

## Research Article

# Biomechanical Effect of an Interlaminar Device on Ranges of Motion, Intradiscal Pressure, and Centers of Rotation

Giancarlo Guizzardi<sup>1</sup>, Sylvain Persohn<sup>2</sup>, Sophie Campana<sup>2,3</sup>, Caspar Aylott<sup>3</sup>, Piero Petrini<sup>4</sup>, and Wafa Skalli<sup>2</sup>

<sup>1</sup>Neurosurgical Department, University and City Hospital Careggi, Largo Brambilla, 50100 Florence, Italy

<sup>2</sup>Laboratoire de Biomécanique Arts et Métiers ParisTech, 151 bd de l'Hôpital 75013 Paris

<sup>3</sup>Gloucestershire Spinal Unit, Gloucester Royal Hospital, United Kingdom

<sup>4</sup>Department of Orthopedics and Traumatology, City Hospital, Città di Castello, Italy

Corresponding Author: Giancarlo Guizzardi; email: euydgu@tin.it

Received 14 January 2015; Accepted 17 March 2015

Academic Editors: Roberto De Santis and Junhui Hu

Copyright © 2015 Giancarlo Guizzardi et al. This is an open access article distributed under the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

**Abstract.** *Introduction.* The IntraSPINE is a new interlaminar device that has been proposed with the aim to decompress the spinal canal without reducing the extension motion. The purpose of this study was therefore to evaluate the biomechanical behavior of L4-L5 spinal units implanted with this interlaminar device, in terms of ranges of motion, intradiscal pressure, and centers of rotation. *Material and Methods.* Six human lumbar spines were harvested within 10 days after death. A specific spine testing device was used to apply moments up to 10 Nm in flexion-extension, lateral bending (left-right flexion) and left-right axial rotation (torsion), with measurement of vertebral 3D motion and of intervertebral disc pressure. Protocol was repeated for each specimen in 5 configurations: intact specimen; after L4-L5 bilateral medial hemifacetotomy and both yellow ligament resection; after implantation of the interlaminar device at the L4-L5 level; after removal of the L4-L5 supraspinous ligament, resection of the posterior third of the disc and addition of an artificial ligament; after device and artificial ligament removal. *Results.* The implant reduced increases in segmental flexion seen following injury particularly when applied with the artificial ligament. Intradiscal pressure reduced following application of the implant without reducing extension range. A small posterior shift of the Mean Centers of Rotation (MCR) was noticed after instrumentation. Torsion and lateral bending range was unaffected by the interlaminar device. *Conclusion.* This biomechanical study yields a better understanding of this interlaminar implant effect. A large clinical trial with follow-up would be required to evaluate and confirm *in vivo* the observed *in vitro* biomechanical behavior of the device.

**Keywords:** Interlaminar device; motion preservation; biomechanics of spine

## 1. Introduction

Common causes of lumbar back pain include disc herniation, disc degeneration, facet joint arthritis, spondylolisthesis,

spondylosis, spondylolysis and spinal stenosis. Surgery is considered when conservative treatment has failed. The surgical strategy is influenced both by the diagnosis and the surgeon's experience. Spinal fusion is widely practiced

but this biomechanically prejudices the adjacent segment and may lead to accelerated degeneration [1–4]. The use of pedicle screw fixation enhances the fusion rate but is not necessarily associated with improved clinical outcome [5]. A wide range of non-fusion techniques has been proposed in the last decade [6]. In particular, interspinous devices are frequently used in the case of mild canal or foramina stenosis, with or without decompression, in order to provide spinal stabilization while still allowing motion at the instrumented level [7, 8]. Usually implanted through a minimally invasive approach, they include various materials and designs. Constrained or not, the aim of such interspinous spacers is to preserve motion while unloading the facet joints, and increase central canal and neuroforaminal dimensions either by flexing the spinal segment or blocking extension [9, 10]; they act as mere spacers able to induce an indirect decompression of structures such dural sac and nerve roots by means of distraction of the spinous processes [11, 12]. Several studies reported the biomechanical behavior of such implants through *in vitro* flexibility tests [12–15]. Despite their different designs, they show similar stabilizing effect and pressure reduction in extension, leaving flexion, lateral bending and torsion amplitudes almost unaffected. Interspinous implants can provide good clinical outcomes but are more reliable when combined with a direct decompression [16]. Failures can occur due to local bone resorption [17] leading to loss of constraint or spinous process fracture [18, 19]; overdistraction may lead to segmental kyphosis [20,21,22 ] with a negative impact on sagittal balance and the physiological axes of rotation. In this paper we analyze a new device (IntraSPINE) with a unique interlaminar location, closer to the normal center of rotation that may have mechanical advantages over a traditional more posteriorly placed interspinous implant by allowing more physiological movement without blocking extension. Furthermore this new device with a core in medical silicone and an outer shell in pure polyethylene terephthalate (PET) shows material properties very suitable for spinal applications. The use of a gel like core and an outer shell reinforced by continuous wounded PET fiber has been proposed as a synthetic intervertebral disc prosthesis. The combination of these materials represents a composite which mimics the architecture of the intervertebral disc and resembles its viscoelastic properties [23] and makes the device able of support/replace the function of the disc itself [24]. The purpose of this study was therefore to evaluate the biomechanical behavior of L4-L5 spinal units implanted with this new interlaminar device, in terms of ranges of motion, intradiscal pressure, and centers of rotation.

## 2. Materials and Methods

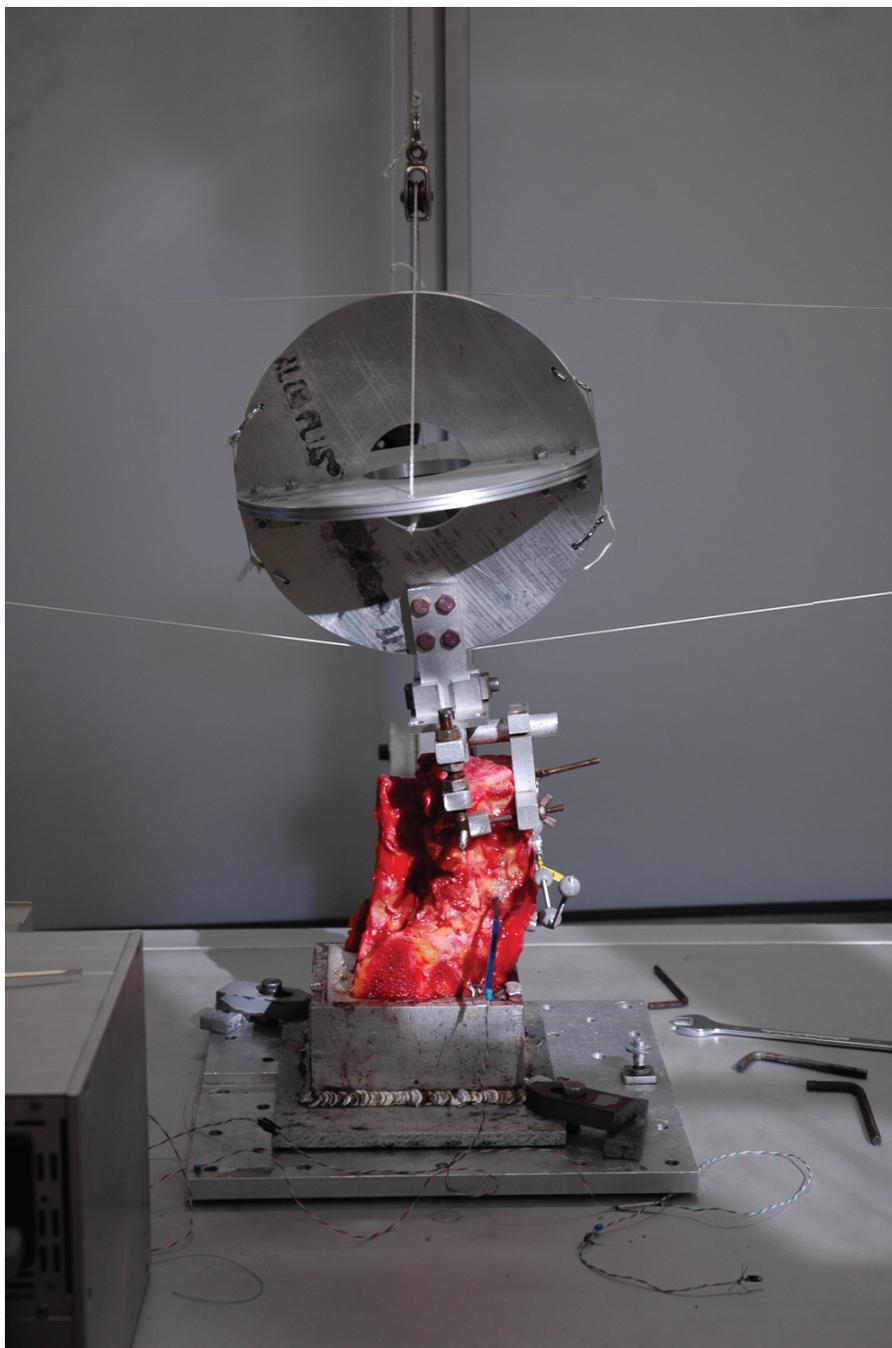
Six L3-S1 human lumbar spines were harvested within 10 days after death. Mean age of the donors, among them 1 male and 5 females, was 60 years (range 55–66 years).

