# Range of motion change after cervical arthroplasty with ProDisc-C and Prestige artificial discs compared with anterior cervical discectomy and fusion

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*Object.* Range of motion (ROM) changes were evaluated at the surgically treated and adjacent segments in cadaveric specimens treated with two different cervical artificial discs compared with those measured in intact spine and fusion models.

*Methods.* Eighteen cadaveric human cervical spines were tested in the intact state for the different modes of motion (extension, flexion, lateral bending, and axial rotation) up to 2 Nm. Three groups of specimens (fitted with either the ProDisc-C or Prestige II cervical artificial disc or submitted to anterior cervical discectomy and fusion [ACDF]) were tested after implantation at C6–7 level. The ROM values were measured at treated and adjacent segments, and these values were then compared with those measured in the intact spine.

*Results.* At the surgically treated segment, the ROM increased after arthroplasty compared with the intact spine in extension (54% in the ProDisc-C group, 47% in the Prestige group) and in flexion (27% in the ProDisc-C group, 10% in the Prestige group). In bending and rotation, the postarthroplasty ROMs were greater than those of the intact spine (10% in the ProDisc-C group and 55% in the Prestige group in bending, 17% in the ProDisc-C group and 50% in the Prestige group in rotation). At the adjacent levels the ROMs decreased in all specimens treated with either artificial disc in all modes of motion (< 10%) except for extension at the inferior the level (29% decrease for ProDisc-C implant, 12% decrease for Prestige disc). The ROM for all motion modes in the ACDF-treated spine decreased at the treated level (range 18–44%) but increased at the adjacent levels (range 3–20%).

*Conclusions.* Both ProDisc-C and Prestige artificial discs were associated with increased ROM at the surgically treated segment compared with the intact spine with or without significance for all modes of testing. In addition, adjacent-level ROM decreased in all modes of motion except extension in specimens fitted with both artificial discs. (*DOI: 10.3171/SPI-07/07/040*)

# KEY WORDS • adjacent-segment degeneration • anterior cervical discectomy and fusion • biomechanical testing • cervical arthroplasty • range of motion

A NTERIOR cervical discectomy and fusion has long been the standard surgical treatment for cervical disc herniations. It has proved to be effective in the relief of pain and resolution of neurological symptoms,<sup>3</sup> but this technique results in a loss of mobility at the surgically treated segment and increased stress on adjacent segments.<sup>11</sup> Hilibrand et al.<sup>17</sup> have reported that junctional changes were observed annually in 2.9% of their patients because of symptomatic adjacent-segment disease follow-

ing ACDF. In addition, Goffin et al.<sup>14</sup> have reported that in 92% of fusion-treated patients, radiography demonstrated evidence of adjacent-segment degenerative disc disease at 5-year follow-up examination. The cause of the adjacent-segment disease appears to be increased shear strain that occurs at levels adjacent to the fusion site.<sup>22</sup>

Cervical arthroplasty has emerged as a promising alternative to fusion in the management of cervical disc herniation. The goals of arthroplasty are to maintain natural ROM of the healthy disc, to decrease the stress on adjacent levels, and to decrease the rate of adjacent-segment disease.

Several cervical artificial discs were developed in the 1990s. Currently, artificial discs can be categorized based on several criteria, such as articulation, material, design, fixation, and kinematics.<sup>25</sup> With respect to material, two

Abbreviations used in this paper: ACDF = anterior cervical discectomy and fusion; IAR = instant axis of rotation; PMMA = polymethylmethacrylate; ROM = range of motion; UHMWPE = ultrahigh molecular weight polyethylene.

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representative types have been developed: metal-on-metal and metal-on-polymer implants (UHMWPE). These two discs are different from several viewpoints.

The Prestige II cervical disc (Medronic Sofamor Danek) is a stainless steel, metal-on-metal semiconstrained-bearing surface. The ProDisc-C cervical Disc (Synthes Spine) is composed of two cobalt-chromium-molybdenum endplates with a metal-on-polyethylene-bearing surface; the polyethylene insert is fixed to the inferior endplate.

