Can cavity-based pedicle screw augmentation decrease screw loosening? A biomechanical in vitro study

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Abstract

Purpose In an osteoporotic vertebral body, cement-augmented pedicle screw fixation could possibly be optimized by the creation of an initial cavity. The aim of this study is to compare three test groups with regard to their loosening characteristics under cyclic loading.

Methods Eighteen human, osteoporotic spine segments were divided in three groups. Flexibility tests and cyclic loading tests were performed with an internal fixator. The screws were fixed after creation a cavity and with cement (cavity-augmented group), without cavity and with cement (augmented group), and without cavity and without cement (control group). Cyclic loading up to 100,000 cycles was applied with a complex loading protocol. Screw loosening was measured with flexibility tests after implantation and after cyclic loading. Cement distribution was visualized from CT scans.

Results In all groups, range of motion increased during cyclic loading, representing significant screw loosening after 100,000 cycles. In both augmented groups, screw loosening was less pronounced than in the control group. The cavity-augmented group showed only a slight tendency of screw loosening, but with smaller variations compared to both other groups. This may be explained with a trend for a more equal and homogeneous cement volume around each tip for the cavity-augmented group.

Conclusion This study demonstrated that creating a cavity may allow a more equal fixation of all pedicle screws with slight reduction of loosening. However, augmentation only through a cannulated screw is almost equivalent, if care is taken that enough cement volume can be pushed out around the tip of the screw.

Keywords Osteoporotic spine · Pedicle screw loosening · Cement augmentation · In vitro experiment · Cyclic testing

Introduction

Significant progress has been made in the surgical treatment of spinal diseases over the last two decades. Minimally invasive procedures have been optimized as a result of research into innovative pedicle screw systems. Spinal diseases with osteoporotic vertebral bodies pose a particular challenge in this context, where pedicle screw loosening seems to be

an issue [1, 2]. Successful use of an internal fixator largely depends on the creation of a solid bony connection between the pedicle screw and the vertebral body [3].

In patients with manifest osteoporosis, however, the anchoring of the pedicle screw in the weakened bone structure poses a problem, since the holding power of screws in bone depends largely on bone quality [4–9]. Changes in bone architecture as a result of osteoporosis often lead to post-operative complications when this technique is used, e.g. the loosening of pedicle screws and subsequent kyphosis and even fractures as result of this loosening [10].

Osteoporosis usually affects elderly patients. On account of demographic developments, the number of world population over 60 years is expected to increase from around 12.3% to 21.5% until 2050. In all European countries, the trend is growing [11]. As a result, the number of osteoporosis patients with associated clinical presentation is also expected to rise. According to studies by Melton et al., every third woman and every fifth man over

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the age of 50 will sustain a fracture due to osteoporosis [12, 13]. The clinical and epidemiologic/economic relevance of medical engineering solutions for this disease will thus significantly increase in future [14].

Pedicle screw systems have been continuously modified in order to compensate for reduced holding power in osteoporotic vertebral bodies. Many different screw designs, positions, diameters, lengths and insertion depths as well as different anchoring methods, torques and augmentation techniques have been tested [15–26].

Of these developments, cement augmentation has become an established standard in today's clinical practice. Augmentation of osteoporotic vertebrae in polymethylmethacrylate (PMMA)-assisted vertebroplasty can significantly increase pedicle screw pull-out forces to levels exceeding the strength of cortical bone [29].

In biomedical studies, satisfactory results have been achieved with the use of bone cement for screw augmentation in the treatment of osteoporotic spines [27–31]. Cook et al. showed that pull-out strength of cemented pedicle screws was up to 250% higher than that of non-cemented screws in control groups. Also, clinical evaluations have demonstrated that the frequency of screw pull-out and pedicle defects decreased when cement-augmented screws were used [32, 33].

