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ISASS Recommendations/Coverage Criteria for Decompression with Interlaminar Stabilization - Coverage Indications, Limitations, and/or Medical Necessity

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Introduction

Broadly defined, lumbar spinal stenosis (LSS) is the progressive narrowing of the spinal canal and neural foramen resulting in pressure upon the nerve(s) leading to pain and/or numbness in the extremities, muscle weakness, bowel and bladder issues, and/or other pain related issues. However, the difficulty arises in that spinal stenosis is a heterogeneous condition with multiple etiologies which may present with disc height loss, facet hypertrophy, spondylolisthesis, retrolisthesis, coronal and/or sagittal plane deformity, and presence of osteophytes and facet cysts. Therefore, there is not a single surgical intervention that addresses all pathological variations of spinal stenosis, rather, there are several methods used to treat LSS. Diagnostic evaluation is needed to determine the correct surgical treatment solution to address anatomical and pathological variation as some patients can be treated by simple decompression while others may require a form of stabilization. This policy statement focuses on one treatment option: decompression with interlaminar stabilization. ISASS does not recommend any particular treatment method; the choice of treatment depends on the patient's pathology and the expertise of the treating surgeon. ISASS recommends shared decision-making between the patient and the surgeon.

Due to a growing elderly population, there is a rising incidence of LSS and varying options of therapeutic pathways. The majority of patients diagnosed with LSS are initially managed conservatively with epidural steroid injections, physical therapy, and modification of activities of daily life. However, several studies have demonstrated that if there is no significant improvement in symptoms after 12 weeks of conservative treatment, generally, symptoms do not improve with time.[1,2] Patients with a diagnosis of LSS who do not experience leg and/or back pain symptom relief from conservative care management and who experience continued worsening of symptoms may be appropriate candidates for surgical treatment. Surgical treatment options include indirect decompression with interspinous distraction devices, direct surgical decompression, direct surgical decompression with interlaminar stabilization, and direct surgical decompression with fusion.

For mild spinal stenosis (or early-stage disease), an interspinous distraction device without an associated concomitant bony decompression may be considered as an alternative option to a decompression-alone procedure. The X-STOP (Medtronic, Memphis, TN) was approved by the FDA in 2006,[3] however Medtronic removed the technology from the market in 2015. At present, the only non-fusion interspinous distraction device available in the United States is the Superion (VertiFlex, San Clemente, CA). Superion has been CE marked since 2007 and following a clinical study of 470 patients, the FDA approved the device for use on May 20, 2015.[4] The data was sufficient for approval of a Category I CPT code effective January 1, 2017. This ISASS policy does not formally address coverage rationale for interspinous distraction devices without decompression pending further data and review of this type of procedural approach in treating LSS.

For patients with mild to moderate stenosis and no instability (absence of spondylolisthesis or presence of a stable spondylolisthesis) direct open or microsurgical decompression of the offending bony and soft tissue pathology is a widely-accepted and com-

monly performed surgical treatment solution.[5] Direct surgical decompression may occasionally lead to instability (caused by continued degenerative processes, excessive facet resection, excess stress on remaining supporting structures, or natural history of LSS disease) which may result in recurrence of stenosis and leg and back pain. In order to achieve satisfactory results, adequate neural decompression and surgical excision of bone and soft tissue causing the stenosis should be the primary goal of surgery.[5] There have been several studies comparing medical/interventional management to surgical decompression that have consistently shown that surgical decompression patients report both significantly better short-term and long-term improvement compared to medical management. In SPORT, Weinstein et al.[6,7] performed concurrent lumbar spinal stenosis prospective studies with a randomized and an observational cohort to study decompression compared to conservative care. At four years follow-up, 60% of decompression alone patients maintained a 15-point improvement in the Oswestry Disability Index (ODI) with a 28% treatment effect over medical management, which was statistically significant. In the decompression group, the re-operation rate ranged from 8% at two years to 13% at four years where 6% was due to recurrent stenosis. However, Modhia[5] reviewed the Medicare database over a four-year period and showed readmission rates of 8 to 10% per year after failed microsurgical decompression for treatment of lumbar spinal stenosis resulting in injections for pain management, revision decompression, or conversion to fusion. Forsth et al.[8] recently published a prospective, randomized study examining LSS patients with and without degenerative spondylolisthesis. Patients were divided into two treatment groups: decompression alone or decompression plus fusion. The results show no clinical differences between the groups at five years follow-up, but 21% of patients in the decompression alone group required revision surgery by a mean of 6.5 years follow up. Further, Ghogawala et al. prospectively studied patients with LSS and a stable spondylolisthesis and found a cumulative reoperation rate of 34% in the decompression alone group.[9]

Pedicle screw fusion is the standard of care treatment for patients with spinal stenosis with significant instability (unstable spondylolisthesis) and concomitant debilitating back pain often associated with sagittal and coronal plane deformity. The addition of instrumentation and fusion to provide a clinically meaningful difference compared to decompression alone in prospective, randomized studies with spondylolisthesis has been established when non-spondylolisthesis patients are within the cohort. Recent findings comparing decompression alone to decompression plus fusion are inconsistent relative to clinical outcomes providing greater improvement over decompression alone.[8,9] Forsth et al. showed significant differences in peri-operative outcomes favoring decompression alone, but no difference in clinical outcomes out to five years follow-up between decompression alone and decompression plus fusion in patients in a mixed patient cohort with and without spondylolisthesis.[8] However, Ghogawala et al. found in patients with Grade 1 spondylolisthesis a greater improvement in SF-36 physical component and ODI at 4 years follow-up that was statistically significant over decompression alone.[9] Both studies however still showed clinically significant reoperation rates in the fusion group, 22% and 14% respectively, but with even higher reoperation rates in the decompression alone cohort.[8,9]

There exists a population of patients who present with moderate to severe stenosis, with concomitant back pain, where decompression alone does not adequately address back pain. Weinstein[6]and Kleinstück[10] suggest that those patients with predominant back pain or facetogenic issues may benefit from stabilization. Interlaminar stabilization after direct decompression is a non-fusion surgical option that can provide the additional stability over decompression alone without the rigidity of an instrumented fusion. Currently, there is one product that has achieved FDA PMA approval for up to a Grade I spondylolisthesis, the coflex (Paradigm Spine, New York, NY). The findings from Kumar[11]comparing decompression alone and decompression with interlaminar stabilization, combined with the publication from Musacchio[12]comparing five-year outcomes of decompression with interlaminar stabilization and decompression plus fusion, provide compelling evidence supporting this as a treatment alternative for select patients with stenosis. Studies have shown that a non-

fusion interlaminar stabilization device maintains motion, reduces both leg and back pain, and preserves foraminal height.[12] Further, the studies have also shown clinical benefit for patients with and without spondylolisthesis.

