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Mobility-Preserving Surgery for Lumbar Spinal Stenosis: WFNS Spine Committee Recommendations

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BACKGROUND: **Although decompression is the basis of surgical treatment for lumbar spinal stenosis (LSS), under various circumstances instrumented fusion is performed as well. The rationale for mobility-preserving operations for LSS is preventing adjacent segment disease (ASD). We review the rationale for mobility preservation in ASD and discuss related topics such as indications for fusion and the evolving role of minimally invasive approaches to lumbar spine decompression. Our focus is on systematic review and consensus discussion of mobility-preserving surgical methods as related to surgery for LSS.**

METHODS: **Groups of spinal surgeons (members of the World Federation of Neurosurgical Societies Spine Committee) performed systematic reviews of dynamic fixation systems, including hybrid constructs, and of interspinous process devices; consensus statements were generated based on the reviews at 2 voting sessions by the committee several months apart. Additional review of background data was performed, and the results summarized in this review.**

RESULTS: **Decompression is the basis of surgical treatment of LSS. Fusion is an option, especially when spondylolisthesis or instability are present, but indications remain controversial. ASD incidence reports show high variability. ASD may represent the natural progression of degenerative disease in many cases. Older age, poor sagittal balance, and multilevel fusion may be associated with more ASD. Dynamic fixation constructs are treatment options that may help prevent ASD.**

INTRODUCTION

Although decompression is the basis of surgical treatment for lumbar spinal stenosis (LSS), under various circumstances instrumented fusion is performed as well. The rationale for mobility-preserving operations for LSS is preventing adjacent segment disease (ASD), because fusion of previously mobile levels may increase the movement and load on adjacent levels. Hence, the concept of ASD needs to be defined and its incidence must be determined. If this is a major problem for patients, investment in motion preservation is important.

The focus of our discussion regarding mobility preservation is on patients in whom some form of stabilization is indicated. However, any systematic review of methods to preserve mobility is limited by the fact that there is no consensus on indications for fusion in patients with LSS.

Therefore, our article starts with an overview of the rationale for mobility preservation in ASD. We then mention and discuss the related topics and controversies, such as indication for fusion and the evolving role of minimally invasive approaches to lumbar spine decompression.

We follow with systematic reviews and consensus discussion of mobility-preserving surgical methods as related to surgery for LSS. In this review, we answer 2 main questions: 1) Is there a role of

Key words
- Adjacent segment disease
- Dynamic stabilization of lumbar spine
- Interspinous process devices
- Lumbar spinal stenosis
- Spinal mobility

Abbreviations and Acronyms
ASD: Adjacent segment disease
HSD: Hybrid stabilization device
IPD: Interspinous process device
LSS: Lumbar spinal stenosis
MISS: Minimally invasive spine surgery
PEEK: Polyether ether ketone

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dynamic fixation implants in LSS surgery? 2) Do dynamic fixation implants prevent ASD in LSS?

METHODS

Because mobility-preserving surgery for LSS cannot be discussed separately from all indications and operative methods specific to LSS, we performed systematic literature reviews on several related topics, by separate teams of experts, followed by a series of discussions to form a consensus.

Using PubMed, Ovid Medline, Cochrane Central Register of Controlled Trials, and Cochrane Database of Systematic Reviews, 3 expert spinal surgeons (S.S., M.Z., and F.C.) reviewed the literature from 2008 to 2018 regarding mobility-preserving surgery in the treatment of LSS. The search using key words "Lumbar spinal stenosis," "mobility preservation," and "dynamic fixation" found 60 articles. Sixteen articles were removed during this phase because they discussed interspinous stabilization devices or other subjects. Seven articles were removed because they had been published >10 years previously. Seven articles were removed because they were published in languages other than English. The remaining 13 articles were reviewed (Figure 1).

Basing on the most significant literature, the panel drafted 10 statements presented in Milan in November 2018. After a preliminary voting session, 6 statements were excluded because of the low evidence of existing literature for making a choice. The remaining statements were then presented and voted on at a committee meeting in Belgrade in March 2019. During the second round of review, the questions to answer were: 1) Are interspinous process devices (IPDs) an effective option in the treatment of spinal stenosis? and 2) Can dynamic rod system reduce the risk of adjacent segment syndrome? Hypothetical range of constructs from more flexible to more rigid illustrated in Figure 2.

