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Biomechanical effect of bone resorption of the spinous process after single-segment interspinous dynamic stabilization device implantation

A finite element analysis

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Abstract

This study aims to explore the influence of bone resorption of the spinous process after single-segment interspinous process device (IPD) implantation on the biomechanics of the lumbar spine.

The 3D finite element model of the lumbar spine (L3-L5) was modified, and 2 models that simulated the presence and absence of bone resorption of the spinous process were developed using an IPD (Wallis). Its biomechanical effects, such as change in range of motion (ROM) and intervertebral disc and facet stress, were introduced at operative (L4/5) and adjacent (L3/4) levels.

Compared with the INT model, the Wallis model and Wallis-BR model had similar ROMs in lateral flexion and rotation. However, the Wallis model had a lower L3–5 ROM in flexion (20.4% lower) and extension (26.4% lower), and L4-L5 ROM in flexion (74.1% lower) and extension (70.8% lower), while the overall ROM of the Wallis-BR model was greater than that of the Wallis model. The stress on the L3/L4 intervertebral disc and facets was similar for all 3 models. Compared with the INT model and Wallis-BR model, the stress on the L4/L5 intervertebral disc and facets under all movements significantly decreased in the Wallis model. The stress on the L5 process was greater than that on the L4 process in both the Wallis model and Wallis-BR model, and the load on the processes that underwent bone resorption was lower than that of the Wallis model.

The function of the IPD slowly decreased with the occurrence of bone resorption of the interspinous process. This bone remodeling may be associated with high stress after IPD implantation.

Abbreviations: ASD = adjacent segment degeneration or diseases, ASD= adjacent segment degeneration, CT = computed tomography, FE = finite element, FEA = finite element analysis, FEMs = finite element models, IPD = interspinous process devices, MRI = magnetic resonance imaging, PEEK = polyetheretherketone, PJK = proximal junctional kyphosis, ROM = range of motion.

Keywords: finite element, interspinous dynamic stabilization device, spinous process bone resorption, Wallis system

1. Introduction

Fusion of the lumbar spine, a conventional and effective surgical technique, has been widely applied to treat various degenerative lumbar diseases in recent years. However, certain well-known complications, such as adjacent segment degeneration (ASD), proximal junctional kyphosis (PJK), and lower back stiffness, can be caused by limited spinal flexibility and excessive pressure on the adjacent segments.[1–3] In order to reduce the incidence of ASD associated with rigid fusion of the lumbar spine, nonfusion, and dynamic flexible interspinous devices for the lumbar spine have been developed. The Wallis system, the second generation of interspinous process implants, either fixes the pathologic lumbar segments or maintains the range of motion (ROM) of symptomatic spinal levels. The rationale for using interspinous process devices (IPDs) is that the spacers reduce the motion of flexion and extension of the symptomatic segments and the pressure on discs and facets, further decreasing the incidence of ASD.[4,5]

The use of interspinous device technology remains under debate. Furthermore, several long-term follow-up studies have revealed numerous drawbacks and complications for the Wallis system. Moreover, several recent reports have shown a significantly higher reoperation rate with IPD use, when compared with traditional lumbar techniques.[6] A clinical study revealed that 13% of patients experienced recurrent lumbar disc herniation at the treated section after receiving Wallis implants at an average of 16 months of follow-up.[7] The Wallis system can reduce, but not eliminate, the ROM of the surgical segment, and can reduce the pressure on facets and discs during flexion and extension. However, during lateral bending, Wallis implants cannot effectively share the pressure on the lumbar intervertebral disc.[8] Short-term results have shown a phenomenon of bone

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resorption in the spinous process of the contact part of the prosthesis, which is characterized by a L5 spinous process bone resorption of approximately 22.93±1.63%.[9] It remains unknown how this bone resorption process might change the stress on the lumbar spine, and whether it is related to complications, especially ASD.

The aim of the present study was to evaluate the biomechanical effects of bone resorption of the spinous process after the implantation of a dynamic IPD using finite element analysis (FEA).

