Dynamic stabilization for degenerative diseases in the lumbar spine: 2 years results

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Abstract

Following lumbar fusion, adjacent segment degeneration has been frequently reported. Dynamic systems are believed to reduce main fusion drawbacks. We conducted a retrospective study on patients with degenerative lumbar disease treated with posterior dynamic stabilization with monoaxial hinged pedicular screws and lumbar decompression. VAS and ODI were used to compare clinical outcomes. As radiological outcomes, LL and SVA were used. 51 patients were included with an average follow-up of 24 months. 13 patients were revised because of postoperative radiculopathy (n=4), subcutaneous hematoma (n=2), L5 screw malposition (n=1) and adjacent segment disease (n=6). The mean ODI score 41 preoperatively compared to 36 postoperatively. The mean VAS scores for back and leg pain were 5.3 and 4.2, respectively compared to 4.5 and 4.0 postoperatively. The mean SVA was 5.3 cm preoperatively, and 5.7 cm postoperatively. The mean LL was 47.5° preoperatively and 45.5° postoperatively. From our data, which fail to show significant improvements and reflect a high revision rate, we cannot generally recommend dynamic stabilization as an alternative to fusion. Comparative trials with longer follow-ups are required.

Introduction

Degenerative lumbar spinal canal stenosis is a degenerative disorder of the spine seen in the elderly population.[1] With increasing age of the population, the number of patients suffering from degenerative disc disease is also increasing.[2]

Degenerative disease of the lumbar spine occurs in many stages, the theory postulates that it begins with disc dehydration which leads to a decrease of the tensile modulus of the annulus fibrosis. This, in turn, causes a decrease in the disc height and later to posterior facet joint subluxation followed by degenerative spondylotic changes. The pain evolving from the degenerated motion segment is linked to its pathologic mobility. The exact relationship between lumbar instability and low back pain with or without leg pain is not well established, however, suppression of this instability can lead to pain relief.[3,4] Lumbar fusion is currently the golden standard for disc degeneration, segmental instability, and spondylolisthesis.[3-5]

However, loss of spinal motion after fusion may lead to a number of sequelae, including accelerated adjacent-level degeneration and pseudarthrosis. It is believed that the elimination of mobility can overload adjacent segments and lead to accelerated degeneration and arthrosis.[6,7] It is estimated that the frequency of ASD (adjacent segment disease) following instrumented lumbar fusions varies between 14% to 70% and pseudarthrosis may reach 30% in certain circumstances.[8,9] Both will often require revision surgery, adding to the patient morbidity and costs.[9]

Also, lumbar fusion with poorly contoured rods or with an excessive distraction of instrumentation may cause loss of lumbar lordosis. This can lead to flat back deformity or fixed sagittal imbalance. This leads to predictable sequelae of postoperative pain, hardware failure, fatigue, and gait disturbance as the patient is unable to stand erect without flexing the knees and extending the hips to compensate for the loss of segmental lordosis.[10]

This emphasizes the concept of having dynamic stabilization, thus simulating the behavior of the normal healthy spine, reducing the stiffness of the instrumentation, it is postulated that a more physiological load transfer occurs, reducing load transferred to adjacent segments. This can be achieved by restricting the extremes of spinal movement, or by dampening the kinetic energy while maintaining the mobility of the spinal segment in a controlled fashion.[11,12]

There are different methods to preserve this slight motion such as total disk replacement, interspinous devices, pedicle screw-based dynamic posterior stabilization (PBDS) or facet joint replacement. The main principle remains the same: anatomic-like flexibility of the vertebral segment.[13]

P. Khoueir summarized the indications of posterior dynamic stabilization in 6 points. i) controlled motion in the iatrogenically destabilized spine. ii) Increased anterior load sharing to augment interbody fusion. iii) Protection and restoration of degenerated facet joints and intervertebral discs. iv) In combination with anterior motion preservation for 360°circumferential motion segment reconstruction. v) Adaptation of stabilization techniques to the aging spine. vi) Prevention of fusion-related sequelae.[11]

