Acta Orthop. Belg., 2020, **88**, 433-440

ORIGINAL STUDY

doi.org/ 10.52628/88.3.6855

Postfusion effect on pullout strength of pedicle screws with expandablepeek shell and conventional screws

Mehmet Fatih Aycan, Arslan Kağan Arslan, Yunus Uslan, Teyfik Demir

From the Department of Mechanical Engineering, Gazi University, Ankara, Turkey

The pullout performance of various pedicle screws after artificial fusion process was investigated in this study. Normal, cannulated (cemented), novel expandable and normal (cemented) pedicle screws were tested. Polyurethane foams (Grade 10 and Grade 40) produced by casting method were used as test materials. The instrumentation of pedicle screws has been carried out with production of foams, simultaneously. For cemented pedicle screws, 3D models were prepared with respect to the anteriosuperior and oblique radiographs by using PMMA before casting procedure. Pullout tests were performed in an Instron 3369 testing device. Load versus displacement graph was recorded and the ultimate force was defined as the pullout strength sustained before failure of screw. As expected, the pullout strengths of pedicle screws in postfusion are higher than before fusion. Pullout strengths increased significantly by artificial fusion in Grade 10 foams compared to Grade 40 foams. Additionally, while the pullout strengths of normal, cannulated and novel expandable pedicle screws increased by artificial fusion, cemented normal pedicle screws had lower pullout values than before fusion in Grade 40 foams. When the cemented normal pedicle screws are excluded, other screws have almost similar pullout strength level. On the other hand, the pedicle screws have different increasing behaviour also, there is no correlation between each other. As a result, the novel expandable pedicle screws can be used instead of normal and cannulated ones due to their performances in non-cemented usage.

Keywords : Pedicle screw; postfusion; polyurethane foam; pullout test; augmentation.

INTRODUCTION

Kyphosis, scoliosis, osteoporosis and vertebral fractures are main spinal disorders that many people suffer from in the world. While the pedicle screws (PS) are good solution for the treatment of these

Acknowledgement: The authors would like to acknowledge to the Efmed (Efspine) Ltd. Sti. for donating the pedicle screws and PMMA.
Statement of Ethics: The authors declare that there is no ethical conflicts.
Disclosure Statement: The authors have no conflicts of interest to declare.
Funding Sources: There is no funding of any research relevant to this study.

■ Mehmet Fatih Aycan[1],
■ Arslan Kağan Arslan[2],
■ Yunus Uslan[3],
■ Teyfik Demir[3]

[1]*Department of Mechanical Engineering, Gazi University, Ankara, Turkey*
[2]*Dr. Sami Ulus Education and Research Hospital, Ankara, Turkey*
[3]*Department of Mechanical Engineering, TOBB University of Economics and Technology*

Correspondence: Mehmet Fatih Aycan, Department of Mechanical Engineering, Gazi University, Eti Mah. Yükseliş Sokak, No:5, 06570, Maltepe, Ankara, Turkey. Tel: +90-312-2237570, Fax: +90-312-2152004
E-mail : mfaycan@gazi.edu.tr

disorders in spinal surgery, there is a critical problem related to pullout failure for spine stabilization. Main aim of the researchers is to enhance the pullout strength of PS. Many researchers studied design parameters and different types of PS for several conditions before. The pullout strength values are effected considerably by changing parameters of PS *(2)*. Outer diameter, pitch diameter, core geometry, thread type, flank overlap area etc. are some of the design parameters commonly investigated by researchers *(3-5)*. There are different screw designs as normal PS (NPS), cannulated PS (CPS) and novel expandable PS (NEPS) used in many experimental studies *(6,7)*. Moreover, bone mineral density (BMD) affects the performance of surgical operation directly such in design parameters of PS. Difficulties emerge in providing higher pullout strength at lower bone quality. Concomitantly, failure of PS occurs at an early time. It was seen that the higher the BMD was, the higher pullout strength achieved *(8)*.