We excluded total disc replacement from consideration for further consensus discussion and review, because of its limited role in the treatment of LSS.

The second round of the review, for the question on IPDs, had the filters of clinical trials, review, full text, 2008–2018, humans. A total of 36 articles were found and 11 of those were judged relevant by 2 reviewers (F.C. and C.A.).

For the topic of spinal motion–preserving surgery with dynamic implant and lumbar spine, the filters were clinical trials, review, full text, 2008–2018, humans. A total of 21 articles were found; after a first review, 10 articles fit with the topic, of which 5 were considered significant by 2 reviewers (F.C. and C.A.).

Additional articles were reviewed on ASD and a minimally invasive approach to lumbar spine decompression (S.S. and B.R.). Those were used to provide wider context and background to the consensus discussions.

Background

Because the main objective of mobility-preserving operations is to prevent ASD, we tried to answer some relevant questions: Is ASD different from natural history and does it exist? If so, how much does fusion alter the natural history of spine degeneration? Is the incidence of ASD affected by the number of levels fused? Is it influenced by the type of fusion performed? Does ASD occur after decompression without fusion? Does ASD change the patients' outcome? At what rate and how much? Do operations that intend to preserve motion (e.g., minimally invasive approaches and dynamic fusion) affect ASD incidence or patient outcomes? When do we need to perform fusion? Is prevention of ASD the only reason to perform minimally invasive surgery?

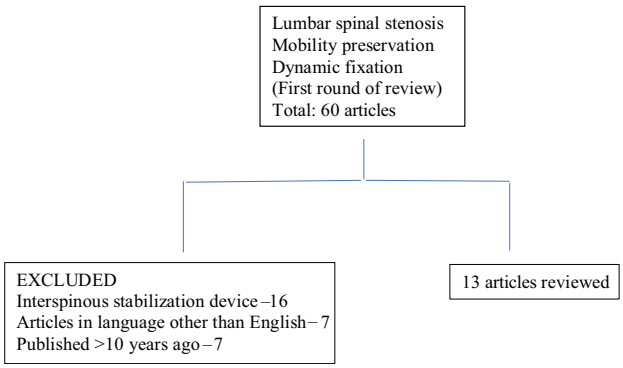


Figure 1. Search strategy.

Definition of ASD. Despite frequent discussions on the problem, there is no universally accepted, validated outcome instrument to diagnose or quantify ASD. Some reasonable attempts at definition have been made.

ASD has been defined as a clinical phenomenon: the presentation of new symptoms referable to an adjacent level after patients have undergone successful surgical treatment of a spinal problem at an index level.[1] It has also been defined as a radiologic finding[2]: a decrease >3 mm in disc height; an intervertebral angle at flexion <5°; progress of slippage >3 mm compared with the preoperative flexion and extension lateral radiographs. In general, 2 terms may be defined: 1) radiologic adjacent segment degeneration, which does not cause any symptoms, and 2) ASD, which causes symptoms.

Clinical Evidence that ASD Exists. A long-term randomized controlled trial (10 years) showed that fusion accelerates

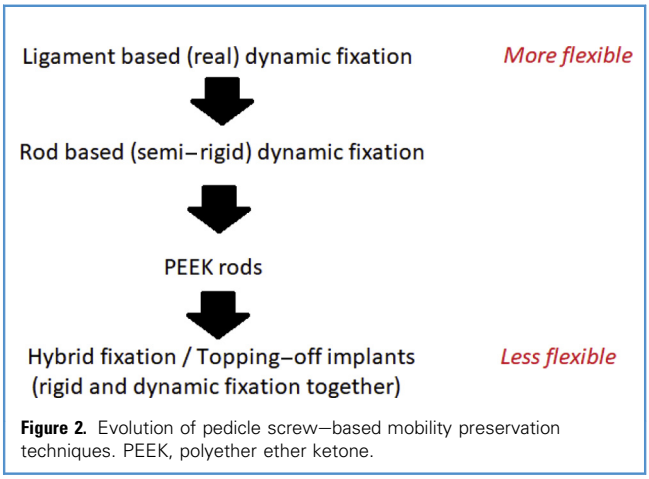


Figure 2. Evolution of pedicle screw–based mobility preservation techniques. PEEK, polyether ether ketone.

degenerative changes at the adjacent level compared with natural history.[3] In that study, the clinical outcome did not seem to be adversely affected by ASD. The rate of ASD after different spinal interventions was similar; we may suspect that ASD represents the natural history of spinal degenerative disease in many cases, or a nonspecific response to surgical intervention. Clinical ASD is less common and the requirement for repeat surgery is rare. Radiologic ASD is common in lumbar spine surgery. The annual incidence of ASD requiring surgery was relatively constant at 1.0% for 10 years after primary surgery in that study.[4] We have not found ASD reported after fusion for trauma in young patients without existing degenerative disease of the spine.

