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BIOMECHANICS

Kinematics of Cervical Total Disc Replacement Adjacent to a Two-Level, Straight *Versus* Lordotic Fusion

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Study Design. *In vitro* biomechanical study.

Objective. To characterize cervical total disc replacement (TDR) kinematics above two-level fusion, and to determine the effect of fusion alignment on TDR response.

Summary of Background Data. Cervical TDR may be a promising alternative for a symptomatic adjacent level after prior multilevel cervical fusion. However, little is known about the TDR kinematics in this setting.

Methods. Eight human cadaveric cervical spines (C2–T1, age: 59 ± 8.6 years) were tested intact, after simulated two-level fusion (C4–C6) in lordotic alignment and then in straight alignment, and after C3–C4 TDR above the C4–C6 fusion in lordotic and straight alignments. Fusion was simulated using an external fixator apparatus, allowing easy adjustment of C4–C6 fusion alignment, and restoration to intact state upon disassembly. Specimens were tested in flexion-extension using hybrid testing protocols.

Results. The external fixator device significantly reduced range of motion (ROM) at C4–C6 to 2.0 ± 0.6°, a reduction of 89 ± 3.0% ($P < 0.05$). Removal of the fusion construct restored the motion response of the spinal segments to their intact state. The C3–C4 TDR resulted in less motion as compared to the intact segment when the disc prosthesis was implanted either as a stand-alone procedure or above a two-level fusion. The decrease in motion of C3–C4 TDR was significant for both lordotic and straight fusions across C4–C6 ($P < 0.05$). Flexion and extension moments needed to bring the cervical spine to similar C2 motion endpoints significantly increased for the TDR above a two-level fusion compared to TDR alone ($P < 0.05$). Lordotic fusion required significantly greater flexion moment, whereas straight fusion required significantly greater extension moment ($P < 0.05$).

Conclusion. TDR placed adjacent to a two-level fusion is subjected to a more challenging biomechanical environment as compared to a stand-alone TDR. An artificial disc used in such a clinical scenario should be able to accommodate the increased moment loads without causing impingement of its endplates or undue wear during the expected life of the prosthesis.

Key words: cervical spine, fusion, total disc replacement, spine biomechanics. **Spine 2011;36:1359–1366**

Anterior cervical discectomy and fusion has been the gold standard for treatment of cervical disc disease and has been associated with high fusion rates and excellent clinical outcomes.[1–5] Evidence, however, suggests that altered mechanics occur at levels adjacent to long cervical fusions resulting in higher stress, hypermobility, and increased intradiscal pressures.[6–11] This has been associated with the finding that levels adjacent to cervical fusions undergo accelerated degenerative changes.[12,13] Cervical total disc replacement (TDR) has been proposed as an alternative to fusion to prevent adjacent segment degeneration.

The theoretical rationale for TDR as an alternative to arthrodesis is the avoidance of junctional degeneration by preservation of motion and by maintenance of normal sagittal alignment and balance at the instrumented segment. In support of this rationale, clinical and biomechanical studies have demonstrated that TDR preserves motion.[14–19]

There is a concern that performing a cervical disc arthroplasty adjacent to multilevel cervical fusion may affect the mechanics of the disc prosthesis and this altered biomechanical environment could lead to accelerated wear of the prosthesis. Hypermobility of a cervical TDR has been shown clinically with subluxation of the prosthesis next to a two-level fusion.[20] Although cervical disc arthroplasty is being performed clinically in this setting, to our knowledge the question of whether

