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Correlation of pull-out strength of cement-augmented pedicle screws with CT-volumetric measurement of cement

Abstract

Background: Cement augmentation of pedicle screws increases fixation strength in an osteoporotic spine. This study was designed to determine the cement distribution and the correlation between the pull-out strength of the augmented screw and the cement volume within polyurethane (PU) foam.

Methods: Twenty-eight cannulated pedicle screws (6×45 mm) (Peter Brehm, Erlangen, Germany) with four holes at the distal end of the screw were augmented with the acrylic Stabilit ER Bone Cement Vertebral Augmentation System (DFine Inc., San Jose, CA, USA) and implanted into open-cell rigid PU foam (Pacific Research Laboratories, Vashon Island, WA, USA) with a density of 0.12 g/cm³, resembling severe osteoporosis. Volumetric measurement of the cement with consideration of the distribution around the screws was done with multislice computed tomography scan (Somatom Definition, Siemens, Erlangen, Germany). Pull-out strength was tested with a servohydraulic system (MTS System Corporation, Eden Prairie, MN, USA), and nonaugmented screws served as control. Pearson’s correlation coefficient with significance level \( \alpha = 0.05 \) and one-way analysis of variance test were used.

Results: We found a high \( r = 0.88 \) and significant \( (p<0.01) \) correlation between the cement volume and the pull-out strength, which increased by more than 5-fold with a volume of 3 ml. The correlation was linear at least up to 4.0 ml, but the possibility of in vivo cement leakage with increasing volume has to be considered. Pressure-controlled cement application might be a tool to avoid this complication. The cement almost completely penetrated the most proximal perforation.

Keywords: cannulated pedicle screw; cement augmentation; cement volume; osteoporosis; pull-out strength.

Introduction

Boucher described the use of pedicle screws in 1959, as did Roy-Camille in 1963 [11, 46]. Since then, the number of instrumentation procedures of the spine has increased steadily. Osteoporosis is of increasing concern in an aging population and bears the risk of early loosening of spinal implants [24, 26, 42, 47]. The quality of the host material has been found to be the most important single factor for implant fixation, which depends on the design, insertion technique, and diameter of the screws [1, 6, 12–15, 29, 53]. The bone screw interval is also important for the anchorage, which deteriorates in osteoporosis [15, 47]. Because the fixation techniques might not be sufficient in the osteoporotic spine, cement augmentation of pedicle screws is indicated, with acrylic cement offering the most rigid...
method of fixation [6, 13, 14, 43, 52]. There is a linear correlation between bone mineral density (BMD) and pull-out strength [14]. In advanced osteoporosis, the positive effect of acrylic cement on fixation strength increases and cement application significantly reduces the influence of the screw design on the stability of fixation [13, 22, 52].

Different cement augmentation techniques for pedicle screws have been described, but there is no agreement on any one method [14, 29, 43]. The kyphoplasty technique and transpedicular retrograde filling distribute more cement to the distal end of the screw than does the vertebroplasty technique, and the area of the cement screw interface was found to be greater for the retrograde application [14, 19, 29]. Recently, improvements in cement preparation have been reported, and cement injection, which is usually done manually with a syringe, has been modified [4, 5, 24]. Up to 90% of the injection pressure is necessary to overcome the resistance within the cannula [4, 5]. The starting volume applied varies between different cements, and the injection force varies between acrylic and ceramic cement [24]. Multiple designs of cannulated screws with different holes for cement augmentation have been examined, but no influence of orientation and size of perforations on the cement flow has been found [19]. Other authors have found an increased cement flow for side holes in comparison with distal end holes [29]. There is less resistance at the proximal hole, leading to an increase in cement flow [29]. An opportunity to increase cement flow could be through lowering of the cement viscosity; however, lowering the viscosity could lead to increased leakage, as well as an increase in diameter [5, 6]. Because different volumes of cement applied are considered to be safe, the recommendations for the volume vary considerably [6, 7, 13–15, 52]. The continuous measurement of pressure and volume application seems important in controlling cement augmentation [29]. There is also no agreement as to which cement volume is necessary to provide the necessary fixation [22, 29, 37]. Unlike strength, the restoration of stiffness was only weakly correlated with applied volume, and a correlation between cement volume and pain relief has not been found [8]. Also, no significant correlation between the applied cement volume and biomechanical features has been found [10, 13, 14]. However, with increasing volume, the complications of extravasation are enhanced, although application of 2.5 to at least 3.0 ml has been considered safe [4, 52]. Increasing the application pressure to overcome higher viscosity might lead to separation of liquid from the suspension, further impairing the delivery of the cement [4]. In the literature, the total cement volume injected into the complete application system is usually what is measured. One study analyzed the morphology of the cement distribution using computed tomography (CT) scan but did not perform biomechanical studies [29]. Because the technique of injection is not standardized, the performance of cement injection is not predictable, and it is not understood why vertebrae with comparable degrees of osteoporosis are not similarly injectable [2, 3].

