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Cadaveric biomechanical studies of ADDISC total lumbar disc prosthesis

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A R T I C L E I N F O

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Range of motion
Motion preservation
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A B S T R A C T

Background: Most total disc replacements provide excessive mobility and not reproduce spinal kinematics, inducing zygapophyseal joint arthritic changes and chronic back pain. In cadaveric lumbosacral spines, we studied if a new lumbar disc prosthesis kinematics mimics the intact intervertebral disc.
Methods: In eight cold preserved cadaveric lumbosacral spines, we registered the movement ranges in flexion, extension, right and left lateral bending, and rotation in the intact status, post-discectomy, and after our prosthesis implantation, comparing them for each specimen.
Findings: Comparing the intact lumbosacral spine with the L_4-L_5 prosthesis implanted specimens, we saw statistically significant differences in lateral bending and right rotation but not in the full range of rotation. Analyzing segments, we also noticed statistically significant differences at L_4-L_5 in flexion-extension and rotation. On the other hand, the L_4-L_5 discectomy, compared to the baseline spine condition, showed a statistically significant mobility increase in flexion, extension, lateral bending, and axial rotation, with an abnormal instantaneous center of rotation, which destabilizes the segment partly due to anterior annulus surgical removal. Disc prosthesis implantation reversed these changes in instantaneous center of rotation, but the prosthesis failed to restore the initial range of motion due to the destabilization of the ligaments in the operated disc.
Interpretation: The ADDISC total disc replacement reproduces the intact disc kinematics and Instantaneous Center of Rotation, but the prosthesis fails to restore the initial range of motion due to ligament destabilization. More studies will be necessary to define a technique that restores the damaged ligaments when implanting the prosthesis.

1. Introduction

Chronic low back pain is prevalent and a frequent cause of temporary sick leave and permanent disability (Luckhaupt et al., 2019). Its multifactorial cause includes all anatomical structures of the spine, including the intervertebral disc (Dai et al., 1992).

Lumbar fusion is an alternative when medical treatment does not control symptoms (Mobbs et al., 2015). However, spinal arthrodesis can follow pseudoarthrosis (Manzur et al., 2019), zygapophyseal joint osteoarthritis (Ma et al., 2019), and adjacent-level disease (Michael et al., 2019).

Surgeons attempted to change the initial fusion of the painful joint by maintaining mobility through disc prosthesis implantation. However, the first total lumbar disc prostheses (Büttner-Janz et al., 1987) presented many problems, minimized through continuous improvements (Charitè) (Link, 2002) and new designs (Bono and Garfin, 2004) (Prodisc™ (Park et al., 2016), Activ-L™ (Lu et al., 2015), Maverick-L™ (Mathews et al., 2004), Cadisc-L™ (McNally et al., 2012a), Baguera-L™ (Fransen et al., 2018), M6-L™ (Schätz et al., 2015)).

Compared to spinal fusion, total disc replacement provides a higher

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reincorporation to the same working post (Guyer et al., 2016), a better quality of life (Clavel et al., 2017), a lower incidence of adjacent-level disease (Gornet et al., 2019), and fewer re-interventions (Radcliff et al., 2018). However, disc prostheses induce mid and long-term zygapophyseal joint osteoarthritic changes at the index and adjoining levels (Botolin et al., 2011). This osteoarthritic changes, causing low back pain after lumbar arthroplasty, have been related to the excessive mobility that accompanies it (Choi et al., 2017a) and is more evident in those with a greater motion range (Charitè) (Choi et al., 2017b) or when the rotation center is not in the intervertebral disc posterior third (Prodisc™ (Rohlmann et al., 2005), Activ-L™ (Zander et al., 2009)).

A disc prosthesis with a range of motion reproducing the intact intervertebral disc will generate a more physiological movement of the spine. It, therefore, will result in less future damage to the adjacent intervertebral discs and zygapophyseal joints. This article describes the kinematics in cadaveric spine specimens before and after implanting the ADDISC total disc prosthesis. We aimed to see if it allowed the expected mobility range. We hypothesized that the mobility of the lumbar spine would be within physiological ranges after the implantation of our prosthesis.

2. Methods

The ADDISC prosthesis (ROA 14SL, La Pedrera, Gijón, Spain) has three components (Fig. 1). We made the upper and lower ones of the Cobalt-Chromium-Molybdenum (CoCr28Mo6) alloy. Its articular surfaces allow movement in the three axes, replicating the mobility range of a healthy lumbar disc. The intermediate polycarbonate-urethane piece, inserted between the two metal parts, absorbs loads and prevents mobility excess, particularly in axial rotation (Figs. 1 and 2). The prosthesis is not in clinical use yet.

Once placed in the test machine, we did not remove the lumbosacral spine anatomical specimens from there until we had performed all tests. We completed the discectomy and the discal prosthesis implantation while the samples remained in the testing machine by a senior qualified neurosurgeon member of the research team.

2.1. Specimens

We undertook the study in eight lumbosacral spine specimens from cold-preserved fresh human cadavers. Donors ranged from 27 to 52 years of age and had no previous lumbosacral spine surgical procedures, trauma, malignancy, infection, or inflammatory disease. We ruled out osteoporosis with a Dual Energy X-ray Absorptiometry (DEXA) scan and discarded specimens with a Z score < 2.5. We analyzed the samples with MRI and did not use those with signs of discal degeneration. After removing all soft tissues except ligaments and discs and leaving all bone structures intact, we sectioned the spine at the L_1-L_2 disc and sacroiliac joints. We customized the implants with the data from lumbar spine AP and L x-rays, CT scans, and Magnetic Resonance Imaging (MRI). We fixed the specimens with acrylic bone cement (SR Triplex Cold, Ivoclar Vivadent AG, FL-9494, Schaan, Liechtenstein) by the L_2 vertebra and sacrum (S_1) to the upper and lower jaws of the testing machine (Fig. 3).

