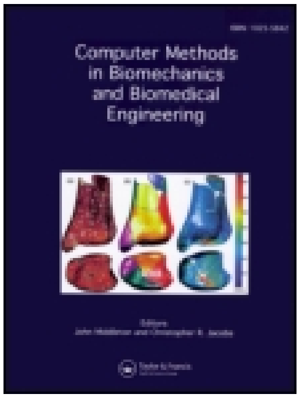

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Lumbar interbody fusion is a common procedure for treating lower back pain related to degenerative disc diseases. The Coflex-F is a recently developed interspinous spacer, the makers of which claim that it can provide stabilisation similar to pedicle screw fixation. Therefore, this study compares the biomechanical behaviour of the Coflex-F device and pedicle screw fixation with transforaminal lumbar interbody fusion (TLIF) or anterior lumbar interbody fusion (ALIF) surgeries by using finite element analysis. The results show that the Coflex-F device combined with ALIF surgery can provide stability similar to the pedicle screw fixation combined with TLIF or ALIF surgery. Also, the posterior instrumentations (Coflex-F and pedicle screw fixation) combined with TLIF surgery had lower stability than when combined with ALIF surgery.

Keywords: interspinous spacer; pedicle screw fixation; transforaminal lumbar interbody fusion; anterior lumbar interbody fusion; finite element analysis; posterior instrumentations

1. Introduction

Lumbar spinal fusion is a common surgical procedure for treating lower back pain caused by degenerative disc disease. The purpose of fusion is to prevent motion in the destabilised segments of spine, which can decrease low back pain caused by motion. Recent treatments of degenerative disc diseases and instabilities have used various approaches, such as anterior lumbar interbody fusion (ALIF), posterior lumbar interbody fusion (PLIF) and transforaminal lumbar interbody fusion (TLIF).

All types of interbody fusion approaches work ideally in combination with posterior pedicle screw fixation to increase stabilisation and fusion rates. It has some disadvantages, including paraspinal muscle dissection and retraction during instrumentation, screw malpositioning, neurologic risk and lengthy operative time with blood loss and increased risk of infection (Phillips et al. 2004). The disadvantages of pedicle screw fixation had led to the development of two new posterior fixations – the translaminar facet screw fixation and transfacet pedicle screw fixation (Ferrara et al. 2003; Aepli et al. 2009; Fan et al. 2010). While these two fixations have similar stability and can improve the disadvantages of pedicle screw fixation, they are technically demanding and dangerous surgical processes. Translaminar facet screw fixation requires long passage through the lamina for the crossing screws before they can traverse the facet joint, necessitating a large surgical field. Transfacet pedicle screw fixation requires considerable risks of neural injury. Thus, the development of other posterior instrumentations is still conducted by researches.

According to recent claims, the Coflex-F device (Paradigm Spine, Wurmlingen, Germany) can provide stabilisation of the posterior spinal elements similar to pedicle screw fixation when used for interbody fusion. The Coflex-F spacer is an interspinous process device with rivets modified from the original Coflex device. The rivets joining the wings of the Coflex device and the spinous processes allow for rigid attachment to the posterior element. It retains the advantages of interspinous process implants and minimally invasive surgery, such as sparing tissue, preserving pedicle anatomy and minimising muscle trauma, blood loss, skin incisions and operating time, thus speeding patient recovery.

Because the PLIF surgical process needs to remove parts of the lamina bone and spinous process to get approach, the Coflex-F cannot be implanted in the interspinous process. Therefore, the purpose of this study is to compare the biomechanical behaviour of the Coflex-F device and the traditional bilateral pedicle screw fixation, in combination with ALIF or TLIF.

2. Materials and methods

2.1 Finite element model of the intact lumbar spine (intact model)

A validated 3D finite element (FE) model of the intact lumbar spine was used (Figure 1(a)). To create this model,

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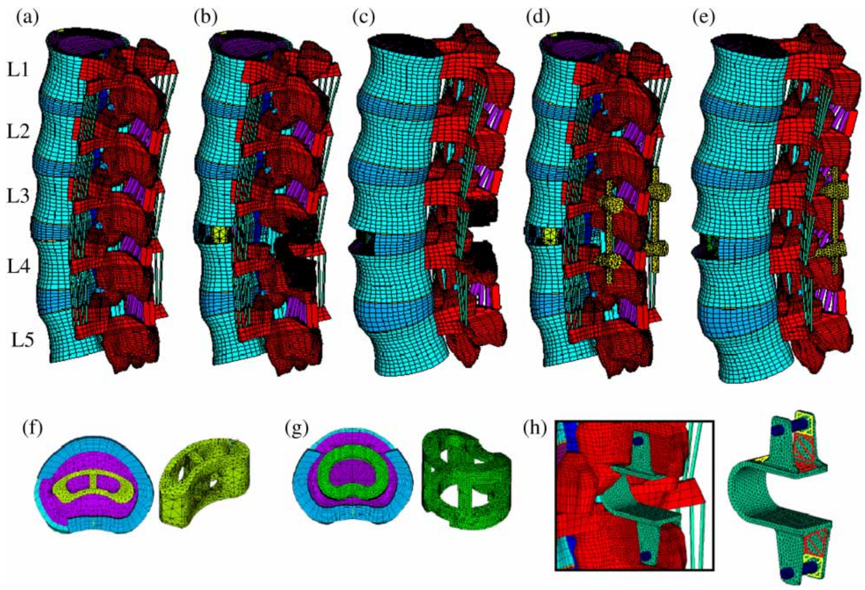

