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Comparative strength analysis of pedicle screw implants using biomechanical tests and finite element analysis

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Abstract - Spinal implants or instrumentation have been used for many years to re-align and stabilize unstable or deformed spines. The use of pedicle screws and spinal rods is one method of fusing the vertebrae in the spine. A pedicle screw is a particular bone screw designed for implementation into a vertebral pedicle. These screws are used to correct a deformity or treat trauma and to immobilize part of the spine to assist fusion by holding vertebrae together. Numerous variations in design have been developed for pedicle screws. These variations affect the load carload-carrying capacity of the pedicle screw system and thus the forces acting on the vertebral column. The Finite Element Method has grown into an important method in biomechanics and biomedical engineering to obtain approximate numerical solutions that predict the response of physical systems subjected to external influences. The objective of the present paper is to compare the load-carrying capacities of two types of pedicle screws commonly used for spinal fusion, namely monoaxial screws and polyaxial screws, using experimental testing, which includes Anterior-Posterior and Flexion-Extension tests according to the ASTM standards and to study the failure of the pedicle subassembly. Moreover, a Finite element model was developed as exact as the experimental environment by adjusting the boundary conditions, contact, and loading parameters. Once the testing and finite element results are studied, the model opens up ways to improve the strength and load-carrying capacity of the pedicle screw.

Keywords: Monoaxial Screw, Polyaxial Screw, Spinal rod, Anterior-Posterior, Flexion-Extension, Tresca stress, Contact pressure

1. INTRODUCTION

Implants are artificial devices manufactured to support or replace any fractured or lost biological part of the body, in contrast to a transplant, which is a transplanted biomedical tissue. The implant is usually made up of biomedical material such as titanium, silicone while in some cases, implants also contain electronics, including artificial pacemakers and cochlear implants [1]. The use of the pedicle screw fixation technique in stabilization and re-alignment of the unstable or deformed spine has been severely increasing in the past few years [2]. A study by Fior Market 2020 has predicted that the market of spinal screws to increase by 30-35% in the upcoming 5 to 6 years [3]. However, there have been significant problems in the practical implementation of the implant, including breakage of the screw and loosening of the screw [4]. This loosening of the screw is mainly because of the strain between the screw and the bone [5,6].

The commonly used implants used by the surgeons may include screws, pins, and plates, which are used to heal broken bones. Implantation of the biomedical device is sometimes subjected to complications and implant failures. The consequences of implant failure depend on the critical nature of the implant and its position in the body [7]. A pedicle screw is a biomedical implant similar to bone screws that attach the rods and plates into the vertebral pedicle and hold the structure together. They add extra support and strength to the fusion while it heals. The pedicle screws are placed in the pedicle vertebrae, a rod is inserted in the head of the screws, and a tightening screw, also called a 'grub screw' is tightened over the head of the screws connecting all the pedicle screws. This prevents the movement of the vertebrae [8]. The pedicle screw instrumentation method is commonly used to fix the spinal vertebrae since it transverse all three columns of the vertebrae representing the rigid attachment of the spine. Also, the rigidity of pedicle fixation allows for the incorporation of fewer normal motion segments in order to achieve stabilization of an abnormal level. Since the pedicle screw system does not require intact dorsal elements, it can be used after a laminectomy or traumatic disruption of laminae, spinous processes, and facets. Though there are major technological advances, the implant failures of the pedicle screw system still occur. The most common problems in pedicle fixation are screw bending, breakage, and loosening. Infection is also another implant-related complication. Failure of pedicle screw by fracture of hardware is reported in 6-7% of cases [7]. The resulting failure mainly occurs because loading exceeds the load-bearing capacity and loosens the screws at its head. Osteoporosis, where bone density is decreased, affects between 5 and 20% of women older than 50. The main problem with these fractures is that due to bone fragility, the plates and screws used to treat them surgically do not sufficiently engage with the bone, or they become loosened due to the mechanical demands of daily life [9]. The pedicle screw is the head, tightening screw, and the screw.

There are two types of Pedicle screws, monoaxial screws, and polyaxial screws. The head of the monoaxial screw is fixed, as shown in Fig. 1(a). In contrast, the head of polyaxial screws is mobile. It can swivel, helping to defray vertebral stress Fig. 1(b) surgeons generally prefer Polyaxial screws due to flexibility and ease of fixation [10].

(a) (b)

Fig -1: (a) Mono axial screw, (b) Polyaxial screw

Spinal pedicle screws are made up of titanium due to their characteristics such as high strength to weight ratio, immunity to corrosion, biocompatibility, and the capacity for joining with bone and tissue. The nonmagnetic property of titanium helps in noninterference during MRI scanning. Clinical experiences indicate that stainless-steel and titanium implants typically incorporate into bone without complications, although a marked inflammation and tissue reaction are observed in humans. The bone repair time around metallic implants is in the range of months, and the integration process is often described in terms of bone in-growth into threads, pores, holes, asperities, etc. Increased bone formation around titanium implants is associated with improved mechanical stability. In contrast, stainless steel appears less readily incorporated and has a comparatively lower mechanical binding strength than titanium in pig spine experiments. Thus, there are indications that stainless-steel implants are not always functionally integrated with the surrounding bone, probably because of a mechanical interface overload and the material chemistry [11].

For a spinal implant, the pedicle screws should have high strength under all possible conditions; thus, the purpose of experimenting with the axial pullout and bending moment test is to investigate the strength of monoaxial and polyaxial pedicle screws and to study the failure in the present study. Two types of tests, Anterior-Posterior and Flexion-Extension, were conducted for the implant assembly. These experimentations evaluated the properties such as elastic load, elastic displacement, yield load, yield displacement, ultimate load, and ultimate displacement, and biomechanical valuation was carried out for five samples of monoaxial and another five samples of polyaxial pedicle screws. The results of the experimentation testing simulation were analyzed to discuss and compare the strength of monoaxial and polyaxial pedicle screws. Additionally, the FE-model was developed to allow the replica of the experimental setup. Therefore, the magnitude and orientation of applied loads and boundary conditions were carefully controlled. The finite element analysis was performed to study the trends of Tresca stresses and contact pressure in the pedicle screw assembly. The CAD model of the pedicle screw and rod was modelled using the three-dimensional software package, CATIA V5R20. The numerical simulation was carried out using the commercial software ANSYS 18, and a modification in the design of the pedicle screw was also suggested [12].

