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ORIGINAL ARTICLE

The effect of design parameters of interspinous implants on kinematics and load bearing: an in vitro study

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Abstract
Introduction A number of concepts with controversy approaches are currently discussed for interspinous stabilization (IPS). However, comparative biomechanical studies among the different systems are rare. Nevertheless, it remains unclear which biomechanical characteristics are influenced by different design features of these implants, such as implant stiffness or an additional tension band. Therefore, the aim of the present study was to compare different interspinous implants to investigate the biomechanical impact of IPS implant design on intersegmental kinematics, such as range of motion, neutral zone, center of rotation (COR), as well as load transfer like intradiscal pressure (IDP), to gain additional experience for clinical indications and limitations.
Material and method Twelve human lumbar spine specimens were tested in a spine loading apparatus. In vitro flexibility testing was performed by applying pure bending moments of 7.5 Nm without and with additional preload of 400 N in the three principal motion planes. Four interspinous implants, Coflex "COF" (Paradigm Spine, Germany), Wallis "WAL" (Abbott Laboratories, France), DIAM "DIA" (Sofamor Danek, France) and InterActiv (Aesculap AG, Germany) with two treatment options (without dorsal tensioning "IAO" and with dorsal tensioning "IAM") were consecutively tested in comparison to the native situation "NAT" and to a defect situation "DEF" of the functional spinal unit. The tested IPS devices are comprised of a compression stiffness range of 133 to 1,674 N/mm and a tensile stiffness range of 0–39 N/mm. Range of motion, neutral zone, center of rotation and intradiscal pressure were analyzed for all instrumentation steps and load cases.
Conclusion For the IPS, we found a correlation between compression stiffness and stabilization in extension. Here, the system with the lowest stiffness, DIA, displayed nearly no stabilization of the treated segment, whereas the system with the highest stiffness, WAL and COF, was most pronounced. This applies also for the correlation between device stiffness and IDP. In flexion only the degree of stabilization is in correlation with the tensile stiffness, whereas the IDP stays constant and is not affected by the different tensile stiffness. IPS is not able to stabilize in the frontal and transversal plane. Furthermore IPS does not substantially alter the location of the COR.

Keywords Interspinous implants · Kinematics · Intradiscal pressure · Biomechanics · Spine

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Introduction

Interspinous stabilization (IPS) has become more popular for spinal surgical intervention with a diverse range of devices. The idea of these devices is to relieve several different pathological conditions, such as spinal stenosis

Grade 1 degenerative spondylolisthesis, discogenic pain, disc herniation and nontraumatic instability by fulfilling a range of biomechanical functions, such as distraction or modification of motion of the treated segment, control of sagittal plane bending without totally preventing such motion or unloading the disc [1, 2].

Early studies of IPS are generally promising for a variety of indications [1, 3, 4]. However, more recent studies have shown that the clinical evidence for these devices is low, suggesting that a clear indication for the use of these kinds of implants is still missing [4–8]. Furthermore, the reported complication rates of up to 38 % lead to the conclusion that use of these devices has to be reconsidered in terms of the quite high reoperation rate of up to 85 % [6, 7, 9] or conversion surgery in comparison to solely performed microsurgical decompression [10].

Nevertheless, there may be good reason for the use of dynamic stabilization, particularly IPS, because of the minimally invasive approach, in conjunction with biological treatment (e.g. cell therapy) [11]. The idea is that dynamic stabilization may provide a mechanically altered environment which is a more suitable for the cells, facilitating regeneration of the intervertebral disc or at least a slowing down of degeneration [1, 11–13].

In the few studies that investigate the biomechanical behavior of interspinous devices, restriction of intersegmental movement and reduction of intradiscal pressure were observed, only in the sagittal plane [14–19].

However, it remains unclear which biomechanical characteristics are influenced by different design features of these implants, such as implant stiffness or an additional tension band. Therefore, the aim of the present study was to compare different interspinous implants to investigate the biomechanical impact of IPS implant design on intersegmental kinematics, such as range of motion (ROM), neutral zone (NZ), center of rotation (COR), as well as load transfer like intradiscal pressure (IDP), to gain additional experience for clinical indications and limitations.

Material and method

Specimens

Twelve fresh-frozen human lumbar functional spinal units, L2/L3 ($n = 6$) and L4/L5 ($n = 6$), from a total of six spines with a mean age of 65.3 (range 54–74), kept at −21 °C in triple sealed bags, were thawed overnight at 6 °C before the test. CT scans did not reveal any fractures, osteophytes, or signs of severe disc degeneration. Soft tissue was removed, leaving the ligaments, capsules and supporting structures intact. To fix the specimens firmly in place on the simulator, the cranial and caudal vertebrae of the functional spinal unit were embedded with a casting resin (Ureol FC 53, Vantico GmbH, Wehr, Germany) in the test fixtures so that segmental motion was not restricted in any way and the intervertebral disc was oriented in the horizontal plane.

