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The Comparison of Pullout Strengths of Various Pedicle Screw Designs on Synthetic Foams and Ovine Vertebrae

Değişik Tipte Dizayn Edilmiş Pedikül Vidalarının Sentetik Köpük ve Koyun Omurgasında Sıyrılma Kuvvetlerinin Karşılaştırılması

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ABSTRACT

AIM: One of the most common problems with transpedicular screws is screw pullout. This study was conducted to measure the pullout strengths of newly designed transpedicular screws.

MATERIAL and METHODS: The design of the three group screws were conical cored standard pedicle screw (Type A), dual threaded pedicle screw (Type B), dual core and dual threaded pedicle screw (Type C), respectively. Polyurethane (PU) blocks in 25 mm and 50 mm thickness were used to investigate the effect of just the pedicle on pullout strength and both distal (vertebral body) and proximal (pedicle) parts of the screw. The screws were also tested in ovine lumbar vertebrae.

RESULTS: Type C screw exhibited 5.9% and 12.9% higher pullout strength than Type A and Type B, and 15.4% and 8.6% higher pullout strength than Type A and Type B, respectively on 25 mm and 50 mm thick PU foam block. Type C also exhibited 74.5% and 22.5% higher pullout strength than Type A and Type B, respectively on the ovine vertebrae.

CONCLUSION: Transpedicular screws redesigned with modified helical angles exhibit higher pullout strength compared to the classical transpedicular screws and can be inserted more rapidly with the same number of screwing rounds result with doubled insertion depth.

KEYWORDS: Pedicle screw, Dual lead, Dual thread

ÖZ

AMAÇ: Transpediküler vidalarla ilgili olarak en sık karşılaşılan sorunlardan biri de vidaların sıyrılmasıdır. Çalışmanın amacı yeni dizayn edilmiş transpediküler vidaların sentetik blok ve koyun vertebrası üzerindeki sıyrılma kuvvetlerinin sonuçlarını incelemektir.

YÖNTEM ve GEREÇLER: Üç farklı pedikül vidası; konik şekilde standard pedikül vidası (Tip A), çift hatveli pedikül vidası (Tip B), çift helisli ve çift hatveli pedikül vidası (Tip C) koyun vertebrası ve sentetik poliüretan (PU) bloklar üzerinde test edildi. PU bloklar 25 mm ve 50 mm olarak; pedikül tutunma ve ayrıca pediküle beraber korpusun tutunma kuvvetini ölçmek amacıyla iki farklı boyda kullanıldı.

BULGULAR: C tipi vidaların 25 mm PU bloklar üzerindeki sıyrılma kuvvetleri A tipi vidalardan %5,9 ve B tipi vidalardan %12,9 daha yüksek bulunurken, 50 mm PU bloklardaki sıyrılma kuvvetleri A tipinden %15,4 ve B tipinden %8,6 daha yüksek bulundu. Ayrıca C tipi vidaların koyun vertebrasında yapılan sıyrılma kuvvetleri tip A' dan %74,5 ve Tip B'den %22,5 daha kuvvetli bulundu.

SONUÇ: Helikal açıyla yeniden dizayn edilen transpediküler vidaların sıyrılma kuvveti klasik vidalara göre daha iyidir. Modifiye edilmiş helikal açılı transpediküler vidaların diğer bir avantajı da aynı tur sayısında iki kat daha fazla yol alması nedeniyle cerrahi süreyi kısaltmasıdır.

ANAHTAR SÖZCÜKLER: Pedikül vidası, Çift helis, Çift hatveli

INTRODUCTION

Patient with scoliosis, degenerative disc disease, vertebral fracture are widely treated by spinal fixation. Pedicle screw is generally used for posterior fixation procedure. Screw loosening, pullout and screw failure are some of the problems that can be seen on spinal fixation with screw.

