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Effect of Two-Level Total Disc Replacement on Cervical Spine Kinematics

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Study Design. Biomechanical study using human cadaver spines.

Objective. To characterize kinematics of cervical spines implanted with total disc replacement (TDR) at 2-levels referencing the implanted and adjacent levels.

Summary of Background Data. Cervical TDR is an appealing alternative to fusion particularly when treating multilevel disease, where the advantages of maintaining motion and reducing adjacent level stresses with TDR are compelling. To our knowledge there are no biomechanical studies evaluating multilevel cervical TDR.

Methods. Six human cadaveric cervical spine specimens (C3–C7, age: 57 ± 12 years) were tested (i) intact, (ii) after TDR (Discover, DePuy, Raynham, MA) at C5–C6, and (iii) after additional TDR at C6–C7. Specimens were subjected to flexion/extension, lateral bending and axial rotation (±1.5 Nm). Segmental range of motion (ROM) was measured using optoelectronic instrumentation and fluoroscopy.

Results. Insertion of TDR at C5–C6 increased flexion/extension ROM of the implanted segment compared with intact (8.6 ± 1.0 *vs.* 12.3 ± 3.3°, $P < 0.025$). The TDR maintained ROM to intact levels in lateral bending (7.4 ± 2.6 *vs* 6.0 ± 1.6, $P > 0.025$) and axial rotation (5.5 ± 1.9 *vs.* 6.0 ± 2.9, $P > 0.025$). The TDR at C5–C6 did not affect ROM at the adjacent levels. Implantation of a second TDR at C6–C7 maintained the ROM at that segment to intact values in flexion/extension (9.6 ± 4.3 *vs.* 11.2 ± 5.5, $P > 0.025$), lateral bending (6.1 ± 4.0 *vs.* 4.1 ± 2.1, $P > 0.025$), and axial rotation (6.7 ± 3.6 *vs.* 5.5 ± 3.7, $P > 0.025$). The second TDR at C6–C7 did not affect the ROM of the prosthesis implanted at C5–C6. Two-level TDR at C5–C6–C7 did not affect the ROM at C4–C5 in flexion/extension or axial rotation, however, in lateral bending a small increase occurred (8.9 ± 3.6 *vs.* 10.1 ± 4.5, $P < 0.025$).

Conclusion. Cervical TDR at 2 levels can provide near-normal mobility at both levels without destabilizing the implanted segments or affecting adjacent segment motions. These observations lend support to the notion that single or multilevel cervical TDR may be advantageous when compared to fusion.

Key words: cervical spine, disc replacement, kinematics, multilevel. **Spine 2009;34:E794–E799**

For decades anterior cervical discectomy and fusion (ACDF) has been considered the gold standard for the surgical treatment of cervical spondylosis causing radiculopathy or myelopathy. Cervical total disc replacement (TDR) has been introduced as an alternative treatment to fusion for degenerative disc disease of the cervical spine and was recently approved in the United States by the Food and Drug Administration (FDA) for the management of single-level cervical spondylosis.

Recent prospective, randomized studies have reported that in the treatment of symptomatic single-level radiculopathy or myelopathy, the results of cervical TDR compare favorably to ACDF using validated outcome measures.[1,2] Patients with multilevel disease have, however, largely been excluded from US FDA IDE trials, despite the fact that this is not an uncommon clinical scenario.

The high success rate and long-term track record of ACDF for the treatment of symptomatic cervical spondylosis, raises the question as to the need for the development of alternate procedures.[3,4] Proponents of artificial disc technology claim that, although cervical arthrodesis is often clinically successful in the short-term, fusion increases biomechanical stresses at adjacent segments which may hasten degeneration at these levels.[5–7] Alternatively, artificial disc replacement maintains motion at the operated level, thereby potentially maintaining adjacent level kinematics and reducing the rate of adjacent level degeneration when compared to fusion. The adverse biomechanical effects of fusion on adjacent mobile levels may be exaggerated when multiple cervical levels are fused. This may suggest a particular role for TDR when multiple level cervical reconstructions are required. However, the biomechanics of the cervical spine implanted with 2-level TDR have not been reported in the literature.