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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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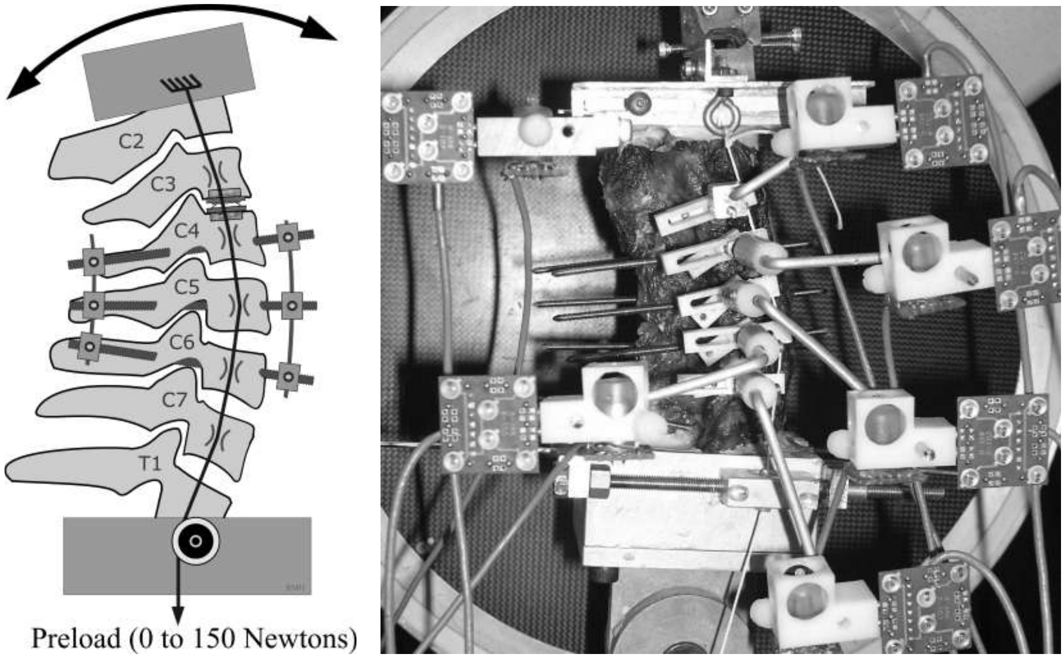

Figure 1. Experimental set-up. **(A)** Schematic presentation showing a TDR implanted above a simulated two-level fusion from C4–C6. **(B)** Cervical spine specimen (C2–T1), showing optoelectronic sensors for motion measurement, follower load cable, and guides for the application of compressive preload.

this is a favorable environment for an artificial cervical disc replacement has not been studied. Thus, the purpose of this study was to investigate the kinematics of a TDR next to a two-level cervical fusion by asking three primary questions. (1) Does a stand-alone TDR at C3–C4 restore physiologic motion as compared to an intact C3–C4 level? (2) Does a TDR alone at C3–C4 behave differently *versus* a TDR above a two-level fusion? (3) Does the alignment (straight *vs*. lordotic) of a two-level fusion alter the kinematics of an adjacent level TDR?

MATERIALS AND METHODS

Specimens and Experimental Setup

Eight fresh frozen human cadaveric cervical spine specimens (C2–T1; six male, two female; age: 59.0 ± 8.6 years) were used for this study. Radiographic screening was performed to exclude specimens with fractures, metastatic disease, bridging osteophytes, or other conditions that could significantly affect the biomechanics of the spine. The specimens were thawed and stripped of the paraspinal musculature while preserving the discs, facet joints, and osteoligamentous structures.

The C2 and T1 vertebrae were mounted in cups using metallic pins and then potted with bone cement in neutral upright alignment. The concept of follower load was used to apply a compressive load to the specimens during flexion-extension[21] (Figure 1A and B). The compressive preload is applied along a path that follows the lordotic curve of the cervical spine. By applying a compressive load along the follower load path, the segmental moments and shear forces due to the preload application are minimized. This allows the spine to support physiologic compressive preloads without damage or instability.[21] The follower load cable guides were attached with 4.0 mm cancellous screws (Synthes, Paoli, PA) placed into the lateral masses of C3–C7 bilaterally. To apply a follower preload, loading cables were attached bilaterally to the top cup. The cables passed freely through the adjustable guides and were connected to loading hangers under the specimen. The cable guides allowed anteroposterior adjustment of the follower preload path to ensure the cables pass through the sagittal plane center of rotation of each motion segment.

The motion of each vertebra relative to the potted T1 vertebra was measured using an optoelectronic motion measurement system (Model 3020, Optotrak, Northern Digital, Waterloo, Ontario, Canada). Biaxial angle sensors (Model 902-45, Applied Geomechanics, Santa Cruz, CA) were mounted on each vertebra to allow real-time feedback for the optimization of the follower preload. A six-component load cell (Model MC3A-6-250, AMTI Inc, Newton, MA) was placed under the specimen to measure the applied load.

A novel external fixator fusion construct (Figures 1A and 2) was then applied by inserting fully threaded 3.5 mm Steinmann pins bilaterally from posterior to anterior through the lamina and vertebral bodies at the C4–C6 levels. Six custom made adjustable connectors were placed bilaterally, both anteriorly and posteriorly, over the Steinmann pins. Through vertical holes in the connectors, four smooth 2-mm steel rods were placed vertically bilaterally, both anteriorly and posteriorly. Set screws in the connectors allowed tightening of the connectors to the Steinmann pins and the smooth steel rods, thereby locking the entire construct. Assembly of this construct allowed easy adjustment of C4–C6 lordosis, while disassembly allowed restoration of the intact state of the specimen. Furthermore, this construct allowed testing of TDR alone, fusion alone, and TDR above fusion of different alignments using a combination of load-control (±1.5 Nm) and displacement-control (DC) test protocols.

