

# Analysis: In Vitro Biomechanical Construct Tests Evaluating Cervical Arthroplasty

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## Abstract

In this paper, the current peer-reviewed literature on in vitro construct testing of cervical arthroplasty (artificial discs) is analyzed. The methods and findings of each study are summarized and analyzed. Thus far, only six peer-reviewed publications on biomechanics of cervical arthroplasty were found utilizing construct testing of cadaveric spines. The most commonly recorded biomechanical parameter in such studies is simple range of motion. However, the axis of rotation, which theoretically is a very important indicator of the behavior of a disc prosthesis, has been entirely ignored. There is some evidence that artificial cervical discs may alter normal motion during flexion and extension when these motions are studied separately, but the majority of studies have reported combined flexion-extension. There is lack of consensus on the most appropriate method of testing constructs to evaluate cervical arthroplasty devices, with three studies using load control, two studies using displacement control and one study using a mixture of the two (hybrid protocol). It is proposed that future experiments on cervical artificial discs should include measurement of axis of rotation, range of motion, neutral zone, angular coupling patterns and facet loads. If adjacent levels are to be studied, physiologic load application is required and pure moment loading should be avoided.

**Keywords** biomechanics, cervical arthroplasty, axis of rotation

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## Introduction

Cervical disc arthroplasty is a relatively new procedure that has not yet received United States Food and Drug Administration approval. With new spinal surgical devices, it is often useful to study the biomechanics of the device after it has been inserted in cadaveric specimens to predict how the device might behave in vivo. As was recognized by McNally (1), the biomechanical assessment of the performance of devices intended for arthroplasty is much more complex than the biomechanical assessment of the performance of devices intended for arthrodesis. In comparing devices for arthrodesis, it is generally assumed that the device that eliminates motion best provides the best environment for fusion. However, in comparing devices for arthroplasty, it should be generally assumed that the device that most closely mimics normal spinal motion induces the least pathology at the level replaced and at adjacent levels.

The most basic parameter for quantifying spinal motion is the angular range of motion (ROM) of the joint in all three standard planes (sagittal, transverse and coronal). The ROM is the amount of movement occurring at the

maximum load applied. Clearly, the motion segment after arthroplasty should have approximately the same ROM as the motion segment had in the normal condition. However, simple ROM provides an incomplete description of spinal motion. A motion segment in which a normal ROM is achieved through rotation that occurs about an abnormal axis of rotation would cause the facets to be forced together or the soft tissues to be stretched unnaturally. Likewise, a motion segment in which a normal ROM is achieved without the normal angular coupling pattern could lead to undesirable strains on surrounding tissues. Another consideration about ROM is how loads were applied in forcing the motion segment to move to its limits of motion. Demonstrating that a motion segment after arthroplasty moves to the same ROM as it did in the normal condition when an unphysiologic load is applied does not mean that it will move to a normal ROM during actual in vivo loading.

At the time of writing, only six biomechanical studies utilizing cadaveric construct testing of cervical disc arthroplasty devices were found in the peer-reviewed literature.

These papers are summarized in the following sections. One additional study (2) utilized cadaveric constructs but performed only pressure profilometry, not motion testing, and was therefore excluded from analysis.

### 1. Intervertebral disc replacement maintains cervical spine kinetics

Puttlitz CM, Rousseau MA, Xu Z, Hu S, Tay BK, Lotz JC. *Spine*. 2004 Dec 15;29(24):2809-2814. Cited in PubMed; PMID 15599283.(3)

#### **Information:**

Pure moments with and without compressive follower loads were applied to six cervical cadaver specimens before and after disc replacement at C4-5 with the ProDisc-C device (Synthes Spine, Paoli, PA). Angular ROM was studied during flexion-extension, lateral bending and axial rotation. In addition, the coupled axial rotational ROM during lateral bending and the coupled lateral bending ROM during axial rotation were studied. This experiment showed that specimens in which the disc was replaced by ProDisc-C had angular ROMs that were approximately the same as normal in each plane and maintained a coupling pattern between lateral bending and axial rotation that was approximately the same as when the native disc was present.

#### **Analysis:**

The authors kept well focused, testing only two conditions (normal and disc replaced) and collecting a small data set. Because controversy exists as to whether a compressive preload should be applied (4), the authors tested specimens with and without preload, leaving it to the reader to decide which data set he or she prefers. The authors chose to report combined flexion-extension ROM rather than separating flexion ROM from extension ROM. As is seen below in a study by different researchers, biomechanical differences may have become apparent had these modes been segmented. The authors recognized the limitations of pure moment loading and did not attempt to study the effect of the device on adjacent levels under pure moment conditions.

