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BIOMECHANICS

A Biomechanical Analysis of an Artificial Disc With a Shock-absorbing Core Property by Using Whole-cervical Spine Finite Element Analysis

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Study Design. A biomechanical comparison among the intact C2 to C7 segments, the C5 to C6 segments implanted with fusion cage, and three different artificial disc replacements (ADRs) by finite element (FE) model creation reflecting the entire cervical spine below C2.

Objective. The aim of this study was to analyze the biomechanical changes in subaxial cervical spine after ADR and to verify the efficacy of a new mobile core artificial disc Baguera C that is designed to absorb shock.

Summary of Background Data. Scarce references could be found and compared regarding the cervical ADR devices' biomechanical differences that are consequently related to their different clinical results.

Methods. One fusion device (CJ cage system, WINNOVA) and three different cervical artificial discs (Prodisc-C Nova (DePuy Synthes), Discocerv (Scient'x/Alphatec), Baguera C (Spineart)) were inserted at C5-6 disc space inside the FE model and analyzed. Hybrid loading conditions, under bending moments of 1 Nm along flexion, extension, lateral bending, and axial rotation with a compressive force of 50 N along the follower loading direction, were used in this study. Biomechanical behaviors such as segmental mobility, facet joint forces, and possible wear debris phenomenon inside the core were investigated.

Results. The segmental motions as well as facet joint forces were exaggerated after ADR regardless of type of the devices. The Baguera C mimicked the intact cervical spine regarding the location of the center of rotation only during the flexion moment. It also showed a relatively wider distribution of the contact area and significantly lower contact pressure distribution on the core than the other two devices. A ''lift off'' phenomenon was noted for other two devices according to the specific loading condition.

Conclusion. The mobile core artificial disc Baguera C can be considered biomechanically superior to other devices by demonstrating no ''lift off'' phenomenon, and significantly lower contact pressure distribution on core.

Key words: artificial disc replacement, cervical spine, finite element analysis, mobile core.

Level of Evidence: N/A

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The device(s)/drug(s) is/are FDA-approved or approved by corresponding national agency for this indication.

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Artificial disc replacement (ADR) has been reported to reduce the occurrence of ASD by preserving range of motion (ROM), and the intradiscal pressure and mobility of the adjacent segment at similar statuses as those of the normal spine.[1–7] However, several new biomechanical problems such as surgical segment degeneration that could untowardly affect long-term clinical consequences due to excessive ROM and subsequent increase in intradiscal or facet joint pressure after ADR have been reported.[3,7–14] Moreover, the results of previous studies are inconclusive regarding the possible different biomechanical effects on postsurgical consequences according to the type of motion-constraint property of the core inside each ADR device. Here, we investigated the biomechanical efficacy of the mobile core cervical artificial disc Baguera C, which is designed to absorb shock.

MATERIALS AND METHODS

A three-dimensional finite element model (FEM) of the cervical spine from C2 to C7 was developed on the basis

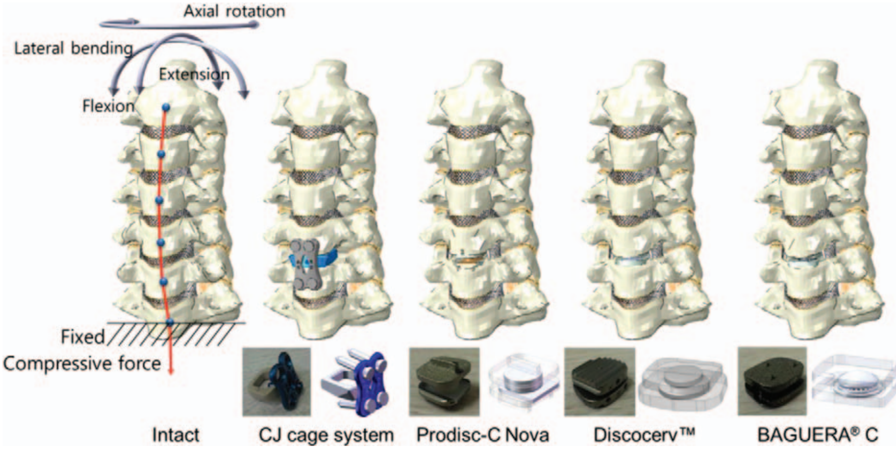

Figure 1. Developed finite element models of the intact cervical spine from C2 to C7 and after insertion of four kinds of implants at the level of C5-6 intervertebral space used in this study. Boundary and loading conditions for the finite element analysis are also depicted.

