

Which is the better posterior lumbar dynamic device: Dynesys or BioFlex?

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Abstract

Objective: The purpose of this study was to analyze the biomechanical characteristics of the lumbar posterior dynamic devices: the Dynesys system and the BioFlex system.

Methods: We validated the FE model of an lumbar spine (L3-S1) established by transferring the data, collected by 3D CT scan, to the FE software ABAQUS and comparing these data with the data from published studies. Then, were reconstructed by the lumbar posterior dynamic devices to analyze the range of motion (ROM) and stress distribution on the lumbar posterior dynamic devices.

Results: The current lumbar FE model was able to measure the biomechanical changes in a follow-up surgery simulation. The total ROM of the surgery simulation models was substantially decreased compared with the total ROM of the intact group, and the Dynesys system group had the closest total ROM to the intact group. The maximal von Mises stress concentrate at the middle part of the screws in Dynesys system, but at the Nitinol memory loop in BioFlex system. The maximal stress level was only 49 MPa in Dynesys system, but 164 MPa in BioFlex system.

Conclusion: Through the comparison of ROM and the stress distribution of the prosthesis, we find that the Dynesys system maybe has a better theoretical outcome.

Introduction

In the past few decades, Spinal fusion with rigid fixation is the primary surgical treatment for lumbar disc disease. However, many studies have demonstrated that spinal fusion with rigid fixation may cause high morbidity and complication rates, such as, stress-shielding, the acceleration of adjacent segments degeneration, loss of motion, fatigue fractures, and changes in the centers of intervertebral rotation [1]. Recent studies have suggested that posterior dynamic devices may provide a better surgical alternatives for lumbar spinal disease [2]. The dynamic systems that can stabilize operated segments, restore the mobility and prevent the adjacent segment degeneration after lumbar operation [3].

Recently, numerous posterior lumbar dynamic devices have been used for the lumbar disc disease. Dynesys system (Zimmer Inc., Minneapolis, MN), it includes titanium alloy pedicle screws and polycarbonate urethane spacers that surround tensioned polypolyester rope. The device has several theoretical advantages, such as preventing adjacent segment degeneration and reducing the failure risk at the bone-implant interface compared to rigid fusion systems[4]. BioFlex System (Bio-Spine, Seoul, Korea), a new dynamic stabilization system consisting of titanium pedicle screws and a Nitinol memory loop[5]. The Nitino memory loop diameter used in this system is 4 mm, and the coiled shapes allow physiological stability during physiological movement [6, 7].

Despite the encouraging clinical outcomes of posterior lumbar dynamic devices, few biomechanical tests have been used in the past to investigate them, and the devices have lacked a detailed internal structural response to external loading. Some studies have examined the ability of the devices to absorb vibrational

and impact loads at adjacent segments, but have little ability to provide viscoelastic properties anywhere near those of a normal hydrated disc. Therefore, It is not yet clear which device could be efficient and beneficial for two-level lumbar spinal disease. Mathematical models such as the finite element (FE) method can be applied to discover structural responses to external loading and, more importantly, to establish an internal structural response such as stress to external loading [8]. Therefore, the purpose of the FE study is targeted to the biomechanical characteristics analysis of the posterior lumbar dynamic devices in two-level injuries: Dynesys system, and BioFlex system.

Materials And Methods

FE modeling and validation

The lumbar spine L3-S1 was developed by the reconstruction of a 3D CT of the lumbar spine of a male subject (age 26, height 177 cm, weight 75 kg). This study was approved by the ethical committee of Southern Medical University. Coronal CT images were taken with space intervals of 0.625 mm. The images were segmented using MIMICS 12.1 (Materialise, Leuven, Belgium) to obtain the boundaries of the skeletal and intervertebral disk surface. The geometry of the skeletal and intervertebral disk components was processed using Geomagic Studio 10.0 (Geomagic, Inc, Research Triangle Park, NC, USA). It was then imported into the FE package ABAQUS v6. 11.1. (SIMULIA Inc, Providence, RI, USA) to build the EF model.

The intact FE model consists of four vertebrae (L3, L4, L5 and S1), five intervertebral discs (L3–L4, L4–L5, and L5–S1), and all the important components of the lumbar spine, such as the cortical bone, cancellous bone, intervertebral discs (consisting of the disc annulus and disc nucleus), and ligaments (anterior and posterior longitudinal ligaments, flaval ligament, facet capsules, intertransverse, interspinous, and supraspinous ligaments).