Researchers have been studying on different pedicle screw types to avoid pullout problem. The screws have different design parameters, such as expandable pedicle screws (6, 23, 24), cylindrical cored screws (1,14), conical cored screws (1,10), and dual core screws (11,14). Researchers are still studying on all of these screw types, but the strongest alternative among these screw designs is expandable screws when considering pullout performances. Expandable screws have great pullout strength in bone because of their contra conical geometry after expansion inside. After inserting the screw through the pedicle, an inner mill is inserted through the cannula of the screw. Then, the inner mill expands the fins on the screw. Although, expandable screws have great pullout strength, there is a problem, which occurs in revision surgery. Newly grown bone tissues between the expanded fins make impossible to unscrew the expandable screw (24).

In this study, three different types of pedicle screws were designed and tested. These are, conical cored screw (Type A), conical cored and dual threaded screw (Type B), dual cored and dual threaded screw (Type C). Ex-vivo tests were applied to all three types of screws. Pullout performance comparisons of these three types of screws were conducted in our clinical biomechanics laboratory. The test medium was ovine cadaveric vertebrae and polyurethane synthetic foams.

MATERIAL and METHOD

In this study, three different pedicle screws (Figure 1A-C), were designed and tested in ovine vertebrae and Grade-20 synthetic polyurethane (PU) foam block as testing medium. All pedicle screws were made of titanium alloy (Ti6Al4V) with 5.5 mm outer diameter and 45 mm length.

The first design was conical cored standard pedicle screw (Type A) (Figure 1A). This was also assumed the base screw to compare the results of newly designed screws. Inner diameter of Type A was 3.1 mm on the distal side, and 3.6 mm on the proximal side. The screw pitch was 2.6 mm, thread height was 0.9 mm, and helical angle was 12°.

The second design was dual threaded screw (Type B) (Figure 1B). Inner diameter of Type B was 2.7 mm on the distal side and 3.4 mm on the proximal side. The screw pitch was 2.6 mm, thread height was 1.05 mm, and helical angle was 18°. Type B was designed to increase pullout strength on the pedicle, compared to Type A, by changing helical angle and duplicating helix. It was also designed to increase the driving speed of the screw.

The third one was a dual core and dual threaded screw (Type C) (Figure 1C). Inner diameter of Type C was 3.4 mm on the distal side and 4.5 mm on the proximal side. The screw pitch was 2.6 mm at the distal side, and 1.8 mm at the proximal side. Type C has 1.1 mm thread height on the distal side, and 0.5 mm on the proximal side. Helical angle was 23° on the distal side, and 19° on the proximal side. Type C was designed to increase the pullout by using the advantage of the pedicle. When considering the coherence on trabecular bone, the main advantage is the flat overlap area of the thread. The relation between the screw's distal and proximal parts and vertebral bone is explained in Figure 3A-C.

PU foams are specified as standard test media for orthopedic devices in ASTM F1839. PU foams were used in two different dimensions. Blocks were in 25 mm and 50 mm thickness. 25 mm thick PU foam blocks were used investigate the effect of just the pedicle on pullout strength. On the other hand, 50 mm thick blocks was used to measure the effect of both distal (vertebral body) and proximal (pedicle) parts of the screw. The screws were pulled out from the blocks by the aid of designed apparatus, which was covering the head of the screws from opposite sides as shown in Figure 4A-C.

Additionally, the screws were tested in 2-year-old healthy ovine lumbar vertebrae as depicted in Figure 4A-C. Ovine vertebrae were used to see the pullout strength of the

