Treatment of degenerative spondylolisthesis: potential impact of dynamic stabilization based on imaging analysis

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Abstract Intraspinous and pedicle screw-based (PSB) dynamic instrumentation systems have been in use for a decade now. By direct or indirect decompression, these devices theoretically establish less painful segmental motion by diminishing pathologic motion and unloading painful disks. Ideally, dynamics should address instability in the early stages of degenerative spondylolisthesis before excessive translation occurs. Evidence to date indicates that Grade II or larger slips requiring decompression should be fused. In addition, multiple segment listhesis, severe coronal plane deformities, increasing age, and osteoporosis have all been listed as potential contraindications to dynamic stabilization. We reviewed the exclusion and inclusion criteria found in various dynamic stabilization studies and investigational drug exemption (IDE) protocols. We summarize the reported limitations for both pedicle- and intraspinous-based systems. We then conducted a retrospective chart and imaging review of 100 consecutive cases undergoing fusion for degenerative spondylolisthesis. All patients in our cohort had been indicated for and eventually underwent decompression of lumbar stenosis secondary to spondylolisthesis. We estimated how many patients in our population would have

been candidates for dynamic stabilization with either interspinous or pedicle-based systems. Using the criteria for instability outlined in the literature, 32 patients demonstrated translation requiring fusion surgery and 24 patients had instability unsuitable for dynamic stabilization. Six patients had two-level slips and were excluded. Two patients had coronal imbalance too great for dynamic systems. Twelve patients were over the age of 80 and 16 demonstrated osteoporosis as diagnosed by bone scan. Finally, we found two of our patients to have vertebral compression fractures adjacent to the site of instrumentation, which is a strict exclusion criteria in all dynamic trials. Thirty-four patients had zero exclusion criteria for intraspinous devices and 23 patients had none for PSB dynamic stabilization. Therefore, we estimate that 34 and 23% of degenerative spondylolisthesis patients indicated for surgery could have been treated with either intraspinous or pedicle-based dynamic devices, respectively.

Keywords Dynamic stabilization · Degenerative spondylolisthesis · Dynamics · Spinal fusion

Introduction

Kirkaldy-Willis divided the spectrum of degenerative changes in the lumbar spine into three distinct phases: (1) temporary dysfunction; (2) instability; and (3) re-stabilization. Stage 1 degeneration is likely to respond to conservative measures. In terms of accepted treatment guidelines, treatment of early stage 2 disease has been a gray area in which conservative measures have been the treatment of choice, but have a diminishing effect. Late stage 2 cases are most likely to be treated with stabilization/fusion surgery. Finally, in stage 3 the role of

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decompression without fusion serves a role. Dynamic stabilization offers an opportunity for more aggressive treatment of patients in the early stage 2 of Kirkaldy-Willis degeneration [9].

Some patients with degenerative spondylolisthesis can be treated with decompression alone or with fusion. A certain number of both groups do not do well. Therefore, we perceive degenerative spondylolisthesis (DS) patients as ideal candidates for evaluating the applicability of dynamic stabilization. Degenerative spondylolisthesis is a segmental destabilization, which is the result of multifactorial degenerative changes in the low lumbar spine. A number of factors have been associated with its development including: disk degeneration, facet joint orientation, gender, ligament hyperlaxity, and physical overactivity [19].

From a pathoanatomic perspective, DS evolves from degeneration of the disk. It eventually reduces its stiffness and places greater stress on the facets. When subjected to shear forces, this may lead to subluxation. Because of the inherent stability of L5 and occasional presence of L5 sacralization, the L4-5 and L3-4 levels are more frequently affected. Progression of a slip results in facet hypertrophy and disk bulging, which in turn contribute to forward displacement of the thecal sac. Imaging studies demonstrate diminished cross-sectional area of the cauda equina, facet degeneration, and hypertrophy, and diffuse disk buckling and degeneration. All of these factors contribute to the symptoms of spinal stenosis and therefore are important in characterizing the extent of the disease.

Fusion the best answer?