### 2. In vitro biomechanics of cervical disc arthroplasty with the ProDisc-C total disc implant

DiAngelo DJ, Foley KT, Morrow BR, Schwab JS, Song J, German JW, et al. *Neurosurg Focus*. 2004 Sept 15;17(3):E7. Cited in PubMed; PMID 15636563.(5)

#### **Information:**

A robotic actuator (6) controlled the displacement of six cadaveric specimens in the normal condition, after arthroplasty (ProDisc-C) and after simulated fusion at C5-6. Dis-

placement of the rostral-most vertebra was controlled to approximate the average translation and rotation observed in vivo during flexion, extension, lateral bending and axial rotation. The moment required to achieve this displacement was recorded. The global stiffness, normalized moment and distribution of angular displacement among levels (replaced levels and adjacent levels) were quantified. This experiment showed that, during loading that replicates generalized in vivo motion in normal specimens, disc arthroplasty with the ProDisc-C implant usually does not affect the distribution of angular displacement among levels, whereas simulated fusion decreases motion at the replaced level and increases motion at adjacent levels. Unexpectedly, after ProDisc-C implantation, 35% more flexion occurred than normal (although statistically insignificant) and 43% less extension occurred (statistically significant).

#### **Analysis:**

The usage of a robotic actuator allows the authors to impart complex loads that probably match in vivo loads of normal specimens better than test equipment in most other laboratories. It should be assumed that a specimen with a disc arthroplasty should also move with the same motion profile as a normal specimen. However, it has not been proven that the same cervical motion profile followed in vivo in normal subjects is also followed in vivo by patients with a fusion. Therefore, it may be an unfair comparison to force specimens with a fusion to displace by the same amount as normal specimens or specimens with arthroplasty. The findings of this study in general corroborate those of Puttlitz et al (**study 1**),(3) but the separate analysis of flexion and extension by DiAngelo et al (5) instead of combined flexion-extension proved to be extremely valuable, demonstrating the only significant difference between intact and ProDisc-C conditions.

### 3. Biomechanical testing of an artificial cervical joint and an anterior cervical plate

DiAngelo DJ, Robertson JT, Metcalf NH, McVay BJ, Davis RC. *J Spinal Disord Tech*. 2003 Aug 16(4):314-323. Cited in PubMed; PMID 12902496.(7)

#### **Information:**

This study was performed in the same laboratory as DiAngelo et al's ProDisc-C study discussed above (**study 2**) and used similar methods, with robotic displacement control of four cadaveric specimens in the normal condition, after arthroplasty (Prestige, Medtronic Sofamor Danek, Memphis, TN) and after simulated fusion at C5-6 (Orion anterior plate, Medtronic Sofamor Danek). Displacement of the rostral-most vertebra was controlled to approximate the average translation and rotation observed in vivo during flexion,

extension and lateral bending, but not during axial rotation. Moment required to achieve in vivo-like displacement was recorded. The stiffness (global) and the distribution of angular displacement at the C5-6 level (normal, replaced or fused) and adjacent levels were quantified. This experiment showed that, during loading that mimics in vivo motion in normal specimens, disc arthroplasty with the Prestige implant does not affect the distribution of angular displacement among levels, whereas simulated fusion causes decreased motion at the replaced level and increased motion at adjacent levels. It also showed that global stiffness may not be a sensitive enough parameter to discern changes caused by a single level within a six-level specimen, even as drastic a change as complete immobilization (fusion) of the single level.

#### **Analysis:**

Axial rotation, which is a common mode of cervical movement, was not studied. This mode would seemingly have been interesting to study with the Prestige device since it provides no constraint against rotation. Because the same methods were used in both DiAngelo et al studies (5,7) (**studies 2 and 3**), it is possible to compare the results of the two studies, ie, the behavior of the ProDisc-C versus Prestige. Results appear similar for the two devices. However, the trend that was observed to be significant in the ProDisc-C study appears to be less pronounced with the Prestige device. Motion segments implanted with the Prestige device showed about 14% more flexion than intact motion segments compared to 35% more flexion after implantation with the ProDisc-C. Motion segments implanted with the Prestige device showed about 11% less extension than intact motion segments compared to 43% less extension after implantation with the ProDisc-C. Such a comparison is limited by low specimen numbers in both studies and other potential confounding factors that may have varied between the studies such as surgical technique and specimen condition.

