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Biomechanical Comparison of Polymethylmethacrylate Augmentation Methods in Failed Pedicle Screw Revision

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ABSTRACT

AIM: To compare biomechanical results between different polymethylmethacrylate (PMMA) augmentation methods on failed lumbar pedicle screw models of animal vertebrae

MATERIAL and METHODS: Thirty lumbar vertebrae were harvested from six calves, and their bone mineral density was measured. 60 Polyaxial pedicle screws were inserted to all vertebrae. Pull-out tests were performed to all specimens on an Instron machine. The specimens were randomly divided into four groups. The same screws used in primary screwing process were labeled and used in revision. Screws in the first group were augmented by injecting PMMA into the failed screw hole with a syringe; screws in the second group by inserting bone graft and roll-shaped PMMA, screws in the third group by inserting bone graft and injecting PMMA with a syringe; and the fourth group by inserting bone graft and injecting PMMA through a fenestrated pedicle screw. The pull-out strength (POS) results of all specimens were recorded and compared with statistical analyses.

RESULTS: The mean BMD of the vertebrae was 1.31 ± 0.225 g/cm^2 and no significant difference was found between the groups ($p>0.05$). The mean POS of the primary screws in the first, second, third, and fourth groups were 2166,5 N/m^2, 2183,5 N/m^2, 2508,5 N/m^2, and 2005c N/m^2 respectively. After the augmentation, the mean POS in the first, second, third and fourth groups were 3839 N/m^2, 2874 N/m^2, 2929 N/m^2 and 3826 N/m^2 respectively. No statistical difference was found between the groups in post-revision POS values ($p>0.05$).

CONCLUSION: There was no significant statistical difference in POS between the augmentation methods.

KEYWORDS: Biomechanical analysis, Augmentation, Pedicle screw, Calf

INTRODUCTION

The increased number of surgical methods applied in vertebral pathologies has also increased the need for revision surgeries. Surgical spinal fixation procedures in the elderly population have significantly risen in recent years and are expected to continuously increase in the future. Complications due to screw loosening or insufficient mechanical stability are common, especially after osteoporotic spine surgery (12,15). Many recovery methods have been described for revision cases (e.g., using larger diameter or longer pedicle screws, strengthening the disrupted screw hole, or redirecting the pedicle screw) (8). In addition to intraoperative strengthening methods of the screw hole,

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materials such as poly(methyl methacrylate) (PMMA), calcium sulfate, calcium phosphate, autogenous, or allogenic bone are frequently used. Among these materials, PMMA is the most widely used in spinal surgeries and adheres to the surrounding trabecular bone, strengthens the fixation, and doubles the force required to remove the screw (3). However, the usage of PMMA may cause bone and neural damage or distant organ embolisms due to its exothermic reaction and polymer release. The use of PMMA is preferred close to the end of its working time while in a dough state to reduce the effect of the exothermic reaction to neighboring tissues and distant organs (11,13). This study aims to biomechanically compare different augmentation methods in terms of the time and method used during daily practice in failed pedicle screw revision procedures.

MATERIAL and METHODS

This study was approved by Institutional Review Board (Project no. DA19/01).

Thirty lumbar vertebrae (L1–L5) were obtained from six 2-year-old calf cadavers. All soft tissue surrounding the bone was cleaned, and each specimen was then labeled and their vertebral level was written on each segment. The bone mineral density (BMD) of all vertebrae included in the study was measured in the anterior–posterior (AP) direction with dual-energy X-ray absorptiometry (DEXA-Hologic QDR 4500; Hologic, Inc., Waltham, MA, USA). In addition, AP X-ray radiographs of all vertebrae were taken to exclude fractures and other bone pathologies (Figure 1). The cleaned and labeled vertebrae were then wrapped in gauze, sealed in plastic bags, and kept in the freezer at –20°C until testing.

Figure 1: AP and lateral views of the vertebrae.

