Clinical Outcomes and Complications After Pedicle-anchored Dynamic or Hybrid Lumbar Spine Stabilization

A Systematic Literature Review

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Study Design: A systematic medline review.

Objective: An overview of pedicle-based dynamic stabilization devices clinical outcomes.

Summary of Background Data: Fusion is the standard instrumentation for many pathologies of the lumbar spine. Worrying rates of failure, including adjacent segment degeneration (ASD), have consistently been reported. The interest for dynamic stabilization came from the need of minimizing the long-term complications related to the restriction of the lumbar motion. However, pedicle-based dynamic stabilization advantages and drawbacks remain controversial.

Materials and Methods: Articles about the clinical outcomes were identified by a comprehensive Medline search. The inclusion criteria were a minimum follow-up of 12 months, indications for lumbar dynamic stabilization, and assessment of clinical outcomes and adverse events. The studied parameters included self-reported outcomes (pain, disability, and satisfaction) and complications.

Results: A total of 46 articles fulfilling the inclusion criteria were reviewed providing results for 2026 patients with a mean follow-up of 33 months. The postoperative improvements in terms of pain and disability were significant. Subjective assessment showed an overall patient satisfaction of 83.4%. Radiographic ASD occurred in 0%–34% of patients. Device breakage occurred in 0%–30%, and device loosening in 0%–72% of patients. The global amount of revision surgeries reached 9.4% mainly for breakage, ASD, or persistent pain, not always associated with screw loosening.

Conclusions: Dynamic stabilization seems as safe and effective but benefits might partly come from decompressive gestures. Reported clinical outcomes seems to be comparable with outcomes published for fusion and no clear evidence of protection of the adjacent segments emerge from this mid-term review. Technical failures are design related but also linked with patient specificities. Relationships between sagittal balance and surgery outcomes are still rarely reported. Dynamic stabilization might display advantages in selected indications, such as moderate degeneration and beginning instability associated with clinical symptoms, but further clinical studies are needed.

Key Words: dynamic stabilization, clinical outcomes, screw loosening, adjacent segment degeneration, device failure

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As fusion is the most frequently used technique to instrument the lumbar spine, the question of dynamic stabilization arose about 2 decades ago with the yearning for a more physiological and balanced proposal for patients.[1] The maintenance of mobility at the instrumented segment is intended to transfer less loads at the adjacent segment thus decreasing the occurrence of adjacent segment degeneration (ASD) sometimes reported for rigid fusion devices. Several innovative concepts broke through such as total disk replacement, interspinous devices, or pedicle screw–based posterior devices. They have the common aim to maintain an anatomic-like flexibility of the vertebral segment but their inner functioning, their indications, and their surgical techniques differ. This review will only address the pedicle-based dynamic stabilization (PBDS) devices.

Until now the common indications of PBDS are moderate disk degeneration (Pfirrmann grade III or IV), mild facet osteoarthritis, low-grade spondylolisthesis, lumbar segmental instability, and dynamic stenosis, associated with clinical symptoms. The hybrid use of dynamic stabilization (1 flexible level adjacent to fused levels) aims to create a transition between a fused segment, a moderately degenerated segment, and the noninstrumented spine. Biomechanical reviews have demonstrated the impact of PBDS devices on the motion

of the lumbar spine.[2] A reduction in the range of motion is expected to protect the instrumented segment without transferring all the loading on the adjacent segment. However, there is still no clear clinical evidence that PBDS has better clinical results than fusion, and the controversy remains.

Several studies have addressed issues linked with nonfusion devices such as screw loosening[3] or ASD.[4] However, the biomechanical and clinical impacts of implant failure are not clear to date.

The purpose of the current review is to give a global overview of the clinical outcomes of PBDS devices, and to list and analyze the specific device-related complications. Reviews about posterior fusion, as the gold standard, are used as an element of comparison.

MATERIALS AND METHODS

Literature Search Protocol

A Medline search was performed using the query described in Figure 1 to find the articles published before January 10, 2013, about the clinical outcomes of dynamic stabilization devices. The reading of each title and abstract enabled the author to delete every publication that was not corresponding to the objectives of the review. The inclusion criteria for the selection were:

- Clinical study except from case reports.
- Indication for lumbar surgery.
- At least 1 group operated with a PBDS device used for dynamic stabilization.

The exclusion criteria were:

- Text of the article not written in English, French, Spanish, or German.
- Impossibility to determine the device used.
- Mean follow-up lower than 12 months.
- Patients already enrolled in another selected study with a longer term follow-up or a larger patient cohort.
- No mention of visual analog scale (VAS) or Oswestry Disability Index (ODI) nor remarks about the rate of complications during or after the surgery.
- Instrumentation with the Graf ligament because of a limitation of hyperflexion only, which is significantly different from other PBDS concepts.

