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ORIGINAL ARTICLE

Non-fusion instrumentation of the lumbar spine with a hinged pedicle screw rod system: an in vitro experiment

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Abstract In advanced stages of degenerative disease of the lumbar spine instrumented spondylodesis is still the golden standard treatment. However, in recent years dynamic stabilisation devices are being implanted to treat the segmental instability due to iatrogenic decompression or segmental degeneration. The purpose of the present study was to investigate the stabilising effect of a classical pedicle screw/rod combination, with a moveable hinge joint connection between the screw and rod allowing one degree of freedom (cosmicMIA). Six human lumbar spines (L2–5) were loaded in a spine tester with pure moments of ±7.5 Nm in lateral bending, flexion/extension and axial rotation. The range of motion (ROM) and the neutral zone were determined for the following states: (1) intact, (2) monosegmental dynamic instrumentation (L4-5), (3) bisegmental dynamic instrumentation (L3–5), (4) bisegmental decompression (L3–5), (5) bisegmental dynamic instrumentation (L3–5) and (6) bisegmental rigid instrumentation (L3–5). Compared to the intact, with monosegmental instrumentation (2) the ROM of the treated segment was reduced to 47, 40 and 77% in lateral bending, flexion/extension and axial rotation, respectively. Bisegmental dynamic instrumentation (3) further reduced the ROM in L4-5 compared to monosegmental instrumentation to 25% (lateral bending), 28% (flexion/extension) and 57% (axial rotation). Bisegmental surgical decompression (4) caused an increase in ROM in both segments (L3–4 and L4–5) to approximately 125% and approximately 135% and 187–234% in lateral bending, flexion/extension and axial rotation, respectively. Compared to the intact state, bisegmental dynamic instrumentation after surgical decompression reduced the ROM of the two-bridged segments to 29–35% in lateral bending and 33–38% in flexion/extension. In axial rotation, the ROM was in the range of the intact specimen (87–117%). A rigid instrumentation (6) further reduced the ROM of the two-bridged segments to 20–30, 23–27 and 50–68% in lateral bending, flexion/extension and axial rotation, respectively. The results of the present study showed that compared to the intact specimen the investigated hinged dynamic stabilisation device reduced the ROM after bisegmental decompression in lateral bending and flexion/extension. Following bisegmental decompression and the thereby caused large rotational instability the device is capable of restoring the motion in axial rotation back to values in the range of the intact motion segments.

Keywords Dynamic stabilisation · Biomechanics · Lumbar spine · Decompression

Introduction

In advanced stages of degenerative disease of the lumbar spine, instrumented spondylodesis is still the golden standard treatment. However, there are well known limitations concerning arthrodesis of a motion segment. Reduction in the overall spinal motion of the patient and resulting redistribution of loads to adjacent segments may lead to premature degeneration of affected segments [6, 9, 12]. To avoid these disadvantages of a rigid fusion the development of non-fusion implants is rapidly increasing. The

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precondition for a good clinical outcome seems to be an implant capable of providing adequate stability while allowing a limited motion. In this context, screw-fixation in the bone should be guaranteed in order to avoid screw loosening or implant fracture [2, 11, 28].

There are several semi-rigid or dynamic posterior implants currently in clinical application or on clinical trial. They are intended to offer an option between an unstabilised decompression or a rigid fusion procedure after decompression. These implants can be divided in interspinous devices and pedicle-based devices [14]. Biomechanical studies have shown, that interspinous devices have a stabilising effect on decompressed segments in extension, but are hardly capable of stabilising a decompressed segment in axial rotation [7, 13, 23, 26, 29]. Laboratory in vitro studies of various posterior devices also mainly show a stabilising effect in flexion/extension and lateral bending and only a limited stabilising effect in axial rotation [3, 18, 20, 24–26, 32].

The implant investigated in the present study (cosmicMIA, Ulrich Medical, Ulm, Germany) is in clinical use since 2002 and intended to perform as a no rigid but stable non-fusion device. It is comprised of a traditional screw rod combination with a hinge joint between screw and rod allowing one degree of freedom. The design of the hinged screw is intended to permit axial load distribution, allow a restricted motion in flexion/extension and lateral bending while limiting axial rotation in the lumbar spine.