#### **4. Multidirectional flexibility analysis of cervical artificial disc reconstruction: in vitro human cadaveric spine model**

Kotani Y, Cunningham BW, Abumi K, Dmitriev AE, Ito M, Hu N, et al. J Neurosurg Spine. 2005 Feb;2(2):188-94. Cited in PubMed; PMID 15739532.(8)

#### **Information:**

Pure moments were applied to seven cervical specimens (1) in normal condition, (2) after C5-6 disc replacement with a fabric disc prototype, (3) after replacement with a bone graft and (4) after graft and anterior plating. Angular ROM and neutral zone (NZ) at the operated level were studied during flexion-extension, lateral bending and axial rotation. Adjacent segment ROM was also quantified. This experiment showed that the fabric disc maintained ROM and NZ that

were not significantly different than normal during axial rotation and lateral bending. During flexion-extension, the fabric disc allowed a greater ROM (but not NZ) than normal. The fabric disc allowed a greater ROM than bone graft or bone graft with plate during all loading modes. Adjacent level motion was unaltered relative to normal in any condition except lateral bending at the rostral adjacent level with the fabric disc, bone graft and graft+plate (greater motion than normal).

#### **Analysis:**

Pure moments are applied evenly to every level of a specimen regardless of whether one or more levels are completely fused or completely destabilized (9). Therefore, no alteration of adjacent level motion would have been expected under pure moment loading in any condition studied, unless alteration of ligamentous tissues at one level could affect the condition of ligamentous tissues at the adjacent level, which has not been demonstrated. The finding that there was no difference in adjacent-level ROM among normal, fabric disc, graft and graft+plate conditions during flexion-extension and axial rotation is therefore not surprising. It is a bit surprising that a difference between normal and all other conditions was found during lateral bending and is unclear why this difference occurred (the authors called this finding "inexplicable"). One possible explanation for the increased adjacent segment motion in this case may be the natural course of tissue degradation during testing. In this study, combined flexion-extension ROM was reported. As with Puttlitz et al (**study 1**),(3) there is some question as to whether segmentation of flexion-extension ROM into flexion ROM and extension ROM might have revealed any differences between normal and disc-replaced conditions analogous to those seen in DiAngelo et al (**study 2**). (5)

#### **5. Cervical disc replacement-porous coated motion prosthesis: a comparative biomechanical analysis showing the key role of the posterior longitudinal ligament**

McAfee PC, Cunningham B, Dmitriev A, Hu N, Woo Kim S, Cappuccino A, et al. Spine. 2003 Oct 15;28(20):S176-85. Cited in PubMed; PMID 14560189.(10)

#### **Information:**

Pure moments were applied to seven cervical specimens (1) in normal condition, (2) after C5-6 discectomy sparing the posterior longitudinal ligament (PLL), (3) after disc replacement with a low-profile porous coated motion (PCM) device (Cervitech, Rockaway, NJ), (4) after removing the PCM and resecting the PLL, (5) after disc replacement with a fixed PCM device, (7) after allograft and (8) after allograft+anterior translational plate. Angular ROM was

studied during flexion-extension, lateral bending and axial rotation. Linear ROM was studied during axial compression. Significant differences in ROM were found between the discectomy conditions with and without resection of the PLL, and between normal condition and discectomy or allograft alone. However, no significant differences were found between normal and PCM-implanted conditions.

### **Analysis:**

Although the title of this study refers to the “key role” of the PLL, this phrase is not meant to apply to the role of the PLL with the PCM device in place. The authors found that the ROM during compression, flexion-extension, lateral bending and axial rotation with a PCM device in place and the PLL intact was not significantly different than the ROM during these modes with a PCM device in place and the PLL resected. Therefore, although PLL resection may change the biomechanics of the uninstrumented motion segment, it does not appear to affect the biomechanics with the PCM device in place. However, this conclusion assumes that the low profile PCM and fixed PCM devices used in sequential steps behave equivalently and provide an equivalent bone-implant interface. The latter assumption especially is questionable because the fixed PCM uses screws to attach the device to bone whereas the low profile PCM uses only a friction fit. Further research is needed to evaluate whether the surgeon should resect the PLL or leave it in place before implanting an artificial disc. As with Puttlitz et al (**study 1**) (3) and Kotani et al (**study 4**) (8), it is unknown whether segmentation of the reported combined flexion-extension ROM into flexion ROM and extension ROM might have revealed any differences between normal and PCM-implanted conditions analogous to those seen for the ProDisc-C in DiAngelo et al (**study 2**). (5)

