



A biomechanical comparison of polymethylmethacrylate-reinforced and expansive pedicle screws in pedicle-screw revisions

Pedikül vida revizyonlarında polimetilmetakrilat ile güçlendirilmiş ve ucu genişleyebilen pedikül vidalarının biyomekanik karşılaştırılması

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Amaç: Pedikül vidalarının revizyonlarında çeşitli yöntemler ve seçenekler kullanılmaktadır. Bunlardan ikisi vidaların çimentoyle güçlendirilmesi ve ucu genişleyebilen pedikül vidalarının (UGPV) kullanılmasıdır. Bu biyomekanik çalışmada, pedikül vida revizyonlarında kullanılan iki farklı tekniğin sıyırma güçleri karşılaştırıldı.

Çalışma planı: Ortalama 15 aylık dört adet dananın lomber omurgalarından, her biri yedi adet omur içeren iki grup oluşturuldu. Omurların sağ pediküllerine 6 mm çaplı monoaksial pedikül vidaları uygulandı ve 10 mm/dk hızında aksiyel sıyırma testi yapıldı, yetmezlik değerleri kaydedildi. Grup 1'deki pediküllerin revizyonu 6 mm'lik pedikül vidası ve polimetilmetakrilat güçlendirmesi ile yapıldı. Grup 2'deki pediküllerin revizyonu ise 7 mm'lik, uç kısımları genişleyebilen pedikül vidaları ile yapıldı. Revizyon sonrasında örneklerle aynı hızda sıyırma testi uygulandı ve değerler kaydedildi.

Sonuçlar: Revizyon öncesi ve sonrası sıyırma güçleri her iki grupta da anlamlı farklılık gösterdi (grup 1'de sırasıyla 2162.9±718.5 N ve 2794.3±979.2 N, p=0.041; grup 2'de 2605.0±487.6 N ve 3327.1±640.8 N, p=0.012). İki grup arasında hem başlangıç sıyırma güçleri hem de revizyon sonrası sıyırma güçleri ortalamaları arasında anlamlı fark bulunmadı (p>0.05).

Çıkarımlar: Pedikül vida revizyonlarında, 1 mm daha geniş UGPV'nin sıyırma gücünün, polimetilmetakrilatla güçlendirilmiş ve revizyon öncesiyle aynı çaptaki pedikül vidalarıyla benzer olduğu görüldü. Uç kısmı genişleyebilen pedikül vidaları, pedikül kırığı ve çimento sızma gibi riskleri taşımaması ve daha kolay uygulanabilmeleri nedeniyle revizyon cerrahisinde tercih edilebilir.

Anahtar sözcükler: Biyomekanik; kemik vidası; sıgır; lomber vertebra/cerrahi; spinal füzyon/enstrümantasyon; omurga/cerrahi.

Objectives: Different techniques and choices exist for revision of pedicle screws, two of which are pedicle screw combined with cement augmentation and expansive pedicle screw fixation. This biomechanical study was designed to compare the pullout strengths of two different revision techniques.

Methods: Fourteen lumbar vertebrae obtained from four calves (mean age 15 months) were divided into two groups equal in number. Monoaxial 6.0-mm pedicle screws were inserted into the right pedicles, and axial pullout testing was performed at a rate of 10 mm/min and failure strengths were recorded. Revision was performed with the same-sized pedicle screws reinforced with polymethylmethacrylate in group 1, and with 7.0-mm expansive pedicle screws in group 2, and pullout testing was repeated to record maximum revision pullout strengths.

Results: The mean pullout strengths recorded before and after revision were significantly different in both groups, being 2,162.9±718.5 N and 2,794.3±979.2 N in group 1 (p=0.041) and 2,605.0±487.6 N and 3,327.1±640.8 N in group 2 (p=0.012), respectively. However, the mean pullout strengths recorded before and after revision did not differ significantly between the two groups (p>0.05).

Conclusion: Our results showed that expansive pedicle screws 1 mm larger in diameter provide similar pullout strengths to those of same-sized, polymethylmethacrylate-reinforced screws in revision of pedicle screw fixation, suggesting that they can be preferred with the additional advantages of ease of application and avoiding risks for pedicle fracture and cement leakage.

