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REVIEW

Pacific Spine and Pain Society (PSPS) Evidence Review of Surgical Treatments for Lumbar Degenerative Spinal Disease: A Narrative Review

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ABSTRACT

Introduction: Interventional treatment options for the lumbar degenerative spine have undergone a significant amount of innovation over the last decade. As new technologies emerge, along with the surgical specialty expansion, there is no manuscript that utilizes a review of surgical treatments with evidence rankings from multiple specialties, namely, the interventional pain and spine communities. Through the Pacific Spine and Pain Society (PSPS), the purpose of this manuscript is to provide a balanced evidence review of available surgical treatments.

Methods: The PSPS Research Committee created a working group that performed a comprehensive literature search on available surgical technologies for the treatment of the degenerative spine, utilizing the ranking assessment based on USPSTF (United States Preventative Services Taskforce) and NASS (North American Spine Society) criteria.

Results: The surgical treatments were separated based on disease process, including treatments for degenerative disc disease, spondylolisthesis, and spinal stenosis.

Conclusions: There is emerging and significant evidence to support multiple approaches to treat the symptomatic lumbar degenerative spine. As new technologies become available, training, education, credentialing, and peer review are essential for optimizing patient safety and successful outcomes.

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Key Summary Points

Low back pain due to degenerative spinal disease is one of the most common and costly forms of musculoskeletal pain, with an individual lifetime prevalence of approximately 49–90%.

There are multiple surgical approaches to the treatment of the symptomatic lumbar degenerative spine but no balanced review article up to this point.

The purpose of this article is to review and grade the current evidence for commercially available surgical treatments in the United States.

Spinal surgery has been the staple in treatment of spinal pathology, now along with newly emerging minimally invasive techniques.

INTRODUCTION

Degenerative disorders of the spine have many etiologies, including hypertrophied ligamentum flavum, facet joint hypertrophy, degenerative disc disease, and osteophyte formation. This cascade of degenerative changes is largely the result of aging, with a multitude of causes [1, 2]. Although symptoms may manifest in adolescence or early adulthood, the majority of patients present in the 6th, 7th, or 8th decades of life [3]. Acquired lumbar spinal stenosis (LSS), which is more prevalent, is a result of degenerative spondylosis, spondylolisthesis, synovial cysts, annular bulges, ligamentum flavum hypertrophy, facet hypertrophy, post-surgical fibrosis, other rheumatological and skeletal conditions, or a combination of these factors [4].

Spine surgery has undergone a significant evolution over the course of the last decade. The adoption of minimally invasive surgical techniques for treatment of lumbar spine pathology has resulted in lower complication rates, less blood loss, quicker recovery, and improved patient outcomes [3]. Although several surgical treatment options exist for those with degenerative spinal disease, discussion regarding patient selection characteristics and considerations has not been performed with a clear working group with equitable representation of surgical and interventional pain backgrounds.

Pacific Spine and Pain Society (PSPS) is a group of specialists that span multiple medical disciplines that diagnose, manage, and treat pain and spine disorders. By enhancing collaboration amongst surgical and interventional pain specialists, the society aims to enhance patient care and embrace innovation. This comprehensive treatment evidence review for lumbar degenerative disease is the first of its kind, assimilating information from both the spine and pain literature. As such, traditional evidence grading strategies were chosen for this pioneering effort, from the pain and spine literature, consistent with those commonly employed in each space.

Through the PSPS, the purpose of this manuscript is to provide a comprehensive evidence review of available surgical treatments for lumbar degenerative disease. This manuscript aims to utilize an unbiased and multidisciplinary approach in reviewing the evidence to foster collaboration between the spine and interventional pain communities. While it is not feasible to include every possible surgical treatment for lumbar degenerative disease, we hope to include the most commonly utilized surgical approaches.

METHODS

The PSPS research committee members assigned, and oversaw the literature search methods, evidence table generation with validated assignment of evidence level based on the USPSTF (United States Preventative Services Taskforce) and NASS (North American Spine

Society) evidence ranking criteria and edited and compiled the manuscript. Therefore, section authors performed a comprehensive literature search of PubMed, Ovid, and Google Scholar using key terms such as "lumbar spine surgery", "lumbosacral spine surgery", "lumbar degenerative disc disease", "spondylolisthesis", "lumbar spine stenosis", "neurogenic claudication", "posterior indirect spinal decompression", "minimally invasive spinal decompression", "interspinous fusion," "interspinous spacer, and "discogenic pain treatment".

Articles were included if they were randomized controlled trials or systematic review and meta-analyses of randomized controlled trials with at least 1 year of follow-up. Retrospective comparative studies, case–control studies, case series, and articles with shorter than 1 year of follow-up were excluded. Prospective comparative studies are included if there were no randomized controlled trials available. For emerging technologies or treatments that lacked prospective randomized data with follow-up greater than a year, the available evidence is described and assigned the appropriate evidence grade. For reference, see Fig. 1.

Ethical Approval

This article is based on previously conducted studies and does not contain any new studies with human participants or animals performed by any of the authors.

RESULTS

Based on literature search, surgical treatments were separated by diagnoses of lumbar (1) degenerative disc disease, (2) spondylolisthesis, (3) spinal stenosis. The evidence ranking was performed by the individual working group authors and by two additional working group members for validation. Sections were defined by disease indication and evidence for each surgical treatment, with grades from USPSTF and NASS. USPSTF is commonly employed in the interventional pain literature as a methodology of criteria [5], where for the neurosurgical and orthopedic communities, the common evidence ranking nomenclature and methodology of the NASS were utilized also, therefore, each study reviewed received two evidence-level rankings.

The Level of Evidence, based on the current USPSTF criteria, adapted by NACC (Neuromodulation Appropriateness Consensus Committee) [6] and PACC (Polyanalgesic Consensus Conference) Guidance [7], as outlined in Tables 1 and 2.

Evidence on Surgical Treatments for Degenerative Disc Disease

Surgical treatment for lumbar degenerative disc disease (DDD) remains controversial. Delamination of the disc and posterior annular fissuring result in low back pain due to the mechanical loading to these areas, eventually resulting in sensitization of annular receptors [9]. During the degenerative cascade, neovascularization, neuronal penetration with unmyelinated nerve fibers and in growth of Schwann cells occurs and this neo-innervation is a potential pain generator [1, 2, 6]. The most recent clinical guidelines from the NASS regarding diagnosis and treatment of low back pain determined that there were no studies to adequately address whether surgical vs. medical treatment alone decreased intensity of pain, decreased the duration of pain, increased the functional outcomes of treatment and improved return-to-work rate.

The two main surgical treatments for lumbar DDD are (1) lumbar fusion, traditional standard surgical treatment, and (2) lumbar disc arthroplasty (LDA), which is also known as total disc replacement (TDR). Lumbar fusion aims to relieve pain by fusing vertebrae together to eliminate movement and thus stabilizing the spinal segment. Although lumbar fusion is the most traditionally used treatment for DDD, drawbacks include reduced range of motion and segmental degeneration with time leading to adjacent segment disease. Various TDR devices aim to alleviate pain by replacing a degenerated intervertebral.

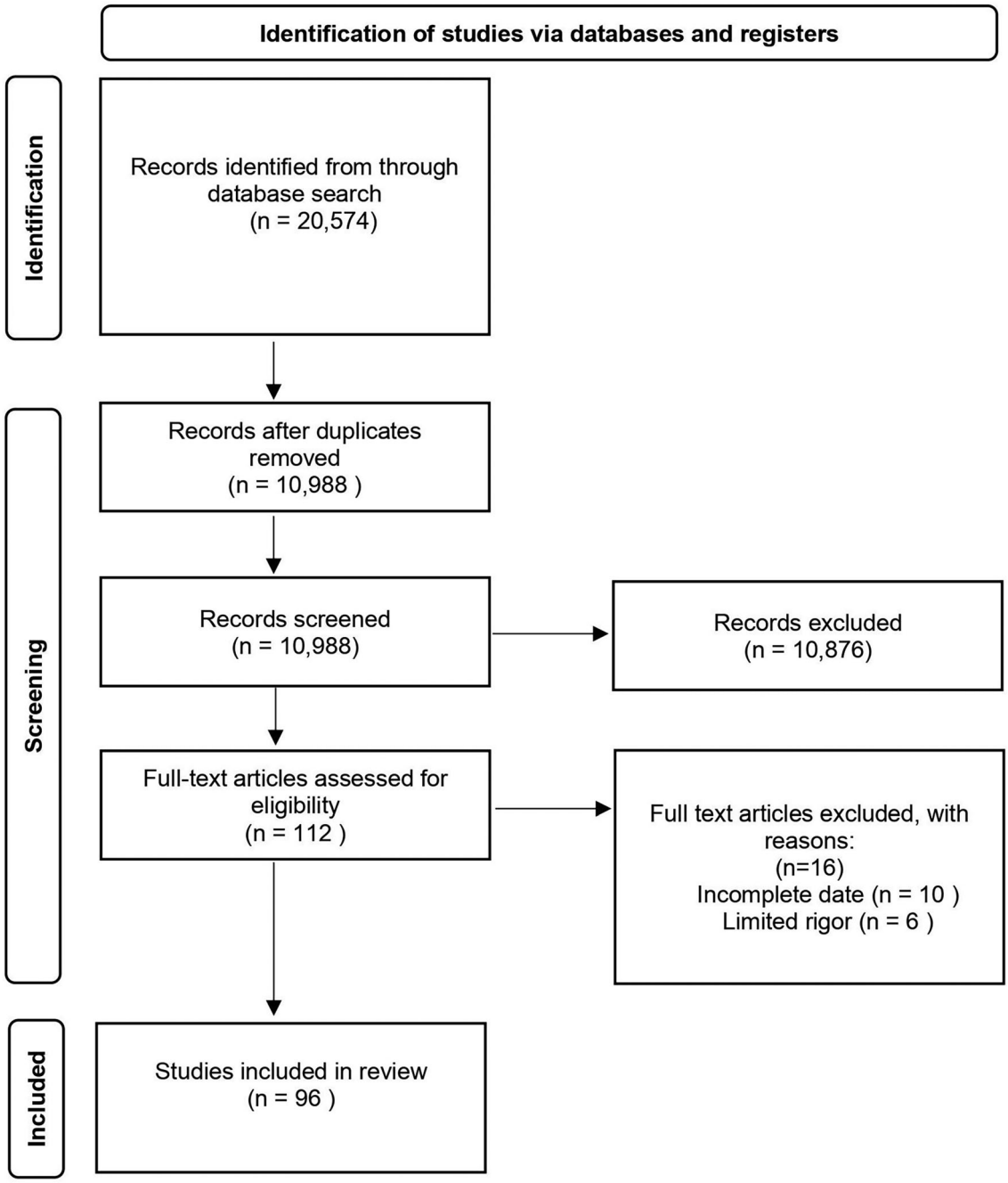

Fig. 1 PRISMA flow diagram for review

disc with a motion-preserving prosthesis. Lumbar TDR is intended to reproduce the biomechanics of an intervertebral disc, thereby avoiding issues with traditional fusion.