Although biomechanical and clinical data on cervical arthroplasty have been widely reported, little comparative data between cervical artificial discs of different materials exist. Our goal in this study was to assess the biomechanical characteristics of the cadaveric spine after cervical arthroplasty, comparing the intact spine and fusion models and determining the differences between the two artificial discs.

#### **Materials and Methods**

Twenty-four human cadaveric cervical spines (C3–T2 specimens) were obtained from Science Care Anatomical and International Biological, Inc. After the specimens containing bone abnormalities were excluded based on anteroposterior and lateral radiography findings, 18 cadaveric spines were used for the study. The specimens were thawed overnight at room temperature, and attached musculature was removed with care to preserve all ligaments.

The whole of each C3–T2 specimen was fixed by drilling and inserting screws in the most superior and most inferior segments (extending into C3–4 and T1–2 levels). The end segments and screws were capped with PMMA (COE tray plastic, GC America), and the PMMA-covered ends were potted in polyester resin (Bondo). The potting fixtures were used to attach the cadaveric spines to a mechanical testing loading frame (MTS 858 Minibionix), and the cadavers were loaded in flexion, extension, left and right lateral bending, and left and right rotation.

#### Discectomy and Artificial Disc Implantation

Anterior C6–7 discectomies were performed using the Smith-Robinson technique. The C6–7 disc space was chosen because the level had the most adequate disc height. Most available human cadaveric spines had significant loss of disc height due to the degenerative process. When radiography was performed in the middle segment of C5–6 and C6–7 in the final 18 selected specimens, C6–7 level exhibited better disc height preservation than C5–6.

The specimens were divided into three groups, each undergoing implantation of an artificial disc implant (ProDisc-C or Prestige) or fusion with the application of an anterior plate system (C3, Spine Vision) and a dense cancellous bone allograft (Osteotech) (Figs. 1 and 2). The 7-mm-high ProDisc-C and 8-mm-high Prestige implants were adequate for the specimens chosen. In the ACDF group, a 7-mm, lordotic, tapered, dense cortical allograft, with a rigid plate system and screw fixation were used to maintain lordosis at the treated level. Artificial discs were placed in a 36°C bath for 24 hours prior to implantation to ensure that they were near biophysiological condition. Each step was performed according to the recommended surgical technique, and C-arm fluoroscopy was used throughout the procedure to verify the correct position of the artificial disc.

#### Biomechanical Testing

Biomechanical tests were performed in the following six modes of motion: flexion, extension, left and right lateral bending, and left and right axial rotation. The maximum moment applied for each mode of motion was 2 Nm, with a 100-N axial preload. Reflective markers were placed on C-6 and C-7, and the MACReflex 3D video motion-tracking system (Qualisys Inc.) was used to capture the displacement of the reflective markers. The change of the angle formed by the sets of markers was determined based on the normal angle formed by the marker planes. Axial compression and axial rotation were applied by the upper-spine fixture, whereas flexion, extension, and lateral bending were created by the rotation of both spine fixtures in the respective coronal and sagittal planes. To stabilize the viscoelastic effect, each mode of testing was performed three times, with only the result of the third test used.

The ROM was determined for each mode of loading. It was defined as the angular deformation in each mode of motion when the maximum load was applied. The ROM values were determined for each specimen as follows: 1) in the intact condition, and 2) after ACDF or artificial disc implantation.

#### Statistical Analysis

The data could not be assumed to be normally distributed due to the sample size, and thus nonparametric statistical methods were used to distinguish significant differences among groups and these results were compared with measurements of the intact spines. The ROM values for each specimen were normalized by dividing them by those of the intact spine. Paired comparisons among treatment groups were made using the Wilcoxon paired t-tests,<sup>2</sup> and statistical significance was assigned at a probability level of less than 0.05. Mean values are presented  $\pm$  the standard error.

