Biomechanical effects of cervical arthroplasty with U-shaped disc implant on segmental range of motion and loading of surrounding soft tissue

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Abstract

Purpose Various design concepts have been adopted in cervical disc prostheses, including sliding articulation and standalone configuration. This study aimed to evaluate the biomechanical effects of the standalone U-shaped configuration on the cervical spine.

Methods Based on an intact finite element model of C3–C7, a standalone U-shaped implant (DCI) was installed at C5–C6 and compared with a sliding articulation design (Prodisc-C) and an anterior fusion system. The range of motion (ROM), adjacent intradiscal pressure (IDP) and capsular ligament strain were calculated under different spinal motions.

Results Compared to the intact configuration, the ROM at C5–C6 was reduced by 90 % after fusion, but increased by

70 % in the Prodisc-C model, while the maximum percentage change in the DCI model was 30 % decrease. At the adjacent segments, up to 32 % increase in ROM happened after fusion, while up to 34 % decrease occurred in Prodisc-C model and 17 % decrease in DCI model. The IDP increased by 11.6 % after fusion, but decreased by 5.6 and 6.3 % in the DCI and Prodisc-C model, respectively. The capsular ligament strain increased by 147 % in Prodisc-C and by 13 % in the DCI model. The DCI implant exhibited a high stress distribution. **Conclusions** Spinal fusion resulted in compensatory increase of ROM at the adjacent sites, thereby elevating the IDP. Prodisc-C resulted in hyper-mobility at the operative site that led to an increase of ligament force and strain. The U-shaped implant could maintain the spinal kinematics and impose minimum influence on the adjacent soft tissues, despite the standalone configuration encountering the disadvantages of high stress distribution.

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Introduction

Cervical disc disease has been traditionally treated by spinal fusion that has been effective in pain relief and resolution of neurological symptoms [1, 2]. However, the annual incidence of adjacent segment degeneration (ASD) appears to be approximately 3 % in patients with spinal fusion [2]. Previous researches attributed this complication to fusion-induced abnormal kinematic character and increase of intradiscal pressure (IDP) at the adjacent level [3, 4], despite that load types and magnitudes may influence the results. As an alternative to spinal fusion, total

disc replacement (TDR) was aimed at restoring segment mobility and load-carrying capacity and was expected to avoid inducing ASD, despite that it has not been proved yet. Currently, more than 20 types of artificial cervical discs have been clinically used [5]. The majority of these artificial discs adopt polymer-on-metal or metal-on-metal design to form a sliding articulation. Despite that these artificial discs have exhibited satisfactory clinical performance, biomechanical studies have shown that the sliding articulation may not well control the motion that will induce hyper-mobility at the operative segment [6–8], and the ligament tension was increased in this situation [8]. The wear debris, which was associated with chronic inflammation, was an inevitable situation caused by the sliding articulation design [9].

To prevent adjacent-level overloading induced by rigid fusion, dynamic stabilization systems have been established, including the U-shaped lumbar interspinous implant and dynamic cervical implants. This technology is still in an early stage of development [10]. In a prospective study, the U-shaped dynamic cervical implant demonstrated satisfactory clinical outcomes with improvement in neck and arm pain in a majority of patients [11]. The biomechanical environment affects the long-term viability of the spinal segment implanted with artificial devices. A biomechanical study showed that the U-shaped lumbar interspinous implant strongly stabilized the flexibility in extension and had almost no effect on flexion, lateral bending and axial rotation, which sufficiently satisfied the design of motion control [10]. However, the biomechanical effects of the standalone U-shaped dynamic cervical implant are still lacking, which is of benefit to the clinician in surgical planning and to the medical instrument developer in optimizing implant configuration. The range of motion (ROM) of the spinal motion segment and adjacent IDP is the most studied parameter in biomechanical investigation of spinal implants [10, 12].

This study evaluated the ROM, adjacent IDP, the force transmitting through the capsular ligament and the ligament strain after arthroplasty with a cervical implant that adopted the standalone U-shaped design. By using finite element model of C3–C7, a comparative study was conducted to compare the U-shaped configuration versus a sliding articulation design and an anterior fusion technique.

Materials and methods

An intact finite element cervical spine of C3–C7 was built as reference and followed with three surgical configurations: implanted with a standalone U-shaped implant (DCI, Paradigm Spine, LLC, New York), a sliding articulation design (Prodisc-C, Synthes Spine Solutions, West Chester,

PA) and an anterior fusion system (allograft/plate) at C5–C6.