Lumbar fusion includes various approaches including but not limited to anterior lumbar interbody fusion (ALIF), oblique lumbar interbody fusion (OLIF), lateral lumbar interbody fusion (LLIF), posterior lumbar interbody fusion

(PLIF), posterolateral lumbar fusion (PLF), transforaminal lumbar interbody fusion (TLIF), and the combined anterior and posterior lumbar fusion (APLF) [10]. More recently, minimally invasive techniques have been widely adopted. Posterior lumbar fusion is typically performed with pedicle screws with intent of stabilization while preserving the disc space. For that reason, posterior instrumentation is not addressed in the DDD section. There is limited comparative evidence for fusion approaches in the context of discogenic low back pain. Comparative evidence mostly investigates surgical fusion versus nonoperative management for discogenic low back pain with still no conclusive recommendations as to which is the most effective [11, 12]. For discogenic pain, precedence has been the ALIF technique, although PLIF and TLIF are also commonly utilized surgical approaches.

A review of major studies comparing lumbar fusion with non-operative management in the treatment of lumbar degenerative disc disease can be found in Table 3.

Summary: There is level I and II evidence indicating that there is no significant difference in pain scores and ODI when comparing lumbar fusions to conservative management in patients with degenerative disc disease. There is level I and II evidence indicating there is a significantly higher complication rate in the lumbar fusion group compared to conservative management.

Table 1 Quality of evidence, based on the USPSTF criteria [1]

Evidence level	Definition
I	At least one controlled and randomized clinical trial with proper design
II-1	Well-designed, controlled, nonrandomized clinical trial
II-2	Cohort or case studies and well-designed controls, preferably multicenter
II-3	Multiple series compared over time, with or without intervention, and surprising results
III	Experience-driven opinions, clinical observations

USPSTF United States Preventative Services Taskforce

Anterior Lumbar Interbody Fusion (ALIF)

With ALIF, the disc space is fused by approaching the spine via an anterior approach. A lower abdominal incision is made to access the peritoneum. The retroperitoneal approach is the most common means of accessing the spine. This involves cutting through the external oblique muscles and retracting the peritoneum and vasculature.

ALIF can restore lumbar lordosis, reduce spondylolisthesis with distraction, and achieve

Table 2 Quality of evidence, based on the NASS criteria [2, 8]

Evidence level	Definition and example
I	High-quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals
	Systematic review of level I RCTs (and study results were homogenous)
II	Lesser-quality RCT (e.g., < 80% follow-up, no blinding, or improper randomization)
	Prospective comparative study
	Systematic review of level II studies or level I studies with inconsistent results
III	Case–control study
	Retrospective comparative study
	Systematic review of level III studies
IV	Case series
V	Expert opinion

NASS North American Spine Society, *RCT* randomized controlled trial

Table 3 Studies comparing lumbar fusion with non-operative management for the treatment of lumbar degenerative disc disease (DDD)

Author/ year	Study design	Sample size (intervention /control)	Indication	Intervention	Control	Outcome measures	Follow-up	Results	Conclusion	USPSTF level of evidence	NASS level of evidence
Xu 2020 [81]	Meta-analysis	808 (485/ 323)	Lumbar DDD	Lumbar fusion (LF)	Conservative management (CM)	ODI VAS-B VAS-L Complications Additional surgery	> 24 months	ODI: no difference (MD, − 7.14; [95% CI − 18.69 to 4.40] $p = 0.23$) VAS-B: no difference (MD, − 0.49; [95% CI − 1.19 to 0.21] $p = 0.17$) VAS-L: no difference (MD, − 0.86; [95% CI − 16.14 to 14.42] $p = 0.91$) Complications: lower in CM group (RR, 21.46; [95% CI 4.34 to 106.04] $p = 0.0002$) Additional surgery: lower in DF group (RR, 0.40; [95% CI, 0.17 to 0.98] $p = 0.04$)	No significant differences in disability or pain outcomes between groups Significantly higher risk of complication in lumbar fusion group Significantly higher risk of requiring future surgery in conservative management group	I	II
Wang 2015 [82]	Meta-analysis	914 (541/ 373)	Lumbar DDD	Lumbar fusion (LF)	Conservative management (CM)	ODI Complications	1–4 years	ODI: no difference (MD 1.94 [95% CI − 6.02 to 2.14]) Complications: RR 22.11 [55.99–81.60]	No significant differences in disability and much higher risk of complications in fusion vs. conservative management	I	II

Table 3 continued

Author/year	Study design	Sample size (intervention/control)	Indication	Intervention	Control	Outcome measures	Follow-up	Results	Conclusion	USPSTF level of evidence	NASS level of evidence
Bydon 2014 [11]	SR	707 (523/103)	Lumbar DDD	Lumbar fusion (LF)	Conservative management (CM)	ODI	1–2 years	ODI: No difference (− 7.39 [95% CI − 20.26, 5.47], $p = 0.26$)	No significant difference in disability	I	II

USPSTF United States Preventative Services Taskforce, *NASS* North American Spine Society, *SR* systematic review, *DDD* degenerative disc disease, *ODI* Oswestry Disability Index, *VAS-B/VAS-L* visual analogue scale for back (B) or leg (L), *MD* mean difference, *CI* confidence interval, *RR* relative risk

coronal and sagittal balance. Caution must be taken due to larger vascular structures that need to be retracted in order to access the anterior disc space. As a result, vascular surgery is often included in the surgical planning. Independent use of ALIF may be utilized, but it is often combined with anterior or posterior fusion or fixation.

The ALIF approach is advantageous in that, unlike the PLIF and PLF approaches, both the paraspinal muscles and their innervation remain undisturbed. Additional advantage over the posterior approach is that nerve root retraction and entrance into the spinal canal is unnecessary and thus avoids the possibility of epidural scarring and perineural fibrosis.

The ideal candidate for ALIF has chronic, disabling back pain of discogenic origin for 1 or 2 lumbar levels with loss of disc height, stability and mobility of the diseased segment or neurological deficit [13]. Burkus et al. completed one of the largest prospective studies on DDD, with 279 patients investigated post-ALIF treatment. Clinical outcomes were based on comparing preoperative and postoperative Oswestry Disability Index (ODI) scores, neurological function, back and leg pain. Authors reported an overall 81% clinical success, and the study had a complication rate of 9% [14]. Several prospective, non-controlled studies validate the use of various types of ALIF devices [15, 16]. Of note, ALIF has been utilized in the presence of spondylolisthesis (discussed in a separate section) and degenerative lumbar scoliosis (not addressed directly in this manuscript). As previously noted, ALIF has also been used in combination with a PLF [17].

Posterior Lumbar Interbody Fusion (PLIF)

One of the original approaches for interbody fusion is PLIF. The posterior approach may be more suitable for degenerative indications requiring a fusion procedure. Patients with segmental instability, recurrent disc herniation, spinal stenosis and pseudoarthrosis may also benefit from a PLIF procedure. A posterior exposure allows for visualization of nerve roots without compromising blood supply. PLIF allows for adequate interbody height restoration and neural decompression while

maintaining posterior support structures [18]. Disadvantages and/or complications of this technique include (1) prolonged retraction may lead to paraspinal muscle denervation, (2) delayed recovery and mobilization due to trauma, (3) potential for neurological sequelae secondary to nerve root injury and/or perineural fibrosis, (4) cerebrospinal fluid leak.

A prospective multicenter clinical study was conducted on eight-seven patients with chronic low back pain due to DDD treated by posterior lumbar interbody fusion (PLIF). Visual Analog Scale and Oswestry Disability Index decreased by 60% and 58%, respectively [19].

In a prospective, nonrandomized clinical series, 89 patients underwent PLIF with an allograft spacer and posterior pedicle fixation. All patients had experienced at least 6 months of low back pain that had been unresponsive to nonsurgical treatment. Follow-up visits were at intervals of 6 weeks, 6 months, 12 months, and 24 months. At each interval, radiographs and patient outcome measures were recorded, including SF-36 Bodily Pain Score, visual analog scale (VAS) pain rating and Oswestry Disability Index (ODI). The authors concluded that PLIF is a safe and effective surgical treatment for low back pain caused by degenerative disc disease when performed with machined allograft spacers and posterior pedicle fixation [20].

Transforaminal Lumbar Interbody Fusion (TLIF)

TLIF is a modification of the PLIF technique where the intervertebral disc is exposed unilaterally through a transforaminal approach with subtotal facetectomy in conjunction with pedicle screw instrumentation. Although risks are similar between these two techniques, a potential advantage of TLIF is less nerve root retraction to place the interbody spacer. Similar to PLIF, contralateral posterolateral fusion can be added to improve fusion rates. Takahashi et al. reported significant improvement with TLIF for the treatment of intractable chronic lumbar discogenic pain [21].

