

Footprint mismatch in lumbar total disc arthroplasty

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Abstract Lumbar disc arthroplasty has become a popular modality for the treatment of degenerative disc disease. The dimensions of the implants are based on early published geometrical measurements of vertebrae; the majority of these were cadaver studies. The fit of the prosthesis in the intervertebral space is of utmost importance. An undersized implant may lead to subsidence, loosening and biomechanical failure due to an incorrect center of rotation. The aim of the present study was to measure the dimensions of lumbar vertebrae based on CT scans and assess the accuracy of match in currently available lumbar disc prostheses. A total of 240 endplates of 120 vertebrae were included in the study. The sagittal and mediolateral diameter of the upper and lower endplates were measured using a digital measuring system. For the levels L4/L5 and L5/S1, an inappropriate size match was noted in 98.8% (Prodisc L) and 97.6% (Charite) with regard to the anteroposterior diameter. Mismatch in the anterior mediolateral diameter was noted in 79.3% (Prodisc L) and 51.2% (Charite) while mismatch in the posterior mediolateral diameter was observed in 91.5% (Prodisc L) and 78% (Charite) of the endplates. Surgeons and manufacturers should be aware of the size mismatch of currently available lumbar disc prostheses, which may endanger the safety and efficacy of the procedure. Larger

footprints of currently available total disc arthroplasties are required.

Keywords Disc arthroplasty · Footprint · Endplate diameter · Lumbar spine

Introduction

Lumbar total disc arthroplasty (TDA) has become an increasingly popular modality for the treatment of lumbar degenerative disc disease and has been suggested as an alternative to lumbar fusion [22, 26]. Of the several types of disc arthroplasty currently in use [13, 28], the most common types of TDA are the Prodisc L (Synthes GmbH, Solothurn, Switzerland) and the Charite (De Puy Johnson & Johnson, LeLocle, Switzerland) [14]. The Maverick disc prosthesis (Medtronic, Tolochenaz, Switzerland), Activ L disc prosthesis (Braun, Melsungen, Germany) and Mobi-disc disc prosthesis (LDR medical, Troyes Cedex, France) are also used.

Disc prostheses are available in various sizes of endplates. The design of the implants' endplates should be oriented to the anatomy of vertebrae. The dimensions of the footprints of the endplates are based on published geometrical measurements of vertebrae; the majority of these are cadaver studies [2, 7].

The importance of the congruence of the implant surface and the endplate geometry has been discussed in previous studies [10, 27].

As the cortical shell has been shown to provide 45–75% of the resistance to axial load, the disc prosthesis should closely match the size of the endplate to prevent subsidence and failure [20].

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Nevertheless, anthropometric data concerning the dimensions of endplates are insufficient.

Digitized computed tomography is a reliable tool to measure lumbar vertebrae and reassess the dimensions of the endplates.

The aim of the current study was to measure the endplates of human lumbar vertebrae using CT scans and digital measurement tools, and assess the matching qualities of currently available lumbar disc prostheses.

Materials and methods

A total of 240 endplates of 120 vertebrae in 22 patients (12 men and 10 women aged 27–65 years; mean age 48.3 years) who had undergone treatment at an outpatient clinic for non-radicular chronic lumbar disc pain were assessed. CT scans were performed between March 2006 and January 2007. Sequential 1.25-mm continuous cross-sectional images were obtained parallel to the endplates of L1 to S1 on a CT unit (GE Medical System-Light Speed VCT).

The images were stored in the Picture Archiving Communication System (PACS). Digital measuring tools were used to define distances (Icoviev software, ITH Icoserve Technology for Healthcare GmbH, Austria).

The upper and lower endplates of lumbar vertebrae from L1 to S1 were measured. Three measurements were performed for each endplate: the anteroposterior diameter (AP) and the mediolateral diameter at two locations:

The AP distance was divided into three parts. Lines perpendicular to the AP diameter were drawn between the anterior and the middle third (ML 1), and between the middle and the posterior third (ML 2), and measured (Fig. 1). Perfect matching of implant size in AP diameter

was considered to be present when the AP diameter of the implant was equivalent to the AP diameter of the endplate. As the annulus is resected anteriorly and posteriorly, but preserved laterally, perfect match in the mediolateral diameter was defined as the prosthesis being 0.5 cm smaller than the vertebral endplate on either side, in sum 1 cm smaller than the endplate.

To establish matching sizes of the endplate we compared vertebral diameters with the dimensions of the most frequently used prosthesis, namely Charite and Prodisc L. As the majority of the disc arthroplasties are performed at L4/L5 and L5/S1 (group 2), matching of endplate sizes and the available sizes of prostheses were determined separately for these two levels. The levels L1/L2, L2/L3 and L3/L4 (group 1) were assigned to a separate group.