Factors that Affect the Development of ASD. Although ASD has traditionally been attributed to fusion, any intervention, including laminectomy alone, could result in ASD. A large study from Sweden reported a rate of 8% at 5 years after laminectomy in a study of 9644 homogenous patients with spinal stenosis.[5]

In certain conditions, ASD is more common. The risk of ASD seems to increase with age, which is attributable to the decreased ability of the spine to accommodate the biomechanical changes induced by a fusion in old age and existing degeneration at multiple segments in older patients[6] (**Table 1**). Existing ASD does not seem to automatically lead to ASD, but degeneration may progress faster under certain circumstances.[7] Multilevel fusion and facet degeneration were associated with increased incidence of ASD and need for reoperation.[8] In that study, revision surgery for ASD was needed in 2.62% of 1069 patients who underwent fusion, and preexisting facet degeneration was the only significant risk factor involved.

Table 1. Potential Risk Factors for Adjacent Segment Disease

Variable	Potential Risk Factor
Preexisting	Age
	Adjacent segment disc degeneration
	Facet degeneration or tropism of adjacent segment
	Gender
	Obesity
	Osteoporosis
	Smoking
	Physical activity
Surgery-related	Number of fusion segments
	Adjacent segment damage during surgery
	Laminectomy adjacent to fusion
	Fusion method
	Sagittal alignment, pelvic tilt, sacral slope, pelvic incidence, lumbar lordosis
	Floating fusion
	Elimination of tension bands

Table 2. Techniques to Reduce Adjacent Segment Disease

Restoration of fusion segment lordotic angle <15	Minimally invasive surgical techniques Preserving posterior complex
Pelvic tilt <24.3 after TLIF	Preservation of muscles, ligaments, and facet joints
Thoracic kyphosis <23.3 after TLIF	Minimal disc distraction for cage placement
Transitional zone between rigid fused construct and mobile adjacent segment	Motion-preserving technologies
Sagittal vertical alignment >50 mm	Anterior fusion

TLIF, transforaminal lumbar interbody fusion.

As we may expect from dynamic considerations, fusion of 3 or 4 levels increased the risk of revision surgery by 3 times compared with single-level fusions.[9] The effect of multilevel fusion seems to be strongest when L5-S1 is left mobile. Edwards et al.[10] followed up 34 patients with fusion extending from the thoracic spine to L5 for an average of 5.6 years and found that L5-S1 disc degeneration occurred in 61% of patients. L4-5 isolated (floating) fusion may also be associated with more ASD, although the evidence for this remains controversial and not as strong as for leaving L5-S1 unfused with a multilevel construct.[11,12]

Methods to Prevent ASD. Min et al.[13] have reported the radiologic ASD incidence in patients with spondylolisthesis. These investigators found that 44% of patients developed radiologic ASD after anterior interbody fusion, and it was significantly lower than 83% incidence after posterior interbody fusion. However, in other studies, the method of fusion (circumferential vs. interbody vs. posterolateral) has not been shown to be associated with increased rate of ASD.[14] We speculate that anterior fusion alone leaves the posterior elements (muscles and ligaments) intact and thus helps maintain a more physiologic alignment.

Less invasive approaches, which are discussed further later, may help prevent ASD by leaving muscles and ligaments relatively intact. An intact lumbar spine, posterior complex (including spinous process, muscle and interspinous ligaments) plays a critical role of a tension band mechanism to resist a greater flexed moment in biomechanical studies.[15]

Preservation or restoration of spinal alignment, especially in the sagittal plane, has been receiving increasing attention over the past decade. Proper sagittal balance is considered to be important in maintaining alignment with minimum energy expenditure and minimal muscle load.[16] Abnormal sagittal alignment after spinal fusion is believed to be a cause of biomechanical alteration and ASD.[17] Not surprisingly, in a study by Soh et al.[18] in patients followed up for >5 years after lumbar spinal fusion, the most important factor in the prevention of ASD was the restoration of fusion segment lordotic angle per level to >15°.