The first known posterior dynamic system is the Graf ligamentoplasty system (Sem Co., Mountrouge, France), which consists of a posterior inductile band that serves as a ligament between two pedicle-based screws. It is composed of 5-to 7-mm titanium screws and looped 8-mm braided polyester bands, where the bands are connected under applied compressive force between the pedicle screws as a ligamentoplasty.[14] After several studies, its insufficiency has been understood. It was then followed in 1991 by transpedicular fixed dynamic neutralization system (Dynesys, Zimmer Spine Inc., Minneapolis, MN, USA).[14] The Dynesys Spine System, like standard frame devices, is fixed in place by using standard pedicle screws made of a titanium alloy. The whole system is stabilized by polyester cords that connect the screw heads through a hollow spacer and

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hold the screws in place. Since then more than 13,000 implantations have been performed worldwide.[15] Figure 1 summarizes the pedicle based dynamic stabilization.[16]

The Cosmic Posterior Dynamic System (Ulrich GmbH & Co, Ulm, Germany) is a PBDS system which has a unique design. Unlike conventional PDS devices. It has a hinged pedicle screw head that allows axial motion and the rods connecting the pedicle screws that are rigid. Stability is assured by the 6.25-mm threaded rod, and non-rigidity is assured by the hinged screw head. This combination of rigid rods and dynamic pedicle screws allows segmental motion, thereby reducing stress at the bone-screw interface. The hinged joint between the head and the threaded part of the pedicle screw allows load sharing between the implant and the anterior vertebral column. The screw threads are coated with calcium phosphate in order to promote ingrowth and assist in long-term fixation (Figure 2).[3,4,12,17]

Laboratory tests have demonstrated that Cosmic® instrumentation allows the same rotation stability as a healthy motion segment, while motion in flexion-extension shows a 65% reduction, and motion in lateral bending shows a 90% reduction compared to the intact spine.[18] Strempel *et al.* delineate the indications to use the dynamic stabilization with the Cosmic system: symptomatic spinal canal stenosis, chronic lumbago in case of discogenic pain or facet syndrome, in combination with spondylodesis or as an extension for a preexisting spondylodesis in case of adjacent segment disease and in recurrent disc herniation.[10] While Bono *et al.* see that the use of posterior dynamic stabilization with cosmic can be extended for treating spondylolisthesis, fractures, tumors, scoliosis, and kyphosis.[3] Strempel also recommended that the use of cosmic posterior dynamic stabilization should only be for a maximum of three segments.[19]

The objective of the present study is to discuss our clinical and radiological results after performing lumbar decompression accompanied by PBDS with the Cosmic® system without fusion in patients with degenerative thoracolumbar spine disease alone or accompanied by spondylolisthesis or degenerative lumbar scoliosis. We focused on the clinical outcome, procedure/implant-related complications, and reoperations.

Materials and Methods

Following institutional board review approval (as part of service evaluation and adhering to Helsinki declaration) we performed a retrospective evaluation of all patients treated in a single institution for degenerative lumbar disease with or without degenerative lumbar scoliosis or degenerative spondylolisthesis from August 2008 to May 2012. We examined patient-oriented outcomes after using a dynamic stabilization with monoaxial hinged pedicular screws (Ulrich GmbH & Co. KG, Ulm, Germany) with microscopic lumbar decompression in all cases in treating elderly

