

# Preliminary Results of a Prospective Clinical and Radiological Study with Roentgen Stereophotogrammetric Analysis (RSA) after Implantation of a Posterior Dynamic Stabilization Device in the Lumbar Spine

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**Abstract:** *Introduction:* Posterior dynamic stabilization (PDS) can be based on interspinous distraction devices (IDD). The goals of these implants are maintaining or restoring intervertebral range of motion (ROM) in a controlled fashion and avoiding a complete restriction of mobility. Clinical and radiological data with the Wallis<sup>®</sup> spacer as one type of IDD have been rarely reported. The goal of this study was to present clinical and radiological data including roentgen stereophotogrammetric analysis (RSA) after a short- to mid-term follow-up period.

*Patients and Methods:* 10 patients were included in this prospective monocentric study and had PDS of the lumbar spine with an IDD (Wallis<sup>®</sup> spacer). Before and soon after operation and 3, 6, and 12 months later clinical and radiological evaluations were performed. Pain and disability were analyzed by use of visual analog scale for back and leg pain, Oswestry Disability Index, Roland-Morris Disability Questionnaire and Short-Form-36 Health Survey. The ROM of the operated levels and the total lumbar spine was determined by use of lateral functional x-ray images with calculation of the differences of the segmental and total lumbar spine angles in flexion and extension. Furthermore, RSA was used to measure the segmental ROM.

*Results:* After a follow-up of 12 months, the results of the pain intensity and the disability and health related quality of life scores showed statistical significant improvement. The segmental angles of the operated levels demonstrated statistical significant reduction in ROM during the different follow-up examinations. The discrepancy of the conventionally determined segmental angles and the data measured by RSA were low with a mean of 1.77°. The mean total lumbar spine angles did not change statistically significantly during the postoperative controls.

*Conclusions:* According to the radiological results of this study, the used implant leads to a posterior dynamic stabilization. The clinical findings are promising, but they are to be interpreted with caution because of the small number of patients and the lack of a control group.

**Keywords:** Functional x-rays, Interspinous distraction device, IDD, Roentgen stereophotogrammetry, Wallis implant.

## INTRODUCTION

The standard surgical interventions to treat back and/or leg pain in degenerative disorders of the lumbar spine are removal of disc prolapses, decompressive procedures in stenotic conditions or fusion techniques to stabilize the affected levels. One of the newer operative options is posterior dynamic stabilization (PDS) which can be based on pedicle screw devices, total facet replacement systems or interspinous distraction devices (IDD). The goals of these implants are maintaining or restoring intervertebral motion in a controlled fashion and avoiding a complete restriction of range of motion (ROM) [1].

However, the indications for PDS are still to be identified. Regarding IDD they are mostly used additionally to decompressive procedures in order to prevent iatrogenic instability and to keep the spine in a rather flexed position and the spinal canal and neural foramina open [2-6]. Several surgeons use IDD as "stand alone" implants without decompression because of the possibility of enlargement of the spinal canal by stretching the ligamentum flavum and the posterior longitudinal ligament [7, 8]. In conditions such as degeneration of the discs and the facet joints IDD are used to protect and restore these structures by unloading the facet joints and in order to relieve pain [1]. Another indication is their application above or below a fusion to prevent accelerated adjacent-segment disease [1].

The first IDD (Wallis<sup>®</sup> spacer) was developed by S negas, introduced in Europe in 1986 and has the

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longest history [9]. After the first-generation device of titanium showed positive results, a second generation of Wallis® implants was fabricated. Currently, this device consists of PEEK (polyetheretherketone) that is more elastic and is less rigid than the previously used titanium material. To date, a controlled randomized study with this Wallis® spacer does not exist although long-term results have been published by Sénégas *et al.* [10].

Roentgen stereophotogrammetric analysis (RSA) was developed by the Swedish surgeon Göran Selvik to study skeletal kinematics *in vivo* [11]. RSA methodology was applied to the spine previously to determine the intersegmental range of motion in subjects during various activities and also to evaluate the remaining segment mobility after treatment with different surgical techniques such as fusion or arthroplasty [12-17]. The results from RSA were compared to implications from conventional radiographs and showed a direct correlation [18]. A quantitative comparison however showed significant differences between the conventional Cobb technique and results from RSA, with the ROM from RSA being overall lower by 60% but also less variable [17, 19].