NPS is the most used PS in spinal surgery operations. In order to enhance the performance of NPS, an additional process like cement augmentation may be used generally. Polymethylmethacrylate (PMMA), calcium phosphate and hydroxyapatite are the most frequently used cement types for the improvement of pullout strength *(9,10)*. Some researchers agree that PMMA is a gold standard for cement types *(11,12)*. While the cement augmentation is a good method for increasing pullout strength in PS instrumentation, there is a risk of cement leakage to the spinal canal *(13)*. CPS, which has a cannula inside and radial hole or slots, is an alternative for cemented NPS in order to decrease the cement leakage risk *(14)*. Many researchers studied on alternative solutions as usage of non-cemented PS because of the risk of cement. It was determined that EPS, which was used in non-cemented conditions, eliminated the problem of cement leakage. EPS proved to have generally higher pullout strength compared to other types of PS. The main problem determined in usage of EPS is that the back twisting of screw due to inverse conical form inside the bone *(15,16)*. Hence, there is a challenge in revision surgery of EPS *(17,18)*. In order to eliminate the disadvantages of EPS in revision operation, Demir *(19)* advised a NEPS design consisting of a core screw and an outer shell made of Poly-Ether-Ether-Ketone (PEEK). The new design called NEPS achieved higher pullout strength than conventional PS including the cemented ones *(20)*.

In biomechanical studies, generally human or animal cadaver and standardized polyurethane (PU) foams were used as a test material. Most studies aimed to find out the early stage performance of PS after instrumentation. Arslan et al. *(21)* and Demir *(22)* advised a PU foam production model, simulating fusion process artificially as in living tissues. The new model provides to investigate postfusion effect on pullout strength by using PU foams. For the sake of clarifying the terminology used in this study; "before fusion" means pullout testing after driving PS to the PU foams and "postfusion" represents the pullout testing after artificial fusion process of PU foam.

In this study, the postfusion effect on pullout strength of NEPS, NPS, CPS and cemented NPS was investigated. Grade 10 (mimics osteoporotic bone) and Grade 40 (mimics healthy bone) were used for artificial fusion processes. The aim of this study is to compare the NEPS with other PS in postfusion condition.

MATERIALS AND METHODS

There are three different screw designs. NPS, CPS with PMMA and NEPS was used in this study. In addition, NPS with PMMA was also used for investigation of augmentation effect over NPS. Figure 1 depicts the PS used. NPS is a conventional screw, which is used in general surgery operations, has no additional specialty like cannula or expandable shells. NPS is made of Ti6Al4V and has 7.5 mm outer diameter and 45 mm length. CPS has the same geometry as the NPS. Additionally, it has a cannula and two radial holes bilaterally at 1.5 mm diameters in its distal. CPS is made of Ti6Al4V as NPS. NEPS designed by Demir consists of a core screw and a shell *(19)*. The NEPS contains a PEEK outer shell with 7.5 mm outer diameter and 60 mm length and a Ti6Al4V core with 4.5 mm outer diameter and 45 mm length. The outer shell's expansion mechanism is designed as two-pin plug

Fig. 1. – Pedicle screws used in this study; normal (right), cannulated (middle) and novel expandable (left).

system. All the PS had polyaxial screw heads, but the tulip heads were removed before fusion process.

PU foams are standard testing materials (stated in ASTM F1839 standard) used to test orthopaedic devices and instruments *(23)*. PU foams were produced with two different densities by casting method and characterized according to the ASTM standard. The foam production and screw insertion were completed simultaneously in artificial fusion application. This method differs from conventional foam production methods as it does not require additional screw insertion. Dies made of stainless steel at the size of 50 mm x 50 mm x 50 mm were used in casting process. Grade 10 (0.16 g/cm^3) and Grade 40 (0.64 g/cm^3) PU foams were used in this study to model osteoporotic and healthy bones, respectively.

The pedicle screw was inserted to the hole on upper cover vertically, then the die was turned down and mixture of polyol and isocyanate, which was prepared in appropriate volume, was poured into it. The last part of the die was covered as soon as possible before overflowing of the chemical mixture. After completion of exothermic reaction (foaming), samples with inserted PS were removed from dies. The foaming procedure is given in Figure 2. Although the curing time of the mixture was 20 minutes; tests were performed at least 24 hours after the curing process.

There is a critical step in production of PU foams. For cemented samples, 3D PMMA models were used to simulate the PMMA distribution around the PS. The process was defined below;

- To observe the cement distribution in calf vertebra and PU foams, anteriosuperior and oblique radiographs were obtained for all samples which produced by conventional method in same conditions before (not for artificial fusion process),
- The shapes and sizes of 3D models were determined according to the radiographs.
- The models were produced by using PMMA and positioned to the screws as in radiographs.