The current experiment sought to characterize the kinematics of human cervical spines implanted with an artificial disc at the C5–C6 and C6–C7 levels, referencing the implanted levels as well as the adjacent levels. We tested the hypotheses that (1) single-level TDR at C5–C6

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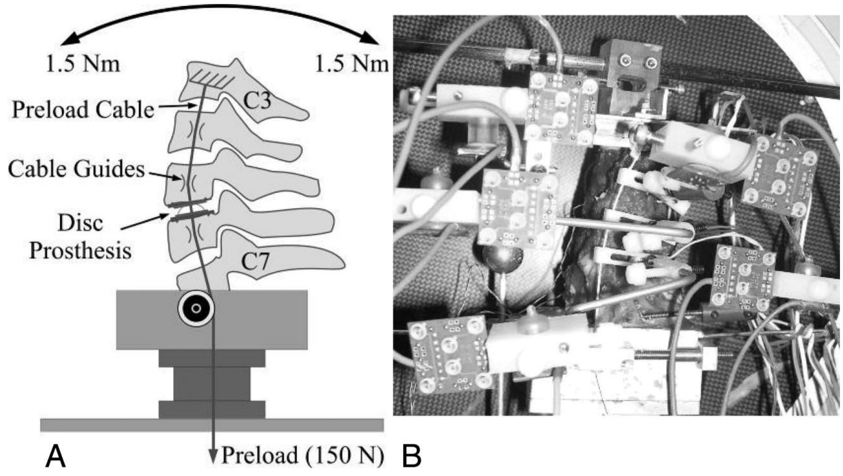

Figure 1. Experimental set-up shown with TDR at C5–C6: (**A**) schematic, (**B**) Specimen photo.

will maintain the motion at the implanted and adjacent segments to their corresponding intact values, (2) a second TDR at C6–C7 will not adversely affect the motion of the first TDR at C5–C6 or adjacent segments, and (3) the second TDR at C6–C7 will maintain the motion at the implanted segment to its intact value.

■ Materials and Methods

Specimens and Experimental Set Up

Six fresh-frozen, human cadaveric cervical spines from C3–C7 (age: 57 ± 12 years, 4 males of 2 females) were used. The specimens had varying levels of pre-existing degenerative changes at C5–C6 and C6–C7, based on anteroposterior (AP) and lateral digital fluoroscopy images. The specimens were thawed at room temperature (20°C) 24 hours before testing. The paravertebral muscles were dissected, while keeping the discs, ligaments and posterior bony structures intact. The C3 and C7 vertebrae were anchored in cups using polymethylmethacrylate and pins.

The specimens were mounted on a 6-component load cell (Model MC3A-6–250, AMTI Multicomponent transducers, AMTI Inc., Watertown, MA) at the caudal end and were free to move in any plane at the proximal end. A moment was applied by controlling the flow of water into bags attached to loading arms fixed to the C3 vertebrae. The apparatus allowed for continuous cycling of the specimen between ±1.5 Nm moment endpoints in flexion/extension, lateral bending, and axial rotation.

The motions of the C3, C4, C5, and C6 vertebrae relative to C7 were measured using an optoelectronic motion measurement system (Optotrak, Northern Digital Inc., Waterloo, Ontario, Canada). In addition, biaxial angle sensors were mounted on each vertebra to allow real-time feedback for the optimization of the preload path. Fluoroscopic imaging (GE OEC 9800 Plus digital fluoroscopy machine) was used during flexion and extension to monitor prosthesis motion. Sequential digital videofluoroscopic images were obtained over the full range of flexion/extension motion.

