Finite Element Study of Matched Paired Posterior Disc Implant and Dynamic Stabilizer (360° Motion Preservation System)

Vijay K. Goel, PhD, Ali Kiapour, MS, Ahmed Faizan, BS, Manoj Krishna, FRCS, MCh(Orth), and Tai Friesem, MD

ABSTRACT

Background

Anterior lumbar disc replacements are used to restore spinal alignment and kinematics of a degenerated segment. Compared to fusion of the segment, disc replacements may prevent adjacent segment degeneration. To resolve some of the deficiencies of anterior lumbar arthroplasty, such as the approach itself, difficulty of revision, and postoperative facet pain, 360° motion preservation systems based on posterior disc and posterior dynamic system (PDS) designs are being pursued. These systems are easier to revise and address all the pain generators in a motion segment, including the nerves, facets, and disc. However, biomechanics of the 360° posterior motion preservation system, including the contributions of the 2 subsystems (disc and PDS), are sparsely reported in the literature.nds.

Methods

An experimentally validated 3-dimensional finite element model of the ligamentous L3-S1 segment was used to investigate the differences in biomechanical behavior of the lumbar spine. A single-level 360° posterior motion preservation system and its individual components in various orientations were simulated and compared with an intact model. Appropriate posterior surgical procedures were simulated. The PDS, a curved device with male and female components, was attached to the pedicle screws. The finite element models were subjected to 400 N of follower load plus 10Nm moment in extension and flexion.

Results

The PDS restored flexion/extension motion to normal. The artificial disc led to increases in range of motion (ROM) compared with the intact model. ROM for the 360° system at the implanted and adjacent levels were similar to those of the respective intact levels. ROM was similar whether the discs were placed (a) both parallel to the midsagittal plane, (b) both angled 20° to the midsagittal plane, and (c) one at 20° and one parallel to the midsagittal plane. However, the stresses were slightly higher in the nonparallel disc configuration than in the parallel disc configuration, both in flexion and extension modes.

Conclusions

Posterior disc replacement with PDS restored the kinematics of the spine at all levels to near normal. In addition, placing the discs in a nonparallel configuration with respect to the midsagittal plane does not affect the functionality of the discs compared with parallel placement. Posterior disc replacement alone is not sufficient to restore the segment biomechanics to normal levels.

Clinical Relevance

Finite element analysis results show that, unlike implants for fusion, PDS and posterior discs together (360° motion preservation system) are needed to preserve ROM. Such systems will prevent adjacent level degeneration and address pain from various spinal components, including facets.

Key Words 360° posterior motion preservation system, posterior artificial disc, posterior dynamic stabilizer, finite element method, lumbar spine, kinematics, biomechanics. ***SAS Journal.*** **Winter 2007;1: 55–61.** DOI: SASJ-2006–0008-RR

INTRODUCTION

Low-back pain is prevalent worldwide.[1] In the United States alone, treatment expenses and costs incurred by patients with low-back pain amount to several billion dollars per year.[2,3] The prevalence of this problem increases as the population ages.[4,5,6]

Spinal fusion with and without spinal instrumentation to prevent or correct spinal deformity and relieve pain is one of the many established procedures for patients who do not respond to conservative treatment protocols. However, fusions are neither fully successful nor without problematic side effects (e.g., pseudoarthroses, donor-site pain). Moreover, there is the concern of accelerated degeneration adjacent to a fused segment, which often necessitates additional fusion surgery.[7–31] To overcome these problems, investigators are pursing alternative treatments.