2. Materials and methods

A total of 3 nonlinear finite element models (FEMs) of the L3-L5 lumbar spine were established in the present study. The FEM consisted of intervertebral discs, posterior elements, and vertebral bodies, which in turn consisted of the cortical bone, cancellous bone, and numerous ligaments. This was developed through the previously validated lumbar spine of the investigators (Fig. 1).[10] The present study was conducted with the approval of the Ethics Committee of our hospital.

3. FEM of the intact lumbar spine

In order to develop this model, serial thin-section computed tomography (CT) scans of the lumbar spine (from L3 to L5) of a 25-year-old healthy male volunteer were obtained. These images were analyzed, and the geometrical surface model of the vertebra was constructed using Mimics 15.0 software (Materialise Inc., Leuven, Belgium). The vertebral surface was smoothed using Geomagic Studio 12.0 software (Geomagic Inc., Research Triangle Park, NC). ANSYS Workbench 15.0 (ANSYS Inc., Canonsburg, PA) was applied to mesh the solid model of the vertebra. The average thicknesses used for the cortical bone were 1.0 mm.[11] The intervertebral discs, including the disc annulus, disc nucleus and endplates, were developed and situated between the vertebras, according to anatomical data. The fiber content of the annulus fibrosis was located at a mean of 24° to 45° from the horizontal plane.[12] Five ligaments simulating the ligamentous structures of the lumbar spine were integrated into this model, including the anterior and posterior longitudinal ligaments, capsular ligaments, ligamentum flavum, and interspinous ligament. The various material properties of these different tissues were obtained from a literature [10] (Table 1). Tension-only spring elements with nonlinear material properties were used to model the ligaments and facet capsules. The material properties and element types used in the FEM of the lumbar spine were based on data obtained from previously references.

In the present study, the bond contact was used to stimulate the interaction of the vertebra and discs. The contact relationship between the articulating surfaces of the joints was set as surface-to-surface contact, and the friction coefficient was set at 0.1.[13]

4. FEM of the Wallis model and Wallis-BR model

The FEM of the intact lumbar spine was developed to stimulate the Wallis model and Wallis-BR model (Fig. 1). The L3-L5 model was

