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Basic Science

# ICR in human cadaveric SPECIMENS: An essential parameter to consider in a new lumbar disc prosthesis DESIGN

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ABSTRACT

*Study design:* Biomechanical study in cadaveric specimens.

*Background:* The commercially available lumbar disc prostheses do not reproduce the intact disc's Instantaneous centre of Rotation (ICR), thus inducing an overload on adjacent anatomical structures, promoting secondary degeneration.

*Aim:* To examine biomechanical testing of cadaveric lumbar spine specimens in order to evaluate and define the ICR of intact lumbar discs.

*Material and Methods:* Twelve cold preserved fresh human cadaveric lumbosacral spine specimens were subjected to computerized tomography (CT), magnetic resonance imaging (MRI) and biomechanical testing. Kinematic studies were performed to analyse range of movements in order to determine ICR.

*Results:* Flexoextension and lateral bending tests showed a positive linear correlation between the angle rotated and the displacement of the ICR in different axes.

*Discussion:* ICR has not been taken into account in any of the available literature regarding lumbar disc prosthesis. Considering our results, neither the actual ball-and-socket nor the withdrawn elastomeric nucleus models fit the biomechanics of the lumbar spine, which could at least in part explain the failure rates of the implants in terms of postoperative failed back syndrome (low back pain). It is reasonable to consider then that an implant should also adapt the equations of the movement of the intact ICR of the joint to the post-surgical ICR.

*Conclusions:* This is the first cadaveric study on the ICR of the human lumbar spine. We have shown that it is feasible to calculate and consider this parameter in order to design future prosthesis with improved clinical and biomechanical characteristics.

## 1. BACKGROUND

Chronic lower back pain is one of the most common medical conditions [26]. Degenerative disc disease is an important cause of chronic low back pain, particularly in relatively young people (below 50 years of age) [50]; and zygapophyseal joint osteoarthritis is an important cause of pain in patients older than 50 [51].

Each spinal segment is composed of three mobile elements: one disc anteriorly and two zygapophyseall joints posteriorly. Under normal conditions, the disc supports about 80% of the load transmitted through the spine [78]. When the intervertebral disc degenerates, it loses its capacity to transmit this load and thus may become a source of low back pain [66].

Lumbar disc arthroplasty was introduced in 1960 [27], although results were not promising until the 1980's [7,36,60,115]. The aim of this surgical procedure is to preserve motion as well as to avoid spinal fusion related complications and side-effects. The first successfully implanted device was the SB Charitè [7,15]. The initial suboptimal results, which occurred due to mechanical failure [7,19,52,101,102], were mitigated by repeatedly improving on the design [60]. Ever since, many other disc

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replacements have been introduced, but only a few have stood the test of time.

Traditionally, total disc implant designs have had a ball and socket mechanism [16], which can be constrained, unconstrained or semi-constrained [111]. These lumbar prostheses do not replicate the features of the intact lumbar disc, particularly in what pertains to the Instantaneous centre of rotation (ICR). Hence, although movement is allowed, it is not within the normal ranges. This is particularly true in the case of 3-piece prostheses where the central portion is oftentimes mobile, compared to 2-piece disc replacements [111]. The characteristics often dictate abnormal patterns of translation and rotation, and different ICR distribution than the intact lumbar disc [65]. The most challenging motion is axial rotation, where excess movement has to be controlled by zygapophyseal joints, unless the implant has some ligament-like components that limit the range of movement (ROM) in this direction [85,111].

Studies have shown that the ICR of the intact lumbar disc is not fixed, but moves constantly during the lumbar spinal movements of flexion, extension, rotation and lateral bending [1,3,79].

Currently, the commercially available lumbar disc prostheses do not accommodate to the natural ICR [80,87,111]. This results in an overload of adjacent anatomical structures, particularly the zygapophyseal joints [12,42,79,86,88]. This has been shown to induce accelerated degeneration and with it chronic lower back pain [79].

The aim of this study is to design a new lumbar disc prosthesis based on the anatomy and biomechanics of the lumbar spine, taking into account the physiological ROM (flexion, extension, lateral bending and axial rotation) as well as the ICR. As values in the literature vary depending on the study and the methods used to collect the data (anatomical preparations, Finite Element Analysis of computerized models, X-rays of live patients), we found it essential to obtain firstly our own data from human lumbosacral cadaveric spines. The design and development of new lumbar disc prostheses is based on this data. New prostheses should reproduce the ROM and ICR characteristics of the intact lumbar disc as closely as possible, aiming to reduce the overload of the adjacent anatomical structures and particularly the zygapophyseal joints.

