Acta Orthop. Belg., 2012, **78**, 230-239

ORIGINAL STUDY

Comparison of Dynesys posterior stabilization and posterior lumbar interbody fusion for spinal stenosis L4L5

Shang-Won Yu, Shih-Chieh Yang, Ching-Hou Ma, Chin-Hsien Wu, Cheng-Yo Yen, Yuan-Kun Tu

From E-Da Hospital/I-Shou University, Jiau-Shu Tsuen, Taiwan, R.O.C.

The aim of this prospective randomized study was to compare the radiological and clinical outcome after treatment of lumbar spinal stenosis L4L5 with or without spondylolisthesis, with either posterior lumbar interbody fusion (PLIF) (26 patients) or Dynesys posterior stabilization (27 patients). Demographic characteristics were comparable in both groups. Dynesys stabilization resulted in significantly higher preservation of motion at the index level ($p < 0.001$), and significantly less ($p < 0.05$) hypermobility at the adjacent segments. Oswestry Disability Index (ODI) and VAS for back and leg pain improved significantly ($p < 0.05$) with both methods, but there was no significant difference between groups. Operation time, blood loss, and length of hospital stay were all significantly ($p < 0.001$) less in the Dynesys group. The latter benefits may be of particular importance for elderly patients, or those with significant comorbidities. Complications were comparable in both groups. Dynesys posterior stabilization was effective for treating spinal stenosis L4L5 with or without spondylolisthesis.

Keywords : lumbar spine ; dynamic stabilization ; Dynesys ; posterior lumbar interbody fusion.

INTRODUCTION

Chronic lumbar back pain due to intervertebral disc degeneration and spinal canal stenosis has been typically treated by fusion of the affected levels if conservative treatment fails. Radiographic fusion rates have been reported to be greater than 95% ; however, successful clinical outcomes are reported in only approximately 70% of cases (*22*). Problems and potential complications with fusion include nonunion, instrumentation failure, infection and donor site pain. Moreover, increased movement at adjacent segments can occur after spinal fusion, and this hypermobility may increase the risk for adjacent segment disease (*5,13,16,19*).

Given the potential disadvantages of fusion, attention has been drawn to techniques which preserve motion. The Dynesys Spinal Stabilization System (Zimmer, Inc., Minneapolis, MN, USA) uses pedicle screws, polyethylene-terephtalate cords, and polycarbonate urethane spacers to stabilize a functional spinal unit (*32*). The system is

■ Shang-Won Yu, MD, Visiting Doctor.
■ Shih-Chieh Yang, MD, PhD, Director Spine Division.
■ Ching-Hou Ma, MD, Director Trauma Division.
■ Chin-Hsien Wu, MD, Visiting Doctor.
■ Cheng-Yo Yen, MD, Chairman Orthop. Dept.
■ Yuan-Kun Tu, MD, PhD, Professor,Superintendant E-Da Hospital.
Department of Orthopaedic Surgery, E-Da Hospital/I-Shou University, Jiau-Shu Tsuen, Taiwan, Republic of China.
Correspondence : Shang-Won Yu, Department of Orthopedic Surgery, E-Da Hospital/I-Shou University, 1, E-Da Road, Jiau-Shu Tsuen, Yan-Chau Shiang, 824, Kaohsiung County, Taiwan, Republic of China.
E-mail : ysw6455@yahoo.com.tw

No benefits or funds were received in support of this study

designed to stabilize the operated segment, while preserving some mobility, thus preserving a greater degree of lumbar mobility than with fusion (*1*). The Dynesys system is indicated for lumbar spinal stenosis with or without spondylolisthesis, and can be used for single or multisegmental disease (*27,32*).

Many clinical studies performed over the past decade have indicated positive outcomes for patients with degenerative disc disease of the lumbar spine treated with the Dynesys system (*2,14,18, 20,25,28,30*). In addition, Di Silvestre *et al* (*8*) found posterior dynamic stabilization with the Dynesys system particularly useful in elderly patients because the technique was less surgically aggressive than fusion. However, Schwarzenbach *et al* (*27*) caution against its use in elderly patients with osteoporotic bone or with severe segmental macroinstability combined with degenerative spondylosis and advanced disc degeneration. Despite the positive results reported with the Dynesys stabilization system, there is concern over the effects of stabilization on adjacent segments. A number of cadaveric, *in vivo*, and modeling studies have provided conflicting results (*1,4,7,15,17,24,29*).