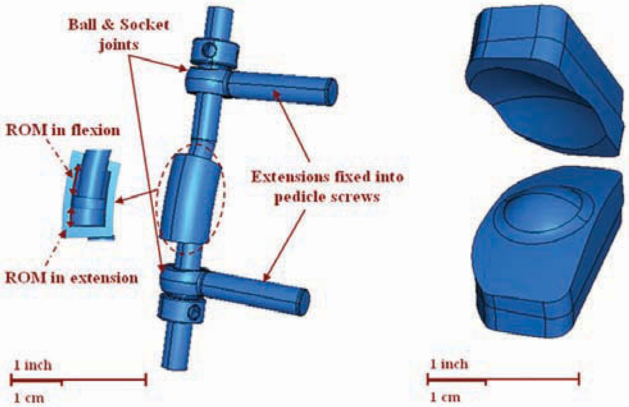
One approach is based in tissue engineering. Attempts have been made to regenerate the nucleus using growth factors, gene therapy, and cell transplantation and scaffolding. Another approach now in clinical use employs artificial discs to mimic normal disc functioning and to avoid undesirable biomechanical changes caused by rigid instrumentation and fusion. Various designs based on different biomechanical approaches have been proposed for artificial discs; clinical and biomechanical data on some of these designs are available.[32–50]

Most studies have used disc designs that require anterior surgical approaches for disc replacement.[33,36,40,51] However, the complexity of the surgical approach, applicability in only a limited patient population, difficulty in revision, and postoperative facet pain are considered to be the main deficiencies of anterior lumbar arthroplasty. To overcome these problems, 360° posterior motion preservation systems consisting of a posterior disc and a posterior dynamic system (PDS) are being pursued. These systems have the advantage of easy revision and address all of the pain generators in a segment, including the nerves, facets, and disc.

We used the finite element (FE) method to compare the biomechanical behavior of an intact ligamentous lumbar spine with implanted spines stabilized with a paired PDS and a matched pair of posterior disc replacements (TruDiscPL; Disc Motion Technologies, Boca Raton, Florida). The effects of the posterior disc and PDS alone also were analyzed. The disc design includes a ball and corresponding multiplanar socket.

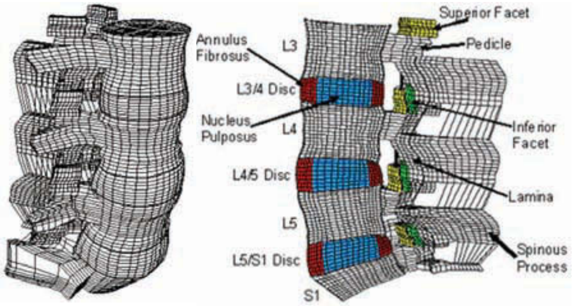
The PDS device has a sliding male–female design with slight clearance between the 2 parts, and 2 spherical joints at both ends (Figure 1). The design allows free motion between the sliding components. However, the design includes a "bumper" at the end of movement of the male within the female housing. In the dynamic system, this bumper serves as a motion limiter in flexion and extension. A scale is shown in Figures 1 and 2 to help estimate the dimensions of the devices and locations within the disc space. It is not practical to provide a detailed drawing showing the curvatures of the disc articulation. The main feature of this combination system is that the center of curvature (instantaneous axis of rotation between male and female parts in the PDS) during flexion/extension matches and mimics the intact center-of-rotation path. The implants are manufactured from a cobalt–chromium alloy.

Figure 1



Posterior dynamic stabilizer (PDS) model including male and female parts attached to ball-and-socket joints at both ends (a). The system is attached to the spinal segment with the help of pedicle screws (see Figure 2). Artificial disc model (a ball and varying radius of curvature in the mating parts) (b). The total system is being developed by Disc Motion Technologies Inc, Boca Raton, Fla.

Figure 2



Finite element (FE) model of implanted spine with artificial disc and posterior dynamic stabilizer (PDS) device: (a) posterior view, (b) lateral view. The lateral view shows the location of the disc and PDS within the segment.