of the previously developed model (Figure 1).[15] The model, which is symmetrical across the mid-sagittal plane, was developed on the basis of a computed tomographic scan of a 1-mm slice sample obtained from a young male volunteer (age, 26 yrs; height, 170 cm; weight, 66 kg). It consists of six spinal bones, endplates, intervertebral discs, six major ligaments, and articular cartilages. Nucleus pulposus, annulus ground substance, and annulus fibrosus in intervertebral disc were modeled using fluid, linear elastic solid, and tension-only elastic truss elements, respectively. Six major ligaments, anterior longitudinal, posterior longitudinal, interspinous, supraspinous, capsular, and flaval ligaments, were attached using tension-only truss element with nonlinear material properties suggested by Goel and Clausen.[16] Articular cartilages were modeled on facet joints with a gap of 0.5 mm between articular cartilages, and three-dimensional surface-to-surface contact conditions were applied on each facet joint.

One anterior plate system (Winnova, Seoul, South Korea) and three artificial discs, namely Prodisc-C Nova (DePuy Synthes, Raynham, USA), Discocerv (Scient'x/Alphatec Spine Inc., USA), and Baguera C (Spineart, Geneva, Switzerland; Figure 1), were chosen. The cores of Prodisc-C Nova and Baguera C were placed on the inferior plates of the artificial discs, while the core of Discocerv was attached to the superior plate in the inferior direction. Three-dimensional computer-aided design (CAD) models for selected implants were developed on the basis of their respective designs and actual shapes. The three-dimensional FEMs of the implants were developed by using the CAD, and published material properties for respective implants were adapted.[16–20] Each implant was inserted at the C5 to C6 motion segment. A high-friction coefficient of 0.8 was applied on the contact condition between the superior plane of the cage and the inferior plane of the C5 vertebra to consider the teeth on the cage (Figure 2).[21]

Artificial discs were inserted with removal of the nucleus pulposus, about 60% of the annulus fibrosus, end plate, and anterior and posterior longitudinal ligaments. Cores of Prodisc-C Nova and Discocerv were fixed on the inferior and superior metal plates. While the contact conditions between the convex surfaces of the cores and the sockets were adapted in case of fixed core artificial discs, the contact conditions between the core and superior metal plates, as well as between the core and the inferior metal plate, were applied in case of Baguera C (Figure 2).

The developed models were tested in hybrid loading conditions, which can generate the same entire rotation angles with the intact cervical spine. First, the bending moments of 1 Nm along flexion, extension, left lateral

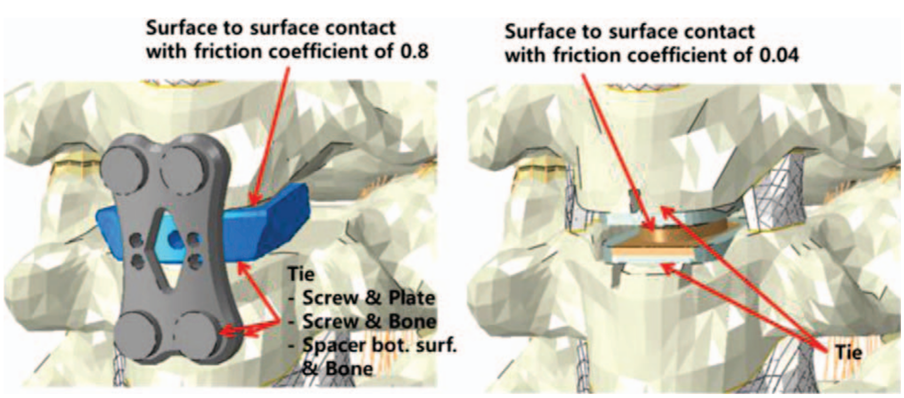

Figure 2. Interface between implants and the spinal bones in cases of the finite element models of the cervical spine with CJ cage system and Prodisc-C Nova.

