



Biomechanical investigation of topping-off technique using an interspinous process device following lumbar interbody fusion under vibration loading

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Abstract

Topping-off technique has been proposed to prevent adjacent-segment degeneration/disease following spine fusion surgery. Nevertheless, few studies have investigated biomechanics of the fusion surgery with topping-off device under whole-body vibration (WBV). This biomechanical study aimed to investigate the vibration characteristics of human lumbar spine after topping-off surgery, and also to evaluate the effect of bony fusion on spine biomechanics. Based on a healthy finite-element model of lumbosacral spine (L1–sacrum), the models of topping-off surgery before and after bony fusion were developed. The simulated surgical procedures consisted of interbody fusion with rigid stabilizer at L4–L5 segment (rigid fusion) and dynamic stabilizer at degenerated L3–L4 segment. An interspinous implant, Device for Intervertebral Assisted Motion (DIAM, Medtronic Inc., Minnesota, USA), was used as the dynamic stabilizer. The stress responses of spine segments and implants under a vertical cyclic load were calculated and analyzed. The results showed that compared with rigid fusion alone, the topping-off technique significantly decreased disc stress at transition segment (L3–L4) as expected, and resulted in a slight increase in disc stress at its supra-adjacent segment (L2–L3). It indicated that the topping-off stabilization using DIAM might provide a good tradeoff between protection of transition segment and deterioration of its supra-adjacent segment during WBV. Also, it was found that bony fusion decreased stress in L4 inferior endplate and rigid stabilizer but had nearly no effect on stress in DIAM and L3–L4 disc, which was helpful to determine the biomechanical differences before and after bony fusion.

Keywords Topping-off · DIAM · Lumbar interbody fusion · Biomechanics · Finite element · Vibration

1 Introduction

Adjacent-segment degeneration/disease (ASD) is a major concern after spine fusion surgery [1]. According to a meta-analysis study [2], the occurrence of radiograph ASD and symptoms ASD was 26.6% and 8.5%, respectively, in lumbar position after the surgery. It implied that the fusion surgery was associated with significant risk of ASD. Although the exact mechanism remains uncertain, biomechanical changes after spine fusion surgery likely played a primary role in developing ASD [3]. Numerous studies, both experimental

and numerical [4–7], suggested that the stress (e.g., disc stress and intradiscal pressure), facet loading, and mobility at adjacent segments of the fusion one were increased. Many researchers believed that the rigid fixation system, commonly used to stabilize the spine after fusion surgeries, increased stiffness of the fixed segment much more than desired and contributed to the abnormal forces and hypermobility at its adjacent segments, thus resulting in the development of ASD [8, 9].

Based on the aforementioned biomechanical evidences for ASD, a new posterior stabilization method named topping-off technique, in terms of hybrid use of the rigid and dynamic stabilizers, was proposed to prevent hypermobility and overstress at the segment adjacent to the fusion level and thus reduce the risk of ASD [10]. In the application of topping-off technique, the fusion segment was immobilized by a rigid stabilizer, and the segment above the fusion level (i.e., transition segment) was further protected by a dynamic

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stabilizer, as illustrated in Fig. 1. The dynamic stabilizer used in topping-off surgery was either a pedicle-based stabilization device (e.g., Dynesys, NFlex, Cosmic) or an interspinous process device (e.g., Coflex, Wallis, DIAM) [11, 12], which had less rigid and could provide the segment with flexibility [13, 14].

To evaluate the biomechanical effect of topping-off technique on spine segments, several experimental and finite-element studies have been conducted in recent years. For example, an *in vitro* experimental study of Kong et al. [15] demonstrated that L5–S1 lumbar fusion with topping-off device using Coflex in L4–L5 was able to restrict range of motion (ROM) for flexion/extension at the transition segment (L4–L5) compared with rigid fusion alone and had no significant effect on ROM at its supra-adjacent segment (L3–L4). A finite-element study of Lee et al. [16] reported that compared with L4–L5 rigid fusion alone, the topping-off technique using NFlex or DIAM in L3–L4 decreased intradiscal pressure at the transition segment (L3–L4) under flexion, extension, lateral bending, and axial rotational moments, but increased the stress at its supra-adjacent segment (L2–L3) in all loading directions except under extension. However, most of these existing biomechanical studies were performed under a static loading condition such as bending and torsion moments, and very few dealt with the condition of whole-body vibration (WBV).

