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The effect of posterior non-fusion instrumentation on segmental shear loading of the lumbar spine

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A B S T R A C T

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Degenerative spondylolisthesis
Facetectomy
Undercutting laminectomy
Non-fusion instrumentation
Anterior shear

Background: Lumbar stenosis and facet osteoarthritis represent indications for decompression and instrumentation. It is unclear if degenerative spondylolisthesis grade I with a remaining disc height could be an indication for non-fusion instrumentation. The purpose of this study was to determine the influence of a mobile pedicle screw based device on lumbar segmental shear loading, thus simulating the condition of spondylolisthesis.

Materials and methods: Six human cadaver specimens were tested in 3 configurations: intact L4–L5 segment, then facetectomy plus undercutting laminectomy, then instrumentation with lesion. A static axial compression of 400 N was applied to the lumbar segment and anterior displacements of L4 on L5 were measured for posterior–anterior shear forces from 0 to 200 N. The slope of the loading curve was assessed to determine shear stiffness.

Results: Homogenous load–displacement curves were obtained for all specimens. The average intact anterior displacement was 1.2 mm. After lesion, the displacement increased by 0.6 mm compared to intact ($P=0.032$). The instrumentation decreased the displacement by 0.5 mm compared to lesion ($P=0.046$). The stiffness's were: 162 N/mm for intact, 106 N/mm for lesion, 148 N/mm for instrumentation. The difference was not significant between instrumented and intact segments ($P=0.591$).

Conclusions: Facetectomy plus undercutting laminectomy decreases segmental shear stiffness and increases anterior translational L4–L5 displacement. Shear stiffness of the instrumented segment is higher with the device and anterior displacements under shear loading are similar to the intact spine. This condition could theoretically be interesting for the simulation of non-fusion instrumentation in degenerative spondylolisthesis.

1. Introduction

Lumbar non-fusion instrumentation systems are aimed to reduce the risk of adjacent segment degeneration secondary to fusion [1]. Total disc replacement can be efficiently indicated in low-back pain caused by discopathy. Nevertheless, the load-sharing complex between the disc and facet joints may lead to recidivating pain if additional moderate facet degeneration is not diagnosed preoperatively [2]. This has spawned an interest in

the development of posterior facet preserving non-fusion systems, which may decrease segmental motion without suppressing it [3–5]. Facet resurfacing and replacement devices have been designed to address severe facet osteoarthritis and subsequent stenosis [6].

Instrumentation is required after facetectomy or arthroectomy because of segmental increase of motion in axial rotation and under shear loading [7,8]. *In vitro* studies and finite element models indicate that posterior non-fusion devices could stabilize a lumbar segment and maintain mobility after partial or total facet resection and laminectomy [9–12]. First clinical trials showed that decompression and non-fusion instrumentation might improve back- and leg-pain, and the quality of life in degenerative spondylolisthesis [13–15]. However, these devices are restricted to segments with a sufficient disc height, and it is not clear to what extent

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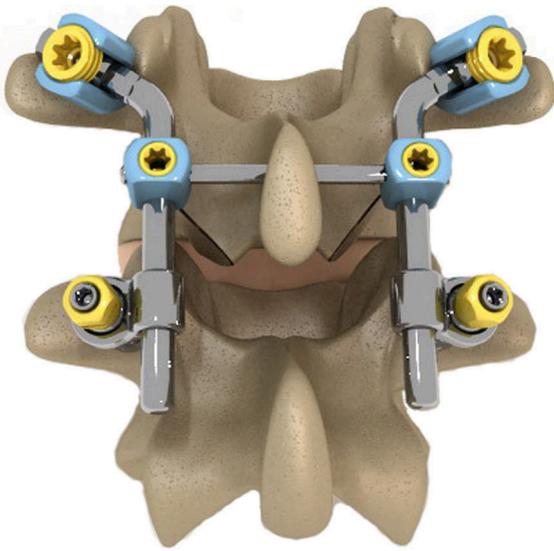


Fig. 1. Non-fusion instrumentation with polyaxial connector linking the rods to caudal screws, thus allowing a three-dimensional movement and stabilization after medial facet resection.

decompression should be performed, since shear forces are transmitted through the implant, which may lead to device-related complications [16].

