New Pedicle Screw Design With Expandable Shell for Low Bone Quality[1]

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1 Background

Spinal fixation is a widely used solution for patients who suffer from vertebral fractures, vertebrectomy, and scoliosis [1]. Although there are existing fixation techniques, frequently used method for spinal fixation is the use of pedicle screws [2]. Durability of fixation is important for life quality of patient. Biomechanical performance of fixation systems plays a major role in this manner. Pullout strength is one of the most important parameters that effect durability of fixation. It depends on several factors such as core geometry, size, bone mineral density (BMD), pitch design, etc. Conical screw cores provide higher pullout strength than cylindrical screw cores. In addition, as much as diameter of screw increases, pullout strength is also increases. BMD is another key factor in terms of pullout strength. Researches revealed that denser bone mediums maintain greater pullout strength, thus screw loose situations are mostly seen on osteoporotic patients. Since host bone mineral density is such an important factor, several methods have been used to overcome screw loosening.

Using cement augmentation in operations is a frequently used method to increase pullout strength [3]. Although the pullout strength is increased, toxic leakage risk to the spinal canal concerns the surgeons.

Previous studies presented that expandable pedicle screws (EPS) provide superior pullout strength. EPS's are formed like an inverse conical geometry inside bones. This feature increases pullout strength, however in case of revision operations, back twisting of screw has resulted detrimentally. Bone in growth takes place through the inverse conic screw core and back twisting the screw became impossible even if inner mill of the screw has been removed. As a result, the screw has to be removed as an expanded condition, which causes bleeding and pedicle fractures.

Implant failures are presented as a leading factor of revision operations. Material selection, design, and manufacturing processes are all have influences on implant success. In last decades, Ti6Al4V alloy is widely used in medical industry, because of superior fatigue strength and corrosion resistance. On the other hand, like all metal elements, Ti6Al4V alloy is much more resistant than bone, which leads to stress concentrations between bone-implant interface. High stress concentration between bone-implant interface reduces osteo-integration, as a result durability. Polyetheretherketone (PEEK) is also a biocompatible polymer, thats resistance is closer to the human bone than metal alloys. Consequently, osteo-integration of PEEK is greater than Ti6Al4V alloy. Bone in growth phenomena is occurring rapidly and sustains durability to the fixation. In addition, fatigue performance of PEEK is considerably successful.

In this study, a novel pedicle screw fixation system was designed and manufactured. This novel screw is maintained by a PEEK outer shell component and a Ti6Al4V core component. It has been aimed that PEEK shell will provide higher pullout strength, vibration absorption, and higher osteo-integration, therefore durability. The core is also another conical cored standard screw. For this study the geometrical conditions of shell is the same with 7,5 mm outer diameter 60 mm long screws. And core called part is again 4,5 mm outer diameter 50 mm long conical cored standard screw. This modular feature maintains the benefits of EPS in terms of pullout strength, but it also overcomes detrimental issues of revision operations.

2 Methods

The novel fixation system was designed as a fixing plug and screw assembly. It contains a PEEK outer shell and a Ti6Al4V core as it is previously described. The outer shell's expansion mechanism is designed as two-pin plug. Shell's both inner and outer surfaces were designed as conical structure. The core was also designed in conical structure and core head is assembled with a standard polyaxial screw head (Fig. 1).

The shell and the core were manufactured by machining. Also suitable surgical hand tools were manufactured.

2.1 Biomechanical Testing. The novel system was tested according to ASTM F543. Polyurethane grade 20 foams were used. 5 mm pretaps were drilled. Mean pullout strength was determined as 957 N ($n = 10$) (Fig. 2).

Student T-test analysis was performed to understand weather difference between two tested groups are significant or not.

