Biomechanical effects of the Coflex™ implantation on the lumbar spine

A nonlinear finite element analysis

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ABSTRACT

الأهداف: دراسة آثار زراعة أداة كوفليكس (Coflex™) في القطع الفقرية وآثارها عليها وعلى القطع الفقرية المجاورة وذلك من الناحية الميكانيكية الحيوية.

الطريقة: أُجريت هذه الدراسة في قسم جراحة تقويم العظام بمعهد شنغهاي لجراحة العظام والكسور في مستشفى رويجين، شنغهاي، الصين وذلك خلال الفترة من سبتمبر 2009م إلى مايو 2010م. لقد قمنا باستخدام النموذج الحاسوبي ثلاثي الأبعاد للقطع الفقرية (L3–S1 segment) وذلك لتمثيل وتحليل السلوك الميكانيكي الحيوي للقطع الفقرية التي زُرعت فيها الأداة ولتمثيل السلوك الميكانيكي الحيوي للقطع الفقرية السليمة التي لم تُزرع فيها الأداة وذلك بعد التأكد من صحة هذا النموذج. وقد تم تعريض هذا النموذج لأنواع مختلفة من الحمل المُحاكى وهي: الثني، والتمدد، والانحناء الجانبي، والتدوير المحوري.

النتائج: أشارت الدراسة بأن كلاً من حركة القطع الفقرية، والضغط ما بين الأقراص، وقوة ضغط مفصل الوجيه في القطع الفقرية المُجاورة للقطع التي زُرعت فيها أداة كوفليكس لم تتأثر كثيراً بزرع هذه الأداة. لقد انخفض مدى الحركة أثناء التمدد انخفاضاً ملحوظاً في القطع الفقرية التي زُرعت فيها الأداة لتصبح بذلك مثل القطع الفقرية السليمة. بالإضافة إلى ذلك فقد تم ملاحظة انخفاضاً ملحوظاً في الضغط ما بين الأقراص أثناء التمدد، وكذلك انخفاضاً في قوة ضغط مفصل الوجيه أثناء التمدد، والانحناء الجانبي، والتدوير المحوري وذلك في القطع الفقرية التي زُرعت فيها الأداة بالمقارنة مع القطع الفقرية السليمة.

خاتمة: تشير هذه الدراسة بأن لزرع أداة كوفليكس في القطع الفقرية تأثيراً فعالاً في تخفيف الحمل على الأقراص أثناء التمدد، وكذلك تخفيف ضغط مفصل الوجيه أثناء التمدد، والانحناء الجانبي، والتدوير المحوري من دون التأثير على القطع الفقرية المُجاورة وذلك في النماذج الحاسوبية المُحاكية لفيسيولوجية القطع الفقرية البشرية.

Objectives: To evaluate the effect of the stabilization of the CoflexTM device on the biomechanical behavior of the instrumented and adjacent spinal segments.

Methods: The study was carried out at the Department of Orthopedics, Shanghai Institute of Traumatology and Orthopedics, Ruijin Hospital, Shanghai, China between September 2009 and May 2010. Upon validation, a finite element model of L3-S1 segment was developed to simulate and analyze the biomechanics of the intact and Coflex™ implanted states subjected to simulate loading of flexion, extension, lateral bending, and axial rotation.

Results: This study predicted that the segmental motion, intradiscal pressure, and facet contact force at the levels adjacent to the Coflex™ implanted level were not significantly affected by the implantation of Coflex™ device. There was a significant decrease in range of motion in extension at the instrumented level of the Coflex™ implanted model relative to the intact model. Furthermore, the level implanted with Coflex™ device showed a significant decrease in intradiscal pressure in extension and a decrease in facet contact force in extended, lateral bending and axial rotational conditions, compared with the intact model.

Conclusions: This study suggests that the Coflex™ device has the potential of effectively unloading the disc in extension and the facet joints in extension, lateral bending, and axial rotation at the Coflex™ implanted level, without deleterious effects on the adjacent segments under the simulated physiological condition.