Anatomic specimens were sealed in plastic bags and stored at  $-20^{\circ}\text{C}$ . Each spine was thawed at  $+6^{\circ}\text{C}$  overnight prior to testing. Soft tissues were removed except ligaments, joint capsules and intervertebral discs which were carefully preserved. Spinal deformities, damage or severe degeneration of the discs and facet joints were excluded macroscopically and radiographically. Experimental protocol using a specific spine testing device well-described elsewhere [25] was then run at room temperature, keeping the anatomic specimens regularly moisturized to prevent drying out. The experimental protocol was designed according to the European Standard for the testing of spinal implants [26] and has been carried out at the ENSAM Institute, Paris, Cofrac\* Accredited Testing Laboratory N° 1.0956 as published elsewhere [27].

S1 was embedded in a metallic mold using low fusion point alloy to ensure rigid fixation to the spine testing machine. A loading system constituted of cables and pulleys was fixed and mounted on the L3 vertebra (Figure 1). Free weights could be attached to the cables to apply loading/unloading cycles ranging from  $-10\text{ Nm}$  up to  $10\text{ Nm}$  (steps of  $1\text{ Nm}$ ), in 3 loading modes: flexion-extension, left-right lateral bending and left-right axial torsion. Three preconditioning loading cycles were applied to the specimen using the same loading protocol before the measurement cycle was started. In order to quantify the motion of L4 with regards to L5, two sets of three reflective spheres were fixed to bended rods which were rigidly screwed into the anterior body of the L4 and L5 vertebrae; an optoelectronic system (Polaris VICRA system; Northern Digital Inc., Waterloo, ON) was used to track the displacements of these markers. A  $1.02\text{ mm}$  ( $.04''$ ) pressure sensor (EPL-D 100; Entran, Fairfield, NJ,  $0-7\text{ bars}$ ) was laterally implanted in the center of L4-L5 intervertebral disc from the right lateral site and attached with one suture stitch in order to prevent its displacement (Figure 2). Pressures were measured continuously during the complete loading-unloading cycle, but only pressure data at each loading increment were recorded to obtain load-pressure curves between maximal flexion and extension. Each curve starts with the unloaded position of the specimen at  $0\text{ Nm}$ , which represents the neutral position between flexion and extension.

Biplanar frontal and sagittal X-Rays of the prepared specimens were acquired using the EOS system (EOS imaging, Paris, France). They were used to perform 3D reconstruction of both vertebrae [28], and to assess the pressure sensor location and the 3D orientation of the marker sets and with regard to spinal anatomic frames (Figure 3a, 3b).

The IntraSpine device (Cousin Biotech, France), is manufactured in medical silicone 65 shore coated by an adherent pure polyethylene terephthalate sleeve and the frontal extremity is further covered by a silicone film that intends to prevent adhesion to the neural structures (Figure 4). The fundamental feature of this device is the difference in compression stiffness between the anterior and the posterior

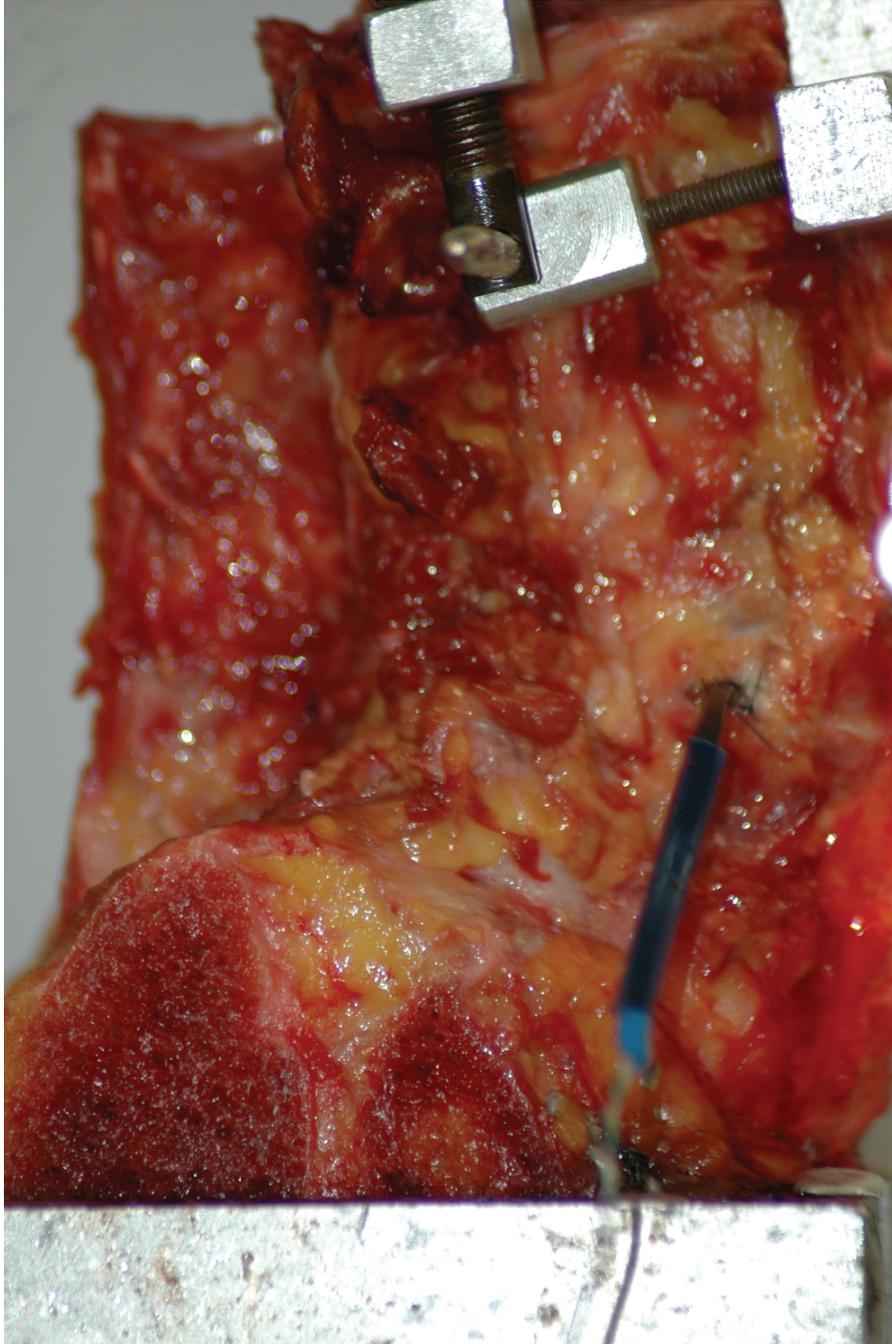


**Figure 1:** The system fixed and mounted.

parts of the device: the anterior part, “the nose”, is rigid and designed to suit the interlaminar space after distraction. The posterior part is triangularly shaped and perforated by a linear cavity to render it more compressible, in order not to restrain spinous process movement in extension (Figure 4b). The additional artificial ligament is a tubular braid of polyester that is used in case of weakness of supraspinous ligament. The surgical technique, as reported by Guizzardi et al. [29], is performed with one-sided approach in the case

of implantation of the device alone or a bilateral approach when using an additional artificial ligament. The surgical procedure as well as the clinical results with 2 year follow up are reported by Guizzardi et al. [29].