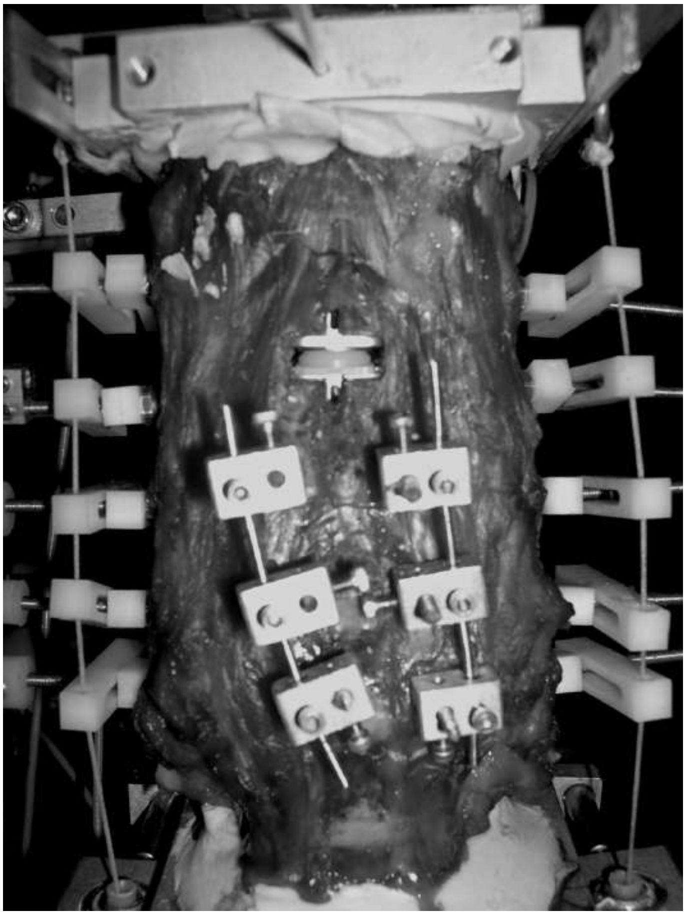

Figure 2. TDR at C3–C4 above a two-level simulated fusion.

Experimental Protocol

Specimens were tested using a combination of load-control and DC test modes depending on the protocol step (Table 1). The load-control test mode simulated a clinical scenario in which the patient's spine would be subjected to the same loads (moment and preload) before and after a surgical procedure. The DC test mode simulated a postoperative clinical scenario in which the patient would attempt to reproduce the preoperative flexion and extension endpoints of the cervical spine.

Two DC test conditions were used in the various steps of the experimental protocol: (1) The flexion and extension endpoints of the intact spine (DC-intact) and (2) The flexion and extension endpoints of a cervical spine specimen with a two-level lordotic fusion across C4–C6 (DC-fusion).

Specimens were tested in the following sequence:

(1) The intact specimen was tested to ±1.5 Nm in flexion and extension under 150 N follower preload. The flexion and extension endpoints of the C2 vertebra were determined using the angle sensors mounted on the upper cup (holding the C2 vertebra). These served as the motion endpoints for one of the two DC conditions (DC-intact).

(2) A simulated two-level lordotic fusion across C4–C6 was then performed using the external fixator fusion construct described earlier and was tested in a load-control protocol. The lordotic fusion alignment was set by locking the external fixator in a position that held the C4–C6 fusion at 3.5° lordosis from the neutral resting posture of that particular specimen.

TABLE 1. Test Protocol

Protocol Step	Surgical Procedure	Test Mode: Load-Control (LC) (Nm)	Test Mode: Displacement-Control (DC)	Outcome Measures
1	Intact spine	±1.5		Segmental motions; C2 flexion-extension endpoints (DC-intact)
2	C4–C6 lordotic fusion	±1.5		Segmental motions; C2 flexion-extension endpoints (DC-lordotic fusion)
3	Removal of fusion		DC-lordotic fusion	Segmental motions; flexion and extension moments
4	C4–C6 straight fusion		DC-lordotic fusion	Segmental motions; flexion and extension moments
5	TDR at C3–C4 above straight fusion		DC-lordotic fusion	Segmental motions; flexion and extension moments
6	TDR at C3–C4 above lordotic fusion		DC-lordotic fusion	Segmental motions; flexion and extension moments
7	Removal of fusion, TDR at C3–C4 alone	±1.5		Segmental motions
8	TDR at C3–C4 alone		DC-intact	Segmental motions; flexion and extension moments
9	TDR at C3–C4 alone		DC-lordotic fusion	Segmental motions; flexion and extension moments

LC indicates load-control; DC, displacement-control.

