Trabecular Bone Strength is not an Independent Predictive Factor for Dynamic Hip Screw Migration—A Prospective Multicenter Cohort Study

Marc A. Müller,[1] Clemens Hengg,[2] Christian Krettek,[3] Detlef van der Velde,[4] Siegfried Eberdorfer,[5] Richard Stange,[6] Gunther O. Hofmann,[7] Andreas Platz,[8] Norbert Suhm[1]

[1]Department of Orthopedic Surgery and Traumatology, University Hospital Basel, Switzerland, [2]Department of Trauma Surgery and Sports Medicine, University Hospital Innsbruck, Austria, [3]Department of Trauma Surgery, Hannover Medical School, Germany, [4]Department of Surgery, Ziekenhuis Groep Twente, Almelo, The Netherlands, [5]Department of Trauma Surgery, Wilhelminenspital, Vienna, Austria, [6]Department of Trauma, Hand and Reconstructive Surgery, University Hospital Münster, Germany, [7]Trauma, Hand and Recovery Surgery Hospital, University of Jena, Germany, [8]Division of Trauma Surgery, Department of Surgery, Stadtspital Triemli, Zurich, Switzerland

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ABSTRACT: This study assessed whether mechanically measured trabecular bone strength is an independent predictor of dynamic hip screw (DHS) stability, i.e., DHS migration (DHSM) after the fixation of proximal femoral fractures. One-hundred and seven patients older than 50 years with proximal femoral fractures were included. During fracture fixation, a mechanical probe (DensiProbe™ Hip) was inserted at the site where the DHS tip would ultimately be positioned. Peak torque to breakaway the trabecular bone was measured. Fracture reduction, primary implant position and postoperative DHSM were assessed by radiographs taken postoperatively, at 6 and 12 weeks after surgery. Univariate regression analysis revealed no association between peak torque and DHSM ($R^2 = 0.025$, $p = 0.135$). DHSM correlated with the primary DHS position, i.e., the distance between the DHS and (i) the central femoral neck axis (CNFAD, $R^2 = 0.230$; $p < 0.0001$) and (ii) the apex of the femoral head ($R^2 = 0.110$; $p = 0.001$). DHSM did not correlate with areal BMD of the contralateral proximal femur. Multivariable regression modeling revealed the CFNAD as predictive factor for screw migration. The primary implant position measured by the CFNAD, rather than DensiProbe™ Hip measured bone strength, is an independent predictor of DHSM. © 2015 Orthopaedic Research Society. Published by Wiley Periodicals, Inc. J Orthop Res

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Even with the advent of new implant technologies, approximately 5% of proximal femoral fracture fixations become unstable and ultimately fail.[1,2] With both intra- and extra-medullary devices, the screw fixing the femoral head-neck fragment to the diaphysis is most prone to instability. When subjected to the axial load of postoperative weight bearing, the hip screw tends to migrate cranially within the femoral head. Ultimately, the hip screw may penetrate into the hip joint, a complication commonly referred to as "cut out".[3]

Inappropriate implant position, an unstable fracture type and fracture reduction into varus are well-known risk factors for fixation failures with extracapsular hip fractures.[2,4–7] An initial distance between the tip of the hip screw and the apex of the femoral head (tip apex distance [TAD]) of more than 25 mm and a primary positioning of the hip screw in the anterior part of the femoral head are thought to be most important determinants of subsequent cut out.[4]

However, most hip fractures occur in patients with osteoporosis and thus impaired bone strength within the proximal femur.[8] Impaired bone strength may in turn impair implant purchase,[9] as a result of inadequate anchoring within the poor trabecular network of the femoral head.[10] Even though experimental studies have suggested an impact of the biomechanical competence of bone on implant stability,[9,11] no in vivo study has effectively explored the role of bone strength as a risk factor for fixation failure in proximal femur fractures. Previous studies relied on dual energy x-ray absorptiometry (DXA)-measured areal bone mineral density (BMD) as a surrogate of bone strength, and could not detect any correlation between proximal femoral areal BMD and fixation failure.[12,13] However, DXA or quantitative computed tomography (QCT) measured BMD only represents a single determinant of the bone's biomechanical competence and thus only explains 65% of all variations of bone strength.[12]

