Original Article

Institution of MECHANICAL ENGINEERS

Journal of ENGINEERING IN MEDICINE

Proc IMechE Part H:
J Engineering in Medicine
2015, Vol. 229(5) 386–394

DOI: 10.1177/0954411915584430
pih.sagepub.com
SAGE

A new alternative to expandable pedicle screws: Expandable poly-ether-ether-ketone shell

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Abstract
Screw pullout is a very common problem in the fixation of sacrum with pedicle screws. The principal cause of this problem is that the cyclic micro motions in the fixation of sacrum are higher than the other regions of the vertebrae that limit the osteo-integration between bone and screw. In addition to that, the bone quality is very poor at sacrum region. This study investigated a possible solution to the pullout problem without the expandable screws' handicaps. Newly designed poly-ether-ether-ketone expandable shell and classical pedicle screws were biomechanically compared. Torsion test, pullout tests, fatigue tests, flexion/extension moment test, axial gripping capacity tests and torsional gripping capacity tests were conducted in accordance with ASTM F543, F1798 and F1717. Standard polyurethane foam and calf vertebrae were used as embedding medium for pullout tests. Classical pedicle screw pullout load on polyurethane foam was 564.8 N compared to the failure load for calf vertebrae's 1264 N. Under the same test conditions, expandable poly-ether-ether-ketone shell system's pullout loads from polyurethane foam and calf vertebrae were 1196.3 and 1890 N, respectively. The pullout values for expandable poly-ether-ether-ketone shell were 33% and 53% higher than classical pedicle screw on polyurethane foam and calf vertebrae, respectively. The expandable poly-ether-ether-ketone shell exhibited endurance on its 90% of yield load. Contrary to poly-ether-ether-ketone shell, classical pedicle screw exhibited endurance on 70% of its yield load. Expandable poly-ether-ether-ketone shell exhibited much higher pullout performance than classical pedicle screw. Fatigue performance of expandable poly-ether-ether-ketone shell is also higher than classical pedicle screw due to damping the micro motion capacity of the poly-ether-ether-ketone. Expandable poly-ether-ether-ketone shell is a safe alternative to all other expandable pedicle screw systems on mechanical perspective.

Keywords
Pedicle screw, pullout, expandable poly-ether-ether-ketone shell and fatigue

Date received: 29 November 2014; accepted: 1 April 2015

Introduction

In this study, previously designed[1] and statically tested novel design called expandable poly-ether-ether-ketone shell (EPEEKS) for low bone quality was investigated under the dynamic loading conditions. Our previous study was aimed to increase the damping capacity of cyclic micro motion of the pedicle screw to increase the rate and amount of osteo-integration. Besides, the secondary objective was to design an expandable system that can be revised easily. For these purposes, a PEEK expandable shell is designed for the classical pedicle screws (CPS). Since polymer shell has obviously higher cyclic micro motion damping capacity, the fusion between shell and vertebra benefits from this. In addition, the micro motions will decrease at the interface between shell and Ti screw. The shell acts as a damper between rigid screw fixation devices and oscillating vertebra. Hence, the expansion mechanism procures higher pullout. On the revision side, CPS can be easily unscrewed from the EPEEKS and replaced with a new one. Keeping the shell inside the pedicle during the revision is the main advantage of this system. This novel system was particularly designed for the sacrum

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region due to the highest cyclic micro motion and lowest bone quality. The proof-of-concept study was completed previously.[1] This is the long-term in-vitro performance measurement of the novel pedicle screw. In addition, the pullout tests were also conducted on calf vertebrae as an ex vivo performance measurement. To submit the author's information, this is the first biomechanical study considering the reduction in cyclic micro motions on a pedicle screw.