We repeated the kinematic studies three times for each specimen: intact spine (PRE), post anterior annulus removal and L_4-L_5 discectomy (ANG), and after ADDISC implantation (POS). The L_4-L_5 disc was selected because it is the one that, in our experience, most commonly needs a complete lumbar disc replacement. We studied the ANG condition because we wanted to know the degree of excessive motion range induced by the surgical maneuvers required to implant the total lumbar disc prosthesis (anterior longitudinal ligament and anterior part of the annulus fibrosus). With these values in hand, we could evaluate how much the ADDISC total disc prosthesis recovered the motion ranges of the intact intervertebral disc.

2.2. Methodology

We conducted the tests at the Biomechanics Institute of Valencia, Valencia, Spain. The testing machine had a motor connected to a flexible torsion cable (Fig. 3), which supplied torque on the upper jaw load cell while the lower jaw fixed the sacrum. We made the support structure with square profiles 45 × 45 mm (Bosch Rexroth AG, Elchingen, Germany), with IGUS KSTM 20 ball joints (RS components GmbH, Frankfurt am Main, Germany) and 004000212-dB cable (BIAX Flexible Power, Stuttgart, Germany) (maximum torque: 1960 Ncm). We performed the

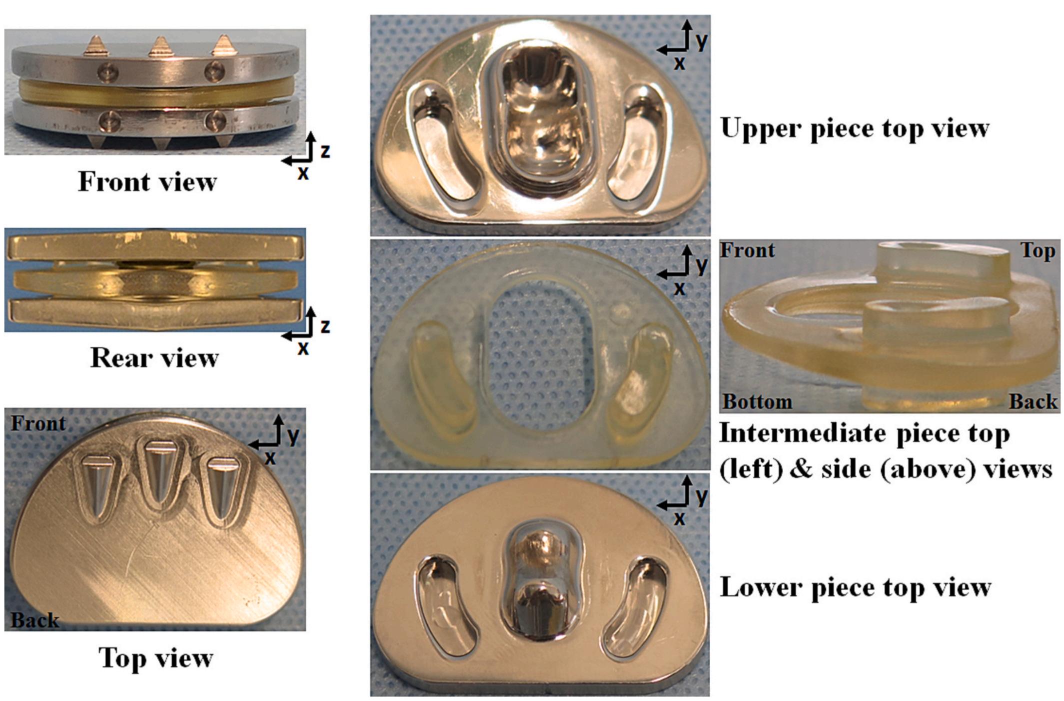

Fig. 1. ADDISC total disc prosthesis.