The DensiProbe™ Hip device was developed in order to measure trabecular bone strength within the proximal femur in a more direct and comprehensive way. Local bone strength is quantified by measurement of the peak torque that is necessary to break away cancellous bone between the wings of the propeller-like probe tip.[14] DensiProbe™ Hip was designed for implementation during hip fracture fixation with a dynamic hip screw (DHS) to perform an intraoperative estimation of the respective hip fracture osteosynthesis' stability. This should allow for preventive measures, such as bone augmentation,[15] against impending fixation failure in a rational and timely manner. In ex vivo studies DensiProbe™ Hip measurements showed high correlations with biomechanical and high resolution computed tomography-based measurements of bone strength.[16] There was also a high correlation between peak torque and load to DHS cut out in a cadaveric hip fracture model exposed to cyclic loading.[16] However, these latter ex vivo findings have never been supported by any in vivo study.

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Correspondence to: Marc Andreas Mueller (T: +41 61 328 78 13; F: +41 61 265 78 29; E-mail: a.mueller@usb.ch)

The aim of this prospective multicenter study was to test the hypothesis that DensiProbe^{TM} Hip measured bone strength is an independent risk factor for postoperative dynamic hip screw migration (DHSM), as a sign of impending fixation failure.

METHODS

Study Design and Inclusion/exclusion Criteria

This was a prospective multicenter cohort study complying with the Oxford Levels of Evidence 3. Patients aged 50 years and older with pertrochanteric or femoral neck fractures eligible for fixation with a 135° DHS were prospectively included from 8 centers around Europe, between October 2008 and June 2011. Enrollment at each of the participating centers ranged from 3 to 32 patients. All included patients provided written informed consent. Exclusion criteria were open hip fractures, pathologic fractures due to primary malignancies or metastatic lesions of the proximal femur, any life-threatening condition, femoral neck length < 90 mm, alcohol and drug abuse and any mental condition impeding patients' cooperation. Additionally, patients with more than seven days between injury and surgery were excluded.

This study was conducted in accordance with the current version of the Declaration of Helsinki and under the laws and regulations enforced by the local ethics committees, and the ICH GCP guidelines and EN ISO14155/2003-2011. Ethical approval was obtained from all local authorities. The study was registered on ClinicalTrials.gov (NCT00822159).

Intraoperative Bone Strength Measurement

Trabecular bone strength was measured intraoperatively using the technique of Suhm et al.[14] After fluoroscopic fracture reduction, a k-wire for subsequent guided insertion of the DHS was drilled into the subchondral bone of the femoral head aiming for the planned screw position. A second wire was inserted in parallel, cranially to the first, in order to compensate for torque applied to the head–neck fragment during insertion of the probe. An 8 mm canulated spiral drill was inserted over the first guide wire to a depth of 45 mm less than the total guide wire length. Then the tip of the DensiProbe^{TM} Hip device (Fig. 1) was advanced over the guide wire to the site where the hip screw tip would ultimately be situated, and forcibly rotated. Peak torque required to break away cancellous bone was recorded using a calibrated digital torque meter (HD-100®, HIOS Inc., Akiyama, Japan). Thereafter, the surgeon completed the DHS implantation. Since the diameter of the DHS is larger than the tip of the DensiProbe^{TM} Hip device, the purchase of the implant was not affected by torque measurement.

Figure 1. The DensiProbe^{TM} Hip device.

Postoperative Rehabilitation

Postoperatively, patients were immediately mobilized under full weight bearing according to their preinjury ambulatory status. Crutches were used as long as needed to ensure the patient's safety.

Radiographic Measurements

Anteroposterior (AP) and lateral radiographs of the affected hip were taken preoperatively, intraoperatively, immediately postoperatively as well as 6 weeks and 3 months after surgery. Radiographs were used to assess primary implant position and subsequent DHSM as described below. Furthermore, one radiologist and one trauma surgeon independently evaluated the perioperative radiographs for fracture type, reduction and stability. Trochanteric fractures were considered stable if there was no posteromedial fragment/comminution and no separation of the greater trochanter from the head neck fragment. Femoral neck fractures were classified as stable if there was valgus impaction or no displacement of the head fragment.

