

Biomechanics of a posture-controlling cervical artificial disc: mechanical, in vitro, and finite-element analysis

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Different methods have been described by numerous investigators for experimentally assessing the kinematics of cervical artificial discs. However, in addition to understanding how artificial discs affect range of motion, it is also clinically relevant to understand how artificial discs affect segmental posture. The purpose of this paper is to describe novel considerations and methods for experimentally assessing cervical spine postural control in the laboratory. These methods, which include mechanical testing, cadaveric testing, and computer modeling studies, are applied in comparing postural biomechanics of a novel postural control arthroplasty (PCA) device versus standard ball-and-socket (BS) and ball-in-trough (BT) arthroplasty devices. The overall body of evidence from this group of tests supports the conclusion that the PCA device does control posture to a particular lordotic position, whereas BS and BT devices move freely through their ranges of motion. (10.3171/2010.3.FOCUS1063)

KEY WORDS • cervical disc arthroplasty • artificial disc •
postural control • segmental kyphosis • biomechanical testing

FIRST-generation cervical arthroplasty devices were designed to maintain motion and simulate normal kinematics. One design consideration that has until recently been ignored is the ability of an arthroplasty device to maintain correct cervical posture. This issue is of concern because clinical evidence has shown that segmental kyphosis may occur weeks to months after cervical arthroplasty.^{4,6,9} Although some have argued that kyphotic deformity after arthroplasty is due to surgeon error and not device design, it would still be desirable for an arthroplasty device to resist loss of lordosis even in the case of poor surgical technique.

A second-generation cervical PCA device (Synergy Disc [Fig. 1]; Synergy Disc Replacement, Inc.) has been developed that is intended to maintain cervical kinematics while also controlling segmental posture. Various methods have been described previously for experimentally assessing the kinematics of cervical artificial discs, including measurement of range of motion, axis of rotation, and other parameters.^{1-3,8} The PCA device has been tested using such methods, and compares favorably kinematically to other arthroplasty devices; although they are pertinent,

results of these tests are not described herein. The purpose of this paper is to describe the special considerations and methods for experimentally assessing postural control, thereby providing outcomes for the PCA versus standard BS and BT devices. These methods have not been described previously, and include mechanical testing, cadaveric testing, and computer modeling studies.

Mechanical Testing of Isolated Devices

The PCA device works to control posture through the design feature of “stability zones” that are adjacent to rounded regions on the top and bottom articulating surfaces. The stability zones are achieved by elongating a spherical surface to contain flattened regions. At angles where the flattened regions are nearly in contact, the PCA is naturally forced toward the equilibrium state of flattened surface against flattened surface. Once at the equilibrium position, less force is required for the device to stay in this position than to move off the stability zone. To evaluate the behavior as the device angulates through each phase of motion from extension through flexion, a simple apparatus was devised that would hold the halves of the PCA or standard arthroplasty device in apposition while applying a compressive load of 79 N (Fig. 2). Adjustment of the position of the mass on the overhanging

Abbreviations used in this paper: BS = ball-and-socket; BT = ball-in-trough; PCA = postural control arthroplasty.



FIG. 1. Postural control arthroplasty device (Synergy Disc; Synergy Disc Replacement, Inc.). The device is composed of titanium endplates and an ultra-high molecular weight polyethylene fiber core.

rail forces the arthroplasty device through a range of angular orientations.

One PCA device, one BT device (Prestige; Medtronic Spine and Biologics), and one BS device (ProDisc-C; Synthes Spine) were evaluated. Applied moment was approximated as the distance of offset multiplied by the constant compressive load, ignoring the restorative counter-moment induced by the springs.

It was found that the PCA but not the BS or BT devices demonstrated a plateau in the angle-versus-moment plot (Fig. 3), indicating that the PCA tended to stay at or near the angle dictated by the stability zone, whereas the standard arthroplasty devices moved freely through all phases of motion, limited only by the friction of the device articulations and the restorative counter-moment

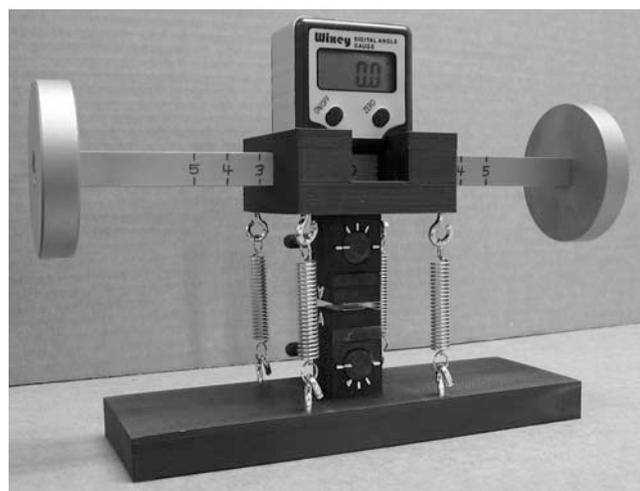


FIG. 2. Mechanical testing apparatus for evaluating postural control in isolated standard arthroplasty and PCA devices. A mass of fixed magnitude and adjustable position is applied by 2 cylindrical weights. The anteroposterior position of the center of gravity of the mass is adjusted by sliding the square bar horizontally through the housing. Springs help maintain equilibrium. Angular orientation is monitored by a digital angle gauge, with 0.1° accuracy (Barry Wixey Development).

