Fixation Strength of PMMA-augmented Pedicle Screws After Depth Adjustment in a Synthetic Bone Model of Osteoporosis

Szu-Han Ying, MD; Hung-Chan Kao, PhD; Ming-Chau Chang, MD; Wing-Kuang Yu, MD; Shih-Tien Wang, MD; Chien-Lin Liu, MD

abstract

Full article available online at Healio.com/Orthopedics. Search: 20120919-21

The purpose of this study was to determine the change of fixation strength after adjusting the height of polymethylmethacrylate (PMMA)-augmented pedicle screws.

Cement-augmented cannulated pedicle screws with or without PMMA augmentation with a radial hole in the distal third of the screw thread were inserted into synthetic bone blocks used to model osteoporosis. Screws were left unchanged (in situ), screwed in 3 threads, or screwed out 3 threads. The change in screw height was made 24 hours after cement placement. Radiographs of the samples were taken before and after screw adjustment, and pullout strength testing was performed. In the cement group, a radiolucent cavity was present after screwing in due to the screw–cement complex migrating downward, whereas no obvious change in the bone–cement complex existed after screwing out. Mean pullout strength was significantly higher in the groups with cement as compared to those without cement. However, in the cement groups, the screw-in group had the lowest mean pullout strength among 3 groups, and the mean pullout strength in the screw-out group was also significantly lower than that in the in situ group (P<.05).

Adjustment of pedicle screw height after cement augmentation in a severely osteoporotic spine can significantly reduce the pullout strength of the screw.
Osteoporosis is common in the aging population, and once spine surgery is indicated due to spondylolisthesis, infection, trauma, or malignancy in the elderly, instrumentation is inevitable. It is challenging for a spine surgeon to place instruments into a spine with severe osteoporosis. Many studies have revealed that complications such as loosening, backout, or migration occur frequently after instrumentation in patients with severe osteoporosis, resulting in a poor clinical outcome.1,2

Pedicle screws are a popular implant for posterior instrumentation, and many methods have been used to increase the fixation strength of pedicle screws in osteoporotic bone, such as hook augmentation, wiring, cement augmentation, and bicortical purchase.1,3,4 Many studies on cement augmentation of pedicle screws have shown that fixation strength and clinical outcomes are better when cement-augmented cannulated pedicle screws are used in osteoporotic bone than with other methods.5-11

When spinal instrumentation is performed in a deformed spine, the height of the pedicle screws must usually be adjusted intraoperatively to set up the system of screws and rods. However, no studies have been performed to determine the effects of screwing in or out with respect to pullout strength when the pedicle screws are augmented with cement or how this may affect the integrity of the screw–cement–bone interface.

The purpose of this study was to determine the change of fixation strength, the degree of loosening, and the morphologic changes after adjusting the height of polymethylmethacrylate (PMMA)-augmented pedicle screws.

**Materials and Methods**

**Specimen Preparation and Experimental Procedure**

Commercially available synthetic bone (Sawbones; Pacific Research Laboratory, Inc, Vashon Island, Washington) with 2 different densities was used to simulate a spinal bone with extreme osteoporosis. The synthetic bone is rigid foam with an open-celled structure resembling that of human cancellous bone. The cell structure is more than 95% open, and the cell size is 1.5 to 2.5 mm. This product has been used for biomechanical studies of cement-augmented cannulated pedicle screw modeling in osteoporotic cancellous bone.12 The lower-density product (.09 g/cc; model #1522-505) has a compressive strength of .11 MPa and a compressive modulus of 6.2 MPa, whereas the higher-density product (.12 g/cc; model #1522-507) has a compressive strength of .28 MPa and a compressive modulus of 18.6 MPa. The standard block size of the synthetic bone is 13×18×4 cm.

For the experiments, the materials were cut into 6×6.5×4-cm pieces. Each density of the synthetic bone was divided into 6 groups, with 10 samples in each group. In the 6 low-density groups (.09 g/cc), the first group (L1) was not augmented with bone cement after placing the pedicle screw; the second group (L2) was prepared in the same way as L1, but the depth of the screw was adjusted 3 threads inward; and the third group (L3) was also prepared in the same way as L1, but the depth of the screw was adjusted 3 threads outward. Group 4 (L4) was prepared in the same way as L1, but the screw was augmented cement; group 5 (L5) was prepared in the same way as L4, but the depth of the screw was adjusted 3 threads inward after 24 hours, the average time it takes for the cement to completely solidify. Group 6 (L6) was prepared in the same way as L4, but the depth of the screw was adjusted 3 threads outward after 24 hours. The high-density samples (.12 g/cc) were also divided into 6 groups (H1-H6) and were prepared as corresponding low-density samples.