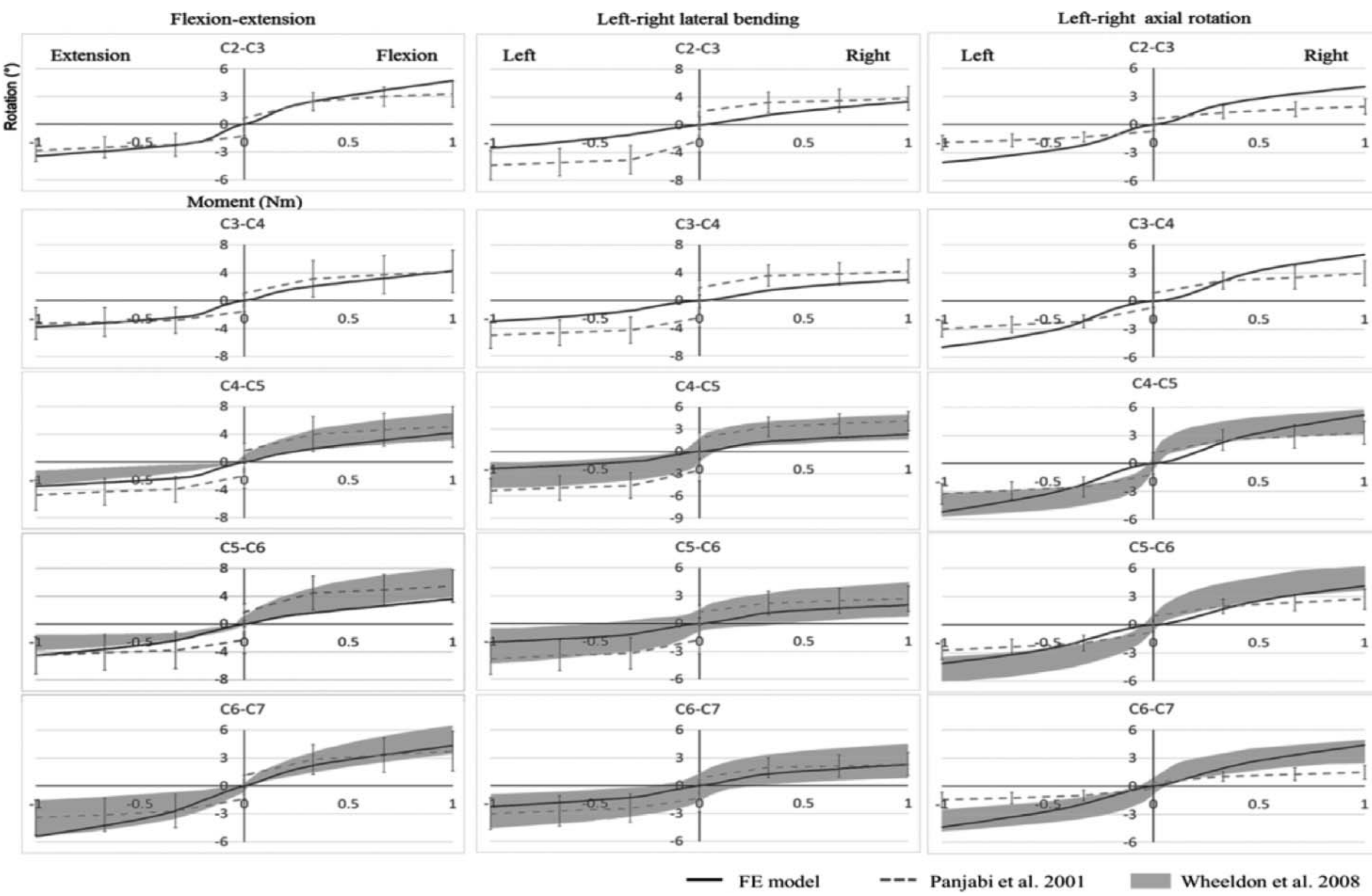

Figure 3. ROMs and moment-rotation curves of the healthy cervical spine FE model predicted in pure bending moment of 1Nm for flexion, extension, lateral bending, and axial rotation and their comparison to the experimental results.

bending, and left axial rotation directions were applied on the superior plane of the C2 vertebra of the intact cervical spine with a compressive force of 50 N along the follower load direction. To analyze the implanted model, the inferior plane of the C7 vertebra of the individual implanted model was fixed. Then, the bending moments for the hybrid loading conditions for each implanted model were predicted under a compressive force of 50 N along the follower load direction and applied to the implanted models (Figure 1). Abaqus/Standard v. 6.10 (Simulia, Providence, RI) and FEMap 10.1.1 (MSC Software Co., Santa Ana, CA) were used for FEM analysis.