Key words: Biomechanics; bone screws; cattle; lumbar vertebrae/surgery; spinal fusion/instrumentation; spine/surgery.

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Boucher used the pedicle screws in 1959 for the first time.^[1,2] Pedicle screw fixation provides three dimensional control of each vertebral motion segment.^[3] Transpedicular screw fixation provides rigid spinal fixation thus it is widely used for surgical treatment of spondylolisthesis, trauma, tumor, and other spinal diseases.^[4] Pedicle screw salvage and revision surgery may be necessary when solid fusion can not be achieved.^[3] Also loosening and pullout of pedicle screws remains a significant challenge in patients with poor bone quality.^[5-8]

Revision of failed pedicle screws can be accomplished in some kinds of ways such as using a larger diameter screw, longer screw, both larger and longer screw, augmentation of failed hole by polymethylmethacrylate (PMMA), hydroxyapatite composite resin cement augmentation, screw coupling.^[3,9-11] These salvage procedures may have some risks such as fracture of pedicle by using larger diameter screw, vascular and visceral injury by violating anterior cortex by using a longer screw, neurological injury from direct compression or thermal effect of extravasated PMMA.^[9] Such risks have not been reported by using expansive pedicle screws.^[12] In the literature we could not reveal any report comparing the mechanical pullout strength of PMMA augmented pedicle screw fixation and expansive pedicle screws (EPS).

In this study we aimed to investigate the pullout strengths of two different pedicle screws salvage procedure including PMMA augmented pedicle screw fixation and expansive pedicle screw fixation.

Materials and methods

Fourteen fresh calf lumbar vertebrae mean age of which were fifteen months at the time of butchering were used in the study. L1 through L5 vertebrae were harvested from the vertebral column of the animals and cleaned off all soft tissues. Radiographies on anteroposterior and lateral planes were made and looked for any congenital or iatrogenic anomalies. We did not encounter any pathological vertebrae. After harvesting, the specimens were stored at -20°C until the operation. Before the operation all specimens were thawed at the room temperature. Vertebrae were separated by excision of intervertebral disc. 14 of the 20 vertebrae were used. Before application of pedicle screws vertebrae were fixed to a special clamp. After that right pedicles of each vertebrae were drilled with 4.5 mm

drill through the long axis of pedicle. 6.0 mm monoaxial pedicle screws (Tasarimmed Spinal System, Istanbul, Turkey) were inserted to the pedicles. The experiment consisted of two groups each including 7 vertebrae. Radiographies of all specimens were made on anteroposterior and lateral planes and evaluated for the positions of the screws. No malpositioned screw was detected. During the experiment a custom made clamp was used to fix the vertebrae. After fixation of vertebrae to the clamp and pulling axis and long axis of the screws was positioned in parallel direction, pullout tests were performed by mechanical testing device (Hounsfield H50KM) in constant rate of 10 mm per minute and forces at the time of failure of the screw (Newton unit) was recorded (Figure 1). All tests and revision pullout tests were performed by same person at Firat University Engineering Faculty, Department of Metallurgical and Materials Engineering.

In group 1 PMMA augmented 6.0 mm x 45 mm pedicle screws were used to repair the failed pedicles. Failed pedicles were first filled with injection of bone cement (Surgical Simplex P Bone Cement; Stryker, Howmedica, Osteonics, Rutherford, NJ, U.S.A), just later conventional 6.0 mm_45 mm screws were inserted. PMMA was allowed to cure 24 hours until biomechanical pullout testing.



Figure 1. Pull out test with mechanical test device (Hounsfield H50KM)

