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Influence of bone quality and pedicle screw design on the fixation strength during Axial Pull-out test: A 2D Axisymmetric FE study

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Abstract— **Pedicle screw fixations are widely used to provide support and improve stability for the treatment of spinal pathologies. The effectiveness of treatment depends on the anchorage strength between the screw and bone. In this study, the influence of pedicle screw half-angle and bone quality on the displacement of fixation and stress transfer are analyzed using a 2D axisymmetric finite element model. The pedicle screw proximal half-angle is varied between 0° and 60° in steps of 10°, along with two different distal half-angles of 30° and 40°. Three bone models are considered for cancellous bone to simulate various degrees of bone quality, namely, poor, moderate and good. The mechanical properties of cortical bone are kept constant throughout the study. The material properties and boundary conditions are applied based on previous studies. Frictional contact is considered between the bone and screw. Results show that, the displacement of fixation is observed to be minimum at a proximal half angle of 0° and maximum at an angle of 60°, independent of bone quality. The highest implant displacement is observed in case of poor bone quality. All the bone model showed similar patterns of stress distribution, with high stress concentration around the first few threads. The highest peak von Mises stress is obtained at a proximal half-angle of 60°. Furthermore, the stress transfer increased with increase in proximal half-angle and bone quality, with maximum stress transfer at a proximal half-angle of 60°. It appears that, this study might aid to improve the design of pedicle screw for treatment of degenerative spinal diseases.**

Clinical Relevance— **This study analyses the impact of bone quality on pedicle screw design**

I. Introduction

Pedicle screw instrumentation has been widely used for treatment of spine misalignments and various spinal degenerative diseases caused by osteoporosis [1]. However, the success of treatment is significantly affected by fixation failure due to pedicle screw loosening, the incidents of which have been reported to be 1 - 15% for non - osteoporotic subjects and higher in osteoporotic subjects [2]. Studies have also reported a decrease in bone quality with aging due to decrease in bone density [3]. The fixation of pedicle screw is characterized by high pull-out strength, which indicates stable anchorage in the screw-bone interface and sufficient stress transfer between the screw and bone. It was reported that high stress transfer improves bone regrowth and remodeling [4]–[6].

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Several experimental studies have reported the influence of various parameters of pedicle screw, including, the length, pitch, diameter, thread shape, angle of insertion and bone quality. It was concluded that the pull-out strength increases with increase in length and diameter and a proximal half-angle of 30° had the highest pull-out strength [7]–[12].

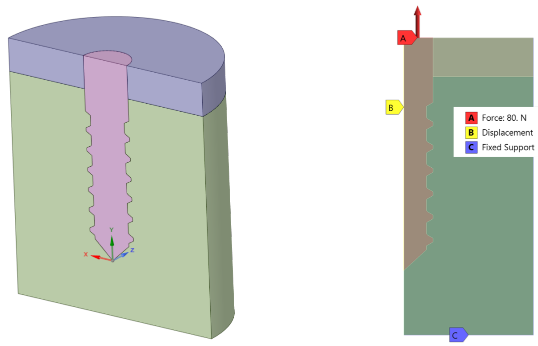
Finite Element (FE) models are widely used for solving complex numerical problems, since manufacturing and testing of different screw designs could be laborious and time consuming. In the field of orthopedic biomechanics, it is used to analyze the fixation strength and stress distribution around the implant. Several studies have employed the use of FE models to analyze the influence of thread shape, insertion angle, bone quality, length and diameter on fixation strength [6], [13]–[15]. Though, the thread shape primarily depends on half-angles, literatures analyzing the effect of half-angles on fixation strength is scarce [6], [7], [16]. Furthermore, fewer studies have reported the variation in displacement and stress distribution around the implant with different bone densities and screw half-angles i.e. Proximal half-angle (PHA) and Distal half-angle (DHA) [5]. Hence, this study attempts to investigate the effect of screw half-angles and bone quality on the displacement of implant and stress distribution in peri-implant region of the bone.