Pedicle screws are the main tools for particular spinal surgeries. Particularly for the spinal stabilization surgeries, pedicle screws are the main fixation devices for the surgeons. The number of pedicle screw used in a surgery is directly correlated with the number of spinal surgeries. With the rise in life expectancy and the number of road accidents, spinal instability observance is increased. Most of these instability problems are observed in the field of pedicle screws. The higher the number of pedicle screws used, the higher the prevalence of screw failure sequence is seen. In the fixation of pedicle screws for higher bone qualities, reaching the required rigidity can be provided by the screw-only solutions. On the other hand, in most instable cases, the bone quality is very poor due to osteoporosis. For such osteoporotic incidents or cases with low bone quality, the main problem is the pullout of the screw. And, screw-only solutions lack rigidity. There are numerous cases reported with pullout failure.[2–4] Researchers studied on several solutions to reduce the sequence of pullout failure. Initially, screw core and thread designs were studied.[5–13] There are several studies concentrated on cement augmentation with various cement types. Several studies were conducted on calcium-based[14–17] and poly-methyl-meta-acrylate[9,18–20] (PMMA) cements.

The design-related studies showed that some modifications on the screw design can increase the pullout performance of screws to some extent. However, the extra strength gained with modification is generally not enough to fix an osteoporotic vertebra. In one of our previous studies,[5] we have reached reliable results after the bone in-growth (fusion) through screw. The main disadvantage in the previous study is the required time (3 months) for the fusion. Pullout is generally within 3 weeks following the surgery. Since there is not enough time for osteo-integration between implant and bone, "providing the instant rigidity" became very crucial. This is why the researchers focused on initial stabilization studies. The first and yet the golden solution stands out as the cement augmentation.

On the cement augmentation side, there are several pros and cons. For instance, initial and strong fixation is the best advantage of the cement augmentation. On the other side, using a chemical subject inside the vertebrae and the heated regions due to exothermic reactions are the main disadvantages of the cement augmentation with the risk of cement leakage through the spinal canal. These disadvantages lead the researchers to more physiological solutions without using foreign substances. The outstanding solution was the use of expandable screws. There are several studies on the use of expandable pedicle screws (EPS) with or without cement augmentation.

Expandable screws have several advantages on fixation, such as initial fixation and extremely high pullout performance.[21,22] Specifically for the osteoporotic cases, expandable screws are widely used. Wu et al.[23] studied on the performance of the expandable screws with clinical cases. At the end of the 1-year follow-up, the conclusion of Wu's study was the excellent clinical results in the fixation strength achieved with EPS. Wu et al.'s[24] another study with 2 years follow-up also supported the results of the previous study. Cook et al.[25] also studied parallel parameters and interpreted similar results with Wu. Gao et al.[26] studied the EPS on the human cadavers with and without calcium-based cement augmentation. They concluded that for the osteopenic and osteoporotic cases, EPS can be used safely. However, for the severely osteoporotic cases, neither the EPS with cement nor the EPS-only applications became efficacious. Contrary to this, Cook et al.[27] interpreted that EPS with PMMA augmentation can be a solution for the severely osteoporotic cases. Koller et al.[28] studied the effect of EPS on pullout performance. Koller et al.[28] conducted the tests on human cadavers and found that distal expansion mechanism significantly increased the pullout strength. There were also design studies to increase the pullout performance of the EPS. Esenkaya et al.[29] studied on the expansion mechanism alternatives with three different designs.

Just after the promotion of expandable screws by the manufacturers, several clinics started to use expandable screws as a miracle solution. However, the real disadvantage had been understood when revision is needed. The revision surgeries are the most important disadvantage of expandable screws especially after the fusion. Wan et al.[30] showed the newly grown bone tissue between the expanded parts of the screw. Bone ingrowth through the expanded parts of the screws made screws unable to close the expansion mechanism. This major problem makes unscrewing nearly impossible. Afterward, researchers started to investigate the EPS as a revision tool. Previously operated and fixed with CPS cases were taken under investigation for the revision operations. Using EPS on the revision, surgeries were studied by several researchers. Bostan et al.[1] are one of those researchers and concluded that using EPS is a good alternative to PMMA augmented fixations on revision surgery.