All the vertebrae were removed from the freezer 24 h before the day of testing, moistened at room temperature, and randomly selected. Both pedicles of each vertebra were used. The insertion points for the pedicle screws on each vertebra were determined by the intersection technique (i.e., the intersection point of the line drawn perpendicular to the lateral of the superior facet joint with the line drawn from the middle of the transverse process). The pedicle screw holes were prepared using a 5.0-mm drill considering the medial angulation of the pedicle, and care was taken to ensure that all walls and the anterior cortex of each vertebra were intact. Sixty 6.5 × 50 mm polyaxial head self-tapping, titanium alloy lumbar pedicle screws were placed in each pedicle (Normmed Medical, Ankara, Turkey). No medial wall penetration, pedicle, or corpus fracture was observed in any vertebrae during the screw insertion phase. All the vertebrae were embedded into cement using 30 aluminum embedding containers prepared in advance following screw placement. The anterior sides of the vertebrae were buried into the cement with both their pedicles facing upward (Figure 2). The cement was left at room temperature for 24 h to harden. The containers with the vertebrae were then placed on the testing device (Instron model no: 8874; Instron Corp, Canton, MA, USA; Figure 3). The tensile force was applied to each pedicle screw in the axial direction within the measurement range of 2 mm/min. The pulling process was continued until total screw pullout

Figure 2: The anterior side of the vertebra buried in the cement with pedicles facing upward.

occurred, and the results were recorded (Figure 4). Primary screw pullout testing of the 30 calf vertebrae was completed without cement breaking, bending of the embedding container, or screw breakage.

The next step of the study was the revision of the disrupted pedicle screw paths. The same screws used for the primary screwing process were also used in the revision process, and the direction of the screw paths was determined by thin rods. The study groups were then randomly divided into four groups with 15 pedicles each.

The first group was augmented by injecting PMMA (Stryker Surgical Simplex® P Radiopaque Bone Cement, Stryker Corporation Kalamazoo, MI, USA) into the failed screw hole with a syringe. The liquid and powder components were mixed for 1 min, and 2–3 cm^3 of PMMA was injected into each pedicle without pressure. The previously labeled screws were then inserted into the pedicle. In the second group, 2–3 cm^3 bone grafts were taken from the spinous process of the vertebrae, crumbled, and applied to the pedicle tract. PMMA was then mixed at room temperature for 6–7 min to reach a doughy state so it could be modeled into a roll by hand. After reaching a relatively doughy state, 2–3 cm^3 of PMMA was shaped into a roll and inserted into the pedicle holes using a rod, and the screws were inserted into the pedicle (Figure 5).

In the third group, the liquid and powder components of PMMA were mixed for 1 min after applying a 2–3 cm^3 bone graft to the pedicle hole in advance from the spinous process, and 2–3 cm^3 of cement was injected into the pedicle screw holes under pressure using a cement syringe. The pedicle screws were inserted afterward. The fourth group was previously