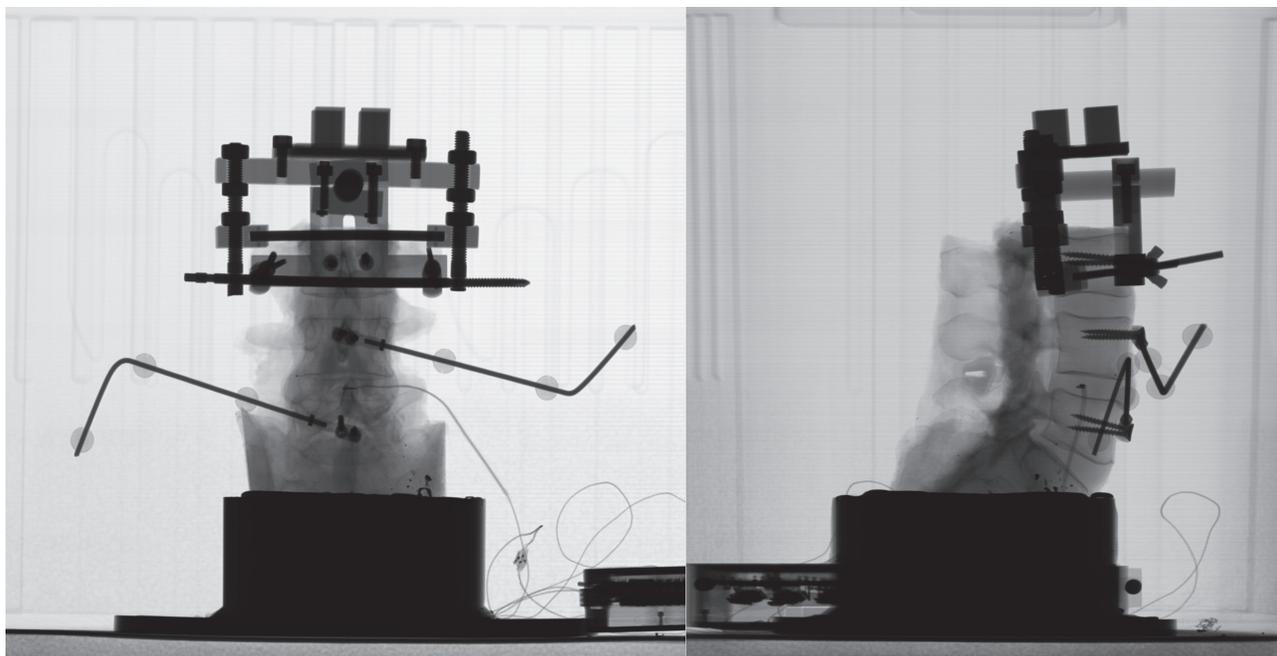
For each anatomic specimen, testing protocol was repeated for 5 configurations: 1) intact specimen (INTACT), 2) after L4-L5 bilateral medial hemifacetotomy (the lower two third of the inferior articular process has been resected) and both yellow ligament resection (INJURY1), 3) after



**Figure 2:** The pressure sensor on site.

implantation of the interlaminar device at the L4-L5 level (INSTR1); 4) after removal of the L4-L5 supraspinous ligament, resection of the posterior third of the disc and addition of an artificial ligament (INSTR2), and 5) after device and artificial ligament removal (INJURY 2). The five configurations were created without disassembling the specimen from the loading equipment. All of them were completed in sequence and each one required 40 minutes to be accomplished as detailed in the following sections.

*2.1. Data processing.* After 3D reconstructions from biplanar X-Rays, each markers coordinate systems (CS) could be related to the anatomical CS of its attached vertebra. Post-processing of both optoelectronic and 3D geometry data were used to quantify L4-L5 intersegmental motion (angular and linear displacements), and to calculate the location of the mean center of rotation (MCR) between full extension and full flexion. The finite helicoidal axis was calculated and the MCR was defined as its intersection with the sagittal plane. In order to allow the comparison between the 6 specimens,



**Figure 3:** Antero-Posterior and Latero-Lateral X-rays of an instrumented L3-S1 lumbar spine, together with the implant, the intradiscal pressure sensor and the optoelectronic markers.

MCR location was expressed as a percentage of L5 vertebral body dimensions depth and vertebral height [25, 30]. In order to differentiate flexion from extension, the neutral position was taken as half of the neutral zone.

**2.2. Statistics.** In order to evaluate the influence of the 4 different configurations compared to the intact one, non-parametric Wilcoxon sign test for paired samples were run for ROM, intradiscal pressure, and MCR locations. Differences were considered as statistically significant when  $P < 0.05$ .

### 3. Results

**3.1. Ranges of Motion.** Ranges of motion (ROM) in flexion, extension, lateral bending and torsion are presented on Figure 5. Mean ROM in flexion was  $7.1^\circ$  ( $4.8^\circ$  to  $10^\circ$ , SD 1.86) in the INTACT configuration, and  $8.1^\circ$  ( $5^\circ$  to  $12^\circ$ , SD 2.53) after INJURY1 (hemifacetctomy+ yellow ligament removal). This motion increase was statistically significant ( $P = 0.005$ ). After instrumentation, flexion mobility decreased to  $5.4^\circ$  ( $3.8^\circ$  to  $6.2^\circ$ , SD 1.07) and  $4.9^\circ$  ( $2.3^\circ$  to  $6.9^\circ$ , SD 1.59), respectively, for INSTR1 (interlaminar device) and INSTR2 (interlaminar device + artificial ligament), with no statistical difference between them ( $P = 0.1$ ). Finally INJURY2 (INJURY 1 + supraspinous + posterior disc resection) led to a significant ROM increase ( $P = 0.001$ ) with a mean value of  $10.6^\circ$  ( $8^\circ$  to  $14^\circ$ , SD 1.95).

In extension, mean ROM was between  $4.1^\circ$  and  $4.9^\circ$  whatever the configuration. Extension was not significantly different between INTACT  $4.4^\circ$  ( $3.7^\circ$  to  $5.1^\circ$ , SD 0.82),

INSTR1  $4.3^\circ$  ( $2.9^\circ$  to  $6.1^\circ$ , SD 0.97) and INSTR2  $4.1^\circ$  ( $3.4^\circ$  to  $5^\circ$ , SD 0.76) configurations. A small increase in extension was seen following INJURY1  $4.8^\circ$  ( $2.9^\circ$  to  $6.4^\circ$ , SD 1.15),  $P = 0.3$  and INJURY2  $4.9^\circ$  ( $2.1^\circ$  to  $6.5^\circ$ , SD 1.45),  $P = 0.2$ .