Primary Hip Screw Position

The position of the hip screw within the femoral head was defined as follows:

Tip Apex Distance

The tip apex distance (TAD) was measured as described by Baumgaertner et al. [17] (Fig. 2a and b).

Parker Ratio

The Parker ratio [6] was measured as shown in Figure 2a and b: On both the AP and lateral view the landmark points A and C were defined at the subchondral periphery of the femoral head. Point B was defined at the intersection of the longitudinal hip screw axis with the line between points A and C. The AB/AC ratio was multiplied by 100 to obtain the screw positions on the AP and lateral radiographs, respectively.

Distance From the Central Femoral Neck Axis

The distance between the hip screw and the central femoral neck axis (CFNAD) in a plane perpendicular to the central femoral neck axis (CFNA, Figure 2c) was calculated using the same parameters/distances as obtained from the two Parker ratio calculations. The AC distances measured in the AP and lateral views (AC_{ap} and AC_{lat}) were divided by two in order to obtain the location of the center of the femoral head in the AP (= $AC_{ap}/2$) and lateral (= $AC_{lat}/2$) views, respectively. In an anatomically reduced fracture, this $AC_{ap}/2$ and $AC_{lat}/2$ points are in line with the CFNA. This distance $AC_{ap}/2$ was subtracted from the AB_{ap} distance in the AP view to obtain the distance of the DHS tip from the CFNA in the AP view ($CNFAD_{ap}$). This procedure was repeated in the lateral view to obtain the distance from CFNA in the lateral view ($CFNAD_{lat}$). Finally, the Pythagorean theorem was used to calculate the combined distance from the CFNA in the AP and lateral views:

$$\mathrm{CFNAD} = \sqrt{CFNAD_{ap}^2 + CFNAD_{lat}^2}$$

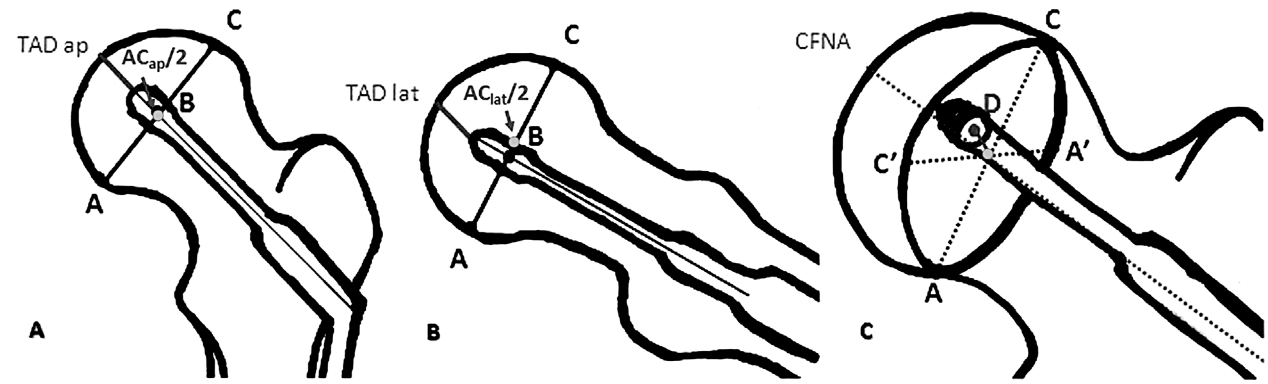

Figure 2. **a/b/c** Calculation of the Parker ratio, center from the femoral neck axis (CFNAD) and tip apex distance (TAD).