Figure 1. FE models: (a) INTACT L1–L5 lumbar spine model; (b) Coflex-F device combined with the TLIF model; (c) Coflex-F device combined with the ALIF model; (d) Pedicle screw fixation combined with the TLIF model; (e) Pedicle screw fixation combined with the ALIF model; (f) AVS-TL cage in the middle portion of the vertebral model; (g) SynCage-Open cage in the middle portion of the vertebral model and (h) Coflex-F device model.

computed tomography scans of the L1–L5 lumbar spine of a middle-aged, healthy man were obtained at 1-mm intervals. The commercially available FE program, ANSYS Inc. (Canonsburg, PA, USA), was used to model the spinal segments. The FE model of the osseoligamentous lumbar spine included the vertebrae, intervertebral discs, endplates, posterior elements and the following ligaments: supraspinous, interspinous, ligamentum flavum, transverse, posterior longitudinal, anterior longitudinal and capsular. The material properties of the lumbar spine were assumed to be homogeneous and a detailed description was presented in our previous studies (Chen et al. 2009; Zhong et al. 2009). The ligaments were simulated using two-node link elements with tension resistance only and the elements were arranged in the anatomic orientation. Eight-node solid elements were used for modelling of the cortical bone, cancellous bone, endplate, posterior bony structure and discs. The disc annulus consisted of fibres embedded in the ground substance. Annular fibres in 12 layers were modelled using two-node link elements with tension resistance only and placed in an anatomic orientation (Eberlein et al. 2001; Schmidt et al. 2006). The nucleus pulposus was modelled as an incompressible fluid with bulk modulus of 1666.7 MPa by an eight-node fluid element. The facet joints were treated as nonlinear 3D contact pairs using surface-to-surface contact elements and the coefficient of friction was set to 0.1.

2.2 FE model of TLIF combined with Coflex-F (Coflex-F + TLIF model)

The intact model was modified to a TLIF model by implanting an AVS-TL cage (Figure 1(f)) (30 mm width × 11 mm depth × 21 mm height; polyetheretherketone (PEEK); Stryker Orthopaedics, Mahwah, NJ, USA) between the L3 and L4 vertebrae. To simulate the standard TLIF procedure, unilateral total facetectomy and partial discectomy were performed at the L3/L4 segment. The left facet joint, ligamentum flavum and partial disc were removed, but the posterior elements, contralateral facet joint, supraspinous ligaments and interspinous ligaments were preserved. The cage–bone interface was modelled by surface-to-surface contact elements to simulate the early postoperative stage after spinal implantation. These contact elements were able to transmit compression, but not tension. The coefficient of friction at the cage–bone interface was set at 0.8 to mimic the effect that the cage's small teeth have on contact surfaces. The higher coefficient of friction (0.8) was used in the contact interface to prevent device-slip motion (Renner et al. 2007). Young's modulus and Poisson's ratio of AVS-TL cage were assigned to be 3.5 GPa and 0.3, respectively.

The TLIF model was again modified to implant the Coflex-F device between the L3 and L4 vertebrae to complete the Coflex-F combined with TLIF model, requiring the removal of supraspinous ligaments and interspinous ligaments (Figure 1(b)). The Coflex-F is available in five sizes from 8–16 mm in 2-mm increments.

In this study, the optimal height for the FE model was 14 mm. Part of the L3/L4 interspinous process was removed to provide sufficient space for implanting the Coflex-F between the interspinous processes. The surface between the spinous processes and the wings of the Coflex-F was modelled as a surface-to-surface contact. The effect of the teeth on the wings of the Coflex-F was simplified by assigning a higher coefficient of friction (0.8) to the wing contact area (Figure 1(h), yellow region) and the coefficient of friction for the rest of the contact regions was set at 0.1 (Figure 1(h), red region). The rivets were modelled as cylinders (diameter = 2.8 mm) and were constrained to both holes on the wings of the Coflex-F and the spinous processes in all degrees of freedom (The degrees of freedom of rivet nodes are interpolated with the corresponding degrees of freedom of the nodes on the Coflex and spinous processes during the execution of ANSYS program). The Coflex-F was constructed using Ti-6Al-4V alloy. Young's modulus and Poisson's ratio were assigned to be 113 GPa and 0.3, respectively.

