

## Biomechanical Behavior of L3-L5 Vertebrae in Six Cadaveric Spines of Fusion Cage with or without Posterolateral and Bilateral Instrumentation

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### Abstract

**Study Design:** *In vitro* biomechanical study. Purpose: This study compared intervertebral motion segment biomechanical behavior in various situations.

**Overview of Literature:** Unilateral pedicle screw systems have demonstrated clinical results equivalent to those of bilateral pedicle screw systems. However, few biomechanical studies of unilateral pedicle screw systems have been performed.

**Methods:** The *in vitro* study involved 6 fresh human cadaveric spines. The ENSAM (Ecole Nationale Supérieure d'Arts et Métiers) procedure and the 2TM (2 têtes micrométriques) spin segment testing machine were used. The test device and protocol are labeled by a quality certification NF EN ISO/CEI 17025.

**Results:** In the *in vitro* study, posterior instrumentation induced systematic reduction of motion for the bilateral and unilateral constructs in all situations.

**Conclusions:** The *in vitro* experimental study enabled the comparison of segment behavior between instrumented and intact segments. Additional posterior CLARIS instrumentation also induced a reduction of ROM, with regard to intact segments, for the 3 types of loads. Then, this decrease of ROM is slightly higher important with bilateral instrumentation than unilateral one. Moreover, unilateral CLARIS instrumentation induced an increase of the coupling motion in lateral bending.

**Keywords:** Spine; *In Vitro* Study; Unilateral Pedicle Screw Fixation; Bilateral Pedicle Screw Fixation; Biomechanical Behavior of Lumbar Spine

### Abbreviations

ENSAM: Ecole Nationale Supérieure d'Arts et Métiers; FSU: Function Spinal Unit; PLIF: Posterior Lumbar Interbody Fusion; ROM: Range of Motion; TLIF: Transforaminal Lumbar Interbody Fusion

### Introduction

Unilateral pedicle screw systems have demonstrated clinical results equivalent to those of bilateral pedicle screw systems. However, few biomechanical studies of unilateral pedicle screw systems have been performed. Therefore, this study compared the intervertebral motion segment biomechanical behavior between the standalone posterolateral single threaded fusion cage (TFC<sup>®</sup>) compared to unilateral and bilateral CLARIS<sup>®</sup> posterior pedicle screw instrumentation. The *in vitro* experimental study involved spinal segments of L3-L5 from 6 fresh human cadaveric spines. Three-dimensional load-displacement curves were assessed in flexion-extension, lateral bending, and torsion, first for intact segments and then for each implant configuration.

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## Materials and Methods

### Experimental study

#### Specimens

Six fresh human cadaveric spines (designated R1-R6, respectively) were used. The cadavers ages ranged from 54 - 67 years, with a mean of 61 years. Segments L3-L5 were used. Radio sterilization with p-rays at 2.5 Mrad was performed before tests. Specimens were sealed hermetically into plastic bags and frozen at -20°C until use. They were then thawed at 4°C for 8 - 12 hours and kept at room temperature at least 30 minutes before testing. Vertebral segments were cleaned of extraneous soft tissues, taking care to keep ligaments, discs, and joint capsules intact. In order to avoid dehydrating the tissues, the specimens were kept moist by a water spray and tests were performed at room temperature.

#### Testing procedures

The ENSAM (Ecole Nationale Supérieure d'Arts et Métiers) procedure and 2TM (2 têtes micrométriques) spine segment testing machine were used, as shown in figure 1. The test device and protocol are labeled by a quality certification NF EN ISO/CEI 17025. Briefly, the lower vertebra was fixed in a container using MCP70 low-fusion-point alloy. To improve fixation, wood screws were fixed on the vertebral body before flowing the alloy.



**Figure 1:** 2TM spine segment testing machine. The test device and protocol are labeled by a quality certification NF EN ISO/CEI 17025.

The six 3D vertebral displacements (3 linear and 3 angular) were measured using a stirrup linked to 2 micrometric heads comprising 6 linear displacement sensors and an angular one. The stirrup was fixed on the upper vertebral body of interest (L4 for the L3-L5 specimens) using 3 screws while insuring approximate coincidence between the stirrup axes and vertebral body. Measurement accuracy was controlled to  $\pm 0.5$  mm for linear displacements and  $\pm 0.5^\circ$  for rotation.