The references of the selected articles have then been reviewed to add relevant related publications to the analysis.

Given the low number of prospective studies with long-term follow-up the decision has been taken to keep the retrospective studies and the short-term studies, with a mean follow-up higher than 12 months, in the analysis.

Within the 279 publications retrieved by the Medline search, and the additional references, a total of 46 clinical studies were included in the review process.

Statistics

Unpaired *t* test was used to compare cohorts following the study design.

Observed Parameters

The parameters observed by each author of the selected articles differ from one article to another. The publications have been classified given the following parameters.

- Clinical outcomes (ODI, VAS, satisfaction).
- Adjacent segment protection.
- Device-related complications (breakages, loosening).
- Revision surgeries.

Some of the included papers present a comparison between a dynamic device group and a control group. These additional data will be used in the Discussion section.

RESULTS

Devices

The 11 different PBDS devices included in the review are listed in Table 1 and the available data in Table 2.

Dynamic Versus Hybrid Use

Most of the devices were used as pure dynamic constructs for spine segmental stabilization. There were 8 papers dealing with hybrid devices (Table 3). Three of these studies[16,29,47] compared the 2 versions of the same device: pure dynamic versus hybrid construct. Among the total 2026 patients included in this systematic review, only 145 had a hybrid construct. Except for 2 papers[24,29] the distinction between dynamic and hybrid use was made for the analysis of the results.

Retrospective Versus Prospective Study

Among the 46 studies 18 were prospective, dealing with a global amount of 641 patients. A total of 16 additional studies were retrospective but dealt with consecutive patients' cohorts: 776 patients were included in this group. The 609 remaining patients were included in retrospective nonconsecutive studies or in studies where the information necessary to conclude was missing (Table 4). Four studies dealt with a comparison with fusion,[4,11,32,46] 1 study compared dynamic stabilization with noninstrumented surgery,[17] and 1 study addressed the issue of performing or not an additional decompression gesture.[31]

Indications

The most encountered indications for surgery were clinical symptoms associated with degenerative disk diseases, spinal stenosis, disk herniation, segmental instability, or low-grade spondylolisthesis. More scarcely, the devices were used for revision surgeries because of adjacent segment pathology or for degenerative scoliosis.

The additional decompressive gestures did not always describe in detail as to what causes an issue in the analysis of the outcomes, especially in terms of pain relieving.

Clinical Outcomes

In this clinical review, 41 studies out of 46 dealt with self-assessment of the clinical outcomes, reporting VAS or ODI scores. Ten studies mentioned patient satisfaction

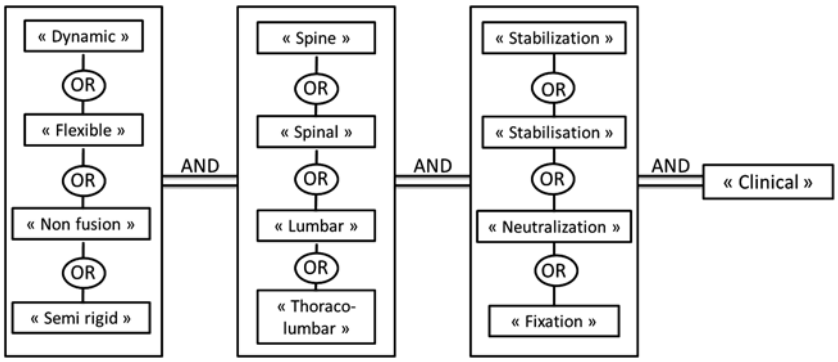

FIGURE 1. Query for the systematic Medline search on the words included in the title or in the abstract of the paper.

through the answer to the question "Would you choose to undergo the same operation now knowing the results?"

The results of the VAS are presented in Table 5. Scores for global VAS were given in 17 studies concerning 747 patients. The mean score varied from 5.8 to 8.6 before surgery, and from 0.8 to 4.2 at a last follow-up of 29.7 months on an average. For 754 other patients (included in 18 studies) VAS scores were separated according to back pain and leg pain. Overall, the mean score for VAS-back varied from 5.4 to 8.3 preoperatively, and from 1.9 to 5.7 at a last follow-up of 28.0 months on an average. The mean score for VAS-leg varied from 4.2 to 8.4 preoperatively, and from 1.0 to 4.7 at last follow-up.

ODI scores were reported in 33 studies concerning 1573 patients. The mean value was comprised between 24.7% and 79.6% before surgery. At a last follow-up of 33.9 months on an average, ODI mean score was between 3.0% and 49.9%. ODI scores are detailed in Table 5.

In the 10 studies dealing with patient's satisfaction analysis, 83.4% of 635 patients answered they would choose to undergo the same operation. Those patients had a mean hindsight of 43.6 months at the time of their answer. The values were comprised between 68%[15] and 94%.[5]

No statistically significant difference has been found for any clinical score between the prospective and the retrospective studies.