2.3 FE model of ALIF combined with Coflex-F (Coflex-F + ALIF model)

The intact model was modified to an ALIF model by implanting a SynCage-Open cage (Figure 1 (g)) (30 mm width × 24 mm depth × 21 mm height; titanium alloy; Synthes spine, Inc.) between the L3 and L4 vertebrae. To simulate the standard ALIF procedure, the L3–L4 segment of the intact model underwent partial discectomy and total nuclectomy by the anterior approach, which included removal of the anterior longitudinal ligament, anterior portions of the annulus and the entire nucleus pulposus. All the other ligaments were preserved. The ALIF cage–bone has the same interface conditions as those of the TLIF cage–bone in Section 2.2. The SynCage-Open cage was constructed out of Ti-6Al-7Nb alloy. Young's modulus and Poisson's ratio were assigned to be 110 GPa and 0.28, respectively. In addition, the ALIF model was modified for implanting the Coflex-F between the L3 and L4 vertebrae to complete the Coflex-F combined with ALIF model. The ALIF model and the TLIF model implant the Coflex-F under the same conditions (Figure 1(c)).

2.4 FE model of TLIF combined with bilateral pedicle screw fixation (Pedicle screw + TLIF model)

The previous TLIF model was combined with bilateral pedicle screws to form the pedicle screw fixation model (Figure 1(d)). The difference between the pedicle screw fixation model and the Coflex-F model is that the pedicle screw fixation model preserves the supraspinous ligaments and interspinous ligaments. The pedicle screws were inserted bilaterally through the pedicles of the L3 and L4 vertebrae. The pedicle screw fixation in this study consisted of two rods (diameter = 4.5 mm) and four pedicle screws (diameter = 6 mm). The pedicle screws were modelled as cylinders. The screw–bone interfaces were designed to be fully constrained (The degrees of freedom of screw nodes are interpolated with the corresponding degrees of freedom of the nodes on the Coflex and spinous processes during the execution of ANSYS program). The pedicle screws were made of Ti-6Al-4V alloy. Young's modulus and Poisson's ratio were assigned to be 113 GPa and 0.3, respectively.

2.5 FE model of ALIF combined with bilateral pedicle screw fixation (Pedicle screw + ALIF model)

The previous ALIF model was combined with bilateral pedicle screws (Figure 1(e)). This model preserved the supraspinous ligaments and interspinous ligaments. Both this model and the previous TLIF model (combined with bilateral pedicle screws) used the same conditions and materials for pedicle screws.

2.6 Boundary and loading conditions

This study adopted and simulated the follower load at each motion segment in the model with two-node thermal link elements. The 400 N compressive follower load was applied to each motion segment through induced contraction in these link elements by decreasing the temperature (Patwardhan et al. 2003; Panjabi et al. 2007). The link elements were attached near the centres of each vertebral body such that each element spanned the mid-plane of the discs. These arrangements directed the construction of a nearly ideal follower load, which remains tangent to the spine curve, loading each spinal segment in nearly pure compression.

A 10-Nm moment was applied to the intact model to mimic physiological motion (Yamamoto et al. 1989). These motions subject the multilevel lumbar spine to a maximal possible load without causing spinal injury. The other implanted models under comparison were subjected to specific moments that produced overall motions that were equal to those of the intact model, using a hybrid test method (Panjabi 2007). The detailed total lumbar range of motions (ROMs) of the intact model under the hybrid test method are 16.36° in flexion, 10.31° in extension, 15.25° in lateral bending to both sides and 8.43° in axial rotation to both sides. These ROMs are a baseline to match the total lumbar motion among the intact and implantation models under the hybrid test method (Table 1). The resulting deviation of ROMs among the three FE models was controlled to within 0.33° in flexion, 0.56° in extension, 0.22° in right lateral bending, 0.24° in left lateral bending, 0.21° in right axial rotation and 0.21° in left axial rotation.

Table 1. Intervertebral ROM and applied moment among various surgical models under the hybrid test method.

Model	ROM (°) L1–L2	L2–L3	L3–L4	L4–L5	Total lumbar ROM (°) (L1–L5)	Moment (Nm)
Flexion						
Intact	3.66	3.78	3.82	5.10	16.36	10
Coflex-F + TLIF	4.37	4.54	0.96	6.38	16.25	12
Coflex-F + ALIF	4.46	4.60	0.92	6.44	16.42	12
Pedicle screw + TLIF	4.40	4.59	0.62	6.48	16.09	12
Pedicle screw + ALIF	4.49	4.66	0.61	6.47	16.23	12
Extension						
Intact	2.27	2.47	2.30	3.27	10.31	10
Coflex-F + TLIF	3.26	3.17	0.43	4.01	10.87	11
Coflex-F + ALIF	3.33	3.01	0.55	3.96	10.85	12
Pedicle screw + TLIF	3.26	3.16	0.27	4.16	10.85	11
Pedicle screw + ALIF	3.32	2.98	0.22	4.09	10.61	12
Right lateral bending						
Intact	3.69	3.59	3.67	4.30	15.25	10
Coflex-F + TLIF	4.08	3.97	2.40	5.00	15.45	11
Coflex-F + ALIF	4.46	4.37	1.26	5.15	15.24	12
Pedicle screw + TLIF	4.47	4.32	1.17	5.50	15.46	12
Pedicle screw + ALIF	4.48	4.35	0.92	5.54	15.29	12
Left lateral bending						
Intact	3.69	3.59	3.67	4.30	15.25	10
Coflex-F + TLIF	4.11	4.03	1.95	5.07	15.16	11
Coflex-F + ALIF	4.46	4.37	1.26	5.15	15.24	12
Pedicle screw + TLIF	4.47	4.38	1.04	5.51	15.40	12
Pedicle screw + ALIF	4.48	4.35	0.92	5.54	15.29	12
Right axial rotation						
Intact	1.81	1.90	2.23	2.49	8.43	10
Coflex-F + TLIF	2.00	2.09	1.52	2.80	8.41	11
Coflex-F + ALIF	2.12	2.19	1.06	2.94	8.31	12
Pedicle screw + TLIF	2.29	2.22	0.81	2.99	8.31	13
Pedicle screw + ALIF	2.38	2.31	0.70	3.13	8.52	14
Left axial rotation						
Intact	1.81	1.90	2.23	2.49	8.43	10
Coflex-F + TLIF	2.01	2.09	1.44	2.81	8.35	11
Coflex-F + ALIF	2.12	2.19	1.06	2.94	8.31	12
Pedicle screw + TLIF	2.29	2.22	0.81	2.99	8.31	13
Pedicle screw + ALIF	2.38	2.31	0.70	3.13	8.52	14

