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Is bone-cement augmentation of screw-anchor fixation systems superior in unstable femoral neck fractures? A biomechanical cadaveric study

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ABSTRACT

Objectives: Improved fixation techniques with optional use of bone cements for implant augmentation have been developed to enhance stability and reduce complication rates after osteosynthesis of femoral neck fractures. This biomechanical study aimed to evaluate the effect of cement augmentation on implant anchorage and overall performance of screw-anchor fixation systems in unstable femoral neck fractures.

Methods: Ten pairs of human cadaveric femora were used to create standardized femoral neck fractures (Pauwels type 3 fractures; AO/OTA 31-B2) with comminution and were fixed by means of a rotationally stable screw-anchor (RoSA) system. The specimens were assigned pairwise to two groups and either augmented with PMMA-based cement (Group 1, augmented) or left without such augmentation (Group 2, control).

Biomechanical testing, simulating physiological loading at four distinct load levels, was performed over 10.000 cycles for each level with the use of a multidimensional force-transducer system. Data was analysed by means of motion tracking.

Results: Stiffness, femoral head rotation, implant migration, femoral neck shortening, and failure load did not differ significantly between the two groups ($p \geq .10$). For both groups, the main failure type was dislocation in the frontal plane with consecutive varus collapse). In the cement-augmented specimens, implant migration and femoral neck shortening were significantly dependent on bone mineral density (BMD), with higher values in osteoporotic bones. There was a correlation between failure load and BMD in cement-augmented specimens.

Conclusion: In screw-anchor fixation of unstable femoral neck fractures, bone-cement augmentation seems to show no additional advantages in regard to stiffness, rotational stability, implant migration, resistance to fracture displacement, femoral neck shortening or failure load.

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Introduction

The treatment strategies for femoral neck fractures are either arthroplasty or osteosynthesis, depending on several factors, such as the patient's age, functional requirements and bone quality [1,2]. For young as well as older adults with good bone stock and undisplaced fractures, head-preserving treatment is preferred, as it is less invasive and associated with good functional outcomes [1–4]. However, the best treatment of choice for unstable fractures remains controversial, particularly in older patients. Despite various improvements in the implant design, insufficient fracture fixation with the use of sliding hip screws (SHS) remains a common complication in the treatment of femoral neck fractures with failure rates of up to 37% within two years [5]. The anchorage of the lag screw within the femoral head plays a crucial role for stability of fixation [6]. Biomechanical studies have shown that the pertinent benefit of a helical blade lies in its rotational stability [7–9]. However, clinically relevant lateral blade migration has also been reported [10], thus restricting the feasibility of intraoperative interfragmentary compression. The rotationally stable screw-anchor (RoSA, Koenigsee Implants, Allendorf, Germany) system is supposed to combine the pull-out strength and compression capability of a lag screw with the improved load ability and rotational stability of a blade [11–13]. In a recent biomechanical study, RoSA showed significantly better performance than SHS fixation with regard to ultimate load at failure and number of cycles survived [14]. Moreover, the former provided higher stiffness and rotational stability as well as less fragment displacement and femoral neck shortening than the latter.

In recent years, bone-cement augmentation strategies have been discussed extensively as a means of enhancing implant anchorage and biomechanical competence as well as reducing the prevalence of failure. In a systematic review on trochanteric fractures [15] and in a multicentre randomized controlled trial [16], no clear improvements in functional outcomes were detected. Several biomechanical studies show some advantages of cement applications in proximal femur fracture fixations [17–22], especially in cases of eccentric implant positioning [17] or low bone mineral density [18]. As a rule, the benefit of additional augmentation techniques depends on both the fracture morphology and the stability of the implant system itself and hence on the stability of the bone/implant construct [23].

Therefore, the aim of this biomechanical study was to evaluate the effect of bone-cement augmentation on the implant anchorage and overall biomechanical performance of a rigid screw-anchor fixation (RoSA) of Pauwels type-3 unstable femoral neck fractures (Fig. 1).

Two central questions were addressed in the present study:

1. Does bone-cement augmentation of rigid systems with high implant stability make any difference in terms of stiffness, load at failure or failure mode?
2. Can differences in implant anchorage be detected and characterized by fragment displacements, femoral head rotation, implant migration or femoral neck shortening?

Materials and methods

Specimen preparation

Ten pairs of fresh-frozen (−20 °C) human cadaveric femora from six female and four male donors aged 74 years ± 14 years (mean ± standard deviation [SD], range 41–87 years) were used.

First, the specimens were defrosted over 24 h at room temperature prior to stripping of all surrounding soft tissue. Radiological examination was performed to exclude any radiographic pathologies and previous fractures, followed by assessment of the bone mineral density (BMD) by dual-energy X-ray absorptiometry (DEXA) (Table 1).