A compressive preload was applied to the specimens during flexion/extension using the follower load technique described by Patwardhan *et al.*[8] The compressive preload was applied along a path that followed the lordotic curve of the cervical spine. By applying a compressive load along the follower load path, the segmental bending moments and shear forces due to the preload application are minimized.[9] The preload was applied using bilateral loading cables attached to the cup holding the C3 vertebra (Figure 1). The cables passed freely through guides anchored to each vertebra and were connected to a loading hanger under the specimen. The cable guide mounts allowed anterior-posterior adjustments of the follower load path. The alignment (optimization) of the preload path was performed by adjusting the cable guides to minimize changes in cervical lordosis when compressive loads up to 150 N were applied to the specimen.

Experimental Protocol

This was a load-control experiment. Each specimen was subjected to flexion/extension, lateral bending, and torsional moments ranging from 0 to ±1.5 Nm for all loading directions at a uniform loading rate of 1.25 Nm/min. The maximum moment magnitude of 1.5 Nm is within the range of moments used in previous biomechanical studies on human cervical spines.[10–12] Flexion/extension was tested under 150 N follower preload. The load-displacement data were acquired until 2 reproducible load-displacement loops were obtained; this required a maximum of 3–4 loading cycles.

After testing the intact spine, a C5–C6 discectomy was performed using standard instruments and disc prosthesis (Discover, DePuy Spine, Raynham, MA) (Figure 2) was implanted according to the manufacturer's recommended technique. The vertebral endplates were scraped clean, but generally preserved. The posterior longitudinal ligament was resected for all implanted segments. Trial sizes were used to estimate the size of the prosthesis footprint. Implant size was determined fluoroscopically and by direct visualization to provide the widest and deepest possible footprint without completely removing the uncinate processes. Next, disc prosthesis was implanted at C5–C6 using specified instruments including Caspar pin distraction. Proper placement was confirmed by fluoroscopy (Figures 3A, B). Care was taken to restore the disc height to the height of the healthy adjacent–level disc without overdistracting the intervertebral space, as determined by anular tension and posterior joint space. After testing the specimen with a TDR at C5–C6, the specimen was then implanted with an additional TDR at C6–C7, leaving the TDR at C5–C6 in place (Figure 3C) and the flexibility tests were repeated as previously described.

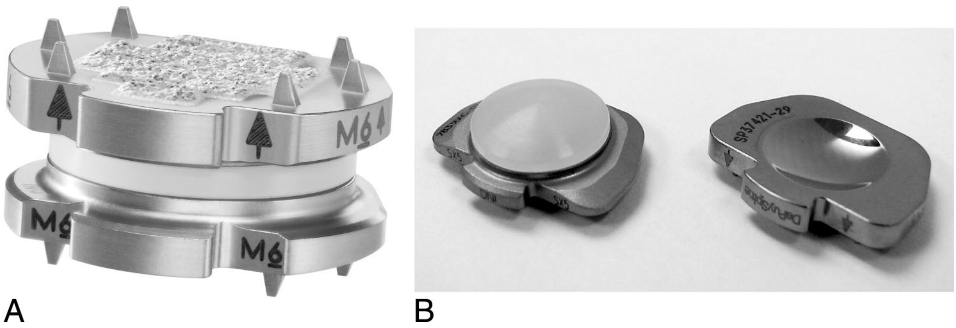

Figure 2. The Discover disc prosthesis (DePuy Spine, Raynham, MA). **A** Assembled (**B**) Components.

