

Dynesys fixation for lumbar spine degeneration

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Abstract The dynamic fixation system Dynesys is utilized in the last 10 years for treatment of degenerative segmental disease of the lumbar spine. Dynesys is a semi-rigid fixation system that allows minimal lengthening and shortening between two segmental pedicle screws as opposed to a rigid metal bar. Thus, the system is regarded to maintain stability and near physiological motion patterns of the lumbar spine. The theoretical advantage of this system is to stabilize the treated segment and to prevent adjacent segment degeneration. The goal of this prospective trial was to evaluate clinical, radiographic, and computed tomography (CT) scan outcomes in 54 consecutive cases. Postoperative complications are discussed in detail. Forty cases were recruited with a mean follow-up of 16 months (range, 12 to 37). Postoperative pain scores (Hannover Activities of Daily Living Questionnaire and VAS for back and leg pain) improved in 29 cases (73%) and was best when dynamic fusion was combined with nerve root decompression. Outcome data were not superior to conventional rigid fusion systems and had a considerable number of complications requiring revision surgery in 27.5% of cases.

Keywords Dynamic stabilization · Dynesys · Lumbar spine · Surgical treatment

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Introduction

The semi-rigid dynamic fixation system Dynesys (Centerpulse/Zimmer, Winterthur, Switzerland) has been developed in 1994 as an alternative to rigid lumbar spine fusion using pedicle screw systems [4]. Degenerative disease of the lumbar spine involves the discs, vertebral bodies (osteochondrosis), and the facet joints and does often lead to painful intervertebral instability as described by Kirkaldy-Willis and Farfan [16]. Dorsal fusion of the affected lumbar spine segment is routinely performed when conservative treatment does not lead to successful pain management.

A mechanically stable fusion of the involved lumbar segments should reduce pain, caused by the treated segment. However, increasing stress of the adjacent segments may cause new instability and pain [8, 9, 10, 12, 13, 20, 21].

Clinical outcome and radiological results after fusion are inhomogeneous and at the time not always satisfactory. Therefore, the efficacy of this surgical treatment is still a matter of discussion.

Taking these problems into account, the ideal treatment should re-establish stability of degenerative lumbar segments with sufficient intervertebral mobility to prevent adjacent segment degeneration. Such a semi-rigid fixation would distribute a load sharing between anterior and posterior elements of the spine. In summary, an ideal semi-rigid fixation system would reconstitute physiologic biomechanics of the entire lumbar spine without development of adjacent segments pathology [7, 25].

A number of implants and internal fixation devices were developed to comply with the above demands including dorsal intervertebral implants, different kinds of disc prostheses, transpedicular stabilization systems such as Graf system, or the above-mentioned Dynesys [6, 15, 18, 19, 26, 27]. The latter consists of conventional pedicle

screws with spherical head holes through which a string (polyethylene terephthalate, PET) is passed. A transparent polyurethane (PCU) sleeve is then passed over the string and fitted between two pedicle screws with 300 N of tension. The identical construct is applied for both left and right side without horizontal fixation. This construct results in a semi-rigid fixation that allows some motion in terms of lateral bending, flexion, and extension and about normal motion in axial rotation of the lumbar spine [11, 24].

Indications for semi-rigid Dynesys fixation of the lumbar spine are similar to other fusion systems and include segmental hypermobility, segmental hypomobility, discopathy with or without functional instability, and one- or multilevel spinal canal stenosis [4]. Due to the semi-rigid nature of the Dynesys system, the spectrum of indications was enhanced. Further indications includes recurrent disc protrusions and isolated spinal canal stenosis in which some instability can be expected postoperatively [1–3, 22, 23].

The goal of this prospective trial was to evaluate clinical and radiographic outcomes in 54 consecutive cases with special focus on different indication groups. Postoperative complications were of particular interest for the present study.

