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Objectives: To evaluate the biomechanical performance of femoral neck system (FNS) in comparison with established methods for fixation of femoral neck fractures in a cadaveric model.

Methods: Twenty pairs of fresh-frozen human cadaveric femora were instrumented either with dynamic hip screw and antirotation screw (DHS-screw), DHS-blade, 3 cannulated screws (3CS) or with FNS in a partially paired design. The specimens were randomized to 2 paired treatment groups based on the bone mineral density (BMD), namely DHS-screw/DHS-blade and FNS/3CS. A reduced unstable femoral neck fracture with postero-caudal comminution, OTA/AO 31–B2.3, 70 degrees Pauwels III, was simulated by cutting 30 degrees distal and 15 degrees posterior wedges. Cyclic axial loading was applied in 16 degrees adduction, starting at 500 N and with progressive peak force increase of 0.1 N/cycle until construct failure. Axial stiffness was measured in the third loading cycle. Femoral neck and leg shortening, and varus tilting and implant migration were calculated by means of optical motion tracking.

Results: Mean axial stiffness was 688.8 ± 132.6 N/mm for DHS-screw, 629.1 ± 94.1 N/mm for DHS-blade, 748.9 ± 211.4 N/mm for FNS, and 584.1 ± 156.6 N/mm for 3CS, with no statistical significances. Cycles until 15-mm leg shortening were comparable for DHS-Screw (20,542 ± 7465), DHS-blade (19,161 ± 3793) and FNS (17,372 ± 2996), however significantly higher than for 3CS (7293 ± 2819), P < 0.001. Similarly, cycles until 15 mm femoral neck shortening were comparable between DHS-screw (20,846 ± 7339), DHS-blade (18,974 ± 4032) and FNS (18,171 ± 2585), and significantly higher than 3CS (8039 ± 2778), P < 0.001.

Conclusions: From a biomechanical point of view, the femoral neck system is a valid alternative to treat unstable femoral neck fractures, representing the advantages of a minimally invasive implant with comparable stability to the 2 DHS systems and superior to cannulated screws.

Key Words: unstable femoral neck fracture, dynamic hip screw, cannulated screws, femoral neck system, biomechanics

INTRODUCTION

The incidence of hip fractures worldwide is estimated to increase to 2.6 million in 2025 of which approximately 50% of cases are femoral neck fractures. This is accompanied by an enormous socioeconomic burden and medical challenge. Orthopedic surgeons have to choose the most effective and affordable implant to treat such fractures. Furthermore, hip joint preserving fixation techniques—especially in younger patients—are associated with major fracture healing complications, such as femoral head necrosis, early implant failure, and nonunions in up to 28% of cases or postoperative morbidity caused by altered hip mechanics.

Implant choice for the fixation of femoral neck fracture is one of the most important management controversies in the treatment of these challenging fractures. As reported in recent questionnaire studies including 540 Orthopaedic Trauma Association (OTA)/Canadian Orthopaedic Association (COA) members and 52 AO-trauma surgeons, geographical differences are present with respect to decision making and operative treatment, especially in cases of unstable Pauwels III fractures, with or without comminution zone in the infero-posterior neck region. Increased rates of fixation failure and nonunions are observed as a result of high shear forces and varus instability. Furthermore, femoral neck shortening and/or varus collapse in cases of fracture union are common and cause adverse functional outcomes due to leg
length discrepancy and shortening of the femoral offset resulting in limping.4

Such fractures are often stabilized with cannulated screws, dynamic hip screw (DHS) with or without antitrotation screw, DHS with blade instead of screw (DHS-blade) or similar implants.7,11–13

Although the DHS-blade has been established as a comparative European gold standard for treatment of unstable femoral neck fractures, the conventional DHS with antitrotation screw (DHS-screw) continues to be an international gold standard for comparison purposes.14–16 Fixation with 3 parallel cannulated screws (3CS) can be used for treatment of unstable displaced subcapital or transcervical femoral neck fractures type OTA/AO 31-B.17 Compared to 3CS, both DHS systems require a larger skin incision with a more extensive soft tissue dissection14,18 while providing the benefit of superior stability.19–22 The role of an ideal minimally invasive implant would be ensuring the required stability of fixation, without pronounced femoral neck shortening or femoral head tilting and rotation. The new minimally invasive implant femoral neck system (FNS), developed for dynamic fixation of femoral neck fractures, combines the advantages of angular stability with a minimally invasive surgical technique (Fig. 1). The implant with its small side plate provides fixation to the femoral shaft while allowing a reduced implant footprint. Fixation of the femoral head is achieved with a screw locked into a bolt in a way allowing these both components to slide together along the plate barrel for dynamic fixation. The device is inserted over one guide wire by using a set of dedicated instruments.

