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Effect of range of motion (ROM) for pedicle-screw fixation on lumbar spine with rigid and semi-rigid rod materials: A finite element study

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Abstract: This study aims to understand the biomechanical effect of pedicle-screw fixation with different implant materials on lumbar spine. FE method is used to develop three-dimensional model of lumbar spine (L1-S). Three level pedicle-screw-rod is attached to the model with two different rods: Stainless Steel (SS) and poly-ether-ether-ketone (PEEK). The implanted models along with intact models are simulated for different physiological conditions such as axial rotation, lateral bending and flexion-extension under ± 6, 8 and 10 Nm moment with 500 N compressive loads. The spinal biomechanics found sensitive to the elastic modulus of the rod material. In case of pedicle screw fixation with SS, the ROM is very less (1.3° for extension and 2.88° for flexion) as compared to natural model. For PEEK rod, ROM is increased 3 to 4 times for axial rotation, 4 to 7 times for lateral bending and 1.8 to 2 times for flexion-extension. SS rods share more load and generate less stress on vertebrae compared and PEEK rods. For pedicle screw fixation, the foramen height does not vary significantly with variation of load and rod materials. SS rods resist the ROM on the implanted region affecting the kinematics of the spine undesirably. The ROM may be improved to some extent by using lower stiffness rod materials like PEEK. However pedicle screw fixation device prevents reducing inter-vertebral foramen height and foramen area, without affected by material stiffness.

1. Introduction

In last few decades, various spinal fixation devices have been developed for different spinal disorders including degenerative disc disease, spondylolisthesis, spondyloysis, and spondylosis that cause chronic lower back pain [1,2,3]. Out of these devices, pedicle screw fixation device (PSFD) has gained its popularity [4]. Generally, Titanium (Ti) and its alloys are used in pedicle screw based
fixation devices to immobilize spinal functional unit (FSU) which prevent pain in that FSU [5]. Stainless Steel (SS) also used as a pedicle screw and cage based fixation material [6,7]. Ti and SS are the most biocompatible materials and are being used as implant material for decades [6,7,8,9,19]. Ti and SS are very stiff compared to bone; as a result Ti rods provide sufficient strength to prevent motion in implanted FSU [5,6,7]. However, many biomechanical studies have shown that, this method of complete immobilization often affects the natural movement and range of motion of that spinal region, which leads to further degeneration of the adjacent FSUs, referred as adjacent segment deterioration (ASD) [10,11,12]. Recently, poly-ether-ether-ketone (PEEK) have been introduced as implant material in the field of orthopedic and spinal implants. PEEK has been reported to be performed successfully in recent clinical studies and is remarked as completely biocompatible [9,13,14,15]. Stiffness of PEEK is very less as compared to Ti, but sufficient to provide stability to implanted FSU. Thus, PEEK can replace traditional Ti as rod material. The flexibility of PEEK rod can increase range of motion (ROM) of implanted FSU and reduce stress to adjacent levels, reducing the risk of ASD [10,16]. The aim of this present study is to investigate biomechanical effect of pedicle-screw fixation with different implant materials on lumbar spine. Finite Element (FE) method is used to develop three-dimensional model of lumbar spine (L1-S). Two level pedicle-screw-rod is attached to the model with two different rods like, Stainless Steel (SS) and poly-ether-ether-ketone (PEEK).. Biomechanical behaviors of these three implants are studied by comparing ROM and stresses on bone and implant under different loading conditions using FE analysis.

2. Material and method
2.1 Finite element modelling
The lumbar spine with sacrum (L1-S) is generate from CT scan data with the help of an image processing software MIMICS® (MaterialiseInc, Belgium) as shown in Fig.1 [6,7]. A three-dimensional FE model of implant (pedicle screw & rod) is developed within ANSYS® software, and fixed at L3-L5 level. The cylindrical pedicle screw having V-shaped thread, with major diameter 6.6 mm, thread pitch 2.5 mm and thread depth 1.6 mm [9,17]. Ten-noded tetrahedral elements are used to mesh the vertebral bodies, inter-vertebral discs (Fig. 2) and implants (Fig. 3). The convergence analysis is done keeping error less than 3% by size controls of the elements. Seven types of ligaments are considering tension only node to node link elements. Those are anterior longitudinal (ALL), posterior longitudinal (PLL), ligamentum flavum (LF), interspinous (ISL), supraspinous (SSL), intertransverse (ITL), and facet capsulary (FCL). The material properties of those element are taken from biswas et al. [9].

