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ORIGINAL STUDY

Dynesys® dynamic stabilization outcomes in degenerative spine surgery

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Dynesys® is a dynamic device used for posterior stabilization of the lumbar spine. The objective of this study was to analyze the clinical and radiological outcomes at a 2-year minimum follow-up.

In this retrospective study, patients operated between 2009 and 2016 with Dynesys® stabilization were included. 5 different etiologies were included: disc herniation, lumbar stenosis, revision for adjacent segment disease (ASD), spondylolisthesis, and scoliosis. Clinical and radiological evaluations were performed. Postoperative complications and revisions were recorded.

136 patients were included: 34 for lumbar spinal stenosis, 19 for disc herniation, 29 degenerative spondylolisthesis, 41 revisions for ASD, and 13 scoliosis. Mean age was 64.8. Average clinical follow-up was 46 months. Postoperative clinical results showed a mean lumbar VAS of 3.07, a mean radicular VAS of 3.01 and an ODI score of 31.8%. The ASD rate was 16.2%, and overall revision rate was 11.8%. 2 cases (1.5%) of screw loosening were identified. Clinical outcomes, ASD rate and revision rate were more favorable in the spondylolisthesis and disc herniation groups.

This study has one of the largest Dynesys® cohort in literature. Spinal dynamic stabilization by Dynesys® presents good long-term clinical and radiological outcomes with a lower rate of complications than previously published cohorts and lumbar fusions. Best indications seem to be degenerative spondylolisthesis.

Keywords: Dynesys; degenerative spine; adjacent disease; dynamic stabilization; lumbar fusion.

INTRODUCTION

Spinal degenerative pathologies affect a large number of patients. There are currently many surgical techniques to manage these conditions with the objective of stabilizing lumbar spine *(1)*. Dynamic devices such as Dynesys® have been available since 1994 and are developed for the surgical treatment of spinal degenerative pathologies such as lumbar stenosis, disc de-generations with or without spondylolisthesis or herniated discs *(1,2)*. They allow stabilization of affected level(s) associated with nerve root decompression. The Dynesys® system includes titanium pedicle screws, polyethylene terephthalate (PET) strings, and urethane poly-carbonate cylinders *(3)*.

In the literature, this device has been proven to improve patients' clinical symptomatology *(4)*. The

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advantages of dynamic stabilization lie in stopping progression of spondylolisthesis (SPL) (if it exists), with shorter operative time and hospital-stay, less blood loss, avoiding morbidity due to bone graft harvesting *(5,6)*. Moreover, as this device allows a conservation of segmental mobility, the stresses are shared and hypermobility on adjacent levels decreases compared to fusions thus delaying adjacent disc degeneration *(3,6,7)*. Finally, a low complication rate is described in the literature, or similar to those described for fusions *(8-10)*.

The main objective of this study was to analyze long-term clinical outcomes of spinal dynamic stabilization by Dynesys®. The secondary objectives were to evaluate complication and long-term revision rate, and to carry out a radiological analysis of the evolution over time of adjacent segments angular mobility, lumbar alignment and facet joints fusion on CT-scan.

MATERIALS AND METHODS

Population

In this retrospective single-center study, patients operated on between 2009 and 2016 with Dynesys® system at one or two levels were included. Surgical procedure was proposed to these patients after a complete medical management of one of the five following etiologies: lumbar stenosis (with associated symptomatic disc degeneration or instability), disc herniation (revision or with associated symptomatic disc degeneration), revision for Adjacent Segment Disease (ASD), degenerative spondylolisthesis (SPL), and scoliosis. Follow-up was performed at 3 months, 6 months, 1 year and then annually with a clinical and radiological evaluation: standard antero-posterior and lateral radiographs of the lumbar spine, and dynamic X-rays, in flexion and extension.

Clinical outcomes data have been collected at last follow-up, including an Oswestry Disability Index (ODI), Lumbar Visual Analog Scale (L-VAS) and Radicular VAS (R-VAS). Intra- and post-operative complications were collected: dural tear, pseudomeningocele, surgical site infection, sensory-motor deficit or sphincter disorders, ASD as defined by Moreau et al *(11)*, overall revision rate and ASD revision rate.