Coverage Rationale for Decompression with Interlaminar Stabilization

For the majority of spinal procedures, the addition of hardware instrumentation has offered the ability to improve effectiveness and sustainability by providing immediate stability. In some cases, a decompression procedure in of itself may create iatrogenic instability, compromising the structural integrity of the posterior elements. Important consideration should be given to the amount and degree of relative facet-driven back pain, presence and grade of spondylolisthesis/retrolisthesis, osteophytes and relative loss of disc height. In stenosis patients where a direct surgical decompression has been deemed medically necessary by the surgeon, and the patient does not present with gross instability (>Grade 1), non-fusion interlaminar stabilization can provide controlled reliable motion. The positioning between the lamina allows the physiological load to be offset from the facet joints, provides direct neurological decompression, and reestablishes the foraminal height.

Two prospective, randomized, multi-center, controlled, Level 1 clinical studies have been conducted to understand the sustainability and durability of decompression (D) with interlaminar stabilization (ILS). Raushmann et al.[13] have recently completed a prospective, randomized, multi-center Level 1 clinical trial comparing decompression alone (DA) to D+ILS at 24-months in a 1:1 randomization of 230 patients. Patients must have failed 3 months of conservative treatment, be greater than 40 years old, report Visual Analog Scale (VAS) back pain ≥ 50, and have radiographically confirmed degenerative spinal stenosis. The primary clinical outcome success (no reoperations, revisions, or injections) was achieved in 82.7% (91/110) of the D+ILS patients compared to 73% (84/115) of the DA patients, trending towards statistical significance (p=0.081). Within the primary outcome, there was a statistically significant difference between the treatments with regard to no lumbar injections where 95.5% (105/110) of the D+ILS patients compared to 87% (100/115) of the DA patients achieved success (p = 0.025). The clinical composite success (CCS) was defined as the primary outcome success and an ODI improvement of at least 15 points. The CCS was achieved in 61.4% in the D+ILS group compared to 49% in the DA group, trending towards statistical significance (p = 0.076). Of the CCS patients, the additional component of no narcotics usage showed a statistically significant difference (p = 0.021) between D+ILS (58.4%) compared to DA (42.2%), and with the further addition of neurological success (no new or increasing neurological deficit), the statistically significant difference becomes more significant with 55.4% of D+ILS compared to 36.3% DA (p = 0.006). Finally, as spinal stenosis is most often related to leg pain, the CCS combined with VAS leg pain success showed a statistically significant difference with 69.3% of the D+ILS group compared to 59.2% of the DA group (p = 0.017). This study provides strong evidence showing the addition of interlaminar stabilization to a decompression procedure has significant advantages in quality of life and durability components for select patients within the LSS continuum.

The United States IDE trial compared decompression plus fusion (DF) to D+ILS for the treatment of moderate to severe lumbar spinal stenosis (47% with a spondylolisthesis and 53% without the presence of a spondylolisthesis), where 322 patients (215 D+ILS /107 DF, respectively) were followed through five years.[12] Clinical outcomes measurements were gathered annually: ODI, leg and back pain VAS, and Zurich Claudication Questionnaire (ZCQ). At the five year follow-up, Musacchio et al.[12] reported over 99% of D+ILS patients achieved pain improvement of at least 20 mm in VAS leg pain and over 80% achieved at least 15-point improvement in ODI. By all patient-derived parameters, the treatments were found equivalent, however a higher percentage of D+ILS patients at all follow-up time points achieved at least 15-point improvement in ODI, and at least 20 mm VAS leg pain and VAS back pain improvement compared to the DF group. The percentage of pa-

tients achieving a clinical improvement of at least 15-points in ODI at three months post operatively was 87% for D+ILS and 74% for DF. Leg pain was immediately and sustainably relieved in both patient groups evidenced by VAS Leg and ZCQ measurements. For the D+ILS group, VAS Leg scores were 76 preoperatively, and 23 at 60 months; for the DF group, VAS Leg scores were 78 preoperatively, and 25 at 60 months. ZCQ (Physical Function) scores in the D+ILS group were 2.8 preoperatively, and 1.7 at 60 months, while ZCQ scores for DF were 2.8 preoperatively, and 1.8 at 60 months. Furthermore, back pain was also immediately and sustainably relieved through facet off-loading in the D+ILS group, with VAS Back scores of 80 preoperatively, and 25 at 60 months. VAS Back scores for DF were 79 preoperatively, and 29 at 60 months.

In terms of reoperations/revisions, the results of Musacchio et al.[12] show the majority of the D+ILS reoperations/revisions occurred within the first year post-operative associated with "learning curve" issues. The "learning curve" group accounted for 19 of the 35 revisions in the D+ILS group including wound-related issues, re-decompression, and/or poor patient selection/surgical planning. In comparison, 6 of the 19 revisions in the fusion group were early surgical issues. The DF group had a 6.5% rate of device-related failure requiring revision and 5.6% late-term (greater than one-year post-operative) ineffective treatment revisions, thereby an effective 12.1% overall revision rate. In comparison, the D+ILS group had a 2.8% rate of device-related revisions and 4.2% late-term ineffective treatment revisions resulting in an effective 7% overall revision rate at 5 years.

Indications/Limitations of Coverage

Patients who have all of the following criteria may be eligible for decompression with interlaminar stabilization:

1. Radiographic confirmation of at least moderate lumbar stenosis, which narrows the central spinal canal at 1 or 2 contiguous levels from L-1 to L-5 that require surgical decompression. Moderate stenosis is defined as > 25% reduction of the anteroposterior dimension compared with the next adjacent normal level, with nerve root crowding compared with the normal level, as determined by the surgeon on CT scanning or MRI.
2. Radiographic confirmation of the absence of gross angular or translatory instability of the spine at index or adjacent levels (instability as defined by White and Panjabi: sagittal plane translation >4.0 mm or 15% or local sagittal plane rotation > 15° at L1–2, L2–3, and L3–4; >20° at L4–5 based on standing flexion-extension radiographs). Improved imaging technologies are able to better refine/detect previously undetected instability and as these technologies become more established, surgeons should expect to refine with specificity and clear delineation of appropriate surgical candidates requiring stabilization.
3. Patients who experience relief in flexion from their symptoms of leg/buttocks/groin pain, with or without back pain, and who have undergone at least 12 weeks of non-operative treatment consisting of non-steroidal anti-inflammatory drugs and at least one of the following: rest, restriction of activities of daily living, physical therapy, or steroid injections.

Decompression with interlaminar stabilization is NOT indicated for patients with the following:

1. More than 2 vertebral levels requiring surgical decompression.
2. Prior surgical procedure that resulted in gross translatory instability of the lumbar spine.
3. Prior fusion, implantation of a total disc replacement, or complete laminectomy at index level.
4. Radiographically compromised vertebral bodies at any lumbar level(s) caused by current or past trauma, tumor, or infection.
5. Severe facet hypertrophy requiring extensive bone removal that would cause gross instability.
6. Radiographic confirmation of gross angular or translatory instability of the spine at index or adjacent levels with sagittal plane translation >4.0 mm as spondylolisthesis or retrolithesis
7. Isthmic spondylolisthesis or spondylolysis (pars fracture).

