DOI: 10.5137/1019-5149.JTN.15649-15.4
Received: 27.07.2015 / Accepted: 25.01.2016
Published Online: 09.05.2016

Original Investigation

Biomechanical Changes in Disc Pressure and Facet Strain after Lumbar Spinal Arthroplasty with Charité™ in the Human Cadaveric Spine under Physiologic Compressive Follower Preload

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ABSTRACT

AIM: Arthroplasty maintains the biomechanical features of a healthy disc, decreases the adjacent segment disease rate, and decreases the accelerated degeneration rate of the neighboring discs in traditional fusion procedures. However, there are only a few reports on adjacent disc pressure (DP) and facet strain (FS) after lumbar arthroplasty under a physiologic compressive preload.

MATERIAL and METHODS: Baseline DP and FS measurements were obtained from five intact cadaveric human lumbosacral spines for different modes of motion. DP was measured by inserting pressure transducer needle tips into the L3–L4 and L5–S1 discs. FS gauges were fixed on both sides of the laminae near the L3–L4, L4–L5, and L5–S1 facet joints. After SB Charité™ III implantation at the L4–L5 level, the measurements were repeated at preload and compared with those of the intact spine.

RESULTS: Under the preload condition, the central DP of the upper disc was decreased during extension and bending, and it significantly increased during rotation ($p < 0.05$). In the lower disc, the central DP insignificantly decreased during bending and increased during extension and flexion. A statistically significant increase in FS was observed during rotation at the operative facet ($p < 0.05$). Compared to the intact spine, all FS values were insignificantly decreased during lateral bending but increased during axial rotation.

CONCLUSION: In an ex-vivo physiologic preload setting, the SB Charité™ III provided relatively inconsistent and sometimes increased DP or FS at the operative and adjacent levels after arthroplasty.

KEYWORDS: Biomechanics, Lumbar spinal arthroplasty, Charité™, Disc pressure, Facet strain, Physiologic compressive follower preload

■ INTRODUCTION

The lumbar arthroplasty technique was developed to maintain the biomechanical features of a healthy disc, to decrease the rate of adjacent segment disease, and to lower the rate of accelerated degeneration of the neighboring discs that occurs in traditional fusion procedures. The follower load path explains how the whole lumbar spine can be lordotic and yet resist large compressive loads. As far as the load path remains within the limited range of the estimated rotation centers of the lumbar segments, the load-carrying capacity of the lumbar spine increases under a compressive follower load (19).

We previously published a biomechanical study on the range of motion (ROM) changes following lumbar spinal arthroplasty

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with Charité™ in a human cadaveric spine under a physiologic compressive follower preload (13). To our knowledge, there are only a few reports on the biomechanical study of adjacent disc pressure (DP) and facet strain (FS) after lumbar arthroplasty under a physiologic compressive preload. The SB Charité™ III was approved by the United States Food and Drug Administration and is one of the newly commercially available lumbar artificial discs (ADs) in the country.

The purpose of this study was to evaluate the biomechanical performance in terms of DP and FS of the preloaded human cadaveric spine implanted with the SB Charité™ III AD and to compare it with the intact spine.

MATERIAL and METHODS

Cadaveric Specimen Preparation

Five human cadaveric lumbosacral spines (2 from men and 3 from women, L2–S2) were obtained from Science Care Anatomical (Phoenix, AZ, USA) and International Biological, Inc. (Grosse Pointe Farms, MI, USA). The Institutional Ethical Committee at the University of Korea reviewed and approved in this work (KUIACUC-2013-170).

Bone mineral density (BMD) was measured via dual-energy radiography absorptiometry.

For biomechanical testing, en-bloc specimens which were stored at -20° C before manipulation, and were maintained moist during all procedures. The paravertebral muscles were removed to expose vertebral facet surfaces, while preserving the facet joints, ligaments, discs, and bone structures.

Fixation and Implantation in the Cadaveric Spine

Each cadaveric spine was fixed by screws to the upper and lower segments. The end segments and screws were placed into two potting fixtures with polymethylmethacrylate (PMMA), and the PMMA covered ends were placed in polyester resin. Before any surgical procedure, load testing was performed to ensure the spine was intact state.