Material and method

Previously designed and statically tested PEEK expandable pedicle screw shells (EPEEKS) were used in this study and compared with CPS. The application technique is specific to this newly designed pedicle screw system. The main parts of the system are described in Figure 1. The first step is the pilot-hole preparation. This is a pre-tapped screwing method. The study was carried out on the screws with 7.5 mm outer diameter and 45 mm in length. The 7.5 × 45 mm screws were inserted through the block or calf vertebrae and back-twisted. Afterward, EPEEKS was inserted through the prepared hole. Then, EPEEKS was fixed for the rotation with a special hand tool and the inner screw was driven inside the shell. Driving the inner screw expands the shell. The inner screw was again a small-sized CPS. For 7.5 × 45 mm EPEEKS, 4.0 × 40 mm CPS (Efmed, Izmir, Turkey) was used as the inner screw. One can use any type of pedicle screw as an inner screw with this system.

Experimental setup

Pullout tests. The pullout test setup is given in Figure 2. Tests were conducted in accordance with ASTM F543.[31] Two different test media were used in this study: polyurethane (PU) foams and calf vertebrae. PU foam is a standard test material for testing of orthopedic implants and characterized in ASTM F1839.[32] Grade 20 PU foams were used to simulate healthy trabecular bone. Calves were attained from Turkish Meat and Fish Association. Angus type, 2 years old and healthy calves were used. Bone mineral densities of the calves were measured with dual-energy X-ray absorptiometry (DEXA), and T-scores were calculated. All specimens were in the range of healthy t-scores. Both new and CPS systems were placed on the vertebrae with the appropriate application technique.

ASTM F1798[33] regulates the standard performance tests on screw head–rod connection. Screw head and rod were assembled with a nut. Three standard test methods are used to state the performance of screw head–rod interface. These are flexion/extension moment tests, axial gripping capacity test and torsional gripping capacity test. These tests do not measure the properties of novel system directly. They were just conducted for control purposes. In other words, ASTM F1798 test methods were performed to show that EPEEKS does not effect the rod–screw head connection. The test methods are given below in detail.

Flexion/extension moment test. The screw was placed at the middle of the 100-mm-long rod and the nut was tightened with 9 N m calibrated torque meter. Afterward, load was applied to screw shaft as described in Figure 3. Load versus displacement values were recorded. Yield point was calculated with 0.22 offset method.

Axial gripping capacity test. The screw was placed at the middle of the 100-mm-long rod and the nut tightened

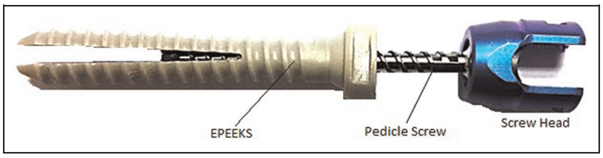

Figure 1. Description of expandable PEEK shell (EPEEKS) system.

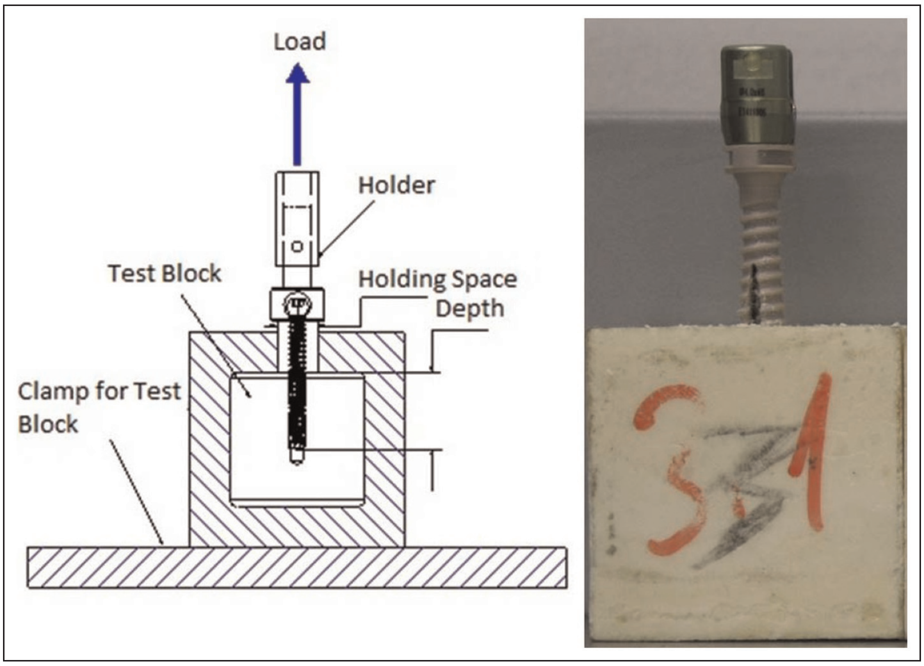

Figure 2. Pullout test setup.

