EXPERIMENTAL STUDY

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Restoration of pull-out strength of the failed pedicle screw: biomechanical comparison of calcium sulfate vs polymethylmethacrylate augmentation

Ümit Özgür GÜLER[1], Alihan DERİNCEK[2], Murat Ali HERSEKLİ[2], Metin ÖZALAY[2], Bekir Murat ÇINAR[2], Emre ACAROĞLU[1]

[1]Department of Orthopedics and Traumatology, Ankara Spine Center, Ankara, Turkey;
[2]Department of Orthopedics and Traumatology, Adana Training and Research Hospital, Başkent University, Adana, Turkey

Objective: The aim of the present study was to compare calcium sulfate (CAS) and polymethylmethacrylate (PMMA) bone cements used for the augmentation of a failed pedicle screw with biomechanical pull-out strength (POS) testing.

Methods: Thirty lumbar vertebrae were harvested from 6 calves and bone mineral densities (BMD) were measured. Primary polyaxial pedicle screws were randomly inserted and pulled out and the POSs of the specimen were recorded. For revision, specimens were randomly assigned to the CAS-augmented pedicle screws group (Group 1) or PMMA-augmented pedicle screw group (Group 2). Pull-out tests were repeated to compare both groups.

Results: Mean BMD of the specimens was 1.006±0.116 g/cm^2. There were no statistically significant differences between BMD results of the two groups (p=0.116). For Group 1, mean POS of primary screws was 2,441.3±936.4 N and was 2,499.5±1,425.1 N after CAS augmentation, demonstrating no statistically significant difference (p=0.865). In Group 2, mean POS of the primary screws was 2,876.6±926.6 N and significantly increased to 3,745.5±1,299.2 N after PMMA augmentation (p=0.047). There was also a significant difference in mean POS between the CAS and PMMA groups (p=0.026).

Conclusion: Although CAS augmentation facilitates a revision screw POS as strong as that of primary screws, it is not as strong as PMMA augmentation.

Key words: Calcium sulfate; pedicle screw; PMMA; pull-out strength.

The use of pedicle screws in the treatment of vertebral diseases has increased in the last two decades. The advantages of pedicle screws include the stable fixation capability until solid fusion is achieved and not requiring an intact lamina or spinous process. However, loosening, pulling out and failure of pedicle screws are relatively frequent problems.[1] In such situations, revision of the pedicle screws during primary or revision surgery may be unavoidable.

Enhancement of the fixation power of the ped-

Correspondence: Ümit Özgür Güler, MD. Ankara Omurga Merkezi, İran Caddesi, 45/2, Kavaklıdere, 06700 Ankara, Turkey.
Tel: +90 312 – 467 04 42 e-mail: umitozgurguler@yahoo.com

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icle screws can be achieved using larger and/or longer pedicle screws or changing the direction of implementation of pedicle trajectory in primary or revision procedures. Pedicle trajectory can be sustained by augmenting the defected pedicle with polymethylmethacrylate (PMMA), hydroxyapatite or calcium sulfate (CAS)/calcium phosphate (CAP) bone cements.[1-10] PMMA is the most frequently used and biomechanically sound method in revision surgery. On the other hand, PMMA may cause side effects such as heat and polymer release, bone necrosis and nerve damage.[11] Injectable calcium salts are a good alternative to PMMA due to their non-exothermic nature and biological cohesion capabilities.

The aim of the present study was to compare CAS and PMMA bone cements used for failed pedicle screw augmentation with biomechanical pull-out strength (POS) testing.

Materials and methods

Approval of the Committee of Research Ethics was obtained for the present study. Thirty lumbar vertebrae (L1-L5) were obtained from 6 two-year-old calf cadavers. All specimens were cleaned of surrounding musculature, ligaments and periosteum and separated into individual vertebrae. Anteroposterior and lateral radiographs were taken to exclude fractures and other pathologies. Bone mineral density (BMD, g/cm^2) of each vertebra was measured in the anterior/posterior direction with dual-energy X-ray absorptiometry (DEXA-Hologic QDR 4500; Hologic, Inc., Waltham, MA, USA) to ensure homogeneous study groups with similar BMD values. Specimens were then wrapped with gauze, sealed in plastic bags, and stored frozen at -20°C in a deep freezer until the testing. Biomechanical tests were performed in two steps.