Loads were applied to the upper vertebra using 220-g dead weights, loading bars, cables, and pulleys in order to apply quasi-static moments of flexion-extension, lateral bending, and torsion. Bars were fixed on the upper vertebra using a frame pressing on the pedicles and upper vertebral body. The loading system did not restrain any vertebral motion. Loads were applied in 1-N•m steps until a maximum of 8 N•m. The loading mode consisted of a complete cycle of loading, unloading, reverse loading (i.e. in the opposite direction), and unloading.

## Implants

Two types of implants were investigated: (1) TFCs sized to the specimen (12 or 14 mm diameter, 21 or 26 mm length), which were placed on the posterolateral; and (2) unilateral or bilateral posterior CLARIS instrumentation (rod and screws diameter: 6 mm).

## Testing protocol

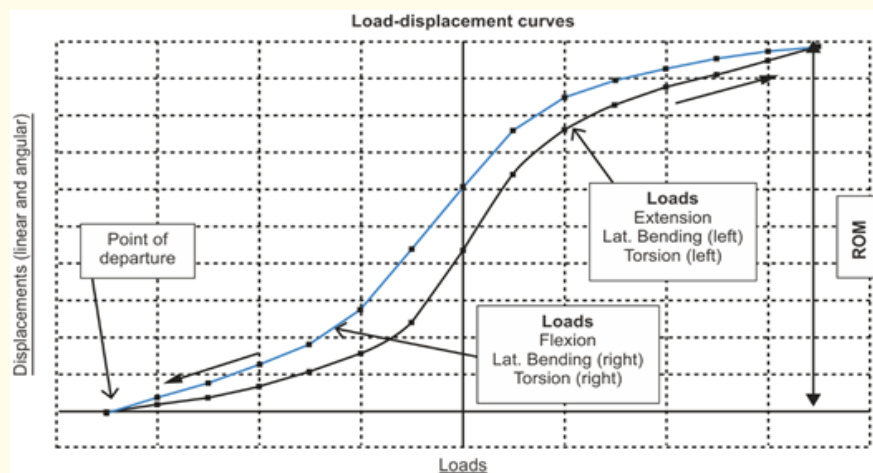
Each specimen was first tested intact. Then, the implants were installed, and the specimen was retested. The testing protocol was as follows: (1) intact; (2) posterolateral TFC inserted from the right-hand side by using transforaminal lumbar interbody fusion (TLIF) procedure; (3) posterolateral TFC with posterior unilateral CLARIS instrumentation (right-hand side) with the left side intact; (4) posterolateral TFC with posterior bilateral CLARIS instrumentation.

Range of motion (ROM) and segment stiffness were calculated from the resultant load-displacement curves in each situation.

## Results and Discussion

### Experimental results

All tests could be performed to the expected 8 N·m loading in all configurations. A typical load-displacement curve from which the ROM was extracted in each case is shown in figure 2.



**Figure 2:** Load-displacement curve.

### Flexion-extension

Flexion-extension motion ranged from 7 - 12° (mean 10°) for intact specimens, as shown in figure 3. For the TFC, motion ranged from 6 - 13° (mean 10°), with a reduction of mobility with regard to intact segments in 3 cases. Additional posterior instrumentation induced a systematic reduction of motion. The ROM was 2 - 5° (mean 4°) and from 3 - 7° (mean 5°) for bilateral and unilateral constructs, respectively. Moreover, a specific coupling motion was observed for instrumentation (frontal rotation ranged from 1 - 4°).