The models of PS samples were given in Figure 3. Approximately 2 ml cement was used for each screw, but there was a cement distribution problem in CPS in practice due to the cannula and hole orientation, also the cement amount was decreased while producing models for CPS in order to make simulation correctly. On the other hand, the core screw was inserted to the outer shell externally and the expansion mechanism of NEPS was actuated before casting process.

Pullout tests were performed using an Instron 3369 testing frame (max load: 50 kN). The pullout test setup is given in Figure 4. Tests were carried out according to the ASTM F543 standard *(24)*. Pullout rate was 5 mm/min. Load versus displacement

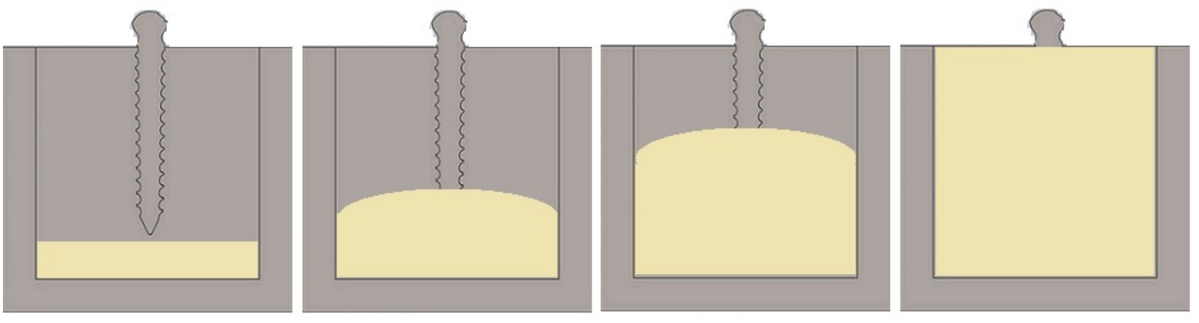

Fig. 2. — Foaming process.

Fig. 3. — PMMA models used in cemented samples.

graph was recorded during the test and point data of this graph was also obtained. The ultimate pullout force was defined as the pullout strength sustained before failure of screw. After the maximum pullout values of each specimen were determined, the mean values and standard deviations were calculated for each group.

RESULTS

The ultimate loads sustained before the failure of screws were defined in pullout testing. The mean loads of the screws inserted to the Grade 10 and Grade 40 PU foams are given in Figure 5 and Figure 6, respectively. Aycan et al *(25)* studied the early-period pullout strength values of the same PSs before; they were also shown in figures to determine fusion effect clearly. The tests were repeated five times for each group. The pullout strengths increased significantly by artificial fusion process in Grade 10 PU foams. The maximum loads of NPS, NEPS, CPS and NPS with PMMA in Grade 10 foams increased from 342 N, 424 N, 399 N and 706 N to 1230 N, 1308 N, 1379 N and 1092 N, respectively. Similarly, the pullout strengths of NPS (from 3637 N to 5057 N), CPS (from 5093 N to 5682 N9 and NEPS (from 4852 N to 5621 N) in Grade 40 PU foams increased by artificial fusion. Unlike all these results, the pullout strength value of NPS with PMMA decreased from 6230 N to 3911 N after fusion process.

DISCUSSION

The postfusion condition is accepted as a scenario of further stages of fixation in spinal surgery. Arslan et al. *(21)* had a hypothesis which simulates the fusion process artificially by using foams in laboratory. Although the hypothesis does not satisfy the fusion properties/conditions theoretically, it provides insight about effects of fusion. The osteointegration in living tissues cannot be simulated as in reality by the artificial fusion process but, the effect of

