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Spine stability after implantation of an interspinous device: an in vitro and finite element biomechanical study

Laboratory investigation

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Object. Interspinous devices are widely used for the treatment of lumbar stenosis. The DIAM spinal stabilization system (Medtronic, Ltd.) is an interspinous implant made of silicone and secured in place with 2 laces. The device can be implanted via posterior access with the sacrifice of the supraspinous ligament (SSL) or via lateral access with preservation of the ligament. The aim of the present work was to evaluate the role of the laces, the SSL, and the device size and positioning to determine the device's ability in reducing segmental lordosis and in stabilizing motion.

Methods. Biomechanical tests were performed in flexion and extension on 8 porcine spines implanted with the DIAM either with or without the laces and the SSL. A finite element model of the human L4–5 spine segments was also created and used to test 2 sizes of the device implanted in 2 different positions in the anteroposterior direction.

Results. Implantation of the DIAM induced a shift toward kyphosis in the neutral position. Laces, the SSL, and device size and placement had a significant influence on the neutral position, the stiffness of the implanted spine, and the positions of the instantaneous centers of rotation.

Conclusions. The shift of the neutral position toward kyphosis may be beneficial in reducing symptoms of spinal stenosis such as radicular pain, sensation disturbance, and loss of strength in the legs. The authors recommend preservation of the SSL and the use of the fixation laces, given their relevant mechanical role. Choosing the proper device size and placement should be achieved by using a correct surgical technique. *(DOI: 10.3171/2010.6.SPINE09885)*

Key Words • **dynamic stabilization** • **lumbar stenosis** • **spine biomechanics** • **interspinous implant**

Surgical treatment for lumbar stenosis is considered when conservative alternatives fail to relieve pain and improve function.[6] The standard surgery is decompression via wide laminectomy.[20] The success rate of this procedure varies from 62 to 70%, and failures are often related to postoperative iatrogenic spinal instability,[6] although they may also result from other causes such as incomplete decompression in improperly selected patients.[14] To limit the effect of iatrogenic instability, decompression is often associated with fixation and fusion.[11]

Interspinous devices are widely used in Europe for the treatment of lumbar stenosis. The purposes of these devices are to provide some stabilization after decompression, to restore foraminal height, and to unload the facet joints.[22] They allow for the preservation of a ROM in the implanted segment, thus avoiding or limiting possible overloading and early degeneration of the adjacent segments as induced by fusion,[10] as confirmed in a previous FE study.[3]

The DIAM spinal stabilization system (Medtronic, Ltd.) is an interspinous implant made of silicone, covered with a polyethylene coat, and secured in place with

Abbreviations used in this paper: FE = finite element; ICR = instantaneous center of rotation; ROM = range of motion; SSL = supraspinous ligament.

This article contains some figures that are displayed in color online but in black and white in the print edition.

2 laces, which is currently used widely in clinical practice in Europe. The device is presently in an FDA-regulated clinical trial in the US. The DIAM can be implanted via posterior access with the sacrifice of the SSL or via lateral access with preservation of the SSL. The DIAM has reportedly been implanted via the lateral access technique without lace fixation, thus assuming that the SSL is able to provide enough stability to the device. Other commercially available devices, such as the X-Stop (Medtronic, Ltd.), are not fixed or crimped to the lateral aspects of the spinous processes and therefore reasonably justify the use of the DIAM. However, whether the different surgical approaches or the size of the device influences the biomechanics of the implanted spine is still unknown.

The aim of the present work was to evaluate the role of the laces, the SSL, placement of the device in the anteroposterior direction, and the device size in determining its ability to reduce local segmental lordosis and stabilize motion. To achieve this aim, biomechanical tests were performed on porcine spines implanted with the DIAM both with and without the laces and the SSL. These evaluations were conducted by calculating the ROM on flexion and extension of the specimens in the different conditions. The significance of the device size and placement in the anteroposterior direction was evaluated using an FE model of the human L4–5 spine segments run in flexion and extension.