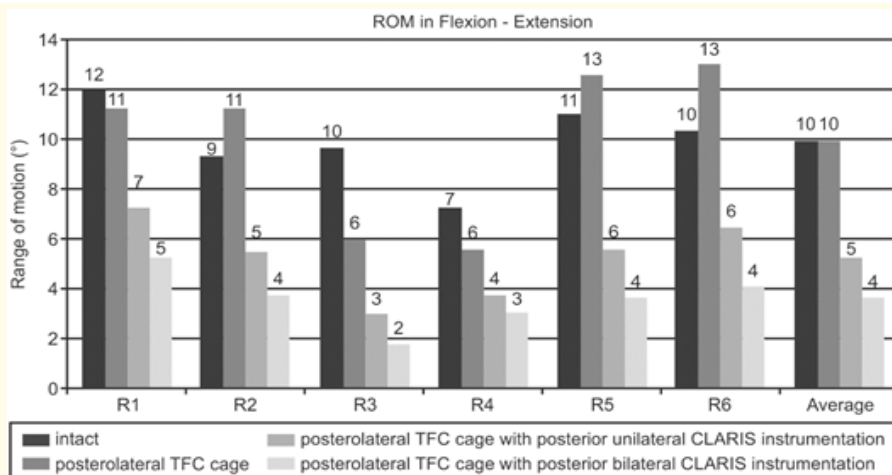


Figure 3: ROM in flexion-extension.

### Left-right lateral bending

Left-right lateral bending motion ranged from 8 - 16° (mean 11°) for intact specimens, as shown in figure 4. For TFC, motion ranged from 5 - 14° (mean 10°), with a reduction of mobility with regard to intact segments in 3 cases. The variation of motion with regard to intact spine ranged from -4° to +4°. Additional posterior instrumentation induced a systematic reduction of motion. Instrumented segment motion ranged from 2 - 9° (mean 4°) and from 3 - 12° (mean 8°) for bilateral and unilateral constructs, respectively.

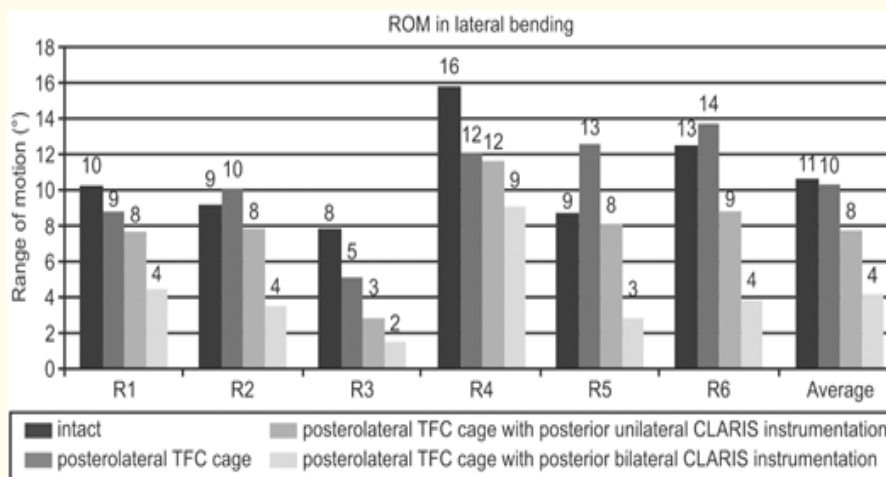
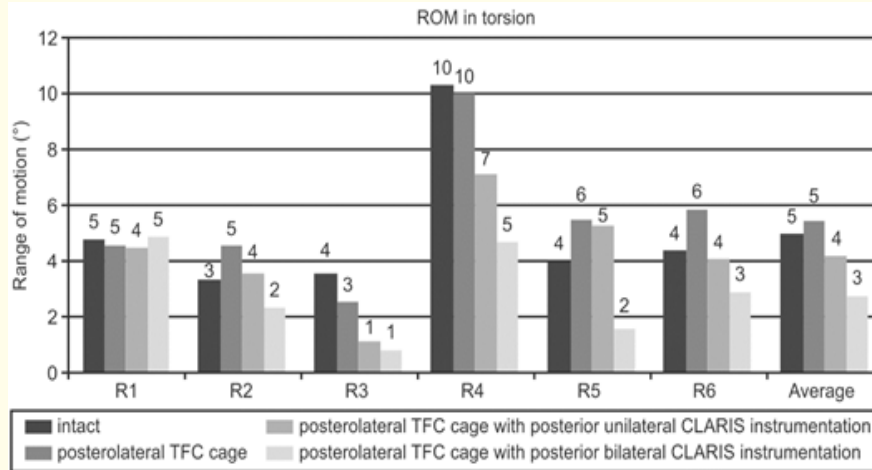


Figure 4: ROM in lateral bending.

