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Original scientific paper

Biomechanical Effects of the Implant Designed for Posterior Dynamic Stabilization of the Lumbar Spine (L4-L5): A Finite Element Analysis Study

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Abstract: This study aims to design a new pedicle-screw-based posterior dynamic stabilization (DS) implant, which can help stabilize the spine normally, using the finite element (FE) method, and to determine and compare its biomechanical effects. Four different implant and device components that maintain the range of motion (ROM) within the standard limits were created with the SOLIDWORKS program, and the ABAQUS CAD simulation program and MATLAB program were used together to calculate the range of motion. In all devices, some rods connect L4-L5 vertebrae and are connected with screws, screws placed in the spines, and pins and nuts that complete the connection of the screws with the rod. Based on computed tomography scan data, robust and different implant-treated models of the lumbar spine were simulated under physiological loading conditions. For all designed devices, the range of motion was measured in axial rotation, lateral bending, and flexion-extension directions, and adjacent level effect and restoration percentages were calculated in all directions. With the iterations in the design of the implant parts, an acceptable 70% restoration percentage in the movement of the spine with the implant has been tried to be achieved in all directions. With the device whose optimum data were obtained, 58% for flexion, 70% for extension, 67%, and 52% for lateral bending and axial rotations, respectively, were achieved. It can be said that the pedicle-screw design realized with this study will be applicable after successful experimental validation and clinical trials.

Keywords: finite element method; lumbar spine; posterior dynamic stabilization; range of motion; restoration

1 INTRODUCTION

Low back pain (LBP), known to affect approximately 637 million people worldwide, is a common public health problem that reduces the quality of life and causes great suffering and high medical expenses [1]. Among the important causes of LBP is Intervertebral disc degeneration (IVDD), which progresses with increasing age. IVDD occurs due to other spinal disorders such as spondylosis, disc herniation, and lumbar spinal stenosis. IVDD can cause pain, neurological deficit, and disability in affected individuals. IVDD includes medical and surgical treatment methods, and the choice of treatment may vary depending on the urgency of the case, cost, and stage of the disease. Surgical methods include disc replacement, fusion, and dynamic stabilization. While a DS device can be considered in mild cases, it would be more appropriate to use fusion and disc replacement for a severe degeneration patient. Current surgical strategies cause various complications besides restoring natural joint mechanics. Therefore, it is known that surgical methods are open to discussion and development. The main purpose of using stabilization devices is to immobilize or fuse one or more segments. In addition, thanks to these devices, it is possible to provide stability between the vertebrae [2]. To solve lumbar spine problems, many researchers have tried to design devices suitable for the lumbar spine that do not restrict human movement too much, while keeping the vertebrae stable. As a result of these studies, Dynesys, Cosmic, Graf system, Accuflex, Bioflex, etc. devices have emerged [3-13]. By using these devices, the movement of the spine has been facilitated, and the ROM of the implanted spine has been increased up to 70% [2]. Schmoelz [14] also evaluated the biomechanical effect of Dynesys on the stabilization of the treated segment in an in vitro study. The BioFlex implant system, produced from a material called Nitinol, shape memory alloys, is an unapproved DS method under investigation [15]. Understanding segmental biomechanics and comparing implants with each other and with the spine is very important for implantation. Therefore, it is necessary to evaluate the biomechanical effects of implants on treated and untreated spine segments before clinical trials. However, it is known that it is impossible to make these evaluations in a living body, and studies on cadavers are also very challenging. It includes disadvantages such as planning experiments, taking samples from cadavers, and selecting them. Even the most careful sample selections will have differences. This means that the compared results are less reliable. In addition, biomechanical tests will be quite expensive and time-consuming. For these reasons, simulation studies are very interesting. The use of FE Analysis is necessary to determine the structural analysis of an implant, bone, or the interaction between the two. Studies are testing the dynamic and rigid implant in vitro and on FE modeling [16, 17]. With the FE method, which plays an important role in the biomechanical evaluation of implants, stress, and tensile strength on the relevant implanted structure can be analyzed under loading scenarios. The necessary parameters for the desired spinal implant development can be presented. Within the scope of this study, it was aimed to design a new posterior DS with the FE method, which aims for flexibility and fixes the vertebrae, which can help reduce pain and deformity. For this purpose, the ROM of four different implants and implant components was measured in all directions, the adjacent level effect in all directions and the restoration percentage were calculated and the implant that met the optimum conditions (implant 4) was determined. Achieving a better, flexible, and balanced ROM of the specified device has been optimized by changing the dimensions of the hole in the upper screw in the design. Titanium material was chosen for the implant designs to be investigated in the study due to its properties such as high specific strength, fracture toughness, and fatigue resistance. In the study, the device components were created with the SOLIDWORKS program, and the ABAQUS CAD simulation program and MATLAB program were used together to calculate the range of motion.

