Eklem Hastalıkları ve Cerrahisi
Joint Diseases and Related Surgery

Experimental Study / *Deneysel Çalışma*

Eklem Hastalık Cerrahisi
2012;23(2):106-110

Revision of the failed pedicle screw in osteoporotic lumbar spine: Biomechanical comparison of kyphoplasty versus transpedicular polymethylmethacrylate augmentation

Osteoporotik lomber omurlarda iflas etmiş pedikül vidasının revizyonu: Kifoplasti ile transpediküler polimetilmetakrilat güçlendirme tekniklerinin biyomekanik karşılaştırması

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Objectives: In this study, we aimed to compare of kyphoplasty versus transpedicular polymethylmethacrylate (PMMA) augmentation biomechanically in the revision of the failed pedicle screw in osteoporotic lumbar spine.

Materials and methods: Bone mineral density (BMD) of lumbar vertebrae collected from four bovines were measured. Each vertebra was decalcified with hydrochloric acid solution to obtain osteoporotic specimens. Primary polyaxial pedicle screws were inserted into the pedicles and pulled out until they failed. The pullout strength results of all specimens were recorded. Revision pedicle screws were randomly inserted into the same pedicles by either pedicle hole PMMA augmented (group 1) or kyphoplasty (Xvoid™) PMMA augmented pedicle screws (group 2). The pullout strength results of all specimens were re-recorded.

Results: The mean BMD significantly decreased from 1.686±227.9 g/cm^2 to 1.432±157.1 g/cm^2 following decalcification (p<0.001). In group 1, the mean pullout strength of primary screws significantly decreased from 3443±1086 N/m^2 to 2088±924 N/m^2 following pedicle screw augmentation (p=0.006). In group 2, the mean pullout strength of primary screws decreased from 3702±1063 N/m^2 to 3664±1057N/m^2 following kyphoplasty augmentation (p=0.934). Pedicle screw augmentation group achieved significantly lower pullout strength values than kyphoplasty pedicle hole augmentation group (p=0.002).

Conclusion: Although pedicle hole PMMA augmentation is the gold standard for the failed screws in an osteoporotic bone, kyphoplasty augmented pedicle screw seems to be more effective method increasing the pullout strength.

Key words: Bone screws; lumbar vertebrae surgery; osteoporosis; treatment failure.

Amaç: Bu çalışmada osteoporotik lomber omurlarda iflas etmiş pedikül vidalarının revizyonunda kifoplasti ile pedikül delik polimetilmetakrilat (PMMA) güçlendirme tekniklerinin biyomekanik karşılaştırması yapıldı.

Gereç ve yöntemler: Dört sığırdan elde edilen lomber omurların kemik mineral yoğunlukları (KMY) ölçüldü. Osteoporotik örnekler elde etmek için, her bir omur hidroklorik asit ile dekalsifiye edildi. Primer poliaksiyel pedikül vidaları pediküllere gönderildi ve iflas edene kadar çektirme işlemi yapıldı. Bütün örneklerin sıyrılma dayanıklılığı kaydedildi. Revizyon pedikül vidaları, pedikül delik PMMA (grup 1) veya kifoplasti (Xvoid™) PMMA (grup 2) güçlendirme tekniklerinden birisi kullanılarak, rastgele aynı deliklere gönderildi. Bütün örneklerin sıyrılma dayanıklılığı yeniden kaydedildi.

Bulgular: Dekalsifikasyon sonrasında ortalama KMY 1.686±227.9 g/cm^2'den 1.432±157.1 g/cm^2'ye inerek, anlamlı olarak azaldı (p<0.001). Grup 1'de primer vidaların ortalama sıyrılma dayanıklılığı 3443±1086 N/m^2 iken, pedikül delik güçlendirilmesinden sonra anlamlı olarak azaldı ve 2088±924 N/m^2 olarak ölçüldü (p=0.006). Grup 2'de ortalama sıyrılma dayanıklılığı 3702±1063 N/m^2 iken, kifoplasti sonrasında 3664±1057 N/m^2 olarak ölçüldü (p=0.934). Pedikül delik revizyonu sıyrılma değerleri, kifoplasti revizyonu ile karşılaştırıldığında da anlamlı olarak daha düşük idi (p=0.002).

Sonuç: Osteoporotik omurlarda sıyrılmış vidaların revizyonunda pedikül delik PMMA güçlendirmesi altın standart olmasına rağmen, kifoplasti güçlendirmesi revizyon vidalarının sıyrılma dayanıklılığını artıran daha etkili bir yöntem gibi görünmektedir.