Methods

Specimens and Loading Apparatus

Eight lumbar porcine spine segments (L2–5), obtained from immature pigs weighing 55–65 kg, were tested. The spine segments were subjected to hemifacetectomy at all levels to simulate mild instability.[22] This configuration of the porcine spine has been successfully validated as a model of the human lumbar spine in flexion and extension.[2]

Tests were performed using a servohydraulic axial-torsional testing machine: the MTS 858 Bionix (MTS Systems). An apparatus able to convert the vertical force produced by the testing machine into moments in flexion and extension combined with compression was designed (Fig. 1). Each spine specimen was glued at its ends into 2 supports, which were connected to the testing machine via a pair of joints and linear guides. The joints allowed rotation of the specimen ends around 2 parallel horizontal axes so that all the movements of the spine were constrained in a single plane. By moving the 2 supports along the guides, the length of the lever arm—that is, the distance between the spine specimen and the loading axis of the testing machine—could be adjusted to set the proper value of the bending moment. By disassembling the 2 supports and rotating them with respect to the joint axes, in-plane movements of flexion and extension were selectively applied to the lumbar spine specimen. While preparing the specimen and potting its ends within the 2 supports, particular care was taken to correctly align the long axis of the specimen to the vertical direction of the testing machine and to guarantee the repeatability of its position.

An optoelectronic system, a BTS Smart-e equipped with Smart Analyzer software (BTS Bioengineering SpA) consisting of 6 infrared emitters and 6 charge-coupled device cameras positioned around the testing machine, was used to determine movements of the segments of the lumbar specimen by tracking the trajectories of spherical markers attached onto the vertebrae. Three markers were positioned on each vertebra: 1 marker in the midline of the vertebral body at half height, and the other markers in the middle of the transverse processes (Fig. 2).

The bending moment applied to the specimen was calculated as the product of the vertical force and its lever arm—that is, the distance between the force axis and the sagittal position of the center of the L3–4 functional spine unit, measured via the optoelectronic system based on the position of the L-3 markers. The value of the lever arm was calculated in real time during each test and was used for the calculation of the applied moment. All the spine specimens were subjected to tests in both flexion and extension; each test consisted of the application of 3 cycles up to a specific moment (3 Nm in both flexion and extension).

The ROM of the specimens was calculated as the difference between the rotation observed for the maximal moment applied and the neutral position both in flexion and extension. The rotation was defined as the angle between L-3 and L-4 in the sagittal plane; the 0 value was defined in the unloaded condition for the intact spine after hemifacetectomy. The neutral position was conventionally determined for each of the configurations described below as the rotation relative to the 0 value.

Tested Configurations

Five configurations were tested for each specimen (Fig. 3) in both flexion and extension after an initial check of the mild instability due to the hemifacetectomy at the considered level. The 5 configurations were as follows: 1) control specimen, the spine after hemifacetectomy; 2) specimen after insertion of the DIAM in L3–4 without laces; 3) specimen implanted with the DIAM and fixation with the laces; 4) specimen implanted with the DIAM, fixation with the laces, and resection of the SSL; and 5) specimen implanted with the DIAM, not fixated with the laces, and resection of the SSL.

The configurations representing the most common clinical uses of the DIAM were 3 and 4, which simulated the lateral access with preservation of the SSL and the standard posterior access, respectively. As stated above, Configuration 2 has also been used, assuming the SSL is sufficient to secure the device in place.

