

Footprint Mismatch of Cervical Disc Prostheses with Chinese Cervical Anatomic Dimensions

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Abstract

Background: The footprint of most prostheses is designed according to Caucasian data. Total disc replacement (TDR) has been performed widely for cervical degenerative diseases in China. It is essential to analyze the match sizes of prostheses footprints and Chinese cervical anatomic dimensions in our study.

Methods: The anatomic dimensions of the C4–C7 segments of 138 patients (age range 16–77 years) in a Chinese population were measured by computed tomography scans. We compared the footprints of the most commonly used cervical disc prostheses (Bryan: Medtronic, Minneapolis, MN, USA; Prestige LP: Medtronic, Fridley, Minnesota, USA; Discover: DePuy, Raynham, MA, USA; Prodisc-C: Synthes, West Chester, PA, USA) in China with Chinese cervical anatomic dimensions and assessed the match of their size.

Results: The mismatch of available dimensions of prostheses and anatomic data of cervical endplates ranged from 17.03% (C4/C5, Prestige LP, Prodisc-C) to 57.61% (C6/C7, Discover) in the anterior-posterior (AP) diameter, and 35.51% (C4/C5, Prodisc-C, Prestige LP) to 94.93% (C6/C7, Bryan) in the center mediolateral (CML) diameter. About 21.01% of endplates were larger than the largest prostheses in the AP diameter and 57.25% in the CML diameter. All available footprints of prostheses except the Bryan with an unfixed height, can accommodate the disc height (DH), however, 36.23% of the middle DH was less than the smallest height of the prostheses. The average disc sagittal angles (DSAs) of C4–C7 junctions were 5.04°, 5.15°, and 4.13° respectively. Only the Discover brand had a built-in 7° lordotic angle, roughly matching with the DSA.

Conclusions: There is a large discrepancy between footprints of prostheses and Chinese cervical anatomic data. In recent years, possible complications of TDR related with mismatch sizes are increasing, such as subsidence, displacement, and heterotopic ossification. Manufacturers of prostheses should introduce or produce additional footprints of prostheses for Chinese TDR.

Key words: Cervical Anatomic Dimensions; Mismatch; Prosthesis; Total Disc Replacement

INTRODUCTION

Anterior cervical discectomy and fusion (ACDF) has been used as the gold standard for the treatment of cervical radiculopathy or myelopathy for decades.^[1,2] However, many follow-up radiographs show that ACDF may lead to adjacent segment degeneration (ASD).^[3,4] In recent years, it has been reported that total disc replacement (TDR) can prevent ASD by decreasing the motion and biomechanical stress of adjacent levels. This method has gradually been introduced for selected patients with cervical spondylopathy.^[5,6] Although long-term clinical follow-up is still needed to identify the effectiveness of TDR, it is popular with surgeons and patients because of spinal motion preservation and shorter hospitalization.

Additional evidence has shown that several complications are related with size mismatch between the anatomic dimensions of the cervical vertebrae and disc prostheses. Among these is subsidence, which is induced by an inappropriate size match directly,^[7] as well as osteoporosis and metabolic bone disease. According to some reports, the footprint of the device should be as large as possible to distribute the axial load.^[8,9] In addition, a mismatch may be associated with abnormal kinematics, which may further change the center of rotation (COR) of cervical vertebrae, and subsequently result in instability of the disc prosthesis, even an increase in stress of the facet joint and of adjacent levels.^[10-12] Study has also shown that a mismatch causes heterotopic ossification and abnormal cervical alignment.^[13]

In China, an increasing number of TDR procedures are performed for cervical degenerative diseases;^[14-16] the correlative anatomic parameters of Chinese cervical