RESULTS

ROMs and moment-rotation curves of the healthy cervical spine model were predicted in pure bending moment of 1 Nm for flexion, extension, lateral bending, and axial rotation and compared with the experimental results (Figure 3).[22,23] The predicted intersegmental ROMs at C2-C3, C3-C4, C4-C5, C5-C6, and C6-C7 were 4.72°, 4.27°, 4.21°, 3.61°, and 4.32°, respectively, in flexion; 3.44°, 3.80°, 3.47°, 4.49°, and 5.43°, respectively, in extension; 3.32°, 3.01°, 2.31°, 2.00°, and 2.28°, respectively, in lateral bending; and 4.03°, 4.93°, 5.17°, 4.11°, and 4.36°, respectively, in axial rotation. The predicted ROMs and moment rotation curves from the healthy cervical spine model showed good agreement with published experimental results.[22,23]

The angles for flexion, extension, lateral bending, and axial rotation upon exertion of 1-Nm bending moments along with a compressive force of 50 N along the follower load direction on the FEM of the cervical spine were 19.7°, 16.2°, 10.8°, and 16.9°, respectively (Figure 4). For all motions, including flexion, extension, lateral bending, and axial rotation, the amount of motion at the C5 to C6 motion segment of the fusion model was only 4% to 27% of that of the intact cervical spine model. As for the adjacent segment next to the cage insertion, the amounts of motion were increased to 13% to 31% for all motions. In contrast, the amount of motion for the C5 to C6 motion segment increased to 21% to 102% of all motions, as those in the intact spine model when applied with ADR, irrespective of the type of device inserted. Moreover, the amount of rotation was decreased in the adjacent segment after ADR insertion.

The center of rotation (COR) location inside the C5 to C6 motion segment during flexion was just below the intervertebral disc space center in the intact spine model (Figure 5). An almost similar spot was located as a COR during flexion when the same segment was replaced with

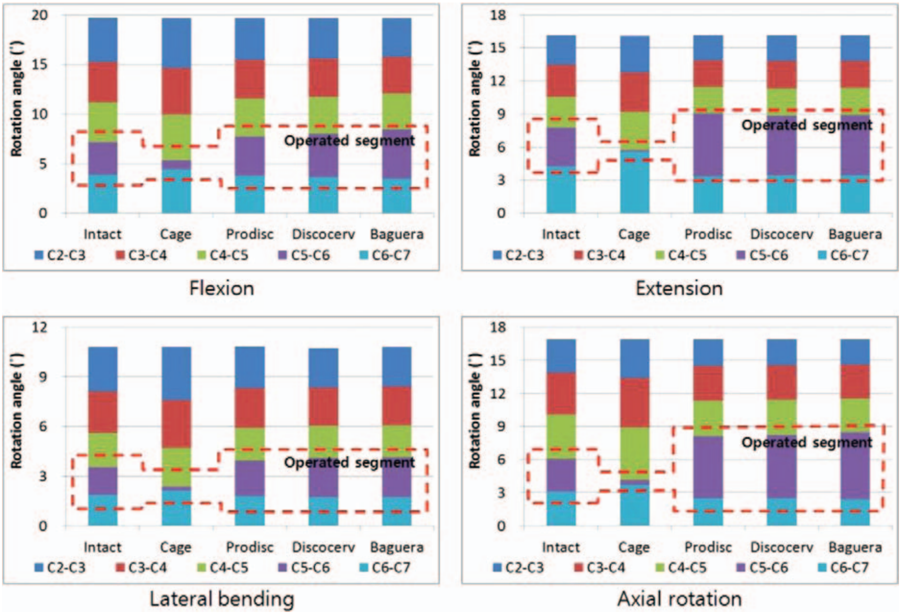

Figure 4. Intersegmental rotation in flexion, extension, lateral bending, and axial rotation.

Baguera C. A relatively lower spot for Prodisc-C Nova and a higher spot for Discocerv were respectively calculated to be the COR. The COR was spotted to be at the upper portion of the C6 vertebral body during extension in the intact cervical spine model. However, the COR during extension was quite different from that of the intact spine model when applied with ADR.

The extension movements increased by 65%, 55%, and 58% as that of the intact cervical spine after the insertion of Prodisc-C Nova, Discocerv, and Baguera C, respectively. Moreover, the amount of motion also increased during lateral bending and axial rotation after the insertion of ADR. These increases in movements could incur an increase in posterior facet joint loading on every modality of motions. The amounts of increases in facet joint force were measured to be 12% (+2.5 N), 37% (+7.5 N), 40% (+8.2 N) during extension, 27% (+4.8 N), 37% (+6.5 N), 34% (+5.9 N) during lateral bending, and 549% (+13.5 N), 505% (+12.4 N), 378% (+9.3 N) during axial rotation after the insertion of Prodisc-C Nova, Discocerv, and Baguera C, respectively (Figure 6). Although the percentage of increase was notably high during axial rotation, the maximum increased magnitude of facet joint force was 13.5 N compared with intact cervical spine model.

