Dynamic Stabilization of the Lumbar Spine

By Balkan Cakir, MD; Marcus Richter, MD; Klaus Huch, MD; Wolfhart Puhl, MD; René Schmidt, MD
ORTHOPEDICS 2006; 29:716
August 2006

Abstract

This study analyzed the outcome of patients treated with total disk replacement and posterior dynamic stabilization. For pathologies of different origin, dynamic stabilization of the lumbar spine is a novel alternative to fusion surgery. Although a physiological reconstruction of the sagittal profile was not always achieved, improvement was seen in all subscales of the clinical outcome measures in both treatment groups. Posterior dynamic stabilization and total disk replacement are promising alternatives to fusion with acceptable morbidity for strictly defined indications.

Despite advances in surgical techniques, fusion is considered neither fully successful nor without side effects (eg, pseudarthroses or donor-site pain). Moreover, some investigators believe that fusion may induce degenerative changes in nearby segments, often necessitating additional fusion surgery. To avoid this cascade and to avoid a loss of segmental motion, new dynamic implants were developed. In addition to other methods (eg, tissue engineering and cell transplantation, which are not yet established), posterior dynamic stabilization with transpedicular screws and total disk replacement are the most popular devices used. One of the main drawbacks of new implants is their unknown clinical outcome. Furthermore, indications suitable for these systems have to be established. This is especially important as the capacity of new implants should not be overstrained before successful results are achieved for a defined pathological condition.

This study analyzed radiological and clinical outcome measures after total disk replacement and posterior dynamic stabilization only for strictly defined pathologies.

Material and Methods

Implants

Total disk replacement (ProDisc; Synthes-Spine Solutions, New York, NY). The implant consists of three components (2 plates and 1 polyethylene inlay) with a ball-and-socket joint principle (Figure 1A). The forged cobalt-chrome plates, coated with pure titanium, are anchored with keel and spikes to the endplates. The inlays consist of ultra-high molecular weight polyethylene with three different heights (10 mm, 12 mm, and 14 mm). Two plate sizes (M and L) with two angulations (6° and 11°) are available (Figure 1B). The implant allows 13° of flexion and 7° of extension from the neutral position (Figure 1A).

Posterior dynamic stabilization (Dynesys; Zimmer, Winterthur, Switzerland). The implant consists of pedicle screws (Ti-Al-Nb-alloy,
Protasul 100, polycarbonate spacer (Sulene-PCU), and polyethylene terephthalate cord (Sulene-PET) (Figure 2). The screws are placed transpedicularly without violating the facet joints that comprise a lateral insertion point of the screws. The distance between the screws is measured, and a spacer with proper length is inserted between the screw heads after the cord is threaded through the spacers and the screw head. The cord is fixed with a grub screw to the screw head after compression of the spacer with 300 N, which is achieved with a special tool. The cord limits flexion ability, whereas the spacer realigns the vertebral bodies with their facet joints and limits the extension.

**Patient Selection**

*Total disk replacement.* Patients were treated with total disk replacement for monosegmental symptomatic degenerative disk disease or postdiskectomy syndrome. The inclusion criteria were as follows: low back pain for at least 12 months, minimum 8 months of conservative therapy, absence of spondylolisthesis and spondylolysis confirmed by computed tomography (CT), absence of antero- or retrolisthesis confirmed by dynamic radiographs, absence of facet joint arthrosis confirmed by CT, no pain relief after facet joint infiltration, monosegmental disk degeneration confirmed by magnetic resonance imaging (MRI) (Figure 3A), absence of intraspinal scar tissue on MRI after postdiskectomy syndrome, and diskography with positive "memory pain" (Figure 3B).

*Posterior dynamic stabilization.* Patients were treated with Dynesys and decompression surgery (undercutting of facet joint and lamina, excision of ligamentum flavum) for degenerative lumbar instability with spinal stenosis. Neither laminectomy nor laminotomy were performed. The inclusion criteria were as follows: spinal claudication with low back pain for at least 12 months, minimum 6 months of conservative therapy, absence of congenital spondylolisthesis with and spondylolysis confirmed by CT, antero- or retrolisthesis on dynamic radiographs (range: 2-5 mm), zygoapophyseal joint arthrosis confirmed by CT (Figure 4A), pain relief after facet joint infiltration with local anesthetic (Figure 4B), and spinal stenosis confirmed by MRI (spinal canal diameter <10 mm) (Figure 4C).