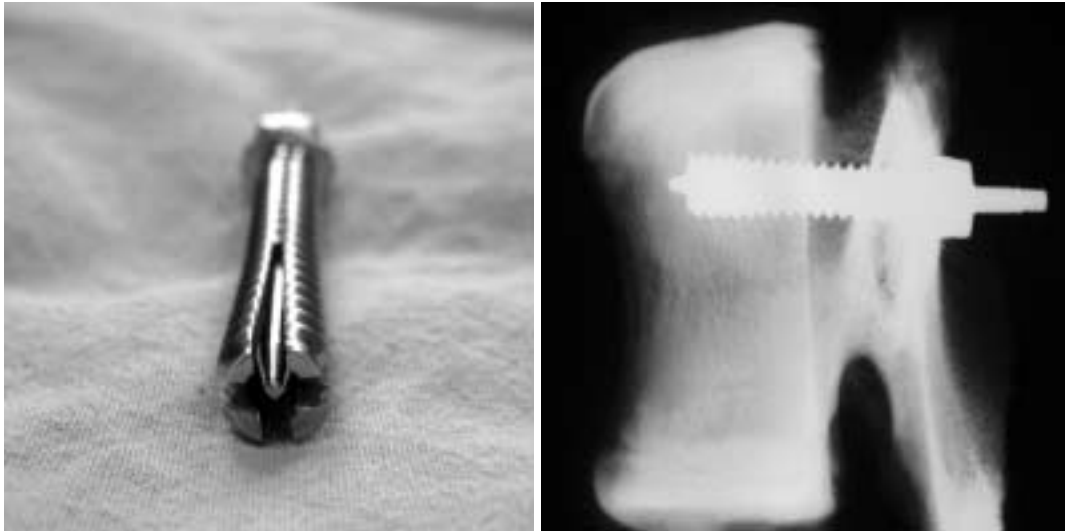


Figure 2. 7.0 mm Expansive pedicle screw (Hipokrat, Izmir, Turkey)

Expansive pedicle screws (7.0 mm_45 mm Hipokrat, Izmir, Turkey) were used in group 2. These screws are composed of two parts. Outer part is cylindrical and empty inside and inner part is a screw mill that provides opening the wings at the distal tip of the outer layer by advancing it through the outer part. Outer diameter of cylindrical outer part is 7.0 mm, inner diameter of the outer part is 6.0 mm, screw length is 45 mm, depth of the threads is 0.5 mm and thread steps were 2.5 mm. Outer surface of the outer part is threaded and anterior portion of the inner surface of the outer part is smooth whereas posterior portion is threaded. Expansion of the distal tip of the outer part occurs by advancing the inner part. This expansion provides 2 mm increment in the anterior portion of the screw (Figure 2).^[13]

After revision of all the pedicles in two groups, axial pullout were performed at the same rate. Maximum pullout strength was recorded when the purchase failure occurred.

Statistical analysis

Test and revision pullout strengths were evaluated

with Kolmogrov-Smirnov test in terms of distribution. Since normal distribution was detected, mean values of test and revision strengths were compared with two independent samples t-test. In each group test and revision strengths were compared with two paired t test. Two ways repeated measures ANOVA test was used to compare two groups in terms changes. Given as means \pm standard error, data were analyzed by using Statistical Package for Social Sciences (SPSS) for Windows software. P-values <0.05 were regarded as statistically significant.

Results

Comparing test and revision pullout strengths in each group revealed statistically significant difference (respectively group 1: 2162.9 ± 718.5 N and 2794.3 ± 979.2 N $p=0.041$, group 2: 2605.0 ± 487.6 N and 3327.1 ± 640.8 N $p=0.012$).

We revealed statistically no significant difference between the pullout test strengths and revision pullout strengths group 1 and group 2 ($p=0.203$, $p=0.252$ respectively). Changes of mean values of test and revision

Table 1. Comparison of test and revision pullout strength in group 1 and 2

	Screw+PMMA (Mean \pm SD)	EPS (Mean \pm SD)	t	p
Test	2162.9 \pm 718.5	2605.0 \pm 487.6	1.347	0.203
Revision	2794.3 \pm 979.2	3327.1 \pm 640.8	1.205	0.252
	t=2.597, p=0.041	t=3.562, p=0.012		
	F=1.877, p=0.196			

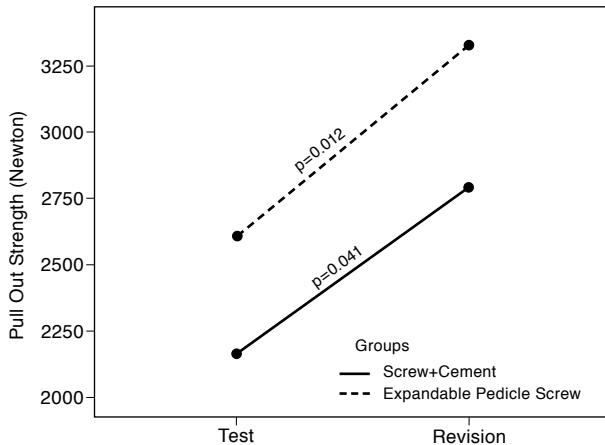


Figure 3. Comparison of pull out test and revision pull out strength in both groups.