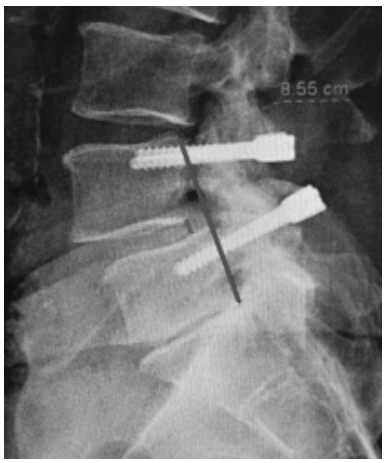

Fig. 1. — Posterior L4-L5 disc height ratio: disc height *(short grey line)* / L4+L5 bodies height *(long grey line)*.

Radiological analysis

Radiographical data were compared between preoperative and at last follow-up. The following parameters have been analyzed: pelvic incidence (PI), L1-S1 lordosis (LL), slip grading for spondylolistheses (in mm) and ratio of anterior and posterior disc height (ratio between height of disc and the two adjacent vertebral bodies, Fig. 1) *(8)*. Further, ranges of motion (ROM) have been compared between preoperative, 3-month postoperative and at last follow-up at the operated level and the adjacent levels above and below. The angle was measured between the upper endplate of the upper vertebra and the lower endplate of the lower vertebra on dynamic X-Rays (flexion and extension) *(8)*. Last, fusion was assessed on CT-scan images at last follow-up.

Surgical technique

All patients have been operated on following the same technique. The patient is positioned in lordosis, as described in the original technique. Although the stenosis is the most important in this position, it reproduces the standing thus allowing fixation in the right position *(3)*. A posterior median approach was performed, as small as possible to

avoid muscle detachment in order to prevent ASD. The procedure begins with pedicle screws placement (6 mm diameter, no hydroxyapatite coating). They were cannulated and implanted using K-wires to prevent mispositioning). Facet joints capsules are kept intact and no decortication is performed. PET ropes are then passed through the urethane polycarbonate rolls. The tensioning according to the graduation given by the tensor was performed in lordosis and caudad (the cylinder size being adapted to the space measured between the screws to respect coronal and sagittal alignment). To respect coronal alignment, both cylinders must have same length. In case of scoliosis, alignment was controlled by adjusting cylinder lengths asymmetrically. Central decompression was then performed, if necessary.

Statistical analysis

Statistical analyzes have been carried out using Stata software (version 14.0). After a descriptive analysis of the cohort, paired Student t-tests were performed to compare variables at the different timepoints.

The appearance of radiological ASD was also sought and relationship with the rate and type of surgical revision. We evaluated correlation between ROM at the operated level and the overlying level and the existence of fusion on the CT-scan. Last, we looked at the results of revision rate, ASD rate, fusion rate and the value of ODI according to the etiology. P-values <0.05 were considered significant.

RESULTS

Population and surgical data

One hundred and thirty-six patients were included, with 92 women and 44 men. Mean age was 64.8 years [27-87]. Thirty-four patients have been included for lumbar stenosis as main etiology (Fig. 2), 19 for disc herniation, 29 for degenerative spondylolisthesis, 41 for ASD (Fig. 3), and 13 for scoliosis. The procedure interested one level for 109 patients (80.1%) and 2 levels for 27 patients (19.9%). Mean clinical follow-up was 46.3 months [12-108]. Fifty-six patients (41.2%) had a previous history of spine surgery (Table 1).

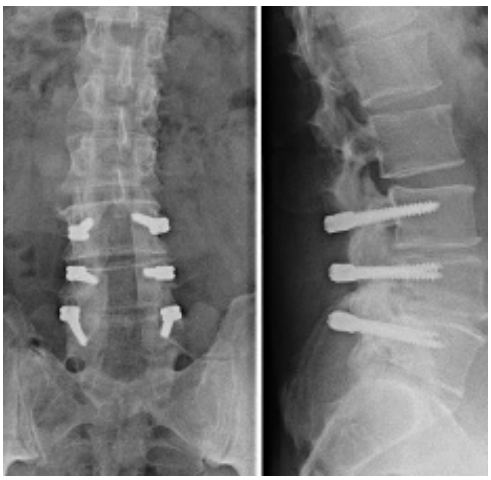

Fig. 2. — AP and lateral X-rays of L3L5 decompression and Dynesys stabilization.