Preservation of sagittal balance, avoidance of laminectomy next to a fusion, and preservation of posterior elements may reduce

Table 3. Type of Mobility Preservation Implants Proposed for Degenerative Spinal Disorders

	Suggested Indication and Current Status
Total disc replacement	Disc degeneration No role in stenosis
Nucleus replacement	Disc degeneration No role in stenosis Product withdrawn from the market
Interspinous distractor	Moderate lumbar spinal stenosis, disc degeneration
Posterior dynamic instruments (pedicle screw based)	Lumbar spinal stenosis, moderate degenerative instability
Facet replacement	Degenerative instability Not approved by U.S. Food and Drug Administration

incidence of ASD. Minimally invasive spine surgery (MISS) may prevent ASD by preservation of posterior elements. MISS and decompression alone, when appropriate for L4-5 stenosis, may prevent floating fusion versus the need for a large fusion that includes S1 (Table 2).

Minimally Invasive Decompression without Fusion for LSS. Minimally invasive approaches aim to achieve decompression similar to that using more open approaches, through a smaller incision, with relative sparing of muscles and ligaments. If our aim is to perform an operation for LSS with preservation of mobility, less invasive approaches without fusion are a strong option.

Even in patients who had degenerative spondylolisthesis, in addition to LSS, minimally invasive decompression is associated with lower reoperation and fusion rates, less slip progression, and greater patient satisfaction than is open surgery.[19] Minimally invasive laminectomy is an effective procedure for the treatment of LSS. Reoperation rates for instability are lower than those reported after open laminectomy. Functional improvement is similar in patients with and without preoperative spondylolisthesis. This procedure can be an alternative to open laminectomy. Routine fusion may not be indicated in all patients with LSS and spondylolisthesis.[20]

The pooled evidence from large reviews suggests that the unilateral minimally invasive approach for bilateral decompression for LSS may be associated with less blood loss and shorter hospital stay, with similar complication profiles to the open approach. These findings warrant verification in large prospective registries and randomized trials.[21,22]

High perceived patient satisfaction with the minimally invasive approach was seen in a prospective blinded registry study by Roitberg et al.,[23] also noted in a meta-analysis by Phan et al.[22]

MISS and ASD. Preservation of sagittal balance, avoidance of laminectomy next to a fusion, and preservation of posterior elements may reduce incidence of ASD. An intact lumbar spine posterior complex (including spinous process, SSL, and ISL) plays the critical role of a tension band mechanism to resist greater flexion movement. Elimination of the tension band effect in the flexion motion causes the accelerated development of ASD. Therefore, MISS may have a role in preventing ASD.

Even in the presence of spondylolisthesis, the indications for fusion remain controversial. In the SLIP (Greenwich Lumbar Stenosis SLIP) study from North America,[24] 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 was laminectomy alone. The findings were mostly caused by a high rate of reoperation in both arms, greater among patients who did not receive fusion at the first operation. The primary outcome (ODI) was the same in both groups at 2 years.[24] A larger study from Sweden, published alongside SLIP in the same issue of *New England Journal of Medicine*,[25] among patients with LSS, 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.

Arguably, the best motion-preserving surgery for lumbar stenosis is decompression alone, with some advantage to a minimally invasive approach. When fusion is needed because of mechanical instability or deformity, there is no consensus on the optimal method to optimize motion preservation and prevent ASD. However, some methods show promise and data supporting their use.

Beyond limiting surgery to decompression alone, several methods have been devised to treat symptomatic degenerative disease of the spine without solid fixation at the operated level. A study of the outcome of total lumbar disc replacement using the CHARITÉ artificial disc (DePuy Spine Inc., Raynham, Massachusetts, USA) with that of anterior lumbar interbody fusion showed no statistical differences in outcome at the 5-year follow-up time point.[26] Ligamentoplasty, as a motion-preserving method, was compared after ≥2 years with fusion; prevention of ASD did not reach statistical significance.[27] The investigators found no definitive association with age of patient or with performing anterior or circumferential fusion. For our systematic review and consensus, we did not focus on disc replacement or varieties of decompression surgery such as ligamentoplasty. Disc replacement is intended as a treatment for disc degeneration but is not specific to spinal stenosis (Table 3).