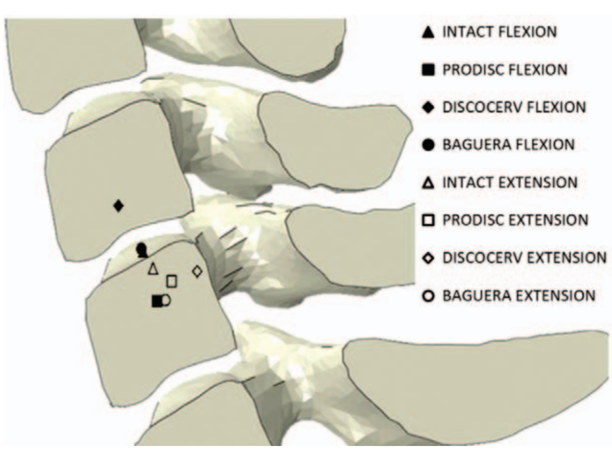

Figure 5. Centers of rotation of the C5-C6 motion segment during flexion and extension.

In the present study, we analyzed the possible risk of core breakage after the comparison between the Prodisc-C Nova and Baguera C devices, which are composed of a polymer-type core, which were reported to have propensity to develop wear debris or disruption. Good contact to the upper plate from the core with well maintenance of the contact area during not only the mere application of the follower load on standing posture but also on every motion process was noted for Baguera C (Table 1). In contrast, a liftoff phenomenon, which is a partial detachment of the socket from the core, was noted for the rest of the two artificial discs during extension (Figure 7). Consequently, the contact area was reduced to barely 5 mm^2 during extension and about 50 mm^2 during standing posture. Therefore, the contact area distribution was relatively wider and the contact pressure distribution on the core was significantly lower with Baguera C than with Prodisc-C Nova device (Table 1). Although the contact pressure on the core was higher for Prodisc-C Nova than for Baguera C on every loading condition, the maximum von Mises stress on the core was higher inside Baguera C than inside Prodisc-C Nova on every loading condition, except extension (Figure 8). The predicted maximum stresses in Bauera C were 46%, 86%, 20%, 50%, and 49% of the yield strength of high density polyethylene (33 MPa) in standing, flexion, extension, lateral bending, and axial rotation, respectively. This phenomenon is supposed to be attributed to the migration and deformation of the core resulted by "shock

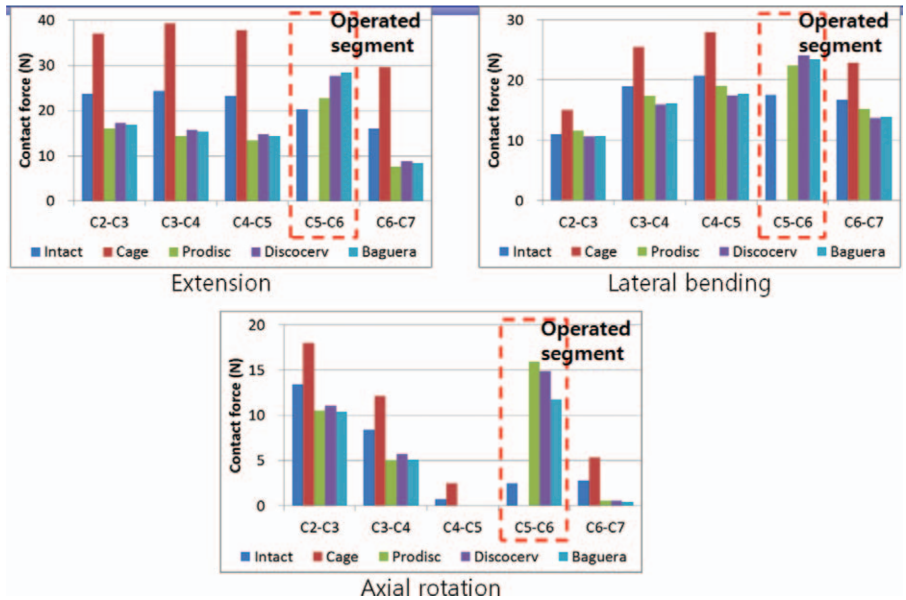

Figure 6. Facet joint forces in extension, lateral bending, and axial rotation.

absorbing" mobile core structural design inside the Baguera C.

