Footprint mismatch in total cervical disc arthroplasty

Martin Thaler · Sebastian Hartmann ·
Michaela Gstöttner · Ricarda Lechner ·
Michael Gabl · Christian Bach

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Abstract

Purpose Cervical disc arthroplasty has become a commonplace surgery for the treatment of cervical radiculopathy and myelopathy. Most manufacturers derive their implant dimensions from early published cadaver studies. Ideal footprint match of the prosthesis is essential for good surgical outcome.

Methods We measured the dimensions of cervical vertebrae from computed tomography (CT) scans and to assess the accuracy of match achieved with the most common cervical disc prostheses [Bryan (Medtronic), Prestige LP (Medtronic), Discover (DePuy) Prodisc-C (Synthes)]. A total of 192 endplates in 24 patients (56.3 years) were assessed. The anterior–posterior and mediolateral diameters of the superior and inferior endplates were measured with a digital measuring system.

Results Overall, 53.5 % of the largest device footprints were smaller in the anterior–posterior diameter and 51.1 % in the mediolateral diameter were smaller than cervical endplate diameters. For levels C5/C6 and C6/C7 an inappropriate size match was noted in 61.9 % as calculated

from the anteroposterior diameter. Mismatch at the center mediolateral diameter was noted in 56.8 %. Of the endplates in the current study up to 58.1 % of C5/C6 and C6/C7, and up to 45.3 % of C3/C4 and C4/C5 were larger than the most frequently implanted cervical disc devices.

Conclusion Surgeons and manufacturers should be aware of the size mismatch in currently available cervical disc prostheses, which may endanger the safety and efficacy of the procedure. Undersizing the prosthetic device may lead to subsidence, loosening, heterotopic ossification and biomechanical failure caused by an incorrect center of rotation and load distribution, affecting the facet joints.

Keywords Cervical disc arthroplasty · Footprint · Mismatch · Vertebral dimensions

Introduction

Artificial cervical disc arthroplasty (ACDA) is an alternate surgical procedure to cervical fusion performed in selected patients suffering from degenerative disc disease. The goals of disc arthroplasty are to restore the intervertebral disc and foraminal height so as to prevent recurrence of nerve root compression [1], and maintain a physiological range of motion, and therefore limit segmental degeneration in adjacent levels [1]. However, artificial cervical disc implants may fail because of device-related complications such as dislocation, subsidence, vertebral body fracture and device wear [2]. Subsidence is the most commonly reported device-related problem with an incidence of 3–10 % [2]. It is sometimes caused not only by inadequate bone quality or improper endplate preparation, but also by inadequate load distribution associated with failure of device design [2]. Although clinical and radiological outcomes as well as

M. Thaler (✉) · M. Gstöttner · R. Lechner
Department of Orthopaedic Surgery, Innsbruck Medical
University, Anichstr. 35, 6020 Innsbruck, Austria
e-mail: martin.thaler@uki.at

S. Hartmann
Department of Neurosurgery, Innsbruck Medical University,
Anichstr. 35, 6020 Innsbruck, Austria

M. Gabl
WIK, Spine Center Kettenbrücke, 6020 Innsbruck, Austria

C. Bach
St. Remigius Krankenhaus Leverkusen, An St. Remigius 26,
51379 Leverkusen, Germany

biomechanical studies of cervical disc prostheses of various implant designs have been extensively investigated in the literature [2], there are still no anthropometric data on endplate dimensions in relation to device dimensions. Most published data are based on geometric measurements of cadaver vertebrae [3, 4]. Currently available disc prostheses have various footprint sizes, derived from the cadaver data. However, the cortical shell provides 45–75 % of the resistance to axial load, and the disc prosthesis should closely match the size of the endplate in order to prevent subsidence and failure [5]. Therefore, the prostheses should have a footprint as large as possible to dissipate the load evenly, rather than in concentrated areas [6]. Of the several types of disc arthroplasty currently in use, the most common are Bryan (Medtronic, Minneapolis, MN, USA), Prestige LP (Medtronic, Fridley, Minnesota, USA), Discover (DePuy, Raynham, MA, USA) and Prodisc-C (Synthes, West Chester, PA, USA). The purpose of our study was to assess cervical vertebrae dimensions with digitised computed tomography and to compare these measurements with the dimensions of currently available cervical arthroplasty prostheses.