WBV is a situation where human body vibrates due to external vibration excitation and is typically present in vehicles [17]. It was demonstrated in previous studies that the

cyclic loading encountered due to WBV exposure could generate higher stress responses in spinal tissues than the static loading with equivalent magnitudes [18, 19]. At present, WBV has been considered a significant risk factor for degenerative lumbar spinal disorders and low back pain [20, 21]. Considering the fact that the patients undergoing lumbar spine surgery may also be exposed to WBV in their daily life and work (e.g., driving a car or riding on a bus), recent years have seen increasing interests and demands in analyzing biomechanical responses of the postsurgical spine to WBV [17, 22, 23]. Accordingly, the goal of this study was to investigate the biomechanics of human lumbar spine (L1–sacrum) after the topping-off surgery under WBV by means of finite-element analysis. In clinical practice, topping-off technique is often used following single-level posterior or transforaminal lumbar interbody fusion (PLIF or TLIF) when ASD has already occurred [12, 24, 25], so the PLIF and TLIF at L4–L5 with a moderately degenerated disc at L3–L4 were considered in this study. In addition, the differences in vibration responses of the implanted spine between early and late postoperative stages (before and after bony fusion) still remained unclear. Therefore, we also evaluated the effect of bony fusion on biomechanics of the implanted spine under WBV.

2 Materials and methods

2.1 Finite-element simulation of surgical procedures and implants

The healthy finite-element model of human lumbosacral spine, developed and validated previously [26], was employed in this study (Fig. 2A). Geometry of the model was reconstructed from computed tomography (CT) scans of a healthy volunteer. The model includes vertebral bodies, posterior bony elements, intervertebral discs, and seven ligaments. Each vertebral body consists of a cancellous inner core surrounded by a cortical shell (including endplate). Each intervertebral disc consists of a nucleus pulposus surrounded by an annulus ground substance comprising fiber layers. Material properties assigned to the spinal components are shown in Table 1.

Using the aforementioned healthy model as a baseline, L4–L5 rigid fusion with a moderately degenerated L3–L4 intervertebral disc was initially simulated. Two interbody fusion approaches, PLIF and TLIF, were considered in this study. To simulate the PLIF surgical procedure, partial laminectomy and medial facetectomy were performed at L4–L5 segment with removal of the entire nucleus, posterior portion of the annulus, supraspinous ligament, interspinous ligament, and ligamentum flavum, and two PLIF cages were inserted into L4–L5 intervertebral space (Fig. 2B). To

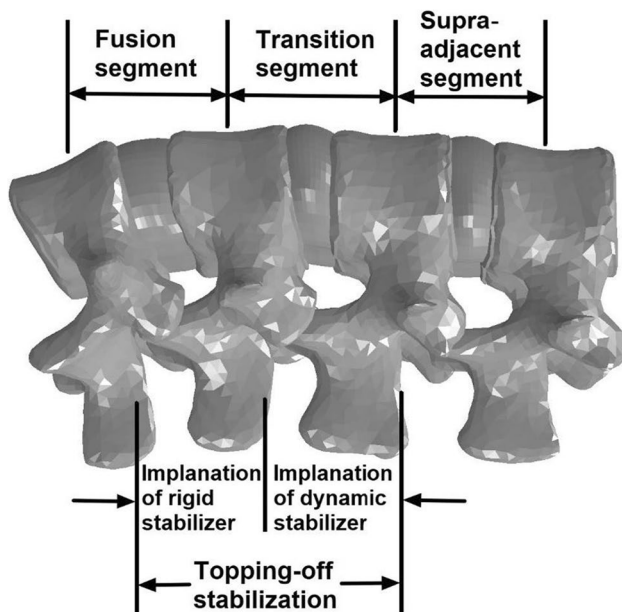


Fig. 1 Graphical illustration of the topping-off technique applied to stabilize the lumbar spine after fusion surgery (lumbar spinal levels L2–L5 are shown)