Until recently, surgical options in the treatment of degenerative lumbar spondylolisthesis have been limited. The two options available to the surgeon had been to either: (1) treat symptoms with conservative measures including physical therapy and injections; or (2) proceed with operative decompression with or without fusion. In prior years, inconsistent fusion rates had been accompanied by unreliable success. With the advent of fusion technologies such as cages and segmental instrumentation, the rate of fusion in degenerative cases now approaches 95%. Unfortunately, the outcomes of fusion surgery have failed to improve at an equal rate. Even the most skilled surgeons achieve only a 50–70% good to excellent outcome with fusion surgery [2, 25]. Also, there is no correlation to attain fusion success and clinical outcome; meaning, not all pseudoarthroses are painful nor are all successful fusions painless [23]. One could argue that if instability alone were the cause of back pain, successful fusion should fix the problem every time. By fusing and stopping all motion (both normal and abnormal) one has not solved the problem. Poor results

associated with fusions have been associated with abnormal loading at the bone–metal interface after cage insertion. Polikeit [17] demonstrated that cage insertion increased the stress and markedly altered the load transfer of the endplates. Similarly, McAfee [12] demonstrated that clinical success of fusion was dependent upon solid bone formation around the cage, resulting in an increase in the area of load transmission and decrease in the load over the footprint of the cage. Sengupta [23] concluded from this data that improvements in back pain in surgery depend more on the creation of a normal loading pattern than from the inhibition of motion.

In addition, fusion carries with it the added risk of adjacent segment disease in the long term. There have been numerous studies examining the risk factors for and consequences of this post-fusion complication including accelerated degeneration of adjacent segments and flat back syndrome [16]. Maintaining the protective effect of segmental motion can theoretically reduce the acceleration of adjacent segment degeneration [24].

Dynamics: unloading, not unmoving

Dynamic stabilization has arisen as a means to alter load transmission across degenerated spinal segments while avoiding the aforementioned problems with fusion. Using variable constructs, this technique has several theoretical advantages over fusion: (1) adjacent level protection [15, 24]; (2) protection of rotatory stress to the sacroiliac joint during sitting [10]; (3) maintenance of normal resting posture [6]; (4) shorter OR time [24]; (5) requirement of fewer levels of treatment, because unlike fusion one can stop below adjacent segments with degeneration [24].

Two classes of dynamic stabilizers, intraspinous- (IS) and pedicle screw-based (PSB) dynamic systems have been in use for almost a decade now outside of North America. These devices theoretically establish less painful segmental motion by diminishing pathologic motion and unloading painful disks. Interspinous distraction devices (X-Stop, Wallis, DIAM, Coflex) function by “inducing flexion” in the degenerative segment and result in less buckling of the ligamentum flavum, offloading of the facets, and reduce IVD pressures [4]. PSB dynamics systems (Graf ligament, Dynesys, Isobar, DSSS, M-brace, TFAS and TOPS) offload spinal units in a fashion similar to pedicle-based posterior instrumentation [20]. Because they do not depend on the presence of posterior elements, pedicle-based systems can be used with posterior decompression.

Whereas randomized studies have shown that fusion is beneficial in degenerative spondylolisthesis with spinal stenosis, it is debatable whether added instrumentation is beneficial [11]. Dynamic systems may combine advantages

Table 1 Summary of exclusion criteria for interspinous (IS) dynamic stabilizers

Exclusion criteria Source	Xstop		Wallis		Coflex	DIAM	Average interspinous exclusion
	Thunder	Zucherman ESJ	Senegas	Spine Health.org	Kim	Singh	
Instability	“instability”	“instability”	No DS	>2 mm on flex/ext	>4 mm	“unstable”	>3 mm translation
Degree of slip	>Grade I	>Grade I	No DS	N/A	>Grade I	>Grade I	>Grade I
Age	N/A	>50	“younger” preference	18–60	No “elderly” (max = 71)	N/A	Age > 80
Scoliosis	>25°	>25°	N/A	>25°	“severe”	“significant”	>25° scoliosis
Quality of bone	Severe OP	Severe OP	OP	Severe OP Dexa < −2.5	OP	OP	Any OP
Fracture of body	Body fx	Path fx	N/A	N/A	N/A	Body fx	Any body fx
Double spondy	N/A	Yes	N/A	Yes	N/A	N/A	Double OK
Other	–	–	No Modic 2 or 3 no L5–S1 lesion	–	–	–	

DS degenerative spondylolisthesis, OP osteoporosis, fx fracture

of both: providing more stability than decompression alone, and being less invasive than instrumented fusion [24].

