Rotationally Stable Screw-Anchor With Locked Trochanteric Stabilizing Plate Versus Proximal Femoral Nail Antirotation in the Treatment of AO/OTA 31A2.2 Fracture: A Biomechanical Evaluation

Matthias Knobe, MD, MSc,* Philipp Nagel,* Klaus-Jürgen Maier, MD,† Gertraud Gradl, MD,* Benjamin Buecking, MD,‡ Tolga T. Sönmez, MD,§ Ali Modabber, MD,§ Andreas Prescher, MD, and Hans-Christoph Pape, MD*

Objectives: Third-generation cephalomedullary nails currently represent the gold standard in the treatment of unstable trochanteric femur fractures. Recently, an extramedullary rotationally stable screw-anchor system (RoSA) has been developed. It was designed to combine the benefits of screw and blade and to improve stability using a locked trochanteric stabilizing plate (TSP). The purpose of this study was to compare the biomechanical behavior of RoSA/TSP and the proximal femoral nail antirotation (PFNA).

Methods: Standardized AO/OTA 31A2.2 fractures were induced by an oscillating saw in 10 paired human specimens (n = 20; mean age = 85 years; range: 71–96 years). The fractures were stabilized by either the RoSA/TSP (Koenigsee Implants, Allendorf, Germany) or the PFNA (DePuy Synthes, Zuchwil, Switzerland). Femurs were positioned in 25 degrees of adduction and 10 degrees of posterior flexion and were cyclically loaded with axial sinusoidal pattern at 0.5 Hz, starting at 300 N, with stepwise increase by 300 N every 500 cycles until bone–implant failure occurred. After every load step, the samples were measured visually and radiographically. Femoral head migration was assessed.

The authors report no conflict of interest.

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Reprints: Matthias Knobe, MD, MSc, Department of Orthopaedic Trauma, University of Aachen Medical Center, 30 Pauwels St, 52074 Aachen, Germany (e-mail: mknobe@ukaachen.de).

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e12 | www.jorthotrauma.com

Results: The stiffness at the load up to the clinically relevant load step of 1800 N (639 ± 378 N/mm (RoSA/TSP) vs. 673 ± 227 N/mm (PFNA); P = 0.542) was comparable, as was the failure load (3000 ± 787 N vs. 3780 ± 874 N; P = 0.059). Up to 1800 N, no femoral head rotation, head migration, or femoral neck shortening were observed either for RoSA/TSP or PFNA. Whereas failure of the PFNA subsumed fractures of the greater trochanter and the lateral wall, a posterior femoral neck fracture with a significantly increased femoral neck shortening (1.7 mm vs. 0 mm; P = 0.012) was the cause of failure with RoSA/TSP. This specific kind of failure was induced by a femoral neck weakening caused by the posterior TSP stabilizing screw.

Conclusions: There was no significant difference in biomechanical properties between the RoSA/TSP and the PFNA for the fracture pattern tested. However, failure modes differed between the 2 implants with greater femoral neck shortening observed in the RoSA/TSP group.

Key Words: proximal femoral nail antirotation, rotationally stable screw-anchor plate system, trochanteric stabilizing plate, screwblade combination, biomechanical testing, unstable trochanteric femoral fracture, cutout

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INTRODUCTION

Despite ongoing improvements of implants, there continues to be a high rate of mechanical complications in the treatment of unstable trochanteric femur fractures.^{1–3} The use of a helical blade was described to improve fixation in osteoporotic bone^{4,5} associated with a low reoperation rate (2.5%–7%).^{2,3,6,7} Biomechanical studies have shown that the pertinent benefit of the blade lies in its rotational stability.^{8,9} Its resistance to pull out forces was rather low,⁹ which restricts the possibility of intraoperative compression. Besides, the migration along the blade axis can cause complications such as cut-through or reverse migration.^{10,11} Furthermore, biomechanical studies found higher failure loads for the intramedullary load carriers,^{12,13} with a more rigid fixation under axial load application in stable and unstable fracture models.¹³ Regardless, there seem to be certain theoretical exceptions for

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From the *Department of Orthopaedic Trauma, University of Aachen Medical Center, Germany; †Department of Surgery, RoMed Hospital Bad Aibling, Germany; ‡Department of Trauma, University Hospital Gießen and Marburg GmbH, Campus Marburg, Germany; and Departments of §Oral and Maxillofacial Surgery, and ||Molecular and Cellular Anatomy, University of Aachen Medical Center, Aachen, Germany.