The degree of lordosis was adjusted using real-time data from the angle sensors. The flexion and extension endpoints of the C2 vertebra were determined under flexion-extension moments of ±1.5 Nm. These served as the endpoints for the second DC condition (DC-lordotic fusion).

(3) The fusion construct was removed and the spine allowed to return to its natural resting posture and tested in DC mode to reach the same flexion and extension endpoints as the specimen with a two-level lordotic fusion (DC-lordotic fusion).
(4) A straight fusion (3.5° kyphosis from neutral posture of the spine but not overall kyphotic) was then applied and tested in DC using the flexion and extension endpoints of the specimen with a two-level lordotic fusion (DC-lordotic fusion).
(5) A TDR was then performed using the ProDisc-C artificial disc replacement (Synthes, Paoli, PA) according to manufacturer specifications at the C3–C4 level, above the simulated two-level straight fusion (Figure 2). This construct was tested in DC mode using the flexion and extension endpoints of the specimen with a two-level lordotic fusion (DC-lordotic fusion).
(6) Next, the TDR at C3–C4 was tested above a two-level lordotic fusion in DC mode (DC-lordotic fusion).
(7) The fusion was then removed and the stand-alone TDR was tested in load-control mode to ±1.5 Nm in flexion-extension.
(8) The stand-alone TDR was then tested in DC mode using the flexion and extension endpoints of the intact spine (DC-intact).
(9) Finally, the stand-alone TDR was tested in DC using the flexion and extension endpoints of the spine with a two-level lordotic fusion (DC-lordotic fusion).

DATA ANALYSIS

The data were analyzed to obtain the angular range of motion (ROM) in flexion-extension at each cervical segment in each tested condition. In addition, flexion and extension moments were measured for the DC test conditions. The statistical analysis was performed using repeated-measures analysis of variance (ANOVA, Systat Software Inc, Richmond, CA). *Post hoc* tests were done where indicated by ANOVA results using Bonferroni correction for multiple comparisons. The level of significance was set as Bonferroni-adjusted two-tailed $\alpha = 0.05$.

Validating the Two-Level Fusion Construct

The following ROM comparisons were made to assess the adequacy of the method utilized in this study to simulate a two-level fusion with the use of the external fixator fusion construct:

(1) C4–C6 in the intact spine (step 1) *versus* C4–C6 lordotic fusion (step 2); both conditions were tested in load-control to ±1.5 Nm moment endpoints and
(2) C4–C6 in the intact spine (step 3) *versus* C4–C6 straight fusion (Step 4); both conditions were tested in DC to the same flexion and extension motion endpoints.

To assess whether the removal of the stabilization apparatus restored the spine's motion response to its intact state, we compared the following:

(3) C4–C6 in the intact spine (step #1) *versus* C4–C6 after removal of the fusion construct (step #7). Both conditions were tested in load-control where all segments experienced the same ±1.5 Nm moment. The motion response of a segment under load-control should remain unaffected in the absence of any alteration to the disc, facet joints, and ligamentous structures of the segment.[22] Therefore, since no such alteration were made at C4–C6, the ROM of these segments in the load-control experiment should not be affected by the presence of a TDR at C3–C4 as was the case for protocol step 7.

As the statistical analyses of C4–C6 ROM motion involved three comparisons, Bonferroni correction for three comparisons was applied when evaluating statistical significance.

We also assessed the effect of the two-level fusion procedure on the motion of the remaining mobile segments. This required a comparison of motions at C2–C3, C3–C4, C6–C7, and C7–T1) when the specimens with and without the two-level fusion were tested to the same flexion and extension motion endpoints (protocol steps 2 *vs.* 3).

Assessment of C3–C4 TDR Performed Alone Versus Above a Two-Level Fusion

The following comparisons were made:

(1) ROM of C3–C4 in the intact spine (step 1) *versus* C3–C4 TDR after the removal of the fusion construct (step 7); both conditions were tested in load-control to ±1.5 Nm moment endpoints.
(2) ROM of intact C3–C4 above a lordotic fusion (step 2) *versus* C3–C4 TDR above a lordotic fusion (step 6); both conditions were tested in DC to the same flexion and extension motion endpoints.
(3) ROM of intact C3–C4 above a straight fusion (step 4) *versus* C3–C4 TDR above a straight fusion (step 5); both conditions were tested in DC to the same flexion and extension motion endpoints.