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vertebrae have also been investigated in many studies by measuring plain radiographs or cadaver specimens. However, there are still few anatomic data using computed tomography (CT) scans and no studies analyzing the match between footprints of the most common cervical prostheses and Chinese cervical anatomic dimensions. In addition, almost all prostheses were designed using Caucasian data. A study showed that Asian cervical vertebrae are smaller than Caucasian vertebrae.^[17] Hence, there may be a large mismatch of available footprints of prostheses and anatomic dimensions of cervical endplates. In the present study, we compared the footprints of the most common prostheses used in China (Bryan: Medtronic, Minneapolis, MN, USA; Prestige LP: Medtronic, Fridley, Minnesota, USA; Discover: DePuy, Raynham, MA, USA; Prodisc-C: Synthes, West Chester, PA, USA) with Chinese anatomic dimensions of cervical vertebrae derived from CT scans.

METHODS

Patient selection

We retrospectively selected 138 Chinese patients (68 males and 70 females, average age 47.3 years old, age range 16–77 years old) with nonradicular chronic neck pain previously seen at our orthopedic outpatient clinic, according to the standard of the study of Thaler *et al.*^[18] All patients underwent CT scans (Philips, 256iCT, The Netherlands) with the following scanning parameters: Rotation 0.5 second, voltage 120 kV, current 250 mA, and slice thickness 0.625 mm. Inclusion criteria were as follows: non-radicular chronic neck pain, no sign of degeneration on CT scans (disc herniation, osteophytes, and ossification of the anterior or posterior longitudinal ligaments), all the cervical spine disc spaces (C1–C7) can be visualized clearly on CT scans. Exclusion criteria were as follows: patients with radiculopathy or myelopathy, destruction of bone induced by tuberculosis, tumors, or bone fracture, congenital cervical anomalies, prior cervical spine surgery.

Radiologic assessment

A total of 414 segments at the C4–C7 levels of 138 patients were measured with Picture Archiving and Communication Systems (PACS, Version 11.0, Carestream Health, Toronto, Canada). The following parameters were measured on CT scans [Figure 1]: (1) The anterior-posterior (AP) diameter of the superior and inferior endplates of C4–C7 in the sagittal CT scans. (2) The center mediolateral (CML) diameter of the superior and inferior endplates of C4–C7 in the coronal CT scans. (3) Disc height (DH) includes the height of anterior/middle/posterior disc space. (4) Disc sagittal angle (DSA) between the inferior endplate of the upper vertebra and the superior endplate of the lower vertebra.

Three groups were formed according to the different segments: C4/C5 (Group 1, G1), C5/C6 (Group 2, G2), C6/C7 (Group 3, G3). We compared the above anatomic parameters with footprints of the most common cervical disc prostheses used in China and analyzed match sizes [Figures 2–6].

Data were analyzed using Excel (Excel 2013/Microsoft/Redmond, USA) software. Figures were created by OriginPro 8 (OriginLab Corporation, USA).

RESULTS

Reviewing the AP diameter we found that the available dimensions of the most common cervical disc prostheses ranged from 12 to 18 mm and the range of the cervical endplate was between 10.64 mm and 22.88 mm [Table 1]. Our measurements showed that 22.58% of cervical endplates did not match the diameter of the prostheses, and 21.01% of endplates were larger than the largest diameter of the prostheses. The greatest mismatch between prostheses and all endplates was 57.61% (Discover), the smallest mismatch was 22.58% (Prodisc-C and Prestige LP). In addition, compared with cervical prostheses, the mismatch of each group ranged from 17.03% at G1 with the Prestige LP and Prodisc-C prostheses to 57.61% at G3 with the Discover prosthesis [Table 2].