Materials and methods

In one neurosurgical center, there were 54 consecutive cases treated with Dynesys lumbar spine stabilization in the time period from May 2001 to April 2005 (Centerpulse/

Zimmer, Winterthur, Switzerland). There were 26 women and 28 man with a mean age of 56 years (range, 28 to 84), who required for stabilization of the lumbar spine. All patients had a minimum period of at least 3 months of failed conservative treatment. Indication for lumbar fusion included stenosis of the spinal canal in 22 cases (41%), degenerative spondylolisthesis Type I according to Meyerding in 14 cases (26%), degeneration of lumbar discs in 9 cases (17%), recurrent herniation of the lumbar disc in 6 cases (11%), and segmental instability in 3 cases (6%) as listed in Table 1. Previous surgery on the lumbar spine was recorded in 20 cases (37%), including 13 discectomies and 7 recurrent discectomies.

Leading symptoms were radiating pain in 44 cases (81%) with nine cases suffering from additional claudication symptoms, lumbago in nine cases (17%), and one case presenting with claudication symptoms only. Neurological deficits were encountered in 33 cases (59%) including motor deficits in 2 cases (4%), sensory deficits in 15 cases (28%), and both in 16 cases (20%).

Dynesys stabilization without nerve root decompression was performed in ten cases (eight cases of degenerated disc disease, one instability, and one spondylolisthesis), nerve root decompression combined with Dynesys implantation was performed in 44 cases (81%), and additional use of intervertebral body cages and autologous cortico-cancellous bone graft (posterior lumbar interbody fusion, PLIF) in 8 cases (15%). There were 78 lumbar segments stabilized in total with the following distribution: 2 L1/2, 5 L2/3, 22 L3/4,

Table 1 Preoperative symptoms, diagnoses and indication for surgery

Preoperative findings		
Complaints in months	Back pain	32.6±33.1 SD
	Leg pain	18.7±26.3 SD
Nicotine abusos	Non smoker	20
	10 cigarettes/day	14
	>10 cigarettes/day	13
Indication for surgery	Stenosis	22
	Disc degeneration	9
	Spondylolisthesis	14
	Instability	3
	Recurrent disc deg.	6
Symptoms	Lumbago	9
	Sciatica	43
	Claudicatio spinalis	9
Neurological deficit <i>n</i> =33	Motor only	2
	Sensory only	15
	Combined	16
	X-ray diagnosis	Spondylolisthesis
	Instability	11 cases
	Stenosis	34 cases
	Scoliosis	3 cases
	Spondylarthrosis	16 cases
	Osteochondrosis	36 cases

36 L4/5, and 13 L5/S1. One level stabilization was performed in 32 cases (59%), two level in 20 cases (37%), and three level in two cases (4%).

All surgeries were performed by three experienced neurosurgeons with the patient placed in prone position. All lumbar spines were approached via a dorsal midline incision and retraction of soft tissues. Pedicle screws were inserted under fluoroscopic guidance, and the PET string together with a PCU sleeve were inserted and secured via screws utilizing a tensioning device that applies 300 N. In all 54 cases, a postoperative computed tomography (CT) scan was performed to confirm proper pedicle screw positioning. Postoperative treatment regime included early mobilization under physiotherapeutic guidance. Sitting and heavy lifting was limited for 6 weeks. Follow-up was scheduled 3, 6, and 12 months postoperatively. All patients answered a specific lumbar spine outcome questionnaire before surgery and at each follow-up including information on pain intensity (Visual Analog Scale, VAS), quantity and quality of pain relief medication, and the ability to walk, mobilize, or participate at work. Further alternative questions included subjective information on the success of the operation such as no complaints at all, considerably improved, not changed at all, or considerably worse. Functional outcome was measured with the Hannover Activities of Daily Living (FFbH) [17].

The FFbH consists of 12 questions according activities of daily living. At least 10 out of the 12 questions have to be answered to obtain an evaluable result. The answer to each question is given in one of three ordered categories: can do without difficulty, can do but with some difficulty, and unable to do or only with help. From these data, a standardized total score, ranging from 0 to 100%, is calculated. Larger values indicate more activity.