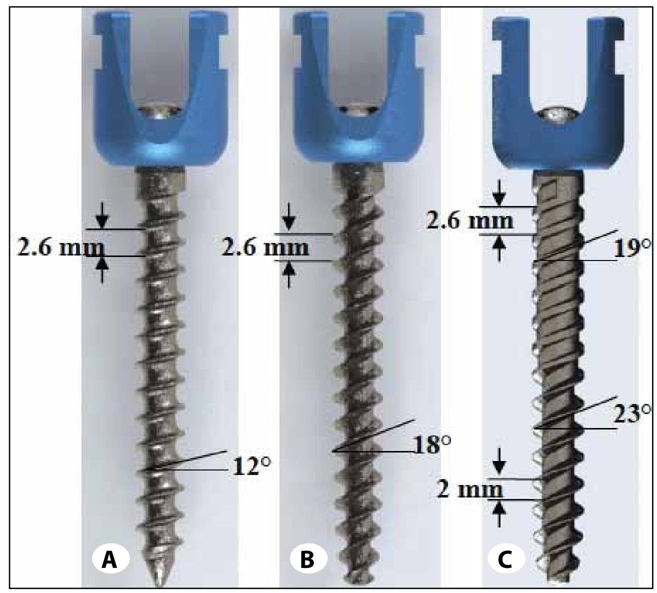

Figure 1: Newly designed pedicle screws. **A)** Type A. **B)** Type B. **C)** Type C.

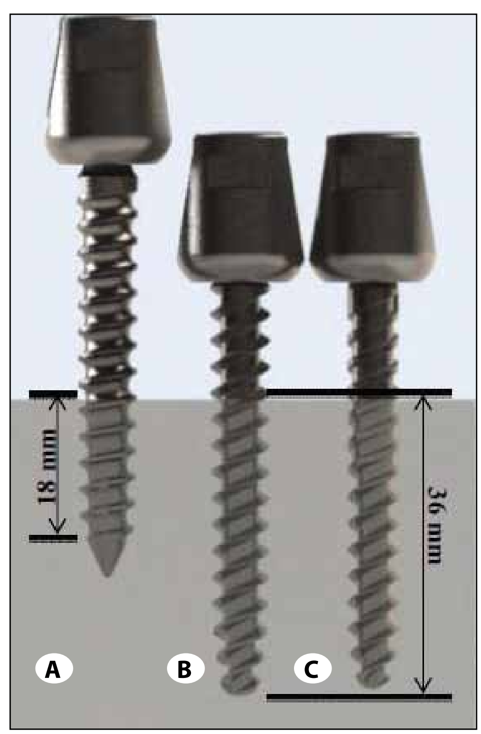

Figure 2: Presentation of insertion speed versus single or dual threaded designs. All screws were screwed with same number of tours. **A)** Type A. **B)** Type B. **C)** Type C.

specimens on fresh frozen soft tissue. After inserting the screws, vertebrae were fixed to the test setup (Figure 4A-C). An appropriate hand tool, which is compatible with designed screws, was used to pullout the pedicle screws as seen in Figure 4A-C. Tested samples can be seen in Figure 5A-C.

Pullout tests were completed by the aid of Instron 3300 testing machine, and load versus displacement plots were recorded by its computer software. Axial tension was applied with 2 mm/min constant cross head speed and yield load was determined with 0.002 offset method.

Torsion tests were conducted to all designed samples to determine the torsional properties according to ASTM F 543 (2). All designed screw systems were tested in accordance with ASTM F1717 (3). Static compression tests and Fatigue tests were applied to all three design types.

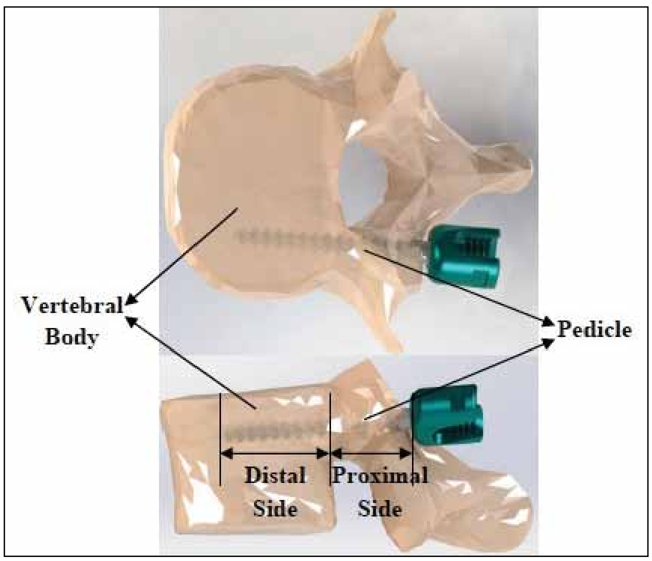

Figure 3: The relation between the screw's distal and proximal sides and vertebral bone.

