mean SF36 PCS improved to 48.1, 50.6 and 52.5 across the 5-year follow-up with significant improvement at all timepoints (P<0.01). In the D + ILD group, the mean pre-operatively SF36 PCS scores were 43.1. At post-operative the mean SF36 PCS score improved to 53.5, 55.7 and 60.5 across the 5-year follow-up with significant improvement at all timepoints (P<0.01).

In the DA group, the mean pre-operatively 36-item short form survey mental component summary (SF36 MCS) were 46.1. At post-operative the mean SF36 MCS improved to 52.3, 54.0 and 55.5 across the 5-year follow-up with significant improvement at all timepoints (P<0.01). In the D + ILD group, the mean pre-operatively SF36 MCS scores were 54.4. At post-operative the mean SF36 MCS score improved to 64.6, 64.9 and 69.5 across the 5-year follow-up with significant improvement at all timepoints (P<0.05).

Comparing the groups, there was significant improvement in D + ILD group in SF36 MCS (P=0.01) but no difference in SF36 PCS (P=0.85).

Table 5 Clinical outcomes between DA and D + ILD

Groups	Clinical outcomes					
	SF36 PCS	P value[†]	SF36 MCS	P value[‡]	VAS	P value[§]
DA						
Preop	36.3 (ref)		46.1 (ref)		5.9 (ref)	
Immediate postop	48.1	<0.01	52.3	<0.01	1.9	<0.01
2-year	50.6	<0.01	54.0	<0.01	1.4	<0.01
5-year	52.5	<0.01	55.5	<0.01	1.1	<0.01
D + ILD						
Preop	43.1 (ref)		54.4 (ref)		6 (ref)	
Immediate postop	53.5	<0.01	64.6	<0.01	1.5	<0.01
2-year	55.7	<0.01	64.9	0.01	1.4	<0.01
5-year	60.5	<0.01	69.5	0.03	1.0	<0.01
P value	–	0.85	–	0.01	–	0.83

[†], P value comparing the post-operative against the pre-operative SF36 PCS; [‡], P value comparing the post-operative against the pre-operative SF36 MCS; [§], P value comparing the post-operative against the pre-operative VAS. DA, decompression alone; D + ILD, decompression with ILD; ILD, interlaminar device; SF36 PCS, 36-item short form survey physical component summary; SF36 MCS, 36-item short form survey mental component summary; VAS, visual analogue scale; ref, reference.

VAS

In the DA group, the mean pre-operatively VAS were 5.9. At post-operative the mean VAS score improved to 1.9, 1.4 and 1.1 across the 5-year follow-up with significant improvement at all timepoints (P<0.01). In the D + ILD group, the mean pre-operatively VAS were 6.0. At post-operative the mean VAS improved to 1.5, 1.4 and 1.0 across the 5-year follow-up with significant improvement at all timepoints (P<0.01). Comparing the groups, there was no significant difference in VAS (P=0.83) (*Table 5*).

Complications

In the DA group, two patients required revision surgery. One patient underwent a revision decompression within 1 year postoperatively for recurrence of symptoms. The other patient underwent a transforaminal interbody fusion (TLIF) and adjacent segment decompression within 2 years postoperatively for progression of symptoms.

In the D + ILD group, there were a total of one patient who required revision surgery. The patient underwent removal of the ILD due to implant migration. There was no patient that required revision surgery due to recurrence of symptoms or adjacent segment disease.

There were no major complications in both groups. There were no patients in our study who required intensive care unit (ICU) stay, had paralysis or permanent disability as a result of the surgery performed.

Discussion

In the treatment of LSS, there has been studies that evaluate the radiological outcomes of ILD alone and studies that compare DA versus the use of an ILD insertion (16-18). However, there are limited studies that evaluate the effect of decompression on sagittal balance, and even fewer studies that describes these outcomes with the use of the ILD (Coflex) device. Our prospective review found that the use of an ILD as an adjunct to decompression surgery resulted in significant improvement in anterior disc, posterior disc and foraminal height with expected focal kyphosis at the level of intervention without a change in sagittal balance at the 5-year timepoint.

The Coflex is a U-shaped ILD that was first designed to stabilize the motion segment and limit spinal hyperextension (1,19,20). When the device undergoes flexion and extension, the arms of the U are compressed in spinal extension and do not undergo distraction in spinal flexion unless there is bony overgrowth of the wings on the spinous processes (1). In extension, the spinous processes move closer together, increasing

the compressive load that is exerted on the U-portion of the implant. When the implant is properly positioned (with the apex at the facet level), the force flows mainly from the lamina directly into the elastic apex of the implant and the force exerted on the spinous processes is low (1).

