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### Finite Element Analysis-Based Evaluation of the Patient-Specific Spinal Rods for a Reduced Risk of Adjacent Segment Disease

Abdullah Tahir ŞENSOY

**ABSTRACT:** Adjacent Segment Disease (ASD) is a postoperative drawback of spinal fusion surgery which yields an increase in the range of motion in the adjacent spinal level. Therefore, the main aim of this study is to investigate the optimum mechanical properties of the spinal rod allowing a reduced rigidity in the spinal fixation level for decreasing the displacement of the adjacent segment. In this study, the spinal fixation system was modelled and attached to L3-L4 level. The elasticity modulus of the rods and the follower load were parametrically defined in order to investigate their optimum values under physiological loading conditions of extension. The maximum displacement value determined for the upper adjacent intervertebral disc was defined as the output parameter. Thereafter, the biomechanical response of the spinal bone-implant complex was simulated using Finite Element Analysis (FEA). Using the parametric FEA results, a polynomial mathematical model was constructed and Response Surface Method (RSM) was used to plot the relationship between input and output parameters. According to the results of the study, the optimum elasticity modulus of the rods and the suggested follower load have been determined as 80.8 GPa and 303.84 N, respectively. The maximum principal strain values obtained in the pedicle screws were 746  $\mu\epsilon$ , 1563  $\mu\epsilon$ , 3037  $\mu\epsilon$  and 2937  $\mu\epsilon$ , respectively. However, since the results are strongly associated with anatomical and biomechanical differences, the proposed patient-specific approach may enhance the accuracy for a more successful spinal fusion surgery operation in terms of minimizing the risk of ASD.

**Keywords:** Adjacent segment disease, spinal implants, finite element analysis, response surface method

Abdullah Tahir ŞENSOY ([Orcid ID: 0000-0002-9371-8307](https://orcid.org/0000-0002-9371-8307)), Samsun University, Faculty of Engineering, Department of Biomedical Engineering, Samsun, Türkiye.

**Corresponding Author:** Abdullah Tahir ŞENSOY, e-mail: tahir.sensoy@samsun.edu.tr

## INTRODUCTION

Fusion surgery has been a widely used spinal fixation technique to improve functional outcomes in patients with various degenerative lumbar disorders (Carreon, Glassman et al. 2008, Lingutla, Pollock et al. 2015). This procedure aims to eliminate the symptoms regarding the destabilization of vertebrae. For this reason, pedicle screws are used to fix the unstable spinal level. However, over-rigid fixation may cause some significant postoperative problems such as proximal junctional kyphosis (PJK), disc degeneration, increased range of motion (ROM) and intradiscal pressure (IDP) (Shen, Fogel, et al. 2019, Wu, Meng et al. 2019, Zhu, Zang, et al. 2019). Adjacent Segment Disease (ASD) is one of the most encountered problems in long-term follow-up, and its solutions are still questionable (Ghiselli, Wang et al. 2004, Metzger, Robinson, et al. 2017). Finite Element Analysis is a common method to estimate the mechanical behavior of the spine under complex loading conditions (Goel and Nyman 2016). Even though one can not exactly simulate the real biomechanical behavior of the spine using this method, the controlled comparative studies give valuable information about the factors affecting the investigated outcome (Mackiewicz, Banach, et al. 2016).

The clinical observations have shown that the rigid fixation of one spinal level leads to an increase in the range of motion at the upper adjacent level (Kumar, Baklanov, et al. 2001, Ghiselli, Wang, et al. 2004), resulting in ASD. Therefore, previous studies have suggested some special dynamic stabilization methods such as anterior dynamic stabilization (ADS), K-rod dynamic stabilization system (KDSS) as well as flexible rod device (FRD) for stability in the lumbar spine (Rana, Biswas et al. 2020, Rana, Roy et al. 2020). It has been claimed in the literature that posterior dynamic stabilization (PSD) offers a better treatment in terms of preventing ASD (Kaner, Sasani, et al. 2010, Zhu, Liu, et al. 2015, Perez-Orribo, Zucherman, et al. 2016). For this reason, various PSD approaches such as "Dynamic Rod-Dynamic Screw", "Dynamic Rod-Rigid Screw" and "Topping-Off" have been developed to get better clinical results. However, the ideal dynamic rod has not yet been introduced (Kaner, Sasani, et al. 2010).

Therefore, the research question of the current study is "What should be the optimum value of elasticity modulus of spinal rods as well as the force value applied in terms of decreasing the displacement in adjacent level". Since each patient has specific tissue characteristics, the rigidity of the rod should be determined considering patient-specific data. Therefore, this study aims to investigate the optimum Patient-Specific Elasticity Modulus (E) value of rods targeting the minimization of the displacement at an upper adjacent level for the 'Dynamic Rod-Dynamic Screw' fusion surgery technique using parametric Finite Element Analysis (FEA), and to introduce a patient-specific posterior spinal fixation system to minimize the risk of ASD.