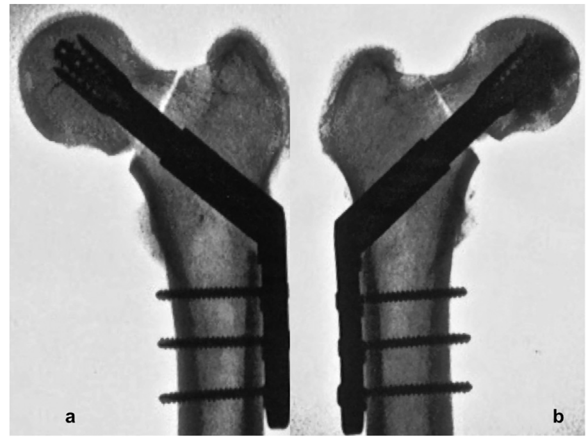

Fig. 1. X-Ray control after surgery. Fig. 1a: Cement-free RoSA; Fig. 1b: Cement-augmented RoSA.

Second, an unstable femoral neck fracture Pauwels 3 type (AO/OTA 31-B2) was simulated in all specimens using an oscillating saw (HB-740 with segmental saw blade HB 500, KUGEL Medical GmbH, Regensburg, Germany). The fracture line was set with 20° angulation to the femoral shaft axis according to the protocol of Windolf et al. [7]. In addition, 30° distal and 15° posterior wedges were cut to resemble comminution (Fig. 2). A consistent fracture setting in all bones was guaranteed by use of a digital protractor (Pollin Electronic GmbH, precision 0.3°, Pförring, Germany) during sawing with a fixed adjustable angulation.

Third, all (fractured) femora received RoSA fixation with a three-hole 129° side plate (Koenigsee Implants, Allendorf, Germany). The implantation was performed according to the manufacturer's guidelines with implant centre-centre positioning in the femoral head and neck and a tip-apex distance (TAD) of less than 25 mm, controlled radiographically by means of a C-arm (Philips BV 300, Philips Medical Systems, 5680 DA Best, The Netherlands) [24]. Hydration of the bones during the instrumentation was guaranteed by continuous sprinkling with 0.9% NaCl solution.

Fourth, the femora were assigned pairwise to two study groups with equal numbers of left and right specimens. Implant augmentation with the use of polymethylmethacrylate (PMMA) based bone cement (V-FIX DH, G-21, San Possidonio, Italy) was performed in Group 1 (cement-augmented RoSA) as described below, whereas the femora in Group 2 (cement-free RoSA; control) were left without such augmentation (Fig. 1). A semi-viscous bone cement was chosen in agreement with previous studies [17,18]. Augmentation was performed by following the manufacturer's manual with the use of a special cement-application system (SPASY™, Koenigsee Implants, Allendorf, Germany). At room temperature, 5 ml syringes were completely filled with freshly compounded bone cement and subsequently attached to the end of the application device for injection of 3 ml cement into the femoral head region through the cannulated screw of the implant system. The cement distribution within the cancellous bone structure was monitored under C-arm visualization. Cement hardening was conducted at room temperature for at least 40 min.

Fifth, the shafts of all femora were cut 30 cm distally from the top of the greater trochanter. The distal end was then embedded in PMMA (Technovit 4006, Heraeus Kulzer GmbH, Wehrheim, Germany) in accordance with previous study protocols [11,12,14] using 10 cm long cylinders.

Sixth, three infrared optical sensors (Nexonar, soft2tec GmbH, Rüsselsheim, Germany) were attached to the femoral head and shaft and the RoSA screw for motion tracking (Fig. 3).

Table 1
Implant location and bone mineral density (BMD).

	Total	RoSA cement-free	RoSA cement-augmented
Number (n)	20	10	10
Implant location (n)			
Right	10	5	5
Left	10	5	5
Bone mineral density (g/cm^2)	0.805	0.821	0.788
T-Score	-1.5	−1.4	−1.6

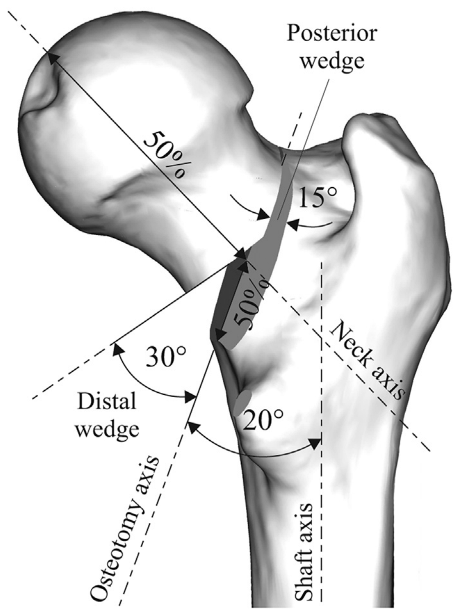

Fig. 2. Osteotomy template. Osteotomy was modified by the protocol of Windolf et al. [7] with a main osteotomy axis of 20° and additional wedges of 30° distal and 15° posterior to the femoral neck.

Biomechanical testing

Biomechanical testing was performed on a material-testing system (MTS 858 Min. Bionix II, MTS Inc., Eden Prairie, MN, USA). The test setup was adopted from a previous study [25] to mimic physiological loading during the human gait according to Bergmann et al. [26,27].