2. Materials and Methods

2.1. Experimental Method

The pedicle screw, rod, and tightening screw are manufactured from Titanium alloy, Ti6Al4V (Wrought titanium 6-Aluminum 4-Vanadium alloy) as specified in the standard ISO 5832. Most of the manufacturers follow the British Standards for developing pedicle screws [13,14]. The experimental testing of subassemblies was carried out as per the standard ASTM F:1798–1997 (Reapproved 2008), "Standard Guide for evaluating the static and fatigue properties of interconnection mechanisms and sub-assemblies used in spinal arthrodesis implants" and that of the assembly was carried out as per the standard ASTM F:1717–09, "Standard test methods for spinal implant constructs in a vertebrectomy model" [15,16].

The length of insertion of the pedicle screws was obtained from the medial guidelines [17]. Examination of the load-deflection curve may reveal laxity in the fixture. The linear portion of the curve will define the straight-line section of the load-displacement curve after the laxity has been removed. The properties including elastic load, elastic displacement, yield load, yield displacement, ultimate load, and ultimate displacement were determined for five samples of monoaxial and polyaxial screws using Anterior-Posterior and Flexion-Extension test, and the data were analyzed using Microsoft Excel. The experimental test was performed using a bi-axial, servo-hydraulic Universal testing machine (UTM). The automated 9.8kN UTM, (Star Testing Systems-Model no STS 248) was connected to windows-based software provided by the Star testing system to obtain the continuous load-displacement graphs.

During the Anterior-Posterior testing, the rod was inserted in the screw head, and the tightening screw was assembled over the rod in the screw head with the tightening torque of 8.5 N.m. Both the ends of the longitudinal element (rod) were clamped rigidly in the fixture, which is firmly mounted on a working table. An article by Krag MH [18] showed that 80% penetration is 32.5% stronger than 50% penetration; hence 80% penetration depth or insertion depth is considered sufficient, and therefore the screw was clamped to suit and inserted up to 80% of the deep as shown in the experimental setup in Fig. 2. The tensile load was applied at a constant rate with the crosshead speed of 25mm/min in the direction of the screw axis until the breaking point was achieved [15,16]. The continuous load-displacement graph was obtained through the window-based software. Five samples of the monoaxial screw and five samples of the polyaxial screw were sustained for the AP test, and load-displacement data was obtained for further comparison. The pullout strength of the screw was defined as the peak of the curve. The corresponding displacement was recorded for each screw, and the pullout stiffness, which can also be described as the rigidity was evaluated from the linear part of the load-displacement curve.

Fig -2: Experimental setup of Anterior-Posterior Test

In the Flexion-Extension Moment Test, the screw and rod were assembled with a tightening torque of 8.5N·m. In order to perform the moment test, both the ends of the rod were rigidly held in the fixture while the fixture was mounted such that the screw axis was perpendicular to the direction of the load vector with the support of an angle plate. The angle plate was firmly mounted on the table and it was adjusted as accurately as possible that the load is applied at the point 25mm from the neck of the screw as seen in the experimental setup (Fig. 3). The FE moment test was performed by applying compressive at the constant crosshead speed rate of 25mm/min till the rupture point was attained. The load versus displacement behavior of the screw assembly was inspected and a continuous graph was obtained through the window-based software. From the knowledge of the load-displacement curve, the stiffness of the screw was evaluated from the linear portion of the curve. The method was repeated for five monoaxial and five polyaxial screw samples. The properties including elastic load, elastic displacement, yield load, yield displacement, ultimate load, and ultimate displacement were assessed for each sample.

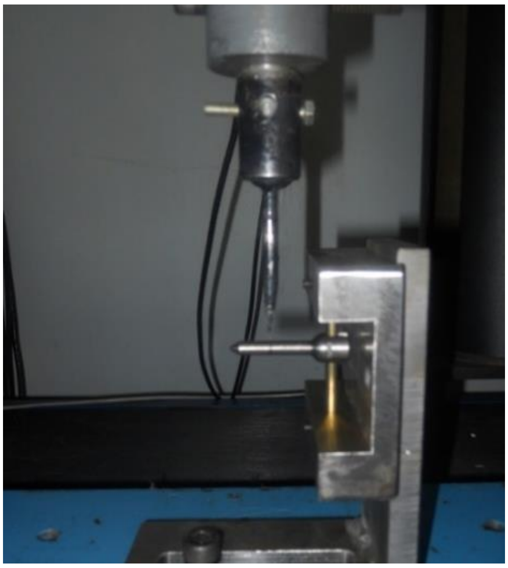

Fig -3: Experimental setup of Flexion-Extension Moment Test

2.2. Prediction of Tresca stresses and contact pressure using FEM

The FEM is an integrated product of mathematical physics, mechanics, computational methods, and computer technology that can almost analyze any complex engineering structure so as to produce the results obtaining various mechanical properties in most of the engineering fields. The core of the finite element method is that it converts the complex continuum having the infinite number of freedoms into a finite number of elements, transforming the infinite number of freedoms into the finite degree of motions thus the structure is discretized into a number of finite elements, also known as meshing. The mechanical properties of the discretized elements are analyzed and the element stiffness matrix is derived. The boundary conditions are applied to the body structure and numerical simulations are performed to solve the algebraic equations of the finite parameters and finally, the stress-strain parameters of elements are evaluated to obtain the output. The purpose of the present work is therefore to develop an FE-model of a pedicle screw and to investigate the numerical behavior of pedicle screw to predict the strength of the pedicle screw under axial pullout and bending conditions.