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M. Knobe and P. Nagel contributed equally to this work.

the use of intramedullary load carriers such as fractures with a lost integrity of the greater trochanter.¹⁴ In extramedullary implants, trochanteric stabilizing plates (TSP) can counteract the eccentric bending stress and significantly reduce the amount of femur shaft medialization.^{15–17} The extramedullary rotationally stable screw-anchor (RoSA; Koenigsee Implants, Allendorf, Germany) combines the benefits of the load and rotational stability of the blade with the advantages of the screw (pull-out resistance and compression capability) in a single load carrier. In a previous study, the comparison of the RoSA implant with the sliding hip screw (SHS) showed benefits regarding stiffness, failure load, and rotational stability.¹⁸ The aim of this study was the biomechanical evaluation of the RoSA system using an additional locked TSP in an unstable A2.2 fracture model in comparison with the established proximal femoral nail antirotation (PFNA). We hypothesized that there would be no differences between RoSA/TSP and PFNA regarding load to failure, axial stiffness as well as the tendency for femoral neck shortening, femoral head migration, and femoral head rotation. The failure mechanism of both implant systems was to be evaluated explicitly.

MATERIALS AND METHODS

Specimen Preparation

After the approval was granted by the Ethics Committee (EK 211/11), 10 pairs of human cadaver femurs of donors (n = 20; 12 men, 8 women) at the mean age of 84.5 years (range: 71-96 years) were obtained from the local anatomical Institute. The geometry of the proximal femur region (head and neck diameters, collum center diaphyseal (CCD) and antetorsion angle) was measured, and additional donor data (body height, weight, and body mass index) were recorded (see Table, Supplemental Digital Content 1, http://links. lww.com/BOT/A494 which shows bone geometry and demographic data of the RoSA/TSP and the PFNA implant-bone constructs). As suggested by other researchers, bone quality was assessed radiographically using the Singh index-as mean of the assessments by 3 surgeons (M.K., K.-J.M., and G.G.).^{18,19} As only bone pairs were used, major differences in the bone quality among the groups were excluded (see Table, Supplemental Digital Content 1, http://links.lww.com/BOT/ A494).^{20,21} Each bone of the pair was randomly assigned to receive an implant, either RoSA/TSP (3-hole; Koenigsee Implants, Allendorf, Germany) or PFNA (11 mm diameter, 200 mm long; DePuy Synthes, Zuchwil, Switzerland). All soft tissue structures were removed from the bones after defrosting them to room temperature for 24 hours. An oscillating saw was used to create a fracture type AO/OTA 31A2.2 (3part fracture with posterior-medial fragmented zone, Evans type IV).^{22,23} A trochanteric osteotomy was performed at an angle of 40 degrees to the femur axis, beginning at the convexity of the greater trochanter, and extending all the way to the lesser trochanter.¹⁸ Furthermore, the lesser trochanter and all medial support were removed (Fig. 1). An intrusion distance of 50% was used (see Fig., Supplemental Digital Content 2, http://links.lww.com/BOT/A495 which shows x-ray and sawbone illustration of the RoSA/TSP implant-bone construct before removing the lesser trochanter to create an A2.2 fracture situation).¹⁴ By intention, a moderately unstable fracture situation (AO/OTA 31A2.2) was chosen as fractures with lesion of the lateral wall (4-part, A3-equivalent) are recommended to be treated only by the intramedullary method.^{2,6,24} The reproducible arrangement of the fracture lines was checked visually and radiographically by digital protractor (Pollin Electronic GmbH, Pfoerring, Germany, accuracy 0.3 degrees) and the lines ran identically.¹⁸

Surgical Technique

All surgical steps were performed by one experienced board certified orthopaedic trauma surgeon (M.K.). The implant position was chosen centrally in the femoral head with a tip-apex distance <25 mm and was controlled radiographically during implantation.²⁵ The required lengths of the lag screws and the femoral neck angles (CCD) were determined individually radiographically, and both sides received the same lengths. The rotationally stable screw-anchor was implanted as described in our earlier work.¹⁸ To counteract the eccentric bending stress,^{15–17,24} a locked trochanteric stabilizing plate (TSP, 4-hole; Koenigsee Implants, Allendorf, Germany) was used in this A2.2 fracture situation (Fig. 2). Each plate was fixed by 2 screws each (distal anterior and distal posterior position, 30 degrees multidirectional for the proximal-distal direction). The PFNA was inserted using the aiming device after reaming of the medullary cavity and was distal locked statically.