Each specimen was attached proximally to the machine actuator via a horizontal linear guide system for free mediolateral translation of the humeral head. Distally, each femur was fixed to the machine base in an upright orientation. The proximal load transfer to the femoral head was realized by means of two force transducers (U10 M,12.5 kN, HBM, Darmstadt, Germany; and SML, 4488 N, Interface, Tegernsee, Germany) acting in axial and mediolateral directions, respectively, through custom-made caps simulating the acetabular anatomy.

A preload of 100 N was applied prior to testing and then maintained throughout the test series to ensure permanent contact between the femoral fragments, corresponding to physiological conditions during the swinging phase [28]. Each femur underwent 10.000 cycles of simulated physiological loading at 1 Hz and four load steps, corresponding to previous in-vivo human gait measurements during the human gait of 75-year-old men weighing 73.3 kg [29]. Exemplified physiological loading profiles of the cycles in both directions are depicted in Fig. 4, while the peak axial forces of the cycles in each step (step 1: mean minus 2 standard deviations [SD] – 45.7 kg; step 2: mean minus 1 SD – 59.5 kg; step 3: mean – 73.3 kg; step 4: mean plus 1 SD – 87.1 kg) are presented in Table 2.

For the femora that were still intact after 10.000 cycles, a final destructive cyclic test was run at 1 Hz with progressive increase of the peak axial force by 1 N (with consecutive medio-lateral increase as well) after every loading cycle, starting at 2030 N. In accordance with previous studies, the failure criterion during the cyclic testing was defined as either vertical/axial fracture dislocation of more than 15 mm (in comparison with the initial

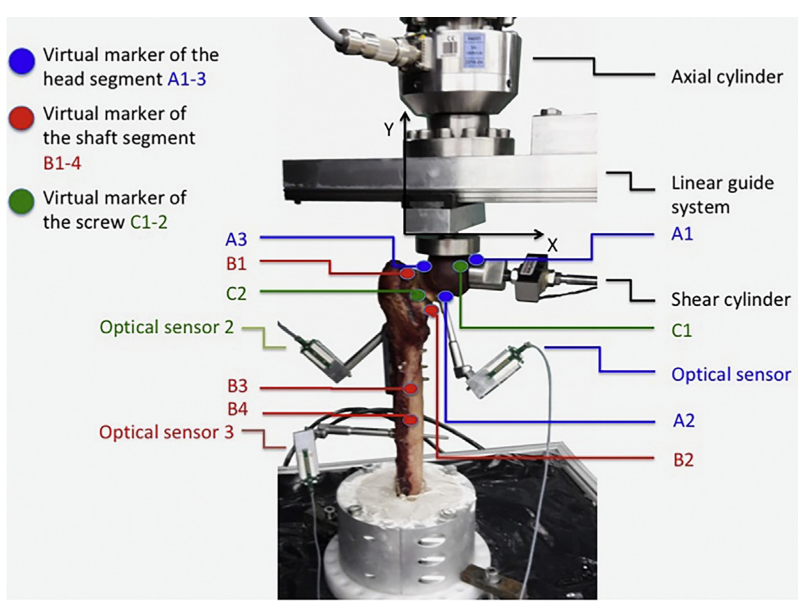

Fig. 3. Model of our new test rig and infrared-marker positioning over the femoral head, neck and shaft region to observe fracture movements during the test loading and changes of implant location.

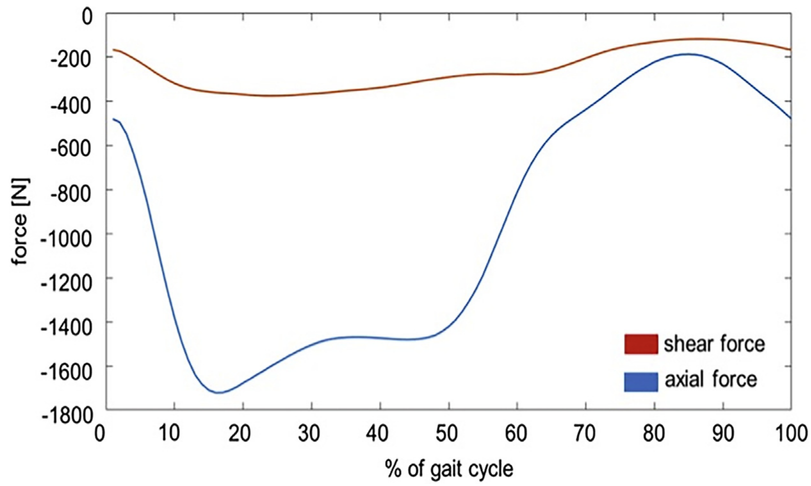

Fig. 4. Force-vector progression curve during simulated walking cycle.

Table 2
Loading set-up executed at all bones.