CONSENSUS TOPICS

Dynamic Stabilization

Dynamic fixation constructs are intended to provide some stability as well as be less rigid than conventional fixation constructs (e.g., titanium pedicle screw and rod systems). They serve to prevent postoperative ASD.

The concept of mobility-preserving devices includes several distinct types: 1) total disc replacement, 2) nucleus replacement, 3) interspinous devices (for distraction and stabilization), 4) posterior dynamic instruments, and 5) facet replacement. The first 2 techniques have no direct role in LSS. Facet replacement is not approved by the U.S. Food and Drug Administration and should still be considered experimental. Regarding total disc

replacement, after the literature review, the committee in Milan stated that there is no role for these devices in the treatment of LSS.[28,29]

Thus, we focus on posterior semi-rigid systems for our current discussion (semi-rigid screw and rod systems as well as non-fusion IPDs).

Evolution of Mobility-Preserving Operative Methods—Dynamic Stabilization Systems Overview. Evolution of lumbar posterior dynamic implants first started with the use braided polyester cables looped around pedicle screws ("Graf ligament").[30] This was a ligament-based dynamic fixation. It was followed by rod-based (semi-rigid) dynamic fixation devices such as the Cosmic system (Ulrich Medical, Ulm, Germany). Polyether ether ketone (PEEK) rods are the next step in dynamism.[31] The recent trend is for hybrid fixation devices or so-called topping-off implants (rigid and dynamic fixation together).[32] A major criticism of mobility-preserving surgeries is the presence of many types, and new models are forthcoming. This situation creates a lack of experience.

The prototype for lumbar posterior dynamic implants is Dynesys from Zimmer (Zimmer Biomet, Warsaw, Indiana, USA). There are mainly 2 basic types: 1) ligament-based systems (Graf ligament [Intech Inc., Rang-du-Fliers, France], Dynesys [Zimmer Biomet], Fulcrum-Assisted Soft Stabilization [FASS]), which use real dynamic stabilization, and 2) screw-rod systems (Isobar [Scient-x, Guyancourt, France], Cosmic, AccuFlex [Globus medical, Audubon, Pennsylvania, USA], Stabilimax [Applied Spine Technologies, New Haven Connecticut, USA], PEEK rod), which use semi-rigid fixation (**Figure 1**).

Dynamic Fixation with Screw and Rod Systems

The rationale of the use of dynamic systems in surgery of LSS is to construct a segmental remodeling of the loads and limit the abnormality in motions and thus hypothetically reduce the risk of ASD, caused by the fusion surgery of $\geq$1 levels. There is a lack of high-value studies regarding this topic, so making any conclusions is challenging.

Korovessis et al.[33] in 2004 made a prospective comparative randomized controlled clinical and radiologic study to analyze short-term results using rigid, semi-rigid, or dynamic instrumentation for patients with degenerative LSS. These investigators compared 3 groups of 45 patients with a mean follow-up of 47 months. They did not find any significant difference in short clinical outcome or radiologic findings with the use of the different techniques in a short area; complications were similar between the groups. In particular, all techniques maintained an adequate sagittal profile. Furthermore, the investigators did not find adjacent segment degeneration in any patients during the follow-up period. Despite this situation, the small number of patients per group did not lend itself the making of any recommendations in favor or against any instrumentation.[33]

In a more recent study, Lawhorne et al.[34] first applied current indication to the use of dynamic systems (both interspinous devices and pedicle screw—based dynamic systems) to a group of 100 patients and then analyzed feasibility and outcome. In particular, these investigators investigated the use of dynamic systems in a phase of degeneration of the lumbar spine in which there was spondylosis without stenosis (early degenerative phase). In these patients, back pain was caused by abnormal load distribution at disc and facet level. Of patients, 34% underwent IPD placement and 23% underwent pedicle based dynamic systems. Reviewing the literature, the investigators found that indications of dynamic stabilization are challenging. The use of dynamic stabilization can be indicated at an early stage of degeneration, with good results for more than one third of patients. The investigators did not analyze the development of ASD. Further studies comparing dynamic stabilization with traditional decompression and fusion are necessary to make any conclusions.[34]