For modeling of vertebral bodies and posterior elements, solid elements were used, and the material was described as isotropic. For cortical bone, shell elements were used. For cancellous bone, solid tetrahedral element was used. To simplify the model, the cortical endplate and cortical shell with 0.5 mm thickness [9] was attached to the solid cancellous elements by sharing the same node. The ligaments in the lumbar spine were incorporated into the FE model as tension-only nonlinear uniaxial connection unit. Their insertion points were chosen to mimic anatomic observations as closely as possible [10, 11]. Each spinal component represented the most commonly used values collected from the literature, and the material and mechanical properties are shown in Table 1[9].

Table 1
Material properties at different positions of the lumbar spinal finite element model

Component	Modulus (MPa)	Poisson's Ratio	Cross sectional area (CSA, mm ²)
Cortical bone	12000	0.3	/
Cancellous bone	100	0.2	/
Annulus (fiber)	4.2	0.4	/
Nucleus pulposus	1	0.499	/
Vertebral endplate	12000	0.3	/
Vertebral posterior structure	3500	0.25	/
Bone graft block	3500	0.25	/
Titanium / Nitinol alloy	110000	0.3	/
polycarbonate urethane spacers	75000	0.3	/
Anterior longitudinal	20	/	63.7
Posterior longitudinal	20	/	20
Intertransverse	58.7	/	3.6
Flavum ligament	19.5	/	40
Interspinous	11.6	/	40
Supraspinous	15	/	30
Capsular	32.9	/	60

With 150 N of axial compression superior to L3, static analysis was conducted by imposing 10 N m of flexion-extension, lateral bending, and axial rotation movements. With all degrees of freedom constrained, the boundary condition was simulated by fixing the inferior surface of the S1 vertebra. The movements and the axial pre-compression forces were loaded onto L3. By using frictionless contact, the facet joints were simulated [12]. To verify the intact model, a comparison of the predicted results with those reported in the literature was performed.

FE model surgery simulation

Our study selected Dynesys System and BioFlex System as the dynamic devices. Dynesys System includes titanium alloy pedicle screws and polycarbonate urethane spacers that surround tensioned polypolyester rope. BioFlex System consisting of titanium pedicle screws and a Nitinol memory loop. To simulate the surgical procedure as closely as possible, the nucleus pulposus was completely removed.

The sizes of screws and rods were confirmed in the intact model. The space position of devices be assembled in the same coordinate system. Based on a validated model of the forementioned EF model, the data were then imported into the FE software package ABAQUS (v 6. 11.1) to build the surgery simulation models. The material properties of polycarbonate urethane spacer, polypolyester rope and nitinol memory loop obtained from previous literature are also shown in Table 1 [13].

Biomechanical comparison

The same boundary and loading conditions were applied to the surgery-simulation models. A precompression of 150 N was imposed on L3 in all simulations. At a pure moment of 10 N m in all directions (flexion-extension, lateral bending, and axial rotation), the simulations were run for each model. The ROM was measured in the intact model and the surgery-simulation models. The stress distribution in the dynamic devices were compared.

Results

FE modeling and validation

The intact model consisted of 32,341 elements and 162,044 nodes (Fig. 1). With the same compressive preload combined with the same pure moment, the study summarize the comparison of the intersegmental responses between the intact model and previously published data under combined flexion–extension, left–right lateral bending, and left–right axial rotation. All the predicted responses were in good agreement with the published data[9, 14]. Figure 2 showed the details of the in vitro data used in the comparison.

FE model surgery simulation

Figure 3 illustrated the dynamic devices and Fig. 4 illustrated surgery-simulated FE models with Dynesys and BioFlex system. In this study, the screws and screw holes were assumed to be fully integrated, their surfaces were simulated by imposing an ideal rough behavior (infinite friction coefficient) to the tiecontact pair, thus preventing extraction. The unit FE size was 0.2 mm, and the total number of FEs was over 3,000,000 for all models so as to incorporate the full details of the complicated lumbar spine.

