Biomechanical Comparison of an Interspinous Device and a Rigid Stabilization on Lumbar Adjacent Segment Range of Motion

Biomechanické srovnání interspinózního implantátu a rigidní stabilizace na rozsah pohybu přilehlých lumbárních segmentů

F. HARTMANN¹, S. O. DIETZ¹, S. KUHN¹, H. HELY², P. M. ROMMENS¹, E. GERCEK¹

¹ Department of Trauma Surgery, Center for Musculoskeletal Surgery, University Medical Centre Mainz, Germany
² Physic Division, University of Applied Sciences Wiesbaden, Germany

ABSTRACT

PURPOSE OF THE STUDY
Decompression surgery with or without fusion is the gold standard treatment of lumbar spinal stenosis, but adjacent segment degeneration has been reported as a long-term complication after fusion. This led to the development of dynamic implants like the interspinous devices. They are supposed to limit extension and expand the spinal canal at the symptomatic level, but with reduced effect on the range of motion of the adjacent segments. The aim of the present study is the evaluation of the biomechanical effects on the range of motion (ROM) of adjacent lumbar segments after decompression and instrumentation with an interspinous device compared to a rigid posterior stabilization device.

MATERIALS AND METHODS
Eight fresh frozen human cadaver lumbar spines (L2-L5) were tested in a spinal testing device with a moment of 7.5 Nm in flexion/extension, lateral bending and rotation with and without a preload. The preload was applied as a follower load of 400N along the curvature of the spine. The range of motion (ROM) of the adjacent segments L2/L3 and L4/L5 was measured with the intact segment L3/L4, after decompression, consisting of resection of the interspinous ligament, flavectomy and bilateral medial facetecomy, and insertion of the Coflex® (Paradigm Spine, Wurmlingen) and after instrumentation with Click X® (Synthes, Umkirch) as well.

RESULTS
The interspinous and the rigid device caused a significant increase of ROM at both adjacent segments during all directions of motion and under follower load, without significant difference between these devices. The ROM of L2/L3 tends to increase more than the ROM of L4/L5 after instrumentation without statistical significance.

DISCUSSION
The “dynamic” Coflex device caused a significant increase of ROM at both adjacent lumbar segments comparable to the increase of ROM after instrumentation with the rigid Click X device. Other in vitro studies observed comparable biomechanical effects on the adjacent segments after fusion, but biomechanical spacer studies concentrated on the “non-compressible” X-Stop® and could not demonstrate a significant adjacent segment effect of this device.

CONCLUSIONS
The hypothesis, that an interspinous device would reduce the stress on adjacent segments compared to a rigid posterior stabilization device, could not be demonstrated with this biomechanical in vitro study. Therefore, the protection of adjacent segments after instrumentation with dynamic devices is still not completely achieved.

Key words: interspinous device; biomechanics; lumbar spinal stenosis; adjacent segment effect.
INTRODUCTION

The gold standard operative treatment of lumbar spinal stenosis (LSS) is decompression with additional posterolateral or posterior interbody fusion in case of unstable spinal segments, although several studies report of long-term complications like adjacent segment degeneration (ASD) (11, 21, 39). The attributed mechanism of the development of ASD is an increased biomechanical stress, since several studies showed that lumbar fusion caused a significant increase of intradiscal pressure, facet loading and mobility of the adjacent segments (3, 5, 7, 12, 14). This biomechanical stress contributes to an increased degeneration of the adjacent segments, which has been demonstrated by in vivo animal studies (23, 29). The authors found increased disc degeneration adjacent to fused segments. Despite several biomechanical and animal studies it is still discussed controversially whether ASD is a consequence of fusion or a natural process of the individual patient, since various retrospective studies based on different methodologies resulted in contradictory conclusions with some authors observing ASD (4, 17, 24, 27, 39) and some not (2, 28, 32, 34). It remains uncertain, if there is a direct correlation between radiologically demonstrated ASD and clinically symptomatic ASD (31) and if the development of an ASD is due to a physiological progression, a biomechanical stress or due to both.