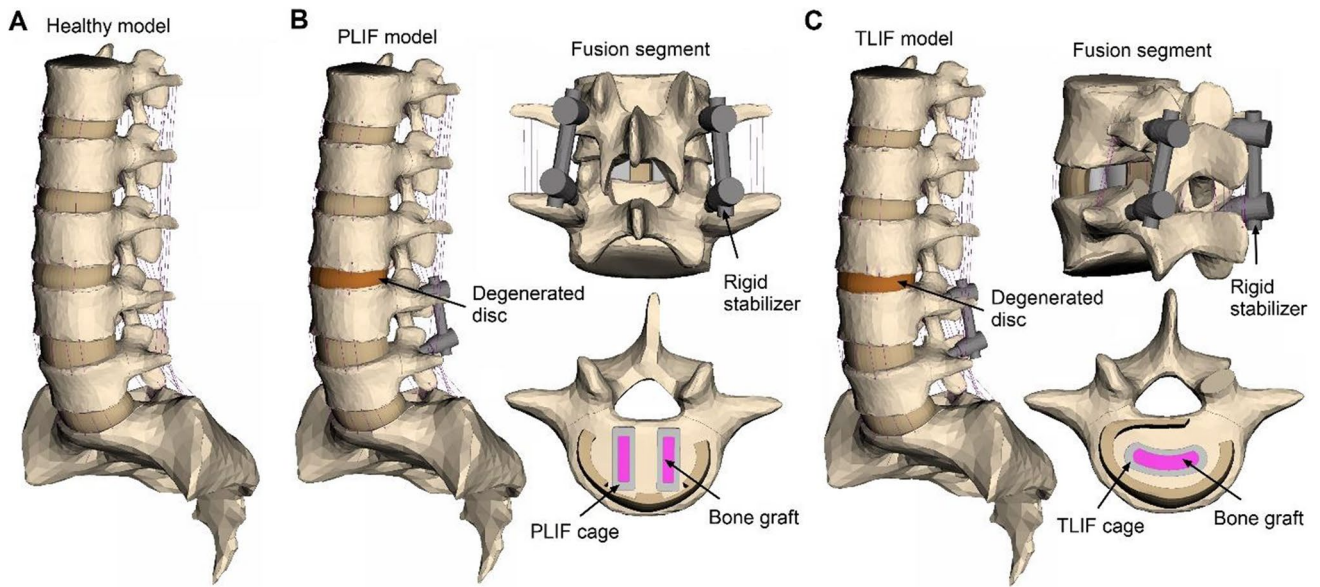


Fig. 2 Finite-element models of the human lumbosacral spine. **A** Healthy model; **B** and **C** rigid fusion models. For the fusion model, intervertebral cage and conventional rigid stabilizer were instrumented at L4–L5 segment, and a moderately degenerated disc was simulated at L3–L4 segment

Table 1 Material properties for the present finite-element models

Component	Young's modulus (MPa)	Poisson's ratio	Cross-sectional area (mm ²)	Density (kg/mm ³)
Bone				
Cortical bone	12,000	0.3		1.7e-6
Cancellous bone	100	0.2		1.1e-6
Endplate	23.8	0.4		1.2e-6
Posterior bony elements	3500	0.25		1.4e-6
Intervertebral disc				
Annulus ground substance	Hyperelastic, Mooney-Rivlin C ₁₀ =0.18, C ₀₁ =0.045			1.05e-6
Nucleus pulposus (healthy)	Hyperelastic, Mooney-Rivlin C ₁₀ =0.12, C ₀₁ =0.03			1.02e-6
Nucleus pulposus (degenerated)	Hyperelastic, Mooney-Rivlin C ₁₀ =0.17, C ₀₁ =0.041			1.02e-6
Annulus fibers	360–550	0.3		1.0e-6
Ligaments				
Anterior longitudinal	7.8(< 12.0%) 20.0(> 12.0%)		63.7	1.0e-6
Posterior longitudinal	10.0(< 11.0%) 20.0(> 11.0%)		20	1.0e-6
Ligamentum flavum	15.0(< 6.2%) 19.5(> 6.2%)		40	1.0e-6
Supraspinous	8.0(< 20.0%) 15(> 20.0%)		30	1.0e-6
Interspinous	10.0(< 14.0%) 11.6(> 14.0%)		40	1.0e-6
Intertransverse	10.0(< 18.0%) 58.7(> 18.0%)		1.8	1.0e-6
Capsular	7.5(< 25.0%) 32.9(> 25.0%)		30	1.0e-6
Implants				
Cage (PEEK)	3600	0.25		1.32e-6
Rigid fixator (titanium)	110,000	0.3		4.5e-6
DIAM (Silicone core covered by polyester)	2100	0.35		1.8e-6