To date, there have been no randomized studies directly comparing radiographic and clinical outcomes of posterior lumbar interbody fusion (PLIF) and Dynesys posterior dynamic stabilization for the treatment of lumbar spinal stenosis, with or without spondylolisthesis, and the effects of the procedures on adjacent segment mobility. Most reports about the advantages of the Dynesys system were retrospective, or compared the Dynesys system with historical series about fusion. In addition, reports on the use of the Dynesys system in Asian populations are rare. This is why the current study fills a hiatus.

MATERIALS AND METHODS

This prospective randomized case-controlled study was performed in a single institution, between September 2006 and March 2010. All patients were operated upon between September 2006 and February 2007. Enrolled patients were randomized to either Dynesys posterior dynamic stabilization or PLIF. The study was approved by the Institutional Review Board of the hospital, and all patients provided written informed consent for participation in the study and surgical procedures.

Criteria for inclusion in the study were : 1) age 38 to 71 years, 2) spinal stenosis with or without grade I degenerative spondylolisthesis L4L5, 3) severe instability (dynamic view > 15°, translation > 4 mm), 4) preoperative Oswestry Disability Index (ODI) > 40, 5), failure of 3 months of conservative treatment, and 6) skeletal maturity. Exclusion criteria were : 1) disease at a level other than L4L5, 2) more than one level of spinal stenosis, 3) > grade I spondylolisthesis, 4) degenerative scoliosis > 10°, 5) systemic disease and/or receiving immunosuppressive medication, and 6) osteoporosis (T-score < -2). All patients above 60 years of age received an osteoporosis evaluation. Those below 60 years of age did not receive an investigation unless they had a risk factor (e.g., metabolic disease, early hysterectomy) or clinical evidence of osteoporosis. In all cases, the presence of spinal stenosis was confirmed by magnetic resonance imaging (MRI).

Treatment allocation was performed before initiation of enrollment. Permuted-block treatment allocation was used to assign participants to each group. A list of sequential numbers was generated using a permuted-block randomization procedure with a block size of 4 in SAS 9.0 (SAS Institute Inc., Cary, NC, USA), with each number randomly assigned to one group. Patients meeting the criteria were randomly assigned in a 1 :1 ratio to the Dynesys group or the PLIF group. All patients were fused or stabilized at the L4L5 level only.

Dynesys implantation was performed according to the directions of the manufacturer (*32*). Simple decompression (interlaminar decompression or laminotomy) was performed in most cases ; however, for cases of severe stenosis or far lateral stenosis, extensive decompression, sometimes including facetectomy, was performed, followed by instrumentation with Dynesys. Each spacer added 1-2 mm to the disc height. Postoperatively, patients in the Dynesys group received a soft support brace (lumbar corset) for 3 months. Patients did not participate in a rehabilitation program, and were instructed that they should avoid bending but otherwise could maintain a normal lifestyle.

PLIF was performed in a standard manner using Synthes Click'X spinal implants. When required, extensive decompression and facetectomy were performed for easy cage insertion. Autologous bone chips obtained from the decompression were used within and around the cage, followed by pedicle screw instrumentation and fixation. Patients in the PLIF group received a hard plastic lumbar brace for 3 months. Although there is no evidence supporting the use of braces postoperatively, it is a routine practice in our country : a brace is believed

to help patients feel secure after surgery. Patients did not participate in a rehabilitation program, and were instructed that they should avoid bending but otherwise could maintain a normal lifestyle.

Primary outcome measures were comparison of radiographic results between Dynesys and PLIF surgery groups at the index, cranial, and caudal levels. Anteroposterior (AP) and sagittal radiographs were obtained preoperatively, and at each follow-up visit. Each radiograph was measured twice, separated by a 1 week interval, by two independent experienced spine surgeons to minimize human errors in measuring. The average value of the measurements was used for analysis. Lateral flexion and extension views were also taken. The range of motion (ROM) in the sagittal (flexion-extension) view was obtained by the following formula : ROM sagittal = angle (extension) – angle (flexion). Motion preservation (%) was defined as ROM (postoperatively) / ROM (preoperatively). Radiographic instability was defined as 1) flexion versus extension > 10°, or 2) flexion versus extension at the spinal ridge > 3-4 mm.

Screw loosening was based on the presence of the double-halo sign on plain radiographs as described by Dakhil-Jerew *et al* (6). Only screw loosening as evidenced by a double-halo sign was included in this study.