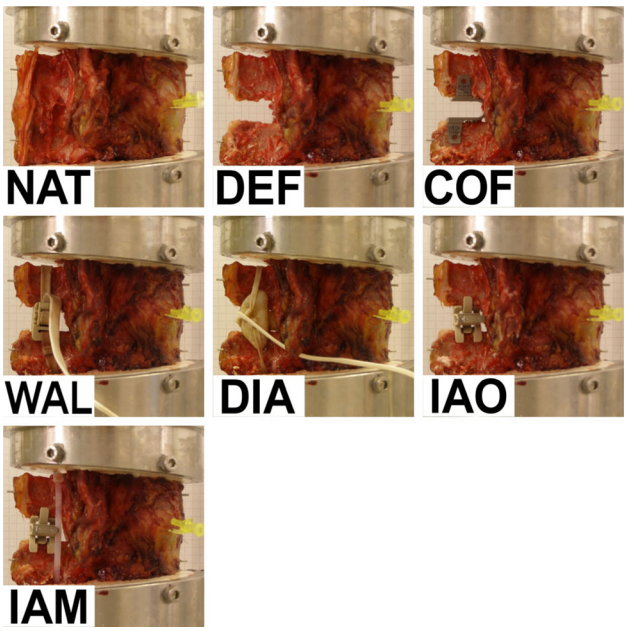

Fig. 1 Segment conditions of the tested specimens: native (NAT), defect (DEF), Coflex (COF), DIAM (DIA), Wallis (WAL), inter Activ without dorsal tensioning (IAO), inter Activ with dorsal tensioning (IAM)

Instrumentation

Four interspinous implants, Coflex "COF" (Paradigm Spine, Germany), Wallis "WAL" (Abbott Laboratories, France), DIAM "DIA" (Sofamor Danek, France) and InterActiv (Aesculap AG, Germany) with two treatment options (without dorsal tensioning "IAO" and with dorsal tensioning "IAM") were consecutively tested in comparison to the native situation "NAT" and to a defect situation "DEF" of the functional spinal unit. The segment condition DEF represents a standardized undercutting decompression as described by Schulte et al. [17] with the addition of the transection and complete removal of the interspinous and supraspinous ligaments (Fig. 1). For each specimen, the interspinous space was measured and the most fitting implant size was chosen. The following instrumentation steps, designated as segment conditions, were performed (Table 1). The native and defect situations were always measured as the first two segment conditions to provide a specimen specific baseline. The instrumentation steps with the interspinous implants (3)–(7) were randomized for each specimen. To allow the effect of the specimen weakening during testing to be captured by

Table 1 Testing order, segment condition and identifier of the tested systems

Testing order	Segment condition	Identifier
(1) First	Native	NAT
(2) Second	Defect	DEF
(3) Random	Coflex	COF
(4) Random	Wallis	WAL
(5) Random	DIAM	DIA
(6) Random	InterActiv without dorsal tensioning	IAO
(7) Random	InterActiv with dorsal tensioning	IAM
(8) Last	Random (3)	

comparing the change of the analyzed parameters, the first implantation step (3) was repeated as the last step (8).

The included interspinous implants comprise a range of design features with respect to implant stiffness and treatment options such as mounting the implant to the anatomical bony structures or giving additional support by a dorsal tension band. The COF is made out of titanium and is U-shaped with rails for the spinous processes and clips on the upper and lower margins that allows for fixation to the bone, which were used for testing. The WAL consists of an H-shaped PEEK (poly ether ether ketone) block inserted between the spinous processes and secured to the processes by means of Dacron cords. The DIA consists of a central X-shaped silicon core coated with polyesther mesh that is positioned between the spinous processes and anchored to the processes by means of two polyesther cords. The IAM/IAO is made of two expandable PEEK wings, which can be distracted in situ to fit various inter spinous heights in an X-shaped manner. The locking of the device is realized by two central locking pins (IAO). For the purpose of this study, an additional tension band was implemented to investigate a possible biomechanical impact (IAM).

The axial stiffness of the devices was measured in a pure axial compression and an axial tensile pre-test. Compression and tensile stiffness were determined in the first linear range between 100 and 200 N, which was assumed to be a clinically relevant loading. The compression stiffness of the implants was as follows: COF: 1,674 ± 33 N/mm; WAL: 1,602 ± 9 N/mm; DIA: 133 ± 63 N/mm; IAM/IAO: 1,141 ± 43 N/mm. The tensile stiffness was WAL: 39 ± 5 N/mm; DIA: 11 ± 4 N/mm; IAM: 32 ± 3 N/mm; IAO: 0 N/mm. The tensile stiffness of the COF was not determined, because of the undefined clamping situation of the clips at the bone-implant interface.

The in vitro test method complies with the testing criteria for spinal implants [20]. The specimens were loaded at room temperature into a servohydraulic spinal simulator based on the principles of Crawford et al. [21], applying pure moments (±7.5 Nm) with a velocity of 3°/s for flexion/extension, lateral bending and axial rotation. This loading was also carried out in a second step with a superimposed axial preload ($F_P = 400$ N). An integrated 6-component load cell (FTD-Delta SI-660-60, Schunk, Germany), located underneath the tested specimen, was used to control the load application of the simulator and to record the moment and force data. The controller of the simulator allows to switch automatically from moment control to angular displacement control, which enables a loading cycle with a defined velocity in the neutral zone and a defined moment at the end points. The kinematics (i.e. the six components of motion according to Panjabi [22]) were measured with a 3D ultrasonic motion analysis system (Zebris, Isny, Germany). Characteristic parameters, range of motion (ROM) and neutral zone (NZ) were analyzed from the hysteresis curves of the third loading cycle.