Anterior discectomy was performed at the L4–L5 level. Posterior osteophytes and posterior longitudinal ligament were excised, and the integrity of the lateral annulus was maintained.

An SB Charité™ III AD (DePuy Spine, Inc., Raynham, MA, USA, Figure 1A) was placed in a 36°C saline bath for 72 h prior to implantation, setting the temperature of the discs close to the biophysiological temperature. The device was implanted into the discectomied space according to the manufacturer's specifications with fluoroscopy (15,16). The optimal position in the anteroposterior plane was at the midline, but it was 2 mm posterior to the midline on the lateral image. This position reproduces the physiologic instantaneous axis of rotation throughout the flexion-extension arc of the normal disc (8).

Biomechanical Test

The potting fixtures of L2 and S2 were attached respectively to the upper and lower spine-loading fixtures of a biomechanical loading frame, and pressure transducer needle tips were inserted into L3–L4 and L5–S1 discs. Each needle had three pressure sensors spaced 10 mm apart to measure pressures in the posterior annulus, disc center, and anterior annulus, having pressure sensors indicated as #1, #2, and #3, respectively (Figure 1A). The needle tips were inserted approximately 2 cm into the disc to ensure that pressure sensor #2 was located in the center of each disc (Figure 1B). Central DP was defined as the value measured from pressure sensor #2, i.e., from the center of the disc.

Six FS gauges were fixed on both sides of the laminae near the facet joints of L3–L4, L4–L5, and L5–S1 (Figure 2). Each gauge measured strain over the specific facet to which it was attached.

The method of applying a compressive follower preload to a multi-segmented spine specimen (L2–S2) was adapted from a formerly published method, so that the path approximates the tangent of the lumbar spine curve (Figure 3) (19).

Thus, the compressive preload was applied along a follower load path rather than a vertical load path. Moments were applied to both L2 and S2 up to 8 Nm with a loading rate of 0.3 Nm/ s, and a constant 400 N axial follower preload was applied throughout the loading condition. These moments were selected as the safe loads for the human cadaveric lumbar spine based on the published data on biomechanical testing (10,12). Axial rotation was determined by the upper spine fixator, whereas flexion, extension, and lateral bending were determined by rotation of both spine fixators in the respective coronal and sagittal planes.

Under the physiologic compressive follower preloaded condition, DP and FS baseline measurements were performed for each intact spine in six modes of motion, i.e., flexion, extension, right/left lateral bending, and right/left axial rotation. To stabilize the viscoelastic effect for each mode of testing, loading was applied three times, and only the result from the third trial was used.

After arthroplasty with the SB Charité™ III at L4–L5, the DP and FS measurements were repeated in the same manner and preload. Data from above, at and below the operative levels was obtained for each specimen after SB Charité™ implantation and was compared with that of the intact spine.

Statistical Analysis

The mean central DP and FS for each specimen group were determined and were normalized by dividing it by those of the intact spine. Results of right and left lateral bending were summed into lateral bending, and those of right and left axial rotation were summed into axial rotation, thus making it four biomechanical modes of motion, i.e. flexion, extension, lateral bending, and axial rotation. Paired comparisons between different treatment groups were made using Wilcoxon paired tests, and a value of $p<0.05$ was considered statistically significant in all analyses. Values were presented as average ± standard deviation (SD)