Geometrical reconstruction and mesh generation

A healthy male volunteer (32 years old, 65 kg and 172 cm) without any radiographic evidence of degenerative sign participated in the present study. The study plan was approved by the ethical committee of the corresponding institute (No. IRB00006761-L2010021). The participant was explained about the research purpose and signed the consent form.

The CT images including the C3–C7 of the subject were obtained at 0.5-mm interval and 0.6-mm resolution using a CT scanner (Brilliance iCT, Philips, Netherlands) and imported into medical image processing software (Mimics 10.1, Materialise Inc., Belgium) to reconstruct the vertebrae geometry volume of C3–C7 (5 vertebrae and 4 intervertebral discs).

A finite element modeling software (ABAQUS 6.9.1, Simulia Inc., US) 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 [13]. The intervertebral disc was constructed as a continuum structure that occupied the intervertebral space and was partitioned into annulus fibrosus and nucleus pulposus in approximately 6-to-4 ratio [14]. The annulus fibrosus was modeled as a composite structure: a matrix of annulus ground substance reinforced with inclined fiber trusses which was assigned with a 19 % volume of the annulus fibrosus and with an inclination between 15°–30° with respect to the transverse plane [13, 14]. Five intervertebral ligaments were incorporated, including anterior longitudinal ligament (ALL), capsular ligament (CL), posterior longitudinal ligament (PLL), flaval ligament (FL) and interspinous ligament (SL), with the suggested insertion site [15, 16].

The geometry of the implants was constructed with the primary dimension (width × length × height) of 14 mm × 12 mm × 6 mm in DCI and 14 mm × 12 mm × 5 mm in Prodisc-C, respectively, and shown in Fig. 1. The metal endplate thickness in DCI and Prodisc-C were 1 and 2 mm, respectively. The radius of the U-shaped feature in DCI was 3 mm and the ball radius in Prodisc-C was 5 mm. The dimension (width × height) of the anterior plate was 12 mm × 25 mm with a thickness of 2 mm.

The cancellous bone and Prodisc-C were meshed into tetrahedron elements (C3D4), while the cortical element was meshed into triangle shell elements (S3). The matrix of annulus ground substance, the nucleus pulposus, the DCI implant and anterior plate were meshed into hexahedron elements (C3D8R). All the ligaments were modeled as

Fig. 1 Finite element model of cervical segments and implants

tension-only axial connector, and the annulus fiber was meshed as tension-only truss elements (T3D2). In the intact cervical spine, the total number of nodes and elements was 49,916 and 127,148, respectively. Convergence within 1 % was achieved in the intact model to make sure that the results based on the present mesh density approached a reasonable solution.

Material property assignment

The non-linear behavior of the ligaments was assigned with the load–deformation curves as in [16]. The DCI and fixation components were made of titanium alloy (Ti6Al4V). The endplate and inlay of Prodisc-C were assigned with the material properties of cobalt alloy (CoCrMo) and ultrahigh molecular weight polyethylene (UHMWPE), respectively. The Young's modulus and Poisson's ratio of all components are listed in Table 1 [13, 16–18].

Implantation and boundary condition

To simulate the surgical modalities, the anterior longitudinal ligament and intervertebral disc were totally excised at C5–C6. The implants of DCI, Prodisc-C and anterior plate/screw/allograft were installed at the corresponding locations according to the suggestion of an experienced surgeon at the excised level (Fig. 1). The DCI and Prodisc-C were installed at the same position. The bone–implant

Table 1 Material properties of the human cervical spine and implants [12, 15, 17, 18]

Component	Young's modulus (MPa)	Poisson's ratio
Cortical bone	12,000	0.29
Cancellous bone	100	0.29
Endplate	1,200	0.29
Matrix of annulus ground substance	3.4	0.40
Nucleus pulposus	1	0.49
Annulus fiber	450	0.45
CoCrMo	220,000	0.32
UHMWPE	1,000	0.49
Ti6Al4 V	114,000	0.35

interfaces and the vertebrae–disc interfaces were assigned with tie constraint, while frictionless sliding contact was applied on the facet joints, uncovertebral joints and the implant–implant interfaces.

The inferior endplate of C7 was fixed at six degrees of freedom in the same way as in vitro experiments [19, 20]. A preliminary load was first applied to the superior endplate center of C3 in the intact cervical model with an axial pre-compression load of 73.6 N and moment of 1.8 Nm in the respective anatomical planes (sagittal, coronal, transverse planes) to simulate the primary spinal motions of flexion, extension, lateral bending and axial torsion [20].