The screws used were 6.2×40-mm injectable cannulated pedicle screws with a 2.5-mm-diameter screw tip (OPS Pedicle Screw; Wellong Instruments Co Ltd, Taipei City, Taiwan) and a radial hole in the distal third of the screw thread (Figure 1). After a 40-mm-deep pilot hole was made using a 3-mm drill, the pedicle screws were placed at the same depth until all of the threads were sunk into the synthetic bone. Polymethylmethacrylate bone cement (Surgical Simplex P; Howmedica International S. de R.L., Limerick, Ireland) was mixed at room temperature. After mixing the liquid and powder, 3 mL of the bone cement, which was in the dough phase and looked like toothpaste, was injected into the samples described previously.

The height of the pedicle screw above the synthetic bone, measured from the proximal end of the pedicle screw to the surface of the synthetic bone, was documented before and after the screw was adjusted. Radiographs were taken 1 day after cement injection, and then again after further adjustment of the screws. SmartIris version 1.2.0.14 medical image software (Taiwan Electronic Data Processing Corporation; New Taipei City, Taiwan) was used to measure the screw height on radiographs; a horizontal line was drawn...
from the surface of the synthetic bone that was perpendicular to the axis of the screw. The height of the screw was defined as the distance between the tail end of the screw to the horizontal line. The measurement was then repeated after adjustment. After taking radiographs of all samples, pullout testing was performed to record the maximum pullout strength.

**Test Apparatus**

Each specimen was tested for failure in axial pullout using the Bionix Servohydraulic Test System (MTS Systems Corporation, Eden Prairie, Minnesota). The test block, with a screw inserted, was placed on a specially designed universal fixture, and the fixture was clamped on the lower side of the testing machine. The screw heads were fixed in a 10-mm cylindrical rod with an inner thread that matched the outer thread of the screw head. The cylindrical rod was then attached to the testing machine with a stranded stainless steel wire (3 mm in diameter) that coincided with the screw axis (Figure 2). After the specimens were mounted, pullout force was applied at a constant crosshead rate of 5 mm/min. The relationship between force and displacement was recorded. The ultimate pullout force was defined as the maximum load sustained before failure.

**Statistical Analysis**

Data were presented as mean±SD. Three states were tested (in situ, screw-in, screw-out) under 4 conditions (.09 g/cc, no cement, control; .12 g/cc, no cement, control; .09 g/cc plus cement; .12 g/cc plus cement). Differences in mean pullout strength among the 3 states were compared using a paired t test for each of the 4 conditions. For a given state, the mean pullout strength among 4 conditions was also compared using a 1-way analysis of variance with a post-hoc pairwise comparison Bonferroni test. A P value less than .05 was considered statistically significant; an adjusted significance level of .01 was used for the pairwise comparisons. Statistical analysis was performed using PASW version 18.0 statistical software (SPSS, Inc, Chicago, Illinois).

**RESULTS**

**Radiographic Changes**

In the screw-in group, all changes appeared at the interface between the bone cement and the synthetic bone (Figures 3A, B). An obvious radiolucent cavity resulting from a space left after movement of the initial cement position was found in 13 screws with remarkable depth change, whereas no remarkable change between the interface of the pedicle screw and the bone cement was noted. Only a minor radiolucent space was found around the bone cement in the screws with less depth change (Figures 3C, D). In the screw-out group, the change was mainly between the pedicle screw and bone cement (Figures 3C, D). No displacement of the cement was found in 19 samples in this group; the screw was only moved out from the cement. No radiolucent space existed between the synthetic bone and bone cement, but a conical radiolucent space was present in the cement (Figure 3D), which was the original space occupied by the screw tip.

**Pullout Strength Testing**

Mean pullout strengths of the 3 states (in situ, screw-in, and screw-out) tested in each of the 4 conditions are shown in Figure 4. In the .09 g/cc control group, mean pullout strength was not different between the states (all, P>.05). In the .12 g/cc control group, mean pullout strength was higher in the screw-in group than in the in situ group (P<.001) and screw-out group (P=.037). In the .09 g/cc plus cement and .12 g/cc plus cement groups, mean pullout strengths were significantly lower in the screw-in groups than in the in situ or screw-out groups (all, P<.01). In addition, in each state, mean pullout strength was significantly higher in the groups with cement compared with those without cement (all, P<.001) (Figure 4).