The aim of this study was to evaluate the biomechanical performance of FNS under cyclic loading in comparison with the existing clinical implants on the market DHS-blade, DHS-screw, and 3CS in a human cadaveric model with unstable fracture type OTA/AO 31–B2.3, Pauwels III, and therefore to verify the safety of the new FNS implant for its proposed indication.

In a biomechanical study of Linke et al,23 the authors compared the DHS-screw against 3CS in a cadaveric model with simulated unstable 31-B2 fractures under cyclic loading. Although initial displacement of the femoral head did not statistically differ between the 2 groups, specimens instrumented with DHS-screw revealed a significantly higher survival probability than those with 3CS. Referring to these results, we hypothesized that no statistical significant difference in axial stiffness would be demonstrated but that all angular stable implants would provide higher loads to failure.

FIGURE 1. The new femoral neck system for femoral neck fracture fixation. Editor's Note: A color image accompanies the online version of this article.

MATERIALS AND METHODS

Specimens

Twenty pairs of fresh-frozen (–20°C) human cadaveric femora from 8 male and 12 female donors, aged 67 ± 4 years (mean ± SD, range 60–73 years), and with body mass index 25 ± 7 (range 15–43) were used in this study. Specimens with severe osteoporosis, grade 3 or 4 osteoarthritis, caput-collum-diaphyseal (CCD) angle lower than 120 degrees or higher than 135 degrees, or previous hip fractures have been excluded. The overall measured CCD angle was 130 ± 3 degrees. Bone mineral density (BMD) was measured in the femoral head via high-resolution peripheral quantitative computed-tomography (HR pQCT) using an XteemeCT (Scanco Medical AG, Brütisellen, Switzerland). The specimens were assigned to 4 study groups with 5 right and 5 left femora each (n = 10) and similar BMD distribution among the groups.

The sample size n = 10 was chosen based on a priori power analysis with the assumption that FNS would fail under 4-fold body weight of an average person, equaling 2800 N. Furthermore, we assumed that a 25% lower performance (2100 N) of constructs in group 3CS compared to FNS clinically would be a meaningful difference, and that a standard deviation of 75% from the mean value, namely 2100 N for FNS and 1575 N for 3CS, could be expected deviations. Based on these assumptions, a sample size of 9 specimens would be necessary to reach significant differences between the 2 groups under a level of significance 0.05 and a power of 0.8. To be more conservative, a sample size of n = 10 seemed appropriate.

Study Groups

The specimens were randomized to 2 paired treatment groups based on the BMD: DHS-screw/DHS-blade and
FNS/3CS. The femora were randomly pairwise assigned to these 2 treatment groups. The paired femora were further randomized to either treatment within the 2 groups. Specimen group assignment is shown in Supplemental Digital Content 1 (see Table, http://links.lww.com/BOT/A813). Although implants used in the DHS-screw group were made of stainless steel (316L), the ones used in the other groups were made of Ti-Al6-Nb7 (TAN) alloy. All implants were produced by the same manufacturer (DePuy Synthes, Zuchwil, Switzerland).