The NeoFacet™ (Clariance, Dainville, France) represents an implant, which is designed for posterior element supplementation if a facet resection is required in addition to undercutting laminectomy. It might be indicated for low-back pain, mainly due to facet osteoarthritis, and sciatica due to lateral recess and/or foraminal stenosis. This system utilizes four pedicle screws with two angulated rods fixed cranially. This implant is made of implantable grade metal components, which address the anatomical requirements of the segments L3–L4 and L4–L5. Traditional pedicle screw fixation is used. Two rods (30° or 45°) are inserted and fixed at the cranial vertebra using polyaxial pedicle screws. These rods are linked to caudal pedicle screws using a polyaxial connector on each side, which allows movements in flexion-extension, lateral bending and axial rotation. A cross-link connects both rods to each other, thus avoiding excessive axial rotation (Fig. 1). Pedicle screws are manufactured of titanium alloy. A titanium plasma spray coating is

applied to the bone interface surfaces of the screws. The other components of the implant are manufactured from a wear-resistant cobalt-chromium-molybdenum alloy.

A previous *in vitro* study demonstrated that this device could preserve flexibility between lumbar vertebrae while restraining motion in axial rotation after facetectomy [17]. It is also important to investigate the shear behavior of this implant, which may be indicated in degenerative spondylolisthesis grade I with a remaining disc height. The purpose of this study was to determine the influence of non-fusion instrumentation on a lumbar segment under shear loading, thus simulating the conditions of degenerative spondylolisthesis treated by facetectomy plus undercutting laminectomy.

2. Materials and methods

Six fresh-frozen human cadaveric L4–L5 spine segments were tested. The average age of the donors was 73.8 years and ranged from 63 to 84 years. There were 5 males and 1 female. The specimens were freshly dissected, sealed in double plastic bags, frozen, and stored at -20°C until testing. The specimens were thawed to 6°C 12 to 14 hours before starting the preparation process. Soft tissues were removed, leaving all ligaments, joint capsules, discs and bony structures intact. Spinal deformities, damage or severe degeneration of the discs and facet joints were excluded macroscopically and radiographically. Median disc heights were ≥ 7 mm on lateral radiographs. The experiment was performed at room temperature, while using a saline solution (NaCl 0.9%) to moisture the disc.

The cranial half of the L4 vertebral body and the caudal half of the L5 vertebral body were embedded in 2 metal containers using polymethylmetacrylate cement (Technovit 3040; Haerus, Hanau, Germany). The median plane of the L4–L5 disc was aligned with an anterior inclination of 10° with regard to the horizontal plane, thus reproducing its sagittal alignment *in vivo*. Biplane radiographs were used to check the orientation of the specimen. Shear loading tests were conducted in a specific spine-testing device that was designed for this purpose. The caudal container, fixed on L5, was rigidly screwed to a table, while the cranial container, fixed on L4, was mounted to a rail, allowing translation in the sagittal plane. A compressive preload of 400 N was applied to the motion segment [10,11,18,19]. Loads were applied to L4 using dead weights placed at the end of loading bars, cables and pulleys, thus inducing an anterior translation of L4 on L5 (Figs. 2 and 3). This system