As the statistical analyses of C3–C4 ROM motion involved three comparisons; Bonferroni correction for three comparisons was applied when evaluating statistical significance.

We also compared the moment loads required to reach the same flexion and extension endpoints in the DC tests for the following conditions:

(1) C3–C4 TDR alone (step 8) *versus* intact (step 1).
(2) C3–C4 TDR above a lordotic fusion (Step 6) *versus* C3–C4 TDR alone (step 9).
(3) C3–C4 TDR above a straight fusion (step 5) *versus* C3–C4 TDR alone (step 9).

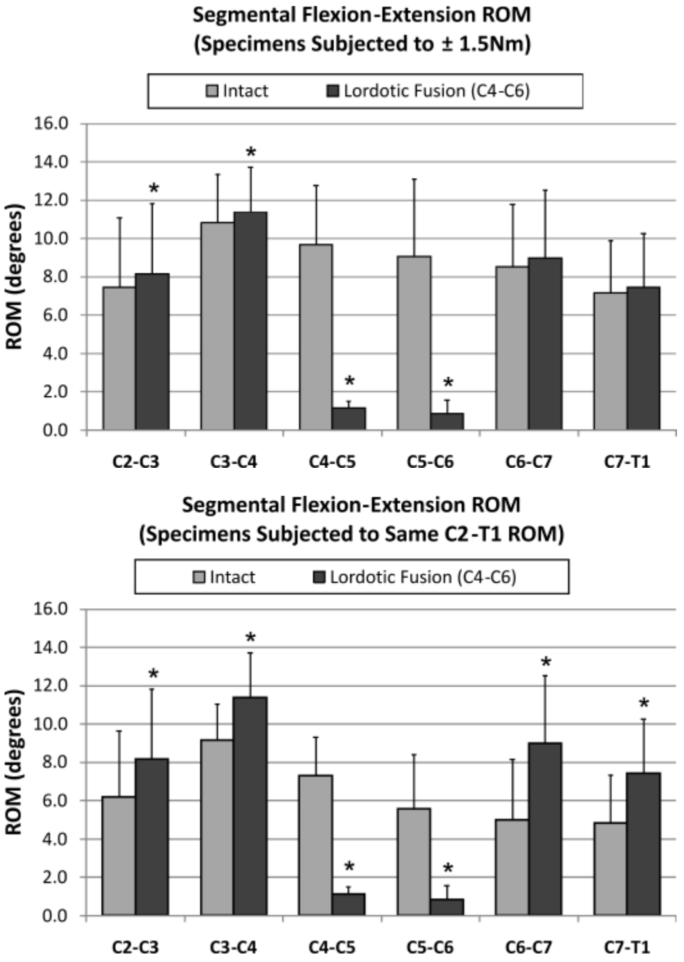

Figure 3. Effect of two-level fusion on the motion of cervical segents. **(A)** Load-control test where the specimens with and without the two-level fusion were tested to the same flexion and extension moments of 1.5 Nm. **(B)** Displacement-control test where the specimens were tested to the same flexion and extension motion endpoints. The fusion construct allowed adequate reduction of segmental motion across C4–C5 and C5–C6, with compensatory increase in motion at other segments, apparent in the displacement-control test. *Indicates statistically significant difference from intact value ($P < 0.05$).

As the statistical analyses of moment data involved three comparisons, Bonferroni correction for three comparisons was applied when evaluating statistical significance.

RESULTS

Effect of Simulated Fusion on Motion Restriction at C4–C6

The fusion construct allowed adequate reduction of segmental motion across C4–C6 under the loads used in the study. In the two-level lordotic fusion simulation, the C4–C6 ROM in flexion-extension was reduced from 18.7 ± 6.7° to 2.0 ± 0.6° ($P < 0.05$), a reduction of 89 ± 3.0% when the specimens were tested in load-control to ±1.5 Nm (Figure 3A). A similar significant reduction in C4–C6 motion of 84 ± 2.8% ($P < 0.05$) was also seen when the specimens were tested in DC to the same flexion and extension endpoints of the C2 vertebra (Figure 3B).

