In vitro evaluation of a ball-and-socket cervical disc prosthesis with cranial geometric center

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Object. Few biomechanical in vitro studies have reported the effects of disc replacement on motion and kinematics of the cervical spine. The purpose of this study was to analyze motion through 3D load-displacement curves before and after implantation of a ball-and-socket cervical disc prosthesis with cranial geometric center; special focus was placed on coupled motion, which is a well-known aspect of normal cervical spine kinematics.

Methods. Six human cervical spines were studied. There were 3 male and 3 female cadaveric specimens (mean age at death 68.5 ± 5 years [range 54–74 years]). The specimens were evaluated sequentially in 2 different conditions: first they were tested intact; then the spinal specimens were tested after implantation of a ball-and-socket cervical disc prosthesis, the Discocerv, at the C5–6 level. Pure moment loading was applied in flexion/extension, left and right axial rotation, and left and right lateral bending. All tests were performed under load control with a 3D measurement system.

Results. No differences were found to be statistically significant after comparison of range of motion between intact and instrumented spines for all loading conditions. The mean range of motion for intact spines was 10.3° in flexion/extension, 5.6° in lateral bending, and 5.4° in axial rotation; that for instrumented spines was 10.4, 5.2, and 4.8°, respectively. No statistical difference was observed for the neutral zone nor stiffness between intact and instrumented spines. Finally, the coupled motions were also preserved during axial rotation and lateral bending, with no significant difference before and after implantation.

Conclusions. This study demonstrated that, under specific testing conditions, a ball-and-socket joint with cranial geometrical center can restore motion in the 3 planes after discectomy in the cervical spine while maintaining physiological coupled motions during axial rotation and lateral bending. (DOI: 10.3171/2009.6.SPINE0949)

Key Words • biomechanics • biomechanical testing • cervical spine • disc prosthesis • artificial disc

Abbreviations used in this paper: ACDF = anterior cervical discectomy and fusion; COR = center of rotation; NZ = neutral zone; ROM = range of motion; TDR = total disc replacement.

Anterior cervical discectomy and fusion is traditionally the gold standard to manage cervical degenerative disease in which radicular pain is refractory to conservative management. However, ACDF can potentially lead to iatrogenic effects such as early adjacent-level degeneration by increasing the stress at adjacent segments.17,28 Symptomatic adjacent-segment degeneration disease has been estimated in ~ 25% of patients in some studies, which have reported an annual incidence of 2.9% per year.16 Goffin et al.14 have found additional radiological degeneration at the adjacent disc levels in 92% of cases and reported a 6.1% reoperation rate at late follow-up after ACDF.

According to several studies evaluating different prosthesis designs, early clinical results after arthroplasty share some similarities, in terms of pain relief and safety, with ACDF.1,2,12,15,28 Because cervical TDR is a relatively new treatment, the major concern today is to obtain a better definition of the indications for this procedure. With this in mind Pracyk and Traynelis29 recently compiled a wide range of indications in an exhaustive review of the literature, among which are the following 3:
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radiculopathy due to discal herniation (soft or hard) or to foraminal osteophytes after failure of preoperative conservative treatment; myelopathy due to discal herniation (soft or hard) producing spinal cord compression; and any combination of these.

The clinical relevance of treating multisegmental diseases with TDR is not yet well established.

From a biomechanical point of view, as observed in the lumbar spine, several studies have demonstrated that fusion could generate an increase in mechanical forces with hypermobility and increase of intradiscal pressure on adjacent discs above and below the intervertebral fused segment, and this may explain the mechanism of early adjacent disc degeneration.4–6,10,38 By restoring some amount of motion in the cervical spine, a disc prosthesis could avoid the reported stresses on adjacent discs, and thus it could be an alternative to intervertebral fusion procedures.9,26,27,33

Only a few studies in the literature have reported the in vitro biomechanical behavior of cervical disc prostheses,4–7,9,23,26,31 and to our knowledge, only 1 study has reported the effect of cervical disc prosthesis on coupled motion.31

A ball-and-socket joint with cranial geometrical center, the Discocerv, was recently introduced by Scient’x. Our objective in the current study was to analyze the effect of this cervical disc prosthesis on the motion at the treated level.

Methods

Materials

Ten adult cervical spines were harvested from fresh human cadavers coming from the department of anatomy of the university (Faculté de Médecine de Lyon Sud, Lyon, France). Each spinal segment included C3–7.