2 MATERIALS AND METHODS

2.1 Finite Element Modeling

The geometric model of the lumbar spine (L1-S1) was created in DICOM format with the help of an image processing software, MIMICS (version 17.0), using CT scan data of a fifty years old, healthy male subject (height: 170 cm and weight: 70 kg). Hexahedral meshes were defined on this model using the IA-FEMESH program [18]. The three-dimensional model is a complex structure that includes components such as the annulus, nucleus, facet joints, intravertebral disc, and ligaments. Three-dimensional linear hexahedral solid elements were defined in this model using the IA-FEMESH program. The main reason for choosing a hexahedral mesh is that it provides better convergence and higher resolution in three-dimensional structures. Rigid pedicle screw and screw components were developed and assembled in the L1-S1 region using ABAQUS (version 17.0) software. The material properties of the spine bodies were taken from MIMICS based on CT scan data. FEM simulations of all implanted and intact spine models were performed to predict their biomechanical properties. The 3D FE model consists of five lumbar vertebrae, five intervertebral discs, one sacrum as well as 7 spinal ligaments including anterior and posterior longitudinal, intertransverse, interspinous, supraspinous, ligamentum flavum, and capsular. It was chosen based on previous studies [19]. The articular cartilage thickness was set to 0.3 mm, and the friction coefficient of the upper and lower articular cartilage friction contact was set to 0.1. The overall model is meshed with hexahedral for intervertebral discs, tetrahedrons for facet joints, and other components with a mesh size of 1 mm. In addition, 693194 elements and 1030241 nodes were implemented. Convergence analysis was performed by resetting the element size controls until the estimation error was less than 4%, and the created L1-S1 model was validated by comparing it with the previous study data. While hyperelastic material properties were selected for Annulus and Nucleus structures, linear elastic (isotropic) material properties were applied for cartilage, ligament, and bone structures. Titanium material was chosen for the posterior DS model design, which has a rigid structure. Material properties of vertebral bodies are extracted from MIMICS based on CT scan data. The material properties of the different ligamants are given in Tab. 1. For the posterior DS design, which has a hard structure, titanium was chosen as a material with high corrosion resistance and biocompatibility, which is also known to have a machinable, flexible, and durable structure. The material and dimensional properties of implant parts containing rods, screws, pins, and nuts are given in Tab. 2. SolidWorks program was used in the design of the implant and implant components. The variation of the shape and size of the screws in the posterior DS implant device was developed according to the percentage of ROM calculated using FE model. First of all, to make the design flexible, the hole in the head of the upper screw is designed to move freely in the *Y* and *Z* directions. In Fig. 1, 4 different 3D device designs investigated are given together. In the first design shown in 1a, the device was only able to move in the *Z* direction, then by changing the size of the hole, it was made more flexible and the device was moved in both directions (Fig. 1a to Fig. 1d). Due to its more flexible structure, studies on implant design will be carried out using the device shown in Fig. 1d.

Table 1 Mechanical properties of different ligaments [19]

Ligaments	Young's modulus / MPa	Poisson's ratio	Area / mm^2
ALL	20	0,3	63,7
PLL	20	0,3	20
IL	12	0,3	40
LF	19,5	0,3	40
SL	15	0,3	30
FCL	33	0,3	30
ITL	59	0,3	1.8
CB	12,000	0,3	-
CaB	100	0,3	-
Cartilage	10	0,4	-
NP	1	0,499	-
AF	4,2	0,3	-

ALL: Anterior longitudinal ligament, PLL: Posterior longitudinal ligament, IL: Interspinous ligament, LF: Ligamentum flavum, SL: Supraspinous ligament, FCL: Facet capsule ligament, ITL: Intertransverse ligament, CB: Cortical Bone, CaB: Cancellous bone, NP: Nucleus pulposus, AF: Annulus fibrosus