The instantaneous center of rotation (COR) was calculated using the velocity pole method based on the Eulerian velocity equation from the 3D-data taken from the third loading cycle. The developed COR algorithm allows the evaluation of the instantaneous centers of rotation during a complete cycle of motion in the three tested principal motion planes. To localize the calculated COR-pathway in relation to the tested functional spinal unit, two reference points were set on the anterior border of the intervertebral disc. Furthermore, the mean COR from the COR-pathway of each single instantaneous COR was calculated representing the centroid of the curves. This reduction to a mean COR allows a simplified comparison of the consecutive tested segment conditions influencing the COR in the respective motion planes. The accuracy of the developed COR algorithm for the determination of an instantaneous COR was ±1 mm^2 in the planar view. This applies to both the data acquisition and the test set-up used. In addition, so as to take into account the different dimensions of the individual specimens, the *X*–*Y* dimensions of each tested intervertebral disc were measured and used to normalize the COR results.

Intradiscal pressure (IDP) within the intervertebral disc was measured at the same time as the kinematics, using a miniature fiber optic pressure transducer (Ø 0.4 mm, pressure range −0.1 to 17 kPa) based on the Fabry–Perot principle (Samba Sensors, Sweden). The transducer tip was inserted ventro-laterally in the nucleus pulposus with an intravascular indwelling cannula, Introcan® W, Ø 0.7 mm (B. Braun, Germany). IDP values were analyzed at three characteristic loading points indentified from the moment vs. IDP plots (maximum, zero and minimum moment).

Additionally, the sagittal tilt after implantation of each segment condition was measured. To quantify the sagittal tilt, markers were applied to the bony structures, posteriorly into the spinous process and anteriorly into the vertebral body. Sagittal photographs were taken in a neutral, unloaded

Table 2 Range of motion (ROM) in (°)—mean ± standard deviation—for all segment conditions, loading directions and load cases

Condition	Flexion	Extension	Flexion/Extension	Lateral bending	Axial rotation
Pure moment—ROM					
NAT	6.78 (±1.91)	−3.07 (±0.56)	9.85 (±2.22)	10.63 (±1.86)	5.61 (±2.73)
DEF	7.95 (±2.19)	−3.56 (±0.70)	11.51 (±2.59)	11.37 (±1.89)	6.00 (±2.75)
COF	5.91 (±1.92)	−2.41 (±0.71)	8.32 (±2.46)	11.76 (±2.17)	6.25 (±3.06)
WAL	4.73 (±1.57)	−2.00 (±0.46)	6.73 (±1.66)	11.64 (±2.08)	6.11 (±3.02)
DIA	5.82 (±1.42)	−3.35 (±0.62)	9.18 (±1.93)	11.75 (±1.94)	6.26 (±3.09)
IAO	6.79 (±1.58)	−2.27 (±0.60)	9.06 (±2.01)	11.88 (±2.02)	6.37 (±3.07)
IAM	3.22 (±1.26)	−2.06 (±0.62)	5.28 (±1.79)	11.42 (±2.03)	5.98 (±3.06)
Pure moment and preload—ROM					
NAT	6.26 (±1.42)	−2.80 (±0.69)	9.06 (±1.83)	8.06 (±2.73)	3.60 (±2.43)
DEF	7.21 (±1.71)	−3.32 (±0.81)	10.53 (±2.19)	8.30 (±2.77)	3.82 (±2.64)
COF	4.75 (±1.48)	−1.60 (±0.42)	6.35 (±1.62)	9.11 (±2.83)	4.55 (±2.72)
WAL	3.59 (±0.81)	−1.48 (±0.53)	5.07 (±1.23)	8.91 (±2.97)	4.43 (±2.74)
DIA	4.81 (±1.09)	−2.68 (±0.59)	7.49 (±1.46)	8.91 (±2.79)	4.43 (±2.77)
IAO	5.48 (±1.15)	−1.78 (±0.54)	7.26 (±1.42)	9.13 (±2.80)	4.57 (±2.81)
IAM	2.41 (±0.78)	−1.46 (±0.47)	3.88 (±1.17)	8.95 (±2.84)	4.51 (±2.76)

Abbreviations are explained in Table 1

situation. From the photographs, the sagittal angle of each segment condition was quantified and depicted as relative alteration in respect to the native situation.

Statistics

The effect of segment condition on ROM, NZ, IDP, sagittal tilt as absolute values and COR as normalized to disc dimensions, was assessed using repeated-measures analysis of variance (ANOVA) with a significance level of $p = 0.05$. Prior to analysis, the normal distribution of the data was verified with p–p plots. A least significance difference test for post hoc analysis was used to determine the differences between specific segment conditions. Additionally, the correlation between axial compression/tensile device stiffness and ROM, IDP and COR was determined by the Spearman's rank correlation coefficient (r_s) with a significance level of $p = 0.05$. All statistical analyses were performed with Statistica 10.0 (StatSoft, Inc.).