Materials and methods

Our study was performed in two parts. In Part 1, we surveyed the literature and current investigational drug exemption (IDE) studies to determine the indications for using dynamic stabilization systems. In Part 2, we retrospectively applied these criteria to a group of 100 consecutive degenerative spondylolisthesis patients who had undergone surgery in our practice. The objective was to estimate the percentage of our DS patients who could have undergone dynamic stabilization with either interspinous or PSB systems.

Part one: review of indications

After reviewing the literature and IDE protocols, we assembled a list of criteria, which are considered in studies using both IS and PSB dynamic stabilization. Most of the listed inclusion/exclusion criteria for dynamic stabilizers are true for any operative DS candidate: they have moderate to severe lumbar spinal stenosis with leg pain, they have failed conservative treatment (NSAIDs, PT, injections), they have had no prior fusion surgery and have no significant comorbidities precluding them from surgery. However, there were several inclusion/exclusion criteria in the dynamic studies that differentiated these patients from other DS patients. They included: (1) instability on flexion/extension radiographs; (2) degree of spondylolisthesis slip; (3) age of patient; (4) degree of scoliosis; (5) degree of

osteoporosis; (6) presence of vertebral body fracture; and (7) the number of levels of slip present. These criteria were uniformly mentioned in the literature and IDE studies of dynamic devices, and it was with these criteria that we determined our estimation of potential utility of dynamic stabilization (Tables 1, 2).

Degree of slip

Dynamic stabilization systems are limited to cases with relatively minor deformity [24]. Ideally, dynamics should address instability in the early stages of degeneration before excessive translation occurs [9, 20]. Schwarzenbach [20] believes that severe segmental instability and advanced disk disease increase the risk of failure in dynamic devices. The dynamic device studies to date have allowed only Grade I slip for interspinous and PSB systems (Table 1). Evidence to date indicates that Grade II or larger slips requiring decompression should be fused [1].

Multiple-level slips

Multiple segment anterolisthesis has not been evaluated in most dynamic studies addressing spondylolisthesis [14, 21]. Patients with multiple-level listhesis will therefore be excluded as dynamic candidates. The Dynesys IDE did allow double-level DS slips; however, the large Dynesys study by Stoll et al. [24] did not.

Coronal deformity

The dynamic stabilizers are designed to stop progression of only minor deformity in the coronal plane [24]. Dynesys has been found to be useful in early stages of degenerative,

Table 2 Summary of exclusion criteria for pedicle screw-based (PSB) dynamic stabilizers

Exclusion criteria	Dynesys		Graf	TOPS	Isobar	Average PSB exclusion
Source	IDE	Stoll EJS	Kim	Khoo	Castellvi	
Instability	“unstable DS”	N/A	N/A	DS	N/A	>10 mm translation
Degree of slip	>Grade I	N/A	>Grade I	>Grade I	>Grade II	>Grade I
Age	20–80	27–85 (average 58)	N/A	40–75	N/A	Age > 80
Scoliosis	>10°	N/A	Any “scoliosis”	>10°	Any “scoliosis”	>10° scoliosis
Quality of bone	OP Dexa < −2.0	N/A	N/A	OP	OP	Any OP
Fracture of body	“body fracture”	N/A	N/A	“compromised” body	“body fracture”	Any body fx
Double spondy	Yes	No (single only)	N/A	No (single only)	N/A	Double OK
Other	Obesity	–	–	–	–	

DS degenerative spondylolisthesis, OP osteoporosis

Table 3 Summary of 100 DS patients

N	100
Male	40
Female	60
Slip percentage (%)	18
(range 0–62.5%)	Meyerding I
Age (range 34–84)	68.1
Lumbar scoliosis	
Average curve (degrees)	12.2 ± 5.6
Osteoporosis (n)	16
Body fracture (n)	2
Level of spondy	
L 3/4	4
L 4/5	86
L 5/1	4
L3/4, L4/5	3
L4/5, L5/1	3

DS degenerative spondylolisthesis

gradual scoliosis, but as the deformity becomes more pronounced, failure is more likely [20]. Currently, the maximum amount of degenerative scoliosis permitted in Dynesys investigational trial is listed as 10°. The same is true for the other PSB devices analyzed here. The interspinous device protocols have uniformly allowed up to 25° of coronal deformity and for this reason we will differ in our threshold for scoliosis between the IS and PSB groups (Table 3).