Radiographs were obtained to exclude pathologically affected spines (tumoral, degenerative or traumatic). Four specimens were excluded because of major degenerative changes and only 6 spines were finally included in the study. There were 3 male and 3 female cadaveric specimens obtained in individuals whose mean age at death was 68.5 ± 5 years (range 54–74 years). Once harvested each spine was immediately conserved in plastic bags at −20°C prior to biomechanical tests. The day before biomechanical testing, all spines were thawed at 4°C for 12 hours.

All soft tissue, particularly paravertebral muscles, was removed while preserving spinal ligaments, joint capsules, and osseous elements.

Implant Characteristics

The implant consists of a constrained device with ball-and-socket joint and cranial geometrical center (Fig. 1). It uses a combination of pure titanium and titanium alloy for endplates and ceramic-on-ceramic bearing surfaces. Implant characteristics limit the motion of flexion/extension to 18° and the motion of lateral bending to 18°; there is no theoretical limitation for axial rotation. Titanium endplates are designed with an anatomical profile characterized by convexity in the sagittal plane for the upper plate and convexity in the frontal plane for the lower plate.

Implant Testing

The C4–6 segment was isolated from the human cadaveric spine. The spinal specimens were then evaluated sequentially in 2 different biomechanical conditions (Fig. 2).

The C4–6 segments were first tested intact, and then they were tested after C5–6 discectomy and implantation of the TDR at the same level. After incision of the anterior longitudinal ligament, the C5–6 intervertebral disc

Fig. 1. Illustrations of the Discocerv device. The implant consists of a constrained device with ball-and-socket joint and cranial geometrical center. Bearing surfaces are ceramic-on-ceramic. Two footprints are available, one 13 × 17 mm and the other 15 × 20 mm.
was removed while preserving the vertebral endplate cortical bone and uncovertebral joints. We also kept intact the posterior edge of adjacent endplates such as posterior longitudinal ligament. The implant was placed with the aim of an optimal position in both frontal and anteroposterior planes. If the prosthesis was not strictly in a median place, it was placed again. The size of the implant was determined by the intervertebral height on preoperative radiographs and was adapted according to the distraction effect during implant positioning. To minimize the effect of variation in the surgical technique, the same surgeon (C.B.) implanted all the prostheses.

The position of the implant could be checked using frontal anteroposterior and lateral radiographs with the EOS biplanar x-ray system (Fig. 3).

All biomechanical testing was performed on the 2TM machine, which was designed in the Laboratory of Biomechanics of the Ecole Nationale Supérieure d’Arts et Métiers (Fig. 4). The protocol for biomechanical tests in the 2TM has already been evaluated and previously described in the literature for the lumbar and cervical spine. The 2TM testing device and protocol have obtained an ISO 17025 quality certification label.

By using a system of weights and pulleys, we successively applied pure moments in flexion and extension, lateral bending, and axial rotation to a 1.6-Nm maximum moment loading with 0.2-Nm steps. All tests were performed under load control with a 3D measurement system. Accuracy in linear and angular measurements was calculated to 0.5 mm and 0.5°, respectively. Typical load-displacement curves were obtained for each different testing condition (Fig. 5). These curves allow the determination of the ROM and the NZ in degrees of rotation for each load case. Range of motion refers to the rotational motion between the maximum flexion and extension moments, between the maximum left and right axial torsion moments, and between the maximum left and right lateral bending moments. The NZ is defined as the difference in angulation at 0 load between the 2 phases of motion and corresponds to the segment of the curve where there

Fig. 2. Six C4–6 segments were isolated from human cadaveric spines and evaluated sequentially in 2 different biomechanical conditions: intact (A) and after implantation of the prosthetic disc at C5–6 (B).

Fig. 3. Anteoposterior and lateral radiographs obtained after implantation of the disc prosthesis at C5–6. The optimal position of the implant can be checked in both the frontal and the sagittal planes. Alignment of the implant with the midline (vertical line) and the degree of facet distraction (closed circle) were specifically verified.
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is low resistance offered by the functional spinal unit and great displacement occurs from minimal load application (Fig. 5). The stiffness was defined as the quotient of the loading to the deformation and was calculated for the elastic zone.