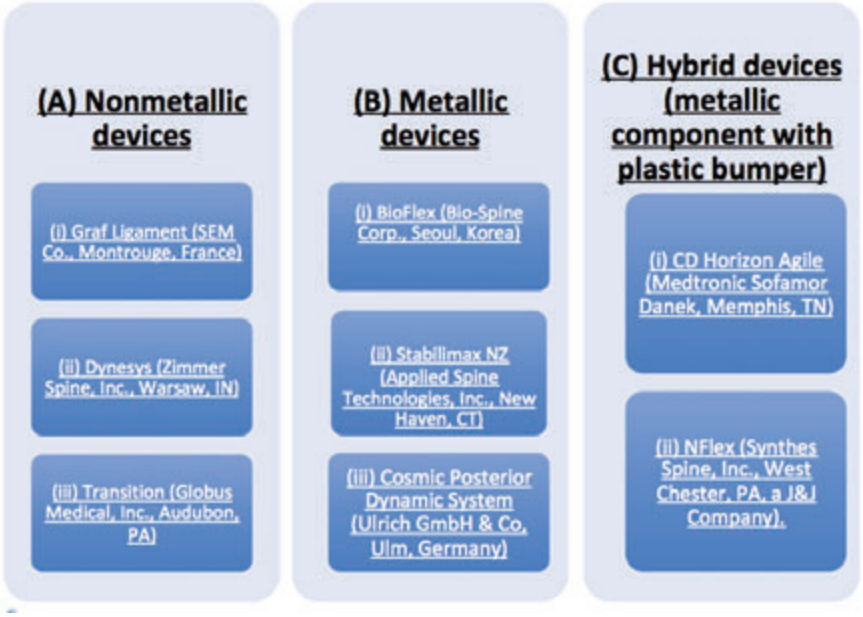

Figure 1. Classification of the pedicle screw-based posterior dynamic stabilization devices.

Figure 2. Hinge mechanism (15 degrees) of the hydroxyapatite coated Cosmic pedicle screw.

Patients with degenerative lumbar disease with or without degenerative lumbar scoliosis or degenerative spondylolisthesis (Grade 1-2). Patients who needed spinal decompression for more than 3 segments or a correction of their spondylolisthesis or scoliosis were excluded. Degenerative disc disease was diagnosed, based on three major radiological criteria reported by Mimura,[20] disc space narrowing, endplate sclerosis and osteophyte formation. Degenerative scoliosis was diagnosed based on radiological measurement of a curve (Cobb angle) more than 10° and spondylolisthesis was classified according to Meyerding grade 0, no slip; grade I, ≥5% and <25%; grade II, 26-50%; grade III, 51-75%; grade IV, 76-100%; and grade V, complete slippage.[21,22] All patients first received conservative management, including patients with prior failed spinal operations. In case of failure of the conservative therapy; mainly insufficient pain relief, surgical intervention was performed. All patients had lumbar degenerative disc disease and neurogenic intermittent claudication. Surgery (stabilization) was performed limited to the diseased levels causing symptoms, based on the preoperative MRI, CT and clinical examination. The dynamic stabilization was done without curve correction or slipping reduction, with a maximum of four levels (Figure 2). We investigated the clinical parameters, such as age, sex, ASA score by reviewing the patients' medical records. The visual analog scale (VAS) and the Oswestry disability index (ODI) were used to compare clinical outcomes. To evaluate radiological outcomes, a standing whole spine plain x-ray was used to measure the following parameters; lumbar lordosis (LL) measuring the Cobb angle between the top of L1 and sacrum (normal range between 33-79°)[23] and sagittal vertical alignment (SVA) which is identified as the horizontal distance between the plumb line from the center of C7 to the posterior superior corner of the sacrum in the sagittal plane.[24] Implant failures such as screw breakage or loosening were recorded with plain x-rays and CT-scans (Figure 3).

Statistical analysis

For statistical analysis, GraphPad Prism (GraphPad Software, San Diego, California, USA) and Microsoft Excel (Microsoft, Redmond, USA) were used. Dependant Student's t-test was performed to compare the preoperative with the postoperative data. The significance level was set to 0.05.

Results

We identified 67 patients with dynamic stabilization with monoaxial hinged pedicular screws and microscopic lumbar decompression, 16 patients were excluded because of a follow-up of less than 6 months or because they didn't complete and return the patient-oriented follow-up questionnaire.

51 patients were included in this study, 19 females and 32 males, aged between 55 and 85 years with a mean age of 72. The average time at final follow-up examination was 24 months, with a range of 6 and 57 months. Among them were 17 patients (33%) had spondylolisthesis (Grade 1-2 Meyerding) while 20 Patients (39%) had adult scoliosis, and 8 (16%) had both. 17 patients (33%) had previous surgery with posterior instrumentation and 14 patients (27%) had previous surgery without posterior instrumentation. One patient had both. The number of performed instrumented levels was between 1 and 4 levels with a mean of 2.25 levels.