Lateral Lumbar Interbody Fusion (LLIF)

LLIF was developed as a trans-psoas approach to the anterior disc space allowing for complete discectomy, distraction, and interbody fusion without the need for an approach surgeon [22]. The lateral aspect of the disc is approached through the psoas muscles with serial dilators and a retractor. Complete diskectomy is performed and a large interbody is placed. There is no need to retract the great vessels or the sympathetic chain. LLIF techniques access the lateral aspect of the disc space via a retroperitoneal, trans-psoas approach and serve as an alternative to ALIF. There is no need to mobilize the great vessels or sympathetic chain and thus serves as a less-invasive alternative to ALIF. Similar to ALIF, advantages LLIF compared to PLF include: preservation of paraspinal muscles, interbody placement without retraction of nerve roots, and essentially no risk of dural injury. The LLIF approach is limited by the iliac crest and thus cannot be performed below L4-5 and is contra-indicated in cases where the lumbar plexus and psoas muscles are positioned past the anterior half of the disc space. Additional anatomical challenges include > grade 2 spondylolisthesis, significant rotatory scoliosis, retroperitoneal scarring, anomalous lateral position of the great vessels and prior fusion of L5/S1. Multiple studies have demonstrated high fusion rates for LLIF including Berjano et al. (2015) showing a fusion rate of 98% in 77 patients using a combination of autologous bone, calcium triphosphate and Attrax (Nuvasive) and Rodgers et al. (2010) with a fusion rate of 93.2% with at 17.3 months utilizing autograft and demineralized bone matrix with bone marrow aspirated from the iliac crest [23, 24]. In a retrospective, single surgeon cohort study of patients undergoing single level ALIF or LLIF for degenerative disc disease or spondylolisthesis, Malham et al. reported equivalent results for relief of back pain (64 vs. 56%), leg pain (65 vs. 57%), ODI (60 vs. 52%), and fusion on CT (100 vs. 95%) at 24-month follow-up [25].

Oblique Lumbar Interbody Fusion (OLIF)

OLIF was developed as an alternative to LLIF and ALIF and approaches the lumbar spine via a

retroperitoneal, anterior to psoas muscle trajectory. A retractor is placed between the great vessels and psoas muscle at the anterolateral aspect of the disc space. Diskectomy is performed and the interbody is placed across the intervertebral space in an oblique anterior to posterior trajectory. OLIF may be performed from L1-S1 and because the approach is anterior to the iliac crest may be an alternative to ALIF at L5/S1 or cases where LLIF may not be performed due to a high-riding iliac crest or anterior lumbar plexus/psoas. Anatomic limitations of OLIF include > grade 1 spondylolisthesis where the overlap of the endplates may limit the space for an oblique interbody and cases of high-grade stenosis where there may be concern that the posteromedial approach could push disc fragments into the central canal or contralateral foramen [10].

OLIF has shown favorable outcomes in VAS and ODI for patients with back pain and radiculopathy caused by spondylosis [26–28]. Fusion rates have been reported to comparable to those for ALIF and LLIF. In 29 patients with OLIF and posterior pedicle screw fixation, Kim et al. reported a 12-month fusion rate of 92.9% [29]. Lin et al. reported a fusion rate of 81.9% at 12 months in 52 patients treated with standalone OLIF [30].

Compared to LLIF, OLIF has been shown to have less risk of postoperative neurological deficits but significantly higher rates of abdominal complications, system failure, and vascular injury [31]. A vascular injury during OLIF, compared to ALIF, is potentially more threatening because with OLIF the access does not permit direct repair and a vascular surgeon is typically not utilized the procedure.

Lumbar Disc Arthroplasty (LDA)

There is no conclusive evidence of LDA superiority over fusion in long-term level I studies. However, studies of LDA have reported satisfactory clinical results and implant survival along with comparable complication profiles to fusion. [32, 33]. The impetus for development of this technique has been motion preservation. Zigler et al. reported adjacent segment degeneration was significantly lower at 5 years for LDA (6.7%) versus APLF (23.8%). In a randomized controlled trial (RCT) Radcliff et al. compared 5-year outcomes for 2-level LDA to 2-level APLF in 229 subjects. The authors found equivalent success rates and a significantly lower rate of re-operation for the LDA group (5.6 vs. 19.1%). In another study, David et al. concluded that the rate of reoperation secondary to adjacent segment disease was ten times lower than the rates for fusion [34]. Other advantages for LDA include the absence of grafting or hardware, which present their own complications [35].

Earlier, some of the initial LDA designs led to inconsistent outcomes. Reasons for implant failures reported included failure of osseointegration, elastomeric tears, and osteolysis [36]. While reportedly lower than fusion, complications rates remain significantly lower than fusion (29.1% for arthroplasty and 50.2% for fusion at 2-year follow-up). Complications include those related to the anterior surgical approach (e.g., vascular injury, nerve root injury, retrograde ejaculation), prosthesis/fusion failure (e.g., subsidence, osteolysis, migration, implant fracture, endplate fracture, pseudoarthrosis), heterotopic ossification (up to 76% at 3 years) both hyper- and hypomobility of the implant, as well as donor site complications [36]. Device failures necessitating repeat operations have been reported at 5.4–6.3%.

Evidence on Surgical Treatments for Spondylolisthesis

The need to fuse patients who have lumbar spinal stenosis (LSS) in the setting of degenerative spondylolisthesis (DS) is one of the most debated topics in the surgical spine community. The concern with standalone decompression for LSS in the setting of DS is inadequate relief of leg pain or persistent back pain secondary to abnormal motion or instability at the decompressed segment. For decades, the surgical treatment of DS was based on a landmark 1991 study by Herkowitz et al. of 50 patients who were randomized to either a decompressive laminectomy or laminectomy plus un-instrumented posterolateral fusion [37]. The study included patients who had a “single level of DS

seen on plain radiographs". The degree of listhesis or kyphosis was not used as a criterion. The authors reported that patients who had a fusion accompanied by a decompression had "more excellent and good" outcomes compared to the decompression alone group. Over the last 15 years, our understanding of DS has evolved to include discerning stable vs. unstable DS, determining predictors of post decompressive instability, and introducing minimally invasive ligament preserving decompressive techniques.

Degenerative spondylolisthesis has traditionally been described as the slipping forward of one lumbar vertebra on another with an intact neural arch, with Meyerding classifying the slippage as grades 1–4 [38]. It is important for clinicians to understand the differences between stable and unstable DS, even though there is no universally accepted standard. Unstable DS is traditionally described as > 10 angulation or 4-mm translation between flexion–extension X-rays. The treatment of stable vs. unstable DS is clouded by the lack of standardization in large-scale clinical studies as some include stable and unstable DS [37–39] while others include only patients with stable DS [40]. The Spine Patient Outcomes Research Trial (SPORT) examined the effectiveness of surgical vs. non-surgical treatment of DS. This study included any patient who had DS shown on lateral radiographs in a standing position [38]. An analysis of patient demographics in this trial revealed that only 47/601 patients (8%) had unstable DS. Despite only 8% of patients presenting with unstable DS, 95% of patients with any DS underwent a fusion.

In 2016, the New England Journal of Medicine (NEJM) published consecutive articles on the surgical treatment of LSS [29, 30]. Försth et al. examined 247 patients as part of the Swedish Spinal Stenosis Study that consisted of 135 patients with both stable and unstable DS [39]. The average pre-operative listhesis measured on radiographs 7.4 mm. Sixty-eight patients underwent decompression and 67 underwent decompression and fusion. Patient-reported outcome (PRO) measures included the VAS, EQ-5D, ZCQ, ODI, and 6-min walk test. At 2 and 5 years, fusion did not result in better PRO than decompression alone. The overall re-operation rate at 6.5 years was 22% in the fusion group and 21% in the decompression group. Most revisions in the fusion group were for adjacent segment stenosis while most of the revisions in the decompression group were for recurrent stenosis or foraminal stenosis. The second NEJM article by Ghogawala et al., reported on a randomized control trial of laminectomy vs. laminectomy and fusion performed across multiple sites in the United States. Contrary to the Forsyth study, only patients who had a grade 1 stable DS were included; patients with > 3 mm of motion on flexion–extension radiographs were specifically excluded. The average slippage was 6 mm with 1.5 mm of translation. Sixty-six patients were included in the study with 35 treated by laminectomy, and 31 treated by laminectomy and fusion. A 1-, 2-, and 4-year follow-up was performed with PRO including SF-36 and ODI. This study demonstrated that fusion was better than decompression for the physical component score (PCS) of the SF-36 at all endpoints, although there were no significant differences in ODI. The authors also reported a re-operation rate of 34% in the decompression group for subsequent instability despite already excluding patients with an unstable DS. It should be noted that decompression in the Ghogawala et al. study was an open laminectomy while 20% of the patients in the Forsyth et al. study received a minimally invasive interspinous ligament sparing decompression [40]. These were the first two large-scale clinical trials that challenged the traditional dogma of the need to fuse all patients with a DS.

Several authors have reported on the predictors of post-operative instability following decompression in patients with a DS [41, 42]. Blumenthal et al. demonstrated in patients with a stable DS that risk factors for progressive instability and re-operation included patients who had greater than > 1.25 mm of motion, disc height > 6.5 mm, or facet angle > 50 degrees (more vertically oriented facet joint). Patients with all three criteria had a re-operation rate of 75%. Inui et al. reported on patients with both stable and unstable DS and found that even in the setting of a minimally invasive decompression, pre-operative translation (on

flexion–extension radiographs) of more than 5 mm led to an 80% risk of postoperative instability. Patients who had an unstable DS, tall disc, fluid filled facets, and vertically oriented facets may be better candidates for a fusion than a decompression and require less reoperation rates at the index level.