No. of load step	Subject's weight	Maximum axial force	Maximum medio-lateral force
1	45.7 kg	1070 N	270 N
2	59.5 kg	1390 N	330 N
3	73.3 kg	1710 N	390 N
4	87.1 kg	2030 N	450 N

specimen's state) or sudden axial force decrease by 30%, femoral shaft fracture, cut-out/cut-through and/or implant failure [11,12,14].

Data acquisition and analysis

Axial (vertical) displacement as well as axial and medio-lateral loads were collected from the machine controllers at 128 Hz. Moreover, based on the optical sensors attached to the specimens, nine virtual markers (VM) were defined on the femoral head, the shaft as well as the RoSA screw (Fig. 3), and their three-dimensional coordinates were tracked at 100 Hz to calculate rotational and translational interfragmentary movements as well as axial implant movements. The amount of data was reduced by its averaging to 10 mean loading gait cycles, with each one of them being representative of 1.000 test cycles. Following, construct stiffness, femoral head rotation, femoral neck shortening, implant screw migration and vertical femoral head displacement were calculated.

Femoral head rotation was evaluated around the screw axis. Implant migration was defined as the movement of the screw tip toward the femoral head surface along the screw axis (axial migration). Stiffness (N/mm) was recorded uninterruptedly at every cycle by correlating operating load to consecutive displacement of the femoral head region. The stiffness of each load step was interpreted after calculating the mean value of the first five cycles. To measure femoral neck shortening, the relationship between the virtual markers C1 and C2 was used, and the alteration in length of this section was calculated (Fig. 3).

Statistical analysis

Statistical analysis was performed using the SPSS software package (v. 25, IBM SPSS, Chicago, IL, USA). Normality of data distribution was checked with the Shapiro-Wilk test. The Wilcoxon Signed-Rank test was used for comparisons between the study groups. In addition, the Spearman test was applied to screen possible correlations of the outcomes with regard to BMD. Fisher's exact test was used to analyse failure load. The results were presented in terms of mean value and standard deviation. The level of significance was set at 0.05 for all statistical tests.

Results

BMD did not differ significantly between the two study groups, $p = .317$. Fig. 5 shows the distribution of the BMD among the used femoral specimens. Radiographic controls showed a centre-centre placement of all implants with a tip-apex distance of 18.1 ± 5.5 mm (mean $\pm$ SD) for the RoSA control and 17.7 ± 3.5 mm for the augmented RoSA femora ($p = .959$).

Stiffness

The results for stiffness showed no significant differences between the two groups (Table 3). No significant correlations between stiffness and BMD were detected in either group (Table 4).

Femoral head rotation

The results for femoral head rotation revealed no significant differences between the two treatment strategies at any load steps (step 1: $p = .153$; step 2: $p = .260$; step 3: $p = .753$; step 4: $p = .144$) (Table 3, Fig. 6a). Moreover, no significant correlations were observed between the BMD and femoral head rotation in the two treatment groups (Table 4).

Implant migration

Although no significant differences in implant migration were observed up to the load level of 2030 N (Table 3), there was a remarkable migration tendency in the cement-augmented group at the lower load Steps 1 and 2 (1.6/3.5 mm vs. 0.5/0.7 mm; n.s.)

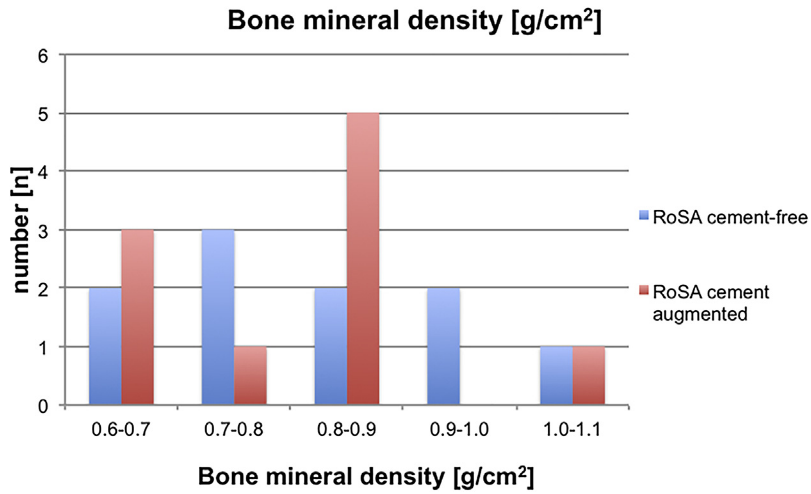

Fig. 5. Distribution of the bone mineral density (BMD).

(Fig. 6b, Table 3). Moreover, migration correlated significantly with BMD in the cement-augmented femurs at all steps (step 1: $p = .016$; step 2: $p = .008$; step 3: $p = .028$; step 4: $p = .047$), but in the cement-free therapy group this significant coherence was noticed only in step 4 ($p = .005$) (Table 4).

