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Rigid and flexible spinal stabilization devices: A biomechanical comparison

Fabio Galbusera[a,b,*], Chiara Maria Bellini[a], Federica Anasetti[a], Cristina Ciavarro[a], Alessio Lovi[a], Marco Brayda-Bruno[a]

[a] IRCCS Istituto Ortopedico Galeazzi, Milan, Italy
[b] Institute of Orthopedic Research and Biomechanics, University of Ulm, Ulm, Germany

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The surgical devices for the treatment of degenerative disc disease are based on different concepts (rods for spine fusion, ROM-restricting or load-bearing devices for dynamic stabilization). In the present work, the effects of some stabilization systems on the biomechanics of the lumbar spine were investigated by means of a finite element model of the L2–L5 spine segment. Pedicular screws and stabilization devices were added at L4–L5. Different rods were considered: stainless steel, titanium, PEEK and the composite ostaPek. Two pedicular devices aimed at motion preservation were also considered: the FlexPLUS and the DSS. All models were loaded by using the hybrid protocol in flexion, extension, lateral bending and axial rotation. The spine biomechanics after implantation resulted significantly sensitive to the design and the materials of the device. The impact of all rods in reducing the ROM was found to be critical (>70% in flexion and extension). The dynamic devices were able to preserve the motion of the segment, but with different performances (ROM reduction from 30% (DSS) to 50% (FlexPLUS)). The shared load was more sensitive to the elastic modulus of the device material than the calculated ROMs (from 7% (PEEK) to 48% (stainless steel)). Regarding devices aimed at motion preservation, the authors suggest to distinguish "flexible" devices, which are able to preserve only a minor fraction (e.g. at most 50%) of the physiological ROM, from "dynamic" devices, which induce a smaller ROM restriction. However, the optimal characteristics of a stabilization device for the treatment of degenerative disc disease still need to be determined by means of basic science and clinical studies.

1. Introduction

Currently, dozens of devices aimed at the surgical treatment of low back pain due to degenerative disc disease (DDD) are available on the market. The most consolidated pedicular instrumentation consists of rigid rods, made of stainless steel or titanium. Fixation with pedicular screws and rods allowed to obtain a very high fusion rate, but did not significantly improve the clinical results with respect to posterolateral or interbody fusion without posterior fixation [1]. Recently, "semirigid" polymeric or composite rods have been introduced, to be used supplemented with bone grafts and/or interbody cages in order to achieve a more successful fusion [2]. Many non-fusion pedicular devices are also available for the treatment of low back pain, and are usually indifferently referred to as "flexible" or "dynamic".

As a matter of fact, low back pain is related to multiple possible causes which in some cases cannot be directly related to specific degenerative phenomena. Instability, originally described as abnormal mobility [3], was then generally identified as hypermobility [1], and considered the critical point to be treated with a stabilization procedure. Spinal fusion is still considered the "gold standard" for the treatment of low back pain. However, Wilke et al. [4] demonstrated that disc degeneration does not generally induce instability of the segment, at least in its early stages. This is confirmed by the fact that the clinical success rate of the stabilization procedure is not strongly related to the fusion rate [1]. Sengupta [5] suggested that the origin of low back pain may be related to an abnormal load sharing pattern. This hypothesis lead to the concept of a "load bearing device" to relieve pain by unloading the suffering anatomical structures. However, basic science studies are needed to confirm the validity of this idea.

The present work is aimed at the investigation of the effects of some of the currently available devices on the motion and load sharing pattern of the lumbar spine. Rigid and semirigid rods and dynamic pedicular devices have been included in the study.

2. Materials and methods

A finite element model of the L2–L5 spine segment was built and validated through comparison to literature data [6–8]. The vertebral geometry was built based on CT images of a healthy

* Corresponding author at: IRCCS Istituto Ortopedico Galeazzi, via Galeazzi 4, 20161 Milan, Italy. Tel.: +39 02 6621 4939; fax: +39 02 6621 4800.
E-mail address: fabio.galbusera@polimi.it (F. Galbusera).

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Table 1
Mechanical properties of the components of the spine model.

