

Application of a Dynamic Pedicle Screw System (DYNESYS™) for Lumbar Segmental Degenerations – Comparison of Clinical and Radiological Results for Different Indications

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Abstract

Introduction

The optimum outcome of a surgical intervention in cases of segment degeneration of the spine is described as follows: "The ultimate solution for re-establishing anterior column stability is to restore not only the anatomy but also the normal mechanical function" [1].

Spondylodesis does not meet the demand. The resulting biomechanical and clinical disadvantages from functional loss of a fused motion segment have been frequently documented. Aside from the post-operative risk of a pseudoarthrosis, there is long-term a high frequency of degenerative alterations in the adjacent segments [2-5]. Furthermore, the indication spectrum for a segment-fusion operation is still controversial because thus far no adequate scientific validation of the present results has been presented [6,7].

Nucleotomy, discectomy, neuroforaminal or spinal decompressions without subsequent fusion are no causal therapy forms in view of the aforementioned demand. In addition, the literature documents that a post-operative occurrence of periradicular adhesions, epidural fibroses and iatrogenic segment instabilities ranging to accelerated segment degenerations is not unusual [8,9].

With the knowledge of these factors various implants have been developed within the last decades designed either to widely maintain or to restore the function of damaged segments. Dorsal interspinous or transpedicular anchored implants were introduced, such the Graf Band [12]. Procedures were also developed, which enabled the replacement of the nucleus pulposus [13,14] or of the entire disk [15].

A general prerequisite associated with the use of these implants is the exact definition of their indication spectrum. With spondylodesis the segment function is sacrificed, however with function maintenance procedures it must be determined to what degree pathomorphological alterations can be compensated for.

The present study was designed with the aim of examining the efficiency and security of a dynamic pedicle screw system (Dynesys™, Centerpulse, Winterthur, Switzerland) as indicated by localization and degree of pre-operative degenerative changes, using clinical and radiological parameters.

Material and Methods

Implant design and biomechanics

The dynamic neutralization system (Dynesys™, Centerpulse, Winterthur, Switzerland) is implemented using pedicle screws anchored in the vertebrae. Cylinder-shaped place holders made of polycarbonate urethane are positioned on both sides between the screw heads. Bands made of polyethylene terephthalate extend through the cavity space, being expanded into the heads of the pedicle screws by means of adjustable screws. The bands serve to limit inclination; reclination is limited by the place holders.

Biomechanical tests [16] have established the reduction of bending stress affecting the segment as well as of horizontal translation. The limitation of inclination and reclination lead both to neutralizing the intra-disk stress as well as to easing the load on the facet joints.

The compression rigidity measures 200 N/mm and is thus comparable to the rigidity of the intact dorsal parts of a motional segment, corresponding to about 20% of an angularly rigid screw-rod-system [17]. Permanent stress tests show after 5 million cycles of distraction-compression a non-significant plastic deformation of the band of 1.2% and of the place holder of 6.5% [17]. If the tension is brought to the prescribed torque of 4 Nm, the force necessary to tear the band requires 1060 N [18,19].

Patients and implant data

70 patients (29 women, 41 men) were included in the present study. The mean age at the time of surgery was 43 (23-72) years. The examination of the patients took place pre-operatively, 3 months post-operatively as well as at follow-up after an average of 33 (18-50) months.

The indication for surgical treatment was viewed as fulfilled in patients with discomforts in the lumbar spine for at least 3 months, which had not responded to an intensive conservative therapy.

The patients were divided into three groups according to morphological diagnosis. Patients with a disk degeneration in stage I according to Modic [20] and with a nucleus pulposus prolapse (n = 26, Group 1A) or re prolapse (n = 9, Group 1B) were assigned to Group 1. Additionally for all patients in group 1 a nucleotomy was performed. Patients with disk degeneration in stage I according to Modic and with a radiologically established spondylarthrosis in the segment to be treated were included in Group 2 (n = 22) of this study. Patients with advanced morphological alterations were assigned to Group 3 (n = 13). High degrees of segment degeneration in stages II or III according to Modic (n = 7) belonged to Group 3A. Group 3B consisted of patients with degenerative spondylolisthesis L4/5 degree I and II according to Meyerding (n = 6). The definition of degenerative spondylolisthesis according to Wiltse [21] formed the basis of this group assignment. In cases of radicular alterations in Group 3B an additional osseous decompression in form of a foraminotomy and/or facettotomy was performed. Absolute spinal stenosis (according to the definition of Verbiest [22]) were not treated with Dynesys™.