An identical CAD model of a pedicle screw was developed using a three-dimensional interactive application (as can be seen in Fig. 4a) Fig. 4b shows the cross-section of the pedicle screw subassembly consisting screw, tightening screw, and the rod. The tightening screw and screw head provided with buttress threads has the advantage to handle extremely high axial thrust in one direction preventing the unscrewing or loosening of the tightening screw.

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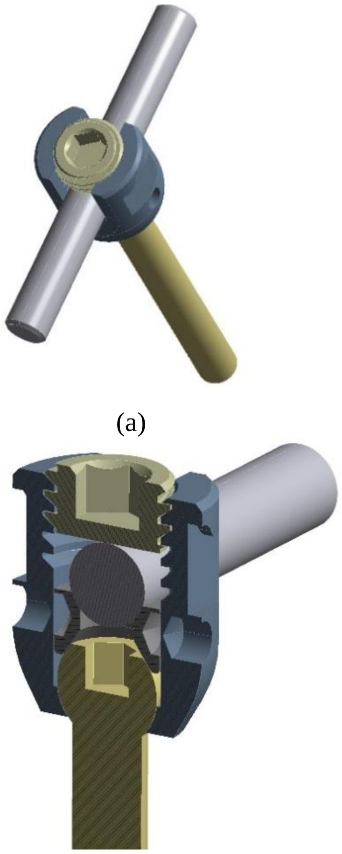


(a)

(b)

Fig -4: CAD-model of (a) Pedicle screw, (b) Cross-section view of the pedicle screw

The developed CAD model was imported in finite element analysis commercial software ANSYS via the IGES interface. The pedicle screw, rod, and tightening screw are made up of Titanium alloy, Ti6Al4V. The implant material was considered isotropic linear elastic nature with the young's modulus = 102 GPa and Poisson's ratio = 0.3 and Density = 4.43E-09 Tones/mm^3 [19]. The material was assigned to each component of the subassembly from the engineering material library. An automatic tetrahedral meshing method was adopted to mesh the screw head, the tightening screw whereas the hexahedral grid was implemented to mesh the rod and the screw. For the optimization of the mesh density, a finer mesh was used in regions with high-stress concentration while coarser mesh was introduced in regions having low or constant stress gradient. The total number of nodes and elements of the meshed model was found to be 27013 and 12290 respectively. The bonded connections were made between the parts considering enough torque was provided to tighten the tightening screw over the fixing rod. The boundary condition application in biomedical FEA is based on the assumptions of pressure and forces acting in the human body as well as the displacement and symmetry boundary conditions based on simplifications in the model. Firstly, the biomechanical performance of the pedicle screw was analyzed by applying loading and boundary conditions for two cases; the Anterior-Posterior test which is the Axial Pullout, and the Flexion-Extension test that is bending. to develop the precise replica of the experimental setup, the boundary conditions including magnitude and direction of loading, contact parameters, displacements were kept as identical as the experimental tests. For the A-P simulation, the end of the rod was constrained for motion in all directions and a force of 2180N was applied uniformly on nodes on the screw in the direction parallel to the axis of the screw at a distance of 18mm from the neck of the crew. For the FE moment test, the end of the rods was fixed and a force of 467N was applied uniformly on nodes of the screw in the direction parallel to the rod axis. The Tresca stresses, deformation, and contact pressure were simulated to analyze the behaviour of the pedicle screw for both A-P and FE moment conditions.

3. Results and Discussion

3.1 Experimental Results

Under the Anterior-Posterior test, five monoaxial screw samples namely APM1, APM2, APM3, APM4, APM5, and five polyaxial screws APP1, APP2, APP3, APP4, APP5 were experimentally tested. Table 1 shows the elastic load, yield load, ultimate load, and the corresponding displacements of all pedicle samples tested under axial pullout loading.

The yield load and ultimate load defines the strength of the screw found out significantly higher for monoaxial screws as compared to the polyaxial screws. For the monoaxial screws, the stiffness which describes the rigidity of the screw was significantly higher than the polyaxial screws. Fig. 5 shows the bar chart representation of the comparison of stiffness of all screw samples in the AP test. The displacement of the screw at the peak that is ultimate load was less than 19.4mm whereas the polyaxial screws were deformed by a maximum of 3.6 mm at the peak load point. It was observed from the experimental results that the monoaxial screw exhibited more load-carrying capacity than the polyaxial screw sample. Furthermore, it was noticeable that the serious erosion or fracture of all the screw samples occurred at the neck of the screw. Many studies have been carried out and found out anatomy and characteristics of pedicle screw screws are directly proportional to the strength and fatigue of the screw. [20-22]. In the fatigue pullout test, the screw shanks were fractured at the neck junction. M. Yamagata et al. 1992 explored that increasing the diameters of the screws increases the strength and maximum load-carrying capacity of the screws [22].

Table -1: Anterior-Posterior Test results

Screw Type	Specimen No	Elastic Load (N)	Elastic Displacement (mm)	Yield Load (N)	Yield Displacement (mm)	Ultimate Load (N)	Ultimate Displacement (mm)
	APM1	1487.9	1.9	2427.6	2.28	6264.16	12.8
	APM2	2678	2.05	4731	2	6640.45	10.4
	APM3	2768	2.54	3622.9	2.94	5911	8.1
	APM4	1666	2.4	2420.9	2.7	4163	6.8
	APM5	1662.5	2.57	3325	2.71	7000.14	10.2
	APP1	300.5	0.84	1915	1.12	2503	2.6
	APP2	248	0.4	1147	1.1	2478.2	2.8
	APP3	273	0.51	1710	0.65	2279	2.5
	APP4	263	0.45	1744	1.15	2148.16	3.6
	APP5	288	0.54	1656	1.07	1915.9	1.2