	E (MPa)	υ	Reference
Cancellous bone	$E_{xx}=140$	$\upsilon_{xy}=0.45$	[23]
	$E_{yy}=140$	$\upsilon_{yz}=0.315$	
	$E_{xx}=200$	$\upsilon_{xz}=0.315$	
Cortical bone	12,000	0.3	[24]
Posterior elements	3500	0.25	[24]
Nucleus pulposus	1	0.499	[25]
Annulus fibrosus—matrix	4.2	0.25	[25]
Annulus fibrosus—fibers	25	0.3	Model calibration [26]
Cartilaginous endplates	23.8	0.4	[23]
Facet cartilage	23.8	0.4	[23]

medium-sized specimen, harvested from a young male cadaver showing no signs of degeneration. Commercial software (Amira 4.1, TGS, San Diego, CA, USA) was employed to convert the CT images into a point cloud describing the bony surfaces. A solid model including the four considered vertebrae was then built by using commercial finite element software (ANSYS 11.0, ANSYS Inc., Canonsburg, PA, USA). Intervertebral discs were added in the intersomatic spaces. All the solid materials were modeled as linear elastic isotropic (Table 1), except the cancellous bone which was modeled as orthotropic. The relevant volumes were meshed with 8-node hexahedral elements with reduced integration (Fig. 1a). 1940 tension-only truss elements with 0.1 mm^2 cross section area were used to model the annular fibers. The actual value of elastic modulus of the fibers was obtained by calibrating the model against literature data obtained in in vitro experiments [6]. Ligaments were modeled as nonlinear spring elements; the force–displacement curves of each ligament were taken from the literature [6]. Ligaments included in the models were the anterior longitudinal, posterior longitudinal, capsular, flaval and interspinous. Facet joints were modeled with surface-based contact elements between the relevant surfaces, without friction. A cartilage layer with thickness 0.2 mm was modeled on top of the bony surfaces in the contact areas [9]. The cartilage surfaces had an initial average gap of 0.6 mm [9].

A mesh sensitivity analysis was performed on a part of the model of the intact spine (functional spine unit L4–L5, including vertebrae, disc and relevant ligaments). Under pure moments of 7.5 Nm in flexion and extension, the chosen mesh led to differences lower than 1% in terms of range of motion (ROM), with respect to a mesh with considerably higher density (30% reduction of the average element edge length). Results obtained were in good agreement with in vitro literature data [7,8] (Fig. 2).

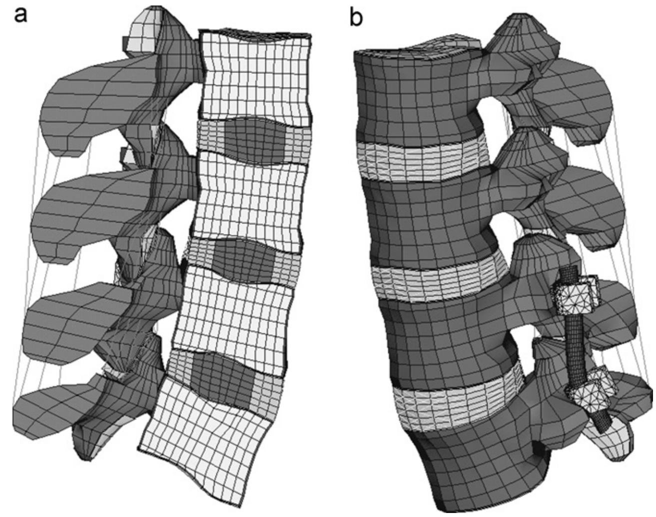

Fig. 1. Finite element model of the L2–L5 spine segment in intact conditions (a) and instrumented at L4–L5 (b).

The model was modified to include pedicular screws and rods at L4–L5 (Fig. 1b). Rods made of different materials were included in the present study: stainless steel, titanium, ostaPek (coLigne AG, Zurich, Switzerland), polyaryletheretherketon (PEEK). All rods had diameter 6 mm. Additionally, two pedicular flexible devices were considered: the FlexPLUS (SpineVision SA, Paris, France) and the DSS (Paradigm Spine GmbH, Wurmlingen, Germany) (Fig. 3). The FlexPLUS device consists of titanium alloy screws and rods including a flexible part, having length of 9 mm, consisting of a titanium cable and a polycarbonate-urethane shell. The DSS has spring-like rods designed to reduce the ROM to a level that should avoid extreme positions leading to pain [10]. The two dynamic devices were modeled with beam elements with mechanical properties matching those of the specific devices. For all rods, the connection between screws and rods was implemented by using a bonded contact. To enhance the comparability of the results, the same generic titanium pedicular screws were included in all models. The material properties of all devices are reported in Table 2.