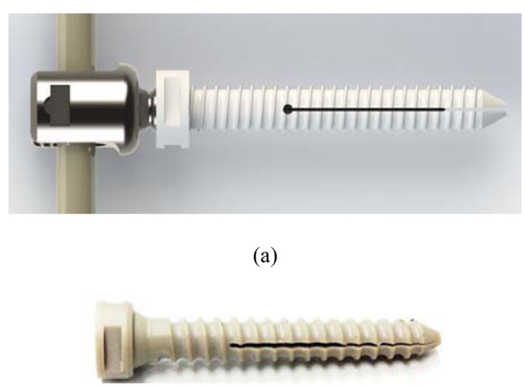
3 Results

Static pullout test results are given in Table 1. Three revisions were completed on first design. Also randomly selected conical core classical pedicle screw (CPS) was selected from our laboratory database. More than 40 different screw designs tested according to ASTM F543, F1798, and F1717. Comparison is also given in Table 1. In addition to this all revised designs' and randomly selected conical core classical pedicle screw's pullout strength given in a graphical form at Fig. 3.

Novel design exhibited significantly higher pullout performance than the classical pedicle screw. ($P \ll 0{,}05$) On the other hand, pullout test results between revision are neither drastically higher nor lower than each other. P values are 0,05 and 0,048 between Rev3-Rev1 and Rev3-Rev-2, respectively.

4 Interpretation

The novel modular fixation system was biomechanically evaluated. Tested specimen's pullout strength was 1196,3 N by



(a)

(b)

Fig. 1 3D model of novel fixation system (*a*) and photograph of manufactured revision (*b*)

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Fig. 2 Photograph of tested sample after static pullout test according to ASTM F543

Table 1 Pullout test results

Sample	Mean pullout strength (N)	Standard deviation
Rev 1 of novel PS	1085.3	93.4
Rev 2 of novel PS	1107.2	62.6
Rev 3 of novel PS	1196.3	72.1
Conical core CPS	564.8	61.4

performing static pullout test according to ASTM F543. This result is drastically higher than the classical pedicle fixation screws. In addition to this, PEEK shell's fusion tendency will provide an extra durability to the system. Furthermore, using a polymer based shell will provide to absorb microvibrations which cause microfractures and accelerate the pullout of screw. This generally occurs in sacrum due to higher loads and vibrations.

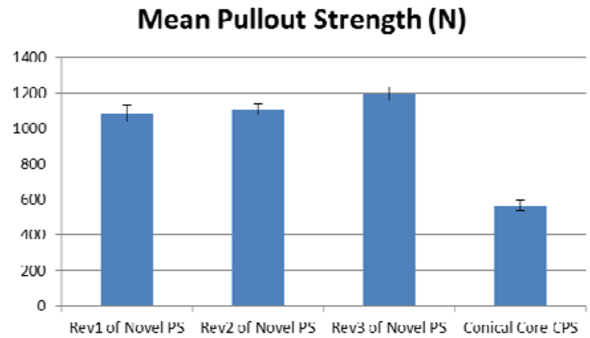

Fig. 3 Mean pullout comparison of revisions and classical pedicle screw

This novel design will provide vibration absorption. Finally, modular design will sustain freedom in revision operations.

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References

[1] Bartleson, J. D., and Gordon Deen, H., 2009, *Spine Disorders Medical and Surgical Management*, Cambridge University Press, New York.
[2] Hu, Y., He, X. F., Ma, W. H., Xu, R. M., Ruan, Y. P., Feng, J. X., and Yang, S. H., 2009, "Comparison Study of Biomechanical Test Among Fixation Techniques of Three Types Screw of Posterior Approach for C2," Zhongguo Gu Shang, **22**(1), pp. 17–20.
[3] Örmeci, M. F., Demir, T., and Arslan, A. K., 2013, "In-Vitro Investigation of Fusion Effect on Pedicle Screws in Terms of Pullout Strength," IWPMEO II: International Workshop on the Physics Based Modeling of Material Properties & Experimental Observations, Antalya, Turkey, May 15–17.

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