Augmentation of pedicle screws with a self-curing Elastomer

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Introduction: In selected cases and in patients suffering from osteoporosis, augmentation of pedicle screws is currently the common method to improve the anchorage of pedicle screws. In most cases augmentation is carried out in situ through cannulated and fenestrated pedicle screws with PMMA cement. However, using this technique of in situ augmentation of pedicle screws bears the risk of cement leakage. Additionally, PMMA is described to have possible toxic effects and can make a revision of the augmented screw in the same vertebra more difficult. To overcome these drawbacks, a modified technique applying a self-curing elastomeric material into a balloon created cavity prior to screw insertion was developed. The aim of the present study was the comparison of the screw anchorage of the two augmentation techniques.

Material and Methods: Nine lumbar vertebral bodies (age 77.7, ±8 and BMD 91.8mg/ccm, ±37.4) were used for testing. Right pedicles were instrumented with monoaxial cannulated and fenestrated pedicle screws (S4, Aesculap) and in situ augmented with 2ml PMMA (Osteofix, Tsunami SRL, Medolla, Italy). Left pedicles were instrumented with monoaxial cannulated pedicle screws (S4, Aesculap). Prior to left screw insertion a cavity was created with a balloon (15mm, Tsunami SRL, Italy) and was filled with 3ml of self-curing elastomer (VK100, BONWRX, USA). Each screw was subjected to a cranio-caudal cyclic load (5mm/s) starting from -50 to 50N while the upper load was increased by 5N every 100 load cycles until failure or 11000 cycles (600N). The relative motion of the screw in the pedicle during cyclic loading was recoded using a 3D motion analysis system mounted to the screw head. After the cyclic loading a pull out test of the cyclically loaded screws was conducted.

Results: During cyclic loading all in situ PMMA augmented screws failed by screw cut out, while in the elastomer group with the balloon cavity technique 4 screws cut out and 5 screws did not fail during cyclic loading. In seven of the nine vertebrae the cavity creation augmentation technique with the elastomer outperformed the in situ PMMA augmentation. The mean cycles to failure were 9824 (±1982.4) and 7401 (±1644.6) for the elastomer and PMMA group, respectively ($p=0.012$). The pullout test showed differences between the two groups in pullout force ($p=0.003$) and displacement ($p=0.002$); with 671.3N ±332.1 and 5.9mm ±4.6 for elastomer group and 1188.6N ±288.1 and 12.3mm ±2.2 for the PMMA group. In the elastomer group the main failure mode was screw pullout, while in the PMMA the main failure mode was pedicle fracture.

Conclusion: Compared to in situ PMMA augmented pedicle screws the modified pedicle screw augmentation technique with self-curing elastomeric silicone and balloon cavity creation resulted in an improvement in pedicle screw anchorage under cyclic cranio-caudal loading. The pullout force after cyclic loading for the PMMA augmented screws was higher with a different failure mode.