Comparison of Pedicle Screw Loosening with vs. without PMMA Augmentation in Osteoporotic Vertebrae

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Introduction:
Pedicle screw fixation for spinal constructs in osteoporotic bones has a significant incidence of loosening.[1] Infusion of polymethylmethacrylate (PMMA) has gained popularity in Europe and Asia. The technique uses cannulated pedicle screws infused with PMMA. Some studies show that this method provides increased strength of fixation, but others claim that it does not improve pullout strength or axial loading. Potential complications of this method include risk of PMMA leaking into the spinal canal or into the venous systemic and finally the exothermic process of PMMA polymerization can cause damage to the bone. These complications have been resolved by using no more than 3ml of PMMA per screw. The purpose of this study was to measure screw loosening and screw anchoring after cyclic loading in osteoporotic vertebral bodies, comparing pedicle screws with and without supplemental PMMA injected around the threads of the screw.

METHODS: Lumbar vertebral bodies from cadavers over the age of 55 were DEXA scanned, and those below 0.9 g/cm^2 bone density were selected as ostoporotic. Each lumbar vertebral body had a 6x55mm pedicle screw inserted on one side. The vertebra was gripped using screws seen in Figure 1. A 5.5 mm titanium rod was applied to each screw and also to a screw 8 cm above which was attached to a rod end connector to simulate a corpectomy and create a “worst case” model of a motion segment unit with posterior construct. The reason for using a corpectomy model was to avoid the large sample variances due to degenerative changes at the facets and vertebral discs in different cadavers as well as the variations related to lumbar level.
These constructs were tested in flexion/extension by applying a sinusoidal cyclic load in load control by the MTS Model 858 MiniBionix II servohydraulic system. The load cycles continued for 5,000 cycles at 1 Hz (about 1.5 hours/specimen), or until a gross failure occurred. Load was applied ±50 N at a lever arm of 50 mm creating a peak moment of 2.5 Nm. The load was applied from the rod which was attached to a linear bearing on the MTS ram to allow the load point to travel with the construct as it moved.

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The construct was positioned so that a lateral view of the vertebral body could be monitored by the Hologic Premiere Mini-C-arm. A video of the fluoroscopic images was recorded at cycle increments of 1, 100, 250, 500, 1000, 2500, and 5000. Relative motions of the screws in the bone were analyzed by ImagePro software from the videos of each interval. This analysis technique had an intra-observer error in the range of 0.5º combined with an accuracy of image resolution of approx. 0.5º, so motion below 1º was considered too small to be detected by this method. After cyclic testing, the vertebra was gripped with insertion instrumentation to align the pedicle screw to the axis of the MTS ram and the screw was pulled out of the bone at a rate of 1 mm/sec until failure. A pedicle screw was constructed of the same size but with a cannula that communicated with holes between the threads so PMMA could be injected into the screw and out through the threads into the cancellous bone of the vertebral body. This screw was placed on the contralateral side of the vertebral body. and 3 cc of PMMA was injected into the cannula. The cyclic loading and the pullout tests were repeated. The differences in measured values from each vertebral body were analyzed by paired Student’s t-test.

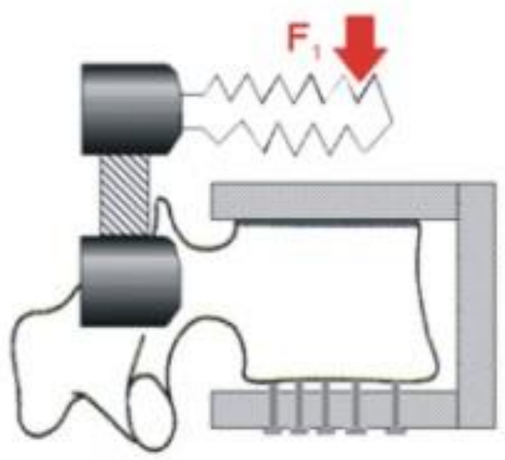

Figure 1 – Setup for cyclic testing.

Results.
Thirty % of the pedicle screws with no PMMA augmentation loosened during cyclic loading. None of the pedicle screws that had PMMA augmentation loosened during the 5,000 cycles. The pullout load for the pedicle screws with no augmentation averaged 451.6 N ± 295.2 (SD). The pullout for the pedicle screws with PMMA augmentation averaged 1133.5 N ±514.5 (SD), see Fig.2. This difference was statistically significant, P < 0.001.

Discussion: Many studies have performed pullout tests on augmented pedicle screws, but this is the first study to perform pullout tests after 5,000 cycles of severe loading. Even after loosening in this study the pedicle screws showed resistance to pullout that was significant (100 – 500 N). Other studies have showed that limiting the volume of PMMA to 3 cc or less provides a safe application to minimize risk of heat damage to the bone and tissues, leakage of PMMA into the spinal canal and vascular system. Fluoroscopy images from this study also showed that injection of 3 cc of PMMA stayed very local to the screw and there was no apparent danger of PMMA leaking outside the vertebral body..

Significance: Although this method is not approved by the FDA in the US, it appears that the mechanical advantage it provides with this injection method which has proven to be safe in European studies is worth developing for US application.

Reference: Kueny, RA, et al. “Influence of the screw augmentation technique and a diameter increase on pedicle screw fixation in the osteoporotic spine: pullout versus fatigue testing”, Eur Spine J (2014) 23:2196–2202

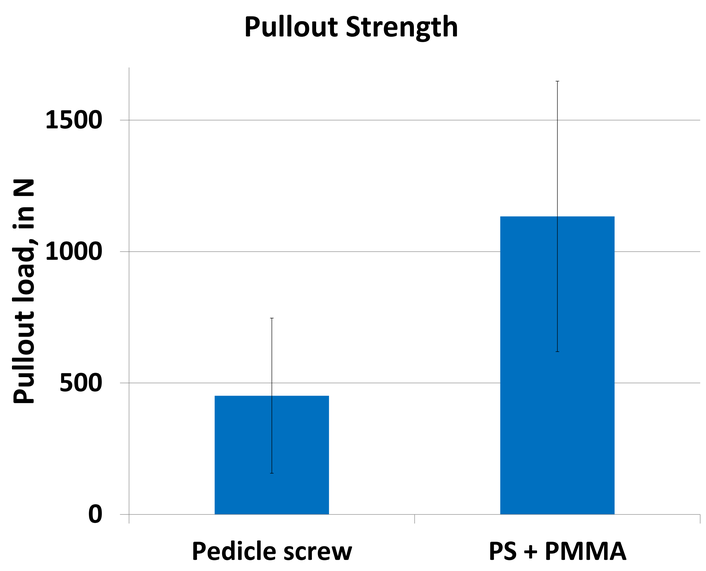

Figure 2 – comparison of pullout force after 5,000 cycles of severe loading.