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Many patients experience discogenic low back pain at some point in their life.[1] Surgical procedures have been indicated in patients who fail to respond to conservative treatment.[1] As a commonly employed operation of the spine, fusion is intended to relieve low pack symptoms secondary to instability.[2] However, numerous patients with low back pain fail to improve symptoms after a successful lumbar fusion.[3] Some studies indicated that the abnormal load transmission across a degenerated lumbar disc rather than the abnormal motion at a symptomatic segment was a possible mechanism for the development of low back symptoms.[4,5] Alteration of the load transmission across the degenerated disc may be a beneficial strategy for treating low back pain. Such strategy could be achieved without the significant loss of the normal spinal kinematics based on the concept of dynamic stabilization.[2,6] Dynamic stabilization devices may alter the load transmission so that certain postures causing low back symptoms are more tolerable, and may lightly limit motion so that painful positions are not experienced.[3] The "U" shaped Coflex™ device (Coflex™, Paradigm Spine, New York, USA) is a typical dynamic stabilization device, and has recently been used to treat low back pain.[7,8] Some short-term clinical results for the Coflex™ implantation appeared to be comparable to those for the fusion.[1,8] However, few reports were related to the biomechanical effects of the Coflex™ implantation on the instrumented and adjacent levels. The target of this study was to investigate the changes in the biomechanical behavior of the lumbosacral spine subject to the implantation of the Coflex™ device under several loading conditions. To this purpose, a finite element study was conducted using 3-dimensional computer models of the L3-S1 spinal unit to simulate the intact condition and the implantation of the Coflex™ device. Simulations were performed by imposing various loading conditions.

Methods. This study was carried out at the Department of Orthopedics, Shanghai Institute of Traumatology and Orthopedics, Ruijin Hospital, Shanghai, China between September 2009 and May 2010. The Institutional Ethics Committee believed this research was only a computer simulation study, and therefore did not need formal ethical approval.

Intact model. A 3-dimensional nonlinear finite element model of a L3-S1 segment was created as an intact model employed for the reference. The geometry was taken from computed tomography (CT) scans. A commercial software (ABAQUS, Inc., Pawtucket, RI, USA) was used to model the osseoligamentous lumbosacral segment. The model components consisted of vertebral body, intervertebral discs, posterior elements, anterior longitudinal ligament, posterior longitudinal ligament, interspinous ligament, supraspinous ligament, ligamentum flavum, and capsular ligaments. The vertebral body was modeled to have a cancellous core covered with the peripheral cortical bone.[9] The bone structure was assumed as a homogeneous material with a symmetric elasto-plastic material law (Johnson-Cook) allowing computing von Mises hardening with extensile damage until potential rupture.[10] Cartilaginous endplates were assumed to overlay the superior and inferior surfaces of the intervertebral disc.[9] The nucleus pulposus was modeled as an almost incompressible continuum, with elastic modulus 1MPa and Poisson ratio 0.499.[9] The annulus was modeled as a composite material according to the previous studies (**Figure 1a**).[11] The 8 layers of annulus fibrosus were modeled by the truss elements in radial directions, and embedded in a matrix of annulus ground substance.[11] The orientation of the fibers varied between 24° and 45° to the transversal plane from the outermost to the innermost annulus region.[11] The fibers were defined as the nonlinear material with an increase in stiffness from the inner layer to the outer layer.[11,12] The models of the nucleus, the annulus, and the vertebrae were assembled with the interacting surfaces defined by tie constraints. To simulate the mechanical behaviors of the facet joints, the frictionless nonlinear contact condition was defined between the surfaces of articular facets.[12] The intervertebral ligaments were modeled as bundles of nonlinear springs based on the biomechanical properties of the ligaments. The nonlinear behavior assumed for the ligaments was only to sustain tensile load, just as most collagen-based tissues.[13] The elements used in the model are summarized in **Table 1**. The material properties of the different tissues were adopted from literatures.