Instability

Translation of greater than 3 mm or 5–10° of rotational movement on lateral flexion-extension radiographs is radiographic evidence of instability [1]. In the past, this definition of instability has been an absolute indication for fusion [5]. Some interspinous dynamic devices even list 2 mm as a contraindication to their use [4]. However, most

of the interspinous IDE's exclude cases of more than 3 mm of translational movement as seen on flexion-extension films including Coflex, XStop, and Wallis. The PSB systems can tolerate more instability and they uniformly do not define a maximum translation as exclusion criteria [7].

Age, osteoporosis, and fracture

Sengupta, a pioneer in dynamics, feels that dynamic stabilization is ideal for younger patients. In a younger patient with longer follow-up and greater physical demands, the likelihood of eventually developing adjacent disease with rigid fixation would be higher [21]. In the older population one may be more inclined to use dynamics in the patient who might be at higher-risk for a more invasive fusion procedure. However, there have been some limitations defined with dynamics in elderly patients with osteoporotic bone [20]. Unlike a fusion implant, a dynamic implant-bone interface will be actively tested on a daily basis for the life of the patient. Currently, most IS and PSB devices have set an upper limit of use around 75–80 years of age for their IDE (TOPS, Dynesys, Coflex, Wallis). All studies have exclusion criteria that include a diagnosis of osteoporosis and or chronic insufficiency fractures of the vertebral bodies [27]. For the purpose of this study, we have defined an age greater than 80, a diagnosis of osteoporosis, or a history of insufficiency fracture as reasons to exclude any type of dynamic stabilization as a surgical option.

Table 1 outlines the exclusion criteria for interspinous dynamic stabilizers while Table 2 outlines the exclusion criteria for PSB dynamic stabilizers.

Part two: radiographic evaluation of 100 degenerative spondylolisthesis patients

We then reviewed and analyzed pre-operative imaging of a cohort who underwent surgery. We conducted a retrospective chart and image review of 169 consecutive cases

performed by the two senior authors (FG and FC) prior to 1 September 2005. Each patient's medical record number, age, and sex were recorded. Outpatient folders as well as the most recent XRs, CTs, and MRIs were reviewed. Radiographic measurements were assessed by an orthopedic surgery chief resident. All measurements on films were performed by hand. Patients with any history of previous lumbar surgery, congenital anomalies, history of infection, trauma or tumor disorder of the spine were excluded. Presence of spondylolysis was another exclusion criteria. All patients in our cohort satisfied indications for and eventually underwent decompression of lumbar stenosis secondary to spondylolisthesis. After excluding the aforementioned patients, 100 patients remained for further evaluation.

Radiographic evaluations

Plain AP and lateral radiographs of the entire lumbar spine were available in all patients. The amount of slip was quantified by the Meyerding classification system and by slip percentage as measured and described by Wiltse and Jackson [26]. If more than one level presented with spondylolisthesis, each slip was recorded and measured separately. All anterior, intervertebral, and posterior lumbar disk heights were recorded. Using lateral upright flexion/extension radiographs, we recorded slip stability and reducibility. This was assessed by remeasuring the slip percentage in both extension and flexion. Unstable slips were defined as >3 mm of anterior translation on flexion films [8]. Maximum forward flexion and extension for each lumbar segment gave us the arc of motion allowed at each level. Cobb angles of structural and fractional coronal curves, curve flexibility, and the presence of lateral listhesis were all documented.