The model of the intact spine was subjected to pure moments of 7.5 Nm in flexion, extension, right lateral bending and right axial rotation [11]. Pure moments in the different directions were then imposed to the models of the instrumented spine, until the global range of motion (L2–L5) equaled that of the intact spine [12]. The rationale of the protocol is based upon the idea that the patient, dur-

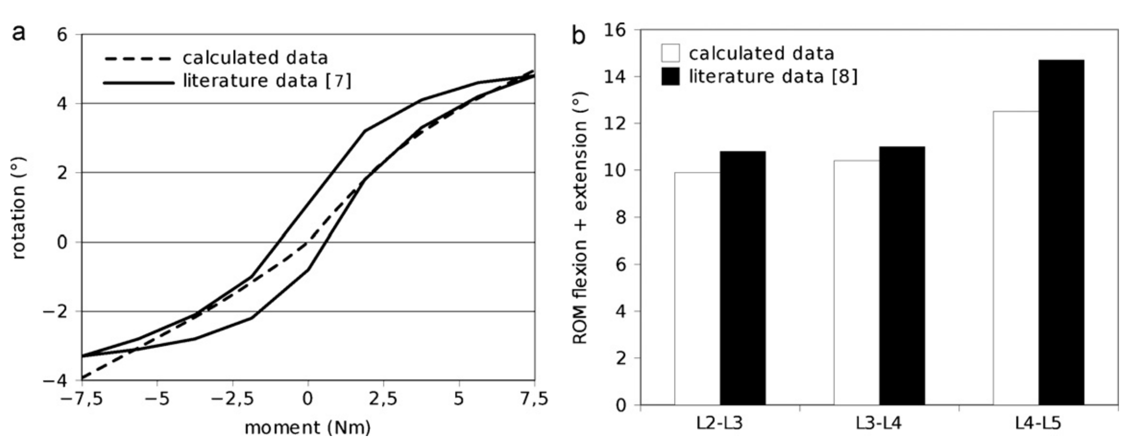

Fig. 2. Moment–rotation curve in flexion–extension at L4–L5 calculated in the present study compared to in vitro literature data [7], obtained by imposing a moment of 7.5 Nm superimposed to a follower load of 280 N (a). Total ROM in flexion–extension calculated with the model at the different lumbar levels, compared to in vitro literature data [8] (b). Both calculated and in vitro results were obtained by imposing a moment of 10 Nm.

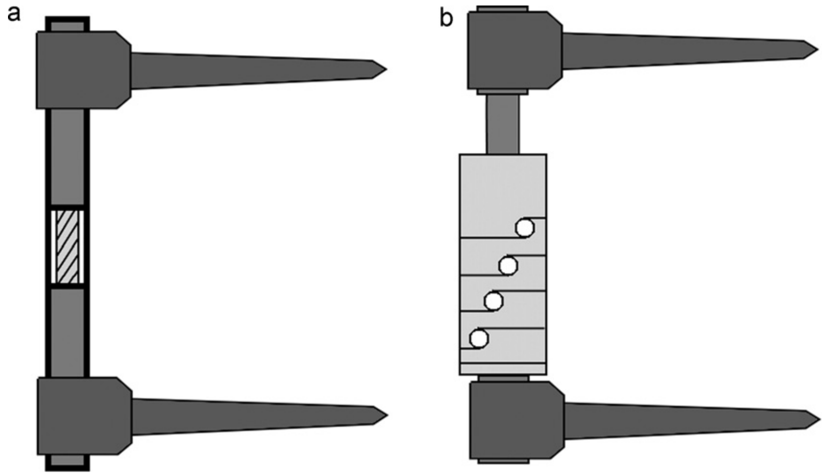

Fig. 3. Schematic drawings of the FlexPLUS (a) and the DSS (b).

Table 2
Mechanical properties of the fixation and dynamic stabilization devices.

	E (MPa)	ν	Stiffness	Reference
Pedicular screws (all models)	110,000	0.3	–	–
Stainless steel rods	210,000	0.3	–	–
Titanium rods	110,000	0.3	–	–
PEEK rods	3500	0.3		[27]
ostaPek rods	45,000	0.3	–	[28]
FlexPLUS	–	–	Not disclosed	[29]
DSS	–	–	Axial: 50 N/mm Bending: 30 N/mm	[10]

ing daily activities after surgery, still tries to move the spine in the same way as before the surgery. By using this protocol, the investigation of the motion compensation on the adjacent segments due to the implantation of the various devices is straightforward. The loads transmitted through the rods and the two dynamic devices were also estimated.