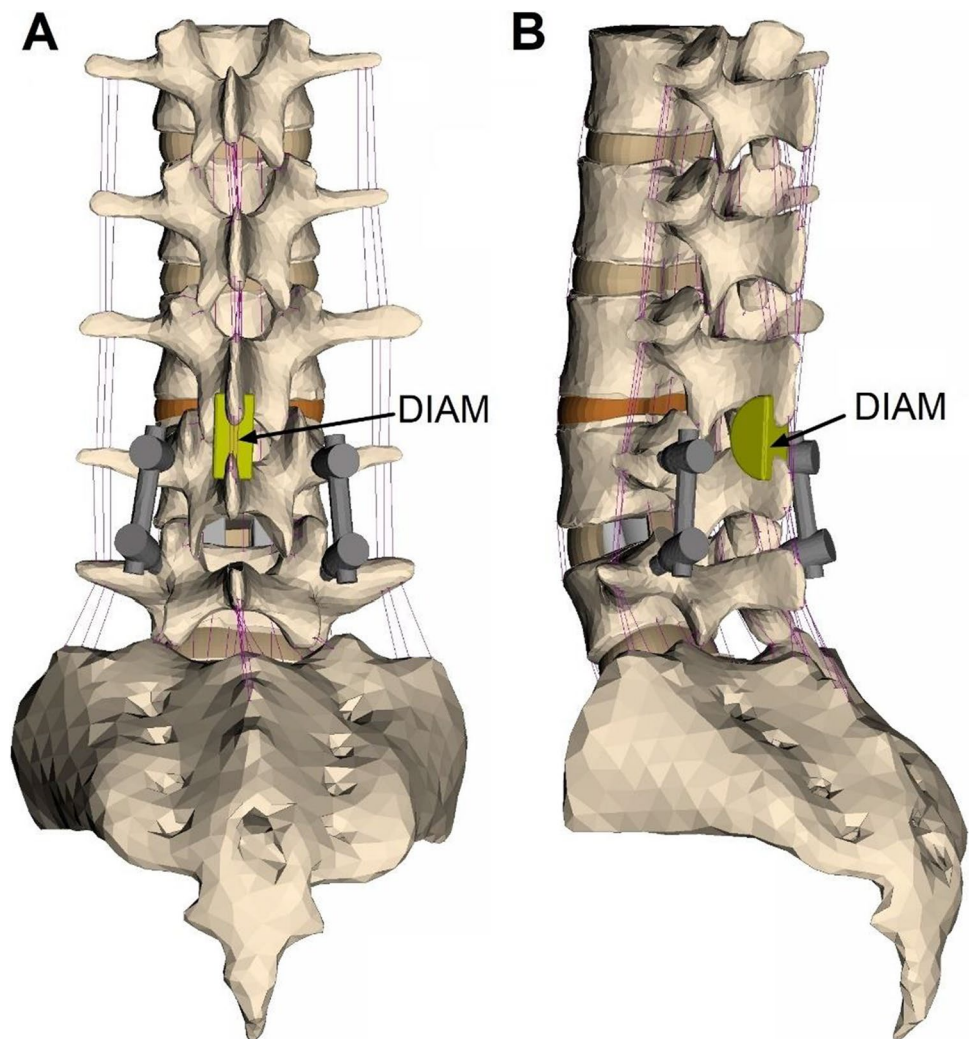
simulate the TLIF surgical procedure, the left facet joint, entire nucleus, and posterior-left portion of the annulus at L4–L5 segment were removed, and a TLIF cage was inserted into L4–L5 intervertebral space (Fig. 2C). The sizes of PLIF and TLIF cages are 25 mm depth \times 9 mm width \times 12 mm height (surface area: 330 mm² for 2 PLIF cage) and 10 mm depth \times 30 mm width \times 12 mm height (surface area: 185 mm²), respectively [27], and all the cages were filled with cancellous bone to simulate the embedded bone graft. For the PLIF and TLIF models, the L4–L5 fusion segment underwent a conventional rigid stabilizer instrumentation using bilateral pedicle screws and titanium rods. Also, a moderate disc degeneration at L3–L4 segment for these two rigid fusion models was simulated by changing the disc height and material property of the nucleus, which has been described in detail in our previous work [28]. Specifically, the height of healthy L3–L4 disc was decreased (about by 33%), and the material values (Young's modulus) of healthy L3–L4 nucleus were increased (from $C_{10}=0.12$, $C_{01}=0.03$ to $C_{10}=0.17$, $C_{01}=0.041$, as shown in Table 1).

Subsequently, based on these developed rigid fusion models (Fig. 2B and C), an interspinous implant, Device for Intervertebral Assisted Motion (DIAM, Medtronic Inc., Minnesota, USA), consisting of a “H”-shape silicone core with a polyester cover [29], was further inserted between spinous process of L3 and L4, where the interspinous ligament was removed for DIAM insertion, to construct the topping-off model (Fig. 3). To prevent instability and secure the prosthesis, DIAM and spinous processes were connected by the tightening ligatures that were modeled using tension-only spring elements [16, 30]. Assigned material properties to the implants in the finite-element models are also shown in Table 1.

2.2 Contact definitions and boundary conditions

The interfaces between the graft and endplate, as well as the cage and endplate were defined as surface-to-surface contact to simulate early postoperative stage after cage placement (before bony fusion). A friction coefficient of 0.3 was

Fig. 3 The topping-off models developed by additionally placing DIAM at L3–L4 segment of the rigid fusion model. **A** PLIF + DIAM; **B** TLIF + DIAM



assigned to the graft-endplate interface to mimic a more physiologic situation [31], where the surfaces of bone graft were not fused to the endplates. A higher friction coefficient of 0.8 was assigned to the cage-endplate interface because the cage has serrations on the contact surfaces that are supposed to prevent motion of the cage [32]. The interface between the DIAM and spinous processes was also defined as surface-to-surface contact with a friction coefficient of 0.2 [29]. The interface between the pedicle screw and vertebra was assumed to be completely bonded via node sharing as a result of successful surgery. In addition, to simulate late postoperative stage after cage placement (after bony fusion), the graft-endplate and cage-endplate interfaces were changed to tie constraint.