Secondary outcome measures were in the first place changes in ODI and visual analogue scale (VAS) for back and leg pain. VAS scores were determined on a scale ranging from 0 (no pain) to 10 (worst pain imaginable). ODI and VAS scores were determined preoperatively and at each follow-up visit. Operation time, blood loss, length of hospital stay, and complications were also compared between the two groups. Patients were followed-up at 3 months, and at 1, 2, and 3 years postoperatively.

Statistical analysis

The per-protocol (PP) population was defined as randomized patients who followed the procedure throughout the study without major deviations. Patients who did not complete follow-up or had incomplete radiographic records were excluded from the analysis. Analysis of the primary and secondary outcomes was based on the PP population. Continuous and categorical variables were compared by the independent two-sample t-test and the chi-square / Fisher's exact test, respectively. Paired t-tests in both groups were used to analyze the results of improvement differences from baseline (pre-op) to the 3-year follow-up. Continuous variables were presented as mean ± standard deviation (SD), while categorical data were represented by number and percentage. All statistical assessments were two-sided and evaluated at the 0.05 level of significant difference. Statistical analyses were performed using SPSS 15.0 statistics software (SPSS Inc, Chicago, IL, USA).

RESULTS

A total of 60 patients meeting the inclusion criteria were prospectively recruited between September 2006 and February 2007. Patients were randomly assigned in a 1:1 ratio to the Dynesys group and the PLIF group : 30 versus 30. Four patients (6.7%) were subsequently excluded from the analysis because they were lost to follow-up, leaving 27 patients in the Dynesys group (10 males and 17 females ; mean age, 52.22 ± 8.32 years) and 29 in the PLIF group (11 males and 18 females ; mean age, 55.52 ± 6.98 years). Two out of 29 patients in the PLIF group did not have a complete follow-up radiographic record, while a third patient had a superficial infection which needed repeat débridement and antibiotics : all three were excluded. Thus, 53 patients (27 in the Dynesys group and 26 in the PLIF group) completed a follow-up of 3 years and were included in the final analysis of radiographic and clinical outcomes. A flow chart of patients in the study is presented in Fig. 1. The demographic and baseline characteristics of both groups (Table I) were similar (all, $p > 0.05$).

Surgery was performed successfully in all patients, and all patients had unremarkable postoperative courses.

Radiological outcome : motion and adjacent level instability

Representative pre- and postoperative images of PLIF and Dynesys placement are shown in Fig. 3 and Fig. 4, respectively. Post-operative radiographs at 36-month follow-up detected instability at the cranial level after PLIF ; on the other hand after Dynesys no sign of adjacent instability L3L4 or L5S1 was seen, while the disc height of L4L5 (operated level) was partially restored and maintained.