The aim of our study was to evaluate cement distribution as proposed and volume using a CT scan to determine the correlation of these parameters with pull-out strength [2]. We further used a new cement application system, which activates the cement within the applicator, making premixing of the cement unnecessary and thus avoiding the disadvantages of different cement viscosity. According to the literature, we used sawbone made of polyurethane (PU) foam for the biomechanical studies [29, 33, 41]. In contrast to human cadaver bone, synthetic bone has a uniform and reproducible structure, excluding interindividually and intrindividually changes of bone architecture and BMD known from cadaveric vertebrae [21, 47]. Although sawbone does not reflect real biomechanics, a comparison of different techniques is possible [6].

Methods

Materials

The necessary number of specimens needed for statistical evaluation was calculated, and 28 pedicle screws (6×45 mm) (WSI-MX/PX-TITAN-Expertise, Peter Brehm, Erlangen, Germany) were used (Figure 1A). For cementation within the sawbone, acrylic Stabilit ER Bone Cement Vertebral Augmentation System (DFine Inc., San Jose, CA, USA) was administered. This technique controls the viscosity of the cement, which is an energy-responsive, polymethylmethacrylate-formulated cement, through the application of radiofrequency energy. A high viscosity is desirable to optimize the penetration of the bone trabecula. The viscosity of the cement is constant for more than 10 min and the cement is delivered by a hydraulic system. The friction within the application system is reduced by Teflon surfacing of the inner diameter of the adapter.

The sawbone used was an open-cell rigid PU foam with a density of 0.12 g/cm³, a strength of 0.28 MPa, and a cell size ranging from 1.5 to 2.5 mm (Pacific Research Laboratories Inc., Vashon Island, WA, USA). The mechanical properties resemble those of severe osteoporosis. The pedicle screws had two round-shaped distal fenestrations of 1.3 mm diameter at 8 and 10 mm proximal to the tip and two
holes with a diameter of 1.1 mm at 12 and 14 mm proximal to the tip, all between the second and fifth threads from the distal end of the screws (Figure 1A and B). The holes were perpendicular to each other. The central canal measured 1.3 mm in diameter. The connector between the screw and the DFine adapter, with a length of 25 mm and a diameter of 2.3 mm, was made of titanium. The maximum pressure, which might be applied for injection, is 545 psi. The system stops automatically when a certain pressure is reached. The dead space within the screw and its connector is 0.17 ml. The 28 pedicle screws were randomly filled with different volumes of cement within the range 0.5 to 4.5 ml (Figure 2).

Volumetric analysis

The volumetric measurement of the cement distribution around the screws was performed using a multislice CT (Somatom Definition, Siemens, Erlangen, Germany) and a volumetric software package on a dedicated three-dimensional workstation (Syngo MMWP, Siemens). Scan parameters were 400 mAs, 140 kV, 64×0.6 mm collimation, and pitch of 0.8. Image parameters were 0.6 mm slice thickness, 0.4 mm reconstruction interval, B70s reconstruction level, and extended CT scale. The volume of the cement was measured in a threshold from 2000 to 7000 Hounsfield Units, excluding the sawbone and screw material from the measurement (Figure 1B and C). This was done within eight different distances (sector thickness, 4 mm; Figure 3) from the tip of the screw.

Biomechanical testing

For the pull-out procedure, the servohydraulic System Bionix Model 810 with a force capacity range of ±50 kN was used (MTS System Corporation; Figure 1D). A preload of 10 N was applied to avoid system-related error in initial displacement measurement, and the velocity was 10 mm/min. The endpoint was defined as a 10-mm displacement. The sawbone was embedded into a holding device to avoid fixation-related deformations during the pull-out procedure (Figure 1D). Ten pedicle screws without cement augmentation served as control.

Statistical analysis

Pearson’s correlation coefficient was used, and the significance level was set at 5%. A one-way analysis of variance test was performed, and according to Bonferroni, α was 0.05.