Range of motion

Compared to the surgery-simulated FE models with Dynesys and BioFlex system, range of motion(ROM) of instrumented levels(L4/5, L5/S1), ROM of adjacent levels (L3/4) and ROM of the total lumbar instrumented levels were measured. Compared with the intact normal model, the total ROM and the ROM of surgical segments had a significant decrease in the Dynesys and Bioflex system in all kinds of active states, but that showed a more decrease in the BioFlex system compared to Dynesys system; compared to the ROM of adjacent levels, the both systems had a little increase, and in the BioFlex system the ROM of adjacent levels increased more than in the Dynesys system. Figure 5

Stress analyses

Qualitative investigation of the stress features on fixation devices can be used to predict the tendency of fracture according to the fixation techniques. Under flexion, extension, left–right lateral bending, and left–right axial rotation conditions, the stress distribution on the fixation devices was shown in Fig. 6. We can evaluate the effect of fixation location on load transfer from the result of stress concentration, the maximal von Mises stress comparisons were showed through Fig. 7. We noted that the screws inserted by Dynesys system had high stress concentration at the middle part of the screw. Screw inserted by BioFlex techniques had high stress concentration at the Nitinol memory loop. Maximal stress level of BioFlex was 164 MPa in flexion condition, while Dynesys was only 41 MPa. Under the other conditions, the differences were as appreciable as in flexion.

Discussion

At present, the effectiveness of posterior dynamic devices is to avoid these adverse effects of rigid fixation, such as: stress-shielding, the acceleration of adjacent segments degeneration, loss of motion, fatigue fractures, and changes in the centers of intervertebral rotation. In this study, our aim was to clear which device has the theoretical advantage for two-level lumbar degenerative disc disease.

To assess the ROM after two-level posterior dynamic surgery to find out how much ROM we can retain, we chose to compare with intact group. Under flexion-extension, lateral bending, and axial torsion conditions, the total ROM and the ROM of surgical segment in the surgery-simulation models decreased to some extent in the present study, but the BioFlex system showed a more decrease compared to Dynesys system. This result is similar with the results from some study [15–17]. Our study showed an encouraging result in that the Dynesys system model had the closest ROM to the intact group. In this regard, the results of this study may indicate Dynesys system can effectively maintain the stability of treatment section and the adjacent segments. We analyze the reason is that the elastic connecting rod in Dynesys system does not contain any metal components, can well restore the normal sequence between segments, retaining spinal motion segment of beneficial activities and disperse the stress of the intervertebral disc, and through the elastic device will compression force into the front behind the separation force.

The dynamic stabilization system have reported good clinical outcomes [7, 18]. Dynamic stabilization system not only can effectively maintain ROM, but also can avoid the stress concentration and stress shelter. EF research suggests that higher stress concentration results in greater risk of fracture on fixation device. Our study showed that maximum von Mises stress was much higher in the BioFlex system, compared with the Dynesys system. For Dynesys, the high stress concentration is at the middle part of the screws (maximal stress level was 40 MPa). For BioFlex, the high stress concentration is at the Nitinol memory loop (maximal stress levels were over than 140 MPa). According to the research results, We analyze the reason is that the Nitinol shape memory loop is a metal rod, unlike the elastic connecting rod in Dynesys system. Reference titanium alloy screws yield strength of 894 ~ 3790 MPa, Both systems in

various working conditions, the stress peak value are far lower than the yield strength of titanium alloy, so the possibility of induced fatigue and fracture screw is relatively low.

Conclusion

In our study, we try to find the best posterior lumbar dynamic devices in these models by analyzing the FE simulation. Through the comparison of ROM and the stress distribution of the dynamic devices, we find that Dynesys system has a better theoretical outcome.

Declarations

Ethics approval and consent to participate

The participant had signed an informed consent and the study was approved by the ethical committee of Southern Medical University

Consent for publication

We have obtained consent signed by the participants to publish.

Availability of data and materials

The datasets generated and /or analyzed during the current study available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

Yang Duan designed the study and analyzed the data. Sujun Qiu, Yingmin Xie and Kaiqin Gong collected the data and helped in analyzed the data. Konghe Hu and Jianjun Li participated in the design of the study and the analysis of the data, and wrote the manuscript. All authors have read and approved the final manuscript and agreed with the contributions mentioned above.

