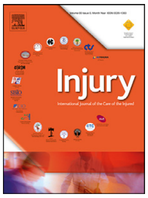
Injury 52 (2021) 1861–1867

Contents lists available at ScienceDirect

Injury

journal homepage: www.elsevier.com/locate/injury



Screw-blade fixation systems for implant anchorage in the femoral head: Horizontal blade orientation provides superior stability

Clemens Schopper[a,b,1,*], Katharina Keck[b,c,1], Ivan Zderic[b], Filippo Migliorini[d], Björn-Christian Link[e], Frank J.P. Beeres[e], Reto Babst[e], Sven Nebelung[f], Daphne Eschbach[g], Tom Knauf[g], Bergita Ganse[h], Carsten Schoeneberg[i], Frank Hildebrand[c], Boyko Gueorguiev[b], Matthias Knobe[e]

[a] *Department for Orthopaedics and Traumatology, Kepler University Hospital GmbH, Johannes Kepler University Linz, Austria*
[b] *AO Research Institute Davos, Switzerland*
[c] *Department of Orthopaedic Trauma, University of Aachen Medical Center, Germany*
[d] *Department of Orthopaedics, University of Aachen Medical Center, Germany*
[e] *Department of Orthopaedics and Trauma Surgery, Lucerne Cantonal Hospital, Switzerland*
[f] *Department of Radiology, University of Aachen Medical Center, Germany*
[g] *Center for Orthopaedics and Trauma Surgery, University Hospital Giessen and Marburg, Germany*
[h] *Innovative Implant Development, Saarland University, Clinics and Institutes of Surgery, Homburg, Germany*
[i] *Department of Orthopaedic and Emergency Surgery, Alfried Krupp Hospital, Essen, Germany*

ARTICLE INFO

Article history:
Accepted 23 April 2021

Keywords:
Rotationally Stable Screw-Anchor
U-Blade
Gamma3 Rotation Control Lag Screw
biomechanical testing
proximal femoral fracture
screw-blade fixation systems

ABSTRACT

Objectives: Despite continual improvement in the methods and devices used for treatment of proximal femoral fractures, unacceptably high failure rates remain. Novel screw-blade implant systems, combining a lag screw with a blade – the latter adding rotational stability to the femoral head – offer improvement of osseous purchase, especially in osteoporotic bone. The aim of this study was to compare biomechanically the head element (HE) anchorage of two screw-blade implant systems differing in blade orientation in the femoral head – vertical versus horizontal.

Methods: Twenty paired human cadaveric femoral heads were assigned to four groups ($n = 10$), implanted with either Rotationally Stable Screw-Anchor HE (RoSA-HE, vertical blade orientation) or Gamma3 Rotation Control Lag Screw (Gamma-RC, horizontal blade orientation) in center or off-center position, and biomechanically tested until failure under progressively increasing cyclic loading at 2 Hz.

Results: Cycles to failure and failure load were significantly higher for Gamma-RC versus RoSA-HE in center position and not significantly different between them in off-center position, $p = 0.03$ and $p = 0.22$, respectively. In center position, the progression of both rotation around implant axis and varus deformation over time demonstrated superiority of the implant with horizontal versus vertical blade orientation. Compared with center positioning, off-center implant placement led to a significant decrease in stiffness, cycles to failure and failure load for Gamma-RC, but not for RoSA-HE, $p < 0.01$ and $p = 0.99$, respectively.

Conclusion: Horizontal blade orientation of screw-blade implant systems demonstrates better anchorage in the femoral head versus vertical blade orientation in center position. As the stability of the implant system with horizontal blade orientation drops sharply in off-center position, central insertion is its placement of choice.

1. Introduction

The incidence of comminuted unstable trochanteric fractures with a basicervical component continues to increase with the increasing rate of elderly population [1,2]. These fractures, often associated with comminution of the posterior cortex, are known

---

[*] Corresponding author at: AO Research Institute (ARI) Davos, Clavadelerstrasse 8, 7270 Davos, Switzerland.

E-mail address: clemens.schopper@hotmail.com (C. Schopper).

[1] Clemens Schopper and Katharina Keck contributed equally to this study.

https://doi.org/10.1016/j.injury.2021.04.058

to be at high risk of fixation failure, including implant cut-out [3]. Therapy failure is mainly caused by varus collapse of the femoral head fragment and/or implant cut-out [4]. Rotational femoral head moments are reported as a precursor for this phenomenon [5–7], together with implant migration and femoral neck shortening [8]. Although some consensus exists about the ideal patient characteristics and the correct operative technique [9], less is known about the ideal features of the osteosynthesis hardware that should be selected for use [5]. The anchorage of the lag screw within the femoral head plays – depending on the implant design – a crucial role for fracture fixation [5]. A novel approach to improve the osseous implant purchase, especially in osteoporotic bone, is introduced with the use of newly developed screw-blade systems combining the advantages of screw and blade components. Compared with blades, screws provide higher pull-out resistance and higher compression forces [6]. On the other hand, blades offer better rotational stability resulting from their volumetric impact effect [10]. Two screw-blade implant systems for proximal femoral fracture fixation are currently available on the market: The Rotationally Stable Screw-Anchor (RoSA, Koenigsee, Allendorf, Germany) and the Gamma3 Rotation Control Lag Screw (Gamma-RC, Stryker, Kalamazoo, MI, USA), the latter used in combination with either the Gamma3 Trochanteric Nail or the Long Length Gamma3 Nail. Both RoSA and the Gamma-RC hip screw systems have proved to increase significantly the migration resistance compared with single screw systems [5,8,11,12]. However, the clinical results, mainly presented by retrospective studies, did not show a conclusive picture in this regard to date [13–15].