ASD

About one out of 3 studies addressed the occurrence of ASD. As the clinical symptoms triggered by ASD were not always detailed, distinction was made between ASD triggering revision surgery and radiographic ASD (Table 6). Rates of symptomatic ASD are obviously lower than radiographic occurrence. Among the different papers, there was a wide range of radiographic ASD occurrence, ranging from 0% to 34% representing a mean of 16% (out of 333 patients, with a mean hindsight of 51 mo). As far as revision surgery for ASD is concerned, the mean occurrence was 3.4%, calculated out of 770 patients at a mean follow-up of 38 months. Even if the global tendency is an increasing rate of ASD with an increasing follow-up, the correlation between mean follow-up and rates of ASD is very low ($R^2 = 0.14$, Fig. 2). No statistically significant difference has been found between retrospective studies and prospective studies concerning the occurrence of ASD.

Mechanical Failure of the Implant

Postoperative complications related to the mechanical failures of the device (rod or screw breakages and screw loosening) are reported in Table 6. There was a wide range of rod breakages varying from 0% to 30%. Predictably enough, no rod breakages were reported for Dynesys because it is radiotransparent. Apart from this device, the global rate of rod breakage was 2.2% (13 out of 610 patients).

Regarding screw breakage, the mean global rate was 1.6% (29 out of 1788 patients).

The mean global rate of screw loosening was 10.1% (163 cases out of 1608 patients) but within a wide range of occurrence from 0% to 72%.

In this review, the rates of mechanical complication seem not to be correlated with the follow-up. There was no statistically significant difference concerning the occurrence

TABLE 1. Pedicle-based Dynamic Stabilization Devices for Reach Results Are Reported in This Review

"Spring-like" metallic devices		Devices with a metallic core and a PCU sleeve	
Accuflex	Globus Medical, Audubon, PA	Agile	Medtronic Sofamor Danek, Memphis, TN
BioFlex	Biospine, Seoul, Korea	Flex +	Spinevision, Antony, France
Dream elastic rod system	Dream STS, Seoul, Korea	Nflex	Synthes Spine, West Chester, PA
Hinged-screw devices		Other dynamic devices	
Safinaz	Medikon AS, Turkey	Isobar	Scient'X Alphatec Spine USA, Maitland, FL
Cosmic	Ulrich Gmbh and Co. KG, Ulm, Germany	Isolock	Scient'X Alphatec Spine USA
PCU + ligament			
Dynesys	Zimmer Spine, Warsaw, IN		

TABLE 2. List of Selected Article, With the Type of Study (Cons., Consecutive Patients), the Number of Patients Included, the Follow-up and the Outcomes They Deal With