8. Degenerative lumbar scoliosis (Cobb angle > 25° lumbar segmental).
9. Osteopenia and Osteoporosis.
10. Back or leg pain of unknown etiology.
11. Axial back pain only, with no leg, buttock, or groin pain.
12. Morbid obesity defined as a body mass index > 40.
13. Active or chronic infection—systemic or local.
14. Known history of Paget disease, osteomalacia, or any other metabolic bone disease (excluding osteopenia, which is addressed above).
15. Rheumatoid arthritis or other autoimmune disease requiring chronic steroid use.
16. Active malignancy: a patient with a history of any invasive malignancy (except nonmelanoma skin cancer), unless he/she has been treated with curative intent and there has been no clinical signs or symptoms of the malignancy for at least 5-years. Patients with a primary bony tumor are excluded as well.
17. Known allergy to titanium alloys or magnetic resonance contrast agents.
18. Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction.

Coding

CPT Codes

Note: New codes are effective January 1, 2017.

- CPT Code 22867: Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level.
- CPT Code 22868: Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level (List separately in addition to code for primary procedure).

Prior to January 1, 2017, the following codes may be considered provisionally by the coder:

- CPT Code 63030: Lumbar laminotomy (hemilaminectomy), 1 interspace.
- CPT Code 63035: Lumbar laminotomy (hemilaminectomy), each additional interspace.
- CPT Code 63047: Lumbar laminectomy, facetectomy and foraminotomy, single vertebral segment.
- CPT Code 63048: Lumbar laminectomy, facetectomy and foraminotomy, each additional segment.
- CPT Code 22899: Unlisted procedure, spine.
- CPT Code 22840: Posterior non-segmental instrumentation.
- CPT Code 0171T: Insertion of posterior spinous process distraction device, lumbar, single level.
- CPT Code 0172T: Insertion of posterior spinous process distraction device, lumbar, each additional level.

Documentation Requirements

- A complete history and physical documenting spinal stenosis clinically, and radiologically, with progressive clinical symptoms even with documented conservative care.
- Radiographic documentation of canal compromise, with MRI or CT evidence of moderate to severe spinal stenosis at one or two contiguous levels with up to Grade 1 spondylolisthesis.
- A course of conservative treatments that include modification of activities, patient education, physical therapy, injection therapy including epidural steroid injections, and oral medication like steroids and non-steroidal anti-inflammatory drugs (NSAIDs).
- Symptomatology greater than 12-weeks with doc-

Table 1. ICD-10-CM Diagnosis Codes.

ICD-10-CM Diagnosis Code	Code Descriptor
M48.06	Spinal stenosis, lumbar region
M99.23	Subluxation stenosis of neural canal of lumbar region
M99.33	Osseous stenosis of neural canal of lumbar region
M99.43	Connective tissue stenosis of neural canal of lumbar region
M99.53	Intervertebral disc stenosis of neural canal of lumbar region
M99.63	Osseous and subluxation stenosis of intervertebral foramina of lumbar region
M99.73	Connective tissue and disc stenosis of intervertebral foramina of lumbar region

umented conservative care, progressive symptomatology, and failure to alleviate symptomatology short of surgical decompression.

Surgeon Qualifications

Decompression with interlaminar stabilization should only be performed by surgeons who are experienced and have undergone training in the use of this device. Only surgeons who are familiar with the implant components, instruments, procedure, clinical applications, biomechanics, adverse events, and risks associated. A lack of adequate experience and/or training may lead to a higher incidence of adverse events.

Summary

Surgeon expertise and proper patient selection are critical to determine the correct surgical treatment solution to address anatomical and pathological variation of patients with LSS. Decompression alone and decompression plus fusion are both established treatments for LSS. The choice to perform decompression alone, decompression with interlaminar stabilization, or decompression plus fusion is the discretionary purview of the spine surgeon and his/her patient.

Lumbar decompression with interlaminar stabilization is recommended for coverage in carefully selected lumbar spinal stenosis patients without gross instability or in which the decompression procedure itself may create iatrogenic instability. The procedure should be performed by a qualified and well-trained spine surgeon after completion of a thorough diagnostic evaluation, documented failure of nonsurgical management and taking into consideration appropriate anatomical and pathological considerations.

It is important for spine surgeons to be able to provide surgical solutions that have proven net health benefits for clearly defined, precisely diagnosed patient cohorts, which in parallel support fiscal responsibility of reducing overall costs to the healthcare system. Further, in considering the evolutionary healthcare environment, ISASS coverage guidance considers the increasing importance of value-based and bundled payment initiatives which incorporate clinical as well as economic value propositions. In select patients within the LSS continuum, decompression with interlaminar stabilization has proven to provide equivalent outcomes with a reduced cost compared to decompression plus fusion.[14,15] Additionally, for patients with significant back pain and associated advanced degenerative segmental disease, decompression with interlaminar stabilization provides benefits beyond decompression alone and may extend the durability of the decompression procedure (Table 2).

Table 2. Publication Table.