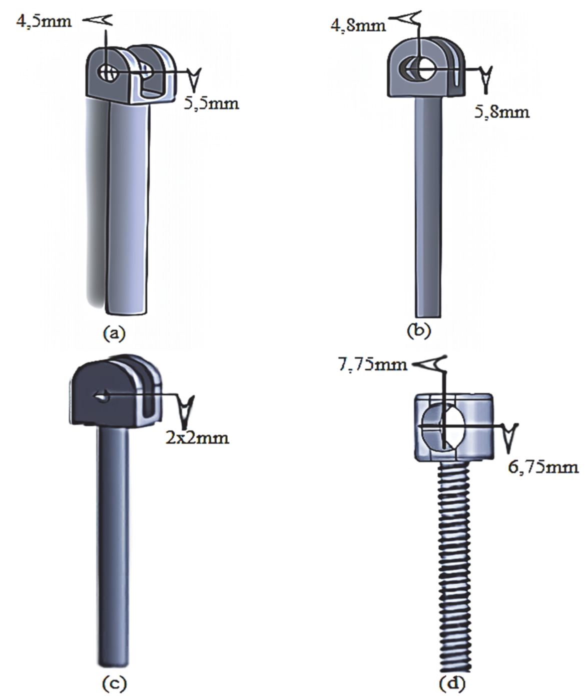

Figure 1 (a) The size of the hole is 4,5 x 5,5 mm, (b) The size of the hole is 4,8 x 5,8 mm, (c) The size of the hole is 2 x 2 mm, (d) The size of the hole is 7,75 x 6,75 mm

2.2 Boundary Conditions

In this study, six physiological loading conditions are considered to simulate lateral bending, flexion extension, and axial rotation. All degrees of freedom on the lower surface of the L5 vertebra are limited to prevent movement. The sets and surfaces used for the interaction of the implant parts, their coupling with each other, and with the lumbar spine are defined as shown in Fig. 2. "Interaction" is defined as segments in which parts move without crossing each other's surfaces, while "couplings" are defined as parts moving together. To simulate all these physiological movements for the implanted and intact models, a bending moment of 1 Nm and a compression force of 400 N between the vertebra were applied to the upper surface of the L1 vertebra. ROM values for all devices were calculated and compared.

Table 2 Materials used, material properties, and dimensions of different parts of implants

Device	Components	Material	Young's Modulus / GPa	Poisson's Ratio	Diameter / mm	Length x Weight x Depth / mm
İmplant 1	Pin	Titanium	106	0,3		17 x4
	Nut	Titanium	106	0,3	4 (inner) 6,5 (outer)	
	Rod	Titanium	106	0,3	4	40 × 6 × 4
İmplant 2	Pin	Titanium	106	0,3		9 × 3
	Nut	Titanium	106	0,3	3 (inner) 6,5 (outer)	
	Rod	Titanium	106	0,3	3	40 × 5 × 2,5
İmplant 3	Pin	Titanium	106	0,3		9,2
	Nut	Titanium	106	0,3	2 (inner) 4 (outer)	
	Rod	Titanium	106	0,3	4,8	40 × 8,5 × 2,5
İmplant 4	Nut	Titanium	106	0,3	3 (inner) 8 (outer)	
	Rod	Titanium	106	0,3		6 × 43 × 2,5

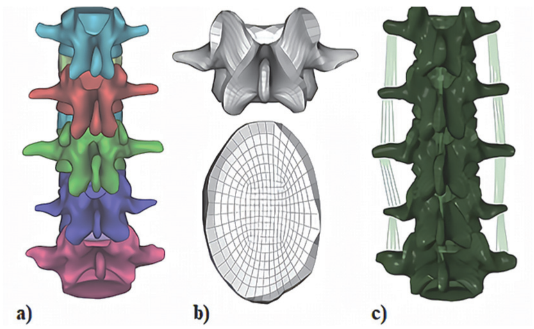

Figure 2 (a) CT scanning process in Mimics (b) mesh fabrication in IA-FEMESH (c) Assignment of material properties in ABAQUS

2.3 Implantation of Devices in the Lumbar Spine to the FE Model

According to the data obtained in the preliminary studies, the ABAQUS program was used to transfer the FE model of the lumbar spine and bring together each part of the device, which exhibits the most flexible structure, as well as to provide the movement of the lumbar spine in six directions, with and without implants. Parts designed in SolidWorks were placed in ABAQUS for the device one by one. To place the parts of the device in the 3D FE model of the lumbar spine, the assembly section of the module part of the ABAQUS program was selected and the designed parts (in. ig format) were transferred to the program. After the device was mounted on the lumbar spine, the mesh of each part was defined as shown in Fig. 3. The final process in ABAQUS is the selection of material properties for the implant parts. Titanium material was chosen for the parts. After the operations were completed, the simulation file was saved in the temporary section in. inp format. The implantation of the device to the L4-L5 vertebra is given in Fig. 4.