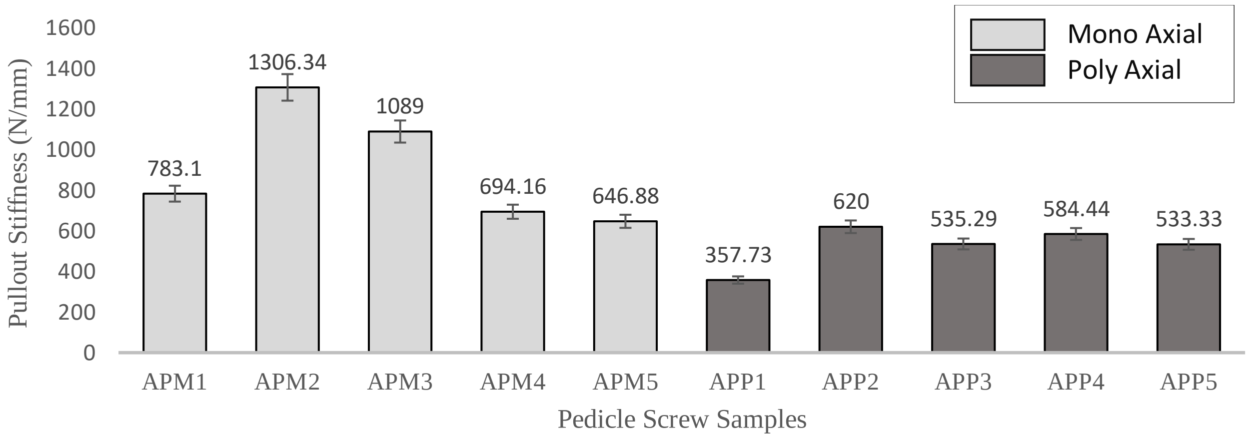


Fig -5: Pullout stiffness of Mono axial and Polyaxial screws obtained for AP Test

Upon testing the screw samples for Flexion-Extension moment, the screw bends due to the eccentric loading while the maximum bending moment acts at the neck of the screw. Table 2 shows the elastic load, yield load, ultimate load and the corresponding deformation of the screw under loading for all the samples of monoaxial and polyaxial screw.

Table -2: Flexion-Extension moment test results

Screw-type	Specimen No	Elastic Load (N)	Elastic Displacement (mm)	Yield Load (N)	Yield Displacement (mm)	Ultimate Load (N)	Ultimate Displacement (mm)
	FEMM1	511.56	2.42	897.68	3.5	1550.36	6.1
	FEMM2	322.42	1.5	550.76	1.5	609.56	2
	FEMM3	513.52	1.62	823.2	1.9	1435.7	4.2
	FEMM4	567.42	1.79	929.04	3	1157.38	4.2
	FEMM5	567.42	3	855.54	3.1	986.86	4.2
	FEMP1	70.56	2.4	219.52	2	325.36	7.2
	FEMP2	88.2	1.9	204.82	1.9	299.88	8
	FEMP3	103.88	1.9	230.3	1.9	301.84	6.65
	FEMP4	109.76	1.33	233.24	2.6	459.62	14.5
	FEMP5	116.62	1.05	177.38	1.5	276.36	6.3

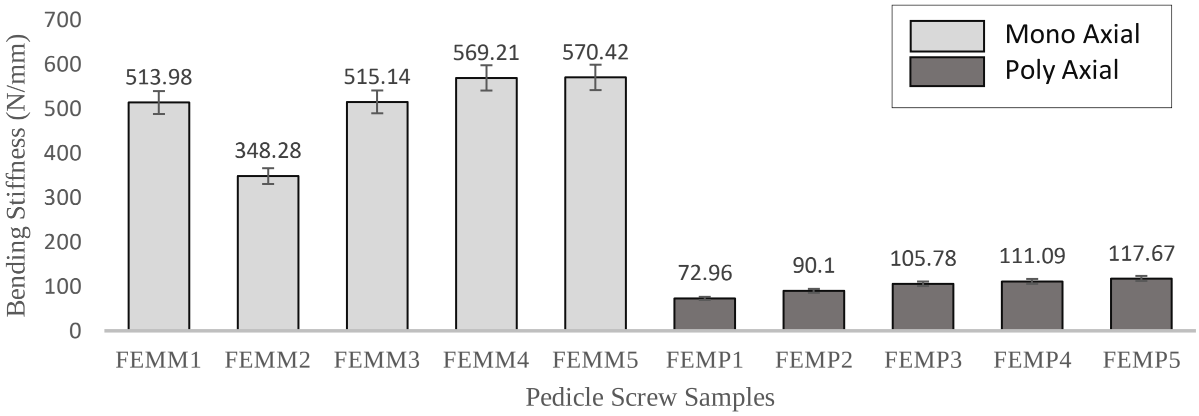


Fig -6: Bending stiffness of mono axial and poly axial screws obtained for FE moment Test

The polyaxial screw samples, wherein FEMM1 deformed the most by 6.1 mm under the ultimate load of 1550.36 N indicating the screw has a maximum strength of 1550.36 N. The polyaxial screw samples were deformed by a maximum of 14.5 mm but under a very low load of 459.62 N signifying that the monoaxial screws have significantly high strength than the polyaxial in FE moment test. Moreover, the stiffness

polyaxial screw occurred at the junction of the screw and the head whereas the nuts of the polyaxial screw subassembly failed before the heads were cut off.

3.2. Finite Element Analysis Results

The replica of the Anterior-Posterior test and Flexion-Extension Moment test was developed and numerical simulation was performed to study the behaviour of the pedicle screw assembly under the loading. In the post-processor, the solver performed a number of numerical equations in order to obtain the simulation results. The interpretation of the results included firstly the maximum Tresca stresses (maximum shear stress) and the deformation in the pedicle screw implant, secondly the contact pressure at the contact surfaces between the pedicle implant components. The results were obtained for both the cases i.e., axial pullout and bending moment.