Measuring the CML diameter we found that the range of measurements of the cervical prostheses and endplate size was 14–19 mm and 13.45–28.18 mm, respectively [Table 1]. We found that 57.73% of cervical endplates were different

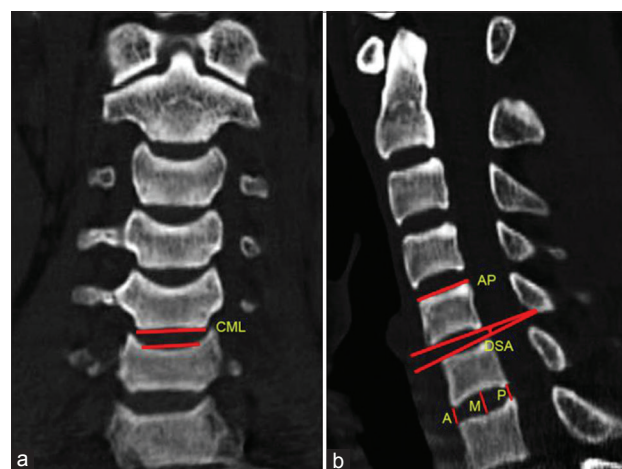


Figure 1: The center mediolateral diameter of the superior and inferior vertebral endplates was measured in the coronal computed tomography (CT) scans (a); the anterior-posterior diameter, disc sagittal angle (DSA) and anterior/middle/posterior disc height (A, M, P) were measured in the sagittal CT scans (b).

Table 1: Anatomic dimension of superior and inferior endplates of the cervical vertebrae: Mean value (Minimal Value, Maximal Value; mm)

Variables	AP	CML
C4 inferior	16.35 (13.28, 20.45)	19.23 (15.32, 24.33)
C5 superior	15.96 (10.64, 20.00)	16.77 (13.45, 20.49)
C5 inferior	16.75 (12.71, 21.30)	20.37 (16.44, 25.81)
C6 superior	16.47 (11.35, 21.03)	18.19 (14.43, 23.96)
C6 inferior	17.11 (12.91, 22.88)	22.65 (17.69, 28.18)
C7 superior	16.86 (11.57, 22.01)	20.78 (14.90, 27.29)

AP: Anterior-posterior; CML: Center mediolateral.

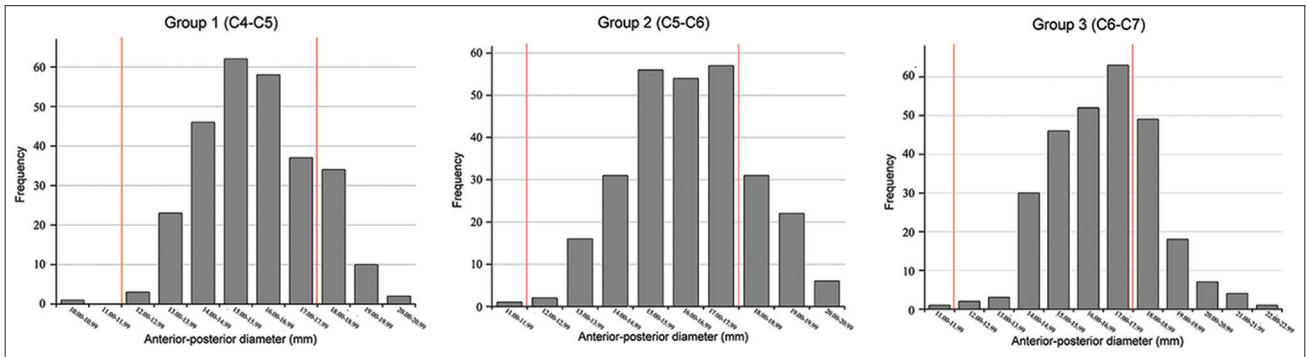


Figure 2: The distribution of the anterior-posterior (AP) diameter of the vertebral endplates between 10 mm and 23 mm in each group. Red lines are the range of available footprints of prostheses at the AP diameter.