Statistical Analysis:

The t-test was applied to decide whether the differences between compared two groups are significant or not. P-values were calculated with this method.

Experimental Results

Pullout test results are given in Table I with mean pullout strength and standard deviation values and comparative exhibition is given in Figure 6.

When considering the pullout test results, Type A exhibited 874 N, 910 N and 431 N on 25 mm thick PU foam block, 50 mm thick PU foam block and ovine vertebrae, respectively. The pullout strength of the screw on 50 mm thick block is 4.12% higher than on 25 mm thick block. This value shows that the pedicle part of the vertebral bone provides 96% of the pullout strength for Type A screws.

On the other hand, the pullout strength of Type B is 820 N on 25 mm thick PU foam block, 967 N in 50 mm PU foam block and 614 N in the ovine vertebrae. The pullout strength of Type B on 50 mm thick block is 17.9% higher than on 25 mm thick block, which means 84.8% of the pullout strength is provided by pedicle for Type B screws.

Furthermore, Type C exhibited the highest values, which are 926 N, 1050 N and 752 N on 25 mm thick PU foam block, 50 mm thick PU foam block and ovine vertebrae, respectively. The pullout strength of Type C on 50 mm thick block is 13.4% higher than on 25 mm thick. This shows that 88.2% of the pullout strength is provided by pedicle for Type C screws.

Additionally, Type B exhibited 6.2% lower pullout strength than Type A, on 25 mm thick PU foam block. Type C exhibited

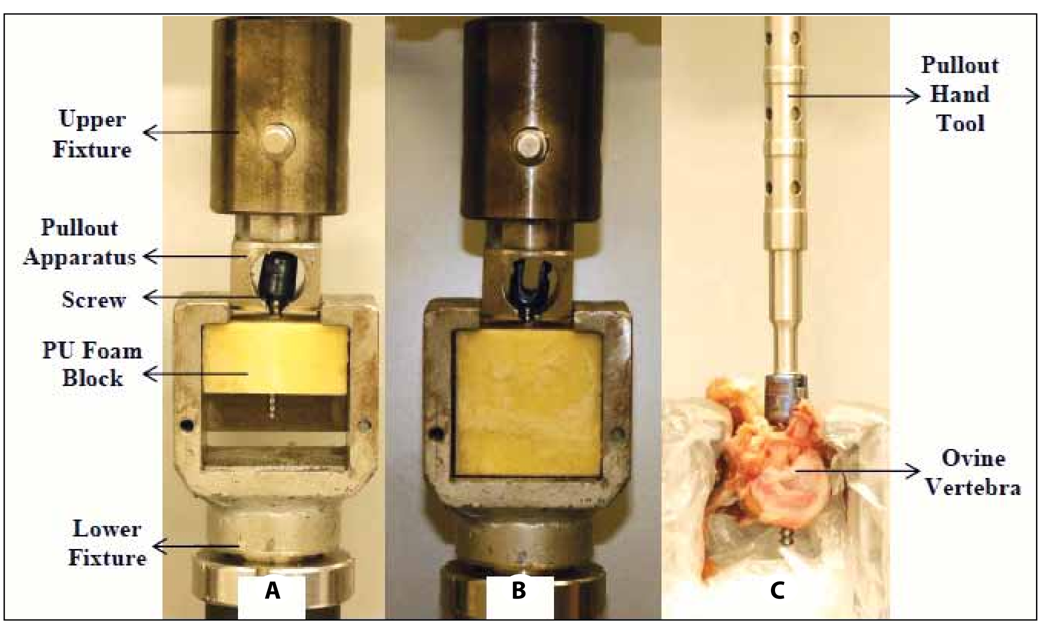

Figure 4: Test Setup.
A) 25 mm PU foam block.
B) 50 mm PU foam block.
C) Ovine vertebrae.