Statistical analysis

Statistical analysis was performed using the Excel software. Mean, minimum and maximum values were determined.

Results

Anteroposterior and mediolateral diameters of the upper and the lower base plates from L1 to S1 are shown in Table 1. The AP diameter of lumbar endplates was found to range between 3.4 and 4.2 cm. The AP diameter of the largest prostheses available is 3.0 cm (Prodisc L) and 3.1 cm (Charite). The same discrepancy between implant size and anatomic dimensions was observed in respect of mediolateral diameters. The mean diameter of S1 was found to be 6.1 cm, whereas the diameter of the largest implant was 4.25 cm (Charite) and 3.9 cm (Prodisc L).

With regard to endplate diameters in group 1, 1.8% (Prodisc L) and 4.4% (Charite) matched in AP dimensions, 57.9% (Prodisc L) and 81.6% (Charite) in the anterior mediolateral diameter (ML 1), and 27.2% (Prodisc L) and 45.6% (Charite) in the posterior mediolateral diameter (ML 2).

With regard to endplate diameters in group 2, 1.2% (Prodisc L) and 2.4% (Charite) matched in AP dimensions, 20.7% (Prodisc L) and 48.8% (Charite) in ML 1, and 8.5% (Prodisc L) and 22.0% (Charite) in ML 2 (Figs. 2, 3, 4).

Discussion

The ideal shape and position of TDA have been extensively discussed in previous reports [12, 25]. Labrom et al. [12] concluded that the strongest part of the vertebrae is close to

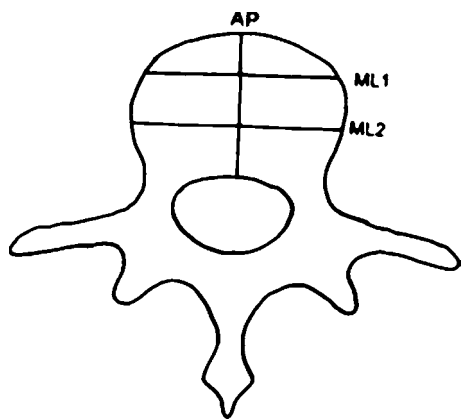
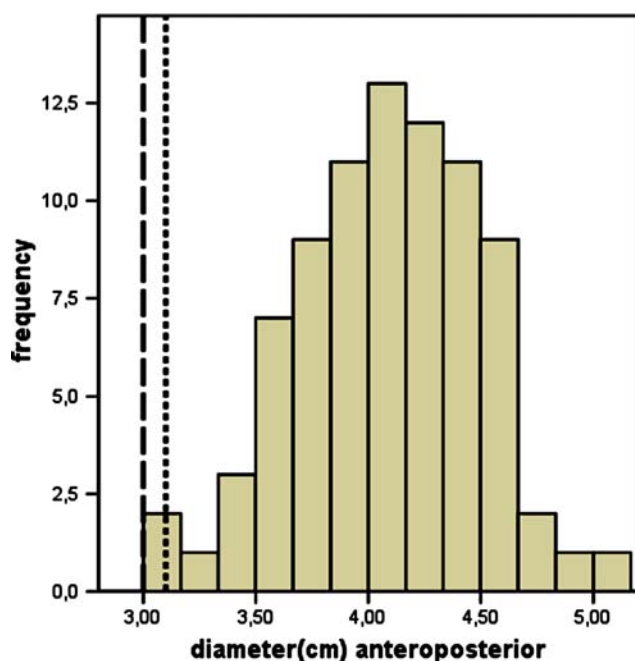
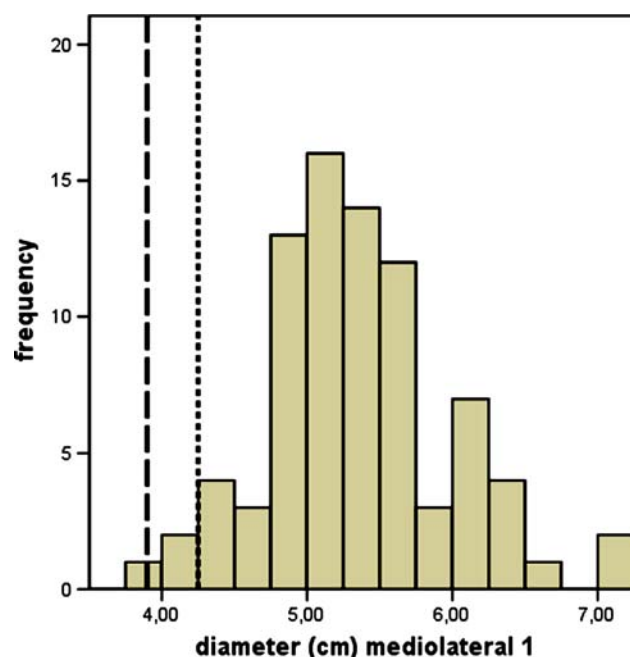