Coflex™ implanted model. The Coflex™ implanted model incorporated the insertion of the Coflex™ device between the spinous processes of the 2 vertebraes (**Figure 1b**). The Coflex™ device shown in **Figure 1c** is made of titanium (Ti6A14V).[14] The geometry and mobility of the Coflex™ device were taken from several actual Coflex™ device currently used in clinical trials. The Coflex™ implanted model was achieved by removing the interspinous ligament at the L4-L5 level, and the properly positioning of this implant with its apex at the facet level. The 4 lateral wings of this implant were tightly crimped on the upper and lower ends of the spinous processes. A Boolean operation was performed to ensure the geometric congruence between the Coflex™ device and the adjacent spinous processes.[15] A high friction contact was assumed at the bone/implant interface.[16] The defect was created by removing bilateral partial lamina and ligamentum flavum to simulate the

spinal canal lateral posterior decompression. Static simulations were carried out by assuming the loading and boundary conditions similar to the intact model.

Boundary and loading condition. In the 2 models, the translational degrees of freedom of the inferior surfaces of the lowermost vertebra had been completely restricted. The intact and the instrumented models were simulated under the load control rather than the displacement control, as suggested by Schmoelz et al.[6] To simulate the physiological conditions, a set of loads was applied to the upper surface of the uppermost vertebral body for the 2 models. In all cases, the 10 N m flexion, 10 N m extension, 10 N m torsion, and 10 N m lateral bending pure moments were applied to the center of the superior surface of L3 vertebral body. The main parameters investigated through the finite element analysis were the intervertebral angular displacements in the 3 main motion planes (flexion, extension, lateral bending, and axial rotation), the intradiscal pressure and the peak contact force on the articular facets. For validation of the Coflex™ implanted model, the other set of loads was applied to the implanted model with 7.5 Nm of pure moment in various loading modes.

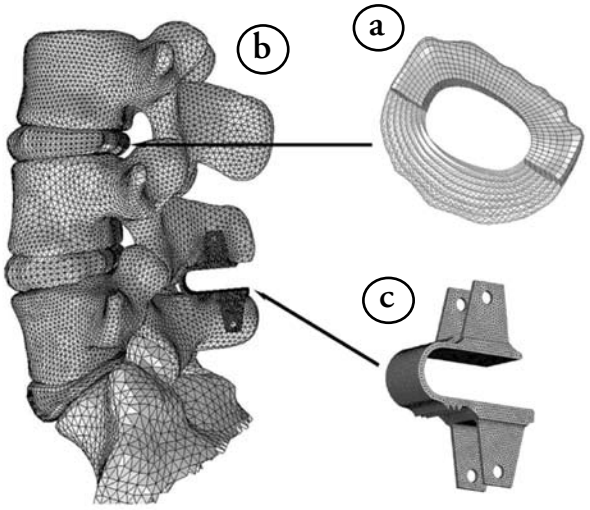

Figure 1 - Three-dimensional finite element model showing **a**) 2 components of the annulus fibrosus shown for the L3-L4 disc, the ground substance and the embedded collagen fibers; **b**) the lumbosacral spine implanted Coflex™ device at L4-L5; **c**) the Coflex™ device.

Results. ***Model validation.*** In a prior study, the finite element model was validated with or without the implantation of the Coflex™ device. The minimum and maximum difference in range of motion (ROM) at all levels between the intact model and various reported data[16-18] were 0.23° and 1.49°. The discrepancy in ROM of the intact model from in vitro or validated finite element method data may likely be due to the consistent differences in the anatomy and biomechanical behavior of spine among individuals. Range of motion at the instrumented level of Coflex™ implanted model was validated with previous cadaveric in vitro tests.[19] The current instrumented model showed slightly stiffer behavior in lateral bending motion compared with the data from the study by Wilke et al.[19] Apart from the lateral bending, the flexion, extension and axial rotation motions at the instrumented level obtained from the current model were within standard deviation of the in vitro study.

Range of motion. For the Coflex™ implanted model, ROM at the instrumented level changed by -11.5% in flexion, -53.2% in extension, -3.4% in lateral bending, and -6.2% in axial rotation, compared with the intact model (**Figure 2a**). Range of motion at the adjacent L3-L4 level changed by +2.3%, +2.6%, +1.6% and +4.5%, and, at the L5-S1 level, it changed by +1.2%, -1.4%,

Table 1 - Material properties and elements assumed for the constitutive parts of the intact and Coflex™ implanted models.