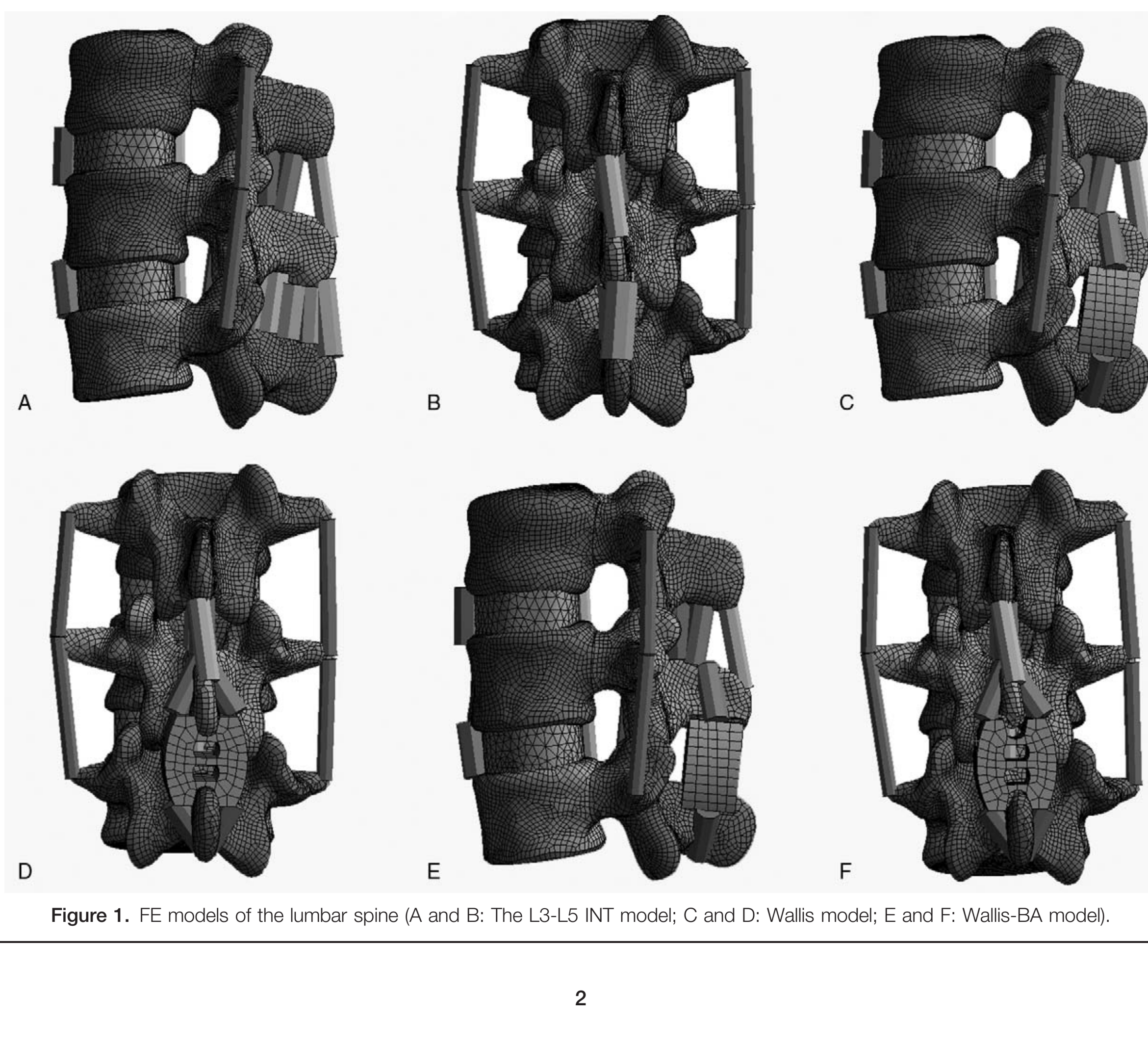

Figure 1. FE models of the lumbar spine (A and B: The L3-L5 INT model; C and D: Wallis model; E and F: Wallis-BA model).

Table 1

Material properties and element types used in the FE model of the lumbar spine.

Material properties	Young Modulus (MPa)	Cross-section, mm^2	Poisson ratio
Cortical bone	Ex = 11,300		Vxy =0.48
	Ey = 11,300		Vxz =0.20
	Ez = 22,000		Vyz =0.20
	Gx = 3800		
	Gy = 5400		
	Gz = 5400		
Cancellous bone	Ex = 140		Vxy =0.45
	Ey = 140		Vxz=0.32
	Ez = 200		Vyz =0.32
	Gx = 48.3		
	Gy = 48.3		
	Gz = 48.3		
Posterior bone	3500		0.25
Nucleus	1.0		0.50
Annulus ground substance	4.2		0.45
Annulus fibers	400		0.30
Endplate	24.0		0.40
Ligament			
Anterior longitudinal	20	63.7	
Posterior longitudinal	20	20.0	
Ligamenta flava	19.5	40.0	
Facet capsules	32.9	30.0	
Interspinous	11.6	40.0	
Supraspinous	15	20.0	
Transverse	58.7	1.8	
PEEK cage (Wallis system)	3500		0.40
Nylon rope (Wallis system)	2400		0.40

used to simulate the Wallis model and Wallis-BR model. In the L3-L5 FEM of the lumbar spine, the L4-L5 posterior segment of the superior segment of the spinous process, interspinous ligament, caudal part of the L4 spinous process, and lateral part of the L5 spinous process were resected. Then, the Wallis system was inserted to obtain the model. On the basis of the Wallis model, the Wallis-BR model was developed by resecting 16% of the L4 spinous process and 22% of the L5 spinous process at the point of contact between the Wallis system and interspinous process.[9]

In the Wallis model and Wallis-BR model, the second-generation interspinous process implant (the Wallis system; 23 mm in height, 15 mm in thickness, and 12 mm in distraction height) was used.[10] The relationship between the Wallis system and contact surface of the upper and lower spinous processes was bonded.