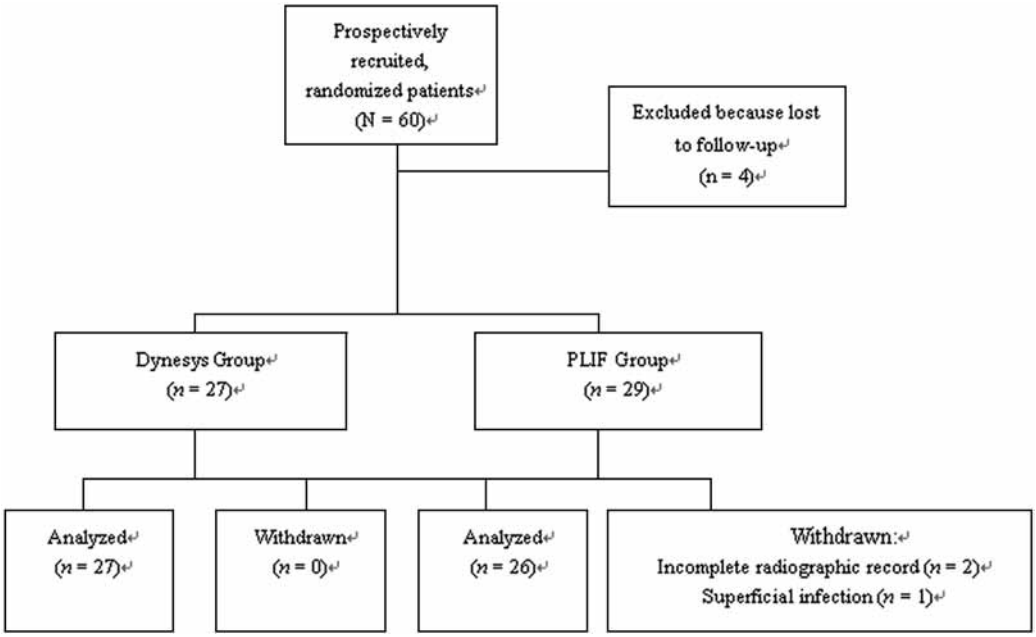

Fig. 1. — Study flow chart

Table I. — Patients' demographics and baseline data

	Dynesys Group (n = 27)	PLIF Group (n = 26)	p
Demographic data			
Mean age (years) ± SD	52.22 ± 8.31	55.52 ± 6.98	0.113 [a]
Mean BMI (kg/m^2) ± SD	25.42 ± 3.40	25.11 ± 2.51	0.710 [a]
Gender			0.945 [b]
Male	10 (37.0%)	11 (37.9%)	
Female	17 (63.0%)	18 (62.1%)	
Spondylolisthesis	11 (40.7%)	13 (44.8%)	0.757 [b]
Baseline data			
Mean ROM (°) ± SD			
Operated level (L4-5)	7.56° ± 1.42	8.03° ± 2.56	0.387 [a]
Cranial level (L3-4)	7.07° ± 2.15	6.69° ± 2.24	0.515 [a]
Caudal level (L5-S1)	7.52° ± 2.34	7.83° ± 2.27	0.622 [a]
Mean ODI ± SD	55.11 ± 5.91	56.41 ± 5.30	0.388 [a]
MeanVAS leg pain ± SD	7.22 ± 1.22	7.66 ± 0.97	0.147 [a]
Mean VAS back pain ± SD	6.63 ± 1.82	6.97 ± 1.97	0.512 [a]

PLIF : posterior lumbar interbody fusion ; BMI : body mass index ; ROM : range of motion ; ODI : Oswestry Disability Index ; VAS : visual analogue scale.

p-values are based on [a]independent two-sample t-test or [b]chi-square test.

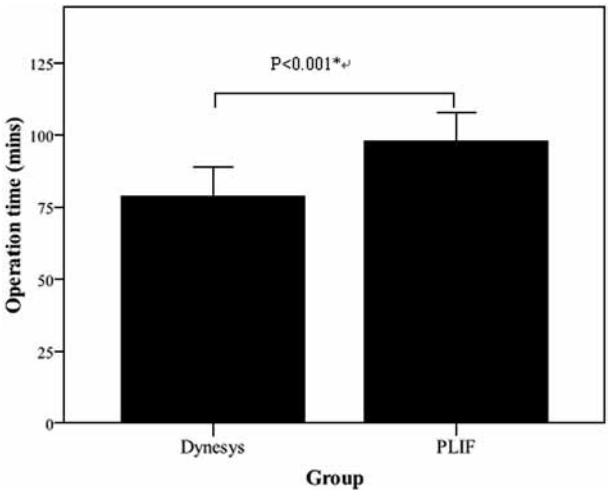

Fig. 2a. — Dynesys and PLIF : significantly less operation time with Dynesys.

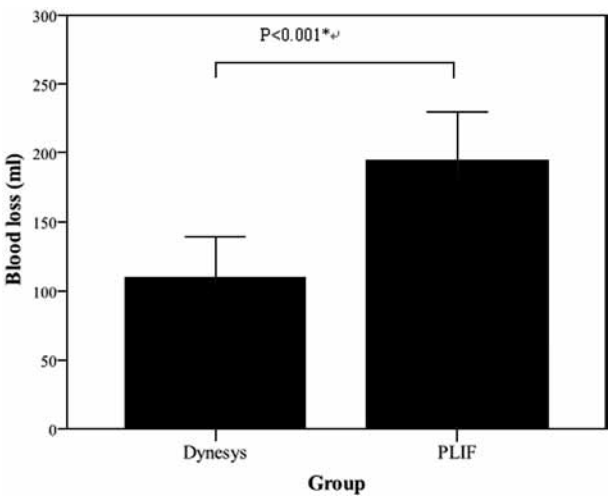

Fig. 2b. — Dynesys and PLIF : significantly less blood loss with Dynesys.