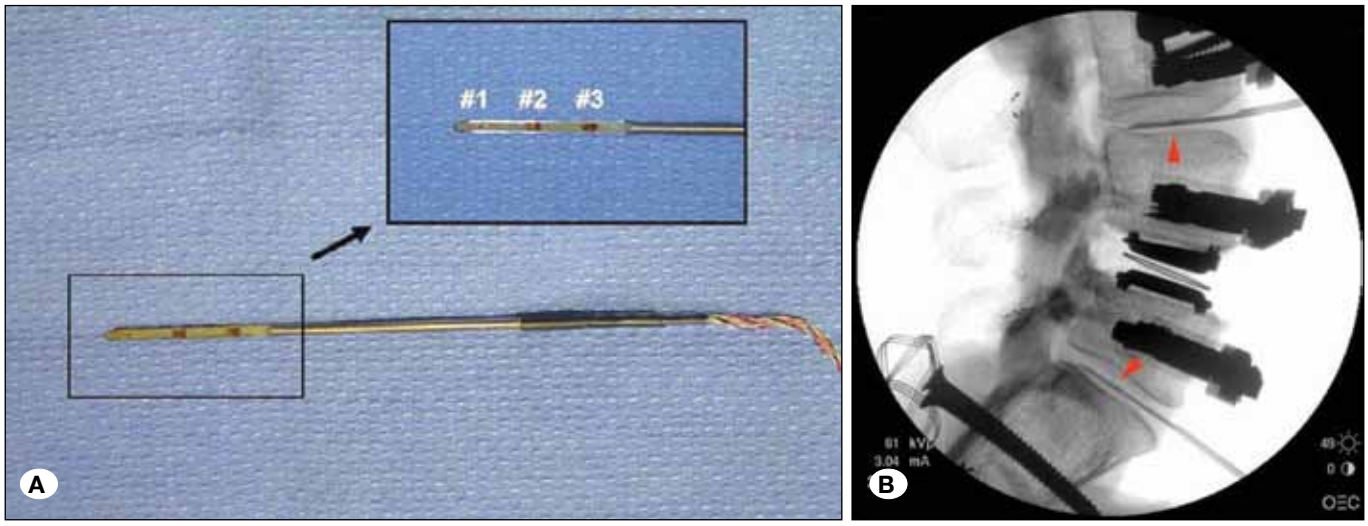

Figure 1: The needle pressure transducer. The position of pressure sensors #1, #2, #3 **(A)**, and the transducer inserted into the spine specimen with a SB Charité™ III artificial disc at L4–L5 **(B)**. The needle tip is inserted so pressure sensor #2 (arrowheads) is positioned in the center of each disc.

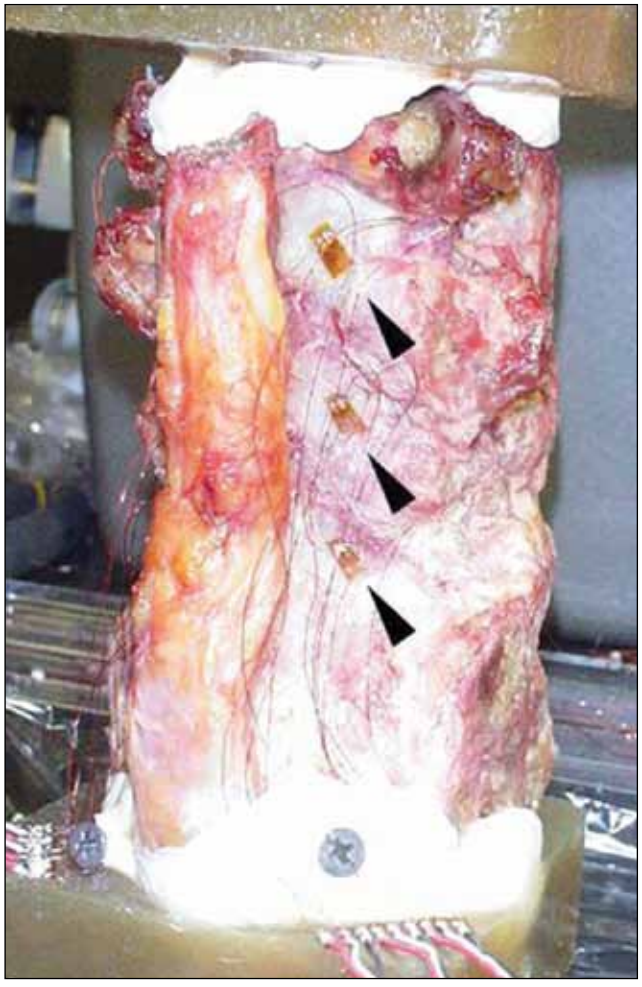

Figure 2: Photograph showing the facet strain gauges (arrowheads) on the right laminae surfaces. Six facet strain gauges are fixed on both sides of the spine on each lamina near the facet joints of L3–L4, L4–L5, and L5–S1.

