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BIOMECHANICAL COMPARISON OF THE COFLEX® AND COFLEX® RIVET DEVICES USING FINITE ELEMENT METHODS

COFLEX VE VİDALI COFLEX'İN SONLU ELEMENLAR MODELİYLE BİYOMEKANİK OLARAK KARŞILAŞTIRILMASI

Ali Kh. ALİ[1],
Ahmet KULDUK[1],
Murat SONGÜR[2],
Necdet ALTUN[1],
Alpaslan ŞENKÖYLÜ[1]

[1]Gazi University Medical School, Orthopedics and Traumatology Department., Ankara
[2]Bülent Ecevit University, Medical School, Orthopedics and Traumatology Department, Zonguldak

SUMMARY

The aim of this study was to analyze the effect of two popular interspinous devices (Coflex® and Coflex® Rivet), considering the range of motion and disc loading characteristics at surgical and adjacent segments, with the finite element method (FEM).

Three functional spinal units in the lumbar region (L3–4 and L4–5) were modeled by FEM. Then, the Coflex® and Coflex® Rivet interspinous devices were modeled and implanted virtually at the L4–5 segment of the lumbar vertebrae by FEM. Flexion, extension, bending, and rotation forces were applied to these two models and one intact vertebral model. The range of motion and disc loading forces at the L3–4 and L4–5 levels were measured and compared in these three models.

There were four main findings of this study: (1) The Coflex® Rivet device provided stability in all movement directions while allowing a range of motion, especially flexion; (2) Coflex® Rivet decreased disc loading as well as range of motion in all plains at the surgical segment; (3) Coflex® Rivet decreased the range of motion and annular stress in the upper adjacent segment; (4) Both devices decreased the range of motion and annular stress in extension, bending, and rotation in both the surgical and upper adjacent segments.

In conclusion, the Coflex® Rivet device decreases the disc loading and range of motion at both the surgical and upper adjacent segments, in comparison with the original Coflex® device in flexion. In extension, bending and rotation, both devices show similar biomechanical characteristics for the same functional spinal units.

Key words: Degenerative disc disease, non-fusion techniques, posterior dynamic stabilization, Coflex®, Coflex® Rivet, finite element model.

Level of evidence: Biomechanical experimental study, Level II

ÖZET

Bu çalışmada interspinöz sistemlerden Coflex® Cihazı ile stabilize edici etkisi daha çok olduğu düşünülen Vidalı Coflex® cihazının alt lomber omurgada eklem hareket açıklığına ve disk yüklenmesine etkilerinin sonlu elemanlar modeliyle (SEM) biyomekanik olarak değerlendirilmesi amaçlanmıştır.

Öncelikle üç adet lomber vertebra (L3-L4-L5) SEM ile modellendi. Bu model üzerinde L4 - L5 spinöz çıkıntılar arasına Coflex® cihazı modellenerek sanal olarak uygulandı. Ardından yine L4-5 seviyesine Vidalı Coflex® modellenerek sanal olarak yerleştirildi. Enstrümante edilmeyen bir model ve enstrümante edilen iki adet modele fleksiyon, ekstansiyon, eğilme ve rotasyon yönünde sanal kuvvetler yüklendi. Her üç modelde L3-4 ve L4 - 5 disklere binen yükler sanal olarak ölçüldü. Yine L3-4 ve L4-5 segmentlerindeki hareket açıklığı da üç planda incelenerek, sonuçlar karşılaştırıldı.

Çalışmada dört temel sonuca varıldı. Bu temel sonuçlar; (1) Vidalı Coflex® özellikle fleksiyonda daha belirgin olmak üzere tüm hareket yönlerinde stabiliteyi sağlar, (2) tüm hareket yönlerinde cerrahi segment diskine binen yük vidalı Coflex® örneklemesinde daha az olduğu tespit edilmiştir, (3) fleksiyon hareketi dâhil olmak üzere vidalı Coflex® üst komşu segmentte Coflex® cihazına göre hem diske binen yükü hem de hareketliliği azaltmıştır, (4) her iki sistemde de fleksiyon hareketi dışındaki tüm hareket yönlerinde üst komşu segmente hem binen yükü ve segment hareketini azaltmaktadır.