DISCUSSION

The use of the FEM of the cervical spine including multi-levels has some advantages such as the feasibility of assessing not only the ROM at the index level but also adjacent segment ROM change.[15,24–27] In the present study, the authors used a hybrid loading condition, which is well acclaimed and frequently used in the recent spinal biomechanical research studies, by applying a bending moment of 1 Nm along flexion, extension, left lateral bending, and left axial rotational directions, with a compressive force of 50 N along the follower load direction after firm fixation of the lower end plate of C7 in the FEM to the base.[15,24–27]

Segmental Motion at the Implanted and Adjacent Levels

The present study revealed an increase in segmental ROM in all directions at the implanted segment during flexion or extension, irrespective of the ADR devices. This is contradictory to the results reported by Galbusera *et al.*,[3,7] who used the FE model of the cervical spine, including three levels, after the insertion of a Bryan disc. However, an FE study by Roussseau *et al.*[13] reported an increase in ROM in the implanted segments of 32% to 36%, a result similar to the finding of our study. Although it seems that the segmental motions at the corresponding replaced level might be exaggerated in FEM, this condition might not be representative clinically due to other stabilizing conditions such as paraspinal supportive structures such as muscles and ligaments. Moreover, this FEM study does not reflect a long-term follow-up result, as it is feasible in clinical follow-up series.

In a 2-year clinical follow-up of ADR for the cervical spine that was recently reported, the ROM of the implanted segments was preservation without affecting the ROM in the adjacent segments.[28] Most of these follow-up results, however, show a slight increase in ROM in the implanted segments with a longer follow-up period,[28–31] suggesting that the ROM increases rather than decreases over time. Accordingly, the present study is closer to what happens under *in vivo* conditions. However, in a recent consensus, the ADR seems to behave similarly to ACDF, instead of playing a significant role of deterring the development of adjacent segment pathology (ASP) by expected preservation of the ROM.[32–35] Ultimately, this development of ASP is the issue for quality of motion, including maintenance of physiological COR, rather than the provision of adequate magnitude or quantity of ROM.

TABLE 1. Contact Area and Maximum Contact Pressure on the Surface of the Core in Prodisc-C Nova and BAGUERA C

	Contact Area (mm^2)		Max. Contact Pressure (MPa)	
	Prodisc-C Nova	BAGUERA C	Prodisc-C Nova	BAGUERA C
Standing	50.4	50.2	1.3	2.6
Flexion	16.0	49.4	11.4	4.4
Extension	5.0	46.2	10.2	1.1
Lateral bending	10.7	48.5	9.1	1.4
Axial rotation	14.7	49.0	7.5	2.8

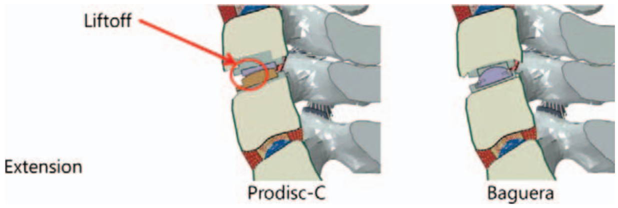

Figure 7. "Lift-off" phenomenon in fixed core type of artificial disc during extension.

Spontaneous Rotation at the Implanted Level

Moumene *et al.*[11] reported the advantage of a mobile-core artificial disc design over a fixed-core design, as it is less sensitive to placement. It spontaneously settles to a proper location by its mobility; therefore, mobile-core stresses were not affected by implant placement, while the fixed-core stresses increased by up to 40%. In the present study, no spontaneous movement was noted at the C5 to C6 level, but it was manifested in the Prodisc-C Nova or Discocerv after the mere application of compressive force of 50 N along the follower load direction. In contrast, translation of the polyethylene core toward posterior direction as much as 0.10 and 0.25 mm during both flexion and extension was shown after replacement with Baguera C, as expected from the results by Moumene *et al.*[11]