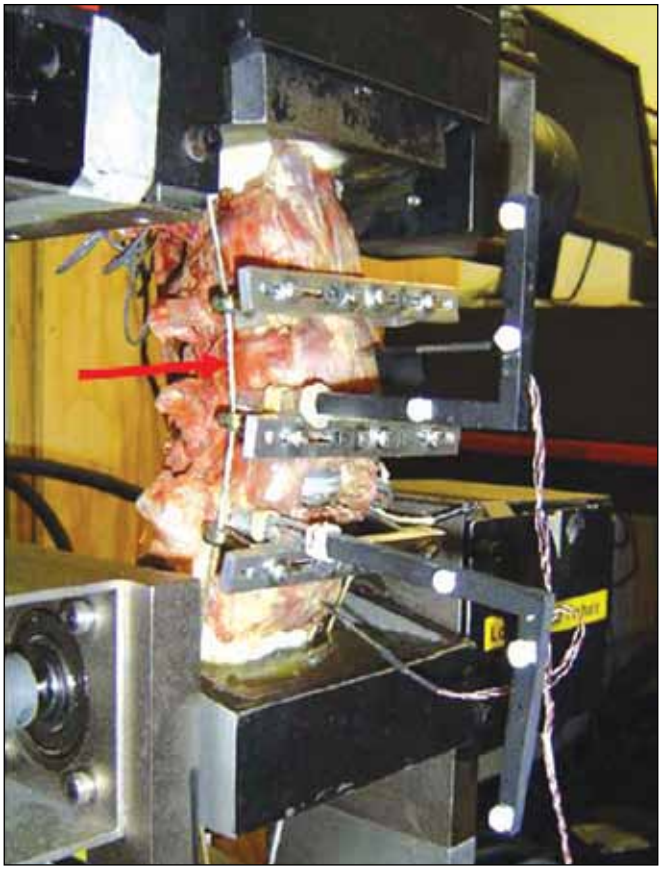

Figure 3: Biomechanical testing of disc pressure and facet strain in the human cadaveric spine implanted with an SB Charité™ III artificial disc at L4–L5 (arrow, the loading cable for the follower preload). The compressive follower preload is applied so its path approximates the tangent of the lumbar spine curve.

RESULTS

Disc Pressure

The DP values (mean±SD) at the upper (L3–L4) and lower (L5–S1) operative level for all specimens were normalized by those of intact spine (Figure 4A, B).

DP at the upper Operative Level (L3–L4): Compared to the intact spine, the central DP was decresed during extension (-30.9±18.9%) and bending (-18.3±8.9%) but increased during rotation (21.7±3.6%) and was equivalent to that of the intact spine during flexion (0.7±13.6%). A statistically significantly high DP was demonstrated in rotation ($p<0.05$) (Figure 4A).

DP at the lower Operative Level (L5–S1): Compared to the intact spine, the central DP was decreased during lateral bending (-15.1±8.0%) and axial rotation (-2.9±19.2%), but increased during extension (33.1±23.6%) and flexion (10.7±25.3%) compared with that of the intact spine. No statistical significance was observed in the DP of the inferior segment (Figure 4B).

Changes in the Central DP according to the Modes of Motion: The central DP of the lower disc increased significantly during extension and flexion compared with that of the upper disc, whereas the latter decreased or was equivalent to that of the intact spine. Conversely, during axial rotation, the lower DP equaled that of the intact spine, whereas the upper DP increased significantly. During lateral bending, the central DP decreased at both the upper and lower level.

Facet Strain

The FS values (mean±SD) at the operative level (L4–L5), the upper (L3–L4) and lower (L5–S1) operative level for all specimens were also normalized by those of intact spine (Figure 5A-C).

FS at the upper Operative Level (L3–L4): The FS was decreased during extension (-14.8±13.9%) and lateral bending (-26.0±9.5%) but increased during flexion (17.0±15.8%) and axial rotation (13.8±9.4%) compared with that of the intact spine. No statistical significance was observed in the FS of the superior facet (Figure 5A).