Bu çalışmada alt lomber vertebralarda fleksiyon hareketinde kullanılan vidalı Coflex® cihazının, original Coflex® cihazına göre hareket açıklığını ve disk yüklenmesini hem cerrahi segmentte hem de üst komşu segmentte belirgin olarak azalttığı bulunmuştur. Her iki cihazın da omurganın ekstansiyon, eğilme ve rotasyon hareketlerinde birbirine belirgin üstünlüğü olmadığı görülmüştür.

Anahtar Kelimeler: Dejeneratif disk hastalığı, non-füzyon teknikler, dinamik stabilizasyon, Coflex®, vidalı Coflex™, sonlu elemanlar modeli

Kanıt Düzey: Biyomekanik deneysel çalışma, Düzey II

Address: Alpaslan Şenköylü, Gazi Üniversitesi Tıp Fakültesi Ortopedi ve Travmatoloji A.D., Beşevler, Ankara
E-mail: drsenkoylu@gmail.com
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INTRODUCTION:

Non-fusion methods include prosthesis methods, total disc prosthesis, NP prosthesis and posterior stabilization devices. Posterior stabilization devices are divided into two groups, pedicle screw-based systems and interspinous tools. It has been suggested that these systems have advantages such as protection of a range of motion, restoring natural disc height, correction of spinal layout, reduction in lower back pain and prevention of adjacent segment degeneration[4,10].

Coflex® is one of the most commonly used interspinous devices. The Coflex® interspinous system is in the shape of a U, and designed to resist physiological loads on the vertebrae[6].

The Coflex® Rivet system is a modified form of the Coflex® system, to increase its stability. When the Coflex® Rivet device is placed, adherence to spinous projections is provided by screws and nuts instead of tightening clamps[3].

Almost all flexible systems defined as potential dynamic stabilizers in recent years have inadequate data regarding their biomechanical purposes. Therefore, there are questions about the clinical effects of these devices, and the biomechanical principals and mechanisms of their designs[9].

A finite element model (FEM) is a computer model that defines the physical properties of any structure. A structure is divided into simple units called elements, and then all elements are transformed into a solid model. These elements are combined and a whole model is constructed[7].

The aim of this study was to compare the effects of the Coflex® and Coflex® Rivet interspinous system devices, considering which has more biomechanical stabilization impact on a range of joint motion and disc loading at the lower lumbar vertebrae, using a finite element model (FEM).

MATERIALS AND METHODS:

First, three lumbar vertebrae (L3, L4 and L5) were modeled using FEM. One Coflex® system (Paradigm Spine, LLC, New York, NY) was modeled and applied between the L4–5 spinous projections in this model. Then, one Coflex® Rivet system (Paradigm Spine, Wurmlingen, Germany) was placed at the same level. Virtual forces for flexion, extension, rotation, and bendingwere loaded into the one model without instrumentation and the two models with instrumentation. In these three models, the loading on the L3–4 and L4–5 discs was virtually measured. Also, the range of motion at the L3–4 and L4–5 levels was investigated separately in these three models, and the results were compared.

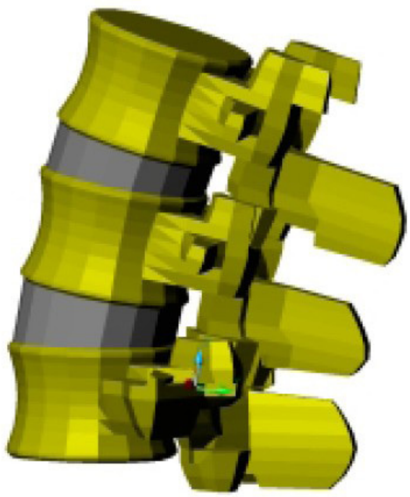
Intact Lumbar Vertebrae SEM:

A male cadaver found in the database of the Visible Human Project (National Library of Medicine, National Inst. of Health, U. S. A.) was transformed into a surface model with CT, MRG and colorful screenings using the 3D-Doctor 3.5.050106 software (Able Software, USA). A solid model was obtained from this surface model using Autodesk AutoCAD 2005 (Autodesk, Inc., USA) (Figure-1).