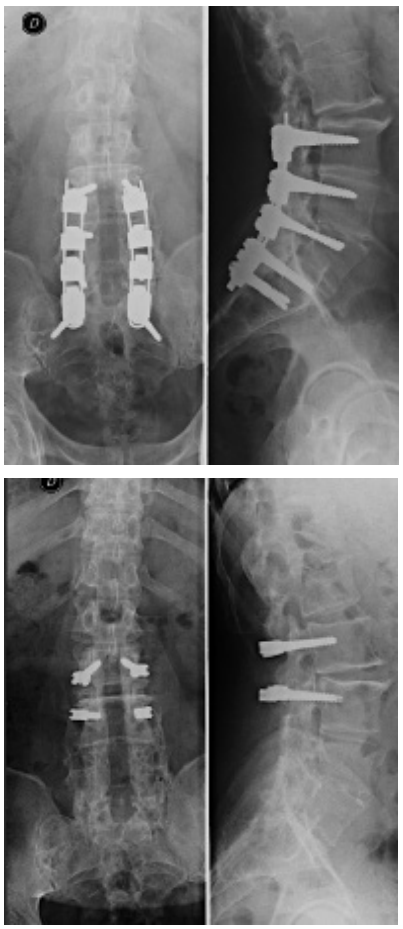

Fig. 3. — AP and lateral views of ASD above a L3S1 fusion *(left side)*. Surgical revision has been performed with hardware removal and Dynesys stabilization at the L2L3 level *(right side)*.

Table 1. — Demographic data of the cohort

	Cohort	Age	BMI	Revision	Single level	Double level
Stenosis	34 (25%)	68.4 [41-83]	25.9 [20-37]	4 (2.9%)	28 (20.6%)	6 (4.4%)
Disc Herniation	19 (13.9%)	45.6 [27-80]	25.9 [21-31]	5 (3.7%)	17 (12.5%)	2 (1.5%)
SPL	29 (21.4%)	70.3 [46-86]	26.4 [17-47]	1 (0.7%)	26 (19.1%)	3 (2.2%)
ASD	41 (30.1%)	65.1 [47-87]	26.1 [19-38]	41 (30.2%)	31 (22.8%)	10 (7.4%)
Scoliosis	13 (9.6%)	70.8 [57-86]	28.2 [21-35]	5 (3.7%)	7 (5.1%)	6 (4.4%)
TOTAL	136	64.8 [27-87]	26.3 [17-47]	56 (41.2%)	109 (80.1%)	27 (19.9%)

"Revision" column indicates number of patients with past lumbar spine surgery history. Percentages refer to the whole cohort. SPL: Spondylolisthesis, ASD: Adjacent Segment Disease.

Table 2. — Clinical outcome data

	Mean	Stenosis	Disc Herniation	SPL	ASD	Scoliosis
L-VAS *(/10)*	**3.07**	2.8	2.2	1.7	4.3	3.6
R-VAS *(/10)*	**3.01**	2.5	2.4	2.6	4.2	2.5
ODI *(%)*	**31.8**	32	24	27	35	40

L-VAS: Lumbar Visual Analog Scale. R-VAS: Radicular Visual Analog Scale.

Table 3. — Ranges of motion

Level	Pre-operative	3 months	Last follow-up
Overlying	11.4°	**10.8°**	**11.9°**
Index	**13.9°**	**16.3°**	**16.3°**
Underlying	14.9°	15.2°	15.5°

Statistically different values are in bold.

Surgical procedure concerned L4L5 level in 55.3% of the cases (75 patients), L3L4 in 27.2% (37 patients), L2L3 in 14.7% (20 patients). Average operating time was 110 minutes [60-210] and average blood loss was 736 mL [150-2120].

Post-operative clinical outcome

Clinical results showed a mean lumbar VAS of 3.07/10, and a mean radicular VAS of 3.01/10. Mean postoperative ODI score was 31.8%. Clinical outcomes were better in SPL and disc herniation groups than in ASD and scoliosis groups (Table 2). The differences between the groups were not statistically significant (p=0.2).

Radiological analysis

Mean Pelvic Incidence was 61.9°. Lumbar lordosis stayed stable over time with respectively means of 48.2°, 47.8° and 48.0° preoperatively, postoperatively and at last follow-up. Among patients included for scoliosis, the average Cobb angle was 29° for main curvature (Fig. 4).

At last follow-up, spondylolistheses did not show significant progression regarding slip grading, with less than 1 mm difference (Fig. 5). The ratios of anterior and posterior disc heights did not vary significantly over time.