Results

Range of motion and neutral zone

The ROM and NZ for all segment conditions, all principal motion planes, and both load cases are summarized in Tables 2 and 3, shown as absolute values (degrees). The changes of segment condition for the treated segment in the pure moment mode relative to the native situation are presented in Fig. 2: ROM, and Fig. 3: NZ. Although the DEF increased the ROM in all motion planes, the differences were not significant. In extension, all devices, with the exception of DIA ($p = 0.2596$), showed a significant reduction of ROM compared to the native situation NAT ($p < 0.01$). In flexion, the two systems with the highest axial stiffness and additional dorsal tension band, WAL ($p = 0.0045$) and IAM ($p = 0.0001$), also showed a significant reduction of ROM. The NZ was significantly reduced in flexion–extension by the WAL ($p = 0.0134$)

Table 3 Neutral zone (NZ) in (°)—mean ± standard deviation—for all segment conditions, segment levels, loading directions and load cases

Condition	Flexion/extension	Lateral bending	Axial rotation
Pure moment—NZ			
NAT	3.29 (±0.50)	4.01 (±0.45)	2.54 (±0.97)
DEF	3.55 (±0.60)	4.15 (±0.57)	2.53 (±0.83)
COF	3.09 (±0.87)	4.86 (±1.41)	2.81 (±1.07)
WAL	2.61 (±0.50)	4.38 (±0.60)	2.68 (±1.14)
DIA	4.10 (±0.70)	4.47 (±0.57)	2.90 (±1.27)
IAO	2.79 (±0.59)	4.33 (±0.43)	2.72 (±1.13)
IAM	2.55 (±0.77)	4.29 (±0.60)	2.69 (±1.26)
Pure moment and preload—NZ			
NAT	2.63 (±0.42)	2.58 (±0.67)	1.62 (±0.69)
DEF	2.80 (±0.48)	2.45 (±0.47)	1.56 (±0.62)
COF	2.01 (±0.32)	2.80 (±0.54)	2.07 (±0.76)
WAL	1.97 (±0.43)	2.70 (±0.52)	2.01 (±0.85)
DIA	3.04 (±0.48)	2.71 (±0.48)	1.87 (±0.80)
IAO	2.14 (±0.36)	2.77 (±0.53)	2.00 (±0.79)
IAM	1.81 (±0.43)	2.75 (±0.54)	1.96 (±0.80)

Abbreviations are explained in Table 1

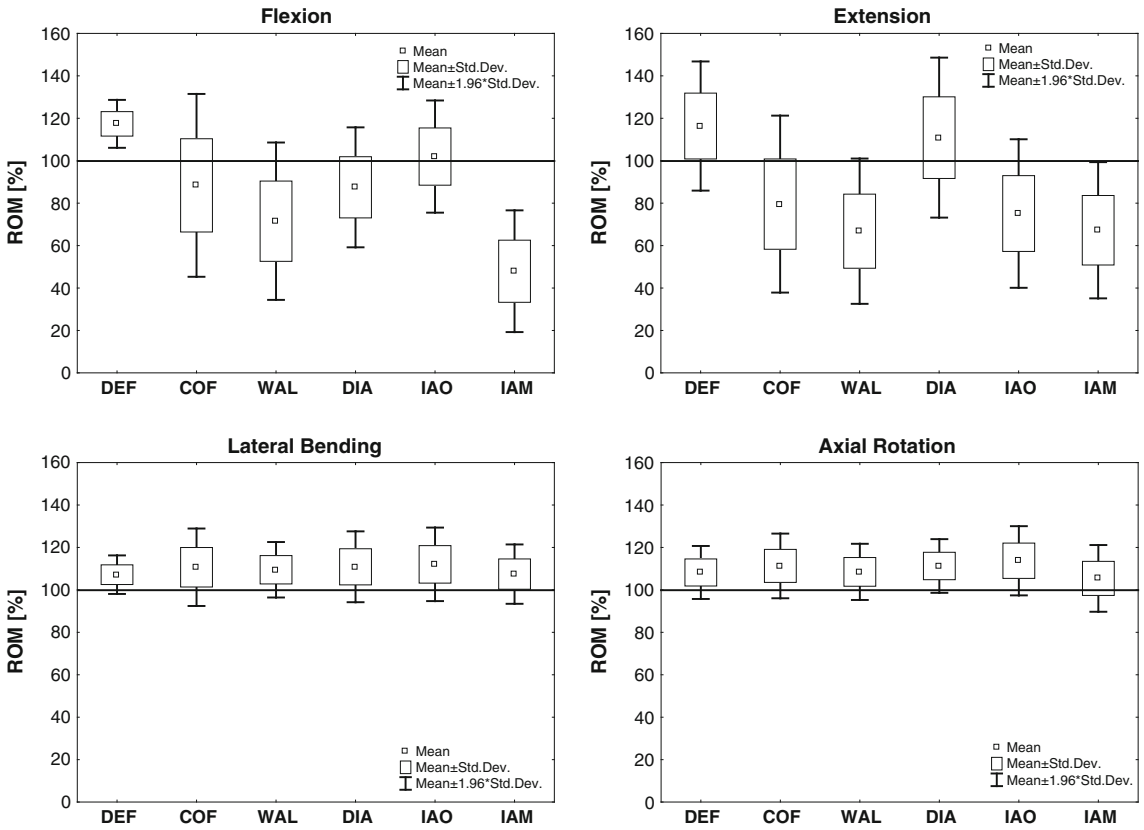

Fig. 2 Range of motion (ROM) of the tested specimens. The different segment conditions are normalized to the native situation representing 100 %. Load case: pure moment. Abbreviations are explained in Table 1