After cutting off the distal part of the femur at 30 cm distance from the tip of the greater trochanter, the femurs were placed in steel cylinders and embedded in



FIGURE 1. Illustration of the test setup and the saw cuts of the unstable trochanteric AO/OTA 31A2.2 fracture.

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FIGURE 2. Photograph of the RoSA/TSP. Left: Rotationally stable screw-anchor, Right: Locked trochanteric stabilizing plate (TSP, 4-hole; Koenigsee implants, Allendorf, Germany).

polymethylmethacrylate (Technovit 4006; Heraeus Kulzer GmbH, Wehrheim, Germany) with a height of 10 cm. To obtain bending moments in the sagittal and frontal planes, to ensure rotational moments under axial force application, and to make the results comparable with published data, the femurs were placed in 25 degrees of adduction and 10 degrees of posterior flexion (Fig. 1).^{5,15,18,21,24,26–28}

Mechanical Testing

The vertical loads were applied to the femurs by a biomechanical testing machine (BZ1-MM14450.ZW04, Force transducer Xforce Type HP, 10 KN nominal force; Zwick GmbH and Co. KG, Ulm, Germany) with a "testXpert II" software package. A custom-made spherical cap, simulating the shape of the acetabulum, was used to achieve equal load distribution on the femoral head (Fig. 1). Initially, the

TABLE 1. Results of the Mechanical Test Series at failure Point (Mean \pm SD)

	RoSA/TSP	PFNA	Р
Failure load, N	3000 ± 787	3780 ± 874	0.059
Failure cycle	4635 ± 1289	6043 ± 1510	0.043
Failure modus			
Posterior femoral neck fracture	10	0	0.001
Lateral wall fracture/greater trochanter	0	9	0.001
Cut-out/Cut-through	1	1	1.000
Deformation of load carrier	0	0	1.000
Dislocation at failure point			
Vertical displacement, mm	5.8 ± 2.1	5.9 ± 1.9	0.826
Femoral neck shortening, mm	1.7 ± 1.7	0 ± 0	0.012
Rotation, degrees	$0.3~\pm~0.9$	0 ± 0	0.343
Axial migration, mm	1.3 ± 1.6	1.8 ± 1.6	0.429
Cranial migration, mm	2.2 ± 2.0	1.4 ± 1.8	0.312
Ventrodorsal migration, mm	0 ± 0	0 ± 0	1.000

e14 | www.jorthotrauma.com

TABLE 2. Results of the Mechanical Test Series at 1800 N, 2.5 Times Body Weight (Mean \pm SD)

	RoSA/TSP	PFNA	
	(n = 10)	(n = 10)	Р
Stiffness, N/mm	639 ± 378	$673~\pm~227$	0.542
Vertical displacement, mm	3.5 ± 1.5	3.0 ± 1.0	0.375
Femoral neck shortening, mm	$0.3~\pm~0.6$	0 ± 0	0.168
Femoral neck angle varization, degrees	0.5 ± 2.2	2.5 ± 7.7	0.178
Rotation, degrees	0 ± 0	0 ± 0	1.000
Axial migration, mm	0 ± 0	0.3 ± 1.1	0.343
Cranial migration, mm	0 ± 0	0.1 ± 0.3	0.343
Ventrodorsal migration, mm	0 ± 0	0 ± 0	1.000

intact femurs were subjected to a load of 700 N (10 cycles, sinusoidal, 0.5 Hz) to obtain reference data for the stiffness evaluation (see Table, Supplemental Digital Content 1, http://links.lww.com/BOT/A494).12 A preload of 100 N was maintained throughout the test series to avoid artificial dislocation and to simulate the physiological minimal load of the hip joint during swinging phase.¹² Then the instrumented femurs were loaded up to 300 N over 500 (sinusoidal) cycles with a frequency of 0.5 Hz. After 5 minutes relaxation, the load was increased stepwise by 300 N (600, 900, 1200, 1500, 1800 N, etc.), every 500 cycles (sinusoidal, 0.5 Hz) until the construct failed. Failure was defined as fracture of the femoral neck or shaft, and/or cut-out/cut-through, and/or implant failure, and/or sudden drop of the load resistance observed at the load-displacement curve.¹⁸ The load step at which failure occurred was defined as the ultimate failure load and the number of cycles until failure was assessed.