COR at the Implanted Level

In vivo experimental results by Anderst *et al.*[36] revealed that the COR between the adjacent vertebrae in asymptomatic control subjects was generally fixed in the superior-inferior (SI) direction, but it translated in the anterior-posterior (AP) direction during flexion-extension. The COR in the SI direction was located near the center of C3 for C2/C3 and moved progressively superior (closer to the intervertebral disc) for each motion segment until C6/C7, where the instant COR (ICR) was located near the top end plate of C7. Meanwhile, analytic research by Jung *et al.*[37] reported that the COR is located in the intervertebral disc midpoint, leading to an inconclusive controversy regarding the COR location in each mobile cervical segment, with different results according to experimental methods. In this study, the COR location inside the C5 to C6 motion segment during flexion was just below the intervertebral disc space center and close to the upper end plate of C6 during extension in the intact cervical spine model. Among the three ADR devices, only Baguera C mimicked the intact cervical spine regarding the COR location only during flexion. However, the COR location during extension was quite different from that of the intact cervical spine model, regardless of device core property. This analysis on the COR definitely has limitations because it is rather close to the instantaneous axis of rotation (IAR), which always starts from neutral posture to a certain axis of motion.

Increase of Facet Joint Stress and Cervical Ligament Tension

The increased ROM in the implanted segments resulted from resection of the strong supporting structures such as ALL and the anterior annulus. Subsequently, the stress sustained by the disc prosthesis and the facet joint in the implanted segments increases.[3,10] An FE study on the "ball-and-socket" cervical disc prostheses suggested that the pressure on the facet joint may increase to 15% to 86% by adjusting the COR and that the posterior COR with a large radius was most effective in lowering the pressure. In a recent study by Lee *et al.*,[15] stress sustained by the facet joint increased by 107% with the Prodisc-C model and by 113% with the Mobi-C model, demonstrating a remarkable stress increase in the ADR segments. Despite all these reported results, such a large increase in facet joint at all adjacent levels as in current study is a surprising phenomenon. This is a reflection of limitation of FE analysis using a ligamentous cervical spine model. A bending moment applying on each motion segment is constant in a ligamentous cervical spine because of removal of spinal muscles. Bending moment applying on the fusion model is bigger than that applying on the intact cervical spine model in hybrid loading conditions. Thus, bigger bending moment resulted in an increase in segmental rotation and facet joint forces at all adjacent levels in the fusion model. This phenomenon is also shown in previously published finite element study for the lumbar spine.[38,39]

Contact Area, Pressure, and Stress Distribution Inside the Core

Detachment of the upper plate from the core, the so-called liftoff phenomenon, has been reported by Bhattacharya *et al.*[40] during their FE analysis of the prediction of wear in artificial disc implants *in situ* by using fixed core-type ADR devices.

After analyzing the three ADR devices, good contact to the upper plate from the core with well maintenance of contact area was observed not only during the mere application of follower load on standing posture but also on every moment application of Baguera C. In contrast, partial contact between the core and upper plate, along with the liftoff phenomenon, was noted on every moment application of Prodisc-C Nova, and during extension and rotation for Discocerv, consequently leading to a higher contact pressure production especially during liftoff.

The distribution of von Mises stress on the core was deviated to the higher contact pressurized zone for Prodisc-C Nova while concentrated to the main central portion of the core containing the 5-mm caliber furrow with low cross-sectional area designed for shock absorption inside Baguera C.

In the analysis of the contact pressure distribution, a higher pressure concentration to the certain region inside the core during specific moment application was noted for Prodisc-C Nova, while a relatively even pressure distribution with lower contact pressure on every moment application was noted for Baguera C, predicting a lower feasibility of wear inside the core over the long term. Indeed, the development of wear debris is related not only to these distributions of contact surface area, pressure, or stress but also to the material property of the core.