## 2. MATERIALS AND METHODS

The study was conducted in several steps:

1 Specimen selection and preparation
2 Anatomical CT studies
3 Biomechanical study: ROM retrieval during flexion, extension, lateral bending and axial rotational movements, as well as ICR evaluation during said tests

### 2.1. Specimen selection and preparation

Twelve lumbo-sacral spine specimens from fresh cadavers, provided by the *Facultat de Medicina i Odontologia, University of Valencia, Spain,* were used. Cadavers were cold preserved since death. Donors' age ranged from 18 to 50 years. Exclusion criteria were previous surgical procedures, trauma, malignancy, infection, demineralization or inflammatory diseases affecting the lumbar and/or sacral spine.

Plain lumbosacral X-ray studies were performed, unless they had been carried out shortly before death. Osteoporosis was ruled out by means of a Dual Energy X-ray Absorptiometry (DEXA) scan of the lumbar and sacral spine areas, counting up from sacrum. In DEXA scan osteoporosis is defined with values of −2.5 or lower, so specimens with these values were discarded. [96]Once specimens were cleared out, all soft tissues except ligaments and intervertebral discs were removed and the spine was sectioned at the $T_{12}$-$L_1$ intervertebral disc and at the sacroiliac joints. The ligaments and soft tissues of the facet capsules were left intact to preserve their anatomical and functional integrity. A number was allocated to each specimen to allow identification during the study.

### 2.2. Morphological baseline mri and ct scan data

After soft tissue removal, CT scan studies were performed with 0.625 mm section images, 1.25 mm collimation, and pitch of 3 (0.75 mm/rotation) from $L_1$ to the coccyx (GE Healthcare, Milwaukee, Wi, USA). The images were 3D reconstructed with an *x-y* matrix $512 \times 512$ in size, an isotropic voxel of $1 \times 1 \times 1$ mm and a slice spacing of 0.5 mm. The CT-scan images were transferred to a computer as Digital Imaging and Communications in Medicine (DICOM). Demineralization was an exclusion criterion, so bone mineral density was assessed. The size and dimensions of each vertebra and the intervertebral disc were measured.

MRI studies were performed with a 1.5 Tesla GE MRI scan (GE Healthcare, Milwaukee, Wi, USA), looking for spinal morphology, disc changes as well as for possible zygapophyseal joint osteoarthritis.

Once all morphological studies were completed, specimens were stored at −25 °C.

CT and MRI scan images were analysed with the program NETEOUS, developed by our group in the *Instituto de Biomecánica de Valencia* (IBV) in collaboration with INGECOT (University of Oviedo, Asturias, Spain).

Morphological data about geometry, morphometry and dimensions of each lumbar and sacral vertebra, with its individual components and particularly the intervertebral discs, were obtained. We calculated antero-posterior (AP) and lateral (L) vertebral end-plate dimensions as well as the height and angulation of each intervertebral disc.

Disc degeneration was evaluated in all specimens to discard those unsuitable for our studies. with a Pfirrmann grade [73] is a known method of classifying disc degeneration in which grades I and II are considered normal discs, grade III with incipient degeneration but grades IV and V with advanced and severe degeneration respectively. Taking this into consideration Pfirrmann grades I and II were acceptable for all levels but III or higher seen MRI studies was acceptable only in the L4-L5 and L5-S1 levels because this is a common scenario when planning lumbar disc replacement. If present at higher levels the specimens were excluded from the present study. All the selected specimens met the above mentioned degeneration criteria

### 2.3. Intervertebral discs baseline: icr evaluation

In preparation for the biomechanical studies, specimens were slowly thawed for 4 - 5 h at room temperature. The studies were carried at 22 - 23 °C, with an environmental humidity of 40%. To prevent unwanted desiccation we sprayed the specimens with 0.9% sodium chloride solution at least every five minutes [46,72,107,111].