Twelve patients were lost to follow-up, and two more patients died during follow-up because of cancer and cardiac failure, leaving 40 cases for evaluation. Follow-up time had a mean of 16 months with a minimum of 1 year and maximum of over 3 years (range, 12 to 37 months). Cases were divided into two groups with one subcohort including all cases with excellent or good outcome scores and another subcohort including all cases with moderate or poor outcomes. Statistical analysis was employed by an independent statistician and included the χ^2 test with Yates correction and *t* test. Significance level was set at a *p* value smaller of 5% ($p < 0.05$). For smaller numbers, an adapted significance level was defined.

Results

Four cases (10%) scored excellent clinical results with no pain at all, 25 cases (62.5%) scored good clinical results

with occasional pain, 8 cases (20%) scored moderate to unchanged clinical results with similar pain, and 3 cases (7.5%) scored worse results postsurgery. Preoperative back pain was existent for a mean of 33 months, and leg pain was existent for a mean of 19 months. Mean back pain VAS score (ranking from 0 to 10 points) improved significantly ($p < 0.001$) by 4.9 points from a mean preoperative score of 8.3 points to a mean postoperative score of 3.4 points. Leg pain also improved significantly ($p < 0.001$) by 4.3 points from a mean preoperative score of 7.2 points to a mean postoperative score of 2.9 points. Function improved significantly from 33.8% preoperatively to 57.7% at latest follow-up as did the average walking distance. Requirements for pain relief medication were considerably reduced, see Table 2 and Figs. 1, 2, 3, 4, 5, and 6.

Further statistical analyses were employed with regards to differences in outcomes depending on cases with prior surgery or cases that were stabilized in more than one segment. There was a trend ($p > 0.05$) for worse outcome in cases that were stabilized in more than one segment and those who underwent prior lumbar spine surgery irrespective of the diagnosis. There were, however, significantly ($p < 0.05$) improved clinical outcomes when Dynesys stabilization was combined with decompression and/or fusion, see Table 3.

Complications

There were no intraoperative complications. Routine postoperative CT scans in all cases showed bilateral partial pedicle fracture and hardware loosening in 1 of 40 cases (2.5%) requiring immediate revision surgery and 360° fusion. During radiographical follow-up, different complications were registered:

One case (2.5%) presented with screw breakage 21 months after surgery, treated with removal of the system. In seven further cases (17.5%) in plain radiographs, screw loosening was suggested. For confirmation, CT scans were obtained and all cases showed signs of screw loosening. Symptoms were in all of these cases remaining and/or progredient lumbar back pain. Because of symptomatic screw loosening, all these cases were revised at a mean follow-up time of 6 months (range, 4 to 9). Treatment of these seven cases included: in two cases, hardware removal only; in one case, hardware removal and additional decompression; and in four cases, a PLIF combined with decompression. In one of these revision cases, a further screw correction was needed, and in another case, chronic infection was suggested. The patient was treated with antibiotics for 3 weeks.

There was a tendency that screw loosening occurs more on younger patients. We found no obvious risk factors like age, osteoporosis, or prior incorrect screw positioning.