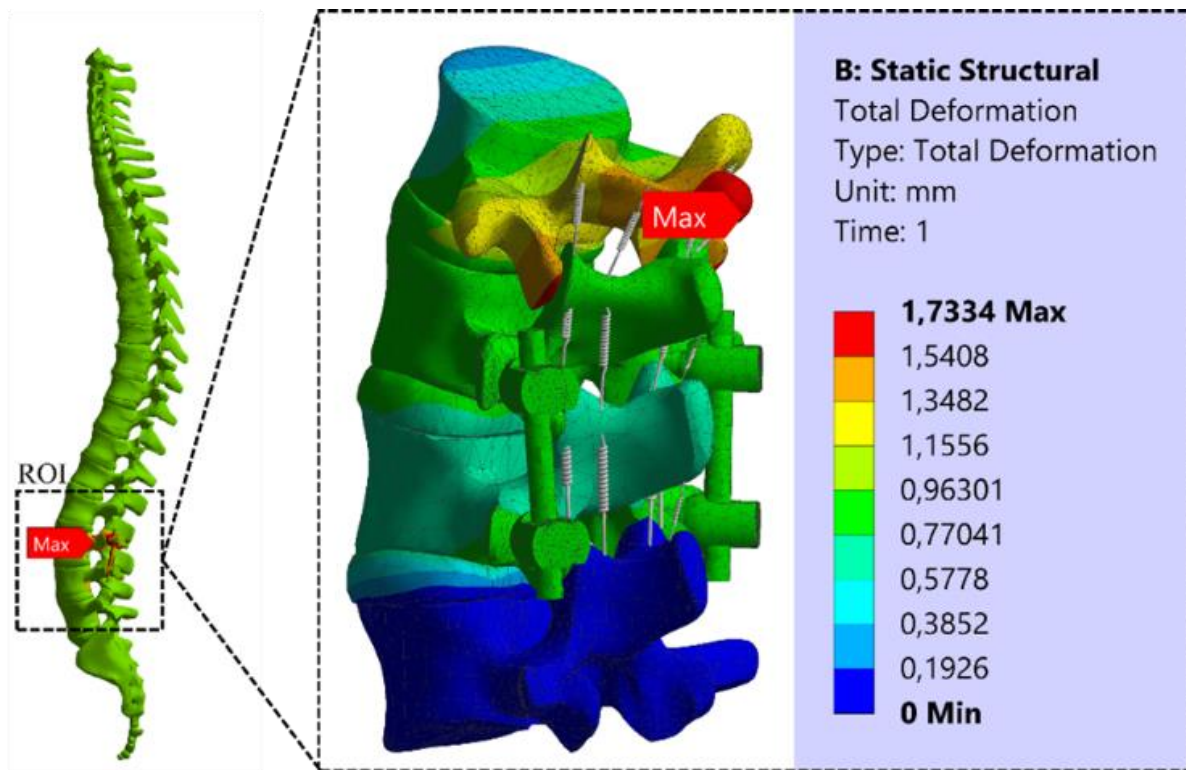
## MATERIALS AND METHODS

A previously created Computer-Aided Design (CAD) of virtual spinal surgery model was used for the FEA studies conducted within the scope of the current study (Sensoy et al. 2015). After assigning appropriate material properties (Table 1.) to the spinal structures and the pedicle screw system an appropriate arbitrary value of 50 N static load was applied from the upper surface of the C-3 vertebrae. Thus, the general stress distribution in the spinal column was obtained and the critical area was determined for model reduction (Fig. 1).

The corpus surfaces of the vertebrae are restricted in directions perpendicular to the spinal axis considering their restriction by ligaments. Another boundary condition is the fixation of the bottom surface of the L5 vertebrae.

**Table 1.** Material properties used for FEA(Zhong, Wei, et al. 2006)

Structure	Elasticity Modulus [GPa]	Poisson's Ratio
Cortical bone	12	0.3
Disc	$4.2 \times 10^{-3}$	0.45
Pedicle screws (Ti-6Al-4V)	114	0.33
Spinal rods (Ti-6Al-4V)	114	0.33

**Figure 1.** Full vertebral column and ROI (spinal levels of L2-L5)

However, considering the complexity of the model and the number of elements; the boundary conditions were redefined by reducing the number of parts and focusing on the most critical Region of Interest (ROI). In order to obtain a more realistic model, posterior and anterior ligaments were attached to the ROI as spring elements (Fig.1) with their stiffness values used in the literature (Zhong, Wei, et al. 2006, Zahari, Latif, et al. 2017). Thereafter, mesh convergence analysis was performed to validate the FE model. For the validation, the intact model was taken into account due to decrease the computational cost. Both stress and displacement-based convergence analysis were done. Iterations were completed in 5 steps with the allowable change of 5%. While the initial FE model consists of 80339 10-node tetrahedral elements, the converged model has 847942 volumetric elements.