#### Results

The normalized ROM at the treated level (C6–7), and the levels superior (C5–6) and inferior (C7–T1) to the treated level are shown in Fig. 3.

#### Range of Motion Findings

*Extension.* Compared with the intact spine, ROM was significantly decreased at the superior level and signifi-

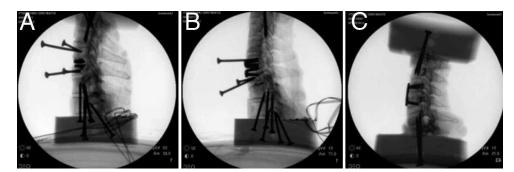


FIG. 1. Lateral radiographs of the ProDisc-C (A), Prestige II (B), and ACDF (C) models.

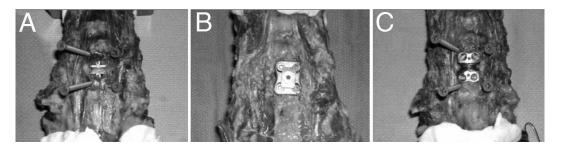


FIG. 2. Anteroposterior photographs demonstrating the ProDisc-C (A), ACDF (B), and Prestige II (C) models.

cantly increased at the same level in ProDisc-C-treated specimens (superior segment  $-10.6 \pm 2.4\%$ , p = 0.028; same-level segment 53.6  $\pm$  14.1%, p = 0.018) and Prestige disc-treated specimens (superior segment  $-9.2 \pm 3.3\%$ , p = 0.038; same-level segment 47.2  $\pm$  20.2%, p = 0.038) (Fig. 3A). At the inferior level, ProDisc-C arthroplasty was associated with a significant decrease in ROM  $(-28.7 \pm 4.2\%, p = 0.018)$ , whereas Prestige disc arthroplasty was associated with a nonsignificant decrease  $(-11.7 \pm 7.7\%, p = 0.173)$ ; ACDF significantly reduced ROM at the same level  $(-33.9 \pm 11.7\%, p = 0.043)$  and increased ROM at both adjacent levels (superior segment  $10.5 \pm 4.3\%$ , p = 0.043; inferior segment  $3.2 \pm 6.2\%$ , p = 0.375). With respect to normalized ROM, the ACDF increased ROM at the superior level (p = 0.018 [ProDisc-C] and p = 0.028 [Prestige disc]) and decreased same-level ROM (p = 0.018 [ProDisc-C] and p = 0.018 [Prestige disc]), which is contrary to the artificial disc model. At the inferior level, the ROM increase was minimal, the difference of which was statistically significant only in contrast with ProDisc-C (p = 0.018).

Flexion. All artificial discs resulted in increased ROM at the surgically treated level (ProDisc-C 26.9  $\pm$  11.3%, p = 0.05; Prestige disc  $10.1 \pm 15.3\%$ , p = 0.508), but only treatment with the ProDisc-C resulted in statistical significance (Fig. 3B). At the superior level, the Prestige disc decreased ROM ( $-4.3 \pm 5.8\%$ , p = 0.333) but the decrease was not significant, whereas ROM associated with the Pro Disc-C was slightly increased (0.6  $\pm$  5.5%, p = 0.161). Inferior-level ROM in both artificial disc-treated specimens was decreased (ProDisc-C  $-6.3 \pm 5.1\%$ , p = 0.327; Prestige disc  $-3.9 \pm 5.3\%$ ; p = 0.139), although the decrease was not significant. In ACDF-treated spines, samelevel ROM decreased ( $-43.8 \pm 12.2\%$ , p = 0.15) whereas adjacent-level ROM increased (superior segment 20.4  $\pm$ 5.2%, p = 0.374; inferior segment 2.0  $\pm$  5.0%, p = 0.594). In ACDF-treated specimens, same-level ROM values were significantly lower than those of all artificial discs (p =0.017 [ProDisc-C] and p = 0.011 [Prestige disc]). There were no significant differences between ACDF and both artificial discs at the superior and inferior adjacent segments (Fig. 3B).