We performed kinematic studies with the photogrammetry system KINESCAN/IBV, analysing in each vertebral segment the range of movement in flexion, extension, right and left lateral bending and axial rotation, as well as the ICR.To allow load application we screwed a polyethylene piece with a semi-spherical seat on the superior $L_1$ end-plate. We potted the coccyx and the sacrum's distal end with acrylic bone cement (**SR Triplex Cold**, Ivoclar Vivadent AG, FL-9494 Schaan; Liechtenstein) making sure that the $L_4$-$L_5$ disc centre plane remained horizontal.

A second base was fixed at the superior portion of the spine (L4) and a 450 mm bar was screwed on. At the ends of this bar 10 Kg weights were hung, in such a way that a flector moment of ±25.5Nm, as well as a 0 to 100 N compression was able to be applied. This simulated physiological loading conditions [11,97,118]. The superior portion of the system was free, in order to allow greater mobility. The weight control was carried out manually. (Fig. 1)

The system movement was obtained by the Kinescan IBV photogrammetry system, inserting clusters of passive markers in each vertebral body (Fig. 2). Additionally, three anatomical markers were secured to each vertebra by means of screws (Fig. 1). These markers were used to define a local system of coordinates in the position of reference.

Each test consisted of the repetition of a cyclic series of flexion and extension movements through the progressive application of the load

**Fig. 1.** Kinematic setup.

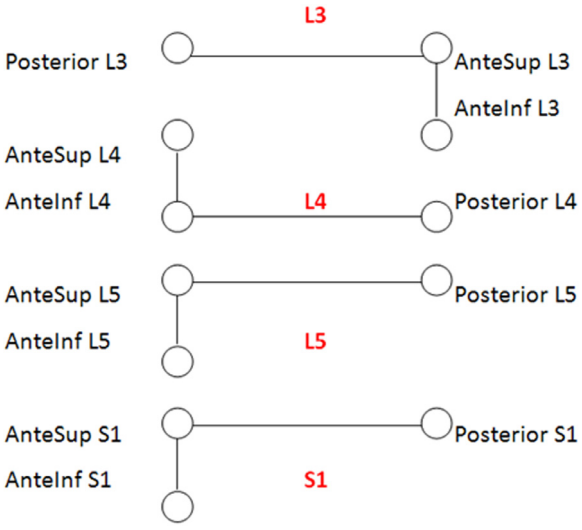


**Fig. 2.** Marker definition.

on either side of the bar. For each test, 5 cycles were completed. The recording frequency used was 25 frames per second, and the recording time was 1 second.

The measurement system was adjusted to cover 0.7 × 0.7 × 0.7 m3, an active area slightly larger than the volume occupied by each specimen. To improve the accuracy of the measurements a procedure based on beam adjustment (Bundle Adjustment) was used, which corrects the optical distortions and provides accuracy in the order of 0.3 mm in the measurement of the coordinates of the markers.

The accuracy in the measurement of the position variables was calculated using the procedure described by [67]. Taking into account the dimensions of the cluster of markers and their number, the estimated errors corresponding to instantaneous values (individual position measurements) were defined as:

- Displacement measurement error sRG = $\sqrt{2}\ 0.3/\sqrt{9} = 0.14$ mm
- Angle measurement error sq = $\sqrt{2}\ 0.3\ /\sqrt{J} = 0.004$ rad = 0.25°; where $J$= moment of inertia of the marker cloud with respect to its centre of gravity

Random errors were reduced using two strategies also previously described by Page et al.: (a) a local adjustment procedure that reduces the instantaneous error by a quarter [69] and (b) the five times repetition of each cycle as well as calculating the average in the geometric domain, in order to obtain the position of the instantaneous rotation axes with an error of a tenth of a millimetre [68].

To obtain the rotation angles of the vertebrae according to the moments applied for each type of test, a vector of a 100 values per second, with a total of 100 values, was exported from each variable that represents the proper rotation of each vertebra. The value of the angles that was taken into account for the analysis will be their average value.

Then, the method described by Page et al. [70] was used to obtain the equations that describe the position of the ICR of each vertebral body, depending on their relative position.

These equations were used for the design of the contact surfaces of the intervertebral disc prosthesis.

The instantaneous axes of rotation of the intervertebral movement in the lumbar spine were then determined, in order to obtain information for the development of an ideal lumbar prosthesis.