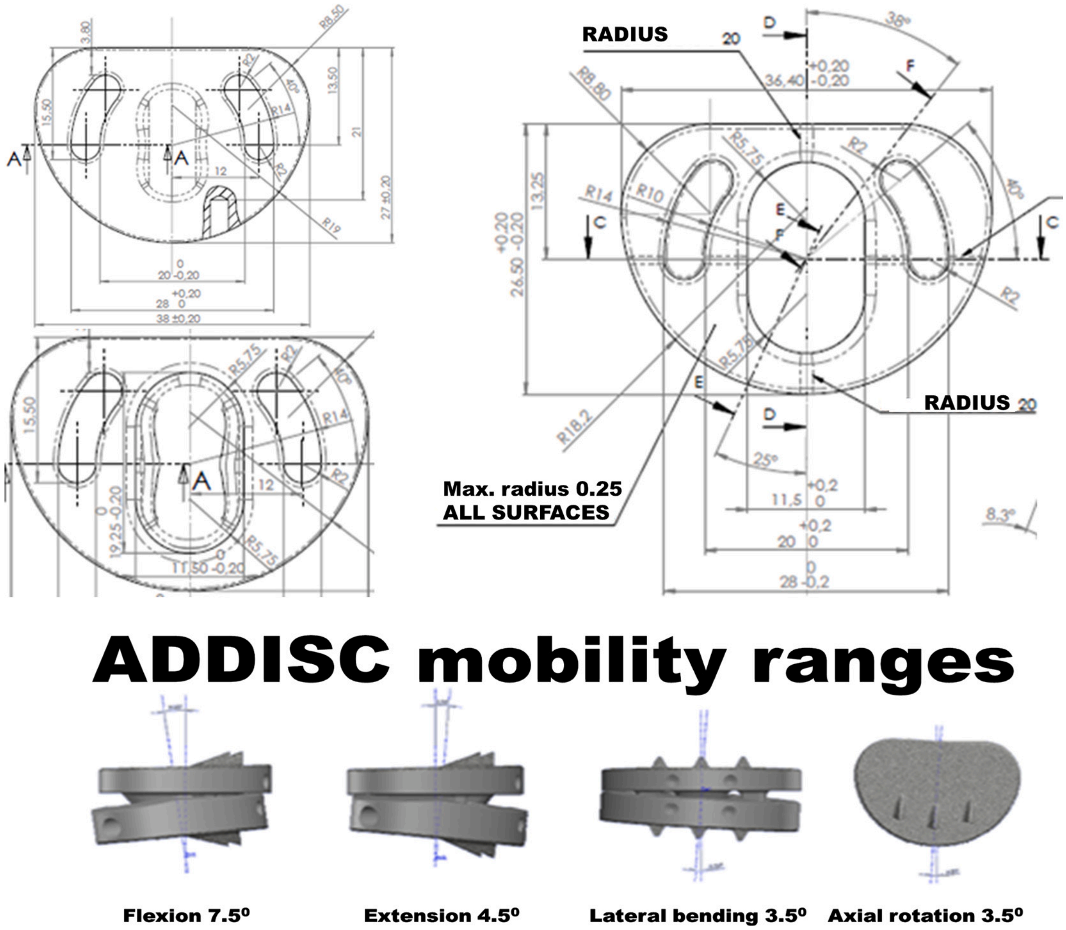

Fig. 2. Drawing and dimensions of the ADDISC complete lumbar disc prosthesis (measurements are in millimeters and angles in degrees). We also show its mobility ranges in each axis.

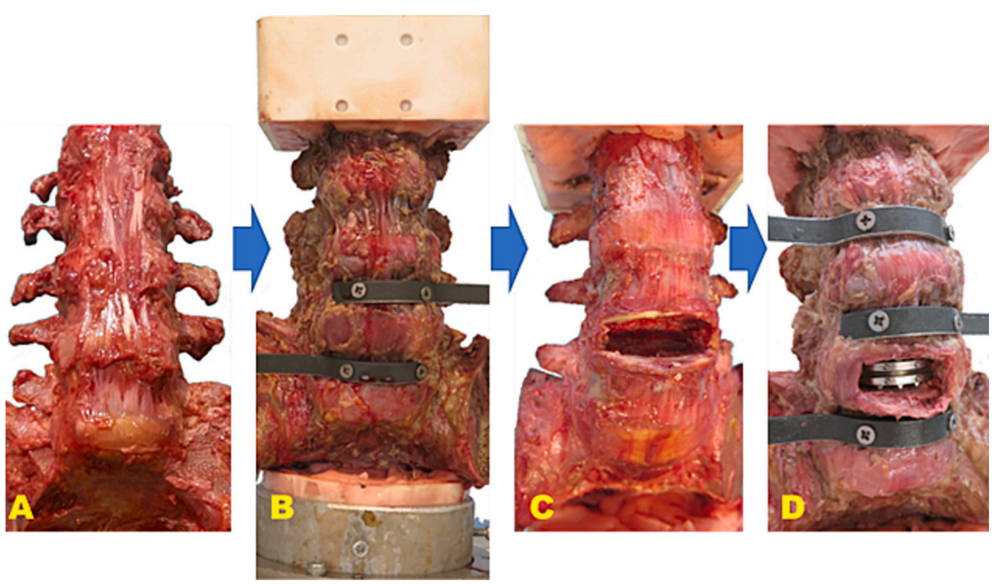

Fig. 3. (A) the intact cadaveric lumbar spine, (B) with the metal pieces to hold the optical markers inserted, (C) after the discectomy, and (D) with ADDISC total disc prosthesis implanted**.**

movement with a motor Nema 23 - 23HS22-2804S-HG50 (Stepperonline Inc., New York, NY, USA) with a 25 Nm maximum torque (absolute 40 Nm), 0.001125° maximum resolution, and 0.036° nominal precision. We calibrated the torque cell once a year, 20 Nm DYJN-130 (CALTSensoR, Pasadena, California, USA) at +/− 10 Nm (range: 2–200 Nm). We used the torque signal to limit and control the test. We modified the motor, cable, and load cell position for the axial rotation movement, aligning it with the vertical axis of the spine (Fig. 3).

The kinematic study used photogrammetry techniques with a camera DMM 22BUC03-ML (The Imaging Source, Bremen, Germany) with 744 × 480 resolution, 30 fps (frames per second) capture frequency, 1 s recording time, and 5.5 mm optics. Once registered, we could review each scene later, export it, import it, and obtain information about it. We captured the movement with ChArUco table markers (OpenCV, Intel Corporation, Mountain View, California, USA) combined with IC Capture software (The Imaging Source, Bremen, Germany). We used the OpenCV library (Garrido-Jurado et al., 2014) to detect each marker. Once we obtained each marker's pose, we calculated the composition of movements to get the relative angle and the ICR, according to Page et al. (Page et al., 2009). Finally, we positioned the markers on the L_3, L_4, and L_5 vertebral bodies and the upper and lower jaws (Fig. 4).