MATERIALS AND METHODS

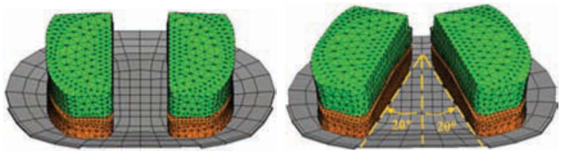
Finite Element Models of the Ligamentous L3-S1 Segment

Our lumbar spine FE model consists of a 3-dimensional element mesh of L3 through S1 and is an extension of the previously experimentally validated model in our laboratory.[40,51,50,53,54] ABAQUS/Standard version 6.5 (ABAQUS Inc, Providence, RI) was used to construct the model. A brief description of the model is presented in the next section.

Intact L3-S1 Finite Element Model

The FE model of intact spine used in our study included 27,540 elements and 32,946 nodes (Figures 3a and 3b). Digital computed tomography was used to scan a healthy ligamentous human lumbar spine without any abnormalities or deformities, including disc degeneration. Brick elements were used to define the mesh; the FE model was symmetric across the midsagittal plane.

Figure 3



Two views of the finite element (FE) model of intact ligamentous L3-S1 segment: (a) 3-dimensional view, (c) a midsagittal cross-sectional view of the model showing important anatomical features.

Table 1

Material Properties Assigned to Various Spinal Components in the Finite Element Model[55–58]

	Young's Modulus (MPa)	Poisson's Ratio
Cortical bone	12000.0	0.3
Cancellous bone	100.0	0.2
Posterior bone	3500.0	0.25
Annulus (ground)	4.2	0.45
Annulus (fiber)	175.0	. . .
Nucleus pulposus	1.0	0.499
Anterior ligament	7.8 (<12%), 20.0 (>12%)	0.3
Posterior ligament	10.0 (<11%), 20.0 (>11%)	0.3
Ligamentum flavum	15.0 (<6.2%), 19.5 (>6.2%)	0.3
Transverse ligament	10.0 (<18%), 58.7 (>18%)	0.3
Capsular ligament	7.5 (<25%), 32.9 (>25%)	0.3
Interspinous ligament	10.0 (<14%), 11.6 (>14%)	0.3
Supraspinous ligament	8.0 (<20%), 15.0 (>20%)	0.3

Material properties of the various tissues (Table 1) were selected from the literature, including from our own experimental data. A lordotic curve of approximately 27° was simulated across the L3-S1 level, with the mid L3-L4 disc plane kept horizontal. The vertebral bodies were defined as cancellous bone cores surrounded by a 0.5-mm-thick cortical shells.

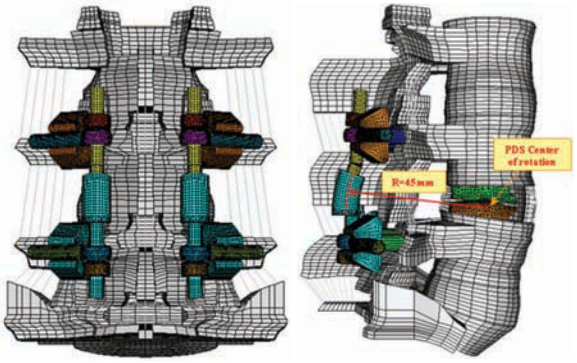
The intervertebral disc annulus was modeled as a composite of a solid matrix with embedded fibers (via the REBAR parameter) in concentric rings around a pseudofluid nucleus. All 7 major spinal ligaments were represented and assigned nonlinear material properties. Naturally changing ligament stiffness (initially low stiffness at low strains followed by increasing stiffness at higher strains) was simulated through the "hypoelastic" material designation, which allowed the definition of axial stiffness as a function of axial strain. Three-dimensional 2-node truss elements were used to construct the ligaments.

The apophyseal (facet) joints were simulated with 3-dimensional gap contact elements. These elements transferred force between nodes along a single direction as a specified gap between these nodes closed. The cartilaginous layer between the facet surfaces was simulated using the "softened contact" parameter, which exponentially adjusts force transfer across the joint depending on the size of the gap. An initial gap of 0.35 mm was specified as reported for cadaveric specimens. At full closure, the joint assumed the same stiffness as the surrounding bone.