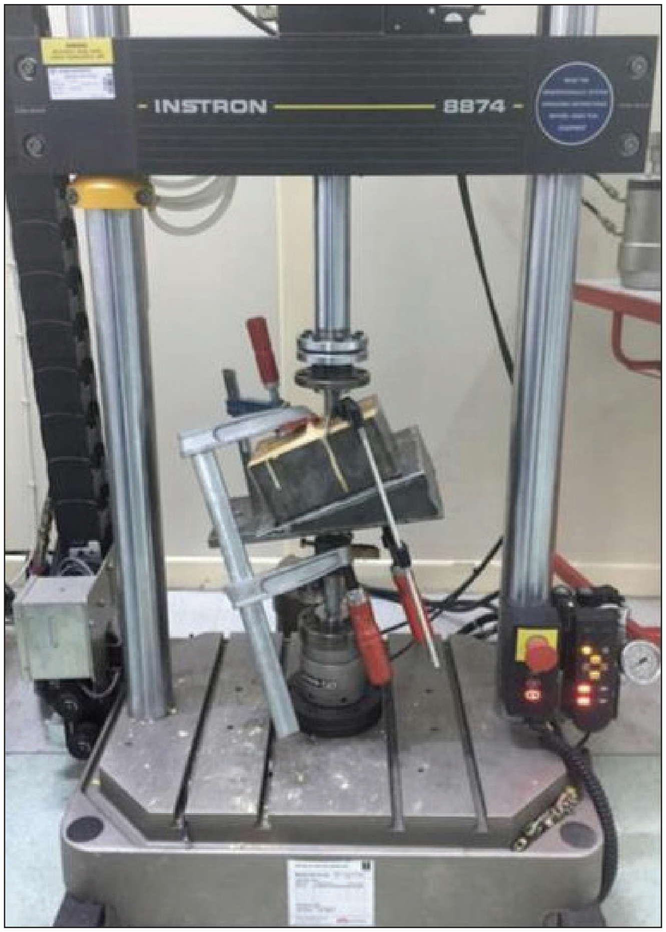

Figure 3: The mechanism set for the pulling process.

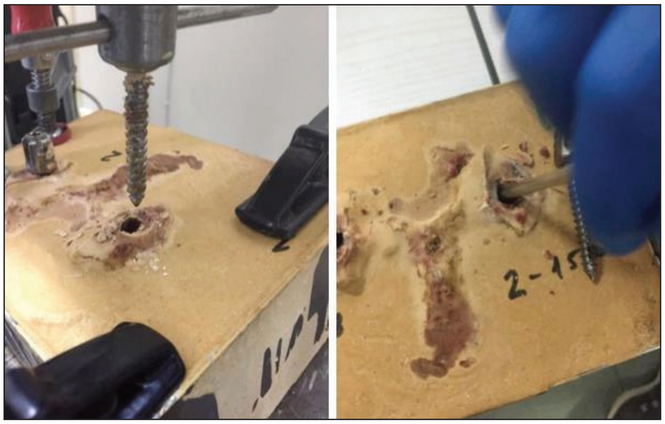

Figure 4: The primary screw pullout.

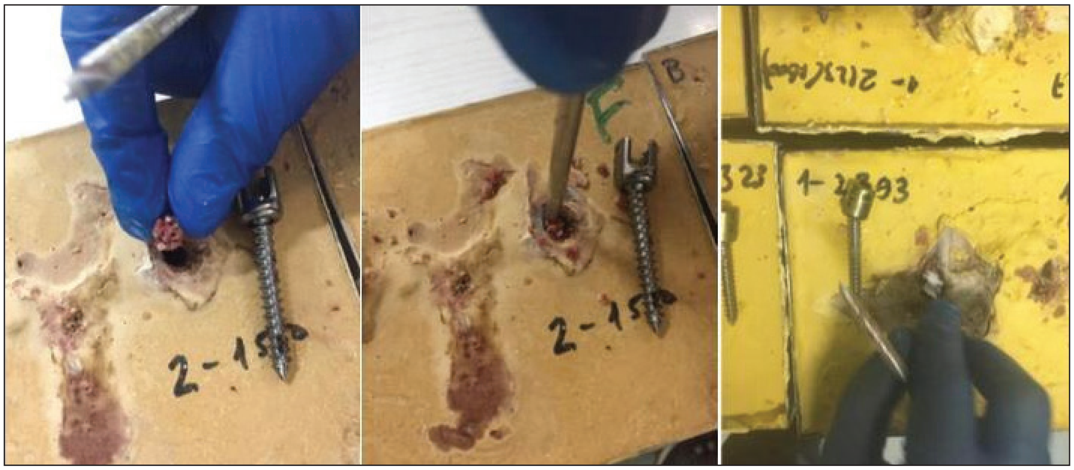

Figure 5: Bone graft and hand-rolled PMMA inserted into the disrupted screw hole.

designated as the group in which fenestrated screws were used. Fenestrated screws were inserted into pedicle holes after applying a 1–2 cm^3 bone graft into the disrupted pedicle tract. Liquid and solid PMMA components were mixed for 1 min and injected into the vertebra through the fenestrated screw.

All specimens were kept at room temperature for 24 h to allow the PMMA cement to completely harden, and then they were set up on the Instron device for the augmented pullout testing. The second pullout tests were completed and no complications (e.g., screw breakage, bone fracture, or test setup failure) were encountered in any of the samples (Figure 6).