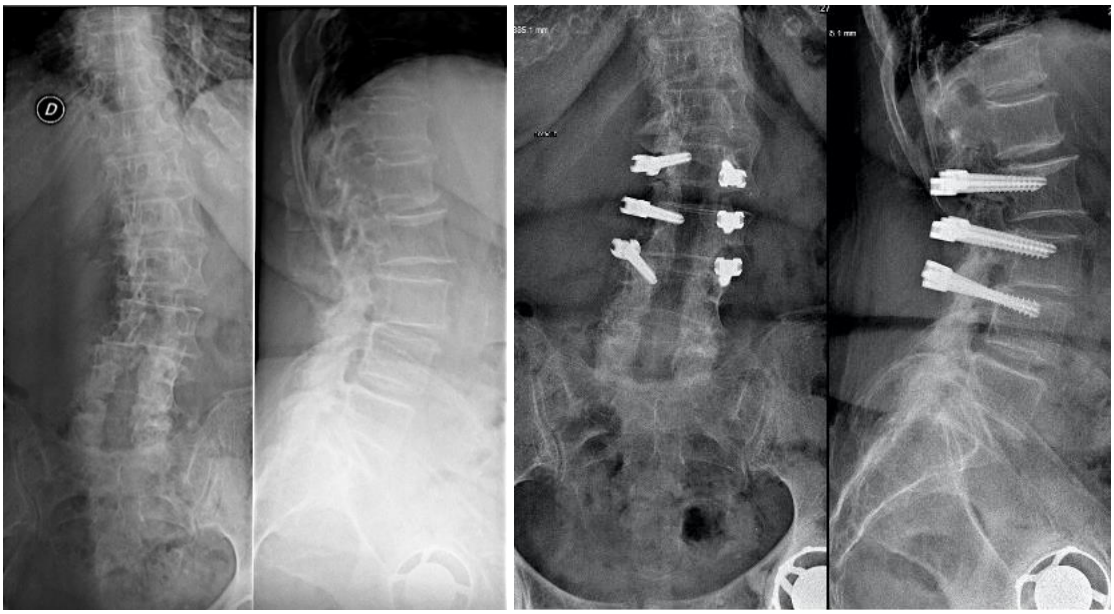

Fig. 4. — Lumbar scoliosis treated with extended decompression and L2L4 Dynesys stabilization

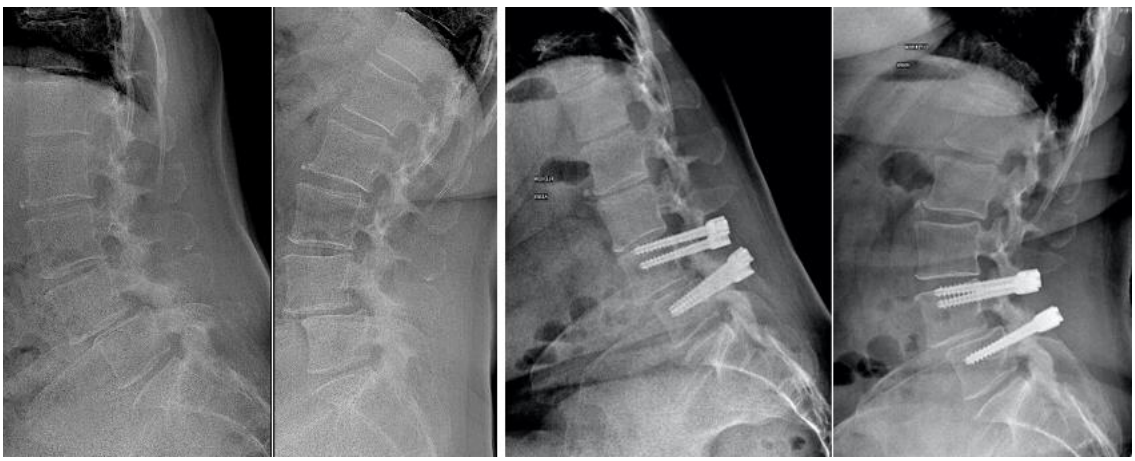

Fig. 5. — Dynamic X-Rays of L4L5 degenerative spondylolisthesis treated by Dynesys stabilization.

