SCIENTIFIC ARTICLE

Can an Endplate-conformed Cervical Cage Provide a Better Biomechanical Environment than a Typical Non-conformed Cage?

A Finite Element Model and Cadaver Study

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Objectives: To evaluate the biomechanical characteristics of endplate-conformed cervical cages by finite element method (FEM) analysis and cadaver study.

Methods: Twelve specimens (C₂–C₇) and a finite element model (C₃–C₇) were subjected to biomechanical evaluations. In the cadaver study, specimens were randomly assigned to intact (I), endplate-conformed (C) and non-conformed (N) groups with C₄₋₅ discs as the treated segments. The morphologies of the endplate-conformed cages were individualized according to CT images of group C and the cages fabricated with a 3-D printer. The non-conformed cages were wedge-shaped and similar to commercially available grafts. Axial pre-compression loads of 73.6 N and moment of 1.8 Nm were used to simulate flexion (FLE), extension (EXT), lateral bending (LB) and axial rotation (AR). Range of motion (ROM) at C₄₋₅ of each specimen was recorded and film sensors fixed between the cages and C₅ superior endplates were used to detect interface stress. A finite element model was built based on the CT data of a healthy male volunteer. The morphologies of the endplate-conformed and wedge-shaped, non-conformed cervical cages were both simulated by a reverse engineering technique and implanted at the segment of C₄₋₅ in the finite element model for biomechanical evaluation. Force loading and grouping were similar to those applied in the cadaver study. ROM of C₄₋₅ in group I were recorded to validate the finite element model. Additionally, maximum cage-endplate interface stresses, stress distribution contours on adjoining endplates, intra-disc stresses and facet loadings at adjacent segments were measured and compared between groups.

Results: In the cadaver study, Group C showed a much lower interface stress in all directions of motion (all $P < 0.05$) and the ROM of C₄₋₅ was smaller in FLE-EXT ($P = 0.001$) but larger in AR ($P = 0.017$). FEM analysis produced similar results: the model implanted with an endplate-conformed cage presented a lower interface stress with a more uniform stress distribution than that implanted with a non-conformed cage. Additionally, intra-disc stress and facet loading at the adjacent segments were obviously increased in both groups C and N, especially those at the supra-jacent segments. However, stress increase was milder in group C than in group N for all directions of motion.

Conclusions: Endplate-conformed cages can decrease cage-endplate interface stress in all directions of motion and increase cervical stability in FLE-EXT. Additionally, adjacent segments are possibly protected because intra-disc stress and facet loading are smaller after endplate-conformed cage implantation. However, axial stability was reduced in group C, indicating that endplate-conformed cage should not be used alone and an anterior plate system is still important in anterior cervical discectomy and fusion.

Key words: Biomechanical; Cadaver study; Cage; Endplate-conformed; Finite element method

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Introduction

When non-invasive conservative treatment has failed, degenerative conditions of the cervical spine, such as degenerative disc disease, cervical spondylotic myelopathy and cervical disc prolapses, are commonly treated by anterior cervical discectomy and fusion^{1,2}. Various interbody spacers, such as cages, are used to provide immediate stability and maintain a constant foraminal height. Moreover, they may contain materials that promote osteoconduction³. However, many authors have reported various complications of cervical interbody cages, subsidence being one of the commonest in the early post-operative period (up to 3 months) after spine instrumentation. Subsidence may decrease an initially good correction of foraminal area and intervertebral disc height, causing other implant-related complications^{4–11}. Some published studies have presented evidence that, in humans, subsidence is associated with bone density, the extent of surgical endplate damage and endplate-implant contact area. Thus, risk factors for postoperative cage subsidence were likely associated with stress shielding effect, impaired integrity of the endplate and insufficient endplate-cage contact area^{11–13}. Accordingly, many authors have redesigned both the material and morphology of cervical cages with the aim of eliminating these risk factors. Initially, improvements aimed at reducing segmental stiffness, preventing stress shielding effect and enhancing interbody fusion were in materials, such as artificial ceramics. However, this is still not widely used commercially and the clinical outcomes remain uncertain¹³.