Statistical Analysis

Data were analyzed using the (IBM) SPSS v20.0 (SPSS Inc, Chicago, IL, USA) statistical package program. The primary pullout forces and the pullout forces after augmentation were analyzed for each group and statistically evaluated by covariance analysis to evaluate whether BMD values affect the pullout forces. The mean value and standard deviation of the pullout load for each group were calculated. The normal distribution of the pullout force values obtained after the augmentation of the failed screw tracts for all four groups was evaluated by the Shapiro–Wilks normality test, and homogeneity was evaluated by the Levenne test (Table I). After providing the hypothesis for both tests, variance analysis was used for statistical evaluation between the groups. The difference between the groups in terms of postrevision results was evaluated by the Kruskal–Wallis test. The Wilcoxon test was used for analyzing the correlation between primary and postrevision results for each group. The power of the study was 0.98, with a 1.48 effect size type 1 error of 0.05. The level of significance was defined as $p<0.05$. (The type 1 error rate was taken as 0.05 to test the statistical hypotheses. A p value <0.05 was considered to be a statistically significant difference.)

RESULTS

The average BMD value was found to be 1.31 ± 0.225 g/cm^2 as a result of the BMD measurement on the vertebrae. The BMD values of the whole group's experiments were compared

Figure 6: Screw samples after the second pullout tests were completed.

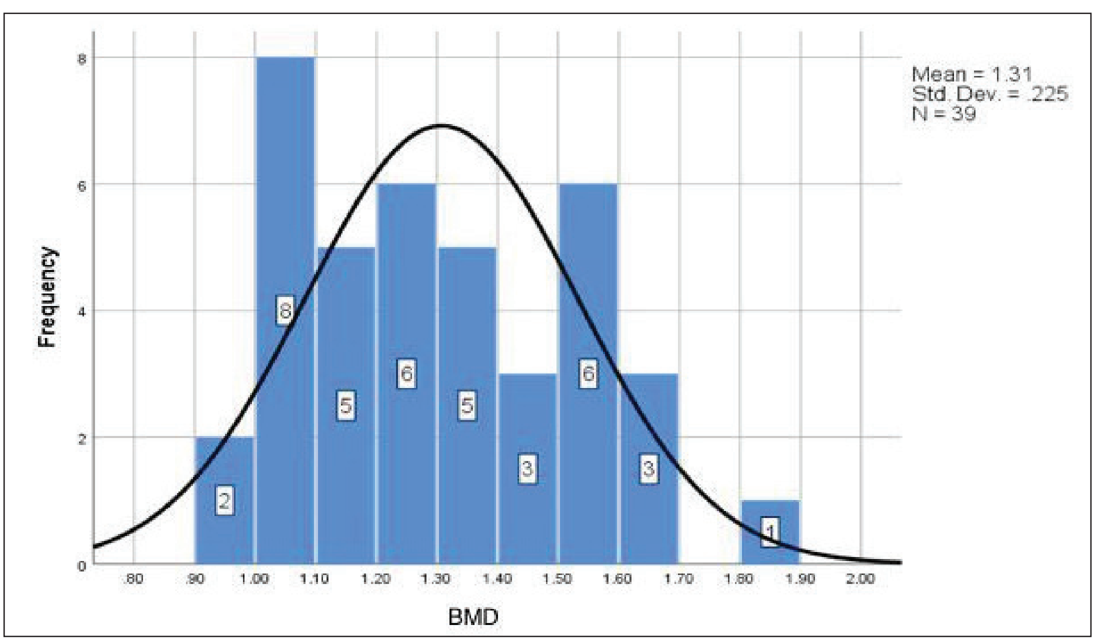

Figure 7: Frequency histogram of BMD measurements of the vertebrae.

and determined that they formed a homogeneous group and showed normal distribution (Figure 7).

The POS of the left and right pedicle screws for both primary and augmented pedicle tracts on each vertebra was statistically evaluated and compared because both pedicles were used. Primary pullout values of the left and right pedicles were compared for all groups and no statistical correlation was found between the sides (Table II; $p>0.05$). Similarly, no correlation was found in terms of the side when comparing postrevision pullout values for all groups ($p>0.05$).