The developed finite-element models were completely fixed at the caudal part of sacrum and were loaded with a compressive follower pre-load of 400 N. Furthermore, additional sinusoidal vertical force of 40 N at the frequency of 5 Hz was applied to simulate WBV condition. The loading scenario has been used and detailedly described in our previous studies [19, 33]. To consider pre-tension of the ligatures for DIAM, an initial tension force of 120 N was applied for secure tightening [16]. Vibration responses of the models were calculated using transient dynamic analysis. The von Mises stress in spine segments and implants was chosen as the evaluation indices, which were collected and plotted as time-dependent curves. As suggested by the literature [18, 34], the stress was defined as the average of the stresses in the elements used to build the corresponding tissues of the models, and vibration amplitude of the stress was defined as

maximum minus minimum values of the obtained dynamic response curve. The commercial finite-element analysis software ABAQUS/Standard (Dassault Systems Simulia Corp., Providence, RI, USA) and pre-processing software ANSA (BETA CAE Systems S.A., Thessaloniki, Greece) were employed in this study.

3 Results

3.1 Biomechanical effect of topping-off technique on transition and its supra-adjacent spine segments

Time-domain dynamic responses of the disc stress at transition segment (L3–L4) and its supra-adjacent segment (L2–L3) are displayed in Fig. 4. The maximum value and vibration amplitude of these response curves were summarized in Fig. 5. Compared with rigid fusion alone, the topping-off technique significantly decreased the stress response at L3–L4 segment as observed from Fig. 4A and B. For example, the maximum stress and vibration amplitude for PLIF with DIAM was 0.198 MPa and 0.071 MPa, respectively, which was 32.9% and 50.7% lower than those (0.295 MPa and 0.144 MPa) for PLIF alone. However, it was observed from Fig. 4C and D that the topping-off technique caused a slight increase in the stress response at L2–L3 segment. For example, the maximum stress and vibration amplitude for PLIF with DIAM were 0.370 MPa and 0.111 MPa, respectively, which was 3.9% and 3.7% higher than those

Fig. 4 Comparison of dynamic responses of the disc stress to the vibration loading between the rigid fusion models and the topping-off models using DIAM. **A** and **B** Disc stress at transition segment (L3–L4); **C** and **D** disc stress at supra-adjacent segment (L2–L3)

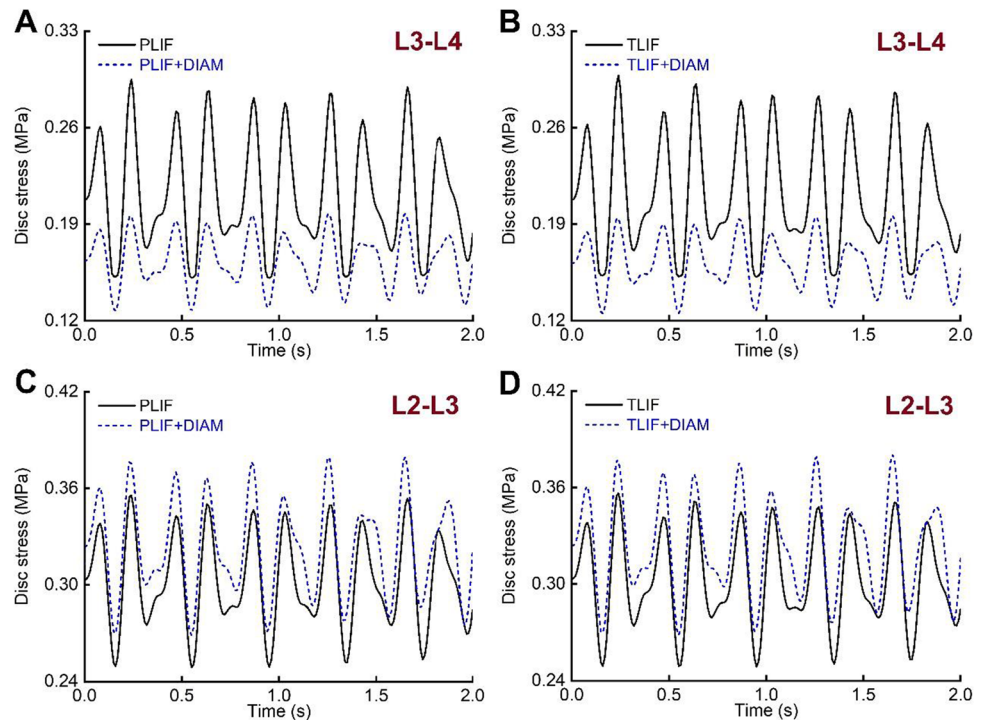
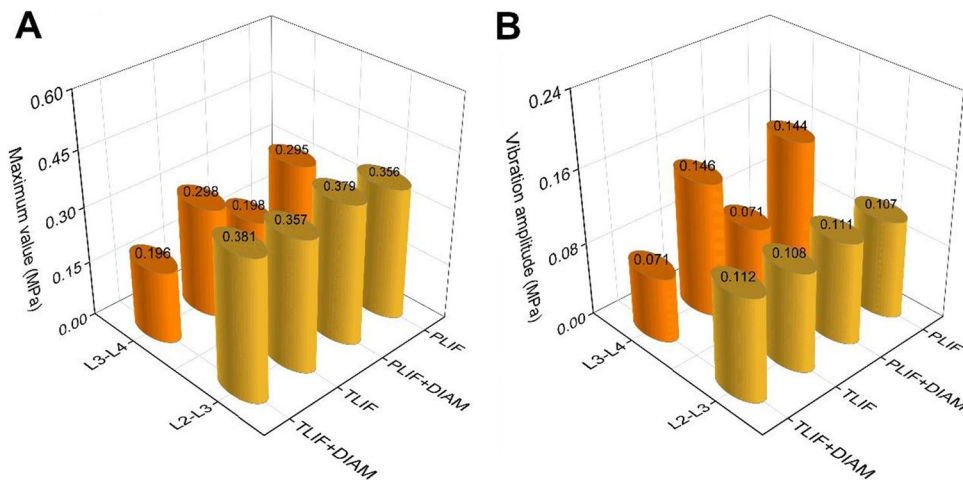