3. Results

3.1 Range of motion

For the Coflex-F combined with TLIF, ROM at the surgical segment (L3/L4) decreased by 75, 81, 35, 47, 32 and 36% in flexion, extension, right lateral bending, left lateral bending, right axial rotation and left axial rotation, respectively, in comparison with the intact model (Figure 2). For the Coflex-F combined with ALIF, ROM at the surgical segment decreased by 75, 77, 66, 66, 52 and 52% in the six physiological motions, respectively.

For the pedicle screw fixation combined with TLIF, ROM at the surgical segment decreased by 83, 88, 68, 71, 64 and 64% in the six physiological motions, respectively. For the pedicle screw fixation combined with ALIF, ROM at the surgical segment decreased by 83, 90, 74, 74, 68 and 68% in the six physiological motions, respectively.

3.2 Von Mises stress distribution on the cage–bone interface

The concentration and distribution pattern of stress changed obviously on the cage–bone interface of the superior surface of the L4 vertebra at the surgical segment for four implant models. In lateral bending, the stresses were concentrated at the same side as lateral bending direction (Figure 3). The Coflex-F shows more significant stresses concentration than pedicle screw fixation, especially when combined with TLIF. In axial rotation, the stresses corresponding to TLIFs were concentrated and correlated with axial rotation direction; on the contrary, the ALIFs show no directional effect (Figure 4). The Coflex-F models result in more significant stresses concentration than pedicle screw fixation models. In flexion, the stresses on the cage–bone interface of the