## 3. RESULTS

None of the specimens showed spinal pathologies or signs of osteoporosis, measured by DEXA and confirmed by MRI and CT studies. The specimens had a mean age of 41.06±6.14SD years (range 31–50 years), a mean body height of 1.73±1.46SD m (range 1.56–1.79 m), and a mean body weight of 73.08±7.93SD kg (range 56–87 kg). The mean BMI was 23.25±1.64SD (range 21.16–27.49).

Tables 1 and 2 contain the specimens' $L_4$, $L_5$ and $S_1$ vertebral body dimensions with their statistical analysis. These data were within normal range and comparable to those available in the literature [5,56,114]. No specimen had any atypical bone morphology or spinal deformity and MRI findings were compatible with normal healthy spines.

Tables 3 and 4 show the results of the rotation angles of the vertebrae according to the moments applied for each type of test. The displayed graphs are standardized, after treatment of the angle values, so that; (a) all coincide in the sign of the slope and (b) all start from the origin of coordinates, in order to compare the values of the vertebrae with each other. For a more detailed representation of the results, it has been preferred to export the values of the variables for later processing in an EXCEL spreadsheet.

Flexion-extension movements at the level of $L_3$-$L_4$, $L_4$-$L_5$ and $L_5$-$S_1$ were analysed.

The obtained data for the three levels are shown in Table 3. In all cases, there was a positive linear correlation between angle rotation and displacement.

The results show that as the lumbar level increases, the angular range decreases. Nevertheless, on all levels the ICR was displaced vertically downwards as the flexoextension movement occurred.

For $L_3/L_4$ level, the Instantaneous Axis of Rotation (IAR) was found to be centred at the middle of the vertebral body, 2.4 cm below the superior vertebrae, whereas at $L_4/L_5$ it was found at 5 mm above the centre and 1.5 cm below the superior vertebral body base. The $L_5/S_1$ IAR was centred approximately at mid-vertebral body, 1.8 cm below the base of the superior vertebral body.

Lateral flexion movements at the level of $L_3$-$L_4$, $L_4$-$L_5$ and $L_5$-$S_1$ were analysed.

The data obtained for the three levels are shown in Table 4. Similar to flexoextension, there was a positive linear correlation between the angle rotated and the displacement.

**Table 1**
Baseline $L_4$ - $L_5$ specimen parameters statistics. All dimensions are provided in millimeters.

| | L4 vertebral body height | L4 vertebral body width | L4 vertebral body depth | L4 spinal canal diameter | L4-L5 disc height |
|---|---|---|---|---|---|
| **N valid** | 12 | 12 | 12 | 12 | 12 |
| **Mean** | 25.40 | 46.35 | 35.15 | 29.11 | 13.47 |
| **Standard Deviation** | 1.23 | 3.05 | 2.15 | 8.65 | 2.27 |
| **Range** | 4.16 | 10.36 | 6.40 | 24.90 | 7.42 |
| **Min** | 23.07 | 40.79 | 32.02 | 10.31 | 8.72 |
| **Max** | 27.23 | 51.15 | 38.42 | 35.21 | 16.14 |

**Table 2**
Baseline $L_5$ - $S_1$ specimen parameters statistics. All dimensions are provided in millimeters.

| | L5 vertebral body height | L5 vertebral body width | L5 vertebral body depth | L5 spinal canal diameter | L5-S1 disc height |
|---|---|---|---|---|---|
| **N valid** | 12 | 12 | 12 | 12 | 12 |
| **Mean** | 21.40 | 52.25 | 34.23 | 36.00 | 11.70 |
| **Standard Deviation** | 2.47 | 4.21 | 1.99 | 2.10 | 2.37 |
| **Range** | 9.32 | 13.28 | 6.57 | 7.27 | 7.06 |
| **Min** | 16.71 | 43.19 | 30.68 | 31.87 | 8.81 |
| **Max** | 26.03 | 56.47 | 37.25 | 39.14 | 15.87 |