Results

One-hundred and sixty-nine consecutive patients with a diagnosis of anterior degenerative spondylolisthesis presented for surgery with the two senior authors (F. C. and F. G.) between the time period of 3 January 2001 and 14 July 2005. Thirty-seven of these patients had undergone prior lumbar surgery, leaving 123 patients. A careful review of the medical histories was undertaken to exclude the diagnoses of rheumatoid arthritis (3), Paget's disease (1), or other underlying metabolic disease that may have contributed to a degenerative pattern. Due to insufficient available imaging, 18 of the remaining patients were excluded from the study. We were left with 100 patients who underwent primary lumbar decompression $\pm$ fusion to address degenerative lumbar spondylolisthesis. 100% of

the patients had a concomitant diagnosis of lumbar spinal stenosis.

Description

As Table 3 demonstrates, our group consisted of 60 females and 40 males. The average age was 68.0 years with a standard deviation of 10.2 years. Six patients had two-level disease. There were no three-level slips. Eighty-six single-level slips occurred at the L4-5 level, whereas four single slips occurred at L3-4 and four single slips at L5-S1. All six double-level slips involved the L4-5 segment.

The mean slip percentage was 17.9% (Meyerding I). Thirty-one patients were deemed unstable with an increase of ≥ 3 mm translation on lateral flexion radiographs. The average arc of motion for slip segments with slips was 6.7° from maximum flexion to maximum extension. The average disk height at the level of the slip decreased from anterior to posterior. The average posterior height was 9.1 mm, the middle disk height was 8.6 mm, and the posterior disk height was 6.5 mm.

Fifty-six (54%) of patients had coronal deformity presenting as lumbar scoliosis. The curves were usually small with an average of 12.5° and a standard deviation of 5.4° .

Candidates for dynamic devices

We conservatively estimated how many of our patients would be candidates for either interspinous or PSB dynamic stabilization. We evaluated each of our 100 cases in the context of the aforementioned exclusion criteria to come up with an estimate of dynamic candidates. Table 3 outlines each step in the exclusion process.

Using the criteria of instability outlined above (more than 3 mm of translation or more than 10° of rotation) we determined that 32 of our 100 patients demonstrated translation consistent with instability. As mentioned above, these patients would be poor candidates for any interspinous device treating spinal stenosis. In contrast, PSB systems can handle relative instability. We determined that 24 of our 100 patients had slips greater than 25%.

Six patients from our cohort had double-level slips and were excluded from interspinous device usage. Some PSB systems have allowed adjacent two-level usage, but not at the level of degenerative spondylolisthesis [20, 24].

In the coronal plane, $>25^\circ$ of scoliosis was found in only two patients from our cohort. However, 39 patients demonstrated curves greater than 10° . Both the TOPS and Dynesys devices are limited to curves less than 10° according to their IDEs. The PSB systems lost a significant number from the cohort with this exclusion criteria. Since the interspinous devices are more tolerant of coronal

Table 4 Exclusion Criteria applied 100 DS patients

100 Degenerative Spondy Patients ∨		
<u>Include</u>		<u>Exclude</u>
68	Instability	32
100	≥ 3mm translation	0
	≥ 10mm translation	
76	> Meyerding I	24
88	Age > 80	12
98	Scoliosis	2
61	< 25 degrees	39
	< 10 degrees	
84	Osteoporosis	16
98	Body Fracture	2
94	Double Spondy	6

Interspinous Candidates:

34%

34 of 100 with no Exclusion Criteria

Pedicle Screw Based Candidates:

23%

23 of 100 with no Exclusion Criteria

*DS = Degenerative Spondylolisthesis

deformity allowing up to 25°, only two cases were excluded from their usage based on scoliosis.

Age and osteoporosis were other factors listed as possible limitations in the application of dynamic stabilization. The age and osteoporosis exclusion criteria are the same for both interspinous and PSB systems. In our group of 100, 12 patients were over the age of 80 and 16 demonstrated osteoporosis as diagnosed by DEXA scan. Finally, we found two of our patients to have vertebral compression fractures adjacent to the site of instrumentation, a strict exclusion criteria in all dynamic trials.