The average primary pullout value for the first group was 2,166.5 and 3,839 N/m^2 after the augmentation when all groups were separately evaluated. Moreover, the average primary pullout value for the second group was 2,183.5 and 2,874 N/m^2 after the augmentation. The average primary pullout value for the third group was 2,508.5 and 2,929 N/m^2 after the augmentation. Furthermore, the average primary pullout value for the fourth group was 2,005 and 3,826 N/m^2 after the augmentation (Table III).

Postrevision values increased in all the groups compared with the primary values, and the only statistical difference was found in the results obtained with fenestrated screws in group 4 ($p<0.05$). In the variance analysis of the postrevision pullout values, no statistical difference between the groups was noted, regardless of the side ($p>0.05$).

DISCUSSION

The importance of transpedicular screw fixation, which has a wide range of applications including trauma, oncology, and deformity-corrective surgery, has significantly increased in the last 20 years. Many studies have been conducted to reveal the pedicle screw fixation forces and the factors affecting those forces. Many cadaver and biomechanical models have been used to study pedicle screw fixation systems (1,4). Moreover, not every pedicular fixation method may need augmentation, but intraoperative reinforcement or postoperative revision surgery is required in some cases (6). In studies conducted, screw loosening causing nonunion or correction loss was found to be between 0.6% and 15% (16). Factors (e.g., pedicle fracture, improper placement of the screw, and osteoporotic bone) have been reported to disrupt pedicle screw fixation. The weakening of bone–metal contact through time is the main cause of screw loosening, especially in osteoporotic bones (5,15). Longer and larger diameter pedicle screws could increase the risk of pedicle injury or neurovascular damage in revision procedures. Therefore, pedicle screws augmented by PMMA appear to be the best way to increase the revision pullout strength (2).

The interaction of a screw with a bone can be evaluated in two different ways as shown in many studies: bending and axial pullout tests. The axial pullout force is directly proportional to the screw length, screw diameter, input torque, and BMD. In a study that compared three revision strategies on failed screws, Hostin et al. reported that pedicle screw revision had greater pullout strength when compared with the revision groups that

Table I: The Normal Distribution of the Pullout Force Values After the Augmentation were Evaluated With Shapiro – Wilks Test and the Homogeneity was Evaluated Wit Levene Test

Distribution between groups	Pull-out strength			
Levene	.797			
In-group distribution	**Group 1**	**Group 2**	**Group 3**	**Group 4**
Shapiro – Wilks	.708	.178	.780	.144

Table II: Pull-Out Strength Comparison of Primary and Augmented Screws in Left and Right Pedicles

Group		rho	p
Group 1	Primary* R & Primary L	-0.497	0.256
	Aug** R & Aug L	-0.075	0.872
Group 2	Primary R & Primary L	0.187	0.697
	Aug R & Aug L	0.578	0.174
Group 3	Primary R & Primary L	0.614	0.057
	Aug R & Aug L	0.651	0.080
Group 4	Primary R & Primary L	0.342	0.408
	Aug R & Aug L	0.505	0.202

**Primary screw pullout strength of the Right and Left pedicle.*
***Augmented screw pullout strength of the Right and Left pedicle.*
Note: *Since we used both pedicles, we statistically evaluated and compared both primary and augmented POS of the left and the right pedicle screws on each vertebra.*

Table III: The Evaluation of Augmented Screws Pull-Out Forces in Each Group

Group		Primary	Augmented	p
Group 1 *(N/m²)*	n	8	8	**0.069**
	Median	2166.5000	3839.0000	
	Minimum	1832.00	1246.00	
	Maximum	3645.00	4903.00	
Group 2 *(N/m²)*	n	8	8	**0.208**
	Median	2183.5000	2874.0000	
	Minimum	1313.00	1299.00	
	Maximum	4900.00	5456.00	
Group 3 *(N/m²)*	n	8	8	**0.208**
	Median	2508.5000	2929.0000	
	Minimum	1516.00	1562.00	
	Maximum	3701.00	6391.00	
Group 4 *(N/m²)*	n	8	8	**0.012**
	Median	2005.0000	3826.0000	
	Minimum	1572.00	1998.00	
	Maximum	3236.00	6279.00	
	p	**0.303**	**0.699**	

changed the trajectories of the failed screw, but also found a 20% pedicle wall breach rate when visually inspected (7). They also reported that the insertional torque and the pullout strengths both increased with an improved BMD and were significantly correlated in all three revision groups. Thus, an increased pullout strength was associated with a higher BMD (7).