Material properties	Young's modulus E (MPa)	Poisson ratio	Element type	References	Years
Endplates	500	0.25	Tetrahedron	Lee et al[9]	2004
Cortical bone	12,000	0.3	Tetrahedron	Chen et al[18]	2001
Cancellous bone	100	0.2	Tetrahedron	Chen et al[18]	2001
Annulus ground substance	4.2	0.45	Tetrahedron	Lee et al[9]	2004
Annulus fiber layers 1-2 (outermost)	550	0.3	Truss	Denozière et al[12]	2006
Annulus fiber layers 3-4	485	0.3	Truss	Denozière et al[12]	2006
Annulus fiber layers 5-6	420	0.3	Truss	Denozière et al[12]	2006
Annulus fiber layers 7-8 (innermost)	360	0.3	Truss	Denozière et al[12]	2006
Nucleus	1	0.499	Tetrahedron	Lee et al[9]	2004
Ligament	Nonlinear		Spring	Rohlmann et al[13]	2005
Coflex™ device (Titanium)	110, 000	0.3	Tetrahedron	Vena et al[14]	2005
Posterior elements	3,500	0.25	Tetrahedron	Lee et al[9]	2004

-1.8% and +2.7% in flexion, extension, lateral bending and axial rotation respectively (**Figures 2b & 2c**).

Intradiscal pressure. The predicted values of average intradiscal pressure in this simulation are shown in **Figure 3**.

For the Coflex™ implanted model, the intradiscal pressure at the instrumented level decreased by 69.7%, (extension -8.2%, flexion -1.1%, and lateral bending and axial rotation -3.4%), relative to the intact model. The intradiscal pressure varied within 5% at both adjacent levels, which were –2.3%, -3.7%, +1.1%, and +2.6% at L3-L4, and -0.4%, +1.1%, +1.8%, and +1.4% at L5-S1 in flexion, extension, lateral bending and axial rotation respectively, compared to the intact model. In addition, numerical results in terms of von Mises stress predicted a significant reduction in the posterior parts of the annulus fibrosus of the L4-L5 segment during extension, for the Coflex™ implanted model, as compared with the intact one (**Figure 4**).

Peak facet contact force. In this simulation, the peak facet contact forces were only predicted in extension, lateral bending, and axial rotation at 3 levels. The predicted values of facet contact forces at the instrumented level and the adjacent levels are shown in **Figure 5**. For the Coflex™ implanted model, the peak facet contact forces varied within 5% at the inferior adjacent level, which were -2.4% in extension, -1.8% lateral bending, and +2.3% in in axial rotation compared to the intact model. At the adjacent level L3-L4, the peak facet contact forces were increased by the implantation of the Coflex™, especially for extension (increased by 8%). At the instrumented level, the peak facet contact forces decreased by 65.9% in extension, 9.1% in lateral bending, and 11.1% in axial rotation, which are relative to the intact model.

Discussion. In this study, a 4-level lumbosacral spine finite element model was established to investigate the biomechanical effects of the Coflex™ implantation on the lumbar spine. This simulation predicts that the Coflex™ implantation does not significantly alter the kinematics, the intradiscal pressures, and facet contact forces at the adjacent levels, whereas it can effectively unloads the intervertebral disc and facet joints at the instrumented level in the extended positions. The numerical results of this study predict that the kinematics of spine at the instrumented level is influenced by the biomechanical interaction of the Coflex™ device, especially in extension and flexion. The overall trend in the motions at the instrumented level of the current model is in a good agreement with that in Wilke's study.[19] In a clinical study, Kong et al[1]