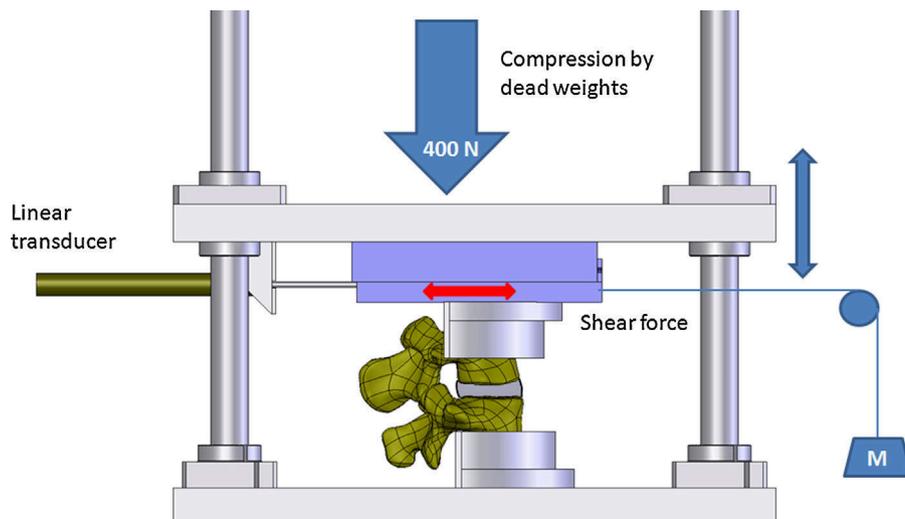


Fig. 2. Experimental setup for *in vitro* shear testing of the L4–L5 segment, with a mobile rail fixed to L4, a linear transducer for measurements of translation of L4 on L5 obtained by anterior traction via a cable and pulley system attached to the rail.

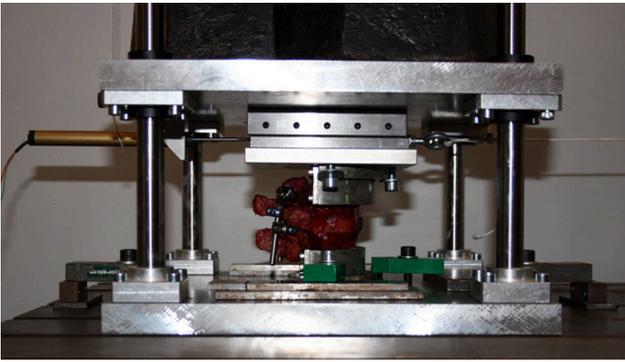


Fig. 3. Instrumented L4-L5 specimen in the spine-testing device.

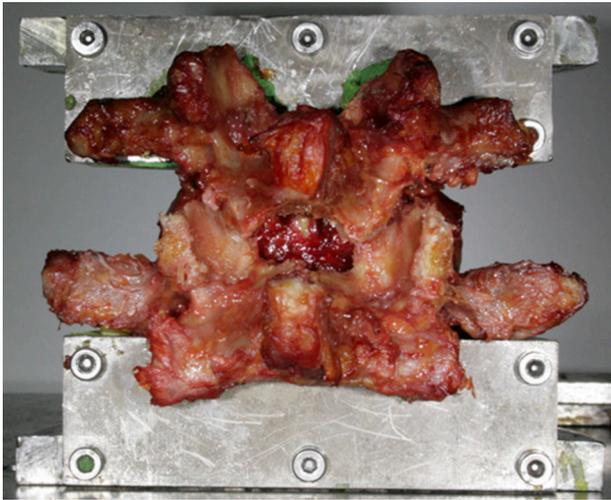


Fig. 4. Lesion applied to L4-L5 by medial facetectomy plus undercutting laminectomy.

allowed applying quasi-static forces in steps of 10 N, with an interval of 15 seconds between each step, until a maximum of 200 N was reached. The maximal anterior displacement and back to neutral position were completed during the same loading-unloading cycle. Three preconditioning cycles were applied to the specimen using the same loading protocol, before the measurement cycle was started. Displacements were measured at the level of the rail using a linear transducer (Vishay Sfernice 50L 4D 202 W00235D 2k Ω ; Vishay Electronic GmbH, Selb, Germany). The measurement accuracy of this system was estimated at 0.1 mm for linear displacements. Load-displacement curves were obtained for loading and unloading cycles. The stiffness was calculated considering the slope of the linear part of the loading curve.

The specimens were tested in 3 configurations: intact specimen, specimen with lesion, instrumented specimen with lesion. The lesion consisted of an L4-L5 medial facetectomy by removing the inferior L4 articular processes. An interlaminar fenestration and yellow ligament resection at the recessus were performed using a Kerisson rongeur, thus simulating an undercutting laminectomy (Fig. 4). The implant was positioned symmetrically between right and left sides. Pedicle screws, with a 6.5 mm diameter and a 45 mm length, were placed parallel to the superior endplate and along a convergent trajectory in the horizontal vertebral plane. The rod system and the polyaxial connectors were mounted to L4 and L5 screws, respectively. Both rods were connected by a rigid cross-link. The position of the implant was documented using biplane radiographs (Fig. 5).