The next step was the digitization of the images taken by each camera. It was necessary to digitize the first scene manually to define the position of each marker. Once done, the program could locate each marker position in the other images in this sequence and digitalize them automatically.

We applied different movements to the lumbosacral spinal column with the angular motor. We studied the flexion-extension, lateral bending, and axial rotation. In each movement cycle, the motor applied an angular displacement until reaching the fixed torque moment limit of 8 Nm measured on the load cell, first in one direction and then in the opposite, registering the angle throughout the entire range of movement. Furthermore, this application allowed the graphical representation of the variables, where we could see the evolution of the rotation angle depending on the applied load and compare these values for the different vertebrae.

For each specimen, condition, and axis, we carried out the following procedure:

First, we establish the neutral position. Then, we established the neutral position for each condition and axis, conditioned the cadaveric spine specimens with five cycles at 10°/s, and logged data with five cycles at 10°/s. The test conditions were five cycles at ten grades/s (5 cycles in Popovich et al. 2013 (Popovich et al., 2013)) and data logging of 5 cycles at ten grades/s. Spine creep deformation did not appear because the rotations that imply a torsion moment applied are not maintained constant over time during the test.

Second, we applied flexion-extension, lateral bending, and axial rotation movements. Each movement cycle consisted of angular displacement until reaching 8 Nm. For movement type, we recorded the images subjecting the spine to increasing loads, starting from the initial state without it (M = 0 Nm) and rising until reaching 8 Nm, respectively. These loads were lower than the maximum physiological ones for human spines, reported as 15 Nm (Yamamoto et al., 1989). Therefore, the load must be lower than the maximum physiological to allow test repetition with the same specimen in different load modes and statuses without injuring it. Consequently, we repeated the tests three times, using only the results of the third one for the analysis to minimize the viscoelastic effects of the materials (Wang et al., 2000). We measured the motion range of each vertebra during the test, particularly at the L_4-L_5 disc, in flexion, extension, lateral flexion, and axial rotation. We calculated the stiffness indirectly, knowing that the maximum torque applied was 8 Nm. We synchronized the torque headpiece and the marker displacement measurement system to calculate the ROM for each vertebral unit and the entire spine.

Once we knew the baseline conditions, we removed the section of the anterior longitudinal ligament covering the L_4-L_5 disc and the anterior part of its annulus fibrosus. Then, we performed a total discectomy to provide the space needed to insert the discal replacement. We left the posterior longitudinal ligament intact. Afterward, after inserting the discal prosthesis, we repeated the same biomechanical studies a third time.

2.3. Study variables

We gathered the data from the complete lumbosacral spine specimens and the L_2-L_3, L_3-L_4, L_4-L_5, and L_5-S_1 spinal segments. In addition, we studied motion range, the 95th minus 5th percentile of the motion range signal, and correlated angle and angular acceleration. Values close to one indicate harmonic movement.

3. Statistical analysis

We evaluated the normality of the parameters using the Shapiro-Wilk and Kolmogorov-Smirnov tests. We calculated the movement angles and parameters with the GNU Octave software and the free statistical analysis software R (R Development Core Team) in combination

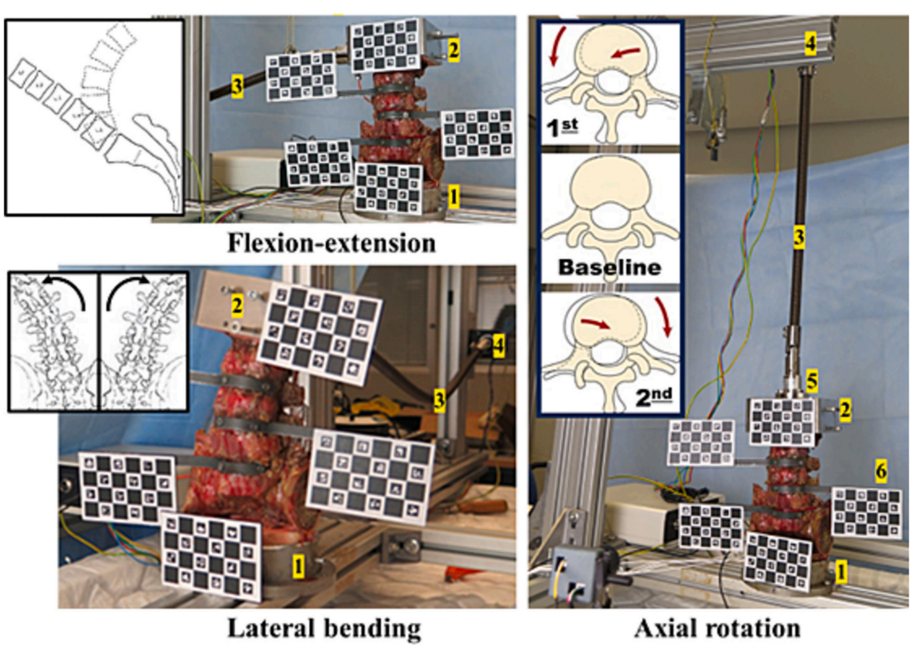

Fig. 4. Cadaveric spine specimen setup for flexion-extension (top left), lateral bending (bottom left), and axial rotation (right). Lower clamp (1), upper clamp (2), cable (3), motor (4), Cardan joint (5), marker (6).

with the Deducer user interface (Fellows, 2012). We performed all statistical analyses using the free software R Commander 3.4.3. Then, we compared the PRE and POS measurements in maximum extension, maximum flexion, right and left lateral bending, and right and left axial rotation with the range in all these movements. The difference between pairs of measurements was the new variable generated. First, we compared the means of each condition and the contrast of those means with the 'Student's paired *t*-test, and we considered statistically significant differences if $p < 0.05$. Later, we performed a one-sample 'Student's test to compare our results with the normal range of motion and our implant mobility estimation.