Therefore, the aim of the present study was to investigate the range of motion (ROM) of mono and bisegmental instrumentations with the cosmicMIA dynamic posterior stabilisation system in an intact functional spinal motion segment, the influence of a bisegmental decompression on the ROM of decompressed segments, to determine the effect of the cosmicMIA system after bisegmental compression on the ROM and compare it to a rigid instrumentation using an internal fixator.

Materials and methods

Six fresh frozen lumbar spine specimens (L2–5) were used to investigate the biomechanical stability of various instrumented states in a spine tester. The mean age of the specimens was 68, ranging from 57 to 78 years. A preoperative computed tomography (CT) scan (GE Lightspeed 16, GE, medical Systems, Waukesha, WI, USA) including European Forearm Phantom calibration (QRM GmbH, Möhrendorf, Germany) was performed to determine the bone mineral density (BMD). Mean measured trabecular BMD was 68.8 mg/ccm (±15.1). Spinal specimens with structural disorders, posttraumatic abnormalities or previous spinal surgery were excluded.

Specimens were vacuum-sealed in double plastic bags and kept frozen at −30°C until testing. Specimens were thawed overnight at 6°C and prepared at room temperature right before testing [21]. All muscular tissue was dissected leaving the discs, capsules, ligaments and other supporting structures intact. To fix the specimens in a spine tester, the cranial half of L2 and the caudal half of L5 were embedded in PMMA cement (Technovit 3040, Heraeus Kulzer, Wehrheim, Germany). Screws for fixation of the three-dimensional motion analysis system (Winbiomechanics, Zebris, Isny, Germany, resolution 0.1°) were mounted to the anterior side of each vertebra.

Loading of the specimens was carried out at room temperature. To avoid dehydration, specimens were kept wet with saline solution throughout the experiment [21, 31]. Biomechanical testing was conducted in a six degree of freedom spine simulator (Fig. 1) according to the recommendation for testing of spinal implants [19, 33]. The setup of the spine tester was described in previous publications [5, 16]. Flexibility tests were performed in the three main motion planes (lateral bending, flexion/extension and axial rotation) with pure bending moments of ±7.5 Nm. In order to minimise the viscoelastic effect only

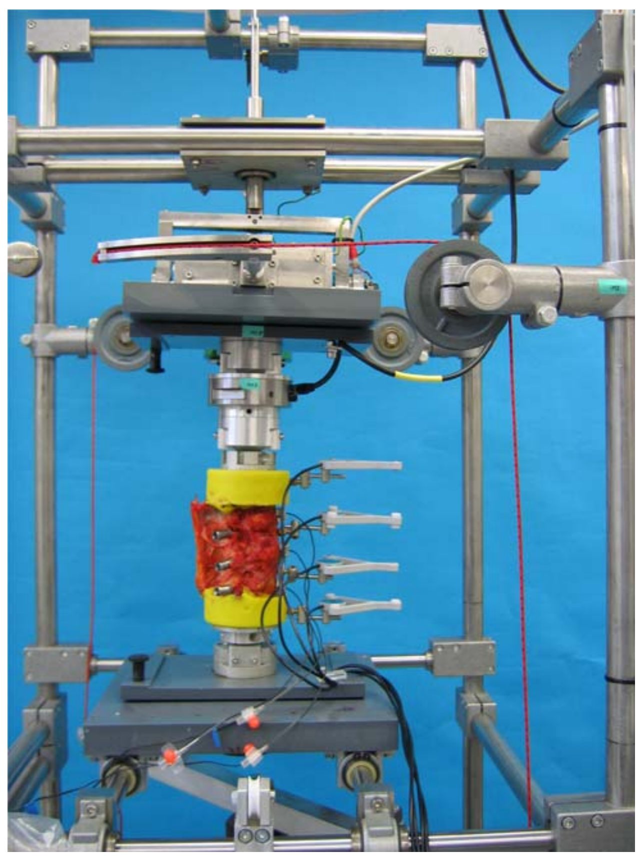

Fig. 1 Test setup of six degree of freedom spine tester showing an intact specimen and the three dimensional motion analysis system fixed to the specimen

the third load cycle was evaluated and used for further analysis. The ROM and neutral zone (NZ) of all motion segments were determined from the hysteresis curves [33].