Finite Element Model

An FE model of the human L4–5 segment was built and used to investigate the effects of the fixation laces, the device size, the positioning of an interspinous spacer resembling the DIAM on the motion, and the locations of the ICRs of the implanted segment in flexion and extension. Since only these motions were considered, a symmetric model with respect to the sagittal plane was built

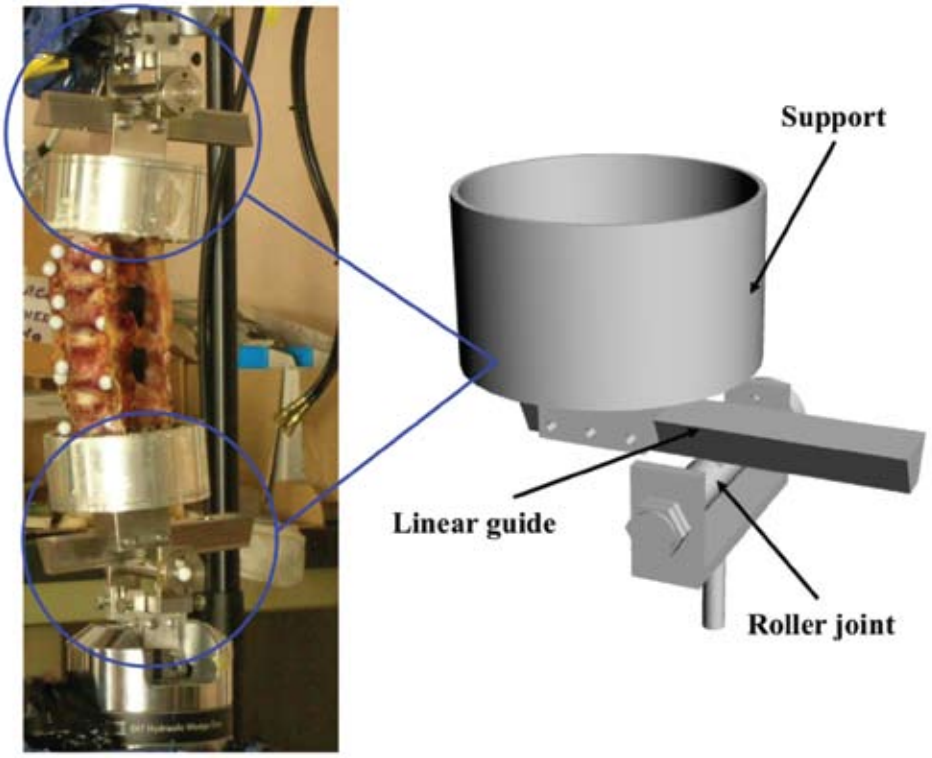

Fig. 1. Photograph and illustration of the apparatus for applying flexion and extension moments to the spine specimen.

(Fig. 4). The values of the mechanical properties of the different materials were taken from the literature (Table 1). Ligaments were modeled as nonlinear springs, and force-displacement data were taken from the literature.[8] Before including the spacer in the model, a validation was performed by loading the model with pure moments of 7.5 Nm in flexion and extension and by comparing the results with published data.[18]

The interspinous device was modeled as a spring having the compressive stiffness of a silicone device with a cross-sectional area similar to that of the DIAM (stiffness coefficient 200 N/mm). Two different cases were simulated: without lace fixation, modeled with a 0 tensile stiffness of the spring; and with lace fixation, for which a tensile stiffness equivalent to the compressive stiffness was assumed. The devices were placed in 2 different positions: one (Position A) representing a nearly standard placement and the other (Position B) modeling a more anterior placement (Fig. 4). Two different sizes were considered (heights of 10 and 14 mm). To model the effect of the spacer size, the spring had a rest length equal to the device size and was precompressed to match the initial distance of the spinous processes at the specific insertion points. In all the instrumented models, the interspinous ligament was removed and the SSL preserved.