Surgical Technique
The femora had been thawed for 24 hours at room temperature and stripped of soft tissue before instrumentation, which was performed in intact specimen state by an experienced surgeon (C.S.) under fluoroscopic control according to the manufacturer’s guidelines for the respective fixation method. Implant length was determined individually, keeping the tip-apex distance less than 20 mm. Two-hole 130 degrees side plates were used in the 2 DHS groups and secured to the femoral shaft with 2 diverging 4.5 mm cortical screws. An additional 6.5-mm cancellous bone screw with distal thread was placed cranially and parallel to the dynamic hip screw at a distance of 10 mm to prevent rotation of the femoral head around the (femoral) neck axis. Rotational stability with DHS-blade fixation was achieved by engaging the interlocking mechanism of the implant with 1.5 N·m torque. One-hole 130 degrees side plates were used for FNS osteosynthesis and fixed to the shaft with 5.0 mm locking screws. For both, the DHS and the FNS constructs a temporary guide wire was placed to prevent femoral head rotation during insertion and tightening of the dynamic components. Three partially threaded 7.3-mm cannulated screws were inserted parallel in the femoral head of each specimen in group 3CS in standard fashion,17 resting the inferior screw on the calcar and using washers to prevent screw heads penetration in the cortex of the greater trochanter. The dynamic components in the DHS-screw and FNS groups were placed 10% inferiorly to the femoral head center in anteroposterior (AP) view and centrally in lateral view, whereas their placement with the DHS-blade fixation method was center–center in both anteroposterior and lateral views.

Osteotomy
An unstable femoral neck fracture 70 degrees Pauwels III, OTA/AO 31-B2.3 was created in all specimens after instrumentation to represent a worst-case scenario for the tested implants. A custom-made saw-guide24 was used for this purpose to perform consistent osteotomies by guiding an oscillating saw in circular slots around the bone and remove 30 degrees distal and 15 degrees posterior femoral neck wedges to eliminate postero medial support as shown in Supplemental Digital Content 2 (see Figure, http://links.lww.com/BOT/A814). All femora were cut distally at the same length of 40 cm and embedded in polymethylmethacrylate (PMMA; Suter Kunststoffe AG, Fraubrunnen, Switzerland). Three marker sets with retro-reflective markers were attached to the femoral head, shaft, and implant for optical motion tracking as shown in Figure 2.

Biomechanical Testing
Biomechanical testing was performed on a servohydraulic test system Bionix 858 (MTS Systems, Eden Prairie, MN) with a 4 kN/20 Nm load cell. Test setup and loading protocol were adapted from previous studies (Fig. 2).24–26 Each specimen was tested in 16 degrees lateral angulation (adduction) of the femoral shaft in accordance with the hip contact forces measured in vivo by Bergmann et al.25 Passive force was applied at the greater trochanter by the use of a bracing to simulate the iliobibial band of the abductor muscles. This bracing consists of 2 parts connected at the region of the greater trochanter, with one part located distally and the other one proximally to the latter. Although the distal part is oriented collinear to the femur axis, the orientation of the proximal part is approximately vertical, resulting in an angulated construct acting like a catching belt for the femur. The latter induces a reaction force, with its vector pointing on the greater trochanter and passing perpendicular to the femur axis in the coronal plane. This reaction force prevents excessive bending in the femoral shaft and concentrates the loading...
The femoral head
Keeping the valley load of each
Axial stiffness (mean
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around the neck and head region. The setup has previously
been introduced by Windolf et al in 2009. The femoral head
was loaded in compression along the machine axis via a spher-
ically shaped polymethylmethacrylate shell cup attached to
the machine actuator. The contact surface of the cup (to bone)
was covered with an electro-conducting foil to detect possible
implant cut-out and interrupt biomechanical testing if neces-
sary. Mediolateral gliding of the shell cup was enabled
through a linear guide attached between the cup and the load
cell, ensuring free centre of the femoral head rotation. The
distal specimen end was attached to the machine frame via
a caradan joint.

The loading protocol of each specimen comprised initial
quasi-static ramped compression loading from 50 to 200 N at
a rate of 15 N/s, followed by cyclic loading at 2 Hz with a
double-peaked physiological compression profile of each
cycle as previously provided. Keeping the valley load of each
cycle at a constant level of 200 N throughout the whole test, the
peak load, starting at 500 N, was progressively increased cycle
by cycle at a rate of 0.1 N/cycle until one of the following 3 test
stop criteria was fulfilled: cutout of the implant tip, 30 mm
relative axial displacement of the machine actuator with respect
to test beginning, or reaching 4000 N compression load. The
application of progressively increasing cyclic loading is re-
ported and found to be useful in previous studies.