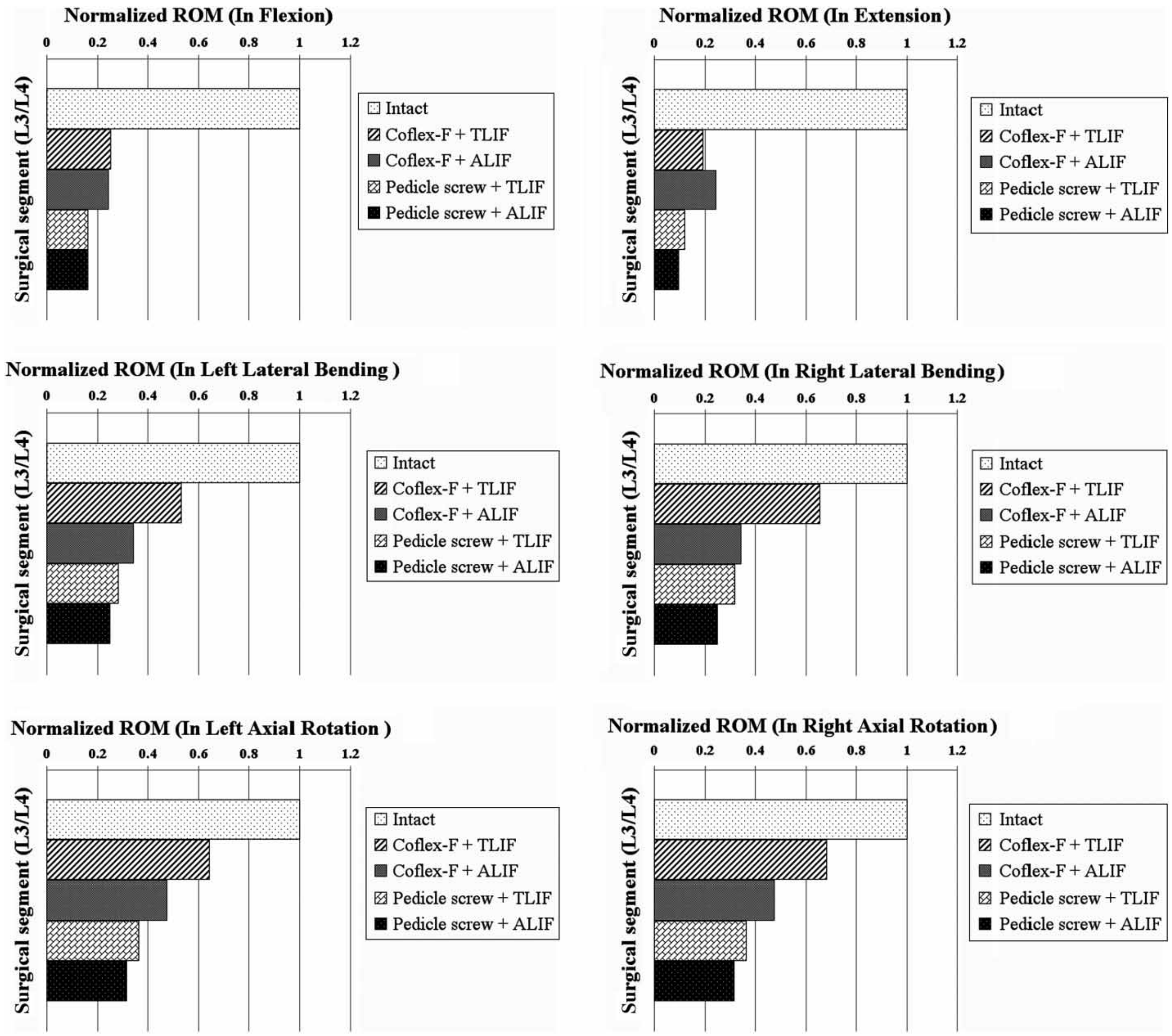

Figure 2. ROM changes among various surgical models under flexion, extension, lateral bending (left and right) and axial rotation (left and right).

L4 vertebra were all concentrated at the anterior side of vertebra for all implant models, especially for the Coflex-F combined with ALIF model (Figure 5). In extension, none of the implant models stress shows significant stress concentration on the cage–bone interface.

3.3 Von Mises stress distribution for the Coflex-F and the pedicle screw

Figure 6 shows the contour plots of von Mises stress values in the Coflex-F devise and the pedicle screw for various loading cases. For all of these cases, the Coflex-F device has higher stresses than the pedicle screw when combined with TLIF or ALIF. Figure 7 shows the maximum von Mises stress values in the Coflex-F and the pedicle screw for various loading cases. For all of these cases, the Coflex-F devise has higher stress than the pedicle screw, when combined with either TLIF or ALIF.

4. Discussion

The present study used an FE lumbar model of the L1–L5 segments to compare the effects of the Coflex-F device and traditional bilateral pedicle screw fixation at the surgical segment after TLIF and ALIF implantation. According to the ROM results, the Coflex-F device combined with the TLIF model had lower stability than all the other models, especially in both directions of lateral bending and axial rotation. On the other hand, the pedicle screw fixation combined with the ALIF showed the highest stability among all models.

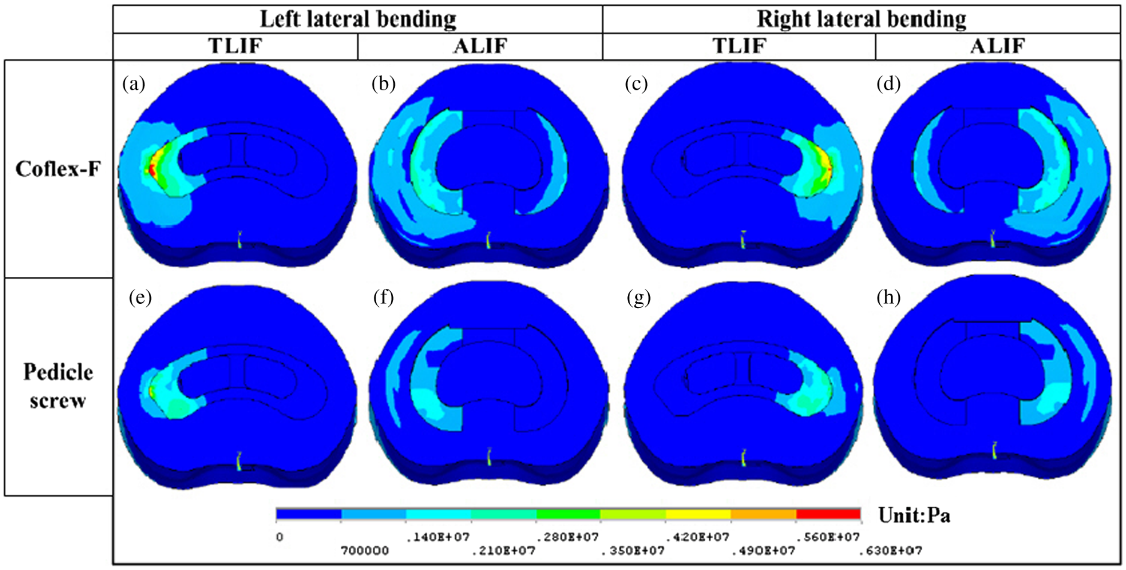

Figure 3. The von Mises stress distribution on the cage–bone interfaces of the superior surface of the L4 vertebra under left lateral bending and right lateral bending.