Eight instrumented models were completely built. Each model was run in flexion and extension in displacement control. A rotation of 5° was applied to the upper endplate of L-4 by using rigid beams, and the lower endplate of L-5 was fixed. Before applying the rotation, a preliminary load step without any load was performed to leave the precompressed spring free to apply a distraction force to the spine segment. The moment required to reach the imposed rotation was recorded for each model. The paths of the ICRs during the load application in flexion and extension were determined by using the Reuleaux method.[17]

Results

In Vitro Testing

After implantation of the DIAM device, all the tested

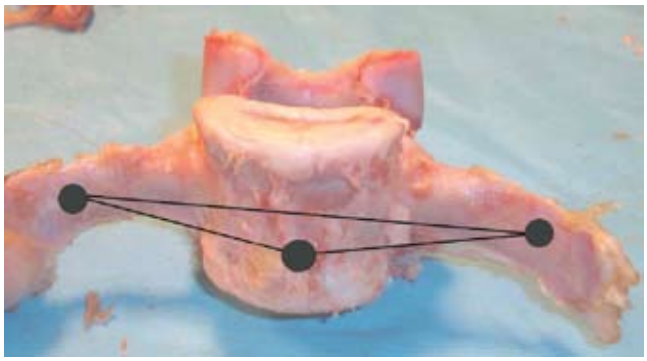

Fig. 2. Photograph showing the position of the markers on the vertebrae: one marker is attached in the midline of the vertebral body at half height, whereas the other markers are positioned in the middle of the transverse processes.

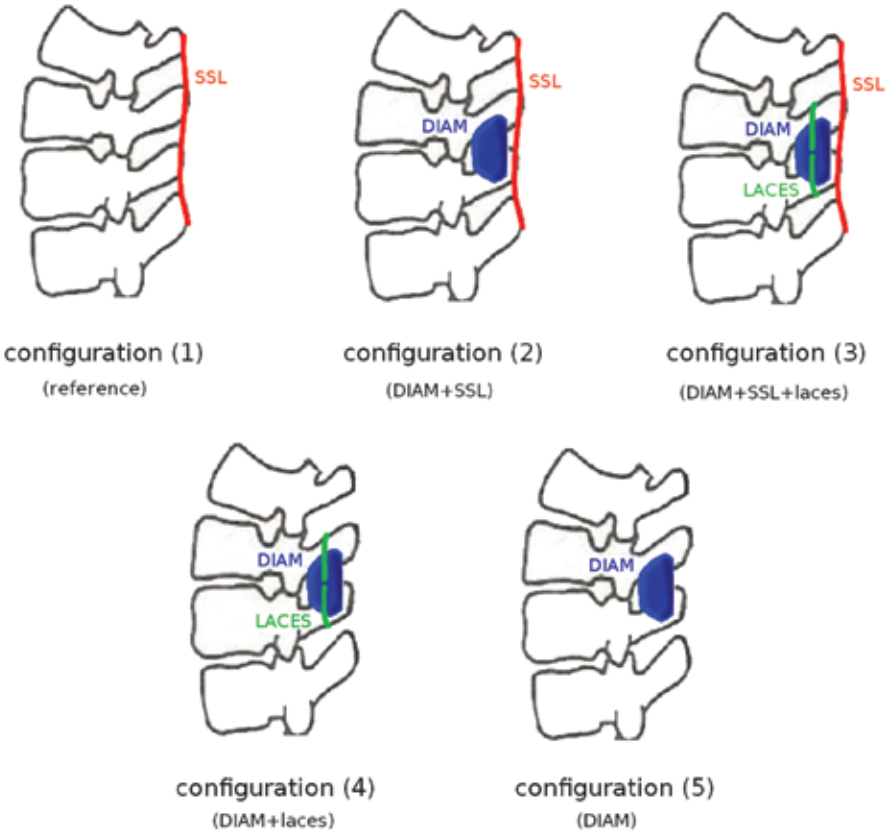

Fig. 3. The 5 tested configurations of the spine specimens: Configuration 1, control specimen; Configuration 2, DIAM with the SSL and without the laces; Configuration 3, DIAM with the SSL and the laces; Configuration 4, DIAM with the laces and without the SSL; and Configuration 5, DIAM without the laces and the SSL.

specimens in all the configurations showed a shift toward kyphosis in the neutral position and a modification of the ROM with reference to Configuration 1, which was considered the 0 value (0° of flexion; Fig. 5).