II. Methodology

A. FE model

Two Dimensional (2D) axisymmetric FE model is used for numerical analysis and design optimization of pedicle screw. The objective of this study is to compare different screw half-angles and bone densities, a simplified 2D model with cancellous and cortical bone region is used. The model consists of a pedicle screw inserted into the bone block, in order to simulate axial pull-out test. The bone and screw geometry are modelled as shown in Fig. 1 (a) using Autodesk Inventor (Autodesk. Autodesk Inventor. San Rafael, CA: Autodesk; 2020). The screw has a major diameter of 4.5 mm, root diameter of 3.5 mm, pitch of 1.8 mm, thread width of 0.3 mm, and root radius of 0.2 mm [7]. The length of the screw is considered to be 18 mm with tip angled at 47.3° to the axis of the screw. The PHA is varied between 0° and 60°, in steps of 10° and DHA of 30° and 40° is considered, while the other geometric parameters of the screw are kept constant.

The bone geometry is constructed by extruding a concentric cylinder around the screw, of length 23 mm and diameter 20 mm. The thickness of cortical bone layer is considered to be 3 mm [4].



(a) (b)

Figure 1. Finite Element model (a) CAD model (b) Loading Condition

B. Material Properties

Table 1 shows the material properties of cortical bone, cancellous bone and pedicle screw. The cancellous bone and screw are considered to be isotropic linear elastic, while cortical bone is considered as anisotropic elastic material [5]. Magnesium alloy screw is used in this study, since it has been reported to have better biocompatibility and load sharing capabilities compared to other metals [6].

C. Loading and Meshing

Fig. 1 (b) depicts the loading conditions applied to the FE model. An axial force of 80 N, is applied on the screw head, to simulate pull-out test. The load applied to the screw represents axial tension, which is lower than the failure force [4], [6]. The model is fixed along the circumferential surface and deformation of the upper surface is unconstrained, similar to experimental fixturing. The screw is free to displace along the vertical direction, while the horizontal displacement and rotation are constrained along the axis of symmetry. Frictional contact is considered between the screw and bone, with a coefficient of friction of 0.2 [5]. The contact between the cortical and cancellous bone is considered to be bonded. Fig. 2 shows the meshed FE model. The model is meshed using 2D quad dominant mesh, refined along the contact region, with a minimum edge length of 0.04 mm and minimum element size of 0.2 mm.

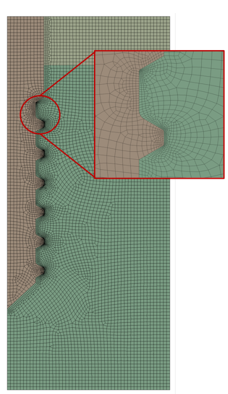


Figure 2. Meshed FE model

The deformation and stress distribution are monitored along the entire model. The stress transferred to the bone can be denoted by a dimensionless value, known as stress transfer parameter (STP). Equation (1) shows the formula used to calculate the STP [4], [6]. It is defined as the ratio of average stress in the bone above the thread to the average stress in the corresponding screw thread.

$$\alpha = \frac{\sigma_{fb}}{\sigma_{ft}} \quad \beta = \frac{\sum_{i=2}^{N} \sigma_{bi}}{\sum_{i=2}^{N} \sigma_{ti}} \tag{1}$$

where, σ_{fb} denotes the von Mises stress in bone above the first thread, σ_{ft} denotes the von Mises stress in the first thread, σ_{bi} denotes the von Mises stress in the bone above the i^{th} thread, σ_{ti} denotes the von Mises stress in i^{th} thread, and N denotes the number of threads in screw.

In this study, only the β STP is used for evaluating the stress transfer between the bone and screw. The analysis is performed using ANSYS 2020 R2 (Academic Student, ANSYS Inc., Canonsburg, PA, USA).