Postoperative Dynamic Hip Screw Migration

DHSM was measured as described by Audigé et al.[18] on consecutive AP radiographs accounting for rotation and flexion of the proximal femur relative to the radiographic beam at the time of radiography. Briefly, a coordinate system was applied to the proximal femur. The DHSM was defined as a change in the distance between point zero and the x/y coordinate of the DHS tip between baseline and follow-up radiographs. The projected DHS dimensions (length of DHS plate from the proximal end to the first screw hole and DHS plate thickness) were used to calculate femoral rotation and flexion. Measured x coordinates were corrected for femoral rotation, y coordinates for flexion, using the principles of trigonometry. A high accuracy was shown for this method, previously[18] with concordance coefficients of 0.98 and 0.91 between estimated and true rotation and estimated and true flexion, respectively. Subsequently, x/y coordinates and implant dimensions were assessed by two radiologists and disagreement was solved by consensus. Due to the high correspondence between DHSM using the 6-week radiograph and 3-month radiographs (intraclass correlation coefficient 0.88 [95%CI: 0.84–0.93]), both measurements were treated as essentially interchangeable, using the maximum value for the main analysis when both assessments were available.

Areal Bone Mineral Density Measurement

DXA measurements of the contralateral hip were made within 6 weeks after surgery to determine local BMD. BMD assessments were not available for 33 patients because of a fracture/implant on the contralateral hip ($n = 8$), illness/incapacity to attend the appointment ($n = 7$), patient noncompliance ($n = 16$), and death ($n = 2$).

STATISTICAL ANALYSES

The sample of 107 eligible patients was considered to have adequate power to assess DensiProbe™ Hip torque, age, and the four primary position variables (TAD, AP and lateral Parker ratio, and CFNAD) as candidate predictors for DHSM, using the rule of an effective sample size of 10 per candidate predictor.[19]

Difference in mean DensiProbe™ Hip torque between patients with and without DHSM was tested using the t test. A threshold of 3 mm for the presence of DHSM was defined, because previous work from our group showed that on radiographs, DHSM was perceived by clinicians only beyond this limit.[18] The association of DensiProbe™ Hip torque and each of the primary position variables with DHSM were assessed using linear regression. For the regression models, DensiProbe™ Hip torque and DHSM values were log transformed in order to simplify the interrelationships. All analyses were performed using Stata version 12.0.

RESULTS

Patient Demographics and Baseline Characteristics

Of a total of 142 patients who initially gave consent to participate in this study, 17 were deemed ineligible and excluded. Of the 125 enrolled patients, 18 more had to be excluded, because they did not have the specified intraoperative evaluation of DensiProbe™ Hip torque. Table 1 lists the demographic characteristics of the remaining 107 patients treated per protocol.

AP and lateral radiographs for the assessment of DHSM and the primary hip screw position were available at 6 weeks and/or 3 months for 89 of these 107 patients. Therefore, regression analyses were restricted to these 89 patients. Reasons for the missing radiographs were death ($n = 4$), illness terminating

Table 1. Demographics and Osteoporosis Risk Factors of the Patients Treated Per Protocol

Patient Characteristics	N (%)
Age (years)	
Mean (SD)	77.3 (11.4)
Gender, n (%)	
Female	76 (71)
Male	31 (29)
Fracture side	
Right	48 (45)
Left	59 (55)
Fracture type	
Femoral neck	52 (49)
AO 31B1 AO 31B2 AO 31B3	34 (32) 14 (13) 4 (4)
Pertrochanteric	54 (51)
AO 31A1 AO 31A2	33 (31) 21 (20)

participation ($n = 5$), withdrawal of consent ($n = 6$) and non-compliance ($n = 3$).

Postoperative Dynamic Hip Screw Migration

The mean (±SD) torque measurement for patients with DHSM ≥ 3 mm (2.77 Nm [±1.55]) was significantly lower than for patients without DHSM ≥ 3 mm (3.47 Nm [±1.67]). No cut outs were noted in the entire patient population.

Densiprobe™ Hip Torque, Primary Position and Dynamic Hip Screw Migration

Univariate Analysis

On the natural scale there appeared to be a non-linear relationship between DensiProbe™ torque values and the continuous DHSM outcome, with the variance of DHSM smaller at higher values of DensiProbe™ Hip torque. Log transformation of both DensiProbe™ Hip torque and DHSM appeared to equalize the variance, but there was no significant association between peak torque and DHSM on the log scale ($R^2 = 0.025$, d.f. [degrees of freedom] = 1, $p = 0.135$) (Fig. 3).

