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Functional and radiographic evaluation of an interspinous device as an adjunct for lumbar interbody fusion procedures

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Abstract: In the last decades, several interspinous process devices were designed as a minimally invasive treatment option for spinal stenosis. In order to minimise surgical trauma, interspinous process devices were recently discussed as an alternative posterior fixation in vertebral interbody fusions. Therefore, the purpose of this study was to evaluate the effect of a newly designed interspinous device with polyester bands (PBs) on range of motion (RoM) and centre of rotation (CoR) of a treated motion segment in comparison with an established interspinous device with spikes (SC) as well as with pedicle screw instrumentation in lumbar fusion procedures. Flexibility tests with an applied pure moment load of 7.5 Nm were performed in six monosegmental thoracolumbar functional spinal units (FSUs) in the following states: (a) native, (b) native with PB device, (c) intervertebral cage with PB device, (d) cage with SC and (e) cage with internal fixator. The resulting RoM was normalised to the native RoM. The CoR was determined of X-ray images taken in maximal flexion and extension during testing. In flexion and extension, the PB device without and with the cage reduced the RoM of the native state to 58% [standard deviation (SD) 17.8] and 53% (SD 15.7), respectively. The SC device further reduced the RoM to 27% (SD 16.8), while the pedicle screw instrumentation had the most reducing effect to 17% (SD 17.2) ($p < 0.01$). In lateral bending and axial rotation, the interspinous devices had the least effect on the RoM. Compared to the native state, for

all instrumentations the CoR showed a small shift towards cranial. In the anterior-posterior direction, the SC device and the pedicle screw instrumentation shifted the CoR towards the posterior wall. The interspinous devices significantly reduced the RoM in flexion/extension, while in axial rotation and lateral bending only the internal fixator had a significant effect on the RoM.

Keywords: adjunct to fusion; centre of rotation; interspinous device; minimally invasive; posterior instrumentation.

Abbreviations: BMD, bone mineral density; CoR, centre of rotation; PB, interspinous device with polyester bands; PMMA, polymethylmethacrylate; RoM, range of motion; SC, interspinous device with spike clamps.

Introduction

Over the past several decades, operative treatment of symptomatic degenerative diseases like spondylolisthesis, spinal stenosis and facet joint arthritis has increased. Concomitant pain and functional impairment turn this spinal pathology to one of the most frequent causes of disability. Intervertebral fusion of affected segments is an established treatment option to address immobilising pain and reduced quality of life by involving placement of an implant (cage) within the intervertebral space. The range of motion (RoM) should be reduced to achieve bony fusion. Adjunctive stabilisation of the posterior complex of the lumbar spine is generally performed [1]. Pedicle screw fixation in lumbar intervertebral fusion procedures is considered to be the current gold standard treatment. By providing increased rigidity in all three main motion directions, the transpedicular stabilisation allows wide decompression in severe lumbar degenerative diseases with moderate to excellent clinical success [2, 3]. However, pedicle screw instrumentation comes at the cost of high invasiveness. Besides high blood loss and longer hospital stay, screw malposition, cerebrospinal fluid leakage, permanent nerve root injury or deep tissue infection led to recent endeavours implicating minimally invasive techniques in order to

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minimise surgical trauma especially in moderate degenerative diseases [4–6]. Recently, interspinous devices have been discussed as an adjunct to lumbar fusion procedures [7–9]. However, because interspinous devices can also have complications such as fractures of the spinous process or device loosening with high revision rates, they are controversially discussed in the literature [10].

The minimally invasive technique and easy application manoeuvre make these implants appealing as an adjunctive procedure in the treatment of symptomatic lumbar degenerative diseases. Several studies investigated the effect on RoM and showed an equal effect of stabilisation in flexion/extension for established interlaminar devices compared to posterior fixation [7, 8, 11–13]. However, RoM is only one part of the kinematics of the spine. Little is known about the centre of rotation (CoR), which is generally not investigated during spinal fusion procedures, although an alteration of CoR changes the segmental kinematics, which can alter facet joint contacts, disc stresses and ligament forces [14].

The purpose of the present biomechanical study was to investigate the effect of a newly designed interspinous device [polyester band (PB)] on RoM and CoR as a stand-alone device and to compare it to an established interspinous device (SC) and to transpedicular fixation as an adjunctive instrument in lumbar fusion procedures in combination with an intervertebral cage.