During the recent few decades, because the process of cage subsidence is separated into the two phases of a rapid initial phase and a long-lasting final phase, the theory that the primary cause of initial subsidence is adjustment of the cage/graft-bony bed interface has prompted much research to focus on the development of anatomical cervical cage configurations; various favorable conclusions have been reported¹¹. However, those previously so-called anatomical cages, which were initially designed to achieve large endplate resisting areas, were frequently evaluated only in animal models. More importantly, their morphologies were not endplate-conformed and there has been relatively little biomechanical investigation of the distribution of endplate-implant interface stresses^{14–17}. Moreover, because of their well enhanced load-bearing surfaces, production of endplate-conformed cages has been identified as the next step in further improving spinal implants¹⁸. Few studies have evaluated endplate-conformed grafts, especially in the cervical spine. To our knowledge, there has been only one report of an incomplete biomechanical comparison between endplate-conformed and non-conformed cages by Agarwal *et al.* using finite element model (FEM) analysis in the lumbar spine and their results indicated that the postoperative subsidence rate is decreased if the graft-endplate contact surface area is maximized¹⁹. As a result, we have taken an additional step: the primary purpose of the current study was to conduct a thorough biomechanical evaluation of cervical cages with

endplate-conformed morphologies and to present the characteristics of endplate-cage interface stress through both cadaver study and FEM analysis.

In addition, cervical stability (ability to carry loads) reportedly affects the distribution of loads at the cage-bone interface; thus, cervical instability is considered to result in postoperative subsidence¹². Traditional cages used alone are believed to have high subsidence rates and other complications such as cage migration and retropulsion^{10,11}. Consequently, anterior plate systems are frequently supplemented to achieve better initial cervical stability, this measure being of proven effectiveness in reducing post-operative cage-related complications^{20,21}. However, anterior plate implantation is also associated with many plate-related complaints as well as adjacent segment degeneration (ASD), which is possibly attributable to increased segmental stiffness^{1,22}. Therefore, if endplate-conformed cervical cages provided better initial cervical stability when used alone, the time-consuming and relatively risky procedure of anterior plate implantation would be unnecessary. Another purpose of the current study was to compare segmental stability between endplate-conformed and non-conformed cages to determine whether this kind of individualized cage can provide better segmental stability when used alone.

Finally, though ASD is one of the primary complications after anterior cervical discectomy and fusion²², a positive correlation between segmental stiffness and ASD is not yet definite^{23–27}. Indeed, it is generally agreed that a stiff segment contributes to hypermobility and increased intra-disc stress in the adjacent segments^{26,28,29}; however, many studies have reported opposite conclusions^{26,30}. Therefore, the impact on adjacent segments of endplate-conformed cages also requires evaluation. Thus, the final purpose of our study was to assess the differences between endplate-conformed and non-conformed cages when used alone in effects on intra-disc stress and facet loading in adjacent segments.

Summarized, our general purpose was to conduct a comprehensive biomechanical study of endplate-conformed cages in the cervical spine both through cadaver study and FEM analysis, our aim being to determine whether this new kind of cervical cage can provide a better biomechanical environment than traditional non-conformed cages.

Materials and Methods

Cadaver Study

Spine Preparation

After excluding those with a medical history such as trauma, malignancy or metabolic disease that could have compromised the mechanical properties of the cervical spine, and those with any obvious radiographic or visible flaws (especially osteophytes, disc narrowing or joint arthrosis) by plain film radiographs, 12 fresh-frozen human cadaveric spines (C₂–C₇) were selected and studied. They were obtained from seven male and five female cadavers (aged 32–48 years) and

stored at -20°C until subsequent use, when they were thawed in double-packed plastic bags in a water bath at 25°C . Dissection was performed carefully so as to preserve all ligaments, joint capsules, discs and osseous structures. The C_2 vertebral body was potted using household wood screws and polymethyl methacrylate in a metal fixture. Similarly, the C_7 vertebral body was potted in a metal fixture and attached to the base of the testing apparatus. The weight of the potting, which was applied rostrally, did not exceed 400 g (Fig. 1A–C).