FS at the Operative Level (L4–L5): The FS was decreased during flexion (-21.8±56.7%) and lateral bending (-21.9±26.9%) but increased during extension (17.8±33.1%) and rotation (51.6±14.6%) compared with that of the intact spine. High FS was observed during rotation, statistically ($p<0.05$) (Figure 5B).

FS at the lower the Operative Level (L5–S1): The FS was decreased during flexion (-22.8±41.5%) and lateral bending (-38.3±20.6%) but slightly increased during extension (5.4±29.9%) and rotation (4.5±19.7%) compared with that of the intact spine. No statistical significance was demonstrated in FS of the inferior facet (Figure 5C).

Changes of FS according to the Modes of Motion: During extension, the FS was decreased at the upper facet but increased at the operative and lower facets. During flexion, the operative and lower FS was decreased, whereas the upper FS was increased.

All the FS values were decreased during lateral bending and increased during axial rotation compared with those of the intact spine, but there were no statistically significant differences.

DISCUSSION

Degenerative disc disease (DDD) associated with disc collapse, herniation, spinal instability, and back pain often requires surgical treatment. Current treatment for lumbar DDD generally consists of discectomy with or without interbody fusion. Fusion procedures, however are not always successful. The incidence of pseudarthrosis following fusion is repored to be under 10% (6,12), and fusion procedures are associated with the risk of dural tears, neural injuries, and chronic back pain and stiffness. Additionally, fusing segments increases strain at the adjacent levels. As strain increases,

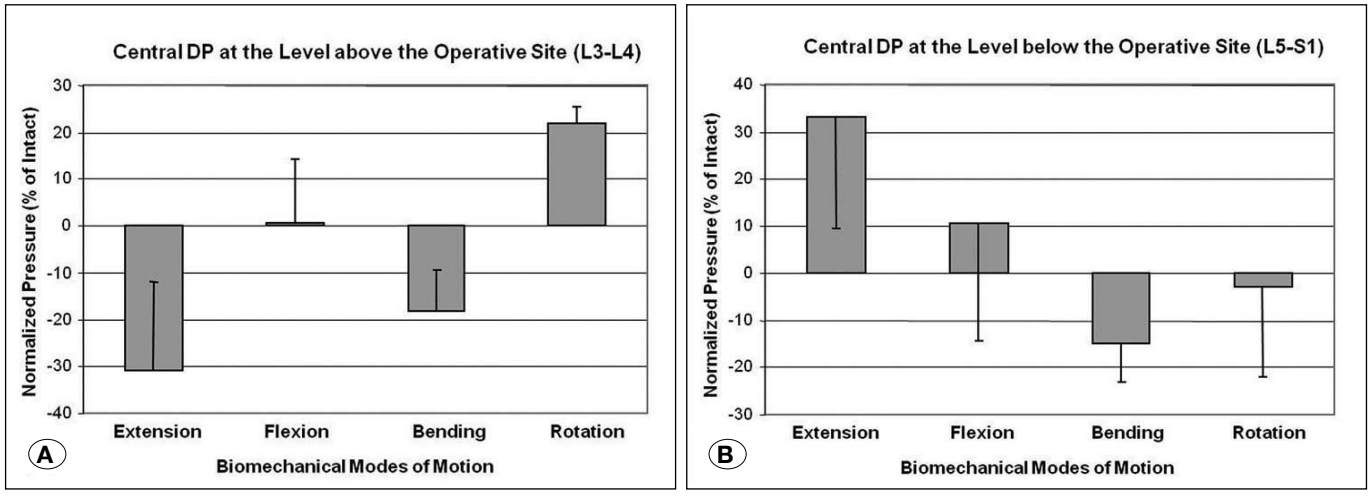

Figure 4: Mean and standard deviation of normalized central disc pressure at L3–L4 **(A)** and L5–S1 **(B)** after arthroplasty with an SB Charité™ III artificial disc at L4–L5 under physiologic compressive follower preload. Bending, right/left lateral bending; rotation, right/left axial rotation. * $p < 0.05$ versus intact spine state.