Prior to fixing the specimens in the spine tester cosmicMIA pedicle screws 6.5 × 45 mm (Ulrich Medical, Ulm, Germany) were implanted in L5, L4 and L3. Lateral and anterior–posterior radiographs (BV25, Philipps, Eindoven, The Netherlands) were taken to ensure correct screw positioning. The dynamic cosmicMIA system is comprised of a classic pedicle screw/rod combination with a hinge joint between the screw and rod allowing one degree of freedom (Fig. 2). The used rod had a diameter of 6 mm and is manufactured of titanium alloy.

As a baseline, first the intact spine was loaded in the spine tester. Subsequently the following states of the specimens were tested:

- dyn_L4-5: monosegmental dynamic stabilisation of L4-5 using the cosmicMIA
- dyn_L3-5: bisegmental dynamic instrumentation of L3-5 using the cosmicMIA
- decomp: decompression of the segments L3-5 by laminectomy L3 + L4 and medial facetectomy L3-4 and L4-5
- ddyn_L3-5: bisegmental dynamic instrumentation of L3-5 after decompression using the cosmicMIA
- dfix_L3-5: bisegmental rigid instrumentation of L3-5 after decompression using an internal fixator (tango, Ulrich Medical, Ulm, Germany) with 7.5 × 45 mm Revision screws and a 6-mm titan-alloy rod.

Fig. 2 CosmicMIA dynamic posterior stabilisation system, showing the hinge joint in the screw/rod connection. The possible motion of the one degree of freedom joint is shown by the *shaded* screws

Statistical analysis was performed using the SPSS software package (release 15.0, SPSS Inc., Chicago, IL, USA). All reported results represent the mean and standard deviation of the measurements. To analyse for differences between the tested states repeated measures analysis of variance (ANOVA) and Bonferroni post hoc analysis was carried out. The level of significance was set to $P < 0.05$.

Results

The ROM and NZ for both manipulated segments (L4–5 and L3–4) in all tested states of the specimens are presented as angular displacements in Table 1. Graphical representation of the ROM and NZ normalised to the intact state of the specimens is shown in Figs. 3, 4. The normalised data are shown in flexion/extension and axial rotation, because normalisation led to similar results and trends in lateral bending and flexion/extension. All data are reported as mean and standard deviation. Due to the loading protocol with pure moments the ROM and NZ of the adjacent untreated segment (L2–3) only showed small non-significant differences between the tested states.

Monosegmental dynamic instrumentation (dyn_L4–5)

In flexion/extension and lateral bending the instrumentation significantly decreased the ROM of the instrumented segment L4-5 to 40 and 47% of the intact specimens ($P < 0.05$), respectively. In axial rotation, the ROM was reduced to 77% of the intact specimens. The ROM of the cranial untreated segments showed no significant differences compared to the intact state in all three motion planes.

Bisegmental dynamic instrumentation (dyn_L3–5)

In the caudal segment, L4-5 bisegmental instrumentation further reduced the ROM in all motion planes compared to the monosegmental instrumentation (dyn_L4–5) to 25, 28 and 57% in lateral bending, flexion/extension and axial rotation, respectively. The cranial segment within the bisegmental instrumentation (L3–4) showed a significant decrease of ROM in lateral bending and flexion/extension to 22 and 23% of the intact ROM ($P < 0.05$). In axial rotation, the ROM was reduced to 66% of the intact specimens.