**Figure 2:** Saw-bone model of bilevel instrumentation with Dynesys. Pedicle-screw with grub screw (1) for the fixation of the cord (2), and universal spacer (3).

**Figure 3:** Degenerative disk disease with "black disk" at level L5-S1 on MRI (A). Degeneration (white arrow) confirmed by "provocation diskography" with "positive memory pain" (B).
Figure 4: Symptomatic facet joint arthrosis confirmed with CT (A) and by pain relief after facet joint infiltration with local anesthetics under fluoroscopic guidance (B). Spinal stenosis confirmed on MRI (spinal canal diameter of 9 mm) (C).

Total disk replacement. Twenty-nine patients (19 women and 10 men) fulfilled the inclusion criteria. Mean patient age was 40.8 years (range: 29-56 years) with a mean follow-up interval of 15.3 months (range: 12-35 months). Eight of 29 patients had previous disk surgery (Table).

Posterior dynamic stabilization. Ten patients (6 women and 4 men) fulfilled the inclusion criteria. Mean patient age was 64.6 years (range: 51.8-77.8 years) with a mean follow-up interval of 21.8 months (range: 12-30 months). A total of 1.6 levels (range: 1-3 levels) were stabilized and 1.6 levels (range: 1-3 levels) were decompressed (Table).

Radiological Evaluation

Pre- and postoperative anteroposterior and lateral radiographs were taken in both groups. Two observers blinded to the data examined radiographs for loosening, migration, spontaneous fusion, and subsidence.

In patients with total disk replacement, total lumbar lordosis and segmental lordosis were measured pre- and postoperatively (Figure 5 A&B). In patients with posterior dynamic stabilization, slippage (millimeters) was measured with regard to the known magnification of 1.15 (Figures 5 C&D).

Figure 5: Sagittal alignment measures pre- and postoperatively after total disk replacement (ProDisc, Figures 1 A&B) and posterior dynamic stabilization (Dynesys, Figures 1 C&D). An increase of total lumbar lordosis (LL) of 3° is accompanied by an increase of segmental lordosis (SL) of 8° (Figures 1 A&B). Postoperatively incomplete reduction of slipping (from 3 mm to 1 mm) after posterior dynamic stabilization.

Clinical Evaluation

The Oswestry Low Back Pain Disability Questionnaire (OQ), Physical Component Summary Scale (PCS), and Mental Component Summary Scale (MCS) of the Short Form 36 Health Survey Questionnaire (SF-36) were
obtained prospectively.

**Data Analysis**

Differences in the clinical outcome measures before and after surgery were tested using Wilcoxon matched-pairs signed-ranks tests for each group. The Mann-Whitney nonparametric test for independent samples was used when comparing the results of both groups (ProDisc versus Dynesys). A $P$ value $<.05$ was considered statistically significant.

**Results**

**Total Disk Replacement**

At latest follow-up no signs of loosening, subsidence, migration, or spontaneous fusion could be detected in any patient by the two independent observers.

An improvement was achieved in the PCS/MCS of the SF-36 (Figures 6 A&B) as in the OQ (Figure 6C). Statistical analysis was performed only for the OQ as this is not possible for the summary scales (PCS and MCS) of SF-36.

Postoperatively no significant change was observed in the mean total lumbar lordosis (preoperatively/postoperatively: 53.7°/55.9°; $P=.084$); however, a significant change was observed in the mean segmental lordosis (preoperatively/postoperatively: 17.9/26.3; $P<.001$). Average blood loss, operation time, and hospitalization are listed in the Table. No implant or surgery-related complication occurred.

**Posterior Dynamic Stabilization**

At latest follow-up no signs of loosening, subsidence of screws, or spontaneous fusion was noted in any patient by the two independent observers.

An improvement was achieved in the PCS/MCS of the SF-36 (Figures 6 A&B) as in the OQ (Figure 6C). Statistical analysis was performed only for the OQ as this is not possible for the summary scales (PCS and MCS) of SF-36.