In a study that compared pullout strengths of pedicle screws following revision with larger screws, Varghese et al. reported that using screws that are 2 mm larger in diameter than the original screws lead to significantly higher pullout strengths. Hence, they recommend using screws that are >1 mm larger in diameter than the index screw to avoid pullout-related implant failures (14).

In the study conducted on cadaver vertebrae, Leichtle et al. compared pullout strengths of cemented solid versus fenestrated pedicle screws in osteoporotic vertebrae. They reported that conventional, solid pedicle screws augmented with high viscosity cement provided results comparable to those using sophisticated and considerably more expensive fenestrated screws concerning the stability in pullout tests in osteoporotic bone (9).

The screws used in the first stage of the current study were reused in the second step to eliminate the effect of the different screw lengths, width, and the number of threads on the pulling force. Like screw properties, the effects of bone quality on pedicle screw pullout forces and the bone factor importance in pedicle screw fixation are other subjects on which many studies have been conducted. The most important factor in screw loosening and nonunion reported in the studies was that the BMD value of the screw-applied group was below 0.674 ± 104 g/cm² (10). All vertebral BMD values in the current study were found to be a homogeneous group (mean 1.31 ± 0.225 g/cm²) after the statistical analysis, and no value was found to disrupt the statistical evaluation. Although the specimen of this study was not an osteoporotic model, the main goal of this study was to test methods that may be beneficial for use on both sides of the bone density spectrum.

Many materials have been used in osteoporotic bones intraoperatively or in postoperative revision cases to strengthen the fixation. The type of cement applied to the failed pedicle screw hole stands out as a recovery method in cases where the screw factor is not changed. The materials used in these cases are usually PMMA, calcium sulfate, hydroxyapatite, and calcium phosphate. PMMA has been shown to provide the highest mechanical strength in both primary and revision cases in many publications. Despite complications, the mechanical stability provided by PMMA has been the preferred augmentation material in revision procedures for years (1,4,6).

The current study expected that the pulling forces of screws augmented with PMMA would be higher than the primary screws. The primary pullout tests were performed on 15 screws inserted into the pedicles in all four groups. The removed screws were used in the second phase of the experiment. This difference was not statistically significant although a numerical difference exists between the primary pulling forces of the pedicle screws and the pulling forces of augmented screws. However, the third group showed a statistically more uniform curve after the augmentation. Thus, the bone graft and roll-shaped dough (PMMA) may have shown stronger adhesive properties compared to the liquid option and increased the stability and possible bone–implant contact. Factors affecting the results were the use of screws with the same diameter and length in both the primary and augmented tests. Moreover, the augmentation material used, PMMA, in all revised groups was the same.

CONCLUSION

This study tested the fixation achieved by augmenting the failed pedicle screw hole with a bone graft and PMMA and compared their pullout strengths. The current study tested whether these augmentation methods have any advantages or disadvantages over each other with different screw types and PMMA application methods and compared the results. Like previous studies, augmentation with PMMA, which is the *gold standard* method, was found to reach higher values compared with the primary pullout force values. No statistically significant differences were detected between the groups when the pullout forces of the groups were compared after augmentation. However, regardless of the type of screw used, applying a bone graft into the failed screw path before applying PMMA and shaping the cement dough into a roll before inserting it into the hole was found to have a statistically more uniform curve. The results were very satisfying. The reinforced fenestrated screws were detected to have slightly shifted to the right in the frequency histogram. However, due to the cost and availability issues of fenestrated screws, inserting a bone graft into the failed pedicle screw hole and applying the doughy roll-shaped cement before inserting a standard pedicle screw was found to be at least as effective as fenestrated screws in augmentation. Although it is not statistically superior, the pullout force achieved by standard pedicle screws with a bone graft and the roll-shaped PMMA was similar to the force achieved by PMMA injected fenestrated screws and is important for clinical use.

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