3. Results

Figs. 4 and 5 report the variation of the calculated ROMs in flexion and extension for all the considered devices, with respect to the ROM values obtained with the model of the intact spine. All the rigid and semirigid rods (stainless steel, titanium, ostaPek, PEEK) significantly reduced the ROMs in a rather similar way (>70% in all cases), despite the large differences in the elastic modulus of the materials. Similar results were obtained in lateral bending (Fig. 6). In axial rotation (Fig. 7), both stainless steel, titanium and ostaPek rods were found to strongly reduce the ROM (>70%), while the PEEK rods induced a smaller ROM reduction (32%). The FlexPLUS and the DSS reduced the ROM in all the considered motions, though preserving a significant mobility with respect to all the rigid and semirigid rods. Generally, the effects of the implantation of the FlexPLUS and the DSS on the spine flexibility were remarkably comparable.

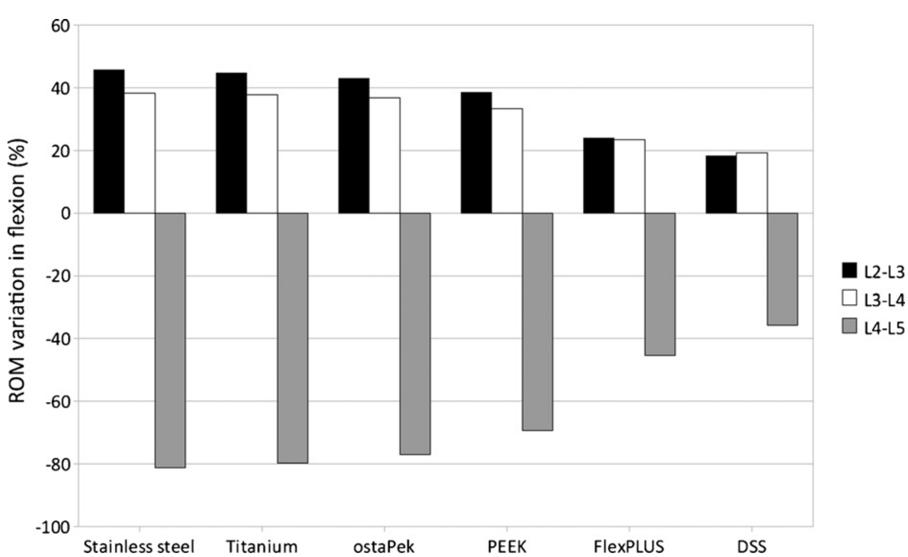

Fig. 4. Calculated ROM variation due to the instrumentation of the lumbar spine in flexion.

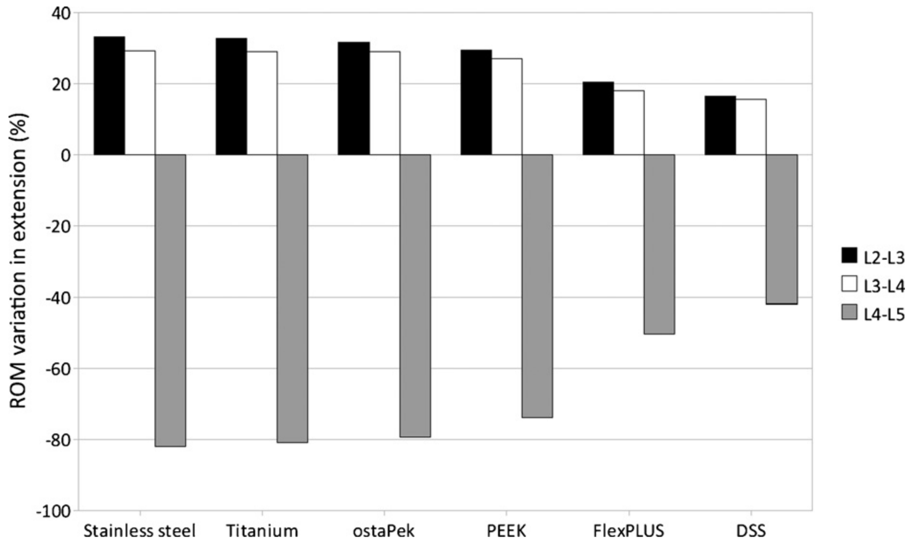

Fig. 5. Calculated ROM variation due to the instrumentation of the lumbar spine in extension.

The adjacent segments compensated the loss of motion at the implanted segment with an increase of the local ROM. Comparable ROM variations were found for the L2–L3 and the L3–L4 segments, for all devices and loads. Similar values of the ROM increases (up to 46%) were found for the different rods in all load directions, except for the PEEK rods in axial rotation, for which the value of the induced hypermobility was about half of those obtained with the other fixation rods. The dynamic devices induced lower motion compensations at the adjacent segments if compared to the fixation rods, but with still significant values (up to 19%).