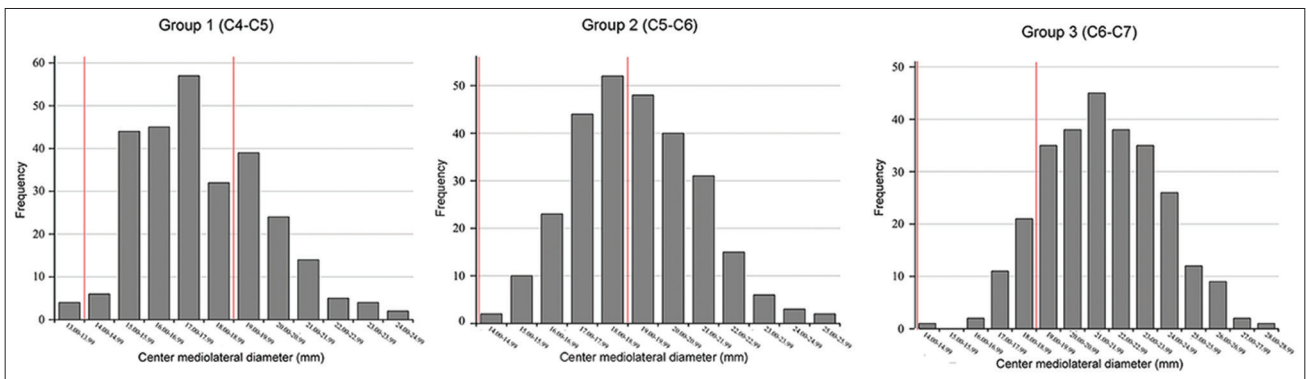


Figure 3: The distribution of the center mediolateral (CML) diameters of the vertebral endplates between 13 mm and 29 mm in each group. Red lines are the range of available footprints of prostheses at the CML diameter.

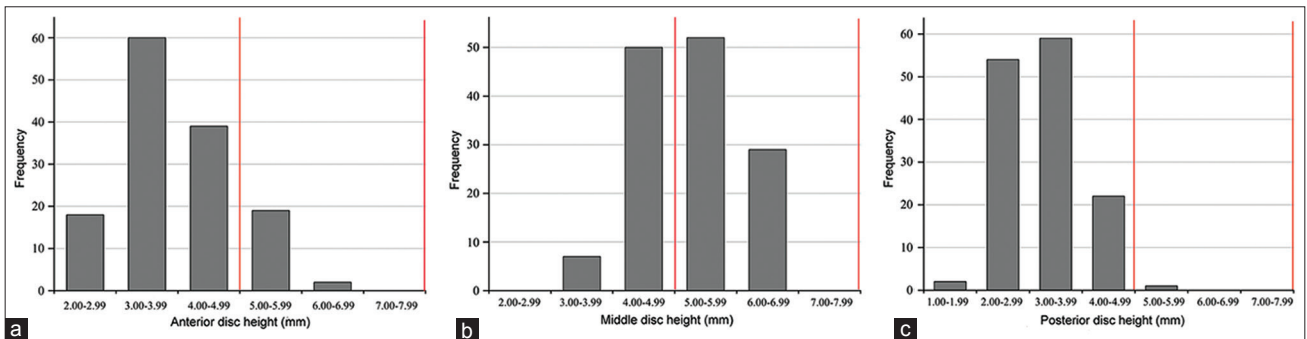


Figure 4: The distribution of the anterior disc height (DH) (a), middle DH (b) and posterior DH (c) at level C4/C5. Red lines are the range of available height of prostheses.