The use of Dynesys™ also required that in Group 1 corresponding clinical discomforts in the sense of a pseudoradicular- or radicular syndrome be present and in Group 1B that no epidural adhesions or periradicular fibroses were evidenced in the magnetic resonance tomography. A surgical prerequisite for patients in Groups 2 and 3 was the indication of a significant pain reduction after a CT-supported facet-infiltration by a local anesthetic [23].

Patients with conditions after decompressing and/or fusing interventions on the lumbar spine were not included in the study. Further exclusion criteria were a chronic pain as of stage II according to Gerbershagen [24], clinical, laboratory-chemical, and/or radiological evidence of osteoporosis or other maladies of bone metabolism, chronic alcohol or drug abuse, a BMI > 30 kg/m², and the presence of malignant tumors.

The dynamic stabilization took place in Group 1 and 2 over a maximum of 2 segments, in Group 3 over at most 3 segments (Tab. 1).

Depending on the size of the vertebrae, pedicle screws with a diameter of 6.4 or 6.0 cm as well as a length of 45 or 50 mm were implanted.

Subjective discomforts and clinical findings

The subjective functional impairment was evaluated with the Oswestry low back pain disability questionnaire according to Fairbank [25]. The quantity of pain was ascertained by means of a visual analogous scale (VAS) [26], on which the patients evaluated the pain they sensed on a scale of 0-10.

The symptoms of pain were clinically divided according to their quality into local, pseudoradicular, and radicular complaints. The results from the neurological examination were classified into "sensory", "motor", and "sensomotor" deficits [27].

Peri-operatively the duration of surgery, the loss of blood from surgery as well as length of hospitalization were recorded. Intra- and post-operative complications, associated with implants or not, were established up to the time of the follow-up.

At the time of follow-up patients were asked about the degree of their satisfaction and about their willingness to undergo the operation again under the same set of circumstances.

Radiological diagnostics

Radiographs of the lumbar spine a/p, and laterally and MRI were performed on all patients pre-operatively, 3 months post-operatively and at the time of follow-up.

In the course of the study the extent of the disk degeneration was evaluated both in the segments treated with DYNESYS™ and well as in the adjacent segments by determining the degree of hydration on the basis of T2-weighted sagittal MRIs according to the method of Luoma [28] and by measuring the disk space height, modified according to Colloca [29] and Mimura [30]. In addition cancellous and cortical reactions were recorded in the area of the endplates according to Modic [20] as well as of the facet joints according to general arthrosis criteria. Newly emerging disk herniations, stenosis alterations in bony, ligament or scar structures, and axis deviations in the frontal and sagittal plane were documented.

Furthermore, alterations of the cortical bone induced by the pedicle screws were registered as well as loosening, dislodgments, and breakages of the implant.

Statistics

A dual factor ANOVA with repeated measurements for dependent and independent variables was performed. The conclusions ascertained were verified by the Friedman-Test. The level of significance was established with $p < 0.05$.

Results

Peri-operative data

The mean duration of surgery lasted 110 (60-170) minutes with an average blood loss of 220 (80-640) ml. Hospitalization lasted on the average 13 (9-19) days.

Complications

With 2 patients there was an intra-operative injury to the dura, which was closed with a primary suture and fibrin glue. A surface wound healing disorder formed the only specific, post-operative early complication observed.

Implant associated complications were registered a total of 5 times, 4 of which involved patients in Group 3 (Tab. 2).

Subjective discomforts and clinical findings

A significant post-operative improvement of subjective functional impairment, judged from the Oswestry score, was established only for Group 1 and 2 ($p < 0.05$). On the other hand, the difference between pre- and post-operative in Group 3 was not significant.