**Table 3**
Summary of the results of the flexion-extension movement analysis.

| | $L_5$-$S_1$ | | $L_4$-$L_5$ | | $L_3$-$L_4$ | |
|---|---|---|---|---|---|---|
| | Rep 1 | Rep 2 | Rep 1 | Rep 2 | Rep 1 | Rep 2 |
| **Angular range (°)** | [−1.5, 4.8] | [−1.5, 4.8] | [−1.5, 2.7] | [−1.1, 3.0] | [−2.1, 1.8] | [−3.4, 2.1] |
| **R adjustment** | 0.997 | 0.997 | 0.999 | 0.999 | 0.999 | 0.996 |
| **$X_{EIR}$ range [EXTENSION, FLEXION] (mm)** | [−3.7, 4.2] | [−3.1, −3.3] | [7.3, 10.8] | [5.8, 9.3] | [−1.8, −4.1] | [−7.1, −9.9] |
| **$Z_{EIR}$ range [EXTENSION, FLEXION] (mm)** | [−22.2, −4.4] | [−23.5, −5.8] | [−10.4, −20.21] | [−9.0, −18.9] | [−29.0, −19.5] | [−25.5, −12.3] |
| **IAR $_{neutral}$ (X, Z) (mm)** | (−4.0, −18.0) | (−3.2, −18.8) | (8.5, −14.1) | (6.7, −11.5) | (−2.9, −23.5) | (−8.1, −17.1) |

**Table 4**
Summary of the results of the lateral bending movement analysis.

| | $L_5$-$S_1$ | | $L_4$-$L_5$ | | $L_3$-$L_4$ | |
|---|---|---|---|---|---|---|
| | Rep 1 | Rep 2 | Rep 1 | Rep 2 | Rep 1 | Rep 2 |
| **Angular range (°)** | [−1.7, 1.1.1] | [−0.8, 1.8] | [−3.2, 1.1] | [−2.7, 1.8] | [−3.5, 4.8] | [−2.3, 5.4] |
| **R adjustment** | 0.970 | 0.971 | 0.986 | 0.986 | 0.9069 | 0.999 |
| **$X_{EIR}$ range [EXT,FLEX] (mm)** | [6.8, 9.4] | [1.8, 3.6] | [1.8, 9.0] | [−0.1, 6.6] | [11.5, 6.9] | [4.3, 0.6] |
| **$Z_{EIR}$ range [EXT,FLEX] (mm)** | [−5.0, −13.3] | [3.9, −3.6] | [−0.4, −6.4] | [−0.9, −6.6] | [1.1, 20.6] | [11.3, 29.1] |
| **IAR $_{neutral}$ (X, Z) (mm)** | (8.4, −10.3) | (2.3, 1.9) | (4.4, −4.8) | (7.1, −4.8) | (9.5, 9.6) | (3.4, 16.6) |

The lateral bending results showed that as the lumbar level increased, so did the angular range. Nevertheless, on all levels the ICR was moved vertically 1 cm up and down during lateral loading. The repetitions showed similar results with respect to the range of movement and IAR. Nevertheless, there was a slight position lag, suggesting the occurrence of permanent deformation during the previous test.

With respect to the IAR, at $L_3/L_4$ level it occupied a horizontal position approximately at the centre of the vertebral body, whereas at $L_4/L_5$ it was slightly deviated towards the left of the origin and a few below the base, and at $L_5/S_1$ level it occupied a fixed position 1 cm below the superior vertebral body and 8 mm off-centred towards the left side.

## 4. DISCUSSION

Degenerative disc disease is a common cause of chronic low back pain [14], and its gold standard treatment is lumbar fusion [47,49,55], which is frequently associated with long term pain recurrence [48,112]. The problem has always been the degeneration of the anatomical structures adjacent to the spinal fusion [39,49] mainly the zygapophyseal joints and the disc. Total lumbar disc replacement was introduced more than 40 years ago [15] attempting to preserve motion. The idea behind it was that motion preservation should mean a smaller risk of adjacent level degeneration. . Incidence of adjacent level disease after lumbar fusion has been reported to range from 11.7% [116], 12.1% [4] to 13.4% [62] at two years to 19.3% ten years follow-up [64]. This has been proven true in many studies [38,43,77,117]. Over the years, the materials used to manufacture them have been improved to reduce complications like subsidence [55,61,75], particulate debris coming from the disc replacement components [101,103,106,110] and vertebral body fractures related with keel-like designs [91,99].

Although there has been a significant improvement, persistent low back pain after a lumbar disc replacement is still fairly frequent [41,63]. The sources of this pain can vary, but one recurring issue is the degeneration of the zygapophyseal joints of the index and adjacent levels [46,71,95]. Several studies have analysed the direct relationship between the height or movement of the disc replacement and the progression of the facet joint degeneration [25,46,80,83].