To the authors' knowledge, no investigation on PDS was conducted with a high-accuracy method such as RSA to date. Therefore, the aim of this study was to present clinical and radiological data including RSA to demonstrate the *in vivo* mobility after implantation of an IDD (Wallis® spacer).

## PATIENTS AND METHODS

After the biometrical calculation of number of cases was proven to be sufficient to allow statistical analysis regarding the radiographic data and after approval by the Local Ethical Committee (Hannover Medical School, Hannover, Germany, No. 4809) we included a total of 10 patients in this prospective monocentric study after having received their informed consent. Indication for operation were therapy resistant or progressive symptoms under conservative treatment over a minimum of three months. Inclusion criteria were back and/or leg pain due to spinal canal stenosis with or without disc prolapse, degenerative spondylolisthesis not more than grade I and facet joint arthrosis (Figure 1). Eight patients had a typical neurogenic intermittent claudication. Exclusion criteria were pain due to traumatic, inflammatory or tumorous pathologies as well as a relevant decrease of the bone mineral density as in osteoporosis which is a contraindication for any kind of IDD. Therefore, all participants underwent Dual-X-Ray-Absorptiometry (DEXA)

(Hologic Discovery™, Hologic Germany GmbH, Frankfurt, Germany) before operation. The mean bone mineral density was 1.078 g/cm<sup>2</sup> (0.834-1.591 g/cm<sup>2</sup>) and the average T-Score was 0.14 (-1.9 to 4.5). The segment L4/5 was affected in 9 cases, only one patient was operated in the level L2/3. The mean age of the 7 women and 3 men was 64.4 years (39.7-77.9 years) and the average body mass index (BMI) was 27.9 kg/m<sup>2</sup> (21.0-38.4 kg/m<sup>2</sup>).

| Diagnosis  | Number |
|--|--------|
| Spinal canal stenosis  | 4      |
| Spinal canal stenosis and disc prolapse                          | 3      |
| Spinal canal stenosis and degenerative spondylolisthesis grade I | 1      |
| Facet joint arthrosis and degenerative spondylolisthesis grade I | 1      |
| Facet joint arthrosis  | 1      |

Figure 1: Diagnosis of the 10 study patients.

## Implant and Operation

The implant used in all patients was the Wallis® spacer (Zimmer Spine SAS, Bordeaux, France) which consists of PEEK (Figure 2). Two tension bands of polyester were wrapped around both adjacent spinous processes for additional fixation. In our series the segmental supra- and interspinous ligaments were incised and completely removed.

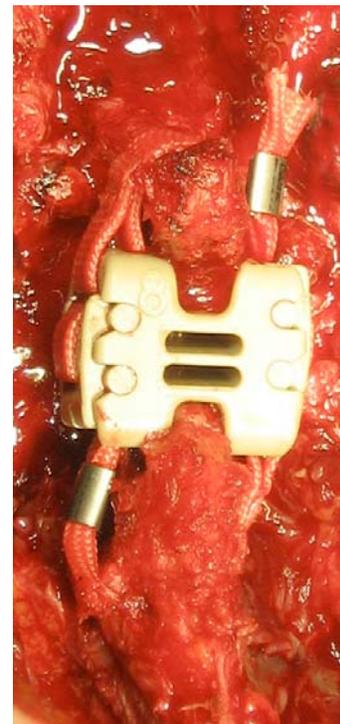


Figure 2: Wallis® spacer fixed by the two tension bands, which are wrapped around both adjacent spinous processes.

8 patients had a predominant spinal canal stenosis which made a mono- or bilateral decompressive surgery in microsurgical technique necessary. In 3 persons a disc prolapse was additionally removed. Both procedures were done before insertion of the Wallis® implant. Only 2 patients obtained the spacer exclusively because of symptomatic facet joint arthrosis without the need for decompression of the neural structures.

For RSA 3 to 5 tantalum markers with a diameter of 1 mm were implanted in the dorsal bony structures (lamina, articular process, spinous process) of each of the adjacent vertebrae of the affected level (Figure 3A, B).

### Measurements

All patients filled out a questionnaire directly after inclusion into the study before operation. Further follow-up dates were planned after 3, 6, 12 and 24 months after surgery. Furthermore, the persons had clinical and neurological examination during each control by the same examiner.