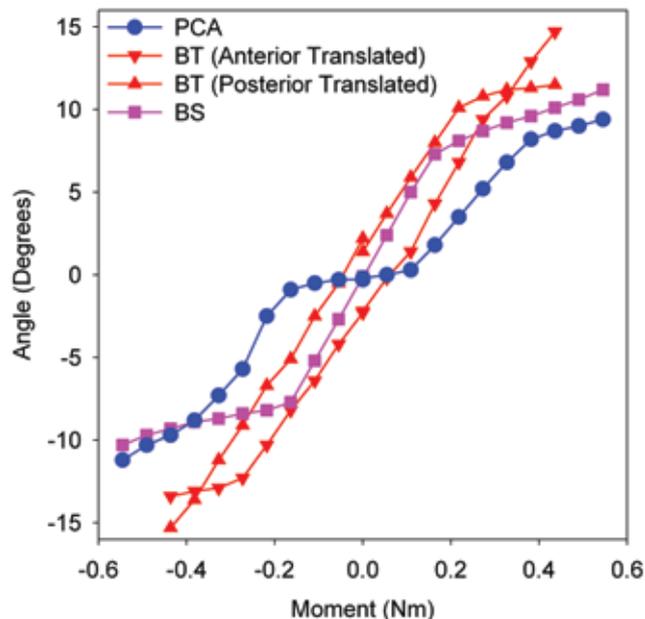


FIG. 3. Graph showing angle versus applied-moment curves for independent devices studied in the mechanical testing apparatus.

produced by the apparatus' stabilizing springs. The plateau in the curve for the PCA extended to approximately ± 0.2 Nm, indicating that within this range of applied moments, the device tended to stay near 0°, the angle at which the flattened articulations were designed to be in contact.

This evaluative mechanical test indicates that the PCA exerts postural control of approximately 0.2 Nm if conditions are ideal, meaning that the stability zones of the device are in contact.

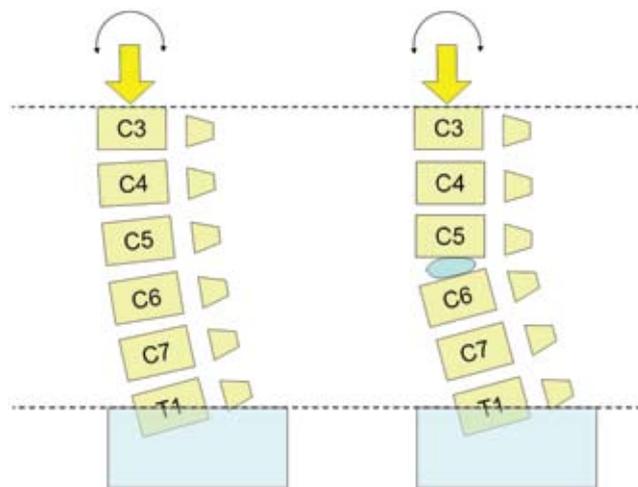


FIG. 4. Schematic of the conditions applied during the neutral upright posture testing protocol. This protocol is based on the assumption that the neutral gaze or global angle (here, C-3 relative to T-1) should remain constant, as indicated by the dashed lines. After device insertion, the same neutral gaze was restored by adjusting the uppermost vertebra relative to the base without applying intersegmental forces. The segmental angle change at the index level was studied to assess the ability of the device to control index-level posture.

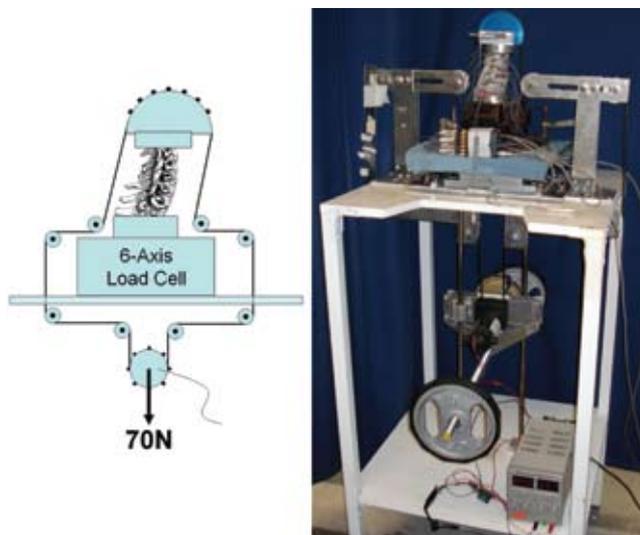


Fig. 5. Simple schematic and photo of the belt apparatus used in experiments for controlling the orientation of the rostralmost vertebra relative to the caudalmost vertebra tested, while simultaneously applying a compressive follower load of 70 N.

In Vitro Cadaveric Testing

To our knowledge, no test has previously been performed or devised specifically to address postural control in vitro in cadaveric specimens. For evaluating spinal postural control, 3 experimental methods were devised and applied.