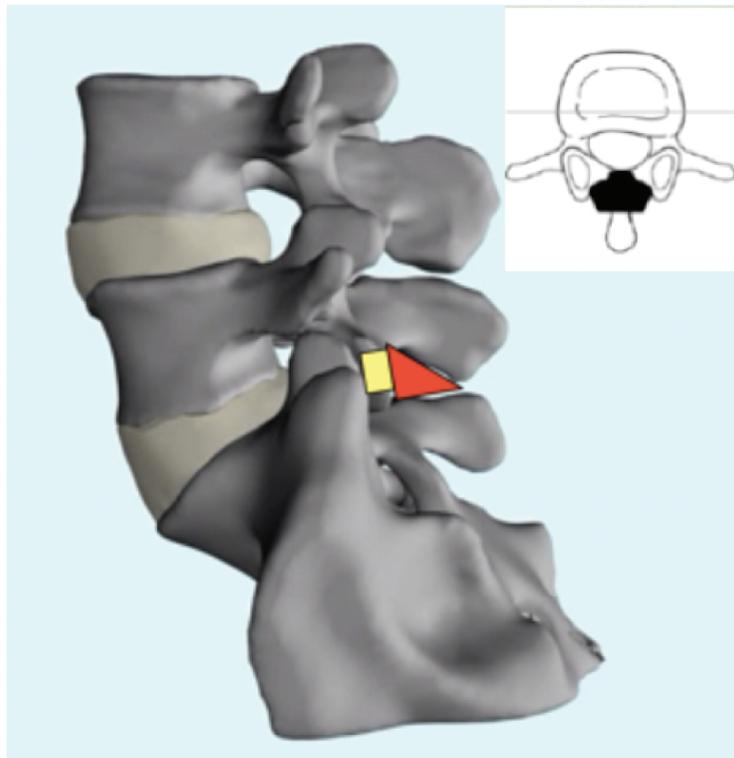
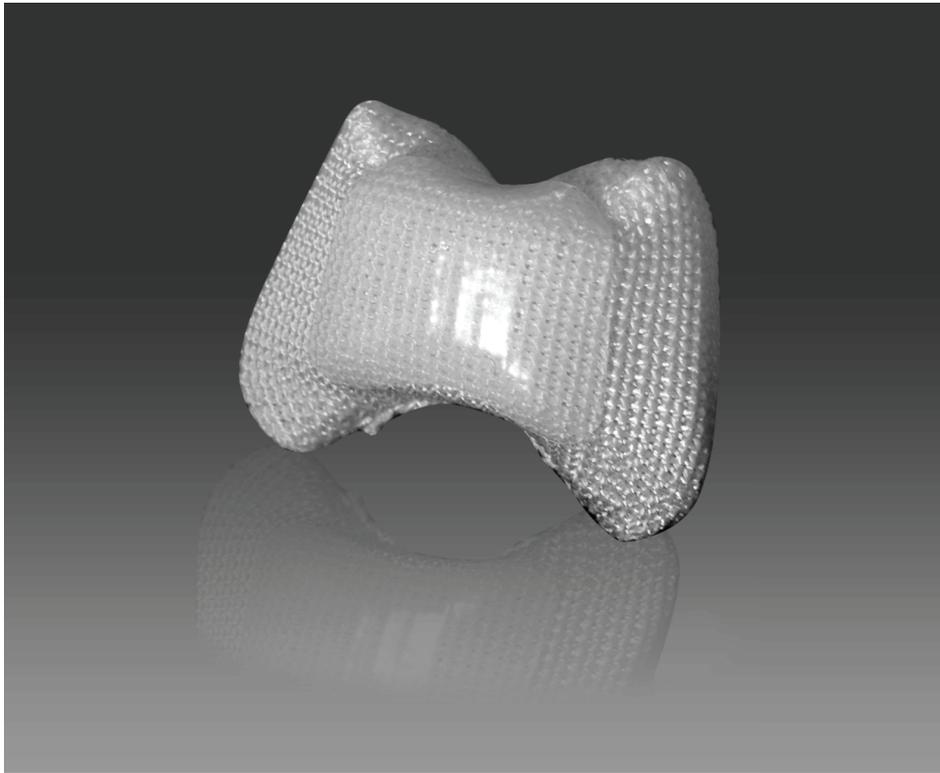
In lateral bending, mean ROM was  $11.1^\circ$  ( $8.2^\circ$  to  $15.8^\circ$ , SD 2.34) in the INTACT configuration, with a small significant increase at  $11.6^\circ$  ( $8.9^\circ$  to  $16^\circ$ , SD 2.29) after INJURY1 ( $P = 0.4$ ). Lateral bending ROM did not vary with INSTR1  $11.6^\circ$  ( $8.7^\circ$  to  $16^\circ$ , SD 2.45) but increased significantly with INSTR 2 to  $14^\circ$  ( $10.4^\circ$  to  $18.2^\circ$ , SD 2.44),  $P = 0.002$ , which is comparable to the ROM of  $14.5^\circ$  measured in the final INJURY2 configuration ( $11.1^\circ$  to  $18.2^\circ$ , SD 2.17).

In torsion, mean ROM was  $5.3^\circ$  ( $3.9^\circ$  to  $8^\circ$ , SD 1.38) in the INTACT configuration. For the 4 other configurations, ROM statistically increased and resulted in 4 comparable values: for INJURY 1 was  $6.9^\circ$  ( $4.9^\circ$  to  $10.9^\circ$ , SD 1.99), for INSTR 1 was  $7.3^\circ$  ( $5.7^\circ$  to  $11^\circ$ , SD 1.77), for INSTR 2 was  $7.8^\circ$  ( $5.5^\circ$  to  $11.6^\circ$ , SD 2.14) and finally for INJURY 2 was  $7.7^\circ$  ( $4.9^\circ$  to  $11^\circ$ , SD 2.10).

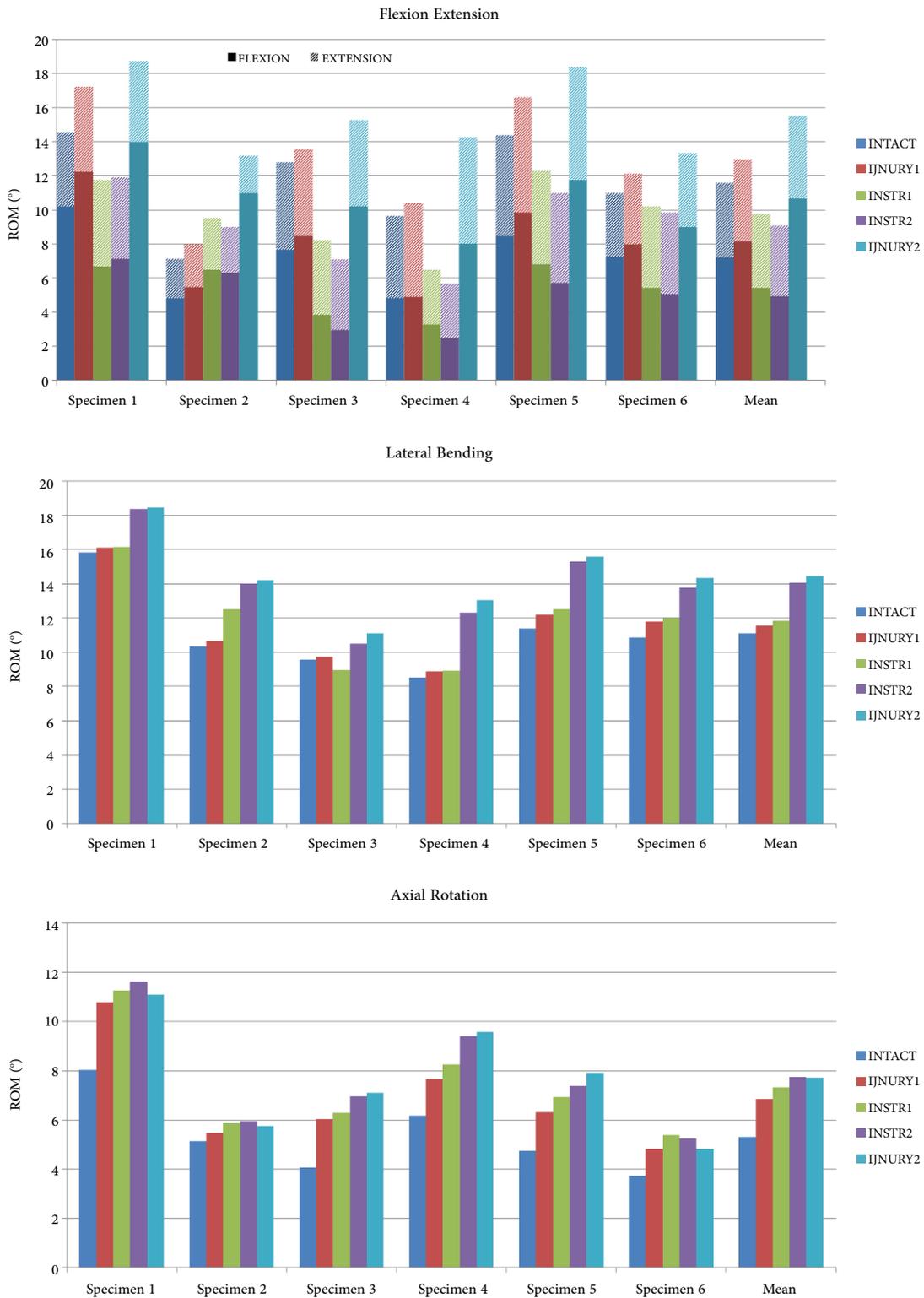
**3.2. Intradiscal pressure in Flexion-Extension.** A typical load-pressure curve is presented in Figure 6.

Pressure pattern during flexion-extension cycles were close in the INTACT and in the INJURY1 state. At 10 Nm, for both INTACT/INJURY1 configurations, mean pressure was 0.27/0.30 MPa in flexion, and 0.20/0.20 MPa in extension.

INSTR1 and INSTR2 configurations led to two different behaviors. With INSTR1 intradiscal pressure in flexion was similar to INTACT and INJURY1 configurations, while INSTR2 resulted in a pressure decrease in flexion; mean



**Figure 4:** a) The IntraSPINE b) 3D reconstruction of the lumbar column with representation of the position of the device: anterior “rigid” nose (yellow) and “compressible” posterior part (red). In the box top view of the position of the IntraSPINE (black).