Pre-operatively there was no significant differences in the scores in all three groups. Correspondingly, the post-operative examinations revealed a significant improvement in each case for Groups 1 and 2 as opposed to Group 3 ($p < 0.05$). A difference between the post-operative examination after three months and the follow-up could not be found in any of the 3 groups (Fig. 1).

Similar results were established with regard to the intensity of pain, using the visual analog scale. Groups 1 and 2 revealed a distinct post-operative pain reduction, the mean value dropping from 8 to 2 ($p < 0.05$), whereas Group 3 did not (VAS post-operatively 6). Here again, there was no significant difference in the 3 groups pre-operatively; post-operatively there was a significant improvement in Groups 1 and 2 as opposed to Group 3 ($p < 0.05$). Between the 2 post-operative examinations no significant difference was established in any group (Fig.2).

In the evaluation of pain quality at the time of the post-operative examination, 66% of the patients in Group 1 (23 of 35) and 82% in Group 2 (18 of 22) indicated that they had gotten rid of all discomforts, whereas in Group 3 at this time only 23% (3 of 13 patients) indicated no further discomforts (Tab. 3).

In Group 1 17% (6 of 25 patients) as well as 9% in Group 2 (2 of 22 patients) still complained of pseudoradicular and radicular pain projection at the time of follow-up. This stood over against 38% (5 of 13 patients) with post-operative radicular and pseudoradicular discomforts in Group 3.

Preoperatively neurological deficits were established exclusively in patients in Group 1 and 3B. At follow-up the neurological examination revealed a total recession of the pre-operative findings in 23 of 50 cases in Group 1. In two further patients with a sensomotor radicular syndrome, only sensory deficits could be established. Neurological deficits induced by surgery or newly emerged in the course of the study were not observed.

A total recession of the neurological deficits took place in 2 of 4 cases among the patients of Group 3B; additionally only sensory deficits remained from a sensomotor radicular syndrome. However a progression of motor deficit from pre-operatively Janda 4 to post-operative Janda 2 occurred in one patient of this group so that after 5 days the Dynesys™ had to be removed, and a ventrodorsal repositioning spondylodesis performed. One patient in this group complained 4 months post-operatively about a new sensory radicular syndrome with significant dermatome related pain. In this case the implant was not removed and a radiculolysis performed.

A distinct difference in the groups was seen in the post-operative satisfaction of the patients (Tab. 4). In Group 1 and 2 90% of the patients were very satisfied or satisfied with the outcome of the operation; in Group 3 this was the case with barely 40%. Three patients (5%) in Groups 1 and 2 indicated they would not undergo the operation again under the same circumstances. In group 3 this was the case in 7 patients (47%).

Radiological findings

The radiological evaluation demonstrated a central position of all the pedicle screws within the pedicle. In one patient in Group 2 there was a loosening of both pedicle screws in S1. A further loosening or breakage of screws was not discovered in the first two groups. Also, no evidence of any progressive segment degeneration was found in Groups 1 and 2. In these groups neither a further disk space height, nor a disk protrusion, nor a disk prolapse could be found in the instrumented levels. Transformations of the cancellous bone to fat tissues and sclerotic bone reactions were also not pictured. Alterations of osseous or ligament stenosis were also not observed in Groups 1 and 2 (Fig. 3 & 4). A progression of the spondylarthrosis already at hand in Group 2 could not be registered.

An increase in the degeneration of the instrumented segments was found in 9 of 13 cases in Group 3. This was linked to the above mentioned loosening of 4 screws in one patient and to a screw breakage in a further patient (Fig. 5). MRI showed at the time of follow-up that a permanent relief of the neural structures was achieved in only 2 of 6 cases (Fig. 6) despite additional osseous decompression performed on the degenerative spondylolistheses.

Post-operative evidence of degenerative alterations of the adjacent segments in the form of axis deviations, bony reorganisation processes, stenosis, spondylarthrosis, degeneration or displacement of disk tissue were established in 3 cases. All 3 cases belonged to Group 3.