In addition, subsequent to every load step and during relaxation, specimens were macroscopically and radiologically evaluated (Philips BV300; Philips Medical Systems, Best, the Netherlands). Three of us (M.K., K.-J.M., and P.N.) evaluated all radiographs using a team-based approach. Measurement of any displacement was performed in 3 planes (see Fig., Supplemental Digital Content 3, http://links.lww.com/BOT/A496 which demonstrates all displacement and migration measurements) [Illustration from Ref. 18 (RoSA in stable trochanteric fractures)].

Fragment Displacement in the Frontal Plane

Vertical displacement of the femoral head with respect to the shaft (D) was computed along the vertical load axis (biomechanical testing machine using software "testXpert II"). All anterior–posterior radiographs were analyzed for neck–shaft angle (varization), femoral neck shortening along the sliding direction of the implant (S), and proximal (A) and distal (B) fracture gap in a magnification-adjusted manner (see **Fig., Supplemental Digital Content 3**, http://links. lww.com/BOT/A496).¹⁸

Fragment Rotation

Before radiographic evaluation, a line was drawn on the surface of the greater trochanter and lying on the plane which passes through the diaphyseal and the screw axes, using

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FIGURE 3. Common failure mechanisms observed for the RoSA/TSP and PFNA treatment groups Left: RoSA/TSP with posterior femoral neck fracture (A), Right: PFNA with lateral wall/greater trochanter fracture (B).

a standard permanent marker (tip diameter 0.4 mm) and a plain guidance (femur was fixed). The distance between the screw axis and the marker was measured on the radiographs (anterior–posterior, distance = b). Using a standard digital caliper (Digital Absolute IP67 150 mm, accuracy 0.01 mm; Mitutoyo, Japan), static rotation was evaluated macroscopically (in the section plane of view 1) after every load step by measuring the distance (distance = a) between the parts of the split line. The resulting rotational angle α was computed with the law of cosines: α = arcos $[1 - (a^2/2b^2)]$, (see Fig., Supplemental Digital Content 3, http://links.lww.com/BOT/A496).¹⁸

Migrational Behavior in the Frontal and Transverse Plane

Migration of the implant tip with respect to the femoral head in axial, cranial, and ventro–dorsal direction was measured in the frontal and transverse plane.

Measurements of stiffness, displacement, rotation, and migration were analyzed for all load steps up to failure. The depiction of the individual ultimate failure load step shows the results of the maximal load on the individual implants (Table 1). In addition, Table 2 exemplarily depicts the results at 1800 N (all RoSA/TSP and all PFNA bone–implant constructs), corresponding to a clinically relevant load for the hip; approximately 2.5 times average body weight (Table 2). Bergmann et al²⁷ studied the in vivo forces acting on the hip joint and found maximum gait loads (4 km/h) of 211%–285% of body weight and mean loads of 238% body weight. In the light of that we studied the behavior of the bone–implant constructs up to failure at loads corresponding to average everyday load^{12,18} and, in addition, the maximum load and number of cycles to failure.¹⁸

Statistics

After testing for normality (Shapiro–Wilk test), paired *t* test was chosen to assess differences between groups concerning the investigated variables (demographics, stiffness, displacement, rotation, migration, load step attained, and number of cycles). Fisher exact test was used to assess differences for categorical variables (failure mode). Data were evaluated by the SPSS, version 21 statistics software. Results are presented as mean and SD. A post hoc power analysis¹⁸ indicated that the given sample size provided 93% power for differences in load to failure (d = 0.7; $\alpha = 0.05$), 99% for stiffness (d = 1.05; $\alpha = 0.05$), and 99% for femoral neck shortening (d = 1.15; $\alpha = 0.05$) using a normal approximation

method (G*Power version 3.1.2; University of Kiel, Kiel, Germany), indicating a total sample size of 16–27 specimens in the prospective A priori power analysis.

All tests were 2-tailed and assessed at the 5% significance level. Because of the exploratory nature of the secondary hypotheses, no adjustment was made to account for multiple testing.

