Biomechanical effect of bone cement augmentation on rotational stability and pull-out strength of the Proximal Femur Nail Antirotation™

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ABSTRACT

Introduction: After surgical treatment of osteoporotic hip fractures, complications such as implant cut-out are reported to be high and implant failure often is associated with poor bone quality. As augmentation is reported to enhance implant anchorage, the aim of our study was to investigate the effect of bone cement augmentation on the rotational stability and the pull-out resistance of the Proximal Femur Nail Antirotation™ (PFNa) blade.

Materials and methods: A total of 18 fresh-frozen femoral heads (mean age 68 years, standard deviation (SD) 8.2) were scanned with quantitative computed tomography (qCT) for bone mineral density (BMD) measurements and instrumented with a PFNa blade. Nine specimens were augmented with a mean volume of 4.4 ml Traumacem V+. After cement consolidation, the blade was rotated for 60° for the rotational test. Subsequently, the blade was extracted from the specimens. Force, torque, displacement and angle were recorded constantly.

Results: In the rotational test, the mean maximum torque in the augmented group (17.2 Nm, SD 5.0) was significantly higher (p = 0.017) than in the non-augmented group (11.7 Nm, SD 3.5). The pull-out test also yielded a significant difference (p = 0.047) between the augmented (maximum pullout force: 2315.2 N, SD 1060.6) and the non-augmented group (1180.4 N, SD 1171.4).

Discussion: Augmentation of femoral heads yielded a significantly superior rotational stability, as well as an enhanced pull-out resistance, compared to the non-augmented state. However, the higher the BMD of the specimens, the lower was the effect of augmentation on the rotational stability. Therefore, augmentation can be a good clinical tool to enhance implant anchorage in osteoporotic bone.

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With increasing age, the incidence of proximal femur fractures is rising. Between the age of 65 and 74 years, the incidence of proximal femur fractures amounts to 0.11% per year, while it is 1.32% over the age of 85 years.1

Despite correct operative treatment, the postoperative complication rate concerning proximal femur surgery was found to be very high. Taking a wide variety of patient conditions and different implant types into consideration, the complication rates in the literature are heterogeneous and range between 0.6% and 14.7%.2–5

The most frequent complications are screw migration with possible varus collapse, screw cut out, the Z-effect, implant breakage or lateral protrusion of the implant.6,7 Due to a frequently documented osteoporotic condition of the patient, one of the most common causes for osteosynthesis failure, with a rate of up to 10.6%,7 is the cutting out of the implant through the cortical bone of the femoral head and neck. This leads to revision surgeries and increased morbidity of the patient.4,8 This complication is further reported to be caused by inadequate reduction, that is, varus malalignment with a caput–collum–diaphysis (CCD) angle >125°, repeated drilling,8 implant malplacement and rotational forces on the implant in the femoral head.2,3,9

Different studies showed beneficial effects of a helical-shaped blade on the cut-out resistance. Mereddy et al. found a cut-out rate of only 3.6% for the Proximal Femur Nail Antirotation™ (PFNa) blade in a clinical study with 62 patients.10 Windolf et al. found significantly less implant migration of the dynamic hip blade compared to the dynamic hip screw (DHS) and explained the better anchorage by volumetric compaction of the trabecular structure during blade insertion.11 Also Al-Munajjed et al. reported a significantly better rotational stability for the PFNa helical blade, compared to the PFN screws. However, pull-out stability was significantly decreased due to destruction of the spongy structure occurring during rotation. Apart from that, the authors described, that an eccentric position of the implant increases the lever arm during daily activities and may cause rotational failure of the implant.12

In various studies, the effect of implant augmentation with cement on fixation failure has been investigated. Augat et al.
showed a significantly reduced total displacement and an enhanced rotational stability of simulated pertrochanteric fracture fixation after augmentation of the osteosynthesis material with low-viscosity polymethyl-methacrylate (PMMA) in cadaveric femora. Stoffel et al. augmented bone via a second canal cranial to the DHS in a pertrochanteric fracture model and reported a significantly higher failure load. Also, von der Linden et al. reported a larger number of cycles until failure after jet lavage and low-viscosity PMMA augmentation of the DHS.