The results of the FE-analysis were plotted as contour images for visualization maximum affected area. The graphics shown in Fig. 7 determines the induced Tresca stresses in the pedicle screw fixation system and its components including the rod, and tightening screw obtained in the Pullout simulation. The maximum equivalent stress induced in the spinal implant assembly was 363.83 MPa maximum of which is acting maximum on the contact surface of the tightening screw (Fig. 7a). The rod is subjected to bending on account of the pulling load at the contact between the tightening screw and the rod

comparison of monoaxial and polyaxial screws as can be seen in Fig. 6 shows monoaxial screws exhibits higher toughness than polyaxial screws. It was observed from the experimental results that the monoaxial screw exhibited more load-carrying capacity than the polyaxial screw sample with comparatively the same screw displacement. From the present study, it was observed that the bending failure in the

inducing stresses of magnitude 335.43 MPa in the rod (Fig. 7b). The screw head is subjected to a maximum stress of 313.02 MPa which may cause splaying of the head portion (Fig. 7c). Stresses are induced at the edges of the tightening (as can be seen in Fig. 7d) on account of the bearing pressure applied by the spinal rod due to its bending during the axial pullout. The maximum deformation in the implant recorded was 0.5657mm while the rod, tightening screw, and screw were deformed by 0.536mm, 0.533mm, and 0.5687mm respectively.

The results were obtained to determine the pressure distribution at the contacts between the rod, tightening screw and the screw. It was assumed during the numerical study that sufficient torque was applied to the tightening screw causing the bounded contact at the screw head assembly. Practically, if sufficient torque is not provided, it may cause the splaying of the screw head. As can be seen in Fig. 8a, the spinal rod tends to bend on account of the axial pulling force, which applies the maximum bearing pressure on the tightening screw amounting to 1197.6 MPa. It was found from the numerical study that no significant pressure distribution was observed between the screw cap and spinal rod i.e., 115.61 MPa (Fig. 8b). The bearing pressure of 18.417 MPa is acting at the thread contact between the screw head and the tightening screw as shown in figure 8c accounting due to the axial pull out of the screw. Also, the spherical contact between the screw and the cap is subjected to Hertzian contact pressure of 22.91 MPa (Fig. 8d).

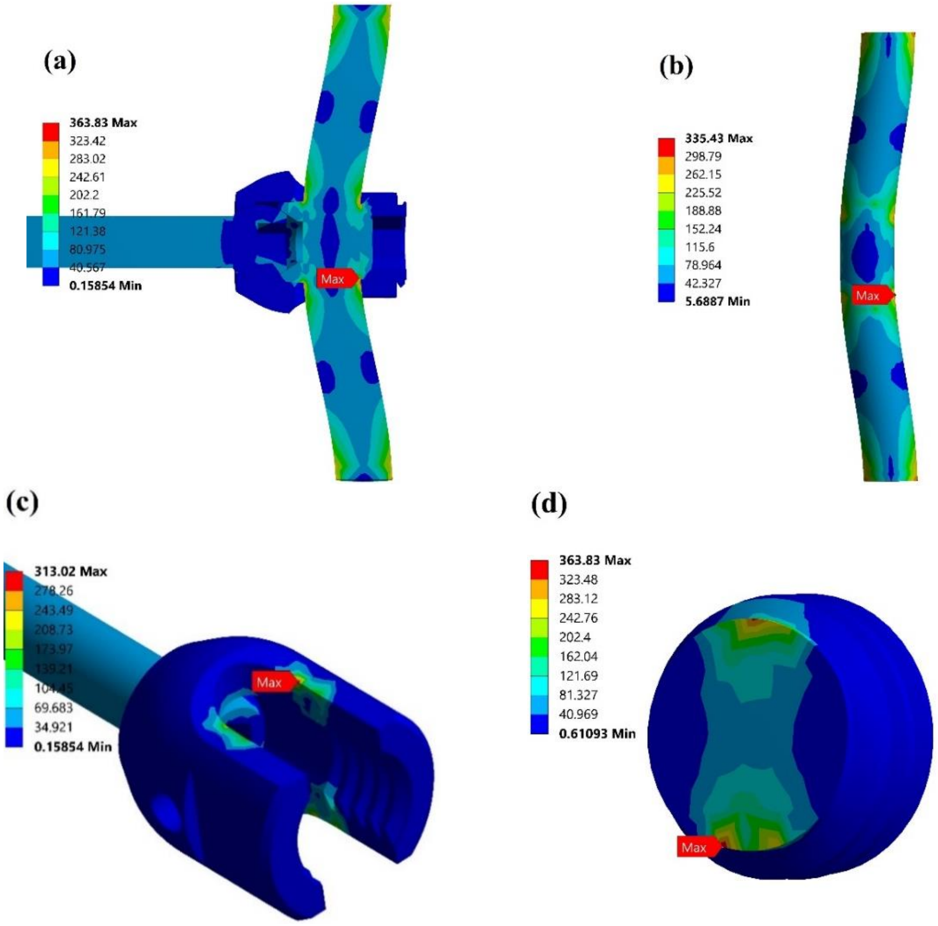
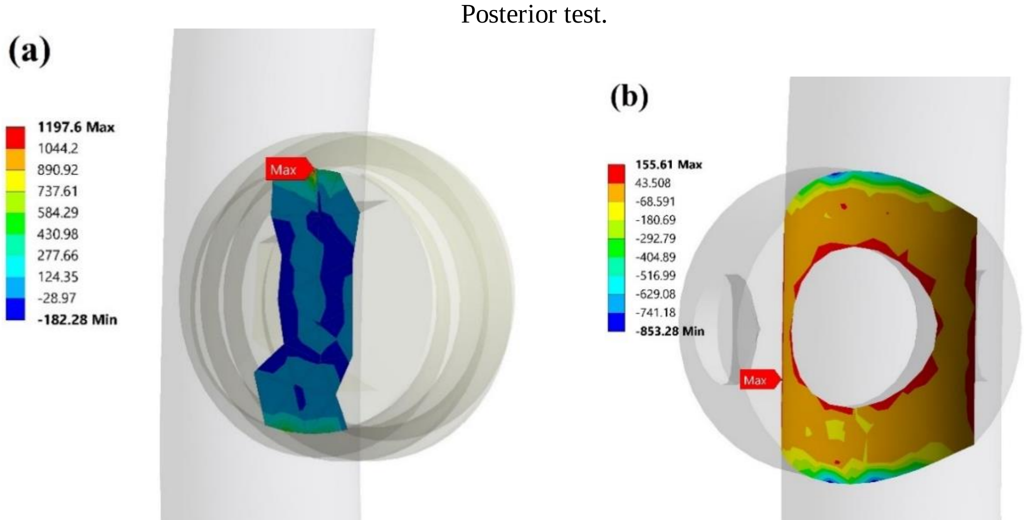