Fig. 1 Measurement of vertebral diameters. AP Anteroposterior distance, ML 1 frontal diameter measured between the anterior and middle third of the AP diameter, ML 2 frontal diameter measured between the middle and the posterior third of the AP diameter

Table 1 Dimension of the upper endplates and base plates of lumbar vertebrae: mean values in cm (min; max)

	AP	ML 1(anterior)	ML 2 (posterior)
L1 upper plate	3.4 (2.81, 4.14)	3.99 (3.48, 4.4)	4.62 (4.19, 4.8)
L1 base plate	3.71 (3.72, 4.41)	4.42 (3.78, 5.97)	5.08 (4.3, 6.14)
L2 upper plate	3.76 (2.98, 4.33)	4.63 (3.81, 5.21)	5.20 (4.31, 6.11)
L2 base plate	3.80 (3.13, 4.56)	4.66 (3.65, 5.52)	5.24 (4.09, 6.28)
L3 upper plate	3.91 (3.06, 4.71)	4.75 (3.81, 5.45)	5.28 (4.34, 6.23)
L3 base plate	3.99 (3.03, 4.9)	4.99 (4.21, 5.83)	5.50 (4.73, 6.16)
L4 upper plate	4.07 (3.28, 4.65)	5.16 (4.1, 6.09)	5.63 (4.74, 6.72)
L4 base plate	3.98 (3.02, 4.48)	5.14 (4.34, 5.91)	5.43 (4.69, 6.25)
L5 upper plate	4.06 (3.14, 4.76)	5.35 (4.22, 6.28)	5.78 (4.39, 6.83)
L5 base plate	4.16 (3.34, 4.91)	5.37 (3.9, 6.33)	5.69 (4.39, 6.79)
S1 upper plate	4.13 (3.49, 5.07)	5.53 (4.13, 7.06)	6.07 (4.83, 6.97)

**Fig. 2** Anteroposterior diameters of disc levels L4/L5 and L5/S1 (group 2): Comparison of vertebral endplate sizes and available sizes of disc prostheses**Fig. 3** Mediolateral diameters between the anterior and the middle third (ML1) of disc levels L4/L5 and L5/S1 (group 2): Comparison of vertebral endplate sizes and available sizes of disc prostheses

the periphery. When the load transferred by the implant exceeds the strength of the vertebral endplate, implant subsidence is known to occur [24]. Greater strength has been observed posterolaterally and close to the periphery, in conjunction with earlier failure of implant positioning in the central region [8, 9, 17, 24].

Polikeit et al. [18] concluded that cages should be designed such that they rely on the strong peripheral part of the endplate for support. Gant et al. [5] determined highly significant regional strength and stiffness differences in the lumbar and sacral endplates, with the center of the endplate being the weakest region. Banse et al. [1] reported the cancellous bone density to be higher in core samples from

the posterior region than those obtained anteriorly or laterally.

On one hand any intervertebral implant should be placed close to the ring apophysis because of its mechanical properties on the other hand the placement of the prosthesis must also refer to the biomechanics of the lumbar motion segment [23].

It is important to mention the biomechanics of total disc arthroplasty especially the importance of the center of rotation. To position the prosthesis posteriorly and thereby theoretically reduce load on facet joints it cannot match exactly to the bone surface. Both, the Prodisc L and the Charite have a symmetrical and central center of rotation. This is in contrast to other designs with a posteriorly