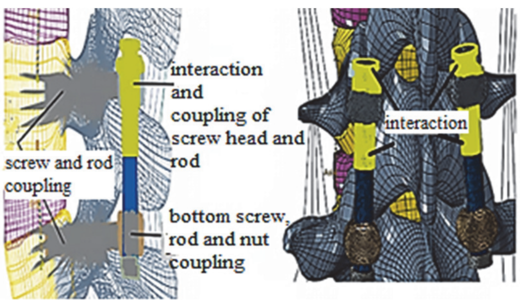

Figure 3 The implantation of the device on the L4-L5 vertebra (a) the coupling of the device parts with each other and with the bone (coupling) (b) the interaction of the parts with each other

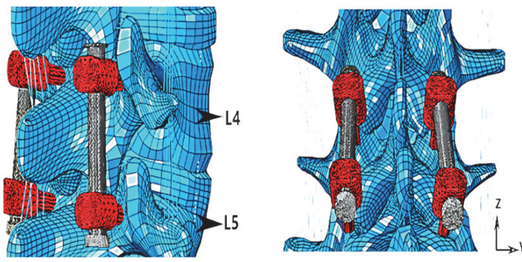

Figure 4 FE model of lumbar spine implanted with the device on a-b L4-L5

2.4 Range of Motion and Adjacent Level Analysis

ROM refers to the amount of motion that a particular joint or body part can measure in degrees. To calculate the ROM value in each direction between L4-L5 vertebrae, the output of ABAQUS was loaded into the MATLAB input file where the codes were written as (.text file). The output of the MATLAB program, on the other hand, was calculated according to the displacement of the determined points, the ROM between all the defined vertebrae. Using Eq. (1), the percentage of adjacent level is obtained, and using Eq. (2), the percentage of restoration is obtained.

$$Percent\ \ Contiguous\ \ Level = \\ = 100 \times \frac{\left(int\, akROM - implantROM\right)}{int\, akROM} \tag{1}$$

$$Re\,storation\ \ Percentage = \\ = 100 - Percent\ \ Contiguous\ \ Level \tag{2}$$