Femoral neck shortening

No significant differences with regard to femoral neck shortening could be observed between cement-free and cement-augmented implantation (Table 3). However, related to migration tendency, femoral neck shortening in the cement-augmented femurs at the lower load steps was high (steps 1 and 2: 1.6/3.7 mm vs. 0.5/0.8 mm; n.s.) (Fig. 6b, Table 3). In the cement-augmented specimens, femoral neck shortening was significantly dependent on the BMD at all steps (step 1: $p = .033$; step 2: $p = .016$; step 3: $p = .028$; step 4: $p = .028$). In cement-free implantations, a significant influence of the BMD on femoral neck shortening was noticed only in step 4 ($p = .019$) (Table 4).

Vertical displacement

The tested groups performed equally in terms of vertical displacement (Table 3). In the cement-free fixation systems, average displacement values from 2.1 mm at step 1 to 5.5 mm at step 4 were reached. The average displacement of the cement-augmented femurs was around 1.8 mm at step 1, whereas displacement increased with the load levels up to 6.9 mm at step 4 (Fig. 6d). In load steps 1 and 2, vertical displacement correlated significantly with BMD in the cement-augmented femurs (step 1: $p = .022$; step 2: $p = .019$) (Table 4).

Table 3
Results of test series (mean ± SD).

	RoSA cement-free	RoSA cement-augmented	p-value
Step 1 (1070N)			
Number of tested bones [n]	10	10	
Femoral head rotation [°]	0.1 ± 0.0	0.1 ± 0.0	.153
Migration [mm]	0.5 ± 1.2	1.6 ± 1.8	.169
Stiffness [N/mm]	218 ± 86	296 ± 203	.285
Femoral neck shortening [mm]	0.5 ± 0.7	1.6 ± 1.8	.103
Vertical displacement [mm]	2.1 ± 1.4	1.8 ± 1.0	.500
Step 2 (1390N)			
Number of tested bones [n]	9	10	
Femoral head rotation [°]	0.3 ± 0.1	0.3 ± 0.1	.260
Migration [mm]	0.7 ± 0.5	3.5 ± 4.1	.110
Stiffness [N/mm]	559 ± 280	743 ± 252	.260
Femoral neck shortening [mm]	0.8 ± 1.1	3.7 ± 4.5	.173
Vertical displacement [mm]	3.1 ± 1.9	4.0 ± 2.3	.953
Step 3 (1710N)			
Number of tested bones [n]	8	8	
Femoral head rotation [°]	0.4 ± 0.1	0.5 ± 0.2	.753
Migration [mm]	1.7 ± 1.1	3.1 ± 3.0	.398
Stiffness [N/mm]	752 ± 304	791 ± 249	.866
Femoral neck shortening [mm]	1.8 ± 1.4	2.9 ± 3.1	.398
Vertical displacement [mm]	4.3 ± 2.5	5.1 ± 2.1	.866
Step 4 (2030N)			
Number of tested bones [n]	6	8	
Femoral head rotation [°]	0.6 ± 0.1	0.7 ± 0.4	.144
Migration [mm]	3.3 ± 3.0	4.4 ± 3.4	.500
Stiffness [N/mm]	968 ± 434	799 ± 235	.500
Femoral neck shortening [mm]	4.2 ± 3.3	4.3 ± 3.5	.686
Vertical displacement [mm]	5.5 ± 1.6	6.9 ± 2.7	.225

Table 4
Spearman correlation test between biomechanical parameters and bone mineral density (BMD): significance p < .05.

	RoSA cement-free (BMD)		RoSA cement-augmented (BMD)	
	p value	correlation coefficient (k)	p value	correlation coefficient (k)
Femoral head rotation				
Step 1 (1070 N)	.960	0.018	.672	−0.153
Step 2 (1390 N)	.444	−0.293	.829	−0.079
Step 3 (1710 N)	.071	−0.714	.610	−0.214
Step 4 (2030 N)	.391	−0.5	.610	−0.214
Migration				
Step 1 (1070 N)	.425	0.285	**.016**	−0.733
Step 2 (1390 N)	.798	0.1	**.008**	−0.782
Step 3 (1710 N)	.570	−0.238	**.028**	−0.762
Step 4 (2030 N)	**.005**	−0.943	**.047**	−0.714
Stiffness				
Step 1 (1070 N)	.117	0.527	.200	0.442
Step 2 (1390 N)	.433	−0.300	.174	0.467
Step 3 (1710 N)	.071	−0.667	.102	0.619
Step 4 (2030 N)	.397	−0.429	.456	0.310
Femoral neck shortening				
Step 1 (1070 N)	.385	0.309	**.033**	−0.673
Step 2 (1390 N)	.284	0.402	**.016**	−0.733
Step 3 (1710 N)	.955	−0.024	**.028**	−0.762
Step 4 (2030 N)	**.019**	−0.886	**.028**	−0.762
Vertical displacement				
Step 1 (1070 N)	.405	−0.297	**.022**	−0.709
Step 2 (1390 N)	.606	−0.2	**.019**	−0.721
Step 3 (1710 N)	.385	0.357	.260	−0.452
Step 4 (2030 N)	.468	−0.371	.243	−0.467
Load at failure	.144	0.497	**.008**	0.782