Fig -7: Trend of Tresca stresses in (a) Pedicle subassembly, (b) Rod, (c) Screw and (d) Tightening screw during Anterior-Posterior test.



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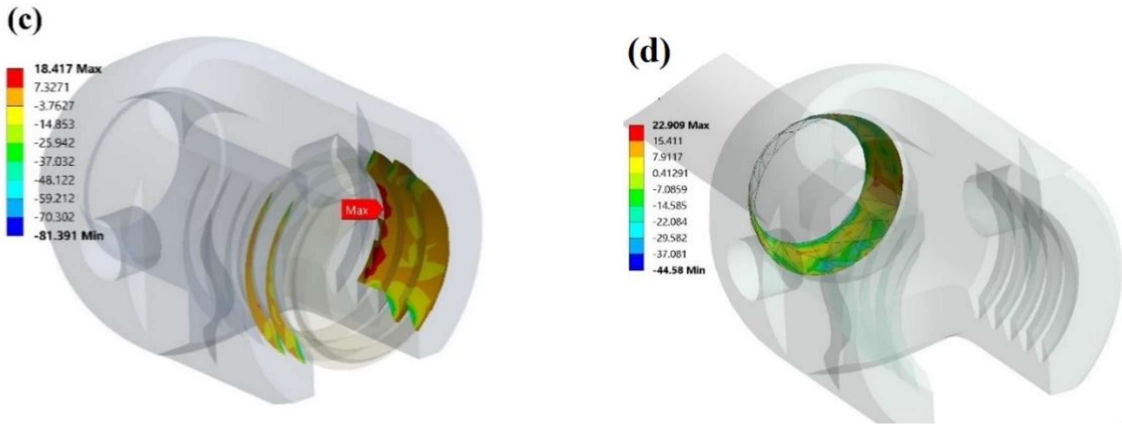
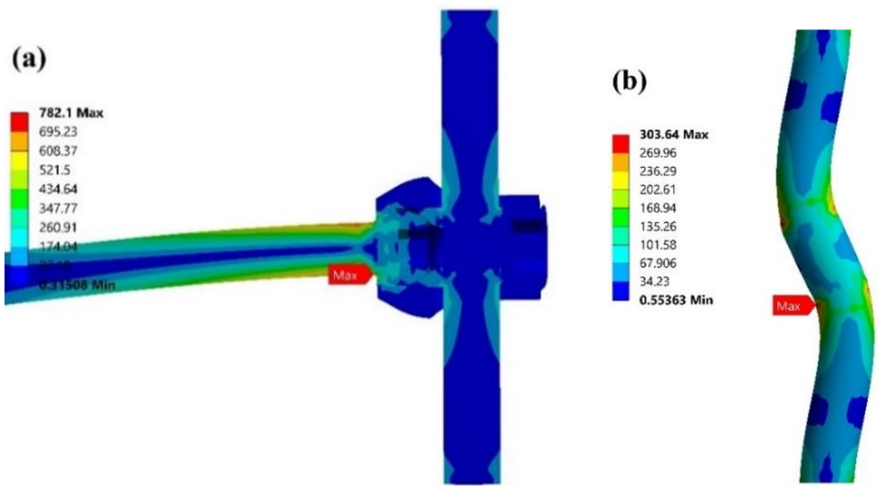


Fig -8: Contact Pressure distribution acting at the contact between (a) Rod and tightening screw, (b) Fixation rod and cap, (c) Threads of tightening screw and screw head (d) Screw and screw head during Anterior-Posterior test.

In the FE moment test simulation, all directional motions were constrained at both the ends of the rod and the force was applied in the direction mutually perpendicular to the axis of the screw and the rod i.e., in the Z direction tends to bend the pedicle implant. Fig. 9a shows the behaviour of the pedicle screw under the specified boundary conditions in which the graphics shows that stress is acting at the threads of the tightening screw amounting to 782.1 MPa. Assuming sufficient torque was provided so as to avoid the slipping of the rod between the screw cap and the tightening screw, bonded contact was considered for the simulation purpose and therefore maximum equivalent stress of 303.64 MPa was registered in the fixation rod (Fig. b). Practically, if sufficient torque is not provided, the rod may slip in between the cap and the tightening screw under the bending conditions. The screw was subjected to bending and the maximum Tresca stress of magnitude 782.1 MPa which further may cause pull out the screw from the spherical joint (Fig. 9c). Stresses are induced at the edges of the tightening (as can be seen in Fig. 9d) in consequence of the bearing pressure caused by the bending of the spinal rod. Because of the applied bending conditions, the implant assembly was subjected to deformation of 10.21 mm maximum at the end of the screw while the rod, tightening screw and tightening screw were deformed by 0.422 mm, 0.652 mm and 10.21 mm respectively.