Materials

A total of 192 endplates in 24 patients (10 men and 14 women aged 26–80 years; average age 56.3 years), who had undergone treatment at an outpatient clinic for non-radicular chronic neck pain, were assessed. For the CT scans a General Electric Lightspeed 16© (GE Healthcare, Wisconsin, USA) was used with 100 kV, 100 mA source, rotation 0.8 s, DFOV 15, noise index 20 and a slice thickness of 0.625 mm. Scan coverage of vertebral levels was from C1 to C7. The images were stored with the picture archiving communication system (PACS). Then digital measuring tools were used to measure distances (Icoviev software, ITH Icoserve Technology for Healthcare GmbH, Austria).

Four measurements were taken for each endplate: the anteroposterior (AP) diameter, the mediolateral diameter at two locations (ML1/2) and the center mediolateral diameter (CML).

First, the AP diameter was divided into three parts. Lines perpendicular to the AP diameter were drawn between the anterior and the middle thirds (ML1), and

Fig. 1 Measurement of vertebral diameters (a), measurement of CML diameter in the coronal CT slide of the upper end plate of C5 referred to the position on the axial CT slide (b). AP Anterior–posterior diameter, ML1 mediolateral diameter 1 (measured between the anterior and middle thirds of the AP diameter, perpendicular to the

AP diameter), ML2 mediolateral diameter 2 (measured between the middle and posterior thirds of the AP diameter, perpendicular to the AP diameter), CML center mediolateral diameter (measured between the anterior and posterior halves of the AP diameter, perpendicular to the AP diameter)

Fig. 2 Anterior–posterior (AP) diameter of disc at levels C3/C4 and C4/C5 (group I). Comparison of vertebral endplates and available disc prosthesis sizes. Red lines mark AP diameters of available footprints of cervical disc prostheses

Fig. 3 Center mediolateral diameters of disc at levels C3/C4 and C4/C5 (group I). Comparison of vertebral endplates and available disc prosthesis sizes. *Red lines* mark mediolateral diameters of available footprints of cervical disc prostheses

Fig. 4 Anterior–posterior (AP) diameter of disc at levels C5/C6 and C6/C7 (group II). Comparison of vertebral endplates and available disc prosthesis sizes. *Red lines* mark AP diameters of available footprints of cervical disc prostheses

Fig. 5 Center mediolateral of disc at levels C5/C6 and C6/C7 (group II). Comparison of vertebral endplates and available disc prosthesis sizes. *Red lines* mark mediolateral diameters of available footprints of cervical disc prostheses

between the middle and the posterior thirds (ML2). Then the AP diameter was divided into two parts. A line perpendicular to the AP diameter was drawn between the anterior and posterior halves (CML). All measurements excluded the uncinate process and degenerative changes at the lateral edges of the vertebrae.

To determine matching sizes of the endplate we compared vertebral diameters with the dimensions of the most frequently used prostheses (Bryan, Prestige LP, Discover, Prodisc-C) Figs. 1, 2, 3, 4, and 5. We organised the vertebral levels into two groups: Group I covering the levels C3/C4 and C4/C5; Group II covering the levels C5/C6 and C6/C7, because the majority of surgical procedures are performed at the levels C5/C6 and C6/C7.

Data were processed using the Statistical Package for Social Sciences (SPSS 17 Norusis/SPSS Inc., Chicago, IL, USA). Figures were created with Excel (Excel 2003/Microsoft/Redmond, USA).