Prior to testing, all vertebrae were removed from the deep freezer and thawed to room temperature for 24 hours. Care was taken to keep the specimens moist throughout the experiment. Pedicle screw insertion points were identified with the help of the intersection method and screws inserted using the Roy-Camille technique in left or right pedicular trajectories under fluoroscope for each vertebra. Polyaxial, self-tapping, titanium pedicle screws (Cezmed Medical, Adana, Turkey) were placed into all vertebrae (Fig. 1). Screw diameter was 6.5 mm and length was 45 mm. No pedicle damage or anterior wall penetration occurred in any of the vertebrae during screw replacement.

Following pedicle screw replacement, all vertebrae were embedded into cement (Amberok Model Stone) from the anterior side (anterior surface in a downward direction and the pedicle entry point as the upper surface) using 30 aluminum embedding containers prepared in advance. Pull-out tests were performed using a material testing instrument (Instron Model No. 4505; Instron Corp., Canton, MA, USA). Each pedicle screw was tested for axial POS at 5 mm/min displacement until total screw pull-out (Fig. 2). Primary screw pull-out testing of the 30 calf vertebrae was completed without breakage in the cement, bending of the embedding container or screw breakage.

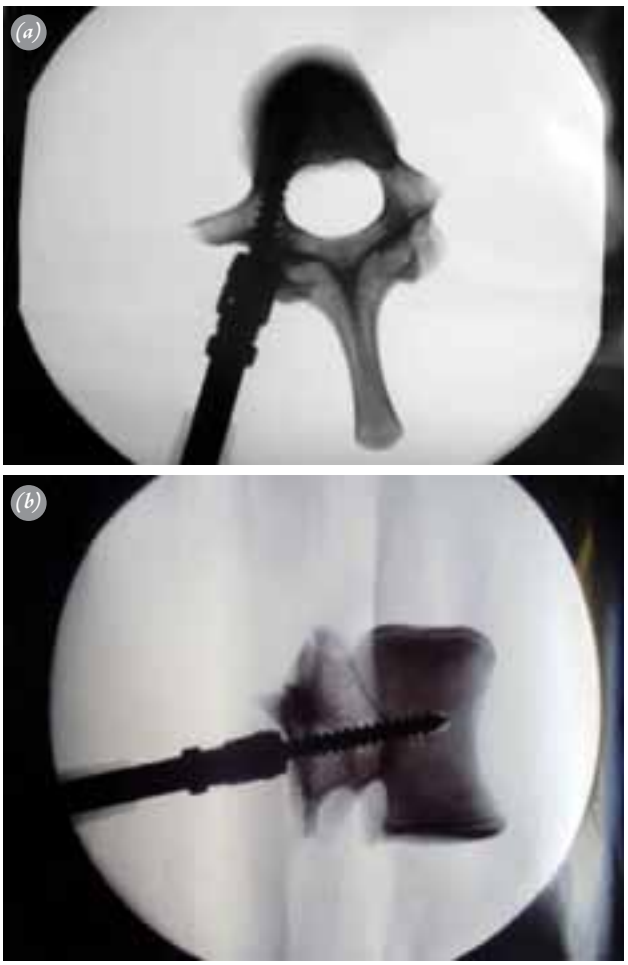

Fig. 1. **(a)** Axial and **(b)** lateral view of the pedicle screw insertion under fluoroscopic imaging.

Vertebrae were then randomly divided into two equal groups receiving CAS (Group1) or PMMA (Group 2) cements. For the second step of the study, no drilling or tapping was used to insert the screws. Screws were used in the same specimens in both stages of the experiment.

In Group 1, 3 cc of CAS bone paste (Minimally Invasive Injectable Graft: MIIG X3; Wright Medical Technology, Inc., Arlington, TN, USA) was inserted into the damaged pedicle holes of each vertebra with-

out any pressure. In Group 2, 3 cc of PMMA cement (SmartSet MV Endurance; DePuy International Ltd., Leeds, UK) was injected into the damaged pedicle holes without any pressure.