Anahtar sözcükler: Kemik vidaları; lomber vertebra cerrahisi; osteoporoz; tedavi başarısızlığı.

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Osteoporosis causes significant morbidity among the elderly population.[1] Osteoporotic vertebral fractures are a leading cause of musculoskeletal dysfunction in the elderly. They also complicate surgical interventions for instability and deformity in spondylolysthesis and degenerative scoliosis.[2] Before the advent of pedicle screws in vertebral surgery many vertebral pathologies were considered inoperable.[3] Osteoporosis decreases the primary fixation strength of pedicle screws.[4] Polymethylmetacrylate (PMMA) or calcium phosphate/sulfate application into the screw trajectory was used to increase primary fixation strength.[5,6]

Loosening, breakage of screws and pseudoarthrosis are the most frequently seen problems over a long period of time.[7] Revision can be accomplished by using larger and/or longer size pedicle screws, sustaining or changing the direction of implementation of pedicle trajectory. Sustaining the pedicle trajectory can be provided by PMMA, hydroxyapatite or calcium sulfate/phosphate bone cements.[8-12] Use of PMMA is the most frequently applied method in revision surgery but has complications such as exothermic polymer release, bone necrosis and nerve damage.[9]

Kyphoplasty is an invasive procedure to treat osteoporotic vertebral fractures. The technique involves the use of specially designed inflatable or expandable cannulas to create a void in the vertebral body for PMMA injection.[3]

Classically, screw holes can be filled with PMMA to increase the fixation strength. If the amount of injected PMMA into the vertebral body and screw trajectory can be increased, higher fixation strength than the classic technique can also be achieved. The latter can be named kyphoplasty augmentation technique and theoretically can result in higher fixation strength. The aim of the present study is biomechanical comparison of two different pedicle screw PMMA augmentation techniques (classical pedicle hole and kyphoplasty vertebral body plus pedicle hole augmentation) for revision of a failed pedicle screw.

MATERIALS AND METHODS

Approval of the Committee of Research Ethics was obtained for the present study. Twenty-two lumbar vertebrae (L1-L5) were obtained from four calf cadavers, with a mean age of two years. Following soft tissue dissection all the specimens were stored at -20 °C in a deep freezer until demineralization procedure. Demineralization and biomechanical tests were performed in the following fashion:

a. Bone mineral density assessment: A standardized demineralization process was used as described by Akbay et al.[13] The pilot hole was drilled with a 4 mm drill at a depth of 45 mm. In none of the specimens were the anterior cortex or pedicle violated. Then, two extra holes at 10 mm depth were drilled at the caudal surface of the vertebral body to facilitate the penetration of decalcified solution into the vertebral body. The bone mineral density (BMD, g/cm^2) of each vertebra was measured by dual energy X-ray absorptiometry (DXA).

b. Demineralization: Each vertebra was fully embedded in jars filled with 700 ml 7.5% hydrochloric acid. After completion of the decalcification process, the vertebrae were carefully washed under tap water and 500 ml saline solution was instilled through the drill hole to completely remove the decalcified solution. Bone mineral density of each vertebra was re-measured and recorded. All the specimens were placed at -20 °C in a freezer until test day.

c. First step (primary screw pullout test): Vertebrae were thawed to room temperature for 24 hours. Polyaxial self-tapping, titanium pedicle screws at 6.5 mm width and 50 mm in length (Cezmed Medical, Adana, Turkey) were driven into one of the pedicles of each vertebra. Following the insertion of the pedicle screws, vertebrae were embedded in cement (Amberok Model Stone) leaving the screw head over the cement surface (Figure 1). Pullout tests were performed by material testing machine (Instron 8516+ material testing system, Kırıkkale University, Mechanical Testing Laboratory, Kırıkkale). Each pedicle screw, fixed to the mechanism, was tested for axial pullout at a speed of 10 mm/min and pulling procedure continued until a sudden drop in recorded load was observed.