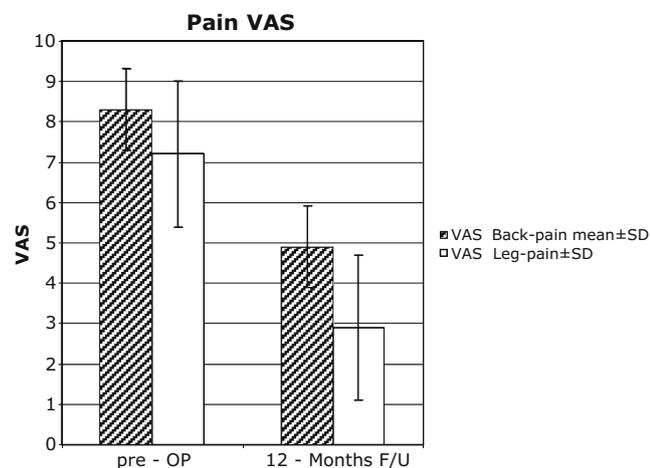
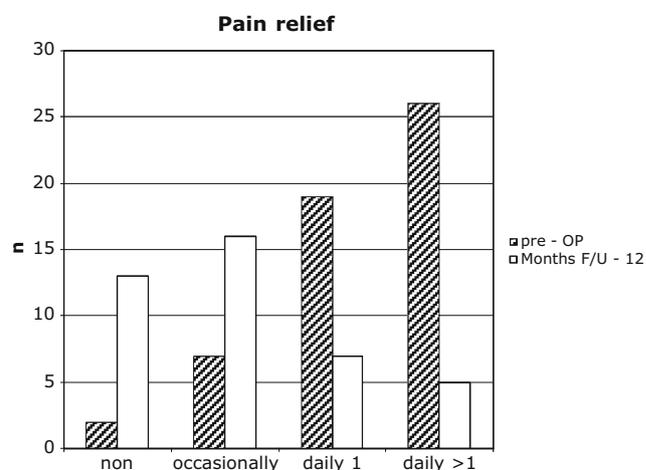
Table 2 Results

Outcome	Pre-OP, <i>n</i> =54	3 months F/U, <i>n</i> =35	6 months F/U, <i>n</i> =17	12 months F/U, <i>n</i> =40
VAS				
Mean back pain±SD	8.3±1.0	5.5±2.8	5.8±2.8	4.9±2.8
Mean leg pain±SD	7.2±1.8	3.1±3.0	3.5±3.2	2.9±3.0
FFbH				
Mean±SD	33.8±16.2	50.3±27.4	44.8±28.3	57.5±31.1
Median	33	50	31	66
Walking				
Support	4	1	0	3
up to 100 m	14	7	2	2
up to 1 km	32	10	10	14
>1 km	4	17	5	22
Pain relief				
None	2	8	3	13
Occasionally	7	12	4	16
Daily 1	19	6	6	7
Daily >	26	9	4	5
Profession				
Yes	9	7		13
Retired	16	16		16
Compensation seek	3	11		4
Compensation done	2	2		6
Off work	20	10		6
Success				
No complaints		4	1	4
Consid. improved		16	7	25
No change		12	8	8
Worse		3	1	3

F/U Follow up

In three cases, additional lumbar surgery was performed despite intact Dynesys stabilization (7.5%): In one case, the Dynesys was extended to the adjacent segment, one case required a lumbar fusion not adjacent to the Dynesys

systems, and one case was decompressed in an adjacent segment due to spinal canal stenosis. In total, there were 27.5% complications partly or mainly associated with the Dynesys system.

**Fig. 1** Visual analog score for back and leg pain preoperatively at 12-month F/U**Fig. 2** Medication before and after operation