Author, Year	Study Design	Country of Origin	Oxford Level of Evidence (LOE)	N	Implant	Technique	Demographics	Results	Complications
Musacchio, 2016	5- year follow up Prospective, multi-center IDE RCT	US	I	344	coflex	Direct decompression via laminectomy w/ subsequent implantation coflex ILS OR Decompression via laminectomy w/ subsequent posterolateral instrumented fusion	Age coflex: 62.1 (41-81) years Age fusion: 64.1 (41-82) years Sex coflex: 106F/109M Sex fusion: 58F/49M Moderate-to-severe lumbar stenosis w/ back pain ODI ≥ 20/50 (40%) VAS ≥ 50/100	5 years, 50.3% of D+ILS vs. 44% of D+PS patients (p>0.35) met the composite success criteria. Reoperation/ revision rates were similar in the two groups (16.3% vs. 17.8%; p >0.90)	There were 3/215 major device related complications in the D+ILS group and 5/107 in the fusion group at Month 60 (1.4% vs. 4.7%; p>0.10); 60 months: no significant difference in the cumulative total occurrences of reoperations/revisions between the D+ILS group 35/215 (16.3%) and D+PS group 19/107 (17.8%) (p>0.90); wound-related reoperations: 7 D+ILS patients (3.3%) and 1 D+PS patient (0.09%); under-treated: 5 D+ILS patients (2.3%) and 2 D+PS patients (1.9%) who underwent early revisions; device-related reoperations: D+ILS group: pars fracture, D+PS group: broken instrumentation; devicerelated reoperations: 6 patients in the D+ILS (2.8%) and 7 patients in the D+PS group (6.5%)
Forsth, 2016	RCT	Sweden	I	247	N/A	Decompression with or without fusion	Age NO DS w/fusion: 66 (57-75) years; Age NO DS w/out fusion: 66 (58-74); Age +DS w/ fusion: 68 (61-75); Age +DS w/out fusion: 67 (60-74) years	No significant difference between the groups in the mean score on the ODI at 2 years (27 in the fusion group and 24 in the decompression-alone group, P=0.24) or in the results of the 6-minute walk test (397 m in the fusion group and 405 m in the decompression-alone group, P=0.72)	Dural tears occurred in 12 patients (11%) in the fusion group and in 13 patients (11%) in the decompression-alone group ; Postoperative wound infection that required treatment with antibiotic agents but not reoperation with wound débridement occurred in 11 patients (10%) in the fusion group and in 5 patients (4%) in the decompression-alone group. Myocardial infarction, stroke, or thromboembolic events occurred in 3 patients (3%) in the fusion group and in 5 patients (4%) in the decompression-alone group; additional lumbar-spine surgery before the end of October 2015: 22% in the fusion group and 21% in the decompression-alone group
Bae, 2016	3-year Follow-up Prospective, multicenter IDE RCT	US	I	344	coflex	Direct decompression via laminectomy w/ subsequent implantation coflex ILS OR Decompression via laminectomy w/ subsequent posterolateral instrumented fusion	Age coflex: 62.1 (41-81) years Age fusion: 64.1 (41-82) years Sex coflex: 106F/109M Sex fusion: 58F/49M Moderate-to-severe lumbar stenosis w/ back pain ODI ≥ 20/50 (40%) VAS ≥ 50/100	Composite clinical success at 36 months was achieved by 62.2% among 196 coflex Interlaminar Stabilization patients and 48.9% among 94 fusion patients (difference = 13.3%, 95% confidence interval, 1.1%-25.5%, P = .03)	Important harms/severe adverse events that were deemed either definitely or probably related to the device occurred in 19 ILS patients (8.8%) and in 16 fusion patients (15%) (Fisher exact test, P = .13). Important harms that were deemed either definitely or probably related to the surgery occurred in 26 ILS patients (12.1%) and 19 fusion patients (17.8%) (P = .18); New or worsening pain at operating site 40% both groups; nonoperative site events were musculoskeletal and neurological events experienced in 64.2% vs 66.4% and 26.0% and 24.3% in ILS and fusion patients; 2 case examples of spinous process fracture after implantation; reoperation for ILS: 16 patients with persistent pain with 7 undergoing reoperation at the index level alone, 8 undergoing reoperation at the index level plus 1 or more adjacent levels, and 1 undergoing reoperation at an adjacent level only; 7 patients with wound issues including 4 wound infections, 2 cerebrospinal fluid leaks, and 1 wound dehiscence; 3 patients with component loosening, and 4 patients with fractures including 2 spinous process fractures and 2 pars fractures; reoperation for fusion: 9 patients with persistent pain with 2 patients undergoing reoperation at the index level alone, 6 patients undergoing reoperation at the index level plus 1 or more adjacent levels, and 1 patient undergoing reoperation at an adjacent level alone; 2 patients underwent reoperation for component failure, including 1 with a broken screw and 1 with screw loosening; 1 patient underwent reoperation for a pars fracture at an adjacent level; and 1 underwent reoperation for a wound hematoma

Author, Year	Study Design	Country of Origin	Oxford Level of Evidence (LOE)	N	Implant	Technique	Demographics	Results	Complications
Sigmundsson, 2016	Prospective register study	Sweden	II	5100	N/A	decompression only OR decompression with fusion	Age: 73 years (SD 9.8); 49.9% male 50.1 % female 88% decompression only, 12% decompression with fusion; Cohort: operated on for CSS from January 2003 to June 2010	4167 satisfied patients and 933 dissatisfied patients; Factors decreasing the likelihood for satisfaction included previous spine surgery OR: 0.4 (95 % CI: 0.3-0.5), smoking OR: 0.6 (95 % CI: 0.4-0.8), unemployment OR: 0.6 (95 % CI: 0.4-0.9), back pain exceeding 1 year OR: 0.6 (95 % CI: 0.4-0.9), back pain predominance OR: 0.7 (95 % CI: 0.5-0.8). Fusion surgery did not predict satisfaction OR: 1.3 (95 % CI: 0.9-1.9). Preoperative self-estimated walking distance >1000 m predicted satisfaction, OR: 2.4 (95 %: 1.6-3.6).	No complications
Ghogawala, 2016	Prospective RCT	US	I	66	N/A	Decompressive laminectomy with or without Instrumented (rigid pedicle screws affixed to titanium alloy rods) lumbar spinal fusion	Age: 67 (50-80) years Grade I lumbar spondylolisthesis (degree of spondylolisthesis, 3 to 14 mm) with lumbar stenosis and neurogenic claudication with or without lumbar radiculopathy	Fusion group had a greater increase in SF-36 physical-component summary scores at 2 years after surgery than did the decompression-alone group (15.2 vs. 9.5, for a difference of 5.7; 95% confidence interval, 0.1 to 11.3; P=0.046); fusion group remained greater at 3 and 4 years More blood loss and longer hospital stays occurred in the fusion group than in the decompression-alone group (P<0.001 for both comparisons). The cumulative rate of reoperation was 14% in the fusion group and 34% in the decompression-alone group (P=0.05).	Fusion group had a lower rate of reoperation over the course of 4 years than did the decompression-alone group (14% vs. 34%, P=0.05); reoperations performed in the decompression-alone group were at the index level to address subsequent clinical instability. In contrast, all the reoperations performed in the fusion group were at an adjacent lumbar level (either disk herniation or clinical instability); surgical complications, blood loss, length of stay, and length of procedure were significantly greater in the fusion group than in the decompression-alone group
Chen, 2016	Retrospective cohort study	China	III	154	coflex	Topping-off surgery (coflex with fusion) (76 patients) OR two-segment fusion surgery (88 patients)	Age: 40–80 years; moderate to severe lumbar spine stenosis; unsuccessful conservative treatment for more than six months; ODI score ≥40 (out of 100); VAS for back pain score ≥50 (out of 100)	Significant differences in clinical outcomes were observed between these two groups at three postoperative years (all, $p < 0.05$). Compared with the fusion group, the topping-off group showed preserved mobility at the coflex™ level ($p = 0.000$), which is associated with less blood loss ($p = 0.000$), shorter duration of surgery ($p = 0.000$) and lower incidence of ASD (Chi-square test, rate topping-off vs fusion = 13.2 vs 26.1 %, $p = 0.039$)	No patients in either of the groups had severe intra-operative or post-operative complications, such as nerve root injury, dural tears, cauda equina injury, vertebral fracture, internal fixation system fracture, loosened screw, malpositioned screw, dislodgement of the interbody device, fixed wing breakage or spinal process fracture
Lee, 2016	Retrospective cohort study	Korea	III	30	coflex	**studied erosion vs. non-erosion after coflex implant	Age: 62.2 (40-82); M/F ratio: 15:15	Erosion group showed substantially higher values in preoperative ADH, postoperative posterior disc height (PDH), and intervertebral foramen height (6.52 mm vs. 8.05 mm; 5.80 mm vs. 8.03 mm; 19.20 mm vs. 21.06 mm). Postoperative ROM and ROM ratio were higher in the erosion group (5.95° vs. 8.47° and 0.659 vs. 0.938).	14 patients (47%) showed erosion at the spinous process–coflex interface after surgery