Decompression (decomp)

In axial rotation decompression significantly increased the ROM in both (L4–5 and L3–4) treated segments to 187 and 234% of the intact specimen ($P < 0.05$). In lateral bending

Table 1 Results of the range of motion (ROM) and neutral zone (NZ) for the two treated segments L4-5 and L3-4

	Intact	Dynamic stabilisation L4-5 (dyn_L4–5)	Dynamic stabilisation L3-5 (dyn_L3–5)	Decompression, laminectomy L4, hemifacetectomy L3–4 and L4–5 (decomp)	Dynamic stabilisation of decompression spanning L3-5 (ddyn_L3–5)	Rigid stabilisation of decompression spanning L3-5 (dfix_L3–5)
Segment L4-5						
Lateral bending						
ROM	8.56 (±2.17)	4.01 (±2.21)	2.16 (±1.86)	10.83 (±2.37)	2.52 (±2.05)	1.72 (±1.39)
NZ	1.80 (±0.70)	1.14 (±0.44)	0.55 (±0.50)	4.13 (±2.19)	0.97 (±1.22)	0.76 (±0.73)
Axial rotation						
ROM	4.63 (±1.84)	3.66 (±2.01)	2.78 (±1.93)	7.68 (±2.45)	3.92 (±2.15)	2.14 (±1.35)
NZ	0.69 (±0.59)	0.60 (±0.37)	0.76 (±0.75)	1.29 (±0.76)	0.85 (±0.52)	0.34 (±0.22)
Flexion						
ROM	5.81 (±1.39)	1.87 (±1.08)	1.49 (±1.25)	5.93 (±1.81)	2.17 (±1.29)	1.39 (±1.07)
NZ	2.01 (±1.66)	0.83 (±0.51)	0.54 (±0.65)	3.63 (±2.58)	0.99 (±0.76)	0.56 (±0.59)
Extension						
ROM	−4.36 (±1.14)	−2.01 (±1.05)	−1.29 (±1.08)	−7.32 (±3.41)	−1.53 (±1.03)	−1.14 (±0.96)
NZ	−1.56 (±0.71)	−0.50 (±0.90)	−0.37 (±0.79)	−4.67 (±3.58)	−0.48 (±0.60)	−0.52 (±0.66)
Segment L3-4						
Lateral bending						
ROM	7.87 (±3.02)	7.93 (±3.39)	1.65 (±0.77)	9.81 (±3.53)	2.97 (±1.73)	2.12 (±1.56)
NZ	1.77 (±1.21)	1.44 (±0.37)	0.40 (±0.29)	3.67 (±2.83)	1.45 (±1.31)	0.88 (±0.77)
Axial rotation						
ROM	3.48 (±1.23)	3.71 (±1.69)	2.27 (±0.64)	7.74 (±2.79)	3.78 (±1.13)	2.20 (±0.59)
NZ	0.51 (±0.22)	0.57 (±0.28)	0.49 (±0.21)	0.99 (±0.54)	0.71 (±0.36)	0.31 (±0.21)
Flexion						
ROM	4.98 (±1.57)	4.61 (±1.91)	0.65 (±0.35)	5.39 (±2.34)	1.08 (±0.56)	0.84 (±0.60)
NZ	1.99 (±2.11)	1.20 (±1.88)	0.35 (±0.19)	3.09 (±3.20)	0.63 (±0.40)	0.31 (±0.22)
Extension						
ROM	−3.05 (±0.74)	−2.90 (±1.16)	−0.98 (±0.49)	−5.06 (±2.68)	−1.31 (±0.53)	−0.86 (±0.49)
NZ	−1.09 (±0.49)	−1.41 (±0.93)	−0.27 (±0.23)	−3.00 (±2.74)	−0.29 (±0.21)	−0.24 (±0.19)

decompression caused in both segments an increase in ROM to 125%, and in flexion/extension in both segments to approximately 135% of the intact state.

Bisegmental dynamic instrumentation after decompression (ddyn_L3–5)

After instrumentation, the ROM in the caudal segment (L4–5) significantly decreased to 29 and 38% of the intact specimens in lateral bending and flexion/extension, respectively ($P < 0.05$). In axial rotation the increase in ROM caused by decompression could be significantly reduced to 87% of the intact specimen ($P < 0.05$). The cranial stabilised segment (L3–4) also showed a significant decrease to 35 and 33% of the intact state in lateral bending and flexion/extension ($P < 0.05$). In axial rotation with the instrumentation the ROM of the decompressed state could be significantly reduced to 117% of the intact state ($P < 0.05$).