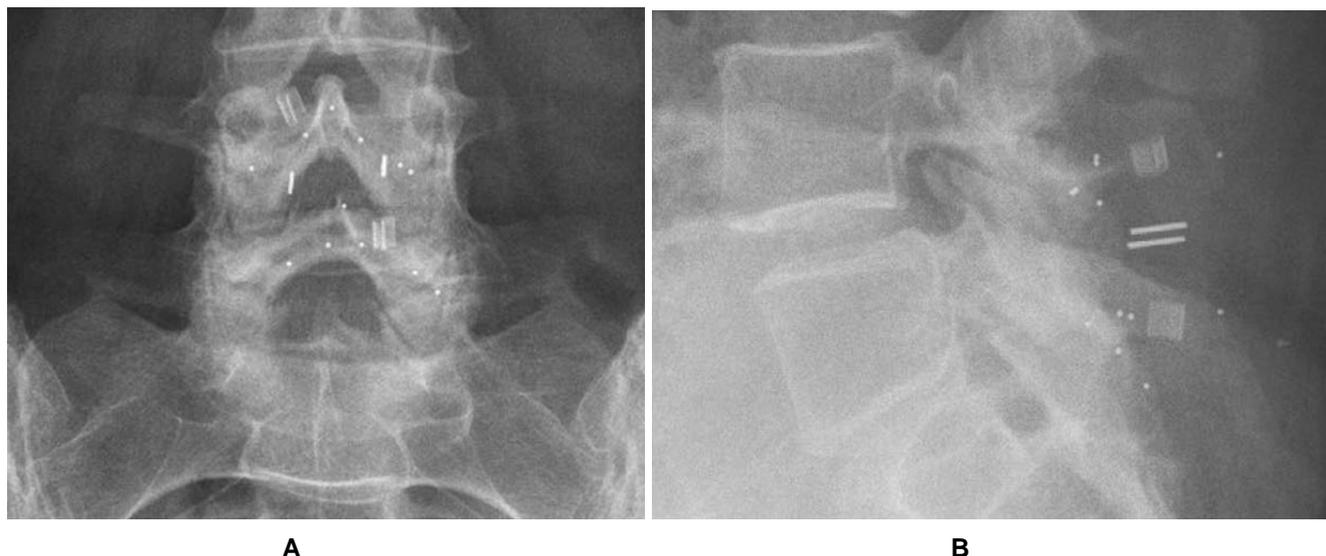
The participants gave self-reported information regarding the pain intensity for back and leg pain which was determined with the visual analog scale (VAS) [20, 21]. The self-reported functional impairment was analyzed on the one hand with the Oswestry Disability Index (ODI) as a 10-item questionnaire resulting in a score out of 50 converted to percentage [20-23]. On the other hand, the Roland-Morris Disability Questionnaire (RM) was used which is a 24-item questionnaire also converted to percentage [24]. The

VAS, ODI and RM are valid and reliable methods of measuring pain and disability [21, 25]. The assessment of health related quality of life was performed with the Short-Form-36 Health Survey (SF-36) which is one of the mostly used prominent instrument in similar outcome studies [26]. Another point of interest was the actual limit of the walking distance which also was documented at each of the control dates.