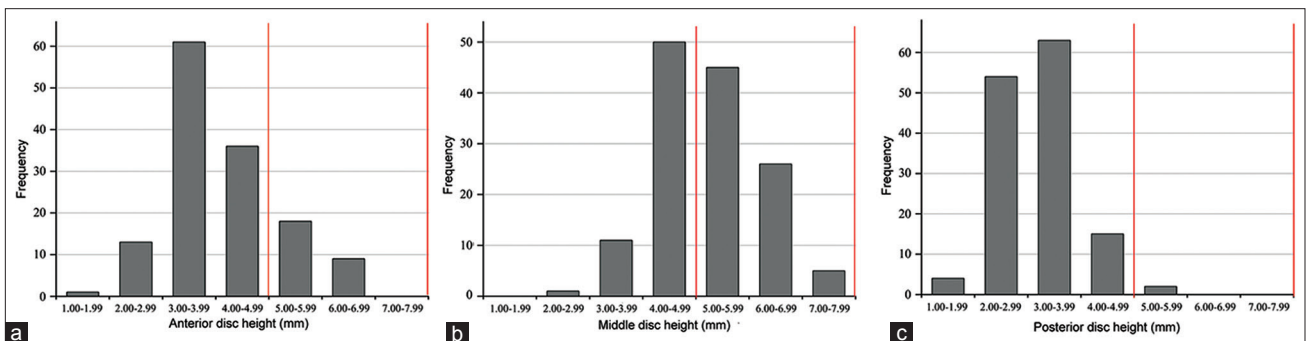


Figure 5: The distribution of the anterior disc height (DH) (a), middle DH (b) and posterior DH (c) at level C5/C6. Red lines are the range of available height of prostheses.

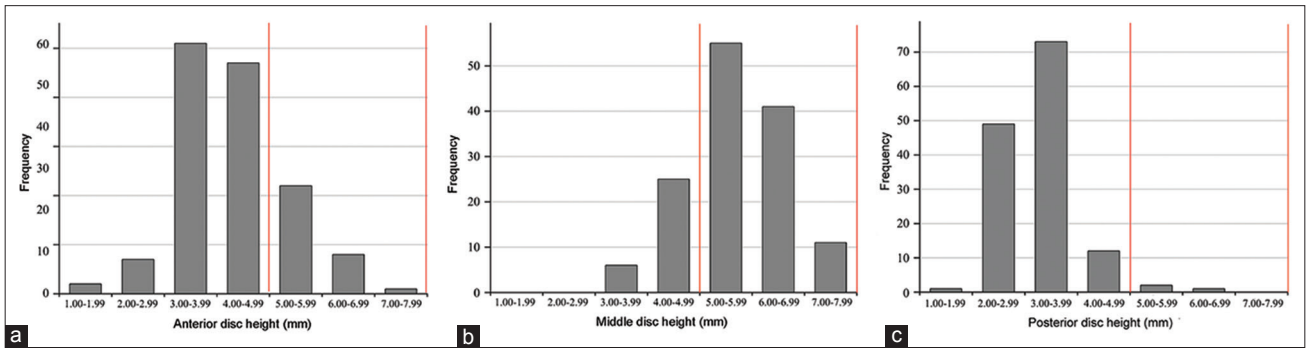


Figure 6: The distribution of the anterior disc height (DH) (a), middle DH (b) and posterior DH (c) at level C6/C7. Red lines are the range of available height of prostheses.

Table 2: The mismatch of dimensions between the cervical disc prosthesis and cervical vertebrae (%)

Groups	AP	CML	ADH	MDH	PDH
Group 1: C4–C5					
Bryan	26.45	44.93	–	–	–
Prodisc-C	17.03	35.51	84.78	41.30	99.28
Prestige LP	17.03	35.51	84.78	41.30	99.28
Discover	43.48	36.96	84.78	41.30	99.28
Group 2: C5–C6					
Bryan	28.26	71.38	–	–	–
Prodisc-C	21.74	53.26	80.43	48.55	98.55
Prestige LP	21.74	53.26	80.43	44.93	98.55
Discover	51.45	59.42	80.43	44.93	98.55
Group 3: C6–C7					
Bryan	45.29	94.93	–	–	–
Prodisc-C	28.99	87.68	78.26	30.43	97.83
Prestige LP	28.99	87.68	77.54	22.46	97.83
Discover	57.61	89.49	77.54	22.46	97.83

AP: Anterior-posterior; CML: Center mediolateral; ADH: Anterior disc height; MDH: Middle disc height; PDH: Posterior disc height.