III. Results and Discussion

In this study, the stress distribution and deformation of the model are estimated for different screw half-angles and bone qualities, by simulating axial pull-out. Fig. 3 (a) shows the stress distribution in the entire screw-bone assembly. It is observed that the stress distribution is similar for all screw half-angles and bone qualities, with high stress concentration near the first few threads, decreasing along the length of the screw. Fig. 3 (b) shows the variation of von Mises stress in screw along the region of contact with the bone. High stress concentration is observed above the first thread, with peak stress decreasing with increase in thread number, irrespective of bone quality.

Fig. 4 (a) represents the percentage change in displacement of implant for various bone qualities and PHAs. The displacement of implant at a PHA of 0° in good quality bone is considered as the baseline for comparison. It is observed that, the displacement of the implant increases with increase in PHA for all bone qualities [5]. This may be due to the increased slippage in the contact region at higher PHAs. The highest displacement was obtained for a PHA of 60° and DHA of 40° in all cases, with a maximum change of 1042% for poor quality bone. In comparison to the baseline model, the maximum percentage change in implant displacement for moderate and good bone quality are 154% and 42% respectively. For a PHA of 60°, the maximum displacement of implant is 702% and 78% higher for cancellous bone with poor and moderate quality, when compared with good quality bone. The decrease in displacement with better bone quality may be attributed to the increased strength of the bone [9], [12].

Fig. 4 (b) and Fig. 4 (c) shows the maximum and average von Mises stress in implant for various bone qualities. It is observed that the maximum von Mises stress increases with increase in half-angle and bone quality. This might be due to higher implant displacement. However, the average von Mises stress of the implant decreases with increase in half-angle and bone quality. This may be attributed to the decrease in normal force on each thread of the implant along the contact region, with first few threads carrying a major portion of the load. This also shows that, lower PHA provides a better load distribution throughout the implant.

TABLE I. MATERIAL PROPERTIES USED IN THE FE MODEL

Material	Youngs Modulus (GPa)			Poisson Ratio			Shear Modulus (GPa)			Reference
Cortical bone	*E11*	*E23*	*E33*	*V12*	*V13*	*V23*	*G12*	*G13*	*G23*	[5]
	17.9	10.1	10.1	0.4	0.4	0.62	3.3	3.3	3.117	
Cancellous bone	0.1 (Poor Quality) 0.5 (Moderate Quality) 1.0 (Good quality)			0.2			-			[5]
Implant (Screw)	45			0.35			-			[6]

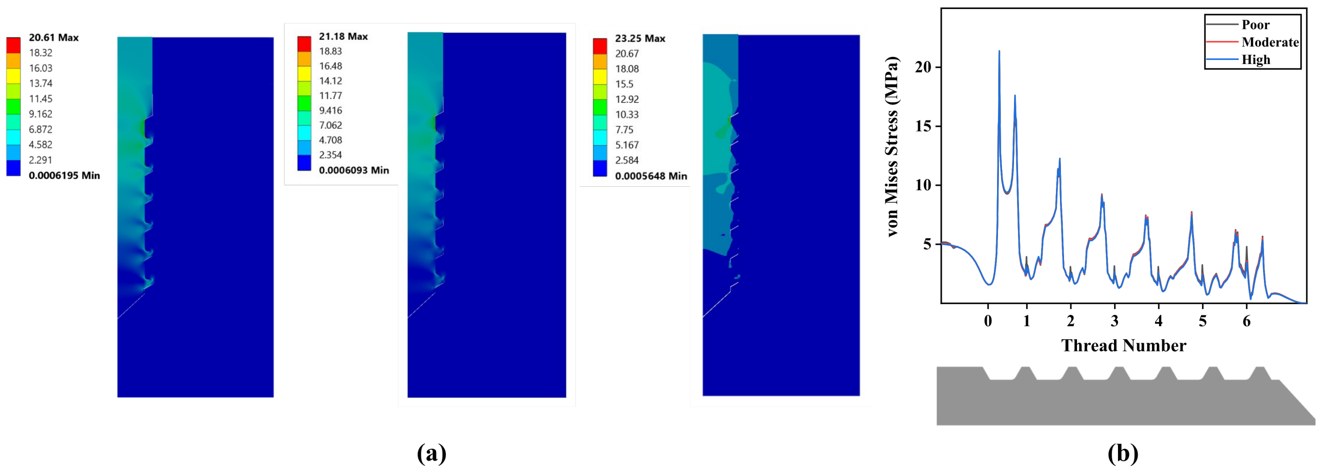


Figure 3. (a) von Mises Stress distribution for proximal half-angles of 0°, 30° and 60° and a distal half-angle of 30° (b) von Mises stress produced in implant along the path of contact for a proximal and distal half-angle of 30°