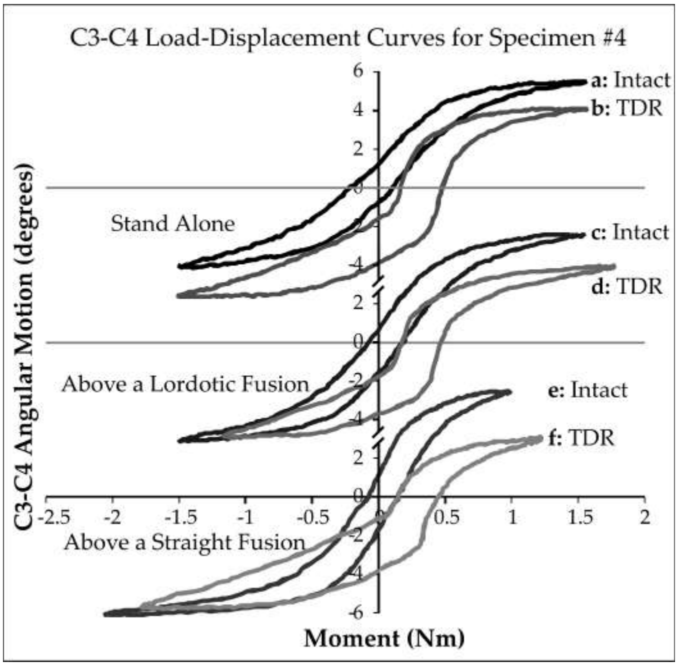

Figure 4. Load *versus* displacement response of the C3–C4 segment—intact and after TDR. Load *versus* displacement curves for a stand-alone TDR *versus* intact C3–C4 are shown in the top panel, whereas the middle and lower panels show the response of the intact C3–C4 and TDR above a two-level (C4–C6) lordotic and straight fusion, respectively.

Effect on Adjacent Mobile Segments

All mobile segments (C2–C3, C3–C4, C6–C7, and C7–T1) experienced compensatory increases in motion ($P < 0.05$) when the specimens with and without the two-level fusion were tested to the same flexion and extension motion endpoints (Figure 3B). The mobile segments also experienced a small increase in motion under the load-control protocol where the specimens with and without the two-level fusion were tested to the same flexion and extension moments of 1.5 Nm (Figure 3A). However, the increase in motion at each mobile segment was significantly greater when the specimens were tested to the same flexion and extension motion endpoints (DC test) ($P < 0.05$).

Effect of Removal of Fusion Construct

Removal of the fusion construct restored the motion response of the spinal segments to their intact state, validating the "reversibility" achieved with this technique from the stabilized condition to the intact condition. This was verified by comparing the total flexion-extension ROM at C4–C6 in the intact state (18.7 ±6.7°) to that measured after removing the fusion construct (19.6 ± 6.1°). The C4–C6 ROM increased by 0.9 ± 0.9°; however, the small increase was well within the specimen variability in the samples used in this study and was not statistically significant ($P > 0.05$).

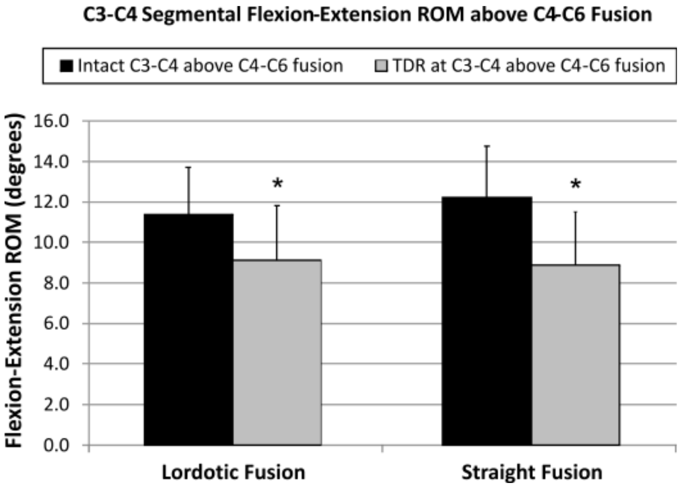

Figure 5. Motion of C3–C4 TDR above the two-level (C4–C6) fusion-–intact and after TDR. Mean values and one standard deviation bars are shown. *Indicates statistically significant difference from intact value ($P < 0.05$).