A traditional laminectomy removes the midline structures including the supraspinous and interspinous ligaments. The advent of minimally invasive decompressions performed through a mini-open incision or tubular retractor has given surgeons the ability to decompress the spine without disrupting stabilizing ligaments. A unilateral laminotomy bilateral decompression (ULBD) is performed through a traditional mini-open unilateral approach followed by decompression of the contralateral side. Theoretically, a ULBD leads to a decreased risk of post decompression instability in patients who have a DS. Kuo et al. reported on a retrospective cohort of 164 patients who underwent a ULBD vs. 437 matched fusion controls in patients with a DS [43]. Although there was no indication of DS grade or stability, the authors reported that at 5-year follow-up the reoperation rate was 10% in ULBD vs. 17% in the Fusion cohort. A systematic review of 37 studies w/1156 patients comparing traditional midline laminectomy vs. ULBD in the setting of DS demonstrated secondary fusion rates of 12.8% and 3.3% in the laminectomy and ULBD groups, respectively [44]. Seventy-two percent of the patients who had an open laminectomy had slippage progress while 0% of patients in the ULBD group progressed. Patients who have a stable DS, collapsed disc, and more horizontally oriented facets may be good candidates for a ULBD rather than a fusion. There still may be a requirement to fuse the index level albeit less than in the setting of an unstable DS.

Some clinicians prefer to fuse patients with a DS when back pain is also a presenting symptom presuming that degenerative disc disease and facet joint arthrosis which often accompanies DS contributes to back pain [45]. Sigmundsson et al. analyzed 1624 patients with stable and unstable DS from the Swedish Spine Registry treated by decompression vs. decompression and fusion [46]. Patients who received a fusion had a greater decrease in low back pain but a similar reduction in leg pain. Similarly, Austevoll reported from a cohort of 294 patients with a fusion vs. 260 with a decompression and found that the fusion group was superior in reducing low back pain at 1 year. There were no statistical differences in leg pain or ODI [47]. The degree of relief from pre-surgical diagnostic injections such as lumbar epidural steroid injections, facet joint injections, and functional anesthetic discogram can be used to help delineate what structural pathology is contributing to back pain in DS. It is important to remember that even though the primary purpose of LSS surgery is to reduce leg pain, decompression alone in the absence of fusion may also decrease low back pain [48].

While there are studies that show that instrumentation increases fusion rates, and that increased fusion rates lead to better PRO, it is still unproven if instrumentation directly correlates to improved PRO. Further study and research are required. Further, there are no studies directly comparing direct vs. indirect decompression.

A review of major studies comparing surgical vs. non-surgical management, as well as surgical management for lumbar degenerative spondylolisthesis can be found in Tables 4 and 5.

> Summary: There is level I and II evidence showing significantly greater improvement in pain and functional scores in patients treated surgically for lumbar DS.

Evidence on Surgical Treatment for Lumbar Spinal Stenosis

The spectrum of surgical and non-surgical procedures in the treatment of LSS has been previously explored by many different groups [49–51]. The North American Spine Society (NASS) has more recently published evidence-based guidelines for the "Diagnosis and Treatment of Lumbar Spinal Stenosis" which elaborates on epidural injections and surgical treatment [49]. Failure of conservative management or worsening of neurological deficits, as in most other types of lumbar pathology,

Table 4 Studies comparing surgical versus non-surgical intervention for lumbar degenerative spondylolisthesis (LDS)

Author/ year	Study design	Sample size (intervention/control)	Indication	Intervention	Control	Outcome measures	Follow-up	Results	Conclusion	USPSTF level of evidence	NASS level of evidence
Weinstein 2007 [38]	RCT Observ	607 (332/275)	LDS	Decompression ± fusion (DF)	Conservative management (CM)	SF-36 ODI Reoperation rate Patient-reported satisfaction	2 years	(Intention to treat analysis, treatment effects) ODI: No difference (2.2; [CI 95%, − 2.3 to 6.8] $p = 0.68$) SF-36 BP: No difference (1.5; [CI 95% − 4.2 to 7.3] $p = 0.52$) **SF-36 PF**: No difference (1.9; [CI 95%, − 3.7 to 7.5] $p = 0.71$) Reoperation rate: 12% (As-treated effects) ODI: Lower in DF (− 16.7; [CI 95% − 19.5 to − 13.9] $p = < 0.001$) SF-36 BP: Higher in DF (18.1; [CI 95% 14.5–21.7] $p = < 0.001$) SF-36 PF: Higher in DF (18.3; [CI 95% 14.6–21.9] $p = < 0.001$)	Patients with degenerative spondylolisthesis and spinal stenosis treated surgically showed substantially greater improvement in pain and function during a period of 2 years than patients treated non-surgically	I	II

Table 4 continued

Author/ year	Study design	Sample size (intervention/control)	Indication	Intervention	Control	Outcome measures	Follow-up	Results	Conclusion	USPSTF level of evidence	NASS level of evidence
Weinstein 2009 [83][a]	RCT Observ	607 (332/275)	LDS	Decompression ± fusion (DF)	Conservative management (CM)	SF-36 ODI Patient-reported satisfaction	4y	(Intention to treat analysis, treatment effects) ODI: No difference (4.1; [CI 95% − 0.8 to 9.1] $p = 0.1$) SF-36 BP: No difference (− 2; [CI 95% − 8.6 to 4.6] $p = 0.56$) SF-36 PF: No difference (− 3.1; [CI 95% − 9.2 to 3] $p = 0.32$) (As-treated effects) ODI: Lower in DF (− 14.3; [CI 95% − 17.5 to − 11.1] $p = < 0.001$) SF-36 BP: Higher in DF (18.1; [CI 95% 14.5–21.7] $p = < 0.001$) SF-36 PF: Higher in DF (18.3; [CI 95% 14.6–21.9] $p = < 0.001$	Patients with degenerative spondylolisthesis and spinal stenosis treated surgically showed substantially greater improvement in pain and function during a period of 4 years than patients treated non-surgically	I	II

USPSTF United States Preventative Services Taskforce, *NASS* North American Spine Society, *RCT* randomized controlled trial, *Observ* observational, *LDS* lumbar degenerative spondylolisthesis, *SF-36* short form health survey (*BP* bodily pain, *PF* physical function), *ODI* Oswestry Disability Index, *CI* confidence interval

[a]The Weinstein 2009 study is a continuation of the Weinstein 2007 study, presenting results at 2 and 4 years

Table 5 Studies comparing lumbar decompression alone (DA) vs. lumbar decompression and fusion (DF)

Author/year	Study design	Sample size (intervention/control)	Indication	Intervention	Control	Outcome measures
Herkowitz 1991 [37]	Prospect/comp	50 (25/25)	LDS	Decompression + fusion (DF) (Posterolateral uninstrumented)	Decompression alone (DA)	VAS-B VAS-L
Försth 2016 [39]	RCT	247 (123/124)	LSS ± LDS	Decompression + fusion (DF)	Decompression alone (DA)	Primary: ODI Secondary: EQ-5D, VAS, ZCQ, 6-min walk test
Ghogawala 2016 [40]	RCT	66 (31/35)	LDS or LSS	Decompression + fusion (DF) (Posterolateral instrumented)	Decompression alone (DA)	Primary: SF-36 Secondary: ODI
Kuo 2019 [43]	Retro cohort	601 (437/164)	LDS + LSS	Decompression + fusion (DF) (instrumented)	Decompression (DA) (Unilateral laminotomy)	Primary: 5-year reoperation rate Secondary: postoperative complication rates, blood loss during surgery, and length of stay
Sigmundsson 2015 [46]	Prospect	839 (594/245)	LDS at L4-5 level	Decompression + fusion (DF) (posterolateral)	Decompression alone (DA)	VAS-B VAS-L EQ-5D ODI SF-36
Austevoll 2017 [47]	RCT (NI)	262 (129/133)	LSS + LDS	Decompression + fusion (DF)	Decompression alone (DA)	Primary: 30% reduction in ODI Secondary: ODI, NRS, ZCQ

Table 5 continued

Author/year	Follow-up	Results	Conclusion	USPSTF level of evidence	NASS level of evidence
Herkowitz 1991 [37]	3 years	Mean VAS-B: 1.3 in DF group vs. 2.5 in DA group Mean VAS-L: 1.0 in DF group vs. 1.7 in DA group	In patients who had concomitant arthrodesis, the results were significantly better with respect to relief of pain in the back and lower limbs	II-1	II
Försth 2016 [39]	5 years	ODI at 2 years: no difference, ($p = 0.24$) 6-min walk test at 2 years: no difference ($p = 0.72$) Reoperation rate at 6.5 years 22% in the DF group 21% in the DA group	Among patients with lumbar spinal stenosis, with or without degenerative spondylolisthesis, decompression surgery plus fusion surgery did not result in better clinical outcomes at 2 years and 5 years than did decompression surgery alone	I	II
Ghogawala 2016 [40]	4 years	SF-36 at 4 years: higher in DF group (MD 7.4; [95% CI 1.2–12.3]; $p = 0.02$) ODI at 4 years: no difference (MD − 9; [95% CI − 18 to 0.1] $p = 0.05$ Reoperation: 14% in DF group vs. 34% in DA group ($p = 0.05$)	Among patients with degenerative grade I spondylolisthesis, the addition of lumbar spinal fusion to laminectomy was associated with slightly greater but clinically meaningful improvement in overall physical health-related quality of life than laminectomy alone	I	II