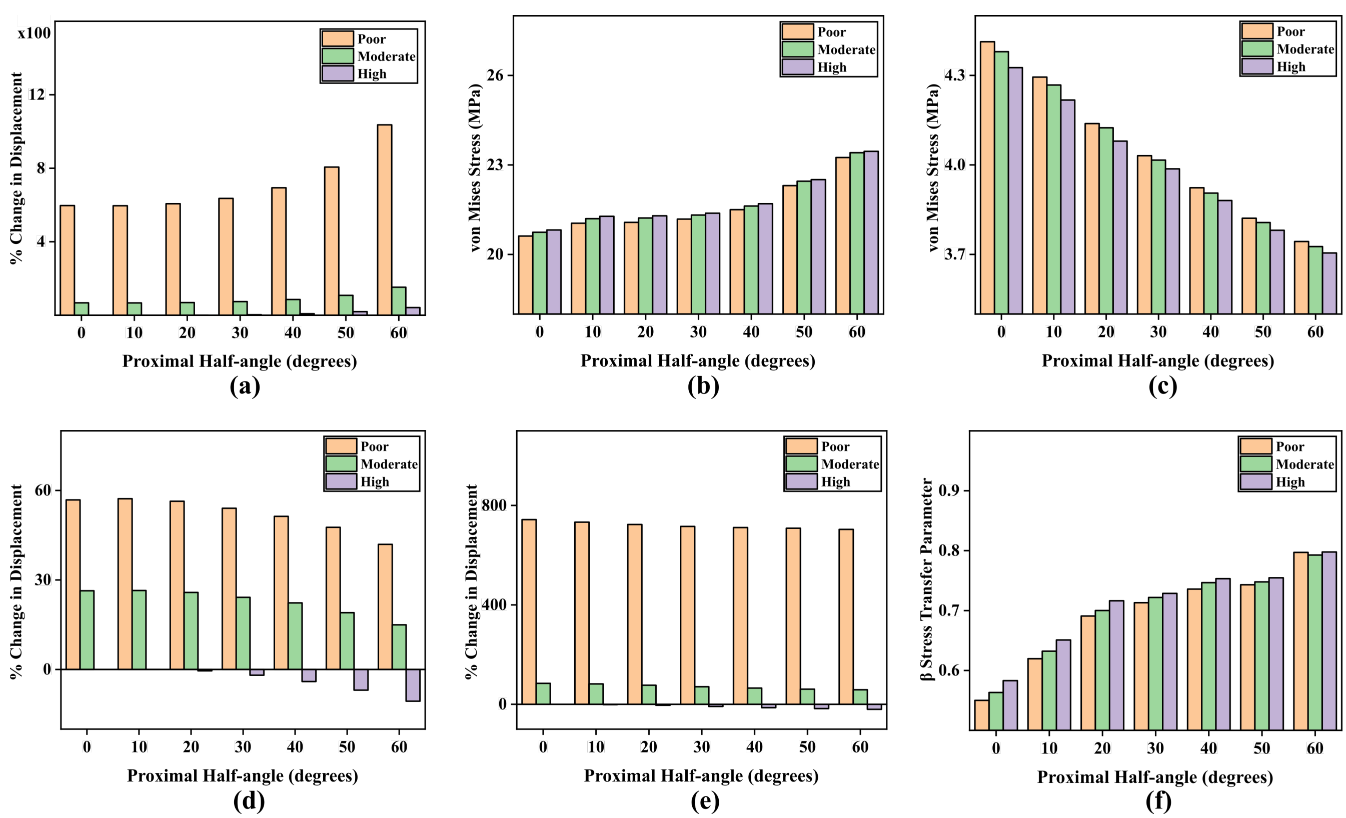


Figure 4. Results obtained for pedicle screw with distal half-angle of 30° (a) Percentage change in implant displacement (b) Maximum von Mises stress in implant (c) Average von Mises stress in implant (d) Percentage change in cortical bone displacement (e) Percentage change in cancellous bone displacement (f) Stress Transfer Parameter