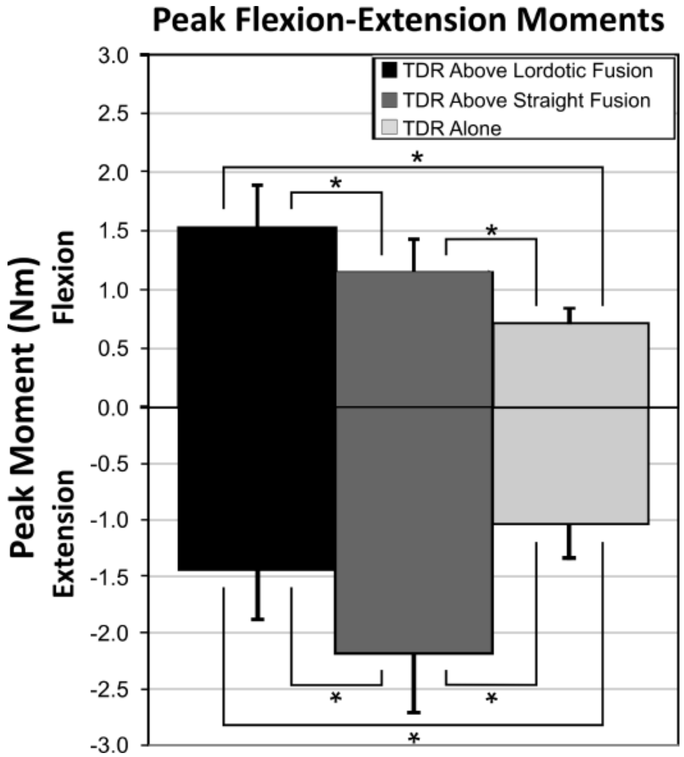

Figure 6. Peak flexion and extension moments required to bring the cervical spine to similar C2 motion endpoints-–TDR above a two-level fusion compared to TDR alone. *Indicates a statistically significant difference ($P < 0.05$).

Motion of C3–C4 Arthroplasty: Stand-Alone and Above a Two-Level Fusion

Flexion-extension ROM at the C3–C4 level was 10.8 ± 2.5° in the intact spine under load-control (±1.5 Nm) with a compressive preload of 150 N. The motion of a stand-alone TDR at C3–C4 (in the absence of fusion at subjacent levels) was 8.8 ± 3.0° ($P = 0.12$, compared to intact) (Figure 4, top panel).

In the DC test where the specimens reached the same flexion and extension motion endpoints, C3–C4 TDR above the C4–C6 fusion yielded less motion when compared to intact C3–C4 above the two-level fusion (Figure 4, middle and lower panels). The decrease in motion of C3–C4 TDR was significant for both lordotic and straight fusions across C4–C6 ($P < 0.05$) (Figure 5), and was associated with a compensatory increase in motion at the adjacent C2–C3 segment for both lordotic and straight fusions ($P < 0.05$).

Spine Loads after C3–C4 Arthroplasty: Stand-Alone and Above a Two-Level Fusion

Flexion and extension moments needed to bring the cervical spine to similar C2 motion endpoints significantly increased for the TDR above a two-level fusion compared to TDR alone ($P < 0.05$). The average flexion moment for the TDR above a straight fusion was significantly lower than the flexion moment for the TDR above a lordotic fusion (1.14 ± 0.28 Nm *vs.* 1.53 ± 0.37, $P < 0.05$). Conversely, the average extension moment for the TDR above a straight fusion was significantly greater than the extension moment for the TDR above a lordotic fusion (2.18 ± 0.53 Nm *vs.* 1.44 ± 0.44, $P < 0.05$) (Figure 6).

DISCUSSION

Although cervical disc replacements have been approved for use in the US in primary, single-level cases, they have been used clinically adjacent to multilevel fusions for the treatment of symptomatic adjacent level disc herniations or cervical spondylosis. Several studies in both clinical and *in vitro* settings have shown that total disc arthroplasty in the cervical spine can reproduce near physiologic angular ROM at the operative segment.[14–17,19] However, to our knowledge, this is the only study that has analyzed the kinematics of a cervical TDR adjacent to a multilevel fusion.

There are several limitations of the current study. First, this was a biomechanical study performed using human cadaveric lumbar spine specimens. Muscles play an important role as dynamic stabilizers of the osteoligamentous spine and affect the *in vivo* spine kinetics. Unfortunately, this active response of muscles is absent in cadaveric specimens. The passive stiffness of the muscle tissue is also variable as these tissues are stripped to a variable degree when the specimens are harvested. Therefore, the extraneous muscle tissues were stripped, leaving the ligamentous and bony tissues intact. We did, however, apply a physiologic preload of 150 N on the cervical spine during the flexion-extension experiment. This preload represents the compressive preload that results from the dynamic stabilizing action of muscles in balancing the weight of the head over the cervical spine.[23]

Second, the two simulated fusion alignments differed by only 7° and may be less than what is clinically seen. Nevertheless, even with a 7° difference we found significant increases in extension moment loading on the TDR adjacent to a lordotic *versus* straight fusion. In this study, a limited difference in the angular alignment of the two fusion constructs was necessary as a greater degree of difference could have increased the risk of ligamentous injury to the specimen during the application of loads, which would have precluded any further testing of the specimen.