Data Acquisition
Machine data in terms of axial displacement and axial
load were acquired at a rate of 128 Hz. Axial stiffness of the
bone–implant construct was derived from the ascending linear
slope of the load–displacement curve in the third loading
cycle, considering settling effects at the beginning of the
cyclic test.

Anteroposterior x-ray images were taken for radiolog-
ical assessment of each specimen by the use of a triggered
C-arm (Siemens Arcadis Vari; Siemens AG, Erlangen,
Germany) at the beginning and the end of the quasi-static
test, and then at timed intervals every 250 cycles during the
cyclic test at the valley load of 200 N.

Relative femoral head movements with respect to bone
shaft and implant were investigated in 6 degrees of freedom
via 3-dimensional (3D) motion tracking analysis using 5
Qualisys ProReflex MCU digital cameras (Qualisys AB,
Gothenburg, Sweden).

Based on the motion tracking data, femoral neck
shortening was calculated along the neck axis from the
movements of a femoral head aspect located in the middle
between the most superior and most inferior femoral head
ostectomy points. Similarly, femoral leg shortening was
derived from the movements of the head centre along the
shaft axis. In addition, numbers of cycles until 15-mm
femoral neck and 15-mm femoral leg shortening were derived
from the magnitude series of these 2 parameters over time.
The lower of the 2 values from each cyclic test was then
defined as cycles until onset of construct failure for the
respective specimen. Type of failure of the bone–implant
constructs was determined by the earlier of the 2 events
(15-mm neck or leg shortening).

The performance of the bone–implant constructs was
further investigated by the parameters of interest varus tilting
and implant migration. Based on the fact that for each specimen
none of the test stop criteria had yet been fulfilled, both outcomes were
evaluated from the motion tracking data at the time point after
5000 cycles. The former (varus tilting) was calculated from the
rotational femoral head movements in coronal plane with respect
to the shaft, whereas the latter (implant migration) was deter-
mined as the magnitude of the 3D translation of the head aspect
which was initially located at the implant tip. All outcomes,
based on the motion tracking data, were derived in valley loading
condition under 200 N compression and calculated with regard
to their values at the beginning of the test after 3 cycles, taken as
reference to consider specimen’s settling effects.

Statistical evaluation upon the parameters of interest
was performed by the use of SPSS software package (IBM
SPSS Statistics V21; IBM, Armonk, NY). Descriptive
statistics was performed to calculate the mean and the
standard deviation (SD) in the study groups. Normal distri-
bution and homogeneity of variance were screened with
Shapiro–Wilk and Levene’s tests, respectively. Statistical
differences between the groups consisting of paired speci-
mens, namely DHS-screw and DHS-blade, respectively FNS
and 3CS, were assessed with paired-samples t test. For the
comparison among all other (independent) groups, the general
linear model univariate analysis of variance test with Bonfer-
roni post hoc correction for multiple comparisons was
applied. BMD was thereby considered as covariate to inves-
tigate the influence on the results. The level of significance
was set to 0.05 for all statistical tests.

RESULTS
All parameters of interest were normally distributed
within each study group and with homogeneous variance
among the 4 groups. Mean BMD values in the groups were

![FIGURE 3. Axial stiffness (mean ± SD) in the 4 study groups.](image)

Editor’s Note: A color image accompanies the online version
of this article.
206.7 ± 47.1 mgHA/cm³ for DHS-screw, 216.3 ± 48.0 mgHA/cm³ for DHS-blade, 214.8 ± 48.4 mgHA/cm³ for FNS, and 208.6 ± 54.8 mgHA/cm³ for 3CS, with no significant differences (P = 0.520).

Axial Stiffness

Mean axial stiffness was 688.8 ± 132.6 N/mm for DHS-screw, 629.1 ± 94.1 N/mm for DHS-blade, 748.9 ± 211.4 N/mm for FNS, and 584.1 ± 156.6 N/mm for 3CS, with no significant differences between the 4 study groups, P = 0.067 (Fig. 3). BMD influenced significantly the axial stiffness as covariate in all study groups, P = 0.017.