After augmentation of all damaged pedicle holes, pedicle screws used in the first step of the study were placed in the same vertebra. All specimens were kept at room temperature for 24 hours to allow the CAS and PMMA cement to harden completely.[12,13] Vertebrae were placed into the Instron machine again as in the primary screw pull-out tests and revision pull-out tests were successfully concluded in 29 vertebrae (Fig. 3a). The polyaxial head of one PMMA-augmented screw detached from the screw body during the pull-out process at 6,415 N and the specimen was excluded from the study (Fig. 3b).

Data were analyzed using the SPSS v17.0 (SPSS Inc, Chicago, IL, USA) statistical package program. The Mann-Whitney U test was used in the comparison of primary and revision screw pull-out results. The Wilcoxon test was used for the evaluation of data obtained from changes in POS of PMMA and CAS revision groups and the Pearson's correlation test for comparison of BMD values with the primary and revision pull-out test results. The level of statistical significance was determined as $p<0.05$.

Results

Mean and standard deviation (SD) BMD of all segments was 1.006 ± 0.116 g/cm^2, suggesting low or osteoporotic bone quality.[14] There was no statistically significant difference in BMD scores between the PMMA and CAS groups ($p=0.116$). When primary and revision pull-out BMD values were compared, a statistically positive correlation was observed between BMD and primary screw pull-out values ($r=0.578$; $p<0.05$).

No incidence of pedicle or lamina fractures was observed. One pedicle screw detached from the screw body in revision testing and its results were excluded from the study. In the CAS group, mean POS of primary screws was $2,441.3\pm936.4$ N (range: 1,317 to 4,634 N) and $2,499.5\pm1,425.1$ N (range: 760 to 5,336 N) for CAS-augmented screws. There was no statistical difference between primary and revision screws POS in Group 1 ($p=0.865$). Mean POS increased from $2,876.6\pm926.6$ N (range: 1,964 to 4,612 N) for primary screws to $3,745.5\pm1,299.2$ N (range: 1,246 to 4,903 N) for revision screws in the PMMA group. This increase was statistically significant ($p=0.047$). Additionally, there was a statistically significant difference in POS values between the CAS and PMMA groups after augmentation ($p=0.026$) (Table 1).

Fig. 2. All vertebrae were embedded into cement from anterior sides and pull-out tests were performed using a material testing instrument. [Color figure can be viewed in the online issue, which is available at www.aott.org.tr]

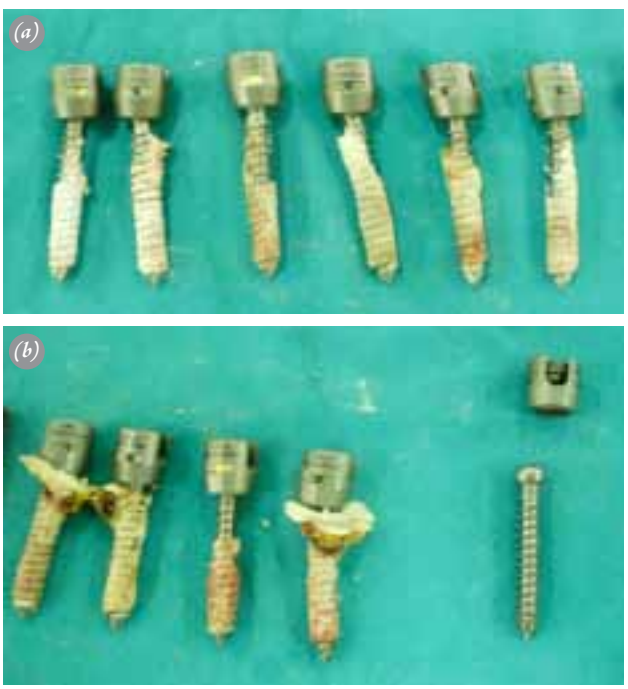

Fig. 3. **(a)** View of the CAS-augmented screws after pull-out test. All the thread of the screw is coated with calcium sulfate cement. **(b)** View of the PMMA-augmented screws after pull-out test. Polyaxial head breaking off was observed during testing procedure in a screw. [Color figure can be viewed in the online issue, which is available at www.aott.org.tr]

Table 1. Statistical analysis of the primary and CAS- and PMMA-augmented revision screws' pull-out strengths (mean±SD).