The aim of this study was to compare biomechanically the isolated head element (HE) anchorage of these two screw-blade implant systems in the femoral head, namely of the fully sheathed RoSA-HE and the partially sheathed Gamma-RC. In addition, it was aimed to analyze their sensitivity towards the accuracy of implantation, investigating two different HE positions in the femoral head for each of the implant systems. Based on the similarities between the two HE designs and the basic lag screw design, each implant was expected to demonstrate comparable failure rates [5]. However, considering the differences in the orientation of the HE components, it was hypothesized that (1) RoSA-HE would be more resistant to rotational moments and (2) Gamma-RC would absorb higher axial loads.

2. Materials and methods

2.1. Implants

RoSA-HE resembles an anchor with a blade, the latter being brought with vertical, craniocaudal orientation, while Gamma-RC combines a lag screw with a U-shaped Clip (U-clip) brought with horizontal, ventrodorsal orientation. Fig. 1a presents RoSA-HE consisting of a 90 mm screw and a 100 mm cannulated vertical blade connected together, while Fig. 1b depicts Gamma-RC, consisting of a 100 mm long screw and a horizontal spreading U-clip of the same length. Despite the similar designs of both implants, RoSA-HE represents rather a blade while Gamma-RC – rather a screw. In addition, they differ from each other in the way the anti-rotation component is inserted in the femoral head. Whereas the blade of RoSA-HE is hammered in with its wings orientated in vertical direction to achieve compaction of the cancellous bone, the U-clip of Gamma-RC is pushed forward using a special inserter, so that its wings, oriented in horizontal direction, are spread and rest in the flutes of the screw.

2.2. Specimens and study groups

Twenty pairs of fresh-frozen (-20°C) human cadaveric femora from 12 male and 8 female donors aged 61.4 years on average (range 31–81 years) were used. Bone mineral density (BMD) was measured in a cylinder with 20 mm diameter and 30 mm length, located centrally in the femoral head, by means of computed tomography (CT, SOMATOM Emotion 6, Siemens Healthcare GmbH, Erlangen, Germany) at a slice thickness of 0.63 mm with the use of a calibration phantom (European Forearm Phantom QRM-BDC/6, QRM GmbH, Möhrendorf, Germany) [16,17]. Based on BMD, the specimens were first randomized to two paired treatment groups, consisting of 10 pairs each, for center or off-center positioning of the implants during their insertion in the femoral head. Second, within each paired group, the two femora of each pair were split for implantation with either RoSA-HE or Gamma-RC, so that an equal number of right and left specimens were allocated for each implant type. As a result, the specimens were assigned to four study groups consisting of 10 specimens each (n=10) and paired in two clusters (paired groups) for implantation with either RoSA-HE or Gamma-RC in center or off-center implant position in the femoral head.

2.3. Surgical technique

Each femur was sawed in the proximal third of the femoral neck orthogonally to the neck axis to collect femoral head fragments of the same length among all specimens.

Implant insertion was performed according to the surgical guidelines of the manufacturers and controlled radiologically. Targeted tip-apex distance (TAD) of all specimens was set to 20 mm [18]. First, the cutting plane of each femoral head was divided in four quadrants defined by distance measurements. Figs. 2 and 3 indicate that for central implant insertion a Kirschner (K-) wire was first placed centrally in the femoral head in both anteroposterior and axial views. Fig. 3 indicates that for off-center implant insertion, the entry point was relocated posteriorly from the center of the femoral head at a distance equal to 50% of the implant diameter.

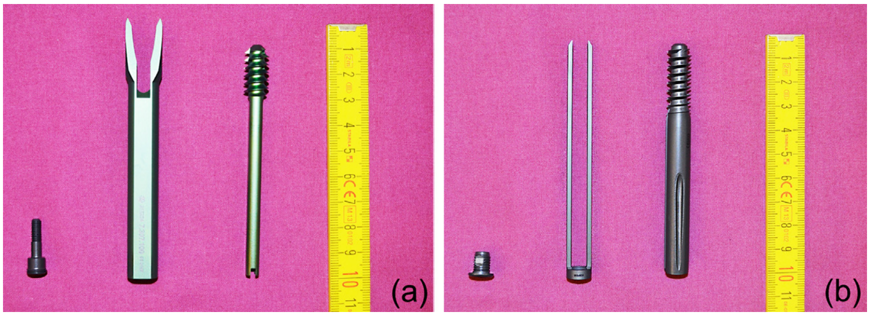


Fig. 1. Photographs of the investigated screw-blade implant systems: (a) RoSA-HE, (b) Gamma-RC.

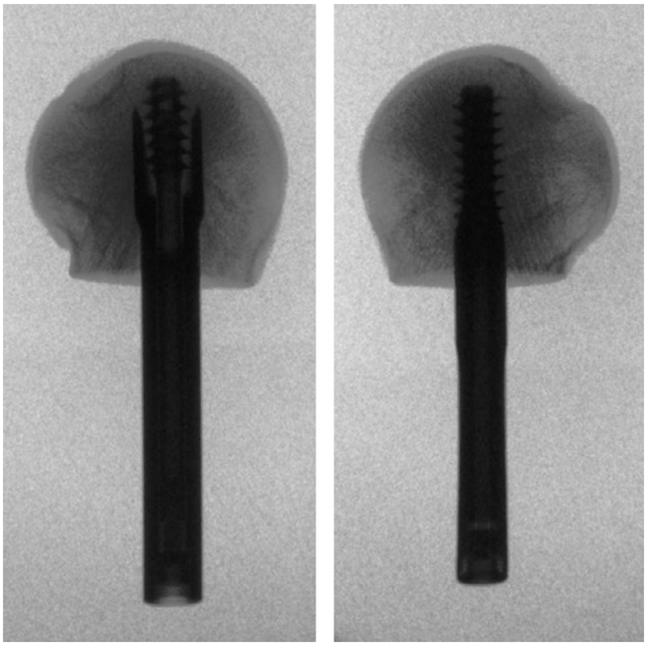


Fig. 2. Anteroposterior X-rays of centrally inserted RoSA-HE (left) and Gamma-RC (right).