Results

The cement volumes within the PU-foam block measured by volumetric CT scan ranged between 0.29 and 4.41 ml (Figure 2). The correlation between the cement volume and the $F_{\text{max}}$ was high, with $r=0.88$, and was highly significant (p<0.01, Figure 2). The pull-out strength $F_{\text{max}}$ ranged between 55 and 356 N (Figure 2). The failure always occurred at the cement-bone interface. The distribution of the cement showed a circular shape around the proximal screw perforation. Most of the cement was found between 12 and 16 mm, followed by a distance of 8−12 and 16−20 mm from the tip of the screw, with no significant difference between the latter (Figure 3). The average relative amount of cement volume in sector four was 39.2%, whereas sector three averaged 28.1% and sector five averaged 21%. These three sectors of 12-mm total length allocated at a distance...
6 mm proximal to the most proximal screw perforation contained 89.3% of the relative cement volume (Figure 3). The configuration of the cement was round-shaped, covering 360 degrees of the screw (Figure 1B and C). The 95% confidence interval ranged between 25.32% and 30.81% for sector three, between 37.03% and 41.40% for sector four, and between 18.59% and 23.42% for sector five. The pull-out strength of the control pedicle screws was $49.8 \pm 2.4$ N, and a load-displacement curve is shown for one screw in comparison with two cement-augmented screws (Figure 4).

**Discussion**

In comparison with cadaver bone, PU foam has a uniform density and structure [19]. Rigid foams collapse elastically and show a linear elastic deformation depending on bending stiffness related to cell walls [23]. At low density, cells form an open-cell microstructure, and transition from open to closed cells takes place at 0.35 g/cm$^3$ [23]. Bone with a volume fraction of solids <70% is classified as cancellous, and a network of rods produces open cells because plates give closed cells [23]. The microstructure of cancellous bone does not entirely match models because it is partially open and better resembles open-cell structure [44, 51]. Closed-cell materials showed comparable elastic behavior within a range of density from 0.12 to 0.32 g/cm$^3$ [23, 51]. Most artificial foams, even those with closed-cell structure, behave like open-cell foam because the edges of the cells contribute more to the biomechanical properties [51]. The open-cell PU foam simulates the interconnecting pores *in vivo* and the biomechanical

![Figure 3](image3.png)

**Figure 3** The relative amount of cement volume in percentage in eight sectors of the screw, each 4 mm in length beginning at the tip of the pedicle screw.
behavior and makes a good model for cement injection as well as for static and fatigue failure [18–20, 28, 45]. The variability of human cancellous bone makes it difficult to exactly determine 0.16 g/cm³ sawbone as osteoporotic or normal density and impedes comparing biomechanical studies between sawbone and human cancellous bone of low density resembling osteoporosis [34, 41]. This supports the decision to use an open-cell foam with a density of 0.12 g/cm³ in the present study. Local differences in bone architecture and pedicle morphology in vivo, which do not correlate with measurement of BMD, especially in osteoporosis, influence the anchorage of pedicle screws in human bone and other biomechanical features [15, 18, 20, 23, 28, 30, 38]. Bone density accounts only partially for variation of strength of trabecular bone because loss of three-dimensional trabecular connectivity in osteoporosis leads to more than a linear decrease in biomechanical properties [21, 23, 48]. Low bone density adversely affects the bone-screw interface because the pull-out forces of screws out of cement are higher [27]. In severe osteoporosis, loosening at the bone-cement interface can be assumed in vivo and was shown in an open-cell sawbone model with density of 0.09 g/cm³, similar to the density of 0.12 g/cm³ used in our study, also giving comparable results for pull-out strength [40, 47]. In moderate osteoporosis, failure at the screw-cement interface was described [40]. A human vertebrae cadaver study showed a much weaker correlation between mineral density and pull-out force compared with our study [36], and the pull-out force from normal human cancellous bone has been shown to be less in comparison with closed-cell foam of density 0.16 g/cm³ [18].