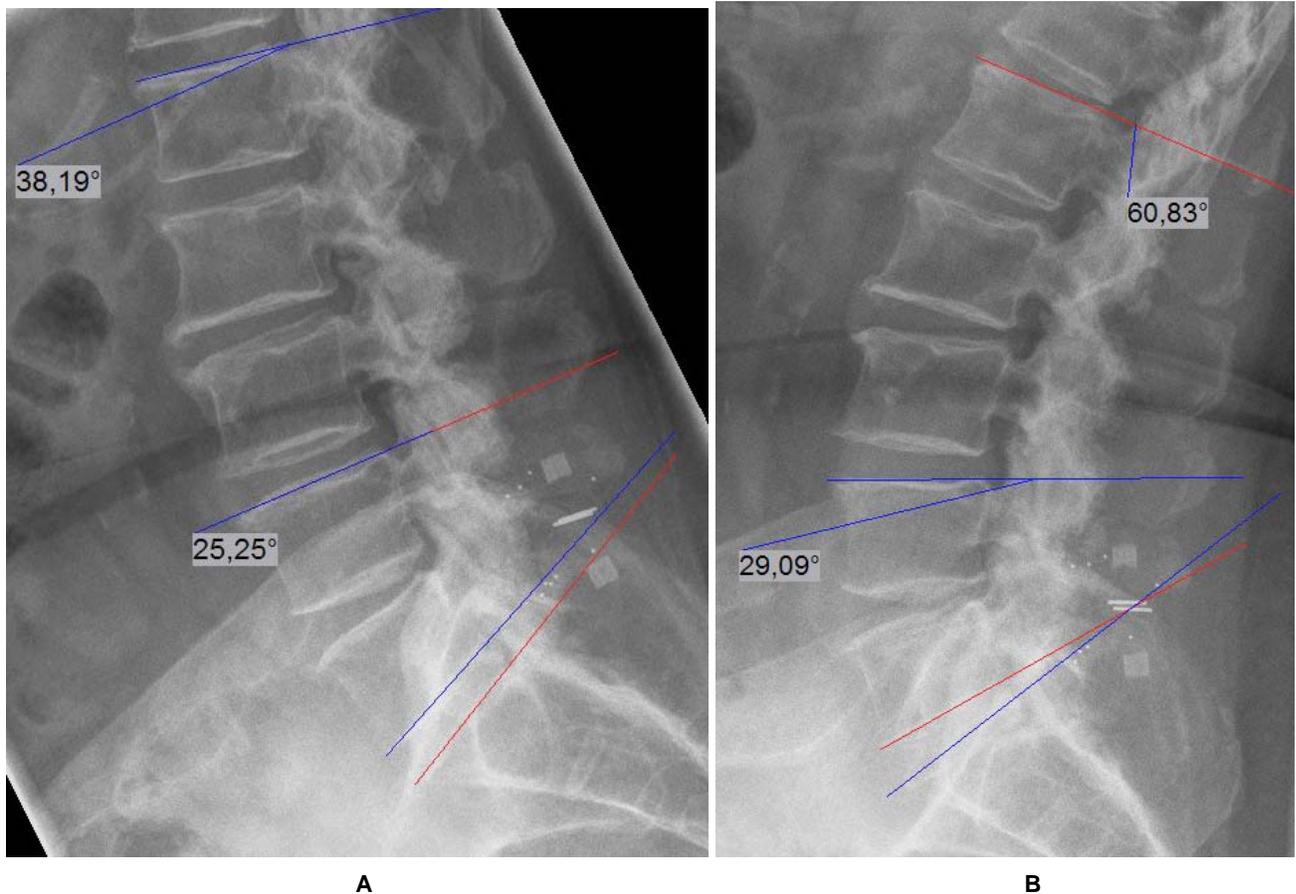
### Radiological Analysis and RSA

The day before operation x-ray images of the total lumbar spine (L1 to S1) in anterior-posterior (a.p.) view and from the lateral side in extension and flexion (functional x-rays) were performed. The functional roentgenograms were repeated in a standardized manner in the short-term postoperative period before discharge. These images were further planned after 3, 6, 12, and 24 months. The angles between the two operated vertebrae (segmental angle) and the angles from L1 to S1 (total lumbar spine angle) were subsequently measured by a clinical image processing software (GEMED-PACS®, GEMED mbH, Bremen, Germany) using the Cobb method (Figure 4A, B) [19]. The mean difference of these data in extension and flexion represented the segmental and total range of motion (ROM) in the sagittal plane and was used for statistical analysis.

For RSA, radiographs were taken in the short-term postoperative period and 3, 6, 12, and 24 months later in a uni-planar setup using a carbon-fiber calibration box (box10, Medis specials). The angle between the x-ray paths was 40 deg. X-ray tubes (Digital Diagnost,



**Figure 3:** Tantalum markers and Wallis® implant shown in postoperative x-rays after operation of the L4/5 level. **A:** anterior-posterior view, **B:** lateral view.