Table 4. — Fusion rate, mechanical complications and revision rates

	Stenosis	Disc Herniation	SPL	ASD	Scoliosis
ASD	3 (8.8%)	1 (5.3%)	5 (17%)	11 (26.8%)	2 (15.4%)
Loosening	0	1 (5.3%)	0	0	1 (7.7%)
Fusion rate (CT-scan)	66.7% (4/6)	0% (0/4)	83.3% (5/6)	88.9% (8/9)	50% (1/2)
Revision rate	14.7% (5/34)	10.5% (2/19)	3.4% (1/29)	14.6% (6/41)	15.4% (2/13)
Revision rate for ASD	2 (5.9%)	1 (5.3%)	1 (3.4%)	5 (12.2%)	1 (7.7%)

Table 5. — Adjacent Segment Disease data

16.2% ASD	Disc height loss > 50%	Junctional SPL >3mm	Overlying Stenosis	PJK > 10°
Distribution	5.1%	7.4%	2.2%	1.5%
Revision rate	28.8%	50%	100%	50%

PJK: Proximal Junctional Kyphosis.

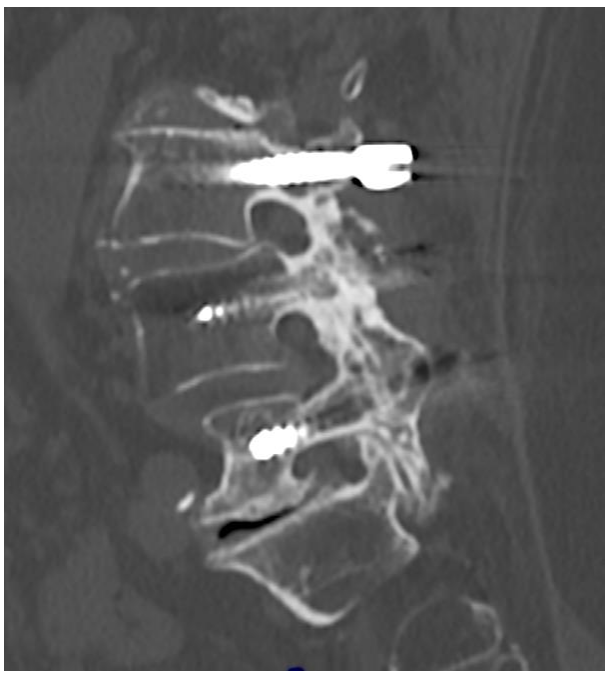

Fig. 6. — Sagittal view of CT-scan showing L3L5 fusion after stabilization with Dynesys.

A statistically significant increase in ROM was noted at the operated level between the preoperative values and those at 3 months ($p<0.001$), stable at last follow-up. A statistically significant increase in ROM at the overlying level between values at 3 months and at last follow-up has also been exhibited ($p=0.04$) (Table 3).

Post-operative CT-scan data was available for 27 patients (19.9%). A facet joints fusion has been highlighted for 66% of them (18 patients) at the operated level (Fig. 6, Table 4). The ASD group presented a significantly higher fusion rate at 88.9% ($p=0.02$).

A 1.5% rate of implant loosening (2 screws) has been noted, without any implant mobilization. There was no statistically significant relationship between fusion rate and ROM (pre- and post-operative) at the operated level as well as the overlying one.

Complications and revisions

Early complications collected included one case of early surgical site infection (0.7%), 2 cases of motor deficit (1.4%), 18 dural tears (13.2%) occurring for 2/3 of the cases if it was a revision procedure, 1 pseudomeningocele (0.7%) and 2 epidural hematomas (1.4%). Late complications included two cases of infection on previous hardware (1.4%), 1 late infection (0.7%) and 22 adjacent segment diseases (16.2%). The overall revision rate was 11.8%. Although no significant difference has been highlighted, revision rate in the spondylolisthesis group was the lowest, at 3.4% ($p=0.06$). Further, ASD rate and revision rates (overall and for ASD) were lower in SPL and disc herniation groups than in ASD and scoliosis groups (Table 4).

Among the ASD complications, 5.1% exhibited disc height loss of more than 50%, 7.4% presented a spondylolisthesis of more than 3mm, which were retrolisthesis for 80% of them, 2.2% had an overlying stenosis and 1.5% exhibited proximal junctional kyphosis >10° (Table 5). Revision rate was significantly higher in the ASD complication group (47.6%) than non-ASD patients (5%) ($p<0.001$). The average time for ASD revision was 40 months. These revisions were mainly one-level extension of laminectomy and Dynesys®, for five patients, or Dynesys® replacement and extended fusions, for three patients (Fig. 7a and 7b).