## **6. Adjacent level intradiscal pressure and segmental kinematics following a cervical total disc arthroplasty: an in vitro human cadaveric model**

Dmitriev AE, Cunningham BW, Hu N, Sell G, Vigna F, McAfee PC. *Spine*. 2005 May 15;30(10):1165-72. Cited in PubMed; PMID 15897831.(11)

### **Information:**

Ten cadaveric specimens were studied (1) intact, (2) after C5-6 disc replacement (PCM device), (3) after allograft dowel insertion and (4) after allograft dowel + anterior cervical plate. A hybrid testing protocol (load control then displacement control) was used in which intact specimens were loaded to 5.0 Nm in flexion-extension, axial rotation and lateral bending to determine the normal ROM. The normal ROM values were then used as the limits of displacement control in each mode after instrumentation (disc prosthesis, bone dowel or

dowel+plate). ROM and NZ were monitored at C5-6; ROM and intradiscal pressures were recorded at C4-5 and C6-7. It was found that intradiscal pressure at adjacent levels remained the same as normal after disc replacement, but significantly increased after inserting a dowel or dowel+plate. It was also found that the ROM and NZ at the operated level remained the same as normal after disc replacement, but significantly decreased after inserting a dowel or dowel+plate

### **Analysis:**

As discussed above with regard to DiAngelo et al (**study 2**) (5) it may be an unfair comparison to force specimens with a fusion to displace by the same amount as normal specimens or specimens with arthroplasty. Therefore, findings that intradiscal pressure and ROM at adjacent levels increased in the arthrodesis conditions may be an artifact of the test method. Nonetheless, this study does validate that the PCM device effectively maintains normal ROM and NZ at the operated level in all loading modes. Flexion was not separated from extension and therefore it is unknown whether the pattern observed in DiAngelo et al (**study 2**) (5) of increased flexion and decreased extension with the ProDisc-C also occurs with the PCM device.

### **Synthesis**

The different authors have taken different approaches to the question of whether load control, displacement control or some combination should be used in these experiments. In studies in which load control is used (**studies 1, 4 and 5, Table 1**), the assumption is that a patient’s muscles would apply the same load to their neck whether their spine moved normally, was fused or had the disc replaced. Thus, the spine should move less when fused and more when an ankylosed motion segment is mobilized. In studies in which displacement control is used (**studies 2, 3 and 6**), the assumption is that a patient would bend his or her neck to the same final angle regardless of whether any of the levels was fused, had a disc replaced or was normal. It is debatable which of these situations actually occurs in patients. Probably, pain also is a consideration—in vivo, a patient may limit the load applied or more likely the angle moved if they experience pain during the movement. Panjabi et al (12) have proposed a “hybrid” protocol for construct testing of spinal arthroplasty. One of the six studies reviewed (**study 6**) incorporated such a protocol. The protocol is termed “hybrid” because, first, load control is used in normal specimens to determine the limiting angles in each mode, after which displacement control is used for testing the remaining conditions. Another name for such a protocol might be “subject-specific displacement control” because it is still essentially a displacement control experiment, but the limiting angles are adjusted to each normal subject instead of being taken from the average response. Such a protocol does not necessarily circumvent

**Table 1. Summary of methods used in each study reviewed**

Study	1	2	3	4	5	6
Prosthesis studied	ProDisc-C	ProDisc-C	Prestige	Fabric	PCM	PCM
Number of specimens	6	6	4	7	7	10
Specimen age in years (mean)	?	75	68	?	68	?
Control Type	Load	Displacement	Displacement	Load	Load	Displacement (hybrid)
Load Applied	Pure moment + compressive follower	Complex (robotic)	Complex (robotic)	Pure moment	Pure moment	Pure moment
Loading modes:						
Flexion		X	X			
Extension		X	X			
Flexion-extension	X	X	X	X	X	X
Lateral bending	X	X	X	X	X	X
Axial rotation	X	X	X	X	X	X
Compression					X	
Limit to load or displacement	1.0 Nm	T1 moment=5Nm; total rotation=40°; total load=75N C5-C6	T1 moment=5Nm; total rotation=40°; total load=75N C5-C6	2.0Nm	2.0Nm	Displace to intact ROM (5 Nm)
Operative level	C4-C5	C5-C6	C5-C6	C5-C6	C5-C6	C5-C6
Outcome measures (operative Level)	ROM, coupling	Angle contribution	Angle contribution	ROM, NZ	ROM	ROM, NZ
Outcome measures (adjacent levels)	None	Angle contribution, global stiffness, normalized movement	Angle contribution, global stiffness, normalized movement	ROM, NZ	None	ROM, intradiscal pressure

problems associated with standard displacement-control experiments. As mentioned above with regard to Studies 2, 3 and 6, a displacement control protocol in which specimens with arthrodesis are forced to undergo unrealistically excessive rotation (although the rotation may have been realistic in the normal condition) is probably an unfair treatment of the fused condition that is likely to bias the experimental findings in favor of the normal and arthroplasty conditions.