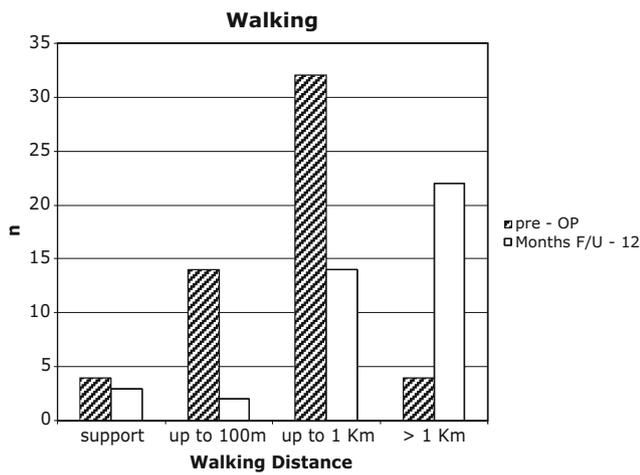


Fig. 3 Improvement of walking distance

Discussion

Degenerative lumbar spine disorders are the most common discomforting diseases worldwide and represent a complex pathology, which leads to considerable morbidities. Most patients suffering from this disease require multiple treatments, bear socio-economic disadvantages, and are not always treated successfully to a state of significantly improved complaints. The vast majority of patients suffer from back pain and/or radicular leg pain with or without neurological deficits. Complaints may improve after conservative treatment options such as physiotherapy, muscle strengthening exercises, local infiltrations, oral pain relief, or a combination of above. Surgical treatment such as decompression and/or fusion is indicated if above measures fail. However, clinical success rates after lumbar spinal surgery vary and can be at times frustrating for both the patient and the surgeon.

Kirkaldy-Willis and Farfan published in 1982 a seven-scale classification system, which describes the progressive

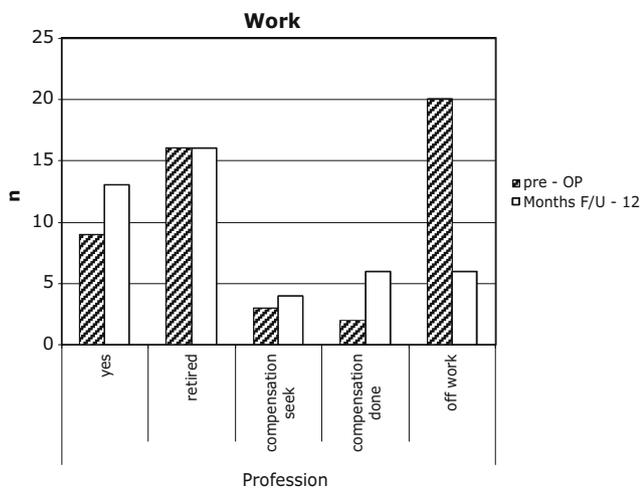


Fig. 4 Status of employment

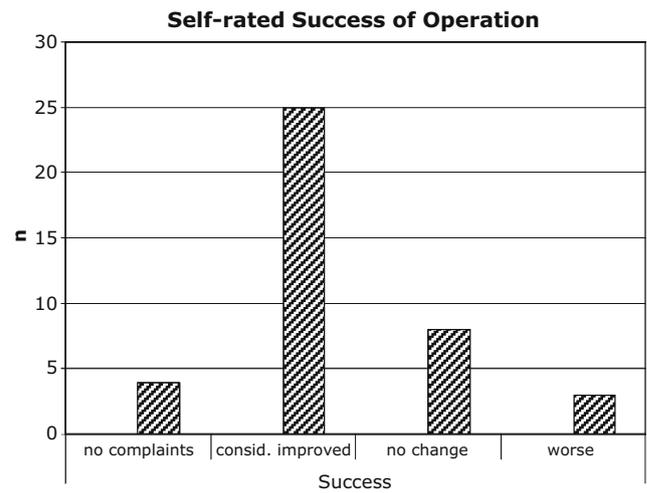


Fig. 5 Self-rated success of the procedure

process of lumbar spine degeneration of the disco-vertebral segment and its resulting clinical implications. This model was developed from a three-phase degeneration and is nowadays utilized for index surgery of the lumbar spine. The indications for a dynamic stabilization system such as Dynesys are isolated segmental degeneration with primary discopathy and with or without hyper- or hypomobility and cases with mono- and multisegmental stenosis [4].