For each individual case in our study, we summed the total number of exclusion criteria for both interspinous and PSB systems. For usage of interspinous devices, the average number of exclusion criteria per case was 1.2. A total of 34 patients (34%) had zero exclusion criteria and were therefore considered potential candidates for interspinous device. In the case of PSB systems, there was an average of 1.1 exclusion criteria per case. Twenty-three of 100

patients (23%) had zero exclusion and therefore would be candidates for pedicle-based dynamic systems (Table 4).

Discussion

Current interest in dynamic stabilization has been driven by dissatisfaction with current techniques addressing lumbar degeneration. Recent publications have shown dynamics to have promise in the treatment of early degenerative lumbar stenosis [3, 18, 27]. Degenerative spondylolisthesis offers a greater challenge for dynamic stabilization for it is a process in which abnormal loading is accompanied by abnormal positioning.

Accurately defining the indications for these new technologies is an ongoing challenge. No studies have identified predictors of success in relation to indications and most are limited in their power secondary to small sample sizes [7].

In the setting of degenerative spondylolisthesis, instability in flexion-extension radiographs has served as an effective indicator for fusion [5]. However, when there is relative stability, is dynamic stabilization a viable option? Dynamic stabilization leaves the spinal segment mobile, and its intention is to alter the load-bearing pattern of the motion segment and control abnormal motion [22]. Successful dynamic stabilization therefore seems to be highly dependent upon the current load distribution across the end-plates. This might be evaluated in the DS spine in two ways. (1) The first involves the congruency of opposing endplates. Do they have irregularities that cause them to buckle? Are there osteophytes that prevent them from loading in a physiologic manner? Have Schmorl's nodes developed? Close examination of AP and lateral radiographs should give an indication of their congruency. (2) The second involves the orientation of opposing endplates. Especially in the setting of spondylolisthesis, it is important to notice whether the endplates are still oriented in parallel planes. In the case of pure anterior translation, the endplates should be for the most part congruent in their loading surfaces regardless of the amount of translation. On the other hand, if the superior body begins to tilt forward or "recline", this causes an increased contact point at the body to body interface. A pressure profilometry study revealed the anisotropic properties of degenerated disks, and showed that patterns of loading, rather than the absolute levels of loading, was related to pain generation in the degenerated spine [13]. Grob [7] proposes that dynamic systems will fail some patients whose pain is the result of high spot-loading in certain positions, rather than movement per se. Fusion, he argues, eliminates all possible moving into painful positions, whereas the potential to trigger such points still exists in dynamic stabilization.

In this conservative estimate, 34% of DS patients would be suitable for intraspinal dynamic devices and 23% candidates for PSB devices. It is important to note that dynamic stabilization devices can and should be employed prior to the need for decompression and fusion. Our estimate therefore does not include the candidates who were not also indicated for surgical decompression. Many surgeons think that in the early stages of disease progression, dynamic devices would be more optimally employed [20, 21]. The enormous growth potential of dynamic stabilization lies in the evolution of surgical indications such that patients who are treated non-surgically today may be treated surgically in the future. In addition, dynamics have a role in revision lumbar disease [20]. Our study was limited to degenerative spondylolisthesis patients with no history of prior surgery.

It is also important to distinguish the different capabilities of the various dynamic devices. The interspinous devices are limited in the amount of decompression that

can be performed, whereas the pedicle-screw bases systems like Dynesys or TOPS can accommodate a more complete decompression. This study used exclusion criteria found for both groups, however, in reality these types of devices are mechanically very different. Additional research is necessary to more clearly define when an interspinous device is preferable to a pedicle-based system.

Our study suggests that over a third of operative cases of degenerative spondylolisthesis could be addressed with dynamic stabilization rather than decompression/fusion. Also, many additional patients could potentially be surgically treated at an earlier stage of disease using dynamic stabilization. Analyzing cases of failed dynamics makes a strong argument for the use of dynamic stabilization. In previous studies, revision of dynamic stabilization has involved simply removing the implants and then successfully converting to fusion [24]. In light of their relative ease of salvage, no potential future surgical options, including arthroplasty, have been eliminated [4]. However, additional clinical trials specifically comparing dynamic stabilization to traditional decompression/fusion are needed to further define the role of dynamic stabilization.

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