Neutral Global Posture Method

The first experimental method for posture testing is based on the assumption that the global upright posture (the posture of the head relative to the shoulders, or of the rostralmost vertebra tested relative to the caudalmost vertebra tested) should remain constant in the normal condition and after disc replacement. In other words, it is assumed that, after placement of an artificial disc, a patient would restore his or her neutral gaze to the same orientation that he or she had used when the spine was healthy and normal. All individual motion segments would be expected to adjust via the path of least resistance to achieve this fixed global posture, meaning that the segmental angles needed to achieve the constant global posture would have various amounts of flexion and extension, depending on the properties of each level (Fig. 4). At the level with the PCA, the angular orientation would be expected to tend toward a flexed or extended position dictated by the device, compensated by extension or flexion at adjacent intact levels to achieve the fixed (0°) global posture.

For this testing protocol, a belt apparatus was used in which a notched belt dictates the position of the notched, semicircular upper fixture relative to the lower fixture that is mounted to the table (Fig. 5). With weights suspended below the table from the belt, the belt applies compression that remains aligned with the axis of the spine because of the positions of the pulleys near the base of the spine. A weight of 70 N (motor and weights combined) was used to represent the weight of the head plus slight muscular contraction.

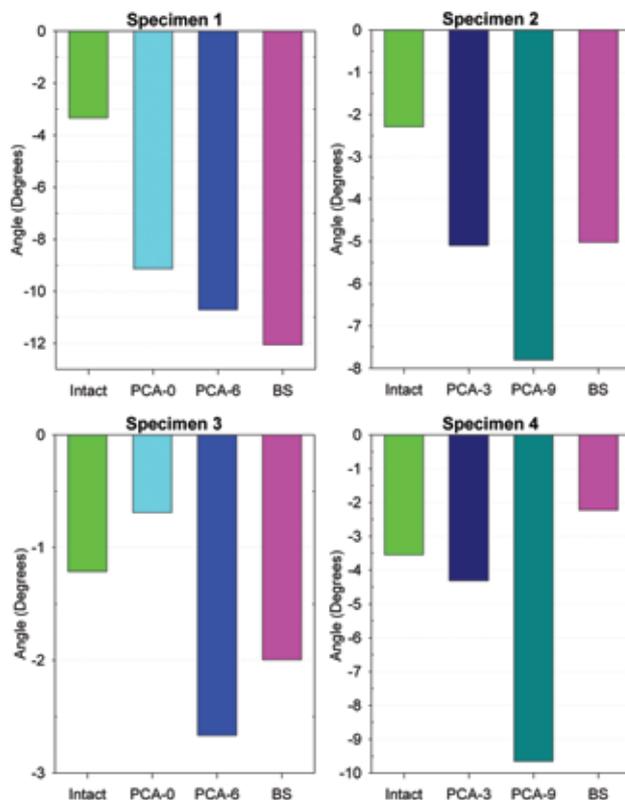


Fig. 6. Bar graphs showing the C5-6 (index level) angle under 70-N compression after restoring global C3-T1 posture to 0°.

The neutral upright (0°) posture, both segmentally and globally, was defined as the posture of the intact unloaded specimen when it was first set up on the test frame after thawing and attachment of optical markers. The positions of the optical markers in this posture were captured and stored for reference throughout the experiment, to enable the global posture to be restored and to study segmental posture changes. Specimens were tested in 4 conditions: 1) intact (4 spines); 2) after insertion of a PCA device with 0° lordosis (PCA-0, 2 spines) or a 3° lordotic PCA (PCA-3, 2 spines); 3) after insertion of a 6° lordotic PCA (PCA-6, 2 spines) or a 9° lordotic PCA (PCA-9, 2 spines); and 4) after insertion of a BS device (ProDisc-C, 4 spines). To allow continuous tracking of posture, arthroplasty devices were removed and inserted with the specimens upright and mounted to the test frame. For testing, 70 N was applied, and then the specimen was moved to a global posture of 0° by using the belt apparatus in each of these conditions, and the index-level segmental angle was evaluated. It was hypothesized that the index-level angle should rest at a position 6° more extended with the PCA-6 device than with the PCA-0 device, or 6° more extended with the PCA-9 device than with the PCA-3 device. It was also hypothesized that the index-level angle should be close to the lordotic angle specified by the device (0°, 3°, 6°, or 9°). Finally, it was hypothesized that the BS device would not tend toward any particular position, and instead, because it offers little postural control, would tend toward either extreme flexion or extreme extension.

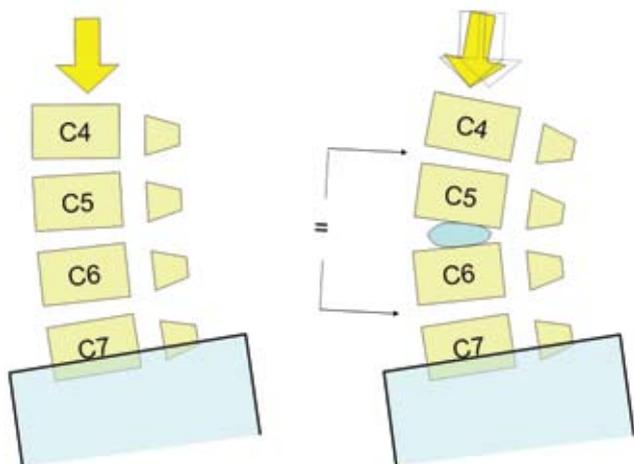


FIG. 7. Schematic of the conditions applied during the neutral balance testing protocol. This protocol is based on the assumption that the neck can be realigned and the forces redistributed so that balance can be obtained for a neutral upright neck posture requiring minimal muscular exertion. As indicated by the “=” and arrows, when completely balanced, the levels adjacent to the index level should be equal, both with a 0° angle (same angle as in the intact neutral upright posture).