The PFNa helical blade provides an enlarged bone–implant interface that leads to enhanced anchorage especially in osteoporotic bones. The rotation of the neck–head fragment, being one cause for implant failure, is stabilised. However, it was shown in a biomechanical setup that after rotation of the implant in the femoral head, the pull-out resistance of the implant was reduced. A beneficial effect of cement augmentation for implants with screws, like the DHS, was already reported. However, the different geometry of the PFNa with its helical-shaped blade provides more proneness to failure after rotation. Therefore, the aim of this study was to investigate the influence of cement augmentation, especially on the rotational stability of the PFNa blade, and also on its pull-out resistance.

Materials and methods

Implant

The PFNa blades (Synthes GmbH, Oberdorf, CH, Germany) used to investigate the effect of bone cement augmentation on rotational and pull-out stability in human femoral heads are made of titanium. The helical-shaped blade is perforated with three radial outlet ports on each flank of the blade, allowing controlled application of the cement through the blade. For clinical use, perforated blades with a length of 75–130 mm are available.

Specimens

For biomechanical testing, 18 fresh-frozen human femoral heads with a mean age of 68 years (standard deviation (SD) 8.2, range 47–80) and a female-to-male ratio of 6 to 12 were used. Specimens were obtained from the local anatomy department. To scan for relevant pathologies, the specimens were subjected to computed tomography (CT) scans (LightSpeed VCT, GE Healthcare, Milwaukee, WI, USA). To determine bone mineral density (BMD) of the specimens, a density phantom was included in the CT scan (European Forearm Phantom, QRM GMBH, Möhrendorf, Germany). Hounsfield values of three regions of interest (ROIs) were measured using the JVision software package (JVision, Version 3.3.16, Agfa, Belgium) and converted into mg cm\(^{-3}\). The ROIs were measured in a planar three-dimensional (3D) reconstruction of the CT scans with two planes aligned with the centre of the femoral neck axis. The first ROI was placed perpendicular to the two other axes as a best-fit circle in the trabecular bone. The diameter was diminished by 15% and placed at the cartilage bone border. The second and third ROIs were placed 5 mm above and below the cartilage bone border. For further analysis, the mean BMD of the three regions of interest was used. The specimens were assigned to two groups with equal BMD distribution (augmented \(n_{\text{aug}} = 9\) and non-augmented \(n_{\text{non}} = 9\)).

Testing procedure

The femoral heads were stored at −20 °C and thawed overnight at 6 °C prior to biomechanical testing. Throughout the experiments, the specimens were kept moist with saline solution. Prior to testing, all soft tissues were removed by means of surgical preparation. The specimens were embedded in a conical-shaped mould using polymethyl-methacrylate cement (PMMA, Technovit 3040, Heareus Kluzer, Werheim/Ts, Germany). The cone axis and the femoral neck axis were aligned. A plane surface of the femoral neck was created with a handsaw perpendicular to the embedding with 2 cm of the neck remaining. Subsequently, the blade placement was predefined in a centre–centre position with a Kirschner wire (K-wire) under image intensifier control (BV 25, Philips, Netherlands). The PFNa blade was then inserted over the K-wire with a servohydraulic testing machine (MTS, 858Mini-Bionix, Erie, MN, USA) and the maximum insertion force was recorded. Correct blade positioning with a tip-apex distance of 8–10 mm and a complete enclosure of cortical bone around the blade threads were verified under image intensifier control (Fig. 1a). The locking mechanism of the blade was tightened according to the manufacturer’s guidelines.

The femoral heads from the augmentation group were then augmented with Traumacem V+ (Synthes GmbH, Oberdorf, CH, Germany) as recommended by the manufacturer’s manual. Augmentation was performed in situ through the placed cannulated blade. Three cement outlet holes are positioned in core of the four blade wings. Generally, it was aimed to augment with 4–5-ml cement (Fig. 1b), if this was permitted by the specimen condition. First, 1.5 ml was placed anteriorly through the side-opening cannula, then the cannula was rotated for 180° and again 1.5 ml of cement was administered. The cannula was withdrawn from the blade for 1 cm and 1 ml of cement was injected to the medial and lateral side. This procedure aimed to achieve a circular placement of cement around the blade. After augmentation, the cement was allowed to consolidate at room temperature for at least 40 min.

For biomechanical testing, the embedded specimens were placed press fit in a custom–made, conically shaped mounting unit and then rigidly fixed to the base of the testing machine (Fig. 2). The blade was fixed to the actuator with a custom-made mounting jig. The rotational test was performed under displacement control, with an actuator displacement of 60° in counter-clockwise direction and a speed of 1° s\(^{-1}\). The rotational test was performed with an initial preload of 100 N. Subsequent to the rotational test, the pull-out test was performed on the same specimen, with a speed of 1 mm s\(^{-1}\), until the whole implant was withdrawn from the femoral head. Time, displacement, angle, force and torque were recorded with a sampling rate of 50 Hz throughout the experiments.