Discussion

The results of the present study regarding the application of Dynesys™ confirm the in vitro findings [16] for patients with initial segment degenerations. It was demonstrated that patients both with a disk prolapse or a recurrence prolapse (Group 1) as well as with a spondylarthrosis (Group 2) could equally profit from the operation. In addition to the very good clinical results, the low complication rate of the procedure, and the lack of degeneration of the adjacent segments through follow-up, there was no progression of any progress of degeneration in the stabilized segments in both indication groups. According to Braithwaite [31] Modic-1 alterations represent a relatively specific sign for a painful disk. Stäbler [32] proved a definite correlation between the Modic-1 alteration and segmental instability. Lang [33] examined patients after a disk operation and documented as well that Type 1 points to an instability. The present results support the conclusion that in this stage a restabilization of the segment was achieved by means of Dynesys™ and thus medium-term a transition into a higher Modic-stage avoided. On the other hand, the application of Dynesys™ is not recommended with a higher degree of osteochondrosis or with degenerative spondylolisthesis.

Patients with an initially degenerated disk and an established nucleus pulposus prolapse or relapse were brought together into Group 1. Clinical studies document that the short- to medium-term probability of an accelerated segment degeneration increases when nucleotomy is performed without the accompanying stabilization [34,35]. It must be anticipated that this development will take on an even more pronounced form in disks which are already damaged. In view of these facts it should be especially emphasized that no progression of disk degeneration with simultaneous stabilization by means of Dynesys™ was observed in any patient in Group 1.

The results of patients with previous surgery in Group 1B showed certain tendencies, but were not significantly poorer than those of Group 1A. However, only patients without epidural or periradicular fibrous adhesion were treated with Dynesys™. In our view the application of Dynesys™ is not indicated when scarred adhesion is present.

The inclusion into Group 2 was based on the radiological parameters for the presence of a spondylarthrosis in addition to the initial emergence of a disk degeneration. In addition, pain regression after infiltration of a local anesthetic was employed as a criterion for the clinical relevance of the morphological finding.

The arthrodesis previously recommended by the literature for the surgical treatment of spondylarthrosis by means of a transpedicular or transarticular screwing is problematical in the long run [36]. However medium- to long-term studies have shown that even dynamic systems are inappropriate for these indications [37-41]. However Dynesys™ is apparently in a position to counteract the pathological process of initial degeneration, the loss of disk space height, and the resulting intra-articular increase of compression in the facet joints [42]. The relief for the degeneratively altered facet joints by means of Dynesys™ established in this study appears to have further clinical significance from the standpoint that the degeneration of the facet joints is to be viewed as a secondary consequence of loss of disk space height [42,44], i.e. a spondylarthrosis without simultaneous disk degeneration is practically not observable.

The results of Group 3 show that the use of the implant is not justified either in combination with osseous decompressions influencing stability or with marked osteochondrosis and degenerative spondylolisthesis because of their functional design. With Dynesys™ a distraction and compression of the ventral and dorsal column is possible in a craniocaudal direction [16]. However anterior, posterior, and lateral translation malpositions cannot be corrected with this implant. Biomechanical data on the possibility of a segmental stabilization after decompression is lacking.

Contrary to spondylodesis, segment mobility remains to a certain extent because of the implant design; however, patients with higher degrees of degenerative findings cannot profit from this. Dynesys™ is not in a position to compensate for the morphological alterations examined in Group 3, nor to stop a progression of the degenerative processes. With these alterations an anatomic reposition can be achieved only with angularly rigid screw-rod connections [45].

The only published work on Dynesys™ to date reports predominately of a high degree of segment degeneration (spinal stenosis 60.2%, degenerative spondylolisthesis 47%) for surgical treatment; additional spinal decompression followed in 67.5% of the cases. Eleven implant-associated complications were described; surgical revision took place in 13 of 83 patients treated with Dynesys™. A direct comparison with the present study is not possible because of the different primary diagnoses and group distribution.

It can be postulated on the basis of the present results that the dynamic neutralization system applied is suitable for hindering the advancement of degenerative processes both for beginning pathological alterations in the anterior spine, such as degenerations and displacement of disk tissue, as well as for initial alterations in the posterior spine, i.e. in the facet joints. To what extent the improvement found in the Oswestry score and in the VAS can be attributed to this set of factors, or to the nucleotomy, or to the positive influence on the spondylarthrosis by means of Dynesys™ is something which cannot be derived from the present results. The application of Dynesys™ is designed to avoid the necessity of a reposition spondylodesis. If a radiologically verified, marked deformity is present, or if an osseous decompression is planned, this system seem not to be indicated.