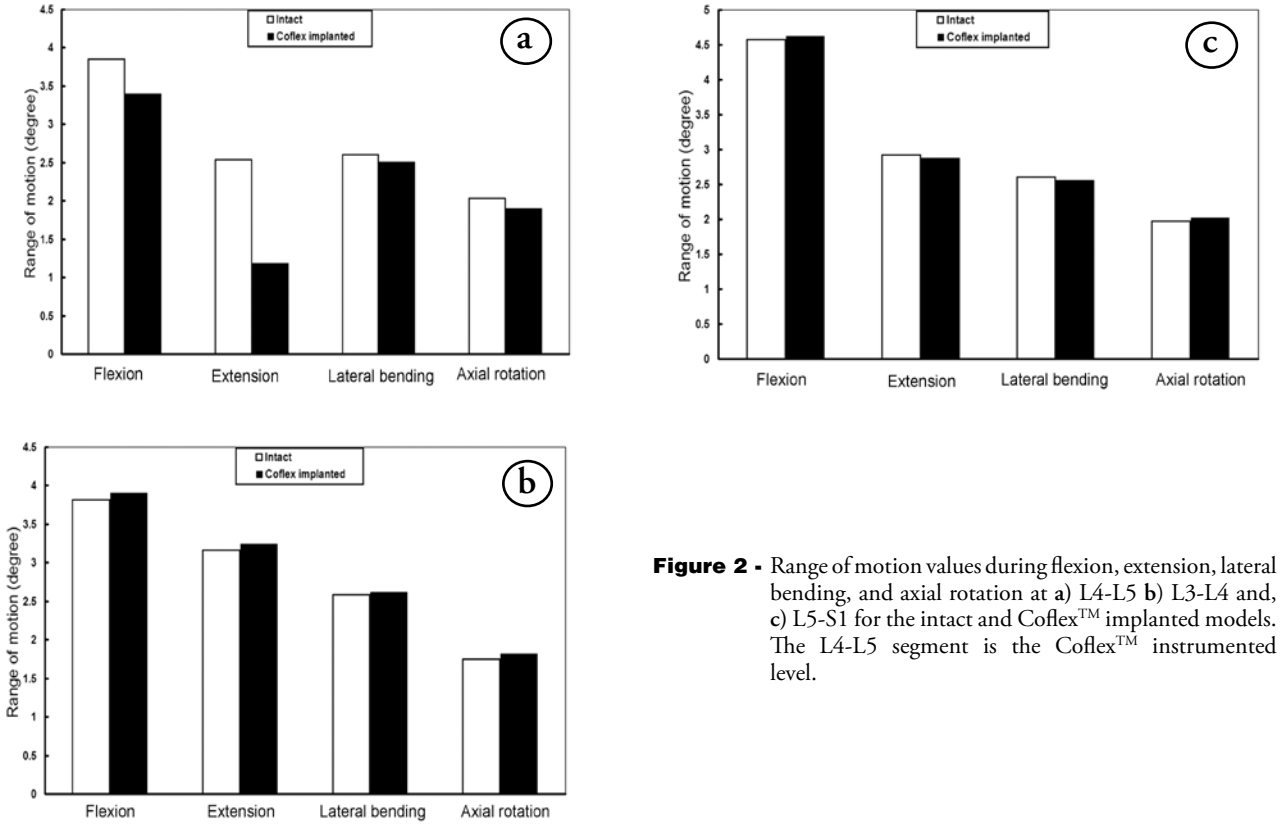

Figure 2 - Range of motion values during flexion, extension, lateral bending, and axial rotation at **a**) L4-L5 **b**) L3-L4 and, **c**) L5-S1 for the intact and Coflex™ implanted models. The L4-L5 segment is the Coflex™ instrumented level.