In this study, material property of the cancellous and cortical bone is considered as linearly elastic. Young’s modulus and density are assigned from MIMICS software based on CT scan data [7,9]. Non-linear material property is used for inter-vertebral disc and the stress-strain curve is shown in Fig. 4 [9]. Stainless Steel (SS) is used for the pedicle-screws, in case of rod SS, and (Poly-Ether-Ether-Ketone) PEEK are used. The dimensions and material properties of the screw and rod are taken from literature [6,7,8,9,17,19]. For the implanted model is consist of 305314 elements connected through 451757 nodes and intact model 303314 elements connected through 449757 nodes. The interfaces between the pedicle-screw and the lumbar vertebrae are conceded friction contact and frictional coefficient is taken 0.3 [9].
2.2 Boundary and loading conditions
Six physiological movements like flexion, extension, left and right lateral bending and clockwise and anticlockwise axial rotation are analyzed in this study. Side portion of the sacrum has been fixed in all directions. To simulate physiological flexion, extension, lateral bending and axial rotational motions for implanted and intact models, 6, 8 and 10 Nm bending moments and 500 N compressive loads are applied on top position of the L1 vertebrae. Total 54 FE simulations are performed and ROM at implanted and compared with the intact model.

3. Results
An analytical method is used to calculate the ROM between the vertebral segments. Create a plane by selecting three nodes in X-Z plane nearest to the centre of gravity of the vertebrae. After deformation another deformed plane is consider taking same nodes. To find out the angle between the two planes, the angle between their normal vectors is considered. $A_1x + B_1y + C_1z + D_1 = 0$ is the original plane.
A_2x + B_2y + C_2z + D_2 = 0 is the deformed plane, then the ROM is the angle ‘α’ between the two planes found by using the given formula,

\[
\cos \alpha = \frac{|A_1 \cdot A_2 + B_1 \cdot B_2 + C_1 \cdot C_2|}{\sqrt{(A_1^2 + B_1^2 + C_1^2)} \sqrt{(A_2^2 + B_2^2 + C_2^2)}}
\]

### 3.1 Flexion-extension

Deformed and unreformed 3D view of the lumbar spine of the intact lumbar spine during flexion is shown in Fig. 5. Under flexion-extension, the ROM is measured at L3 vertebra with respect to L5 vertebra. The ROM for the L3-L5 Level during flexion-extension is shown in Fig. 6. Under flexion, the moment increase from 6 Nm to 10 Nm for the intact model, ROM from 15° to 20° and under extension the ROM varied from -2.2° to -7.7°. For implanted models the ROM varied from 2.7° to 3° for SS, and 5.1° to 6.2° for PEEK rod during flexion and -1.7° to -1.3° for SS, and -2.2° to -1.1° for PEEK rod under extension restively.

**Figure 5.** Deformed shape of the intact lumbar spine during Flexion.

**Figure 6.** Variations of ROM during flexion-extension.

### 3.2 Lateral bending

**Figure 7.** Variations of ROM during left-right lateral bending.
ROM for the L3-L5 segment of the intact model under lateral bending exhibited from 4.1° to 7.6° during left side bending and -4.1° to -7.5° during right side bending with increase of moment from 6 Nm to 10 Nm as shown in Fig. 7. With implanted models ROM varied from 0.18° to 0.3° for SS, and 1.3° to 2.2° for PEEK rod in left side bending.

3.3 Axial rotation

The ROM for the L3-L5 Level during axial rotation is shown in Fig. 8. Under axial rotation ROM is measured at L3 vertebra with respect to L5 vertebra. The ROM varied from -3.8° to -5.4° for clockwise rotation and 3° to 5° for anti-clockwise rotation with the increase of moment from 6 Nm to 10 Nm for intact model. For implanted models, the ROM varied from 0.3° to 0.6° for SS, and 1.4° to 2.4° for PEEK rod during anti-clockwise rotation.