Sagittal alignment

The focus on sagittal misalignment first gained attention in adult spinal deformity correction for its association with negative health related quality of life (HRQoL) and increased disability (7,19,21-23). In particular, those with increased SVA and PI – LL mismatch have a strong correlation with adverse patient reported outcomes (24,25). In patients who do not have a full length radiograph films, the PI – LL mismatch is used as it correlates strongly with SVA (26). This has garnered increased attention within lumbar spinal decompression surgery with aims to achieve global sagittal balance and positive patient-reported outcomes. Several studies report favourable sagittal alignment improvement after decompression surgery. Ogura *et al*. reported a 2-year study following lumbar decompression with 13 out of 29 patients who improved from mismatched alignment (SVA >50 mm) to appropriate alignment (SVA <50 mm) (4,27-29). Bouknaitir *et al.* reported improvement in SVA from a mean of 52.3 to 33.9 mm and PI – LL mismatch with a mean of 8.4° preoperatively to 5.8° in short-term outcomes of 6 months (4). Chang *et al.* similarly reported improvements in mean SVA from 27 to 25 mm and PI – LL from 14.4° to 10.2° at 6 months post operatively (27). In our cohort, the DA group had no statistical improvement PI – LL from 10.2° to 9.7°.

In the D + ILD group, mean PI – LL initially increased immediate postoperatively from 9.4° to 13.2°, which we attributed to their compensatory stance due to postoperative pain. However, the PI – LL reverted back to baseline at 9.4° and 9.5° at 2- and 5-year with no significant difference. In addition, there was no significant difference in pelvic tilt, pelvic incidence and sacral slope. In addition, our cohort has close to normal preoperative PI – LL, thus having lesser potential for improvement in PI – LL. This is supported by Salimi *et al.* who reported an initial improvement in sagittal alignment with a SVA from 51.5 to 36.1 mm at 2 years, however reverted back to 50.6 mm at the 5-year mark with no significant difference from preoperative (10). Crawford *et al.* also reported no difference in sacral inclination or regional sagittal balance up to the 12-month follow-up in 40 patients after an interspinous device (DIAM) insertion (30). One exception was Schulte *et al.* who reported a study of 20 patients who underwent insertion of an interspinous device (X-STOP) and found 2.0 cm improvement sagittal alignment at 6 weeks post-operative by measuring the C7 plumb line against sacral one vertebrae (31). However, this was a short-term outcome paper and this improvement in sagittal alignment may not be maintained found in our study and Salimi *et al.* (10). In the available literature, there has been no other study that directly compared the sagittal balance using PI – LL, pelvic tilt, pelvic incidence and sacral slope between decompression surgery alone versus decompression with the insertion of ILD. In our study, we found that there was no significant difference sagittal balance in both decompressions alone and with the use of an ILD.

Lordosis

The ILDs have been introduced into the market as an intermediate between DA and instrumented fusion, negating the complications of fusion surgery. However, it has yet to maintained its popularity due to mixed results in the short-run and limited studies on its long-term effects. In addition, the ILD can cause focal kyphosis which may impact the patient's overall natural lordosis and sagittal alignment (31-33). Crawford *et al.* studied 40 patients after lumbar surgery augmented with the DIAM device and showed an early postoperative reduction in the index disc angle by 2.2 degrees that was not sustained out to 1 year. They observed that this change to the spinal alignment was unrelated to the improvement in pain or function (30). Sobottke *et al*. also found similar flattening initially at the index segment by 3.8 degrees and appeared to revert towards preoperative values by 6 and 12 months (33). Our study echoed a similar trend with a reduction of sagittal angle at immediate postoperative by 4.0 degrees with a resolution back to baseline at 2 and 5 years. This focal kyphosis is expected and supported by previous biomechanical studies as the implant serves as a posterior element distractor, to offload the posterior column and limited lumbar extension. It is postulated that the reversion back to baseline may signify diminished biomechanical effect over time, due to device-settling after resuming one's habitual upright postures. However, clinical improvement in back pain and functional scores were still observed to the 24-month mark despite radiological reversion (30). Although the nature of an ILD insertion causes focal kyphosis, it only resulted in a localised mechanical effect and left the overall lumbar lordosis unchanged. This has been observed in our study

with no change in pelvic incidence, pelvic tilt and overall lumbar lordosis. These similar findings have also been echoed by multiple studies (30,31,34).