3 RESULTS

After the spine was fixed in the S1 vertebra, a load was applied to the upper surface of the L1 vertebra in 6 directions (flexion-extension/extension, right-left lateral bending, right-left axial rotation). In an intact and implanted lumbar spine, the ROM in all directions was calculated by applying a bending moment of 1 Nm to the upper surface of the L1 vertebra. Percent adjacent level Eq. (1) and percent restoration Eq. (2) were obtained using the ROM between implanted vertebrae (L4-L5). By evaluating the percentage of restoration, it can be understood to what extent the implants can maintain their ROM. The ROM value and percent restoration in the intact and loaded spine for four devices are given in Tab. 3. The first device is a relatively rigid device with freedom of movement only in the *Z* direction. The results show that this implant design is not flexible enough. Studies indicate that the restoration of a flexible device should be close to 70% in all movements. Therefore, the first device is not suitable for implantation as it restricts the range of motion. Since the second device can move in *Z* and *Y* directions, it shows more flexibility compared to the first device. In flexion extension, the range of motion of the lumbar spine implanted with the first device resulted in a significant reduction in L4-L5. While it showed a restoration of 17% in flexion and 8% in extension, flexion of 53% and extension of extension provided restoration of up to 33% in the second device. In lateral bending, the results in the second device reached a value close to 70% restoration. A similar increase is seen in the right and left axial rotations. Therefore, especially increasing the size of the hole in the head of the screw by 0,3 mm (from 4,5 mm to 4,8 mm and from 5,5 mm to 5,8 mm) made the device more flexible. In the third device, the percentage of restoration between the L4-L5 spines was calculated as 66% for right and left lateral bending. According to the second device, right and left lateral bending increased from 65% and 63% to 66%. However, as seen in Tab. 4, the percentage of restoration between L4-L5 vertebrae decreased from 55% to 54% in the right axial rotation and from 54% to 49% in the left lateral rotation. Moving the hole in the screw head, which provides the range of motion, to the rod in the second device did not significantly affect the restoration percentage in other directions except the extension direction. Therefore, the range of motion was found to be almost the same as the second device. In the fourth device, it is seen that the restoration percentage between L4-L5 spines is 61% in right-left external rotations, an average of 75% in left-handle lateral bending values, 68% in flexion, and 75% in extension values, and the best restoration percentages are obtained with this device. As a result of the preliminary trials, the adjacent level and restoration percentages were checked in the fourth device, where we obtained the optimum flexibility, and gradual changes were made in the pedicle screw heads to reach the range of motion of a normal spine as much as possible and to bring the restoration percentage closer to 70% in all directions after implantation. While the screw opening in the 4th device has dimensions of 7 mm × 8 mm (4.1), the mobility gained by these dimensions is 2 mm in the *Z* direction and 1 mm in the *Y* direction. When the screw opening of the 4th device was determined as 6,5 mm × 7,5 mm (4.2), the movement ability of the screw was 1,5 mm in the *Z* direction and 0,5 mm in the *Y* direction. Finally, in the final design device (4.3), where the screw opening was determined as 6,75 mm × 7,75 mm, the movement was determined as 1,75 mm in the *Z* direction and 0,75 mm in the *Y* direction. The restoration percentages obtained as a result of the design of the 4th device according to the different screw openings are given in Tab. 3. ROM between L4 and L5 vertebrae with and without implants is given in Fig. 5. In Fig. 6, restoration values between L4-L5 vertebrae of implanted devices are given in %. It is seen that more than 70% restoration is achieved in right-left lateral bending and extension in the implanted device 4.1. By evaluating the percentage of restoration, it can be understood to what extent the implants can maintain their range of motion. Since this may cause instability in implantation, it is not suitable for implantation in the lumbar spine. If the implanted device 4.2 is examined, it is seen that there is a 13% and 10% reduction in fixation and extension, respectively, compared to the implanted 4.1. In addition, it was observed that there was an average reduction of 20% in right and left lateral rotations and 14% in axial rotations. With these data, it is possible to say that this device is not flexible enough. In the third trial (implanted 4.3), the dimensions of the hole were increased by 0,25 mm in both directions compared to the second trial, allowing the device to move 1,75 mm in the *Z* direction and 0,75 mm in the *Y* direction, thus the device gained a more flexible structure. The third implanted device with the highest mobility approaches 70%, which is considered the best restoration percentage in all directions, and it is possible to say that the best restoration value is obtained from this implant.

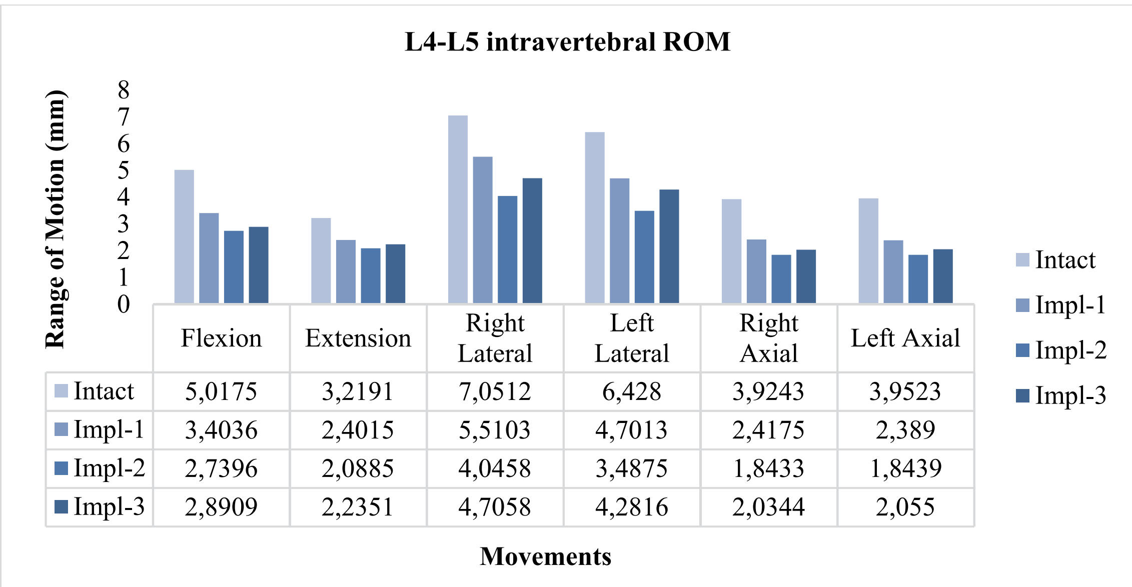

Figure 5 ROM in mm in flexion-extension, right-left lateral flexion, and right-left axial rotation of the L4-L5 vertebrae of the device-implanted spine with three different dimensions (impl 1, impl 2, and impl 3)