revision strengths in the two groups was not statistically significant ($p=0.196$) (Table 1, Figure 3)

Discussion

Since it provides three dimensional control and rigid fixation, transpedicular screw fixation is widely used in the treatment of many spinal disease.^[1,2,4] Loosening at bone screw interface remains a significant challenge especially in osteoporotic spine.^[14] Many biomechanical study have been performed to overcome this problem. These studies mostly have been performed in aged and osteoporotic human spinal.^[3,412] However, since it is difficult to obtain human cadaver in our country, this study was performed on calve lumbar spine. Calve spine is suggested to be suitable models for biomechanical studies.^[8,15] Axial pullout strength and insertional torque are important parameters determining the stability of bone screw interface and after implantation cyclic loading may lead to reduction of this strength.^[16-18] Removal and reinsertion of pedicle screw reduces insertional torque over 34%, especially in revision surgery this may cause greater mechanical consequences.^[12] Bone loss as a result of removal of pedicle screw in revision surgery may lead to implant failure and pseudoarthrosis.^[19] Poly et al. recommended 2 mm larger pedicle screw reinsertion after removal of a pedicle screw in order to restore stable fixation.^[9] However, it is difficult to fit the 2 mm larger screw without complication and pedicle fracture.^[3] Therefore 1 mm larger and 5-10 mm longer screws are also recommended in revision surgery.^[9] Talu et al. reported similar results supporting this suggestion^[20]. Since screw coupling increases pullout

strength, it may be used in revision surgery or primary in mild to moderately osteoporotic spines.^[11]

PMMA augmented pedicle screw fixation was reported to be the most effective method in terms of axial pull out strength in the revision of failed pedicle screws.^[21-24] In the present study same size PMMA augmented pedicle screws revealed significantly increase in axial pull out strength. An injectable calcium phosphate bone cement for augmentation of pedicle fixation appears to be superior to PMMA due to its low exothermic curing temperature and better long term mechanical properties.^[14]

Expansive pedicle screws significantly improves fixation strength without harming pedicle by increasing bone screw interface due to radial expansion of distal tip in the cancellous bone.^[12] Pedicle failure do not occur due to this feature. It was suggested that EPS are effective in increasing fixation strength in osteoporotic spine, revision surgery and in cases of removal and reinsertion of pedicle screws.^[12,13,25] Biomechanical study of Lei and Wu reported that 2.1 mm expansion of tip of the screw (6.5_40mm) provides 48.4%, 40.8%, 25.3% increment in axial pullout strength as compared to USS, Tenor, CDH conventional screws, respectively.^[25] Limited number of clinical studies are available regarding EPS. Cook et al. used 57 expansive pedicle screw in 14 patient, 5 of whom were osteoporotic patient and 4 were revision surgery.^[3] Fusion was detected in 13 patients at an average of 32.1 months. 93% successful clinical results and 2 screw breakage was observed. Biomechanical part of the same study suggested that EPS provides 50% increment in pullout strength in osteoporotic spine. Authors suggested these results to be promising for the future studies. In the biomechanical study of Esenkaya et al. they found that 6.5 mm Alici pedicle screws provide average of 3115.8 N pullout strength, whereas 0.5 mm larger EPS provide 2136.2 N pull out strength which means 0.5 mm larger EPS do not contribute to stabile fixation.^[13] However, in our study significant increment in pullout strength in revision group with 1 mm larger EPS was detected.

In conclusion 1 mm larger expansive screws provide similiar pullout strengths compared to PMMA augmented same size pedicle screws for repairing a failed pedicle. However, in order to widely use of EPS more, prospective and long term results are necessary.