References	Type of Study	Device	No. Patients	Mean FU	Minimum FU	Maximum FU	Reported Clinical Outcomes	Reported Postoperative Complications
Benezech and Mitulescu[5]	Retrospective	Isolock	33	45	35	88	Satisfaction	Breakage, loosening, revision, ASD
Bordes-Monmeneu et al[6]	Retrospective	Dynesys	94	18	14	24	ODI	*
Bothmann et al[7]	Prospective	Dynesys	40	16	12	37	VAS-back/VAS-leg	Breakage, loosening, revision, ASD
Cakir et al[8]	Retrospective	Dynesys	10	22	12	30	ODI	Breakage, loosening, revision
Cansever et al[9]	Retrospective	Dream Elastic	25	12	12	12	No	ASD
Coe et al[10]	Retrospective—cons.	Nflex	72	26	23	34	ODI, VAS	Breakage, loosening, revision, ASD
DiSilvestre et al[11]	Retrospective—cons.	Dynesys	32	64			ODI, VAS-back/VAS-leg	Breakage, loosening, revision, ASD
Dubois et al[12]	Prospective	Dynesys	57	13	2	31	No	Breakage, loosening, revision, ASD
Fay et al[13]	Retrospective—cons.	Dynesys	38	41	30	58	ODI, VAS-back/VAS-leg	Breakage, loosening, revision
Fayyazi et al[14]	Prospective	Dynesys	6	24	24	24	ODI, VAS-back/VAS-leg	*
Grob et al[15]	Retrospective—cons.	Dynesys	31	34	24	43	VAS-back/VAS-leg, satisfaction	Breakage, loosening, revision
Hoff et al[16]	Prospective	Agile	37	24	24	24	ODI, VAS-back/VAS-leg	Breakage, revision
Hoff et al[17]	Prospective comparative	Dynesys	29	122			ODI, VAS	Breakage, revision, ASD
Hoppe et al[18]	Retrospective—cons.	Dynesys	39	86	60	134	ODI, satisfaction	Breakage, revision, ASD
Hu et al[19]	Retrospective—cons.	Dynesys	32	16	6	23	ODI, VAS-back/VAS-leg	Breakage, loosening, revision
Hudson et al[20]	Prospective	Isobar	22	21	12	24	ODI, VAS	Breakage, loosening, revision
Kaner et al[21]	Prospective	Agile	15	19	12	25	ODI, VAS	Breakage, revision
Kaner et al[22]	Prospective	Cosmic	30	43	22	66	ODI, VAS	Breakage, loosening, revision
Kaner et al[23]	Prospective	Cosmic	26	38	24	55	ODI, VAS	Revision
Kim et al[24]	Retrospective	BioFlex	46	12	12	12	ODI, VAS	Breakage
Kim et al[25]	Retrospective—cons.	Dynesys	21	31			ODI, VAS	Breakage
Klockner and Beck[26]	Retrospective	Dynesys	20	12	11	21	VAS, satisfaction	Loosening, revision
Ko et al[27]	Retrospective—cons.	Dynesys	71	17	8	29	ODI, VAS	Breakage, loosening, revision
Kocak et al[3]	Retrospective	Dynesys	19	12	12	12	ODI	Loosening, revision
Lee et al[28]	Retrospective—cons.	Dynesys	19	27	16	35	ODI, VAS	Breakage, loosening, revision
Li et al[29]	Retrospective—cons.	Isobar	36	24	12	36	ODI, VAS-back/VAS-leg	Breakage, revision, ASD
Lutz et al[30]	Retrospective—cons.	Dynesys	50	58	6	91	No	Breakage, loosening, revision
Maleci et al[31]	Retrospective—cons.	Cosmic	139	24	24	24	ODI, VAS, satisfaction	Breakage, loosening, revision, ASD
Ozer et al[32]	Retrospective	Safinaze	19	24	24	24	ODI, VAS	Breakage, loosening, revision
Park et al[33]	Retrospective—cons.	Bioflex	27	12			VAS-back/VAS-leg	Breakage, revision
Putzier et al[34]	Retrospective	Dynesys	70	33	18	50	VAS, satisfaction	Breakage, loosening, revision
Putzier et al[4]	Prospective comparative	Dynesys	22	76	60	91	ODI, VAS	Breakage, loosening, revision, ASD
Reyes et al[35]	Prospective	Accuflex	18	24	24	24	ODI, VAS-back/VAS-leg	Breakage, revision
Ricart and Serwier[36]	Prospective	Dynesys	25	34	24	72	No	Breakage, revision
Sapkas et al[37]	Retrospective	Dynesys	66	36	13	55	ODI, satisfaction	Breakage, loosening, revision
Sapkas et al[38]	Retrospective	Dynesys	107	82	12	132	ODI, Satisfaction	Breakage, loosening, revision
Schaeren et al[39]	Prospective	Dynesys	26	52	48	57	VAS	Breakage, loosening, revision, ASD
Schwarzenbach et al[40]	Retrospective—cons.	Dynesys	31	39	24	90	ODI, VAS-back/VAS-leg	Breakage, loosening, revision, ASD
Stoffel et al[41]	Retrospective	Cosmic	100	15			ODI, VAS	Breakage, loosening, revision, ASD
Stoll et al[42]	Prospective	Dynesys	83	38	11	79	ODI, VAS-back/VAS-leg	Breakage, loosening, revision, ASD
Welch et al[43]	Prospective	Dynesys	101	12	12	12		Breakage, loosening, revision

							ODI, VAS-back/VAS-leg, satisfaction	
Wu et al[44]	Retrospective—cons.	Dynesys	126	37			ODI, VAS-back/VAS-leg	Breakage, loosening, revision
Würgler-Hauri et al[45]	Prospective	Dynesys	37	12	12	12	VAS-back/VAS-leg	Breakage, revision
Yu et al[46]	Prospective comparative	Dynesys	35	36	36	36	ODI, VAS-back/VAS-leg	Breakage, loosening, revision, ASD
Zagra et al[47]	Prospective	Flex+	32	12	12	12	ODI, VAS-back/VAS-leg	Breakage, loosening, revision
Zhang et al[48]	Retrospective—cons.	BioFlex	12	23	12	33	VAS-back/VAS-leg	*
Total no. patients: 2026 patients		For each criteria:					ODI: 1573 (34)	Breakage: 1788 (34)
Mean follow-up: 33 mo [12–122]		No. patients included in cohorts (mean follow-up) (mo)					VAS: 747 (30)	Loosening: 1608 (34)
							VAS-leg/VAS-back: 754 (28)	Revision: 1822 (34)
							Satisfaction: 635 (44)	ASD: 799 (36)

*Nothing to report.
Calculation of the patient cohorts for each criterion.
ASD indicates adjacent segment degeneration; FU, follow-up; ODI, Oswestry Disability Index; VAS, visual analog scale.