A possible approach, using cement-augmented screws, is to create a cavity in the vertebral body, which is subsequently filled with a self-curing elastomer when the pedicle screw is implanted. In contrast to the conventional method, in which cement flows into the trabecular structure of the vertebra without creation of a cavity, a better anchoring in the bone and less loosening is expected (with the new method creating an initial cavity) [34].

Sandmann et al. verified that one advantage of balloon-guided cement augmentation of iliosacral screws in the treatment of insufficiency fractures of the sacrum was the much stronger bone–screw interface compared to other procedures and was biomechanically superior against vertical shear stress [35]. This last study explained an interesting method, but using a balloon kyphoplasty system is expensive for preparing the osteoporotic vertebral bone.

Therefore, we thought about a technique being simple and cheap. Performing a defined cavity in the vertebral body with a commercially produced thread cutter should have a positive effect on screw loosening in order to be augmented through the fenestrated screw. In our study concept, we compared monosegmental osteoporotic lumbar spine specimens divided in three groups with cement-augmented pedicle screws using the thread cutter, only cement augmented and without any augmentation. The focus is on the loosening behaviour of the three groups under continuous cyclic dynamic loading [36, 37]. An

increase in range of motion (ROM) during cyclic loading—not pull-out strength—was chosen as a parameter for loosening.

The goal of this study was to demonstrate whether the creation of a cavity with subsequent cement augmentation has a positive effect on screw loosening.

Material and methods

Specimens and implants

A total of 18 fresh human motion segments from 16 osteoporotic lumbar spines in an age range between 50 and 87 years with a bone density between 35.5 and 79.8 mg Ca-HA/cm³ were distributed into three equal groups with matched age, bone density. Each group consisted of two lumbar spinal segments L2–L3, L3–L4 and L4–L5 equally distributed. Another selection criterion, with the help of x-rays, was a similar size of the vertebrae and the pedicles in order to allow the use of the same screw size with a diameter of 6.5 mm and a length of 45 mm.

All screws were polyaxially, cannulated and fenestrated with six holes in the distal third of the thread to allow augmentation with bone cement (KyphX®HV-RTM; Medtronic, Minneapolis, USA). The segments were bridged using a standard monosegmental internal fixator (Medtronic, Minneapolis, USA). The rigid screw connection of the fixator was achieved with two pre-bent longitudinal rods (5.5 mm in diameter, 50 mm in length) fixed in position with four locking screws.

Preparation and implantation

During preparation of the specimens, all osteoligamentous structures and the intervertebral disks were preserved [38]. Subsequently, the specimens were embedded in PMMA (Technovit 3040, Heraeus Kulzer, Wehrheim, Germany) for fixation in the testing machines.

Three different surgical techniques for implanting pedicle screws in human osteoporotic lumbar vertebrae were compared:

In a **cavity-augmented group** (with cavity and with cement in the vertebral body), a special thread cutter with a diameter of 6.5 mm and an extendable blade, which can produce by turning the cutter a cavity with a of diameter 10.5 mm in the distal third of the pre-drilled hole. This cavity could be filled with bone cement to augment the screw in a standardized cement volume (Fig. 1).

In an **augmented group** (without cavity and with cement in the vertebral body), the screws were augmented with a standard cement augmentation using the experimental procedure based on the same principle as in the cavity-augmented

Fig. 1 Schematic lateral view of the surgical procedure in the cavity-augmented group

group, but an ordinary thread cutter with a diameter of 6.5 mm was used before inserting the bone cement to guarantee the same study conditions (Fig. 2).

Fig. 2 Schematic lateral view of the surgical procedure in the augmented group

For both cement augmentation, syringes were filled with 1.8 ml of bone cement (KyphX®HV-RTM; Medtronic, Minneapolis, USA), to ensure that 1.5 ml of bone cement can be injected as an anchoring medium between screw and bone (the rest remained in the screw core).

In a **control group** (without cavity and without cement in the vertebral body), also an ordinary thread cutter with a diameter of 6.5 mm was used (Fig. 3).