Fig. 2 ROM of present intact cervical spine and published in vitro experimental data [19–21]

The extreme rotational angle of C3 in this preliminary setting was extracted. Following displacement loading protocol [12], the aforementioned rotational angle of C3 was imposed on the upper endplate center of C3 vertebra in all simulated modalities. The finite element cervical models and implants are presented in Fig. 1.

Results

The ROM and IDP in the intact cervical spine model

The ROM of each functional spinal unit in the intact model, accompanied with in vitro experimental data [19–21], is shown in Fig. 2. The ROM of the present study fell within the standard deviation of the experimental data, despite that the standard deviation associated with the experimental studies was high, due to the inter-subject and inter-study differences. The maximum IDP in the intact condition was observed in flexion with a value of 1.88 MPa that was close to McNally's in vitro testing value of 1.8 MPa [22].

The maximum rotational displacement of C3 in the intact cervical model imposed a moment of 1.8 Nm, which was 17.9° in flexion, 10.3° in extension, 10.3° in axial rotation and 10.9° in lateral bending. Whereafter, by imposing the rotation displacement load, the ROM in flexion–extension, left–right lateral bending, left–right axial rotation and the IDP on the extreme status in the surgical altered configurations were extracted to analyze. The force transmitting through the capsular ligament and the ligament strain was also calculated.

ROM at operative and adjacent motion segment units

The ROM is shown in Fig. 3. At the operative segment (C5–C6), with respect to intact configuration, DCI produced a small increase of 7 % ROM in flexion–extension, while there were 30 and 20 % decreases in axial rotation and lateral bending. In Prodisc-C model, a large increase of 108 % was observed in flexion–extension, while 74 and 73 % increase was shown during axial

rotation and lateral bending, respectively. The fusion model exhibited a consistent reduction of between 90 and 91 % in all motions.

At the inferior adjacent level (C6–C7), the ROM increased by 29, 4 and 12 % in flexion–extension, axial rotation and lateral bending, respectively, after anterior fusion. A decrease between 19 and 25 % during all motions were observed in the Prodisc-C model. The changes in ROM at this motion segment unit in the DCI model were less than 7 %.

At the superior adjacent level (C4–C5), the ROM increased by 32 % in axial rotation, but decreased by 3 and 6 % during flexion–extension and lateral bending, respectively, in the fusion model. However, a 22 % increase in flexion–extension, 14 % in axial rotation and 18 % in lateral bending were observed at the C3–C4 level. The result indicated that fusion had a greater effect on ROM at C3–C4 than at C4–C5 in flexion–extension and lateral bending. In the Prodisc-C model, the ROM decreased by 34 % in flexion–extension, 31 % in lateral bending, and 9 % in axial rotation at C4–C5. It was decreased by 23, 9 and 16 % in flexion–extension, lateral bending and axial rotation, respectively, at C3–C4. It was indicated that the ROM at all superior adjacent levels was decreased by total disc replacement with Prodisc-C. In the DCI model, the ROM at the C4–C5 level decreased by 21 and 17 % in flexion–extension and lateral bending, respectively, but increased by 19 % during axial torsion. An increases of 4, 11 and 3 % in flexion–extension, lateral bending and axial rotation, respectively, was observed at C3–C4 in the DCI model. The change trend of ROM in DCI model was similar to that in the fusion model. The secondary superior adjacent level (C3–C4) was more affected than the first superior adjacent level (C4–C5), with the exception in axial rotation.

Intradiscal pressure

As shown in Fig. 4, the maximum IDP in all of the four models was observed during flexion. This value in the intact model was 1.88 MPa. From the superior to the inferior level, the IDP progressively reduced in each of

Fig. 3 ROM in flexion–extension, left–right axial rotation and left–right lateral bending

Fig. 4 IDP at adjacent motion segments during flexion (FL), extension (EX), axial rotation (AR) and lateral bending (LB)

Fig. 5 The tension force transfer through the capsular ligament

the four models. The IDP at adjacent motion segment units during flexion increased by 10.3 and 12.1 % in the fusion model, but decreased by 6.3 and 7.5 % in the Prodisc-C model and by 5.6 and 6.9 % in the DCI model. The IDP after arthroplasty with Prodiscs-C and with DCI did not differ obviously. The fusion surgery markedly increased IDP at the adjacent level, which is a potential adverse factor inducing adjacent segment degeneration.

The capsular ligament force and strain at the operative segment

The maximum force transmitting through the capsular ligament was observed during flexion in all of the four models (Fig. 5). Relative to the intact model, this value increased by 42 and 20 % in the Prodisc-C and DCI model, respectively. This value decreased by more than 70 % after fusion in all the spinal motions (flexion, extension, axial torsion and lateral bending), while in the Prodisc-C model

Fig. 6 Capsular ligament strain of different spinal motions

the ligament force increased by more than 42 % during all the motions.