**DISCUSSION**

In this study, the pullout strength of cement-augmented cannulated pedicle screws, either in situ, screwed in, or screwed out, was significantly higher than that of screws without bone cement augmentation. However, this study also showed that after depth adjustment of the cement-augmented cannulated screws, either screwed in or screwed out, the pullout strength of the screw is decreased because the primary stable structure formed by the screw–cement–bone complex is damaged. These results are consistent with many studies that have shown that PMMA cement augmentation of pedicle screws increases fixation strength in a severely osteoporotic bone.12–16 Burval et al5 reported that the use of PMMA can increase the fixation strength of pedicle screws by 2- to 3-fold in osteoporotic vertebrae. However, when pedicle screws are placed...
into an osteoporotic spine, an increased risk exists of screw loosening, pullout, and fixation failure; and osteoporosis has been considered a contraindication for pedicle screw fixation. Many methods have been examined for improving fixation strength in osteoporotic bone, including expandable pedicle screws, various screw and rod configurations, and screws with different thread designs.

Various studies using different methods have examined the biomechanics of pedicle screw fixation. One study reported that cyclic fatigue loading results in a 20% decrease in pullout load in healthy, nonosteoporotic vertebrae, whereas the decrease is 33% in those with osteoporosis. In a study of short and long iliac screws by Zheng et al, the authors reported a markedly lower maximum pullout strength of short screws after fatigue conditioning; however, no difference was noted when short screw fixation was done with cement augmentation. Chapman et al reported that the pullout screw of pedicle screws inserted into cancellous bone was related to the major diameter of the screw, the length of engagement of the thread, the shear strength of the material the screw is inserted in, and a thread shape factor that is related to screw depth and pitch. The results showed that decreasing thread pitch or increasing thread depth increases screw purchase strength. They also reported that tapping porous material decreased the pullout force.

Zhang et al used finite element modeling to examine the effects of bone materials on screw pullout strength in the spine and found that the effects of purchase length on the pullout strength were different for different bone material, indicating that the bone material has a significant effect on the stability of the screw. Polikeit et al also used a finite element model to study the effects of cement injection into vertebral bodies to treat osteoporotic compression factors and found that although the cement restores the strength of the treated vertebrae, it leads to an increased endplate bulge and altered load transfer in the adjacent vertebra.

In the groups with cement augmentation in the current study, the pullout strength of the screw-in group was significantly decreased compared with that of the screws in situ, whereas the difference between the screw-out group and in situ was much smaller. This finding is compatible with the changes seen on the radiographs, which showed that screwing in resulted in remarkable destruction to the bone–cement interface, which is the main source
of screw stability. In contrast, in the screw-out group, no obvious damage existed to the bone–cement interface. This finding also suggests that removing a cement-augmented cannulated pedicle screw in severe osteoporotic bone is possible and may not cause significant destruction to the bone, which is consistent with a previous study. Cho et al.31 also examined backing out pedicle screws augmented with PMMA in a cadaveric study and reported no pedicle or lamina fractures, but the study did not examine the bone–cement–screw interface.

The results of the current study suggest that height adjustment of a cement-augmented cannulated pedicle screw should not be performed because it can significantly influence the stability of the screw. To ensure the stability of a pedicle screw, the ideal method is to pilot assemble the whole structure of the screw-rod system and adjust the screw height if necessary before cement injection. Although this method may increase the operative time, it can prevent the immediate loosening of the pedicle screw in severely osteoporotic bone. When screw adjustment is unavoidable, screw-out is preferable to screw-in with respect to the influence on screw stability. Another alternative is to use a side loading system, which has an opened proximal screw end. Cement augmentation can then be performed after assembling the entire screw-rod system.

The results of the current study also demonstrated that pullout strength was not statistically different between the 2 groups with different simulated bone density, either in situ, screw-in, or screw-out. This suggests that the difference in the synthetic bone density (.09 vs .12 g/cc) is too minor to have a significant mechanical difference in fixation strength of the screw.

This study had some limitations. The synthetic bone block used in this study has no cortical bone structure. In addition, the open cell form tested is weaker than human osteoporotic bone, and dry testing conditions without the influence of bodily fluids may not model the physiologic state accurately.32 The amount of cement used in this study was 3 mL, and a different amount may influence screw stability in a different manner. Although axial pull-out tests are commonly used method for evaluating the fixation strength of spinal screws, clinical screw failures may result from bending and shear loads on the screws; straight pullout force rarely occurs in the clinical setting.

**CONCLUSION**

The current study revealed that screw height adjustment after cement augmentation, either screw-in or screw-out, will decrease screw stability, particularly when screwed in. Screw-in results in damage to the bone–cement complex, whereas screw-out leaves the bone–cement complex intact. The results suggest that height adjustment of pedicle screws after cement hardening should not be performed.

**REFERENCES**