and IAM ($p = 0.0078$) but significantly increased by the DIA ($p = 0.0035$), compared to NAT, whereas the DEF, COF and IAO showed no significant difference. In extension a correlation could be determined between compression stiffness of the devices and stabilization with $r_s = -0.5445$ ($p < 0.0001$) and in flexion between tensile stiffness of the devices and stabilization with $r_s = -0.5805$ ($p < 0.0001$). In the frontal and transversal motion planes, neither a significant change in ROM and NZ for all segment conditions nor a correlation between device stiffness and stabilization was observed. In the load case with additional preload, the ROM results for extension remain the same as without preload, comparing the systems to NAT. In flexion, however, the ROM for all tested systems was significantly reduced (COF, WAL, DIA, IAM; $p < 0.005$) except that of IAO ($p = 0.1322$). Whereas the NZ of DIA stays significantly increased ($p = 0.02$), all other systems showed a significant reduction ($p < 0.005$) compared to NAT.

Intradiscal pressure

Intradiscal pressure (IDP) results for flexion/extension, lateral bending and axial rotation (Fig. 4) are shown as absolute values for all segment conditions in the pure moment loading mode. In extension, all devices (COF, WAL, DIA, IAO, IAM) reduced the IDP significantly ($p < 0.005$) compared to NAT and DEF with a significant correlation between compression stiffness of the device and IDP ($r_s = -0.3615$, $p = 0.0045$). In all other loading directions, such as flexion, left and right lateral bending and left and right axial rotation neither change in IDP for all segment conditions nor a correlation between device stiffness and IDP could be determined. Also in the neutral state, compared to the native situation, the average change of IDP was 3 % (±11.5 %) for all segment conditions, loading directions and loading modes. Furthermore, in the load case with additional preload, the IDP was still significantly reduced in extension by COF, WAL, IAO and IAM ($p < 0.05$), whereas not by DIA ($p = 0.2038$). In all other loading directions, additional preload had no effect.

Center of rotation

The mean COR results for the three main loading directions and the pure moment loading case are depicted normalized to the disc dimensions (Fig. 5). In flexion/extension, WAL ($p = 0.0029$) and IAM ($p < 0.0001$) shifted the location of

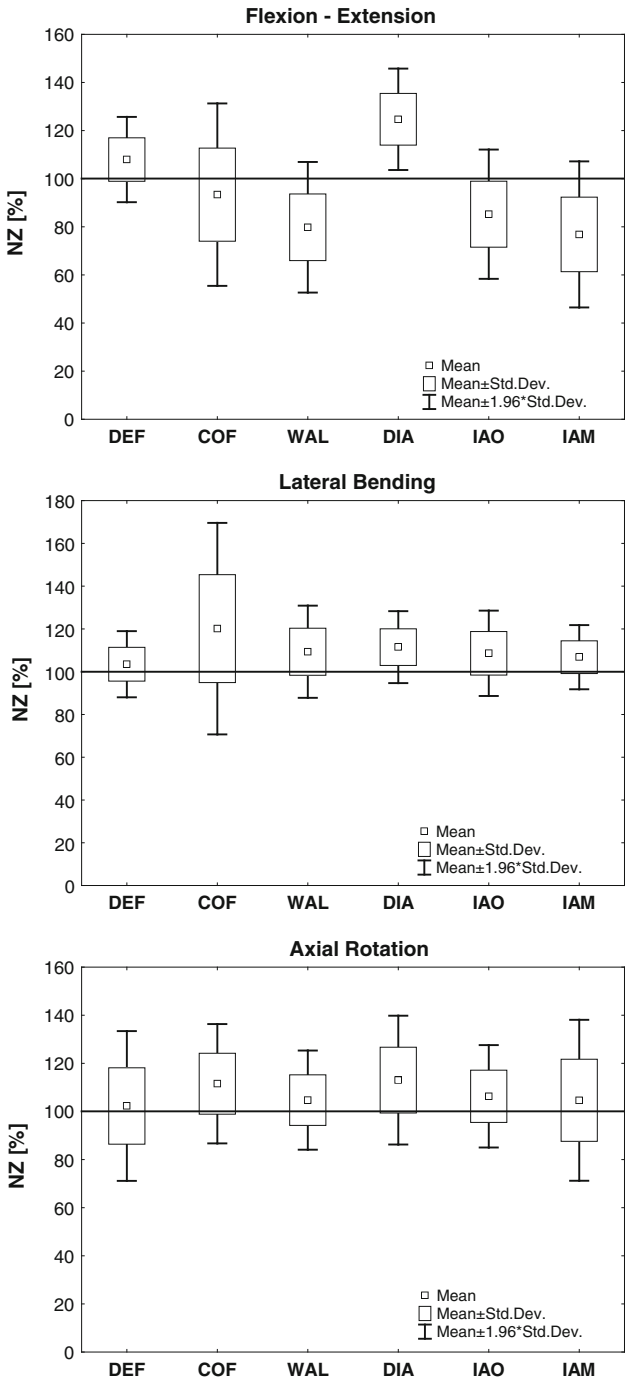

Fig. 3 Neutral zone (NZ) of the tested specimens. The different segment conditions are normalized to the native situation representing 100 %. Load case: pure moment. Abbreviations are explained in Table 1