The Contact-pressure results were obtained to determine the pressure distribution at the contacts between the rod, tightening screw and the screw. Due to the bending condition, the maximum pressure is distributed by the rod on the tightening screw amounting to 453.79 MPa which further may cause splaying of the screw head (Fig. 10a). It can be seen from Fig. 10b, the pressure is distributed at the contact between the screw cap and the rod amounting 1172Mpa. Also, maximum bearing pressure amounting 169.99MPa is acting at the contact between the threads of the tightening screw and screw head (Fig. 10c). The rod tends to bend (as shown in Fig. 10d) enforces pressure of 1937MPa on the head of the screw which further may lead to splaying of the screw head and the tightening screw may cut off from the head similar to the failure observed during experimental testing.



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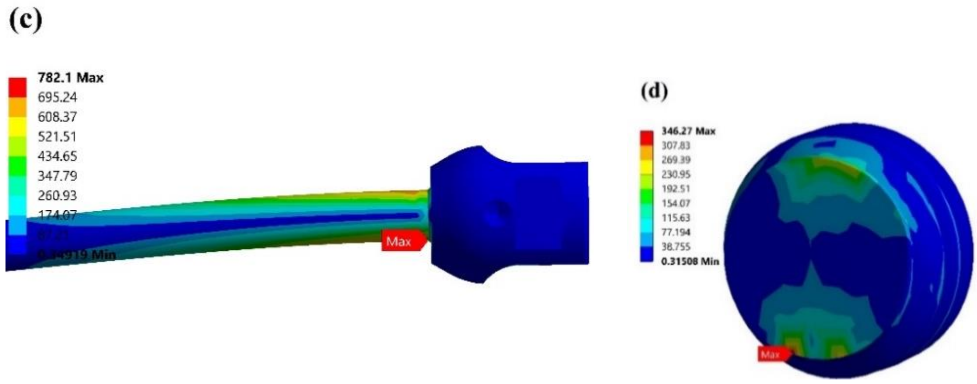

Fig -9: The trend of tresca stresses in (a) Implant assembly, (b) Rod, (c) Screw and (d) Tightening screw during the Flexion-Extension moment test.

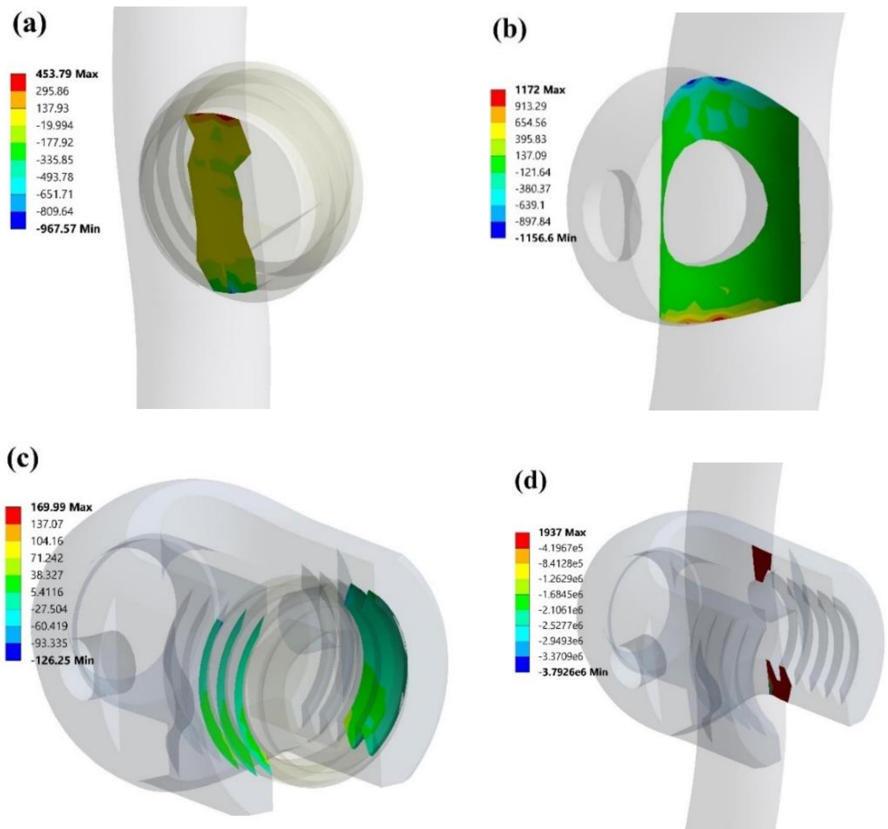

Fig -10: Contact Pressure distribution acting at the contact between (a) Rod and tightening screw, (b) Fixation rod and cap, (c) Threads of tightening screw and screw head (d) Rod and screw head during Flexion-Extension Test.

4. CONCLUSION

In the present study, the experimental study was carried out on monoaxial and polyaxial screw samples to investigate their strength under axial pull-out and flexion-extension moment tests. Furthermore, the finite element analysis was carried out to identify the Tresca stress criterion, which was used to determine the failure at the elemental level. In contrast, the boundary conditions of the finite element model were adjusted as exact as the experimental setup. The experimental results clearly showed that the monoaxial screw has significantly high strength and stiffness than the polyaxial screw in both the practical tests where the stiffness represents the rigidity of the screw. It was found out that the load-carrying capacity in the anterior-posterior direction was 10.9% higher for monoaxial screws than polyaxial screws, and the flexion-extension moment is 2.9 times higher for mono screw than the poly screw for the same tightening torque.

The Finite Element Method was found to predict the Tresca stresses and the contact pressure at the heavily stressed element areas. It was observed that the monoaxial screw fractured at the junction of the shank and the head, the strength of which can be increased by reducing the stress concentration at the neck by providing a larger fillet or increasing the diameter of the shank portion. The results from the simulation of the flexion-extension moment test showed that the tulip of the pedicle screw expanded and caused loss of contact between the tightening screw and the pedicle screw head. This failure mode matches the manner of failure observed during experimental testing. Moreover, the simulation results obtained from the anterior-posterior test suggest that the spinal rod of the implant assembly exhibits high deformation and stress, which supports the observations during experimental testing.