The Dynesys fixation system represents a pedicle screw system that offers a semi-rigid and, therefore, near physiologic motion pattern of the fused lumbar spine segments. It has been developed according to a natural three-phase degeneration process of the lumbar spine. Intersegmental motion is increasingly controlled and reduces discovertebral dyskinesia. [5, 7] There are a number of publications dealing with this particular device. The designer group reported positive clinical and radiographic outcomes in 83 cases with index spinal stenosis and

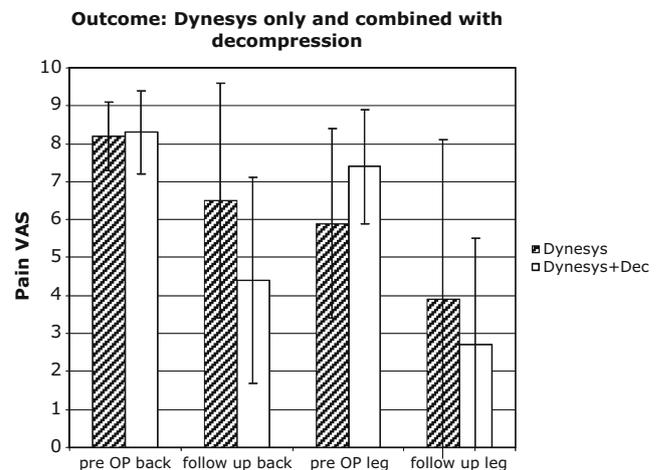


Fig. 6 Visual analog score for back and leg pain preoperative and at 12 month

Table 3 Differences in outcome depending on previous surgery, multi-segmental surgery, and Dynesys alone or combination with decompression

	VAS back pain		VAS leg pain		FFbH ^a (%)		Results after 12 months			p value		
	Pre-OP	Follow-up	Pre-OP	Follow-up	Pre-OP	Follow-up	No complaints	Consid. improved	No change		Worse	n follow-up 12 months
Previous operation(s)	20	8.4±1.1	6±2.2	7.2±1.5	3.3±3.1	35.4±17.2	52.5±29.6	0	9	2	1	n=12
No previous operation	34	8.2±1	4.4±3	7.1±2	2.8±3.1	32.9±16	59.6±32	4	16	6	2	n=28
1 segment operated	33	8.3±1.1	5±2.9	7.2±1.9	3.2±3	30.2±15.4	53±32.6	1	17	4	2	n=24
>1 segment	21	8.2±1	4.8±2.9	7.1±1.7	2.5±3.3	39.5±16.5	64.1±28.3	3	8	4	1	n=16
Dynesys only	10	8.2±0.9	6.5±3.1	5.9±2.5	3.9±4.2	38.4±15.5	35.1±28	0	3	3	2	n=8
Dynesys + Decompression	44	8.3±1.1	4.4±2.7	7.4±1.5	2.7±2.8	32.8±16.6	63±29.6	4	22	5	1	n=32

Mean±SD

^a Funktionsfragebogen Hannover (Activities of Daily Living Questionnaire) 0–100%* χ^2 -test

degenerative discopathy and reported significantly improved pain scores (VAS and Oswestry). [28] However, aseptic loosening of pedicle screws in eight cases and numerous revision surgeries were also noted.

Grob et al. [14] reported outcomes in 31 Dynesys cases with 2 years follow-up and observed satisfactory results in 50%. There were hints that multisegmental fixation and no additional decompression were responsible for poor results in two-third of these failures. Revision surgery was high with 19% and was comparable with routine devices. It was further discussed that the indication for Dynesys is not clearly defined.

Putzier et al. [23] compared Dynesys stabilization in three subgroups with different lumbar spine diagnoses and found good results in cases with discopathy and spondylarthrosis only, excluding severe segmental degeneration. Revision surgery for implant failure was counted in 5 of 70 cases (7%). In a further study, the same authors compared nucleotomy with and without a combination of dynamic stabilization and found worse long-time results in the group with nucleotomy only. Data were accumulated according to MODIC I degeneration as well as VAS and Oswestry scores after a mean of 34 months follow-up. It was noted that lumbar spine degeneration deteriorated faster without dynamic stabilization [22]. Cakir et al. compared two subgroups of ten cases each with spinal stenosis. One group was treated with decompression and dynamic stabilization and the other with decompression and conventional antero-dorsal fusion. There was no difference in clinical outcomes and particularly no advantage when using the Dynesys system [23]. In cases with chronic lumbar back pain, Fritzell et al. [9] reported improved clinical results after fusion in 63% of cases with an improvement of pain score by 32%.

