AUGMENTATION OF PEDICLE SCREW FIXATION WITH A BIOACTIVE CEMENT

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Introduction
Pedicle screws are commonly used in posterior internal fixation systems to stabilise the spine for fusion procedures. Rigid fixation systems place high requirements on the load-carrying capacity at the screw-bone interface. Poor bone quality decreases the integrity of this interface, increasing screw micromotion and consequently reducing screw stability and possibly fusion success. In severely osteopenic bone, pedicle screw use may be ruled out completely.

To improve the chances of successful fixation, trabecular bone stock can be augmented with cement to increase stiffness and strength. Traditionally, polymethylmethacrylate (PMMA) has been used, however the exothermic in situ polymerization process poses a hazard to nearby neural elements. Screw revision is complicated by the fact that cement removal involves significant damage to the surrounding bony structures. More recently, the suitability of non-exothermic bioactive cements for pedicle screw augmentation has been investigated. These provide a safer alternative to PMMA along with superior osseointegration.

This study examines the effect of augmentation with an hydroxyapatite composite resin cement (CAP) on in vitro pedicle screw fixation. The influence of bone mineral density and screw insertion torque in predicting implant-bone interface strength was considered.

Methods
Synergy VLS pedicle screws (Interpore Cross International, Irvine, CA, USA; 5.5 mm outer diameter, 37 mm engagement length) were inserted into thirty-five cadaveric human lumbar vertebrae. Prior to pedicle screw insertion, the bone mineral density (BMD) of each vertebra was measured in a number of regions as identified by Figure 1A.

Figure 1. (A) Regions selected for BMD measurement by DEXA. (B) Experimental setup.

One pedicle at each level was assigned and injected with approximately 1.5 ml of CAP cement (Kuraray Co., Kurashiki, Japan) into a probe hole, while the contralateral side was used as the control. Peak torque was recorded during screw insertion. Caudo-cephalad loading of ±1 mm was performed at 2 Hz for 1600 cycles with each pedicle screw using a servohydraulic materials testing machine (MTS 858 Mini Bionix, MTS Systems Corporation, Eden Prairie, MN, USA) (Figure 1B). The initial load, rate of load decay during the first 400 cycles, and post-cycling load were the mechanical measures used to describe the strength of the implant-bone interface. Force-time data was sampled at 20 Hz. Reconstruction of the data was performed using a spline interpolation function (Matlab v5.2, The Mathworks, Inc., Natick, MA, USA).

Results
Matched paired t-tests revealed a significant difference between the results for the control and augmented pedicles ($P < 0.05$). The initial load on the CAP augmented screw increased by about 16% above the control value ($N = 19$), while the load measured after 1600 cycles was 65% greater for the CAP augmented screw ($N = 18$). The decay rate decreased by 59% in the augmented cases ($N = 19$), suggesting the screw-bone interface in the controls decreases much more rapidly.

ANOVA and Tukey HSD tests revealed that the mean BMD of the midbody region of the vertebral body were significantly different from that of the left pedicle ($P = 0.011$) and substantially different from the right pedicle ($P = 0.054$). The mechanical properties of the cement-augmented screws were found to relinquish dependence on the initial bone properties.

A secondary result of the study showed that BMD correlated with the mechanical measures (MAX: all regions; MIN: all but pedicle; DECAY: all but pedicle). Insertion torque correlated with BMD (all regions), also correlating with MIN and DECAY variables. BMD and insertion torque were used as variables to predict the mechanical measures. Linear combinations of pedicle BMD, entire vertebral body BMD and insertion torque were found to predict the mechanical properties of the control screws (MAX: pedicle and entire vertebral body BMD; torque; MIN: insertion torque only; DECAY: vertebral body and pedicle BMD).

Discussion
CAP cement augmentation of pedicle screws increases the stiffness and stability of the bone-screw interface. The low exothermic reaction and biocompatibility of this cement provides advantages over PMMA. CAP augmentation may allow for rigid spinal fixation in poor quality bone and potentially greater fusion success. The use of BMD and insertion torque pre-and intraoperatively to ascertain when cement augmentation is required may reduce the occurrence of pedicle screw failure in osteopenic bone.

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Statistical analysis was performed using Statistica (StatSoft, Inc., Tulsa, OK, USA). The statistical significance level was set at $P < 0.05$. The mechanical measures (initial peak load [MAX], final load after 1600 cycles [MIN] and initial decay rate [DECAY]) for the cement-augmented and control pedicles of each vertebra were compared using a two-tailed paired t-test. Non-parametric tests (Wilcoxon matched pairs test and Sign test) were used to verify the results. One-way analysis of variance (ANOVA) and a post hoc comparison of means (Tukey honestly significant difference (HSD) quantified the difference in BMD over the six regions. Pearson’s correlation coefficients were calculated for regional BMD against the mechanical measures, insertion torque against regional BMD, and insertion torque against mechanical measures. Multiple linear regression was performed to determine the capability of a linear combination of regional BMD and insertion torque in estimation of mechanical properties.

Figure 2. Effect of cement augmentation on mechanical measures.

* Represents significantly different means (paired t-test).