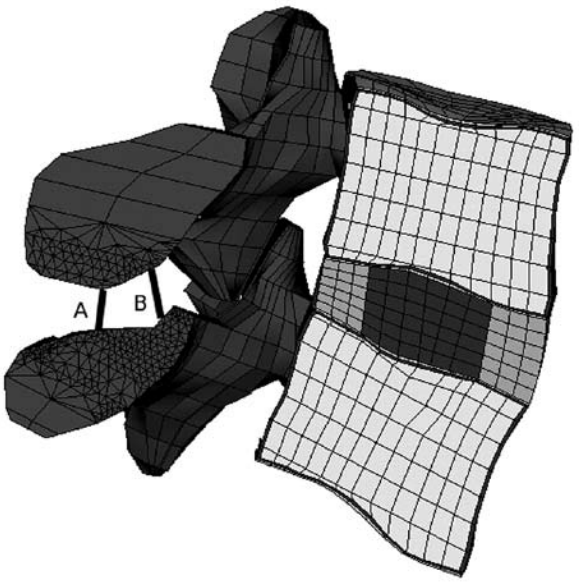

Fig. 4. An FE model of the L4–5 segment. Both A and B represent positions where the device was placed.

If the SSL was preserved (Configuration 2), the neutral position was more flexed, from 0° to 2.5°, as compared with Configuration 1. The ROMs both in flexion and extension reached a value comparable to the ROM in the configuration without the DIAM, with slight reductions of 6% in flexion and 5% in extension.

The use of the laces (Configuration 3) induced a less flexed neutral position with a reduction of 40%, as compared with Configuration 2. We also observed a 33% reduction in the ROM in flexion and a 57% recovery in extension.

After cutting the SSL (Configuration 4), with respect to Configuration 3, the neutral position was more flexed by 47%. The ROM in flexion increased by over 20%, whereas it decreased by 12% compared with Configuration 2, that is, without the laces and with the SSL. The ROM in extension decreased by 48%, while it was comparable with that in Configuration 2.

Without the SSL and the laces (Configuration 5) the neutral position was more flexed, with an increase of 260% with respect to Configuration 3. With respect to Configuration 4, in flexion, cutting the laces clearly did not change the ROM, which decreased by less than 6%. In extension the excessive flexed condition of the neutral position increased the ROM by more than 48%.

Finite Element Model

The reaction moments due to the application of the

TABLE 1: Mechanical properties of the components of the FE model

Property	E (MPa)*	ν†	Authors & Year
cancellous bone	E_{xx} = 140 E_{yy} = 140 E_{xx} = 200	ν_{xy} = 0.45 ν_{yz} = 0.315 ν_{xz} = 0.315	Lu et al., 1996
cortical bone	12000	0.3	Cowin, 2001
posterior elements	3500	0.25	Cowin, 2001
nucleus pulposus	1	0.499	Pitzen et al., 2002
anulus fibrosus, matrix	4.2	0.25	Pitzen et al., 2002
anulus fibrosus, fibers	25	0.3	Cheung et al., 2003‡
cartilaginous endplates	23.8	0.4	Lu et al., 1996

* Elastic modulus; describes the elastic response of material.
† Poisson ratio; describes the elastic response of material.
‡ Model calibration.

rotation are shown in Fig. 6 for the 2 different sizes of the DIAM-like device implanted in Positions A (standard placement) and B (more anterior placement).

In flexion, the moment values obtained with the implanted models were generally higher than in the intact case; however, more uniform moment values were obtained if the laces were removed. In the case of the 10-mm device, a more anterior position (Position B) led to a lower moment value (–15% with laces, –14% without laces) with respect to Position A. The 14-mm device induced a higher average stiffness of the segment for Position B if compared with the more posterior position (Position A; +19% with laces, +11% without laces).