TABLE 3. Number of Patients Included in Studies Reporting the Use of the PBDS Device in a Hybrid Manner

		Type of Construct	
References	**Device**	**Pure Dynamic**	**Hybrid**
Hoff et al[16]	Agile	17	20
Hudson et al[20]	Isobar	0	22
Kaner et al[21]	Agile	0	15
Kim et al[24]	Bioflex	?	?
Li et al[29]	Isobar	23	13
Putzier et al[4]	Dynesys	0	22
Schwarzenbach et al[40]	Dynesys	0	31
Zagra et al[47]	Flex+	10	22

? indicates unknown distribution.

of complications between retrospective and prospective studies.

Revision Surgery

The number of patients who underwent a revision surgery is reported in Table 6. Overall, the mean global rate of revision was 9.4% including different rationales for revision surgeries (complications, device failure, or ASD). Rates of symptomatic complications leading to revision surgeries are lower than rates of complications seen on imaging but we cannot know what will be the evolution on the long term, for instance for patients with signs of degeneration at mid-term follow-up.

DISCUSSION

As nonfusion devices are the subject of growing questioning, our aim was to perform a review of the clinical literature to understand the outcomes and complications linked with this family of devices. As many meta-analysis, the main limitations of this study were the high variability of protocols and the lack of long-term randomized controlled studies, limiting conclusions especially concerning the degeneration of adjacent segments, which is the main endpoint of dynamic devices. Moreover, additional surgical decompressions were sometimes performed or the surgical procedure not detailed, making it difficult to distinguish the benefits of the decompression from the benefits of the instrumentation. Last, the variability of designs available on the market and the major differences from one device to another has to be kept in mind even if all the results are here summarized together.

Nevertheless, despite those limitations, our review enabled us to highlight some key points in the understanding of dynamic stabilization outcomes.

TABLE 4. Type of Study

Type	**Studies**	**Patients**
Prospective	15	555
Prospective comparative	3	86
Retrospective	12	609
Retrospective consecutive	16	776
Total	46	2026

TABLE 5. Clinical Outcomes Reported in Each Publication (Mean Scores Assessed Preoperatively and at Last FU)

Type	References	Patients	Mean FU	VAS-Back Pre	VAS-Back Last FU	VAS-Leg Pre	VAS-Leg Last FU	VAS Pre	VAS Last FU	ODI Pre	ODI Last FU
Dynamic											
< 2 y follow-up	Klockner and Beck[26]	20	12					8.3	3.1		
	Zagra et al[47]	10	12	7.9	2.8	4.2	1.0			39.0	3.0
	Kim et al[24]	46	12					7.3	1.4	35.2	12.1
	Kocak et al [3]	19	12							54	37.6
	Welch et al[43]	101	12	5.4	3	8	2.6			56.5	26.3
	Wurgler-Hauri et al[45]	37	12	6.7	4	8.4	3.1				
	Park et al[33]	27	12	6.5	3.3	7.4	2				
	Stoffel et al[41]	100	15					6.5	2.1	51	21
	Bothmann et al[7]	40	16	8.3	3.4	7.2	2.9				
	Hu et al[19]	32	16	7.3	3.5	7.6	3.2			69	28
	Ko et al[27]	71	17					5.8	2.7	50.4	25.3
	Bordes-Monmeneu et al[6]	94	18							56.8	21.4
	Cakir et al[8]	10	22							54	33
	Zhang et al[48]	12	23	6.9	2.4	7.3	1.8				
< 3 y	Hoff et al[16]	17	24		3.7		3.1				27.2
	Fayyazi et al[14]	6	24	5.5	2.3	7.6	2.1			40	22
	Maleci et al[31]	139	24					7.3	2.5	48.9	22.5
	Ozer et al[32]	19	24					6.7	1.1	64.5	8.6
	Reyes et al[35]	18	24	7.9	2.8	4.2	1			55	24
	Coe et al[10]	72	26					8.1	3.8	44.5	21.8
	Lee et al[28]	19	27					8.5	2.2	79.6	22.2
	Kim et al[25]	21	31					8.6	4.2	24.7	13
	Putzier et al[34]	70	33					8	3		
	Grob et al[15]	31	34	7	3.8	6.6	4.7				
< 4 y	Yu et al[46]	35	36	7.26	3.55	7.03	3.07			59.1	29.2
	Sapkas et al[37]	66	36							55	22
	Wu et al[44]	126	37	6.3	2.5	7.1	2.1			52.4	22.3
	Kaner et al[22]	26	38					7.4	0.8	73.4	9.3
	Stoll et al[42]	83	38	7.4	3.1	6.9	2.4			55.4	22.9
	Fay et al[13]	38	41	6	1.9	7.4	2.5			50.6	27.3
	Kaner et al[23]	30	43					7.1	0.8	63.7	8.9
< 5 y	Schaeren et al[39]	26	52					8	2.5		
	Lutz et al[30]	50	58								
< 10 y	DiSilvestre et al[11]	32	64	6.7	3.4	6.8	4.2			51.6	27.7
	Sapkas et al[38]	107	82							57	22
	Hoppe et al[18]	39	86								17.5
>10 y	Hoff et al[17]	29	122					7.8	3.6	72	28
			Minimum	5.4	1.9	4.2	1	5.8	0.8	24.7	3
			Maximum	8.3	4	8.4	4.7	8.6	4.2	79.6	37.6
Hybrid											
	Zagra et al[47]	22	12	7.7	0.8	5.3	1.1			50.2	14.6
	Kaner et al[21]	15	19					6.9	1	65.9	8.3
	Hudson et al[20]	22	21					6.1	3.4	49.9	22.3
	Hoff et al[16]	20	24		5.7		4.5				49.9
	Schwarzenbach et al[40]	31	39	7.3	3.4	6	2.3			51.6	28.7
	Putzier et al[4]	22	76					7.5	3.5	70	35
			Minimum	7.3	0.8	5.3	1.1	6.1	1	49.9	8.3
			Maximum	7.7	5.7	6	4.5	7.5	3.5	70	49.9