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Figures

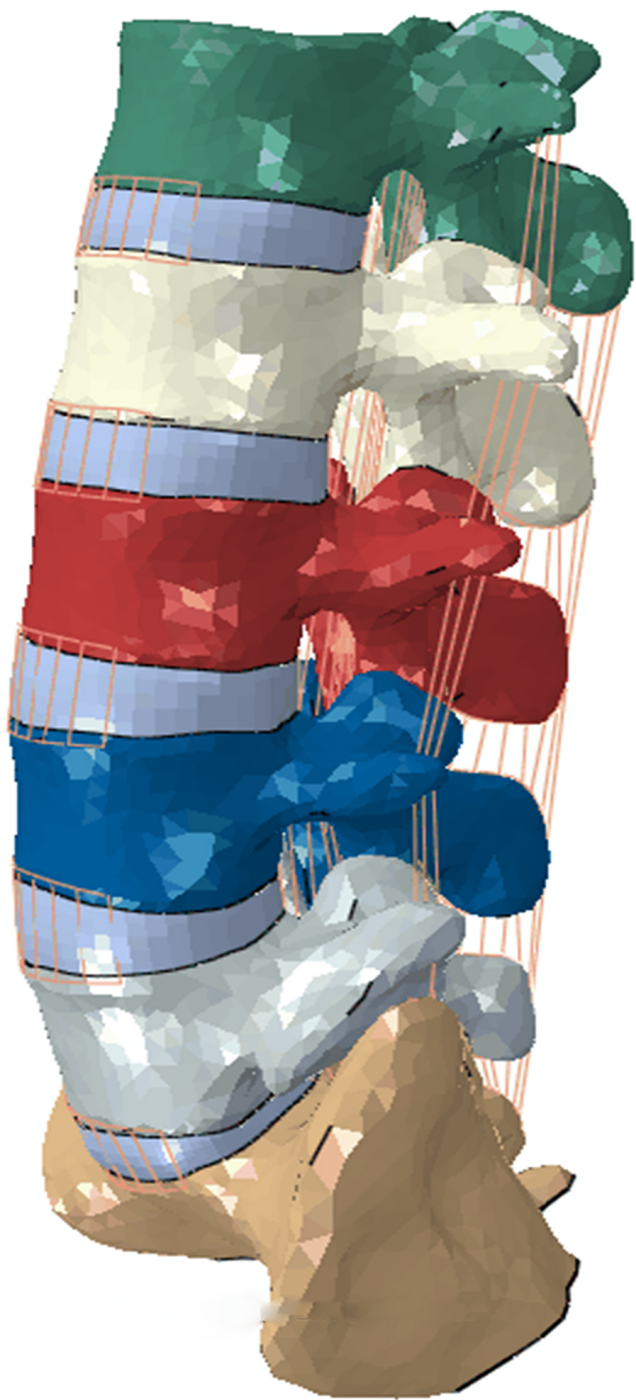


Figure 1

The intact FE model.