Implanted Models

The intact L3-S1 model was modified to simulate several implanted models. The first set of models included the simulations for the PDS alone and the disc alone. Facets were removed to simulate bilateral facetetcomy in implanted models. The other simulations were for the 360° posterior motion preservation system (PDS plus artificial discs) in which disc were placed (a) both parallel to the midsagittal plane ("parallel"), (b) both angled 20° to midsagittal plane ("angled nonparallel"), and (c) one at 20° and one parallel to the midsagittal plane ("mixed nonparallel") (Figure 4). The solid models of implants were transferred into the commercial ABAQUS version 6.5 software. For these models, a pair of artificial discs was placed at the L4-L5 level using a posterior surgical procedure (removal of the entire nucleus, partial posterior annulus, posterior longitudinal ligament, and total bilateral facetectomy; all of the other ligaments were left intact). The superior and inferior surfaces of the upper and lower artificial disc components, respectively, were tied to the adjacent endplates to simulate solid fusion. The PDS devices were oriented parallel to one other with equal medial distance from midsagittal plane. The male and female parts on each side were anchored to L4 and L5 pedicle screws, respectively (Figures 2a and 2b).

Figure 4



Different artificial disc configurations simulated in the finite element (FE) models; (a) parallel to midsagittal plane, (b) 20° offset from midsagittal plane, (c) 20° offset and parallel to midsagittal plane.

The interaction property "HARD-CONTACT" in ABAQUS was used to define the interactions across the following:

1. Contact surfaces between superior and inferior artificial disc components

2. Male and female components in PDS

3. Ball-and-socket joint surfaces attached to the components in PDS

Boundary and Loading Conditions

The lowermost surface (bottom layer of S1) was fixed. Compressive loads were applied through evenly distributed concentrated loads on all uppermost L3 nodes. The load was kept normal to the vertebral body surface and, thus, acted as a follower load. A compressive force of 400 N and 10 Nm bending moment was applied to implanted and intact models to simulate physiological flexion, extension, lateral bending, and axial rotation motions. Motions at various levels were computed for all the cases and compared with the intact model. Stresses in various components of the systems also were investigated.

RESULTS

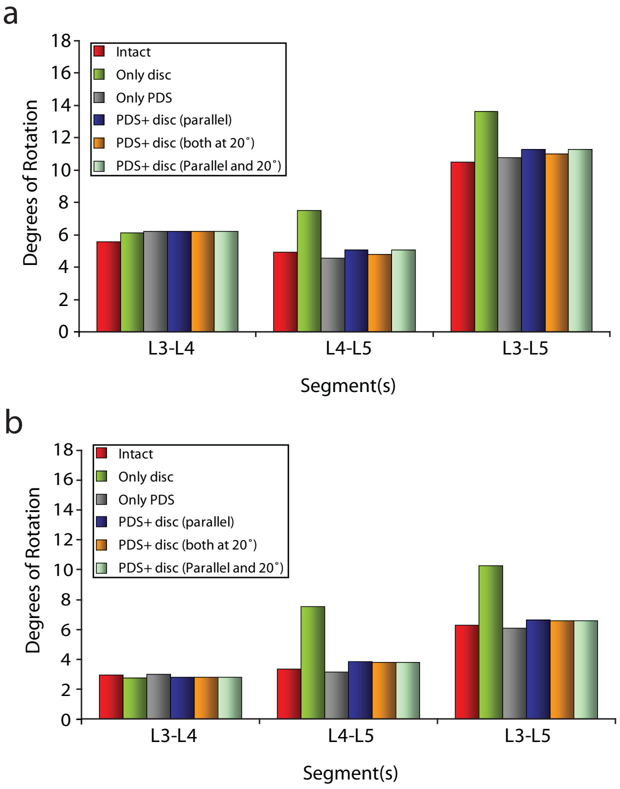
The PDS alone condition restored range of motion (ROM) to normal (Figures 5a and b). In models with the disc alone, ROM increased by approximately 3° in flexion and approximately 4° in extension, compared with the intact and PDS models. For the 360° posterior motion preservation models, the parallel condition had almost the same ROM as the nonparallel disc configurations. For example, in flexion, the motion of L4-L5 segment was approximately 5° for the intact and implanted models. At the adjacent segment, L3-L4, the motion was 5.5° for intact and 6.2° for implanted models. In extension, ROM for the intact and implanted models were similar (approximately 3.5°) at L4-L5, and 2.8° at L3-L4.