RESULTS

Demography and Bone Geometry

With respect to the bone geometry and the demographic data, there were no differences between the groups (see **Table, Supplemental Digital Content 1**, http://links.lww. com/BOT/A494). The tip–apex distance after instrumentation was not different between RoSA/TSP (20.3 ± 4.2 mm) and PFNA (22.5 ± 4.9 mm) (P = 0.103). Also the postoperative femoral neck angle (CCD) failed to show any difference between the implants (RoSA/TSP 125.3 ± 8.3 degrees vs. PFNA 125.0 ± 8.0 degrees; P = 0.477).

Stiffness

The mean stiffness at the load up to the clinically relevant load step of 1800 N did not reveal any difference between the implants (Table 2).

Failure Load and Failure Mode

All tested implants resisted at least the 1800 N load step. The earliest failures occurred with RoSA/TSP at the 2100 N load step and with PFNA at the 2400 N load step. The failure load tended to be higher after PFNA implantation. The fractures with intramedullary treatment proved to have higher stability as far as the total number of completed cycles to failure was concerned (P = 0.043; Table 1).

We found a significant difference in failure mode between both implants (P = 0.001; Table 1). Whereas with RoSA/TSP, a posterior femoral neck fracture was the failure mode in all cases (in one case in combination with a cutout), fracture of the lateral wall and the greater trochanter, respectively, proved to be the principle failure mechanism with PFNA (Fig. 3). In one case, a cut-through occurred with the intramedullary helical blade implant.

Fragment Displacement in the Frontal Plane

At failure load, RoSA/TSP treated fractures, unlike PFNA, had significant femoral neck shortening (Table 1).

www.jorthotrauma.com | e15

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There were no differences between the implants as regarding vertical displacement and femoral neck angle (CCD) varization, either at 1800 N or at the individual failure point.

Fragment Rotation

Rotation moments did not exist in both implants. There was a rotation of 3 degrees merely of one RoSA/TSP implant.

Migration of the Load Carrier

Whereas almost no migration movements of the implant were found either with RoSA/TSP or PFNA up to the load step of 1800 N (Table 2), migration movements of 1.3–2.2 mm occurred at the individual failure points. No significant difference between the implants was found either in axial or cranial direction (Table 1).

DISCUSSION

In this study, the biomechanical behavior of the RoSA/ TSP was comparable with the PFNA focusing on a clinically relevant load up to 1800 N. By choosing 1800 N, we assumed full weight bearing in patients.^{14,18,27,28} At this load, head rotation, head migration, femoral neck shortening, and stiffness were comparable between groups. However, the failure mode differed significantly (Table 1 and Fig. 3). With the PFNA, 9 cases of lateral wall and greater trochanter fracture were observed. With RoSA/TSP, failure was preceded by a posterior fracture of the femoral neck together with increased femoral neck shortening at the failure point.

Despite unacceptably high reoperation rates of the SHS of up to 25%, there is still a lack of clinical evidence-based treatment recommendations for unstable trochanteric femur fractures, classified at least as AO/OTA-A2.1,29 Biomechanical studies showed benefits of the helical blade mainly as far as rotational stability was concerned,^{8,9} with pull-out resistance being fairly low.⁹ Their principal migration along the blade axis can lead to complications such as cut-through or reverse migration,¹¹ and the capability of intraoperative compression is limited. Based on these findings, the rotationally stable screw-anchor (RoSA) was developed.¹⁸ Benefits of the blade as far as loading and rotational stability are concerned, mainly also in osteoporotic bone, and combined with those of the screw (pull-out resistance and compression capability) in a single-load carrier. A biomechanical evaluation of the primary stability of the RoSA implant in comparison with the standard implant in stable trochanteric femur fractures (SHS) revealed higher stiffness and failure load with higher rotational resistance.¹⁸ Despite that migration moments had occurred that could be precursors of cutout.9,18

The 3780 N failure load of the PFNA correspond to 5 times body weight and the 3000 N of the RoSA/TSP to 4 times body weight, whereas everyday hip loads are achieved at 50%–350% of the body weight.^{27,28} The difference in failure load is probably based on the iatrogenic breach of the posterior femoral neck using the posterior TSP stabilizing screw in the RoSA/TSP constructs (Fig. 3) rather than on the specific anchor mechanisms of the load carriers in the femoral head. Differences in study protocols hinder comparison of maximum loads of implants described in the literature.