The lower surface of the L5 vertebrae was fixed (Erbulut and Erbulut 2014) and compression force was applied using the follower load approach (Patwardhan, Havey, et al. 1999). Compression force value was parametrically defined between 300 N and 600 N considering different values used in the literature (Rohlmann, Neller, et al. 2002, Zhong, Hung, et al. 2013, Erbulut, Zafarparandeh, et al. 2015). For each force level, it was assumed that the compressive follower load was tangential to the lumbar spine curve. Additionally, a pure bending moment of 10 Nm (Erbulut, Zafarparandeh, et al. 2015) was applied to simulate the extension case. On the other hand, the maximum displacement of the disk between L2 and L3 (the upper adjacent segment) was defined as an output parameter to investigate the

mechanical behavior of the adjacent segment. The elasticity modulus (E) of the rods was also parametrically defined to find out its optimum value.

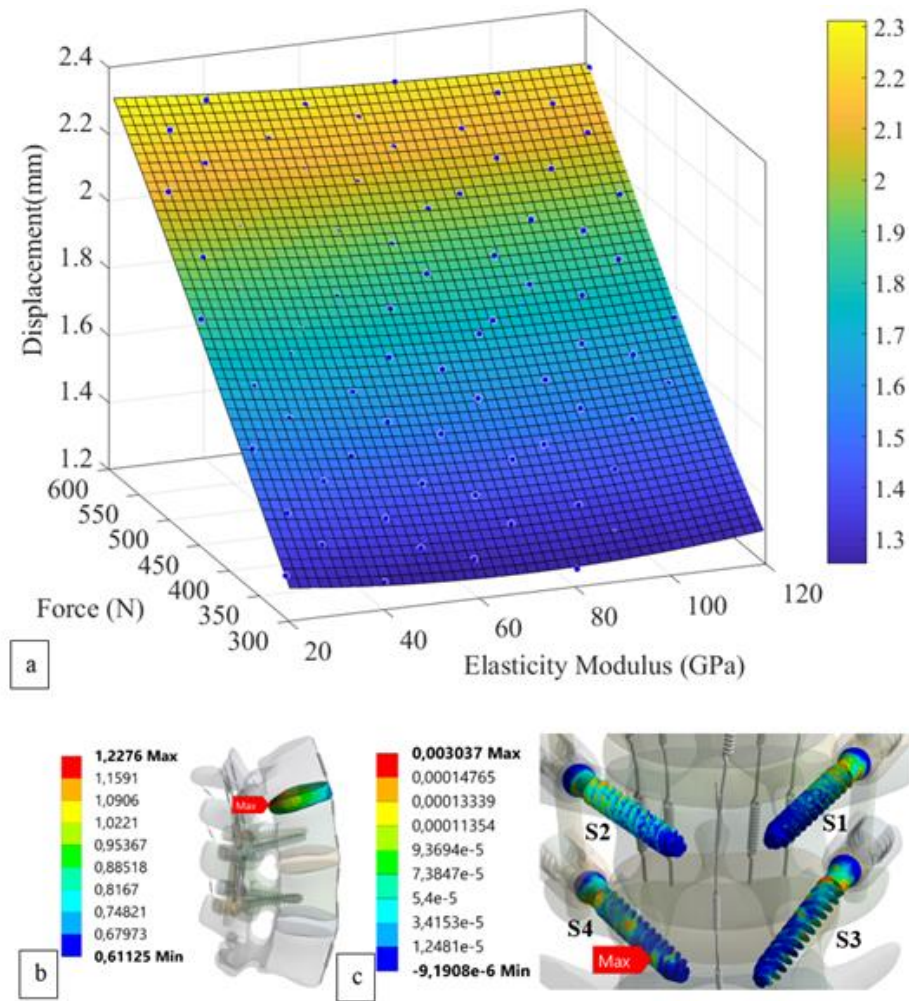
**RESULTS AND DISCUSSION**

**Numerical Results**

In this study, the optimal stiffness value for spinal rods requiring the most effective physiological operation was examined. Since dynamic loading conditions strongly affect the deformations that occurred in adjacent segment discs, a multiobjective optimization process was preferred in this study. The optimum results obtained for the specific case considered in this study were determined as 80.88 GPa for the Elasticity modulus of the rod and 303,84 N for the force applied. However, it is no wonder that these values will change according to anatomical differences and loading conditions. Using the parametric FEA results, a polynomial mathematical model was conducted as follows;