FU indicates follow-up; ODI, Oswestry Disability Index; VAS, visual analog scale.

Clinical Outcomes

Although VAS remains a self-assessment of the pain with all bias implied, a significant reduction of the pain was underlined in every study. The ODI can be analyzed following 5 categories[49]: minimal disability (0%–20%), moderate disability (20%–40%), severe disability (40%–60%), crippled (60%–80%), bed-bound (80%–100%). On an average, the mean ODI score at last follow-up corresponds to a moderate disability. Ozer et al's[32] retrospective study and Putzier et al's[4] prospective comparative study between fusion and dynamic stabilization did not show superiority of any device. Only Yu et al's[46] retrospective comparison between Dynesys and PLIF underlined a significantly better clinical improvement for Dynesys group. Carreon et al[50] performed a meta-analysis of the literature about prospective studies comparing fusion with conservative

TABLE 6. Occurrence of Device-related Complications and Corresponding Rates

Type	References	Patients	Mean Follow-up	Rod Breakage [n (%)]	Screw Breakage [n (%)]	Screw Loosening [n (%)]	Additional Surgery [n (%)]	ASD Revision/ Radio [n (%)]
Dynamic								
Follow-up	Klockner and Beck[26]	20	12	*	*	1 (5)	1 (5)	*
< 2 y	Zagra et al[47]	12	12	0	0	0	0	*
	Cansever et al[9]	25	12	*	*	*	*	0/*
	Kim et al[24]	46	12	0	0	*	*	*
	Kocak et al[3]	19	12	*	*	1 (5)	2 (10)	*
	Welch et al[43]	101	12	0	0	0	11 (10)	*
	Wurgler-Hauri et al[45]	37	12	0	4 (10)	*	6 (16)	*
	Park et al[33]	27	12	1 (3)	1 (3)	*	1 (3)	*
	Dubois et al[12]	57	13	0	0	0	4 (7)	0/2 (3)
	Stoffel et al[41]	100	15	0	0	2 (2)	10 (10)	6 (6)/*
	Bothmann et al[7]	40	16	0	1 (2)	7 (17)	12 (30)	1 (2)/*
	Hu et al[19]	32	16	0	0	0	0	*
	Ko et al[27]	71	17	0	0	14 (19)	0	*
	Cakir et al[8]	10	22	0	0	0	0	*
< 3 y	Hoff et al[16]	17	24	4 (23.5)	0	*	2 (11.8)	*
	Maleci et al[31]	139	24	0	2 (1)	11 (7)	11 (7)	1 (0)/*
	Ozer et al[32]	19	24	0	0	2 (10)	0	*
	Reyes et al[35]	18	24	1 (5)	3 (16)	*	4 (22)	*
	Coe et al[10]	72	26	1 (1)	0	1 (1)	4 (5)	1 (1)/*
	Lee et al[28]	19	27	0	0	0	3 (15)	*
	Kim et al[25]	21	30	0	0	*	*	*
	Putzier et al[34]	70	33	0	1 (1)	2 (2)	5 (7)	*
	Grob et al[15]	31	34	0	0	4 (12)	6 (19)	*
	Ricart and Serwier[36]	25	34	0	0	*	1 (4)	*
< 4 y	Yu et al[46]	35	36	0	0	5 (14)	0	6 (17)/*
	Sapkas et al[37]	66	36	0	0	3 (4)	2 (3)	*
	Wu et al[44]	126	37	0	3 (2)	25 (19)	1 (0)	*
	Kaner et al[22]	26	38	*	*	*	2 (7)	*
	Stoll et al[42]	83	38	0	0	7 (8)	17 (20)	7 (8)/*
	Fay et al[13]	38	41	0	0	8 (21)	0	*
	Kaner et al 2010[23]	30	43	0	0	1 (3)	0	*
	Benezech and Mitulescu[5]	33	45	0	3 (9)	1 (3)	0	0/1
< 5 y	Schaeren et al[39]	26	52	0	1 (3)	1 (3)	3 (11)	0/9 (34)
	Lutz et al[30]	50	58	0	2 (4)	36 (72)	17 (34)	*
> 5 y	DiSilvestre et al[11]	32	64	0	0	0	2 (6.3)	0/*
	Sapkas et al[38]	107	82	0	0	22 (20.6)	6 (5.6)	*
	Hoppe et al[18]	39	86	0	1 (2.6)	3 (7.7)	8 (20.5)	5 (12.8)/11 (28)
	Hoff et al[17]	29	122	*	6 (20.7)	*	10 (34.5)	0/6 (20.7)
	Minimum–maximum			0%–23.5%	0%–16%	0%–72%	0%–34%	0%–17%/0%–34%
Hybrid								
	Zagra et al[47]	22	12	0	0	0	1 (4.5)	*
	Kaner et al[21]	15	19	0	1 (6)	*	1 (6)	*
	Hudson et al[20]	22	21	0	0	1 (4)	8 (36)	*
	Hoff et al[16]	20	24	6 (30)	0	*	2 (10)	*
	Schwarzenbach et al[40]	31	39	0	0	1 (3)	3 (9)	0
	Putzier et al[4]	22	76	0	0	0	1 (4)	0/2 (9)
	Minimum–maximum			0%–30%	0%–6%	0%–4%	0%–36%	0/0%–9%