![Figure 8. Variations of ROM during axial rotation.](image)

3.4 Von-Mises stresses of the implant and bone

It is observed that the maximum von-Mises stresses in the lower level (L4-L5) PEEK rod under 500 N compressive load and 10 Nm moment are 40, 23, 20 and 25 MPa during axial rotation, lateral bending, flexion and extension respectively as given in Table 1. These values are well below the yield stress value of 95 MPa for the PEEK [18].

| 500N Compressive and ±10Nm loading | SS rod Stress (MPa) | PEEK rod Stress (MPa) | Bone Stress (MPa) |
|-----------------------------------|--------------------|----------------------|------------------|
| Axial rotation                    | 164                | 40                   | 4.5              |
| Bending moment                    | 125                | 23                   | 4                |
| Flexion                           | 105                | 20                   | 3.5              |
| Extension                         | 100                | 25                   | 3                |

Table 1. Maximum von-Mises stress for bone and implant (rod) during axial rotation,
4. Discussion

In this study, two FE models (intact and implanted) are considered for check for their stability as implant materials in terms of stress and flexibility. 500 N compressive load and -10 Nm to 10 Nm moments are applied for realistic analysis. For all implanted models ROM is much lesser than the intact model during axial rotation. There is a massive change in ROM as compared to SS and PEEK implant. In case of PEEK rod ROM is increased 3.7 times compared to SS rod. Between the all implant models, PEEK material is better motion perseverance during axial rotation as the ROM has 49% of the intact model.

Galbusera et al. studied the ROM of L2-L5 spinal segment with single level pedicle screw at L4-L5 level. Stainless steel, titanium, PEEK and the composite ostaPek were considered as rod materials. The models were subjected to pure moments of 7.5Nm in flexion, extension, right lateral bending and right axial rotation. Stainless steel, titanium and ostaPek rods reduced the ROM strongly (>70%), while the PEEK rod induced a smaller ROM reduction (32%) [19].

Dmitriev et al. studied experimentally cadaveric human lumbar spine (L2-S1) with multi level pedicle screw (CD Horizon™) fixation at L3-L4-L5. They loaded the model with ±8 Nm in flexion-extension, lateral bending and axial rotation. ROM at L3-L4 and L4-L5 level were 1.5° and 1.9° respectively in axial rotation [20]. But in present study, the ROM at L3-L5 level is observed as 1.2° for SS and 4° for PEEK rod under ±8 Nm load in axial rotation.

In case of lateral bending, intact model and implanted model with SS, maximum ROM of 7.6° and 0.33° respectively are observed. The ROM is increased 6.6 times using PEEK rod compared to SS rod. The maximum ROM for PEEK rod is 29% of the intact model. The PEEK implant provided better spinal flexibility compared to SS implant. Alapan et al. FE studied the ROM of L4–L5 intact spine segment under a 7.5 Nm moment in axial rotation, lateral bending and flexion-extension. They obtained a ROM of 9.4° during lateral bending [21]. Pedicle screw fixation under 7.5 Nm pure moment, Kang et al. Conclude that, PEEK and CFR-PEEK rod systems reduce the possibility of breakage of the pedicle screw and provide more flexibility to the lumbar spine, compared to Titanium rod [22]. Similarly, Chang et al. also compared Titanium rod to PEEK rod and concluded the same [23].

5. Conclusion

In this study of the effect of pedicle-screw fixation with different rod materials during axial rotation, lateral bending and flexion-extension, it is observed that the ROM is very less in the implanted model with SS rod in comparison with PEEK materials and intact spine. This indicates that the SS rod is stiff compared to PEEK rods. So it is suggested that PEEK rod may be used to get better ROM and thus mobility. The Stress values of the PEEK rod are below the yield stress value so it may be considered for a better implant design after subsequent fatigue testing and experimental validation.

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