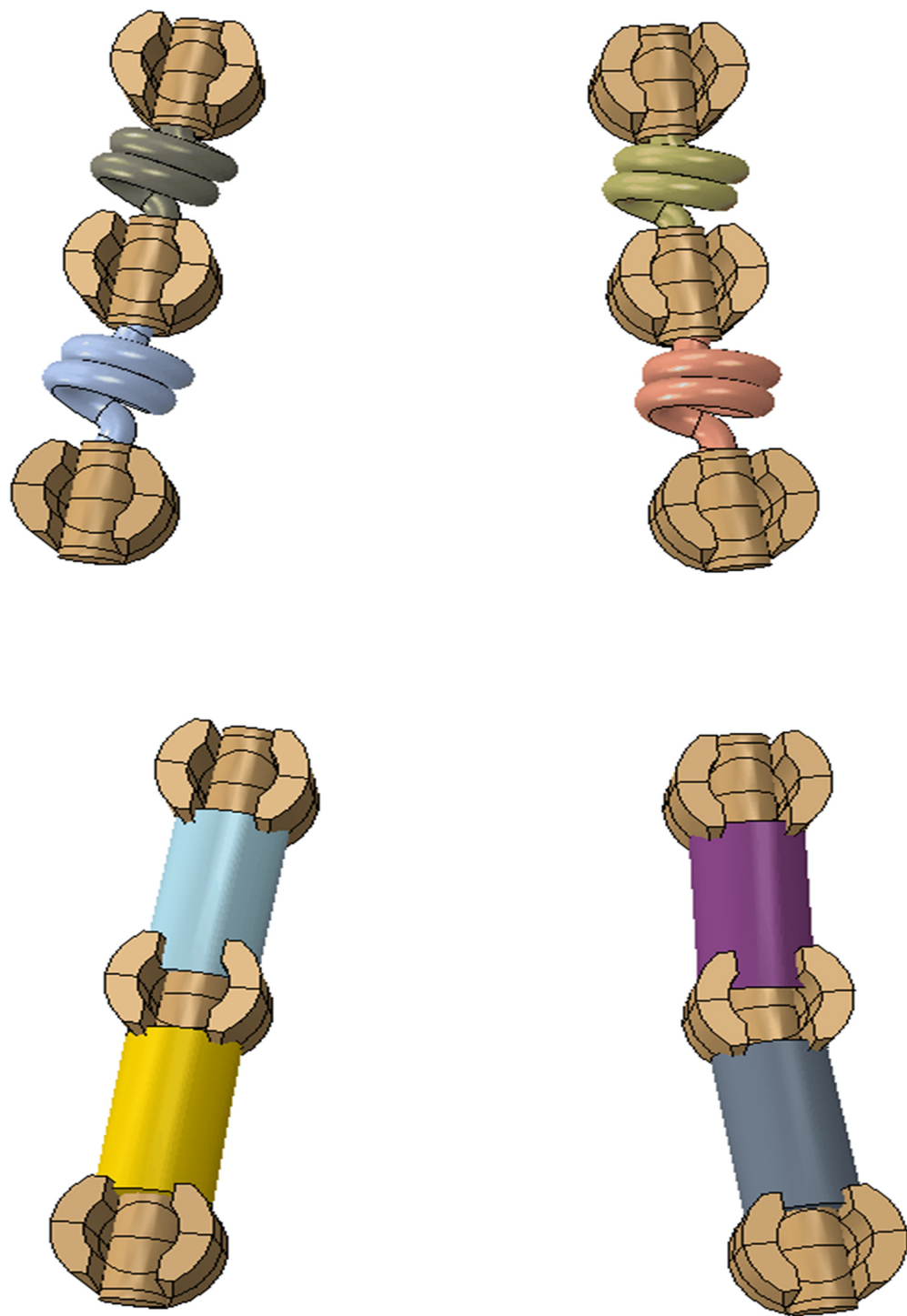


Figure 2

Dynesys system and BioFlex system.

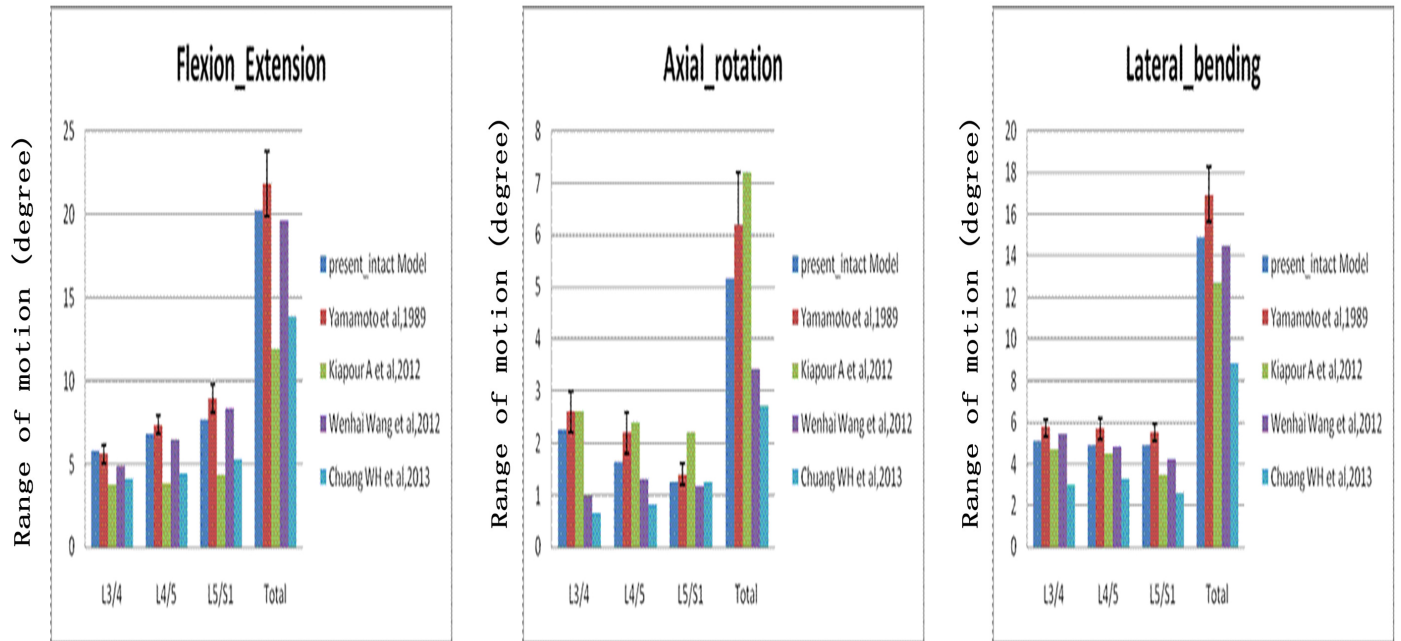


Figure 3

The details of the previous data used in the comparison.