5.9% and 12.9% higher pullout strength than Type A and Type B, respectively.

Similarly, Type B exhibited 6.3% higher pullout strength than Type A, on 50 mm thick PU foam block. Type C exhibited 15.4% and 8.6% higher pullout strength than Type A and Type B, respectively.

As for PU blocks, Type B exhibited 42.5% higher pullout strength than Type A, on the ovine vertebrae. Type C exhibited 74.5% and 22.5% higher pullout strength than Type A and Type B, respectively.

Type A was designed as standard conical core pedicle screw; Type B and Type C were designed as novel screws. It was aimed to increase the pullout strength by newly designed screws, but the wane (6.2%), between Type A and Type B on 25 mm thick PU foam block, occurred due to the proximal parts of the screws. Inner diameters of Type A and Type B were 3.6 mm and 3.4 mm, respectively. Thus Type A exhibited higher pullout strength.

Additionally, Fatigue tests conducted in accordance with ASTM F1717. Endurance limit for fatigue tests were 408 N, 412N and 414N for designs Type A, Type B and Type C, respectively and was accepted to be as safe as conventional screw types.

Similarly, Torsion test completed in accordance with ASTM F543. Torsional strength of tested designs were 12.05 Nm, 13,56 Nm and 12.94 Nm for Type A, Type B and Type C, respectively. Required torsional strength was 9Nm for this type of screws according to the ASTM F543. This provides all designed screws are safe for use.

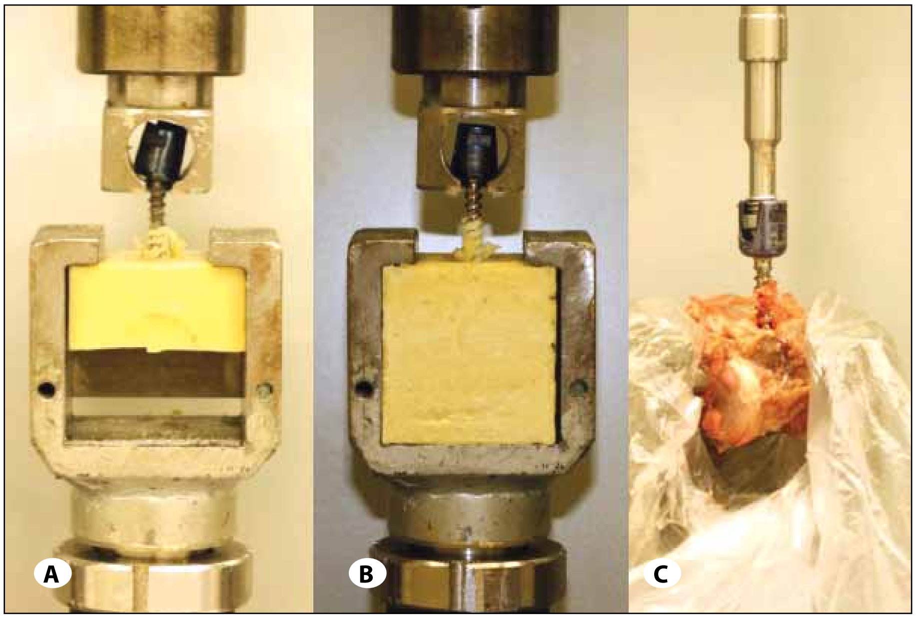

Figure 5: Tested specimens. **A)** 25 mm PU foam. **B)** 50 mm PU foam. **C)** Ovine vertebrae.