In all 4 specimens studied, the PCA with a more lordotic design found a more lordotic posture than the PCA with a less lordotic design (Fig. 6). The difference in resting angles between low and high postural control devices (that is, between PCA-0 and PCA-6 or between PCA-3 and PCA-9) was $2.9 \pm 1.7^\circ$. The magnitude (absolute value) of deviation of the resting angle from the target (designed) angle under a 70-N load averaged $2.9 \pm 2.9^\circ$ for PCA devices.

It was found that the PCA device caused a shift in the index-level posture, although the difference between devices intended for 6° separation was found to average 3°. Precise control to the posture dictated by the device was not observed, probably because it is more difficult to immobilize a dissected specimen to a fixed neutral posture during surgery than to immobilize an actual patient, especially with devices being inserted while specimens were upright. As predicted, the BS did not tend toward any particular position. In one case (Specimen 1), the BS condition was the most extremely extended; in another case (Specimen 4), it was the most extremely flexed. In this experimental method, long specimens (5 levels) were used so that the index level would have a better chance to find its “sweet spot.” Theoretically, as long as the balance of the specimen is within a reasonable range, the index level should tend toward that spot.

Neutral Balance Method

The second experimental method for posture testing is based on the assumption that the loading of the spine should be consistently balanced regardless of the condition of the index level (Fig. 7). In other words, there should always be a way in which an individual can position the head and neck so that posture is naturally balanced with minimal muscular effort. Unlike the neutral global posture method, where balance refers to segmental

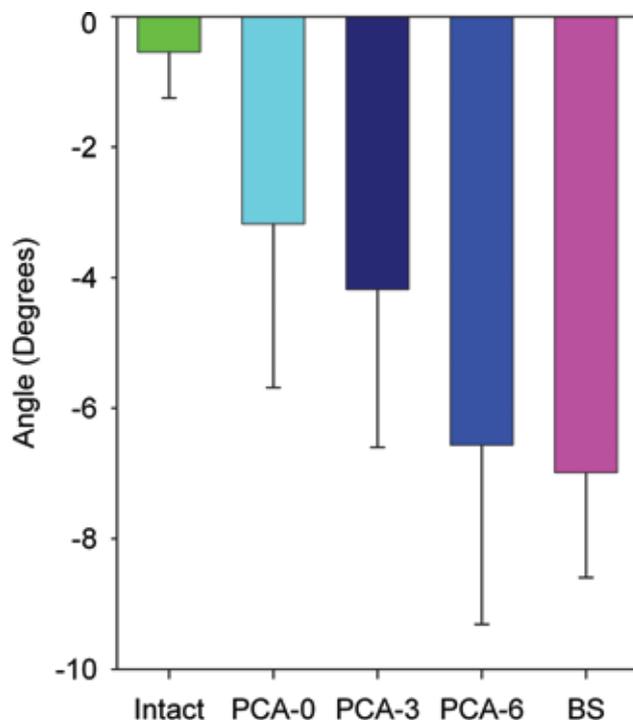


FIG. 8. Bar graph showing the mean postural change after rebalancing during each condition tested using the neutral balance method. Error bars show SDs.

angles summing to 0°, in the second method, “balanced” is defined to mean that all except the index level return to their neutral posture. Because in general, balancing a long stack of objects is more difficult than balancing a small stack, shorter specimens (C4–7) were used for this experimental method.

For this testing protocol, the belt apparatus (Fig. 5) was also used; by driving the belt in small increments with the motor, the angle of the rostral adjacent level was adjusted to be balanced (same angle as the neutral posture). The anteroposterior position of the upper notched pulley on the rostral potting fixture was then adjusted and the belt repositioned until the caudal adjacent level was simultaneously balanced (previously recorded segmental neutral posture). Four specimens were tested intact, with 0°, 3°, and 6° PCA, and with BS. Hypotheses were similar to those for the neutral global posture experimental method. It was hypothesized that the index level should balance at an angle that was more extended when using a more lordotic device. That is, the balance angle with a 6° device should be more extended than the balance angle with a 3° device, which in turn should be more extended than the balance angle with a 0° device. It was also hypothesized that the index-level angle should be close to the lordotic angle specified by the device (0°, 3°, or 6°). Finally, it was hypothesized that the BS would not tend toward any particular position, and instead, because it offers little postural control, would tend toward either extreme flexion or extreme extension.

In all 4 specimens, insertion of a more lordotic PCA device led to a more extended balance position (Fig. 8). The magnitude (absolute value) of the deviation from the

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target lordotic angle with PCA devices was $3.2 \pm 2.5^\circ$ for the 0° device, $2.1 \pm 2^\circ$ for the 3° device, and $2.1 \pm 1.8^\circ$ for the 6° device (average overall deviation $2.5 \pm 2^\circ$). The BS device tended toward the most extended position of the conditions tested.