This solid model was transferred into the Ansys 12.0.1 software (Ansys Inc., USA). A lumbar vertebral FEM includes vertebrae, intervertebral discs, end plates, and posterior elements and ligaments (supraspinous and interspinous ligaments, ligamentum flavum, transverse ligament, posterior longitudinal ligament, and anterior longitudinal ligament).

The material properties were accepted as isotropic and homogenous, and the necessary data were obtained from the literature(Table-1)[12].

Figure-1. Solid model



Ligaments were modeled as two-point elements counteracting to pulling, and the locations were arranged according to anatomical data obtained from the literature. Ligament sectional areas were taken from the literature and are described in Table-1.

For modeling the cortical bone, cancellous bone, end plates, and discs, 20-point elements were used. The annulus fibrosis was composed of layers that were placed at a 30° angle to each other and responded only to pulling. These layers were embedded into the filler material as seven layers. To identify these layers, reinforcement element modeling of the Ansys program was used.

Material	Young module	Poisson constant	Section area
Cortical bone	120000	0.3	-
Cancellous bone	100	0.2	-
Posterior elements	3500	0.25	-
İntervertebral **Disc**			
Nucleus	1	0.499	
Ground substance	4.2	0.45	
Annulus fibers	450	-	0.76
End plate	24	0.4	
Ligaments			
ALL	20	-	63.7
PLL	20	-	20
TL	58.7	-	3.6
LF	19.5	-	40
ISL	11.6	-	40
SSL	15	-	30
KL	32.9	-	60
Titanium	110000	0.28	-

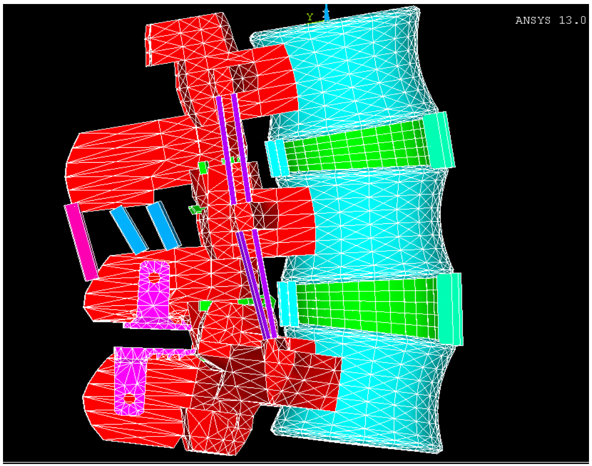
Table-1. ALL: Anterior longitudinal ligament, PLL: Posterior longitudinal ligament, TL: Transverse ligament, LF: Ligamentum flavum, ISL: İnterspinous ligament, SSL: Supraspinous ligament, KL: Capsular ligament (Vadapalli S, Sairyo K, Goel VK, Robon M, Biyani A, Kandha A, et al. Biomechanical rationale for using polyetheretherketone (PEEK) spacers for lumbar interbody fusion – A finite element study. Spine 2006, vol 31, no 26, p E993).

The facet joint was modeled as a non-linear 3D contact area that had 0.1 friction-constant and surface-to-surface friction. 0.5 mm distances were defined between the facet joint surfaces.

The interspinous tool was modeled as titanium. An 8 mm length was used, suitable to the vertebrae modeled in the FEM (Figure-2). The Coflex® Rivet differs from the original Coflex® device in that clamps are attached to the spinous projection using two screws.

In modeling, solid180, link180, reinf265, targe170 and conta174 solutions were used for solid elements, connections, annulus fibers, and interacting surfaces, respectively.

Figure-2. FEM-simulated Coflex® device



The intact model was composed of 77,283 connection points and 48,173 elements. The Coflex®-applied model was composed of 71,594 connection points and 43,076 elements[1,12].

Coflex® interspinous device modelling:

To model a Coflex® device, interspinous and supraspinous connections between the L4 and L5 segments were removed operatively. An 8 mm length of material present on the market in five different lengths, 8–16 mm, was used due to its compliance to the FEM interspinous space. The device was modeled as titanium, and the Young module was accepted as 110 GPa and the Poisson ratio as 0.3.