5. Boundary and loading conditions

In the L3-L5 FEM, Wallis model and Wallis-BR model, the inferior surface of the L5 vertebral body was fixed. An axial load of 500 N, which corresponds to the upper body weight of a healthy adult, was imposed on the L3 vertebral body in these models. Moreover, 10-Nm flexion, extension, rotation, and lateral bending movements were applied to the superior surface of the L3 vertebral body. The ROM of the lumbar spine, stress of the bilateral facet joint, intervertebral disc, and the L4-L5 spinous process were measured.

6. Statistical analysis

For convenience, the FE numerical value was derived for use in nonparametric tests. The collected data were analyzed using SPSS 20.0 software (SPSS, Inc, Chicago, IL). $P < .05$ was considered statistically significant.

7. Results

7.1. Validation results of the model

The FEM was validated by comparing the ROM of the whole lumbar spine with previously published studies. The predicted results of the L3-L5 FEM had a good agreement with previous experimental studies [14–17] (Table 2).

7.2. Stress on the facets

For all models, similar stress on the facets during all motions was observed at the L3-L4 level, and the difference was not statistically significant (Fig. 2A). However, statistically significant differences were observed for the stress on the facets ($P < .05$) at the L4-L5 level of the Wallis model and Wallis-BR model in extension, lateral bending, and rotation, but not flexion ($P = .61$).

Compared with the facet stress in the Wallis model, the L4-L5 facet stress in the Wallis-BR model was similar in flexion, but with significantly increased extension, rotation, and lateral bending. In addition, the L4-L5 facet stress of the INT model was greater than that of the Wallis-BR model, and there was a significant difference in all motions, except in flexion (Fig. 2B).

7.3. Stress on the intervertebral discs

The 3 surgical simulations did not significantly differ in terms of the von Mises stresses on the annulus of the L3-L4 disc in all motions (Fig. 2C). The stresses on the L4-L5 disc were significantly reduced in the Wallis models ($P < .05$). When combined with the Wallis-BR model, the L4-L5 disc stresses of the Wallis model significantly decreased in all motions. In extension, the stresses on the L4-L5 disc for the INT model were greater than those for the Wallis-BR model (Fig. 2D).

7.4. Range of motion (ROM)

In the present study, INT model data were used as baseline values for describing the ROM changes in these FEMs. For example, ROM change rate = (ROMWALLIS - ROMINT) / (ROMINT) × 100 (%), where ROMWALLIS and ROMINT represent the

Table 2

Comparison of ROM between the INT model and previous experimental studies.

	Torque, Nm	Flexion, Nm/°	Extension, Nm/°	Lateral flexion, Nm/°	Rotation, Nm/°
This study (L3-L5)	10	1.91	2.9	2.38	3.31
Yamamoto et al[14] (L1-L5)	10	1.75	3.22	2.44	5.26
Heth et al[15] (L2-S1)	6	1.10	2.35	1.33	2.61
Zhang et al (L3 -L5)	10	1.62	3.03	2.50	4.45
Dong[17]	10	2.35	3.58	2.86	8.98