Table 5 continued

Author/year	Follow-up	Results	Conclusion	USPSTF level of evidence	NASS level of evidence
Kuo 2019 [43]	5 years	Reoperation rate at 5 years: 17.2% in DF group vs. 10.4% in DA group Reoperations were more frequent at the index surgical level in DA group Reoperations were more common at an adjacent level in DF group Complications rate: no difference Blood loss: less in DA group Length of stay: less in DA group No difference in postoperative complication rates. Both groups tended to have fusion reoperations	For patients with stable LDS and LSS, unilateral laminotomy for bilateral decompression is a viable, durable option compared to fusion with decreased blood loss and length stay, as well as a lower reoperation rate at 5-year follow-up	II-2	III
Sigmundsson 2015 [46]	2 years	VAS-B at 2 years in patients with PLP: less back pain in fusion group (− 6.3 [95% CI 1.7 to 14.4], $p < 0.13$) ODI at 1y in patients with PBP: improved in fusion group (− 5.7[95% CI 1.6–9.9], $p < 0.006$) no difference in ODI at 2 years VAS- L, EQ-5D at 2 years: no difference	Patients with PBP in DF group report better outcomes but failed to reach MCID Patients with PLP report more improvement in terms of back pain with fusion compared to decompression alone @2 years: no significant difference between the DF vs. DA groups Greater loss to follow-up in DF group could potentially bias these findings	II-2	III

Table 5 continued

Author/year	Follow-up	Results	Conclusion	USPSTF level of evidence	NASS level of evidence
Austevoll 2017 [47]	1 year	(Modified intention-to-treat population) > 30% reduction in ODI: 71.4% in DA group vs. 72.9% in DF group (MD − 1.4. [95% CI − 12.2 to 9.4]) (Per-protocol population) > 30% reduction in ODI: 75.5% in DA group and 75.5% in DF group (MD 0.0, [95% CI − 11.4 to 11.4])	Unable to conclude that DA is as good as DF. However, the small differences in the groups' effect sizes suggest that a considerable number of patients can be treated with DA	II-1	II

USPSTF United States Preventative Services Taskforce, *NASS* North American Spine Society, *Prospect* prospective, *Comp* comparative, *RCT* randomized controlled trial, *Retro* retrospective, *NI* non-inferiority, *LDS* lumbar degenerative spondylolisthesis, *LSS* lumbar spinal stenosis, *VAS* visual analogue scale for back (B) or leg (L), *ODI* Oswestry Disability Index, *EQ-5D* Euro-Qol-5D questionnaire (measures quality of life), *ZCQ* Zurich Claudication Questionnaire, *SF-36* Short Form Health Survey, *NRS* numeric pain rating scale, *PLP* primary leg pain, *PBP* primary back pain, *MCID* minimal clinically important difference
CI: confidence interval

warrants consideration for interventional and surgical treatment options. A recent guideline suggests the use of minimally invasive treatments as an alternative to more traditional and open surgical procedures [52], particularly addressing the use of percutaneous indirect and direct decompression.

Surgical Decompression with and without Fusion

Surgical decompression remains the "gold standard" treatment for LSS. The main aim of decompression for LSS is to relieve impingement of neural structures and compression of vascular elements by freeing up space within the spinal canal [53–57]. This is accomplished by removing posterior spinal elements such as laminae, facets, ligaments, synovial cysts, and osteophytes. There are a multitude of open and minimally invasive procedures by which this can be accomplished, including traditional laminectomy, bilateral laminotomy, bilateral decompression with unilateral laminotomy, laminoplasty, and indirect decompression with lateral lumbar interbody fusion [56, 58]. Among these, there is no particular approach which is convincingly superior for LSS, and the ultimate choice of procedure often comes down to individual surgeon preference and case presentation [53, 59, 60]

Although decompressive surgery has been performed worldwide for well over a century, there have been very few high-quality studies demonstrating its efficacy. Unlike many of the novel therapies described above, there is no industry to sponsor randomized controlled studies for decompression. Malimivarra et al. published the first randomized trial that compared the effectiveness of traditional surgery in comparison with nonoperative and conservative treatment for spinal stenosis [61]. In this multicenter trial, 94 patients with LSS were randomized to undergo surgery (laminectomy $n = 40$, laminectomy with instrumented fusion $n = 10$) or nonoperative treatment ($n = 44$). Although both treatment groups showed improvement, patients in the surgery group had a more favorable outcome at 2 years.

Patients in the surgical group had better disability (11.3, 95% confidence interval [CI] 4.3–18.4), leg pain (1.7, 95% CI, 0.4–3.0), and back pain (2.3, 95% CI 1.1–3.6) scores at the 1-year follow-up. The surgical group advantage was slightly less in all three variables at the 2-year follow-up: disability (7.8, 95% CI 0.8–14.9), leg pain (1.5, 95% CI 0.3–2.8), and back pain (2.1, 95% CI 1.0–3.3). There was no significant difference between the walking ability of both groups.

The Maine Lumbar Spine Study prospectively studied a cohort of 148 patients with symptomatic lumbar stenosis [62]. In this non-randomized cohort study, 81 patients were treated surgically and 67 treated nonsurgically. The surgical cohort tended to present with more severe symptoms, imaging findings, and worse functional status. At 1 year, 55% of the patient's that underwent surgical treatment showed definite improvement in their predominant symptoms compared to only 28% in the nonsurgical group ($p = 0.003$). Patient's in the surgical group had the maximum benefit from surgery at the 3-month follow-up. There was minimal improvement in both symptoms and functional status in the non-surgical group. At the 8–10-year follow-up, patients in the surgical arm of the study showed greater leg pain relief and back-related functional status. However, there was no statistically significant difference for low back pain relief, predominant symptom improvement and satisfaction between the two groups.

The Spine Patient Outcomes Research Trial (SPORT) reported on the 2-year outcomes of patients with spinal stenosis without degenerative spondylolisthesis to compare the efficacy of surgical versus nonsurgical treatment [63]. In this multicenter RCT, 289 patients were enrolled in the randomized cohort, and 365 patients were enrolled in the observational cohort. At the 2-year mark, the intention-to-treat analysis showed no significant difference in change on physical function or on the Oswestry Disability Index. However, the randomized cohort did show a significant improvement favoring surgical treatment with better results on the SF-36 scale for bodily pain (7.8, 95% CI 1.5–14.). The study had a high crossover rate with 43% of the patients initially randomized to receive nonsurgical care undergoing surgical treatment and

only 67% of patients randomly assigned to receive surgical treatment having undergone surgery. The combined cohorts, when adjusted for potential confounders, in the as-treated analysis did show a significant advantage in all primary outcomes (change in bodily pain, physical function, and ODI) for the surgical treatment group at the 3-month mark. These changes continued to remain significant at the 2- and 4-year follow-up.

Fusion, in addition to decompression, is often considered when mechanical back pain is the predominant presenting symptom. Further, pre-existing instability, spondylolisthesis, scoliosis, foraminal stenosis necessitating resection of greater than 50% of the facet joint leading to iatrogenic instability may support the need for fusion.

Försth et al. randomized 247 with LSS at one or two adjacent vertebral levels to either decompression plus fusion surgery (fusion group) or decompression surgery alone (decompression-alone group) [29]. At the 2-year follow-up, there was no significant difference in the ODI (27 vs. 24, $p = 0.24$) and 6-min walk test (397 vs. 405 m, $p = 0.72$) scores between the fusion and decompression-alone groups. The presence or absence of spondylolisthesis did not have an effect on the results. There was no significant difference in the clinical outcomes or the need for further surgery between the groups at the 5-year follow-up. However, the addition of fusion surgery along with decompression was associated with longer hospitalization, longer operative times, increased bleeding, and higher surgical costs.

Fusion is often considered an option for patients with LSS and spondylolisthesis with or without evidence of pre-existing radiographic instability. The Spinal Laminectomy versus Instrumented Pedicle Screw Fusion (SLIP) Trial randomized 66 patients who had stable degenerative grades 1–2 spondylolisthesis and symptomatic lumbar spinal stenosis to undergo either decompressive laminectomy alone or laminectomy with posterolateral instrumented fusion [40]. At the 2-year follow-up, the group that underwent instrumented pedicle screw fusion had a significantly greater increase in SF-36 physical component summary (15.2) vs. the decompression-alone group (9.5, 95% confidence interval, 0.1–11.3; $p = 0.046$). This increase in the SF-36 physical component remained at the 3- and 4-year follow-up visits ($p = 0.02$ for both years). However, there was no difference between the two groups with respect to reduction in disability related to back pain. The changes in the Oswestry Disability Index scores did not differ significantly between the groups at the 2-year follow-up (− 17.9 in the decompression-alone group and − 26.3 in the fusion group, $p = 0.06$). The study did note that there was increased blood loss and longer hospital stay in the fusion group when compared to the decompression-alone group ($p < 0.001$ for both comparisons). The rate of reoperation was also significantly higher ($p = 0.05$) in the decompression alone group (34%) when compared to the fusion group (14%).

Several systematic reviews have compared decompression alone versus decompression with fusion [64, 65]. Current literature suggests that the addition of fusion in the management of LSS yields no clinical improvements over decompression alone. The addition of fusion did result in longer duration of operation, increased blood loss, and a higher incidence of complications.

However, a meta-analysis that included four RCTs comparing the two treatments in the setting of degenerative spondylolisthesis found that fusion had advantages of improvement of clinical satisfaction, as well as reduction of postoperative leg pain, with similar complication rate to decompression alone [66]. Taken together, the systematic reviews are limited by a paucity of included studies, inconsistency in the type of fusion or instrumentation placed, heterogeneity of the included patients, and the lack of a clear definition for "stability" vs. "instability" in LSS [17].

Ultimately, whether a surgeon opts for decompression alone or in combination with fusion for LSS comes down to a combination of mechanical factors, symptomatology, radiographic findings, and personal preference. The latter is a significant factor involved in the choice of procedure because there is not definitive evidence that laminectomy alone is superior to fusion for LSS, or vice versa.