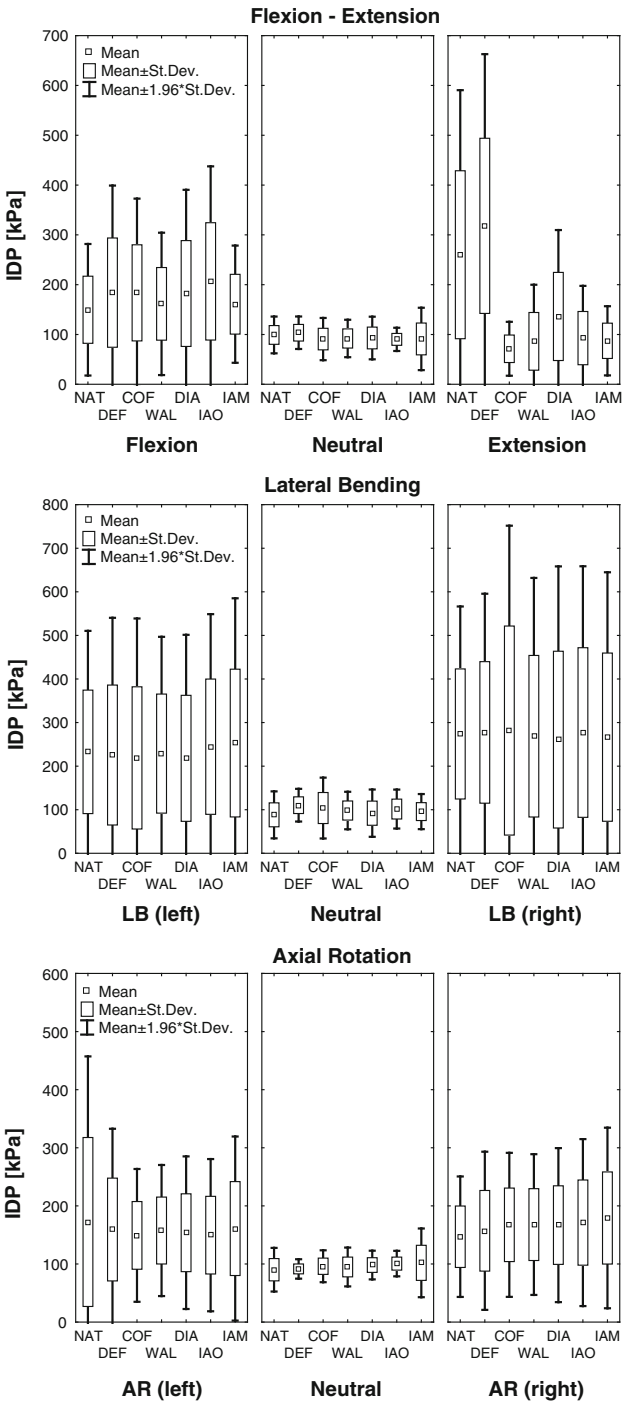

Fig. 4 Intradiscal pressure (IDP) for all segment conditions as absolute values (kPa) of the tested specimens at maximum moment (flexion, LB *left*, AR *left*), zero moment (neutral) and minimum moment (extension, LB *right*, AR *right*). Load case: pure moment. Abbreviations are explained in Table 1

the mean COR(x) significantly towards the dorsal structures and a significant cranial shift of the COR(z) could be observed for WAL ($p = 0.0084$) and COF ($p = 0.0476$) compared to NAT. For all other loading directions and modes, no significant difference for the segment conditions on the location of the COR could be determined. Furthermore, there was no correlation found for implant stiffness (compression/tensile) and location of COR for the three loading directions and the two loading modes.