Implants

Six specimens were randomly picked and scanned by CT (interval 0.5 mm; thickness 0.625 mm; 256 slices; Siemens, Erlangen, Germany). The endplate-conformed cages were built according to the CT images by Mimics 10.1, Materialise, Leuven, Belgium) and CATIA V5 (Dassault, France). Cages were fabricated by 3-D printing (Objet30 Pro; Stratasys, Rehovot, Israel) using fast prototyping materials. The geometry of non-conformed cages was similar to a commercially available graft (Cervios; Synthes, DePuy Spine, Raynham, MA, USA) and was also fabricated by using the same materials (Fig. 1D–G). Cages of various dimensions were made (width $\times$ length $\times$ height: [14–16] mm $\times$ 13 mm $\times$ [5–9] mm) and the appropriate sizes were chosen for cage implantation.

Surgical Procedure

Each specimen was positioned in the supine, gently clamped and decompressed with a single level discectomy of C_{4-5} . After incision of the ventral annulus, disc material was removed using rongeurs and curettes. The posterior

longitudinal ligament was preserved and a cervical interbody fusion cage implanted.

Test Setup

Biomechanical testing was conducted in three groups named intact (I), implanted with endplate-conformed cages (C) and non-conformed cages (N) (Fig. 2A). Those that had been scanned by CT were implanted with endplate-conformed cages and tested as group C (Fig. 2B); the remaining six specimens were first tested intact (group I), after which they were implanted with non-conformed cages and tested as group N. Testing was performed by a non-destructive method using a non-constrained testing apparatus described elsewhere in detail²⁸. Pure bending moments were applied about the appropriate anatomic axes to induce flexion (FLE), extension (EXT), left and right lateral bending (LB) and left and right axial rotation (AR). Tension was applied to the cables with a uniaxial testing device. Moments were calculated by multiplying the applied force by the radius of the pulley on the spine-testing apparatus.

To measure the stress on the endplate–cage interface, a film stress sensor (Tekscan, South Boston, MA, USA) was put between the inferior surface of the cage and the superior endplate of C_5 . Maximum stress was recorded in all three groups by custom-made computer software (Fig. 2E–G).

Markers were rigidly attached in a non-collinear arrangement to the vertebral bodies of C_4 and C_5 to evaluate the range of motion (ROM) of C_{4-5} . Three-dimensional displacements of C_4 and C_5 were measured using two cameras and recorded with a computerized motion analysis system. Angular displacement of the upper vertebrae in relation to the lower vertebrae was determined from marker positions by using custom-made computer software (Fig. 2C,D).

Fig. 1 Treated cervical specimens and morphologies of different cages. (A–C) Fresh-frozen human cadaveric spines after being thawed, skeletonized and fixed. (D–F) Endplate-conformed cage fabricated by 3-D printer. (G) Non-conformed cage fabricated by 3-D printer.

Fig. 2 Biomechanical evaluations in cadaver study. (A) General view of the whole biomechanical testing setup. (B) Specimen with new cage implanted. (C) Markers are attached to the C4 and C5 vertebra bodies. (D) Schematic representation of vertebra bodies of C4, C5 and the locations of the markers facing one of the cameras. ROM of C4-5 was calculated according to the displacement of the markers in all directions. (E-G) Stress at endplate-cage interface was measured by a film sensor.

Study Protocol

Tests were conducted in the three groups. A compressive preload of 75 N was applied to represent the average weight of the human head. Moments were applied in a quasistatic manner in increments of 1–1.8 Nm. At each step, three cycles were applied, the first two being preconditioning cycles; data was collected only in the third cycle. Data collected included ROM of C4–5, and maximal interface stress on the C5 superior endplate in FLE, EXT, LB and AR.

Finite Element Analysis

Geometrical Reconstruction and Mesh Generation

A healthy male volunteer (23 years old, 60 kg and 172 cm) without obvious radiographic evidence of cervical degeneration participated in the present study. Images of C3–C7 were obtained at 0.5 mm interval and 0.625 mm resolution using a CT scanner (256 slices, Siemens). The images were then imported into medical image processing software (Mimics 10.1, Materialise to reconstruct the vertebrae geometry volume of C3–C7 (five vertebrae and four intervertebral discs). The finite element model was then created as a reference³¹. Briefly, ABAQUS 6.10 (Simulia, Indianapolis, IN, USA) was used to build and mesh the cervical spine components and implant. The vertebrae were made up of a solid volume (cancellous bone) and a layer of shell (cortical bone and endplate) with a thickness of 0.4 mm. The intervertebral disc was constructed as a continuum structure that occupied the intervertebral space and was partitioned into annulus fibrosus and nucleus pulposus in an approximately 6-to-4 ratio. The annulus fibrosus was modeled as a composite structure: a matrix of annulus ground substance reinforced with inclined fiber trusses that was assigned a 19% volume of the annulus fibrosus and with an inclination between 15° and 30° with respect to the transverse plane. Ligaments, including the anterior longitudinal ligament, capsular ligament, posterior longitudinal ligament, ligamentum flavum and interspinous ligament, were also incorporated with the suggested insertion sites³². All ligaments were modeled as