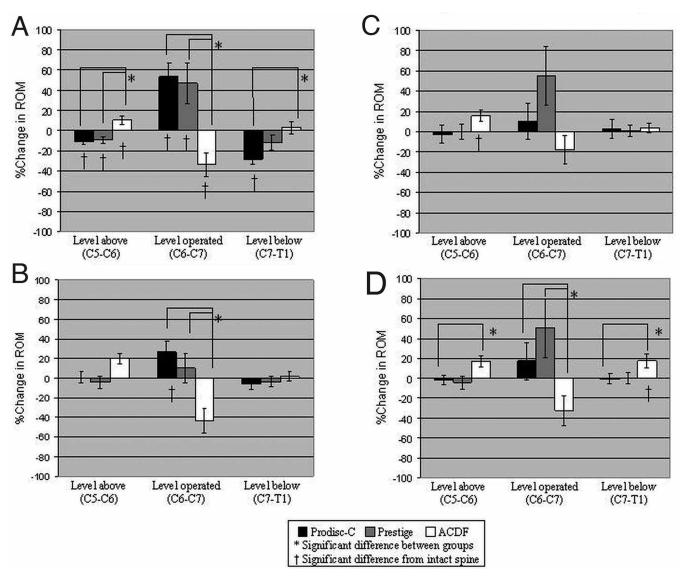
*Lateral Bending.* Same-level ROM in both ProDisc-C (10.3  $\pm$  18.3%) and Prestige disc (55.2  $\pm$  29.0%) groups increased whereas that in the ACDF group decreased (-18.1  $\pm$  14.2%), but none of the changes were significant (Fig. 3C). Superior-level ROM in the ProDisc-C group (-2.3  $\pm$  8.8%) decreased, whereas ROM values in Prestige disc (0.04  $\pm$  8.1%) and ACDF (15.9  $\pm$  5.6%) groups

increased, but only ACDF had statistical significant difference compared with that of intact spine (p = 0.036). Inferior-level ROM increased in all treatment groups (ProDisc-C 2.7  $\pm$  9.1%; Prestige disc 0.8  $\pm$  5.5%; and ACDF 4.0  $\pm$  4.6%), although no change was statistically significant (Fig. 3C).

Axial Rotation. Same-level ROM increased in both artificial disc-treated groups (ProDisc-C 17.2 ± 18.6%; Prestige disc  $50.0 \pm 29.3\%$ ) but decreased in the ACDF group ( $-32.8 \pm 15.0\%$ ), although all values were not statistically significant compared with the intact spine (Fig. 3D). The ROM in the ACDF group was significantly lower than that in both arthroplasty groups at the same level (p =0.012 [ProDisc-C] and p = 0.011 [Prestige disc]). At the superior level, ROM associated with ACDF was increased  $(16.6 \pm 5.9\%)$ , whereas ROM values associated with Pro Disc-C arthroplasty ( $-1.9 \pm 4.7\%$ ) and Prestige disc arthroplasty  $(-4.4 \pm 6.8\%)$  were decreased, although without significance. The ROM in the ACDF-treated spines was significantly higher than that in ProDisc-C-treated spines (p = 0.017). At the inferior level, the ROM associated with the Prestige disc  $(0.01 \pm 5.7\%)$  was slightly increased, whereas that associated with the ProDisc-C was slightly decreased ( $-0.9 \pm 5.0\%$ ), and the ROM in the ACDF group (17.4  $\pm$  7.3%) was significantly increased compared with the intact spine (p = 0.021). The ROM in the ACDF group was significantly greater than that in the ProDisc-C group (p = 0.05) (Fig. 3D).