No significant reduction of slippage could be achieved by posterior dynamic stabilization. A significant improvement was achieved in all clinical outcome measures (Figure 6). The preoperative average "slippage" of 2.8 mm (range: 1-5 mm) was reduced to 1.6 mm (range: 0-3 mm) postoperatively, measured on lateral radiographs in standing position. Average blood loss, operation time, and hospitalization are listed in the Table.
Table

<table>
<thead>
<tr>
<th></th>
<th>ProDisc (n=29)</th>
<th>Dynesys (n=10)</th>
<th>P value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>19</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>10</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Age (yr)</td>
<td>40.8</td>
<td>64.6</td>
<td></td>
</tr>
<tr>
<td>Follow up (mo)</td>
<td>15.3</td>
<td>21.8</td>
<td></td>
</tr>
<tr>
<td>Levels operated</td>
<td>1.0</td>
<td>1.6</td>
<td></td>
</tr>
<tr>
<td>Hospital stay (d)</td>
<td>7.5</td>
<td>19.3</td>
<td>.01</td>
</tr>
<tr>
<td>Duration of surgery (min)</td>
<td>108</td>
<td>16.3</td>
<td>.01</td>
</tr>
<tr>
<td>Blood loss (mL)</td>
<td>154</td>
<td>922</td>
<td>.01</td>
</tr>
<tr>
<td>Segmental lordosis (°)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>18</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Postoperative</td>
<td>26</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lumbar lordosis (°)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>54</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Postoperative</td>
<td>56</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Listhesis (mm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>2.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Postoperative</td>
<td>1.6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Mann-Whitney nonparametric test for independent samples.

With the exception of one dura lesion during decompression, no implant or surgery-related complication occurred. The dura lesion was closed with Tacho-Comb and the postoperative course was uneventful.

Discussion

The postulated principles of posterior, transpedicular dynamic stabilization with Dynesys are:

- establish a mobile load transfer,
- establish control of motion of the segment in all planes, and
- induce stability.

Based on these postulated principles and several recommendations, patients with degenerative listhesis and concomitant spinal stenosis were treated with posterior dynamic stabilization/decompression. Although the meta-analysis reported by Mardjetko et al concluded that fusion significantly improves patient satisfaction in degenerative listhesis with concomitant spinal stenosis, some authors feel that decompression alone would be sufficient to treat this pathology.

Some authors favor an additional fusion, as a concomitant symptomatic zygoapophyseal joint...
arthrosis at that level can be treated with a fusion and further destabilizing of the motion segment with further slipping is avoided. Therefore, dynamic stabilization appears to be a possible solution compared to both therapeutic extremes of sole decompression versus decompression with fusion, as increased stability can be expected compared to sole decompression.

It is noteworthy that an anatomical reposition was not achieved while further slipping was avoided in all patients (Table). Nevertheless, the clinical improvement of patients in the current study without anatomical reposition is in accordance with the results of other studies, as they also could not find an association between the amount of reduction and the clinical outcome after lumbar fusion for degenerative listhesis. Moreover, significant unsatisfactory results were observed especially in patients with further "slipping" compared to patients without slipping.

Posterior dynamic stabilization is a promising alternative in treating symptomatic zygoapophyseal joint arthrosis without the fusion-specific complications (e.g., pseudarthrosis, graft-site morbidity, and adjacent segment degeneration) and restabilizing the motion segment compared to sole decompressive surgery. Long-term studies are needed to evaluate whether posterior dynamic stabilization will result in less adjacent segment degeneration compared to fusion, if further slippage in degenerative listhesis can be avoided; and if a possible hardware failure would lead to a long-term problem, as single components of the system must withstand higher strain than an internal fixator in fusion.

Compared to posterior dynamic stabilization, the aim of total disk replacement is not a control, but rather a free segmental motion in all planes. Stability after total disk replacement is not solely achieved by the implant itself, as in posterior dynamic stabilization. Stability after total disk replacement is achieved by a physiological realignment of the motion segment thereby increasing the tension of the supporting structures of the motion segment, like capsules, ligaments, and the anulus. Therefore, predicted and expected changes after total disk replacement occur with preservation of mobility:

- restoration/maintenance of physiological lumbar lordosis and
- restoration/maintenance of physiological segmental lordosis.