The values of the moments imposed in the application of the hybrid protocol to reach the global ROMs calculated with the model of the intact spine are shown in Fig. 8. These moment values reflected the differences in the stiffness of the instrumented models. Comparable moment values were found for all the fixation rods. Lower moments were required for the two dynamic devices in the application of the hybrid protocol.

Fig. 9 shows the ratio between the bending moment acting in the different devices and the applied moment in flexion and extension. These results obtained with the different rods appeared to be more sensitive to the elastic modulus of the material than the calculated ROMs. Stainless steel and titanium rods were subjected from 23% to 48% of the total load, coherently with literature studies [13,14]. PEEK rods sustained 7–10% of the load; ostaPek was found to lie halfway between PEEK and titanium, coherently with the differences in elastic modulus among the considered materials. Both FlexPLUS and DSS shared a significant fraction of the bending load, similar to that obtained for the PEEK rods, thus proving to be efficient as load bearing devices.

Fig. 10 shows contour plots of the von Mises stress in the L3–L4 intervertebral disc for the various configurations, in flexion and extension. The fixation rods, both rigid and semirigid, induced a marked increase of the von Mises stress in the disc. The stress distribution appeared not to be strongly influenced by the stiffness of the stabilization devices. The FlexPLUS and the DSS altered the stress values in the adjacent disc to a lesser, but still significant, degree.

4. Discussion

The currently available surgical devices for the treatment of DDD are based on different concepts (rigid or semirigid rods for spine

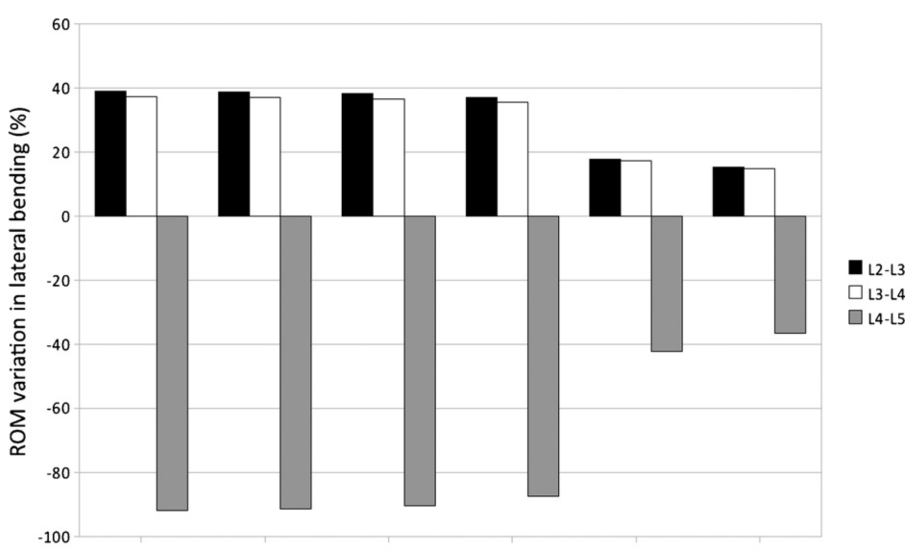

Fig. 6. Calculated ROM variation due to the instrumentation of the lumbar spine in lateral bending.

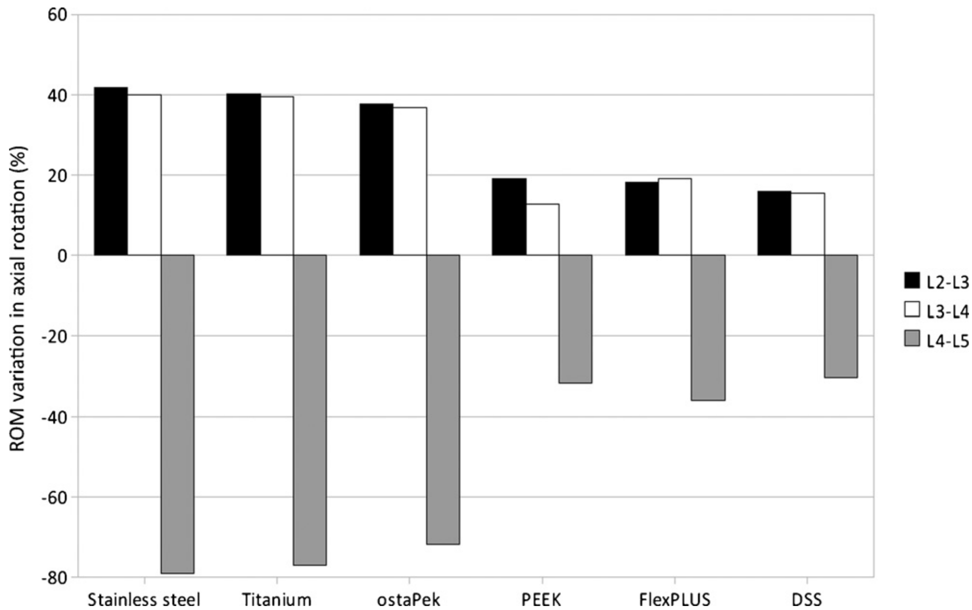

Fig. 7. Calculated ROM variation due to the instrumentation of the lumbar spine in axial rotation.