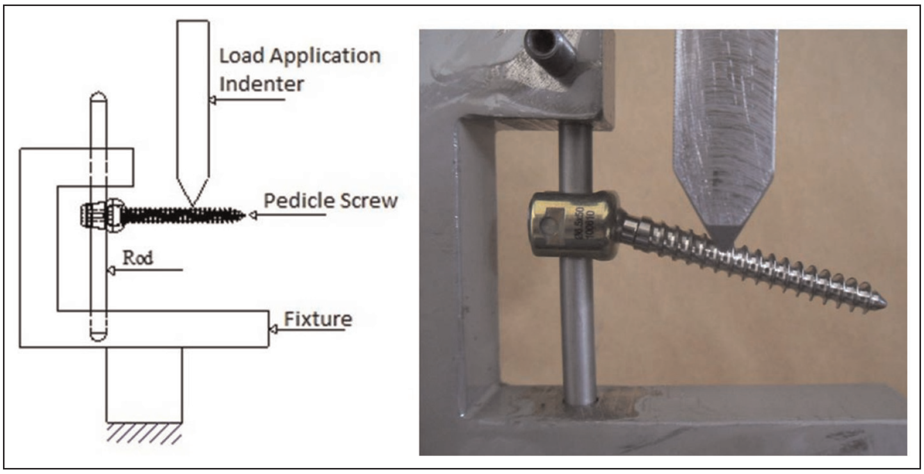

Figure 3. Flexion/extension test setup.

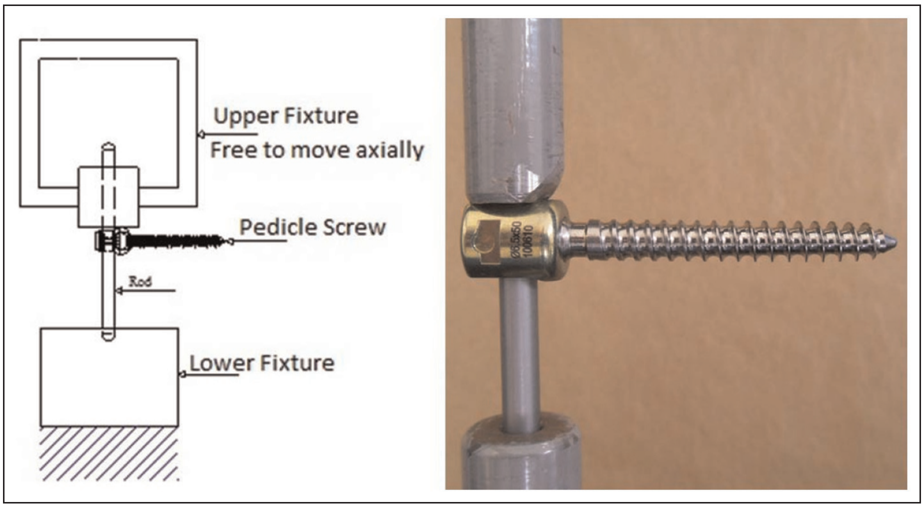

Figure 4. Axial gripping capacity test setup.

with 9 N m calibrated torque meter. Afterward, load was applied to screw head to slip on the rod as described in Figure 4. Load versus displacement values were recorded. Slip load was determined.

Torsional gripping capacity test. The screw was placed at the middle of the 100-mm-long rod and the nut was tightened with 9 N m calibrated torque meter. Afterward, screw head was twisted on the rod as described in Figure 5. Torque versus angle of twist values were recorded. Slip torque was determined.

Fatigue tests. Vertebrectomy models were prepared as described in ASTM F1717.[34] Figure 6 represents the static bending tests and fatigue tests. Before the fatigue tests, vertebrectomy models were tested statically as seen in Figure 6. The yield loads of both systems were determined with offset method. Then, fatigue tests were started with the load of 75% of yield load. Loading frequency was 10 Hz and wave form was sinusoidal. The load ratio for fatigue tests was 0.1. Endurance limit of both systems was determined.