A surface-to-surface interaction was provided between the spinous projections and the wings of the Coflex® device. The friction constant between the wings and spinous projections was taken as 0.8 and the effect of the teeth on the wings was reduced. For the remaining parts, the friction constant was taken as 0.1.

Coflex® Rivet modeling:

The Coflex® Rivet differs from the original Coflex® device in that clamps are attached to the spinous projection using two screws. The device was modeled as titanium, and the Young module was accepted as 110 GPa and the Poisson ratio as 0.3. Screws were made in the forms of cylinders and placed into the holes on the clamps. During implementation of the ANSYS program, the degrees of node freedom of the screws were maintained as compatible with the freedom of node on the Coflex® and spinous projection (Figure-3).

Limitation and Loading Conditions:

The L5 vertebral base was locked in every direction. In line with the indications in the literature, 6N moments were applied to simulate 400N loading, flexion, extension, bending, and axial rotation for axial compression. The model was analyzed to obtain the amount of movement at the L4–5 segment and the Von Mises stress distribution on the L4–5 disc and upper adjacent segment (Figure-4).

Figure-3. FEM-simulated Coflex® Rivet device

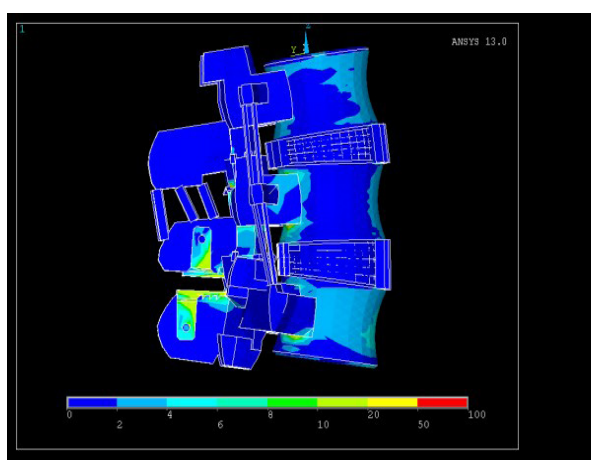
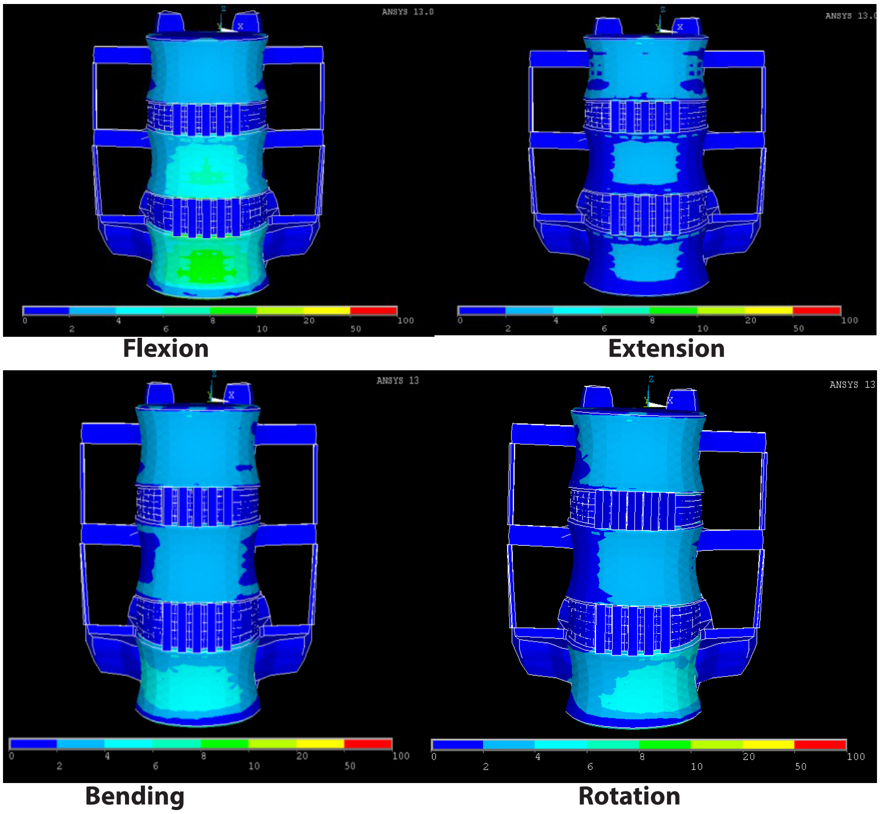