4. Results

Below, we offer the angles rotated by each vertebra as a function of the moments applied for each test. After processing the values of those angles, we created normalized graphs with the slope sign to compare the values between vertebrae.

4.1. Whole lumbosacral spine specimen kinematic study

All mobility range samples presented a normal distribution, with $p > 0.05$ (Table 1).

4.2. Whole lumbosacral spine specimen flexion-extension

We found no statistically significant differences between PRE and POS for the right and left lateral bending, maximum extension, maximum flexion, and range, but the maximum extension increased, and the maximum flexion diminished in all specimens. Finally, the range of motion, maximum extension, and flexion rose, but the mean difference was not noteworthy. In addition, the *t*-test did not detect statistically significant differences in any of the parameters (Table 2).

4.2.1. Whole lumbosacral spine specimen lateral bending

We found no statistically significant differences between PRE and POS for right and left lateral bending that was present for the range of movement (Table 2).

Table 1
ROM values for each specimen for flexion-extension, lateral bending, and rotation ranges (angles in degrees). PRE (intact lumbosacral spine status), POS (after ADDISC total disc prosthesis implantation).

Condition	Sample	RANGE FLEXION-EXTENSION Mean	SD	RANGE LATERAL BENDING Mean	SD	RANGE AXIAL ROTATION Mean	SD
PRE	587	59.9	0.3	56.7	0.2	21.7	0.2
	759	45.8	0.3	37.2	0.3	27.8	0.3
	765	44.6	0.1	48.6	0.4	16.1	0.1
	778	36.4	0.1	32.3	0.7	10.1	0.4
	779	46.2	0.1	54.7	0.3	18.2	0.3
	781	50.2	0.2	39.7	0.4	15.8	0.1
	782	41.5	0.2	46.3	0.2	14.7	0.2
	791	52.3	0.1	42.8	0.5	20.0	0.1
POS	587	63.8	0.4	59.2	1.4	39.3	0.3
	759	45.1	0.2	40.6	0.2	24.5	0.3
	765	54.4	0.2	52.1	0.3	30.2	0.3
	778	45.1	0.2	38.0	0.1	23.0	0.3
	779	51.4	0.2	52.7	0.2	20.2	0.4
	781	52.7	0.1	40.5	0.4	16.9	0.1
	782	45.2	0.1	48.3	0.1	13.8	0.3
	791	53.7	0.3	45.9	0.3	19.8	0.1
TOTAL							
PRE		47.1	7.1	44.8	8.4	18.0	5.2
POS		51.4	6.4	47.2	7.2	23.4	8.0

Table 2
Maximum extension, maximum flexion, left and right lateral bending, left and right rotation (angles in degrees), and range for PRE and POS conditions of the kinematic study of the whole lumbar spinal column specimens. PRE (intact lumbosacral spine status), POS (after ADDISC total disc prosthesis implantation).

Measure	PRE Mean	PRE SD	POS Mean	POS SD	t-value	Mean difference	*p*-value
FLEXION-EXTENSION RANGE	47.1	7.1	51.4	6.4	1.274	4.318	0.223
LATERAL BENDING RANGE	44.8	8.4	47.2	7.2	0.603	2.379	0.556
AXIAL ROTATION RANGE	18.0	5.2	23.4	8.0	1.582	5.400	0.1393

4.2.2. Whole lumbosacral spine specimen axial rotation

There were no statistically significant differences in any measurements in the axial rotation movement (Table 2), although the total range of motion increased from the PRE to the POS condition.

Using the Student's *t*-test to analyze each anatomical lumbosacral spine specimen, we found that the lumbar spine mobility after the prosthetic implantation had a mean range of 52.1^o (CI 95% 48.40–55.78^o) in flexion-extension, 47.51^o (CI 95% 43.38–51.64^o) in lateral bending and 24.26^o (CI 95% 19.20–29.32^o) in axial rotation.

4.3. Kinematic study by spinal segments

4.3.1. Flexion-extension by spinal segments

Comparing the PRE and POS conditions, the studied discs, particularly the L_4-L_5 segment flexion-extension, where we implanted the ADDISC disc prosthesis, showed no statistically significant differences (Table 3).

4.3.2. Lateral bending by spinal segments

Again, comparing the PRE and POS conditions, the *t*-test showed no statistically significant differences in any of the studied discs (Table 3).

4.3.3. Axial rotation by spinal segments

The motion range in the axial rotation increased in all specimens in the L_4-L_5 level, where we implanted the ADDISC disc prosthesis, but with no statistically significant differences in this or any of the remaining lumbar discs (Table 3).

4.4. Stiffnesses

We calculated them indirectly using maximum moments and displacements. We aimed to rule out any softening or degradation of the anatomical lumbosacral spine specimens that might occur during the tests or possibly as a result of them. In Table 4, we see that the changes were minor in flexion-extension and lateral bending. Still, in axial rotation, stiffness decreased to half, probably due to the axial loads, as this allows excessive mobility that the ADDISC prosthesis cannot control. As we showed in Fig. 2, this prosthesis, by design, cannot rotate axially $>3.5^\circ$ in each direction. Thus, devoid of any axial load, the vertebral endplates of the nearby vertebra turned axially in excess as the anchoring teeth of this disc prosthesis partially eroded the bone in this type of movement.