Toggling test. Pedicle screws are under the toggling effect when placed in vertebrae. Toggling decreases the pullout performance of screw due to its adverse effect on screw–bone interface. Several researchers studied the effect of toggling on pullout performance.[35–37] Toggling tests were conducted as described in Figure 7. Each screw was loaded with 100 N maximum toggling load with sinusoidal load form with 10 Hz loading frequency. The load ratio was 0.1 between minimum and maximum loading conditions. Screws were toggled for 1,000,000 cycles and then pulled out.

Statistical analysis. Student's t-test was applied to data set to indicate whether the difference between two groups is significant or not. If $p \leqslant 0.05$, then the difference was accepted as significant.

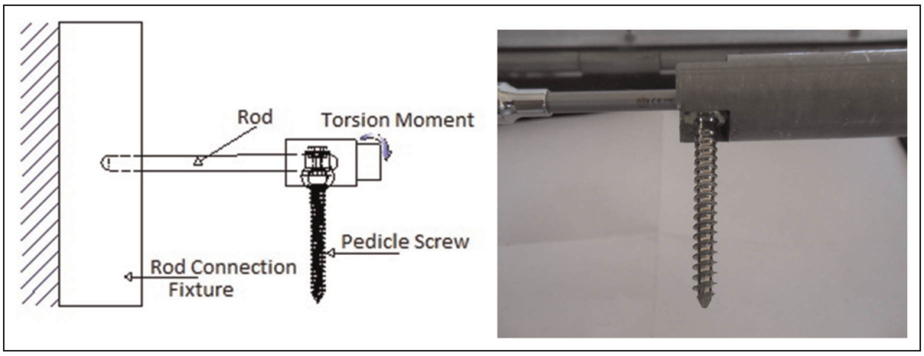

Figure 5. Torsional gripping capacity test setup.

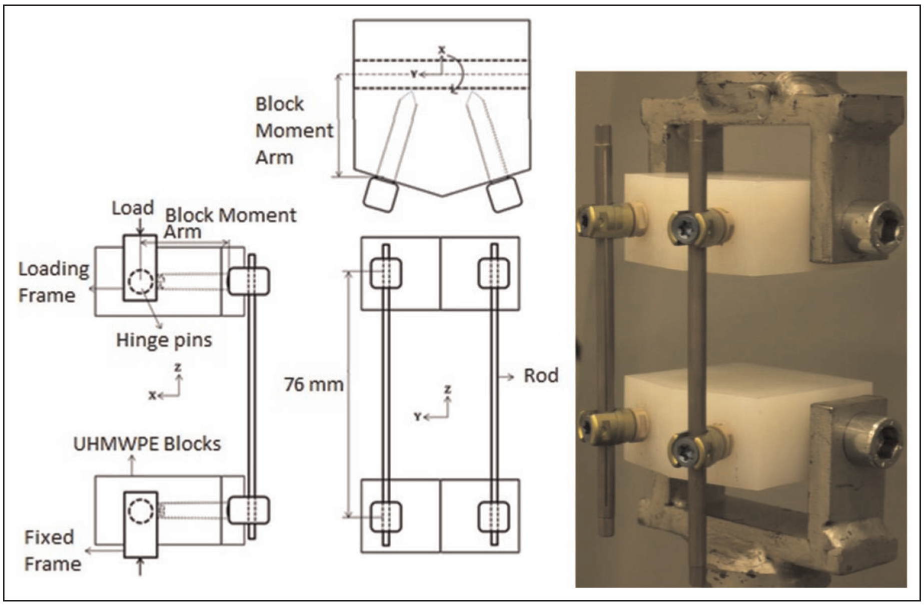

Figure 6. Vertebrectomy model for the static bending and fatigue tests.