A review of major studies comparing different types of surgical management for lumbar spinal stenosis can be found in Table 5.

Summary: There are mixed results showing whether or not decompression plus fusion versus decompression alone improved pain and function scores in patients with lumbar DS.

Percutaneously Implanted Interspinous Spacers

Interspinous spacers (ISS) were originally developed as an alternative to posterior decompression and fusion. In the evolution of the ISS, there have been various types of sizes, shapes and materials used. Presently, ISS can be characterized as static or dynamic, with both providing distraction of the interspinous space, leading to flexion or anti-extension at the targeted spinal level. Biomechanically, this increases the cross-sectional area in both the central canal and neural foramen, and results in tightening of the ligamentum flavum. This prevents buckling of the ligamentum flavum along the posterior canal, which further leads to opening of the central canal [67].

Static devices are made of non-compressive materials [68], while dynamic implant devices have a degree of compression. Examples of static ISS devices include X-Stop (Medtronic), Wallis (Zimmer), and Superion (Boston Scientific); whereas the DIAM (Medtronic) implant is considered to be a dynamic ISS [69].

The X-stop device was historically one of the most popular ISS devices in the United States. Though X-stop is no longer on the market, it bears mentioning here to understand the evolution of ISS. Initial data showed promising results on short-term follow-up, but this did not translate to long-term symptomatic relief. Furthermore, complications rates were found to be high, including issues of spinous process fracture, heterotopic ossification with possible intrusion of bone within the central and foraminal spaces, dislocation, spinous process erosion, infection, and neurological sequelae [70].

Since the discontinuation of X-stop, there has been a resurgence of ISS brought to market both static and dynamic, with modifications to help prevent the aforementioned list of complications. With the advent of improved technology and less invasive methods of placement, there presently is a need for a new classification of ISS devices by the method in which they are implanted; percutaneous ISS and open ISS.

The Superion implant is a percutaneously implanted interspinous spacer that is FDA approved for treatment of neurogenic claudication in the presence of moderate degenerative LSS (L1-L5). The use of Superion has been compared to the X-stop device and showed similar improvement outcomes at the 2-year follow-up [71, 72]. A study comparing the two devices showed more patients in the Superion group (63 of 120 patients, 52.5%) achieved statistically significant ($p = 0.023$) Composite Clinical Success (CCS) when compared to the X-Stop cohort (40 of 120, 38%) at the 36-month follow-up. CCS was defined as a clinically significant improvement in two of the three domains including the Zurich Claudication Questionnaire (ZCQ); no reoperations, revision, removals, or supplemental fixation at the treated level(s); no major implant or procedure-related complications; and no significant confounding treatments such as epidural injections, nerve blocks or rhizotomies. At the 5-year follow-up, 84% of patients (74 of 88) Leg and back pain success rates (50% or greater relief) were seen in 80% (68 of 85) and 65% (55 of 85), in Superion and X-stop groups, respectively.

Review of present evidence supports the use of percutaneously implanted interspinous spacer devices in patients with radiological evidence of mild-to-moderate degenerative LSS and no worse than a grade I spondylolisthesis, with flexion-based relief of neurogenic claudication symptoms. For patients who do not fit these criteria, or exhibit any of the aforementioned contraindications, other interventional or surgical treatment options should be highly considered.

A review of major studies comparing different types of interspinous spacers can be found in Table 6. A review of major studies comparing interspinous spacers to lumbar decompression can be found in Table 7.

Table 6 Studies comparing different types of interspinous spacers (ISS)

Author/year	Study design	Sample size (intervention/control)	Indication	Intervention	Control	Outcome measures
Patel 2015 [72]	RCT	250 (123/127)	Moderate LSS with < grade 1 LDS	Indirect decompression with Superion interspinous spacer	Indirect decompression with X-stop interspinous spacer	ZCQ Secondary ODI VAS-Leg VAS-Back Patient satisfaction Radiographic findings Reoperations Adverse events
Nunley 2017[a] [84]	RCT	88	Moderate LSS with < grade 1 LDS	Indirect decompression with Superion interspinous spacer	Indirect decompression with X-stop interspinous spacer	ZCQ Secondary ODI VAS-Leg VAS-Back Patient satisfaction Adverse events (AE)

Table 6 continued

Author/year	Follow-up	Results	Conclusion	USPSTF level of evidence	NASS level of evidence
Patel 2015 [72]	2 years	Primary ZCQ ($p < 0.001$) 34% in Superion vs. 36% in X-Stop group Secondary outcomes ODI: No difference between groups VAS-L: No difference between groups VAS-B: No difference between groups Pt satisfaction: No difference between groups Radiographic findings: No dislodgments Reoperation rate by 24 months: Superion 23.2% vs. X-Stop18.9% AE: similar between both groups	Both interspinous spacers effectively alleviated pain and improved back function to a similar degree through 2 years in patients with moderate LSS who were unresponsive to conservative care	I	II

Table 6 continued

Author/year	Follow-up	Results	Conclusion	USPSTF level of evidence	NASS level of evidence
Nunley 2017[a] [84]	5 years	ZCQ: no statistical difference between groups ODI: No difference between groups VAS-L: No difference between groups VAS-B: No difference between groups Patient satisfaction: No difference AE: Similar between both groups	Demonstrated sustained benefit of the intervention to 5 years	I	II

USPSTF United States Preventative Services Taskforce, *NASS* North American Spine Society, *RCT* randomized controlled trial, *ISS* Interspinous Spacer, *LSS* lumbar spinal stenosis, *LDS* lumbar degenerative spondylolisthesis, *ZCQ* Zurich Claudication Questionnaire, *ODI* Oswestry Disability Index, *VAS* Visual Analogue Scale for back (B) or leg (L)

[a]Nunley 2017 is a continuation of the Patel 2014 study which follows patients out to 5 years

Table 7 Studies comparing interspinous spacers against decompression alone for the treatment of lumbar spinal stenosis (LSS)

Author/year	Study design	Sample size (intervention/control)	Indication	Intervention	Control	Outcome measures
Schneck 2021 [85]	RCT	159 (80/79)	LSS with neurogenic claudication	Indirect decompression with interspinous spacer (ISP)	Decompression alone (DA)	ZCQ RMDQ VAS-B VAS-L Likert recovery score McGill pain score Complications Reoperations
Meyer 2018 [86]	RCT	163 (82/21)	LSS with neurogenic claudication	Indirect decompression with interspinous spacer (ISS)	Decompression alone (DA)	ΔZCQ VAS SF-36 Reoperation OR time EBL

Table 7 continued

Author/year	Follow-up	Results	Conclusion	USPSTF level of evidence	NASS level of evidence
Schneck 2021 [85]	5 years	ZCQ: ISP 68% vs. DA 56%, $p = 0.42$ RMDQ: ISP 7.0 vs. DA 8.6, p = N/A VAS-B: ISP 26 vs. DA 38, $p = 0.02$ VAS-L: ISP 24 vs. DA 32, $p = 0.12$ Likert: ISP 65% vs. DA 63%, $p = 0.72$ McGill: ISP 10 vs. DA 11, p = N/A Re-op: ISP 29% vs. DA 13%, $p = 0.04$	ISS provides similar improvements in symptom burden as bony decompression. Long-term VAS scores were better in the ISS group, however there was substantial reoperation rate the ISS group compared to BD	I	II
Meyer 2018 [86]	2 years	ΔZCQ: at 12 and 24 m ISS − 32.3%, − 37.5% vs. DA − 37.9%, − 35.2% *ISS group not significantly inferior at 12 months ($p = 0.172$) or 24 months ($p = 0.005$) OR time (min) ($p < 0.001$) ISS 23.5 vs. DA 69.9 EBL (ml) ($p < 0.001$): ISS 6.0 vs. DA 188.6 Walking distance, VAS-L and -B: significantly decreased in both groups, but did not differ between groups Reoperations (p = n/a) ISS 20.5% vs. DA 9.7% *All ISS reoperations due to persistent symptoms or device-related complication	Although both groups had significant improvements in ZCQ compared to baseline, this study did not meet the noninferiority threshold for ISS at 24 months. The ISS also had more frequent incidence of treatment failures requiring reoperation	I	II

USPSTF United States Preventative Services Taskforce, *NASS* North American Spine Society, *RCT* randomized controlled trial, *LSS* lumbar spinal stenosis, *ZCQ* Zurich Claudication Questionnaire, *RMDQ* modified Roland-Morris Disability Questionnaire, *VAS* visual analogue scale for back (B) or leg (L), *ODI* Oswestry Disability Index, *SF-36* Short Form Health Survey, *EBL* estimated blood loss

Summary: There is level I and II evidence suggesting improved pain and function scores over 2 and 5 years with the treatment of ISS for LSS with stable LDS.

Percutaneous Image-Guided Lumbar Decompression (PILD)

Percutaneous image-guided lumbar decompression (PILD) is a decompressive strategy to treat neurogenic claudication and spinal stenosis that focuses on removal of the ligamentum flavum. The ligamentum flavum PILD is not intended to debulk lateral foramen or primary bony abnormalities [73, 74]. Ligamentum flavum is very commonly a contributor to the radiographic evidence of spinal stenosis, with estimates as high as 85% [75]. In order to be a candidate for removal (or debulking) the ligamentum, the degree of hypertrophy needs to be 2.5 mm or greater, in the presence of neurogenic claudication.

To date, there have been multiple studies demonstrating the efficacy of this approach [75–77]. There have been three randomized prospective studies investigating percutaneous lumbar decompression of the ligamentum flavum to treat symptomatic spinal stenosis, compared to conservative management or epidural steroid injection.

In addition to reporting superiority to lumbar epidural steroid injections at 1 year, the results had continued improvements at 2 years [75, 77]. In the 2-year MiDAS ENCORE study, Staats et al. followed 143 Medicare patients with central LSS having undergone the MILD procedure. Study patients were required to be 65 years or older and Medicare beneficiaries. Significant improvements were seen in the study endpoints.