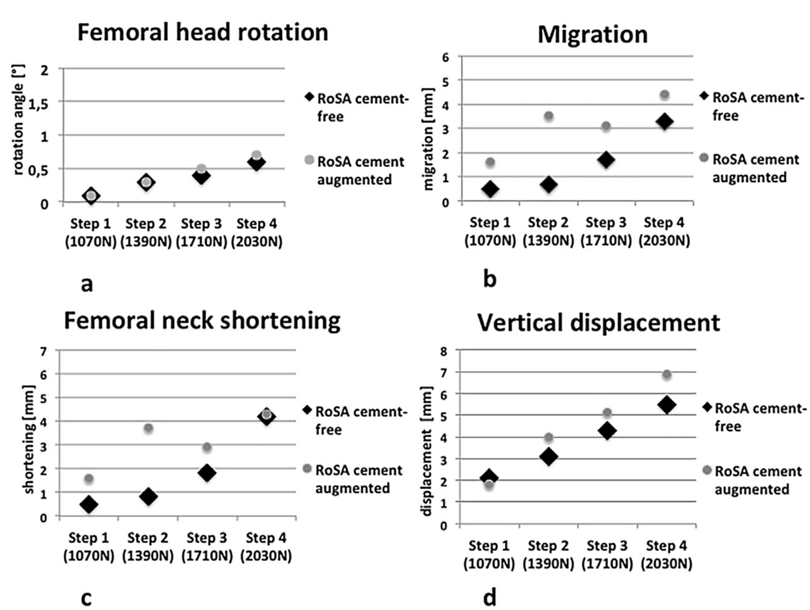

Fig. 6. Biomechanical parameters measured during load-step setup. Fig. 6a: Femoral head rotation; Fig. 6b: Migration; Fig. 6c: Femoral neck shortening; Fig. 6d: Vertical displacement.

Load at failure and failure mode

BMD of failed specimens in the cyclic loading test (n = 7) was 0.75 g/cm^2 in comparison to 0.83 g/cm^2 (p = .317) in specimens survived (n = 13).

The 'load-to-failure' test, which was performed in the five cement-free and eight cement-augmented bones that survived all four steps of cyclical loading, resulted in comparable outcomes between the two groups. A maximum load after continuously increased (by 1 N) peak force after every simulated gait cycle was measured in the cement-free specimens at 4430 N (±803 N) compared to 4278 N (±993 N) in the augmented-osteosynthesis group (p = .686). Including all specimens (inclusive specimens with failure in the cyclic loading test; resulting in 10 versus 10 bones), failure load was 3070 N (±1560 N) in the cement-free RoSA systems and 3732 N (±1447 N) in the cement-augmented implants (p = .103). In the cement-augmented specimens, this failure load showed a significant positive correlation with the BMD (cement-free RoSA: p = .144; cement-augmented RoSA: p = .008) (Table 4).

Concerning failure mechanisms, primarily dislocations of the femoral head in the frontal plane with varus collapse (fragment displacement of more than 15 mm and failure of osteosynthesis; cement-free RoSA: n = 7 vs. cement-augmented RoSA: n = 9) were registered, but there were no significant differences in failure modes when using additional cement augmentation (p = .582). Cut-out was detected in both groups (cement free: n = 2 vs. cement augmented: n = 1). In one non-cemented specimen, cut-out failure was combined with a load-carrier deformation (n = 1). One case of femoral-shaft fracture was detected in the non-cemented group (n = 1).

Discussion

Arthroplasty is preferred over internal fixation in elderly patients with severe comorbidity, osteoporosis and a displaced femoral neck fracture [1,2,5]. However, controversies make it difficult to determine which treatment is optimal for active patients between 60 and 80 years [30]. Sliding hip screws are preferred over cancellous screws in displaced fractures [1,3,4], however, the complication rates remain high [2,5]. In recent years, cement-augmentation strategies were developed to improve implant anchorage in bone. However, controversy still exists, and the benefit of the additional augmentation procedures depends on the stability of the fracture and the implant construct itself [23]. Hence, evaluation of the efficacy of additional cement augmentation in RoSA screw-anchor fixation devices, which are considered as very stable and rigid [11–14], would be of scientific importance.

For this purpose, a multidirectional force-vector strain simulating the human gait cycle was performed using human cadaver femurs, and biomechanical stability parameters were recorded uninterruptedly. In this study, the specimens with cement-augmented RoSA in unstable AO/OTA 31-B2 (Pauwels type-3) femoral neck fractures showed no significant advantages in comparison to cement-free implants in terms of stiffness, femoral head rotation, screw migration and resistance to femoral neck shortening or vertical displacement. In addition, there were no differences regarding failure load and failure mode. However, for migration, femoral neck shortening and in part for vertical displacement, a significant dependence on bone quality in cement-augmented implants was detected, having higher dynamics in osteoporotic bone. A lower BMD was associated with a lower failure load in cement-augmented specimens.