2.4. Biomechanical testing

Biomechanical testing was performed on a servohydraulic test system (MTS Mini Bionix II; MTS Systems, Eden Prairie, MN, USA) with a 25 kN load cell, using a test setupl adopted from previous work [19,20] to simulate an unstable trochanteric fracture with lack of medial support and load sharing at the fracture gap (Fig. 4). The implant shafts were inserted in flange sleeves rigidly mounted to a base fixture inclined 149° to the vertical to mimic a 130° caput-column-diaphyseal angle, a 16° resultant joint load vector orientation to the vertical, and 3° lateral inclination of the femoral shaft axis. The implants were free to slide along their shaft axis without rotating around it during testing.

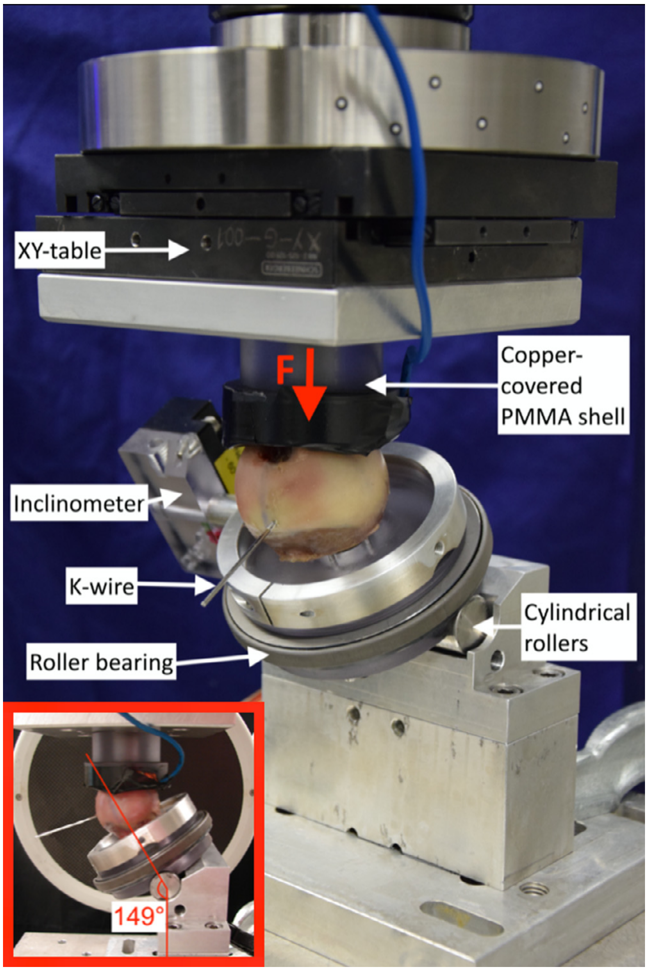


Fig. 4. Setup with a specimen mounted for biomechanical testing; embedded image visualizes 149° implant shaft inclination to the vertical.

The femoral heads were attached to spikes on a polycarbonate plate resting on a roller bearing – allowing rotational movement of the plate and the femoral head around its axis – and on two cylindrical rollers allowing varus-valgus tilting. An inclinometer (8.IS40.23321, Kübler Group GmbH, Villingen-Schwenningen, Germany) was attached to the polycarbonate plate for data acquisition to monitor the rotational and varus-valgus movements of the femoral head. A K-wire was inserted in the femoral head in the frontal plane for better radiological visualization of varus-valgus deformations. Axial loading was transferred to the specimens by a polymethylmethacrylate shell covered with a copper foil for electrical detection of possible implant cut-out and interruption of the biomechanical test if necessary. The loading protocol implemented destructive cyclic axial loading along the machine actuator axis at 2 Hz. The profile of each loading cycle reflected a loading trajectory from *in vivo* measurements at the human hip transferred to

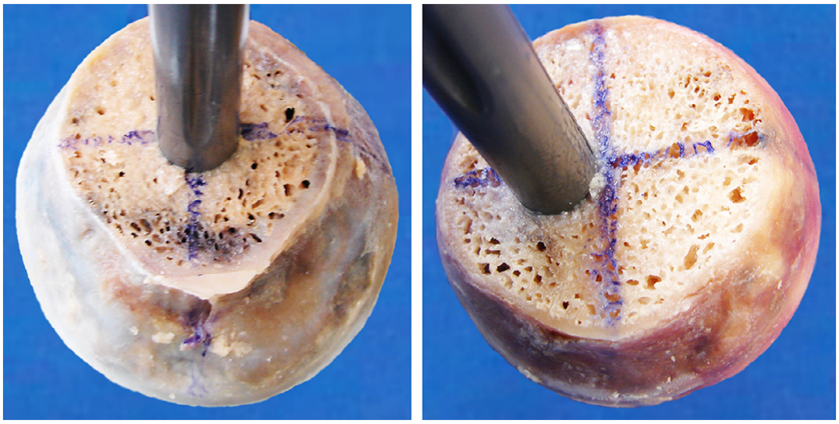


Fig. 3. Photographs of Gamma-RC inserted in center (left) and off-center (right) position.

Table 1
Age, BMD and head fragment length distribution in the four study groups with Gamma-RC and RoSA-HE implanted in center and off-center position, presented in terms of mean value and standard deviation.