Bisegmental rigid instrumentation after decompression (dfix_L3–5)

In all motion planes, the rigid instrumentation further reduced the ROM compared to the dynamic instrumentation. Normalised to the intact specimen the ROM for the caudal segment (L4–5) was reduced to 20, 27 and 50%, for the cranial instrumented segment (L3–4) to 30, 23 and 68% in lateral bending, flexion/extension and axial rotation, respectively.

Discussion

Numerous non-fusion posterior dynamic stabilisation systems were introduced to the market in recent years. However, up to date there are no blinded randomised clinical studies showing an improved outcome of dynamic stabilisations compared to fusion surgeries. From a biomechanical point of

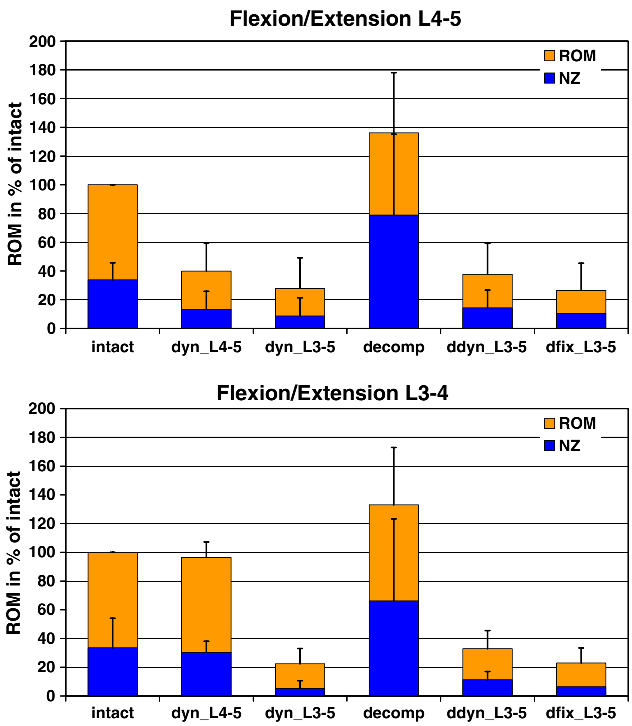

Fig. 3 Range of motion and neutral zone in flexion/extension for the segments L4–5 and L3–4 normalised to the intact state

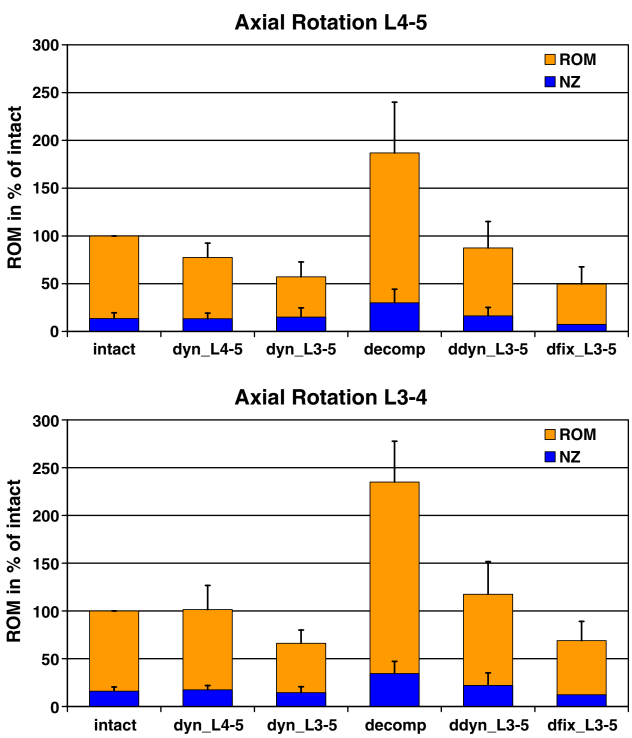

Fig. 4 Range of motion and neutral zone in axial rotation for the segment L4–5 normalised to the intact state