After the implantation of the screws, the fixator rods were mounted and the correct position and the depth of cavities were checked by CT scanning corresponding to the "up-and-in" method according to Krag et al. [39].

Test procedure

Flexibility tests were performed in a custom-made spine loading simulator in the intact state, directly after implantation, and after different steps of dynamic loading (Fig. 4a) [40]. The specimens were loaded with pure moments of ± 3.75 Nm (recommended for osteoporotic specimens) in right/left lateral bending, flexion/extension and left/right axial rotation without follower load [38]. During loading, the specimens were allowed to move unconstrained in the five uncontrolled degrees of freedom. Two load cycles were applied for preconditioning, and the evaluation was carried out from the third cycle.

For **cyclic loading**, each of the specimens was mounted in a dynamic material testing machine (Instron 8871, Instron Wolpert GmbH, Darmstadt, Germany) (Fig. 4b) [41, 42]. During cyclic loading, the specimens turned clockwise around its own axis (360°/min) and were loaded sinusoidally

Fig. 3 Schematic lateral view of the surgical procedure in the control group

Fig. 4 **a** The custom-made spine tester with a plastic model for the flexibility tests and an exemplary load–displacement curve of an evaluated specimen. **b** The dynamic material testing machine with a plastic model for the cyclic loading tests

between 100 and 600 N with a lever arm of 0.03 m and a frequency of 5 Hz.

With this set-up, the specimen was turning around its axis clockwise and therefore passed through all positions, starting from flexion into more and more lateral bending to the left until it reaches extension (this point of time is presented in Fig. 4). Then, it continues more and more in to lateral bending to the right until it finally reaches flexion again. This further continues until the number of cycles has been reached.

Loosening of the implants was to be examined and evaluated on the basis of changes in ROM. Both range of motion (ROM) and neutral zone (NZ) of each specimen were normalized to the individual ROM value directly after implantation (100%). Normalization was carried out in order to quantify the effect after cyclic loading and to simplify comparability with regard to the primary stability directly after implantation.

ROM and NZ in the three tested groups were investigated and compared directly after implantation and after 20,000, 40,000, 60,000 and 100,000 loading cycles [41, 42]. In reality, 100,000 load cycles correspond to a load over a period of 3 months in the elderly [42].

Throughout the entire experiment, the specimens were kept moist with saline-soaked gauze [43].

Cement distribution

Cement distribution and the environment of the cement–screw complex in the vertebral body were checked by CT-scanning before and after cyclic loading. The CT sequences were analysed using reconstruction software (Amira® 5.2.2.).

The volume of the cement, which surrounds the screw, was quantified using the CT images. Since it was difficult to distinguish between the gray values of the isolated cement and screw, first the combined volume of the cement and fixation device was segmented. Then, the volume of the isolated fixation device (without cement) was subtracted to finally gain only the cement surrounding the screw. The

volume of the isolated fixation device ($12,066 \pm 161 \text{ mm}^3$) was obtained from the control group.

Statistical analysis

For statistical analysis, we compared only primary stability with the state after 100,000 cycles.

The Wilcoxon signed-rank test was used within each group. The Kruskal–Wallis test was used between the groups. The cement distribution of the two augmented groups was analysed with the Mann–Whitney U-Test. The level of significance was $p \leq 0.05$, since we could not assume a normal distribution of measurement results with a sample size of $n = 6$ specimens per group. While this study was explorative, the p values were not corrected for multiple comparisons and therefore they only indicate trends.

The intermediate steps after 20,000 and 40,000 and 60,000 load cycles were evaluated only in order to detect a potential failure of the tested pedicle screws.

Results

Range of motion and loosening behaviour

Implantation of the fixator stabilized the bridged segments in each of the three motion planes in all groups compared to the intact state and cyclic loading increased continuously, in most cases significantly, the ROM, representing a strong trend of screw loosening (Figs. 5, 6, 7). In general, the increase during flexion/extension and lateral bending was greater than during axial rotation.