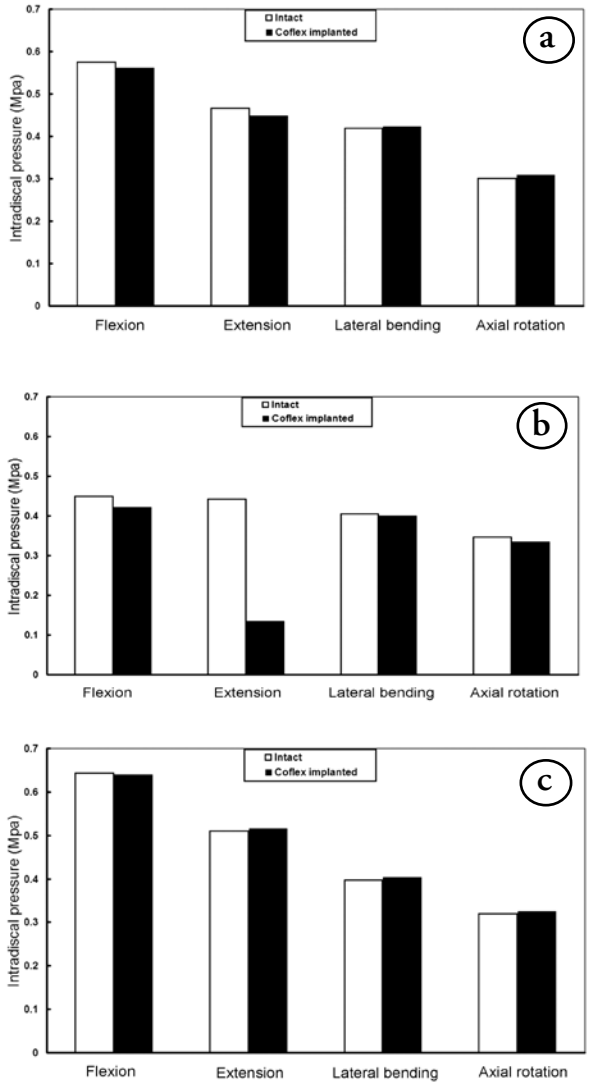

Figure 3 - Comparison of the predicted average intradiscal pressure between the 2 models during flexion, extension, lateral bending, and axial rotation at **a**) L4-L5, **b**) L3-L4 and, **c**) L5-S1. The L4-L5 segment is the Coflex™ instrumented level.

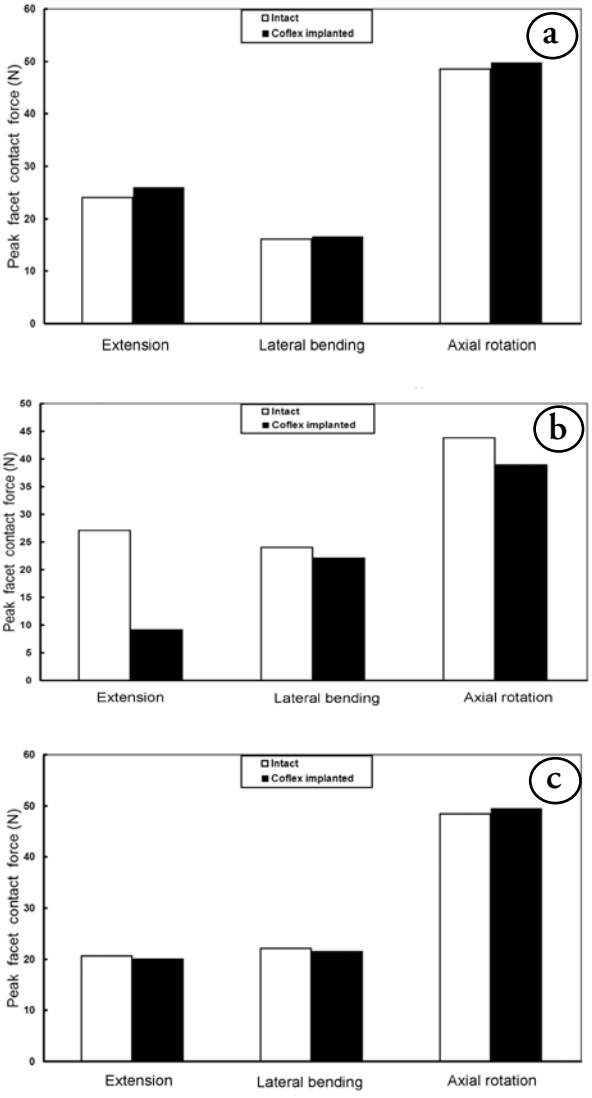

Figure 5 - Comparison of the predicted peak facet contact forces between the 2 finite element models during extension, lateral bending, and axial rotation at **a**) L5-S1, **b**) L3-L4, and **c**) L4-L5. The L4-L5 segment is the Coflex™ instrumented level.