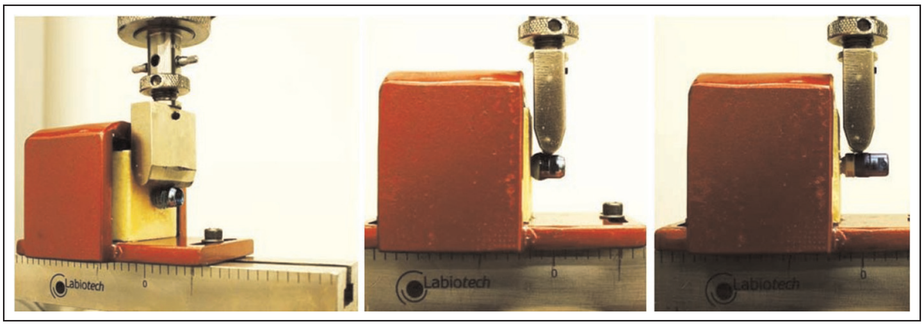

Figure 7. Toggling test setup. Isometric view of toggling setup (left), normal pedicle screw (middle) and EPEEKS with pedicle screw (right) on toggling setup.

Results

The pullout test results are given in Table 1. CPS pullout load on PU foam was 564.8 N compared to the failure load for calf vertebrae's 1264 N. Under the same test conditions, EPEEKS system's pullout loads from PU foam and calf vertebrae are 1196.3 and 1890 N, respectively. The pullout values for EPEEKS were 33% and 53% higher than CPS on PU foam and calf vertebrae, respectively. The reason behind it is the expanded contra-conical geometry of the PEEK shell. There are two main reasons for the difference on PU and calf tests. First, calf tests have a higher standard deviation

Table 1. Pullout test results before toggling.

Screw type	Medium	Mean pullout load (N)	Standard deviation
Classical screw	PU foam	564.8	61.4
	Calf	1264	294.3
Expandable shell	PU foam	1196.3	72.1
	Calf	1890	501.3

PU: polyurethane.

Table 2. Pullout test results after toggling.

Screw type	Medium	Mean pullout load (N)	Standard deviation
Classical screw	PU foam	422	50.1
Expandable shell	PU foam	993	62.4

PU: polyurethane.

and this was due to the non-uniformity of the real bone tissue. Although all bones are healthy, there are still bone quality differences between calves, and the calf samples were randomly selected from vertebral segments of different animals. The second reason is the lack of a cortical shell on PU foams. Cortical layer of the vertebrae has a significant effect on pullout. However, there is still a significant difference ($p \ll 0.005$) between pullout performance of CPS and EPEEKS.

The pullout tests are conducted to determine the initial stability of the pedicle screw. However, the long-term performance of the screw is also crucial. To see the effect of cyclic loads on long time span, making a comparison on toggling and fatigue tests is more adequate. Pullout performances after toggling both EPEEKS and CPS are given in Table 2. It is obvious that there is a significant difference between EPEEKS and CPS. Toggling decreased the pullout loads for both systems. However, the pullout drawback was 25% and 17% for CPS and EPEEKS, respectively. Toggling tests were just performed on PU foams for uniformity and to avoid the adverse effects of environmental conditions on soft tissue. The EPEEKS procured its initial stability more than CPS after cyclic loading. Since the PEEK is a micro motion damping polymer, the interface between PEEK shell and PU foam is deformed on cyclic loads less than the CPS–PU foam couple. This result is the best indicator of the cyclic micro motion damping effect of PEEK.

The results of flexion/extension moment tests, axial gripping capacity test and torsional gripping capacity tests are given in Table 3. The screw head–rod connection was the same for both systems. According to the ASTM F1798,[33] screw head interface tests showed that the system covers the requirements. Actually, the system is Conformité Européenne (CE) certified and those tests were just conducted to be sure.

Table 3. Standard properties of screw head–rod connection.