Although the results of the current study regarding total disk replacement are in accordance with other studies reporting favorable short-term clinical outcome after total disk replacement for degenerative disk disease, the predicted physiological realignment of the motion segment was not always achieved. In fact only 72% of the patients showed a physiological segmental lordosis if 30° was considered as the upper range for a physiological segmental lordosis with regard to the literature. It is noteworthy that an average increase of 11° after implantation of Charité-total disk replacement also was reported by Hopf et al. The superior role of segmental lordosis after total disk replacement is supported by van Ooij et al who analyzed 27 patients with unsatisfactory results after insertion of a Charité disk prosthesis and addressed the recurrent or persistent back and leg pain among others to a hyperlordosis of the operated segment. In some patients they observed hyperlordosis of the operated segment that resulted in an opening of the facet joint in the superior part and a compression in the inferior part of the joints that could possibly lead to facet joint arthrosis.

In addition to segmental lordosis, attention should be given to the adjacent segments after total disk replacement. The significant increase in segmental lordosis by maintaining the lumbar lordosis postoperatively in our study group indicates a change in the adjacent segments. The current study does not answer the question if the changes in the adjacent segments result in a physiological and desired alignment. As the role of these findings remains unclear, even for a clearly defined indication, and long-term results have not yet been reported, total disk replacement should not be taken into consideration for a variety of indications as proposed by some authors. The same is true for...
posterior dynamic stabilization, with reported promising results for different pathologies \textsuperscript{10,25} as the postoperative results of these studies cannot be attributed to a certain pathology. In the current study a clinically and radiologically defined pathology was analyzed and the clinical results are attributable to the posterior dynamic stabilization with the Dynesys for these patient group.

When comparing the clinical results of both systems; a tendency towards better postoperative results can be seen after total disk replacement compared to posterior dynamic stabilization. This was most evident when comparing the physical component summary of SF-36 (Figure 6A) and the OQ (Figure 6C) postoperatively. Although the postoperative results of OQ were significantly better for the ProDisc group (ProDisc: 23.1±20.1 versus Dynesys: 31.4±26.3; P=0.028), the average improvement in the OQ scale was not statistically different (P=0.65). Moreover, no significant differences could be observed when comparing the mental component summary of SF-36 (Figure 6B). The difference in postoperative OQ may be explained by the fact that the average patient age was younger in the total disk replacement group and therefore the comorbidities were less frequent compared to the patients with posterior dynamic stabilization. Moreover, the morbidity of the procedure was higher in the Dynesys group, with statistically significant higher blood loss, longer operation duration, and longer period of hospitalization (Table).

It is noteworthy that total disk replacement and posterior dynamic stabilization do not compete with each other as treatment options and are used only with respect to the pathological condition. The postulated biomechanical principle of total disk replacement is different compared to posterior dynamic stabilization, with the exception of "mobile load transfer," which is the aim of both systems. Care should be taken not to overstrain the capability of a new system (by using it for various indications), before successful results are achieved with one clearly defined pathological condition.

Conclusion

Total disk replacement and posterior dynamic stabilization are promising alternatives to fusion in strictly defined pathologies. The indications are different for use in treating degenerative disk disease of the lumbar spine, as the biomechanical principle of both systems is different. Total disk replacement should only be considered for a clear diskogenic problem with intact posterior elements, whereas the posterior dynamic stabilization system is a possible solution for patients with clearly defined posterior pathologies. Although promising short-term results are achieved with both systems, neither system is able to restore the physiological situation that perhaps will affect long-term results. Therefore careful observation of patients with a strictly defined pathology will aid the surgeon in seeking possible fiacilities of these new implants.

What is already known on this topic

- The goal of dynamic stabilization devices is to prevent adjacent segment degeneration, a problem associated with spinal fusion.
- Good short-term results have been reported using ProDisc and Dynesys.

What this article adds

- Both ProDisc and Dynesys are not always capable of restoring the physiological segmental balance of the operated level.
- Although good short-term clinical outcome is unaffected, long-term outcome remains questionable.

References


Authors

Drs Cakir, Richter, Huch, Puhl, and Schmidt are from the Department of Orthopedics and Spinal Cord Injuries, University of Ulm, Germany.

Reprint requests: Balkan Cakir, MD, Department of Orthopedics and Spinal Cord Injuries, University of Ulm, Oberer Eselsberg 45, Ulm 89081, Germany.

Copyright ©2006 SLACK Incorporated. All rights reserved.