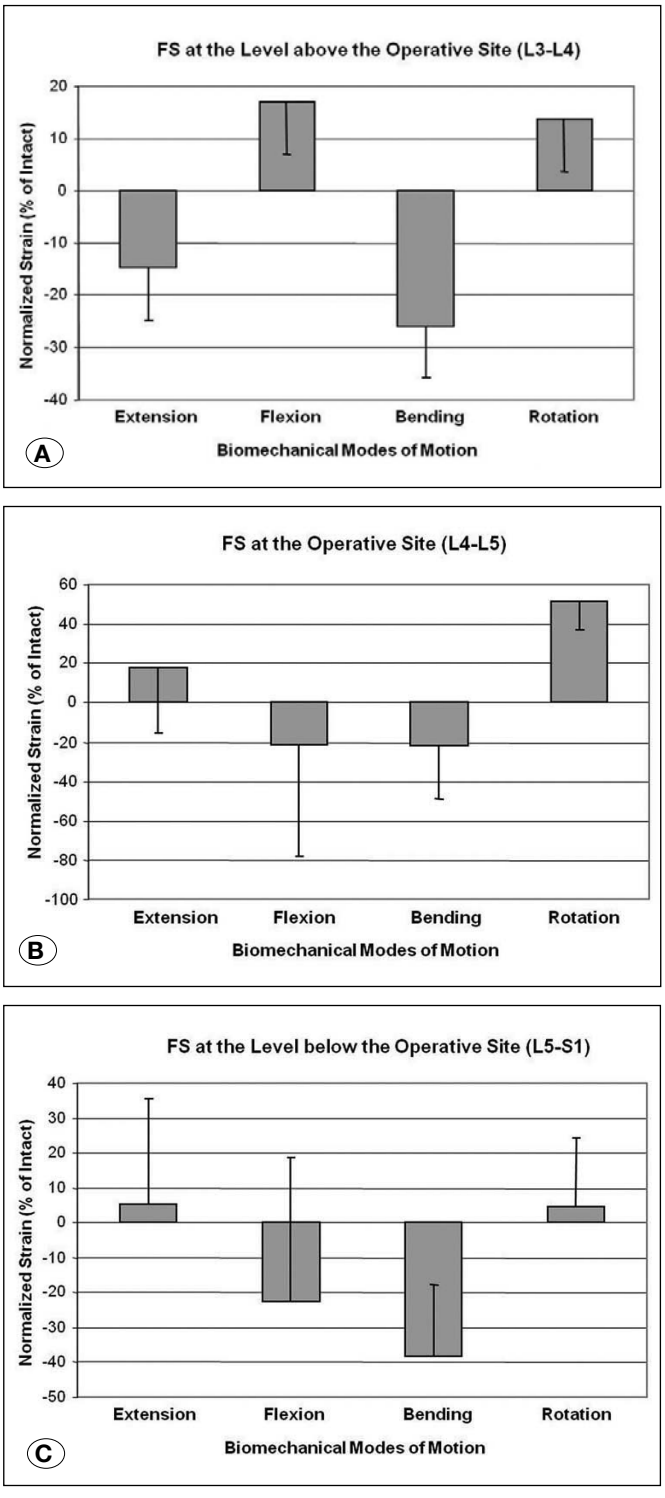

Figure 5: Mean and standard deviation of normalized facet strain at L3–L4 **(A)**, L4–L5 **(B)**, and L5–S1 **(C)** facets after implanting an SB Charité™ III at L4–L5 under physiologic compressive follower preload. Bending, right/left lateral bending; rotation, right/left axial rotation. $^{*}p < 0.05$ versus intact spine state.

fusion promotes an increase in disoder of adjacent level, thus patients may develop symptomatic DDD, eventually. This degeneration process at adjacent levels has been reported in the cervical and lumbar degerative spine after fusion (11,12,14), and it may require the advent of arthroplasty. The purpose of arthroplasty is to enable neural decompression and to replicate biomechanical performance of the normal disc while preventing adjacent degenerative changes.

The SB Charité™ III allows unloading of the posterior facet structures during this normal replication of motion and slight off-center implant positioning (7). It has also been reported to restore motion at the level of the intact segment in flexion-extension and lateral bending, and increase motion in axial rotation at the operative level (3). These previous studies, however, were conducted under standard yet not physiologic or biomechanical conditions.