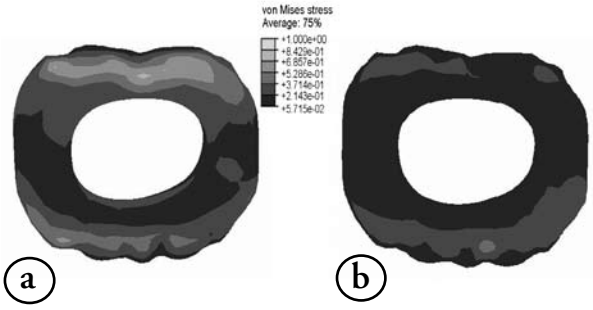

Figure 4 - Von Mises stress distributions of the annulus fibrosus at L4-L5 during extension, for the a) intact and b) Coflex™ implanted model.

found the Coflex™ device implantation significantly decreased the ROM in the extension-flexion plane at the Coflex™ instrumented level based on the radiological outcomes. This is identical with the present study. With regard to the adjacent segment motions, the Coflex™ implanted model shows that the variations in the ROM in all motion planes were less than 5% at the adjacent levels compared with the intact model. These results are similar to the findings by Kong et al.[1] They compared the preoperative and postoperative ROM via radiological method.[1] They found the ROM changes following the Coflex™ device implantation at the levels adjacent to the Coflex™ implanted level did not reach significance.[1] The numerical results of this study predict

that the implantation of the Coflex™ device reduces the intradiscal pressure at the implant level in extension and flexion, as well as the peak facet contact forces at the instrumented level in extension, lateral bending, and axial rotation. Especially, the implanted Coflex™ device significantly unloads the disc and facets at the implant level in the extended position. This means that portion of the load shifted posteriorly, and the Coflex™device shares the load with the intervertebral disc and the facet joints. Unloading the posterior annulus (**Figure 4**) and the lumbar facet joints as a result of the Coflex™ implantation may be beneficial to alleviate the pain caused by the overloading across the degenerative disc and facets.[3,20] The clinically observed increase in the disc height following the surgical implantation of the Coflex™ device further indicates that this implant may have the biomechanical ability of unloading the disc and facets.[1,8] At the superior intact level L3-L4, this simulation predicts that a rise in peak facet contact force in extension, lateral bending and axial rotation, accompanied by a slight reduction in terms of intradiscal pressure in flexion and extension. This may be related to the modification of the motional angles of the spinal segments after the insertion of this implant. These undesired changes appear minor, therefore, may or may not lead to degeneration at the adjacent level.

In comparison with fusion, the Coflex™ device may stabilize the motion segment of spine, without the deleterious effects on adjacent spinal segments and the significant loss of motion caused by spinal fusion surgery.[3,7] As a result, the Coflex™ device may be a promising alternative method for the treatment of discogenic low back pain. Some encouraging clinical outcomes for the treatment of low back pain with the use of the Coflex™ implantation appeared to further support the clinical application of this device.[1,8]

This study focused on the biomechanical effects of the insertion of the Coflex™ device itself on the healthy L3-S1 segment. Commonly, the spinal segments of the patients with low back pain treated by the Coflex™ device are under a degenerative state.

To investigate the effects of the Coflex™ device implantation on the degenerated spinal segments, further study is needed to compare the different degenerative states.

The limitation of this finite element model is related to the assumed loading conditions. To better understand the biomechanical effects of the Coflex™ device implantation, further researches should be needed to take the involved musculoskeletal system into consideration and simulate the lumbar spine under a hybrid loading condition, which may be more approximate to the in vivo condition.

In conclusion, the predicted results suggest that the Coflex™ device is capable of unloading the disc in extension, and the facet joints in extension, lateral bending and axial rotation at the Coflex™ instrumented level effectively, but has minor effects on ROM and intradiscal pressure in lateral bending and axial rotation. The adjacent segments do not seem to be significantly influenced by the implantation of the Coflex™ device under the described loading conditions. The models used in current study may be promising in future work to assess potential biomechanical effects of various existing devices and improve the design of new dynamical stabilization system, as well as the simulation of the device implantation.

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