**Figure 4:** Measurement of the segmental and total lumbar angle in the lateral roentgenogram with the Cobb method. **A:** Flexion, **B:** Extension

Philips) exposed standard photostimulated luminescence plates with the dimension of 350x430 mm without the use of scatter grids. The plates were digitized resulting in an 8 bit gray-scale image with a resolution of 125 dpi. X-ray cathode voltage was 125 kV and time-current was 40 mAs. No double examinations were conducted to minimize x-ray exposure of the patients. Patients were positioned in standardized extension and flexion position lying on the right side by an experienced examiner [27]. They lay on a flat table with the calibration box directly under the examined area of interest. Spinal segment motion was calculated using the MBRSA software (Version 3.31, Medis specials) with a standard protocol and a single examiner. Accepted calibration thresholds were below 0.2 mm for fiducial markers and 1.0 mm for control markers. The markers in the upper and lower vertebrae constituted the rigid bodies. Rigid body match threshold was 0.50 mm, with one exception where 0.57 mm was required. The lower rigid body was used as reference, with the coordinate system aligned to the calibration box. Rotations around the z-axis (perpendicular to the image plane) were calculated, whereas positive rotation corresponds to flexion.

### Statistical Analysis

The results of the clinical scores and the difference of the radiographic angles measured on functional roentgenograms at the several follow-up dates were compared with the initial values using the t-test for related samples. A significance level of  $p < 0.05$  was chosen.

## RESULTS

### Clinical Results

All 10 patients had an uneventful intraoperative course. Only one person had a wound healing problem without an infection which was cured with local revision surgery. Complications related to the implant such as loosening or dislocation did not occur. Also, a spinous process fracture was not observed. One male patient was excluded from the study within the first 3 months because of conversion to fusion surgery due to failure of improvement of his preoperative complaints. No person had any postoperative neurological complication such as sensory or motor deficits.

To date, 9 patients had their 6 month follow-up, 8 participants their 12 and 3 their 24 month control. Therefore, follow-up data of the 8 patients who had their 12 month control examinations are presented in the following chapter.

### Walking Distance

The walking distance was limited in all but two of the 10 patients before surgery with a mean of 182 m. After 12 months, 5 patients had no more restrictions in walking. In the other 3 persons, the average walking distance had increased to at least 1000 m.

### Outcome Data (Scores)

Regarding the results of the VAS, we observed a statistically significant decrease in back pain intensity with a mean value of 6.0 before operation and of 1.3 12 months after surgery ( $p=0.004$ ). The patients also showed a trend to improvement concerning leg pain, which was not statistically significant with an average value of 4.7 before operation and of 2.0 12 months later ( $p=0.058$ ).

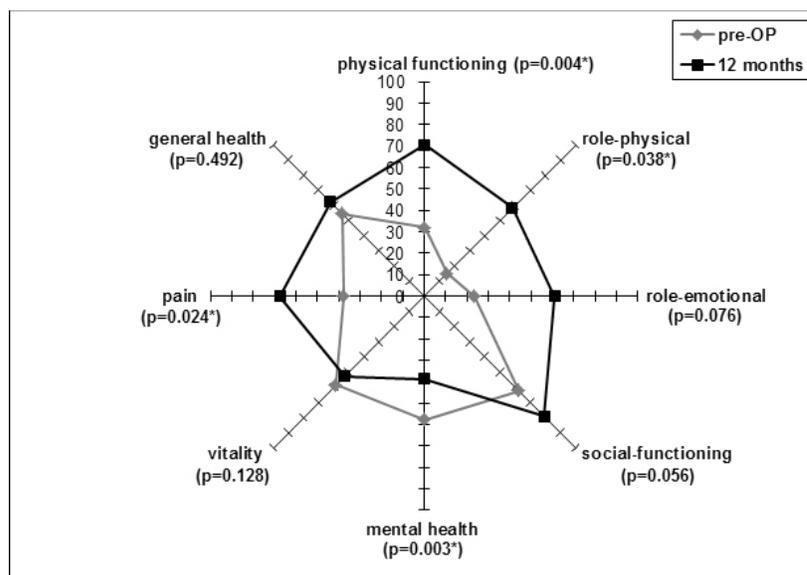
The functional disability according to the ODI and RM was also decreased both with statistical significance. The mean value of the ODI before operation was 40.0% and 12 months later was 9.2% ( $p=0.002$ ). The average value of the RM was 55.2% at the beginning and 17.1% at the one year follow-up ( $p=0.002$ ). The data from the SF-36 indicated improvement in six of the eight items (all but for mental health and vitality) with statistical significant differences

with regard to physical functioning, role-physical and pain (Figure 5).