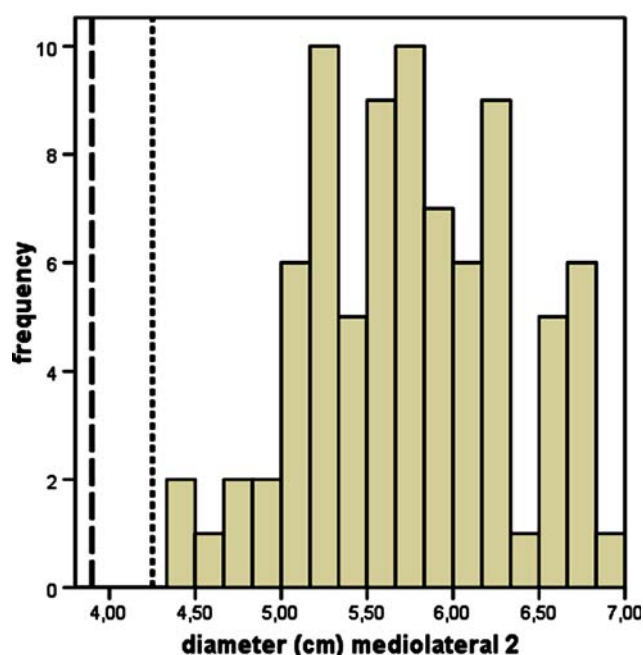


Fig. 4 Mediolateral diameters between the middle and the posterior third (ML 2) of disc levels L4/L5 and L5/S1 (group 2): Comparison of vertebral endplate sizes and available sizes of disc prostheses

shifted center of rotation. Semi-constrained disc replacements (Prodisc L, Maverick, Flexicore) have a fixed center of rotation. The kinematics of such implants is sensitive to the surgeon's placement of the disc and the disc design (radius and position of the ball). Even slight malpositioning, too far anteriorly or posteriorly can result in a decreased ROM or overloading of the posterior elements [5, 11]. Unconstrained implants such as the SB Charite and the Mobidisc seem to be more forgiving and can compensate for small errors in placement. Finite element analysis of constrained TDR demonstrated that flexion extension motion decreased by >15% when the prosthesis was shifted 8 mm anteriorly from the optimal position [5]. On the other hand unconstrained TDRs have a mobile IAR that could compensate for small errors in implant placement [11]. Dooris et al. [5] found that facet loads were more sensitive to the anteroposterior location of the artificial disc than the amount of annulus removed. Under axial load 2.5 times higher facet loads were predicted for an anteriorly placed implant than for the intact model whereas the facets were unloaded for a posteriorly placed implant. Cinotti et al. [4] found that the amount of motion was related to device size, device positioning within the disc space, and the patients' postoperative treatment program. ROM was greatest at segments where the prosthesis covered 80% or more of the vertebral endplate and when it was implanted slightly posterior to the center of the disc space.

From a biomechanical point of view, an implant with the largest possible surface area appears to be best to avoid

Table 2 Available endplate sizes of Charite disc prostheses (cm)

Charite, De Puy	Size 1	Size 2	Size 3	Size 4	Size 5
Anteroposterior diameter	2.3	2.5	2.7	2.9	3.1
Mediolateral diameter	2.85	3.15	3.55	3.85	4.25

Table 3 Available endplate sizes of Prodisc L disc prostheses (cm)

Prodisc L, Synthes	Size M	Size L
Anteroposterior diameter	2.7	3.0
Mediolateral diameter	3.45	3.90

Table 4 Available endplate sizes of Maverick disc prostheses (cm)

Maverick, Medtronic	Small	Medium	Large
Anteroposterior diameter	2.5	2.7	3.0
Mediolateral diameter	3.2	3.5	3.9

Table 5 Available endplate sizes of Activ L disc prostheses (cm)

Active L, Braun	Small	Medium	Large	X large
Anteroposterior diameter	2.6	2.8	3.0	3.2
Mediolateral diameter	3.1	3.45	3.9	4.0

Table 6 Available endplate sizes of Mobidisc disc prostheses (cm)

Mobidisc, LDR medical	Size T4	Size T6	Size T8
Anteroposterior diameter	2.4	2.7	3.0
Mediolateral diameter	2.9	3.4	3.9

subsidence into the vertebral body, as the circumference would provide a brace for the strongest areas in the periphery. Zhou et al. [27] stated that an excessively small implant may collapse into the center of the vertebral body whereas an excessively large one is a challenge in terms of surgical implantation. It should also be considered that larger implants may cause approach related complications which are often present in the surgical field for larger implant size insertion (bleeding, big vessels dislocation, sympathetic chain retraction).