In extension, all device sizes and positions led to higher moment values if compared with the intact case. In Position A, a 60% higher moment value was obtained for the 14-mm device as compared with the 10-mm size. Placement in the more anterior position (Position B) led to a higher moment value (+33%) for the 10-mm size and a lower moment (–46%) for the 14-mm size.

Concerning the influence of the position on spine stiffness, the opposite behavior was observed between the 10- and 14-mm devices in both flexion and extension. This result may be related to the different distances between the spinous processes in the 2 positions: the 14-mm device is oversized in Position B in this specific model, thus leading to a high flexed neutral position and a stiffening of the spine segment during flexion. Contrastingly, the 10-mm device had a limited effect in Position B on the neutral position and thus on the flexion motion.

Figure 7 features graphic visualization of the locations of the ICRs in flexion (with and without lace fixation) and in extension for the 2 different device sizes implanted in Positions A and B. Generally, all device sizes and positions led to a shift of the ICR paths toward the posterior direction, in both flexion and extension. Without the laces, the ICRs in flexion approached those of the intact spine segment, going toward the center of the disc. This result is very likely due to the less significant kinematic role of the device in flexion when implanted without the laces. The 14-mm device in both Positions A and B led to more limited movements of the ICRs during flexion and extension. This result would probably imply a more pronounced pivot role of the larger-sized device during motion as compared with the smaller one.

Discussion

Although clinical and surgical recommendations

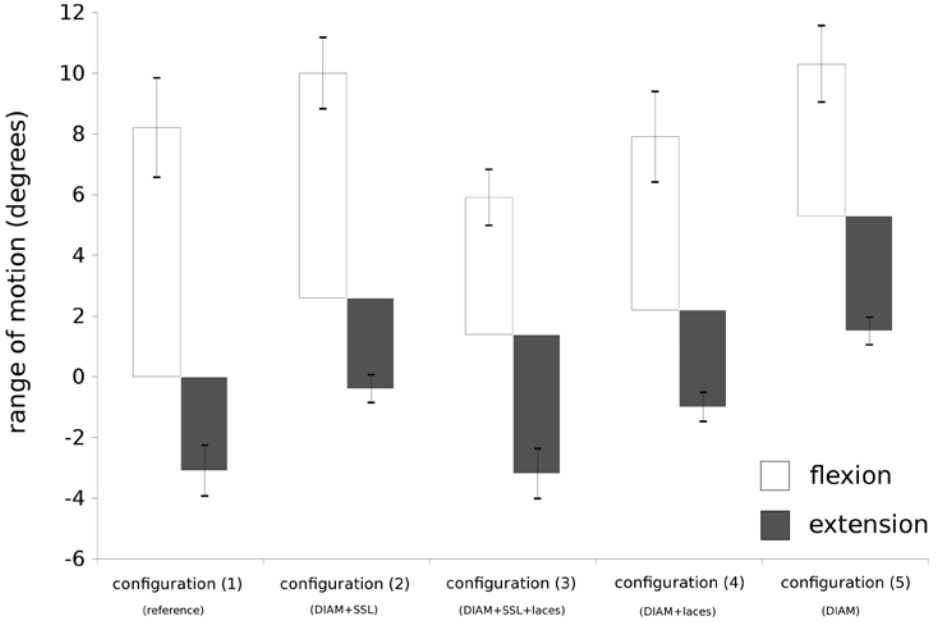

Fig. 5. Graph showing the ROMs (mean values and standard deviations) measured for the 5 configurations in flexion and extension. The border between the flexion and extension bars represents the average shift in the neutral position of the specific configuration with respect to Configuration 1.