**Figure 5:** Ranges of Motion of each specimen and mean values in Flexion/ Extension, Lateral Bending and Axial Rotation in five configurations.

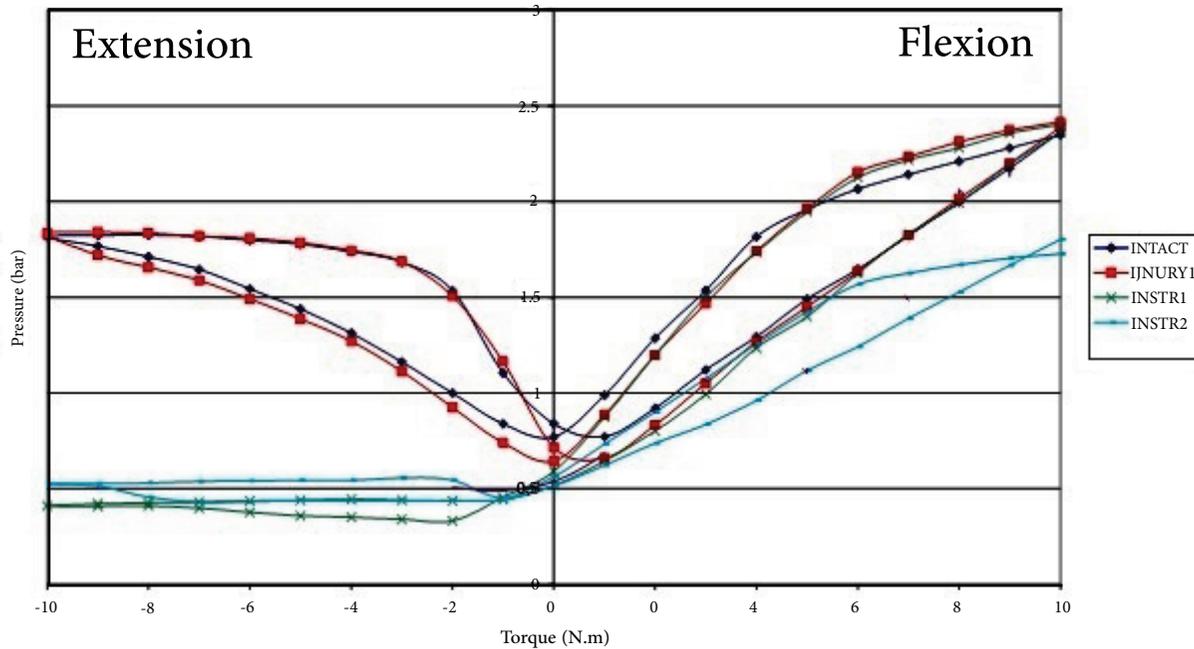


Figure 6: Typical pressure curves during Flexion-Extension for the 4 configurations.

Table 1: Maximal Intradiscal pressure (MPa) during Flexion-Extension and analysis of instrumented/injury conditions compared to intact specimens. (In INJURY2 configuration, the intervertebral disc lesion induced a displacement of the pressure sensor and the results were therefore discarded).

Configuration	Mean ± SD	Minimum	Maximum	Difference with Intact	P*
INTACT	0.27 ± 0.04	0.21	0.35		
INJURY 1	0.30 ± 0.04	0.24	0.36	+ 0.03*	0.036*
INSTR1 (without artificial ligament)	0.27 ± 0.08	0.12	0.34	+ 0	0.834
INSTR2 (with artificial ligament)	0.13 ± 0.06	0.06	0.19	- 0.14*	0.036*

\*Wilcoxon test significant:  $P < 0.05$ .

pressure at 10 Nm was 0.27 MPa and 0.13 MPa for INSTR1 and INSTR2, respectively. In extension, both instrumented states generated a significant decrease of pressure, with a common mean pressure of 0.06 MPa.

Results regarding maximum intradiscal pressure and  $P$  values are detailed in Table 1.

#### 4. Mean Centers of Rotation (MCR) in Flexion-Extension

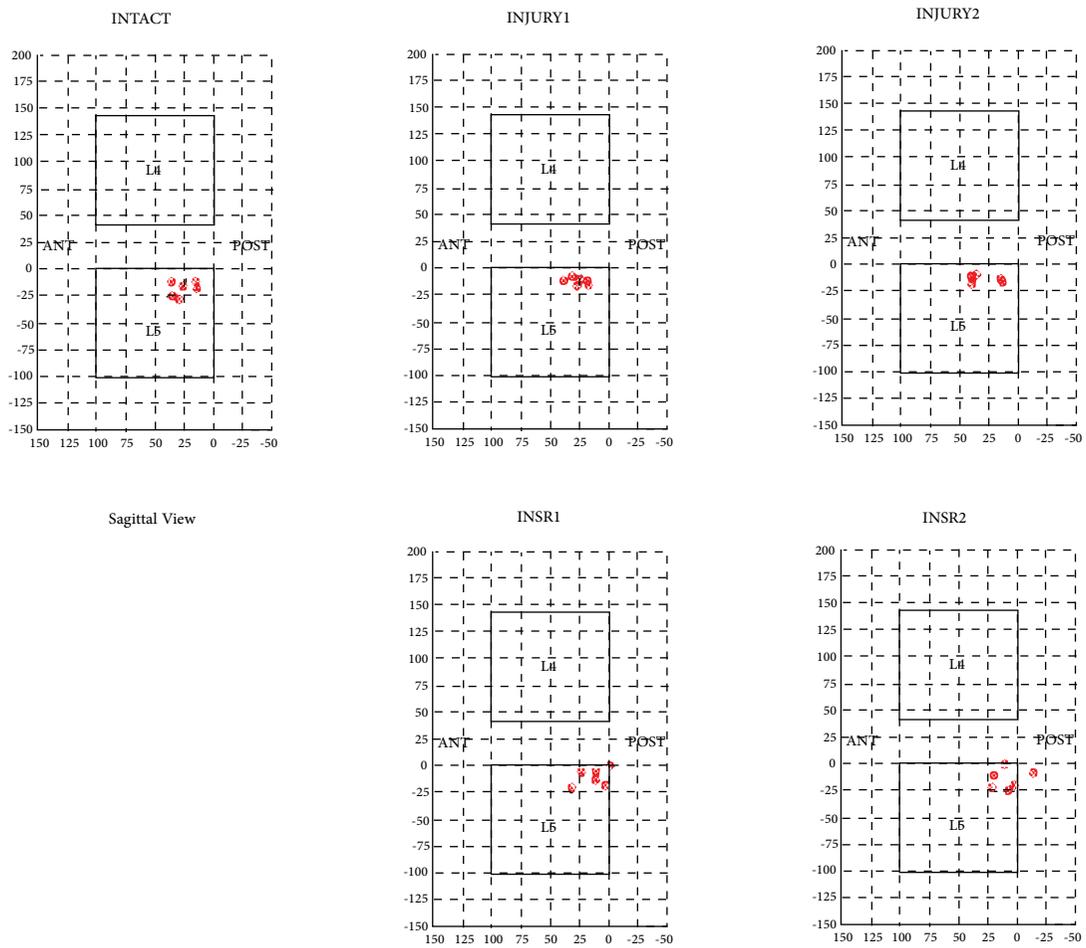
The locations of the 6 MCR determined from full extension to full flexion in the 5 configurations are presented on Figure 7.

In the INTACT configuration, mean MCR position was within the L5 vertebral body, in its posterior quarter (27% of the total postero-anterior depth) just below the superior endplate of L5 (17% of the total vertebral height). After both INJURY1 and INJURY2, a small cranial displacement of MCR was seen (now average 12% of total vertebral height),

with the postero-anterior location remaining unchanged. In both instrumented configurations (INSTR1 and INSTR2), a similar small cranial shift of MCR was seen (average 11% of total vertebral height) with a significant posterior displacement of MCR (average 11% of total postero-anterior depth). The detailed relevant percentages and  $p$  values are reported in Table 2.

#### 5. Discussion

This cadaveric study reported the biomechanical behavior of six L4-L5 spinal units whose flexibility under load was tested first intact then in two injured and two instrumented configurations. Like interspinous implants the interlaminar implant under test is a non-fusion device and should not be compared to a transpedicular fixation and fusion arthrodesis. While interspinous devices were not tested in this study the observations may lead the reader to make comparisons with similar studies dealing with the biomechanics behavior of



**Figure 7:** Location of MCR during Flexion-Extension with schematic representation of L4 and L5 vertebrae and L4/L5 intervertebral disc in sagittal view.