Statistical analysis

For statistical analysis, SPSS 15.0 (version 15.0.1, SPSS Inc.) was used. Data were tested for normal distribution with a Kolmogorov–Smirnov test; homogeneity of variances was tested using a Levene test. An analysis of variance (ANOVA) was used to test for group homogeneity. For comparison of the two groups, a \(t\)-test (for normally distributed data) or a Mann–Whitney \(U\)-test (non-normally distributed data) was performed. Coherencies between investigated parameters were tested with a bivariate Pearson correlation. The level for significant results was set to \(p < 0.05\).

Results

The distribution of BMD and insertion force of the two different groups are displayed in Table 1. There was no statistically significant difference between the two groups (ANOVA, BMD \(p = 0.931\), insertion force \(p = 0.861\)).

Mean cement volume used for augmentation was 4.4 ml (SD 1.1, min. 2 ml, max. 5.5 ml). The cement volume applicable to the femoral heads varied according to the BMD of the specimens, revealing a significant correlation (\(r = 0.533, p = 0.023\)).
Rotational test

Maximum torque values per experiment were used for further analysis. The mean maximum torque in the augmented group was 17.2 Nm (SD 5.0, range 11–27.8 Nm). In the non-augmented group, the mean maximum torque amounted to 11.7 Nm (SD 3.5, range 5.9–17.2 Nm). The difference between the two groups was statistically significant ($t$-test, $p = 0.017$). The results are listed in Table 1. A graph displaying the results of the rotational test is shown in Fig. 3a.

Pull-out test

The mean maximum pull-out force during pull out, subsequent to the rotational test, was 2315.2 N (SD 1060.6, range 798.6–4125.3 N) in the augmented group and 1180.4 N (SD 1171.4, range 254.2–3468.6 N).

Table 1. A graph displaying the results of the rotational test is shown in Fig. 3a.

Table 1. Distribution of gender, BMD, age and insertion force in the augmented and the non augmented group and results of the rotational and pull-out test (SD – standard deviation).

<table>
<thead>
<tr>
<th>Gender distribution</th>
<th>Augmented group</th>
<th>Non augmented group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Female</td>
<td>4</td>
</tr>
<tr>
<td>Age</td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>BMD in mg/cm³</td>
<td>1292.1</td>
<td>50.9</td>
</tr>
<tr>
<td>Insertion force in N</td>
<td>3451.7</td>
<td>1292.1</td>
</tr>
<tr>
<td>Torque in Nm</td>
<td>17.2</td>
<td>5.0</td>
</tr>
<tr>
<td>Pull-out force in N</td>
<td>2315.2</td>
<td>1060.6</td>
</tr>
</tbody>
</table>

Operative therapy after proximal femur fractures in patients with osteoporosis is associated with a high number of secondary implant displacements to the point of cut-outs. Our study showed a beneficial effect of cement augmentation, resulting in a superior rotational stability and an enhanced pull-out resistance of the PFNa compared to the unaugmented state. Mean values of maximum torque and maximum pull-out force for the non-augmented group (11.7 Nm and 1180.4 N) are comparable to the results of Al-Munajjed et al. with 12 Nm and 1600 N, respectively, for a rotational and a pull-out test of the PFNa. Stoffel et al. investigated the effect of augmentation on the DHS with a superiorly placed augmentation canal. They reported similar trends; however, direct comparison of the values is not possible due to the different augmentation techniques and a different fixation principle of the implant.

The cement distribution was better in femoral heads with a low BMD. However, due to the small number of specimens, a cut-off value could not yet be found and has to be investigated in further studies. Moreover, as shown in Fig. 4, augmentation yields a benefit, especially in osteoporotic specimens. Therefore, the indication for augmentation is recommended to be restricted to a collective of patients with diagnosed osteoporosis. In this context, there is an evident need for a simple and reliable pre- or intra-operative determination of local bone quality. One promising approach for this problem might be intra-operative measurements of bone strength as reported by Suhm et al. Stoffel et al. developed an algorithm recommending screw augmentation over a tip-apex distance of 25 mm. As a preoperative screening tool, quantitative computed tomography (qCT) measurements in the femoral head could be considered. Furthermore, plain radiographic indices such as the cortical index might give a preoperative overview of bone quality. Moreover, in case of augmenting bone with a high BMD the risk of complications such as embolism might increase due to higher pressure during cement application. This pressure could further be reduced by jet lavage prior to augmentation, to reduce the resistance in the bone as discussed by Benneker et al. for vertebral bodies. Irrigation also leads to a more homogeneous distribution of the cement in the vertebral body and the femoral head. However, two studies note that high-pressure irrigation itself might lead to fat embolism and destruction of the trabecular structure.