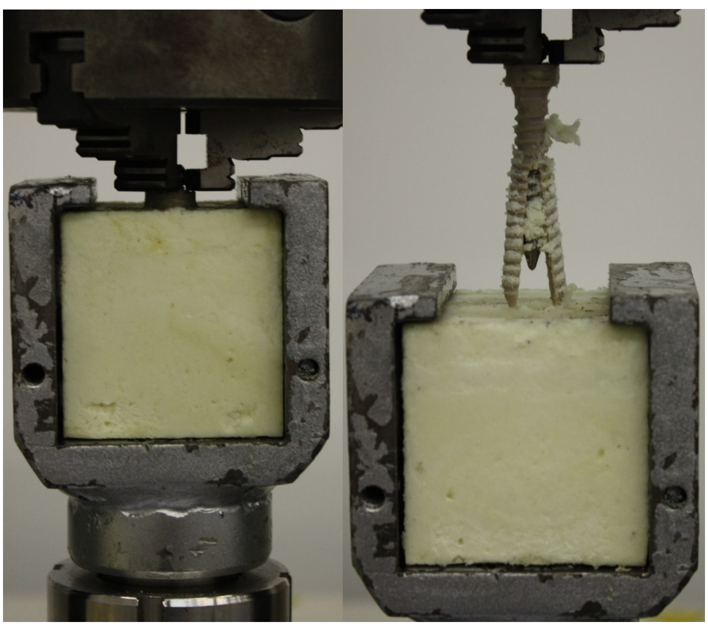

Fig. 4. — The pullout test setup (before and after testing).

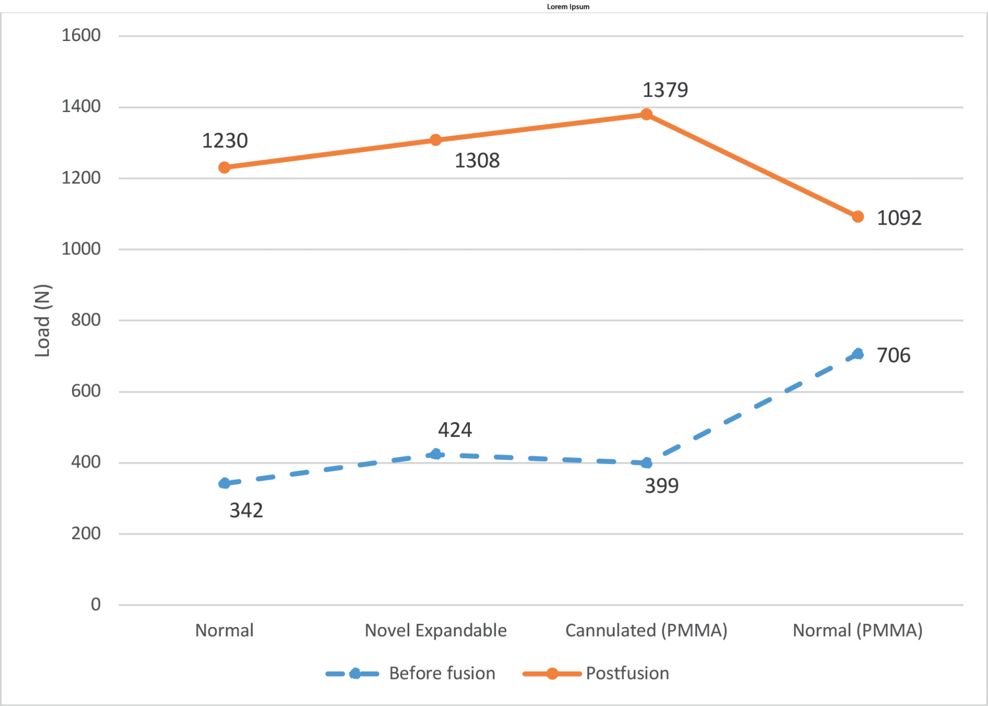

Fig. 5. — The pullout loads of screws in Grade 10 PU foam.