**Table 2:** Position of average MCR In Flexion-Extension, expressed as a percentage or L5 postero-antior (P.A.) dimension and L5 mean vertebral height (V.H).

Configuration	% of L5 P.A. dimension		% of L5 mean V.H.	
	Mean ± SD (Min/Max)	Difference intact	Mean ± SD (Min/Max)	Difference intact
INTACT	+2 7.4 ±9.3 (15.8/36.9)	---	+17.0±5.0 (-26.8/-10.3)	-
INJURY1	+28.0±8.4 (18.9/40.8)	+0.6 <i>P</i> = 0.529	-11.9±3.5 (-16.5/-6.9)	+5.1 <i>P</i> = 0.142
INSTR1 (without artificial ligament)	+13.6±12.6 (-1.2/32.4)	-13.8* <i>P</i> = 0.036	-9.7±8.2 (-20.0±1.2)	+7.3 <i>P</i> = 0.208
INSTR2 (with Artificial ligament)	+8.1±13.0 (-14.1/21.6)	-19.3* <i>P</i> = 0.036*	-13.2±9.3 (-20.0/1.2)	+3.8 <i>P</i> = 0.675
INJURY2	+29.5±12.9 (12.6/39.3)	+2.1 <i>P</i> = 0.836	-11.6±3.1 (-16.0/-7.6)	+5.4 <i>P</i> = 0.402

\*Wilcoxon significant test if *P* < 0.05.

interspinous devices [11–14]. A published experience on comparison between interspinous and interlaminar devices highlight how in tests *in vitro*, the use of such interspinous devices brings to a reduction of the ROM in extension and the inability to control it during flexion, axial rotation and lateral bending. The results are undoubtedly in favour of interlaminar rather than interspinous systems and this seems obvious if we consider simply the different distances of the two types of implants from the axis of instantaneous rotation. These same results were possible to perceive also thanks to a very sophisticated reconstruction of the physiological movement of the mobile segment L4/L5. With the help of mathematicians and computer technicians Authors were then able to pass onto static rendering and dynamic rendering, thus obtaining a true model of the movement in flexion/extension of the subject. On this model were carried out the studies on the axis of instantaneous rotation, consistent with the results of the present Study, and on how it gets influenced with the use of interspinous and interlaminar devices [27].

The interlaminar device under test is different from interspinous devices in that it is designed to be positioned in an interlaminar rather than interspinous position. This means that the implant is resting in a more anterior position than an interspinous implant. Ranges of motion were measured in order to evaluate the stabilizing effect of an interlaminar device, reinforced or not with an artificial ligament. Intradiscal pressure and centers of rotation provided additional information to assess the effect for such a non-fusion device. This *in vitro* analysis was conducted with all the limitations commonly encountered when running spine experimental testing. Muscular effects were not taken into account, nor the self-balancing aptitude of an individual according to their own morphological parameters [31]. However, *in vitro* experiments provide an objective and controlled evaluation of the implant with similar conditions for all anatomic specimens.

In the intact configuration, the ranges of motion measured at the L4-L5 level were comparable to values previously reported [25, 32, 33]. The bilateral medial hemifacetectomy combined with both yellow ligament resection (INJURY1), was carried out to simulate a decompressive surgical procedure, and generated a moderate ROM increase mainly in flexion and torsion. Those findings are in agreement with Fuchs et al., who evaluated the influence of graded facetectomies at the L3-L4 level with supraspinous ligament preservation; in their study, lateral bending and extension were almost unaffected by facetectomy, while the stabilizing role of lumbar facets was predominantly seen during axial rotation and, to a lesser extent, during flexion. After resection of the supraspinous ligament (INJURY2), a strong stabilizing structure able to restrict flexion [34] a higher ROM increase was indeed noticed in flexion; this observation corroborates the study of Abumi et al. [35] who tested graded facetectomy with supraspinous ligament division. The INJURY2 configura-

tion also induced a ROM augmentation in lateral bending, probably due to the combined effects of the supraspinous ligament removal and the partial resection of the L4-L5 intervertebral disc.

The first instrumented configuration (INSTR1) showed that extension motion was not significantly different compared to the intact configuration. This result appears to differ from reported interspinous spacer tests which show a reduction in extension, which may result in load increase in the spinous process [36]. The value of this comparison is limited by the fact that an interspinous spacer was not tested in this study however previous interspinous device studies have used very similar biomechanical set-up and protocols. The difference may be due both to the more anterior location (interlaminar rather than interspinous) and to the deformation capacity of the posterior part of the silicone device. The interlaminar implant therefore does not block extension, which suggests that the increase of foraminal area yielded by the implant may not necessarily result in over loading of the spinous process. In flexion, the mean range of motion was reduced by 1.7° compared to the intact configuration. In torsion, a 2° to 3° increase of rotation was observed; this increase is probably related to the opening of the laminar space and consequently augmentation or ‘unlocking’ of the facet joints.

The second instrumented configuration (INSTR2) evaluated the stabilizing effect of an artificial ligament combined with the interlaminar device following both supraspinous ligament removal and posterior disc resection. Resection of the posterior third of the disc resembles the situation following discectomy. The supraspinous ligament may be removed during a spinal decompression to improve surgical access or not infrequently is a deficient structure in the ageing spine where spinous process enlargement and abutment may lead to abrasive thinning. The combination of injury (INJURY2) led to the greatest increase in flexion and lateral bending. The application of the artificial ligament (INSTR2) eliminated the large increase in flexion seen following supraspinous ligament removal and resection of the posterior third of the disc but did not reduce the increase in lateral bending and torsion. Extension was not significantly affected by application of the artificial ligament. This could be related to the stiffness of such an artificial ligament with a different elasticity and geometry than the native one, and the way it was tightened. Further investigation could help understanding this observation.

Ligamentoplasty may be indicated when the supraspinous ligament is injured and its role is to be compensated [37]. Better understanding of the radiology and pathology of the normal ageing process as manifested in the spinous processes, and awareness of these alterations as a potential source of low back pain [38] could prevent misdiagnosis of inflammatory conditions that may affect this region. Indeed, the importance of degeneration of the interspinous ligaments of the lumbar spine as a cause of pain is emphasized in

a recent paper on the classification of different degrees of this frequent pathology [39]. Finally in a recent study Aylott [40] demonstrated that the dimensions of the lumbar spinous process (LSP) change with age, with an increase in LSP height and even more impressive of its width. There is an inverse relationship between lumbar lordosis and LSP height. For all these reasons the use of a ligament can be relevant in this intermediate stage of the degenerative cascade in order to restore the lordosis and contribute to the reduction of pain.

Intradiscal pressures were measured during flexion and extension. These measurements are dependent both on the position of the pressure transducer within the nucleus and the state of disc degeneration and provide further comparative information between test configurations. In the intact state, both the recorded magnitudes and the typical shape of the curves were similar to the results reported by Schmoelz et al. [41]. As expected, facetectomy did not modify the pressure distribution. Intradiscal pressure reduced following implantation of the interlaminar device (INSTR1) and significantly when using the artificial ligament (INSTR2). Extension movement was unaffected by either configuration with greater restraint in flexion provided by the artificial ligament. This phenomenon suggests a decompressive action of the implant due to the transfer of the mechanical function from the intervertebral disc to the implant, whose shape progressively deforms during extension to still permit motion. The addition of the artificial ligament resulted in a pressure reduction in flexion, probably initiated by the restricted flexion ROM that moderates the intervertebral disc bulging; behavior in extension was unchanged compared to INJURY1, as a consequence of the fact that the artificial ligament has no compressive stiffness.