#### ProDisc-C and Prestige Disc Arthroplasty

In extension, a greater increase in ROM at the same level and greater decrease in ROM at the adjacent levels were observed in the ProDisc-C group than in the Prestige disc group, but a statistical difference was not achieved. In flexion, there was no statistically significant difference in ROM change at each level when examining the two arthroplasty groups. In lateral bending, the Prestige disc was associated with a greater increase in ROM than ProDisc-C at the same level; however, the ROM change was not different at adjacent levels. In axial rotation, a greater ROM increase in the Prestige disc group was seen at the same level, but the change was not different at the adjacent levels. When the analysis was limited to the same level, the ProDisc-C was associated with a greater ROM change than the Prestige disc in flexion and extension modes, but the ROM change was greater in the Prestige disc group than in ProDisc-C group when bending and rotation were calculated.



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FIG. 3. Graphs showing ROM change in extension (A), flexion (B), lateral bending (C), and rotation (D). A: The ROM decreased at the superior level and increased at the same level in ProDisc-C and Prestige disc groups; the changes were statistically significant. At the inferior level, ProDisc-C ROM significantly decreased. B: The ProDisc-C significantly increased ROM at the surgically treated level. At other segments, the ROM change was not significant. C: The arthroplasty models showed no significant ROM change. D: With respect to intact specimens, all models exhibited no significant ROM change. Compared with the fusion model, the ProDisc-C produced a statistically significant difference in ROM at all levels. The Prestige disc exhibited different ROM change only at the treated segment.

#### Discussion

#### Adequateness of Test Protocol

The debate continues on the ideal method of in vitro testing. We opted for a load-control with a pure moment method and a vertical compressive preload. DiAngelo and Foley,<sup>5</sup> however, used a displacement-control method, insisting that their data were closer to in vivo ROM values in the cervical spine. Miura and colleagues<sup>24</sup> recently described a method in which they simulate in vivo cervical spine kinematics using a follower-preload and pure-moment protocol. To verify the validity of our protocol, we

compared our findings with currently available in vivo data.

In flexion/extension mode, the ROM at the lower cervical segments (C4–7) increased slightly in magnitude as the spine moved in the caudal direction with a pure-moment method. This pattern is different from that revealed by in vivo data. For the in vivo data, the ROM is greatest at the C4–5 and C5–6 levels. In pure-moment mode with a follower-path preload, however, the greatest ROM is seen at C6–7.<sup>10,21,34</sup> In examining our data we found that the ROM values in intact spine were 19.23  $\pm$  8.87° at the C5–6 level, 8.58  $\pm$  4.47° at the C6–7 level, and 9.31  $\pm$  3.70° at the C7–T1 level. These data match well with in vivo data. In rotation mode, the ROM is greatest at C6–7 and C5–6 in in vivo data, but the ROM is greatest at C6–7 in pure-moment mode. Our data show that the ROMs in intact spine are  $8.05 \pm 3.44^{\circ}$  at C5–6,  $4.35 \pm 2.75^{\circ}$  at C6–7, and  $6.43 \pm 1.98^{\circ}$  at C7–T1. The data derived using our pure-moment/vertical compressive preload agree well with in vivo data.

An important feature of the follower-load concept is to pass a compressive load through the moving center of rotation of each motion segment unit. In the a study published by Miura et al.,<sup>24</sup> the IAR was placed near the lateral masses and remained fixed for the flexion/extension test. The use of the follower load to study the instrumented multilevel cervical spine, however, may artificially confer greater stability to the spine than that present in vivo.<sup>4</sup> Disc replacement or motion reservation devices may or may not have a fixed axis of rotation. The location of the follower load relative to the rotational axis directly affects how the device transfers load and maintains joint stability. Furthermore, although the follower load is traditionally applied to the flexion/extension plane, its load-transferring capacity also affects how the load and motion respond in the transverse and frontal planes.<sup>5,6</sup> DiAngelo et al.<sup>7</sup> have previously shown that the IAR error can be greater (as high as  $\pm$  10 mm) for small angular changes (2–3°) and that the IAR position is significantly different in flexion than in extension. They have proposed their own method of a displacement-control method. In comparing our data with the normalized moment data published by these investigators, decreased moments with an artificial disc joint correlated with our increased ROM with a predetermined (2-Nm) moment in all modes of motion.