In these six studies, between four and 10 specimens were tested and, as acknowledged by at least one group of authors (Puttlitz et al, **study 1**) (3), any observed lack of significant differences might have been because of low statistical power and false-negative error rather than true lack of difference. This problem is common to in vitro human cadaveric experimentation because of cost and unavailability of specimens. Typically, it is assumed that any subtle differences that might exist but might not show up until more specimens are studied are probably clinically inconsequential. This limitation should be kept in mind when drawing conclusions from such experiments.

In all six studies reviewed, neither axis of rotation nor facet loads were recorded and it is therefore unknown whether the observed movement in each plane after arthroplasty occurred in a normal pattern. As mentioned earlier, movement in which the facet articulations are forced together pathologically could lead to eventual problems at the motion segment in which the disc was replaced. Information about the location of the axis of rotation gives indirect evidence about facet loads because a motion segment moving with a normal axis of rotation probably has normal facet loading. However, the axis of rotation does not provide quantitative data on the magnitude of any facet loads and therefore it is preferable to actually measure facet loads directly if possible. Axis of rotation is a difficult and noisy parameter to estimate.(13) However, it has been quantified in evaluating motion-sparing operative procedures (14,15) and spinal injuries.(16) Some data have been presented but not yet published on axis of rotation before and after disc replacement.(17) Facet loading is also a difficult parameter to estimate, requiring either disruption of the facet capsule

and insertion of a sensor (18) or placement of three or more strain gauges on the lamina and tedious calibration at the end of testing.(19) Of these two options, the former is less appealing scientifically because facet disruption and insertion of foreign objects into the facet joint may unpredictably alter spinal motion. No publications or presentations were found using either technique to measure facet loads before and after disc arthroplasty.

In the studies reviewed, the ages of specimens tested should be considered. In three of six studies, the mean age was over 68 years; in the remaining three studies, the age of specimens was not provided (**Table 1**). An age of 68 years is somewhat older than the typical age of patients receiving such implants. For example, the mean age of patients receiving ProDisc-C in a recent clinical study (20) was 49 years (range 31-66 years). Being more flexible, younger native discs may have responded differently at the replaced and adjacent levels. Greater dissimilarity from disc prostheses (which typically exhibit low friction) would be predicted in older native discs.

The studies that were reviewed provided basic information about the biomechanics of cervical disc prostheses, mostly focusing on the amount of movement allowed by the devices. Because both the amount of movement and the pattern of movement are important considerations in evaluating disc arthroplasty, it is recommended that future in vitro experiments evaluating disc arthroplasty should, if possible, include an expanded set of measured parameters to address both considerations. For example, a protocol could include measurement of ROM and NZ to evaluate the amount of movement and measurement of coupling, axis of rotation and facet loads to evaluate the pattern of movement. Although long-term clinical data are not yet available to assess whether artificial discs that cause abnormal patterns of movement are more likely to fail or fuse than artificial discs mimicking normal motion patterns, the best approach scientifically is to assume that these factors matter and to characterize the biomechanics of the devices as completely as possible in the laboratory.

A protocol for meaningful study of the effect of arthroplasty (or arthrodesis) on adjacent levels is not trivial to design. As mentioned earlier, pure moments should not be used to draw conclusions about adjacent levels. However, it is suggested that they be used in a modified hybrid protocol. Unlike the described hybrid protocol in which the displacement under a particular load in the normal condition is used later as the limit after disc replacement, it is recommended that new global limiting angles be determined using load control with pure moments in each condition tested, whether levels within the construct are destabilized or fused. Then, a loading apparatus for applying approximately physiologic loads (6,21) can be used in displacement control with the limits set from the corresponding pure moment test condition. These displacement limits should not force unrealistically

high loads on any level, but, because of in vivo-like application, the loads would be distributed differently among levels than pure moments. The effect of fusion or arthroplasty on adjacent levels may then be evaluated with greater validity through measurement of alterations in intradiscal pressure, axis of rotation, facet loads, and distribution of ROM among levels. Such a protocol is currently underway in this author's laboratory.

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