330 pedicle screws were implanted into 165 vertebrae (Th11-S1) to dynamically stabilize one (n=9), two (n=23), three segments (n=17), or four segments (n=2),

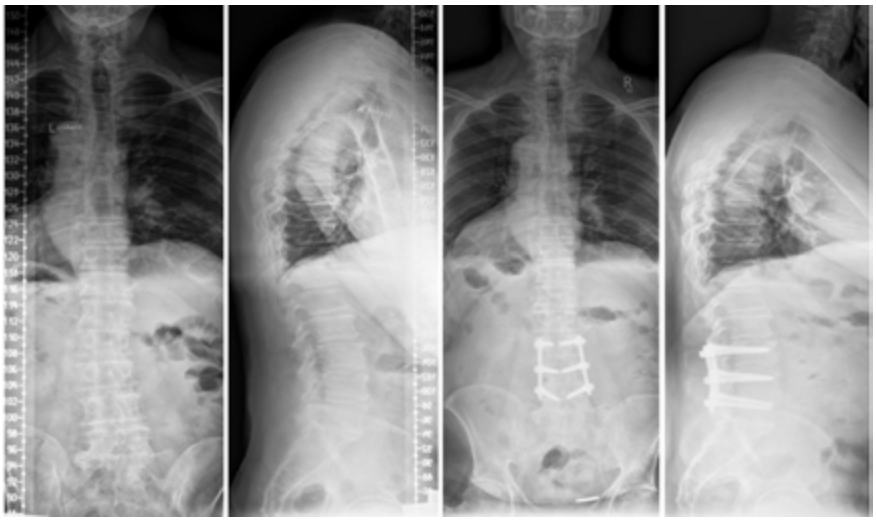

Figure 3. Example of a 74-year-old male patient with a degenerative spinal canal stenosis L1-S1, 24 months after spinal decompression and dynamic stabilization L3-L5.

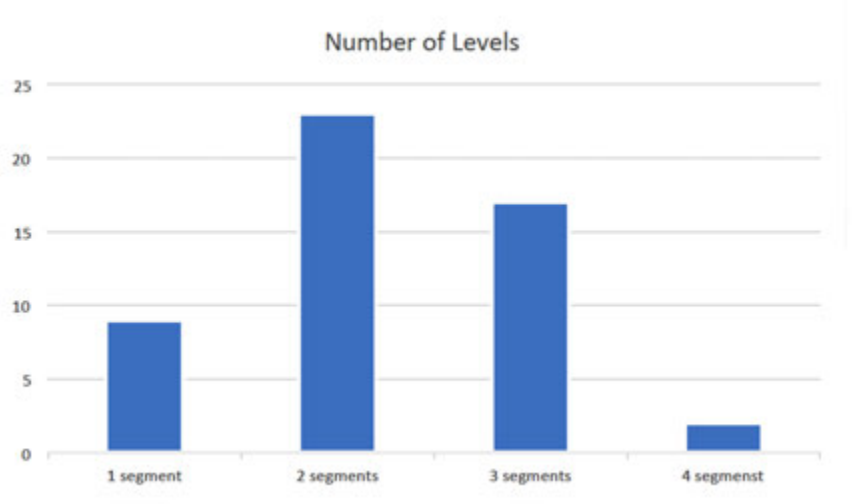

Figure 4. Number of operated segments.

respectively (Figure 4). Early reoperation within the first days after primary surgery was necessary for 7 patients. The indications for re-intervention were a revision of symptomatic misplaced screws (n=1), revision of hematomas, or impaired wound healing, respectively (n=2), and postoperative neurological deterioration (n=4). Late reoperation was necessary for 6 patients. The indication was adjacent segment disease (n=6), from these 6 patients; two were with screw loosening (n=2). For detailed data see Table 1. The mean ODI score 41 preoperatively compared to 36 postoperatively. The mean VAS scores for back and leg pain were 5.3 and 4.2, respectively compared to 4.5 and 4.0 postoperatively.

Compared with preoperative assessments, ODI and VAS scores in the last follow-up control were without significant differences. For detailed data see Table 2.

The final angular values (in the latest follow-up examination) of LL and SVA were not significantly changed, the mean SVA was 5.3 cm preoperatively, and 5.7 cm postoperatively. The mean LL was 47.5° preoperatively and 45.5° postoperatively. Exact values are summarized in Table 3.

There were no significant differences in respect to ODI, VAS, LL or SVA for pre- and postoperative values. Nevertheless, we saw a tendency to a 5% lower ODI, whereas SVA showed no difference.