DISCUSSION

This series analyzed one of the largest Dynesys® cohort of the literature, with a follow-up of more than 2 years. Except meta-analyzes, only Kuo

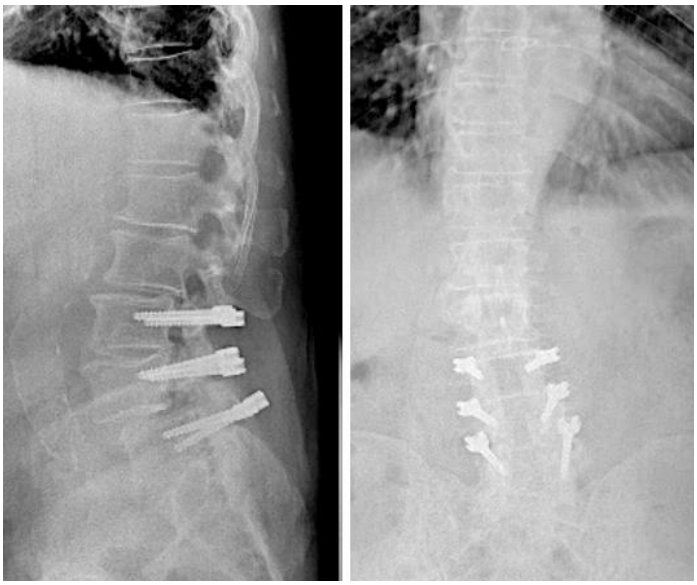

Fig. 7a. — Lateral and AP view of a 2-level Dynesys construct, with retrolisthesis at the overlying level, at 2 years post-op.

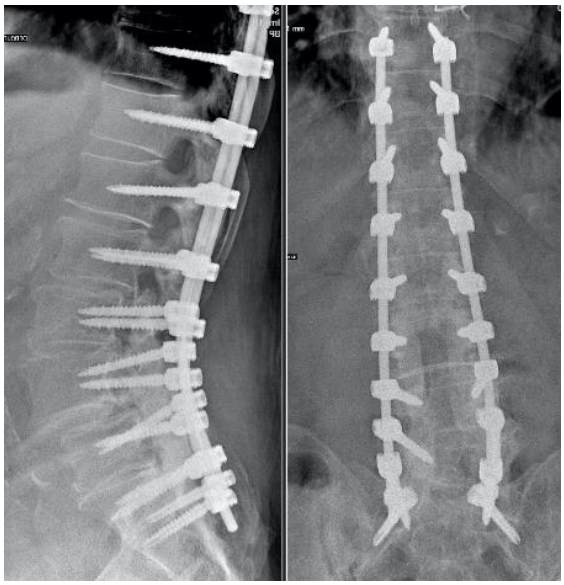

Fig. 7b. — X-rays after revision procedure by extended T10-S1 fusion.

presented a series of 206 patients with a mean follow-up of 51 months *(12)*. The majority of studies have series counting less than 100 patients or a follow-up shorter than 36 months. Two studies have results over 7 years but with a reduced number of patients *(13)*.

The average operating time (110 min) corresponds to those found in the literature (109 min for Zhang and 141 min for Yang *(8,12)*). The average blood loss (736 mL) seems greater than other studies (250 mL for Hsieh *(14)* or 386 mL for Yang *(15)*). However, in these 2 studies, the average blood loss given was the intraoperative data while our data accounted the blood loss during and after the surgery. In addition, the Wiltse approach is known to be less hemorrhagic than median approach, used in this study.

The postoperative clinical results in this study are favorable, and consistent with the literature. However, slightly better results can be noted in some studies concerning lumbar and radicular VAS at around 2/10 *(4,15,16)* and postoperative ODI scores around 15-20% *(7,14,17)*. Nevertheless, these studies have a shorter follow-up and the ASD group in the present study (30.1% of the whole cohort) is a group with worse results, which affects our overall results. More, Lee studied clinical outcomes of 15 ASD patients treated with Dynesys® and showed similar results to ours with a VAS around 4.2/10 and an ODI score at 35% *(18)*. Clinical outcome, as per ODI, L-VAS and R-VAS, were better in the SPL and disc herniation group. The ODI scores were the poorest in the scoliosis and the ASD groups, respectively 40% and 35%.