A review of major studies on posterior image-guided lumbar decompression (PILD) can be found in Table 8.

Summary: There is level I and II evidence suggesting improved pain and function scores in patients with LSS with neurogenic claudication with the treatment of PILD.

Lumbar Posterior Interspinous Fixation (PISF)

The use of interspinous fixation systems have been proposed as an alternative to pedicle screw fixation in patients undergoing decompression for the treatment of LSS in the presence of spondylolisthesis with or without dynamic instability [35, 36, 78]. Further, interspinous fusion devices have been around for several years as a method of supplemental fixation following lumbar laminectomy or interbody fusion [78]. While pedicle screw fixation constructs are still the most widely used and biomechanically sound method of stabilization, the use of interspinous fusion systems has been proposed to allow for stabilization results with reduced risk. These devices are used at a single level in the thoracic and lumbar spine (T1-S1) for adjunctive fixation in interbody fusion. These devices have been used for degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis with or without dynamic instability, trauma (i.e., fracture or dislocation), and/or tumor.

The use of interspinous fixation devices has been more recently proposed as a means to distract the spinous processes for patients with LSS. Implantation is accomplished by a percutaneous posterior or posterolateral approach, allowing for bony fusion along the spinous processes spanning the index level, along with the barrel of the device. Currently available interspinous fixation devices are intended to be used with bone graft material to provide immobilization and stabilization of the spinal segments and are not intended for stand-alone use. The safety and efficacy of the use of interspinous fixation devices are currently being studied.

A review of major studies on interspinous fixation devices can be found in Table 9.

Summary: There is level II and III evidence suggesting improvement in pain and function scores in patients with DDD plus LSS or LDS treated with PISF.

Table 8 Studies on posterior image-guided lumbar decompression (PILD)

Author/year	Study design	Sample size (intervention/control)	Indication	Intervention	Control	Outcome measures
Deer 2021 [73]	RCT	155 (77/78)	LSS with neurogenic claudication	MILD + CM	CM	Walking Tolerance Test AE
Pope 2021 [87]	Retro	147 (80/67)	LSS with neurogenic claudication	MILD without epidurogram	MILD with epidurogram	Incidence of Nerve injury Infection Hematoma Death Allergy to contrast
Benaymin 2016 [88]	RCT	302 (149/153)	LSS with neurogenic claudication	MILD procedure	Lumbar interlaminar steroid injections (LESI)	ODI NPRS ZCQ-SS ZCQ-PF ZCQ-PS AE
Brown 2012 [89]	RCT	38 (21/17)	LSS with neurogenic claudication	MILD procedure	Lumbar interlaminar steroid injections (LESI)	VAS ODI ZCQ

Table 8 continued

Author/year	Follow-up	Results	Conclusion	USPSTF level of evidence	NASS level of evidence
Deer 2021 [73]	180d	Walking tolerance test at 6 months 3× more patients in MILD group able to complete 1 less patient able to in CMM group ($p < 0.001$) No device or procedure-related adverse events in I or C groups	At 6 months, the MILD Procedure combined with CMM provided statistically superior objective real-world outcomes versus CMM-Alone	I	II
Pope 2021 [87]	90d	No reported complications day of the procedure, at 2-week follow-up, or 3-month follow-up (± 2 weeks) for either the epidurogram or no-epidurogram MILD treatment groups with both bilateral and multilevel treatment groups	MILD was safe to be performed with or without epidurogram	II-2	III

Table 8 continued

Author/year	Follow-up	Results	Conclusion	USPSTF level of evidence	NASS level of evidence
Benaymin 2016 [88]	1y	ODI: ($p < 0.001$) 58% in MILD vs. 27.1% in LESI group NPRS: ($p < 0.001$) 57.3% in MILD vs. 27.1% in LESI group ZCQ-SS: ($p < 0.001$) 51.7% in MILD vs. 31.8% in LESI group ZCQ-PF: ($p < 0.001$) 44.1% in MILD vs. 17.8% in LESI group ZCQ-PS: ($p < 0.001$) 61.5% in MILD vs. 33.1% in LESI group AE: no difference between MILD and LESI groups	MILD was found to provide durable pain relief at 1 year and was found to be statistically superior to LESI. There were no differences in safety between LESI and MILD	I	II

Table 8 continued

Author/year	Follow-up	Results	Conclusion	USPSTF level of evidence	NASS level of evidence
Brown 2012 [89]	6w, 12w	VAS at 6 and 12 weeks MILD group: 3.8 and 3.4 (baseline 6.3) LESI group 6.3 (no 12-week due to crossover) (baseline 6.4) *No difference between group (p = 0.54) but did have within-group improvement ODI at 6 and 12 weeks MILD group: 27.4 and 18.6 (baseline 38.8) LESI group: 34.8 (no 12-week due to crossover) (baseline: 40.5) *No difference between group (p = 0.86) but did have within-group improvement ZCQ at 6 weeks MILD group: 58.8% > 2.5 LESI group: 41.2% > 2.5 *No statistical difference ($p > 0.05$)	MILD provides better pain reduction and improved functional mobility vs. treatment with ESI based on within-group statistically significate improvement. Though no statistical difference was found between MILD and LESI groups	I	II

USPSTF United States Preventative Services Taskforce, *NASS* North American Spine Society, *RCT* randomized controlled trial, *Retro* retrospective, *LSS* lumbar spinal stenosis, *MILD* minimally invasive lumbar decompression, *CM* conservative management, *AE* adverse events, *ODI* Oswestry Disability Index, *NPRS* Numeric Pain Rating Scale, *ZCQ* Zurich Claudication Questionnaire (*SS* symptom severity, *PF* physical function, *PS* patient satisfaction), *VAS* Visual Analogue Scale

Table 9 Studies on interspinous process (ISP) fixation/fusion devices

Author/year	Study design	Sample size (intervention/control)	Indication	Intervention	Control	Outcome measures
Sclafani 2014 [90]	Retro	53	Lumbar DDD + LSS, herniated disc, or LDS	Polyaxial interspinous fusion system	N/A	VAS McNab outcome score
Kim 2012 [91]	Retro	76 (40/36)	Lumbar DDD + LSS, herniated disc, or LDS	Interspinous fusion device with posterior lumbar interbody fusion (IFD)	Spinal fusion with pedicle screw fixation	VAS K-ODI Dynamic lateral radiographs

Author/year	Follow-up	Results	Conclusion	USPSTF level of evidence	NASS level of evidence
Sclafani 2014 [90]	1 y	VAS: Pre-op 7.2, Post-op 4.5, p 0.0001 McNab: Excellent 6, Good 18, Fair 21, Poor 5	The polyaxial interspinous fusion system produces significant clinical improvement when employed to treat patients with stenosis, herniated disc, or low-grade spondylolisthesis	II-3	III
Kim 2012 [91]	1–2 years	VAS: IFD pre-op 7.16, post-op 1.3. Pedicle screw pre-op 8.03, post-op 1.2, $p < 0.05$ K-ODI: reduced significantly in equal amounts in both groups, $p < 0.05$ Radiological outcome: No significant difference Higher incidence of adjacent segmental degeneration in pedicle screw group than the IFD group ($p = 0.029$)	Posterior IFD has several advantages over the pedicle screw fixation in terms of skin incision, muscle dissection and short operative time and less intraoperative estimated blood loss and may be a favorable technique to replace the pedicle screw fixation in selective case	II-3	III

USPSTF United States Preventative Services Taskforce, *NASS* North American Spine Society, *Prospect* Prospective, *Obs* observational, *Retro* retrospective, *DDD* Degenerative Disc Disease, *LSS* lumbar spinal stenosis, *LDS* lumbar degenerative spondylolisthesis, *AEs* adverse events, *VAS* Visual Analogue Score (pain scale), *VAS-L* Visual Analogue Scale for Leg pain, *VAS-B* Visual Analogue Scale for Back pain, *ZCQ* Zurich Claudication Questionnaire, *ODI* Oswestry Disability Index, *K-ODI* Korean Oswestry Disability Index, *PROMIS 29* Patient-Reported Outcomes Measurement Information System, *PGIC* Patient Global Impression of Change

Table 10 Randomized controlled trials comparing decompression with Coflex interlaminar stabilization versus decompression alone or with fusion in patients with moderate-to-severe lumbar spinal stenosis (LSS)

Author/year	Study design	Sample size (intervention/control)	Indication	Intervention	Control	Outcome measure
Grinberg 2020 [92]	RCT	141 (84/57)	LSS ± < grade I LDS	Decompression with interlaminar stabilization (ILS)	Decompression with fusion (DF)	Intraoperative data
						CCS
						VAS-L
Simon 2018 [93]	RCT	116 (77/39)	2-level LSS ± < grade I LDS	2-level Decompression with interlaminar stabilization (ILS)	Decompression with fusion (DF)	ΔODI > 15
						VAS-L
						VAS-B
						ZCQ
						SF-12
						CCS
						Reoperations
Schmidt 2018 [79]	RCT	230 (115/115)	LSS ± < grade I LDS	Decompression with interlaminar stabilization (ILS)	Decompression alone (DA)	ΔODI > 15
						ZCQ success
						ΔVAS > 20
						CCS
Musacchio 2016 [80]	RCT	322 (215/107)	Moderate–severe LSS < grade I LDS	Decompression with interlaminar stabilization (ILS)	Decompression with fusion (DF)	CCS
						VAS
						ODI
						ZCQ
						SF-12

