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The quantity of bone cement influences the anchorage of augmented pedicle screws in the osteoporotic spine: A biomechanical human cadaveric study

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ABSTRACT

Background: The aim of this comparative biomechanical human cadaveric study was to investigate the anchorage of augmented screws with two different volumes of bone cement. For this purpose the effect of cranio-caudal loadings on pedicle screws was evaluated and axial pullout tests were performed.

Methods: A total of 50 pedicle screws (25 augmented/25 non-augmented) were instrumented into osteoporotic vertebra of fresh human cadavers. The augmented screws were grounded by two different volumes of bone cement (1.5cm^3 vs 4cm^3). Biomechanical performance was assessed by performing a cyclic loading protocol (frequency: 3 Hz, load range: 20–200 N, number of cycles: 100,000), followed by axial pullout (13 augmented/11 non-augmented) or by either directly measuring axial pullout strength (12 augmented/12 non-augmented).

Findings: The median T-score of the specimens was −4.25 (range: −6.38 to −2.4). Pullout tests with and without cyclic preloading showed significantly increased pullout strength in augmented screws (Fmax: augmented: 1159 N (SD 395 N); non-augmented: 532 N (SD 297 N); $p < 0.05$). No significant difference in the pullout strength was found concerning the quantity of cement (Fmax (direct pullout): 4.0 cm^3: 1463 N (SD 307 N); 1.5 cm^3: 1214 N (SD 236 N); $p > 0.05$). The pullout strength significantly decreased in high-volume augmented screws after cyclic loading (Fmax (4.0 cm^3): direct pullout 1463 N (SD 307 N); cyclic preload: 902 N (SD 435 N); $p < 0.05$).

Interpretation: Biomechanical advantages of augmented pedicle screws can also be found after cyclic preload. However, our results indicate that the anchoring stability of high-volume augmented pedicle screws after cyclic loading is disadvantageous compared to moderate augmented screws; thus high-volume augmentation should be avoided.

1. Introduction

The surgical treatment of unstable osteoporotic spine fractures remains demanding (Liu et al., 2011). Screw loosening and progressive kyphotic deformity due to poor bone quality are frequently encountered (Liu et al., 2011; ZX et al., 2012). Pedicle screw augmentation appears beneficial in cases of severe osteoporosis; however the biomechanical effect of augmented screws has always been tested under non-physiological conditions with pure screw pullout, neglecting axial cyclic loading. Furthermore, there is still a controversy concerning the optimal volume of bone cement (Bostelmann et al., 2017; Pare et al., 2011; Wittenberg et al., 1993; Zindrick et al., 1986).

Most biomechanical studies are focused on pullout tests to investigate the anchoring stability of pedicle screws (Becker et al., 2008; Frankel et al., 2007; Leichtle et al., 2016; Pare et al., 2011). However, it must be taken into account that the pullout strength itself only supplies information about the fixation of the screw immediately after implantation and represents a non-physiological force. Other studies try to overcome this problem by simulating cranio-caudal in vivo loadings with so-called toggling tests were cyclic loadings are transmitted to the screw (Bostelmann et al., 2017; Burval et al., 2007; Takigawa et al., 2007). Unfortunately, biomechanical studies with a high number of cycles simulating postsurgical mobilization over approximately two weeks and consecutive pullout tests are rare (Karami et al., 2015).

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The primary objective of our study was to simulate the effect of cranio-caudal forces on pedicle screws. Therefore a biomechanical long term setup was realized and the properties of augmented and non-augmented pedicle screws were compared. The secondary objective was to investigate the behavior of augmented screws considering two different volumes of bone cement.

2. Methods

In total 50 pedicle screws (20 lumbar, 18 lower (T8-T12) and 12 upper thoracic screws (T3-T7)) were instrumented into 25 vertebrae of five fresh frozen human cadaveric thoracolumbar spines (three male and two female). In accordance to Panjabi et al. the spines were stored in sealed bags at − 18 °C (Panjabi et al., 1985). After the cadavers were thawed, bone mineral density (BMD) was measured by a 3-D Quantitative computed tomography (QCT) (Siemens, SOMATOM Definition AS, Erlangen, Germany). The region of interest was determinated according to Pacman.

Subsequently, all soft tissue structures except the longitudinal ligaments were resected from the spines and each vertebra was transdiscally separated.

Once the preparation was completed pedicle screw placement was performed under radiological guidance. Multiaxial titanium pedicle screws (CD HORIZON LEGACY Anterior Spinal System, Medtronic, Memphis, TN) were used for all vertebral bodies.

Screws were placed bilaterally into the vertebrae. A non-fenestrated pedicle screw was inserted on one side while an augmented fenestrated screw was placed on the contralateral side (Fig. 1). This strategy has already been utilized in previous studies (Pare et al., 2011) and allows reduction of the bias between the groups regarding screw length and diameter, respectively anatomy and density of the vertebral bodies.