Using a similar fracture model, Hoffmann et al reported failure loads of 1600 N for the Intertan nail and 1400 N for the Gamma3 nail. However, the number of cycles was much higher in their study.²³ However, with respect to trochanteric femur fractures with an intact greater trochanter, intramedullary load carriers with their shorter lever arm have a theoretical advantage over extramedullary implants. Nails share compression and tension, but also torsion moments, with the surrounding tissue while stabilizing the fracture at the same time.14,29 Unlike Goffin et al14 (Gamma3 nail vs. SHS as finite element analysis, Evans IV), this study was not able to show differences between intramedullary and extramedullary implants as far as stiffness was concerned, with identical vertical displacement of the head-neck fragment and without differences regarding cutout (Tables 1 and 2). Besides, the stiffness and failure load levels were similar to those in our previous study (stable fracture model, RoSA without TSP).¹⁸ It seems that the locked TSP is in a position to compensate the additional dorsomedial instability of an A2.2 fracture very well.

Whereas with RoSA/TSP, a posterior fracture of the femoral neck forced the abortion of the tests in all cases, the primary failure mode with PFNA was a fracture of the lateral wall and the greater trochanter, respectively (Fig. 3). Fractures of the lateral wall produced intraoperatively occurred in 30% of cases with PFNA in our clinical study but were without negative impact either on the reoperation rate or the medium-term function.⁶ Maybe the intramedullary load carrier prevents lateralization of the head-neck fragment by direct blockage with these unstable fracture forms in the clinical environment (equivalent to an A3 fracture after fracture of the lateral wall) and thereby phenomena such as shaft medialization and varus collapse.³⁰ However, in biomechanical test series under maximum load, the system collapses with a medial migration of the intramedullary components, and the proximal-lateral osseous structures fail.^{23,31} A weakening of these structures by the intramedullary load carrier results in a lack of a proximal buttress for the nail and unstable calcar support with an increased risk of varus.^{14,23,24}

In contrast, TSP counteract this eccentric bending stress and medialize the load in unstable proximal femur fractures.^{15–17} As observed in a previous study using a stable fracture pattern, the predominant mechanism of failure for the extramedullary RoSA implant proved once more to be a fracture of the femoral neck with fracture collapse.¹⁸ The additional locked TSP in the RoSA group proved to be protective against potential greater trochanter or lateral wall fractures. However, the posterior TSP locking screws caused failure of the posterior femoral neck with increased femoral neck shortening at high load steps in all cases (Table 1). The fracture line in the femoral neck was running parallel with the posterior TSP screw from lateral to medial, which suggests an initial weakening of the posterior femoral neck region due to the insertion of the screw (Fig. 3). The fragility of the posterior femoral neck region and the reduced resistance to the application of load were also found by other authors.^{12,26,32} Shorter screws or "ventralization" of the posterior-distal TSP hole by the manufacturer could be helpful in attaining even higher load steps preventing damage of the posterior femoral neck. However, a repetitive load of at least 3 times body

e16 | www.jorthotrauma.com

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weight was necessary to cause failure, a load, rarely reached during early rehabilitation. We found no difference in cutout rates in this biomechanical study between the implants (one each) and no deformation of the load carrier. Whereas cutout occurred in the RoSA system in 3 cases in the previous study,¹⁸ the additional TSP seems to adequately stabilize and back the unstable fracture situation. In trochanteric fractures, where the integrity of the greater trochanter is lost, the RoSA/TSP is probably advantageous in clinical practice. Recently, a computational study has shown that failure with an intramedullary device is more likely than with the SHS for Evans' type V fractures.¹⁴

The evaluation of migration trends supports a sensitive assessment of the stability of biomechanical fracture models.³³ Other authors had described head rotation moments⁵ and migration trends⁸ as precursors of cutout in proximal femur fractures. In a recent study focusing on intramedullary implants, the major movements observed were rotation of the femoral head around the lag screw.²³ In contrast, there were no rotational movements either with the PFNA or with the extramedullary screw-anchor system in this study, which suggests a high rotational stability of both implants. In addition, as regarding the migration moments, no differences could be found between PFNA and Ro-SA/TSP at comparable load steps. Assuming a limit of 0.5 mm for a relevant migration trend,^{5,34} these moments existed in both implants for the axial and the proximal direction in load steps greater than 2100 N (3 times body weight).