Parameter	Group			
	Center		Off-center	
	Gamma-RC	RoSA-HE	Gamma-RC	RoSA-HE
Age [years]	62.4±16.7	62.4±16.7	60.4±12.6	60.4±12.6
BMD [mgHA/cm^3]	283.1±52.1	280.4±55.1	293.2±59.5	285.4±53.2
Head fragment length [mm]	38.9±6.0	38.9±6.1	41.5±3.3	41.3±3.3

the femoral head [21]. Starting at 1000 N, the peak load of each cycle progressively increased by 0.1 N/cycle, whereas its valley load remained constant at 100 N [21]. The test was stopped at either 10 mm axial displacement of the machine actuator, 10° varus deformation, 15° rotation of the femoral head around implant axis, or cut-out. Each one of these stop criteria was considered as provoking a distinct failure at the bone-implant interface to allow meaningful retrospective evaluation.

2.5. Data acquisition and analysis

Machine data in terms of axial load and displacement were recorded at 64 Hz. In addition, the test was paused for five seconds after every period of 25 cycles at a valley load to record femoral head rotation around implant axis and varus-valgus deformation with the use of the inclinometer. Moreover, anteroposterior X-rays were taken every 250 cycles with the use of a triggered C-arm.

Initial stiffness of the bone-implant construct was calculated from the ascending linear part of the load-displacement curve between 400 N and 600 N during the first loading cycle. In addition, rotation of the femoral head fragment around the implant axis was evaluated together with its varus-valgus deformation at peak cyclic loads of 1800 N, 2600 N and 3400 N. Clinically relevant failure criterion was defined as either 5° varus-valgus deformation, 10° femoral head rotation around implant axis, or implant cut-out, depending on which of these three events occurred first during testing [19,22]. Correspondingly, the clinically relevant failure mode was identified as either varus-valgus collapse, rotation failure or cut-out. The number of cycles until fulfillment of the failure criterion was defined as cycles to failure. The peak load of the corresponding cycle identifying the clinically relevant failure was defined as clinically relevant failure load.

Normality of data distribution was checked and proven with Shapiro-Wilk test. Paired-Samples T-test was used to detect significant differences between the paired groups. One-Way Analysis of Variance (ANOVA) with Bonferroni Post Hoc test for multiple comparisons was performed to identify significant differences between the non-paired groups. General Linear Model Repeated Measures with Bonferroni Post Hoc test for multiple comparisons was applied to check for significant changes in the progression of the femoral head rotation and varus-valgus deformation in each study group among the three cyclic load levels of 1800 N, 2600 N and 3400 N. Fisher's exact test was used to screen for significant differences between the groups with regard to the failure mode. Level of significance was set at 0.05 for all statistical tests.

3. Results

Age, BMD and length of the femoral head fragment did not differ significantly among the four groups, $p \geq 0.35$ (Table 1). Centrally inserted implants were placed with a significantly lower TAD (11.8±2.8 mm (mean±standard deviation)) compared to off-center positioning (16.3±2.9 mm), $p < 0.01$.

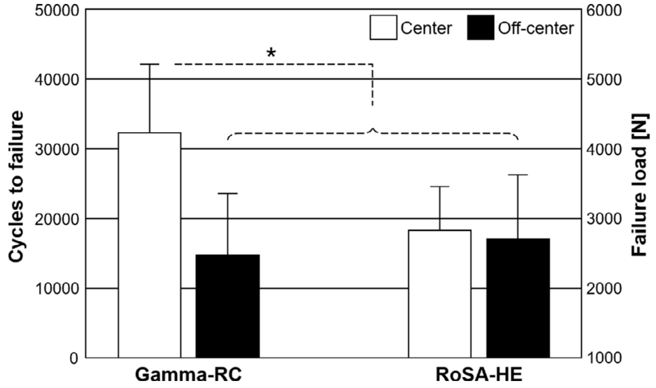


Fig. 5. Cycles to failure and failure load in the four study groups with Gamma-RC and RoSA-HE implanted in center and off-center position, presented in terms of mean value and standard deviation, with a star indicating significant differences.

3.1. Initial stiffness

Initial stiffness of the centrally implanted RoSA-HE (1402±228 N/mm) and Gamma-RC (1254±142 N/mm) did not differ significantly, $p = 0.10$ (Table 2). In contrast, it was significantly higher following off-center implantation with RoSA-HE (1250±450 N/mm) versus Gamma-RC (843±227 N/mm), $p = 0.01$. Compared to its central insertion, the off-center implant placement resulted in significantly decrease in stiffness for Gamma-RC, but not for RoSA-HE, $p = 0.01$ and $p = 0.99$, respectively.

3.2. Rotation around implant axis and varus deformation

In each study group, both rotation around implant axis and varus deformation increased significantly between the three progressively increasing cyclic load levels of 1800 N, 2600 N and 3400 N, $p < 0.01$ (Table 2). For both Gamma-RC and RoSA-HE, rotation around implant axis after off-center implantation was significantly bigger compared with central insertion at each of these load levels, $p \leq 0.03$. In addition, compared with central insertion, off-center implant placement demonstrated significantly bigger varus deformation at any of the three load levels for Gamma-RC, but not for RoSA-HE, $p \leq 0.04$ and $p \geq 0.16$, respectively. Moreover, following central implantation at each of the load levels, both rotation around implant axis and varus deformation were significantly smaller for Gamma-RC versus RoSA-HE, $p \leq 0.04$. In contrast, they were not significantly different between the two implants after off-center insertion, $p \geq 0.21$.