view, this could be due to the rotational stability of non-fusion or dynamic implants. Results of in the literature reported in vitro experiments indicate the least motion restricting effect of the implants in axial rotation, no matter if an intact or a destabilised segment was instrumented [3, 20, 25, 26, 30]. The presently investigated cosmic system is in clinical use since 2002. Scifert et al. carried out a biomechanical study of a similar hinged pedicle screw/rod design using bovine lumbar spinal specimens and reported of an enhanced load sharing [27]. Therefore, the aim of the present study was to determine the effect of the second generation cosmicMIA system on the segmental motion of an intact specimen, as well as if the increase in ROM caused by a bisegmental decompression can be reduced using the cosmicMIA system. Overall we found that the investigated device had a motion restricting effect on intact spinal motion systems in all motion planes. The reduction in ROM is most pronounced in flexion/extension, followed by lateral bending and axial rotation. Compared to the intact ROM the bisegmental surgical decompression (comprised of laminectomy L3 + L4 and medial facetectomy L3-4 and L4-5) caused an increase in ROM in lateral bending and flexion/extension while causing a significant increase in axial rotation. In flexion/extension and lateral bending the cosmicMIA system significantly reduced the ROM compared to the intact specimen and the decompressed state. In axial rotation the tested system significantly reduced the ROM after decompression to values in the range of the intact specimen. Subsequent instrumentation with a rigid posterior fixation system further reduced the ROM in all motion planes compared to the cosmicMIA instrumentation.

The intact ROM of the tested motion segments in the present study in all motion planes was comparable to the range of values reported in the literature for testing of specimens with pure bending moments [4, 15, 18, 22, 24, 25].

Comparing the effect of the dynamic posterior stabilisation systems on the ROM in an intact segment (dyn_L4–5) with other devices reported in the literature showed a slightly higher reduction in ROM for the cosmicMIA system compared to the DSS (Paradignum Spine, Wurmlingen, Germany) investigated by Wilke et al. [30]. In flexion, extension, lateral bending and axial rotation they showed a decrease in ROM by 54, 39, 45 and 7% compared to 68, 54, 53 and 23% in the present study, respectively. However, it should be kept in mind that the values reported for both devices were measured in an instrumented intact segment without decompression.

By extending the monosegmental dynamic instrumentation in cranial direction to a bisegmental instrumentation (dyn_L3–5) not only the overall ROM of the spine was reduced, it also had an additional motion restricting effect on the caudal instrumented segment compared to the monosegmental instrumentation. This is in contrast to the in vitro results reported by Cheng et al. [3] for the Dynesys and can possibly be explained by the design of the

cosmicMIA system with a hinge joint in the screw head allowing only one degree of freedom. Compared to monosegmental instrumentation, bisegmental instrumentation of the cosmicMIA system has three instead of two hinge joints on each rod. Therefore, the motion restricting effect in each of the two segments is larger than only for one isolated stabilised segment. Additionally, alignment of the rotational axes of the two hinge joints of one segment has an influence on the resulting ROM. Theoretically, perfect alignment permits limited motion in flexion/extension while restricting motion in the other two planes. However, due to technical and anatomical reasons perfect alignment of the hinge joint axes will hardly be possible.

The decompression procedure of the present study (decomp) certainly represents a maximised decompression scenario (comprising a laminectomy L3 + L4 and medial facetectomy L3–4 and L4–5) and resulted in an iatrogenic induced severe instability, in particular in axial rotation (187–234% of intact). This effect is in line with results by Fuchs et al. [7], who reported an increase in ROM in axial rotation to 227% in a decompressed segment after bilateral total facetectomy. In flexion/extension and lateral bending their decompression resulted in a slightly smaller increase in ROM (121 and 107%) compared to our study (135 and 125%). The difference of the two studies could be due to a larger extent of the decompression in the present study as it also encompassed laminectomy of L3 + L4, and the loading mode applied by Fuchs et al. [7] included an additional compressive load of 700N superimposed to the pure moments. The instability of the present study after decompression is also similar to those reported by Quint et al. [24] conducting an in vitro study and by Zander et al. [34] in a finite element study. Adams and Hutton [1] concluded of an in vitro study that axial rotation of the lumbar spine is resisted primarily by the facet joints. This finding emphasises the clinical need of stabilisation after bilateral decompression with facetectomy.