The variation of motion after disc replacement was expressed as follows: $100 \times (\text{ROM of intact spine} - \text{ROM of instrumented spine})/\text{ROM of intact spine}$.

Statistical Analysis

Statistical comparison of ROM between intact and instrumented spines was carried out using the paired Wilcoxon test. All probability values were considered statistically significant at $p < 0.05$.

Results

The 6 moments were grouped into 3 pairs: flexion/extension, left/right axial rotation, and left/right lateral bending.

Range of motion for the intact and disc prosthesis spines during flexion/extension, lateral bending, and axial rotation were analyzed and are summarized in detail in (Fig. 6). In flexion/extension the mean ROM for intact specimens was $10.3 \pm 3.4^\circ$ (range 5.9–15.8$^\circ$), whereas the mean ROM for spines fitted with prostheses was $10.4 \pm 2.3^\circ$ (range 6.6–13$^\circ$); in lateral bending the means were $5.6 \pm 0.7^\circ$ (range 4.5–6.3$^\circ$) and $5.2 \pm 1.7^\circ$ (2.2–6.7$^\circ$), respectively; and in axial rotation the means were $5.4 \pm 1.1^\circ$ (range 3.6–6.7$^\circ$) and $4.8 \pm 1.1^\circ$ (range 3–6$^\circ$), respectively. No significant statistical difference was found between the 2 tested conditions for all the 3 loading cases.

Compared with intact conditions, the NZ for instrumented spines was reduced in flexion/extension, lateral...
bending, and axial rotation from 5.8 ± 3.8 to 4.3 ± 1.9°; from 3 ± 0.5 to 2.4° ± 1.2°; and from 4.7 ± 2.4 to 3.4 ± 1.4°, respectively. However, the difference was not significant (Fig. 7).

No significant changes were observed for the stiffness between the 2 testing conditions (Fig. 8).

Concerning coupled motions, for intact specimens the mean coupled axial rotation during lateral bending motion was 1.9 ± 0.7°, which represented 34% of the main motion. The mean of this coupled motion after implantation of the prosthetic disc was 1.1 ± 0.6°, corresponding to 21% of the main rotation. The difference was not statistically significant (Fig. 9).

During axial rotation for intact spines the mean coupled lateral bending was 3 ± 0.7°, corresponding to 56% of the main motion. The mean value for instrumented spines was 2.8 ± 1.1°, corresponding to 58% of the main motion. No statistical difference was found between intact and instrumented spines (Fig. 9).

The mean variation of intervertebral motion between the 2 testing conditions was 2% (range −38 to +53%) in flexion/extension, −5% (range −60 to +18%) in lateral bending, and −9% (range −22 to +15%) in axial rotation.

**Discussion**

Despite ACDF’s excellent clinical results, this procedure may increase strain on adjacent levels and potentially accelerate degenerative changes. We know that controversy surrounds adjacent-level degeneration, because it may be the result of the natural progression of degenerative cervical disease rather than necessarily be related to the fusion procedure. However, it has been well established through biomechanical studies that fusion at 1 level is associated with an increase in the motion and stresses at an adjacent level.⁴,¹⁰,¹⁶,³⁹ Therefore, because a cervical disc prosthesis restores some amount of intervertebral motion at the instrumented level, this could theoretically preserve adjacent levels from excessive motion, reduce the incidence of adjacent-segment disease, and be an interesting alternative to fusion.
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In Vitro Protocol

The objective of this study was to evaluate the in vitro effects of a ball-and-socket total-disc arthroplasty on cervical joint kinematics. Using pure moment loading, instead of linear forces, and 3D load-displacement curves in our protocol allowed a satisfying evaluation of 3D kinematics of the cervical spine. As recommended by Goel et al. and Wilke et al., the application of pure moments ensures that the load magnitude does not vary along the spinal segment and that spinal specimens are free to move in an unconstrained manner, simulating more closely in vivo conditions. Additionally, our protocol allowed measurement of 3D angular and linear displacement for each load case and determination of ROM not only for the main motion but also for coupled motions.

The values of the intact model in our study were comparable to those reported in the literature, suggesting the reliability of our in vitro model.