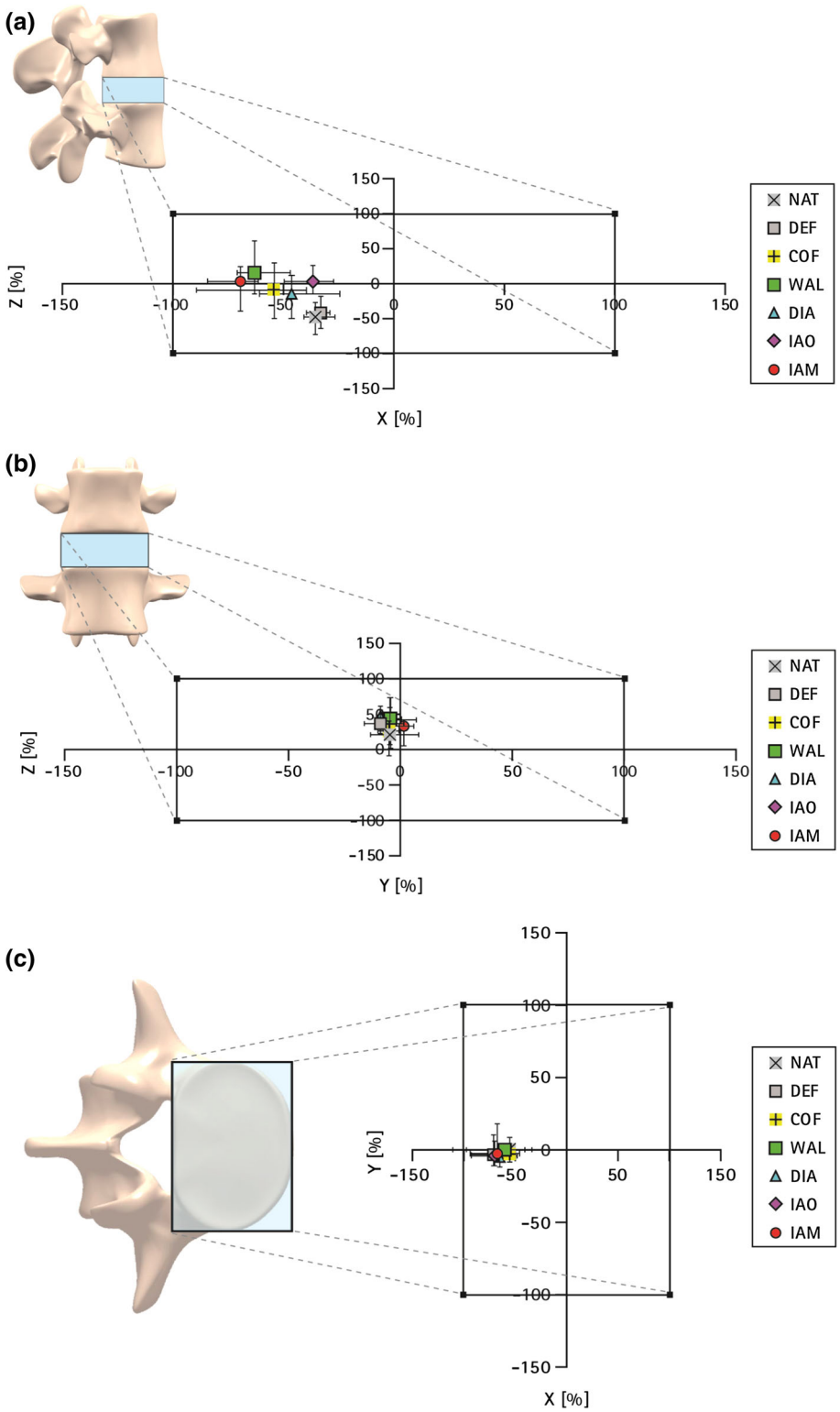

Fig. 5 Center of rotation (COR) for all segment conditions of the tested specimens in **a** flexion–extension, **b** lateral bending and **c** axial rotation. Load case: pure moment. Abbreviations are explained in Table 1

Sagittal tilt

The change in the sagittal profile due to the alteration of segment conditions is shown in Fig. 6. The DEF, WAL and IAM ($p > 0.2$) did not lead to a change in the sagittal profile after implantation compared to NAT, whereas COF, DIA and IAO ($p < 0.02$) exhibited a significant sagittal tilt in direction of kyphosis.

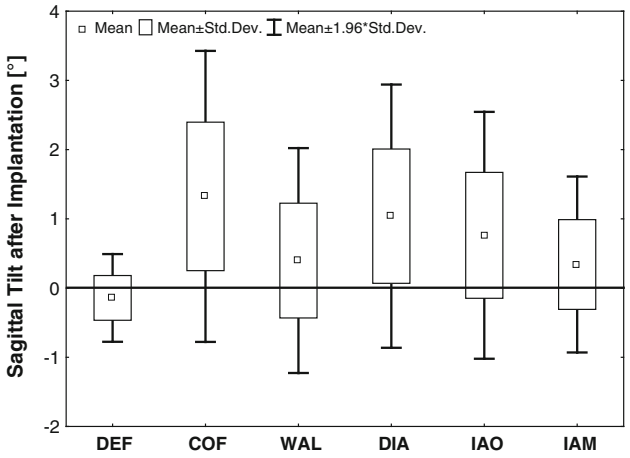

Fig. 6 Sagittal tilt of the tested specimens in relation to the native situation after implantation in the unloaded state—positive values represent kyphosis, negative values represent lordosis

Discussion

The aim of this study was to investigate the effect of different IPS implants on the kinematic response and load transfer within the treated (L4–L5 and L2–L3) segment. The protocol was designed to allow a direct side-by-side comparison of interspinous instrumentations in the same specimen, changing only the IPS device. To this effect, we performed a standardized defect situation consisting of a decompression procedure and removal of the interspinous and supraspinous ligaments. A number of concepts with controversial approaches are currently being discussed for IPS. However, comparative biomechanical studies among the different systems are rare. The current study is, to our knowledge, the first to provide a direct comparison of such systems in the same specimen.

To test five systems on the same specimen could be seen as a limitation of the current study as segment weakening could possibly occur, causing an increase of intersegmental motion during testing. In order to address this issue, we repeated testing of the randomly first chosen implant (3) after all IPS were tested (see Step 8, Table 1). Interestingly, all tested parameters (e.g. ROM, NZ, COR, IDP) increased by no more than 4 % (range 0.25–4 %) during the whole test procedure comparing the last and the first implantation steps. Hence, segment weakening of the specimens can be excluded and the results are representative for comparison.