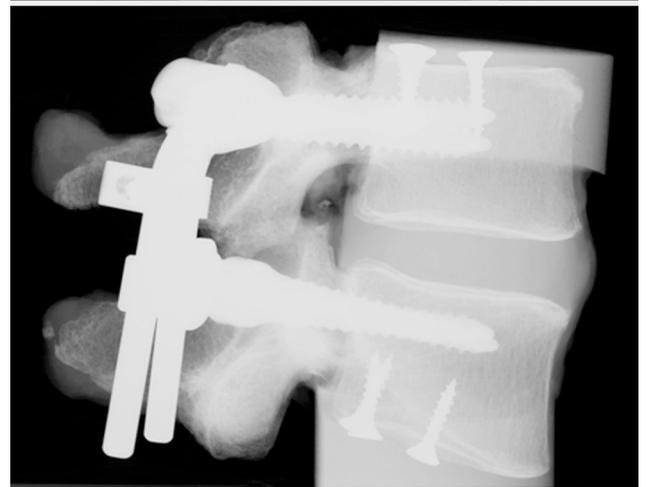
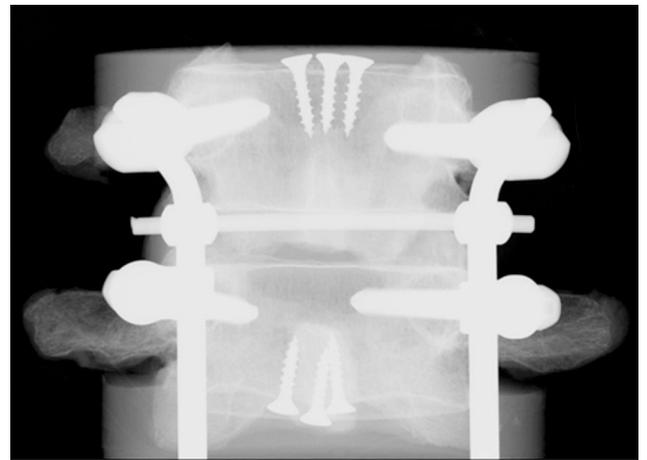


Fig. 5. Antero-posterior and lateral radiographs of instrumented L4-L5 segment with lesion and vertebral bodies embedded in Poly Methyl MethAcrylate (PMMA).

Statistical evaluation was performed with R Software Version 2011 (R Foundation for Statistical Computing, Vienna, Austria). After checking homogeneity of variances using a non-parametric Fligner-Killeen test, the Wilcoxon rank test was used for paired samples to compare maximal displacements and stiffness's between different configurations. Unilateral tests for superiority were used. The significance level was set at 0.05 for all tests.

3. Results

3.1. Displacement

Load-displacement curves were obtained for anterior translation and back to neutral position. A hysteresis phenomenon was observed for each configuration since the unloading curve was not superimposed on the loading curve. Loading curves were comparable for the six intact specimens (Fig. 6). The variances were homogenous for maximal displacements ($P=0.194$). Table 1 demonstrates average, median and extreme values obtained for each configuration. Fig. 7 represents average load-displacement curves and Fig. 8 shows individual values obtained for each specimen. The lesion led to an average increase of 0.6 mm compared to the intact L4-L5 segment ($P=0.032$). The instrumented segment with lesion increased the average displacement by 0.1 mm compared to the intact spine ($P=0.468$). The instrumentation decreased the average displacement by 0.5 mm compared to the lesion alone ($P=0.046$).