It was found that the PCA device caused a shift in the index-level posture. However, the absolute resting angle did not precisely match the target designed for the device. As with the neutral global posture method, deviation from absolute target angle may have been related to inserting devices with specimens upright. Relative shifts in angle when switching between devices were less than the angular differences designed into the devices (Fig. 8): in going from a 0° to a 3° device, the angular shift averaged $2 \pm 1.6^\circ$; in going from a 0° to a 6° device, the angular shift averaged $3.9 \pm 2.1^\circ$. As predicted, the BS tended toward an extreme—in this case, the most extended posture of the conditions tested. From these findings it is unclear whether the neutral global posture or the neutral balance method is a superior technique. Both methods are fairly easily implemented, and both seem capable of detecting differences in postural control. The neutral global posture method should perform better with longer specimens, because additional motion segments provide an easier path for the index level to find a specific posture. Conversely, the neutral balance method should perform better with shorter specimens, because it becomes difficult to find a balanced position when attempting to balance more than just the segment immediately adjacent to the index. Length of specimens is also a consideration in the third experimental method, described next, which can be used in conjunction with either of the first 2 methods.

Dynamic Extension-to-Flexion Method

The third experimental method was based on the assumption that when the spine moves dynamically from extension through flexion, a PCA device would force the index level to snap in and out of a “sweet spot” at which posture is preferred. Clinically, such behavior would mean that even as the patient moves his or her neck through flexion and extension, the index level would prefer to stay at or near the angle dictated by the device. Conversely, a relatively low-friction arthroplasty would allow the index level to move even more rapidly than normal through the level’s preferred angular orientation.

For this testing protocol, both the 6 short (C4–7) and the 4 long (C3–T1) specimens were dynamically moved with the belt apparatus (Fig. 5) by using a 70-N follower load. Specimens were moved through a range of global extension and flexion positions that represented the non-destructive physiological range as previously determined for that specimen by using pure moments or manual loading. Such testing was repeated in the normal condition, after PCA implantation (0° and 6° devices; 3° and 9° devices; or 0° , 3° , and 6° devices [2, 2, and 6 specimens, respectively]), and after BS implantation. The index-level angle was plotted versus the global angle. It was hypothesized that plateaus in the index- versus global-angle curves (that is, regions where the index level moves relatively little while the whole spine continues moving) would be

more prominent than normal after PCA implantation and less prominent than normal after BS implantation. It was also hypothesized that plateaus would occur at more extended index-level angles after implanting more lordotic devices.

Plateaus that were indistinct after implantation of BS devices were apparent after implantation of the PCA device (Fig. 9). In all cases, plateaus occurred at an angle that was more extended after implantation of more lordotic devices. In normal and implanted conditions, plateaus were less distinct and steeper in short than in long specimens. Typically, the slope of the curve was steeper through regions of postural influence after BS implantation than in the normal condition or after PCA implantation, indicating the least resistance to motion in that region with the BS device (for example, see curves for Specimens 2 and 10). Through these regions, slopes for the normal condition were typically steeper than with PCA devices implanted.

Some index- versus global-angle curves for the dynamic extension-to-flexion method indicate that the PCA device provided postural control. Note, for example, the clear plateaus separated by approximately 6° for PCA devices, compared with the absence of a plateau for BS in Specimen 1. However, results were inconsistent among all the specimens, probably due to the varying size and fit of devices. One advantage of the dynamic extension-to-flexion method is that it is probably less sensitive to malpositioning of the upper fixture (as long as position remains consistent among conditions) than either the neutral upright method or the neutral balance method. An additional advantage is that this method is easily studied in conjunction with either or both of the other methods. A disadvantage is that it is difficult to define and extract parameters from the index- versus global-angle curves to allow a simplified comparison among specimens (hence the need to plot all 10 curves for comparison). In longer specimens it is sometimes possible to pick out the approximate plateau value from the curves (see Specimen 1). However, clear plateau values are not present in the short specimens (Specimens 5–10), and are not always apparent in long ones (see Specimen 4). It might also be desirable to extract the slope of the curve through the region of postural influence for comparison, but it is not always clear where the region of postural influence begins and ends, and in some cases there are ambiguous multiple slopes through this region.

Finite-Element Modeling

With finite-element modeling, it is possible to isolate effects that are due only to device differences from other competing effects (experimental artifact). An experimentally validated, ligamentous, intact C3–7 finite-element model⁵ was used to study how the PCA differed from standard arthroplasty devices in its ability to maintain posture.

Model geometry was defined from digitized CT images of a cadaveric specimen, and consisted of 24,732 nodes and 21,895 elements (Fig. 10). A lordotic curve was simulated across C3–7 by assigning segmental angles as follows: C3–4, 7° ; C4–5, 4° ; C5–6, 5° ; and C6–7, 6° . The