fusion, ROM-restricting or load-bearing devices for dynamic stabilization, both interspinous or based on pedicular screws). This is reflected in the different biomechanical conditions induced in the implanted spine.

The impact of all rigid (stainless steel, titanium) and semirigid (PEEK, ostaPek) rods in reducing the ROM was found to be critical (from 72% for PEEK rods to 83% for stainless steel rods in flexion). This result is coherent with data published by Schmidt et al. [9] and Rohlmann et al. [15], who found that only fixation devices with a very low stiffness influenced the ROM markedly.

Despite the rather similar behavior of the different rods in restricting the ROM, significant differences in the load sharing behavior were detected between rigid and semirigid rods. In particular, the fraction of load shared by the PEEK rods was found to be very low. ostaPek, being significantly stiffer than PEEK, sustained a greater portion of the load, but still rather limited. As a matter of fact, the recent advances in composite material technology made possible the development of rods with the desired mechanical properties, thus sharing a specific load fraction. However, as for the ROMs, the optimal value of load to be shared by the rods is currently unknown. Both basic science, clinical and biomechanical studies are needed to fill in this lack of knowledge [16].

No significant differences in the ROM variations at the adjacent segments were observed among all the fixation rods, both rigid and semirigid. Thus, based on the present results, the use of semirigid rods to prevent early degeneration of the adjacent segments may not be effective. However, semirigid rods may be convenient with respect to rigid rods in stimulating bone fusion and unloading the screw-bone interface, thus limiting screw loosening, despite there is no clinical evidence of this advantage [17].

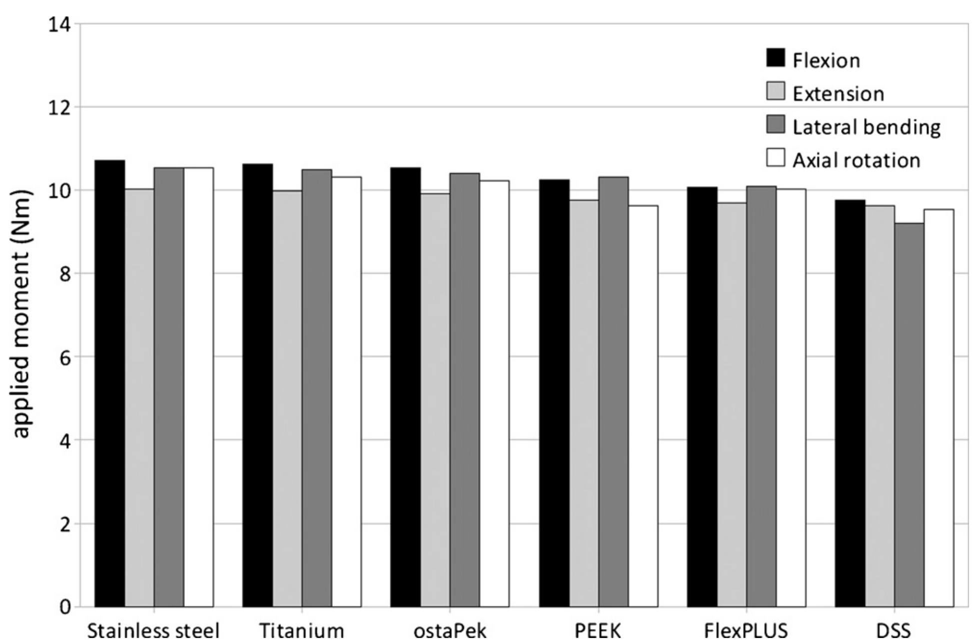

Fig. 8. Moments applied to the instrumented models in order to obtain the global (L2–L5) ROMs calculated with the model of the intact spine.