REFERENCES

[1] Robert W. Gaines Jr. The Use of Pedicle-Screw Internal Fixation for the Operative Treatment of Spinal Disorders. J Bone Joint Surg Am. 2000; 82:1458.

[2] Verma K, Boniello A, Rihn J. Emerging Techniques for Posterior Fixation of the Lumbar Spine. J Am Acad Orthop Surg. 2016 Jun;24(6):357-64. doi: 10.5435/JAAOS-D-14-00378. PMID: 27077477. DOI: 10.5435/JAAOS-D-14-00378.

[3] Fior Markets (2020). Global Pedicle Screw System Market by Product, Surgery Type, Indication, Application, Region, Industry Analysis, Size, Share, Growth, Trends, and Forecast 2018 to 2025 – Fior Markets.

[4] Prud'homme M, Barrios C, Rouch P, Charles YP, Steib JP, Skalli W. Clinical Outcomes and Complications After Pedicle-anchored Dynamic or Hybrid Lumbar Spine Stabilization: A Systematic Literature Review. J Spinal Disord Tech. 2015 Oct;28(8):E439-48. doi: 10.1097/BSD.0000000000000092. PMID: 25093644.

[5] Villa T, La Barbera L, Galbusera F. Comparative analysis of international standards for the fatigue testing of posterior spinal fixation systems. Spine J. 2014 Apr;14(4):695-704. doi: 10.1016/j.spinee.2013.08.032. Epub 2013 Nov 21. PMID: 24268390.

[6] Schizas C, Tzinieris N, Tsiridis E, Kosmopoulos V. Minimally invasive versus open transforaminal lumbar interbody fusion: evaluating initial experience. Int Orthop. 2009 Dec;33(6):1683-8. doi: 10.1007/s00264-008-0687-8. Epub 2008 Nov 21. PMID: 19023571; PMCID: PMC2899194.

[7] A. Rohlmann, G. Bergmann, F. Graichen, H.-M. Mayer. Placing a bone graft more posteriorly may reduce the risk of pedicle screw breakage: analysis of an unexpected case of pedicle screw breakage. Journal of Biomechanics 31 (1998) 763-767.

[8] Dr. Sanjay Dhar. Operative guidelines. S. H. Pitkar Orthotools Pvt. Ltd.

[9] Yánez A, Carta JA, Garcés G. Biomechanical evaluation of a new system to improve screw fixation in osteoporotic bones. Med Eng Phys. 2010 Jun;32(5):532-41. doi: 10.1016/j.medengphy.2010.02.014. Epub 2010 Mar 15. PMID: 20227321.

[10] Engin Çetin, Mustafa Özkaya,Ümit Özgür Güler,Emre AcaroLlu,and Teyfik Demir, "Evaluation of the Effect of Fixation Angle between Polyaxial Pedicle Screw Head and Rod on the Failure of Screw-Rod Connection", Applied Bionics and Biomechanics, Volume-2015, Article ID 150649.

[11] P. Tengvall, B. Skoglund, A. Askendal, P. Aspenberg. Surface immobilized bisphosphonate improves stainless-steel screw fixation in rats. Biomaterials 25 (2004) 2133–2138.

[12] Amit Nemade, Azim Shikalgar, Saurebh Sancheti, Swapnil P. Wadkar, Biomechanical analysis of spinal pedicle screws under static compression and tensile bending, Materials Today: Proceedings, Volume 47, Part 14, 2021, Pages 4778-4785, ISSN 2214-7853, https://doi.org/10.1016/j.matpr.2021.05.681.

[13] British Standards Institution, Implants for Osteosynthesis. Part 5, Bone Screws and Auxiliary Equipment, (Section 5.3, Specification for the Dimensions of Screws Having Hexagonal Drive Connection, Spherical Under Surfaces and Asymmetrical Thread), British Standards Institution, London, UK, 1991.

[14] Chatzistergos PE, Magnissalis EA, Kourkoulis SK. A parametric study of cylindrical pedicle screw design implications on the pullout performance using an experimentally validated finite-element model. Med Eng Phys. 2010 Mar;32(2):145-54. doi: 10.1016/j.medengphy.2009.11.003. Epub 2009 Nov 27. PMID: 19945333.

[15] ASTM F1717-09, Standard test methods for spinal constructs in a vertrectomy model.

[16] ASTM F1798-97(Reapproved 2008), Evaluation the static and fatigue properties of interconnection mechanisms and subassemblies used in spinal artrodesis implants.

[17] Gertzbein SD, Robbins SE. Accuracy of pedicular screw placement in vivo. Spine (Phila Pa 1976). 1990 Jan;15(1):11-4. doi: 10.1097/00007632-199001000-00004. PMID: 2326693.

[18] Krag MH, Beynnon BD, Pope MH, et al. An internal fixator for posterior application to short segments of the thoracic, lumbar, or lumbosacral spine: design and testing, Clin Orthopaedics 986;203:75-98.

[19] Niinomi, M., and Boehlert, C. J. (2015). "Titanium alloys for biomedical applications," in Advances in Metallic Biomaterials: Tissues, Materials and Biological Reactions. Springer Series in Biomaterials Science and Engineering, eds M. Niinomi, T. Narushima, and M. Nakai (Berlin: Springer), 179–213. doi: 10.1007/978-3-662-46836-4_8.

[20] S. Soshi, R. Shiba, H. Kondo, and K. Murota, "An experimental study on transpedicular screw fixation in relation to osteoporosis of the lumbar spine," Spine, vol. 16, no. 11, pp. 1335–1341, 1991.

[21] J. N. Weinstein, B. L. Rydevik, and W. Rauschning, "Anatomic and technical considerations of pedicle screw fixation," Clinical Orthopaedics and Related Research, pp. 34–46, 1992.

[22] M. Yamagata, H. Kitahara, S. Minami et al., "Mechanical stability of the pedicle screw fixation systems for the lumbar spine," Spine, vol. 17, no. 3, pp. S51–S54, 1992