In flexion/extension, the ROM increased by 89% for the cavity-augmented group and 95% for the conventionally augmented group, which was much less for both than compared to the non-augmented control group with a nearly twofold increase by 173% (Fig. 5).

In lateral bending, the ROM increased even more by 101% for the cavity-augmented group and 102% for the

Fig. 5 Comparison of normalized ROM values in % (median and ranges) at ± 3.75 Nm of the three groups ($n=6$) after each test cycle in flexion/extension. $*p \leq 0.05$

Fig. 6 Comparison of normalized ROM values in % (median and ranges) at ± 3.75 Nm of the three groups ($n=6$) after each test cycle in lateral bending. $*p \leq 0.05$

conventionally augmented group, which was also much less than in the non-augmented control by 169% (Fig. 6).

In axial rotation the ROM the loosening effect seems to be fairly low for all groups, almost none for the augmented groups and slight but still significant for the non-augmented control by 54% (Fig. 7).

Interpreting these results, there seems to be a slight trend for less screw loosening for the cavity-augmented compared to the augmented group and a clear trend for superior conditions for the augmented groups compared to the non-augmented control group. However, these differences were

statistically not significant probably due to the low number of tested specimens.

Cement distribution

The evaluation of the CT scans with the implanted specimens showed in the cavity-augmented group an average cement volume of $4245 \pm 1207 \text{ mm}^3$ surrounding the four screws in each treated segment and in the augmented group an average cement volume of $3690 \pm 1104 \text{ mm}^3$ (Table 1). The differences were statistically not significant.

Fig. 7 Comparison of normalized ROM values in % (median and ranges) at ± 3.75 Nm of the three groups ($n=6$) after each test cycle in axial rotation. * $p \leq 0.05$

Table 1 Single values with mean and standard deviation of the injected cement volume from the cavity-augmented and the augmented group

Cavity-augmented group	Specimens	1305 (L2–L3)	1498 (L2–L3)	1243 (L3–L4)	1302 (L3–L4)	288 (L4–L5)	1137 (L4–L5)	Mean $\pm$ SD
	Cement volume in mm^3	3593	2512	5423	4151	5792	4000	4245 ± 1207
Augmented group	Specimens	1097 (L2–L3)	1164 (L2–L3)	718 (L3–L4)	1499 (L3–L4)	1496 (L4–L5)	1498 (L4–L5)	Mean $\pm$ SD
	Cement volume in mm^3	4753	3097	4840	4384	2788	2278	3690 ± 1104

The implanted specimens of the cavity-augmented group demonstrated a more equal cement distribution around the tip of all screws in the same vertebrae (Fig. 8). This is not necessarily the case for all specimens in the augmented group, where sometimes screw tips have less or almost no cement (e.g. specimen 1164 and 1496).

It was further observed that loosening due to cyclic loading affected the entire cement–screw construct in the vertebral body but did not occur between screw and cement.

Discussion

This study showed a slight trend for less screw loosening when a screw is augmented in a prepared cavity, compared to when cement is only injected through a cannulated screw. But there is a clear trend of superior conditions for both augmented groups compared to the non-augmented control group.

The obvious advantage of the cavity seems to be a more equal cement distribution around each screw tip in the individual vertebra. Therefore, a more standardized cement volume can be expected. However, the blade, which creates the

cavity, may smoothen the cement–bone interface because the bone material rubbed off is squeezed into the hollow spaces in the cancellous bone of the vertebra and creates a defined cement border. Therefore, it seems that also the augmented screws group may have an advantage, because the indentation of the cement in the cancellous bone may be more pronounced. This explains that the difference of the results is not as clear as maybe expected. As a quintessence, the effect of the cavity showed a slightly better fixation, which was not statistically significant between the groups.