Figure-4. Front view of all movements after loading in the Coflex®-applied model



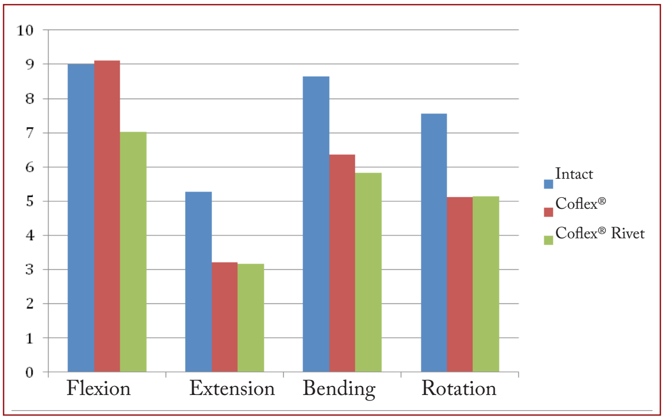
RESULTS:

The results were compared in terms of range of motion, disc loading, and the effect on the upper adjacent segment. These comparisons were evaluated separately for four main movements of the vertebrae: flexion, extension, bending, and rotation.

The results of disc loading and range of motion in the surgical segment:

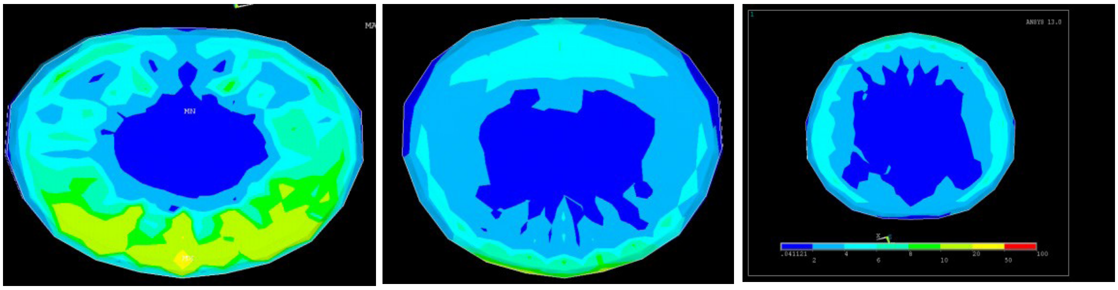
The effect of the applied implants on disc loading was investigated with the FEM model and the results were compared with the normal loading values obtained for an intact vertebra (Figure-5).

Figure-5. The comparison of the effects of all movements on disc loading in terms of Mpa



On flexion, it was recorded as an average of 8.98 MPa in a normal disc, 9.11 MPa with Coflex® and 7.03 MPa with Coflex® Rivet. According to these data, it was observed that Coflex® increased the load on the disc at a ratio of 1%, and Coflex® Rivet reduced the load on the disc at a ratio of 22% (Figure-6).

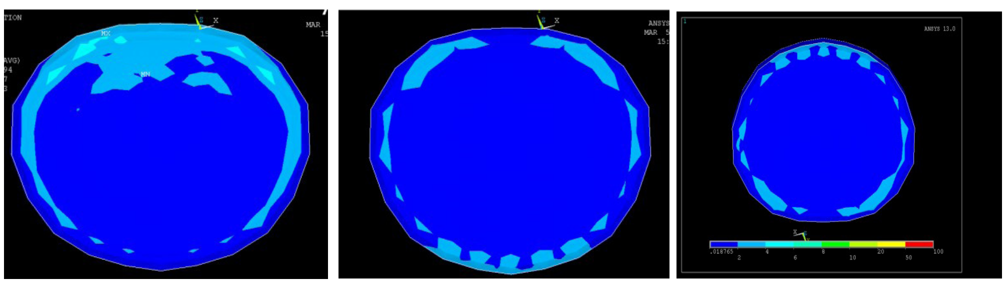
Figure-6. Von Mises stress color diagram of end plate loading in three different groups during flexion of FEM-simulated vertebral models. An absolute loading on the anterior is observed in intact vertebra.