Subgroup calculations with grouping for spondylolisthesis, previous surgery or scoliosis also showed no significant differences for pre-and postop between these values. For detailed data see Table 4.

Discussion

The objective of this study is to discuss our clinical and radiological results after performing lumbar decompression accompanied by PBDS using (Cosmic® posterior dynamic system) without fusion in elderly patients with degenerative disc disease in the lumbar spine. Thus, we aim to achieve spinal stability without performing fusion or correction and to prevent pain caused by abnormal motion. The focus of this study is on clinical outcome, implant-related complication, procedure-related complications, and reoperations.

There are different types of dynamic stabilization systems in the lumbar spine. Cosmic implants are PBDS. It is significant to note this distinction when reviewing the results of the literature in comparison to our study. In contrary to our expectations, we did not find a significant difference between preoperative and postoperative clinical and radiological scores in our study cohort.

Von Strempel evaluated a series of 134 patients with a follow-up between 12 and 24 months, who had undergone PBDS with the cosmic implant. He found that ODI improved from 25.4 to 17.0 and VAS from 5.7 to 2.9.[3] After performing PBDS with Cosmic implants on 30 patients with a mean follow-up of 43 months, Kaner et al report-

Table 1. The postoperative complications in the patient cohort which needed a revision surgery.

Complications	N. patients	% complications	% total patients
Persistent stenosis/post op. radiculopathy	4	31	8
Implant Malposition	1	8	2
Adjacent segment disease	6	46	12
Hematoma/Infection	2	15	4
Overall	13	100	25

Table 2. Summary of clinical outcome scores.

Clinical outcome	Preop		Postop		P-value
	Mean	SD	Mean	SD	
Oswestry disability index	40.82	22.38	35.92	25.65	0.289
VAS Back pain	5.29	2.95	4.5	3.36	0.445
VAS Leg pain	4.21	2.31	4.01	3.4	0.738

Table 3. Summary of radiological outcome scores.

Radiological outcome	Preop		Postop		P-value
	Mean	SD	Mean	SD	
Lumbar lordosis	47.50	16.45	45.6	15.35	0.077
Sagittal Vertical Axis (cm)	5.28	3.39	5.74	4.61	0.223

Table 4. Summary of radiological outcome scores.

Type of data	Preop		Postop		P-value
	Mean	SD	Mean	SD	
Spondylolisthesis					
Oswestry disability index	26.92	6.80	31.80	6.80	0.450
VAS Back pain	4.90	1.80	4.20	0.95	0.97
VAS Leg pain	3.50	2.60	3.20	0.85	0.422
Lumbar lordosis	57.38	2.31	52.79	2.61	0.0756
Sagittal Vertical Axis (cm)	4.83	0.83	5.48	1.00	0.176
Previous surgery					
Oswestry disability index	59.00	13.00	51.60	11.79	0.289
VAS Back pain	5.50		6.20	1.66	0.445
VAS Leg pain	6.00	1.00	7.83	0.47	0.738
Lumbar lordosis	50.57	4.95	49.29	3.99	0.064
Sagittal Vertical Axis (cm)	4.80	1.56	7.07	1.29	0.239
Scoliosis					
Oswestry disability index	36.17	17.57	40.67	5.54	0.904
VAS Back pain	5.50	2.75	5.47	0.74	0.896
VAS Leg pain	4.50	2.47	5.27	0.81	0.972
Lumbar lordosis	47.47	3.67	44.93	3.34	0.086
Sagittal Vertical Axis (cm)	5.47	0.79	6.49	0.98	0.190

ed significant improvements in the ODI and VAS scores in the last follow-up control, with an ODI of 63.7 preoperatively and 8.9 after 24 months postoperatively and VAS of 7 preoperatively and 0.7 24 months postoperatively.[1]

In contrast, our results failed to show significant changes in ODI (from 40.8 to 35.9), VAS back pain (from 5.2 to 4.5), and VAS leg pain (from 4.2 to 4.0).