Materials and methods

Specimens

Six monosegmental functional spine units [three females and three males (3x Th12/L1; 3x L2/L3) with a mean age of 56.2 (standard deviation [SD] 1.39) years and a mean bone mineral density (BMD) of 96.1 mg/ccm (SD 18.6)] were used for biomechanical testing. The specimens were obtained from the local department of anatomy by donors, who had given their informed consent to use their bodies for scientific and educational purposes prior to death. Quantitative computer tomography scan (qCT, GE Healthcare, Lightspeed VCT16, Waukesha, WI, USA) was performed to exclude specimens with reduced disc height and severe bony degeneration and to assess trabecular BMD by using a European forearm phantom calibration. Specimens with a mean BMD below 75 mg/ccm were excluded. The double shrink wrapped specimens were frozen at -20°C .

Prior to testing, the specimens were thawed over night at $+6^{\circ}\text{C}$. Soft tissue was removed. Ligaments, joint capsules and other supporting tissue were preserved. The upper half of the cranial vertebra and the lower half of the caudal vertebra were embedded in polymethylmethacrylate (PMMA) (Technovit 3040, Heraeus Kulzer GmbH, Wehrheim, Germany). During embedding, attention was paid to align the disc horizontally and not to cover anatomical landmarks for pedicle screw instrumentation. The cured PMMA embeddings were

equipped on both sides with flanges and mounted in the spine simulator. At the ventral side of both embeddings, a three-dimensional (3D) motion analysis system (Zebris, Winbiomechanics, Isny, Germany) was attached.

Implants

Two different interspinous implants were tested in the present biomechanical study: first, an interspinous device (SMS, QSpine, Northants, UK) with PB fixation around the upper and the lower spinous processes (PB) and, second, an established interspinous device (X-plate®, X-spine®, Miamisburg, OH, USA), consisting of two plates with spikes clamping the spinous processes (SC) and thereby provide stability. Intervertebral fusion was simulated by a curved cage (CAP, HPI Implants, Scionzier, France), with the cage height being chosen intraoperatively to best fit anatomical structures. For the internal fixation, established polyaxial pedicle screws ($1 \times \varnothing 5.0 \text{ mm} \times 40 \text{ mm}$, $5 \times \varnothing 5.0 \text{ mm} \times 45 \text{ mm}$) (REED, HPI Implants, Scionzier, France) and titanium rods ($\varnothing 5.5 \text{ mm}$) were used.

Flexibility testing

All flexibility tests were carried out in a six-degree-of-freedom spine tester. Specimens were loaded with pure moments, applied by a stepper motor. A six-component load cell with feedback control was connected to the stepper motor to control the loading of the specimens [15–17].

Flexibility tests were carried out with pure moments of $\pm 7.5 \text{ Nm}$ in the three main motion planes (lateral bending, flexion/extension and axial rotation). Specimens were subjected to three load cycles in each motion direction. All flexibility tests were carried out at room temperature and specimens were kept moist with physiological saline solution during testing (Figure 1).

Intersegmental motion was measured using an ultrasound-based motion analysis system (Winbiomechanics, Zebris, Isny, Germany) with a sampling rate of 60 Hz. From the recorded data, the RoM was determined for the third load cycle. The biomechanical testing of the spines was carried out according to the recommendations for testing of spinal implants [18].

The following states were tested:

1. Native (NA).
2. Native with PB device (NS).
3. Intervertebral cage (TLIF) with PB device (CS).
4. Intervertebral cage with SC (CX).
5. Intervertebral cage with bilateral pedicle screw fixation (CP).

All specimens were tested in the same order of the test states. The order was not changed as an alteration would have increased the instability and might have challenged the subsequent states (e.g. implanting the SC prior to the PB device could have weakened the interspinous process due to the spikes of the SC).

Instrumentation technique

For implantation of the first interspinous devices, the intra- and supraspinous ligaments were cut. The size of the PB device was

Figure 1: Spine tester used for flexibility testing with pure moment loading.