Previous studies described the role of rotational movements and migration tendencies as precursors to cut-out [8,9,31]. However, we observed varus displacement with fracture collapse more than cut-out (n = 3) in all RoSA systems, with and without cement (failure pattern: p = .582). Hence, we assume that migration and especially femoral neck shortening, which when excessive, leads to fracture collapse before cut-out occurs, play key roles in early failure. Previous publications using a uniaxial loading model had already shown a significantly lower femoral head rotation in screw-anchor devices compared to SHS implants [11,14]. With the new test rig that used a multidirectional force-vector strain to simulate the human gait cycle, in this study we could demonstrate a minimal rotation tendency (0.6–0.7° at 2030 N) of RoSA systems, with no further improvement by cement augmentation. Therefore, our data suggest that migration tendencies rather than rotational tendencies are precursors to femoral neck shortening with consecutive fracture collapse. However, femoral neck shortening and consecutive migration (or vice versa) are thus closely linked [12] (Fig. 6b and c). At load Step 4 (2030 N), migration (3.3 mm) and femoral neck shortening (4.2 mm) in cementless RoSA systems were of remarkable amount and higher than reported previously [11,12,14]. It is known that multiaxial loading reduces migration resistance when compared to uniaxial test results [6]. However, an additional cement augmentation did not reduce these dynamic responses to multiaxial loading but rather tended to increase it.

In the past, many biomechanical investigations suggested a clear benefit from applying cement to the bone/screw interface [16–18,20,21]. Von der Linden et al. reported a better survival of augmented sliding hip screw constructs during cyclic testing, enhancing the implant anchorage [22]. Stoffel et al. showed advantages such as an increase of 42% in cut-out resistance in cement-augmented dynamic hip screws [21]. PMMA-augmented helical blades increased the cut-out resistance in human cadaveric femoral heads [18]. In bones with off-centric positioning of the blade (PFNA, polyurethane foam specimens with low density), these advantages were even more accentuated [17]. However, Fensky et al. reported no advantage from cement augmentation of the PFNA in trochanteric femur fractures with regard to failure load and axial displacement [20]. Furthermore, in a femoral neck fracture model, bone-cement augmentation of cannulated screws did not show any improvement in construct stability with an enhanced screw tilting due to the absence of a side plate [23]. In constructs with an angular stable load carrier, such as SHS, screw purchase in the femoral head represents the weak point. Consequently, reinforcement of the region with bone cement adds stability to the SHS construct [23]. However, in screw-anchor systems, this weak point is addressed by a rigid implant anchoring in the bone structure [11–14]. With the RoSA system, both the blade, with its square profile, and the screw function as load carriers, allowing greater forces to be absorbed. In previous biomechanical studies in trochanteric femoral fractures, the screw-anchor implant showed benefits with regard to stiffness, failure load and rotational stability [11,12]. In a recent study testing unstable femoral neck fractures using biomechanical composite sawbones, screw-anchor fixation turned out to provide the highest stiffness and rotational stability and the least fragment displacement, head migration and femoral neck shortening in comparison to SHS-screw and SHS-blade systems [14]. In the present study, screw-anchor failure loads (cement-free RoSA: 3070 N; cement-augmented RoSA: 3732 N) were comparable to those reported for screw systems (SHS 3505 N) in the literature [30]. Kunapuli et al. [32] and Nowotarski et al. [33] used composite sawbones to study femoral neck fracture fixations and reported 1900 N and 2300 N failure loads for SHS constructs, respectively. Hence, because of the high primary stability of screw-anchor systems, an additional cement augmentation may not further improve the implant anchorage.

Our results underline the conclusions of Hoffmann-Fliri et al., who stated that augmentation of implants cannot be considered as a general cure in osteoporotic fracture management [23]. Notably, fracture location and pattern and the biomechanical surrounding as well as the implant itself seem to be critical factors influencing the outcome [23]. In this light, and facing a posterior comminution, devices that have favourable capabilities (e.g., allow fracture impaction, as does the screw-anchor) may reduce the complication rate in displaced femoral neck fractures [34]. Because varying contact surfaces to the bone and differences in anchorage, resistance and mode of migration exist between implants, significant clinical differences may be expected. As each turn of the thread in screws contributes to the surface area, the total contact surface of the screw is about four times as large as that of a single helical blade [6]. In screw-anchor systems, the use of the blade (i.e., anchor) design additionally enlarges the contact surface of the screw in the superior/inferior direction, increasing the resistance against the hip force and the rotational strength at the interface between implant and bone [6,11,12].

However, in older individuals, bone quality tends to be compromised by osteoporosis. Failure can be associated with low BMD [20]. In the study of Sermon et al. using PFNA blades in cement-augmented specimens (in contrast to cementless implants), no correlation was observed between BMD and cycles to failure, supporting the idea that augmentation reduces the impact of bone quality on the implant purchase [18]. In contrast, we found a dependence of failure on BMD in cement-augmented in comparison to cement-free specimens with RoSA instrumentation. Furthermore, using cyclic loading, there was an unexpected negative correlation between bone quality, migration and femoral neck shortening in cement-augmented but to a lesser extent in cement-free screw-anchor systems. The reasons are not fully understood but may be associated with the increased implant surface and with the special anchorage mechanism in screw-anchors. With the driving of the screw into the femoral head, the surrounding trabecula structure undergoes a first volumetric compaction. The following step of hammering in the rectangular blade over the screw leads to a second, more powerful bone compaction, making the implant/bone construct much more stable. Bone cement injected under pressure and generating a temperature increase potentially disintegrates this rigid implant/bone interface to some extent, developing its own interface. Obviously, this process seems to occur more extensively in specimens with lower bone density.