The comparison of radiographic (primary) outcomes between the two groups is shown in Table III. A statistically significant decrease of the ROM at the operated level from preoperatively to the 3-year follow-up was observed in both the Dynesys group and the PLIF group (both, $p < 0.001$). These data suggest that both the Dynesys system and PLIF are able to stabilize an unstable segment, but the Dynesys group can maintain partial ROM after surgery. A significant difference in motion preservation at the operated level was found between the Dynesys and PLIF group at 3-year follow-up ($65.06 \pm 14.72\%$ vs. $15.99 \pm 10.21\%$, respectively ; $p < 0.001$). These data suggest that the Dynesys system can preserve a greater ROM than PLIF at the operated level.

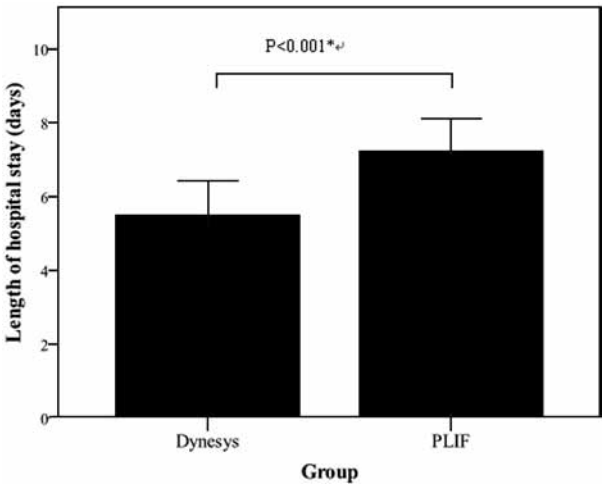

Fig. 2c. — Dynesys and PLIF : significantly less hospital stay with Dynesys.

The percentage of cranial level motion preservation at 3-year follow-up was significantly different between the Dynesys and PLIF group ($111.95 \pm 30.41\%$ versus $140.22 \pm 47.12\%$, respectively ; $p = 0.012$). The percentage of caudal level motion preservation at 3-year follow-up was also significantly different between the Dynesys and PLIF group ($103.49 \pm 25.42\%$ versus $119.12 \pm 26.33\%$, respectively ; $p = 0.032$).

Clinical outcome : ODI, VAS, operation time, blood loss, hospital stay, complications

Statistically significant improvements in ODI and VAS leg and back pain scores (Table III) were found for both groups at the 3-year follow-up as compared to preoperative values (all : $p < 0.05$). However, the degree of improvement in all indices was similar between the Dynesys group and the PLIF group at 3-year follow-up (all : $p > 0.05$).

Table II. — Complications by group

	Dynesys group (n = 27)	PLIF group (n = 26)	p
Radiological instability			
at cranial level	1 (3.7%)	6 (20.7%)	0.103
at caudal level	0 (0.0%)	1 (3.4%)	1.000
Re-operation	0 (0.0%)	3 (10.3%)	0.237
Screw loosening	1 (3.7%)	1 (3.4%)	1.000
Dural tear	0 (0.0%)	1 (3.4%)	1.000

PLIF : posterior lumbar interbody fusion. Data are displayed as number (percentage).
p-values are based on Fisher's exact test.