Consistent with the ligament force, the capsular ligament strain (tension) increased by more than 63 % in the Prodisc-C model, but decreased by more than 70 % in the fusion situation. As shown in Fig. 6 the maximum strain was observed during lateral bending in the intact, fusion and DCI models, while an extremely high strain (0.58ε) was protruded during extension situation in the Prodisc-C model. The maximum ligament strain increased by nearly 150 % in the Prodisc-C model, while it just increased by 12.6 % in the DCI situation.

The facet joint contact force in extension

In the present study, the facet joint contact force in extension increased in both the fusion and DCI models relative to the intact condition (Table 2), while the value

Table 2 Facet joint contact force in extension (N)

	C3/C4	C4/C5	C5/C6	C6/C7
Intact	75.6	69.8	85.9	99.4
Fusion	132.4	145.4	111.3	150.1
Prodisc-C	61.4	67.5	100.1	80.1
DCI	119.7	134.0	151.5	139.5

did not extremely increase at the adjacent segment in the Prodisc-C model.

The stress distribution in the implants

The maximum von Mises stress was 479.6 and 675.6 MPa in the DCI and Prodisc-C, respectively, and both were observed on flexion, while in lateral bending it had a maximum value of 51.9 MPa in the anterior screw/plate system (Fig. 7). Stress concentration was observed at the anterior peripheral region in the Prodisc-C prosthesis and the majority of the regions showed much lower stresses.

Discussion

In the present study, the authors primarily focused on the ROM and IDP at the adjacent segment after three different surgical techniques based on a physiological cervical model of C3–C7. At first, the ROM and IDP were validated in the physiological intact condition by matching with the experimental data [19–22]. The ROM of the present study fell within the standard deviation of the experimental data [19–21], which meant that the physiological model could be confidentially used to represent statistical individuals in considering spinal motions. The standard error

measurements associated with these experimental studies were usually high, due to the inter-subject and inter-study differences, making model validation difficult. As such, the authors did more rigorous validation by comparing the IDP that depends on both kinematic and material considerations. The maximum IDP in the physiological model was close to McNally's in vitro measurement [22]. Since finite element modeling is good in comparison study and ROM and IDP were consistent with published physical experimental data, the present physiological model was entitled to a high measure of confidence to represent statistical individuals and simulate different surgical techniques.

Spinal fusion is one of the standard treatments for degenerative disc disease. However, as the present study showed, this technique extensively constrained the motion of the operative segment as reflected by about 90 % reduction in ROM during all kinematic motions of the spine. The restricted motion was compensated by the adjacent motion segment, with up to 30 % increase of ROM. The compensatory increase of ROM caused more than 10 % increase of IDP at the adjacent segments. A similar finding was reported by Dmitriev et al. [4] that IDP was increased in both the superior and inferior adjacent levels. The increase of IDP was believed to be associated with adjacent-segment degeneration after spinal fusion, despite that controversies remain [1, 2]. A meaningful finding was that the ROM at the C3–C4 motion segment units was more affected than the direct adjacent segments of C4–C5 and C6–C7 during flexion, extension and lateral bending, which was consistent with the result in the previous in vitro study conducted by DiAngelo et al. [12]. Moreover, C4–C5 was more affected or compensated at the rotational direction.

As an alternative to spinal fusion, TDR aimed to restore disc height and mobility of the degenerative motion

Fig. 7 Stress distribution in the implants

segment unit, and the previous studies concluded that TDR could maintain kinematic motion [23, 24]. In the present study, TDR with the ball-in-socket sliding articulation-designed artificial disc of Prodisc-C had well demonstrated its function as reflected by the maintained spinal kinematic motion in the operative site. However, the ROM increased by 70–100 % relative to the intact condition, possibly indicated with a hyper-mobility situation. The hyper-mobility was a direct negative factor that increased the strain in the capsular ligament. Under the hyper-mobility situation, the force transmitting through the capsular ligament increased more than 40 % relative to intact condition, which means that the sliding articulation configuration would change the force transmit mode at the operative level. Similar results were reported in the previous studies. Recently published *in vivo* studies reported that a significant increase in segmental ROM at the surgical level was observed after total disc replacement with Prodisc-C [25, 26]. *In vitro* studies showed that the ROM at the Prodisc-C implanted level increased by 61 % in flexion–extension [27], and the global flexibility significantly increased in extension [12]. It was reported that the ROM increased significantly at the Prodisc-C treated level and decreased significantly at both the superior and inferior adjacent levels in another *in vitro* study [6]. Modest increases (2–15 %) were observed at the Prodisc-C treated level in a finite element study [28]. An apparent increase of facet joint force and ligament tension was also reported at the operative segments [8]. Unlike the fusion condition, the hyper-mobility of the operative site was reversely compensated by a reduced ROM at the adjacent site. The reduction at the inferior segment was more consistent with about one-fifth in all direction, while the superior segment had a reduction ranging from 10 to 35 %. In terms of IDP, the implantation of Prodisc-C had more than 6 % reduction, which may represent alleviation to adjacent segments. The *in vitro* study by Dmitriev et al. [4] also reported a slight reduction of IDP at the adjacent segment in the TDR situation. The coincident results of the present study and previous researches about Prodisc-C implanted cervical spine was a specific evidence to prove the reasonableness of the present prediction.