Height

The key role of the ILD is to reduce the stress on the posterior column and increase the intervertebral space and the nerve root canal, thus alleviating the symptoms of radiculopathy. There have already been multiple clinical studies to support the improvement in functional outcomes and pain (16,32). Our study further supports these claims with radiological evidence. Compared to DA, the use of the Coflex device as an adjunct had significant improvement in anterior disc height, posterior disc height and foraminal height across time. Similar short-term radiological studies found improvement in foraminal height and posterior disc height in the immediate postoperative period (35-38). The improvements in foraminal and disc height is expected and has been indirectly supported in biomechanical analysis where they found significant reduction in the peak stress of the index intervertebral disc with the use of Coflex (39). However, some studies found that these radiological improvements reverted back to their preoperative levels (33,35,36). Celik *et al.* concluded that the clinical benefit postoperatively may be attributed to the decompression itself and not the adjunct use of the Coflex device (35). In contrary, our study found that DA did not result in increase in anterior, posterior disc height nor foraminal height. The use of the Coflex resulted in an increase in posterior disc height and foraminal height that was maintained postoperatively up to the 5-year mark (35). This was echoed by Schmidt *et al.* who reported similar findings whereby the ILD (Coflex) group maintained foraminal and disc height while the DA group had significant loss in foraminal and disc height at the 2-year mark (40).

Clinical outcomes

The spectrum of surgical treatment for LSS up to grade I spondylolisthesis can range from decompression only, to D + ILD or minimally invasive/open decompression with instrumentation and fusion (41). Current literature has limited information on long term outcomes in patients who underwent D + ILD. Kumar *et al.* reported 116 patients (DA *vs.* D + ILD) and found no significant difference in clinically outcomes between the two, namely—Oswestry disability index (ODI), EuroQoL-5d (Eq5d) and SF-36. However there was a significant improvement in VAS back pain in the D + ILD group (42). Röder *et al.* analysed 50 matched pairs of patients (DA *vs.* D + ILD) and found that although there was an improvement in outcome scores pre and post operation, the postoperative satisfaction and quality of life scores between the two groups had no statistically significant difference (43). Schmidt *et al.* reported a 2-year study and found no significant difference between DA *vs.* D + ILD in VAS, ODI and Zürich Claudication Questionnaire (ZCQ) scores (40).

Our 5-year study found that in both the DA group and the interlaminar group had improvements in SF36 PCS, SF36 MCS and VAS. Comparing between the groups, the interlaminar group had significant improvement in SF36 MCS and no significant difference in SF36 PCS and VAS. We postulate that D + ILD cohort experienced improvement in social functioning and mental health as a reflection of significant improvement in SF36 MCS. This is in conjunction with improved intervertebral height with maintained sagittal balance postoperatively. Although the use of an ILD introduced focal kyphosis, D + ILD group did not have significant difference compared to the DA group in physical function or bodily pain which reflects the SF36 PCS and VAS. We would not overemphasize the correlation of a single clinical outcome, namely SF36 MCS scores to the improvement in radiological parameters.

To our knowledge, this is the first study to compare the sagittal alignment parameters and clinical outcomes between DA and decompression with the use of an ILD (Coflex).

Limitations

Our study is limited by a small sample size, however it is still comparable and even exceeds several existing studies (30,31). Randomization of patients in the two groups would have further strengthened the study. However, our study prioritised patient's autonomy in their choice of ILD insertion and provided adequate information between both options to reduce the chances of comprehension bias. The observers were given a fixed comprehensive protocol for patient assessment during the collection of clinical data so as to not introduce further bias. The patients who were lost to follow-up adds to selection bias and may skew the data. However, in our country and institution, patients who re-present for recurrence or worsening of symptoms/complications of the index surgery are referred back to the index surgeon. Thus, it is more likely that they remained similar to their last follow-up with favourable results. In addition, our country has an integrated patient care software

system underpinning the major hospitals where clinical and radiological data can be assessed and traced, thereby making it fully possible for us to avail any information regarding patient's worsening or re-presentation to another hospital. A single surgeon (N.K.) cohort study reduced the generalisability but has an added advantage of minimising technical bias.

Conclusions

In the management of lumbar stenosis, we surmise the use of an ILD (namely Coflex) as an adjunct device compared to DA had significant improvement in anterior disc, posterior disc and foraminal height that was maintained at 5 years. The insertion of an ILD does introduce negligible focal kyphosis at the level of intervention without change in the overall lumbar lordosis and sagittal balance at 5 years.

Acknowledgments

Funding: None.

Footnote

Reporting Checklist: The authors have completed the TREND reporting checklist. Available at https://jss.amegroups.com/article/view/10.21037/jss-24-33/rc

Data Sharing Statement: Available at https://jss.amegroups.com/article/view/10.21037/jss-24-33/dss

Peer Review File: Available at https://jss.amegroups.com/article/view/10.21037/jss-24-33/prf

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://jss.amegroups.com/article/view/10.21037/jss-24-33/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the institutional ethical committee (DSRB reference 2020/00995) and informed consent was taken from all the patients.

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Cite this article as: Chua CXK, Rajoo MS, Thomas AC, Lee SJK, Liang S, Kumar N. Five-year radiological outcomes between decompression alone and decompression with an interlaminar device for lumbar spinal stenosis. J Spine Surg 2024;10(3):488-500. doi: 10.21037/jss-24-33