Table 10 continued

Author/year	Follow-up	Results	Conclusion	USPSTF Level of Evidence	NASS Level of Evidence
Grinberg 2020 [92]	5 years	OR time: ILS 100.4 vs. DF 153.1 min, $p < 0.0001$ EBL: ILS 106 vs. DF 358 cc, $p < 0.0001$ LOS: ILS 2.07 vs. DF 3.30, $p < 0.0001$ CCS: ILS 52.7% vs. DF 46.8%, $p = 0.53$ Revision rate: ILS 11.9% vs. DF 14%, p not provided VAS-L: ILS 22.4 vs. DF 21.0, p not provided	Decompression with ILS performed equally to decompression with fusion in patients 65 years or older	I	II
Simon 2018 [93]	5y	CCS: ILS 55.1% vs. DF 36.4%, $p = 0.077$ ΔODI ≥ 15: ILS 86.7% vs. DF 92.9%, $p = 0.1$ No Reoperation/ESI: ILS 68.8% vs. DF 51.3%, $p = 0.065$ ΔVAS-B: ILS 59.8 vs. DF 58.9 ΔVAS-L: Not significantly different between groups, exact numbers not provided *Statistically significant decreases in VAS-B & L occurred in both groups SF-12: Within each group, SF-12 was significantly better than baseline, numbers not provided ZCQ: Significant differences in physical functions score at 6 weeks only (1.76 vs. 2.00, $p = 0.039$)	The 2-level decompression with interlaminar stabilization group performed similarly in patient-reported outcome measures, reoperation rate, and additional epidural steroid injection rates at 5 years	I	II

Table 10 continued

Author/year	Follow-up	Results	Conclusion	USPSTF Level of Evidence	NASS Level of Evidence
Schmidt 2018 [79]	2 years	CCS: ILS 58.4% vs. DA 41.7%, $p = 0.017$ No analgesic injection: ILS 95.5% vs. DA 85.2%, $p = 0.01$ ΔODI ≥ 15: ILS 75.6% vs. DA 70.4%, $p = 0.47$ ZCQ Success: ILS 80.2% vs. DA 81.7%, $p = 0.821$ ΔVAS-L ≥ 20: ILS 85.4% vs. DA 76.1%, $p = 0.14$ ΔVAS-B ≥ 20: ILS 69.5 vs. DA 73.3, $p = 0.48$	Decompression + interlaminar stabilization resulted in significantly higher CCS score, and similar outcomes in patient-reported outcome measures compared to decompression alone. Furthermore, there was a significantly lower rate of postoperative ESI, facet injection, or nerve root block in the interlaminar stabilization group	I	II
Musacchio 2016 [80]	5y	CCS: ILS 50.3% vs. DF 44%, $p > 0.35$ ΔODI ≥ 15: ILS 80.6% vs. DF 74.5%, $p > 0.4$ ΔVAS-B ≥ 20: ILS 85.2% vs. DF 77.8%, $p > 0.25$ ΔVAS-L ≥ 20: ILS 99.2% vs. DF 96.2%, $p > 0.2$ SF-12: Stable, similar improvements from prior time points, specific data not provided ΔZCQ-SS: Favored ILS, $p < 0.01$ ΔZCQ-PF: Favored ILS at 2 years ($p < 0.01$), not at 5 years ΔZCQ-PS: Favored ILS at 3 years ($p < 0.03$), not at 5 years Reoperation rate: ILS 16.3% vs. DF 17.8%, $p > 0.9$ Majority (∼ 70%) of ILS re-ops occurred before 2 years	Decompression with ILS (with Coflex) produces outcomes similar to decompression with pedicle screw fixation. Significant improvements in ODI, VAS, and ZCQ occurred in both groups and were sustained for 5-year follow-up. Reoperation and complication rates were similar between groups	I	II

USPSTF United States Preventative Services Taskforce, *NASS* North American Spine Society, *RCT* Randomized Controlled Trial, *LSS* lumbar spinal stenosis, *LDS* lumbar degenerative spondylolisthesis, *CCS* Clinical Composite Success, *VAS-L* Visual Analogue Scale for Leg pain, *VAS-B* Visual Analogue Scale for Back pain, *ODI* Oswestry Disability Index, *OR time* operating room time, *EBL* estimated blood loss, *LOS* length of stay, *ZCQ* Zurich Claudication Questionnaire (*s* symptom, *pf* physical function, *ps* patient satisfaction), *SF-12* Short Form Health Survey, *ESI* epidural steroid injection

Decompression with Surgical Interlaminar Devices

The Coflex device (Paradigm Spine, New York) is an interlaminar device approved in the lumbar spine from L1 through L5 [79, 80]. Patient selection includes those who have moderate limitations or impairment from spinal stenosis that is improved in flexion. The procedure includes decompression of the stenosis before stabilization with the Coflex device. It can be placed at 1–2 contiguous levels. It is generally accepted for use in patients with up to a grade I spondylolisthesis. It is also avoided with those patients who have had previous decompression, dynamic instability, or severe osteoporosis.

Placement of the device is done via an open approach with a midline incision with minimal removal of spinous process. A laminotomy is performed to decompress the neural structures while maintaining the presence of the spinous process above and below, as well as the central lamina.

The Coflex device was compared to lumbar laminectomy for moderate LSS in a 2-year, multicenter, randomized controlled trial [79]. Patients with moderate to severe spinal stenosis were included and were followed for 2 years. Primary and secondary endpoints were compared within the two groups. Primary endpoints included a composite of four measures including Oswestry Disability Index, secondary surgery or injections, neurological status, and adverse events related to the procedure or device. Secondary endpoints included visual analog scale (VAS) scores, Zürich Claudication Questionnaire (ZCQ) scores, narcotic usage, walking tolerance, and radiographs. There was no significant difference in patient-reported outcomes (ODI, VAS, ZCQ) between the two groups. However, the Coflex cohort did show superiority in the primary endpoints and led to two times the improvement in walking distance as compared to decompression alone. Furthermore, patients in the decompression alone group were more likely to undergo a secondary intervention or injections and were associated with a higher rate of opioid use.

The Coflex device with decompression was also studied in a multicenter, randomized controlled trial in which it was compared to decompression with pedicle screw fusion [80]. Patients with moderate to severe lumbar stenosis at 1 to 2 contiguous levels were evaluated and followed for 5 years. The study looked at four main endpoints including ODI, repeat surgery, further lumbar injections, or adverse events. At the 5-year follow-up, 50.3% of patients in the Coflex group and 44% of patients in the pedicle screw fusion group met all 4 endpoints. ZCQ scores were significantly better in the Coflex cohort. However, the two groups were similar when it came to reoperate rates, improvements in ODI, VAS, and SF-12.

A review of major studies comparing interlaminar stabilization vs. surgery alone can be found in Table 10.

Summary: There is level I and II evidence indicating improved pain and function scores in patients with LSS with grade I LDS treated with the Coflex device.

CONCLUSIONS

Degeneration within the spine is largely the result of time and aging with a cascade of events that include hypertrophied ligamentum flavum, facet joint hypertrophy, degenerative disc disease, and osteophyte formation. Perhaps more prevalent, and a contributing factor, is lumbar spinal stenosis that includes degenerative spondylosis, spondylolisthesis, synovial cysts, annular bulges, ligamentum flavum hypertrophy, facet hypertrophy, post-surgical fibrosis, or a combination of these factors. Spinal surgery has been a staple in the treatment of spinal pathology, but it has also undergone changes in its utility and approach over time.

Minimally invasive techniques have grown tremendously, as highlighted in this paper. Some have level one evidence, while others have none. There is level I and II evidence indicating there is no significant difference in

pain scores and ODI when comparing lumbar fusions to conservative management in patients with degenerative disc disease. There is level I and II evidence showing significantly greater improvement in pain and functional scores in patients treated surgically for lumbar DS. There are mixed results showing whether decompression plus fusion versus decompression alone improved pain and function scores in patients with lumbar DS. There is level I and II evidence suggesting improved pain and function scores over 2 and 5 years with the treatment of ISS for LSS with stable LD. There is level I and II evidence suggesting improved pain and function scores in patients with LSS with neurogenic claudication with the treatment of PILD.

All too often, we ask or have been asked the question "where is the evidence?" It is up to the physician stewardship of our spine and pain space to demand the generation of data and to practice evidence-based guidelines. With this also comes an important consideration for training, appreciation for mechanics of the spine, and to develop a team to help manage potential complications with surgical care. We need to embrace this emerging field and approach it responsibly and civilly.

Through PSPS this evidence review may help outline the evidence for transitional and emerging surgical treatment options for the degenerative spine. It is by no means exhaustive, but purposeful to qualify the strength of evidence available for treatment, and to begin to develop a common language for both spine and pain communities.

Although the review was extensive, this paper did have some limitations. The manuscript is confined to lumbar spine pathology, focusing solely on degenerative disc disease, spondylolisthesis and spinal stenosis. In an effort to publish a concise manuscript featuring the most commonly used approaches, certain surgical techniques, including endoscopic techniques were omitted. Due to the scope of the review, the PSPS committee also did not include any recommendations in this manuscript. Future publications can be considered to include these omitted techniques and recommendations.

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Declarations

Conflict of Interest. Michael J Dorsi serves as a consultant for Abbott, Camber Spine, Life Spine, Nevro, Nuvasive. Patrick Buchanan serves as a consultant and principal investigator for Abbott and PainTEQ. Chau Vu serves as a consultant for Saluda Medical; consultant and principal investigator for PainTEQ. Harjot S Bhandal serves as a consultant for Saluda Medica and principal investigator for Aurora Spine. David W Lee serves as a consultant for Medtronic, Boston Scientific, Mainstay Medical, Petal Surgical; speakers bureau for Abbott. Samir Sheth serves as consultant for SPR, Boston Scientific, Medtronic, and Vertos. Phil M Shumsky serves as a consultant for Saluda Medical. Nolan J Brown has no disclosures or conflicts of interest. Alexander Himstead has no disclosures or conflicts of interest. Ryan Mattie serves as a

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