Some research groups have reported that currently marketed artificial lumbar disc replacements allow movement above the physiological ranges and do not mimic the ICR of the intact lumbar disc [1,88]. Hence, it is key to investigate how to improve physiological ranges of prostheses while reducing the incidence and severity of adjacent level degeneration, and with it the recurrence of lower back pain.

Most of the currently designed lumbar disc prosthesis do not restrict axial rotation (Charité, Activ-L, Baguera), so this excess of rotational movement has to be controlled by the zygapophyseall joints. Ligament-based prosthesis (i.e. M6-L$^{TM}$) control this type of movement but their elastomeric nucleus might undergo long-term degeneration and rupture [13,89].

With these considerations in mind, complete lumbar disc prostheses can be categorized into two main groups: those that have an elastomeric nucleus and those inspired in the hip joint ball-and-socket principle. This first group of disc replacements (M6-L™, Spinal Kinetics, Sunnyvale, California, USA; Cadisc-L™, Ranier Technology, Cambridge, UK; Freedom Lumbar Disc™, Axiomed Spine, Cleveland, OH, USA) attempt to reproduce the characteristics of the native intervertebral disc. Their main risk is that in the long term the elastomeric nucleus or the artificial annulus might detach from the metallic endplates [89]. This has already happened in the past with other models, forcing their market removal [20,23] (Acroflex™, Acromed Corporation, Cleveland, OH, USA). Thus, it is not an ideal long term solution, particularly because most of the patients who are operated on are middle-aged so lumbar disc prostheses should last at least 30 to 40 years, since removing and replacing lumbar disc prosthesis is a very dangerous endeavour [9,19,76].

The implants of the second group, inspired in the ball-and-socket principle, are usually composed of three elements: two metallic endplates and a middle piece. This middle piece can either (1) move freely (SB III Charité™, DePuy Spine, Inc., Raynham, MA, USA), (2) move in a semi-constrained form (ProDisc-L™, Synthes Spine, West Chester, NY, USA; Activ L™, Aesculap, Tütlingen, Germany; Baguera™, Spineart, Geneva, Switzerland) or (3) do not move at all (Maverick™, Medtronic SofamorDanek, Inc., Memphis, TN, USA). Devices with a mobile core (Charité III™) induce in extension a zygapophyseal joint overload, and thus can accelerate the degeneration of this joint [72]. The lumbar disc prostheses with a fixed central piece (Maverick™) do not overload these joints as much, but their centre of rotation is fixed. Thus, they do not reproduce the native intervertebral disc kinematics, as its ICR moves anteriorly in flexion and posteriorly in extension [21]. This also fosters adjacent anatomical structure overload and degeneration. Facet joint pressure increases in flexion, extension and lateral bending proportionally to the diminution in the radius of the articular surface of the artificial lumbar disc, and decreases in axial rotation [16]. This radius is bigger for SB Charité™ and Prodisc L™, intermediate for Activ L™ and Baguera™ and minimal for Maverick™.

The limitations of the ball-and-socket lumbar disc prostheses currently available in the market are [16]:

- Inability to reproduce normal spinal kinematic and biomechanical features [16,88]. As a result ligaments, muscles and zygapophyseal joints have to stand non-physiological loads [32,53,76,82,92], inducing a 20% complication rate [28]long term need of reoperation in 12.1% [18] and a 13.7% of patients being dissatisfied [94].
- Excessive range of motion, particularly in axial rotation [16]. This must be limited by muscles, ligaments and zygapophyseal joints that support overloads with long term degenerative changes [21,79]. In fact, one of the most common causes of lumbar disc arthroplasty failure is persistent low back pain [108] originating from the facet joints [42,86].
- Dislocation or migration [17,22,32,35,36,52,57,76,81,84,100,102]. This was more common with the non-constrained devices (Charité™) [24], and is favored in case of over-sizing the implant's height [21].
- Wear, tear and deformation [6,31,52,81,101,115]. Both metallic and non-metallic debris induce a local inflammatory reaction with osteolysis [54,101] leading to implant loosening, migration and/or subsidence [103,110]. The amount of debris is bigger in the prostheses with a ultra-high molecular weight polyethylene (UHMWPe) core (Charité™, Prodisc L™, Activ L™, Baguera™) [101,106] and smaller with the metal on metal prosthesis (Maverick™) [8]. Nevertheless, the metallic ions released from the prosthesis can induce systemic reactions, particularly in the case of Cobalt-Chromium-Molybdenum ($CoCr_{28}Mo_6$ alloy) metal on metal prosthesis [29]. The response has been to cover the articular surfaces with carbon-like diamonds (Baguera™) [30,40], but still needs further improvements.