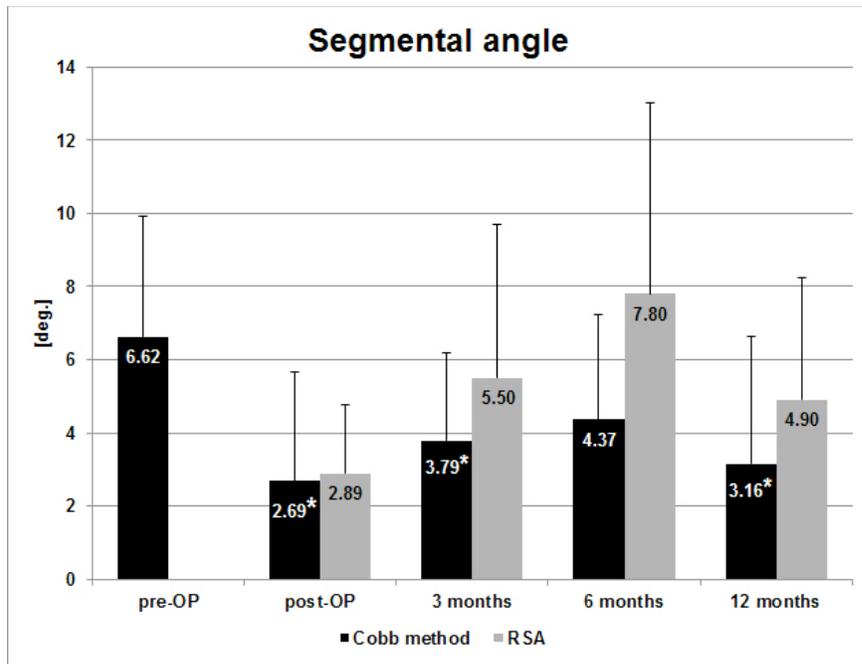
### Radiological Results and RSA

The mean segmental angle of the affected level (difference between flexion and extension) before surgery was measured by Cobb's method and was  $6.62^\circ \pm 3.30^\circ$ . The development of the average segmental angles during the different time points (before surgery, a few days after operation and 3, 6, and 12 months later) is shown in Figure 6. The angles which were measured according to Cobb's method were compared to the preoperative value and statistically analyzed and they showed a clearly decreased ROM to each control date after surgery. Directly postoperatively and after 3 and 12 months the segmental ROM was even statistically significantly lower ( $2.69^\circ \pm 2.96^\circ$  with  $p=0.010$  directly postoperatively,  $3.79^\circ \pm 2.38^\circ$  with  $p=0.034$  after 3 months,  $4.37^\circ \pm 2.88^\circ$  with  $p=0.161$  after 6 months,  $3.16^\circ \pm 3.48^\circ$  with  $p=0.040$  after 12 months).

Regarding the segmental angles which were calculated by RSA and related to the initial angles which had been measured with the Cobb method, we also observed a reduction of ROM after surgery ( $2.89^\circ \pm 1.89^\circ$ ) and 3 ( $5.50^\circ \pm 4.21^\circ$ ) and 12 months later ( $4.90^\circ \pm 3.33^\circ$ ), but not after 6 months ( $7.80^\circ \pm 5.23^\circ$ ). As the tantalum markers were not in place before surgery during the time of the preoperative x-ray images, we could not perform statistical analysis to find out any significant differences to the initial values. The discrepancy of the conventionally determined



**Figure 5:** SF-36 before operation and 12 months later (pre-OP means preoperatively). \*indicates statistical significant difference between the two time points.