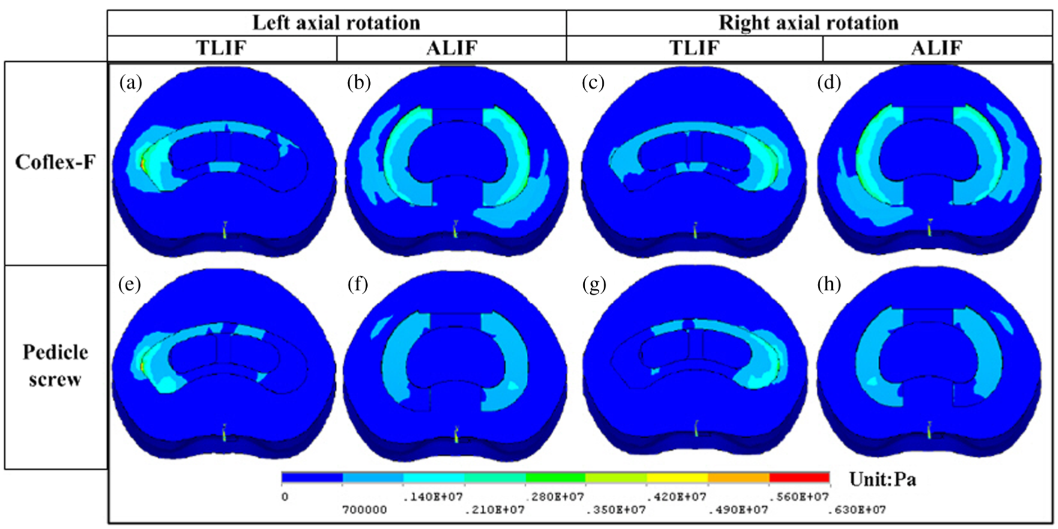

Figure 4. The von Mises stress distribution on the cage–bone interfaces of the superior surface of the L4 vertebra under left axial rotation and right axial rotation.

The primary factor in the Coflex-F results is the fixed position of its implantation. The motion segment, composed of two adjacent vertebrae and the associated soft tissues, is the functional unit of the spine. Each motion segment has three joints. It has a triangular stack of articulations, with symphysis joints between vertebral bodies on the anterior side and two sliding facet joints on the posterior side. The Coflex-F has rivets joining its wings to the spinous processes. The rivets can attach the implant more rigidly to the posterior spinous processes. However, the vertebral bodies of anterior side sustain the majority of the weight. Therefore, the rivets cannot provide sufficient stiffness in the motion segment for two adjacent vertebrae because the locations of attachment are within the posterior element, which is not as strong as vertebral bodies. However, pedicle screw fixation can fix vertebral bodies and, therefore, provide sufficient stiffness in the motion segment for two adjacent vertebrae.

The geometry of the Coflex-F device supports a different function – its U-shaped structure retains the same design and flexibility of the Coflex, thus making it more flexible and deformable than pedicle screw fixation. Figure 6 shows the von Mises stress of the Coflex-F and the pedicle screw for various loading cases. In all of these cases, the Coflex-F has higher stress than the pedicle screw when combined with TLIF or ALIF. Figure 7 shows the

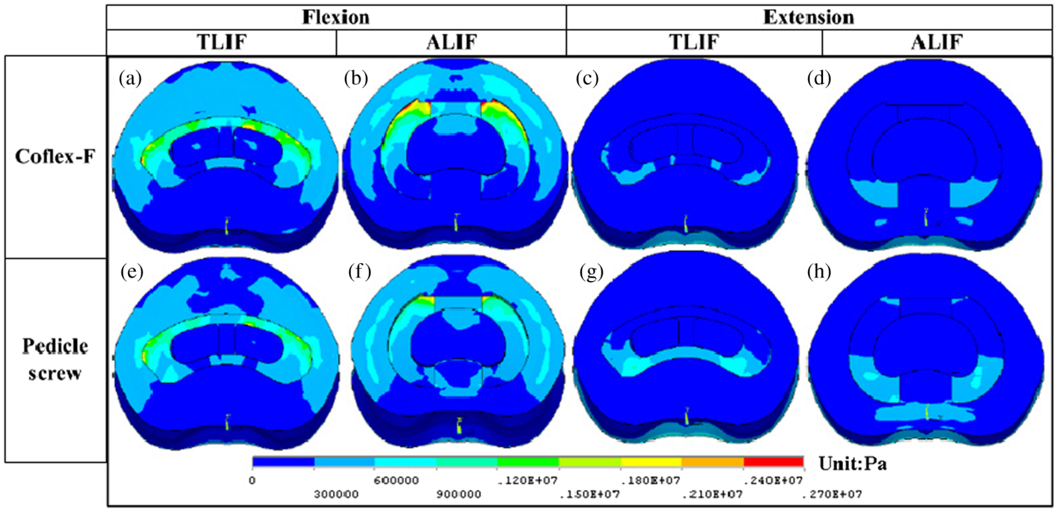

Figure 5. The von Mises stress distribution on the cage–bone interfaces of the superior surface of the L4 vertebra under flexion and extension.

von Mises stress of the Coflex-F and the pedicle screw for various loading cases. The Coflex-F has higher von Mises stress than the pedicle screw. Therefore, the fixed position and geometry of implantation have a great influence on stress distribution for Coflex-F.