*Not mentioned by the author.
ASD indicates adjacent segment degeneration.

treatments. Preoperative score was on an average 45.5% (range, 42.0–48.4). The improvement was 18.3% (range, 8.9–24.5) in the surgical group and 8.1% (range, 2.8–13.3) in the conservative group. In this review the mean preoperative score was a little bit higher (53.8%; range, 24.7–79.6) and the mean improvement was 31.8% (range, 11.7–64.1). If we only keep the 5 studies with a mean preoperative ODI comprised between 40% and 50% (307 patients are concerned) the mean preoperative ODI is 46.6% (range, 40–49.9) and the mean improvement is 26.0% (range, 18–38.8). This seems as a higher improvement than for fusion and conservative care but patients cohorts and indications should be analyzed in details to conclude.

Moreover, 83.4% of interviewed patients would choose to undergo the same procedure again, now knowing the results, which indicates that patients are satisfied.

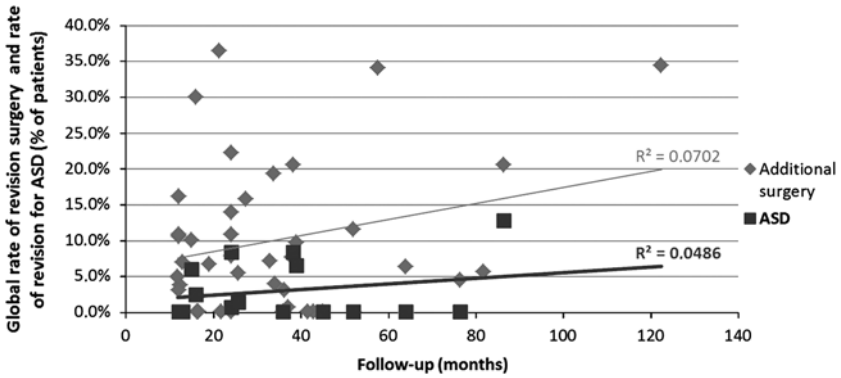

FIGURE 2. Global rates of revision and rates of revision for adjacent segment degeneration reported given the mean follow-up for studies addressing those topics only (linear correlation coefficient R^2 are indicated).

Influence on Adjacent Segment

Even if adjacent segment protection is one of the main purposes of dynamic stabilization, only 16 studies mentioned the issue of ASD. A total of 16% of patients were reported as showing ASD, not always symptomatic still the accurate definition remains very controversial. However, the global rate of revision for ASD (3.4% at 38 mo) is lower than the rates reported by Park et al[51] in their literature review (5.2%–18.5% of symptomatic ASD even with only 60 mo of follow-up). In their prospective comparative study between dynamic stabilization and noninstrumented decompression Hoff et al[17] highlighted a significantly higher rate of ASD for Dynesys group and Putzier et al[4] observed a higher rate of radiographic ASD in the fusion group.

