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Bora Bostan
Gaziosmanpaşa Üniversitesi

Irfan Esenkaya
Inönü Üniversitesi

Taner Gunes
Gaziosmanpaşa Üniversitesi

Mehmet Erdem
Gaziosmanpaşa Üniversitesi

Murat Asci
Gaziosmanpaşa Üniversitesi

See next page for additional authors

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Authors

Bora Bostan, Irfan Esenkaya, Taner Gunes, Mehmet Erdem, Murat Asci, Mehmet Halidun Kelestemur, and Cengiz Sen



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

Bora BOSTAN, İrfan ESENKAYA,¹ Taner GUNES, Mehmet ERDEM,
Murat ASCI, M. Halidun KELESTEMUR,² Cengiz SEN

Gaziosmanpaşa University Medical School, Department of Orthopaedics and Traumatology;

¹Inonu University Medical School, Department of Orthopaedics and Traumatology; ²Fırat University Engineering Faculty, Department of Metallurgical and Materials Engineering

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.

Correspondence / Yazışma adresi: Dr. Bora Bostan. Gaziosmanpaşa University Medical School, Department of Orthopaedics and Traumatology, Tokat, Turkey. Phone: +90356 - 212 95 00 e-mail: borabostan@gmail.com

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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)

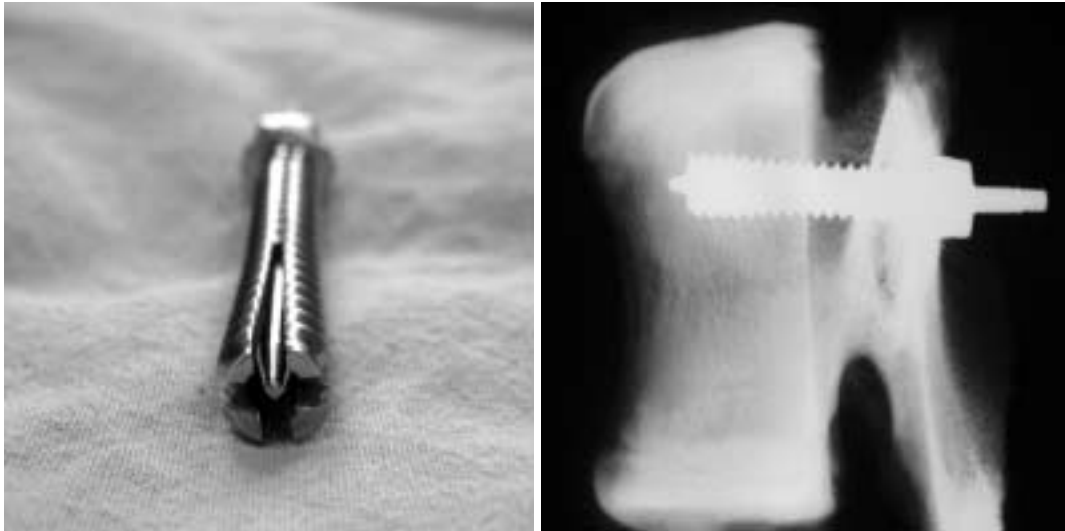


Figure 2. 7.0 mm Expansive pedicle screw (Hipokrat, Izmir, Turkey)

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			

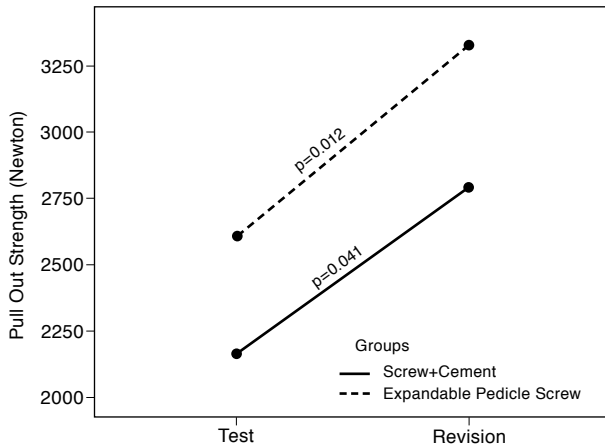


Figure 3. Comparison of pull out test and revision pull out strength in both groups.

sion 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.

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