Fig. 4 (d) represents the displacement of cortical bone for various PHAs and cancellous bone qualities. It is seen that the displacement of cortical bone decreases with increase in PHA and bone quality. The model with a PHA of 0° and poor bone quality, resulted in a maximum increase in displacement of 58%. The lowest displacement in cortical bone is observed for the model with a PHA of 60° and good quality cancellous bone.

Fig. 4 (e) shows the percentage change in displacement of cancellous bone for different PHAs and bone qualities. It is observed that, similar to cortical bone, the displacement of cancellous bone also decreases with increase in PHA and bone density. In comparison to the baseline model, the displacement of poor quality cancellous bone increased by 704% (PHA 60°) – 743% (PHA 0°), while that of moderate quality cancellous bone increased by 58% (PHA 60°) – 84% (PHA 0°).

The decrease in displacement of cortical and cancellous bone with increase in PHA may be attributed to the increased slippage at higher PHAs. Also, for a moderate/high quality cancellous bone, the displacement of both cortical and cancellous bone decreases due to higher strength of the latter. Furthermore, the difference in displacement and stress transfer between the considered DHAs is negligible, with a maximum change of 2%.

Fig. 4 (f) shows the β STPs for various PHAs and bone qualities. It is observed that, the β STP increases with increase in PHA, with 60° having the highest β STP value. Furthermore, for a particular half-angle, the β STP is higher for good quality bone compared to other bone qualities.

IV. Conclusion

In this study, the influence of pedicle screw half-angle and bone quality on displacement of fixation and stress transfer is evaluated using 2D axisymmetric FE model. It is observed that the impact of DHA on displacement and stress transfer is negligible in comparison to PHA. The displacement of implant is minimum for a PHA of 0°, which denotes stable anchorage between bone and screw. However, the stress transfer is maximum for a PHA of 60°. Hence, for selection of optimal half-angle, a trade-off between displacement and stress transfer has to be considered.

From this study, it can be concluded that a PHA of 0° can be used in case of poor quality cancellous bone, since stable anchorage is considered as the preliminary criteria for successful pedicle screw fixation. However, a PHA of 60° can be considered for moderate/good quality cancellous bone, since the change in implant displacement is negligible compared to that of poor quality bone and higher stress transfer would stimulate faster bone regrowth. This study can be extended for design optimization of patient-specific pedicle screws, using 3D models obtained from CT images.

References

[1] K. Verma, A. Boniello, and J. Rihn, "Emerging techniques for posterior fixation of the lumbar spine," *J. Am. Acad. Orthop. Surg.*, vol. 24, no. 6, pp. 357–364, 2016, doi: 10.5435/JAAOS-D-14-00378.

[2] F. Galbusera, D. Volkheimer, S. Reitmaier, N. Berger-Roscher, A. Kienle, and H. J. Wilke, "Pedicle screw loosening: a clinically relevant complication?," *Eur. Spine J.*, vol. 24, no. 5, pp. 1005–1016, 2015, doi: 10.1007/s00586-015-3768-6.

[3] H. Chen, X. Zhou, H. Fujita, M. Onozuka, and K. Y. Kubo, "Age-related changes in trabecular and cortical bone microstructure," *Int. J. Endocrinol.*, vol. 2013, p. 213234, 2013, doi: 10.1155/2013/213234.

[4] K. Haase and G. Rouhi, "Prediction of stress shielding around an orthopedic screw: Using stress and strain energy density as mechanical stimuli," *Comput. Biol. Med.*, vol. 43, no. 11, p. 1748, 2013, doi: 10.1016/j.compbiomed.2013.07.032.