Fig. 5 Comparison of **A** maximum value and **B** vibration amplitude of the dynamic response curves in terms of disc stress (illustrated in Fig. 4) between the rigid fusion models and the topping-off models using DIAM



(0.356 MPa and 0.107 MPa) for PLIF alone. From Figs. 4 and 5, it was also found that there was no obvious difference in the disc stress at both L3–L4 and L2–L3 between PLIF and TLIF.

3.2 Biomechanical effect of bony fusion on the topping-off models

Time-domain dynamic responses of the stress in L4 inferior endplate, rigid stabilizer, DIAM, and L3–L4 disc before and after bony fusion for the topping-off models are displayed in Fig. 6. The maximum value and vibration amplitude of these response curves are listed in Table 2. As demonstrated, the

bony fusion significantly decreased the stress responses of endplate and rigid stabilizer (Fig. 6A and B). For example, the maximum stress in L4 inferior endplate and rigid stabilizer for PLIF with DIAM after bony fusion was 0.73 MPa and 5.2 MPa, respectively, which was 54.9% and 59.4% lower than those (1.62 MPa and 12.8 MPa) before bony fusion, and the corresponding vibration amplitude after bony fusion was 0.19 MPa and 1.5 MPa, respectively, which was 9.5% and 16.7% lower than those (0.21 MPa and 1.8 MPa) before bony fusion. However, the bony fusion had nearly no effect on stress responses of DIAM and L3–L4 disc (Fig. 6C and D). To demonstrate the differences in the stress distribution before and after bony fusion, contour plots of the stress

Fig. 6 Comparison of stress responses in the topping-off models to the vibration loading before and after bony fusion. **A** Stress in L4 inferior endplate; **B** stress in rigid stabilizer; **C** stress in DIAM; **D** stress in L3–L4 disc

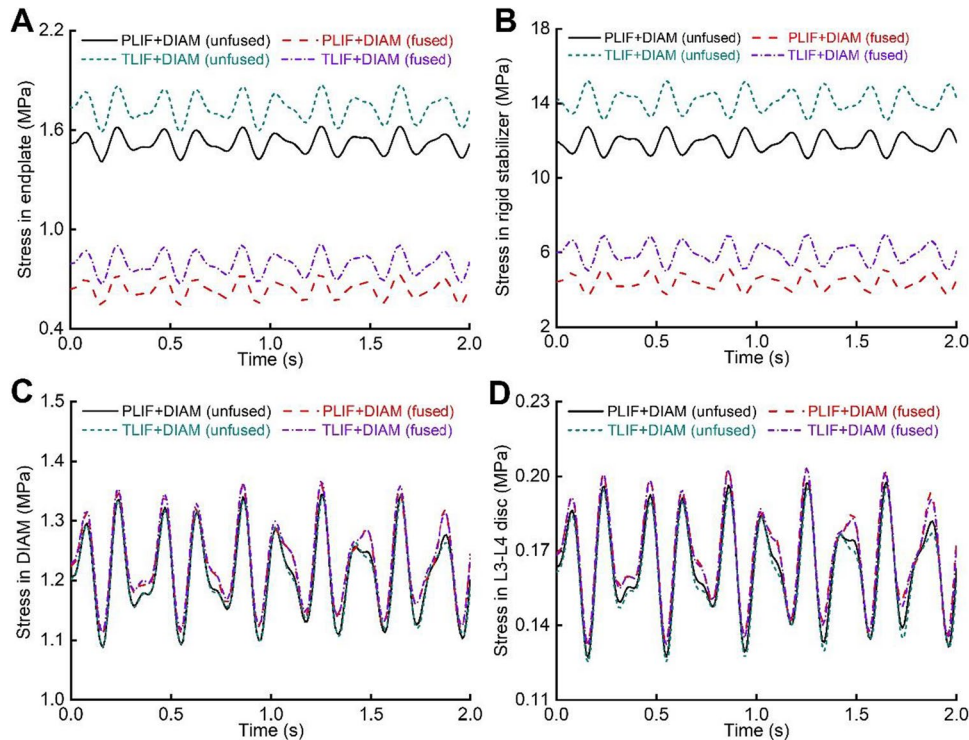


Table 2 The maximum and minimum values and vibration amplitude (maximum minus minimum) of the stress response curves illustrated in Fig. 6 (Unit: MPa)