Translational and rotational degrees of freedom are marked with green and yellow arrows, respectively, and application of pure moment loading with red arrows.

individually chosen depending on the height of the interspinous space by using a sample size following the manufacturer's guidelines. After placement of the device, the upper and lower interspinous processes were encircled by the PB and the PBs were tightened and fixed according to the manufacturer's guidelines. After the first flexibility testing (test state 2), the curved cage was implanted in an extraforaminal lumbar interbody fusion (ELIF) procedure with an incision on the postero-lateral annulus of 1.0–1.5 cm without compromising the facet joint or capsule [19]. The endplate was prepared with standard surgical tools prior to cage implantation. The cage sizes were measured with standard surgical tools (test state 3). Then, the PB device was removed and the appropriately sized SC device was placed in the interspinous space according to the manufacturer's guidelines. After verifying the implant position, the spiked locking plate was tightened with the set screw.

Pedicle screws were inserted with standard surgical tools. With regard to anatomical landmarks, the entry point was broached with a starter awl. With a 3-mm awl, a pilot hole was cut. The length of the pedicle screw was individually chosen. All implant positions were controlled by a post implantation fluoroscopy of the specimens.

Centre of rotation

The CoR in full flexion/extension motion was determined of functional X-rays taken in the spine simulator under maximum flexion

and extension loading. The X-rays were evaluated using a semi-automated software [functional X-ray analysis (FXA) by ACES GmbH, Germany]. The positional changes in CoR were calculated in two directions. The cranial-caudal direction extends from the upper to the lower posterior wall and the posterior-anterior direction from the upper posterior wall to the upper anterior wall. The position in these directions was measured, normalised to the vertebral body size and expressed in percentage (Figure 3).

Statistical analysis

For statistical evaluation of the RoM, a repeated measurement analysis of variance (ANOVA) with a Bonferroni post-hoc test was carried out using SPSS v22 (IBM Statistics). The significance level was set to 0.05.

Results

To compensate for the interspecimen variation, the results of the RoM were normalised to the native uninstrumented specimen and are reported in percentage of the native state (Figure 2). Absolute magnitudes of the measured RoM in degrees are presented in Table 1.

RoM in lateral bending

For normalised values in lateral bending, the mean RoM of the stand-alone PB, the cage with PB and the cage with SC state ranged between 99% and 106% of the native

Figure 2: RoM normalised to the native state in lateral bending, flexion/extension and axial rotation.

Statistically significant differences are indicated with an asterisk.

Figure 3: Example of calculated centre of rotation in all tested states for one specimen.

NA, native; NS, native with SMS device; CS, SMS device with cage; CX, X-plate with cage; CP, pedicle screw instrumentation with cage.

Table 1: Changes in RoM in flexion/extension, axial rotation and lateral bending of the five tested states in degrees.

Condition motion	Flexion/extension	Axial rotation	Lateral bending
Native (NA)	8.5 (± 2.5)	4.3 (± 2.2)	10.1 (± 2.6)
Native with PB device (NS)	4.9 (± 1.9)	4.7 (± 2.8)	10.0 (± 2.5)
PB device with cage (CS)	4.4 (± 1.8)	5.1 (± 2.2)	10.9 (± 4.5)
SC with cage (CX)	3.3 (± 2.9)	4.7 (± 2.0)	10.5 (± 4.7)
PS with cage (CP)	2.3 (± 1.5)	3.2 (± 1.4)	5.0 (± 2.8)

state and not significantly different from the RoM of the untreated segment ($p=1.0$).

The mean RoM was 99.7% (SD 2.2) for the PB as stand-alone, 106.8% (SD 26.6) for the cage with additional PB and 102.4 (SD 31.7) for the cage with additional X-plate, whereas the cage with an additional pedicle screw system showed a significant reduction of RoM to 49.5% (SD 22.3) of the native state ($p<0.026$) (Figure 2).

RoM in flexion/extension

For normalised values in flexion/extension, all instrumentations caused a significant reduction of RoM ($p<0.018$). Instrumentation with the PB device as stand-alone caused a reduction to 57.6% (SD 17.8). For the implantation of the specimen with an additional cage and the PB device, the RoM was further reduced to 52.7% (SD 15.7), while for the cage and the SC the RoM was 27.4% (SD 16.8) of the native state. The greatest reduction of RoM was measured for the cage with additional pedicle screw fixation [17.4 (SD 17.2)].

RoM in axial rotation

For normalised to the native state values in axial rotations, none of the instrumentations caused a significant reduction of RoM ($p=1.0$). While all interspinous devices

caused a slight increase in RoM, the pedicle screw instrumentation resulted in a reduction of RoM compared to the native state.