Flexion/ extension moment	Flexion extension moment (N m)	Standard deviation
	12.75	0.769
Axial torque gripping capacity	Slip torque (N m)	
	6.77	2.27
Axial slip capacity	Slip load (N)	
	2001	168.4

Static flexion/extension moment test results for vertebrectomy models are given in Table 4. Yield load and displacement are the main criteria for such comparison. The CPS exhibited significantly higher ($p = 0.032$) yield load than EPEEKS. In addition to this, the yield displacement of CPS was less than the EPEEKS. However, both systems were inside the safe region for normal physiologic load ranges. Due to the fact that both systems are acceptable on static results, comparison may be carried out on fatigue performances of both systems. Endurance limit curves can be seen in Figure 8. The EPEEKS exhibits the endurance on its 90% of its bending yield load. Contrary to EPEEKS, CPS exhibited endurance on 70% of its bending yield load. The difference between endurance loads was insignificant ($p > 0.5$). This shows that both systems have similar fatigue performances on endurance load. When endurance ratios to the bending yield loads are compared, the EPEEKS provided higher performance.

Discussion

The comparison of pullout performance was carried out between EPEEKS and CPS. Standard tests were conducted for both systems. ASTM F1798[33] tests were carried out to state the reliability of the tested screws. Main comparison was based on the pullout and fatigue performances of the systems. EPEEKS exhibited higher pullout results than CPS when tested on both calf and PU foams. For the tests conducted on calf vertebrae, EPEEKS exhibited 33% higher performance. Similarly, for the tests conducted on PU foam, EPEEKS exhibited 53% higher pullout load. There is a significant ($p \ll 0.05$) difference between two systems. These values are for the initial stability of the systems. Cyclic loading has certain effects on pullout performance. To understand the effect of toggling, pullout tests were completed after 1,000,000 cycles of toggling with 100 N loads. There is again significant ($p = 0.03$) difference between EPEEKS and CPS. EPEEKS exhibited 43% higher pullout after toggling. Cyclic micro motion damping capacity of PEEK may be the reason of this difference. It is obvious that PEEK is more capable of micro motion damping than Ti alloys. This may be because of the protected screw–PU foam interface. There are several studies conducted on EPS in the literature. For instance, Koller et al.[28] studied on human

Table 4. Subassembly flexion/extension moment test comparison between classical pedicle screw and expandable PEEK shell.

	Mean yield load (N)	Standard deviation	Mean yield displacement (mm)	Standard deviation	Mean ultimate load (N)	Standard deviation	Mean ultimate displacement (mm)	Standard deviation
Classical pedicle screw	342	31.4	5.14	0.12	594	71.2	18.3	2.1
Expandable shell	254	11.92	7.57	0.08	526	82.4	21.2	2.2

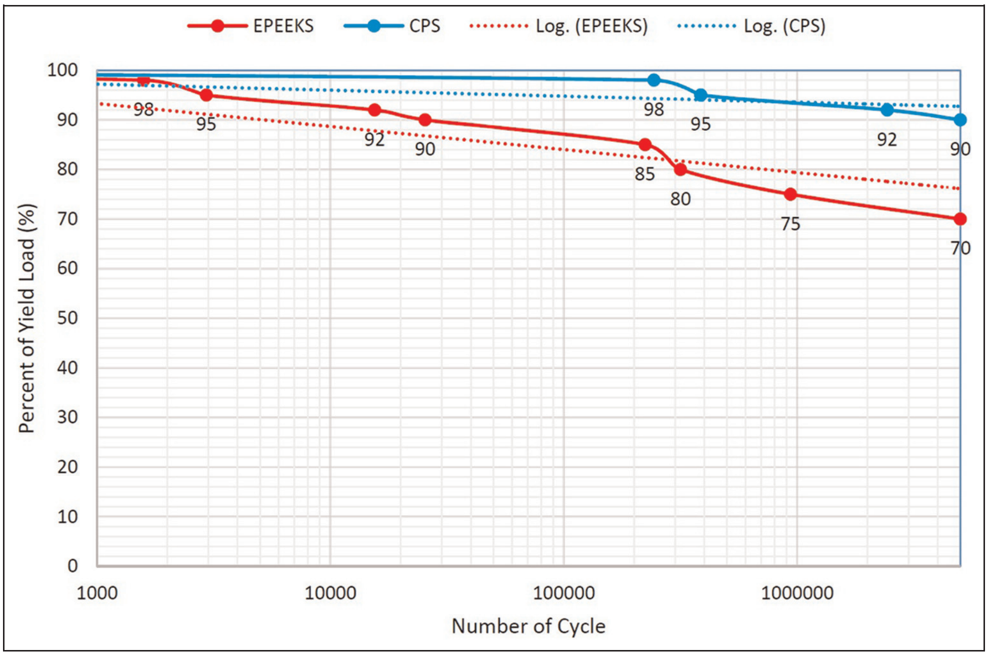

Figure 8. Endurance limit curves for both classical pedicle screw and expandable PEEK shell on the fatigue tests.