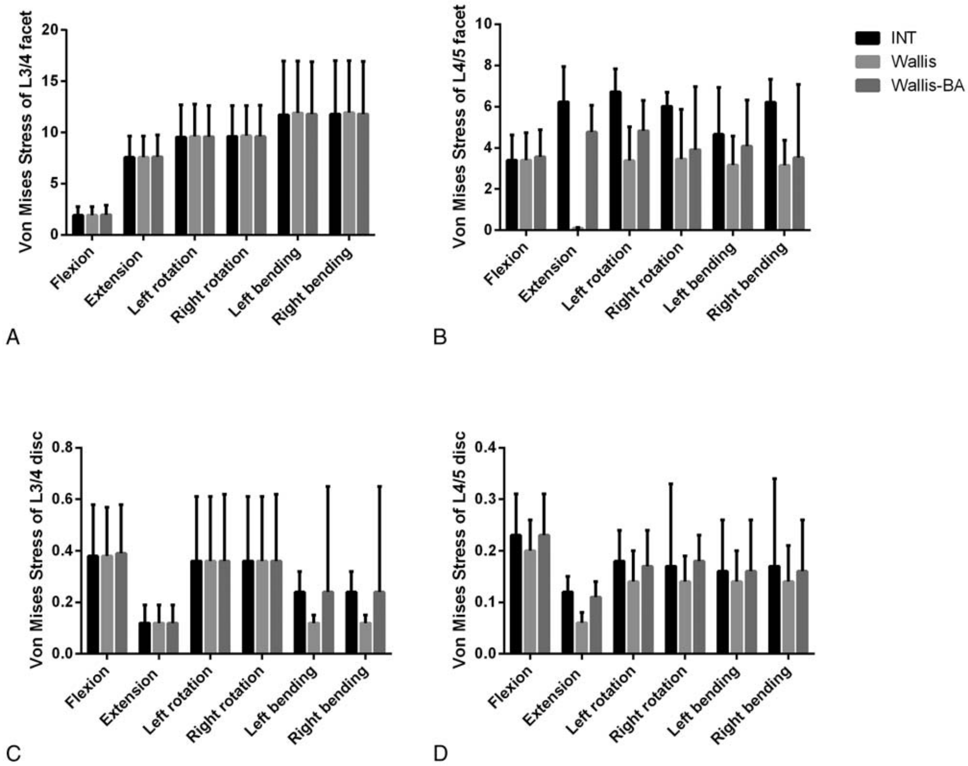

Figure 2. (A) Comparison of facet stress at the L3/4 level in three models. (B) Comparison of facet stress at the L4/5 level in the 3 models. (C) Comparison of disc stress at the L3/4 level in the INT model and Wallis model and the Wallis-BA model. (D) Comparison of disc stress at the L4/5 level in the INT model and Wallis model and the Wallis-BA model.

ROM for each motion segment in the Wallis model and INT model, respectively.[18]

Compared with the ROM of the INT model, the ROMs of the Wallis and Wallis-BR models at L3-L4, L4-L5, and L3-L5 were similar in lateral bending and rotation. The ROM was < 5%. The L3–5 ROM of the Wallis model was 20.4% lower in flexion and 26.4% lower in extension, while the L4-L5 ROM was 74.1% lower in flexion and 70.8% lower in extension, when compared with the INT model. However, the L3-L4 ROM was 18.9% higher in flexion and 19.2% higher in extension. Between the Wallis and Wallis-BR models, the ROMs of L3-L4, L4-L5, and L3-L5 increased more than 20% in flexion and extension. Similar ROM (<5%) change rates in extension were observed for the Wallis-BR and INT models. However, the ROM change of the Wallis-BR model was 6.69% higher in flexion (Fig. 3).

7.5. Stress on the spinous process

In the Wallis and Wallis-BR models, there was a significant difference in L4 and L5 spinous process stress with the flexion, extension, rotation, and lateral bending movements. Moreover, the stress on the spinous process in the Wallis model was greater than that in the Wallis-BR model, and the difference was statistically significant ($P < .001$, Fig. 4).