Beside this ongoing discussion the biomechanical studies encouraged the hypothesis that the preservation of a certain motion of the treated segment would reduce the stress on the adjacent segments, which would decelerate the adjacent segment degeneration. This led to the development of various dynamic stabilization devices and interspinous devices (6, 18) comparable to the development of vertebral fractures. Actual interspinous devices are not developed for the stabilization of the spinal segment, but they are supposed to limit the motion in the instrumented segment and reduce the biomechanical effect on the adjacent segment(s). They are developed for the stabilization of the spine, which are rejected to minimize viscoelastic effects of the adjacent segments (8). The hypothesis of the present study was that an interspinous device would reduce biomechanical stress on adjacent lumbar segments compared to a rigid posterior stabilization device. Therefore the aim of the present biomechanical in vitro study was the evaluation of the range of motion of adjacent lumbar segments after instrumentation with an interspinous device compared to a rigid posterior stabilization device.

MATERIALS AND METHODS

The study was performed with eight fresh human lumbar cadaver spines extending from L2 to L5, which were extracted at the time of the post mortem autopsy. During the explantation the surrounding soft tissue was removed without damaging the ligamentous structures. After the macroscopic visual inspection the specimen were screened via fluoroscopy. The exclusion criteria for the cadaver were deformities, fractures, tumors, loss of disc height, dorsventral displacement, osteophyte formation, hypertrophic facet arthritis and scoliosis. At the day of testing the cryoconserved specimens were gradually thawed to room temperature. Five female and three male lumbar spines with a mean age of 64 years were kept moist with saline solution during the testing procedure.

Biomechanical testing was performed in a spinal testing device (Fig. 1) by fixating the specimen with the lower end to the base frame and the upper end to a cardan joint (15, 16). The cardan joint consists of three swivel joints, which include an angle sensor, a force-torque sensor and a drive to load the specimen for all directions of motion. The positioning of the integrated sensors allows a continuous assessment of forces and moments applied to the spine, so that possible off-axis loads can be recorded. The drive of the cardan joint is made up of a step motor, a harmonic drive gearing and an e-coupling. The guide element for the cardan joint allows free lateral and axial movement and can be uncoupled from the drive unit to allow the fixation of the specimen in its neutral position. A PID controlled balance weight prevents the cardan joint from loading the specimen with its own weight.

The control programme LabVIEW® (National Instruments Germany GmbH, München, Germany) monitored the simulator and the data acquisition. The three-dimensional motion analysis CMS 70 System® (Zebris Medical GmbH, Isny, Germany) was fixed with Kirschner wires to each vertebral body to measure the range of motion (ROM) of each spinal segment (Fig. 1). The data acquisition of the angle sensors, force-torque sensors and the CMS 70 System® was synchronized with 10 Hz.

The testing routine based on the flexibility test protocol of Panjabi (26) by measuring the quantity of displacement (range of motion = ROM) after applying a pure moment of ±7.5 Nm in extension-flexion, lateral bending and rotation (13, 36). The loading of the specimen was performed by the step motor, which rotated the correlating cardan joint with constant angular velocity until the predetermined set point (7.5 Nm in this study) was reached and the programme reversed the direction of motion. Each series of measurement consisted of 3 motion cycles with one cycle before and after testing, which were rejected to minimize viscoelastic effects of the specimen. After testing all three dimensions another series in extension-flexion was performed with the simulation of a physiologic preload of 400N. This was realized by inducing an optimized follower load along the curvature of the spine using cable and weights (Fig. 1) (10, 26). Lateral bending and rotation is not performed with follower load in our testing device, because preceding studies and other study groups showed increased friction and restoring forces, which reduced the ROM with increasing follower load (8, 16, 30).
After fixation of the specimen in the spinal testing device the test routine started with the intact spine in extension-flexion and proceeded with lateral bending, rotation and extension-flexion with follower load. Then the interspinous Coflex® (Paradigm Spine, Wurmlingen, Germany) device was implanted into the segment L3/L4 (Fig. 2). The insertion of this device at the intraspinous ligament was carried out strictly according to the instructions of the manufacturers with resection of the interspinous ligament, detachment of the supraspinous ligament and additional decompression consisting of flavectomy and bilateral medial facetectomy.

The interspinous device was tested in extension-flexion, lateral bending, rotation and extension-flexion with follower load. After that the spine was tested without device in extension-flexion. Finally the posterior pedicle screw rod system Click X® (Synthes, Umkirch, Germany) was implanted (Fig. 3). The 6.2 mm titanium pedicle screws were inserted into L3 and L4 and connected by longitudinal titanium rods. After the posterior instrumentation of L3/L4 the testing proceeded with extension-flexion, lateral bending, rotation and extension-flexion with follower load. The procedure concluded with the testing of the spine without any device in all three directions of motion.