Data Analysis

The load-displacement data were analyzed to obtain the angular range of motion (ROM) at the C4–C5, C5–C6, and C6–C7 segments in flexion/extension, lateral bending, and axial rotation. The statistical analysis was performed using repeated-measures analysis of variance (ANOVA, Systat Software Inc., Richmond, CA) with 3 levels of treatment (intact, single level TDR at C5–C6, 2-level TDR at C5–C6 and C6–C7). *Post hoc* tests were done where indicated by ANOVA results using Bonferroni correction for multiple comparisons. The following pair-wise comparisons on segmental ROM were made for implanted and adjacent levels: (1) intact spine *versus* single level TDR and (2) single-level TDR *versus* 2-level TDR. The level of significance was $\alpha = 0.025$ (after Bonferroni correction for 2 comparisons). This was done separately for flexion/extension, lateral bending, and axial rotation within each segment's ROM data sets because no comparisons across the 3 load types nor across the 3 different segments were intended.

■ Results

Effect of Single-Level TDR on Implanted and Adjacent Segments

The flexion/extension angular ROM of the C5–C6 segment under a 150 N preload significantly increased from an intact value of 8.6 ± 1.0 to 12.3 ± 3.3° after disc prosthesis implantation ($P < 0.025$) (Table 1). The TDR did not significantly affect the angular ROM of the implanted level compared with intact in lateral bending (7.4 ± 2.6 *vs.* 6.0 ± 1.6°, $P > 0.025$) (Table 1). The TDR maintained the angular ROM of the implanted segment to the intact value in axial rotation (5.5 ± 1.9 *vs.* 6.0 ± 2.9°, $P > 0.025$) (Table 1).

The TDR at C5–C6 did not significantly affect the angular ROM at C6–C7 from its intact value in flexion/extension (9.0 ± 4.3 *vs.* 9.6 ± 4.3°, $P > 0.025$), lateral bending (6.6 ± 3.7 *vs.* 6.1 ± 4.0, $P > 0.025$), or axial rotation (6.3 ± 3.1 *vs.* 6.7 ± 3.6°, $P > 0.025$) (Table 2). The C5–C6 TDR also did not affect the angular ROM at C4–C5 from its intact value in flexion/extension (10.2 ± 1.8 *vs.* 10.7 ± 1.4°, $P > 0.025$), lateral bending (8.5 ± 3.6 *vs.* 8.9 ± 3.6°, $P > 0.025$), or axial rotation (7.9 ± 1.9 *vs.* 7.2 ± 2.5°, $P > 0.025$) (Table 3).

Effect of Two-Level TDR on Implanted and Adjacent Segments

Implantation of a second disc prosthesis at C6–C7 (in addition to the C5–C6 TDR) maintained the ROM at the C6–C7 segment to intact (pre C6–C7surgical) values in flexion/extension (9.6 ± 4.3 *vs.* 11.2 ± 5.5°, $P > 0.025$), lateral bending (6.1 ± 4.0 *vs.* 4.1 ± 2.1°, $P > 0.025$), and axial rotation (6.7 ± 3.6 *vs.* 5.5 ± 3.7°, $P > 0.025$) (Table 2).

The second TDR performed at C6–C7 did not affect the ROM of the first TDR that was in the adjacent segment (C5–C6). The ROM of the C5–C6 TDR remained unaffected in flexion/extension (12.3 ± 3.3 *vs.* 12.6 ± 3.9°, $P > 0.025$), lateral bending (6.0 ± 1.6 *vs.* 6.3 ± 1.9°, $P > 0.025$), and axial rotation (6.0 ± 2.9 *vs.* 5.2 ± 3.8°, $P > 0.025$) (Table 1). The 2-level TDR at C5–C6–C7 also did