d. Second step (revision screw pullout test): Primary screw pullout testing was performed without complications. The vertebrae were randomly divided into two groups; classic PMMA pedicle hole augmentation and kyphoplasty PMMA augmentation technique. Group 1: 2cc PMMA cement (Smart Set MV Endurance, Depuy International Ltd, England) was injected into the pedicle hole applying no pressure. A pedicle screw at the same length and width as the original one was driven into the hole. Group 2: Using the failed pedicle screws' hole, Xvoid™ (Cavity Creation System, Stryker) expander was inserted into the vertebral body. To achieve best cavity creation, the expander was used in five different directions. After cavity creation, 4 cc bone cement was injected into the vertebra body and pedicle without pressurization. A pedicle screw of the same length and width as the original one was

Figure 1. Pedicle screw was fastened to the upper jaw by a U-shaped apparel. The blue cube in the metal box is the Amberok model stone containing the embedded vertebra. The blue cube is secured in the metal box while the box helped to fasten to the lower jaw.

driven into the pedicle hole. Revision pullout test was successfully concluded in 22 vertebrae.

The data of the study were analyzed using Statistical Package for the Social Sciences (SPSS Inc, Chicago, IL, USA) for Windows 17.0 version software. The paired t-test was used in the comparison of results obtained after primary and secondary pullout strength (POS). Student t-test was used for the evaluation of data obtained from changes in POS of pedicle hole PMMA and kyphoplasty PMMA augmentation revision groups. The level of statistical significance was set at $p<0.05$.

RESULTS

The mean BMD result of the specimens significantly decreased from 1.686±227.9 g/cm^2 to 1.432±157.1 g/cm^2 after decalcification ($p<0.001$). The decrease corresponds to 17% decrease in BMD. Vertebrae were grouped in to two, forming two homogeneous groups with respect to BMD. The BMD values were positively correlated with the primary screw pullout values ($r=0.83$; $p<0.001$). However, no significant difference was obtained between BMD score and both revision techniques ($p=0.808$).

The mean POS of primary screws in group 1 was 3443±1086 N/m^2. After pedicle hole PMMA augmentation, the mean POS was significantly decreased to 2088±924N/m^2 ($p=0.006$). The mean POS of primary screws in group 2 was 3702±1063 N/m^2. After kyphoplasty PMMA augmentation, the mean POS was decreased to 3664±107 N/m^2 ($p=0.934$). Additionally, kyphoplasty PMMA pedicle augmentation technique achieved significantly higher POS than pedicle hole augmentation technique ($p=0.002$).

DISCUSSION

Osteoporotics are a special group of patients in which pedicle screw application can have serious initial and secondary stability concerns. Poor bone quality jeopardizes the screw-bone osteointegration. The end-result is screw pullout or loosening leading to mechanical instability. The revision rate ranges from 0.6% to 11%.[14] Revision of a failed pedicle screw in an osteoporotic patient is a challenge for the orthopedic surgeon. This study explored biomechanical superiority of kyphoplasty PMMA augmentation over pedicle hole PMMA augmentation in the setting of a failed pedicle screw revision.

Kyphoplasty PMMA augmentation had higher POS than classical pedicle hole PMMA augmentation (3664±107N/m^2 versus 2088±924N/m^2, $p=0.002$). During primary pullout, the pedicle screw which has been engaged to the bone by its threads removes the bone between its threads. This creates a cylindyrical hole just equal or somewhat larger than the original pedicle screw. Actually in vivo loosening of a pedicle screw occurs due to repetitive triplanar movements. This generally creates a hole from which the screw can be easily extracted manually. In classic pedicle hole augmentation PMMA in the hole fills the spaces between the screw threads during screw driving. When pulled out screws were examined it was seen that screws used in kyphoplasty group were totally covered by PMMA while in the classic pedicle augmentation group PMMA was laid in only between screw threads (Figure 2a, b). This was due to the fact that in the kyphoplasty augmentation group the screw trajectory at its distal end was enlarged with expandable instruments. This created a void around the screws. During screw driving the threads can be fully immersed in PMMA in this void. The increased PMMA diameter around the screw acted as a constraint to pullout during secondary testing (Figure 3a, b).