The PB device as stand-alone resulted in a mean RoM of 105.3% (SD 13.34), the cage with the PB device increased the RoM to 123.6%, the cage with the SC showed 115.89% (SD 42.83), while the pedicle screw system caused a reduction to 84.8% (SD 37.8). The difference of the cage with the PB device and the cage with pedicle screws was significant ($p=0.02$) (Figure 2).

Centre of rotation (CoR)

An exemplary evaluation of the CoR for the five states in full flexion and full extension is shown in Figure 3. The collected data were not normally distributed and therefore a statistical evaluation of the limited sample size was not very meaningful, and only descriptive data of the CoR location normalised in percentage of the vertebral body size in the anterior-posterior and cranio-caudal directions are reported (Table 2).

For the native state, the CoR was located in the centre of the vertebral body in the anterior-posterior direction (41.0%) and in the cranio-caudal direction slightly caudal of the lower endplate (−20.5%).

In the anterior-posterior direction, all instrumentations resulted in a posterior shift of the CoR compared

Table 2: Median values of CoR in the posterior-anterior direction and cranio-caudal direction in percentage.

Condition direction	Posterior-anterior direction in % (range min–max)	Cranio-caudal direction in % (range min–max)
Native (NA)	41.0 (33.0–54.0)	–20.5 (–28.0 to 23.0)
Native with PB device (NS)	33.0 (2.0–43.0)	3.0 (–49.0 to 19.0)
PB device with cage (CS)	39.0 (11.0–49.0)	6.5 (–53.0 to 38.0)
SC with cage (CX)	–9.0 (–47.0 to 20.0)	4.5 (–30.0 to 100.0)
PS with cage (CP)	3.0 (–35.0 to 25.0)	–8.5 (–53.0 to 36.0)

to the native state (Figure 4). The instrumentation with the PB device as stand-alone and in combination with a cage caused a slight shift of the CoR towards the posterior wall (8.0% for the PB device stand-alone, 2.0% for PB with cage). While compared to the native state, the instrumentation with the cage in combination with the SC or pedicle screw fixation resulted in a marked shift of the CoR towards the posterior wall (–50.0% for the SC device and –38.0% for pedicle screw fixation).

In the cranio-caudal direction, all instrumentations showed a small shift of the CoR towards the cranial direction (PB without cage 23.5%, PB with cage 27.0%, SC with cage 25.0% and pedicle screw fixation with cage 12.0%) (Figure 4).

Discussion

The present biomechanical study investigated the stabilising effect of a new interspinous device on the RoM and CoR of lumbar spine specimen in *in vitro* experiments. The test setup included an interspinous device as a stand-alone procedure and as an adjunctive procedure

to intervertebral fusion and compared it to an established interspinous device and pedicle screw fixation, which can be considered as the current gold standard in fusion procedures. Flexibility tests were accomplished in flexion/extension, axial rotation and lateral bending. Alterations in the CoR were measured using lateral X-rays in maximal flexion and maximal extension.

In summary, the interspinous device (PB) was capable of significantly reducing the RoM of the treated segment in flexion/extension compared to the native intact state. The established spacer (SC) limited the RoM in flexion and extension to the range of the pedicle screw instrumentation. In lateral bending and axial rotation, the interspinous devices did not show any significant effect on RoM, while the pedicle screw instrumentation reduced the RoM noticeably.

Over the last decades, interbody fusion of degenerative affected segments of the lumbar spine has gained popularity. Early return to work, short lengths of hospital stay and less blood loss during spinal fusion procedures have become more important. Therefore, minimally invasive procedures are attractive in order to minimise surgical trauma.

Several previous studies have described the effect of interspinous devices on RoM with and without cage implantation and compared it to pedicle screw fixation. Techy et al. showed a significant decrease (74%) in RoM in flexion/extension after implantation of an interspinous device as an adjunct to interbody fusion without any significant changes in RoM in lateral bending and axial rotation. Compared to bilateral pedicle screw instrumentation, they showed that interspinous devices can provide a comparable reduction of RoM in flexion and extension [8]. Doulgeris et al. compared an interspinous device to bilateral pedicle screw instrumentation for lateral lumbar interbody fusion procedures. They showed an equivalent performance of both instrumentations in flexion and extension. In lateral bending, pedicle screw insertion showed a decreased RoM compared to the interspinous device [12]. Wilke et al. compared four different interspinous devices in terms of flexibility and intradiscal pressure in the intact, defect and instrumented

Figure 4: Effect on CoR for the stand-alone interspinous device and all instrumentations in the anterior-posterior and cranial-caudal directions normalised to the vertebral body size.