After screw placement, the augmentation of the fenestrated screws was implemented and either 1.5 cm^3 or 4.0 cm^3 of bone cement (KYPHON HV-R Bone Cement, Kyphon, Sunnyvale, CA) was injected (Fig. 1). Bone cement application was performed only after the viscosity was hardened appropriate. For this purpose a dull surface and a sticky structure of the cement was checked clinically. All biomechanical tests were carried out only after the cement had completely cured (> 2 h after cement application).

To achieve optimal alignment of the vertebral body for the biomechanical test procedure, the vertebral bodies were embedded in two-component methyl methacrylate resin (PMMA Technovit 3040, Heraeus Kulzer, Wehrheim, Germany).

The vertebrae were randomized regarding the volume of bone cement and the test protocol (cyclic loading or direct pullout tests).

2.1. Biomechanical setup

Biomechanical performance was assessed by either directly measuring axial pullout strength or by performing a standardized cyclic loading protocol followed by axial pullout testing. All pullout tests were performed using an established material testing machine (ZMART. PRO, Zwick/Roell, Haan, Germany). The maximum pullout strength (Fmax) was determined in axial alignment to the pedicle screw.

Cyclic loading tests were performed using a vertical servo-pneumatic actuator (Dyna-Mess, Stolberg, Germany). In order to be able to expose the multiaxial screw head to a permanent load, the longitudinal rod was fixed in the screw head with a locking screw. Then the punch of the actuator was placed on the screw head from above, resulting in a cranio-caudal loading direction of the applied force (Fig. 2). In order to expose a permanent load, a preload of 20 N was applied to the specimens. At a frequency of 3 Hz and in a load range up to 200 N, the pedicle screws were subjected to a maximum of 100.000 loadings. Since the physiological load on a normal spine is estimated to be 1 to 3 million cycles over a year, 100.000 cycles are approximately equivalent to a period of a two-week mobilization (Kostuik and Smith, 1991). The load frequency of 3 Hz is located in the physiological rage and is frequently used within biomechanical studies (Bai et al., 2001; Burval et al., 2007; Wittenberg et al., 1993). The load range between 20 N and 200 N was selected as it corresponds to the load on a pedicle screw of a

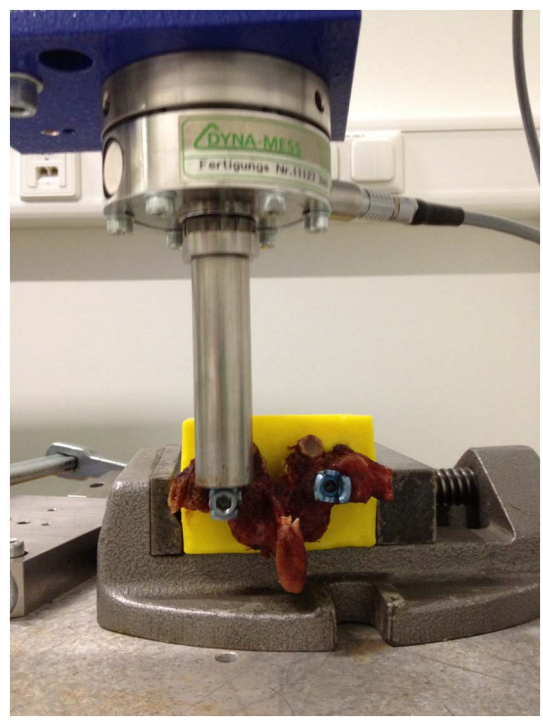

Fig. 2. Illustration of the cyclic loading setup.

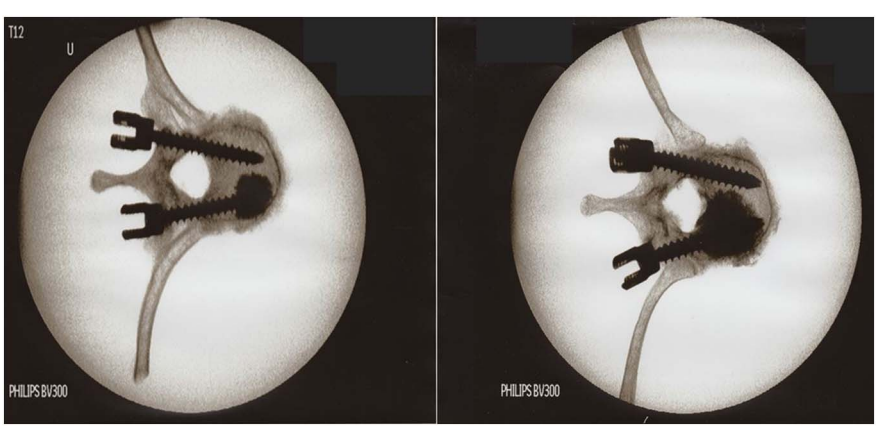

Fig. 1. Axial X-rays of two vertebrae by way of illustration of the pedicle screw placement in augmented and non-augmented technique. On the left: Augmentation with 1.5 cm^3, on the right: Augmentation with 4 cm^3.

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