Initial POS of screws by classic transpedicular and kyphoplasty PMMA augmentation were compared in an osteoporotic vertebra model.[3] They found a nearly two-fold increase in initial POS of screws in the kyphoplasty augmentation group. Also both augmentation techniques yielded higher initial POS than the unaugmented control group. Others also reported similar findings.[15,16] In this study, although secondary POS in both augmentation groups were inferior to the primary POS, results of the kyphoplasty group were very close to the primary results with no significant difference. This is consistent with a study in which POS were compared when pressurized

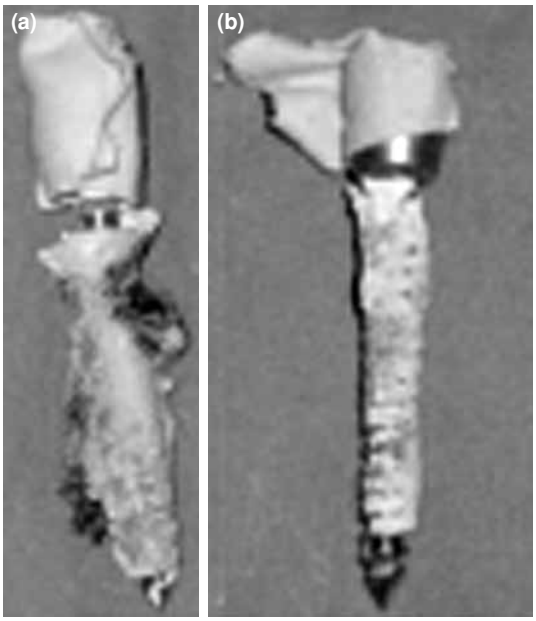

Figure 2. Photographs of pedicle screws after revision pull outs. **(a)** Screw used for kyphoplasty polymethylmetacrylate augmentation. **(b)** Screw used for transpedicular polymethylmetacrylate augmentation.

and nonpressurized PMMA was used to augment revision pedicle screws.[16] In their study while the nonpressurized augmentation group could reach only 95% of control value, the pressurized augmentation group doubled the control value. In this study we used nonpressurized kyphoplasty augmentation and reached 98% of primary pullout value. In osteoporotics, revision pedicle screw augmentation has different considerations than primary pedicle screw augmentation.[11,17] Initial POS can be increased with PMMA augmentation compared to the nonaugmented group in a primary pedicle screw augmentation setting. But in a revision pedicle screw augmentation setting primary POS values can be reached only by kyphoplasty PMMA augmentation. The relationship between bone and metal, especially in the osteoporotic bone was described as the weak point of the system.[4] Axial pullout strength is correlated with screw length, screw diameter, insertional torque and BMD.[16,18] In osteoporotics, in a revision setting, longer and larger screws can be dangerous because of increased risk of pedicle injury and neurovascular damage. Then augmentation of the bone-metal interface by PMMA seems to be the best way to increase the revision POS. Kyphoplasty PMMA augmentation offers the chance of delivering a higher volume of PMMA than classic transpedicular augmentation.

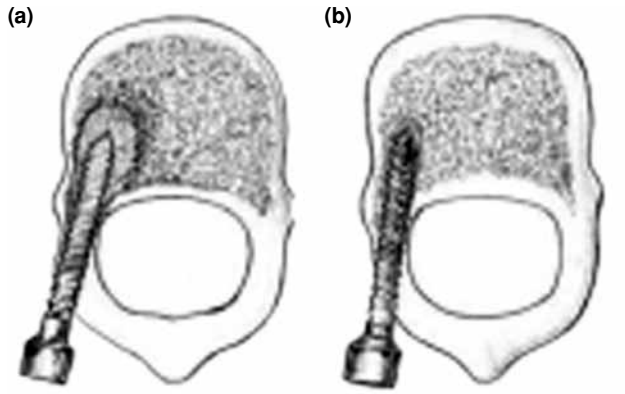

Figure 3. Schematic representation of two PMMA augmentation techniques. **(a)** polymethylmetacrylate filled void around the screw resists distraction of screw from screw trajectory. **(b)** Interface between screw and trajectory wall was very shallow and this resulted in polymethylmetacrylate accumulation only between screw threads.

The significance of the correlation between POS and BMD was emphasized in numerous pedicle screw fixation-related studies.[4,19] Bone mineral density was reported to play important roles in the screw loosening and reunion. The positive correlation found between BMD values and primary screw POS was not observed for revision screws. The effect of BMD on revision screw POS had less impact than the effect of both augmentation techniques used in this study.

In conclusion, in an osteoporotic vertebra, kyphoplasty augmentation gives higher revision pullout values than transpedicular augmentation. Actually kyphoplasty augmentation restores the primary pull out strength in a revision setting. Nonpressurized kyphoplasty transpedicular vertebral body PMMA augmentation was biomechanically superior and might be the choice of augmentation technique in osteoporotics.

Declaration of conflicting interests

The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

Funding

The authors received no financial support for the research and/or authorship of this article.

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