In our kinematic study, we analysed the biomechanics of the intact lumbar disc with a special emphasis on the ICR. From the results obtained in our study we concluded that the measured vertebral movement during the flexoextension movements corresponds on all cases to a rotation around an axis whose horizontal position is centred at a position of mid-vertebral body. On the other hand, the Instantaneous Axis of Rotation (IAR) is slightly variable due to a small horizontal displacement of the vertebrae as flexion occurs. The IAR is not equal on the three vertebrae, which may be due to small displacements that appear to be different depending on the specimen analysed and may be due to the state of conservation of the specimens.

The ICR distribution has been studied and applied as a diagnostic tool since 1994 [109], who measured the spinal cervical kinematics of healthy and pathological patients that had been subject to cervical injuries, such as whiplash injuries. Many other researchers, such as Abouhossein et al. [1], Inoue et al. [45], Ahmadi et al. [2] and Bifulco et al. [10], have studied the kinematics of the lumbar spinal ICR distribution, but each one designed a different testing method and obtained the results with a different model, so the results are slightly different.

The variations observed between our results and those found in the literature can occur due to multiple factors. For example, our study comprised vertebral bodies with ligamentous structures but without muscles, and this provides a closer situation to the live patient [44]. Meanwhile those based on X-rays of live subjects [3,113] do consider this interaction. Nevertheless, the studies reported in the past with finite element analysis [1], or those based on X-rays of live patients [3,113] provide data with limited reliability as confirmed by [1]. Thus, despite the limitations of being cadaveric, the results in our human lumbar spines represent a more accurate approach to obtaining the ICR distribution of a healthy spine, since the others are theoretical (FEA) or animal. Nevertheless, our model can still be improved, as living muscles can change both situation and values [98,105]. Thus, we can consider our results valid in order to properly design the new prostheses taking into consideration the specimen's ICR obtained from human spine cadaveric specimens under 50 years of age.

Having said that, there is a need of an innovative design of the geometry to ensure a correct position of the instantaneous centers of rotation. Our study helps to establish the specifications to design an improved lumbar disc prosthesis capable of reproducing the movement of vertebrae that would most closely resemble real life.

Regarding the clinical specifications, the implant must minimize the following:

- Current surgical issues such as vascular lesions, hematomas and post-surgical infection rates [19,34,74]
- Probability of neurological damage including radiculopathy, dysesthesia, impotence or retrograde ejaculation [33]
- Mechanical problems such as vertebral body fractures, overloading of the articular facets, end plate penetration, dislocation/migration of the implant or any of its components, wear and mechanical failure of joint components [35,91]
- Degenerative problems including arthrosis, adjacent level degeneration, osteolysis secondary to implant wear [93]

With respect to the biomechanical specifications, based on our study, the implant should meet the following requirements:

- Adapts the equations of the movement of the intact ICR of the joint to the post-surgical ICR [3,88]
- Behaves as a shock absorbing mechanism [58]
- Allows the load absorption within the implant so that adjacent levels do not overload [11]
- Biocompatible [37]
- Low implant wear [104]
- Different sizes to adapt to different patient geometries [59]
- Non-complex geometry in order to be readily manufactured [90]

## 5. STRENGTHS AND LIMITATIONS

One of the main strengths of this study is that real life was emulated. Many studies have been carried out in order to obtain the ICR distribution, but most were mathematical and theoretical models. Another strength of this study is that, when carrying out the lumbar artificial disc replacement implants design, the ICR was taken into consideration. This results in a better adaptation of the physiological loading patters and ROM of adjacent levels of a healthy lumbar spine. All of this should reduce the overloading on the zygapophyseal joints of the index and adjacent levels, thus reducing post-operative pain and implant failure.

On the other hand, the specimens did not have the muscular support and soft tissue coverage which live patients would have. Data from live patients should be collected to further refine this design.

## 6. CONCLUSIONS

ICR has not been taken into account in any of the available literature regarding lumbar disc prosthesis.

In this study we have shown that it is feasible to calculate and consider this parameter in order to design future prosthesis, with improved clinical and biomechanical characteristics.

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