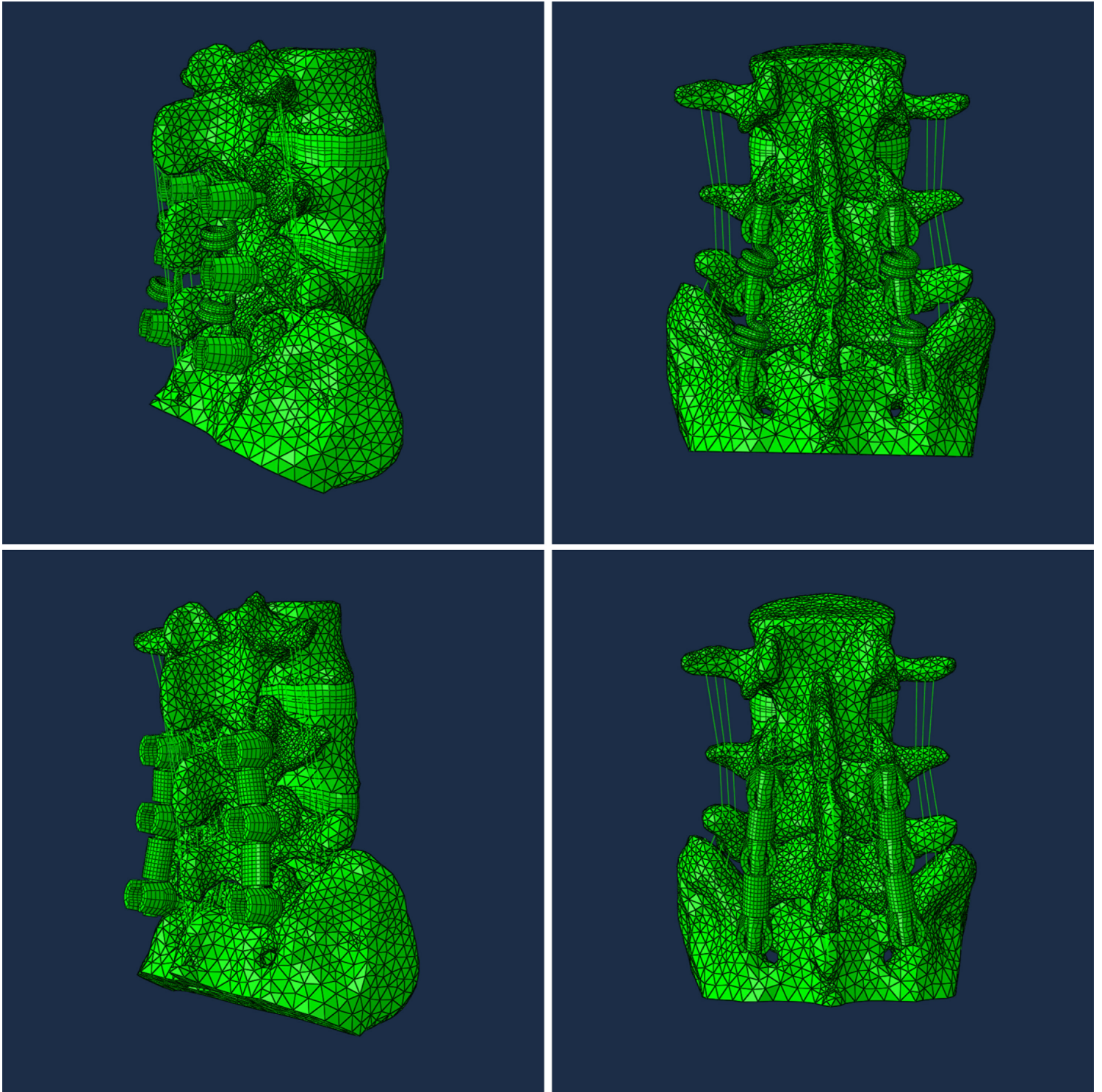


Figure 4

FE models with Dynesys system and BioFlex system.