Femoral Neck Shortening

Mean numbers of cycles to 15-mm neck shortening were 20,846 ± 7339 for DHS-screw, 18,974 ± 4032 for DHS-blade, 18,171 ± 2585 for FNS, and 8039 ± 2778 for 3CS, as illustrated in Figure 4. DHS-screw, DHS-blade, and FNS revealed significantly higher values than 3CS, P < 0.001. On the other hand, no significant differences were detected between these 3 groups, P ≥ 0.688. BMD was found to have significant influence on cycles to 15-mm neck shortening as a covariate, P = 0.005.

Leg Shortening

Mean numbers of cycles to 15-mm leg shortening were 20,542 ± 7465 for DHS-screw, 19,161 ± 3793 for DHS-blade, 17,372 ± 2996 for FNS, and 7293 ± 2819 for 3CS, as illustrated in Figure 4. DHS-screw, DHS-blade, and FNS fixations resulted in significant higher values than 3CS, P < 0.001, with no detected significant differences between these 3 groups, P ≥ 0.487. BMD influenced significantly as covariate cycles to 15-mm leg shortening in all study groups, P = 0.013.

Onset of Construct Failure

Mean numbers of cycles to onset of construct failure were 20,485 ± 7474 for DHS-screw, 18,731 ± 3884 for DHS-blade, 17,353 ± 2989 for FNS, and 7293 ± 2819 for 3CS. The corresponding failure load values were 2548.5 ± 747.4 N for DHS-screw, 2373.1 ± 388.4 N for DHS-blade, 2235.3 ± 298.9 N for FNS, and 1229.3 ± 281.9 N for 3CS. DHS-screw, DHS-blade, and FNS revealed significantly higher values than 3CS, P < 0.001. On the other hand, no significant differences were detected between these 3 groups, P ≥ 0.379. BMD was found to have a significant influence on cycles to onset of construct failure as a covariate, P = 0.008.

Varus Tilting

Mean values for varus tilting after 5000 cycles were 0.91 ± 0.53 degrees for DHS-screw, 1.46 ± 0.20 degrees for DHS-blade, 2.89 ± 0.98 degrees for FNS, and 5.28 ± 2.17 degrees for 3CS. DHS-screw, DHS-blade, and FNS revealed significant lower values than 3CS, P ≤ 0.004. In addition, varus tilting after DHS-screw osteosynthesis was significantly lower compared to DHS-blade and FNS, and significantly lower after DHS-blade fixation in comparison with FNS, P ≤ 0.032. BMD showed no significant influence on varus tilting as covariate, P = 0.797.

Implant Migration

Mean values for implant migration after 5000 cycles were 0.30 ± 0.26 mm for DHS-screw, 0.64 ± 0.53 mm for DHS-blade, 0.67 ± 0.50 mm for FNS, and 3.98 ± 5.07 mm for 3CS. Significantly higher migration was detected after 3CS osteosynthesis compared to DHS-screw, P = 0.036. No further significances were observed among the 4 fixation methods, P ≥ 0.073. BMD showed no significant influence on implant migration as covariate, P = 0.932.

Type of Failure

Construct failure was registered in 28 cases as 15-mm femoral leg shortening and in 8 cases as 15-mm femoral neck shortening. In 4 cases, the test stop criterion of 30-mm machine actuator displacement was fulfilled before reaching any of the other failure criteria. No catastrophic fractures were observed in any of the specimens by the time point of failure onset.

Representative radiographic images before testing and after failure onset are shown in Fig. 5. Failure type in each of these 4 differently fixed cases was 15-mm leg shortening, caused by either sintering of the femoral heads instrumented with DHS-screw, DHS-blade, and FNS along the implant axis with engagement of the sliding implant mechanism, or backing-out and toggling of the 3CS, resulting in cutting through the calcar region with a peri-implant fracture.