Surprisingly enough, no real relationship between the follow-up and the rate of revision for ASD seem to arise through this review, this might be explained by the discrepancies between the different studies (cohort size, indications, surgical techniques, etc.) Moreover, we can wonder how the 16% of patients with radiographic signs of ASD will evolve in the coming years. Among the few studies with a follow-up higher than 60 months, radiographic ASD was between 7%[4] and 28%[18] and revision surgery between 0%[4,11] and 12.8%.[18] Adjacent segment pathologies and the influence of instrumentation as compared with natural history are still a moot point.[52]

The issue of motion preservation has been assessed in a few studies of this selection.[13,27,28,35] Unfortunately, no study looked for a correlation between the occurrence of ASD and the motion of the instrumented segment.

Beyond the use of a soft stabilization transferring fewer loads than fusion, the key for the reduction of loads is an "economical" sagittal balance.[53,54] "Noneconomical fusion," with for instance hypolordosis, more accurately than "fusion," could be charged with an increased ASD. Correlations between the sagittal alignment changes and the occurrence of ASD have been underlined by Kumar et al[55] in their series where 36.1% of patients had radiographic ASD and 16.8% of patients needed revision surgery at 5.2 years. Although assessment of sagittal alignment has a critical importance, measurements are rarely reported in clinical papers about dynamic stabilization.

Discrepancies between radiographic and symptomatic degeneration leading to revision surgery are in accordance with the rates of degenerated segments observed in asymptomatic population, especially with an increasing age.[56,57]

Device-related Complications

The overall amount of device breakages (screw or rod) is around 2.3%. As far as rigid devices are concerned, Esses et al[58] reported an overall rate of screw breakage of 2.9%. The design of the device is obviously a critical parameter for mechanical and biomechanical behavior; for instance, a too high rate of breakage triggered the withdrawal from the market of 1 dynamic device.[16]

The 9.6% of patients who showed signs of screw loosening did not always had clinical symptoms. Nevertheless it has been highlighted that screw loosening can bring about late infections implying revision surgeries.[30] The osseous quality has a direct impact on screw loosening[59] but was rarely reported. A literature review about Dynesys[3] found between 0% and 17% of screw loosening with a maximum rate of revision surgery of 12.9%. The stiffness of the devices[60,61] might be positively correlated with the rates of screw loosening. In contrary, a high stiffness might also account for the good short-term clinical outcomes as it preserves the preoperative distraction thus unloading the anatomic structures. This underlines that a good compromise in terms of stiffness has to be determined. With the current knowledge of the biomechanical behavior of the instrumented lumbar spine, several influencing parameters for mechanical failure can be suggested:

- First, the design of dynamic implants that varies a lot from one to another. For instance, it has been suggested that the axial stiffness has a direct impact on the motion of the segment.[62] The importance of shear stresses on devices is also becoming more and more pointed to.[16] Moreover in vitro testing underlines that shear resistance decreases with the degeneration of the segment,[63] which make shear resistance a key point

of the device failure. This also raises the question of implant design validation before marketing.

- Then the preoperative surgical technique and the preconstraining of the device when locked in the screws might increase the applying loads. As fusion is not expected to occur after dynamic stabilization, the devices are exposed as long as they are implanted.
- The patient's pathology and the related instability may also trigger shear loading of the device especially in the sagittal plane.
- As described by Legaye and Duval-Beaupere,[64] there is a critical correlation between balance and muscular forces occurring to compensate the gravity. This obviously implies a difference in loads applied on the device and transfer on adjacent segments. What is more, in vitro studies demonstrated that the dynamic stabilization triggered a posterior shift of the axis of rotation.[60] These changes can have different influences given the preoperative balance of the patient. The structures overloaded vary given the back type of the patient as described by Roussouly et al.[65] For instance a high lordosis predisposes the patient to overloading of the posterior structures. This type might also induce overloading of the instrumentation in shear. Last, the flexibility of the device might prevent from achieving the expected segmental lordosis thus triggering hyperlordosis at the adjacent level. Umehara et al[66] found through an in vitro study that hypolordosis increased the loading on posterior structures of the adjacent segment. This issue has also been addressed in a radiologic comparative study between 2 dynamic devices[67] showing that hybrid stabilization might be interesting for long constructs to better preserve lordosis.
- Last, patient's daily activity or punctual overloading conditions (sports, fall, etc.) also play their part in the loading of the device.

This literature review gives a global overview of short-term clinical outcomes of PBDS devices that seem to be noninferior to fusion devices in terms of clinical improvement and postoperative complications. Despite the differences between design choices, similar biomechanical issues can arise. More and more evidences show that the success of the surgery might be patient specific. The indications for dynamic stabilization have to be reconsidered and a particular attention has to be paid to patient condition such as spine balance or level of instability to increase the success rates of dynamic stabilization. Finally, the understanding of the biomechanics, in particular the impact on adjacent segment has to be continued and analyzed in the light of long-term clinical outcomes.

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