The results of the ROM after bisegmental decompression and subsequent instrumentation with the cosmicMIA system are not directly comparable to other studies published in the literature due to different defect models and different testing conditions (e.g. additional axial preload). However, related to other studies [20, 25] the present results indicate that the cosmicMIA system is likely to decrease the ROM in axial rotation to a greater extent than other non-fusion devices. Normalised to the intact state the results in axial rotation for the Dynesys published by Schmoelz et al. [25] showed a comparable increase in ROM for the defect model (approximately 220%) and no reduction of the ROM to the range of the intact specimen after instrumentation with the Dynesys. Whereas in flexion/extension and lateral bending the effect of their defect model and subsequent instrumentation was in the range measured in the present study. However, the defect model of the Dynesys study included dissection of the ligament supraspinous, ligament interspinous, ligament flavum, tenotomy of facet joint and nucleotomy, while in the present study the decompression was comprised of a laminectomy L4 and hemifacetectomy of L3-4 and L4-5. In an in vitro study of the Stabilimax posterior dynamic stabilisation device, Panjabi et al., [20] reported an increase of 120–130% of the intact ROM after decompression (dissection of ligament supraspinous, ligament interspinous, ligament flavum and 50% medial facetectomy L4-5) and a reduction of ROM after dynamic instrumentation to approximately 60% of the intact state in flexion/extension and lateral bending, while in axial rotation the device was not effective in reducing the ROM of the treated motion segment [20].

Instrumentation of the destabilised segment with a rigid instrumentation showed a further decrease in ROM in all motion planes compared to the dynamic instrumentation. For rigid instrumentation, the cosmic screws were removed and replaced by larger revision screws. Therefore, one might speculate that the motion restricting effect of the rigid instrumentation is underestimated. However, the ROM for the rigid instrumentation in the present study is comparable with the ROM reported for rigid instrumentation in the literature [20, 25]. Meyers et al. evaluated the load sharing in posterior dynamic stabilisation devices using instrumented pedicle screws [17]. They reported a marked interaction between the amount of constraint provided by the device and subsequent load sharing with the spine. An increasing constraint of the device (causing a reduction in ROM) resulted in higher pedicle screw loads and therefore a higher risk of loosening at the bone–screw interface [17].

All specimens in the present study were tested with pure moment loading without any axial preload. This follows internationally accepted guidelines and recommendations for testing of spinal implants [10, 19, 33], even though this might not ideally represent the in vivo loading it is a standardised testing method and allows the comparison of results carried out in different institutions.

Fujiwara et al. [8] found that changes in the ROM due to segmental degeneration differs in the three main motion planes. They found axial rotation to be mostly affected by degeneration and reported an increase in motion due to degeneration. Therefore, Schulte et al. [26] hypothesised that semi-rigid or dynamic implants should primarily aim to reduce ROM in axial rotation. The present study of the cosmicMIA system showed that the design intention of primarily limiting motion in axial rotation could not be demonstrated biomechanically, as the reduction of ROM was significant in lateral bending and flexion/extension and least pronounced in axial rotation. Nevertheless, after

bisegmental decompression it restored the ROM in axial rotation to the range of the intact segment. Therefore, questions on the clinical effectiveness and possible benefit of the tested device have to be addressed in a clinical trial.

Conclusion

Monosegmental instrumentation of an intact segment with the cosmicMIA system resulted in a reduced ROM in all three motion planes. Extending the instrumentation to encompass two segments led to a further decrease in motion in both bridged segments. The bisegmental decompression applied in the present study caused an increase in ROM in all motion planes, most pronounced in axial rotation. Instrumentation of the defect with a hinged dynamic instrumentation resulted in a reduction of ROM in flexion/extension and lateral bending compared to the intact specimen and in axial rotation to a restoration of the ROM in the range of the intact segment. Subsequent instrumentation with a rigid internal fixator caused a further decrease in ROM in all motion planes.

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