4.5. ICR and movement analysis

4.5.1. Flexion-Extension

Figure 1S shows an increase in flexion-extension mobility in the POS condition (prosthesis plus anterior annulus removal, red line)

Table 3
Mean extension, maximum lateral bending, and axial rotation ranges (angles in degrees) for the PRE and POS conditions of the kinematic study by spinal segments under 8 Nm. PRE (intact lumbosacral spine status), POS (after ADDISC total disc prosthesis implantation).

	Segment	PRE		POS		t-value	Mean differences PRE-POS	p-value
		Mean	SD	Mean	SD			
RANGE FLEXION-EXTENSION	L_2-L_3	9.4	4.2	10.3	2.4	0.356	0.877	0.736
	L_3-L_4	8.9	1.0	7.5	3.5	−0.751	1.402	0.501
	L_4-L_5	10.5	3.5	19.1	6.6	2.279	8.539	0.076
	L_5-S_1	16.6	4.1	14.3	1.5	−1.053	2.324	0.354
RANGE LATERAL BENDING	L_2-L_3	18.7	13.0	13.8	5.2	−0.693	4.861	0.526
	L_3-L_4	15.5	6.3	25.3	10.1	0.947	9.823	0.405
	L_4-L_5	11.3	2.0	18.9	8.2	1.776	7.553	0.163
	L_5-S_1	7.9	1.9	7.5	1.4	−0.345	0.425	0.724
RANGE AXIAL ROTATION	L_2-L_3	8.0	3.2	3.7	2.5	−0.868	4.376	0.442
	L_3-L_4	4.1	3.1	13.4	6.6	1.678	9.313	0.177
	L_4-L_5	4.4	3.0	16.0	6.0	3.463	11.621	0.062
	L_5–S_1	4.0	1.4	3.9	0.9	−0.152	0.135	0.885

Table 4
Results of the maximum, neutral, and minimum stiffness values for the PRE and POS conditions of the whole spine kinematic study under 8 Nm. PRE (intact lumbosacral spine status), POS (after ADDISC total disc prosthesis implantation).

		Torque (N m)			Stiffness (Nm/°)		
		Maximum	Neutral	Minimum	Maximum zone	Neutral zone	Minimum zone
FLEXION-EXTENSION	PRE	7.58	1.17	−7.28	0.21	0.08	0.31
	POS	7.76	1.17	−7.41	0.18	0.08	0.34
LATERAL BENDING	PRE	7.33	0.77	−7.39	0.26	0.13	0.26
	POS	7.57	0.17	−7.19	0.23	0.06	0.28
AXIAL ROTATION	PRE	7.64	0.73	−7.30	0.62	0.23	0.81
	POS	7.64	0.18	−7.27	0.36	0.03	0.41

concerning the PRE status. The changes, though, are minor.

There are changes in the ICR trajectory in the vertical and anterior-posterior planes in the PRE and POS condition comparison of the samples in the flexion-extension movement. However, these differences could be due to the damage generated in the anterior longitudinal ligament and the anterior annulus necessary to perform the discectomy before implantation and not to the disc prosthesis itself. Thus, the implanted spine would have a behavior like that of the physiological one.

The comparison shows greater mobility in the flexion-extension plane, indicating that the prosthesis provides greater mobility (or less restriction) than the intact intervertebral disc. Regarding the displacement of the ICR, the trajectory is remarkably similar, indicating the prosthesis's rotation behavior is like that of the undamaged spinal condition.

Figs. 2S and 3S show the ICR displacement over time (cycles) and angle (motion range) on the x-axis. In the POS condition, a lateral tilting of the ICR occurs.

In the ICR displacement graphs on the y-axis (Figs. 4S and 5S), we observe a similar pattern in the ICR displacement in the vertical plane in the PRE and POS conditions.

In the z-axis, we observed a similar pattern in the ICR displacement in the anterior-posterior plane in the PRE and POS conditions (Fig. 6S and Fig. 7S).

4.5.2. Lateral bending

Figure 8S shows the ICR displacement in the lateral bending in the x (side-to-side) and y (vertical) axes. Again, there are minor differences between the PRE and the POS at a qualitative level.

4.5.3. Axial rotation

We show below (Fig. 9S) the ICR displacement in the x (side-to-side) and y (vertical) axes in the axial rotation movement (Fig. 16). In the same way, as in lateral flexion, there are no differences between the PRE and the POS at a qualitative level.

4.5.4. ROM

We present here a new prosthesis design that has two centers of rotation that we consider a novel contribution. We will now present the ROM results after ADDISC implantation, showing that this system of two centers of rotation provides spinal biomechanics that are closer to ones of the intact intervertebral disc.

In Fig. 10S, we show the ROM in flexion and extension (Fig. 10S), lateral bending (Fig. 11S), and axial rotation (Fig. 12S) at the L_4-L_5 disc before (PRE) and after (POS) implant insertion as an example of the prosthesis's effect on the spine's mobility and its similarity with the healthy spine. In all the previous graphs, the non-linear behavior of the column is shown. At low moments, the spine stiffness is low, and at moments close to 2 Nm in all loading modes, its stiffness increases noticeably. This behavior is normal for the spine to avoid large rotations that could cause spinal disc damage.