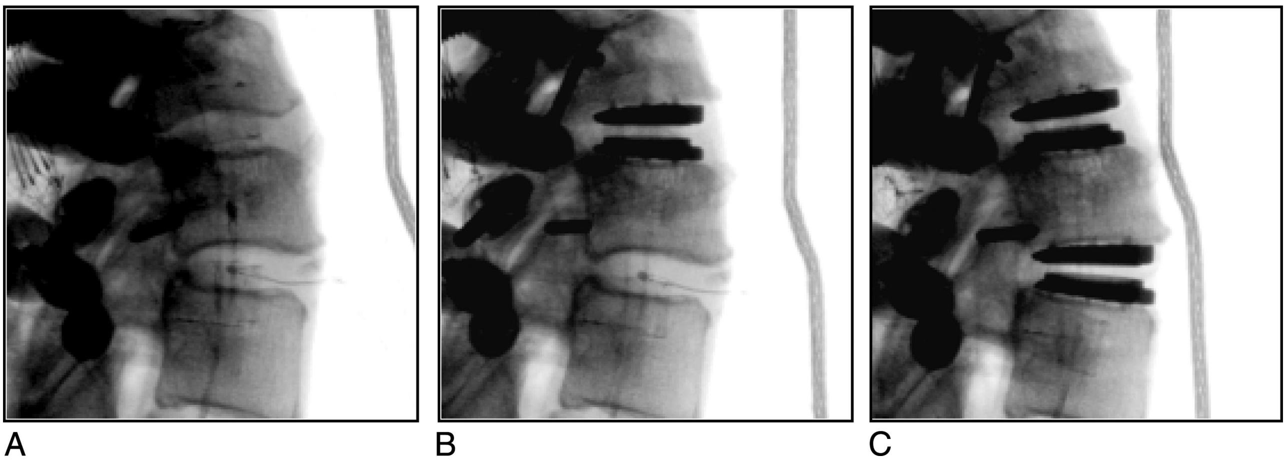

Figure 3. A specimen with 1-level and two-level TDR. **A** Intact (**B**) TDR at C5–C6 (**C**) TDR at C6–C7.

Table 1. Total Range of Motion of C5–C6 in Flexion/Extension, Lateral Bending, and Axial Rotation: Intact, TDR at C5–C6; TDR at C5–C6 and C6–C7

Test Conditions				C5–C6 Range of Motion (Deg)		
Protocol Step	C4–C5	C5–C6	C6–C7	Flexion/Extension	Lateral Bending	Axial Rotation
1	Intact	Intact	Intact	8.6 ± 1.0	7.4 ± 2.6	5.5 ± 1.9
2	Intact	TDR	Intact	12.3 ± 3.3*	6.0 ± 1.6	6.0 ± 2.9
(1 *vs.* 2)				$P = 0.016$	$P = 0.041$	$P = 0.195$
3	Intact	TDR	TDR	12.6 ± 3.9	6.3 ± 1.9	5.2 ± 3.8
(2 *vs.* 3)				$P = 0.266$	$P = 0.266$	$P = 0.099$

*Significantly different than intact (alpha = 0.025 after correction for 2 comparisons).

Table 3. Total Range of Motion of C4–C5 in Flexion/Extension, Lateral Bending, and Axial Rotation: Intact, TDR at C5–C6; TDR at C5–C6 and C6–C7

Test Conditions				C4–C5 Range of Motion (Deg)		
Protocol Step	C4–C5	C5–C6	C6–C7	Flexion/Extension	Lateral Bending	Axial Rotation
1	Intact	Intact	Intact	10.2 ± 1.8	8.5 ± 3.6	7.9 ± 1.9
2	Intact	TDR	Intact	10.7 ± 1.4	8.9 ± 3.6	7.2 ± 2.5
(1 *vs.* 2)				$P = 0.049$	$P = 0.177$	$P = 0.153$
3	Intact	TDR	TDR	10.8 ± 1.3	10.1 ± 4.5*	7.7 ± 1.9
(2 *vs.* 3)				$P = 0.475$	$P = 0.011$	$P = 0.319$

*Significantly different value compared to ROM after first TDR at C5–C6 (alpha = 0.025 after correction for 2 comparisons).

not affect the angular ROM at C4–C5 from its values after the first TDR at C5–C6 in flexion/extension (10.7 ± 1.4 *vs.* 10.8 ± 1.3°, $P > 0.025$) or axial rotation (7.2 ± 2.5 *vs.* 7.7 ± 1.9°, $P > 0.025$). However, in lateral bending a small but statistically significant increase was noted (8.9 ± 3.6 *vs.* 10.1 ± 4.5°, $P < 0.025$) (Table 3).