Intact vertebra Coflex® Coflex® Rivet

On extension, it was recorded as an average of 5.26 MPa in a normal disc, 3.20 MPa with Coflex® and 3.16 MPa with Coflex® Rivet. According to these data, it was observed that Coflex® reduced the load on the disc at a ratio of 39% and Coflex® Rivet reduced it at a ratio of 40% (Figure-7).

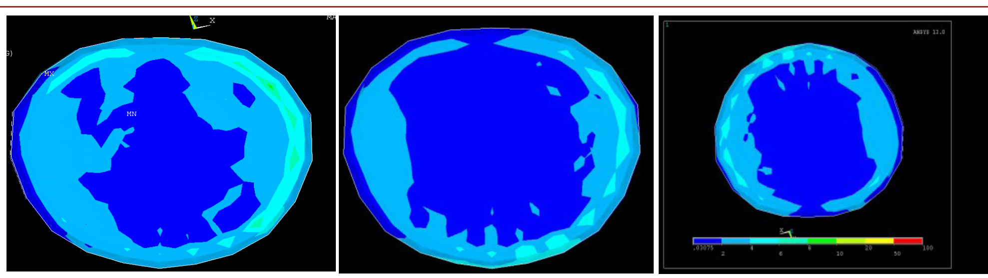
Figure-7. Von Mises stress graphs of extension movement of FEM-simulated vertebral models. It seems that the loading in extension is nearly the same in all groups.



Intact vertebra Coflex® Coflex® Rivet

On bending, the loading was recorded as 8.7 MPa in a normal disc, 6.4 MPa with Coflex® and 5.8 MPa with Coflex® Rivet. In the light of these data, it was observed that Coflex® Rivet reduced disc loading at a ratio of 34% and Coflex® reduced it at a ratio of 26% (Figure-8).

Figure-8. Von Mises stress graphs of bending movement of FEM-simulated vertebral models. It seems that anterior loading does not vary much between the groups.



Intact vertebra Coflex® Coflex® Rivet

On rotation, the loading was recorded as 4.4 MPa in a normal disc, 5.2 MPa with Coflex® and 5.2 MPa with Coflex® Rivet. In the light of these findings, Coflex® Rivet and Coflex® reduced disc loading at a ratio of 32%.

On flexion, the displacement amount was recorded as 0.8 cm for an intact vertebra, 0.96 cm with Coflex® and 0.62 cm with Coflex® Rivet. According to these findings, while Coflex® increased the range of motion at a ratio of 19%, Coflex® Rivet limited the range of motion at a ratio of 23%.

On extension, the displacement amount was recorded as 0.38 cm for an intact vertebra, 0.36 cm with Coflex® and 0.34 cm with Coflex® Rivet. According to these data, while Coflex® reduced the range of motion by a ratio of 5%, Coflex® Rivet reduced it by a ratio of 8.4%.

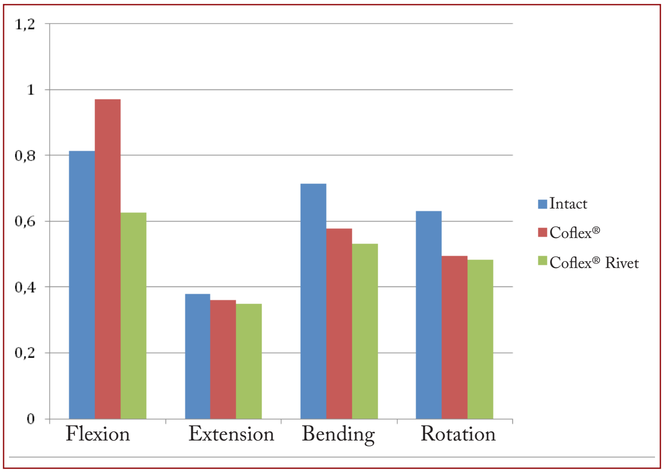
On bending, the displacement amount was found to be 0.7 cm for an intact vertebra, 0.57 cm with Coflex® and 0.53 cm with Coflex® Rivet. In the light of these findings, while Coflex® resulted in a 19% reduction in the range of motion, Coflex® Rivet showed a 25% reduction.