The overall results of our study indicate improvement of pain (VAS) and functional outcomes after Dynesys stabilization, but unsatisfactory results compare favorably with those found in above publications. Back pain improved significantly ($p<0.001$) by 41% and leg pain improved significantly ($p<0.001$) by 59%. Functional scores improved significantly ($p<0.001$) from 33.8 to 57.5%. Improved subjective scores were encountered in 73% of cases with no or little pain.

Comparing the subgroup with and without additional decompression, the decompression group shows significant clinical improvement (in 81% of our cases) and in functional outcome (average 30% improvement). Outcome was inferior, when Dynesys was not combined with decompression. In this study, the clinical improvement was only 38% and functional outcome got worse on an average of 3%.

In accordance with the experiences in the literature, we could confirm a high percentage of failures and revision

surgery when utilizing the Dynesys system [14, 28]. Pedicle screw loosening was a particular and frequent complication in our group and was noted in 7 (17.5%) out of 40 cases. The initial placement of the pedicle screws were confirmed by postoperative CT scans in all cases. Only in one case we found initial incorrect screw positioning. In another case, fracture of a pedicle occurs.

Stoll et al. [28] reported of adjacent segment instability in seven cases, which required further revision and fusion surgery. In our cohort, there were 3 cases (7.5%) out of 40 that required similar treatment. Biodynamic cadaver test actually demonstrated higher rigidity as opposed to physiological values. In comparison with rigid external fixation, there is some increased motion after Dynesys stabilization as far as extension and axial rotation of the lumbar segments is concerned. However, there were marginal differences only, when data were compared with regards to flexion and no difference at all was noted for lateral flexions. [14, 18, 24] Summarizing these data suggests that Dynesys stabilization is probably not as semi-rigid as promised.

In eight cases (20%) of our series, a so-called hybrid fusion was performed with simultaneous dynamic stabilization and intervertebral fusion (PLIF) with cages and autologous bone chips in one of the stabilized segments. Five of these eight cases had excellent clinical results at latest follow-up, and three did neither improve nor deteriorate. Pedicle screw loosening was noted in one case, which has been revised and treated with rigid fixation.

Dynamic stabilization alone leads to significantly inferior clinical results than compared with combined decompressions, as mentioned before. According to our data collection, it is therefore strongly recommended to decompress nerve root compression and/or spinal canal stenosis during semi-rigid stabilization surgery. The role of the semi-rigid stabilization for improved outcomes is not clear, when a combined procedure is performed. Improved clinical outcomes depend considerably from decompression and stabilization. We are, therefore, not able to demonstrate the isolated success of the Dynesys treatment, particularly as combined procedures had significantly superior results when compared with Dynesys stabilization alone.

Taking indications for surgery into account, Dynesys stabilization had best results in cases with spinal stenosis or recurrent disc herniation. Progressive spondylolisthesis and instability did not benefit considerably from Dynesys stabilization. An index that was also reported from Grob et al. [14] and Putzier et al. [23], who confirmed inferior results in these indications.

The present study shows some limitations: On the one hand, there is a spectrum of various indications, and on the other hand, there are different treatment subgroups (only Dynesys, combination with decompression and combination with PLIF) with the consequence of small subgroups.

Beside these limitations, all screws were followed-up with plain X-rays and CT scans. In consequence of this, the present study is detecting screw loosening very precisely.

In summary, it remains to be questioned whether lumbar stabilization with the Dynesys system weighs the majority of success after surgery, particularly when less invasive alternative surgery shows similar clinical outcomes. [19, 29] Since more than 10 years clinical use of Dynesys, we need to conclude that it is still unclear what indications for Dynesys stabilization are suitable.

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