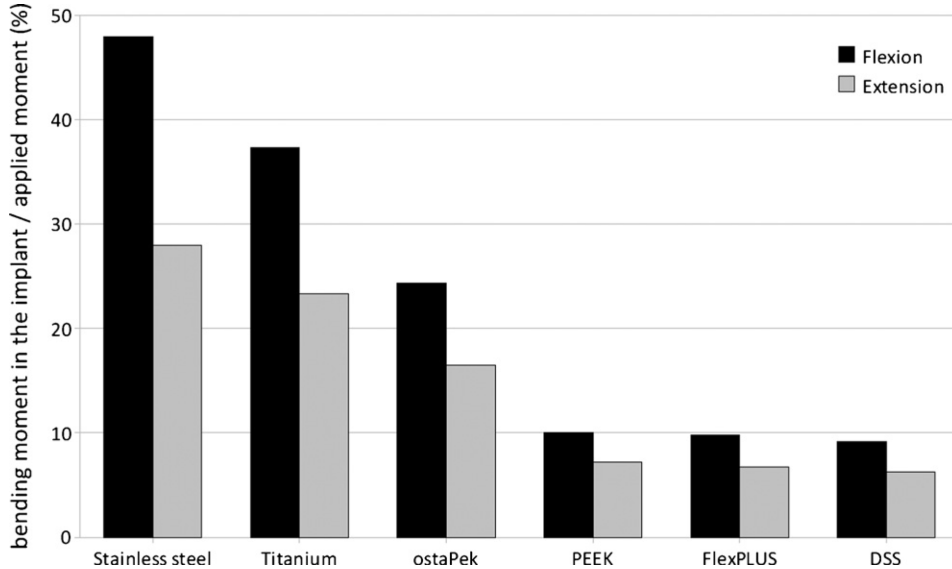

Fig. 9. Ratio between the bending moment within the device and the applied load in flexion and extension.

As expected, the dynamic devices were able to partially preserve the mobility of the segment, in a comparable way. Other devices, e.g. the Dynesys (Zimmer, Inc., Warsaw, IN, USA), have higher stiffness values [18] that may induce a stronger ROM limitation. Concerning this type of devices, the definition "dynamic stabilization" may be considered misleading. We suggest "flexible" instead of "dynamic" as a better description for devices able to preserve only a minor fraction (e.g. at most 50%) of the physiological flexibility. The natural application of such devices may be the treatment of minor instability. The ROM limitation induced by the FlexPLUS and the DSS implantation, though significant, was compatible with a close-to-physiological motion of the segment, but avoiding the extreme positions that could lead to pain. This finding is comparable with the results of experimental tests conducted on interspinous devices [19], which generally restricted the motion to some extent in extension while preserving a nearly physiological ROM in flexion, lateral bending and axial rotation. In the authors' opinion, these devices may be more adequately classified as "dynamic". However, the authors believe that "dynamic" may be a misleading word from an engineering point of view, since it suggests a time or velocity dependency which is actually not existent.

A comprehensive clinical interpretation of the significance of this motion-based classification system is beyond the scope of the work, and probably not currently feasible. Motion-preserving devices are expected to exhibit a trade-off behavior between ROM preservation and shared load. Highly flexible, truly "dynamic" systems as the FlexPLUS and the DSS are able to share only a minor fraction of the load. Stiffer, only "flexible" implants may be able to sustain a greater load part, at the cost of a higher mobility limitation. As a matter of fact, the amount of the desirable ROM reduction for dynamic stabilization is still an open question [16]. The concept itself of the dynamic stabilization device as a ROM-limiting or a load-bearing device is still controversially discussed [1]. These fundamental questions should be addressed by means of basic science studies.

Some limitations of the present study could be identified. Validation of the model was partially carried out by comparison with in vitro data obtained with a moment of 7.5 Nm superimposed to a follower load of 280 N, in contrast to the present study in which pure moments were employed. However, the follower load was found to have a minor influence on the intersegmental rotation [6]. Another limitation pertains to the intertransverse ligament, which may have a significant stabilizing role in lateral bending [20], but was not included in the model.

All the models here presented are based on a healthy spine. As a matter of fact, the healthy condition is supposed not to require a surgical treatment. The degeneration of the intervertebral discs or the implantation of bone grafts or interbody cages, in the case of lumbar fusion, are expected to alter the load sharing pattern of the lumbar spine. The use of healthy, highly flexible disc instead of stiffer, degenerated discs or units including intersomatic fixation devices might probably lead to an overestimation of the loads in the rods and an underestimation on the effects of the adjacent