NA, native; NS, native with SMS device; CS, SMS device with cage; CX, X-plate with cage; CP, pedicle screw instrumentation with cage.

states. All tested implants showed a stabilising effect in flexion and extension and the intradiscal pressure varied mainly in extension [20]. Our results stand in accordance with the above-mentioned studies, although the tested interspinous devices differed in design and application technique. Furthermore, the magnitude of applied pure moment loading was different (± 5 vs. ± 7.5 Nm). In view of current knowledge, none of the recent studies have investigated the influence of interspinous devices on the CoR during biomechanical testing. Finite elements studies showed that CoR alterations influence kinematics and load sharing characteristics of the affected segment and can violate the balanced interactions between facet pressures, disc stresses and ligament forces leading to progressive degenerative diseases like adjacent segment degeneration [14, 21]. Alapan et al. reported that minimal soft tissue violation of the lumbar spine can already cause changes in the CoR. In their finite element model, the CoR was located mainly on the posterior third of the vertebral body and showed a shift towards the posterior-superior direction, while stabilising ligaments of the lumbar spine were removed. These results for the change in CoR location could be confirmed in the present study. The CoR of the native state was located in the posterior third of the vertebral body. After insertion of the devices, the CoR slightly shifted towards the cranial direction. Instrumentation with the SC and the pedicle screws showed a shift towards the posterior wall. However, the PB device was comparable to the native state. These findings may represent the relative rigidity and stiffness in adjunctive posterior procedures during lumbar fusions. Only limited data are available concerning the effect of changes in CoR on load sharing of the lumbar spine. Furthermore, the magnitude of stiffness required in an instrumented segment to achieve lumbar fusion remains unknown. Limited micro-motion at the cage-bone interface may promote bony fusion and avoid non-union [22]. Interspinous devices may combine limited motion and CoR preserving effects by providing a minimally invasive surgical approach. Despite their reduced stability compared to pedicle screws, they may be an alternative in fusion procedures in selected patients with moderate degenerative disease. However, the use of interspinous devices still remains controversial and for their use as an adjunct to fusion, complications such as interspinous process fractures or device loosening could arise. A successful treatment with interspinous devices requires a thoughtful patient selection. Patients with osteoporosis at risk of spinous process fractures, spondylolisthesis above grade 2 and severe degenerative diseases are not recommended to be treated with interspinous devices. These exclusion criteria

exclude a non-negligible proportion of the patient population suffering from degenerative spine diseases [10, 23, 24]. It has to be pointed out that, in the present study, the average BMD was 96.1 mg/ccm and therefore in the range for osteopenic vertebrae [25]. However, no fracture of the spinous process or early failure of pedicle screw fixation strength was observed throughout the testing.

There are limitations to the study. First, the different instrumented states were all tested in the same order. This was owed to the different anchoring principles of the interspinous devices. An alteration of instrumentation would have led to increased instability due to different application manoeuvres of the interspinous devices and the possible weakness of the vertebral body after removal of the pedicle screws. This could have distorted the results. Second, the number of test samples was limited; however, the biomechanical investigation was conducted in a controlled laboratory environment without multiple confounding variables as in clinical trials. Therefore, it might be assumed that if a limited number of specimens in a controlled laboratory setting does not show a difference, the clinical impact of the difference will also likely be negligible [26]. Furthermore, the test setup included repetitive flexibility testing at nondestructive load levels. Fatigue testing under cyclic loading was not carried out, as it would have multiplied the number of required specimens and prohibited the repetitive testing of one specimen with varying instrumentations. The collected data of the CoR locations after instrumentation were not normally distributed with outliers. Therefore, a statistical evaluation was not meaningful and only descriptive statistics with the median of the results was presented.

Further biomechanical and animal models as well as prospective clinical trials with long-term follow-up should be initiated to investigate the influence of interspinous devices on RoM and CoR in lumbar interbody fusion procedures.

Interspinous devices can reduce the RoM in the extension/flexion direction. Selected designs of interspinous devices intended to be an adjunct to fusion may be an alternative to rigid posterior stabilisation in order to reduce surgical trauma. Further biomechanical and clinical evidence, especially a long-term follow-up, is required to investigate the effect of changes in RoM and CoR in fusion procedures in patients.

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