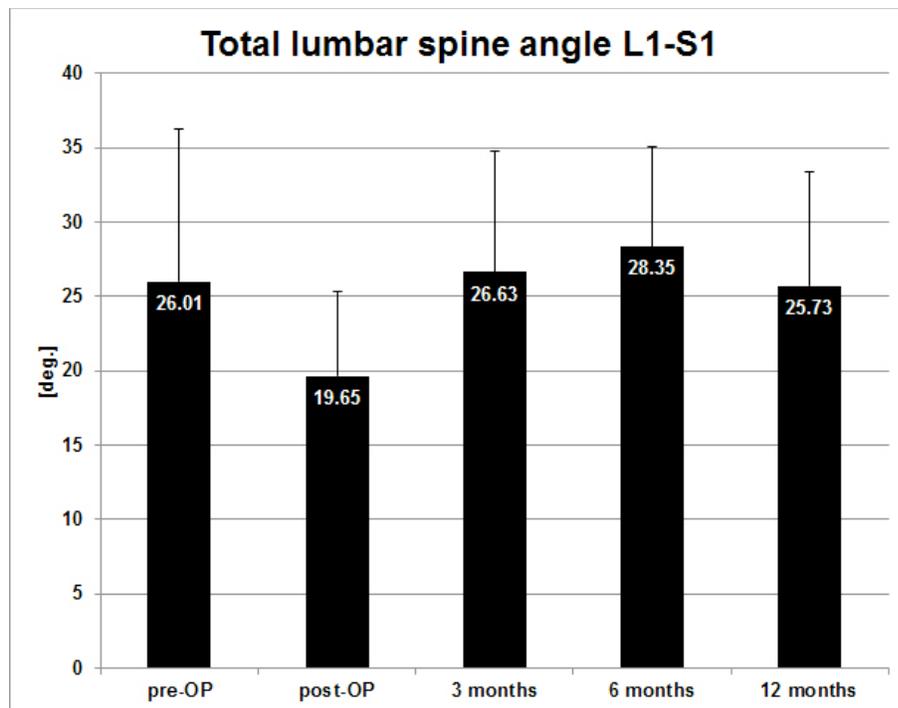


**Figure 6:** Development of the segmental angles in degree (deg.) to the different time points (pre-OP means preoperatively, post-OP means soon after surgery) measured by the Cobb method and RSA. \*indicates statistical significant difference compared to the initial angle.

segmental angles and the data measured by RSA were low with a mean of 1.77° (0.20° to 3.43°). The quality of the RSA was assured by determining mean rigid body error (0.31 ± 0.49 mm) and condition number (80 ± 21).

The mean difference of the ROM of the total lumbar spine (difference between flexion and extension) before

implantation of the Wallis® spacer was 26.01° ± 10.29°, measured by the Cobb method (Figure 7). A few days after operation the motion was statistically not significantly reduced to 19.65° ± 5.67°. After 3, 6, and 12 months, the average difference of the angle L1-S1 was not statistically significantly different to the initial



**Figure 7:** Development of the total angles in degree (deg.) to the different time points (pre-OP means preoperatively, post-OP means soon after surgery) measured by the Cobb method L1 to S1.

value ( $26.63^\circ \pm 8.19^\circ$  after 3 months,  $28.35^\circ \pm 6.77^\circ$  after 6 months,  $25.73^\circ \pm 7.68^\circ$  after 12 months).

## DISCUSSION

The aim of our study was to demonstrate clinical and radiographic results after PDS with an IDD with the main focus of assessment of remaining ROM on the affected level with Cobb's method and with high-accuracy RSA as well as for the whole lumbar spine with Cobb's technique.

The clinical data of our patients showed overall good results with regard to the changes in the walking distance, pain intensity as well as scores of functional disability and life quality with almost always significant improvement twelve months after PDS with an IDD (Wallis® spacer). However, the demonstrated clinical findings are not to be overestimated because of the monocentric study design without a control group and the small number of patients.

The authors are not aware of data from prospective randomized trials only with the Wallis® implant without additional fusion procedures to date. In contrast, there are some prospective case control or randomized studies with other types of IDD such as the Coflex™, DIAM or X STOP, with or without additional decompressive techniques [8, 28-30]. The reported results were not uniform with both similar findings between the two compared treatment groups and with superior outcome after IDD. That explains why the relevance and the indication of IDD have not been clearly defined yet.

Regarding clinical evaluations with the Wallis® implant, S negas *et al.* published long-term results of 241 patients and reported an actuarial survivorship of this system of 82.8% at 10 years and of 75.9% at 14 years [10]. No further information concerning clinical or radiological findings were given in this paper.

In another retrospective study Sobottke *et al.* reported clinical and radiological outcome data in 129 patients treated with three different kinds of IDD without decompression procedure with only 18 persons (14.0%) who received the Wallis® spacer [7]. In all three groups a statistical significant decrease of pain intensity was observed up to the latest average follow-up of 18.8 months. Directly after operation, a significant increase in foraminal height, foraminal width and foraminal cross-sectional area was seen with remaining over the entire follow-up period independent of the used IDD. The intervertebral angle measured by the

Cobb method was significantly reduced shortly after surgery and also after a mean time period of 7.2 months. In the Wallis® spacer group, the mean preoperative segmental angle was  $9.28^\circ$ . It was reduced directly after surgery to an average of  $4.75^\circ$ , and after a mean time interval of 7.2 months the intervertebral angle was slightly increased to  $6.65^\circ$ .