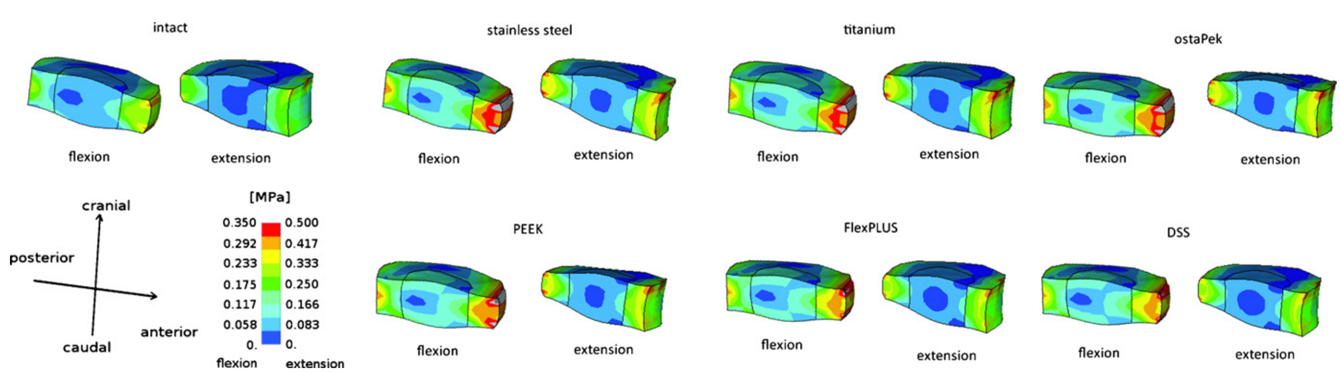

Fig. 10. von Mises stress in the L3–L4 intervertebral disc in flexion and extension calculated for the spine in intact conditions and after stabilization at L4–L5.

levels. A stabilizing effect which is less sensitive to the material of the employed posterior rods might be expected if an interbody fixation and fusion is considered. However, this modeling approach has been chosen due to the lack of a standard model of disc degeneration and to ensure comparability with in vitro studies which are usually conducted on not severely degenerated spines [13,21]. Furthermore, the use of the same spine model may be useful to provide a common framework for the comparison of devices which may have different clinical indications. Despite these advantages of the chosen approach, it should be noted that the simulated conditions are not representative of a clinical scenario requiring a surgical stabilization.

The relatively low values of shared load obtained with all models may be related to the hybrid loading protocol based on pure moments [13] and rotations [12]. Including a compressive preload may lead to a different partition of the loads between the anterior column and the rods. The use itself of a hybrid protocol is controversial. In a pure load-controlled protocol, the same moment is imposed to all spinal levels included in the model. In this way, the implanted device has no influence on the adjacent segments [12]. However, the results of displacement-controlled protocols are sensitive to the number of implanted and non-implanted units included in the model. This topic is still heavily debated [12,21].

The FlexPLUS and the DSS were modeled with beam and spring elements, thus simplifying some aspects of the mechanics of the devices. The nonlinear characteristics of these devices were neglected. Other widely used dynamic stabilization devices, for which complete biomechanical data were not available, were not considered. Simple constitutive laws were used for the nucleus pulposus and the ground substance of the annulus fibrosus, while more sophisticated and accurate models are available [22]. Due to this limitation, and since the models were validated only by comparison with ROM data, the authors chose not to investigate the stress distribution inside the intervertebral discs. Furthermore, the bone–screw and screw–rod interfaces were considered as ideally bonded, thus not allowing for micromotions. This assumption, which determines a stiffer construct than in reality, may alter both the calculated mobility and the load sharing pattern. The pure moment loading protocol, though widely used [11], is not aimed to replicate the complex loads occurring *in vivo*. These loads may either enhance or reduce the differences between the various stabilization devices, with effects that cannot be predicted with the current models. Despite these limitations, a comparative evaluation of the results obtained for the different devices can be considered reliable, due to the homogeneity of the simulation conditions.

5. Conclusions

The spine biomechanics after stabilization is significantly sensitive to the design and the materials of the device, in terms of ROM and shared load in the spine segments. We suggest to distinguish "flexible" devices, which are able to preserve only a minor fraction (e.g. at most 50%) of the physiological ROM, from "dynamic" devices, which induce a smaller ROM restriction. Despite the high number of different devices belonging to both categories that are available on the market, the optimal characteristics of a stabilization device for the treatment of DDD still need to be determined by means of basic science and clinical studies.

Conflicts of interest

All the authors (Fabio Galbusera, Chiara M. Bellini, Federica Anasetti, Cristina Ciavarro, Alessio Lovi, Marco Brayda-Bruno) have no proprietary, financial, professional or other personal interest of any nature or kind in any product, service and/or company that could be construed as influencing the position presented in, or the review of, the present manuscript.

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