Although bone cement is widely used to enhance screw purchase, it yields some disadvantages such as not being an absorbable material or exhibiting exothermic reactions during
hardening. The possible alternative of calcium phosphate cement, indeed, yields the advantage of no heat generation. However, its inferior mechanical properties concerning shear and tension do not make calcium phosphate a reasonable alternative in implant augmentation, as especially shear is occurring at the implant–bone interface. Additionally, anteriorly and medially oriented shear forces are occurring in the proximal femur.21,22 Regarding heat generation after cement augmentation, Boner et al. showed that no critical temperatures are occurring at the bone–cement interface up to a cement layer thickness of 5 mm. Additionally, up to a cement volume of 6 cc no critical temperatures were recorded outside the cement.23 The geometry of the implant material is important as well, as the implant is capable of absorbing some of the generated heat.24 Also, trabecular blood circulation provides a good heat convection with the surrounding tissues.25

One limitation of the study might be the test set-up performed as a pull-out test, as it is directly opposed to the cut-out of the implant material. However, the failure mechanism for tension is the same as for compression as long as the implant is anchored in trabecular bone. Additionally, by using a compression test and pushing the blade through the cortical bone, a variable, not being of immediate concern for cut-out, would have been added to the experiment. The use of a head-only model was already described by von der Linden et al. and has the advantage of eliminating factors such as fracture sintering or proximal femur bending not being detrimental to cement setting or mechanical properties.15

When addressing augmentation of implants, one major concern is a potential revision surgery. According to von der Linden et al., potential postoperative complications necessitating revision surgery should not yield any complications as the salvage procedure usually is total joint replacement.15 In the case of the presented study, the whole cement remained inside the femoral head and was not withdrawn from the specimen during blade extraction. It is assumed that also joint-preserving revision surgeries can be conducted without problems, as the cement inside the bone might allow a more firm anchorage of other implants than in osteoporotic bone only.

A topic to be addressed in further studies is the deliberate placement of the augmentation material in the femoral head. A cannulated implant, as used in the presented study, has the advantage of correct definite blade placement prior to augmentation; as reported by Harrington, cement placement through the drill hole yields the risk of exuding cement. Cement might settle at the fracture site and interfere with periosteal bone healing. Stoffel et al. reported an increased risk of cement penetration into the hip joint, leading to severe clinical complications such as rapid osteoarthritis onset.14

Administering the cement through the loosened implant, as performed by some authors,15,21,27 could again induce high pressure and increase the probability of complications. However, some authors placed the cement around the whole implant, as it was done in the presented study. Stoffel et al. reported very promising results with cement placed superior to a DHS, increasing the failure load by 42%. To our knowledge, it is not yet investigated if cement placement at a selected location might further enhance implant purchase. This issue has to be addressed in further studies.

Lindner et al. analysed clinical experiences with different augmentation techniques in a literature review ([28], citing [29–33]). They described lower failure rates after PMMA augmentation with no significant osteonecrosis rates. For calcium phosphate cement, an increased stability with less varus angulation was reported. Re-operation rates, however, were higher in the augmented group and causes for re-operation shifted from loss of reduction to non-union and avascular necrosis. Additionally, lower pain scores and a better Short Form (36) Health Survey (SF-36) score were found.

To gain valid information on the effectiveness of PFNa augmentation in osteoporotic patients, prospective clinical studies have to be performed in the future.

Conclusion

The results of the presented study show a superior rotational stability as well as an enhanced pull-out resistance of the augmented PFNa blade compared to the non-augmented state. This is especially verifiable in osteoporotic specimens, as the benefit of augmentation decreases with rising BMD. Therefore, from a biomechanical point of view, augmentation of the PFNa blade can be a good clinical tool to enhance implant anchorage, as long as the indication is restricted to a collective of patients with osteoporosis.

Conflict of interest statement

The authors have no conflicts of interest to declare.

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