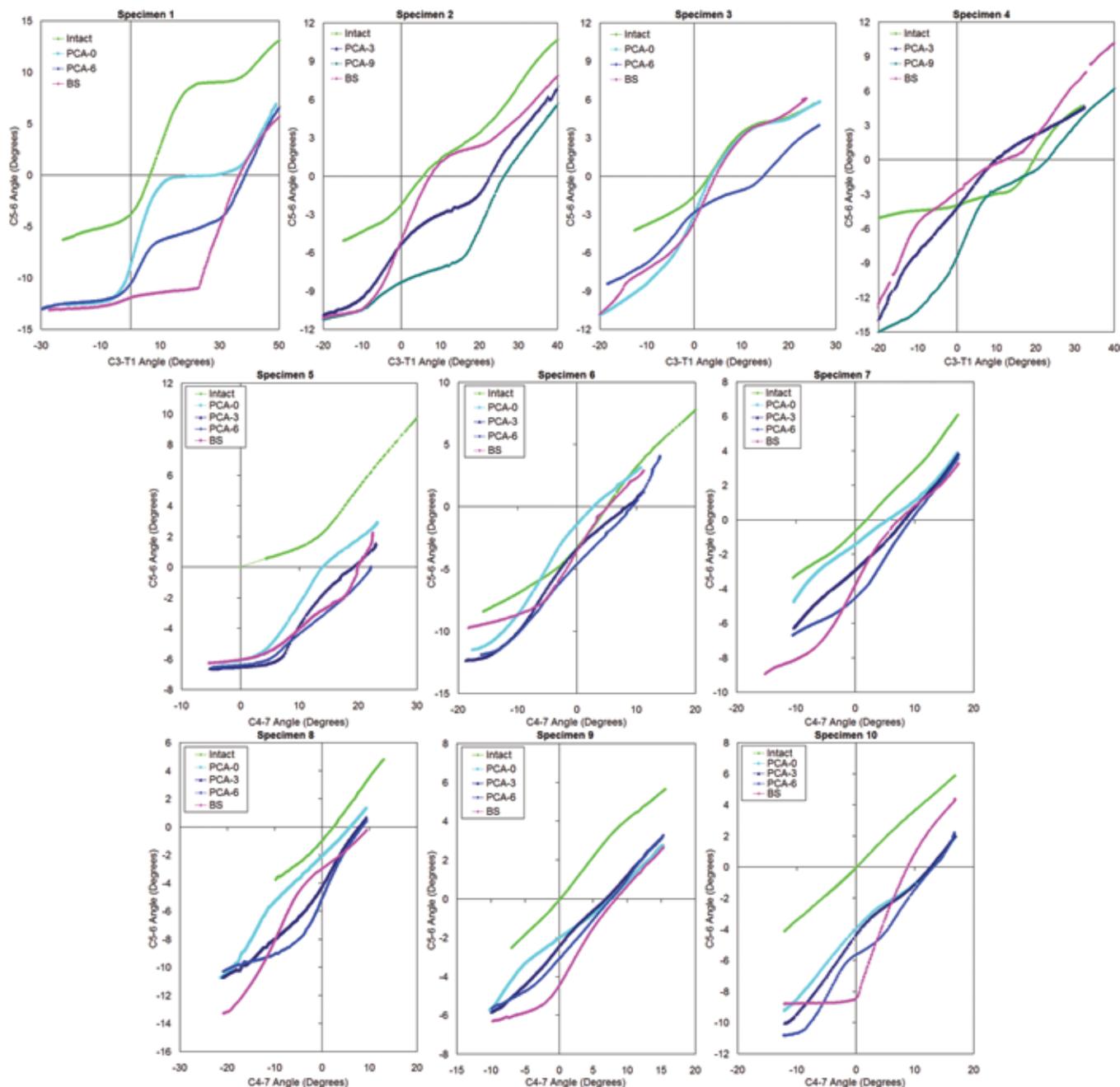


Fig. 9. Charts showing the index- versus global-angle curves for all specimens. Specimens 1–4 spanned 5 levels (C3–T1), whereas Specimens 5–10 spanned 3 levels (C4–7). The index level in all specimens was C5–6.

apophyseal (facet) joints were simulated with 3D gap contact elements. The facets were oriented at approximately 45° from the horizontal plane, with some variation in the sagittal plane alignment, according to CT geometry. The annulus fibrosus was modeled as a composite configuration wherein a series of fibers simulating the lamellae of the disc were embedded in a ground substance surrounding a more gelatinous nucleus region. Each layer of ground substance contained 2 alternating layers of 4 fibers arranged at ± 65° from the transverse plane, with an overall fiber content of 20% of the annular volume assumed; fiber elements were defined to be active only in

tension. The Luschka joints were simulated by creating a space between the annulus horizontal layers around the uncinete processes and placing gap elements in the resulting fissures. The elements adjacent to the fissures were reinforced with fibers that were aligned approximately parallel to the fissure to simulate Luschka joints. All 7 major ligaments were represented in the intact spine model: anterior longitudinal, posterior longitudinal, intertransverse, ligamentum flavum, interspinous, supraspinous, and capsular. The ligaments were modeled as 3D, 2-node truss elements and assigned nonlinear material properties such that at low strains, the ligaments exhibited low stiff-