#### Change in ROM After Arthroplasty and Fusion

Based on previous experiments, intact spines have ROM and neutral zone values, respectively, of 7 and 3° for flexion, 4 and 2° for extension, 5° and 1 to 2° for lateral bending, and 6° and 1 to 2° for axial rotation.<sup>32</sup> Spines affected by discectomy and fusion generally have significantly reduced ROM.

After arthroplasty, the ROM values were increased or maintained in the surgically treated segment and mildly decreased at adjacent levels. In cases of ProDisc-C treatment, the significant ROM increase was observed in flexion/extension mode at the treated segment, but the increase was negligible in bending and rotation modes (Fig. 3C and D). However, with respect to Prestige disc, the ROM increased significantly in extension, bending, and rotation (Fig. 3A, C, and D). The ROM increase was definite only in extension irrespective of the type of artificial disc (Fig. 3A). Although it is difficult to determine the precise reason for the difference in ROM in flexion and in extension, it is possible that the posterior elements limit the ROM in flexion. McAfee et al.<sup>23</sup> reported on the segmental biomechanics of a C5-6 porous-coated motion disc. The axial rotational ROM was approximately 130% of the intact spine, and flexion/extension ROM was 85 to 95% of the intact segment. Kotani and colleagues<sup>19</sup> reported the biomechanical findings of another artificial disc, the 3D fabric disc. In their experiment, the ROM increased 45% more than the intact spine in flexion/extension mode and 22% more in axial rotational mode. Despite the artificial disc used, it is difficult to attribute the adverse sequelae to

increased ROM at the index level. Although facet joint strain has been demonstrated in the lumbar spine, the same effects cannot be shown in the cervical spine.

The ROM increase that was seen at the adjacent levels after fusion was more prominent at the superior (C5-6) segment than the inferior (C7-T1) segment in all modes of motion. This phenomenon can be explained by the intact spine data in which the ROM values were 13.56° at the C5-6 level, 6.84° at the C6-7 level, and 7.61° at the C7-T1. The mobile segment (C5-6) can move more for the compensatory increase of ROM. In one experiment in which investigators performed C5-6 fusion, the compensatory ROM increase was greater at the superior level in flexion,<sup>5</sup> but it was greater at the inferior level in extension. Based on these data, we can conclude that the adjacent-level compensatory movement occurs differently depending on the fusion level and mode of motion.

Increased motion at the levels adjacent to the fusion site has been, for decades, the subject of considerable discussion and research. Clinical data on adjacent-segment disease after ACDF have been accrued by many authors. Radiological changes have been reported in to up to 50% of the ACDF-treated patients with 10-years of follow-up.<sup>18</sup> The reoperation rate due to symptomatic adjacent-segment disease ranges from 5 to 20%.<sup>3,12,15,18</sup> This is in contrast to the reoperation rate of 1% associated with posterior discectomy procedures in which segmental motion is preserved.<sup>26,31</sup>

#### Material Characteristics of Metal-on-Metal Compared With Metal-on-Polymer Discs

Metals provide the necessary strength, ductility, and toughness needed for load bearing, whereas some polymers provide low-friction surfaces for articulation and shock absorption. Le Huec et al.<sup>20</sup> compared the shockabsorption capacity of lumbar total disc replacement using a UHMWPE core compared with a metal-on-metal design. They found no difference between the two designs, demonstrating the limited shock-absorbing capacity of polyethylene. Stainless steel is associated with good ductility but poor corrosion resistance. Although metal-onmetal implants are associated with potential metal debris and increased systemic concentrations of metal ions, the purpose of this design is to avoid the increased particulate wear debris found in devices of the metal-polymer design.9.27 Cobalt alloys have been shown to have good wear resistance, making them useful for articulation with a UHMWPE surface. Whereas UHMWPE is useful for providing low-friction surfaces, there are concerns with wear debris.9,16