### Left-right axial torque

Left-right axial torque motion ranged from 3° - 10° (mean 5°) for intact specimens, as shown in figure 5. For TFC, motion ranged from 3 - 10° (mean 5°), with a slight reduction of mobility with regard to intact segments in 3 cases. The variation of motion with regard to intact spine ranged from -1° to +2°. Instrumented segment motion ranged from 1 - 5° (mean 3°) and 1 - 7° (mean 4°) for bilateral and unilateral constructs, respectively.



**Figure 5: ROM in torsion.**

Our *in-vitro* study allows us to compare segment behavior between instrumented segments and intact ones. For TFC cage, there is slight decrease of ROM with regard to intact segments in flexion, extension and lateral bending. But no significant evolution concerning axial torque. Moreover, a slight decrease of coupling motion in left-right axial torque. Additional posterior CLARIS instrumentation also induced a reduction of ROM, with regard to intact segments, for the 3 types of loads. Then, this decrease of ROM is slightly higher important with bilateral instrumentation than unilateral one. Moreover, unilateral CLARIS instrumentation induced an increase of the coupling motion in lateral bending. Bilateral CLARIS induced an important decrease of ROM in left-right axial torque (Table 1).

	<b>Flexion-Extension</b>	<b>Left-light lateral bending</b>	<b>Left-right axial torque</b>
Posterolateral TFC cage / INTACT	+26% to -39% (+2° to -4°)	+45% to -35% (+4° to -4°)	+38% to -29% (+2° to -1°)
Posterolateral TFC cage+posterior unilateral Claris instrumentation / INTACT	-38% to -70% (-3° to -7°)	-7% to -64% (-1° to -5°)	+33% to -69% (+1° to -3°)
Posterolateral TFC cage+posterior bilateral Claris instrumentation / INTACT	-56% to -82% (-4° to -8°)	-42% to -81% (-5° to -9°)	+2% to -77% (0° to -5°)

**Table 1: Evolution of ROM in each configuration and loads.**

In the late 1970s, Panjabi, *et al.* developed a 3D model for analyzing the motion and stability of the spine. Until the late 1990s, almost all spine levels had been investigated by *in vitro* biomechanical studies. Furthermore, *in vivo* biomechanical studies such as motion analysis and *in vivo* load measurement have also progressed; however, they have advanced less than *in vitro* studies. A clear understanding of the anatomy and biomechanics at each spine level is important to provide appropriate treatment for a wide variety of spine diseases.

**Intervertebral motion and coupled motion**

Spinal column motion is generated by the summation of several intervertebral motion segments, each involving 2 adjacent vertebrae; motion cannot be realized by single motion segment. In other words, each motion segment contributes to the motion of the spinal column.

The loads applied to each motion segment are quantified into 12 components comprising 6 moments around and 6 translational forces along the x, y, and z axes. The ROM of each load condition is primarily determined by the structure of the articular surface of the facet

joint. In principle, the cervical spine allows for flexion, extension, lateral bending, and rotation; the thoracic spine allows for lateral bending, rotation, and slight flexion and extension; and the lumbar spine allows for flexion, extension, and lateral bending. White and Panjabi investigated the ROM at each spine level and report that the ROMs of flexion and extension are greater in the cervical and lumbar regions; meanwhile, the ROMs of lateral bending are not significantly different among regions, and those for rotation are limited in the lumbar region [1].