The spine movement first occurred in extension with the intact specimen starting from a position at a moment of zero N m slightly in flexion. We applied positive extension moments up to values close to 8 Nm, then unloaded and applied flexion loads. After implanting the ADDISC disc prosthesis, we see that the spine had a 10^o extension angle at zero moments, reaching 22^o at maximum extension. In flexion, compared to the intact spine, the maximum angle achieved after disc prosthesis implantation is reduced by 5^o with the maximum applied moment of 8 N m. If we eliminate the initial extension induced by the implant implantation, the spine will have a similar behavior before and after disc prosthesis insertion. The reason for this 10^o extension angle could be due to the fact that the posterior longitudinal ligament was spared so that on inserting the disc prosthesis, it acted like a fulcrum, forcing the disc into extension. Removing this ligament is not advisable as it would have increased the segmental instability even further. This additional damage to the vertebral ligamentous structures must be done in case of disc herniation in the course of a total disc prosthesis implantation. Still, it must not be done regularly for fear of inducing excessive spinal mobility.

4.6. Removal of the annulus

When we analyze the mobility of the whole lumbosacral spine after the removal of the anterior longitudinal ligament and the anterior part of the annulus fibrosus (ANG) in the L_4-L_5 segment, we observe that the range of movement derived from this segment increases (Table 5).

We calculated the difference in the motion range between the PRE and ANG values to assess the degree of instability due to the anterior longitudinal ligament and the anterior part of the annulus fibrosus removal. We observed a difference of 13.007° for the flexion-extension range ($p = 0.00034$), an 8.848° difference for the lateral bending range ($p = 0.004$), and a 13.517° difference for the axial rotation range ($p = 0.00068$). Comparing the discectomy ANG with the POS condition (after ADDISC insertion), we see a difference of 4.468° ($p = 0.042$) for the flexion-extension range, 1.295° ($p = 0.43$) for the lateral bending range and 1.896° ($p = 0.37$).

5. Discussion

Spinal fusion, the standard treatment for chronic low back pain secondary to degenerative disc disease, is often accompanied by adjacent level mid and long-term problems related to the mobility loss of the fused segment or segments and the increased load and mobility of adjacent ones (Lee and Choi, 2015). Therefore, nowadays, experts recommend a semirigid or dynamic fusion on the level adjacent to a spinal fusion, mainly if this fusion is extensive (Gertzbein et al., 1996). Therefore, to solve the spinal pathology, maintaining mobility and function of the affected level is an option to consider.

The first total disc replacement ball-and-socket designs allowed excessive mobility (Schmidt et al., 2012)' which had to be controlled by the zygapophyseal joints (Choi et al., 2017a). Unfortunately, that overloaded these joints and induced osteoarthritic changes, causing mid- and long-term chronic low back pain (Försth et al., 2020).

In analyzing the lumbar disc prosthesis currently available in the market, there are few studies on their actual mobility range (Dmitriev et al., 2008; Hitchon et al., 2005; Zander et al., 2009). All the assessments suffer from limitations inherent to *ex vivo* human cadaveric lumbar spine studies (Dmitriev et al., 2008; Ha et al., 2009; Hitchon et al., 2005; McNally et al., 2012b; Tsitsopoulos et al., 2012; Wilke et al., 2012a; Yao et al., 2014). Some do not describe the machine used (Tsitsopoulos et al., 2012; Wilke et al., 2012a; Yao et al., 2014), but for most, it is custom-made by the research team (Dmitriev et al., 2008; Ha et al., 2009; McNally et al., 2012b; Panjabi et al., 2007a; Panjabi et al., 2007b), as is our case. The regulations followed have been the ASTM Method F 2346–05, ASTM WK7479, ISO ISO/TC 150 / SC 5, and more recently, the ASTM F 2346:2018 (ASTM F 2346: 2018, n.d.). Research groups have reported that the total disc arthroplasty (CharitéTM (Panjabi et al., 2007a), Maveric™ (Dmitriev et al., 2008), Prodisc-LTM (Panjabi et al., 2007b)) provides index level movement ranges close to the intact disc with no significant adjacent level biomechanical changes contrarywise to the spinal arthrodesis of the same levels (Dmitriev et al., 2008; Panjabi et al., 2007a; Panjabi et al., 2007b). It is interesting to note that with two-level Charité disc prosthesis implantation, there was excess mobility that exceeded what was expected from a single disc implantation (Panjabi et al., 2007a). The ADDISC total disc replacement improves the movement ranges with respect to other total disc prostheses, with results even closer to those of the intact intervertebral lumbar disc.

In ball-and-socket total disc replacements, as the ball radius increases, it diminishes the movement range in flexion, extension, and lateral bending, but it increases in axial rotation (Choi et al., 2017a), precisely the most harmful movement for the facet joints. The ideal situation would be a disc prosthesis with the same mobility ranges as the intact intervertebral disc, which does not rely on the facet joints to limit the excessive motion ranges (Botolin et al., 2011; Dreischarf et al., 2015). The ball radius for a ball-and-socket design should be below 12 mm (Moghadas et al., 2012).

Unfortunately, most discal replacements are far from reproducing the intact disc biomechanics (Lazennec et al., 2013), and in this situation, the zygapophyseal joints must restrain the excessive movement range, particularly in axial rotation (Patwardhan et al., 2012).