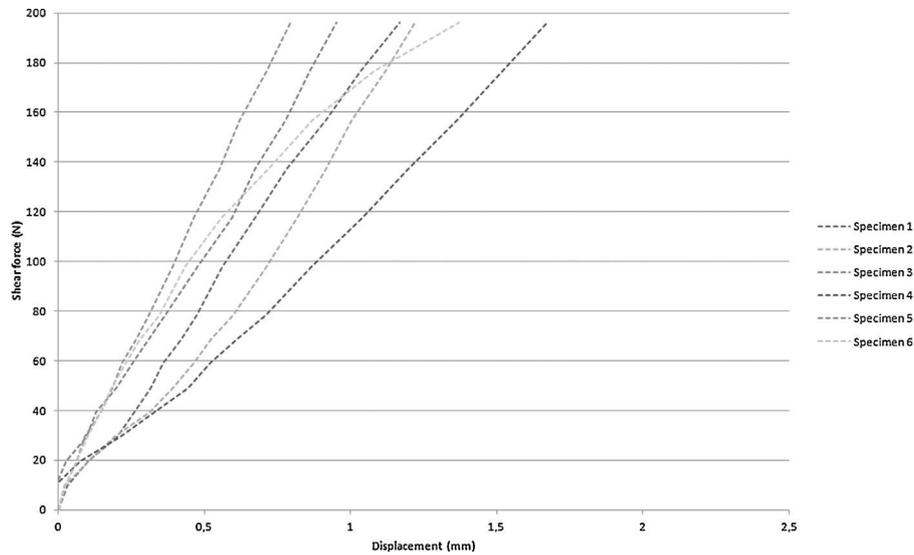


Fig. 6. Load-displacement curves during loading from 0 N to 200 N for each specimen.

Table 1
Maximal anterior displacement (mm) at 200 N.

Configuration	Average	Median	Minimum	Maximum	Difference with intact	<i>P</i> -value ^a
Intact	1.2	1.2	0.8	1.7	–	–
Lesion	1.8	1.7	1.1	2.5	+0.6 [+49%]	0.032
Instrumented	1.3	1.2	0.8	2.4	+0.1 [+6%]	0.468

^a Wilcoxon test significant if $P < 0.05$.

3.2. Stiffness

The variances were homogenous for stiffness's ($P = 0.717$). Values for each configuration are demonstrated in Table 2. The lesion decreased the stiffness by 56 N/mm on average compared to the intact L4–L5 segment ($P = 0.032$). The difference between the instrumented and the intact segment was 14 N/mm ($P = 0.591$). The average stiffness of the instrumented segment increased by 42 N/mm compared to the lesion without instrumentation ($P = 0.046$).

4. Discussion

The indication for posterior non-fusion devices has been emphasized in lateral recess and/or foraminal stenosis associated with osteoarthritis of the facet joints. The surgical treatment of this lumbar degenerative pathology usually requires a decompression of the canal, and an additional partial or complete resection of the facet joints if these are mainly responsible for back pain. This implies a stabilization using a posterior instrumentation and fusion to avoid segmental hypermobility of the treated segment. The

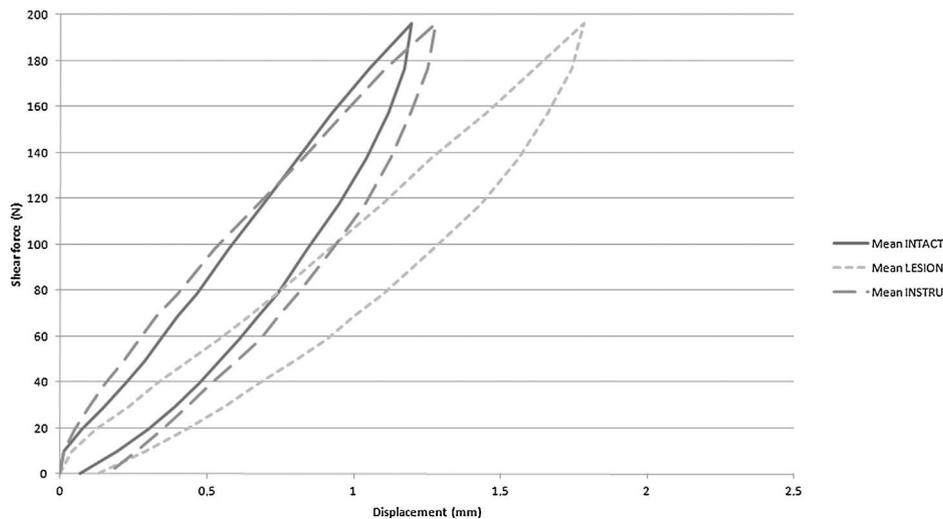


Fig. 7. Average load-displacement curves for 6 specimens showing the 3 configurations.