Comparison With Data From the Literature

We found no statistical difference between the ROMs of intact and implant-treated spines, suggesting that motion provided by the prosthesis was comparable to that of the intact spine after application of loads in the 3 planes. Additionally, according to the definition of instability by Panjabi and colleagues (instability was defined as an increase of the NZ in a load-displacement curve), no instability was observed following implantation of the disc prosthesis. Although only few biomechanical in vitro studies have reported the effects of disc replacement on motion and kinematics of the cervical spine, our results were consistent with data published in the literature.

In 2003 DiAngelo et al. reported an in vitro human cadaveric study investigating the Prestige device (Medtronic Sofamor Danek). Four C2–T1 specimens were loaded under displacement control in flexion/extension and lateral bending and tested in 3 different conditions: intact, with a prosthesis implanted at C5–6, and with fusion at C5–6. No data were recorded for coupled motion, and axial rotation was not investigated. In contrast to fused spines, the authors found that spines instrumented with the cervical prosthesis demonstrated no difference of ROM compared with intact spines for all modes of loading at the treated and adjacent levels. However, for in vitro evaluations, it has been recommended to test at least 6 specimens to allow conclusive statistical analysis to be performed.

One year later, DiAngelo et al. published an in vitro study comparing the ROM of 6 human cervical spines tested under the same protocol in 3 conditions: intact, with a ProDisc-C device (Synthes) at C5–6, and after fusion at C5–6. The spinal specimens were tested under displacement control in 3 motion planes. No data were recorded for coupled motion. As expected, compared with the intact and ProDisc-C specimens, fusion was associated with a significant reduction of ROM at the instrumented
level, whereas a significant increase of ROM was noted at the adjacent levels. No difference was observed between intact and instrumented spines except in extension.

The only in vitro study investigating coupled motion in the cervical spine, as in our study, has been reported by Puttlitz et al. They tested 6 human C2–7 spinal segments by applying a 1-Nm pure moment in 2 different testing conditions: intact or instrumented with ProDisc-C at C4–5. Pure moments were applied in flexion/extension, axial rotation, and lateral bending. The authors found no significant difference in ROM between intact and instrumented spines for the 3 loading conditions. In addition, and as observed in our study, investigators found that motion coupling, especially present in the cervical spine, was preserved, and it was concluded that ball-and-socket designs could replicate physiological motion at the affected and adjacent levels.

Coupled motion is considered to be the motion in a plane that is secondary to the plane of the main motion. The importance of coupled motion is a well-known aspect of normal cervical spine kinematics and has been widely investigated. Two kinds of coupled motions are especially well known in the lower cervical spine: axial rotation in the same direction as the applied lateral bending and lateral bending in the same direction as the applied axial rotation. Watier performed a systematic review of studies involving mechanical behavior of the normal cervical spine and reported that coupled axial rotation during lateral bending ranged from 30 to 50% of the main motion and that coupled lateral bending during axial rotation ranged from 60 to 70% of the main motion for C4–5, C5–6, and C6–7 levels. In the present study the part of coupled motion during lateral bending and axial rotation after implantation of the prosthesis was comparable with those measured for intact spines, suggesting the capacity of a ball-and-socket design to restore physiological motion of the cervical spine.

In 2005, Dmitirev et al. carried out an experimental study to compare the in vitro effects of a cervical ball-and-socket prosthesis and a plate/bone graft fusion. Ten human cervical spinal specimens were tested under displacement control by applying 3D pure moments. In contrast to fusion conditions, the authors found that ROM following implantation of the prosthesis was similar to intact ROM at treated and adjacent levels. However, data concerning coupled motions were not reported in this study.

**Influence of Implant Design and Surgical Technique**

Cervical disc prostheses are classically divided into constrained designs, characterized by a fixed COR during motion (considering bearing surfaces remain congruent), and unconstrained designs, with the COR free to move. Constrained disc prostheses (typical ball-and-socket design like the Discocerv implant) consist of a 3-degrees-of-freedom joint, permitting motion in theoretical 3D rotations but no translation. By limiting anteroposterior translation, these devices may limit ROM but also provide more stability and reduce facet loading. Although complete restoration of natural kinematics is unlikely with 3-degrees-of-freedom joints, we found that such designs could restore the extent of main and coupled motions in the 3D motions.