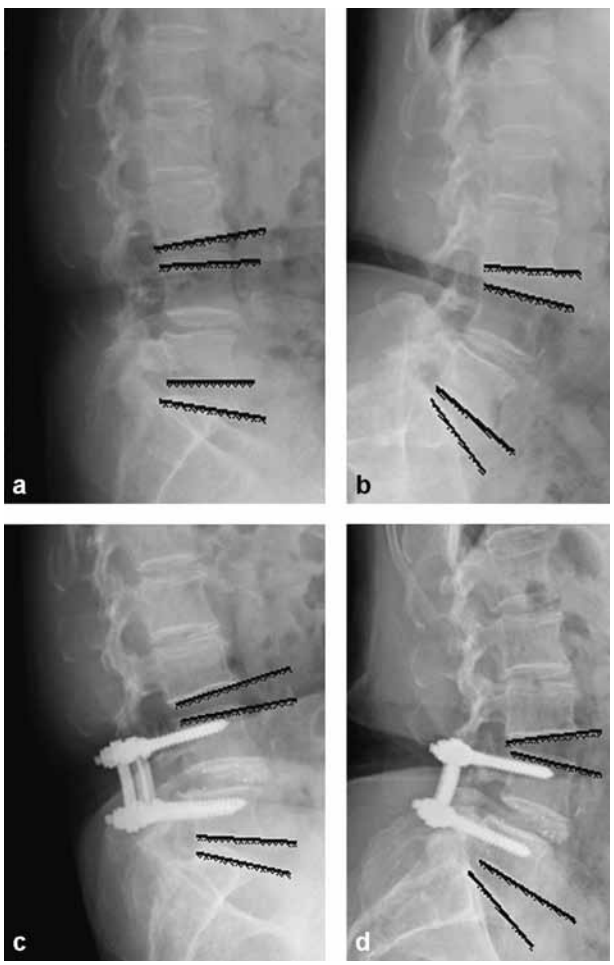

Fig. 3. — A representative case of PLIF**.** Lateral plain radiographs showing : (a) pre-operative flexion ; (b) pre-operative extension : no instability at levels L3L4 and L5S1 ; (c) postoperative flexion at 36-month follow-up ; (d) postoperative extension at 36-month follow-up : instability (more than 15°) was detected at the cranial level.

The operation time, blood loss, and length of hospital stay were all significantly less (Fig. 2) (all : $p < 0.001$) in the Dynesys group as compared to the PLIF group (78.56 ± 10.34 minutes versus 97.72 ± 9.99 minutes ; 110.37 ± 28.72 ml versus 194.3 ± 35.271 ml, and 5.48 ± 0.94 days versus 7.21 ± 0.90 days, respectively).

Complications

There was no significant difference in complications such as radiographic instability, re-operation, screw loosening, and dural tears between the Dynesys and the PLIF group (Table II) (all : $p > 0.05$). One case of screw loosening in a Dynesys implantation was identified on radiographs taken 3 months postoperatively. The patient was asymptomatic, and no revision surgery was performed. One case of screw loosening also occurred in the PLIF group. The patient was asymptomatic, and successful fusion was achieved, thus no revision surgery was required. One dural tear also occurred in the PLIF group during interbody cage insertion, and was managed without further complications. In the Dynesys group, there was one case of radiographic instability at/or over the adjacent level. The patient experienced moderate back pain ; however, no subsequent surgery was required. In the PLIF group, however, there were 6 cases of radiographic instability, and 3 patients underwent re-operation of the adjacent levels.