A proper biomechanical behavior of an intervertebral functional unit is not restricted to spinal ranges of motion correctly restored: the quality and the pattern of motion are also of great importance. Hence, alterations of the kinematics can induce long-term complications, such as arthrosis or instability. Spinal patterns of motion can be described using mean centers of rotation (MCR) position, which are abundantly reported in flexion-extension [42]. In the present study, mean MCR position during intact flexion-extension was close to the superior endplate of L5, in the posterior half of the vertebral body; this location was comparable to the MCR reported by Tournier et al [30] in an *in vivo* study, at the L4-L5 level. Following both INJURY1 and INJURY2, a mild upward shift of mean MCR position was recorded during the entire trajectory from full extension to full flexion; postero-anterior position remained unchanged. Charles et al. [25] had also reported a vertical shift of MCR after performing a medial facetectomy. Once instrumented, MCR moved posteriorly; this shift was more important with the presence of the artificial ligament than without it. Presumably posterior constraint by the artificial ligament reduces normal distraction of the posterior elements in flexion and anterior migration of the instant axis of rotation and shifts the fulcrum

of rotation closer to the implant. A more posteriorly located implant (such as an interspinous positioned device) would have a more posterior fulcrum, leading to less anterior migration of the center of rotation in flexion and more abnormal segmental movement. Specifically, if the axes of rotation are modified by surgery, the physiological load sharing system prevailing in a native spinal vertebral unit may change, inducing stresses distribution in the structures that can differ in direction and amplitudes.

In a retrospective study on patients with herniated disc operated on by microdiscectomy with or without the placement of the Intraspine, Authors underlined the ability of the prosthesis to favourably influence the outcome as regard to the low back pain recurrence, and its capacity to prevent the rapid collapse of the disc space also supporting the discal pump [24]. Other recent publications certify the good results of Intraspine after failure of conservative therapy and as a first choice over more invasive surgical operations, especially in the first phases of degenerative cascade in order to slow down its natural evolution [27].

## 6. Conclusion

The effect of an anteriorly located interlaminar device was investigated. Increases in segmental flexion and intradiscal pressure following injury were reduced by the implant particularly when the artificial ligament was also applied. The implant reduced intradiscal pressure in extension, regardless of the artificial ligament, without blocking extension range. The device did not mitigate increases in segmental torsion and lateral bending following injury. The implant led to a small posterior migration of the mean center of rotation, particularly when the artificial ligament was used, but this may be less than expected due to the interlaminar location.

This study yields a better understanding of the effect of an interlaminar implant, with its unique anterior location, on segmental biomechanics, allowing some comparison to be made with similar *in vitro* testing of interspinous devices. A large clinical trial would be useful to confirm that the observed *in vitro* biomechanical effects of the implant are replicated *in vivo*.

## References

- [1] J. Anandjiwala, J. Y. Seo, K. Y. Ha, I. S. Oh, and D. C. Shin, Adjacent segment degeneration after instrumented posterolateral lumbar fusion: a prospective cohort study with a minimum five-year follow-up, *European Spine Journal*, **20**, no. 11, 1951–1960, (2011).
- [2] P. Park, H. J. Garton, V. C. Gala, J. T. Hoff, and J. E. McGillicuddy, Adjacent segment disease after lumbar or lumbosacral fusion: review of the literature, *Spine*, **29**, no. 17, 1938–1944, (2004).
- [3] T. W. Throckmorton, A. S. Hilibrand, G. A. Mencio, A. Hodge, and D. M. Spengler, The impact of adjacent level

- disc degeneration on health status outcomes following lumbar fusion, *Spine*, **28**, no. 22, 2546–2550, (2003).
- [4] S. Hillibrand and M. Robbins, Adjacent segment degeneration and adjacent segment disease: the consequence of spinal fusion, *The Spine Journal*, **4**, S190–S194, (2004).
- [5] N. Boos and J. K. Webb, Pedicle screw fixation in spinal disorders: a European view, *European Spine Journal*, **6**, 2–12, (1997).
- [6] H. M. Mayer and A. Korge, Non-fusion technology in degenerative lumbar spinal disorders: facts, questions, challenges, *European Spine Journal*, **2**, supplement 11, S85–S91, (2002).
- [7] D. P. Lindsey, K. E. Swanson, P. Fuchs, K. Y. Hsu, J. F. Zucherman, and S. A. Yerby, The effects of an interspinous implant on the kinematics of the instrumented and adjacent levels in the lumbar spine, *Spine*, **28**, no. 19, 2192–2197, (2003).
- [8] K. E. Swanson, D. P. Lindsey, K. Y. Hsu, J. F. Zucherman, and S. A. Yerby, The effects of an interspinous implant on intervertebral disc pressures, **28**, no. 1, 26–32, (2003).
- [9] G. Guizzardi and P. Petrini, DIAM Spinal stabilization system, in *Motion Preservation Surgery of the Spine: Advanced Techniques and Controversies*, 519–522, Saunders Elseviers, 2007.
- [10] R. Gunzburg, Laminarthrectomy, *European Spine Journal*, **18**, no. 12, 1993–1994, (2009).
- [11] F. C. Tamburrelli, L. Proietti, and C. A. Logroscino, Critical analysis of lumbar interspinous devices failures: a retrospective study, *European Spine Journal*, **20**, supplement 1, S27–S35, (2011).
- [12] F. Hartmann, S. O. Dietz, H. Hely, P. M. Rommens, and E. Gercek, Biomechanical effect of different interspinous devices on lumbar spinal range of motion under preload conditions, *Archives of Orthopaedic and Trauma Surgery*, **131**, no. 7, 917–926, (2011).
- [13] H. J. Wilke, J. Drumm, K. Häussler, C. Mack, W. I. Steudel, and A. Kettler, Biomechanical effect of different lumbar interspinous implants on flexibility and intradiscal pressure, *European Spine Journal*, **17**, no. 8, 1049–1056, (2008).
- [14] S. W. Park, T. J. Lim, and J. Park, A biomechanical study of the instrumented and adjacent lumbar levels after in-space interspinous spacer insertion, *Journal of Neurosurgery: Spine*, **12**, no. 5, 560–569, (2010).
- [15] T. Kai-Jow, M. Hideki, G. L. Lavery, and W. C. Hutton, A biomechanical evaluation of an interspinous device (Coflex Device) used to stabilize the lumbar spine, *Paradigm Spine Journal*, **1**, 1–4, (2006).
- [16] S. M. Kabir, S. R. Gupta, and A. T. Casey, Lumbar interspinous spacers: a systematic review of clinical and biomechanical evidence, *Spine*, **35**, no. 25, E1499–E1506, (2010).
- [17] R. Sobottke, M. Röllinghoff, J. Siewe, et al., Clinical outcomes and quality of life 1 year after open microsurgical decompression or implantation of an intraspinal stand-alone spacer, *Minimally Invasive Neurosurgery*, **53**, no. 4, 179–183, (2010).
- [18] G. M. V. Barbagallo, G. Olindo, L. Corbino, and V. Albanese, Analysis of complications in patients treated with the Xstop interspinous process decompression system: proposal for a novel anatomic scoring system for patients selection and review of literature, *Neurosurgery*, **65**, no. 1, 111–120, (2009).
- [19] D. H. Kim, M. Tantsorski, J. Shaw, et al., Occult spinous process fractures associated with interspinous process spacers, *Spine*, **36**, no. 16, E1080–E1085, (2011).
- [20] L. M. Schulte, J. R. O'Brien, L. E. Matteini, and W. D. Yu, Change in sagittal balance with placement of an interspinous spacer, *Spine*, **36**, no. 20, 1302–1305, (2011).
- [21] F. Anasetti, F. Galbusera, H. N. Aziz, C. M. Bellini, A. Addis, T. Villa, M. Teli, A. Lovi, and M. Brayda-Bruno, Spine stability after implantation of an interspinous device: an in vitro and finite element biomechanical study, *Journal of Neurosurgery: Spine*, **13**, no. 5, 568–575, (2010).
- [22] R. J. Crawford, R. I. Price, and K. P. Singer, The effect of interspinous implant surgery on back surface shape and radiographic lumbar curvature, *Clinical Biomechanics*, **24**, no. 6, 467–472, (2009).
- [23] A. Gloria, R. De Santis, L. Ambrosio, F. Causa, and K. E. Tanner, A multi-component fiber-reinforced PHEMA-based hydrogel/HAPEXTM device for customized intervertebral disc prosthesis, *Journal of Biomaterials Applications*, **25**, no. 8, 795–810, (2011).
- [24] O. V. Corriero, R. Morichi, A. Vagaggini, L. Paoli, and G. Guizzardi, Lumbar herniated disc treated by microdiscectomy alone or microdiscectomy plus an interlaminar shock absorbing device: retrospective study with minimum 3-years follow-up, *Journal of Spine*, **3**, p. 159, (2014).
- [25] Y. P. Charles, S. Persohn, J. P. Steib, C. Mazel, and W. Skalli, Influence of an auxiliary facet system on lumbar spine biomechanics, *Spine*, **36**, no. 9, 690–699, (2011).
- [26] H. -J. Wilke, K. Wenger, and L. Claes, Testing criteria for spinal implants: recommendations for the standardization of in vitro stability testing of spinal implants, *European Spine Journal*, **7**, 148–154, (1998).
- [27] G. Guizzardi and P. Petrini, Biomechanical consideration on posterior motion preservation systems. Interspinous versus interlaminar devices, *Columna*, **1**, no. 2, 31–38, (2011).
- [28] L. Humbert, J. A. De Guise, B. Aubert, B. Godbout, and W. Skalli, 3D reconstruction of the spine from biplanar X-rays using parametric models based on transversal and longitudinal inferences, *Medical Engineering & Physics*, **31**, no. 6, 681–687, (2009).
- [29] G. Guizzardi, R. Morichi, S. Pradella, B. Piccardi, E. Amoruso, M. Ceccarelli, C. M. Mattioli, M. Spezia, and P. Petrini, IntraSPINE, an interlaminar, not interspinous, posterior motion preservation device in lumbar DDD: indications and clinical results (over 2 year follow-up), *Neurocirurgia*, **18**, 13–19, (2011).
- [30] C. Tournier, S. Aunoble, J. C. Le Huec, et al., Total disk arthroplasty: consequences for sagittal balance and lumbar spine movement, *European Spine Journal*, **16**, no. 3, 411–421, (2007).
- [31] V. Lafage, F. Schwab, S. Vira, A. Patel, B. Ungar, and J. P. Farcy, Spino-pelvic parameters after surgery can be predicted: a preliminary formula and validation of standing alignment, *Spine*, **36**, no. 13, 1037–1045, (2011).
- [32] I. Yamamoto, M. M. Panjabi, T. Crisco, and T. Oxland, Three-dimensional movements of the whole lumbar spine and lumbosacral joint, *Spine*, **14**, no. 11, 1256–1260, (1989).
- [33] M. Mimura, M. M. Panjabi, T. R. Oxland, J. J. Crisco, I. Yamamoto, and A. Vasavada, Disc degeneration affects the multidirectional flexibility of the lumbar spine, *Spine*, **19**, no. 12, 1371–1380, (1994).
- [34] P. D. Fuchs, D. P. Lindsey, K. Y. Hsu, J. F. Zucherman, and S. A. Yerby, The use of an interspinous implant in conjunction with a graded facetectomy procedure, *Spine*, **30**, no. 11, 1266–1274, (2005).