In evaluating the standalone U-shaped implant, the ROM at the operative level showed smaller change compared with the spinal fusion and arthroplasty with Prodisc-C. Since the change was relatively close, the compensation on ROM was also small. The change of ROM at the inferior segment was <7 %. The main compensation segment appeared at the C4–C5 region with <20 % changes. Similar to that of Prodisc-C, DCI could result in about 5 % reduction of IDP during flexion. Compared with Prodisc-C, the force transmitted through the capsular ligament after arthroplasty with DCI was also close to the intact

condition, which showed that this surgery could not change the force transfer path in flexion. Compared with the doubled maximum ligament strain in the implantation with Prodisc-C, the 12.6 % increase in the DCI model is a neglectful situation. The predicted result suggested that DCI could better maintain the biomechanical environment. This advocated the clinical evaluation that the standalone U-Shaped design could reduce the incidence of adjacent disc disease and maintain spinal kinematic motion. Despite that the maximum stress (479.6 MPa) was inferior to the fatigue strength (in air) of Ti6Al4V, which was in excess of 500 MPa [29], and no device fractures or permanent deformations were observed in the international multicenter prospective study [11], the large region with high stress distribution was an unfavorable characteristic of DCI implant in considering the physiological environments or more serious loading conditions, which would induce the risk of implant failure.

The force transferring through the facet joint at the adjacent segment was much higher in the DCI and fusion models relative to the physiological model in extension (Table 2), while the compression force transferring through the disc decreased, demonstrated by the extreme decrease of IDP in this situation. In conclusion, both spinal fusion and DCI replacement techniques would change the force transfer path of the adjacent motion segments in extension.

Although a more complicated load-and-displacement scenario would be encountered in daily situation, pure load or displacement controls were still the most common testing protocols for fixation instrument and artificial disc [12]. For the cervical region, the follower preload may range from 50 to 100 N [30]. However, the quality of the measured data with and without preloads is similar [30]. In the present study, undertaking the pure compressive load of 73.6 N, the ROM was between 0 and 0.6°, less than the motion of undergoing 1.8 Nm moments, and the IDP was 0.5 MPa that is about 28 % of the maximum value in flexion. However, construct testing should be conducted with a follower load whenever possible [30].

Although the simplified material property, such as isotropic and homogeneous bony and ligamentous structures, would induce some limitation on the stress distribution, it had little influence in analyzing ROM. Since the simulated composite structure of intervertebral disc was as close as the natural disc, despite that the linear brick element of nucleus pulposus limited the pressure distribution, the present physiological model could provide a comparable maximum IDP with *in vitro* testing. As a comparison study, adopting the maximum IDP to analyze could weaken such a limitation. Despite that facet joint degeneration may combine with disc degeneration, the present study focused on the effect of three different surgical techniques for disc degeneration. Considering the character of cartilage and

synovial fluid, the interaction of articular surfaces was considered as frictionless sliding contact, ignoring facet joint degeneration. The finite element cervical model in this study may adequately present a primary evaluation on different surgical modalities. Future study should consider a physiological boundary condition, taking muscle force and complicated load-and-displacement into account.

Conclusion

In summary, the prediction in this study showed that spinal fusion inevitably restricted the motion of the operative segment and resulted in compensation movement to the adjacent site, notwithstanding the increased adjacent IDP that possibly led to disc degeneration. Prodisc-C had over-released the ROM and resulted in hyper-mobility at the operative site that led to an increase of ligament strain (tension) and ligament force, despite that it alleviated adjacent disc pressure. The DCI implant could better maintain the spinal kinematic motion, maintain load transfer pattern in flexion and impose minimum influence on the adjacent soft tissues, despite encountering some disadvantages including high stress distribution and change of load transfer path at the adjacent segment in extension.

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Conflict of interest None.

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