Author, Year	Study Design	Country of Origin	Oxford Level of Evidence (LOE)	N	Implant	Technique	Demographics	Results	Complications
Bae, 2015	Retrospective analysis of RCT	US	I	344	coflex	Decompression w/ interlaminar stabilization OR decompression with fusion	230 and 114 patients receiving ILS and fusion respectively during the enrollment period from 2006 through 2010 at 21 participating US sites; moderate to severe stenosis, age range from 40-80; ODI score ≥ 40 (out of 100), VAS for back pain of ≥ 50mm (out of 100mm), failing ≥ 6 months of conservative care including ≥ 1 epidural steroid injection, no prior decompression surgery, up to a Grade 1 stable spondylolisthesis	48 month cumulative rates of index level second surgeries were 16.1% (SE = 2.6%; 35/215) and 14.9% (3.6%; 15/107) for ILS and fusion, respectively; patients with no index level re-operations or lumbar steroid injections, 86.2% (106/123) of ILS and 72.4% (42/58) of fusion subjects had a clinically significant improvement in ODI scores (p = 0.038)	Through 48 months, adverse events rates were similar in both cohorts, although the incidence of events that were deemed 'definitely or probably related to the implant' occurred in 14.9% (32/215) ILS patients and in 20.6% (22/107) of fusion patients (p = 0.21). Events that were classified as 'severe' occurred in 8.8% of the ILS population and 15.0% of the fusion population (p = 0.13)
Sigmundsson, 2015	Retrospective register study	Sweden	III	839	N/A	**Compared PLP and PBP in patients who got either decompression alone or decompression with fusion	Age D PLP: 73.8 (SD 9.3); Age DF PLP: 68.8 (SD 8.7); Age D PBP: 73.2 (SD 10.6); Age DF PBP: 69.1 (SD 9.1); Gender: PLP M: D: 38, DF: 59; F: D: 87; DF: 200; PBP M: D: 31; DF: 62; F: D 89; DF: 270; older than 50 years operated for DS at the L4–L5 level with either decompression only (D) or decompression and instrumented posterolateral fusion (DF)	Patients with PLP reported a 7.9-mm more improvement on the VAS for BP with fusion, compared with D (95% confidence interval [CI], 0.7–15.2), p=.03; patients with PBP benefited from adding fusion in terms of BP 7.1 (95% CI, 0.3–13.9, p=.04), LP 8.8 (2–15.7, p=.01), the ODI 5.7 (1.6–9.9, p=.006), and the EQ-5D 0.09 (1.7–0.02, p=.02) at the 1-year follow-up as the DF group reported greater change in the outcome compared with the D group	No complications

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Kumar, 2014	Prospective cohort study	Singapore	II	46	coflex	Spinal decompression with coflex implantation vs. decompression alone	Symptomatic LSS; The mean age of the patients in the coflex and the comparison group was 57.9 years (range, 40-74 years) and 61.8 years (range, 49-78 years; p=0.127), respectively. The male:female ratio in the respective groups was 13:9 (n=22, coflex group) and 14:10 (n=24, comparison group, p=0.958).	Mean ODI score in the coflex group improved from 51.73 preoperatively to 22.91, 22.64 and 17.36 at six months, one year, and two years; mean ODI score in the comparison group improved from 49.58 preoperatively to 32.17, 30.08, and 28.50 at six months, one year, and two years; mean difference in ODI improvement between the two groups was 10.4 (95% confidence interval [CI], 8.8-12.1), being greater in the coflex group	One patient in the coflex group (dural puncture) and four patients in the comparison group (3-dural puncture and 1-deep infection) had procedure related complications. The incidence of complications in the two groups was not significantly different (p=0.35)
Patil, 2014	Retrospective comparative study	US	III	498	N/A	Compare reoperations, complications, and costs between LSS patients undergoing ID placement versus laminectomy	Lumbar spinal stenosis; MarketScan database (2007-2009); age: 73 years	Longer length of stay was observed in the laminectomy cohort (2.5 days vs. 1.6 days, p<.0001), whereas ID patients accrued higher costs at index hospitalization ($17,674 vs. $12,670, p=.0001). Index hospitalization (7.5% vs. 3.5%, p=.099) and 90-day (9.2% vs. 3.5%, p=.028) complications were higher in the laminectomy cohort compared with the ID cohort. The ID patients had significantly higher reoperation rates than laminectomy patients at 12 months follow-up (12.6% vs. 5.8%, p=.026) and incurred higher cumulative costs than laminectomy patients at 12 months follow-up ($39,173 vs. $34,324, p=.289)	Overall reoperation rate was 22.1% for all patients that had an initial ID placed ; most common type of reoperation was laminectomy (12.1%), followed by new ID placement (10.4%), revision interbody fusion (6.0%), and new interbody fusion (3.6%). Complications occurred in 16 (3.2%) patients at index hospitalization, 51 (10.2%) patients within 30 days, and in 51 (11.2%) patients within 90 days; total of 348 patients with at least 18 months follow-up, half of which underwent direct decompression via laminectomy and the other half indirect decompression by ID; patients who underwent laminectomy spent significantly more days at index hospitalization than patients who underwent ID placement (2.49 vs. 1.58, p<.0001)
Schmier, 2014	Retrospective comparative cohort	US	III	344	coflex	coflex Interlaminar Stabilization Device vs. instrumented posterolateral fusion	Clinical data input was obtained from results reported in Davis et al. that describe a randomized Investigational Device Exemption (IDE) clinical trial comparing coflex to instrumented fusion	Five-year costs were lower for patients implanted with coflex compared to those undergoing fusion. Average Medicare payments over 5 years were estimated at $15,182 for coflex compared to $26,863 for the fusion control, a difference of $11,681. Mean quality-adjusted life years were higher for coflex patients compared to controls (3.02 vs 2.97). Results indicate that patients implanted with the coflex device derive more utility, on average, than those treated with fusion, but at substantially lower costs	No complications