	Mean pull-out strength of the primary screws (N)	Mean pull-out strength of the revision screws (N)	p*
CAS group	2,441.3±936.4	2,499.5±1,425.1	>0.05
PMMA group	2,876.6±926.6	3,745.5±1,299.2	<0.05
p†	>0.05	<0.05	

CAS: Calcium sulfate; PMMA: Polymethylmethacrylate; *: Wilcoxon test; †: Mann-Whitney U-test.

Discussion

The majority of subjects with pedicle screw fixation do not require revision. However, intraoperative or postoperative augmentation is necessary in some cases. Loosened screws, pedicle breakage, inappropriate screw placement or osteoporotic bone generally result in loss of correction or nonunion. The relationship between bone and the metal of the pedicle screws, especially in osteoporotic bone, has been described as a weakness of the system.[15,16] Several recent studies have shown that for revision procedures, the use of materials creating favorable biomechanical properties can be used for pedicle screw augmentation.[6,7,17]

In general, the compounds of PMMA or hydroxyapatite and CAS or CAP are used in revision surgery. In the literature, augmentation with PMMA was reported to provide the highest mechanical strength in both primary and revision cases.[5,6,18,19] Although stability and availability of PMMA and its efficiency in increasing POS have been ascertained, complications resulting from PMMA use create some limitations on its use in spinal surgery. PMMA is an exothermic polymer and may lead to bone necrosis, toxin release and/or neural injury.[8] However, bone graft materials made from CAS or CAP are potential alternatives to PMMA. They have high biological incorporation and are not exothermic. Therefore, they do not have the potential risk of thermal damage to bones or nerves. Additionally, CAS bone graft requires a short period of preparation and long period of hardening processes.[10] Still, both PMMA and bioabsorbable cement are widely used by spine surgeons for augmentation in revision procedures or in osteoporotic patients. The use of CAS bone graft materials is relatively new and has not been as well studied as PMMA.

Few articles comparing CAS and PMMA have been published in the literature.[6,17] Both processes were applied as primary pedicle screw augmentation techniques in our study, but not as a salvage process. Additionally, in the previous studies, BMD values were not measured, vertebrae were predicted to be osteoporotic before the process, and the effect of bone density on POS was not discussed. In contrast with previous reports, a statistically significant difference was found between CAS and PMMA in our study.

In the recent articles, axial POS was correlated with screw length, screw diameter, insertional torque and BMD.[20-22] They concluded that while the use of larger diameter screws increased the insertional torque, increasing screw length did not have an effect on the insertional torque. Additionally, they reported that larger diameter and full-threaded screw insertion deep enough to fit into the anterior vertebral cortex provided the most secure fixation and that the incidence of non-union was increased when BMD was below 0.674±1.04 g/cm^2. In the present study, the same CAS- and PMMA-augmented pedicle screws were used in both the primary and revision fixations in order to ensure that screw length and diameter did not affect screw POS. Additionally, BMD values were taken for all vertebrae and a statistically positive correlation was detected between BMD and primary pedicle screws while there was no correlation between the BMD and revision screw pull-out values. We, therefore, concluded that BMD did not affect PMMA- and CAS-supported pedicle screw pull-out values.

This study had some limitations. First, we compared only two types of cements despite the availability on the market of other types of cements. Second, animal vertebrae were used in the study while human cadaver vertebrae would have more clinical use.

In conclusion, PMMA, as a material of pedicle screw salvage, has been recognized as the golden standard due to its easy availability, low cost and superiority of augmentation. Although not as strong as PMMA augmentation, POS of revision screws with CAS-augmented bone cement is as strong as that of primary screws. Injectable calcium salts give no exothermic reaction and have high biocompatibility and, consequently, a lower risk of complication. The use of these materials is promising for the future.

Conflicts of Interest: No conflicts declared.

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