Accordingly, the implantation of Dynesys™ does not represent a procedure in competition with fusion, rather a valuable supplement in the area of spinal surgery, when the proper indications are present.

Table 1

Number of patients per treated level by means of Dynesys™. Group 1: initial disk generation and disk prolaps, group 2: initial disk degeneration and spondylarthrosis, group 3: osteochondrosis (stage \geq II acc. To Modic), degenerative spondylarthrosis

Segment operated on	Group 1	Group 2	Group 3	Total
L3-S1	0	0	2	2
L4-S1	3	8	1	12
L4-L5	12	9	7	28
L5-S1	20	5	3	28

Table 2

Complications and re-operations per patient group

Group	Complications	No. of patients	Revision surgery
Group 1	<ul style="list-style-type: none"> • Dura leakage • Superficial wound infection 	2 1	<ul style="list-style-type: none"> • None • none
Group 2	<ul style="list-style-type: none"> • Screw loosening 	1 (2 screws)	<ul style="list-style-type: none"> • Complete implant removal
Group 3	<ul style="list-style-type: none"> • Screw loosening • Screw breakage • Newly developed radicular syndrome • Progressive motor radicular syndrome 	1 (4 screws) 1 1 1	<ul style="list-style-type: none"> • Complete implant removal • Dorsoventral spondylodesis • Radiculolysis • Dorsoventral spondylodesis

Figure 1

Subjective evaluation of functional impairment by means of the Oswestry score.

- Total
- Group 1
- Group 2
- Group3

- Pre-op
- 3 months post-op
- follow-up

Figure 2

Evaluation of pain intensity by means of Visual Analog Scale (VAS)

- Total
- Group 1
- Group 2
- Group3

- Pre-op
- 3 months post-op
- follow-up

Table 3

Description of pain quality pre-operatively, 3 months post-op and at the time of follow-up by patient group. Stated in number of patients

pain	Group 1			Group 2			Group 3		
	Pre-op	3 mo	Follow-up	Pre-op	3 mo	Follow-up	Pre-op	3 mo	Follow-up
None	0	23	23	0	17	18	0	3	3
Lumbar	0	6	6	9	3	2	3	5	5
Pseudo-radicular	20	3	3	13	2	2	6	3	2
Radicular	15	3	3	0	0	0	4	2	3

Table 4

Description of patients' satisfaction with the outcome of the operation at the time of follow-up by patient group

satisfaction	Group 1			Group 2			Group 3		
	n	%		n	%		n	%	
Very satisfied	21	60		15	68		1	8	
satisfied	11	31		5	22		4	31	
Unsatisfied	3	9		1	5		5	38	
Very unsatisfied	0	0		1	5		3	23	
Total	35	100		22	100		13	100	

Figure 3 a-e

33-year old patient with senso-motoric radicular syndrome, nucleus pulposus prolaps and initial osteochondrosis L5/S1 (a,b). 31 months after nucleotomy and Dynesys™ no re prolaps, no deterioration of osteochondrosis (c-e).

Figure 4 a-e

Incipient disk degeneration (Modic I) and spondylarthrosis in a 45-year old patient (a,b). 29 months postoperatively uncomplaining. No morphological alterations, neither in the instrumented nor in the adjacent level (c-e).

Figure 5 a-g

51-year old female patient with bilateral chronic lumbar pseudo-radicular syndrome and distinctive osteochondrosis L5/S1 (Modic II) (a). Uncomplaining for 5 months after dynamic neutralization L5/S1, than increased pain. Progression of osteochondrosis (b) and screw breakage S1 (c,d). Implant removal 21 months post-operatively and dorsoventral spondylodesis.

Figure 6 a-d

Degenerative Spondylolisthesis L4/L5 with consecutive spinal canal stenosis (a,b) in a 39-year old female. Six months post-operatively sensory L4-syndrom right. No reposition of slippage by the mean of x-rays (c), nerve root alteration L4 right can be determined on MRI (d). Hereupon neuroforaminal decompression L4/5 right, implant left in place.