In our patient group, we also observed a statistical significant decrease of the segmental angle shortly after operation (from  $6.62^\circ$  to  $2.69^\circ$ ) which correlates well to the above mentioned data from Sobottke *et al.* [7]. During the entire follow-up this reduction remained and showed only slight increased values over the course. After twelve months, the segmental angle was still significantly lowered ( $3.16^\circ$ ) compared to the initial value. Also this slight increase corresponds well to the data from literature [7]. This observation is a strong factor for the assumption that IDD have the capability to stabilize the lumbar spine dynamically in the operated levels. However, a relevant influence on the mobility of the total lumbar spine was not observed in our study during the entire follow-up period, because the changes of the total ROM L1 to S1 were not statistically significantly different at all. The non-significant reduction of ROM directly after surgery might be an effect of any patient's discomfort or wound pain a few days after the surgical procedure and can prevent performing full extension and flexion.

Because of the lack of tantalum markers in x-ray images before operation, we cannot directly correlate the postoperative RSA-data of the segmental angles to the initial values. The RSA-data were constantly higher than the values measured by the Cobb method which is different to a comparative study with patients after lumbar arthroplasty by Park *et al.* who observed a mean difference in segmental angles of  $2.4^\circ$  between RSA and digital Cobb technique with lower values for RSA [17]. However, the overall discrepancy of the conventionally determined segmental angles and the data measured by RSA was low in our patients ( $1.77^\circ$ ). While the Cobb method generally has an intra- and inter-observer variability up to  $8.8^\circ$  RSA is known to be the most exact method for motion analysis with an accuracy between  $0.15^\circ$  and  $1.15^\circ$  [31, 32]. A relevant disadvantage of the standard RSA-technique is the fact that reference values never exist before operation, because only after the tantalum markers had been inserted into any bony structure RSA can be performed with the need of a special radiographic setup. A possible circumvention would be the use of model-based RSA utilizing 3D CT images of the affected vertebrae.

When we analyze the radiological findings which demonstrated a reduced segmental ROM after implantation of an IDD and when we correlate these with the knowledge from suitable experimental *in vitro* studies, we can identify the reasons for this radiographic behaviour. Wilke *et al.* performed a biomechanical study of four different types of IDD [33]. They had shown a significant reduction of extension (more than 50%) demonstrating a stabilizing effect. In flexion, only the Wallis® spacer tended to restabilize the specimens to the values of the intact conditions. In all four implants no stabilizing effect was observed in lateral bending or axial rotation but the intradiscal pressure was strongly reduced in extension. The findings were similar in another *in vitro* and also finite-element analysis performed by Lafage *et al.* [34]. They tested only the Wallis® implant and also showed reduced segmental ROM with the spacer mainly in flexion-extension without suppressing the mobility and observed lowered stress in the disc. These results were confirmed in a study by Schulte *et al.* who tested the Wallis® spacer against intact situation, decompression and a semi-rigid pedicle-screw based system [5]. The biomechanical analysis again showed a primary stabilizing effect after PDS with restriction of ROM mainly in the sagittal plane. In summary, the biomechanically proven stabilizing effect of IDD induces the radiographically detectable reduction of segmental mobility of the affected level. In contrast to the cited experimental studies, our radiological evaluation further demonstrated that the stabilizing influence of an IDD is not only temporarily but also has a mid-term effect with the duration of a minimum of 12 months. After the end of data acquisition after 24 months we maybe can present similar findings as a proof of a permanent stabilizing effect.

In conclusion and according to the radiological results of this study, the used Wallis® implant leads to a posterior dynamic stabilization expressed by almost always statistically significant reduction of segmental ROM of the operated levels. The clinical findings are promising, but they should be interpreted with caution because of the small number of patients and the lack of a control group.

## ACKNOWLEDGEMENTS

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## CONFLICTS OF INTEREST

The authors declare to have no conflicts of interest.

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