The ROM of the segments L2/L3 and L4/L5 during extension-flexion, lateral bending and rotation (as well as during extension-flexion with follower load) was calculated with the signal of the main direction of motion of the CMS 70 System®, whereas the data of the angle sensors of the cardan joint were analyzed for the ROM of the whole specimen. The calculated data were imported into a common software program (MS Office Excel Version 2003®) which diagrammed the values. The results for all axes of the motion segments L2/L3 and L4/L5 were displayed into diagrams and the ROM of each implant was compared against the intact spine and against each other. Due to the well known interindividual variability of the specimens the comparison has been performed intraindividual against the ROM of the intact condition defined as 100%.

Since the study was performed with only eight specimens a normal distribution of data could not be assumed. Therefore median values with ranges were reported and for statistical analysis the Wilcoxon signed rank test was used to compare the intact condition against the implanted condition. The statistical analysis was performed with SPSS for Windows® Version 15.0 and a “p”-value of less than 0.05 was considered significant.

RESULTS

The preparation and implantation of Coflex in the segment L3/L4 causes a significant increase of ROM during extension-flexion in the adjacent segment L2/L3 to a median ROM of 166% (Fig. 4) and in the adjacent seg-
ment L4/L5 to a median ROM of 140% (Fig. 5) compared to the intact spine (100%). The implantation of the Click X device causes a significant increase of ROM during extension-flexion in the adjacent segment L2/L3 to a median ROM of 178% (Fig. 4) and in the adjacent segment L4/L5 to a median ROM of 139% (Fig. 5).

During lateral bending Coflex significantly increases the median ROM of the segment L2/L3 to 144% and the median ROM of the segment L4/L5 to 147%. The Click X device also leads to a significant increase of the median ROM of L2/L3 to 145% and of L4/L5 to 147% during lateral bending.

These findings are similar to the significant increases of ROM during rotation. Here, the Coflex device causes a median ROM of 139% in the segment L2/L3 and a median ROM of 140% in the segment L4/L5. The Click X device also leads to a significant increase of the median ROM of L2/L3 to 145% and of L4/L5 to 147% during lateral bending.

The comparison of the ROM of both implants against each other showed no significant differences during all directions of motion in both adjacent segments.

**DISCUSSION**

Numerous *in vitro* studies evaluated the biomechanical changes at the adjacent segments after single segment and multisegmental fusion and described increased ROM, increased facet loading and increased intradiscal pressure after fusion (3, 5, 7, 14, 35). These findings after fusion are in correspondence to the present study, where the posterior instrumentation with Click X® at segment L3/L4 caused a significant increase of ROM at the adjacent segments L2/L3 and L4/L5 during extension-flexion, lateral bending, rotation and extension-flexion with a follower load of 400 N.

A few biomechanical *in vitro* studies in the literature evaluated adjacent segment effects of interspinous devices, but they are restricted to the X-Stop® (Tikom, Fürth, Germany). Wiseman *et al.* evaluated the facet loading of human cadaver lumbar spine after instrumentation with X-Stop® (38). They inserted pressure films into the facet joints of the instrumented (L3/4) and adjacent (L2/3, L4/5) segments and applied moments of 15 Nm with a preload of 700 N during flexion and extension. However, a significant change of the mean pressure in the facet joints of the adjacent segments could not be demonstrated. Swanson *et al.* applied a moment of 7.5 Nm and a preload of 700 N during flexion and extension and measured the disc pressure in the adjacent segments L2/3 and L4/5 after implantation of the X-Stop® into segment L3/4 (33). They could not observe significant changes in the disc pressure at the adjacent segments, so that they proposed a redirection of the load away from the disc to the spinous processes due to its design as a non-compressible spacer.