Table 3 Range of motion (mm) and percentage of restoration in flexion-extension, right-left lateral bending, and right-left axial rotation of the implanted spine in the first three devices

		Intact / mm	Implant / mm	Restoration percentage / %
1. Device: L4-L5 Intervertebral ROM / mm	Flexion	5,0175	0,8452	17
	Extension	3,2191	0,2489	8
	Left Lateral Bend	6,428	1,398	22
	Right Lateral Bend	7,0512	1,0141	15
	Right Axial Rotation	3,9243	0,3407	9
	Left Axial Rotation	3,9523	0,3322	9
2. Device: L4-L5 Intervertebral ROM / mm	Flexion	5,0175	2,6611	53
	Extension	3,2191	1,0607	33
	Left Lateral Bend	6,428	4,3342	68
	Right Lateral Bend	7,0521	4,5814	65
	Right Axial Rotation	3,9243	2,1381	55
	Left Axial Rotation	3,9523	2,1173	54
3. Device: L4-L5 Intervertebral ROM / mm	Flexion	5,0175	2,3335	47
	Extension	3,2191	1,5941	50
	Left Lateral Bend	6,428	4,2574	66
	Right Lateral Bend	7,0512	4,6499	66
	Right Axial Rotation	3,9243	2,089	54
	Left Axial Rotation	3,9523	1,94	49
4. Device: L4-L5 Intervertebral ROM (mm)	Flexion	5,0175	3,4036	68
	Extension	3,2191	2,4015	75
	Left Lateral Bend	6,428	4,7013	73
	Right Lateral Bend	7,0512	5,5103	78
	Right Axial Rotation	3,9243	2,4175	62
	Left Axial Rotation	3,9523	2,389	60

Table 4 Restoration percentages obtained according to different screw openings of 4 devices

		Implant 4.1 Restoration Percentages / %	Implant 4.2 Restoration Percentages / %	Implant 4.3 Restoration Percentages / %
Restoration Percentages of Different Sizes of The 4. Device.	Flexion	68	55	58
	Extension	75	65	70
	Left Lateral Bend	73	54	67
	Right Lateral Bend	78	57	67
	Right Axial Rotation	62	47	52
	Left Axial Rotation	60	47	52

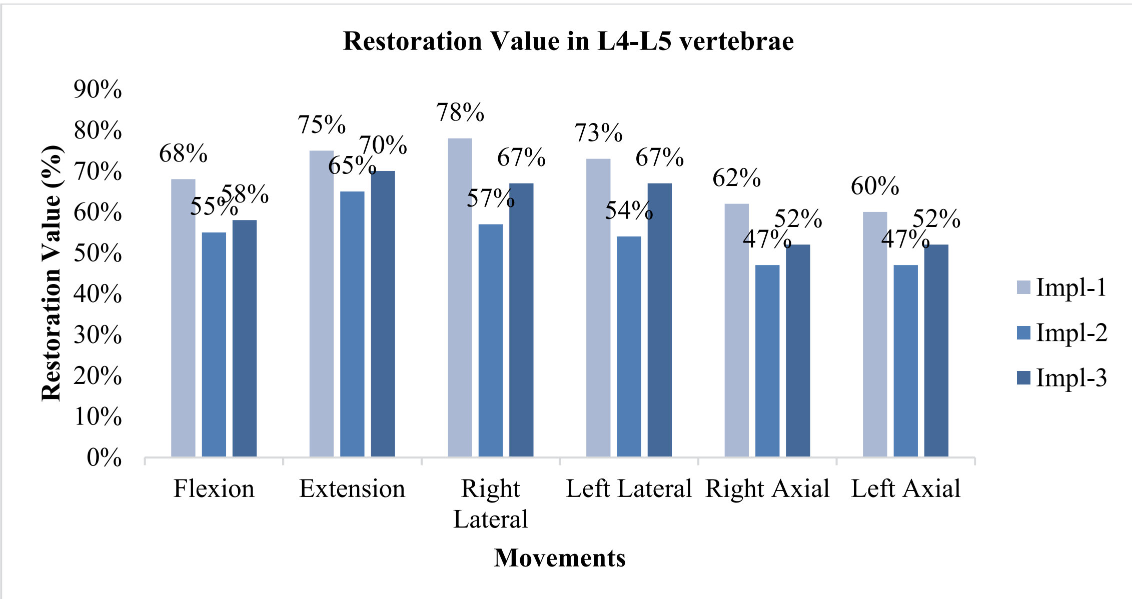

Figure 6 Percent restoration value in L4-L5 vertebrae of all three implant devices