from the available sizes of prostheses, and 57.25% of endplates were larger than the largest footprint of all implant devices. Comparing cervical endplate sizes of each group with the available sizes of prostheses, the smallest and the greatest mismatches were 35.51% at G1 with the Prodisc-C and Prestige LP and 94.93% at G3 with the Bryan, respectively [Table 2]. In each group, the mismatch ratio of the inferior endplates and prostheses was larger than the superior endplates and prostheses for the CML diameter. The highest mismatch was 99.26% at the C6 inferior endplate with the Bryan and the smallest mismatch was 14.49% at the C5 superior endplate with the Prodisc-C and Prestige LP.

Regarding DH, the available sizes of prostheses, except for the Bryan with an unfixed height, ranged from 5 mm to 8 mm. The highest measured DH was 7.75 mm in the patients; hence, the height of the prostheses can accommodate the highest DH of each group [Table 3]. However, 36.23% of the middle DH (MDH) was lower than the lowest height of the prostheses. In addition, both anterior and posterior DHs (ADH and PDH) were lower than the MDH; 80.92%

for the ADH and 98.55% for the PDH of the intervertebral height were smaller than the smallest prostheses.

Reviewing the DSA, we found that the average angles of G1 to G3 were 5.04°, 5.15°, and 4.13° in the sagittal CT scans [Table 3]. The built-in 7° lordotic angle of the Discover almost corresponds with the DSA.

DISCUSSION

For several decades, ACDF has been regarded as the gold standard for the treatment of cervical radiculopathy or myelopathy.^[1,2] Although it is reported that ACDF provided effective osseous fusion and clinical outcomes, reduction of neck motion and increasing the ASD restricted the usage of ACDF.^[3,4] With the goals of motion preservation and ASD prevention, TDR was introduced for selected patients with cervical degenerative disease. Although long-term follow-up is still needed to identify the effectiveness of TDR, several studies showed that it was advantageous for preventing ASD and maintaining a range of motion.^[5,6] In 2003, TDR was first performed in single level cervical myelopathy in China. Since then, many types of cervical prostheses have been introduced, and several studies in China have shown their excellent clinical efficacy.^[14-16]

There are an increasing number of complications with the wide application of TDR, which may be related to the footprint of the device.^[7] Considering the biomechanics, some studies have shown that the largest surface of the prosthesis with the endplate can reduce the possibility of subsidence.^[8,9] An inappropriate match between the cervical prosthesis and cervical endplate can concentrate the load and induce subsidence, which may further result in loss of motion of the affected segment and an increase in ASD. There has been little subsidence reported until now. However, the rate of heterotrophic ossification (HO) is very high, up to 76.2% three years after TDR.^[13] The exact reason for HO remains unclear; the small prosthesis size may be related to the occurrence of HO.^[13] We consider the indirect reason for HO to be the loss of movement of the treated intervertebral segment induced by subsidence; the direct reason is the hyperlordotic position of the treated segment, owing to a smaller prosthesis. However, a larger prosthesis can

Table 3: Anatomic dimension of the intervertebral segment: Mean value (Minimal Value, Maximal Value; mm)

Groups	ADH	MDH	PDH	DSA
Group 1: C4–C5	3.95 (2.23, 6.64)	5.22 (3.14, 6.95)	3.28 (1.93, 5.12)	5.04 (–5.12, 19.21)
Group 2: C5–C6	4.07 (1.97, 6.84)	5.23 (2.78, 7.31)	3.16 (1.68, 5.60)	5.15 (–1.83, 17.59)
Group 3: C6–C7	4.29 (1.64, 7.21)	5.72 (3.20, 7.75)	3.24 (1.73, 6.50)	4.13 (–3.71, 15.44)

ADH: Anterior disc height; MDH: Middle disc height; PDH: Posterior disc height; DSA: Disc sagittal angle.