Stress response	PLIF + DIAM (unfused)	PLIF + DIAM (fused)	TLIF + DIAM (unfused)	TLIF + DIAM (fused)
In L4 inferior endplate				
Max	1.62	0.73	1.87	0.91
Min	1.41	0.54	1.59	0.67
VA	0.21	0.19	0.26	0.24
In rigid stabilizer				
Max	12.8	5.2	15.3	6.9
Min	11.0	3.7	13.0	5.0
VA	1.8	1.5	2.3	1.9
In DIAM				
Max	1.34	1.36	1.34	1.37
Min	1.09	1.11	1.09	1.11
VA	0.25	0.25	0.25	0.26
In L3–L4 disc				
Max	0.198	0.204	0.196	0.203
Min	0.127	0.132	0.125	0.132
VA	0.071	0.072	0.071	0.071

Max, maximum value; *Min*, minimum value; *VA*, vibration amplitude

in L4 inferior endplate and rigid stabilizer are presented in Fig. 7, which depicts high stress concentration before bony fusion, whereas low stress concentration was observed after bony fusion. In addition, from Figs. 6 and 7 and Table 2, it was also found that the PLIF led to lower stress in L4 inferior endplate and rigid stabilizer than TLIF.

4 Discussion

In our previous studies, biomechanical responses of lumbar spine after single-level interbody fusion surgery supplemented with a conventional single-level rigid stabilizer to WBV had been investigated [23]. Furthermore, in the present study, a biomechanical comparison between the conventional rigid stabilization and the topping-off stabilization was conducted under WBV. It was found that vibration characteristics of the investigated spine segments were different between the rigid fusion and topping-off models (Figs. 4 and 5). As expected, dynamic response of the disc stress at transition segment (L3–L4) was significantly lower in the topping-off model than that in the rigid fusion model (Figs. 4A and B and 5), implying that the dynamic stabilizer (DIAM) helped to absorb much of the vibration energy. This is because the DIAM device suppressed mechanical compensation from fusion segment (L4–L5) to transition segment. The present predicted results showed a consistent trend with previous studies conducted under static loading (bending and torsion moments) [34, 35], indicating that the dynamic stabilizer used in topping-off stabilization can show loading-sharing ability at transition segment regardless of

loading condition. In contrast, dynamic response of the disc stress at supra-adjacent segment (L2–L3) was slightly higher when using the topping-off technique (Figs. 4C and D and 5). This is because the increased stiffness due to DIAM instrumentation at transition segment induced mechanical compensation to its supra-adjacent segment. Previous studies reported that the protection of transition segment and the deterioration of its supra-adjacent segment was a tradeoff problem for the topping-off technique [34, 36, 37]. Overall, the present results, in terms of significantly decreased stress at transition segment and slightly increased stress at its supra-adjacent segment, indicated that the topping-off stabilization using DIAM might provide a good tradeoff between the protection and deterioration under vibration loading. Also, the present study provided a biomechanical evidence for the effectiveness of topping-off technique in preventing ASD after the fusion surgery [10, 12].

By reviewing the published finite-element simulation studies concerning lumbar interbody fusion, the current authors found that according to whether or not the graft was fused to the endplate, either a surface-to-surface contact [31, 32, 38] or a tie constraint [7, 9, 16] was defined between the surfaces of graft and endplate to simulate early or late postoperative stage. However, few studies explored the biomechanical differences between these two definitions. Also, only the tie constraint was considered in our previous finite-element studies associated with WBV [23]. Therefore, in the present study we tried to compare the definition of tie constraint with the definition of surface-to-surface contact. In other words, the difference in biomechanics of the implanted spine before and after bony fusion was investigated. It was