tension-only axial connectors whereas the annulus fiber was meshed as tension-only truss elements. In the intact cervical spine, the total number of nodes and elements was 48, 706 and 120, 138 respectively.

Endplate-conformed cages were modeled according to endplate geometry (Fig. 3B), but the endplate was kept intact; whereas non-conformed (wedge-shaped) cages were designed in the part module of Abaqus, using morphology similar to that used in the cadaver study (Fig. 3A). Appropriate sizes for the non-conformed cages (width × length × height: 15 mm × 13 mm × 6 mm) were chosen by

Fig. 3 Simulations of (A) non-conformed and (B) endplate-conformed cages.

comparing the resulting model with lateral radiographs obtained from patients who had previously undergone implantation before; the endplate-conformed cages were the same sizes.

Material Property Assignment

The material properties assumed for the various components are listed in Table 1. The material of both the endplate-conformed cage and wedge-shaped cages was poly(ether-ether-ketone) (PEEK)^{21,32}.

Implantation and Boundary Condition

Necessary changes were made to the finite element model to accommodate surgical placement of the grafts. The anterior longitudinal ligaments and intervertebral discs were totally excised at C₄₋₅ to simulate the surgical procedures. Both endplate-conformed and non-conformed grafts were implanted in the intervertebral space where the maximum

surface of both the endplates was in contact with the grafts' surfaces. The conformed and non-conformed grafts implanted in the C₄₋₅ finite element model are shown in Fig. 4, in which the difference between endplate-conformed and non-conformed grafts is shown schematically. The conformed grafts fit perfectly with the endplates, whereas the non-conformed grafts are not in continuous surface contact with the endplate. The endplate-implant interfaces and the vertebrae-disc interfaces were assigned with tie constraint, whereas frictionless sliding contact was applied on the facet and uncovertebral joints and implant-implant interfaces.

Study Protocol

In the finite element model, the bottom of the C₇ vertebra was fixed and biomechanical tests were conducted as in groups I, C and N. Similarly, a preliminary load was first applied to the superior endplate center of C₃ with an axial pre-compression load of 73.6 N and moment of 1.8 Nm in the respective anatomical planes (sagittal, coronal and transverse planes) to simulate the primary spinal motions of FLE, EXT, LB and axial torsion³³. After the model had converged, postprocessing was conducted to collect all the required data: (i) total ROM for FLE-EXT, LB and AR at C₄₋₅ in group I; (ii) maximal Von Mises stress value on the adjoining endplates, adjacent disks and facet joints (facet loading) in groups N and C; and (iii) Von Mises stress contour plots on both adjoining endplates in groups N and C in FLE-EXT.

Statistical Analyses

One-way ANOVA was used to compare the ROM of C₄₋₅ among the three groups in the cadaver study followed by

Component	Young's modulus (MPa)	Poisson's ratio
Cortical bone	12,000	0.29
Cancellous bone	100	0.29
Endplate	1200	0.29
Matrix of annulus ground substance	3.4	0.40
Nucleus pulposus	1	0.49
Annulus fiber	450	0.45
PEEK	3700	0.3

Fig. 4 Coronal and sagittal views give a schematic representation of the differences between (A) non-conformed and (B) endplate-conformed grafts. Finite element model showing (C) non-conformed and (D) conformed grafts implanted in the C₄₋₅ space.

determining the least significant difference. An independent *t*-test was used for comparing the maximal stress on the interfaces of different cages and the superior endplates of C₅. $P < 0.05$ was defined as significantly different.