3.3. Cycles to failure and failure load

In the centrally implanted groups, Gamma-RC resulted in significantly more cycles to failure and higher failure load (32310±9848 cycles and 4231±985 N) compared to RoSA-HE (18350±6229 cycles and 2835±623 N), $p = 0.03$. On the other hand, these two outcomes were not significantly different in the off-center groups between Gamma-RC (14756±8845 cycles and 2476±885 N) and RoSA-HE (17067±9257 cycles and 2707±926 N), $p = 0.22$ (Table 2). Compared to its central insertion, the off-center placement resulted in a significant decrease in cycles to failure and failure load for Gamma-RC, but not for RoSA-HE, $p < 0.01$ and $p = 0.99$, respectively (Fig. 5).

3.4. Failure mode

In the centrally implanted groups, Gamma-RC failed in three cases due to rotation and in seven cases due to varus collapse,

Table 2
Initial stiffness, rotation around implant axis, varus deformation, cycles to failure and failure load in the four study groups with Gamma-RC and RoSA-HE implanted in center and off-center position, presented in terms of mean value and standard deviation.

Outcome		Center		Off-center	
		Gamma-RC	RoSA-HE	Gamma-RC	RoSA-HE
Initial stiffness [N/mm]		1254±142	1402±228	843±227	1250±450
Rotation [°]	At 1800 N	0.4±0.3	0.8±0.5	3.3±2.6	2.9±2.1
	At 2600 N	0.9±0.7	2.8±1.5	7.2±4.3	6.3±3.7
	At 3400 N	2.1±1.9	3.7±2.1	10.4±5.5	9.5±5.1
Varus [°]	At 1800 N	0.3±0.2	0.9±0.7	0.7±0.4	0.8±0.6
	At 2600 N	1.3±1.0	2.9±2.3	2.4±1.6	2.6±1.9
	At 3400 N	2.4±1.8	4.3±2.8	4.2±2.7	4.1±2.6
Cycles to failure		32310±9848	18350±6229	14756±8845	17067±9257
Failure load [N]		4231±985	2835±623	2476±885	2707±926

whereas RoSA-HE failed once in rotation and in nine cases due to varus collapse, $p = 0.58$.

In the off-center groups, Gamma-RC failed in nine cases due to rotation and once due to varus collapse, whereas RoSA-HE failed in eight cases due to rotation and twice due to varus collapse, $p = 0.95$.

No cut-out failure was observed after either center or off-center implant positioning. However, for both implants, failure mode in central position was significantly different compared to off-center position ($p \leq 0.02$), with more failure due rotation in eccentric position.

4. Discussion

Proximal femoral fractures represent an uprising global issue as the population in the western high income counries continuously ages, resulting in higher rates of morbidity and mortality in the elderly [23]. Apart from general health issues, this is going to lead to specific complications including delayed unions and non-unions in the region of the proximal femur [23,24]. Delayed bone healing after osteosynthesis can be detected in up to 5% of the cases with proximal femoral fractures, related to revision operations of high complexity including implant replacement and grafting procedures [25,26]. These issues, more likely to occur in the future, represent a major contribution to the costs of the health system with a serious socioeconomic burden [23,27]. To date, different surgical procedures are available to address such injuries, prevent limb shortening and enhance early postoperative mobilization [27]. Recently developed screw-blade implant systems combine the advantages of the well-known principles of screw and blade anchorage in the femoral head. The current study was performed to investigate the biomechanical behavior of two screw-blade head elements featuring implants available on the market, using a human cadaveric model under dynamic loading conditions. The main raised question was whether the different orientation of their blade component (vertical versus horizontal) would result in a significantly different biomechanical behavior. Each implant was inserted centrally and eccentrically in the femoral head fragment to explore its sensitivity towards the accuracy of implantation as compared with previous findings [28].

Being with a horizontal blade orientation, Gamma-RC was superior to RoSA-HE (featuring vertical orientation) with regard to cycles to failure, failure load, rotation around implant axis and varus deformation in central position. On the other hand, eccentric implant positioning of the horizontally aligned Gamma-RC led to significant decrease in stiffness and failure load. Moreover, with its vertical blade orientation RoSA-HE reacted less sensitively to varus-valgus stress considering both center and off-center implant positioning.

In center implant position, the superiority of the implant with horizontal blade orientation was clearly demonstrated in terms of less rotation and varus deformation over the three selected progressively increasing cyclic load levels. However, in the course of increasing rotational moments in off-center position this advantage disappeared, resulting in a non-significant difference between the two implants. Previous studies reported on RoSA rotational behavior following central placement in the femoral head [8,11,12]. While two of them, applying different methodical setting and using complete femora, did not observe any rotational movements [11,12], the third one [8] reported 2° rotation under 1800 N and 3° rotation under 2700 N axial load, which are comparable with our findings (0.8° under 1800 N and 2.8° under 2600 N). Compared with superior implant positioning, inferior and posterior implant positions result in lower von Mises stress in the implant itself, with a smaller volume of cancellous bone strained to yielding in the femoral head [29]. This could be a reason for the superiority of the horizontal over the vertical alignment of the screw-blade head element regarding both rotation and varus deformity.

The average number of cycles to failure and failure load of the centrally inserted RoSA-HE in the current study are in agreement with the findings of a previous investigation on complete human cadaveric femur models tested with a different loading protocol [11]. However, in another study investigating RoSA in artificial femora (4th generation, Sawbones, Malmö, Sweden) applying the same previous loading protocol, remarkably high numbers of cycles to failure and failure load were reported, which might have been due to the simulated better bone quality [8]. Bergmann *et al* measured *in vivo* hip contact forces during different activities, such as walking, climbing upstairs and going downstairs [21]. The average reported load during walking was 238% of the body weight (BW), whereas climbing upstairs and going downstairs are related to even higher loads of 251% BW and 260% BW, respectively. The failure loads of the implants tested in the current study correspond to approximately up to 5-fold BW for Gamma-RC and 3.5-fold BW for RoSA-HE.