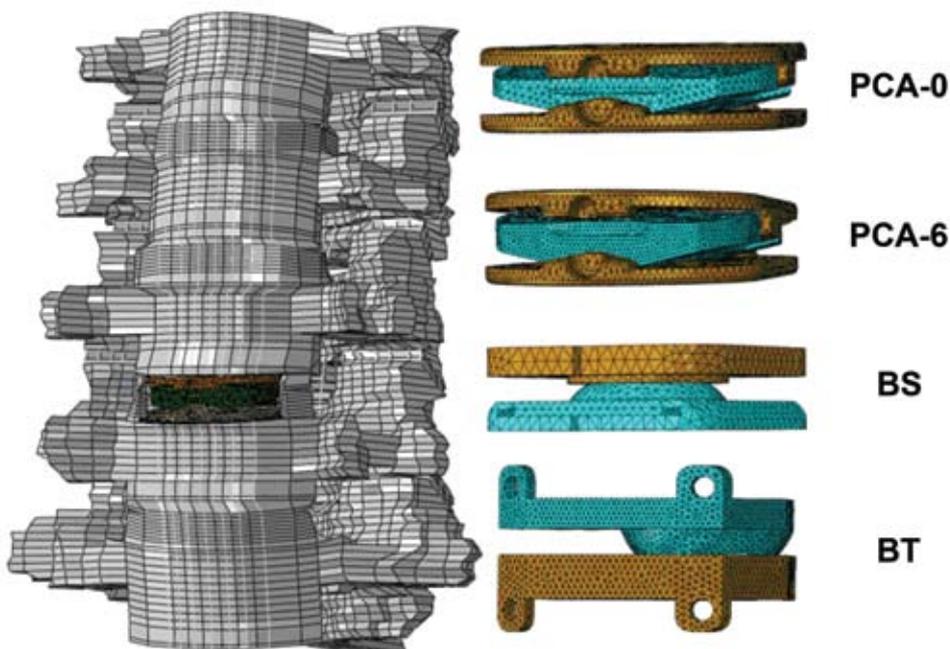


Fig. 10. Schematics showing the geometry of the C3–7 finite-element model with 4 different artificial disc designs applied at C5–6.

ness, but as the strains increased, the ligament stiffness also increased. Material properties were chosen from data published in the literature and were assumed to be homogeneous and isotropic.

Models were defined to simulate intact spines and those with 4 conditions of arthroplasty at C5–6: 1) PCA-0; 2) PCA-6; 3) BS; and 4) BT. The PCA-0 condition had parallel metal endplates, whereas PCA-6 had a 6° built-in lordosis between the endplates. Both PCA-0 and PCA-6 had a polymer core. The BS had an inferior polymeric ball and a superior metal socket, and the BT had a metal ball on a superior endplate, with an elongated inferior trough. All arthroplasty devices were positioned (“inserted”) in models after making room for them by removing bone and disc elements without altering segmental lordosis; devices were oriented in their neutral (midrange) positions, and metal endplates were considered fused to bone.

Boundary conditions were set such that the C-7 vertebra was completely constrained in all 6 degrees of freedom at the inferior endplate, inferior facets, and inferior part of the spinous process while loads were applied to C-3 in 2 steps to simulate precompression and bending. A set of nonlinear springs that followed the curvature of the spine was used to apply a 73.6-N compressive load to simulate precompression. Springs were defined bilaterally through the estimated instantaneous center of rotation of each segment, mimicking the follower load method.⁷ While under compression, a bending moment of 1.5 Nm was applied on the superior face of the C-3 vertebra to simulate physiological flexion/extension, lateral bending, and axial rotation. The follower load and boundary conditions were the same for all intact and implanted models. Simulations were run using Abaqus software (SIMULIA).

Compressive loading of 73.6 N applied to models

that were initially at neutral posture at C5–6 (-5°) resulted in less than 1° of extension for intact, PCA-0, and PCA-6 conditions; 3° of extension for BS; and 1.2° of flexion for BT (Fig. 11). This finding indicates that the PCA devices provide better postural control at a set angle than intact, BS, or BT conditions. The BS appeared to have excessive and rapid motion compared with the intact condition near the neutral position; the PCA-0, PCA-6, and BT demonstrated index-level angle-versus-moment curves similar to the intact condition (Fig. 12). The PCA-0 and PCA-6 curves differed from each other during extension, with PCA-6 showing more extension than PCA-0 at positions slightly more extended than neutral. This behavior was milder than was observed in cadaveric specimens or in isolated device tests, because PCA devices were inserted in finite-element models in neutral orientations, whereas in cadaveric specimens and the benchtop testing apparatus, they were inserted with device endplates parallel to bony (or fixture) endplates. Inflections in the angle-versus-moment curves in the PCA finite-element model results therefore represent the motion segment shifting between the different flattened regions of the PCA devices, but well-separated plateaus would not be expected.

Discussion

The purpose of this paper was both to describe methods used to investigate postural control of an artificial disc, and to present postural results for the Synergy PCA device compared with standard BS and BT designs. Because of the novelty of the testing paradigm, test methods and device designs were both under development during this study, limiting the ability to collect large sets of data. For example, only 4 specimens were tested using the neu-

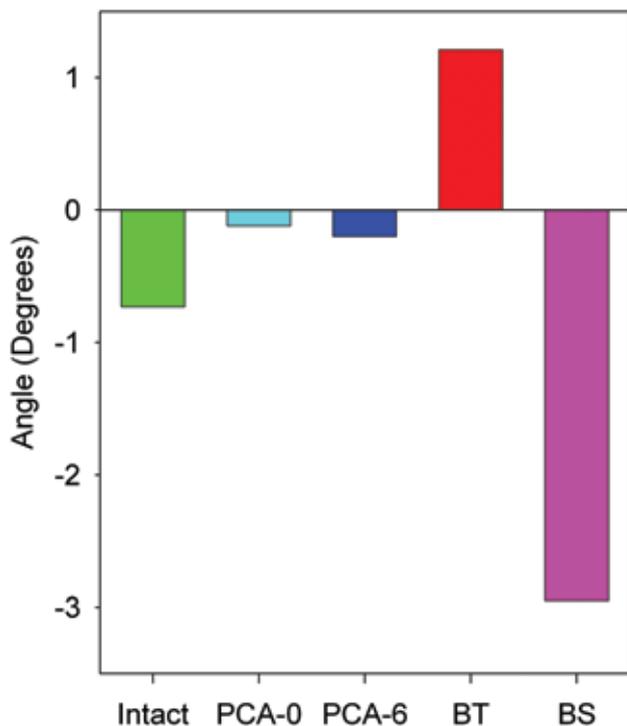


Fig. 11. Bar graph showing the change in neutral angle at C5-6 (initially -5°) after applying 73.6 N of compression and no moment.