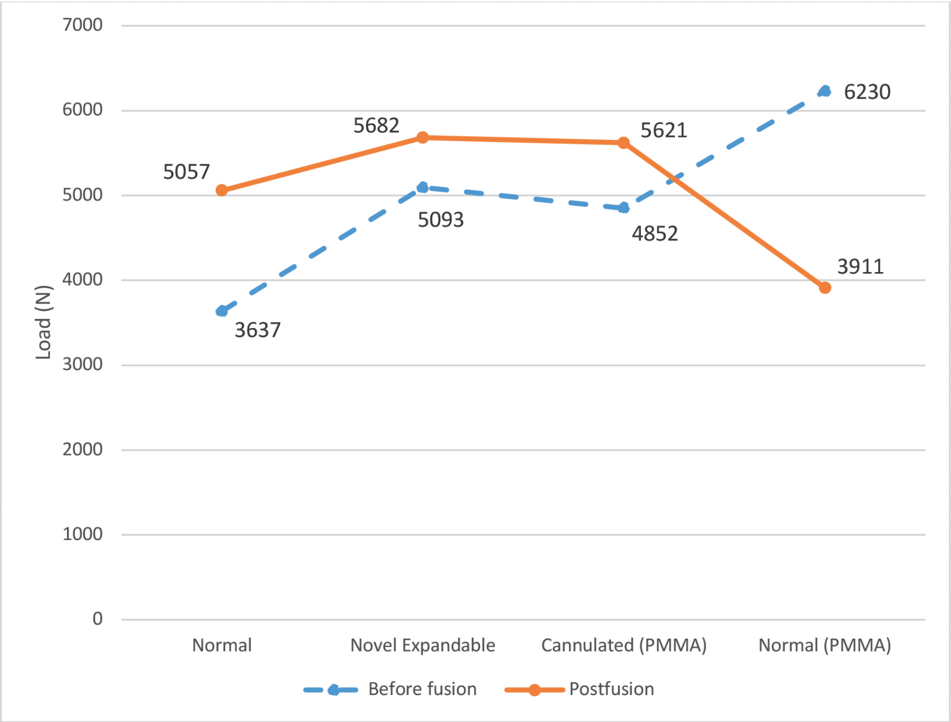

Fig. 6. — The pullout loads of screws in Grade 40 PU foam.

fusion on pullout behaviour becomes predictable by artificial fusion for the researchers.

Three different PS types (NPS, CPS and NEPS) were tested in this study. The PSs were tested after artificial a fusion process and the pullout strengths were compared with the early period pullout results. For both of PU foams, the pullout strengths of NPS, CPS and NEPS increased by the artificial fusion process. The increase rates in artificial fusion were higher than possible fusion in living tissue. The main reason of the difference between the two values is the artificial process occurring rapidly and by high internal pressure. While the exact pullout strength value reached after fusion in bone is not determined, the positive effect of fusion is confirmed. The increase tendency in pullout strength of PS by fusion process was theorised in laboratory environment. Demir *(22)* investigated the NPS and some CPS without cement augmentation after artificial fusion process in Grade 10 and Grade 40 foams and he determined that the fusion process increased the maximum load level PS reached. It was determined that the increase of strength in Grade 10 was higher than in Grade 40. For the same sized dies, the Grade 10 foams had higher foaming capacity with regard to Grade 40 foams. In other words, the Grade 10 foams foamed much more than Grade 40 in unit time. Arslan et al. *(21)* tested different types of NPS and CPS in Grade 10, Grade 20 and Grade 40 PU foams and determined that the pullout strengths increased by increasing foam density (grade). Meanwhile the percentage increase of strengths decreased by increasing foam grades.

Demir *(19)* investigated the performance of NEPS and CPS in Grade 20 foam comparatively. He determined that NEPS had much higher performance than CPS and conventional EPS in early period condition. While the NEPS had higher pullout strength than other PS after artificial process in Grade 10 foams, NPS and CPS had almost same pullout values with NEPS. In other words, there was no significant difference between the PS types. Similarly, the difference between pullout strengths of CPS and NEPS in Grade 40 foams was not statistically significant. The fusion process in living tissue completes in 24 weeks in average *(26)*, concomitant to that the interface between bone and screw have a chance to bond well. Thus, the bonding structure would be better for PS in living tissue than foams due to retarded fusion. In artificial fusion, the process occurs rapidly and completes in a short time.