This study showed that ROM was significantly increased at last follow-up at the Dynesys® level and the overlying one. Conversely, several studies have shown a ROM decrease at the operated level *(8,15,19)*. G. Dubois initially hypothesized a disc rehydration after placement of a Dynesys® system, but Fay showed, after analysis of MRI signal, low disc rehydration in patients over 65 years old (population close to that of our study) *(16)*.

At last follow-up, a high fusion rate at the operated level has been identified on CT-scan images, at 66%. There was no significant association between the presence of fusion and ROM, at the operated level nor at the overlying level. However, the absence of significance may be explained by the few number of CT-scan available.

Fay also reported a 54.3% CT-scan fusion rate in a cohort of 70 patients at 29 months follow-up *(20)*. Patients over 60 years had a higher risk

of arthrodesis (OR 12.42), with no clinical consequence. In addition, Saint-Pierre described a fusion rate of 17% in a cohort of 52 patients at a follow-up of 92 months, with an average fusion time of 65 months *(13)*. It can be hypothesized that contact of polycarbonate urethane cylinders on facet joints could promote slow bone fusion.

The overall revision rate was 11.8%, con-sistent with literature as Stoll published a 19.3% revision rate, and Di Silvestre described a 6.9% rate in a cohort of 29 patients with a 54 months follow-up *(10,21)*.

In the literature, Dynesys® implants loosening is defined by a double halo image on the AP X-ray or CT-scan axial cuts *(12)*. In this study, only 2 cases of loosening were found (1.5%), without mobilization of the implants. This rate is much lower than the data in literature: 13.8% for Di Silvestre *(21)*, 20.4% for Kuo *(12)*. In addition, Kuo described loosening risk factors: PI-LL mismatch and screws placed in S1 *(12)*.

A radiological ASD incidence of 16.2% was found, of which 1/3 had surgical revision. ASD patients were not all symptomatic. Indeed, no significant relationship has been highlighted between ASD and ODI score. Nevertheless, Saint-Pierre has shown significantly better clinical outcomes in patients without ASD *(13)*. The rates of ASD in literature are heterogeneous, 47% at 4 years for Kim [19] versus 6% at 53 months for Zhang *(8)*. This can probably be explained by the heterogeneity of the definitions used. Saint-Pierre found 28.9% ASD at 45 months and described risk factors for ASD: pre-operative existence of ASD, neurological deficit, surgical revision and multiple degenerative levels *(13)*.

The revision rate for ASD (6.6%) was lower than in the literature (8.4% for Stoll *(10)*). However, we note that 1/3 of the ASD in this study were revised, which coincides with Pham's study in which 40.6% of ASD were revised *(9)*. Incidence of ASD and revision rate (overall and for ASD) were lower in SPL and disc herniation groups. Conversely, the incidence of ASD and revision rate for ASD appear to be higher in the group of patients operated for ASD.

Literature often fails to demonstrate a significant difference between fusion and dynamic stabilization. Indeed, improvement in VAS and ODI is often similar in both groups *(22)*. Some studies even exhibit a higher ODI score in the Dynesys® group than PLIF *(15,23)*. Regarding surgical technique, fusion operating time is longer with greater blood loss *(8)*. In a majority of studies, adjacent levels hypermobility is described as lower in the Dynesys® group than fusion group *(6,22)*. The incidence of ASD appears to be higher in the PLIF group (15% versus 6% *(8)*). Other studies showed an identical rate of complications between the 2 groups *(22)*. Last, studies show a higher complication rate, as demonstrated by Guigui, with a complication rate of 23% of which 3.6% of mechanical complications in lumbar and lumbosacral fusions with major risk factors (overweight, co-morbidities and the extent of fusion) *(24)*.

The limitations of this study lie in the cohort size, reducing study power and making it difficult to show statistically significant differences between the groups. The retrospective nature is also a limitation of this study. In addition, the lack of preoperative clinical data precludes comparison with postoperative data.

CONCLUSION

Spinal dynamic stabilization with Dynesys® presents good long-term clinical and radiological outcomes with a low rate of complications, after thorough selection of patients and indications. Optimal indication of Dynesys® appears to be degenerative spondylolisthesis.

One of the main goals of dynamic stabilization in degenerative spine surgery is the prevention of ASD, avoiding higher morbidity fusion procedures.

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