Third, the study was performed using only one type of artificial disc prosthesis (ProDisc-C). The design of the disc prosthesis may influence the results to some extent, and one should exercise caution in generalizing the results of this study to all disc designs.

We used a novel stabilization device to investigate the effects of two-level fusion on the adjacent TDR. The goals of the stabilization device were three-fold: (1) simulate the loss of motion as a result of fusion across C4–C6, (2) allow easy adjustment of the alignment (lordotic *vs.* straight) across the fused segments, and (3) allow reversibility to intact response upon disassembly of the apparatus. All three goals were accomplished in this study. Furthermore, we observed compensatory increases in motion of remaining mobile segments when the specimens with and without the two-level fusion were tested to the same flexion and extension motion endpoints. These results are consistent with previous observations of this compensatory phenomenon after fusion of one or more segments.[8,11,14,24,25]

The C3–C4 TDR resulted in less motion as compared to the intact segment when the disc prosthesis was implanted either as a stand-alone procedure or above a two-level fusion. The decrease in C3–C4 motion after disc replacement was associated with a compensatory increase in the motion at other segments, reaching significance at the adjacent C2–C3 segment in all cases. Similar observations were made in previous studies of stand-alone TDR using the ProDisc-C prosthesis.[14,15] These previous studies found decreased motion at the implanted level in extension compared to the intact spine, and this decrease in motion was compensated by increased motion at adjacent levels. On the basis of our experience in biomechanical testing of artificial cervical disc prostheses, the ROM of the implanted segment depends on multiple factors that include prosthesis design features as well as variability in surgical technique. In this study, the ROM of the implanted segment was reduced by on average 2° to 3° compared to intact. This may be secondary to the selected height of the prosthesis relative to the native disc height and a narrow window made in the anterior annulus for the insertion of the prosthesis. A narrow annular window (as opposed to complete wide discectomy) resulted in the maintenance of the anterolateral annular fibers to serve as a tension band in providing stability in extension after TDR. However, this may have contributed to a decrease in motion.

TDR above a two-level fusion, whether lordotic or straight, was subjected to larger flexion and extension moments as compared to TDR alone at C3–C4. This is a direct result of the loss of global cervical spine motion after a two-level fusion. Thus, if a patient attempted to maintain the physiologic ROM of the cervical spine after a two-level fusion, the disc prosthesis adjacent to the fusion would experience larger moments than it would when used as a stand-alone procedure.

The alignment of the two-level fusion did not significantly affect the total flexion-extension motion of the TDR (9.1 ± 2.7° *vs.* 8.9 ± 2.6°; $P > 0.05$). However, the fusion alignment significantly affected the moments needed to achieve the same endpoints of the cervical spine motion. The flexion moment was significantly greater for a TDR above a lordotic fusion, whereas the extension moment was significantly greater for a TDR above a straight fusion. This suggests that more effort is required to bring the spine with a TDR into extension when the spine is fused in a straight alignment and conversely more effort is required to bring the spine into flexion when fused in a lordotic alignment. The increased loading may adversely affect the wear of the TDR by inducing impingement of the prosthesis components at the limits of motion, particularly in extension.

The results show that when a TDR is placed adjacent to a two-level fusion, it is subjected to a more challenging biomechanical environment as compared to a stand-alone TDR. An artificial disc used in such a clinical scenario must be able to accommodate the increased moment loads without causing impingement of its endplates, particularly in extension. Furthermore, the mechanical design of the components of the disc prosthesis should take into account the increased loads to prevent mechanical failures or undue wear during the expected life of the prosthesis.

➢ Key Points

- ☐ C3–C4 TDR resulted in less motion than the intact segment when the disc prosthesis was implanted either as a stand-alone procedure or above a two-level lordotic or straight fusion.
- ☐ The alignment of the two-level fusion did not significantly affect the total flexion-extension motion of the TDR.
- ☐ Flexion and extension moments needed to bring the cervical spine to similar C2 motion endpoints significantly increased for the TDR above a two-level fusion compared to TDR alone.
- ☐ Lordotic fusion required significantly greater flexion moment, while straight fusion required significantly greater extension moment.
- ☐ TDR placed adjacent to a two-level fusion is subjected to a more challenging biomechanical environment as compared to a stand-alone TDR.

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