NPS with PMMA had different pullout behaviour with regard to the other PS. While the pullout strength of cemented NPS increased lesser than others in Grade 10 foam, it decreased in Grade 40 foam by artificial fusion unexpectedly. The general distribution of pullout values in early-stage condition differed from in postfusion condition and it was decided that the main reason was the 3D model application made before the fusion process. Interface performances between foam and PMMA or screw and PMMA were critical points for defining pullout strength of PS *(27)*. The stronger the interface bond, the higher the pullout strength achieved. It was seen that there was an interface problem between PMMA and foam. PMMA did not diffuse to the foam as in conventional foam production method. Christensen et al. *(28)* determined that titanium PS had a good capability for bonding with bone tissue. The increase of the PMMA amount on the screw surface decreased the bonding performance of PS due to obstructing on the interface between screw and foam. Demir *(22)* studied possible usage of cementless CPS in his study. The cement augmentation and fusion effect on pullout strength were investigated and it was concluded that when the fusion occurred successfully, there was no need for using cement augmentation in types of CPS. Wan et al. *(29)* compared the performance of EPS and NPS instrumented to spine of sheep. They investigated bone ingrowth between the expanded parts of the screw in living tissue. The growing of bone tissue around the shell made screw unable to remove from the bone easily. Also, the osteointegration enhanced the pullout strength of EPS as in usage of CPS without cement augmentation.

CONCLUSION

The pullout strengths of screws for both foams increased by artificial fusion. It is hypothesized that the pullout success of PS will enhance by fusion in living tissue. Compared to other screws, NPS with PMMA have different pullout change trends. All

PS except for cemented NPS have approximately similar pullout strength values in postfusion. The NEPS may be a good alternative to the cemented PS due to its pullout value after the fusion process with respect to the initial condition. Not using living tissues for the fusion process is the main limitation of this study.