Two adjacent vertebral bodies, the intervertebral disc separating them, and the ligaments connecting them make up the basic motion unit of the spinal column. This motion unit is also known as the function spinal unit (FSU). Spine biomechanics can be investigated according to the three-dimensional kinematic response of the FSU. Most previous studies have focused on the functional anatomy and biomechanics of the FSU, particularly in the lumbar region as it is subjected to greater load than the upper parts. The three-dimensional motion of each segment can be analyzed using the right-handed orthogonal coordinate system. The motion is described as a combination of rotation (around the 3 axes) and translation (along the 3 axes) [1]. The motion of each segment is a complex combination of main motion (rotation) and coupled motion (translation). The ROM and motion pattern of each FSU is determined by the shape, ligaments, and viscoelasticity of the intervertebral disc. Panjabi, *et al.* [2] conducted an *in vitro* study of coupled motion. Regarding *in vivo* studies, a research group at Osaka University studied the coupled motion associated with rotation around the long axis of the spinal column and lateral bending from the cervical to lumbar spine [3-6].

### Spinal column stability

The spinal column is supported by intrinsic factors (i.e. intrinsic stabilizers) and extrinsic factors (i.e. extrinsic stabilizer). The intrinsic factors are divided into anterior and posterior elements. The anterior elements include vertebral body, vertebral disc, and anterior and posterior longitudinal ligaments. Meanwhile, the posterior elements include the facet joint, ligamentum flavum, vertebral arch, spinous process, and supraspinous and interspinous ligaments. Differences in the shapes of facet joints among spine levels are the major factor influencing the motion of each FSU [7-10].

Extrinsic factors (i.e. control by the neuromuscular system) also play an important role in stabilizing the spinal column. Lucas, *et al.* [11] demonstrate that the spinal column (i.e. ligamentous spine) is extremely unstable when the trunk muscles and thorax are removed and that it is easily deformed by a small external force. However, it is noteworthy that most previous studies of spine stability are *in vitro* studies. The major shortcoming of *in vitro* studies is that control by the neuromuscular system cannot be analyzed.

Nevertheless, intrinsic factors play a smaller role in intervertebral stability in *in vivo* studies (under the control of the neuromuscular system) than the conditions in *in vitro* studies. When the magnitudes of an intrinsic factor for spinal stability are parameterized as  $x$  and those of the other intrinsic factor as  $X$ , the stability of the ligamentous spine (*in vitro*) without neuromuscular system control is expressed as  $X + x$ . When the magnitudes of neuromuscular control are parameterized as  $Y$ , the stability of spine *in vivo* is expressed as  $X + x + Y$ . Accordingly,  $x / (X + x) > x / (X + x + Y)$ . Thus, an intrinsic factor  $x$  plays a greater role in spinal stability in *in vitro* studies than *in vivo* studies.

To date, few studies have investigated the role of the neuromuscular system in spinal stability. If the results of experiment using human cadaveric spines are directly applied to the living body, the role of each intrinsic factor will be overestimated; our experimental study is not an exception, and thus the results should be interpreted cautiously. In addition, many *in vitro* studies used only a single cadaveric spine specimen. Therefore, it is difficult to determine whether the results from such studies are due to deformation behavior unique to the specimen or if they can be generalized to the behavior of human spine in general. On the other hand, our study used 6 cadaveric specimens after careful examination of their quality. Therefore, our findings can be generalized to the actual behavior of the human lumbar spine, although further studies using more samples should be performed.

On the basis of the findings of biomechanical studies on spinal stability, spinal instrumentation has been applied to keep the spine rigid after spinal fusion surgery in clinical practice. Lumbar fusion with pedicle screw instrumentation became widely used in the late 1980s. The effect of intervertebral fusion is greatest on the immediately adjacent intervertebral motion segments. In addition, the effect



is greater in rotated positions (i.e. flexion, extension, lateral bending, left and right rotation, and rotation around the long axis) than in the normal spinal alignment. Oda, *et al.* [12] performed an *in vivo* experiment examining the effects of spinal fusion and kyphotic deformity; they found that kyphotic posterolateral fusion causes abnormal stress distribution in the adjacent motion segment and early degenerative changes in the facet joint. In addition, Sudo, *et al.* [13] report that the construct stiffness and increased number of fused segments in the reconstruction method are associated with increased adjacent-level intradiscal pressure and laminar strain. Hussain, *et al.* [14], who used a finite element method, report cervical fusion is associated with increased intradiscal pressure at the segments immediately superior and inferior to the multiple fusion and increased load to the facet joints.