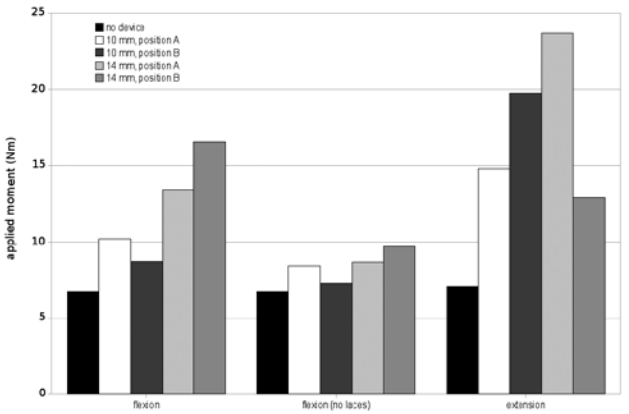

Fig. 6. Bar graph demonstrating the moment values required to reach the imposed rotation for the intact spine segment and the spine implanted with the 10- or 14-mm device in the Positions A and B in Fig. 4.

should not be based on biomechanical evaluations alone, some indications can be extrapolated from our results. Since the SSL and the laces had an important mechanical role, the ligament should be preserved and the laces utilized. Choosing the correct device size and its proper positioning are crucial.

The DIAM induced a shift toward kyphosis in the neutral position. Other interspinous devices (X Stop, Wallis, Abbott Spine; and Coflex, Paradigm Spine GmbH) were reportedly unable to induce a significantly less lordotic neutral position at the implanted level according to a literature study.[22] Although these data cannot be directly compared with the current findings because of the different testing conditions, the DIAM was found to reduce local lordosis in that study, in agreement with our results. This shift in the neutral position may be useful in relieving symptoms such as bilateral radicular pain, sensation disturbance, and loss of strength in the legs.[12] However, an excessively kyphotic neutral position may overload the intervertebral disc, possibly leading to early degeneration.[19] An alteration of overall lumbar lordosis related to segmental modification of the neutral position may be expected as well.

The shift of the neutral position was related to the size and positioning of the device. Small devices contributed to spine stabilization only to a limited extent, while too-large devices could induce a kyphotic neutral position with the risk of disc overloading. Device placement played a relevant role in determining both the neutral position and spine flexibility, mainly because of the variable distance between the spinous processes in the different positions. However, this parameter is not likely to be easily controlled during the surgery, given the anatomical constraints and the high variability between the different patients. To achieve correct implantation and to avoid an overestimation of the device size, we recommend using the provided templates rather than the operating positions, which induce excessive spinal flexion.

Based on the present results, the use of the fixation laces should be recommended, given their proven importance in stabilizing the spine and to ensure device stability in the immediate postoperative period while preventing migration in the anteroposterior direction when the fibrotic capsule enclosing the DIAM is not yet formed. Therefore, implantation of the DIAM without laces fixation, usually performed to preserve greater mobility of the treated spine unit while maintaining the shift of the neutral position, is highly questionable. Furthermore, the presence or absence of the SSL had a significant influence on the mechanical behavior of the implanted spine both in flexion and extension. Thus, the surgical approach that allows for its preservation may be preferred, both to minimize the surgery's invasiveness and to achieve greater spinal stabilization.

The present study was conducted using animal spine specimens. The use of human specimens is generally believed to provide more accurate results.[9] As a matter