The reports on wear debris are limited. In vitro wearing tests by investigators at Medtronic Sofamor Danek have demonstrated a mean wear rate for the metal-on-metal device of  $0.46 \pm 0.29 \text{ mm}^3$ /million cycle, whereas that for the poly-on-metal device was  $0.97 \pm 0.87 \text{ mm}^3$ /million cycle.<sup>25</sup> In the explant analysis with the polymer-based Bryan disc and the metal Prestige ST, however, the wear rates were significantly lower in vivo compared with simulator-tested devices involving both discs.<sup>1</sup> The ProDisc-C ROM allows for physiological restoration of the spinal segment as follows:  $\pm 10^{\circ}$  in flexion/extension,  $\pm 10^{\circ}$  in lateral bending, and no limitation in axial rotation. The

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ball-and-trough design of the Prestige ST provides relatively unconstrained motion comparable with that of a normal cervical spinal segment.<sup>29</sup>

# Clinical and Biomechanical Data on ROM After Arthroplasty

Clinical evidence that motion is preserved in the treated spinal segments has been documented in a small group of patients, despite short follow-up periods.8 In early clinical results from European trials of cervical arthroplasty with the Bryan disc, the ROM was reportedly preserved in 88% of patients who underwent single-level surgery and 86% of those who underwent two-level surgery at the 1-year follow-up interval.<sup>13</sup> Clinical evidence associated with the Prestige cervical disc indicates that there was an overall reduction in motion at the adjacent levels in patients who underwent joint replacement, although this reduction was compensated by the movement of the artificial disc itself;<sup>28,35</sup> in the fusion group, however, there was an increase of adjacent-segment motion by 5% at 6 months and 15% at 1 year. Clinical results after ProDisc-C arthroplasty have been reported in cases involving a 12-month follow-up period.<sup>2</sup> Bertagnoli and colleagues<sup>2</sup> found that the motion of the affected discs was increased from 4° preoperatively to 12° postoperatively.

Previous biomechanical studies regarding arthroplasty and ROM are limited. DiAngelo and colleagues<sup>6,7</sup> have evaluated the motion parameters of the Prestige disc and ProDisc-C implant independently. With implantation of the artificial cervical joint, the motion patterns at the level of interest remained unchanged from those of the intact spine for all modes of testing. The ROM with ProDisc-C was similar to intact spine in flexion/extension and showed an increase in bending and rotation.<sup>6</sup>

Other authors have presented biomechanical evidence that physiological motion can be retained after ProDisc-C arthroplasty.<sup>30</sup> The maintenance of motion at a decompressed interspace can result in improved load transfer and reduced stress on the adjacent intervertebral discs and posterior elements.<sup>33</sup> Only Wigfield et al.<sup>36</sup> have demonstrated adjacent-segment biomechanics after conducting artificial disc replacement. In their study, the internal stress distribution at the adjacent segment was compared between spinal fusion and artificial disc.

#### Conclusions

This study has several pitfalls that are equivalent to other biomechanical studies. These are sample sizes, in vitro experimentation, spinal specimens in the absence of muscle, and no evaluation of wear and tear. Certain conclusions, however, can be drawn.

1) The ACDF model shows decreased motion across the fusion level relative to the intact spine and arthroplasty models. The reduced motion was compensated for by an increase in motion at the adjacent segments.

2) The use of ProDisc-C and Prestige artificial discs increased ROM at the surgically treated segment compared with the intact spine with or without significance in all modes of testing.

3) The difference in the ROM change was not observed between the two different artificial disc types.

In theory, the decrease in adjacent-segment motion asso-

ciated with the artificial disc should reduce the incidence of adjacent-segment disease. This remains to be firmly demonstrated in future studies.

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