The maximum von Mises stresses in implants for each loading case are presented in Table 2. When the disc was simulated alone, stresses were relatively low compared to conditions with PDS and disc implanted together. For the parallel and mixed nonparallel disc placement conditions, the maximum stress in disc occurred in extension rather than flexion. For the angled nonparallel model, the discs had almost the same maximum von Mises stress in flexion and extension as in the parallel condition. The locations of maximum contact stress across the discs for various cases are shown in Figure 6.

DISCUSSION

We laid the foundation in our earlier studies for the idea that FE analyses and in vitro cadaveric testing are complementary techniques and, thus, are well suited to characterize the complex biomechanical behavior of the spine and its components, including internal stresses and strains.[40,51–53,59,60] Like cadaver investigations, FE models also have several limitations (e.g., they do not account for variations in the geometry of the specimens, such as facet orientations and material properties). However, for the dimensions of a given intact model, the predicted data are in reasonable agreement with the results from in vitro investigations. Thus, the use of an experimentally validated intact FE model can provide very useful information for the many clinical questions raised as total disc replacement continues to become more common in clinical practice. Many variables, such as effects on adjacent level degeneration, will take years or decades to define. The FE analysis allows for evaluation of motion and load changes that can be anticipated

Figure 5



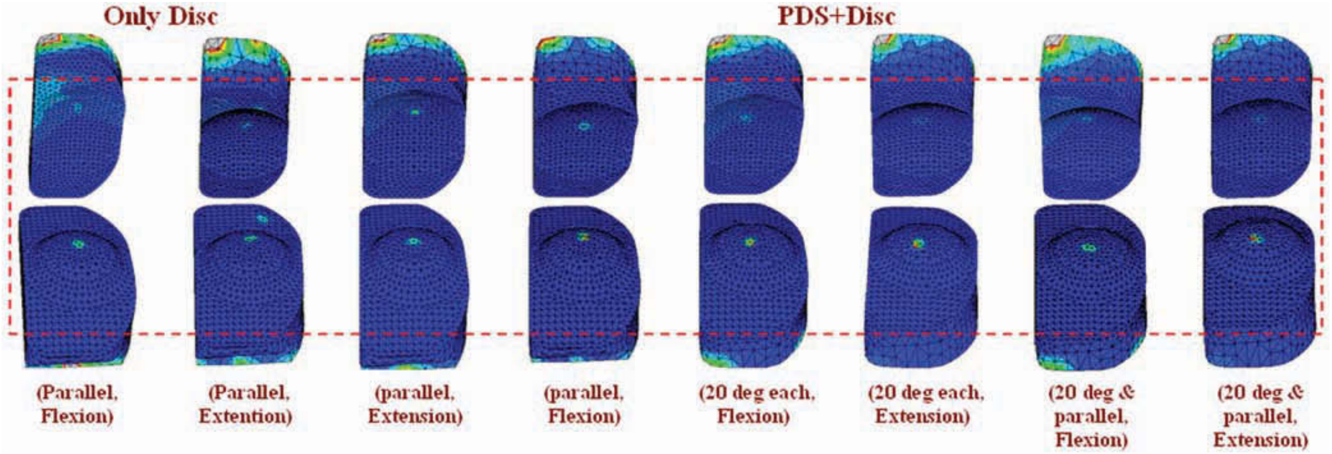
Motion at different levels in intact and implanted models: (a) flexion, (b) extension.