For implants with ball-and-socket design, the location of the COR determines the segmental kinematics of the functional spinal unit—that is, the relative displacement of the upper vertebra in reference to the lower vertebra, theoretically around the COR. In the cases of designs with a caudal COR, using finite element modeling of the cervical spine, some authors have demonstrated the impact of specific geometrical parameters on biomechanical behavior of the functional spinal unit. Moumene et al. (unpublished data, 2008) reported the impact of the radius of curvature (distance from the COR to the implant’s bearing surfaces) and found that a large implant radius (19-mm) resulted in more horizontal translation and potential kinematic conflict in flexion, whereas small implant radius (5.5-mm) resulted in more vertical translation and potential kinematic conflict in extension. He suggested that a 10.5-mm optimal radius could create kinematic agreement with the facets in both flexion and extension. Rousseau et al. investigated the effect of an anteroposterior location of the COR and observed that a posterior center (3 mm from the middle of the interverte-
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Bral space) combined with large implant radius (10 mm) was associated with the lowest facet loads. They underlined that these results could vary depending on from individual specificities. To our knowledge, no similar finite element study is available for TDR involving a cranial geometrical center.

In vivo investigations have demonstrated that the mean COR in flexion and extension was located just below the upper endplate of the lower vertebra, whereas in lateral bending it was located above the intervertebral space.2,24,25 Compared with implants containing a caudal geometrical center, the use of a cervical prosthesis with a cranial geometrical center should allow more physiological kinematics in the frontal plane, theoretically avoiding uncovertebral conflict (Fig. 10). Snyder et al.24 have suggested that the uncinates could potentially limit intervertebral motion after TDR, particularly in lateral bending, and could therefore serve as a source of progressive spondylosis. They confirmed these kinematic data in an in vitro experimental study comparing ROM of intact spines, those instrumented after TDR, and those after partial/complete resection of the uncinates. These authors therefore proposed complete resection of the uncinates, at least on 1 side, after TDR to avoid kinematic conflict in the uncovertebral area and to completely restore extent of 3D motions. However, removal of the uncinate structures is associated with consistent risk of injury of the vertebral artery. This potentially dangerous surgical procedure appears to be unnecessary when using a design similar to the Discocerv with cranial geometrical center. Although investigation of COR location in lateral bending is not easy to perform because of coupled motions, these data have to be confirmed through in vivo studies.

In addition to implant design, the surgical technique may have an impact on biomechanical behavior of cervical disc prostheses.22 The following 2 parameters appear to depend directly on the surgical technique, specifically implant positioning in both frontal and sagittal planes, as well as intervertebral distraction performed during implant insertion. Undersizing the implant may reduce the immediate and primary implant stability, thus becoming exposed to the risk of migration whereas oversizing may reduce intervertebral motion by excessively “pretensioning” the intervertebral ligaments and joint capsules. Lateral offset of the prosthesis may induce abnormal kinematics with asymmetrical load distribution and overloading the uncus joint and facets on the opposite side. Further studies are needed to determine the influence of anteroposterior positioning when using designs similar to the Discocerv implant.

Limitations of the Study

Our study demonstrated the capacity of the prosthesis to restore 3D motion in the cervical spine; however, our study focused mainly on the extent of motion with limited consideration given to the quality of motion except for coupling motion, stiffness, and NZ. Additional studies are particularly required to investigate the impact of a cranial geometrical center with special attention to the positioning of the COR and facet kinematics.

Otherwise, in vitro tests cannot simulate the effect of human musculature and, therefore, one should be cautious in making direct comparisons between our results and in vivo conditions.

Perspectives

In this study the mean variation of ROM between intact and instrumented groups was very low (< 10%) for the 3 load conditions. However, we observed that in some cases variation was > 50%, with a significant decrease or increase of motion after implantation of the device. This variability may underscore the impact of various factors such as implant positioning, intervertebral distraction after implantation, and/or facet morphology. This in turn emphasizes the necessity of an adapted size and the positioning of the prosthetic disc in vivo. A finite element analysis modeling could help us better understand the mechanical behavior of the device and especially help in analyzing the impact of different parameters on intervertebral motion and facet loading. This work is in progress.

Conclusions

Finally, future clinical studies and other fundamental research will be necessary to confirm long-term safety of ball-and-socket designs, but this experimental study provided initial insight into the capacity of a ball-and-socket prosthesis with a cranial geometrical center to restore 3D motion in the cervical spine, with a particular focus on physiological coupling motions.

Disclosure

Scient’X Co. provided research support for this work to Dr. Skalli. Dr. Perrin is a consultant for Scient’X Co.

References