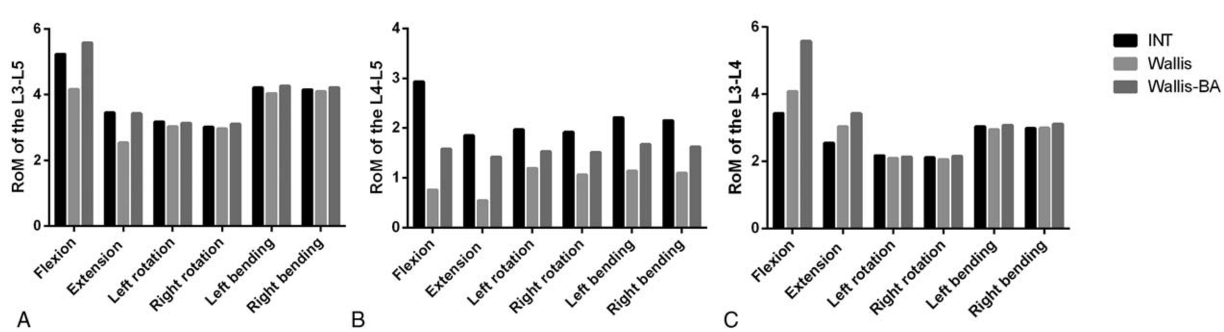

Figure 3. (A) Comparison of ROM at the L3-L5 level in the 3 models. (B) Comparison of ROM at the L4/5 level in the INT model and Wallis model and the Wallis-BA model. C: Comparison of ROM at the L3/4 level in the INT model and Wallis model and the Wallis-BA model.

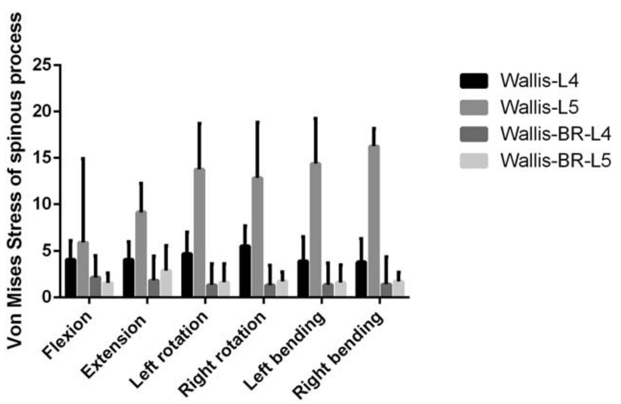

Figure 4. Comparison of spinous process stress in the Wallis model and the Wallis-BA model.

8. Discussion

The lumbar spinal fusion technique has been widely used to treat lumbar degenerative diseases, spondylolisthesis, spinal instability, and other congenital diseases, as it was first proposed by Hibbs in 1911. Many clinical studies and biomechanical tests of lumbar fusion have shown that this method has various advantages, such as a prominent curative effect, low recurrence rate, and high resulting stability of the lumbar spine. Furthermore, clinical studies have shown similar long-term follow-up results with conservative treatment.[19] However, lumbar spinal fusion has also been associated with a series of problems, including adjacent segment degeneration or diseases (ASD), pseudarthrosis, implant failure, sagittal spinal imbalance or kyphosis, and other complications. Moreover, the incidence of postoperative complications is higher than 68%, and the incidence of symptomatic ASD is approximately 10%.[20,21] Nakashima et al[22] carried out more than 5 years of studies that suggested that the incidence of imaging-confirmed ASD was 24% to 68%. ASD is a common long-term complication of spinal fusion. The adjustments of facet loading, the fretting wear between the prostheses and bones, and the increased pressure on the segments adjacent to the fusion mass have been considered to play a key role in the etiology of ASD.[23] Several clinical studies have reported that the incidence of radiographic ASD was 4.1% to 15% in patients who were implanted with an IPD, which was significantly lower than the incidence among patients who did not have an interspinous spacer.[5,6] Long-term results revealed that IPDs are safe and effective, and that these could play a key role in preventing accelerated ASD due to the protective effects of retaining segmental motion.[24]

As a type of nonfusion interspinous process implant, the Wallis system can reduce the flexion and extension of symptomatic spinal levels, while retaining some of the actions of the pathologic segments and reducing intradiscal stress, facet load, and ROM at the adjacent segments, thereby avoiding or delaying ASD. However, several clinical studies have shown that postoperative complications following a Wallis interspinous implantation may include spinous process fracture, prosthesis loosening, recurrent lumbar disc herniation, and osteoporotic fractures of the adjacent segments.[7,25] Lafage et al[26] studied the biomechanical effects of the Wallis system through the biomechanical and FE analyses of interspinous implants in vitro. Results revealed that the Wallis system could reduce the ROM of the symptomatic spinal level during flexion and extension, but it increased the stress of the related spinous process at the same time.[26] In the present series, a clinical study, which comprised of 44 patients with a 1-year follow-up, revealed that surgical segments treated with a Wallis implant presented with spinous process bone resorption.