ALIF and TLIF are two common surgeries for achieving interbody arthrodesis. In the present study, a posterior instrumentation in combination with ALIF can provide higher stability than a posterior instrumentation in combination with TLIF. The ALIF procedure with anterior surgical approach allows expansion of disc space; it can use a larger cage to increase the contact area of cage–bone interface. The larger contact area distributes the load over the cage–bone interface area of the vertebra bone. Consequently, an ALIF cage does not create stress concentration on the cage–bone interface at the surgical segment. On the other hand, the TLIF procedure prohibited the use of a large cage because a cage pathway would create limitations for the surgery. The TLIF procedure can only utilise cages with long and thin contact area on the cage–bone interface. Therefore, the TLIF cage suffers from stress concentration on the cage–bone interface at the surgical segment.

In extension, the stress concentration of all the models diminished between the cage–bone interfaces. In flexion, the stress concentration of all the models increased at the anterior side of the cage–bone interface. A posterior instrumentation combined with ALIF has higher stress concentration than a posterior instrumentation combined with TLIF. This is primarily due to flexion or extension motion. The posterior instrumentation and interbody cage share the same extension motion. Posterior instrumentation sustains most of the load transferred in extension, therefore, reducing the stress concentration of all the models. In contrast, the anterior interbody cage sustains most of the load transferred in flexion, therefore, resulting in the stress concentration in the ALIF model at the cage–bone interface, especially with Coflex-F implantation. The Coflex-F sustains larger moment than pedicle screw fixation because the fixed position of the Coflex-F in the posterior interspinous processes causes a longer moment arm.

PEEK material has recently gained popularity for use in implants because of its mechanical properties. One of the PEEK material's biggest advantages is that its modulus of elasticity ($E = 3.5$ GPa) is closer to that of cortical bone ($E = 12$ GPa) and cancellous bone ($E = 0.14$ GPa) compared with that of titanium ($E = 113$ GPa). Vadapalli et al. (2006) performed an FE investigation to study the effect of different spacer materials property. The results from that study indicate that PEEK spacers provide initial stability similar to titanium spacers, and, therefore, might minimise the chances of subsidence. The present study uses two cage materials: titanium for the ALIF cage and PEEK for the TLIF cage for stability. This study's results are identical to Vadapallis's results, i.e. both cage materials provide similar stability when combined with pedicle screw fixation. However, the materials of these two cages do not provide similar stability when combined with the Coflex-F; the titanium cage (ALIF) provides higher stability than PEEK cage (TLIF).

Several limitations in the present study are related to the simplified and idealised material properties during simulation, such as the linearised behaviour of the spinal ligaments and pure elastic intact discs without degeneration (Chen et al. 2001, 2009; Zhong et al. 2009). Furthermore, the degree of gripping force applied between the wings of the Coflex-F device and the spinous process is determined by the clamping force that is applied by the surgeon, which is difficult to measure, and there have been