Fig. 5 Comparison of ROM in group I between FEM, cadaver study and previous report³⁴.

Result

The ROM of C₄₋₅ in the intact model, accompanied by previously *in vitro* experimental data³⁴, is shown in Fig. 5. The ROM of the present study fell within the standard deviation of the experimental data, indicating that the present model is reliable and can be used in further experiments.

Maximum Stress and Stress Distribution on Cage-endplate Interface

A comparison of maximum Von Mises stresses developed on cage-endplate interfaces is shown in Fig. 6A,B. In the cadaver study, stress on the surface of C₅ superior endplate was significantly reduced in FLE ($P = 0.045$), EXT ($P = 0.025$), LB ($P = 0.031$) and AR ($P = 0.014$) from. Similar results were observed in FEM analysis, which showed more pronounced stress reduction on the C₄ inferior endplate than on the C₅ superior endplate (Fig. 6C).

Stress contour diagrams in FLE and EXT in groups N and C are shown in Fig. 7. In group N, stress was

Fig. 6 (A) Maximum von Mises stress on endplate-cage interface (left: C₄ inferior endplate; right: C₅ superior endplate) according to FEM analysis. (B) Maximum von Mises stress on endplate-cage interface of C₅ superior endplate from cadaver study: stress on the surface of the C₅ superior endplate is significantly reduced in FLE ($P = 0.045$), EXT ($P = 0.025$), LB ($P = 0.031$) and AR ($P = 0.014$). (C) Maximum ratio of decrease in stress on C₄ inferior and C₅ superior endplate according to FEM analysis. Ratio of decrease in stress (%) = (Stress in group N – Stress in group C) / Stress in group N × 100%.

Fig. 7 Von Mises stress contours of endplates in FLE and EXT (in MPa). (A, C, E, G) C₄ inferior endplate; (B, D, F, H) C₅ superior endplate; (A–D) FLE; (E–H) EXT; (A, B, E, F) Group N; (C, D, G, H) Group C; I: Stress signal that was recorded by the film sensor in the interface between the inferior surface of the cage and superior endplate of C₅.

concentrated in the anterior region of the endplate, whereas in group C, it was more uniformly distributed.

ROM of C₄₋₅

As shown in Fig. 8, ROM of C₄₋₅ were significantly reduced in both groups N and C in FEX–EXT and LB ($P = 0.000$ and 0.013). Group C had a lower ROM than group N in FEX–EXT ($P = 0.001$). There was no different in ROM of LB between groups N and C ($P = 0.6$). Group C had a higher ROM than group N ($P = 0.017$) in AR and this was even comparable to that in group I ($P = 0.365$).

Intra-disc Stress and Facet Loading at Adjacent Levels

The intra-disc stresses at C₃₋₄ (supra-jacent) and C₅₋₆ (infra-jacent) are shown in Fig. 9, which shows that both intra-disc stress and facet loading at adjacent levels were greater in groups C and N than in group I. Additionally, as shown in Fig. 10, both non-conformed and conformed cages had greater intra-disc stress and facet loading at C₃₋₄ than C₅₋₆ in most conditions. Furthermore, group C had lower intra-disc and facet loading than group N, as is shown in Fig. 9.

Discussion

Subsidence rates reportedly range from 8% to 34%, the highest subsidence rate occurring after cage-alone stabilization, which sometimes leads to unacceptable complications^{8,12}. One of the major reasons for subsidence is non-

Fig. 8 ROM in group I, N and C from cadaver study. *, significant difference between the two indicated groups ($P < 0.05$).

anatomical matching between the cage and cervical endplate¹⁴. The objective of this study was to identify the effect of vertebral endplate-conformed graft surface on endplate stress and evaluate cervical biomechanical changes after implantation of such cages.

Reduced and Uniformly Distributed Cage-endplate Interface Stress

Agarwal *et al.* conducted a series of biomechanical tests in the lumbar spine and reported that increased endplate-graft

Fig. 9 (A, B) Intra-disc stress in adjacent levels and (C, D) facet loading at C₃₋₄ and C₅₋₆.

conformity reduces the maximal stress on the endplate and creates uniform stress distribution on endplate surfaces, which is consistent with what we observed in our study¹⁹. Interestingly, though this theory has long been accepted²⁸, cages with maximal endplate-graft contact areas have rarely been studied; even Agarwal *et al.* only evaluated endplate-graft interface stress in FLE and EXT¹⁹.