Results

Mean values of AP, ML1, ML2 and CML diameters of the upper and the lower endplates from C3 to C7 are shown in Table 1. The AP diameter of cervical endplates ranged between 1.02 and 2.38 cm. The largest available AP diameter of cervical disc prosthesis was 1.8 cm (Bryan, Prodisc-C). The mediolateral diameters ranged from 0.56 to 3.57 cm, while the largest mediolateral diameter of an arthroplasty device was 1.9 cm (Prodisc-C). Upper cervical endplates showed lower values for mediolateral (ML1, ML2, CML) diameters ranging from 0.56 to 2.74 cm.

Regarding AP diameter, 43.7 % of Bryan and Prodisc-C footprints, 60.4 % of Discover, and 100 % of Prestige footprints did not match anatomic dimensions.

Regarding the mediolateral diameters the mismatch of available footprints of arthroplasty devices and anatomic dimensions ranged from 36.9 % (Prodisc: ML1 diameter) to 64.6 % (Discover: CML diameter). With regard to all implant sizes, only 44.5 % matched at the CML diameter,

54.7 % at the ML1 diameter, and 47.4 % at the ML2 diameter (Table 2).

In group I highest matching between ACDA and vertebral diameters was 78.1 % (Bryan and Prodisc-C) for the AP diameter, 57.7 % for the CML diameter (Prodisc-C), 72.9 % for the ML1 diameter (Prodisc-C), and 62.5 % for the ML2 diameter. In group II highest matching was found for the AP diameter in 56.7 % (Bryan and Prodisc-C), for the CML diameter in 45.8 % (Prodisc-C), for the ML1 diameter in 53.1 % (Prodisc-C), and for the ML2 diameter in 48.9 % (Prodisc-C).

Manifest differences were found between mediolateral diameters of upper and lower endplates and footprint dimensions of the Bryan Disc, the Prestige LP, the Discover artificial disc and the Prodisc-C. A mismatch between upper endplate dimensions and these three artificial disc devices was detected in only 13.5 % (Prodisc-C) to 27 % (Discover) for the CML diameter, in 14.6 % (Prodisc-C) to 19.8 % (Discover) for the ML1 diameter and in 12.5 % (Prodisc-C) to 19.8 % (Discover) for the ML2 diameter.

Discussion

Despite the success of cervical fusion procedures for functional recovery and pain relief in patients, this procedure still limits cervical mobility [2]. There is a clear clinical evidence that fusion increases the stress on the non-operated discs [7] and therefore adversely impacts the rate of adjacent disc degeneration, which may be a result of the disease and of the mechanical effects of fusion surgery [8]. Therefore, ACDA has become an increasingly commonplace procedure for the treatment of cervical radiculopathy and myelopathy associated with degenerative disc disease [2]. Disc replacement has the potential to restore joint mechanics, alignment and foraminal height. In addition, ACDA appears to lessen adverse loading and changes in range of motion at adjacent segments by preserving motion and improving function in the treated level [6]. Clinical

Table 1 Dimension of superior (sup-e) and inferior (inf-e) endplates of cervical vertebrae: mean values in cm (minimal value; maximal value)

	AP	ML1	ML2	CML
C3 inf-e	1.65 (1.34, 2.33)	1.85 (1.50, 2.48)	2.09 (1.64, 2.93)	2.07 (1.66, 2.84)
C4 sup-e	1.58 (1.27, 2.38)	1.53 (1.01, 2.12)	1.25 (0.59, 1.96)	1.44 (0.89, 2.21)
C4 inf-e	1.67 (1.34, 2.14)	1.96 (1.54, 2.91)	2.11 (1.57, 2.78)	2.12 (1.82, 2.86)
C5 sup-e	1.65 (1.28, 2.18)	1.54 (1.21, 1.97)	1.19 (0.65, 18.9)	1.38 (0.98, 2.11)
C5 inf-e	1.68 (1.28, 2.02)	2.05 (1.51, 2.83)	2.13 (1.50, 3.26)	2.17 (1.60, 3.07)
C6 sup-e	1.69 (1.02, 2.05)	1.55 (0.94, 2.34)	1.37 (1.0, 2.34)	1.46 (0.56, 2.23)
C6 inf-e	1.77 (1.35, 2.08)	2.20 (1.46, 2.68)	2.28 (1.39, 3.38)	2.41 (1.53, 3.57)
C7 sup-e	1.77 (1.34, 2.19)	1.6 (0.97, 2.74)	1.49 (0.73, 2.64)	1.65 (1.04, 2.42)