References

1. 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* 1996;21:1962-8.
2. 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* 1990;15:195-201.
3. Cook SD, Salkeld SL, Whitecloud TS 3rd, Barbera J. Biomechanical evaluation and preliminary clinical experience with an expansive pedicle screw design. *J Spinal Disord* 2000;13:230-6.
4. Soshi S, Shiba R, Kondo H, Murota K. An experimental study on transpedicular screw fixation in relation to osteoporosis of the lumbar spine. *Spine* 1991;16:1335-41.
5. 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* 1992;77:860-70.
6. Esses SI, Sachs BL, Dreyzin V. Complications associated with the technique of pedicle screw fixation. A selected survey of ABS members. *Spine* 1993;18:2231-8.
7. 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* 2000;25:858-64.
8. Wittenberg RH, Shea M, Swartz DE, Lee KS, White AA 3rd, Hayes WC. Importance of bone mineral density in instrumented spine fusions. *Spine* 1991;16:647-52.
9. Polly DW Jr, Orchowski JR, Ellenbogen RG. Revision pedicle screws. Bigger, longer shims-what is best? *Spine* 1998;23:1374-9.
10. Turner AW, Gillies RM, Svehla MJ, Saito M, Walsh WR. Hydroxyapatite composite resin cement augmentation of pedicle screw fixation. *Clin Orthop Relat Res* 2003;(406):253-61.
11. Suzuki T, Abe E, Okuyama K, Sato K. Improving the pull-out strength of pedicle screws by screw coupling. *J Spinal Disord* 2001;14:399-403.
12. Cook SD, Barbera J, Rubi M, Salkeld SL, Whitecloud TS 3rd. Lumbosacral fixation using expandable pedicle screws. An alternative in reoperation and osteoporosis. *Spine J* 2001;1:109-14.
13. Esenkaya İ, Denizhan Y, Kaygusuz MA, Yetmez M, Keleştemur MH. Comparison of the pull-out strengths of three different screws in pedicular screw revisions: a biomechanical study. [Article in Turkish] *Acta Orthop Traumatol Turc* 2006;40:72-81.
14. 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* 2004;29:212-6.
15. Coe JD, Warden KE, Herzig MA, McAfee PC. Influence of bone mineral density on the fixation of thoracolumbar implants. A comparative study of transpedicular screws, laminar hooks, and spinous process wires. *Spine* 1990;15:902-7.
16. Roy-Camille R, Saillant G, Mazel C. Internal fixation of the lumbar spine with pedicle screw plating. *Clin Orthop Relat Res* 1986;(203):7-17.
17. Uthoff HK. Mechanical factors influencing the holding power of screws in compact bone. *J Bone Joint Surg Br* 1973;55:633-9.
18. Zdeblick TA, Kunz DN, Cooke ME, McCabe R. Pedicle screw pullout strength. Correlation with insertional torque. *Spine* 1993;18:1673-6.
19. Yerby SA, Toh E, McLain RF. Revision of failed pedicle screws using hydroxyapatite cement. A biomechanical analysis. *Spine* 1998;23:1657-61.
20. Talu U, Kaya I, Dikici F, Sar C. Pedicle screw salvage: the effect of depth and diameter on pull-out strength: a biomechanical study. [Article in Turkish] *Acta Orthop Traumatol Turc* 2000;34:300-7.
21. Pfeifer BA, Krag MH, Johnson C. Repair of failed transpedicle screw fixation. A biomechanical study comparing polymethylmethacrylate, milled bone, and matchstick bone reconstruction. *Spine* 1994;19:350-3.
22. Frankel BM, D'Agostino S, Wang C. A biomechanical cadaveric analysis of polymethylmethacrylate-augmented pedicle screw fixation. *J Neurosurg Spine* 2007;7:47-53.
23. Evans SL, Hunt CM, Ahuja S. Bone cement or bone substitute augmentation of pedicle screws improves pullout strength in posterior spinal fixation. *J Mater Sci Mater Med* 2002;13:1143-5.
24. Yi XD, Lu HL, Gong SY. Effect of pedicle screw fixation with bone cement in lumbar. *Zhonghua Wai Ke Za Zhi* 2004;42(23):1427-9. [Abstract]
25. Lei W, Wu ZX. Biomechanical evaluation of an expansive pedicle screw in calf vertebrae. *Eur Spine J* 2006;15:321-26.