Others have reported that the lumbar spine became unstable in the frontal plane under a vertical load of <100N, far below the physiologic loads estimated in vivo (2). This follower load path explains how the entire lumbar spine can be lordotic and yet resist large compressive loads. Patwardhan et al. also demonstrated that the addition of a compressive preload significantly improved the stabilizing properties of stand-alone anterior lumbar interbody fusion cages (18).

In a former biomechanical studies of arthroplasty without follower preload, Hitchon et al. (12) reported that no difference was noted in the ROM at L3–L4 irrespective of manipulations at the L4–L5 level. This result emphasizes that in load-controlled conditions involving the pure moment application, any manipulation at the operative level does not result in motion compensation at adjacent levels. Displacement-controlled studies have demonstrated an increase in motion and intradiscal pressure at adjacent levels (5). It is speculated that this increase in motion and intradiscal pressure following fusion may contribute to the development of DDD at adjacent levels (14). AD implantation in place of instrumentation and fusion may contribute to reducing the incidence of adjacent segment DDD that often accompanies the latter (12).

Asymmetric and localized concentrations of stresses within the disc have been shown to accompany higher incidence of disc prolapse (17). Cunningham et al. reported that adjacent segment pressures increased by up to 55% after posterior instrumentation in a cadaveric lumbar spine (4), and animal studies have shown that posterior instrumentation at a single lumbar level significantly increases facet loading and facet motion adjacent to the fused level (5,17).

Increased intradiscal pressure at adjacent segments following fusion of the lumbar spine segments has been reported previously (1,4). Rao et al. reported that paired anterior tapered cage insertion in the lumbar spine induced significant increases in adjacent segment motion and intradiscal pressure, which is most definite with flexion loading (20). In their study with the Charité™ AD using a hybrid testing protocol, Goel et al. demonstrated that the decrease in the facet loads at the instrumented level was less than that at the adjacent levels (9).

There are only a few reports on the biomechanical study of adjacent DP and FS after lumbar arthroplasty under a physiologic preload. In the current study, the authors evaluated DP and FS changes in the human cadaveric spine implanted with the SB Charité™ III AD under a physiologic compressive follower preload, and compared it with the intact spine. Theoretically, to reduce the incidence of adjacent segment disease, a compensatory decrease in the adjacent segment DP and FS with the use of an AD is required. In our study, however, in an ex vivo physiologic preload setting, the SB Charité™ III AD provided a relatively inconsistent and undesirable increase in DP and FS at the operative segment and levels above and below the arthroplasty. The central DP was decreased during extension and bending at the superior disc and during bending at the inferior disc, but no statistical significance was demonstrated. The FS also decreased during extension and bending at the superior facet and during flexion and bending at the operative and inferior facets, but no statistical significance was demonstrated. A feasible explanation for this result would be the asymmetrical loading cases due to subtle instrument misalignment despite the effort to construct an ideal cadaveric implanted model. In such cases, there can be an unexpected increase in DP and FS due to motion at the implanted and adjacent levels, resulting in an asymmetrical contact force at the facet joints. Additionally, similar to other biomechanical studies, our study has several disadvantages such as a small sample size, ex vivo cadaveric experimentation status, spinal specimens without muscle being used, and no evaluation of wear and tear.

In addition to the above-mentioned limitations, arthroplasty using SB Charité™ III AD may be associated with potential complications such as subsidence and migration of the metal footplates into the vertebral body and facet arthrosis at the implanted level.

Further investigations that involve larger sample sizes and comparative biomechanical analyses of physiologic compressive follower preload and no preload conditions should be performed in the future.

CONCLUSION

Biomechanical performances of the intact spine and the SB Charité™ III-implanted spine were compared under the physiologic preload condition in terms of central DP and FS at the operative and adjacent segments.

Our results indicated that in an ex-vivo physiologic compressive follower preload setting, the SB Charité™ III AD provides a relatively inconsistent and even undesirable increase of DP or FS at the operative segment and levels above and below the arthroplasty.

ACKNOWLEDGMENT

This study was supported by a grant from the Korea University School of Medicine, Republic of Korea (K1300161).

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