Author, Year	Study Design	Country of Origin	Oxford Level of Evidence (LOE)	N	Implant	Technique	Demographics	Results	Complications
Davis, 2013	Prospective, multicenter IDE RT	US	I	150	coflex	coflex Interlaminar Stabilization OR laminectomy and PSF	Only the subset of patients from this overall cohort with Grade 1 spondylolisthesis (99 in the coflex group and 51 in the fusion group); mean ages of the coflex and fusion cohorts were 63.1 ± 7.9 years and 65.0 ± 8.5 years; coflex cohort, there were 58 women and 41 men compared with 32 women and 19 men in the fusion cohort	ODI: baseline: coflex cohort had an average score of 21.1 compared with 22.7 for fusions (p = 0.66) ; percentage of patients that achieved a 15-point reduction in ODI at 2 years from baseline was 86.1% for coflex and 81.0% for fusion (p = 0.60); ZCQ: coflex cohort performed significantly better than fusion controls with respect to ZCQ patient satisfaction at 24 months (p = 0.05); SF-12: no significant differences at any pre- or postoperative time point; VAS: coflex subjects experienced a 55-point improvement in the back VAS score compared with 58 points for fusions (p > 0.05) at 24 months	Overall rate of operative site AEs between the groups was similar for coflex (43.4%) and fusions (37.3%, p = 0.49). The rate of severe adverse events that were definitely or probably related to the implant was 9.1% in the coflex group and 7.8% in the fusion group (p = 1.0). Wound-related problems were seen in 14.1% of coflex patients compared with 13.7% in the fusion controls (p = 1.0). The rate of spinous process fracture in the coflex cohort was 18% (18 of 99); however, by 24 months 7 of these 18 fractures had healed; CCS for patients experiencing a spinous process fracture was 61.1% (11 of 18), compared with 63.2% (48 of 76, p = 1.00) in the cohort without a fracture; 6.4% of coflex subjects experienced device movement greater than 5 mm at 24 months. Wound-related problems included wound drainage, superficial infection, dehiscence, seroma, and delayed healing of incision. Only 1 patient had an irrigation and debridement procedure due to wound dehiscence. Within the fusion control group, a total of 29% (15 of 51) developed a pseudarthrosis; overall reoperation rate was 14.1% (14 of 99) and 5.9% (3 of 51) for the coflex and fusion controls, respectively (p = 0.18)
Davis, 2013	Prospective, multicenter IDE RT	US	I	322	coflex	coflex Interlaminar Stabilization OR laminectomy and PSF	Three hundred twenty-two patients (215 coflex and 107 fusions) from 21 sites in the United States were enrolled between 2006 and 2010.; average age (standard deviation, range) for the coflex cohort was 62.1 (9.2, 41–81) years, while the average age for the fusion control cohort was 64.1 (9.0, 41–82) years	At 24 months ODI: coflex: 22.0; fusion: 26.7, P = 0.075; greater proportion of patients taking coflex achieving a 15-point reduction in ODI at 24 months (coflex: 85.8%; fusion: 76.7%, P = 0.08; 24 months, SF-12 scores had improved significantly more from baseline in the coflex cohort (15.5 points) compared with fusion controls (12.6, P = 0.050), Significant improvements in the coflex cohort compared with fusion controls were also seen at 6 weeks (P = 0.048), 3 months (P = 0.032); early postoperative period: coflex cohort had a trend toward significantly lower VAS back pain scores at 3 months (P = 0.062) and 6 months (P = 0.063). VAS leg pain score was significantly better in the coflex cohort at 3 months (P = 0.019) and a trend at 6 months (P = 0.058); index level range of motion was maintained with coflex, while fusion subjects exhibited an expected significant decrease in the index level range of motion.fusion group demonstrated significantly greater superior adjacent level range of motion when compared with coflex (P = 0.002); 24 months, 135 of 204 coflex subjects (66.2%) and 60 of 104 (57.7%) fusion controls met the criteria for overall study success, demonstrating noninferiority (posterior probability = 0.999).	Operative site adverse event: 49.3% coflex vs. 43.9% fusion; adverse event definitely/probably related to the implant: 13.5% coflex vs. 18.7% fusion; adverse event definitely/probably related to the surgery: 23.7% coflex vs. 30.8% fusion; rate of spinous process fracture was 14.0% in the coflex group, however, 48% of these had healed radiographically at 2 years; 0 to 24 months postoperatively, the reoperation rate for coflex was 23/215 (10.7%) compared with 8 of 107 for fusion (7.5%, P = 0.426). Among the 23 patients with reoperations within the coflex group, there were 13 conversion to a primary lumbar fusion, 6 irrigation and debridements for wound-related issues (5 with retention of the device), and 6 revision decompressions (4 with device removal)

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Moojen, 2013	Prospective, multicenter RCT	Netherlands	I	159	coflex	Is interspinous process device implantation more effective in the short term than conventional surgical decompression for patients with intermittent neurogenic claudication due to lumbar spinal stenosis	Patients with intermittent neurogenic claudication due to lumbar spinal stenosis after failed conservative treatment (Foraminal Enlargement Lumbar Interspinosus distraXion: FELIX trial); Age: 40 and 85 years with at least three months of intermittent neurogenic claudication due to single or two level degenerative lumbar canal stenosis and an indication for surgery	Eight weeks, the success rate according to the Zurich Claudication Questionnaire for the interspinous process device group (63%, 95% confidence interval 51% to 73%) was not superior to that for standard bony decompression (72%, 60% to 81%); repeat surgery rate in the interspinous implant group was substantially higher (n=21; 29%) than that in the conventional group (n=6; 8%) in the early post-surgical period (P<0.001); Surgery time (24 min) was shorter in the interspinous process device group than for bony decompression (43 min) (P<0.001). Blood loss was less in the interspinous process device group (10-50 mL) than in the bony decompression group (50-100 mL) (P<0.001)	Five direct (that is, during the initial hospital stay) postoperative complications occurred in the interspinous process device: one patient with short term (48 hours) unexplained visual disturbance, one patient with self limiting pseudoradicular pain in the other leg, and three patients with interspinous process fractures during interspinous process device placement; Direct postoperative complications occurred in six patients in the bony decompression group: two patients with direct epidural hematoma needing reoperation and four patients with dural tears without further consequences. Late reoperation due to absence of recovery was indicated and performed in 21/73 (29%) cases in the interspinous process device group compared with 6/72 (8%) in the bony decompression group (P<0.001)
Tian, 2013	Retrospective cohort study	China	III	32	coflex	Single-level (L4-5) implantation of a coflex device for the treatment of lumbar spinal stenosis	13 women and 19 men; age: 60.3 years (range 45–75 years); conservative treatment for at least 3 months had failed;	32 patients with follow-up times of 24-57 months, HO was detectable in 26 (81.2%). Among these 26 patients, HO was in the lateral space of the spinous process but not in the interspinous space in 8, HO was in the interspinous space but did not bridge the adjacent spinous process in 16, and interspinous fusion occurred at the level of the device in 2	No patients needed revision or removal of the implants; no fractures or loosening of the implant occurred
Auerbach, 2013	Systematic review using Level I data	US	V	1055?	coflex	Investigators for the coflex IDE trial classified the severity of adverse events (mild, moderate, or severe) and their relationship to the surgery and device (unrelated, unlikely, possibly, probably, or definitely). An independent CEC, composed of three spine surgeons without affiliation to the study sponsor, reviewed and reclassified all adverse event reports submitted by the investigators	independent CEC, composed of three spine surgeons without affiliation to the study sponsor, reviewed and reclassified all adverse event reports submitted by the investigators.	CEC reclassified the level of severity, relation to the surgery, and/or relation to the device in 394 (37.3%) of 1055 reported adverse events	