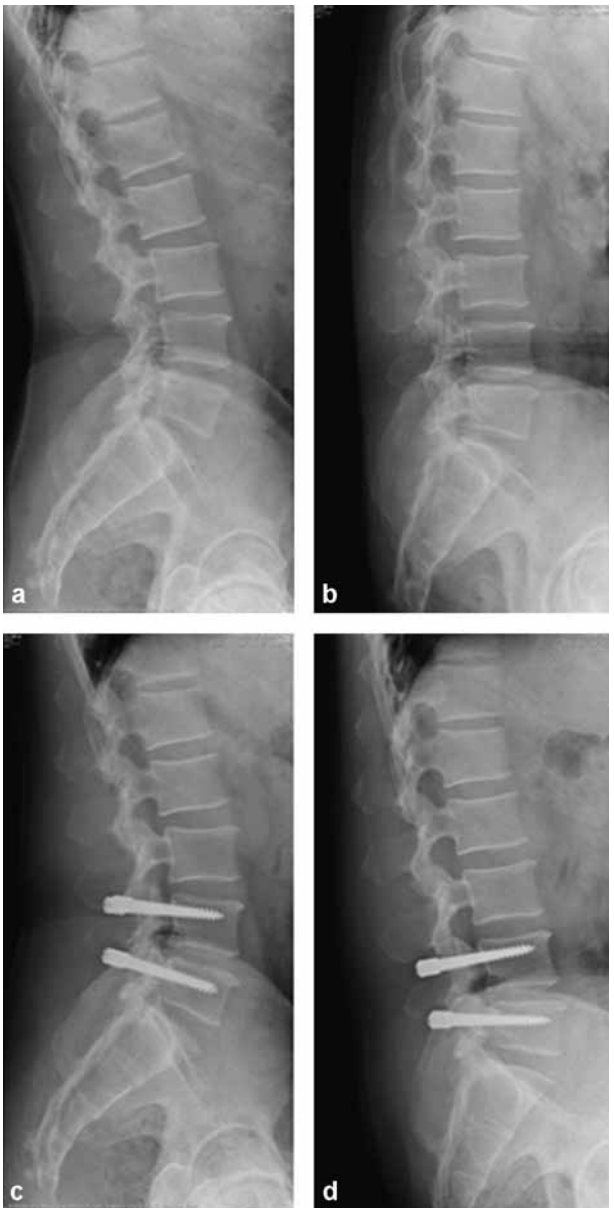

Fig. 4. — A representative case of Dynesys surgery. Radiographs showing : (a) preoperative extension ; (b) preoperative flexion : stenosis L4L5 for which the patient underwent Dynesys surgery ; (c) postoperative extension view at 36-month follow-up ; (d) postoperative flexion view at 36-month follow-up : no adjacent instability L3L4 or L5S1, and partial restoration of the disc height L4L5 (operated level).

DISCUSSION

Radiological outcome : motion and adjacent level instability

Dynesis resulted in higher preservation of motion *at the index level*. This finding is predicted by the design of the device, and consistent with reports in the literature. Contrary to fusion, which results in a solid connection of the operative levels, Dynesys stabilizes the index level, while the flexible cords and spacers allow a limited range of motion (*32*). Lee *et al* (*14*) reported the results of 20 consecutive patients treated with the Dynesys system, and found at a mean follow-up of 27.25 ± 5.16 months that the system allowed preservation of motion of the stabilized segments and improvement of the clinical variables ODI and VAS for pain. Contrary to these findings, Schaeren *et al* (*23*) found no motion at the operated level in 19 Dynesis patients with a minimum 4-year follow-up.

Dynesys led to less hypermobility (flexion/ extension) in the *adjacent cranial* segment. In the *adjacent caudal* segment almost no change of mobility was noted with Dynesys stabilization, whereas only a slight increase of mobility was noted with PLIF. Reports regarding the mobility and degeneration of adjacent segments after Dynesys implantation are conflicting. Fusion results in increased stress in adjacent segments and subsequent hypermobility and adjacent segment disease (*3*). Some authors have suggested that preservation of motion at the operative level can prevent degeneration at the adjacent segments by decreasing stress and resulting hypermobility (*28*). Beastall *et al* (*1*) studied 24 patients, treated with the Dynesys system, with positional magnetic resonance imaging preoperatively, and at 9 months postoperatively ; they found no significant increase in mobility at the adjacent levels. In a cadaveric study, Schmoelz *et al* (*24*) reported that Dynesys stabilization did not increase the mobility of adjacent segments. On the contrary, Schaeren *et al* (*23*) studied 19 Dynesys patients with a minimum 4-year follow-up and found new signs of degeneration in adjacent motion segments in 47% of the patients, a rate similar to that reported after lumbar fusion (*21*). Similarly, Kumar *et al* (*12*)

Table III. — Radiological and clinical outcomes at 3-year follow-up

	Dynesys group (n = 27)	PLIF group (n = 26)	p
Radiological outcome			
Motion preservation (%)			
Operated level (L4-5)	65.06 % ± 14.72*	15.99% ± 10.21*	< 0.001**
Cranial level (L3-4)	111.95% ± 30.41	140.22% ± 47.12*	0.012**
Caudal level (L5-S1)	103.49% ± 25.42	119.12% ± 26.33*	0.032**
Clinical outcome			
Oswestry Disability Index	-32.74 ± 8.63*	-29.31 ± 12.72*	0.254
VAS leg pain	-5.37 ± 1.42*	-5.08 ± 1.55*	0.475
VAS back pain	-4.33 ± 2.37*	-4.15 ± 2.77*	0.801

PLIF : posterior lumbar interbody fusion ; VAS : visual analogue scale.
Data are displayed as mean ± standard deviation.
* Significant difference between pre- and postoperative condition in each group, $p < 0.05$.
** Significant difference between Dynesys and PLIF groups using independent two-sample t-test, $p < 0.05$.

studied 32 patients with the Dynesys system and also noted continued degeneration at the index and adjacent segments, but believed that the further changes may be a result of the natural progression of the disease. Liu *et al* (*15*) used a displacement-controlled finite element analysis to evaluate the mechanical behavior of the lumbar spine after Dynesys placement and found preservation of motion and sufficient stability at the operated level, but greater ROM, annulus stress, and facet loading in the adjacent levels.