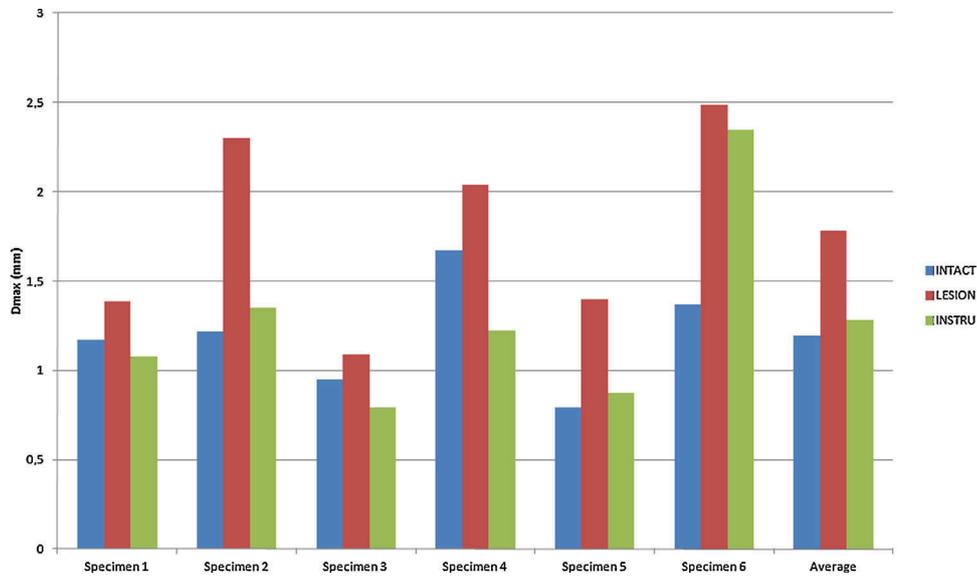


Fig. 8. Maximal displacements (Dmax) at 200 N for each specimen and their average for the different configurations.

rationale behind pedicle screw based mobile systems would be the stabilization of the lumbar segment while preserving a certain amount of segmental mobility, and thus preventing adjacent segment degeneration [18]. Nevertheless, the protective effect of these non-fusion devices on adjacent levels has not been clearly demonstrated to date. The influence of these devices on segmental kinematics of the lumbar spine mainly depends on the implant's design: flexion-extension and lateral bending are usually slightly decreased, whereas axial rotation is only limited by systems with a cross-link component [9–12,20]. However, this property seems essential for the stabilization of the lumbar segment when performing a facetectomy [7]. On the other hand, shear loading increases mobility of the lumbar segment after facet resection [8,19], and posterior-anterior displacements may have an influence on the implant's function. This would be clinically relevant if degenerative spondylolisthesis grade I with an associated stenosis was considered as an indication for posterior non-fusion instrumentation.

Hasegawa et al. [20] investigated lumbar segmental hypermobility *in vivo* by using intra-operative biomechanical data compared to preoperative radiological parameters. Opening of degenerated facet joints on axial computed tomography images and degenerative spondylolisthesis were found to be the strongest predictors for an unstable segment. Furthermore, the Pfirrmann grade of degenerated discs on magnetic resonance imaging was investigated. Segments with grades 3 and 4, which correspond to mild and moderate disc degeneration, were more prone to being hypermobile than those with a grade 5. The concept of posterior mobile instrumentation could be interesting for patients with stenosis and moderate discopathy, presenting these risk factors for segmental hypermobility. We therefore focused on an *in vitro* model

analyzing anterior shear stress, which might reproduce the clinical indication of degenerative spondylolisthesis with moderate disc degeneration, treated by posterior decompression and non-fusion instrumentation.

Both *in vitro* and finite element studies have shown that the shear stiffness of a lumbar segment is reduced after posterior decompression techniques [8,19,21,22]. van Solinge et al. [21] used a porcine model of the lumbar spine to demonstrate that laminectomy and partial facetectomy resulted in a decrease of shear stiffness of 9% at a preload of 1600 N. Bisshop et al. [22] used a similar testing protocol for human cadaveric L2–L3 and L4–L5 segments, and showed that shear stiffness was decreased after laminectomy compared to the intact spine in mild disc degeneration based on the Pfirrmann grade. In contrast to that, severe degeneration appeared to enhance shear stiffness rather than reducing it. Moreover, the amount of preload needs to be considered since axial compression influences the stiffness, the hysteresis area and the linearity of the load-displacement relationship of the lumbar motion segments [23]. Lu et al. [19] analyzed the influence of posterior versus anterior element resection on shear stiffness of human lumbar motion segments. The complete removal of facet joints and posterior ligaments led to an average decrease of stiffness in anterior shear of 77.7% compared to an intact spine. After complete section of the disc including anterior and posterior longitudinal ligaments, anterior shear stiffness decreased by 22.8% on average. Furthermore, the resection of posterior elements approximately doubled anterior displacements (+117%) when the specimens were loaded to 250 N. These results stress the importance of the facet joints, the supraspinous, interspinous and yellow ligaments for shear stability. Nevertheless, anterior and posterior elements do not act independently of one another in resisting anterior shear, but the

Table 2
Stiffness during posterior-anterior loading (N/mm).