The reason why Gamma-RC resisted higher failure loads than RoSA-HE in center implant position seems to be associated with the different orientation of its U-clip compared with the blade of RoSA-HE. For vertical load absorption, an enlargement of the contact surface in vertical direction is of advantage. This feature is inherent to the design of Gamma-RC, as its U-clip is inserted horizontally. This finding is in agreement with the work by Born *et al* who highlighted that application of the U-clip resulted in a 15% higher migration resistance compared with the Standard Gamma3 Lag Screw. It was concluded that both higher resistance and rotational strength have arisen from the increased contact surface in vertical direction [5].

The off-center groups were included in this study to investigate the influence of implant malpositioning – associated with a greater TAD – on the biomechanical behavior of the tested constructs [18]. Multiple studies have shown that a TAD bigger than 25 mm is a significant predictor of cut-out failure and mobilization of the lag screw [18,30–33]. Even though authors emphasize the importance of a TAD being less than 25 mm in order to reduce reoperation [33] and cut-out [32] rates, bigger TAD values are frequently observed [31,33–35]. Schmidt-Rohlfing *et al* reported a TAD of less than 25 mm in only 16% of the patients undergoing internal fixation after trochanteric femoral fractures [33]. In the study by Aicale and Maffulli this rate was even 53% [31], which emphasizes the necessity of experimental evaluation of incorrect implantation.

In the present study, the change from center to off-center positioning led to a significant decrease in the cycles to failure, failure load and stiffness for Gamma-RC, whereas specimens implanted with RoSA-HE did not demonstrate this effect. Hence, RoSA-HE reacted less sensitively to the change from centric to eccentric implantation than Gamma-RC. A reason for this result might be the geometry of RoSA-HE, which generally offers a larger contact surface with the bone than Gamma-RC. In addition, RoSA-HE has a larger volume, possibly leading to a larger volumetric impact effect during implantation. However, despite its higher sensitivity towards the accuracy of implantation, the biomechanical performance of Gamma-RC was still comparable with RoSA-HE in eccentric position. Gamma-RC benefits from a central position by having higher stability in terms of rotation around implant axis and varus deformation. However, with increasing rotational moments in off-center position its stability drops sharply. Consequently, for screw-blade implant systems with a blade oriented horizontally, central insertion seems to be the placement of choice from a biomechanical perspective.

Two different failure modes were observed in the current study – failure due to rotation around implant axis and varus collapse of the femoral head fragment. While rotational failure was mainly found after off-center implantation, varus collapse was the predominant failure mode following central implant positioning.

According to previous studies testing centrally inserted RoSA implants in complete femur specimens, fracture collapse with additional femoral neck fracture [11], varus collapse [36] and cut-out [8,11] were observed as modes of failure. Varus collapse with additional femoral neck fracture seems to be a typical failure mechanism for vertically aligned implants, as well as for such intramedullary systems as the TRIGEN INTERTAN Intertrochanteric Antegrade Nail (Smith and Nephew Inc, Andover, MA, USA) [37]. No rotational failure or only a small tendency towards it were previously reported, which is in agreement with our findings for the centrally implanted RoSA-HE [8,11,12].

In a biomechanical study testing Gamma-RC along with other implants in synthetic femoral head models under cyclic loading, Gamma-RC failed due to varus collapse and predominantly migrated in cephalad direction [5].

The first existing clinical study on RoSA investigated mechanical complication rates following its use in combination with a trochanteric stabilizing plate (TSP) for fixation of unstable trochanteric fractures [13]. Advantages of the RoSA-TSP implant system were its high primary stability and limited femoral neck shortening, whereas the rigidity of the construct was commented as potential disadvantage, possibly impeding bone healing. Overall, it was concluded that the RoSA-TSP might be a good extramedullary alternative for both primary fixation of unstable trochanteric fractures and use in revision cases [13]. In a recent clinical study Lang *et al* reported a mechanical complication rate of 2.9% for Gamma-RC systems [15]. Compared with the Standard Gamma3 Lag Screw systems, their cut-out rate was not significantly reduced (2.2% versus 3.7%) while the operation time was prolonged [14]. Han *et al* found low cut-out rates of 0.6% for Gamma-RC systems versus comparable cephalomedullary nails [4]. All in all, Lang *et al* did not justify the use of Gamma-RC given its longer time of surgery, whereas others authors considered it being a good option for trochanteric fracture fixation with comparable [38] or even superior [39] performance versus other implant systems.

This study has some limitations inherent to those for all cadaveric investigations with limited sample size, being incapable to completely simulate *in vivo* situations with surrounding soft tissue following a bone fracture. In addition, some of the used cadaveric specimens originated from rather younger donors and were with slightly better bone quality, not being representative for the typical patient population suffering from trochanteric femoral fractures. Further, a femoral head fragment was used instead of a full femur to concentrate on the investigation of the implant anchorage within the femoral head. For the same reason, isolated implant head elements were tested, although these fixation devices are designed for use in combination with other implant components, such as nail shafts or lateral supporting plates. Besides, the tested model represented rather an intracapsular femoral neck fracture than a trochanteric fracture, for which both investigated screw-blade implant systems (especially Gamma-RC) are most commonly used. However, the incidence of comminuted trochanteric fractures with a basicervical component continues to increase steadily [1,2]. Finally, the bone-implant constructs were tested under progressively increasing cyclic loading to failure, in contrast to *in vivo* situations where single extreme loads can occur, for example during stumbling [40].

5. Conclusion

From a biomechanical perspective, being a screw-blade implant system with horizontal blade orientation, Gamma-RC demonstrates better anchorage in the femoral head versus RoSA-HE in central position. As the stability of Gamma-RC drops sharply in off-center position, central insertion is its placement of choice. In contrast, RoSA-HE, with its vertical blade orientation, seems to react less sensitively to suboptimal implant insertion.