Our results indicate less hypermobility in the cranial segment compared to PLIF, which is likely because Dynesys is able to share the load exhibited in L4L5, and does not carry an excessive load to L3L4. However, the Dynesys system is stiffer initially (at 3-months follow-up), and thus can carry more load to L3L4 in the beginning. As the system relaxes and adapts with time, the system becomes more flexible and the load on the cranial level decreases. In the caudal segment, the change of mobility in the sagittal plane was small for both systems ; the Dynesys group demonstrated almost no change, whereas the PLIF group demonstrated a slight increase in mobility. It is clear from the results of prior studies, as well as of our own, that long-term studies of adjacent segment mobility and disease after Dynesys implantation are mandatory.

Clinical outcome. ODI, VAS, operation time, blood loss, hospital stay, complications

While the majority of studies have indicated positive results with the Dynesys system, some reports have indicated that results are no better than those obtained with typical fusion. Würgler-Hauri *et al* (*31*) studied 37 patients with acquired lumbar stenosis, segmental instability, and degenerative disc disease who underwent lumbar microsurgical decompression and Dynesys implantation. They reported that patients experienced a reduction of radicular pain, but a worsening of lumbar pain and that 27% of patients mentioned a poor outcome. In addition, at 1-year, 19% of patients required revision surgery. Grob *et al* (*10*) retrospectively studied 31 Dynesys patients, with at least 2-years of follow-up, with a mailed follow-up questionnaire. Within the 2-year period, 19% of patients either had or were scheduled for revision surgery, and only half of the patients stated that the operation had improved their overall quality of life ; less than half reported improvement in their functional capacity.

In the current study, ODI and VAS for back and leg pain improved significantly in both groups at 3-year follow-up. This improvement was comparable between the two groups, indicating that both procedures are effective for the treatment of lumbar stenosis L4L5. This significant improvement in ODI and VAS with Dynesys stabilization is consistent with many reports in the literature (*2,14,18,20, 25,28,30*). However, at 3 months postoperatively the VAS back pain scores were better in the Dynesys group (data not shown), suggesting that the system provides better relief in the early postoperative period. Probably because the Dynesys device provides immediate stabilization of the diseased segment, and neutralizes the abnormal forces caused by the pathological bony and soft tissue changes which cause back pain (*9,15,20,26,28,30,32*). On the other hand, PLIF requires successful fusion to achieve a completely stable segment to eliminate back pain.

The authors found that operation time was shorter in the Dynesys group, probably because there is no need for endplate preparation and insertion of an interbody device or bone grafting. Less blood loss in the Dynesys group is logical because insertion of the Dynesys device requires less bone and soft tissue dissection as compared to PLIF. Likewise, the shorter hospital stay in the Dynesys group is most likely due to the fact that the insertion of the device is less invasive as compared to PLIF (*23,25,30*). Although both Dynesys and PLIF require insertion of pedicle screws and rods (or spacers), Dynesys does not require insertion of an interbody fusion device or bone grafting, and is therefore relatively less invasive.

Complications

Complications were comparable in the two groups. One case of *screw loosening* after an L4L5 Dynesys implantation was identified on radiographs taken 3 months postoperatively. According to Dakhil-Jerew *et al* (*6*), Dynesys screw loosening should be confirmed with a "double-halo" sign. However, in our case, only a "single-halo" sign was detected, thus we believe that the screw and construct were secondarily stabilized by the soft tissues. Ko *et al* (*11*) studied screw loosening after implantation of the Dynesys system in 71 patients who underwent decompression for 1- or 2-level lumbar spondylosis. They found radiographic evidence of screw loosening in 19.7% of the patients (4.6% of screws) ; however, screw loosening had no adverse impact on clinical improvement. In our study, one case of screw loosening also occurred in the PLIF group, and no revision surgery was required. One *dural tear* occurred in the PLIF group during interbody cage insertion. Dural tear is a known complication of PLIF, whereas it is not likely to occur with implantation of the Dynesys system. Though there was no significant difference in *adjacent level instability* between the groups, there was one case of adjacent level instability in the Dynesys group as compared to 6 in the PLIF group. Of the 6 cases in the PLIF group, 3 patients underwent re-operation of the adjacent levels. We believe that this can be explained by the fact that PLIF increases load on adjacent levels, which speeds up further degeneration, especially in cranial segments, whereas the Dynesys seems to stabilize the index level without transferring excessive load to adjacent segments.

Weaknesses

Weaknesses of this study are : a short follow-up (3 years), potential errors in measuring radiographic mobility, stenosis not calculated as a percentage of the spinal canal, small patient numbers, no intention to treat analysis.

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