Hoppe et al.[35] performed a retrospective analysis of prospectively collected clinical data on 39 patients operated on at the L4-L5 level with a long follow-up period (mean, 7.2 years). These investigators found a good outcome in >85% of patients. ASD was diagnosed at the L5/S1 (17.9%) and L3/4 (28.2%) segments but only 6 patients required reintervention because of symptoms. One screw breakage and 4 cases of symptomatic screw loosening were observed; the overall reoperation rate was 21%. However, these results came from a limited number of patients with short instrumentation, so their value is limited.[35]

Veresciagina et al.[36] carried out a prospective observational cohort study to analyze long-term outcome using pedicle screw—based dynamic systems. These investigators performed a study on long-term follow-up in 127 patients and compared their results with the existing literature. They concluded that the use of dynamic stabilization had some advantage in a selected group of patients and in particular in the elderly, with a good clinical and radiologic outcome. These systems could maintain adequate stability to prevent progression of spondylolisthesis in those patients who underwent decompressive surgery without specific indications to fusion. However, in the long-term, they did not find a protective role against ASD, which is one of the reasons for the introduction of such systems, and the reoperation rate was comparable to that of posterior fusion surgery.[36]

Liu et al.[37] analyzed Dynesys dynamic stabilization versus instrumented fusion for the treatment of degenerative lumbar spine diseases in 221 patients with 2 years follow-up. These investigators reported that the Dynesys dynamic stabilization system was cost-effective compared with instrumented lumbar fusion for treatment of single-level degenerative lumbar disorders (level 3 evidence).

A study by Tu et al.[38] of 83 patients (43 in the Dynesys group, 40 in the minimally invasive surgery transforaminal lumbar interbody fusion group) and 3 years follow-up found that Dynesys stabilization resulted in significantly higher preservation of motion at the index level and significantly less hypermobility at the adjacent segments. However, there was no significant difference between the groups in clinical outcome (level 3 evidence).

Hybrid Constructs

The topping-off technique is a new concept. This is a supplementary dynamic instrumentation of the segment cranial to the rigid instrumentation. This technique may be performed by applying dynamic or less rigid fixation such as a hybrid stabilization device (HSD) or IPD for the purpose of avoiding ASD proximal to the fusion construct.

Dobran et al.[39] searched for the incidence of adjacent segment degeneration after the use of a versatile dynamic HSD in lumbar stenosis in 21 patients with 5–8 years follow-up. In this hybrid fixation series, the incidence of ASD was 4.76% (level 3 evidence).

Another study[31] reported that the use of a topping-off device did not reduce the incidence of ASD (level 3 evidence). In 22 patients with a PEEK-based dynamism and 2 years follow-up, the rate of implant failure was 4 cases (18%), and ASD of the segment cranial to the topping off was 3 cases (15%).

Aygun et al.[40] also examined the prevention of segment disease by hybrid constructs. These investigators used pedicle screw fusion in 59 patients (group 1) and pedicle screw fusion plus dynamic pedicle screws (group 2) in 42 patients. Radiologic adjacent segment degeneration was found in 14% (8/59) (group 1) and 11.9% (5/42) (group 2) in caudal segments. Cranial segment degeneration was found in 10% of patients in group 1 (6/59) and 7% of patients in group 2 (3/42). The addition of a dynamic screw to the posterior instrumentation system increased the length of the instrument and the number of segments that were affected. The results were not statistically significant to prevent adjacent segment degeneration (level 3 evidence).

Kashkoush et al.[41] reviewed 66 cases of posterior lumbar instrumentation with the Dynesys Transition Optima implants. In their patient group with a mean follow-up of 5 years, 10 patients (15%) subsequently underwent conversion of the dynamic stabilization portion of their Dynesys Transition Optima instrumentation to rigid spinal arthrodesis (level 4 evidence).

A systematic review by Chou et al.[42] divided articles into 3 groups: 1) fusion alone, 2) topping off using dynamic screws or HSD, 3) topping off using IPD. The fusion-alone group had a statistically higher incidence of radiographic (52.6%) and symptomatic (11.6%) ASD at the index level and a higher incidence (8.1%) of revision surgery. HSD (10.5%) and fusion groups (24.7%) had statistically higher incidences of radiographic ASD at the supra-adjacent level than did the IPD group (1%). The findings suggested that the topping-off technique may decrease the occurrence of ASD at the proximal motion segments. However, the investigators stressed that higher-quality prospective randomized trials are required before wide clinical application.