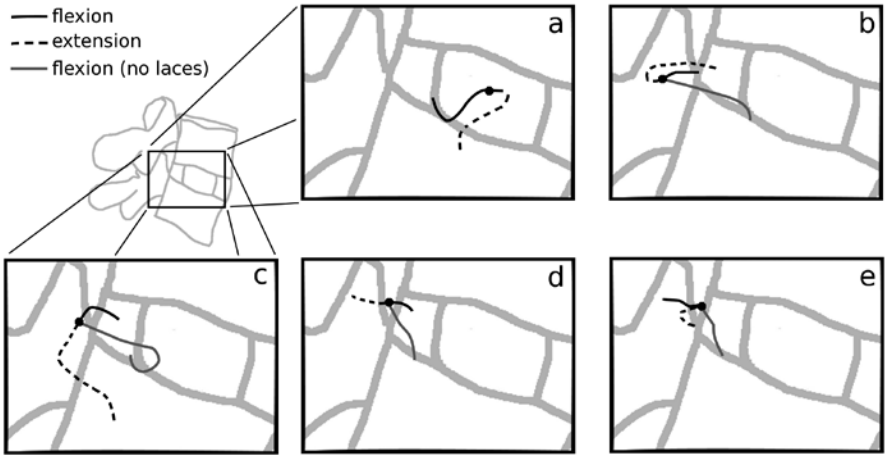

Fig. 7. Positions of the ICRs during flexion with the laces, flexion without the laces, and extension for no device implanted (a), a 10-mm device in Position A (b), a 10-mm device implanted in Position B (c), a 14-mm device implanted in Position A (d), and a 14-mm device implanted in Position B (e).

of fact, animal models can reveal trends in results in a comparative way, but should not be used to obtain results from either a quantitative or a statistical point of view.

Note, however, that animal models can be convenient as compared with human specimens because of their wide availability and lower cost. Furthermore, specimens obtained from animals of the same age and breed under the same conditions usually allow for a higher repeatability of the experiments because of the greater homogeneity of the population in terms of the level of physical activity, diet, disc degeneration, and bone mineral content.[4,9] Porcine specimens have been successfully used as models for biomechanical testing of human spine instrumentation techniques, spinal instability, and spinal fusion.[1] Pedicular screws with standard diameters have been reported to be difficult to use in porcine spines; however, DIAM devices in standard sizes were easily implanted in the porcine specimens in the present study. The hemifacetectomy procedure was found to induce a kinematics of the porcine spine more similar to that of the human spine by using FE models.[2]

A limitation of the present in vitro study concerns the loading protocol. The developed loading apparatus, based on an eccentric axial actuator, was able to apply a combination of compression and flexion-extension moment up to a specified moment value. Other spine testers described in the literature have applied pure moments[23] or moments combined with a compressive preload[21] or a follower load.[15] But the present study was based only on the analysis of the ROMs in correspondence with the maximal moment, and thus the loading path to reach the maximal load values was not significant for the considered results. Since quasistatic loads were applied and preconditioning of the specimens was performed, viscoelastic effects could also be neglected.

Concerning the limitations of the FE model, a simplified approach was used to represent the device. Furthermore, its mechanical properties were not revealed by the manufacturer, and their values were assumed in the present study. The ICRs obtained with the model of the intact spine were located near the center of the disc, a finding that differs from a previous report.[17] This may be due to the different shape and initial gap of the facet joints, which had a smaller influence in the extension motion as compared with that in the earlier report. All of these limitations have a direct impact on the accuracy of the FE results, which should not be intended as precise absolute values, but are still able to describe trends due to the variation in device size and placement.

Conclusions

The implantation of a correctly sized and positioned DIAM induced a shift toward kyphosis in the neutral position. This shift may be beneficial in reducing symptoms of spinal stenosis such as radicular pain, sensation disturbance, and loss of strength in the legs. We recommend preservation of the SSL and the use of fixation laces because of their relevant mechanical role. Choosing the proper device size and placement should be achieved by using an appropriate surgical technique.

Disclosure

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Author contributions to the study and manuscript preparation include the following. Conception and design: Anasetti, Galbusera, Aziz, Bellini, Brayda-Bruno. Acquisition of data: Anasetti, Galbusera. Analysis and interpretation of data: Anasetti, Galbusera. Drafting the article: Anasetti, Galbusera, Aziz. Critically revising the article: Anasetti, Galbusera, Bellini. Reviewed final version of the manuscript and approved it for submission: all authors. Statistical analysis: Anasetti, Galbusera. Administrative/technical/material support: Addis, Villa, Teli, Lovi. Study supervision: Brayda-Bruno.

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