■ Discussion

The current study confirms that implantation of a single-level cervical TDR will provide near normal mobility at the implanted level without affecting adjacent level kinematics when compared to the intact spine. Importantly, we have shown that a TDR implanted at a second level displayed near normal kinematics and did not affect the behavior of the previously implanted TDR or the intact adjacent levels. TDR at 2 levels can therefore provide near-normal mobility at both levels without destabilizing the implanted segments or affecting adjacent segment kinematics under the loads investigated in the study.

These results for TDR are in contradistinction to a number of biomechanical studies that have shown that cervical fusion substantially alters adjacent level kinematics. DiAngelo *et al*[13] showed that simulated single-level anterior cervical fusion increased lateral bending and extension at the adjacent level when compared with the intact spine. Eck *et al*[14] found a 73% and 45% increase in intradiscal pressure at levels cephalad and caudal to a simulated fusion respectively. Dmitriev *et al*[15] reported significant increases in intradiscal pressure at the proximal C4–C5 and distal C6–C7 adjacent levels following stabilization of C5–C6 when compared with the intact condition. This effect was most pronounced for flexion/extension loading. Significant increases in ROM both proximal and distal to the arthrodesis reconstruction when compared with the intact control were observed. These studies were performed under a displacement-control regimen in which the spine was forced to the same global motion endpoints pre- and postintervention to highlight the compensatory motions in the remaining mobile segments after 1 or more levels have been fused. In the present study we used a load-control protocol wherein the moments applied to the spine were the same pre- and postintervention. The adjacent segments did not show a significant change in motions compared to intact after 1- and 2-level arthroplasty. Further, the fact that none of the implanted segments had a significant decrease in motion relative to intact values, suggests an undisturbed distribution of motion across the entire cervical spine. It remains unclear whether the load- or displacement-control methodology has greater clinically applicability.

Table 2. Total Range of Motion of C6–C7 in Flexion/Extension, Lateral Bending, and Axial Rotation: Intact, TDR at C5–C6; TDR at C5–C6 and C6–C7

Test Conditions				C6–C7 Range of Motion (Deg)		
Protocol Step	C4–C5	C5–C6	C6–C7	Flexion/Extension	Lateral Bending	Axial Rotation
1	Intact	Intact	Intact	9.0 ± 4.3	6.6 ± 3.7	6.3 ± 3.1
2	Intact	TDR	Intact	9.6 ± 4.3	6.1 ± 4.0	6.7 ± 3.6
(1 *vs.* 2)				$P = 0.070$	$P = 0.114$	$P = 0.166$
3	Intact	TDR	TDR	11.2 ± 5.5	4.1 ± 2.1	5.5 ± 3.7
(2 *vs.* 3)				$P = 0.222$	$P = 0.147$	$P = 0.124$

There have been a few reports of the kinematic effects of a 1-level cervical TDR. Puttlitz *et al*[11] tested the Prodisc-C (Synthes, West Chester, PA) in human cadaver spines using pure bending moments with and without a compressive follower load. They showed that flexion/extension and axial rotation at the treated segment were not changed after implantation of the TDR at a single-level when compared to the intact spine, whereas lateral bending was decreased without the follower load when compared to the intact spine. Similarly, DiAngelo *et al*[13] using a displacement-control protocol showed retained motion at the treated level after implantation of the Prestige Cervical Disc (Medtronic Sofamor Danek, Memphis, TN) without alterations in motions at the adjacent levels in 4 human cervical spines.

Chang *et al*[12] used a load-control protocol to determine the effects of TDR using the Prestige and ProDisc-C implants, finding significant increases in extension (but not flexion) at the involved level (C6–C7) and significant decreases at the adjacent superior levels for both discs. Findings were similar for other motions, but not statistically significant. Similarly, arthrodesis of the same level caused increases in motion at the adjacent levels. The authors suggested that the contrary changes in motion between the implanted and adjacent levels were compensatory.