In a recent paper Punt et al. [19] registered 39 cases with subsidence of the disc prosthesis in a series of 75 patients, 24 of them due to the inadequate size of the endplates. It remained unclear however, whether suboptimal sizing, placement, initial surgical technique or historical limitations in instrumentation and/or sizing availability were the main reason for subsidence. In another paper reporting 27 patients with failed TDR Van Ooij et al. [25] found that

Table 7 Measurement of vertebral diameters comparison with the published literature (cm)

Author	Materials and methods	L1/L2 L3/L4		L4/L5 L5/S1	
		ap	ml	ap	ml
Berry et al. [2]	30 skeletons, cadaver study	4.52 4.96	3.19 3.39	5.12 5.34	3.49 3.51
Gilad et al. [6]	157 spines, X ray	3.38 3.47	3.35 3.46	3.46 3.40	3.39 3.43
Panjabi et al. [16]	12 skeletons, cadaver study	3.41 3.53	4.12 4.41	3.55 3.47	4.66 4.73
Zhou et al. [27]	126 patients, L3/L4 L5/S1 CT scans	3.23 (2.44 0.18)	4.32 (3.23 5.33)	3.57 (2.88 4 78)	5.22 (4.23 6.71)
Actual series	240 endplates, CT scans	3.4 3.99	3.99 4.99	4.07 4.13	5.16 5.53

ap anteroposterior diameter, ml mediolateral diameter

67% had significant subsidence. The authors felt that subsidence was a significant contributor to poor outcomes following TDR.

Currently there are five different total disc replacements available for the lumbar spine: the Prodisc L (Synthes GmbH), the Charite (De Puy Johnson & Johnson), the Maverick (Medtronic), the Activ L (Braun) and Mobidisc (LDR medical) disc prosthesis. As Charite and Prodisc L are the most widely used types, only these were included in the present study. However, the footprints of the other three types of implants are quite similar to the Charite and Prodisc L prostheses (Tables 2, 3, 4, 5, 6, 7). In the current study, up to 98% of the endplates were larger than the largest available size of the two most frequently implanted TDAs (Charite, Prodisc L; Tables 2, 3).

Most intervertebral disc replacements are done in the levels L4/5 and L5/S1. However, there are also series about multilevel TDR with a very good clinical outcome [3]. Therefore, the authors decided to investigate all levels of the lumbar spine.

In the present series of 220 endplates, only 10 endplates were sufficiently matched in terms of their anteroposterior diameter, but were too small in mediolateral diameter. A total of 26 endplates matched in terms of their mediolateral diameter, but were too large in anteroposterior diameter.

With regard to the determination of the size of disc prostheses, the majority of the manufactures refer to old publications on anthropometric measurements. These reports comprise small numbers of cases and were largely cadaver studies [2, 16, 21] or based on plain radiographs [6, 7, 15] (Table 2). Berry et al. measured 240 vertebrae in 30 skeletons using vernier and outside calipers. Besides the anteroposterior and mediolateral diameter of the vertebral body, the pedicle size was measured for the purpose of designing spinal instruments. The anteroposterior diameters ranged from 3.95 cm in L1 to 5.34 cm in L5, the mediolateral diameters from 28.9 mm in L3 to 35.1 mm in L5 [2]. Panjabi et al. measured the dimensions in 60

cadaveric vertebrae. The anteroposterior diameters of L1 to L5 ranged from 3.41 to 3.55 cm, the mediolateral diameters from 4.12 to 4.73 cm [16]. Scoles et al. [21] measured thoracic and lumbar vertebrae in 50 cadaveric vertebral columns from patients aged 20–40 years.

Gilad et al. [6] measured X-rays of 157 lumbar and 141 cervical spines. However, X-ray measurements are not comparable with CT scans because of magnification errors and the absence of the third dimension in the former. Zhou et al. investigated the dimensions of lumbar vertebrae on 126 CT scans in patients aged 22–80 years, and observed an increase in endplate width and depth from the third to the fifth lumbar vertebra. The anteroposterior diameter ranged from 3.08 cm in L3 to 3.83 cm in L5 while the mediolateral diameter ranged from 4.09 cm in L3 to 5.31 cm in L5. The vertebral surface was measured in scans of only ten patients [27]. The current authors are not aware of any study comparing CT measurements of lumbar vertebrae with the size of the footprints of lumbar TDA.

In the actual trial, a surprisingly small percentage of endplates sufficiently matched the endplate of the largest available disc prostheses. Particularly in group 2 which included the levels L4/L5 and L5/S1, there was a mean mismatch of 0.85 cm in AP direction and a mismatch of 0.5 cm in ML direction.

This discrepancy led to more central positioning of the prosthesis in the intervertebral space. Subsidence and implant migration into the vertebral body is a potential complication of implant mismatch, significantly reducing the safety and efficacy of the procedure. Preoperative matching of the size of the patient's vertebra scheduled for TDA matches with the footprint of the available TDA is strongly recommended. In case of mismatch TDA should not be performed.

The manufacturers of TDA are urged to produce larger footprints for TDA to obtain a larger number of matches for patients scheduled for TDA.

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