cadavers and the maximum pullout was 910.3 N. The bone mineral density of the cadaver was 0.67 g/cm^3 which means that the bone was healthy. Our EPEEKS exhibited 1890 N pullout and this is nearly two times higher than the screw's pullout of Koller et al.'s[28] study. Similarly, Cook et al.[27] also tested EPS on human cadavers with and without PMMA augmentation. All tested samples exhibited maximum 330.83 N pullout loads. Wu et al.[24] also conducted pullout tests with human cadaveric specimens with EPS. EPS were tested with and without PMMA augmentation. The highest value of pullout was 1200.71 N. The EPEEKS exhibited much higher pullout performance than all those screw types. A study with a similar embedding medium was performed by Esenkaya et al.[29] Healthy calf vertebrae were used in Esenkaya et al.'s[29] study. Screws were placed with and without tapping to the lumbar calf vertebrae and the pullout values were 1850.6 and 2136.2 N for tapped and non-tapped applications, respectively. These values indicate that tapping decreases the pullout strength. Tapped screw's performance was very close (2% less) to EPEEKS's performance. However, revision advantage of the EPEEKS is still obvious. Another study with similar embedding medium was completed by Lei and Wu.[22] Again fresh calf vertebrae were used in Lei's study. The mean pullout value for the screws was approximately 2600 N. This is 30% higher than EPEEKS. Ultrahigh bone mineral density (~2.1 g/cm^2) may be the reason behind this result of tested calf vertebrae. Bostan et al.[1] also studied on calf vertebrae and the pullout values were very similar to Lei and Wu.[22] When comparing all these studies, EPEEKS is a reasonable alternative to all other systems on the pullout values.

On the fatigue performance of EPEEKS, the results looked promising. The comparison carried out on CPS and EPEEKS showed that the fatigue performance of the EPEEKS is much higher than that of CPS. The endurance limits were 70% and 90% of yield load for EPEEKS and CPS, respectively. The reason is the cyclic micro motion damping capacity of the PEEK shell. Absorbing the cyclic micro motion procures the holding strength of the screws to some extent.

To sum up, EPEEKS exhibited much higher performance than CPS as expected. In addition, EPEEKS showed reasonable pullout performance when compared with similar studies about EPS in the literature. On the other hand, EPEEKS has great advantage on revision surgeries and cyclic micro motion damping. This is a great alternative to commercially available EPS and also CPS for osteoporotic incidents.

Conclusion

This study covers the standard ASTM tests on a newly designed EPEEKS and CPS. Pullout tests were conducted for EPEEKS and CPS on synthetic foams and cadaveric calf vertebrae. EPEEKS and CPS were also compared on fatigue performances. CPS exhibited slightly higher fatigue performance than EPEEKS. When the comparison was carried out on pullout performances, EPEEKS exhibited much higher pullout strength than CPS. Pullout performance comparison is also carried out after the cyclic toggling loading. Pullout after toggling performance of EPEEKS is also higher than CPS due to micro motion damping capacity of the PEEK. Decreasing the cyclic micro motions by EPEEKS will increase the osteo-integration; thus, the fusion will be faster compared to less osteo-integrated screwing systems. EPEEKS is a safe alternative to all other EPS systems on mechanical perspective. However, the actual damping properties of EPEEKS should be measured. In addition, the finite element modeling of newly developed system will be a great future work of this study. Another drawback about the EPEEKS may be the need of hole preparation. The preparation of holes for the shell may lengthen the surgery. Finally, living animal tests should be conducted before the usage of EPEEKS.

Acknowledgement

The author acknowledges the EFMED Medical Devices for the preparation of the test samples.

Declaration of conflicting interests

The author declares that there is no conflict of interest.

Funding

The author acknowledges Turkish Science Foundation (TUBITAK) for the financial support for the study with project number 111M583.

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