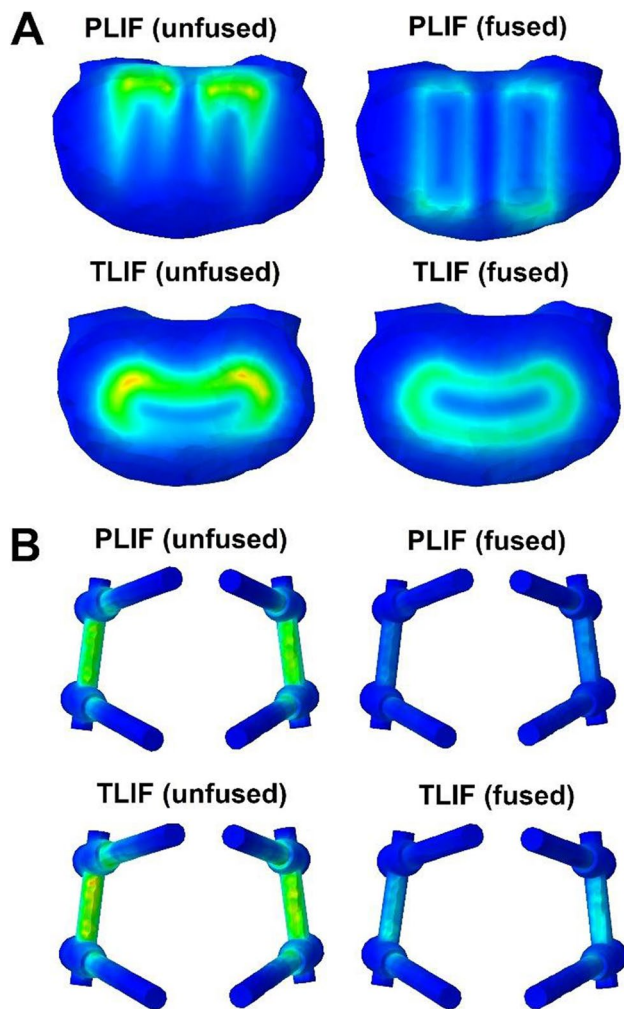


Fig. 7 Comparison of stress distribution in the topping-off models before and after bony fusion. **A** Contour plots of the stress in L4 inferior endplate; **B** contour plots of the stress in rigid stabilizer (step time was 0.75 s)

found that the bony fusion decreased dynamic responses of the stress in L4 inferior endplate and rigid stabilizer (Fig. 6A and B and Table 2), implying that the bony fusion is helpful in reducing the risk of bone failure and breakage for the rigid stabilizer. Moreover, a more uniform stress distribution in the endplate was observed after the bony fusion (Fig. 7). This might be attributed to the difference in load afforded by the graft before and after bony fusion. When the graft was not fused to the endplate, it could transmit compression force only, but after fusion, the graft could help to control the distraction and rotation forces. Because compressive stiffness of this fused level was not affected, dynamic responses of the stress in DIAM and L3–L4 disc at the transition segment was nearly unchanged (Fig. 6C and D and Table 2). In addition, recent *in vitro* experimental studies reported that the lumbar interbody fusion procedures using cage designs with larger footprint size had higher subsidence resistance [27,

39]. The results presented in Figs. 6A and 7A and Table 2 also showed that the endplate stress in cage-endplate interface for PLIF (having a larger cage footprint) was lower than that for TLIF. It implies that the PLIF might face lower risk of cage subsidence than TLIF, which was consistent with the abovementioned experimental results. Due to the fact that larger footprint interbody devices allow for higher loading sharing through anterior column and thus decrease the loading sharing through posterior fixation system [38], the PLIF led to lower stress in rigid stabilizer than TLIF (Figs. 6B and 7B and Table 2).

There were some limitations and potential future direction for the present study. Finite-element model geometry was obtained from a unique specimen, so the computed absolute values might be unrepresentative of an average person. Nevertheless, the tendency of the predicted results was not affected because all the investigated models were constructed based on the same intact model. Like many other finite-element studies, the present models also did not include the degenerative changes caused by osteophytes, endplate sclerosis, and annular tears due to limitation of data source. In addition, the topping-off technique using pedicle-based dynamic stabilization device was not investigated here, which might present different biomechanical behavior compared with the present interspinous process device, and we will try to reveal their biomechanical differences in the following study. Also, the effect of WBV and these different posterior stabilization devices on biomechanical responses of lumbar paraspinal muscles of the patients undergoing the fusion surgery will be investigated using an *in vivo* experimental method in the future work.

5 Conclusion

The present study attempted to quantitatively evaluate the effect of topping-off stabilization and bony fusion on biomechanics of the implanted lumbar spine exposed to vertical WBV by means of finite-element analysis. In conclusion, under the vibration loading, the topping-off technique using DIAM device provided a good tradeoff between protection of transition segment (L3–L4) and deterioration of supra-adjacent segment (L2–L3). The bony fusion altered vibration characteristics of the fusion segment (L4–L5), at which the dynamic responses of stress in endplate and rigid stabilizer were significantly decreased. However, the bony fusion had little effect on the stress response of DIAM and L3–L4 disc at the transition level. These findings may be helpful in understanding biomechanics of the topping-off stabilization and determining biomechanical differences of the implanted lumbar spine before and after bony fusion during WBV, and thus may provide a reference regarding

lumbar vibration protection of the patients undergoing the surgical instrumentation for clinical studies.

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Declarations

Conflict of interest The authors declare no competing interests.

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