Table 2 Cervical disc arthroplasty dimensions differing from anatomic diameters of cervical vertebrae (in percent)

	AP	CML	ML1	ML2
Group I: C3–C5				
Bryan	21.87	53.13	39.58	48.96
Prodisc-C	21.87	42.72	27.08	37.5
Prestige LP	100	53.13	39.58	48.96
Discover	61.45	53.13	42.71	55.21
Group II: C5–C7				
Bryan	43.75	60.42	54.17	58.33
Prodisc-C	43.75	54.17	46.88	51.04
Prestige LP	100	60.42	54.17	58.33
Discover	60.41	64.58	53.13	62.5

success rates of approximately 90 % have been reported following implantation of cervical disc prostheses [9]. Despite these excellent success rates, artificial cervical disc implants may fail from device-related complications such as dislocation, subsidence, vertebral body fracture, heterotopic ossification, spontaneous fusion and device wear [2]. Heterotopic ossification [10], delayed fusion around cervical disc prosthesis [11], asymmetric endplate preparation resulting in postoperative kyphosis, and reduction of vertebral body height [12] have all been encountered in the previous reports. Mehren et al. reported an ossification rate of 49.4 % one year after implantation of disc device and suspected an even higher rate of spontaneous fusion after long-term follow-up [13]. The reported incidence of spontaneous fusion after ACDA varies from 18 % after 4 years [14] to 60 % after 5 years following implantation [15]. To minimise failures in ACDA, good implant design is required. A wide variety of designs and materials are used, and the ideal shape, position and biomechanics of ACDA have been extensively discussed in the previous reports [6, 12, 16].

Subsidence and migration is a commonly reported complication in lumbar total disc arthroplasty. It remains unclear whether suboptimal sizing is the main reason for subsidence. A recent study showed that currently available lumbar disc prostheses are much smaller than lumbar endplates regarding anteroposterior and mediolateral diameter [17]. From a biomechanical point of view, an implant with the largest possible surface area appears best to avoid subsidence into the vertebral body, as the circumference would provide a brace for the strongest areas in the periphery [18]. Inadequate endplate design can equally contribute to subsidence as a result of extremely concentrated stress [2]. Subsidence is most frequently reported within the first 3 months after surgery, while reports on late subsidence are rare [9]. Clinically, inadequate determination of preoperative bone quality, such as in patients with

osteopenia or osteoporosis, is considered a risk factor for subsidence of the prosthesis [9]. Extensive work has been aimed at studying the graft endplate interface and the risk of subsidence. The regional anatomic and biomechanical variations of the endplates are very important and well understood. It has been shown that the posterior and the lateral aspects of the cervical endplate are thicker and stronger than are the anterior aspect and the middle of the endplate [19].

Like in lumbar devices, the majority of the manufacturers derive the size of their disc prostheses from early publications on anthropometric measurements. Those reports investigated small number of cases and were largely cadaver studies or based on plain radiographs [3, 4]. CT evaluation of bony structures is more accurate, and determination of lumbar endplate dimensions showed a large discrepancy to those of lumbar arthroplasty devices [20]. In the present trial, a surprisingly small percentage of endplates matched the endplate of the largest available disc prosthesis. Overall, endplate measures provided a mean anterior–posterior diameter of 1.64 cm (range: 1.02–2.33 cm). The largest anterior–posterior diameter of the investigated disc arthroplasties was 1.8 cm (Prodisc-C, Bryan). Mean mediolateral diameter was 1.83 cm (range 0.56–3.57 cm). Regarding the extreme values a mismatch of 0.53 cm was seen in AP direction and a mismatch of 1.67 cm in center medial and mediolateral directions. In group II, which covered levels C5/C6 and C6/C7, the mismatch percentage was surprisingly high.