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Celik, 2012	Retrospective cohort	Turkey	III	20	coflex	Microsurgical bilateral foraminotomy; Co exTM IDD was placed in interspinous space with amount of interspinous distraction.	20 patients (9 female and 11 male) with spinal stenosis were included in the study. The mean age was 60 (range 47-74). In 4 patients, L3-L4 level and in 16 patients, L4-L5 level was implanted	Mean preoperative VAS was 7.85 and fell to 1.7 a month after surgery ($p < 0.0001$). At the last follow-up the mean VAS score was 1.65 ($p < 0.0001$). The mean foraminal heights were measured 19.95 mm preoperatively and 25.05 mm a month after surgery ($p < 0.0001$). The mean foraminal height was 21.60 mm at the last follow-up ($p=0.002$). The mean lumbar lordosis were measured 32.05 and 34.3 degrees at preoperative and a month after surgery respectively ($p=0.155$). The mean lumbar lordosis was 32 (±5.99) degrees at the last follow-up ($p=0.974$)	No major complications occurred; 1 superficial wound infection was treated with antibiotics; 1 dural tear was treated with myofascial flap; No implant-related complication was occurred
Maida, 2012	Case report	Italy	IV	1	coflex	Abnormal osseous tuberosity was subsequently detected surrounding the L4 and L5 spinous processes. The interspinous/interlaminar coflex device implanted at that level was not detectable; resect the new bone formation with a chisel; “U-shaped” part of the device was completely filled by bone; resection of device; dura mater was all covered by interlaminar bone removed using Kerrison rongeurs; gross-total resection of the new bone formation; L4-L5 laminectomy with facet joints preservation and L3, S1 undercutting performed	58 year-old man presented with a 6-month history of progressively worsening low back pain; VAS: 8/10; 2008: microsurgical decompressive undercutting and implantation of an interspinous/interlaminar coflex device because of L4-L5 stenosis; 2011: recurrence of motor weakness with the L5 myotome affected, decreased Achilles and patellar reflexes, and neurogenic claudication; mature ossification of the device with relevant restenosis	Resection of the pathologic bone formation resulted in a rapid neurological recovery (VAS 3/10), and the patient could then walk independently; 2-month followup, the patient had a great reduction in pain and disability	HO after implantation of an interspinous/interlaminar dynamic device (case report)

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Tosteson 2011	Cost-effectiveness analysis of a randomized plus observational cohort trial	US	I	??		For SpS, the protocol surgical intervention was a standard posterior laminectomy. For DS, the protocol surgery was the same procedure with or without bilateral single-level fusion with or without instrumentation. For IDH, the protocol surgical intervention was a standard open discectomy	18 and older with well-defined symptoms, physical findings and imaging-confirmed diagnosis of spinal stenosis either alone (SpS) or associated with degenerative spondylolisthesis (DS), or diagnosis of intervertebral disc herniation (IDH); A total of 414/ 634 (65.3%) SpS, 391/601 (65.1%) DS and 789/1,192 (66.2%) IDH participants underwent surgery	SPS QALY gain 0.22; 95% confidence interval, CI: 0.15, 0.34; DS QALY gain 0.34, 95% CI: 0.30, 0.47; and IDH QALY gain 0.34, 95% CI: 0.31, 0.38; Costs per QALY gained decreased for SPS from $77,600 at 2 years to $59,400 (95% CI: $37,059, $125,162) at 4 years, for DS from $115,600 to $64,300 per QALY (95% CI: $32,864, $83,117), and for IDH from $34,355 to $20,600 per QALY (95% CI: $4,539, $33,088)	For SpS, 43 (10.4%) patients underwent 47 additional surgeries; for DS, 48 (12.3%) patients had 52 additional surgeries, and for IDH 70 (8.9%) patients had 82 repeat surgeries. In each case, the majority of repeat surgeries were within 2 years of the initial surgery with a substantial minority occurring after 2 years, including 32.6% of SpS, 20.8% of DS and 24.4% of IDH repeat procedures
Richter, 2010	Prospective comparative study	Germany	II	60	coflex	Posterior decompression surgery through a midline approach and microsurgical bilateral decompression with and without coflex™ interspinous device was implanted in one or two levels	Age of 40–80 with one or two level stenosis were included and no previous surgery at the lumbar spine took place. Patients with a stable degenerative spondylolisthesis grade one were included	All patients increased in function and developed a lower ODI over time, repeated measure ANOVA ($F(1) = 63.9$; $p < 0.001$); all patients increased in function and developed a lower RMS over time, repeated measure ANOVA ($F(1) = 24.2$; $p < 0.001$); all patients had less pain and lower VAS values over time, repeated measure ANOVA ($F(1) = 50,5$; $p < 0.001$); all patients had a prolonged WD over time, repeated measure ANOVA ($F(1) = 33.1$; $p < 0.001$)	coflex group: one implant-related complication with dislocation of the implant due to fracture of the spinous process; coflex™ group: two revisions with pedicle screw fusion of the segment were necessary; undercutting group: one patient had to be instrumented and fused; both groups we saw one cerebral spinal fluid leak
Weinstein 2010	Randomized trial and concurrent observational cohort study	US	I	654: 289 (RC) 365 (OC)		Standard decompressive laminectomy or standard non-operative care	Surgical candidates with a history of at least 12 weeks of symptoms and spinal stenosis without spondylolisthesis (as confirmed on imaging); Age: randomized: 65.5 (10.5), observational: 63.9 (12.5)	Randomized and observational cohorts' as-treated treatment effects were similar at 4 years: Bodily Pain: RC 11.4 (95% CI, 5.1 to 17.6) vs. OC 14.9 (95% CI, 9.3 to 20.5), Physical Function: RC 8.0 (95% CI, 1.7 to 14.3) vs. OC 10.1 (95% CI, 4.7 to 15.5), Oswestry Disability Index: RC −7.8 (-12.9, −2.6) vs. OC −11.5 (-15.8, −7.3); clinically significant advantages for surgery previously reported were maintained through 4 years, with treatment effects for BP 12.6 (95% CI, 8.5 to 16.7); PF 8.6 (95% CI, 4.6 to 12.6); and ODI −9.4 (95% CI, −12.6, to −6.2)	Most common surgical complication was dural tear (9%). The 4-year reoperation rate was 13%.; Over four years, there were 12 deaths in the non-operative group within 4 years of enrollment compared to 23 expected based on age-gender specific mortality rates, and 15 deaths in the surgery group within 4 years of surgery, compared to 29 expected; All 27 deaths were independently reviewed and 23 were judged not to be treatment-related. Four deaths were of unknown cause and unknown treatment relation but occurred 1203, 1192, 855, 501 days post-surgery/enrollment. Three of these deaths were in patients who had had surgery and one was in a patient who had not had surgery.