It is interesting to note the complete absence of migration moments with RoSA/TSP at the clinically relevant load step of 1800 N, whereas values up to 0.9 mm for the cranial direction were obtained in our previous study (RoSAwithout a TSP) (Table 2).18 An excessive femoral neck shortening and consecutive migration are hereby closely linked. Actually due to the more rigid RoSA/TSP and its fixation, femoral neck shortening was reduced from 2.2 mm to 0.3 mm at that load step in comparison with the earlier study.¹⁸ By limiting the (often exceeding) fracture impaction and thereby the neck shortening due to the support screws of the TSP, the tendency to migrate is reduced, increasing the resistance to cutout.^{10,35} Theoretically, the increased stiffness of the RoSA/ TSP construct itself could increase the migration tendency in the femoral head. However, keeping the femoral neck length constant by reducing all interfragmentary movement due to the long locked TSP screws and by lateral fixation on both the distal and proximal fragment becomes more important biomechanically. In addition, the increase of the rotational resistance can reduce migration and thereby prevent cutout.8,34,35

LIMITATIONS

Even if the Singh index for osteoporosis classification is established and used frequently,¹⁸ dual x-ray absorptiometry may be a more precise method of measuring bone density. As the Singh index correlates with the success of the operation,¹⁹ we believe that our categorization is adequate for this. However, using the Singh index, it is perhaps not possible to differentiate between osteoporotic and normal bone quality, although we used geriatric specimens (84.5 years, 71–96 years). In addition, the paired comparison with known donor parameters makes difference in the bone structure less

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prominent.²⁰ Besides, soft tissue and ligaments were removed for a standardized osteotomy and a simple experimental setup, which of course is not the case in a real patient. Thus, neglecting these forces represents a worst case scenario for the testing of bone-implant constructs.²³ Therefore, the principal application of force was uniaxially vertical, without simulation of forces of hip abduction or the simulation of the human gait. However, dynamic multiple plane models of force application may produce different results.³³ Furthermore, unstable trochanteric fractures are probably better fixed using a long statically locked nail with a screw instead of a blade. Although biomechanical studies support the use of a long, distally locked cephalomedullary nail, it is important to note that long nails cost approximately 4 times the amount of the SHS, and the clinical investigation of these implants has failed to demonstrate a significant advantage over the SHS or over short nails in terms of complication rate and functional outcomes for most of trochanteric fracture types.^{36,37} Every preparation was aligned at 25 degrees adduction on the coronary plane and 10 degrees on the sagittal plane to ensure comparison with published data.^{5,15,18,21,24,26} A varus angulation of 9 degrees and an angle of 16 degrees of the resulting hip contact force F_H relative to the vertical line were simulated.^{5,24,27} Nevertheless, different test setups can be found in the literature, which makes studies more difficult to compare. Similarly, there is a wide variety of cyclic load application, from 1 to 100,000 cycles per load step.^{10,15,18,23,34} Morlock et al³⁸ showed that walking accounts only for 10% of the daily activities (6048 steps) and is divided into 286 sequences per 12 hours (patients after elective total hip replacement, age 62.5 years). The number of cycles for each load step chosen for our model attained a mean total number of cycles equivalent to the daily number of steps of an average patient, whereas failure started at 3000 cycles, which would then be equivalent to half a day of normal activity. However, it should be assumed that geriatric patients are distinctly less mobile after trochanteric femur fracture than younger patients after elective endoprosthesis.35,38 Not considered in this study were nonrecurrent maximum loads with peak forces equal to 8 or 9 times body weight, which means that falls and near-falls were excluded.²⁷

CONCLUSIONS

The biomechanical in vitro comparison of the PFNA and the RoSA/TSP in an unstable trochanteric femur fracture model revealed no statistically significant differences in terms of stiffness, head rotation, or head migration. The observed failures of the PFNA system resulted in fractures in the area of the greater trochanter and the lateral wall. In contrast, RoSA/TSP failures were associated with posterior femoral neck fractures and resulted in a more sustained femoral neck shortening. The results of our evaluation will have to be substantiated by further biomechanical and clinical trials, especially to analyze the additional value of bone cement with these implants.

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