Table 2

Maximum Stresses in Implants in Different Models

Stress in Discs (Load: 400 N Compression + 10 Nm Bending)	Maximum Von Mises Stress (Mpa)	
	Flexion	Extension
Only disc	134.5	128.2
PDS + parallel discs	166.1	244.1
PDS + 20° angled discs	220.4	224.4
PDS + parallel and 20° angled discs	149.1	269.6

Figure 6



Location of maximum contact stresses between disc components for parallel and nonparallel disc configurations in flexion and extension modes (within the red box) (see Table 2 for the magnitude of the stresses).

and that can help predict potential effects of clinical scenarios and provide a relatively inexpensive tool for the design and development of an implant from its conception to prototype for further evaluation.

Our FE analysis indicates that the posterior disc alone cannot restore motion to the normal state. The use of a 360° motion preservation system (posterior disc replacement along with PDS) appears to restore kinematics of the spine to near normal. In the implanted models, the motion at a level adjacent to implanted level was nearly the same as the intact model. The results also show that the TruDiscPL discs function equally well when the discs are misaligned and not parallel to each other with regard to the midsagittal plane. This simulates their insertion from a far lateral transforaminal lumbar interbody fusion approach, where the midline is spared and the facet is removed to place the discs. This approach has additional advantages in that the neural structures need minimal retraction and there is a thorough decompression of the exiting nerves root. Placing discs exactly parallel to one other is very difficult in clinical practice, as magnetic resonance imaging scans of postoperative patients with implanted posterior lumbar interbody fusion cages have shown.

Posterior lumbar arthroplasty is a true total disc replacement and has several potential advantages over anterior lumbar arthroplasty (Table 3). Several other points are worthy of note when interpreting the results. Our results may be moderated in the presence of muscles, which were not simulated in this study. The FE analysis model validation was performed with specimens from cadavers aged more than 65 years. The surgical intervention, like pretension, may alter the biomechanics of the instrumented segment, in particular that of the annular and ligamentous structures. Our study did not address the effects of other surgical variables (e.g., size and position). The segment length included in the model was L3-S1. The extension of this model to the L1-S1 segment may provide further insight into the segment biomechanics. Thus, the current study results should be viewed as a comparative analysis between implanted and intact models.

Table 3

Comparison of Advantages and Disadvantages of Posterior and Anterior Lumbar Arthroplasty

Posterior Lumbar Arthroplasty With 360° Posterior Motion Preservation System	Anterior Lumbar Arthroplasty
Deals with all 3 pain generators: disc, nerve, and facet joint	Deals only with disc
Can be easily revised via an ALIF	Revision is difficult
Approach familiar to spine surgeons	Often needs a separate approach surgeon
Fewer contraindications than anterior arthroplasty	Applicable to a limited number of patients
Can be done even with facet degeneration	Facet degeneration a contraindication; postoperative facet pain a possibility

Note. ALIF = anterior lumbar interbody fusion.

Our study also suggests additional investigations dealing with other parameters and settings, such as size and different positioning of the discs inside the segment, as well as different settings of the PDS device, loading modes, other disc designs, and motion preservation systems to gain an in-depth understanding of the issues at hand.

In summary, posterior disc implantation alone is not effective in restoring motion to normal. A 360° motion preservation system consisting of posterior discs and PDS devices will not only restore motion to normal but also help address other limitations such as the facet pain that may result from anterior disc arthroplasty. Thus, 360° posterior lumbar arthroplasty offers several advantages over anterior arthroplasty (Table 3).

Additional studies, such as the cadaver evaluation and other FDA-suggested studies, are essential to lend further support to the design concept.[61]

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