Tensile strength does not depend on density, whereas compressive strength does, and tensile mechanical properties are less compared with compression [30]. Different regions of human vertebrae were predictive for fatigue or static failure, and the weakest areas were relevant for failure because density alone does not account for variation of strength of trabecular bone [21, 38]. Elastic modulus and strength were found proportional to density in an open-cell structure, and the biomechanical behavior of synthetic vertebrae appeared similar to that of human cadaver vertebrae [28, 31]. Sawbone enables direct comparison of different implants [29]. We used sawbone with interconnecting pores and a density of 0.12 g/cm³, resembling severe osteoporosis, whereas 0.15 g/cm³ is considered low density and 0.22 g/cm³ is considered medium density [1, 41, 42], because human trabecular bone has a density ranging from 0.05 to 0.3 g/cm³ [28]. Young’s modulus of human cancellous bone varies between 1.1 and 9800 MPa [25, 41] and ranges between 15.1 and 151.4 MPa for closed-cell foam with a density of 0.16 and 0.32 g/cm³ because the mean values for 7.7-mm PU-foam cylinder were 0.7 MPa for 0.09 g/cm³, 41 MPa for 0.16 g/cm³, and 145 MPa for 0.32 g/cm³ [41]. Higher densities were measured for human subchondral trabecular bone, which is not representative for human cancellous bone of different location because the density of cancellous bone within the femur was between 0.1 and 1.0 g/cm³ [30, 34, 39]. A linear relationship was found between axial failure parameter in synthetic closed-cell cancellous bone for densities ranging from 0.08 to 0.48 g/cm³, and the type of fracture for lower densities between 0.08 and 0.24 g/cm³ appeared similar [39]. Thus PU foam closely resembles human bone, and open-cell as well as closed-cell types should be considered as osteoporosis model [28, 41]. In osteoporosis, the strength of different types of screw anchorage became more obvious [45], and the number of trabeculae as well as the connectivity were reduced [48], although low-density trabecular bone resembles open-cell foam [23]. The typical relative density of an open-cell structure is <0.13, and that of closed cells is above 0.20 [23]. The biomechanical behavior of augmented pedicle screws in severely osteoporotic artificial bone of 0.09 g/cm³ has been studied, and cadaver studies have shown an interindividually variable in biomechanical behavior [22, 40]. Sawbone offers the opportunity to study biomechanical features and cement distribution excluding these variables. Polyethylene cylinders according to ASTM F1717-96 have also been used instead of human vertebrae, and the range of allowable densities has been widened [16, 17]. A clinical investigation of cement-augmented screws revealed significantly different percentage filling of vertebra volume with a high standard deviation, indicating considerable intraindividual and interindividual changes in vivo [29].
Acrylic or ceramic cement can be used for augmentation of pedicle screws, but a polymethylmethacrylate cement provides a more stable fixation [6, 43]. With decreasing BMD, the correlation between bone quality and pull-out strength changes, and with increasing osteoporosis, an improvement in the pull-out force due to cement augmentation was pronounced [13, 22, 45]. Many studies have applied pull-out strength in the human cadaver model, and a few examiners have tested the effect of cyclic loading followed by pull-out [9, 32, 35, 36, 40, 49]. Some studies testing pull-out strength from PU foam have been performed, recommending varying cement volumes [27, 35].

The injection force correlates with the diameter of the syringe, with a 1-ml syringe reaching a maximum of 1.7 MPa [29]. A maximum pressure up to 170 N can be applied manually [5]. A faster injection rate does not increase the cement flow, as it raises the initial pressure from the beginning and an increasing pressure leads to separation of liquid from a suspension [4, 5, 24]. A conical diameter of the screw was found to be beneficial, but the difference in the cement distribution is minimal, whereas most of the cement tends to be delivered through the proximal hole [24, 29].

We used a new application technique with radiofrequency activation of the cement, creating a uniform viscosity prior to injection of the cement into the screw. The application system provided high pressure, making the injection of high-viscosity cement possible, first to avoid leakage of cement in vivo and second to create a good interface between cement and bone [5]. Increasing cement viscosity decreases the risk of leakage but correlates with increased yield stress [2, 4]. Although improvements in cement application systems have been made, syringes generating limited manual pressure are still being used [4, 5]. The volume of cement delivered is below a pressure of 200 N, and the total time of injection varies between different cements [24]. In our study, the application was performed until the pressure limit of 4.45 MPa was reached. Because the size and architecture of each vertebra vary, it can be assumed that the ideal cement volume for best fixation is variable as well. Important factors for standardization are control of pressure and volume during the application [5]. No dependence of cement flow on orientation and the liquid-phase separation mechanism should be noticed [2]. Measurement of pressure and volume during cement application should give further information to standardize and improve the augmentation.

According to the literature, a cement volume between 1 and 3 ml can be recommended for augmentation. The volume of 1 ml correlated with a nearly 150-N pull-out
strength, and a linear correlation between cement volume and pull-out strength was found, with up to 4 ml of cement correlating with more than 300 N (Figure 2). Comparable results for pull-out strength of noncannulated screws from open-cell sawbone of similar density to ours, after manual application of cement, were reported because manual packing of cement in closed-cell sawbone of 0.16 g/cm³ density improved the pull-out strength of pedicle screws to a smaller extent relatively [27, 50]. The application of more cement could increase leakage in vivo, so the cement volume should be limited to restore biomechanical features necessary under loading conditions in vivo. The control of pressure and volume might be useful in applying the maximum volume of cement, which does not lead to local complications.

Conclusion

A cement volume of 2–3 ml increased the pull-out strength of augmented pedicle screws significantly, whereas a volume of 0.5 ml did not when compared with pedicle screws without cement augmentation. An increase beyond 3 ml increased the pull-out strength further, as the correlation was linear, at least up to a 4 ml volume. The linear correlation suggests that an increase in cement volume would be beneficial for improving pull-out strength, and a pressure-guided cement application could address the maximum volume of cement to avoid leakage in vivo.

Conflict of interest statement

No conflicts of interest are declared.

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