[5] Y. N. Becker, N. Motsch, J. Hausmann, and U. P. Breuer, "Hybrid composite pedicle screw - finite element modelling with parametric optimization," *Informatics Med. Unlocked*, vol. 18, p. 100290, 2020, doi: 10.1016/j.imu.2020.100290.

[6] E. Tetteh and M. B. A. McCullough, "Impact of screw thread shape on stress transfer in bone: a finite element study," *Comput. Methods Biomech. Biomed. Engin.*, vol. 23, no. 9, pp. 518–523, 2020, doi: 10.1080/10255842.2020.1743980.

[7] Y. Wang, R. Mori, N. Ozoe, T. Nakai, and Y. Uchio, "Proximal half angle of the screw thread is a critical design variable affecting the pull-out strength of cancellous bone screws," *Clin. Biomech.*, vol. 24, no. 9, pp. 781–785, 2009, doi: 10.1016/j.clinbiomech.2009.07.008.

[8] P. S. D. Patel, D. E. T. Shepherd, and D. W. L. Hukins, "The effect of screw insertion angle and thread type on the pullout strength of bone screws in normal and osteoporotic cancellous bone models," *Med. Eng. Phys.*, vol. 32, no. 8, pp. 822–828, 2010, doi: 10.1016/j.medengphy.2010.05.005.

[9] Y. Y. Kim, W. S. Choi, and K. W. Rhyu, "Assessment of pedicle screw pullout strength based on various screw designs and bone densities - An ex vivo biomechanical study," *Spine J.*, vol. 12, no. 2, pp. 164–168, 2012, doi: 10.1016/j.spinee.2012.01.014.

[10] L. Weiser *et al.*, "Insufficient stability of pedicle screws in osteoporotic vertebrae: biomechanical correlation of bone mineral density and pedicle screw fixation strength," *Eur. Spine J.*, vol. 26, no. 11, pp. 2891–2897, 2017, doi: 10.1007/s00586-017-5091-x

[11] F. Shen, H. J. Kim, K. T. Kang, and J. S. Yeom, "Comparison of the pullout strength of pedicle screws according to the thread design for various degrees of bone quality," *Appl. Sci.*, vol. 9, no. 8, p. 1525, 2019, doi: 10.3390/app9081525.

[12] F. Addevico, M. Morandi, M. Scaglione, and G. F. Solitro, "Screw insertion torque as parameter to judge the fixation. Assessment of torque and pull-out strength in different bone densities and screw-pitches," *Clin. Biomech.*, vol. 72, no. December 2019, pp. 130–135, 2020, doi: 10.1016/j.clinbiomech.2019.12.004.

[13] M. Xu, J. Yang, I. H. Lieberman, and R. Haddas, "Finite element method-based study of pedicle screw–bone connection in pullout test and physiological spinal loads," *Med. Eng. Phys.*, vol. 67, pp. 11–21, 2019, doi: 10.1016/j.medengphy.2019.03.004.

[14] J. A. López-Campos, A. Segade, E. Casarejos, J. R. Fernández, J. A. Vilán, and P. Izquierdo, "Finite element study of a threaded fastening: The case of surgical screws in bone," *Symmetry (Basel).*, vol. 10, no. 8, pp. 1–13, 2018, doi: 10.3390/sym10080335.

[15] J. Widmer, M. R. Fasser, E. Croci, J. Spirig, J. G. Snedeker, and M. Farshad, "Individualized prediction of pedicle screw fixation strength with a finite element model," *Comput. Methods Biomech. Biomed. Engin.*, vol. 23, no. 4, pp. 155–167, 2020, doi: 10.1080/10255842.2019.1709173.

[16] H. Makaram and R. Swaminathan, "Analysis on the effect of half angle on the displacement of pedicle screw during axial pull-out test in cancellous bone using 2D axisymmetric FE model," *Biomed. Sci. Instrum.*, vol. 57, no. 2, pp. 153–158, 2021, doi: 10.34107/BiomedSciInstrum.57.04153.