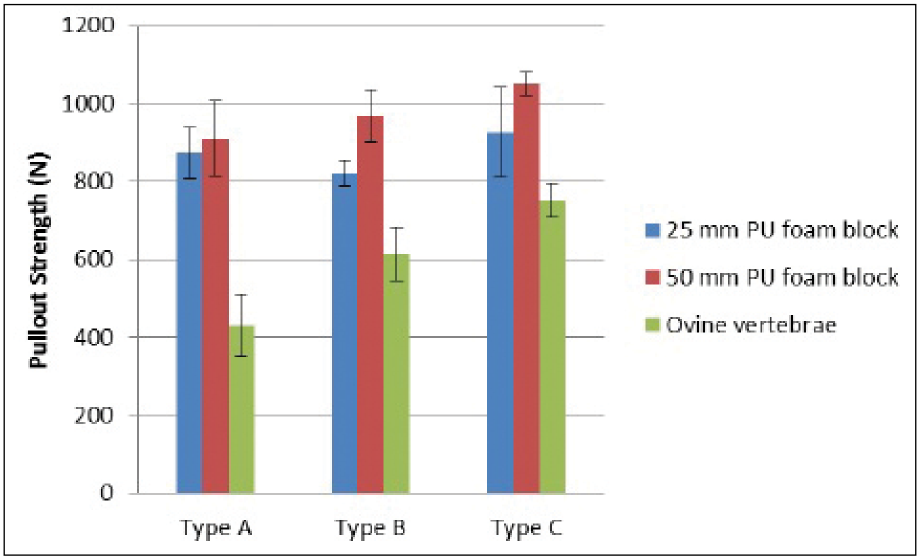

Figure 6: Comparative exhibition of pullout test results.

Table I: Test Results

		Pullout Strength (N)		
		Type A	**Type B**	**Type C**
25 mm PU foam block	mean	874	820	926
	std	66	33	116
50 mm PU foam block	mean	910	967	1050
	std	96	68	31
Ovine vertebrae	mean	431	614	752
	std	79	70	43

DISCUSSION

Transpedicular screws have been in use for many years for the treatment of deformities, degenerative diseases, tumours and spine fractures (15). Pedicle screws ensure a three dimensional control over the vertebral motion segment in addition to a rigid stabilization.

Screws inserted in the bone may get loose in time and even end up broken, which leads to pseudoarthrosis before fusion takes place in the fixated sections. And eventually, pseudoarthrosis causes instrument failure. Some series reported transpedicular screw associated instrument failure rate as 0.8%, while others reported higher rates amounting up to 11% (10). Screw pullout is one of the most common problems encountered by surgeons in the clinical follow-up of patients (8, 16, 18).

Classical transpedicular screws are cylinder shaped. Pullout strength is associated with the shape of the screw, and its internal and external diameter, thread profile and pitches. Conical screws are designed for a better adaptation to the pedicle anatomy and improved pullout strength (1). Conical screws tighten the surrounding bone in each insertion round. The pullout strength is improved through such tightening. Studies revealed that conical screws yield better pullout strength compared to the cylinder shaped screws (1, 21). Main factors improving the screw pullout strength are the surface area of instrument bone contact, number of threads and the external diameter of the screw. In their biomechanical study, Kwok et al. (13) found out that compared to 5 mm screws, 6.0 mm screws yielded 47% higher pullout strength.

Researchers keep changing design parameters to find the most suitable screw type. Brasiliense et al. (5) studied on dual-threaded pedicle screw, and compared it with standard pedicle screws. It was known that 80% of craniocaudal stiffness and 60% of pullout strength were provided by cortical bone in the pedicle (5). Brasiliense et al. (5) designed and tested dual-threaded pedicle screw and compared the test results with single-threaded pedicle screw. According to the test results of this study, screw insertion torque was 183% greater with dual-threaded than with single-threaded screws when tests are conducted on human cadavers (5). Single-threaded screws pulled out at 93% of the force needed to pull out dual-threaded screws (5).

A new type of screw was designed, and tested by researchers in a recent study. It was designed to improve the pullout strength by a natural process. The design included holes, which were drilled normal to the longitudinal axis of core to provide bone fusion through. This study only covered in vitro tests since the aim of the study was to see the change of mechanical properties between the drilled screws and the solid cored screws (9).