The ACDA device should have as large a footprint as possible to transfer weight from the center of the endplate to its stronger periphery [6]. It has already been reported that ideal footprint dimensions not only result in a significant reduction in subsidence, but also improve biomechanical loads [20]. Although subsidence of cervical disc devices, this kind of complication may increase with the imminent approval and widespread use of these devices. Unlike interbody bone grafts, where a certain amount of settling is tolerable and potentially increases the fusion rate, a settled cervical disc replacement will not function properly if it migrates. Subtle migration of an artificial disc may lead more frequently to spontaneous fusion. Subsidence can result in loss of motion at the implanted disc and potentially increases stress at the adjacent levels due to loss of sagittal balance [19]. Kim [20] stated that 64 % of patients with preoperative lordotic sagittal orientation of the functional spinal unit were not able to maintain lordosis following total disc replacement. Link [16] suggested using a rectangular footprint size in cervical arthroplasty in order to cover as much as possible of the cervical endplate, because bending forces are much stronger in the lateral aspect of cervical vertebrae than in thoracic or lumbar vertebrae. In addition, cervical endplates fail at loads lower

than those typically measured for compressive failure of cervical grafts [21]. Due to the large range of lateral flexion in the cervical spine, the lateral portion surrounded by the uncinat process is also one of the strongest parts of the endplate [22]. For this reason, footprints should be as large as possible to minimise the failure of cervical endplates. It should also be remembered that larger implants can cause approach-related complications (bleeding, lesions of adjacent structures: laryngeal nerve, esophagus, trachea), which can occur in the surgical field for larger implant size insertion.

Currently, the most common types of ACDA are the Bryan disc (Medtronic, Minneapolis, MN), the Prestige LP disc (Medtronic), the Discover disc (DePuy, Raynham, MA) and the Prodisc-C (Synthes, West Chester, PA)*.

Comparison of these implants shows some differences in implant design, anchorage technique and load distribution. With the Prestige LP disc, high contact stress occurs at the posterior aspects of the endplate. Prostheses with midline keel fixation on the endplate, like the Prodisc-C, significantly induce contact stress at the anterior corners of the endplate, which is due to the geometry of the anchorage. The Bryan disc showed greater mobility during motion, which may increase load sharing of facet and/or uncovertebral joints [2]. Therefore, a cervical disc device should be placed close to the ring apophysis because of its mechanical properties and due to the biomechanics of the cervical motion segment [23]. Of the endplates in the current study up to 58 % in group II and up to 45 % in group I were larger than the most frequently implanted cervical disc devices*. Most footprints have to refer to the upper endplate dimensions, because the uncinat process limits the footprint size. Our results show a mismatch in upper endplate diameters in only 18.7 % regarding the mediolateral diameters and in 53.5 % regarding the AP diameter.

The center of rotation in total disc arthroplasty is also an important biomechanical factor [24]. In cervical disc arthroplasty the center of rotation depends on prosthesis type and movement. Axial position of the center of rotation influences spine flexibility in all loading conditions and the facet force in extension, lateral bending and axial rotation. The anteroposterior position was found to influence spinal flexibility in flexion and extension and the facet force in lateral bending and axial rotation, while the lateral position was not significant. Proper positioning of the artificial disc during surgery, in particular in the anteroposterior direction, was found to be of critical importance [25]. The footprint mismatches found in the present study largely cause prostheses to be more centrally positioned in the intervertebral space. Potential consequences of such a discrepancy are subsidence, migration, wrong load distribution affecting the facet joints, loss of sagittal balance,

and heterotopic ossification due to insufficient range of motion of the functional spinal unit.

We strongly recommend preoperative matching of the patient's vertebrae with the footprint dimensions of the intended cervical disc device. TDA manufacturers are urged to produce larger footprints in order to minimise footprint mismatches in cervical disc arthroplasty.

Conflict of interest None.

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