Configuration	Average	Median	Minimum	Maximum	Difference with intact	P-value ^a
Intact	162	164	112	242	–	–
Lesion	106	113	81	172	–56 [–34%]	0.032
Instrumented	148	165	81	240	–14 [–8%]	0.591

^a Wilcoxon test significant if $P < 0.05$.

intervertebral segment is rather a composite structure with its different components functioning in cooperation, which are further guided by surrounding muscles *in vivo*. The findings in our study are in line with the previously mentioned results, showing reduced shear strength and stiffness of the spine after realizing a medial facetectomy in combination with an undercutting laminectomy. The configuration of a moderate discopathy leading to lower shear stiffness *in vitro* has consequences for the instrumentation of a hypermobile segment *in vivo*. This would reflect the clinical indication of a degenerative spondylolisthesis with a disc degeneration grade Pfirrmann 3 or 4, facet osteoarthritis, lateral recess and/or foraminal stenosis, which would be carried out for posterior non-fusion instrumentation.

The influence of non-fusion instrumentations on shear stress is not well understood to date and it has never been analyzed for posterior mobile devices to our knowledge, although load transmission in posterior-anterior direction and axial rotation appears crucial for their function. Schilling et al. [24] have analyzed the effect of design parameters of posterior dynamic stabilization systems and demonstrated a correlation between axial stiffness and inter-segmental motion restriction in the sagittal plane, but not in the transversal plane. This may be due to the fact that dynamic stabilization systems are not provided with a cross-link in contrast to the mobile system in our study. Furthermore, these authors showed that the specific design dictated the implants shear properties. Implants using a spacer locked into place by a cord between the screws had a lower shear resistance than those using a spring mechanism restricting translational movements. The implant in the present study restricted anterior shear displacements of the lumbar segment treated by medial facetectomy and undercutting laminectomy. This indicated that the polyaxial connector might allow movements in flexion-extension, lateral bending and axial rotation, but that it also limits the effect of anterior shear stress. Furthermore, the properties of the rod itself are important for the load transfer characteristics between the implant and the lumbar spine. Melnyk et al. [25] investigated the influence of rod material and geometry on shear stiffness up to 250 N (under 300 N axial compression) in human lumbar segments that had been treated *in vitro* by partial facet resection, undercutting laminectomy and nucleotomy. The implants supported greater shear forces as the specimen was destabilized. Lower shear loads were transferred to the spine with 5.5 mm titanium rods (stiffest configuration) compared to 6.35 × 7.2 mm oblong PEEK rods (intermediate stiffness) and 5.5 mm round PEEK rods (low stiffness). The measured anterior displacements were inferior to 2 mm and comparable to the results of the instrument spine in our study at similar loading conditions. The rods of the present non-fusion device have a 5 mm diameter and are made of a cobalt-chromium-molybdenum alloy, which has a higher stiffness than titanium.

Although the technical characteristics of the implant are important for shear resistance, the surgical procedure itself also needs to be adapted, thus providing a complete neurological decompression but the lowest possible destabilization of the lumbar segment. The undercutting or complete laminectomy itself does not create an unstable situation if there is no listhesis of the treated segment. Only the combination with a facet resection, required for far lateral and foraminal decompression, may necessitate stabilization by an implant.

5. Conclusion

The combination of partial facet resection plus undercutting laminectomy decreases segmental shear stiffness and increases the anterior translational displacement of L4 on L5 under shear loading. The shear stiffness of the instrumented lumbar segment tends

to increase with the posterior non-fusion device and anterior displacement tends to decrease under shear loading. This condition could theoretically be interesting for the simulation of posterior non-fusion instrumentation in degenerative spondylolisthesis.

Disclosure of interest

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Y.P. Charles is consultant for Clariance.

J.-P. Steib is a board member of Clariance.

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