On the other hand, the mass and distribution of the cement inside the femoral head also plays a crucial role in terms of implant-anchorage enhancement. A recently published study declared cementation of the implant tip and cranial side to be the most promising location for stability [35]. Fig. 7**a** shows the optimal cement distribution of the screw-anchor device in a cellular foam. However, in specimens with higher BMD, because of bone-substance compaction during the hammering in of the anchor component, some emersion points of the cannulated RoSA screw could be blocked, impeding the cement emergence (Fig. 7b). Therefore, we hypothesize that the screw-anchor implant design impedes a controlled cementation of the screw tip and cranial side and subsequently lowers the effect of augmentation. However, the role of bone compaction in implant anchorage is not entirely clarified [7] and may be diminished under cyclic loading using single-blade designs [36].

In the past, clinical studies have focused mainly on augmentation in trochanteric fractures, and the results were promising. Lee et al. reported reduced femoral neck shortening and varus collapse of the proximal femoral head fragment in augmented SHS devices [37]. Gupta et al. showed no intra- or postoperative complications in augmented SHS systems with good functional results (Salvati and Wilson score) after 18 months [38]. However, augmentation did not generally improve patients' functional capacity [15,16,39], although it may have the potential to prevent reoperations by strengthening the osteosynthesis construct [16].

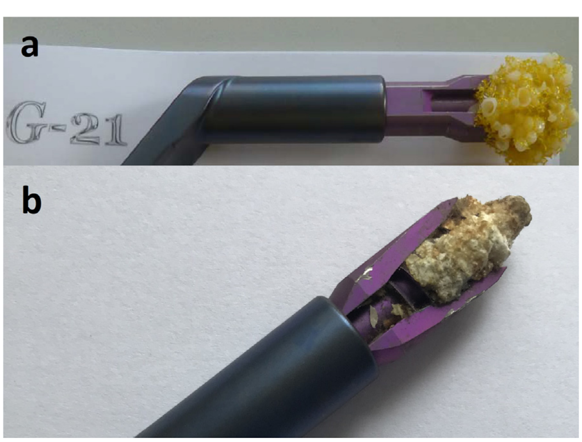

Fig. 7. Cement distribution of the augmented screw-anchor device. Fig. 7a: Optimal distribution in a cellular foam; Fig. 7b: Specimen with impeded distribution.

Limitations

The bone mineral density of our specimens was comparable to tested femora in other publications (0.8 g/cm^2; T-Score: -1.5) (Table 1, Fig. 5) [20,30], and 16 of the 20 specimens had values more than one standard deviation below the mean gender peaks for young men (0.98 g/cm^2 $\pm$ 0.12 g/cm^2) and women (0.92 g/cm^2 $\pm$ 0.10 g/cm^2) [40]. However, Bonnaire et al. proposed a critical value of BMD between 260 and 370 mg/cm^3 calcium-hydroxyapatite, based on QCT measurements at the centre of the femoral head, as being comparable to 0.6 g/cm^2 measured by DEXA in the proximal femur [41]. In this light, our specimens represent only a mild to moderate osteoporotic situation, limiting the explanatory power as regards a severe reduction of bone quality. However, comparison of failure load in bones with low BMD (five pairs with BMD below the median 0.81 g/cm^2) showed no significant difference too (RoSA cement-free 2379 N $\pm$ 1261 N versus RoSA cement-augmented 2927 N $\pm$ 1532 N; p = .104).

The mass and distribution of cement augmentation is a possible influencing factor of the test results. Due to dependency on the BMD and inner impaction of the femoral head region, it was not always possible to apply the same standard portions of cement inside the femoral heads. As mentioned before, cementation of the implant tip and cranial side is the most promising location for prevention of failure [35]. In our study, the cement distribution followed no uniform pattern (Fig. 7). However, the daily routine of femoral neck surgery is rife with exactly these problems of diverse biomechanical patient settings.

Conclusion

The present study shows no considerable advantage from additional cement augmentation to primary stable screw-anchor devices such as RoSA. In a multidirectional gait-simulation scenario, bone-cement augmentation did not enhance implant anchorage with regard to femoral head rotation, screw migration, stiffness, femoral neck shortening or vertical displacement. No crucial influence on prevention of typical failure characteristics or increase of failure load could be addressed by the additional cement-augmented treatment strategy.

Conflicts of interest

The authors declare that they have no conflicts of interest.

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Ethical approval

Approval was granted by the Ethics Committee of the RWTH Aachen university hospital (EK 211/11).

Informed consent

Not applicable.

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