DISCUSSION

All angular stable, extramedullary devices (DHS-screw, DHS-blade or FNS) have shown similar results in fracture fixation for the parameters cycles to failure, femoral neck, and femoral leg shortening and significant superiority compared to the 3CS construct in our biomechanical evaluation. These
results confirm some biomechanical studies reporting overall higher construct stability for the DHS with antirotation screw compared to 3CS in human cadavers and synthetic femora.29 The importance of an antirotation screw was shown by Bonnaire et al22 in a matched pair biomechanical study reporting reduced fracture dislocation and load to failure rate for DHS constructs with versus without an antirotation screw.

Nevertheless, the bone–implant interface seems to be the weakest link in the chain, as shown in the load to failure mechanisms discussed below. With introduction of helical-shaped femoral neck blades, improved implant anchorage and reduced cutout rates in osteoporotic bones could be observed by enlarging the bone–implant surface and by volumetric impaction of the peri-implant bone zone during blade insertion.24,28,30 Less femoral head migrations were reported for blades used in sliding hip screw (SHS) constructs for femoral neck fractures and in proximal femur nails for pertrochanteric fractures.24,30 A significant superiority of the blade could not be observed in our study, most likely based on the exclusion of specimens with severe osteoporosis and due to the additional use of an antirotation screw in the DHS group, which substitutes the positive effects of a blocked DHS-blade construct to prevent the femoral head torsion around the blade axis.

Worth mentioning is the significant less varus tilting for DHS-screw compared to the DHS-blade and FNS. A possible reason for this would be that the parallel screw orientation in DHS-screw facilitates a 2-point fixation in the fracture zone of the femoral head fragment in the coronal plane compared to DHS-blade and FNS with only 1-point fixation because both screw and bolt of the FNS converge in this region. Furthermore, specific differences in the failure modes were observed. The angular stable devices predominantly lead to cutouts, whereas 3CS lead to screw back-outs and toggling, as reported in recent biomechanical studies.19–21,24,31 Because direct comparison with other studies is not feasible because of diversity in parameters used, our approach highlights the evaluation of the new FNS implant in a direct biomechanical comparison with established devices on the market (DHS-screw, DHS-blade, and 3CS).

FNS was developed with the intention to combine advantages of different existing constructs, such as the minimally invasive insertion technique and retention of more viable bone known for 3CS with the increased fracture fixation properties of the 2 DHS systems. This new concept of femoral neck fracture fixation still emphasizes the biology of fracture healing by initial fracture compression.

Our study has both strengths and limitations. The limitations are similar to those inherent to all cadaveric studies. A limited number of specimens were used, thus restricting generalization to actual patients. In addition, soft tissues like joint capsule and ligaments were not simulated, but are essential for the hip stabilization and function. Moreover, in the DHS-screw group, the implant was made of stainless steel, whereas all other implants were made of titanium. Furthermore, the significance of this study is limited to the extent that femoral neck fractures mainly occur in older people and arthroplasty is therefore more commonly applied than fracture fixation. Finally, in group 3CS, the inferior screw was not always optimally placed within 1–2 mm distance to the inferior femoral neck. Its placement was, however, at least adequate and clinically rather accepted than a guide wire repositioning, which would have further weakened the bone, and together with it the screw fixation.

Strengths of the study are the use of matched pairs of fresh-frozen human cadaveric femora to minimize the inter-individual and intra-individual variances and acquire...
significant biomechanical differences for current implants and the new FNS construct. Furthermore, a well-established and approved test setup and fracture model with a worst-case fracture type was used. The simulation of the iliotibial band is appropriate because the different failure modes observed in our biomechanical setup represent the described failure mechanisms in vivo. The iliotibial band shifts bending moments from the femoral shaft to the neck region and therefore prevents artificial, setup related shaft fractures.

To conclude, the FNS showed significantly higher overall construct stability compared to 3CS in an unstable femoral neck fracture model. This biomechanical superiority may be beneficial in clinical use. Furthermore, no significant difference between the FNS and the 2 DHS systems was observed with regard to the clinically most relevant parameters. We therefore would recommend one of the angular stable devices in disfavor of 3CS for fixation of unstable femoral neck fractures, as it was confirmed by other studies in the past. Whether the observed marginal, but statistically significant biomechanical differences in varus tilting between the DHS-screw, DHS-blade, and FNS are of clinical relevance have to be evaluated in further clinical studies.

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