4 DISCUSSION

Dynamic stabilization provides vital support for the spine in case of spinal deformity or degenerative discs. In this area, there are many studies conducted in recent years for the PDS of the lumbar spine. The use of the FEM in the design of spinal implants is a more practical method than in vitro and in vivo applications for examining the ROM of the implanted spine. Predictions can be made about the effects of spinal implant design on the spine for in vitro and in vivo applications. Evaluation of the implanted spine using the FEM before in vivo and in vitro applications of the designed implants can provide researchers with information about the effectiveness of the implant design and save time. With the device designed in this study, the percentage of restoration was found to be 54% for axial rotation and between 58% and 70% for other directions. Similar studies in the literature show that the implants used in the PDS of the spine are still in the research phase. Jayanta et.al. [19] The biomechanical effect of pedicle screw fixation, which was developed from PEEK (as poly-ether-ether-ketone) material, was examined with a three-dimensional FEM of the lumbar spine (L1-S1), and the restoration percentage was determined as 48%. Therefore, it is seen that the restoration percentage of the device designed by us gives better results than the PEEK implant. It can be predicted that a device made of titanium alloy with these dimensions can better restore the ROM in flexion extension, lateral bending, and axial rotation. Moumene and Harms [20] used FEM to determine the biomechanical effect of PDS by measuring the stress and ROM on a segment adjacent to a fusion before and after PDS instrumentation. Among the results, it was stated that the ROM values during lateral bending, axial rotation, and flexion were 2,1; 3,7; and 4,0 mm, respectively. The determination of the biomechanical behavior of L4-L5 pedicular screws and stabilization systems by FEM was evaluated using different rods (stainless steel, titanium, PEEK, composite ostaPek). All bars are critical in reducing ROM. In flexion, it has been reported that PEEK bars strongly reduce ROM by more than 72%, while this value is more than 83% for stainless steel bars. It also revealed that pedicle-based dynamic stabilizers (PBDSs) reduce ROM during flexion extension by approximately 40% to 50% compared to the intact spine [21]. Alapan et al (2014) examined the FE model of the intact spine (L4-L5) level and obtained 9,4 ROM in lateral bending under a moment of 7,5 Nm [22].

5 CONCLUSION

In this study, the biomechanical effects of the designed PDS device on the lumbar spine of the FEM were investigated. Implant parts were created with the SOLIDWORKS program and the ABAQUS CAD simulation program and MATLAB program were used together to calculate the range of motion. In the study, FEM was also developed on the non-implant spine model to control flexibility and stability. 1Nm momentum was applied with 400 N compression between vertebrae. Before starting the study, the range of motion in all directions was measured for five different devices with different designs, and the adjacent level effect and restoration percentages in all directions were calculated for each device. As a result of the calculations, the device with the best performance was selected. The mobility of the implanted devices was investigated by determining different screw openings for this device, and it was determined that the highest mobility was the implant 4,3 device with a screw opening of 6,75 mm × 7,75 mm. This study aimed to develop a new PDS device that could provide restoration at the optimum level. Therefore, the implant was designed for use in L4-L5 spines, and restoration levels were compared in each direction. It is aimed to increase the ROM of the spine to 70% by providing the movement of the implant system in the *Z* and *Y* directions by designing the groove at the head of the implant screws to be located in the sagittal plane. In this device, 58% restoration is calculated for flexion and 70% for elongation. In lateral bending and axial rotations, values of 67% and 52% were reached, respectively. It has been observed that the flexible design in two directions, provides greater restoration of the segmented ROM. The results have not been experimentally verified by us. Therefore, the parameters and findings revealed by FEM need to be confirmed by in vitro experimental study. The future aim of this study is to design devices that will cover two or more vertebrae and provide up to 70% flexibility in all directions for patients suffering from multiple disc or spine diseases along with the planning of the experimental study.

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