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Kabir, 2010	Systematic review of Level II and Level III study	United Kingdom	III			Evaluate the current biomechanical and clinical evidence available on the use and effectiveness of lumbar interspinous devices and to recommend indications for their use	A systematic review of clinical and biomechanical studies was done using the following key words: interspinous implants, interspinous devices, interspinous spacers, dynamic stabilization, X-STOP, coflex, Wallis, DIAM. The database inclusions were MEDLINE, CINAHL (Cumulative Index to Nursing and Allied Health Literature), and PubMed	Largest number of studies has been with the X-STOP device. The biomechanical studies with all the devices showed that ISPs have a beneficial effect on the kinematics of the degenerative spine. Apart from 2 randomized controlled trials, the other studies with the X-STOP device were not of high methodologic quality. Nevertheless, analysis of these studies showed that X-STOP may improve outcome when compared to nonoperative treatment in select group of patients aged 50 or over, with radiologically confirmed lumbar canal stenosis and neurogenic claudication, who have improvement of their symptoms in flexion. Studies on the other devices show satisfactory outcome to varying degrees. However, due to small number and poor design of the studies, it is difficult to clearly define indications for their use in lumbar degenerative disease	
Adelt, 2010	Retrospective cohort	Germany	III			STUDY IS IN GERMAN	Retrospective review of patients treated with coflex which match IDE inclusion/exclusion		
Cabraja, 2009	Case-series	Germany	IV	143		Percutaneous facet joint denervation (PFJD). If pain persisted, they were offered implantation of an interspinous device (coflex) and/or repeat PFJD	Patients with verified single level LFJS at level L4–5; Forty-one patients with LFJS at L4–5 underwent PFJD. Twenty patients with persisting pain underwent a subsequent surgery for implantation of an interspinous device. Five patients with recurrent pain at 6–12 months opted for an additional PFJD	Clinical outcome improved significantly in the surgically treated patients; however, it did not differ compared with patients receiving PFJD only after 24 months; 7-day follow-up: 40 of 41 (98%) patients experienced a relief of back pain greater than 50% according to the VAS; 3 months of follow-up, only 18 of 41 (44%) patients reported of a relief of back pain greater than 50%; defining success as a reduction of 50% or more in the ODI and VAS, only 9 of the 20 (45%) coflex patients were successful on the ODI, and only 7 of 20 (35%) were successful on VAS 2 years after surgery. Using the criteria of 50% reduction in ODI or VAS, similar results were found in the non-surgical patients [8 of 21 (38%) according to ODI and 8 of 21 (38%) according to VAS]	Three surgical patients with a secondary poor outcome within 3 months after implantation of a coflex device received an additional posterior semi-dynamic stabilization; No surgical- or device-related complications were observed

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Chung, 2009	Case-report	Korea	IV	1	coflex	Observed fractures of bilateral inferior articular processes of L4 during operation. Before revision, we chose decompression level of spinal stenosis through selective root block. After, she underwent posterior decompression and posterior segmental fixation from L3 to S1	64-year-old woman diagnosis of spinal stenosis and degenerative spondylolisthesis at L4-L5; decompressive laminotomy with instrumentation of interspinous implant (coflex); 6 years later presented with low back pain and radiating pain in left leg; spinal central canal and foraminal narrowing found at L3-L4, L4-L5, and L5-S1; bilateral inferior articular processes of L4; metallic artifact showing interspinous implant/ surrounding fluid collection; perineural adhesion following decompression on central canal and neural foramen	Symptoms were relieved after revision; unclear whether interspinous implant increases the possibility of articular process fracture	(Case report) Case of bilateral stress fractures of lumbar posterior facet after implantation of interspinous process device; unclear whether previous interspinous process device may cause bilateral stress fracture of posterior facet
Weinstein 2008	Randomized trial and concurrent observational cohort study	US	I	654: 289 (RC) 365 (OC)		Standard posterior decompressive laminectomy OR nonsurgical "usual care:" active physical therapy, education or counseling with home exercise instruction, and the administration of nonsteroidal antiinflammatory drugs, if tolerated	289 randomized cohort; 365 observational cohort; RC 138 surgical group, 151 nonsurgical group; OC: 219 patients initially chose surgery and 146 patients initially chose non-operative care; Surgical candidates with a history of at least 12 weeks of symptoms and spinal stenosis without spondylolisthesis (as confirmed on imaging); Age: randomized: 65.5 (10.5), observational: 63.9 (12.5)	Patients who underwent surgery showed significantly more improvement in all primary outcomes than did patients who were treated nonsurgically: as-treated: mean differences in change from baseline in the randomized and observational cohorts were similar at 2 years: bodily pain, 11.7 (95% CI, 6.2 to 17.2) in the randomized group versus 15.3 (95% CI, 10.4 to 20.2) in the observational group; physical function, 8.1 (95% CI, 2.8 to 13.5) in the randomized group versus 13.6 (95% CI, 8.7 to 18.4) in the observational group; and Oswestry Disability Index, −8.7 (95% CI, −13.3 to −4.0) in the randomized group versus −13.1 (95% CI, −16.9 to −9.2) in the observational group; intention-to-treat: surgery : at 2 years mean difference in change from baseline 7.8 (95% confidence interval [CI], 1.5 to 14.1) SF-36	10% of patients required transfusions intraoperatively and 5% postoperatively. The most common surgical complication was dural tear, in 9% of patients. At 2 years, reoperation had occurred in 8% of patients; fewer than half of these operations were for recurrent stenosis; At 2 years, there were seven deaths in the nonsurgical group and six in the surgical group, one of which occurred within 3 months after surgery. The deaths were reviewed and 12 were judged not to be treatment-related. The one death of unknown cause occurred 501 days after surgery

Author, Year	Study Design	Country of Origin	Oxford Level of Evidence (LOE)	N	Implant	Technique	Demographics	Results	Complications
Kong, 2007	Retrospective cohort study	Korea	III	42	coflex	Posterior lumbar interbody fusion (PLIF) with interbody cages: Polyetherether-ketone implants or CH cage, followed by pedicle screw fixation OR Foraminal decompression with partial laminotomy w/ coflex implant	Patients having degenerative spinal stenosis with mild segmental instabilit who underwent implantation of coflex™ OR PLIF at L4-5 between January 2000 and December 2003; PLIF: 24 patients 8 males and 16 female patients who ranged in age from 38 to 78 yr (mean 56.0 yr) at the time of surgery; coflex™ group: 18 patients, 3 males and 15 females, who ranged in age from 40 to 71 yr (mean 61.7 yr)	Significant improvement in the VAS and ODI scores for lower leg pain and low back pain in both groups ($p<0.05$), no difference in outcome between two groups;coflex™ group, the PDH on standing radiographs increased significantly from preoperative 7.8 mm to postoperative 9.1 mm ($p<0.05$), whereas in the PLIF group, the PDH was determined according to the inserted cage size (9-14 mm); ROM at the upper adjacent segment (L3-4) in the PLIF group increased significantly after surgery ($p<0.05$), whereas the ROM in the coflex™ group did not increase at this level	No surgical complication in either groups

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Disclosures

Richard Guyer, MD reports serving as a one-day Faculty Trainer for Paradigm Spine. Frank P. Cammisa, Jr., MD reports investments in Paradigm Spine. Michael Musacchio, MD reports consulting fees and speaking honoraria from Paradigm Spine and Medtronic LLC. Morgan P. Lorio, MD, FACS reports no disclosures.

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