Furthermore, the created defect situation plays a role in the restabilization characteristics of the IPS. We are aware that for the tested systems an individual recommendation from the manufacturer is given, especially the handling of the supraspinous ligament. However, with the goal to evaluate the systems unique mechanical behavior it was mandatory to create a standardized and constant defect situation.

For the IPS, we found a correlation between compression stiffness and stabilization only in extension. Here, the system with the lowest stiffness, DIA, displayed nearly no stabilization of the treated segment, whereas the system with the highest stiffness, WAL and COF, was most pronounced. This applies also for the correlation between device stiffness and IDP. For flexion, it was observed that stabilization of the IPS is in correlation with the tensile stiffness, but the IDP stayed constant without correlation to tensile stiffness. In the transverse and frontal planes, the systems behaved differently, that is, we did not find any stabilization nor correlation between stiffness and stabilization. Furthermore, the location of the COR was almost not affected by the IPS in all evaluated loading directions and loading modes.

The native ROM of the functional spinal units tested in the present study was, in all motion planes, comparable to the values reported in the literature for in vitro testing of specimens in pure moment loading modes [23–26] and pure moment with additional preload [23, 26, 27].

In addition, the ROM data reported here on WAL are consistent with the results of Schulte et al. [17], where WAL shows nearly the same stabilizing effect in flexion and extension, but very limited stabilization in lateral bending and axial rotation. In contrast to our findings, Wilke et al. [14] reported a significant stabilizing effect of DIA, WAL and COF, only in extension (for all systems about 50 % compared to NAT), but they do not stabilize in all other loading directions, particularly in flexion. A possible reason for the contrary findings could be the different used test protocols. In the present study a consecutive testing of the implants was carried out to ensure the same baseline for comparison, whereas in the study of Wilke et al. [14] the tested implants were divided into individual implant groups with implantations according to the manufacturers' recommendations.

In lateral bending and axial rotation the DEF increased intersegmental motion, but none of the IPS could compensate this and stayed on the level of DEF. The loading mode with additional preload showed the same results by trend.

The effect of IPS design parameters on IDP is only given in extension, which is in agreement with the current literature [14, 15]. Furthermore, our data showed that IPS reduced IDP according to their axial stiffness with higher IPS stiffness resulting in higher release of IDP. In all other loading directions, neither implant stiffness nor the additional tensioning affected the IDP.

The influence of IPS design parameters on the location of the mean COR is almost negligible. Only the systems with a tensile stiffness >30 N/mm shifted the mean COR towards the dorsal structures within the intervertebral disc space. Therefore, it might be reasonably assumed that an

overloading of the facet joints after IPS device implantation is unlikely.

The sagittal profile after implantation seems to be governed by the dorsal tensioning. IPS without tensioning or tensioning in combination with low compression stiffness tends to lead the segment in the direction of kyphosis. But the fact that there are differences in the nominal height of the implants to the real height after implantation, due to the specific alignment of the devices at the spinous process, is more reasonable leading to the kyphotic position after implantation.

The tested specimens were from relative old donors, increasing the risk of degeneration, especially of the intervertebral disc. Prior to testing they were CT scanned and visually inspected for signs of severe disc degeneration and excluded if such were found. We were aware that the age of the specimens and the accompanied age-related disc degeneration were not ideal to collect reliable data on IDP as the large standard deviation in the IDP measurements shows. Nevertheless, we did not think it would have a significant impact on the kinematic response. In addition, previous studies have shown that degeneration of the intervertebral disc has only a minimal effect on the ROM [28] and may even result in a decrease in a severe case [25].

Clinical data for IPS show mixed outcomes ranging from good [1, 3, 4] to poor [4–8], which could be attributed to the different clinical indications. Obviously, the latter (e.g., disc degeneration, spinal stenosis with or without degenerative spondylolisthesis, etc.) together with the clinical procedure (e.g., with or without decompression, nucleotomy, etc.) is critical for the outcome, but the ability of the systems to restrict or allow movement to a certain degree is also a factor (e.g., if the pain comes from rotation, but the dynamic system does not restrict it, radicular pain may persist).

Although it remains unclear which stiffness or design will prove the most successful for interspinous stabilization of the spine, we believe that it is essential to restrict the movement of the treated segment in all motion planes, inferior to that of the native situation, to compensate for the ROM increase from decompression and to minimize abnormal movement or instability. Therefore, it is debatable that the IPS has clinical success for dynamic stabilization even in combination with cell therapy because only stabilization in the sagittal plane could be achieved with this kind of implant.

Conclusion

A correlation was found between compression stiffness and intersegmental stabilization and reduction of IDP for extension. There the system with the lowest stiffness displayed the lowest stabilization and reduction of the IDP of the treated segment, whereas the system with the highest stiffness was most pronounced. In flexion only the degree of stabilization is in correlation with the tensile stiffness, whereas the IDP stays constant and is not affected by the different tensile stiffness. IPS is not able to stabilize in the frontal and transversal plane. Furthermore IPS does not substantially alter the location of the COR.

Conflict of interest The authors CS, TMG and WB are employees of the Aesculap AG, Tuttlingen, Germany.

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