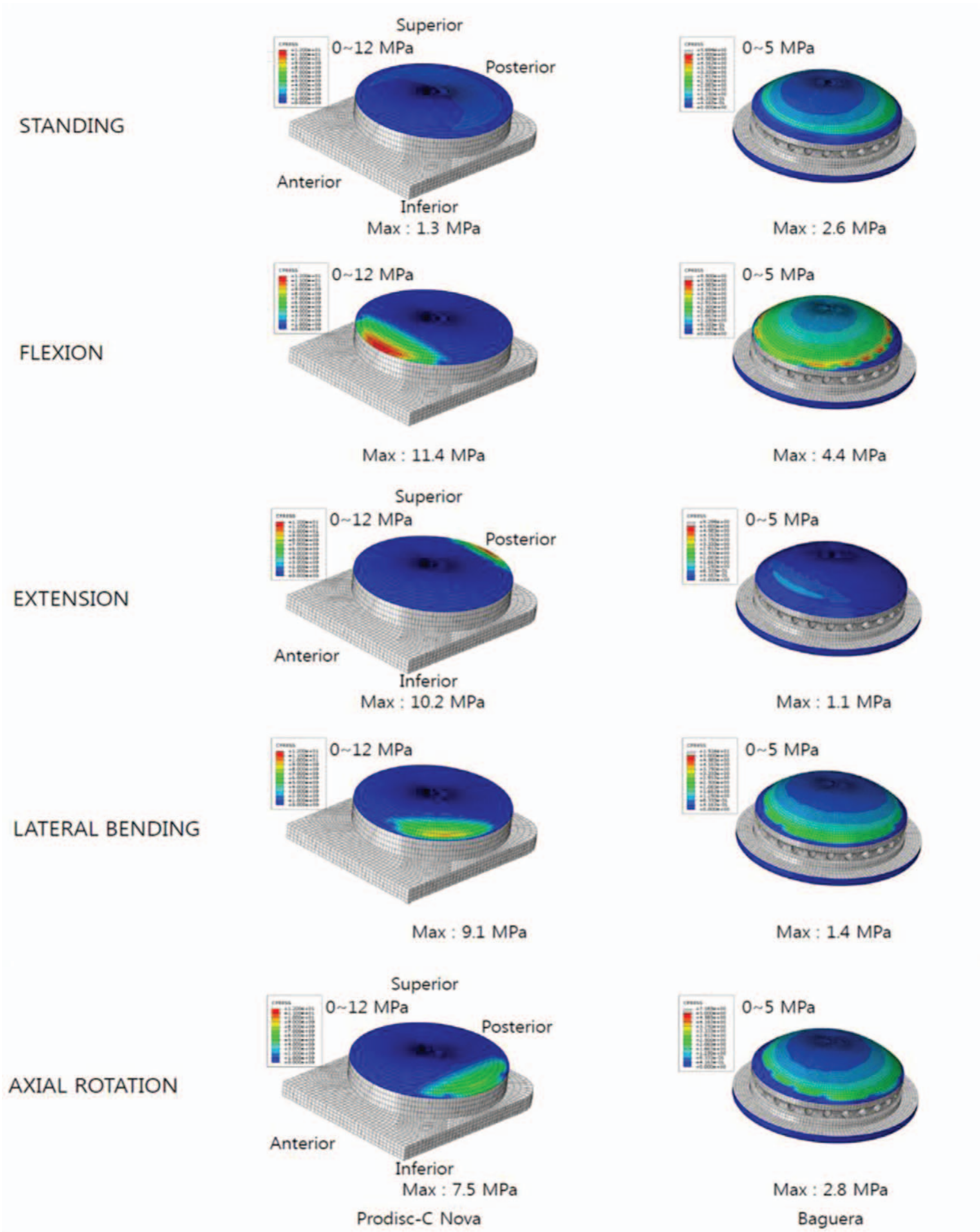

Figure 8. Distribution of von-Mises stress on the cores in Prodisc-C Nova and Baguera C.

Summary

According to the results of this study, Baguera C could be definitely differentiated from other devices especially in terms of mimicking physiological COR during flexion movement or wider von Mises stress distribution over the core. However, despite these benefits, it is still nonphysiological, far from fully mimicking the natural motion of intact cervical spine in various aspects. A more sophisticated design of an artificial disc is required to eliminate the exaggerated ROM, COR deviation, or increase in facet contact force in order to create an ideal cervical artificial disc that can maintain the originality of natural motion and preventing ASP.

CONCLUSION

Currently, there is no ideal cervical artificial disc that completely mimics the natural motion of the intact human cervical spine, although Baguera C has a mobile-core mechanical property and a shock-absorbing function. However, no liftoff phenomenon, spontaneous movement during the basic loading condition of the follower load only during standing, and significantly lower contact pressure distribution on the core was observed, which can be interpreted as the lower feasibility of wear inside the core over the long term.

➢ Key Points

- The use of FE model of the cervical spine reflecting whole cervical level is very useful for simultaneous observation of ROM changes both in index and adjacent cervical level.
- The segmental motions as well as facet joint forces at the operated segment were exaggerated after ADR regardless of type of the devices.
- Due to its design for mobile core and shock absorbing function, the Baguera C was differentiated from other fixed type devices by demonstrating no "lift off" phenomenon nor spontaneous movement under the basic loading condition.
- The Baguera C also showed a significantly wider contact area and lower contact pressure distribution on the core than the fixed core type devices, predicting a lower feasibility of the development of the wear inside the core in the long-term follow-up.

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