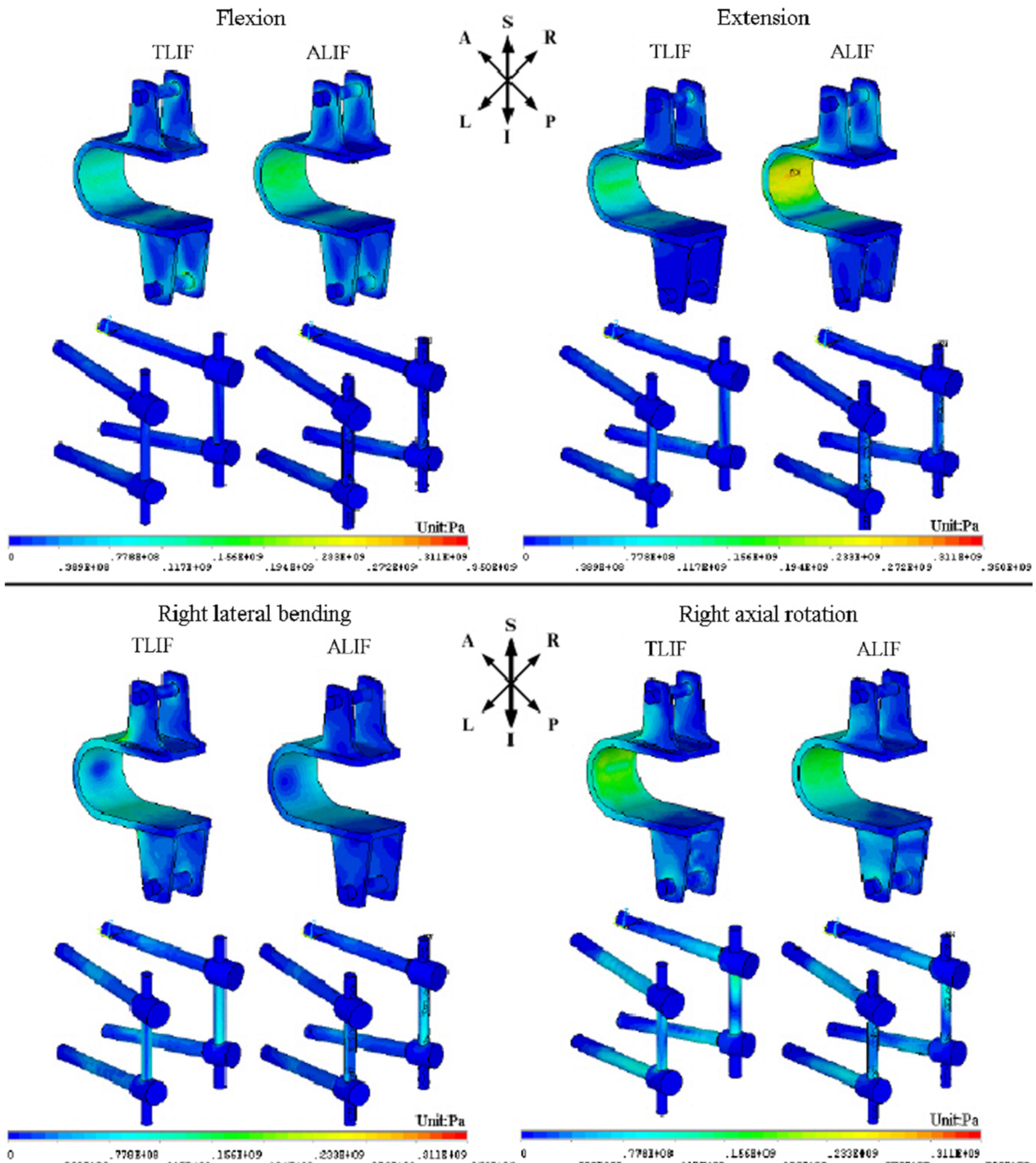

Figure 6. The von Mises stress distribution in the Coflex-F device and the pedicle screw fixation under flexion, extension, right lateral bending and right axial rotation.

different results presented in previous studies (Tsai et al. 2006; Kettler et al. 2008; Wilke et al. 2008). In addition, for the determination of gripping force, bone strength and geometry of the spinous process must also be considered. In this study, the degree of the gripping force was simplified, and only the friction conditions between the teeth on the wings of the Coflex-F device and the spinous process were considered. The coefficient of friction used here was based on the results of a previous study on friction parameters between the cage and the bone (Chen et al. 2009). In addition, our simplified simulation of gripping force ignored the pre-force between the teeth of the wings and the spinous processes, as well as the inward and outward deformations of both side flanks of the Coflex-F device. The loading conditions in the present FE simulations were similar to those of the traditional *in vitro* tests. Thus, muscle contraction and pelvic movement were not included in the present study. Furthermore, FE models should be interpreted only as a trend because of the variability among different human tissues.

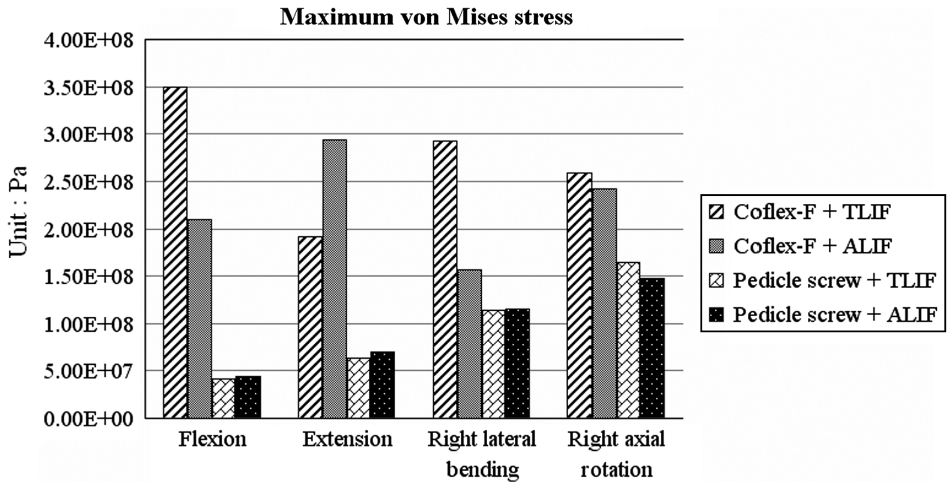

Figure 7. The maximum von Mises stress of the Coflex-F device and pedicle screw under flexion, extension, right lateral bending and right axial rotation.

5. Conclusions

This study compares the Coflex-F device and pedicle screw fixation when combined with TLIF and ALIF. This study shows that in six physiological motions, a Coflex-F device combined with ALIF can provide stability similar to a pedicle screw fixation in combination with TLIF or ALIF. Furthermore, the larger stress at the cage–bone interface for the Coflex-F combined with TLIF causes the exclusion of the pedicle screw fixation. The Coflex-F device combined with ALIF is preferable for providing stability in spine fusions.

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