As the clinical outcome depends on several factors besides the implant design, such as quality of reduction, duration of surgery, soft tissue damage, potential wound infections and other postoperative complications [41], further prospective randomized clinical trials need to be conducted in order to make clear recommendations for the clinical use of these two screw-blade implant systems.

Declaration of Competing Interest

The authors declare no conflict of interest.

Acknowledgements

The authors are not compensated and there are no other institutional subsidies, corporate affiliations, or funding sources supporting this work unless clearly documented and disclosed. This investigation was performed with the assistance of the AO Foundation. Koenigsee provided their implants for this study. The authors thank Jana Schader and Guillermo Rosenberg Sanchez for assistance with the surgeries.

References

[1] Hu SJ, Yu GR, Zhang SM. Surgical treatment of basicervical intertrochanteric fractures of the proximal femur with cephalomeduallary hip nails. Orthop Surg 2013;5(2):124–9.

[2] Blair B, Koval KJ, Kummer F, Zuckermann JD. Basicervical fractures of the proximal femur. A biomechanical study of 3 internal fixation techniques. Clin Orthop Relat Res 1994(306):256–63.

[3] Han S-B, Jung JK, Jang CY, Kwak DK, Kim JW, Yoo JH. Gamma3 nail with U-Blade (RC) lag screw is effective with better surgical outcomes in trochanteric hip fractures. Scientific Reports 2020(10).
[4] Haynes RC, Pöll RG, Miles AW, Weston RB. Failure of femoral head fixation: a cadaveric analysis of lag screw cut-out with the gamma locking nail and AO dynamic hip screw. Injury 1997;28(5-6):337–41.
[5] Born CT, Karich B, Bauer C, von Oldenburg G, Augat P. Hip screw migration testing: first results for hip screws and helical blades utilizing a new oscillating test method. J Orthop Res 2011;29(5):760–6.
[6] O'Neill F, Condon F, McGloughlin T, Lenehan B, Coffey JC, Walsh M. Dynamic hip screw versus DHS blade: a biomechanical comparison of the fixation achieved by each implant in bone. J Bone Joint Surg Br 2011;93(5):616–21.
[7] Lenich A, Bachmeier S, Prantl L, Nerlich M, Hammer J, Mayr, et al. Is the rotation of the femoral head a potential initiation for cutting out? A theoretical and experimental approach. BMC Musculoskelet Disord 2011;12:79.
[8] Knobe M, Altgassen S, Maier KJ, Gradl-Dietsch G, Kaczmarek C, Nebelung S, et al. Screw-blade fixation systems in Pauwels three femoral neck fractures: a biomechanical evaluation. Int Orthop 2018;42(2):409–18.
[9] Knobe M, Gradl G, Ladenburger A, Tarkin IS, Pape HC. Unstable intertrochanteric femur fractures: is there a consensus on definition and treatment in Germany? Clin Orthop Relat Res 2013;471(9):2831–40.
[10] Stoffel K, Zderic I, Gras F, Sommer C, Eberli U, Mueller D, et al. Biomechanical Evaluation of the Femoral Neck System in Unstable Pauwels III Femoral Neck Fractures: A Comparison with the Dynamic Hip Screw and Cannulated Screws. J Orthop Trauma 2017;31(3):131–7.
[11] Knobe M, Gradl G, Maier KJ, Drescher W, Janssen-Troy A, Prescher A, et al. Rotationally stable screw-anchor versus sliding hip screw plate systems in stable trochanteric femur fractures: a biomechanical evaluation. J Orthop Trauma 2013;27(6):e127–36.
[12] Knobe M, Nagel P, Maier KJ, Gradl G, Buecking B, Sonmez TT, et al. 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. J Orthop Trauma 2016;30(1):e12–18.
[13] Maier KJ, Bücking B, Horst K, Andruszkow H, Hildebrand F, Knobe M. [The rotationally stable screw-anchor with trochanteric stabilizing plate (RoSA/TSP): First results in unstable trochanteric femur fractures], 120. Unfallchirurg; 2017. p. 1054–64.
[14] Lang NW, Arthold C, Joest J, Gormasz A, Boesmueller S, Hajdu S, et al. Does an additional antirotation U-Blade (RC) lag screw improve treatment of AO/OTA 31 A1-3 fractures with gamma 3 nail? Injury 2016;47(12):2733–8.
[15] Lang NW, Breuer R, Beiglboeck H, Munteanu A, Hajdu S, Windhager R, et al. Migration of the Lag Screw after Intramedullary Treatment of AO/OTA 31.A2.1-3 Pertrochanteric Fractures Does Not Result in Higher Incidence of Cut-Outs, Regardless of Which Implant Was Used: A Comparison of Gamma Nail with and without U-Blade (RC) Lag Screw and Proximal Femur Nail Antirotation (PFNA). J Clin Med 2019;8(5).
[16] Cann CE, Genant HK. Precise measurement of vertebral mineral content using computed tomography. Journal of computer assisted tomography 1980;4(4):493–500.
[17] Kalender WA, Suess C. A new calibration phantom for quantitative computed tomography. Med Phys 1987;14(5):863–6.
[18] Baumgaertner MR, Curtin SL, Lindskog DM, Keggi JM. The value of the tip-apex distance in predicting failure of fixation of peritrochanteric fractures of the hip. J Bone Joint Surg Am 1995;77(7):1058–64.
[19] Sermon A, Boner V, Boger A, Schwieger C, Boonen S, Broos PL, et al. Potential of polymethylmethacrylate cement-augmented helical proximal femoral nail antirotation blades to improve implant stability–a biomechanical investigation in human cadaveric femoral heads. J Trauma Acute Care Surg 2012;72(2):E54–9.