The Coflex® device differs from the X-Stop® in design, because it is a compressible U-shaped device with clips, which are tightened around the spinous processes during insertion. First clinical studies of the Coflex device supposed a stabilization of minor or potential instability after decompression and protection of the adjacent segment. This could not be demonstrated in case of advanced instability or spondylolisthesis (19). A subsequent biomechanical *in vitro* study by Wilke *et al.* evaluated the ROM of the instrumented segment after decompression and implantation of different interspinous devices, including Coflex®, by applying a moment of 7.5Nm without preload in all directions of motion (37). They showed that the implantation of Coflex® into a segment with a decompression defect caused stabilization during extension motion, but this effect could not be proven during flexion, lateral bending and rotation. In a preceding study we confirmed these findings for Coflex® at the instrumented segment L3/4, but we observed a significant increase of ROM of the whole specimen (L2-L5) during extension-flexion, rotation and lateral bending (15).
A clinical study compared patients having degenerative spinal stenosis with mild segmental instability who underwent implantation of Coflex® or posterior lumbar interbody fusion (PLIF) after foraminal decompression with partial laminotomy in segment L4/L5 (18). Beside a comparable clinical outcome after 1 year follow up, the authors found a significant decrease of ROM at the instrumented segment in the PLIF group and in the Coflex® group on extension-flexion radiographs, but the amount of decrease in the Coflex group was not as much as in the PLIF group. In the upper adjacent segment L3/4 the PLIF group showed a significant increase of ROM, whereas the Coflex® group showed no difference between pre- and postoperative ROM. Therefore the authors assumed that PLIF in contrast to Coflex® would cause an accelerated degeneration of the adjacent segment. In contrast to this clinical study our biomechanical study performed the instrumentation in segment L3/L4 and showed a significant increase of ROM of the adjacent segments L2/L3 and L4/L5 for both the Coflex® device and Click X® device during all directions of motion and after application of the follower load. The segments L2/L3, L3/L4 and L4/L5 were chosen in our study for a better comparability, because segment L5/S1 differs from the cranial segments in its motion behavior due to its anatomic characteristics. In addition, biomechanical in vitro tests only reflect the acute postoperative status and cannot predict the biological long-term effects. Therefore, our results can only be compared to the results of Kong et al. (20) to a limited extent.

In the present study Coflex® and Click X® tend to cause a higher, however statistically non-significant, ROM in the cranial than in the caudal adjacent segment during flexion-extension, especially after application of the follower load. Several long-term studies also observed an accelerated degeneration at the cranial segments compared to the caudal segments after lumbar fusion on different levels (4, 31). Some authors propose that this effect is caused by the physiologically increased mobility of cranial segments compared to caudal segments in the lumbar spine (22). Our test protocol itself could provide another explanation for the cephalocaudal difference in the increase of segmental ROM. In our spinal testing device the moment of 7.5 Nm is applied on top of the specimens, which could produce a greater load condition at the upper level than at the lower level, but this effect could not be observed in preceding studies (9, 15, 16).

During lateral bending and rotation the increase of ROM showed no difference between the cranial and caudal segment for both the Coflex® and Click X® device, which is similar to the results of biomechanical and clinical studies of posterior fusion devices (3, 31).

A limitation of the present study is the number of measured specimens. The statistical tendencies between the interspinous and the internal fixation device might become significant by the use of higher numbers of specimens, but this is restricted by the limited availability of human cadaver specimens. For the evaluation of dynamic implants the centre of rotation (COR) is also relevant and will be the purpose of future studies.

In conclusion, the hypothesis, that an interspinous device would reduce the stress on adjacent segments compared to a rigid posterior stabilization device, could not be demonstrated in this biomechanical in vitro study. This may imply that interspinous devices may cause the same adjacent segment degeneration as rigid devices, with the limitation that biomechanical or radiographic evidence of degenerative changes do not necessarily correlate with symptoms. Future studies and the actual prospective multicenter study (1), which compares the clinical outcome after microsurgical decompression with and without Coflex®, will have to evaluate the clinical long-term effects and the clear definition of indications for interspinous devices as an alternative to standard fusion surgery.

CONCLUSIONS

In this biomechanical in vitro study both the dynamic Coflex® device and the rigid Click X® device caused a significant increase of ROM at both adjacent lumbar segments, but without significant difference between them. Therefore the Coflex® could not protect the adjacent segments from biomechanical stress after instrumentation. The study has its limitation in the number of evaluated cadaver specimens and the unpredictability of biological long-term effects. An actual multicenter randomized controlled trial will hopefully be able to define the indications and to evaluate the clinical long-term effects of interspinous devices.

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