REFERENCES

1. **Hu Y, He XF, Ma WH, Xu RM, Ruan YP, Feng JX, *et al.*** Comparison study of biomechanical test among fixation techniques of three types screw of posterior approach for C2. *Zhongguo Gu Shang*. 2009; 22: 17-20.
2. **Demir T, Başgül C.** The pullout performance of pedicle screws. 1st ed. London: Springer International Publishing. 2015; 11-21.
3. **Abshire BB, McLain RF, Valdevit A, Kambic HE.** Characteristics of pullout failure in conical and cylindrical pedicle screws after full insertion and back-out. *Spine J.* 2001; 1: 408-414.
4. **Kim YY, Choi WS, Rhyu KW.** Assesment of pedicle screw pullout strength based on various screw designs and bone densities. *The Spine Journal.* 2012; 12: 164-168.
5. **Mehta H, Santos E, Ledonio C, Sembrano J, Ellingson A, Pare P, *et al.*** Biomechanical analysis of pedicle screw thread differential design in an osteoporotic cadaver model. *Clinical Biomechanics.* 2012; 27: 234-240.
6. **Yaman O, Demir T, Arslan AK, İyidiker MA, Tolunay T, Camuşcu N, *et al.*** On the pullout strength comparison of various pedicle screw designs on synthetic foams and ovine vertebrae. *Turkish Neurosurgery.* 2015; 25: 532-538.
7. **Tolunay T, Arslan AK, Yaman O, Dalbayrak S, Demir T.** Biomechanical Performance of Various Cement-Augmented Cannulated Pedicle Screw Designs for Osteoporotic Bones. *Spine Deformity.* 2015; 3: 205-210.
8. **Cook S, Salkeld S, Stanley T, Faciane A, Miller S.** Biomechanical study of pedicle screw fixation in severely osteoporotic bone. *The Spine Journal.* 2004; 4: 402-408.
9. **Rohmiller M, Schwalm D, Glattes C, Elalayli T, Spengler M.** Evaluation of calcium sulfate paste for augmentation of lumbar pedicle screw pullout strength. *Spine J.* 2002; 2: 255-260.
10. **Jang SH, Lee JH, Cho JY, Lee HY, Lee SH.** The Efficacy of Hydroxyapatite for Screw Augmentation in Osteoporotic Patients. *Neurologia Medico-Chirurgica.* 2013; 53: 875-881
11. **Choma TJ, Pfeiffer FM, Swope RW, Hirner JP.** Pedicle screw design and cement augmentation in osteoporotic vertebrae: effects of fenestrations and cement viscosity on fixation and extraction. *Spine* (Phila Pa 1976). 2012; 37: E1628-32.
12. **Chen LH, Tai CL, Lee DM, Lai PL, Lee YC, Niu CC, *et al.*** Pullout strength of pedicle screws with cement augmentation in severe osteoporosis: A comparative study between cannulated screws with cement injection and solid screws with cement pre-filling. *BMC Musculoskelet Disord*. 2011; 12: 33.
13. **Yan YB, Teo EC, Qiu TX, Wu ZX, Qi W, Liu D, *et al.*** Finite element study on the amount of injection cement during the pedicle screw augmentation. *J Spinal Disord Tech.* 2013; 26: 29-36.
14. **Arslan AK, Demir T, Örmeci F, İnce E, Toraman MF.** Biomechanical performance of various cement augmented cannulated pedicle screw designs for osteoporotic bones. 15th International Conference on Advances in Materials Processing Technologies 2012; 22-26 September, Wollongong, Australia.
15. **Gao M, Li X, Zhen P, Wu Z, Zhou S, Tian Q, *et al.*** Biomechanical study on effects of bone mineral density on fixation strength of expansive pedicle screw. Chinese Journal of Reparative and Reconstructive *Surgery.* 2013; 27: 969-973.
16. **Wu Z, Gao M, Sang H, Ma Z, Cui G, Zhang Y, *et al.*** Surgical treatment of osteoporotic thoracolumbar compressive fractures with open vertebral cement augmentation of expandable pedicle screw fixation: A biomechanical study and a 2-year follow-up of 20 patients. *Journal of Surgical Research.* 2012; 173: 91-98.
17. **Chen YL, Chen WC, Chou CW, Chen JW, Chang CM, Lai YS, *et al.*** Biomechanical study of expandable pedicle screw fixation in severe osteoporotic bone comparing with conventional and cement-augmented pedicle screws. *Med Eng Phys*. 2014; 36: 1416-1420.
18. **Vishnubhotla S, McGarry WB, Mahar AT, Gelb DE.** A titanium expandable pedicle screw improves initial pullout strength as compared with standard pedicle screws. *The Spine Journal.* 2011; 11: 777-781.
19. **Demir T.** A New Alternative to Expandable Pedicle Screws: Expandable Poly-ether-ether-ketone shell. *Proc Inst Mech Eng H.* 2015; 229: 386-394.
20. **Demir T, Örmeci F.** New Pedicle Screw Design with Expandable Shell for Low Bone Quality. *J. Med. Devices.* 2014; 8: MED-14-1026.
21. **Arslan AK, Demir T, Örmeci MF, Camuşcu N, Türeyen K.** Postfusion pullout strength comparison of a novel pedicle screw with classical pedicle screws on synthetic foams. *J Engineering in Medicine.* 2012; 227: 114-119.
22. **Demir T.** Possible usage of Cannulated pedicle screws without cement augmentation. *Applied Bionics and Biomechanics.* 2014; 11: 149-155.
23. **ASTM F1839.** Standard specification for rigid polyurethane foam for use as a standard material for testing orthopedic devices and instruments, 2012.
24. **ASTM F543**. Standard specification and test methods for metallic medical bone screws, 2014.
25. **Aycan MF, Tolunay T, Demir T, Yaman ME, Usta Y.** Pullout performance comparison of novel expandable pedicle screw with expandable poly-ether-ether-ketone shells and cement-augmented pedicle screws. *Proc Inst Mech Eng H*. 2017; 231: 169-175.

26. **Khana S, Lane, J.** Spinal fusion surgery: animal models for tissue-engineered bone constructs. *Biomaterials*. 2004; 25: 1475–1485.
27. **Liu GM, Kong N, Zhang XY, Bai HT, Yao Y, Han HZ, *et al.*** Extracellular matrix-coating pedicle screws conduct and induce osteogenesis. *Eur J Orthop Surg Traumatol.* 2014; 24 Suppl 1: S173-182
28. **Christensen FB, Dalstra M, Sejling F, Overgaard S, Bünger C.** Titanium-alloy enhances bone-pedicle screw fixation: mechanical and histomorphometrical results of titanium-alloy versus stainless steel. *Eur Spine J.* 2000; 9: 97-103.
29. **Wan S, Lei W, Wu Z, Liu D, Gao M, Fu S.** Biomechanical and histological evaluation of an expandable pedicle screw in osteoporotic spine in sheep. *Eur Spine J.* 2010; 19: 2122–2129.