Our findings are in line with clinical trials with similar procedures, e.g. a kyphoplasty for screw augmentation confirmed better results concerning loosening rates [35]. In biomechanical studies, satisfactory results have been achieved with the use of bone cement for screw augmentation in the treatment of osteoporotic spines [27–31]. PMMA-assisted vertebroplasty showed that augmentation of osteoporotic vertebrae can significantly increase pedicle screw pull-out forces to levels exceeding the strength of cortical bone [29]. It could also be shown that pull-out strength of cemented pedicle screws was up to 250% higher than that of non-cemented screws in control groups [8]. Other evaluations were able to demonstrate that the

Cavity-augmented group

Augmented group

Fig. 8 Reconstruction from CT scans of cement distribution around the screw tips of the cavity-augmented and the augmented group

frequency of screw pull-out and pedicle defects decreased when cement-augmented screws were used [32, 33].

The literature also includes several studies on the strength of pedicle screw anchors in human osteoporotic vertebral bodies, but most of these studies are confined to the pull-out strength of screw fixation systems [8, 15, 27–29]. In this context, pull-out strength is regarded as an indicator of a temporarily stable screw–bone connection [7, 15–17, 20, 29, 44].

However, this kind of test only considers the primary stability and does not necessarily simulate realistic loading conditions which act on the screws.

In the meantime, more and more dynamic test methods have been established, such as toggle tests or more sophisticated set-ups by applying bending moments to single screws, which were implanted in isolated vertebrae [25, 31, 34, 45–47].

Bostelmann et al. performed a study with the purpose to assess the fixation effects of different augmentation techniques (including percutaneous cement application) and to investigate pedicle screw loosening under physiological cyclic cranio-caudal loading with single vertebral bodies. By the cranio-caudal cyclic loading, failure of the pedicle screws occurred by screw cut through the superior endplate and the characteristic "windshield-wiper effect", typically observed in clinical practice, could be reproduced [31]. Liebsch et al. established with their novel mechanical testing model a promising method for the standardized testing of pedicle screws regarding screw loosening for

cases where the screw rotates around a point close to the screw entry point [47].

In this study, we used a more complex cyclic loading set-up with monosegmental cadaver specimens and complete instrumentation of fixators as already used in a previous study [37]. The specimens were tested at the start of the test in flexion. By rotating around its axis, this was continuously merging in lateral bending, afterwards merging into extension, then into lateral bending, finally coming back to flexion and so on. This mimics more closely the physiological conditions rather than a pull-out test or a toggle test with single screws.

Nevertheless, this method has its limitation. Patients probably move more after a fixation than simulated with the applied number of load cycles.

By using this cyclic testing method, however, we were able to observe a continuous screw loosening in all groups over 100,000 load cycles. These 100,000 cycles were able, because we applied the bending moments with a frequency of 5 Hz. This frequency was chosen to limit the total testing time to about 8 h, including preparation, the necessary radiographs and several flexibility tests [43]. With more load cycles, autolysis processes would have impaired the results. However, this number of load cycles correspond to an in vivo time period of 5–6 weeks for a young person and perhaps 3 months for an elderly person [41, 42]. A frequency of 5 Hz does not represent the situation in daily life, because we walk with roughly 1 Hz and we move during our daily activities, which results in higher bending moments with a

much lower frequency in a very arbitrary way. Therefore, we do not allow relaxation of the bony structures as this might occur in vivo. Furthermore, we cannot simulate healing processes with an in vitro experiment. However, we believe this is an acceptable compromise as it rather represents a worst-case scenario.

In summary, this study demonstrated that creating a cavity at the tip of a screw may guarantee a more equal cement distribution of each screw in the same vertebra. However, augmentation only through a cannulated screw is almost equivalent, if care is taken that enough cement volume can be pushed out around the tip of the screw.

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Compliance with ethical standards

Ethical approval The study was approved by the ethical committee board of the University of Ulm (No. 227/12).

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