On rotation, the displacement amount was found to be 0.63 cm in an intact vertebra, 0.5 cm with Coflex® and 0.48 cm with Coflex® Rivet. According to these findings, a 21–23% reduction in the range of motion of bending movements was observed with both systems (Figure-9).

The results of disc loading of the upper adjacent segment and range of joint motion:

On flexion, the disc loading on the upper adjacent segment was measured as 4.84 MPa in an intact vertebra, 5.24 MPa with Coflex® and 3.71 MPa with Coflex® Rivet. According to these data, although there was an 8% increase with Coflex®, there was a 23% decrease with a Coflex® Rivet device.

Figure-9. The comparison of displacement at the L4–5 joint level on all movements

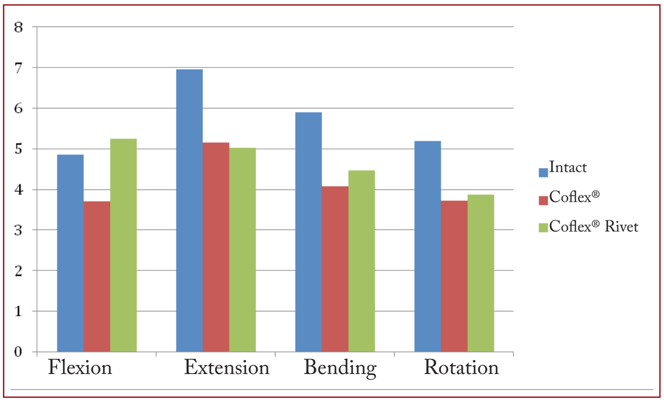


On extension, disc loading on the upper adjacent segment was found to be 6.95 MPa in an intact vertebra, 5.01 MPa with Coflex® and 5.15 MPa with Coflex® Rivet. In the light of these findings, it was observed that a 25–28% reduction was present with both systems.

On bending, the disc loading on the upper adjacent segment was measured as 5.89 MPa in an intact vertebra, 4.47 MPa with Coflex® and 4.08 MPa with Coflex® Rivet. According to these findings, a 24% reduction with the Coflex® interspinous device and a 30% reduction with the Coflex® Rivet device were observed.

On rotation, the disc loading on the upper adjacent segment was measured as 5.19 MPa in an intact vertebra, 3.87 MPa with Coflex® and 3.71 MPa with Coflex® Rivet. In the light of these data, a 25% reduction with Coflex® and a 28% reduction with Coflex® Rivet were observed (Figure-10).

Figure-10. The comparison of the effects of all movements on L3–4 disc loading.



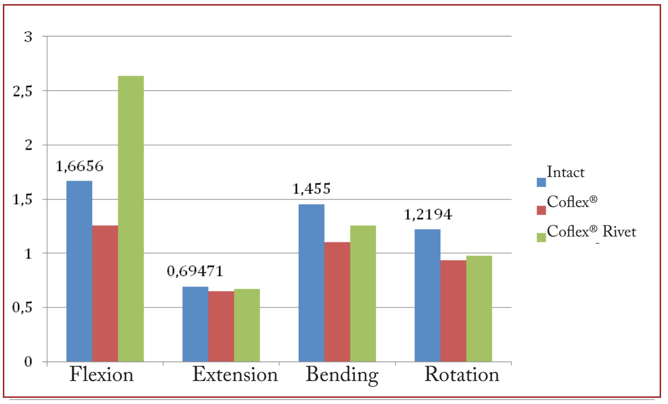
On flexion, the range of motion in the upper adjacent segment was measured as 1.66 cm in an intact vertebrae, 2.6 cm with Coflex®, and 1.25 cm with Coflex® Rivet. Therefore, a 24% reduction in the range of motion in this region was found on application of Coflex® Rivet, and a 58% increase was observed with the Coflex® device.