Loosening in dynamic stabilization systems is not uncommon. In a retrospective study of 126 patients (658 screws), screws of 25 patients (19.8%) loosened.[43] Older patients or those with diabetes have higher rates of screw loosening.

A study by Kim et al.[44] of 25 patients with minimum 5 years follow-up (Interspinous U [currently Coflex, Paradigm Spine, New York, New York, USA], 18 patients; DIAM [Medtronic Ltd., Memphis, Tennessee, USA], 7 patients), patient satisfaction was 50% for the interspinous distractor device, and 43% in the DIAM group. The investigators concluded that long-term follow-up Interspinous U and DIAM showed low patient satisfaction and poor radiologic outcomes.

Semi-rigid or dynamic fixation of the lumbar spine is intended to stabilize the motion segment without fusion. The optimal rigidity is not well known. Its main aim to decrease the incidence of radiologic or clinical adjacent segment degeneration has not been supported yet with high-quality articles. Dynamic rod and screw systems require further studies. They are still a relatively rigid construct. Screw loosening may occur. Furthermore, dynamic rod and screw systems did not seem to change the rate of further operations.

Based on the presented literature and personal clinical experience the committee voted as follows:

Statement 1. ASD incidence reports display high variability. It may be rare with single-level fusion or in patients with minimal degenerative disease. Risk factors are: Floating L4-L5 fusion, poor sagittal balance, multilevel fusion. This statement reached a strong positive consensus (25% voted Likert scale grade 5, 25% voted grade 4, and 50% voted grade 3).

Statement 2. Dynamic fusion constructs are treatment options that may help to prevent ASD. This statement reached positive consensus (33% voted Likert scale grade 5, 45% voted grade 4, and 22% voted grade 3).

Interspinous Devices

Interspinous devices have been extensively studied. One recent work[45] comparing decompression and fusion with the Coflex system dynamic fixation in a 78-patient cohort and 1 year follow-up commented that dynamic fixation Coflex treatment can reduce the influence on adjacent segments and delay degeneration (level 3 evidence).

Wilke et al.[46] investigated the biomechanical effects of 4 different types of IPD. In particular, they analyzed the primary stabilizing effect for the lumbar spine and the intradiscal pressure of the motion segment in in vitro flexibility tests. All implants showed similar effects. As expected, all 4 interspinous implants examined had the best stabilizing effect in extension, whereas less stability was achieved in flexion. Also, for the unloading of intradiscal pressure, the most significant effect was in extension but there little effect on range of motion and intradiscal pressure in flexion, lateral bending, and axial rotation.[46]

Kabir et al.[47] performed a systematic review of clinical and biomechanical studies and analyzed the main outcome based on validated patient-related questionnaires and biomechanical studies to evaluate the effects of interspinous devices on the kinematics of the spine. These investigators found only 2 studies of high methodology quality and a lack of data regarding long-term follow-up, revision surgery, complications, and failure. They concluded that interspinous devices may have a potentially beneficial effect only in a select group of patients with degenerative disease of the lumbar spine. However, further studies are needed to clearly indicate their use in clinical practice.[47]

National Association of Spine Specialists guidelines[48] state that there is insufficient evidence to make a recommendation for or against the placement of interspinous devices in patients with LSS.

Moojen et al.[49] studied the effect of interspinous devices in neurogenic claudication in 159 patients with a follow-up period of 8 weeks, in a randomized multicenter prospective controlled trial. These investigators did not find any superiority of the interspinous devices in respect to standard decompression (63% vs. 72%), and furthermore at a second follow-up, only 48% persisted with successful recovery with a high reoperation

rate. Based on these facts, Moojen et al. posed the question "Why use interspinous devices instead of performing decompressive surgery as first-line treatment?".[49]

Gazzeri et al.[50] carried out a review to provide a comprehensive overview on interspinous implants, their mechanisms of action, safety, cost, and effectiveness in the treatment of LSS and degenerative disc diseases. These investigators found that although the initial reports represented the interspinous device as a safe, effective, and minimally invasive surgical alternative for relief of neurologic symptoms in patients with low-back degenerative diseases, recent studies have shown less impressive clinical results and a higher rate of failure than initially reported. Gazzeri et al.'s[50] conclusion is similar to that of Moojen et al.,[49] that there is not sufficient evidence to conclude whether any beneficial effect from interspinous process decompression provides significant advantages over laminectomy.