Some techniques for avoiding screw pullout include the use of thicker and/or longer screws (20, 21, 22). Polly et al. (17) recommended to use 2 mm wider screws in order to re-ensure stability once the screw is out.

However, 1 mm wider and 5-10 mm longer screws can be used since it is difficult to insert a 2 mm wider screw at the same distance while avoiding pedicle fracture (19, 21).

In our study Type B was designed to increase pullout strength on the pedicle, compared to Type A by changing the helical angle and duplicating helix. Type C was customized to increase pullout strength both through the pedicle and in the vertebral body by changing helical angle, screw pitch and thread height.

Blocks that imitated normal human bone were used in our study. With a view to measure pedicle and corpus and the effect of pedicle structure on pullout strength, PU foams were used in two different dimensions. Blocks were in 25 mm and 50 mm thickness. 25 mm thick PU foam blocks were used to investigate the effect of just the pedicle on pullout strength. On the other hand, 50 mm thick blocks was used to measure the effect of both distal (vertebral body) and proximal (pedicle) parts of the screw. The highest pullout strength values were seen on dual core and dual threaded pedicle screw on both PU foams and ovine vertebra. Type C screw exhibited 5.9% and 12.9% higher pullout strength than Type A and Type B, respectively on 25 mm thick PU foam block and 15.4% and 8.6% higher pullout strength than Type A and Type B, respectively on 50 mm thick PU foam block. And also Type C exhibited 74.5% and 22.5% higher pullout strength than Type A and Type B, respectively on the ovine vertebrae. Type B exhibited 6.3% higher pullout strength than Type A, on 50 mm thick PU foam block and 42.5% higher pullout strength than Type A, on the ovine vertebrae but exhibited 6.2% lower pullout strength than Type A, on 25 mm thick PU foam block. The difference between two groups was due to inner diameters of Type A and Type B was 3.6 mm and 3.4 mm, respectively. Thus Type A exhibited higher pullout strength.

The size of the screw, bone structure, pedicle structure and the surgery technique are the factors having an influence on the pullout strength. Surgeons usually take out the screw intraoperatively to check the screw depth. However, as screws are taken out and re-inserted, the pullout strength decreases (7). On the other hand, Abshire et al. (1) reported that partial or complete removal of screws did not influence pullout strength. One method of screw insertion employed by surgeons is the insertion of small screws without tapping once access is provided to the corpus by using a pedicle finder, and subsequent insertion of a screw with a larger diameter. For surgeons using this technique, it is the speed that matters during the insertion and taking out of the screw. Type B and Type C were designed to raise driving speed of the screw, by changing helical angle and duplicating helix. The advantage of double helix, namely dual thread is the insertion speed. On fixing a screw through a block, turning screwdriver for a full round corresponds to specific insertion depth. Employing a dual thread on such a screw results with doubled insertion depth with same screwing round.

CONCLUSION

Transpedicular screws redesigned with modified helical angles exhibit higher pullout strength compared to the classical transpedicular screws. Modified helical angles are an advantage during surgery, since the transpedicular screw can be inserted more rapidly with the same number of screwing rounds result with doubled insertion depth.