On extension, the range of motion in the upper adjacent segment was found to be 0.7 cm in an intact vertebra, 0.67 cm with Coflex®, and 0.65 cm with Coflex® Rivet. According to these data, while a 6.5% reduction was present with Coflex® Rivet, a 3.25% reduction was present with Coflex®.

On bending, the range of motion in the upper adjacent segment was found to be 1.45 cm in an intact vertebra, 1.25 cm with Coflex®, and 1 cm with Coflex® Rivet. A 14% reduction was observed with Coflex®, and a 27% reduction was observed with Coflex® Rivet.

On rotation, the range of motion in the upper adjacent segment was measured as 1.2 cm in an intact vertebra, 1 cm with Coflex®, and 0.9 cm with Coflex® Rivet. According to these findings, a 20% reduction in the range of motion in this region was observed with both systems (Figure-11).

Figure-11. The comparison of displacement at the L3–4 joint level in all movements.



DISCUSSION:

Although fusion surgery is a standard treatment for degenerative disc disease, consideration of alternative treatment options has become widespread due to complications that develop after fusion. Dynamic stabilization tools are included among these methods[10]. Although dynamic stabilization systems have been used for a while, data about their biomechanical features are limited. Therefore, there are still questions about their efficacies in the treatment of a degenerative lumbar spine[8].

When the literature is screened, there are limited numbers of *in vitro* studies about the flexibility Coflex® device. These studies show variable results about the biomechanical effects of the Coflex® device[5].

In our study, a reduction in the range of motion and disc loading was obtained at the levels to which Coflex® was applied, except for flexion. This result was compatible with the results of a cadaver study conducted by Tsai et al.[1].

Unlike the original Coflex®, when we evaluate our results, we observe that the Coflex® Rivet system absolutely decreases the range of motion and disc loading on the segment in flexion movements.

On extension, both systems reduce the disc loading on the surgical segment at a high ratio. The reason is that the load distribution in the lower lumbar vertebrae is mostly on the posterior arcus of the vertebrae[2]. This finding shows that these devices become the tools carrying the load in extension movements, which is not a desirable situation because normal load distribution cannot be provided, and the possibility of device failure increases.

In a cadaver study carried out by Kettler et al., they compared the Coflex® Rivet and original Coflex® devices using the L2–3 and L3–4 vertebrae (n=12). They found that the Coflex® Rivet system provided stability in all directions of movement[3]. Similarly, we observed the same results in our study.

The other aspect of our study considers the effect of the two different interspinous devices on disc loading and the range of segment motion of the upper adjacent segment. In a FEM study by Tsai et al., they observed an increase in load distribution and range of motion of the upper adjacent segment with the use of these two devices on extension movements[5]. In our study, we found that disc loading and the range of motion of the upper adjacent segment was reduced with both devices for all movement directions except flexion.

The weak points of this study are that the pelvic structures and upper lumbar vertebrae were not included in the model, and a normal disc was modeled while a degenerative disc and facet were not considered. To resolve this, there is a need for further studies that will include the sacrum and pelvis into the lumbar vertebral models. Another weak point is that standardization is a difficult variable, as the amount of tightening of the clamps of the Coflex® device depends on the surgeon and the geometry of the spinous projections.

There are four primary conclusions of this study:
1. The Coflex® Rivet device markedly provides stability in all movement directions, especially in flexion movements;

2. The load on the surgical segment disc was less for all movement directions in the Coflex® Rivet sample;

3. The Coflex® Rivet device reduced disc loading and motion in the upper adjacent segment for all movements, including flexion, compared to the Coflex® device;

4. In all movement directions except flexion, both systems reduced the disc loading and segment motion of the upper adjacent segment.

In this study, it was found that the Coflex® Rivet device, used for flexion movement of the lower lumbar vertebrae, markedly reduced the range of motion and disc loading for both the surgical segment and the upper adjacent segment when compared to the original Coflex® device. Both systems showed no significant advantages over each other in terms of the extension, bending and rotation movements of the vertebrae.

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