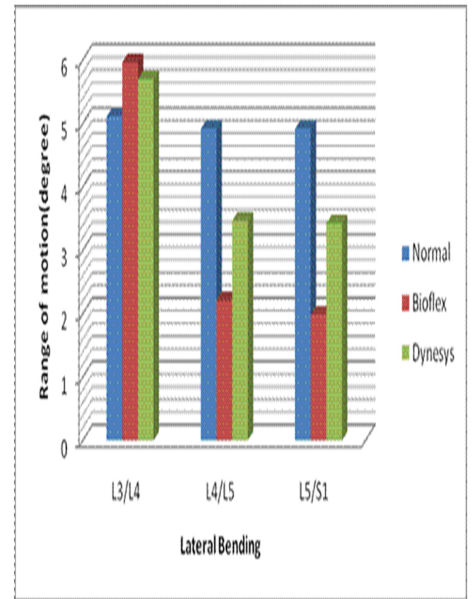
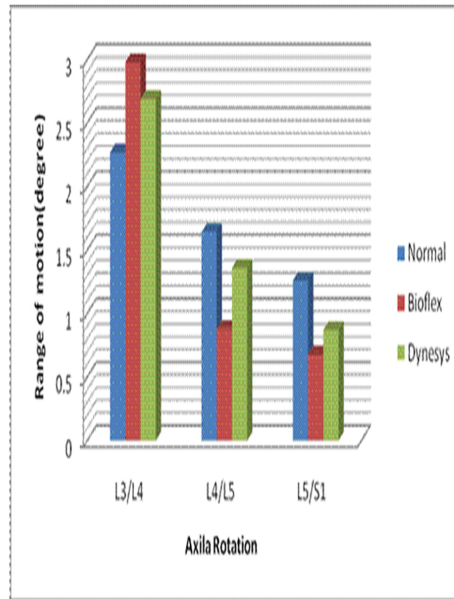
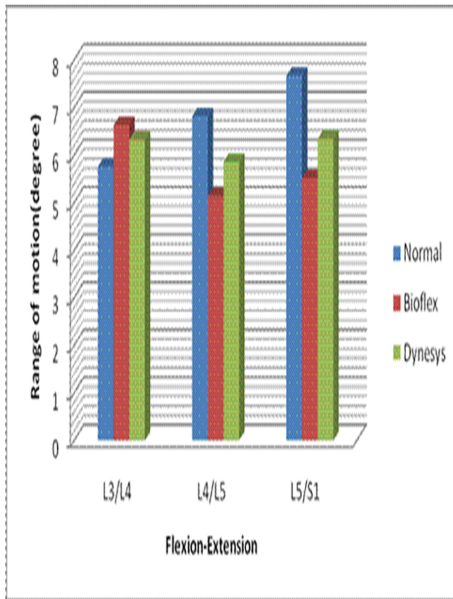


Figure 5

Range of motion of the segments under different conditions.