Another interesting finding is that stress seems to be reduced more on the superior endplate (C₄ inferior endplate) than on the inferior endplate (C₅ superior endplate) after implantation of endplate-conformed cages, a finding that has also previously been accepted¹⁹. This finding is clinically important because interbody cages tend to subside at the superior endplate^{7,8}; thus, decreasing endplate-cage interface stress at the superior endplate indicates the likelihood of preventing postoperative cage subsidence. Moreover, the fact that stress on endplate-conformed grafts is more uniformly distributed in FLE-EXT, and not concentrated in the endplate anterior region as was observed in group N, also indicates the likelihood of reducing the incidence of graft

subsidence. This is because subsidence always occurs in the anterior part of the endplate because the endplate is thinner there and bone density is lower in the anterior and central parts of the cervical endplates than in the posterior and peripheral areas^{35,36}.

In the current study, the variations in absolute values between FEM and cadaver study may have been attributable to the different material properties of the cages. However, our results are supported by previous reports and comprehensively indicate that endplate-conformed cervical cages do reduce the incidence of postoperative cage subsidence.

Changed Segmental Stability

Postoperative cervical stability is very important and the anterior plate is always used to increase postoperative stability and decrease cage subsidence³⁷. However, anterior plates are associated with many complications^{20,21,37,38}. Thus, the fact that endplate-conformed cages provide better cervical stability than the traditional wedged cages and can therefore be used

Fig. 10 Ratio of increase in intra-disc stress = (Stress in group C or N–stress in group I)/stress in group I $\times$ 100%. (A, C) Ratio of increase in intra-disc stress. (B, D) Ratio of increase in facet loading. (A, B) Ratios of increase in intra-disc stress and facet loading in Group N. (C, D) Ratios of increase in intra-disc stress and facet loading in Group C.

alone constitutes an additional advantage. According to our experiment and FEM analysis results, though ROMs in FLE–EXT and LB both decrease significantly after implantation of any type of cage, group C had a much lower ROM than group N, indicating that endplate-conformed cages provide better cervical stability in FLE–EXT. This is consistent with the findings of previous studies and is attributable to the larger graft–endplate contact area¹⁹. However, the ROMs of AR in group C were much larger than those in group N, possibly also because of the larger contact surface resulting in lower pressure and thus decreasing friction force. Thus, although better segmental stability was achieved in FLE–EXT in group C, the increased ROM in AR is a reminder that it may not be appropriate to use this type of cage alone and that an anterior plate system may still be useful.

Less Adverse Influence on Adjacent Segments

Though stable segmental fixation is necessary for bony fusion, a stiff segment may result in increased intra-disc stress and facet loading at adjacent levels, thus contributing to

ASD^{22,26,28,29,39–41}. However, some authors also reported that less stiff segments such as result from arthroplasty and other motion-preserving systems are not necessarily associated with a lower incidence of ASD in both the cervical and lumbar spine^{26,30,42}. It was therefore also important for us to evaluate the effect of endplate-conformed cages on adjacent segments, a factor that was not assessed by Agarwal *et al.*¹⁹. We found that both intra-disc stress and facet loading increased at adjacent segments, especially at the supra-jacent segment, which is consistent with the findings of previous studies^{43,44}. However, we also found that the stress increase inside the adjacent discs and facet joints was lower in group C than in group N, indicating that endplate-conformed cages may, to a degree, prevent the development of ASD. Nevertheless, further research is still necessary, not only because of the intrinsic limitations of FEM analysis, but also because little biomechanical evaluation of endplate-conformed cages has been published thus far.

In conclusion, endplate-conformed cages significantly reduce cage–endplate interface stress and provide a more uniform stress distribution compared with non-conformed

cage. They also provide better spinal stability in FLE-EXT except in AR. The mildly increased adjacent intra-disc stress and facet loading after endplate-conformed cage implantation indicates that use of this type of cervical cage is a

possible means of preventing ASD. Generally speaking, endplate-conformed cages decrease cage subsidence and protect adjacent segments from degeneration but cannot be used alone because of their inferior stability in AR.

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