tral global posture method, and within this group, certain specimens were only given 2 of 4 PCA device designs. However, it is still possible to identify trends that hold true consistently for the entire dataset.

One uniformly consistent trend is that when 2 or 3 different PCA devices were tested in a cadaveric specimen, the devices with more lordotic designs found static postures that were more lordotic. For example, the static posture with a PCA-0 device in place was at an angle less extended than the static posture of the same specimen with a PCA-6 device in place. This finding was true in all of the 4 specimens tested with the neutral global posture method (Fig. 6), and also in all of the 4 specimens tested with the neutral balance method (Fig. 8). In finite-element modeling, the static posture did not differ between devices (Fig. 11). However, in the finite-element analysis, devices were incorporated into spine models with the articulating stability zones already in apposition at the neutral posture.

Another consistent trend is that the index-level angle with the PCA in place tended to have a plateau or range through which the non-index-level angles changed more rapidly than the index-level angle. This plateau in all 10 cases in cadaveric tests was more extended with PCA devices of more lordotic design (Fig. 9). For example, the index- versus global-angle curves coincided in some regions for PCA-0, PCA-3, and PCA-6 devices, and then were disparate in other regions; these disparate regions always showed that PCA-6 was more extended than PCA-3, and that PCA-3 was more extended than PCA-0. The clearest plateau occurred in the mechanical test of the isolated device (Fig. 3), in which behavior was fully dictated by the device, without the influence of any surrounding tissues.

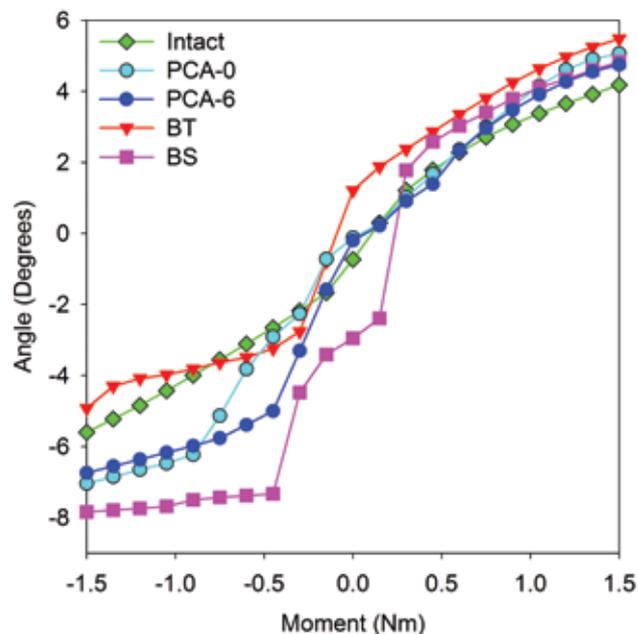


Fig. 12. Chart showing the C5-6 angle versus applied moment in each simulation. Negative angles correspond to extension and positive angles correspond to flexion.

Finite-element modeling showed only a slight separation between angle-versus-moment curves for PCA-0 and PCA-6 (Fig. 12). The reason for smaller differences is that the vertebral bodies were initially positioned with the PCA resting at its designed angle. Therefore, the finite-element output effectively modeled a 0° and a 6° patient, not a correction of 6° in a 0° patient.

Conclusions

No examples of laboratory posture testing exist in the spinal biomechanics literature. To study the ability of the PCA device to influence cervical posture, new methods were therefore devised, and were applied to isolated devices, cadaveric constructs, and finite-element models. The posture testing techniques each provide evidence that the PCA device provides a greater degree of postural control than the intact condition or BS. From this work, it is unclear whether there is a preferred method for future testing, because each method has certain advantages and disadvantages. Clearly, one method should be selected, and that method should be studied in a larger set of specimens to provide more definitive findings, with statistical support and better control of error sources.

Disclosure

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Author contributions to the study and manuscript preparation include the following. Conception and design: NR Crawford, JD Arnett, JA Butters, VK Goel, N Duggal. Acquisition of data: NR Crawford, JD Arnett, LA Ferrara, N Kulkarni, N Duggal. Analysis and interpretation of data: NR Crawford, JD Arnett, LA Ferrara, N Kulkarni, N Duggal. Drafting the article: NR Crawford. Critically revising the article: JD Arnett, JA Butters, LA Ferrara, N Duggal.

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Reviewed final version of the manuscript and approved it for submission: VK Goel. Administrative/technical/material support: JA Butters, LA Ferrara, N Duggal. Study supervision: NR Crawford, VK Goel.

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