After placement of a Discover TDR at either 1 or 2–levels, slightly increased ROM in flexion/extension at the implanted level/s when compared with the intact spine was observed. The spines used in this study were from older subjects (mean age: 57 ± 12 years) with degenerative changes often present. Degenerative changes in the cervical spine contribute to segmental stiffness,[17] so that increases in the average sagittal plane ROM in flexion/extension may be interpreted as a restoration of motion due to removal of these constraints. Because the cadaver ROM results after TDR implantation were still within measured physiologic ROM[18–20] this increase in motion does not constitute instability. In the current study the PLL which has been shown to contribute to spinal stability[21] was transected. Furthermore, muscle forces acting on the cervical spine *in vivo* may dampen any increased ROM observed in cadaver testing.

In the current study lateral bending was decreased after the Discover TDR; however, statistical significance was not reached. A study[11] of a ball and socket cervical TDR device (Prodisc-C) also showed reduced lateral bending at C4–C5 after TDR. Finite element models,[22] as well as cadaveric testing[10,23] have demonstrated the importance of the uncovertebral joints in guiding this coupled motion. These joints may cause a shift in the center of rotation during lateral bending which the device does not fully replicate. In addition, restoration of disc height by TDR may place the lateral anulus, which is not typically resected during TDR implantation, under tension which may limit lateral bending. Interestingly, the decreased lateral bending at the implanted C5–C6–C7 levels was accompanied by a small, but significant increase in lateral bending at the intact C4–C5 level. It is possible that differences in uncovertebral anatomy at upper *versus* lower cervical levels may significantly change how TDR implantation affects lateral bending ROM.

Interpretation of the results requires some consideration of the study limitations. Biomechanical testing at best mimics the immediate postoperative condition and, therefore changes in the soft tissues, such as anular scar tissue formation, and bony remodeling, are not incorporated, although anular relaxation may be largely accounted for.[24] A second notable limitation of biomechanical testing is the inability to fully replicate physiologic loading. Although application of the follower load provides a key element of the *in vivo* environment,[8] the complicated musculature of the neck creates loading conditions nearly impossible to reproduce completely on a cadaveric spine in the laboratory. More complicated testing setups are possible,[25] but current and commonly employed methods lean toward pure moment control with follower load application techniques, reflecting a balance between physiologic behavior, experimental limitations, and rationales that emphasize a repeatable technique.

Recent prospective, randomized studies using validated outcome measures including neurologic success, pain, function and return to work have shown that in the treatment of single-level radiculopathy or myelopathy the clinical results of cervical TDR compare favorably to ACDF.[1,2] To date there have been no reports of 2-level TDR within the context of a rigorous controlled FDA IDE study, although Pimenta *et al* have reported a case series with excellent clinical results for multiple level cervical disc replacement.[26] They claimed that the outcomes for multiple level disc replacement actually exceeded those seen with single-level procedures.

When treating multilevel cervical disease, the advantages of maintaining motion and reducing adjacent level stress transmission by reconstruction with TDR as compared to fusion may be even more compelling than for single level pathology. The current study provides a biomechanical rationale for 2-level TDR in the cervical spine.

■ Key Points

- Although clinical reviews of the surgical management of cervical spondylosis suggest that single and 2-level procedures are likely to occur in nearly equal proportion, there is little data on the biomechanics of 2-level cervical TDR.
- This biomechanical study quantified the effects of single and 2-level cervical TDR on cervical spine motion.
- Single level implantation was found to restore motion at the implanted level to near normal values and a second cervical TDR did not produce significant changes in kinematics of the previously implanted TDR.
- Adjacent levels appeared to be unaffected by single- or 2-level cervical TDR disc replacement.

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