$$F_{disp} = \beta_0 + \beta_1x_1 + \beta_2x_2 + \beta_3(x_1)^2 + \beta_4x_1x_2 + \beta_5(x_1)^3 + \beta_6(x_1)^2x_2 \dots\dots\dots (1)$$

where,  $x_1$  denotes the elasticity modulus of the rods,  $x_2$  is the compression force value and  $F_{disp}$  is the max displacement value determined for L2-L3 intervertebral disk.  $\beta_i$  values represent the coefficient terms and are as 0.2307,  $-2.016 \times 10^{-3}$ ,  $3.664 \times 10^{-3}$ ,  $2.963 \times 10^{-5}$ ,  $-3.993 \times 10^{-6}$ ,  $1.303 \times 10^{-7}$ ,  $1.763 \times 10^{-8}$ , respectively. Using Eq. (1), a response surface plot was obtained (Fig.2)



**Figure 2.** (a) Response surface plot of the design points (b)Maximum displacement determined in L2-L3 disk (c) Maximum Principle Strain determined in pedicle screws

When the results are examined, it can be said that decrement or increment from the optimum elasticity modulus value of the rods (80.8 Gpa) resulted in an increased displacement in the adjacent segment. As expected, the increased force also yielded increased mobility of the adjacent segment. The maximum principal strain values obtained in the pedicle screws were 746  $\mu\epsilon$ , 1563  $\mu\epsilon$ , 3037  $\mu\epsilon$  and 2937  $\mu\epsilon$  for S1, S2, S3, and S4, respectively. It was reported in the literature that high levels of strain ( $>4000 \mu\epsilon$ ) may cause screw loosening risk under cyclical loading. The assessment of the present study indicates that the operation holds no risk of fatigue failure since all strains determined for screws are lower than the screw loosening strain limit (Ramos, Duarte, et al. 2015). Maximum displacement was determined as 1.22 mm in the posterior upper surface of the L2-L3 disc. This result evidences the pain of patients with lumbar hernia in case of extension motion. Since the spinal cord is located on the posterior side of the vertebral column, the pressure of bulged lumbar intervertebral disc on nerves results in pain. To avoid this, the patient should be more careful, especially in case of motion.

It should be mentioned that soft tissues such as muscles and nerves are missing in the model. Many researchers argued in previous studies that, especially muscle tissue has a considerable effect on spine biomechanics (Rohlmann, Nabil Boustani et al. 2010, Han, Zander, et al. 2012, Caprara, Moschini, et al. 2020). Previous researchers had presented an inverse dynamics approach to estimate the muscle forces (Buchanan, Lloyd, et al. 2005). However, these studies also have some limitations regarding the nature of the method (Buchanan, Lloyd, et al. 2004). On the other hand, it is pretty difficult to define the material properties of these tissues and to process the images because of their highly anisotropic and viscoelastic behaviors. Another limitation that should be mentioned is the contact formulations defined. Even though the assumption of frictional contact between bone-implant interface is more common, it was defined as bonded due to the computational expense of the parametrization. Additionally, since this study focused just on two parameters which are the pure compression load and elasticity modulus of the rods, response surface plots may differ when complex loading conditions are taken into account.

For future studies, flexion, lateral bending and rotation cases can also be defined as moments to investigate the optimum mechanical properties of the rods under complex loading conditions (Niemeyer, Wilke, et al. 2012). Additionally, thanks to the sub-modeling FEA approach, model size can be reduced, therefore more realistic contact definitions at the bone-screw interface may be done. Moreover, using the aforementioned parametric FEA, various spinal surgery techniques such as ‘Dynamic Rod-Dynamic Screw’, ‘Dynamic Rod-Rigid Screw’ and ‘Topping-off’ can be compared in terms of ASD risk.

Another point that should be discussed is the method for adjusting the elasticity modulus of the rods for each patient. As well known, the elastic modulus is a material property. Therefore, the mechanical behavior of all bulk isotropic rods manufactured from the same material should be the same. However, by adjusting the porosity level of the geometry using advanced manufacturing methods such as selective laser melting, the effective elastic modulus of the spinal rods may be adjusted for patient-specific purposes.

## CONCLUSION

The findings of this paper demonstrate that lumbar spinal fixation using pedicle screws yields an increase in the range of motion at the adjacent segment. The results of the present study also have shown that the use of appropriate flexible rods for lumbar spinal implants may minimize the risk of ASD. Therefore, the elasticity modulus value of the rods used for lumbar spinal fixation should be determined for each patient individually to get better results in terms of postoperative undesired outcomes. Moreover, considering the optimum force value determined and as shown in Fig. 2a, it should be

recommended to overweight patients that they reach their ideal weights before the operation. For further studies, the scope of the study may be extended by considering other spinal regions such as thoracic and cervical levels in order to generalize the concept for multi-level spinal surgery.

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