On the basis of the above studies, it can be hypothesized that lumbar spinal stability after IPD implantation may be affected by spinous process absorption in the adjacent segments. For these reasons, in the present study, the investigators developed an FEM of bone resorption of the L4 and L5 spinous process after the implantation of Wallis interspinous implants based on the intact lumbar model and clinical research data obtained from 44 patients who were followed up. The influence of spine bone resorption on the corresponding stress load could be investigated by comparing the stress changes in the lumbar spine before and after bone resorption.

9. Stress on the intervertebral disc

Lumbar disc herniation recurrence, prosthesis loosening, and adjacent segment compression fractures are common postoperative complications of Wallis implants.[5,7,25] The reported incidence of the postoperative recurrence of intervertebral disc herniation was 13% after Wallis implantation.[7] Normally, the lumbar intervertebral disc bears 80% of the axial stress of the lumbar spine. The etiology of lumbar degeneration remains unclear, but high pressure in the lumbar disc has been considered to play a key role. Moreover, the hypothesis behind the use of the Wallis spacer is that increasing the distance of the intervertebral disc with the implantation of an IPD between spines can avoid lumbar fusion and distribute the axial stress of the lumbar intervertebral disc. However, in the present study, it was found that during the early period after the implantation of the Wallis system, the intervertebral disc pressure during various motion states significantly decreased. Furthermore, the intervertebral disc pressure in all types of motion states were significantly elevated in cases of bone resorption, reaching or even exceeding normal lumbar intervertebral disc stress levels. The exception was that these stress levels were lower than the normal lumbar intervertebral disc stress in the posterior extension state. This result could be correlated with the recurrence of lumbar disc herniation.

10. Stress on the facet

Several recent studies have found that facet stress during posterior extension is significantly higher than during flexion.[27] In addition, facet stress alters as the body position is changed and reaches its maximum in the posterior extension position. A recent FE analysis study revealed that facet stress in adjacent segments after lumbar fusion increased by 80% to 90% and 20% to 90% in the posterior extension and rotation, respectively.[28] In the same way, another study has proven that the facet stress on the adjacent segment after lumbar fusion significantly increased in a biomechanical experiment in vitro.[29] Moreover, Wiseman et al revealed changes in facet stress after interspinous process implantation, suggesting that facet stress could slightly decrease along with the implantation of IPDs at the surgical segment with no obvious influence on the adjacent segment facet.[30] In the present study, the same stress changes were found. That is, in every motion state, except flexion, postoperative facet stress decreased, compared with preoperative facet stress. Furthermore, there was no significant difference in postoperative facet stress in the flexion state. Moreover, after bone resorption occurred, facet stress was significantly greater than before bone resorption. The most significant stress change occurred in the posterior extension condition. To some extent, these findings explain the causes of the stress on the facets of the lumbar vertebra after IPD implantation.