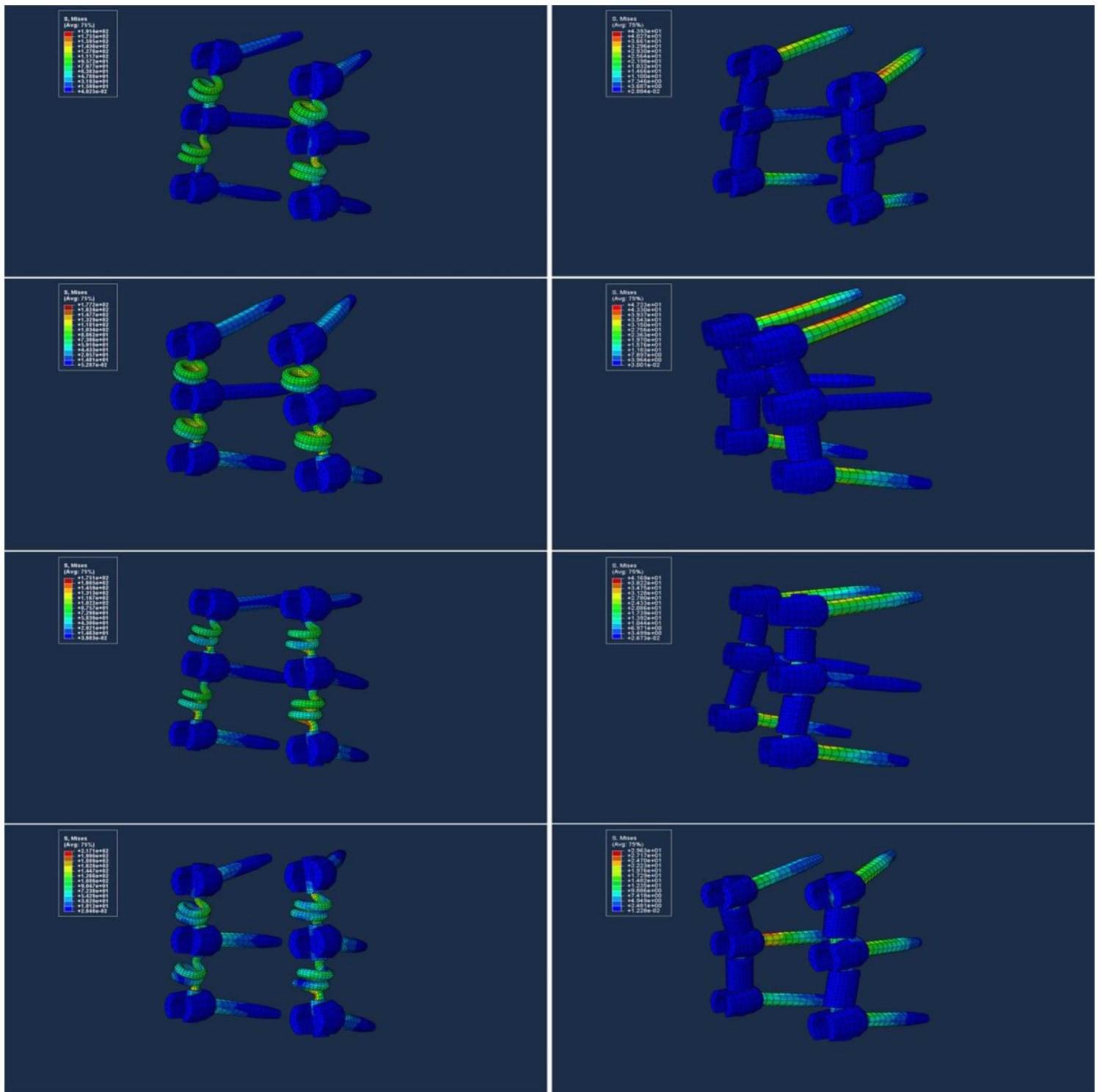


Figure 6

The stress distribution in Dynesys system and BioFlex system.

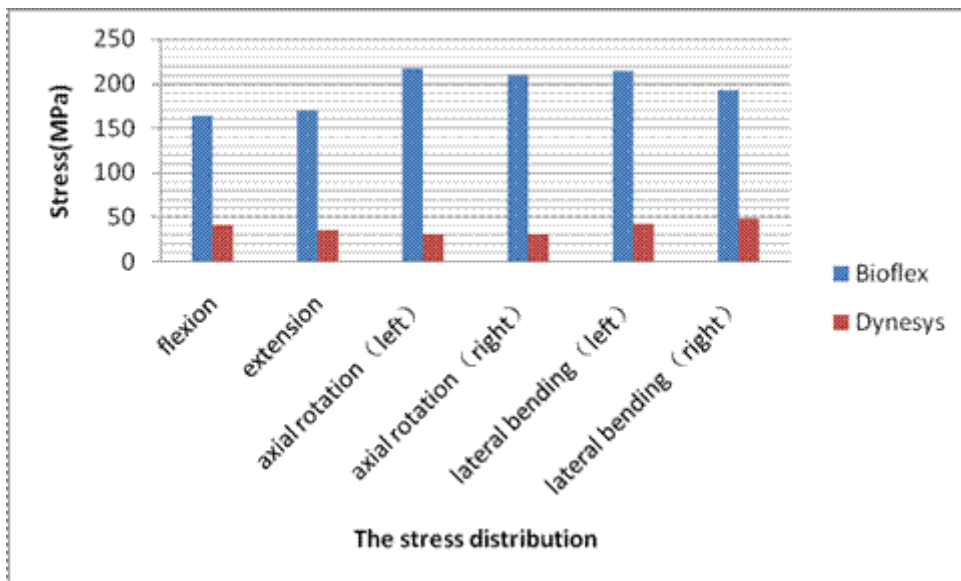


Figure 7

The maximal von Mises stress in Dynesys system and BioFlex system under different conditions.