When we analyzed the dimensions of the spine carefully, it was observed that when the prosthesis was placed, there was an increase in the extension at zero moment due to the fact that the height of the prosthesis was 2 mm lower than that corresponding to the height of the disc, and this caused a repositioning of the spine at extension, which is what is reflected in Fig. 10S. By eliminating this initial excess extension, the behavior of the prosthesis is similar to that of the intact spine.

In our study, all the vertebral units analyzed, except for L_4-L_5, the maximum angles for 8 Nm remain stable in all load modes. However, for L_4-L_5, the angles increase due to the ligament and annulus fibrosus surgical damage necessary to insert the total disc prosthesis, as seen in Table 5, increasing the maximum angles to 8 Nm. The conclusion is that we should minimize the anterior annulus damage as much as possible when inserting any total disc prosthesis.

We see that after implantation, our prosthesis provides ICR very close to those of the intact spine, indicating that it fulfilled one of our design requirements. This feature represents an improvement compared to other total lumbar disc prostheses currently available in the market.

Shock absorption, a property of the intact intervertebral disc (Brzuszkiewicz-Kuźmicka et al., 2018), is another issue to consider. It is almost inexistent in ball-and-socket designs. Although present in elastomeric replacements (Lazennec, 2020), it comes at the price that the elastomeric nucleus suffers deterioration over time with the risk of extrusion (Grassner et al., 2018). The ADDISC total disc replacement provides shock absorption due to its intermediate polyurethane carbonate piece.

With the data available in the literature, no lumbar disc prosthesis reproduces the intact lumbar disc physiological range of movements (ASTM F 2346: 2018, n.d.; Choi et al., 2017b; Dreischarf et al., 2015; Ha et al., 2009; Lazennec et al., 2013; Moghadas et al., 2012; Tsitsopoulos et al., 2012). ADDISC seems an improvement but still does not fully reproduce the intact lumbar disc movement range. Future clinical studies will clarify the value of these results.

A final concern is the long-term degeneration of the adjacent segments, particularly the zygapophyseal joints. We have already done the Finite Element Analysis and published it (Vanaclocha et al., 2023). We need to measure the pressures induced in these joints after ADDISC implantation. However, biomechanical studies in cadaveric spines are acute, so long-term clinical trials are required.

Table 5
Maximum mobility of the L_4-L_5 segment in the PRE, ANG, and POS conditions. We express the values by degrees of movement (angles in degrees) under 8 Nm. PRE (intact lumbosacral spine status), POS (after ADDISC total disc prosthesis implantation). The lower line shows the ADDISC mobility ranges.

	FLEXION-EXTENSION RANGE		LATERAL BENDING RANGE		AXIAL ROTATION RANGE	
	Mean	SD	Mean	SD	Mean	SD
PRE	10.594^0	3.508	11.375^0	2.098^0	4.417^0	3.006^0
ANG	23.601^0	5.343^0	20.223^0	4.220^0	17.934^0	2.381^0
POS	19.133^0	6.617^0	18.928^0	8.241^0	16.038^0	6.001^0
ADDISC prosthesis	12.000^0	–	7.000^0	–	7.000^0	–

5.1. Limitations

The number of anatomical specimens is limited, and we collected the data with no muscle or soft tissue influences. Besides, we must consider the potential effects of repeated freezing and thawing. In addition, it is an acute study, and long-term data are missing. The lack of significant difference in kinematics between PRE and POS can be due to the small sample size and a large scatter in the data. Therefore, there was no sample size calculation. Furthermore, cadaveric specimens cannot provide long-term data. Thus, we plan to repeat this study in live patients after ADDISC implantation.

5.2. Strengths

Each cadaveric lumbosacral spine serves as its control. The data have been collected objectively with photogrammetry techniques. We created an *ad hoc* machine to better adapt to our specific needs.

6. Conclusions

The ADDISC total disc replacement can potentially mimic intact disc kinematics and ICR but does not entirely reproduce them.

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Pablo Jorda-Gomez: Methodology, Formal analysis, Data curation. **Vicente Vanaclocha:** Writing – review & editing, Writing – original draft, Validation, Formal analysis, Data curation, Conceptualization. **Amparo Vanaclocha:** Writing – review & editing, Writing – original draft, Software, Methodology, Investigation, Data curation. **Carlos M. Atienza:** Validation, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Conceptualization. **Vicente Belloch:** Writing – review & editing, Writing – original draft, Validation, Formal analysis, Data curation, Conceptualization. **Juan-Manuel Santabarbara:** Validation, Supervision, Project administration, Methodology, Investigation. **Carlos Barrios:** Writing – review & editing, Validation, Supervision, Methodology, Investigation. **Nieves Saiz-Sapena:** Writing – review & editing, Visualization, Validation, Supervision, Project administration. **Enrique Medina-Ripoll:** Writing – review & editing, Writing – original draft, Validation, Formal analysis, Data curation, Conceptualization. **Leyre Vanaclocha:** Writing – review & editing, Writing – original draft, Methodology, Formal analysis, Data curation.

Declaration of competing interest

All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interests (such as honoraria; educational grants; participation in speaker's bureaus; membership, employment, consultancies, stock ownership, membership of a company board of directors, membership of an advisory board or committee for a company, and consultancy for or receipt of speaker's fees from a company or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interests (such as personal or professional relationships, affiliations, knowledge or belief(s) in the subject matter or materials discussed in this manuscript. The authors have no conflicts of interest to declare.

ADDISC prosthesis, but the intellectual property belongs to the company ROA 14SL, La Pedrera, Gijón, Spain, which has not commercially manufactured the prosthesis yet. Professor V Vanaclocha has not received any honoraria or compensation for his work or invention.

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