- [35] K. Abumi, M. M. Panjabi, K. M. Kramer, J. Duranceau, T. Oxland, and J. J. Crisco, Biomechanical evaluation of lumbar spinal stability after graded facetectomies, *Spine*, **15**, no. 11, 1142–1147, (1990).
- [36] V. Lafage, N. Gangnet, S. J. S n gas, F. Lavaste, and W. Skalli, New interspinous implant evaluation using an in vitro biomechanical study combined with a finite-element analysis, *Spine*, **32**, no. 16, 1706–1713, (2007).
- [37] H. Graf, Lumbar instability surgical treatment without fusion: soft system stabilization, *Rachis*, **4**, 123–137, (1992).
- [38] D. Sartoris, D. Resnick, R. Tyson, and P. Haghghi, Age-related alterations in the vertebral spinous processes and intervening soft tissues: radiologic-pathologic correlation, *American Journal of Roentgenology*, **145**, no. 5, 1025–1030, (1985).
- [39] G. Keorochana, C. Taghavi, S. T. Tzeng, K. B. Lee, J. C. Liao, J. H. Yoo, and C. J. Wang, MRI classification of interspinous ligament degeneration of the lumbar spine: intraobserver and interobserver reliability and the frequency of disagreement, *European Spine Journal*, **19**, 1740–1745, (2010).
- [40] C. E. W. Aylott, R. Puna, P. A. Robertson, and C. Walker, Spinous process morphology: the effect of ageing through adulthood on spinous process size relationship to sagittal alignment, *European Spine Journal*, **21**, 1007–1012, (2012).
- [41] W. Schmoelz, J. F. Huber, T. Nydegger, L. Claes, and H. J. Wilke, Influence of a dynamic stabilisation system on load bearing of a bridged disc: an in vitro study of intradiscal pressure, *European Spine Journal*, **15**, no. 8, 1276–1285, (2006).
- [42] M. J. Pearcy and N. Bogduk, Instantaneous axes of rotation of the lumbar intervertebral joints, *Spine*, **134**, 1033–1041, (1988).

Editor-in-Chief  
Mostafa Z. Badr, USA

Geographical Editors  
Christopher Corton, USA  
Jörg Mey, Spain  
Marcelo H. Napimoga, Brazil  
Nanping Wang, China

#### Associate Editors

Leggy A. Arnold, USA  
Yaacov Barak, USA  
Thomas Burris, USA  
Ignacio Camacho-Arroyo, Mexico  
John Cidlowski, USA  
Lluís Fajas Coll, Switzerland  
Frédéric Flamant, France  
Mario Galigniana, Argentina  
Jan-Åke Gustafsson, USA  
Anton Jetten, USA  
Stafford Lightman, UK  
Jian-xing Ma, USA  
Sridhar Mani, USA  
Iain J. McEwan, UK  
Antonio Moschetta, Italy  
Bryce M. Paschal, USA  
Didier Picard, Switzerland  
Ralph Rühl, Hungary  
Bart Staels, France  
Jiemin Wong, China  
Wen Xie, USA

#### Editorial Board

Brian J. Aleskievich, USA  
Jeffrey Arterburn, USA  
Frank Beier, Canada  
Robert G. Bennett, USA  
Carlos Bocos, Spain  
Julius Brtko, Slovakia  
Moray Campbell, USA  
Thomas Chang, Canada  
Taosheng Chen, USA  
Hueng-Sik Choi, Republic of Korea  
Colin Clyne, Australia  
Austin Cooney, USA  
Pietro Cozzini, Italy  
Maurizio Crestani, Italy  
Paul D. Drew, USA  
Nouridine Faresse, Switzerland  
Grace Guo, USA  
Heather Hostetler, USA  
Wendong Huang, USA  
Young Jeong, USA  
Hiroki Kakuta, Japan  
Yuichiro Kanno, Japan  
Jae B. Kim, Republic of Korea  
Douglas Kojetin, USA  
Christopher Lau, USA  
Antigone Lazou, Greece  
Chih-Hao Lee, USA  
Xiaoying Li, China  
Yong Li, China  
Nick Z. Lu, USA  
Makoto Makishima, Japan  
Goldis Malek, USA  
Shaker A. Mousa, USA  
Zafar Nawaz, USA  
Noa Noy, USA  
Sergio A. Oñate, Chile  
Eric Ortlund, USA  
Richard P. Phipps, USA  
Eric Prossnitz, USA  
Brian G. Rowan, USA  
Enrique Saez, USA  
Edwin R. Sanchez, USA  
Andrea Sinz, Germany  
Knut Steffensen, Sweden  
Cecilia Williams, USA  
Bingfang Yan, USA  
Xiao-kun Zhang, USA  
Chun-Li Zhang, USA  
Changcheng Zhou, USA

# Nuclear Receptor Research

## About the Journal

*Nuclear Receptor Research* is a peer-reviewed open access journal that publishes high-quality, original research and review articles covering all aspects of research involving all members of the nuclear receptor superfamily.

The editorial board of *Nuclear Receptor Research* has over 70 scientists representing a wide-scope of interest and expertise in the field, from 20 countries around the world.

*Nuclear Receptor Research* has a fully automated Manuscript Management System (MMS) which makes submission and reviewing as well as tracking of manuscripts an easy, efficient and prompt process to the advantage of the authors. Published articles in *Nuclear Receptor Research* are available in different formats including full-text HTML, full-text PDF, full-text ePUB, full-text XML, and Mobi.

## Free Advertising

100% Free of Charge

Advertise, in *Nuclear Receptor Research*, positions available in your laboratory, a position you are seeking, supplies and equipment as well as meetings and conferences related to the field of nuclear receptor research.

For more information about advertising in *Nuclear Receptor Research* please visit the journal website at: <http://www.agialpress.com/journals/nrr/>

For advertising in *Nuclear Receptor Research* please send your ad to [nrr.ad@agialpress.com](mailto:nrr.ad@agialpress.com)

## Contact

Editor-in-Chief: [badrm@umkc.edu](mailto:badrm@umkc.edu)

Editorial Office: [nrr@agialpress.com](mailto:nrr@agialpress.com)