Kaner found also a statistically significant difference radiologically comparing with preoperative values, there were statistically significant differences between follow-up lumbar lordosis scores, they measured a mean lumbar lordosis of 49.5° preoperatively and a mean of 48,7° postoperatively.[1] We measured a mean lumbar lordosis of 47.5 preoperatively and a mean of 45,6 postoperatively. With regards to the SVA, we measured a mean of 5.3 cm preoperatively compared to 5.7 cm postoperatively. We did not find in the literature any recent comparative data. It is still important to mention that Patients outcome/ Health-related quality of life (HRQL) parameters as VAS and ODI are strongly related with restoring the sagittal balance, (25) as the Cosmic® posterior dynamic system can only be applied for a maximum of 4 segments, correction of the sagittal balance cannot be achieved. This, however, can explain the non-significant change in HRQL.

Zhi-Jie Zhou and et al performed a meta-analysis including 31 studies which showed that the pooled incidence of ASDeg (adjacent segment degeneration) and ASD following PBDS procedure was 16.4% and 5.5% respectively. Data from comparative studies showed a significantly lower incidence of ASDeg and nonsignificant lower incidence of ASD following PBDS than following fusion surgery. Furthermore, the additional PBDS devices implanted adjacent to fusion could significantly reduce the risk of reoperation due to adjacent segment degeneration caused by fusion.[26]

Compared to our collected data in the follow-up, we found the incidence of ASD requiring revision surgery after performing the PBDS with cosmic was 11.7%.

The difference in ASDeg rate compared to ASDIs rate is not unexpected, as not all degenerative cases convert into symptomatic conditions.[26]

Stoffel *et al*. reported complications on 103 patients operated between April 2006 and December 2007 using the Cosmic system for painful degenerative segmental instability, spinal stenosis, and degenerative spondylolisthesis. Early reoperations in 12 patients were due to 3 misplaced screws, 8 CSF leaks/hematomas/wound problems, 1 misjudged adjacent segment stenosis. Reoperations within the follow-up period (3-17 months) were necessary for 10 other patients due to newly developed complaints. 6 of these 10 patients, were revised due to symptomatic adjacent segment disease, whereas 2 patients due to persistent stenosis/disk protrusion. The further 2 patients' revision surgeries were indicated due to symptomatic screw loosening.[4]

Kaner reported minor complications, including a subcutaneous wound infection in 2 cases, a dural tear in 2 cases, cerebrospinal fluid fistulas in 1 case, a urinary tract infection in 1 case, and urinary retention in 1 case. He observed L5 screw loosening in 1 of the 3-level decompression cases. No screw breakage was observed and no revision surgery was performed in any of these cases.[1]

Von Strempel found from the 134 patients treated with PDS using cosmic that Seven patients in the Cosmic group had signs of screw loosening or failure (5%); compared to our study (4%) who required also a revision procedure

Stoffel *et al.* suggest that the high revision rate is not surprising. He postulates a number of possible reason for this, including i) patients who need multisegmental stabilization are by nature more prone to multisegmental spinal degeneration, ii) many patients in this cohort have scoliosis, thereby altering the biomechanical advantage of the system (load transfer) which is limited to one degree of freedom. Multiplanar deformities may abate this load transfer mechanism, iii) longer constructs confer more stress to adjacent levels biomechanically, iv) however, in our cohort, the revision rate was even higher with 13/51 patients.

The high rate of complications together with the non-significant change in the ODI and VAS can be explained by the fact that 60% (31 patients) of our population had previous surgery and the vast majority belong to the elderly population.

In a comparative review between dynamic stabilization and spinal fusion (the accepted gold standard), Chou *et al*. found no significant differences between fusion and dynamic stabilization with regards to VAS, ODI, complications, and reoperations. However, surgical complications, excluding ASD, and complications requiring reoperation were higher in those who had fusion.[27]

Conclusions

In this retrospective study, we report outcome data from 51 patients who were operated using PBDS. Our data fail to show significant improvements in terms of VAS and ODI or radiological parameters, and we encountered a high rate of complications.

However, the complications were not directly related to the dynamic stabilization technology. Due to its theoretically favorable biomechanics, there might be still a place for PBDS as it provides an acceptable outcome in a selected group of patients.

A prospective randomized trial comparing types of dynamic stabilization, especially with respect to the number of instrumented level and age group, would be useful. Additionally, randomized trials comparing posterior dynamic and rigid systems should be performed for patients with multilevel degenerative stenosis. Longer follow-ups might be needed to detect differences in the rate of adjacent segment disease.

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