[20] Sommers MB, Roth C, Hall H, Kam BC, Ehmke LW, Krieg JC, et al. A laboratory model to evaluate cutout resistance of implants for pertrochanteric fracture fixation. J Orthop Trauma 2004;18(6):361–8.
[21] Bergmann G, Deuretzbacher G, Heller M, Graichen F, Rohlmann A, Strauss J, et al. Hip contact forces and gait patterns from routine activities. J Biomech 2001;34(7):859–71.
[22] Sermon A, Boner V, Schwieger C, Boger A, Boonen S, Broos P, et al. Biomechanical evaluation of bone-cement augmented Proximal Femoral Nail Antirotation blades in a polyurethane foam model with low density. Clin Biomech (Bristol, Avon) 2012;27(1):71–6.
[23] Maiettini D, Bisaccia M, Caraffa A, Rinonapoli G, Piscitelli L, Bisaccia O, et al. Feasibility and Value of Radiographic Union Score Hip Fracture after Treatment with Intramedullary Nail of Stable Hip Fractures. Acta Inform Med 2016;24(6):394–6.
[24] Blomfeldt R, Törnkvist H, Ponzer S, Söderqvist A, Tidermar J. Comparison of internal fixation with total hip replacement for displaced femoral neck fractures. Randomized, controlled trial performed at four years. J Bone Joint Surg Am 2005;87(8):1680–8.
[25] Rollo G, Tartaglia N, Falzarano G, Pichierri P, Stasi A, Medici A, et al. The challenge of non-union in subtrochanteric fractures with breakage of intramedullary nail: evaluation of outcomes in surgery revision with angled blade plate and allograft bone strut. Eur J Trauma Emerg Surg 2017;43:853–61.
[26] Maniscalco P, Rivera F, D'Ascola J, Del Vecchio EO. Failure of intertrochanteric nailing due to distal nail jamming. Orthopaed Traumatol 2013;14:71–4.
[27] Lanzetti RM, Caraffa A, Lupariello D, Ceccarini P, Gambaracci G, Meccariello G, et al. Comparison between locked and unlocked intramedullary nails in intertrochanteric fractures. Eur J Orthop Surg Traumatol 2018;28(4):649–58.
[28] Parker MJ. Evidence-based results depending on the implant used for stabilizing femoral neck fractures. Injury-International Journal of the Care of the Injured 2002;33:15–18.
[29] Lee PY, Lin KJ, Wei HW, Hu JJ, Chen WC, Tsai CL, et al. Biomechanical effect of different femoral neck blade position on the fixation of intertrochanteric fracture: a finite element analysis. Biomed Tech (Berl) 2016;61(3):331–6.
[30] Knobe M, Drescher W, Heussen N, Sellei RM, Pape HC. Is helical blade nailing superior to locked minimally invasive plating in unstable pertrochanteric fractures? Clin Orthop Relat Res 2012;470(8):2302–12.
[31] Aicale R, Maffulli N. Greater rate of cephalic screw mobilisation following proximal femoral nailing in hip fractures with a tip-apex distance (TAD) and a calcar referenced TAD greater than 25 mm. J Orthop Surg Res 2018;13(1):106.
[32] Geller JA, Saifi C, Morrison TA, Macaulay W. Tip-apex distance of intramedullary devices as a predictor of cut-out failure in the treatment of peritrochanteric elderly hip fractures. Int Orthop 2010;34(5):719–22.
[33] Schmidt-Rohlfing B, Heussen N, Knobe M, Pfeifer R, Kaneshige JR, Pape HC. Reoperation rate after internal fixation of intertrochanteric femur fractures with the percutaneous compression plate: what are the risk factors? J Orthop Trauma 2013;27(6):312–17.
[34] Caruso G, Bonomo M, Valpiani G, Salvatori G, Gildone A, Lorusso V, et al. A six-year retrospective analysis of cut-out risk predictors in cephalomedullary nailing for pertrochanteric fractures: Can the tip-apex distance (TAD) still be considered the best parameter? Bone Joint Res 2017;6(8):481–8.
[35] Turgut A, Kalenderer O, Karapinar L, Kumbaraci M, Akkan HA, Agus H. Which factor is most important for occurrence of cutout complications in patients treated with proximal femoral nail antirotation? Retrospective analysis of 298 patients. Arch Orthop Trauma Surg 2016;136(5):623–30.
[36] Knobe M, Bettag S, Kammerlander C, Altgassen S, Maier KJ, Nebelung S, et al. Is bone-cement augmentation of screw-anchor fixation systems superior in unstable femoral neck fractures? A biomechanical cadaveric study. Injury 2019;50(2):292–300.
[37] Knobe M, Gradl G, Buecking B, Gackstatter S, Sönmez TT, Ghassemi A, et al. Locked minimally invasive plating versus fourth generation nailing in the treatment of AO/OTA 31A2.2 fractures: A biomechanical comparison of PCCP(®) and Intertan nail(®). Injury 2015;46(8):1475–82.
[38] Yoo J, Kim S, Choi J, Hwang J. Gamma 3 U-Blade lag screws in patients with trochanteric femur fractures: are rotation control lag screws better than others? J Orthop Surg Res 2019;14(1):440.
[39] Haynes RC, Pöll RG, Miles AW, Weston RB. Failure of femoral head fixation: a cadaveric analysis of lag screw cut-out with the gamma locking nail and AO dynamic hip screw. Injury 1997;28(5-6):337–41.
[40] Bergmann G, Graichen F, Rohlmann A, Bender A, Heinlein B, Duda GN, et al. Realistic loads for testing hip implants. Biomed Mater Eng 2010;20(2):65–75.
[41] Knobe M, Siebert CH. [Hip fractures in the elderly: Osteosynthesis versus joint replacement]. Orthopade 2014;43(4):314–24.