Minimally invasive TLIF has recently become widely used as a lumbar interbody fusion technique. More recently, TLIF with unilateral pedicle screw fixation was developed as an even less invasive procedure [15,16]. The TLIF with unilateral fixation procedure requires resection of the facet joint. Studies comparing spine stability after unilateral pedicle screw fixation with the conventional bilateral fixation procedure report the unilateral fixation procedure is useful and effective [17-22]. TLIF with unilateral fixation has the advantages of reduced operation time, insertion error rate, and cost. Furthermore, the unilateral fixation procedure is also reported to be effective in for 1- or 2-level fixation [17,18]. Goel, *et al.* [17] report unilateral fixation is less rigid and less likely to reduce stress shielding of the vertebral bodies than bilateral fixation. Chen, *et al.* [19] conducted a biomechanical study comparing the effects of posterior lumbar interbody fusion (PLIF, 2 cages) with unilateral fixation (2 cages) in pigs. They found no significant differences in compression, extension, lateral bending, or axial rotation between procedures; meanwhile, there was a significant difference in flexion, although the stiffness was more preserved than in the controls. Harris, *et al.* [18] conducted a biomechanical study of TLIF with unilateral fixation and report the fixation strength is sufficiently preserved in flexion, extension, and lateral bending but deficient in rotation; therefore, they suggest spinal stability reconstruction may not be effective in preserving rotation. A comparative study of the flexibility of L4/5 between bilateral and unilateral fixation procedures using a human anatomical model indicates that the fixation strength of unilateral fixation in flexion, lateral bending, and rotation is half, similar, and inferior to those of bilateral fixation, respectively [21]. In addition, Zhao, *et al.* [22] report TLIF with unilateral fixation using 1 cage is more biochemically rigid than PLIF with bilateral pedicle screw fixation. In contrast, Slucky, *et al.* [23] report that the stiffness of unilateral fixation is half that of bilateral fixation and that the fixation strength is weak when in a rotated position.

The present experimental study did not examine the effects of cage shape or positioning. Two types of cages are clinically available: boomerang- and box-shaped cages. Kettler, *et al.* [24] conducted a biomechanical study examining the effects of cage shape and report that the stability after implantation of boomerang-shaped cages did not differ significantly from that of 2 PLIF box-shaped cages after implantation. Regarding the effects of cage positioning, Polly, *et al.* [25] recommend anterior positioning to maintain mechanical stability and normal anterior curvature. However, in clinical practice, cages are often positioned at the depression area of the endplate because of the anatomical shape of the endplate in the vertebral body, although this positioning does not provide good stability [26]. Therefore, further biomechanical studies on the effects of cage shape and positioning are required.

We are planning similar experiments using cages with different heights and shapes. The cortical bone trajectory technique for lumbar pedicle screw instrumentation is recently becoming increasingly used. Several biomechanical studies report the cortical bone trajectory technique is superior to traditional pedicle screw fixation with respect to screw insertion torque and pullout characteristics [27-29]. The present study used traditional pedicle screw instrumentation. We are planning a biomechanical study to compare the cortical bone trajectory technique and the traditional methods (i.e. bilateral and unilateral fixation) using cadaveric spines.

Additional *in vivo* biomechanical studies are required to clarify the present findings. However, as mentioned previously, if the results of *in vitro* studies are directly applied to *in vivo* conditions in which neuromuscular system control is excluded, the effects of the intrinsic factors on spinal stability will be overestimated. In addition, there are many limitations related to ethical aspects when conducting *in vivo* studies.

### Conclusion

The *in vitro* experimental study enabled the comparison of segment behavior between instrumented intact spine segments. Additional posterior CLARIS instrumentation also induced a reduction of ROM, with regard to intact segments, for the 3 types of loads. Then, this decrease of ROM is slightly higher important with bilateral instrumentation than unilateral one. Moreover, unilateral CLARIS instrumentation induced an increase of the coupling motion in lateral bending.

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None.

### Conflict of Interest

The authors have no potential conflicts of interest relevant to this article to declare. The engineers of ENSAM were funded to aid this project. Part of the funding went towards operating machines and other equipment within their research department. Funding was provided for research engineer salaries and not for data analysis, manuscript writing, or specific avenues.

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