11. Stress on the spinous process

The advantage of Wallis system implants is its ability to retain the flexion and posterior extension motions of the surgical segment, while increasing the stress on the surgical spinous process.[8,26] The Wallis system absorbs some of the axial stresses of the spine. The stress load transmitted from the cranial to caudal segments of the spine is mainly concentrated on the spinous process of the surgical segments, and the caudal segment experiences the greatest stress. In addition, the bundling belt of the Wallis device is fixed on the spinous process, increasing the stress on the spinous process and prosthesis. In the present study, it was found that before the bone resorption of the spinous process, stress was greater in the L5 spinous process than in the L4 spinous process. Tanne et al[31] found in 1990 that traction and compression stress were associated with bone resorption. Their FE analysis revealed that increased local stress could correspondingly lead to bone resorption and bone remodeling. Furthermore, through FE studies and animal experiments, Takuma et al[32] proposed that these mechanical stress changes resulted in bone resorption and bone remodeling. According to the data obtained from the present experiment model, immediately after surgery, there was no obvious difference between the L4 and L5 spinous process under the upright condition. However, when the flexion and extension positions were compared, the stress on the surgical segment obviously increased, and the stress on the L5 spinous process was greater than the stress on the L4 spinous process. After bone resorption, stress at the L4 and L5 spinous process was significantly lower, compared with that before bone resorption, and there was no statistically significant difference between L4 and L5. As the Wallis nylon bind belt limits spine motion, stress on the L4 spinous process was greater than that on the L5 spinous process under flexion. In the extension state, stress on the spinous process was significantly greater than that in the flexion state.

In comparing the Wallis and Wallis-BR groups, it was found that spinal stress after bone resorption was significantly lower than that before bone resorption occurred. This finding illustrates that the extent of bone resorption might be associated with stress.

12. ROM of the lumbar spine

Second-generation interspinous process implants (the Wallis system) are made of polyetheretherketone (PEEK), and are developed to decrease the gap in the spinous processes, absorb part of the load of the corresponding segment's intervertebral disc and facets, limit the extension of the segment, and restrict excessive flexion through the spine bundling belts.[33,34] The Wallis device reduces the stress on the surgical segment's intervertebral disc and facet, while retaining a certain ROM in the corresponding segment. When spinal bone resorption occurs, the spinous process cannot provide stable stress transmission, which causes biomechanical changes in the surgical segment and increases the stress on its intervertebral disc and facet, thereby changing the motion of the surgical segment. In the present study, compared with normal lumbar ROM, the motion of the spinal model with the Wallis implantation was reduced to more than 1° in the flexion and posterior extension states. In the short-term, Wallis implantation could limit the lumbar flexion and posterior extension motions to provide stability for the lumbar spine.

Figure 5. (A) The magnetic resonance imaging (MRI) for the 54-year-old Chinese woman is shown. (B) The X-ray at postoperative 1 month is shown.

However, the ROM after bone resorption was greater than 1° in the flexion state. Compared with lumbar ROM during the early postoperative period, the motion of the lumbar spine with bone resorption obviously increased. This could indicate a decrease in the ability of the Wallis device to reduce the motion of the segment and decrease stress on the disc and facet.

13. Case presentation

A 54-year-old Chinese woman visited our hospital due to a 6-month history of low back pain and right-sided sciatica. The lumbar plain film revealed osteophyte formation without instability on the lateral dynamic X-ray. The magnetic resonance imaging (MRI) revealed that the bulging L4/L5 level right-sided lumbar intervertebral disc, the facets, and the yellow ligaments hypertrophy caused lumbar canal stenosis (Fig. 5A). The patient was diagnosed with sciatica induced by lumbar canal stenosis. The JOA score was 18 and the VAS score was 6. The patient was treated with a Wallis system implantation at the L4/L5 segment. The symptoms of lumbalgia and sciatica significantly improved after surgery. In addition, the JOA score was 25 and the VAS score was 1. The X-ray results at postoperative one month revealed the Wallis system was placed well. After 1 year, the patient sought for an evaluation at our Outpatient Department for the reoccurrence of right-sided sciatic pain. The lumbar plain film revealed a decrease in disc space height and the spinous process bone resorption at the L4-L5 level. The MRI revealed L4/L5 segment disc prolapse (Fig. 5B).

Bone resorption of the spinous process after the implantation of the Wallis device refers to a process of bone remodeling associated with stresses that may be related to postoperative intervertebral disc and facet degeneration, recurring lumbar disc herniation, and postoperative low back pain. After bone resorption, the function of the Wallis device may gradually decrease.

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