compress the anterior tissues (laryngeal nerve, esophagus, and trachea) and posterior dural sac.^[18] The footprint and placement of the prosthesis can also influence the COR of the cervical vertebrae, with both smaller and larger implants resulting in abnormal cervical alignment and kinematics, and subsequently changing the COR. Some studies also reported that the increased load of the facet joint and adjacent segment is related to the change in COR, even leading to facet joint arthrosis and ASD.^[10–12]

Considering the above, it is important that the footprint of the cervical prostheses matches well with the sizes of the cervical endplates. However, most prostheses were designed according to the anatomic diameter of Caucasians.^[19] Through measuring the anatomic dimension of cervical vertebrae of Chinese Singaporeans, Tan *et al.*^[20] showed that it was approximately 9.3%–11% for the AP diameter of the upper endplate and 3.2%–15% for the lower endplate, smaller than the measurements in the Caucasian data. Kim *et al.*^[17] also reported that the width of the upper cervical endplate in Koreans was smaller than in Caucasians. Hence, there may be many endplates of cervical vertebrae smaller than the smallest prosthesis.^[19]

Thaler *et al.*^[18] measured the anatomic dimension of cervical endplates of 24 patients in Austria; a large discrepancy was shown between cervical endplate dimensions and available prostheses sizes. In the present study, there were also a surprisingly large percentage of mismatches between them. Eight hundred and twenty-eight endplates in C4–C7 segments were measured in our study and the average AP diameter was 16.58 mm (range 10.64–22.88 mm). A significant number (22.58%) of cervical endplate measurements in the AP diameter did not match any implant size; 93.05% of the above endplates were larger than the largest footprint of the prostheses. The mean CML diameter was 16.67 mm (range 13.45–28.18 mm). The 99.17% of endplates were larger than the largest prosthesis among 57.73% of all endplates mismatching with the available sizes of prostheses. The CML diameter was significantly larger than the AP diameter in the same cervical endplate; hence, the CML diameter in a prosthesis should be larger than the AP diameter, such as Prodisc-C, Prestige LP and Discover, which can keep the surface area between the endplate and the prosthesis as large as possible to distract the axial load.

The MDH of the intervertebral segment is the standard to implant the prosthesis; in the present study, 36.23% of the MDH was still lower than the smallest height of the prostheses. In addition, the most commonly used height of

the prostheses in our clinical practice was 6 mm and the height of the investigated devices ranged from 5 mm to 8 mm (Prestige LP, Discover, and Prodisc-C). Consequently, there may be higher prostheses implanted, which can influence the range of motion and cause postoperative discomfort through stressing the joint capsules and ligaments of Luschka joints and facet joints. However, further studies are required to identify the kinetic characteristic of a very low artificial disc. The cervical endplates have an arched shape, high in the middle and lower at the ends; there may be over-milling of the anterior and posterior endplates when preparing the flat endplates for implantation of prostheses. Therefore, a convex prosthesis, such as PCM (Cervitech, Rockaway, NJ, USA), matches well with the concave cervical endplates.^[21,22]

Different lordotic intervertebral angles form the cervical lordosis in the neutral position. In the present study, the intervertebral sagittal angles of the C4–C7 segments were 5.04°, 5.15°, and 4.13°, respectively. The most common cervical prostheses, except for Discover, which has a built-in 7.0° lordotic angle,^[23] have two parallel end plates. However, the mobile artificial disc may be effectively adapted to the cervical alignment; several studies showed that almost all available prostheses can retain cervical lordosis effectively.^[23–25] Further studies are required to identify whether or not Discover maintains lordosis better than other prostheses.

There is a slight difference in the dimensions of prostheses in China compared to the sizes of prostheses in other countries. The majority of Chinese cervical anatomic sizes are smaller than in Caucasians; hence, the problems defined with Caucasian patients are likely to be different with the problems found in the present study due to differences in anatomy. According to the results of this study, we propose that manufacturers of prostheses should introduce or produce smaller and larger footprints for Chinese TDR.

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