In addition, many recent studies have reached similar conclusions. Phan et al.,[51] in their meta-analysis of 11 comparative studies, found no differences between interspinous devices and decompressive surgery in particular for mid-term to long-term, with fewer surgical complications but higher reoperation rates and costs. These investigators concluded that the role of interspinous devices as stand-alone or adjunct devices for LSS surgery needs to be scrutinized, with careful consideration of the risks, benefits, and costs before implantation. The implant could be a suitable option for elderly patients.[51]

Other studies concluded that the use of interspinous devices could be an effective option in patients not eligible for standard open surgery.[52-54]

Meyer et al.[55] in 2017 reached a different conclusion regarding the effects of IPDs in intermittent neurogenic claudication. These investigators performed a multicenter international randomized controlled trial of 163 patients comparing implantation of interspinous devices and decompressive surgery with a follow-up period of 24 months. They showed that a minimally invasive percutaneous interspinous device was safe and noninferior to stand-alone decompressive surgery for patients with degenerative LSS with intermittent neurogenic claudication. This finding confirms 3 recent randomized controlled trials showing that an interspinous device as well as open decompression achieve similar results in relieving symptoms in highly selected patients, but at the price of a higher reoperation rate for interspinous devices (29%–26% to 6%–8% at 12 and 24 months, respectively).[55]

Laratta et al.[56] performed a retrospective database study. They found a progressive decline in the use of interspinous devices from 2008 to 2014 in the United States. In addition, the total costs for the procedure increased by 28%. These investigators stated that this fixation method showed improved efficacy versus nonoperative modalities, but recent literature shows increased cost-effectiveness and decreased reoperation rates with traditional bony decompression.[56]

The statement regarding the use of IPDs that was presented in Milan ("Stand-alone interspinous devices have an indication in treatment of LSS without instability") was excluded from the voting session in Belgrade because of the low evidence of literature necessary for making a recommendation.

CONCLUSIONS

The scientific data available do not yet provide information regarding the role of dynamic fixation implants in LSS surgery. Outcomes of low-class studies comparing rigid fixation with dynamic fixation devices are similar. The new shift to hybrid fixations should further be evaluated. Therefore, we conclude that dynamic fixation implants may prevent ASD in LSS, but the conclusion remains at the option level, and overall clinical outcome may not be significantly affected. Before recommending wide use of dynamic fixation implants, long-term outcome registry results and multicenter controlled studies are necessary.

Strong claims regarding dynamic fusion devices and interspinous devices about prevention of adjacent level disease do not have adequate support in the literature to make a recommendation, and no new standard of care can be established.

Although there are no conclusive data, the maintenance or restoration of sagittal balance as well as MISS approaches preserving posterior elements seems to play a role in preventing ASD and must be taken into consideration.

WORLD FEDERATION OF NEUROSURGICAL SOCIETIES SPINE COMMITTEE RECOMMENDATIONS

* Decompression is the basis of surgical treatment of lumbar spinal stenosis.
* Fusion is an option, especially when spondylolisthesis or instability are present, but indications remain controversial.
* Adjacent segment disease (ASD) incidence reports display high variability. ASD may represent the natural progression of degenerative disease in many cases. It may be rare with single-level fusion (except "floating fusion" at L4-5), or in patients with minimal degenerative disease. Older age, poor sagittal balance, multilevel fusion may be associated with more ASD.
* Dynamic fixation constructs are treatment options that may help to prevent ASD.

DECLARATION OF COMPETING INTEREST

The authors declare that the article content was composed in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

CRediT AUTHORSHIP CONTRIBUTION STATEMENT

Ben Roitberg: Writing - original draft, Writing - review & editing. **Mehmet Zileli:** Writing - original draft, Writing - review & editing. **Salman Sharif:** Writing - original draft, Writing - review & editing. **Carla Anania:** Writing - original draft, Writing - review & editing. **Maurizio Fornari:** Writing - original draft, Writing - review & editing. **Francesco Costa:** Writing - original draft, Writing - review & editing.

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