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REFERENCES

1. 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 1: 408-414, 2001
2. ASTM Standards, F543-07. Standard specification and test methods for metallic medical bone screws, 2002
3. ASTM Standards, F1717-10. Standard test methods for spinal implant constructs in vertebrectomy model, 2010
4. Bai BO, Jazrawi L, Kummer FJ, Spivak J: The use of an injectable, biodegradable calcium phosphate bone substitute for the prophylactic augmentation of osteoporotic vertebrae and the management of vertebral compression fractures. Spine 24: 1521, 1999
5. Brasiliense LB, Lazaro BC, Reyes PM, Newcomb AG, Turner JL, Crandall DG, Crawford NR: Characteristics of immediate and fatigue strength of a dual-threaded pedicle screw in cadaveric spine. Spine J 13(8):947-956, 2013
6. Cook SD, Barbera J, Rubi M, Salkeld SL, Whitecloud TS: Lumbosacral fixation using expandable pedicle screws: An alternative in reoperation and osteoporosis. Spine 1: 109-114, 2001
7. Daftari TK, Horton WC, Hutton WC: Correlations between screw hole preparation, torque of insertion, and pullout strength for spinal screws. J Spinal Disord 7(2):139-145, 1994
8. Dickman CA, Fessler RG, Macmillan M, Haid RW: Transpedicular screw-rod fixation of the lumbar spine: Operative technique and outcome in 104 cases. J Neurosurg 77: 860-870, 1992
9. Evans SL, Hunt CM, Ahuja S: Bone cement or bone substitute augmentation of pedicle screws improves pullout strength in posterior spinal fixation. Materials Science 13: 1143-1145, 2002
10. Hsu CC, Chao CK, Wang JL, Hou SM, Tsai YT, Lin J: Increase of pullout strength of spinal pedicle screws with conical core: Biomechanical tests and finite element analyses. Orthopedic Research 23: 788-794, 2005
11. Jacob AT, Ingalhalikar AV, Morgan JH, Channon S, Lim TH, Torner JC, Hitchon PW: Biomechanical comparison of single- and dual-lead pedicle screws in cadaveric spine. Neurosurg Spine 8: 52-57, 2008
12. Jung YM, Shin DA, Hahn B, Kim TG, Huh R, Chung SS: Serious complication of cement augmentation for damaged pilot hole. Yonsei Medical Journal 51: 466-468, 2010
13. Kwok AWL, Finkelstein JA, Woodside T, Hearn TC, Hu RW: Insertional torque and pull-out strengths of conical and cylindrical pedicle screws in cadaveric bone. Spine 21: 2429–2434, 1996
14. Lill CA, Schneider E, Goldhahn J, Haslemann A, Zeifang F: Mechanical performance of cylindrical and dual core pedicle screws in calf and human vertebrae. Arch Orthop Trauma Surg 126: 686-694, 2006
15. Myers BS, Belmont PJ Jr, Richardson WJ, Yu JR, Harper KD, Nightingale RW: The role of imaging and in situ biomechanical testing in assessing pedicle screw pull-out strength. Spine 21: 1962-1968, 1996
16. Okuyama K, Abe E, Suzuki T, Tamura Y, Chiba M, Sato K: Can insertional torque predict screw loosening and related failures? An in vivo study of pedicle screw fixation augmenting posterior lumbar interbody fusion. Spine 25: 858-864, 2000
17. Polly DW Jr, Orchowski JR, Ellenbogen RG: Revision pedicle screws. Bigger, longer shims-what is best? Spine 23: 1374-1379, 1998
18. Renner SM, Lim TH, Kim WJ, Katolik L, An HS, Andersson GB: Augmentation of pedicle screw fixation strength using an injectable calcium phosphate cement as a function of injection timing and method. Spine (Phila Pa 1976) 29(11):E212-216, 2004

19. Skinner R, Maybee J, Transfeldt E, Venter R, Chalmers W: Experimental pullout testing and comparison of variables in transpedicular screw fixation: A biomechanical study. Spine 15:195-201, 1990
20. Suzuki T, Abe E, Okuyama K, Sato K: Improving the pullout strength of pedicle screws by screw coupling. J Spinal Disord 14:399-403, 2001
21. Talu U, Kaya I, Dikici F, Sar C: Pedicle screw salvage: The effect of depth and diameter on on pull-out strength: A biomechanical study. Acta Orthop Traumatol Turc 34: 300-307, 2000 (in Turkish)
22. Turner AW, Gillies RM, Svehla MJ, Saito M, Walsh WR: Hydroxyapatite composite resin cement augmentation of pedicle screw fixation. Clin Orthop Relat Res 406: 253-261, 2003
23. Vishnubhotla S, McGarry WB, Mahar AT, Gelb DE: A titanium expandable pedicle screw improves initial pullout strength as compared with standard pedicle screws. Spine 11: 777-781, 2011
24. 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 19: 2122-2129, 2010