A linear relationship was observed between baseline TAD measurements and log DHSM ($R^2 = 0.110$, d.f. = 1, $p = 0.001$). Fracture stability strongly influenced the linear relationship between TAD and log DHSM with a stronger relationship for unstable fractures ($R^2 = 0.362$, d.f. = 1, $p < 0.001$) and a weak, non-significant relationship for stable fractures ($R^2 = 0.035$, d.f. = 1, $p = 0.148$). A weak relationship was also found between AP Parker ratio and log DHSM ($R^2 = 0.075$, d.f. = 2, $p = 0.031$), with both inferior and superior screw tip positions corresponding to higher DHSM. In addition, there was a relationship between the lateral Parker ratio and log DHSM ($R^2 = 0.101$, d.f. = 2, $p = 0.009$) with very posterior screw positions corresponding to higher DHSM. There was a significant association between the distance from the CFNA and log DHSM ($R^2 = 0.209$, d.f. = 1, $p < 0.001$) with positions nearer to the center of the femoral head corresponding to lower migration (Fig. 3).

Multiple Variable Regression Analysis

The full predictive model is outlined in Table 2 and highlights that only 26% of the variability associated with screw migration is accounted for by all included variables. After removal of the variables of age, TAD and torque, there was no change in the model (i.e., $R^2 = 0.260$), however, removal of the CNFAD variable led to a decrease in R^2 suggesting that this parameter is the most important element in this specific model for predicting screw migration.

Peak Torque and Screw Position

Patients with higher torque (i.e., indicative to good bone quality) tended to have a more central primary screw position as indicated in Figure 4. A weak significant relationship was observed between CFNAD and log DensiProbe™ Hip torque measurements ($R^2 = 0.130$, $p < 0.0001$).

Other Factors

Fracture reduction: The median difference of the neck–shaft ankle (NSA) between the injured and uninjured side was 1.00° (range: −6.00–15.00). There was no significant correlation between NSA difference and log DHSM.

Fracture type: Fracture specific analysis did not improve the observed weak association between peak torque and DHSM (trochanteric fractures: $R^2 = 0.020$, $p = 0.354$; femoral neck fractures: $R^2 = 0.072$, $p = 0.069$).

Fracture stability: Fracture stability did not influence the association between peak torque and log DHSM (stable fractures: $R^2 = 0.020$, d.f. = 1, $p = 0.275$; unstable fractures: $R^2 = 0.051$, d.f. = 1, $p = 0.203$).

Areal BMD: There were no significant correlations between areal BMD of the femoral neck, Ward's triangle and trochanteric area and postoperative log DHSM (Table 3).

DISCUSSION

The goal of this study was to assess whether bone strength measured using the DensiProbe™ Hip device is an independent predictor of cranial hip screw migration as a sign of impending fixation failure after fixation of a proximal femoral fracture. Contrary to our hypothesis, our analyses revealed no significant association between peak torque measured by DensiProbe™ Hip and postoperative DHSM suggesting that peak torque—and thus local bone strength—was not an independent predictor of screw migration. Although a simple t test showed an association of mean torque with DHSM, more advanced univariate and multivariate regression analyses could not prove a true prognostic effect of DensiProbe™ Hip measured peak torque/bone strength in DHSM. No changes were seen after separate analyses of stable and unstable fractures. Likewise, the association between peak torque and DHSM did not improve when the initial fracture type was taken into account. These in vivo findings are contrary to the results of an ex vivo study previously conducted by us, which demonstrated clear correlations between peak torque measurements and load to cut out.[16] In a multicenter in vivo study involving multiple Densiprobe™ Hip operators and patients with variable physical conditions, the increased variability of peak torque measurements and postoperative loading conditions may obscure correlations between peak torque and DHSM.

Also, no correlation was observed between DHSM and areal BMD within the proximal femur as another surrogate of local bone strength. This finding was not unexpected because of the known limitations of measured areal BMD describing the mechanical competence of trabecular bone at a specific site. A systematic review by Goldhahn et al.[20] could not identify any clinical study showing a significant difference between patients with or without normal areal BMD with respect to secondary implant migration after fracture

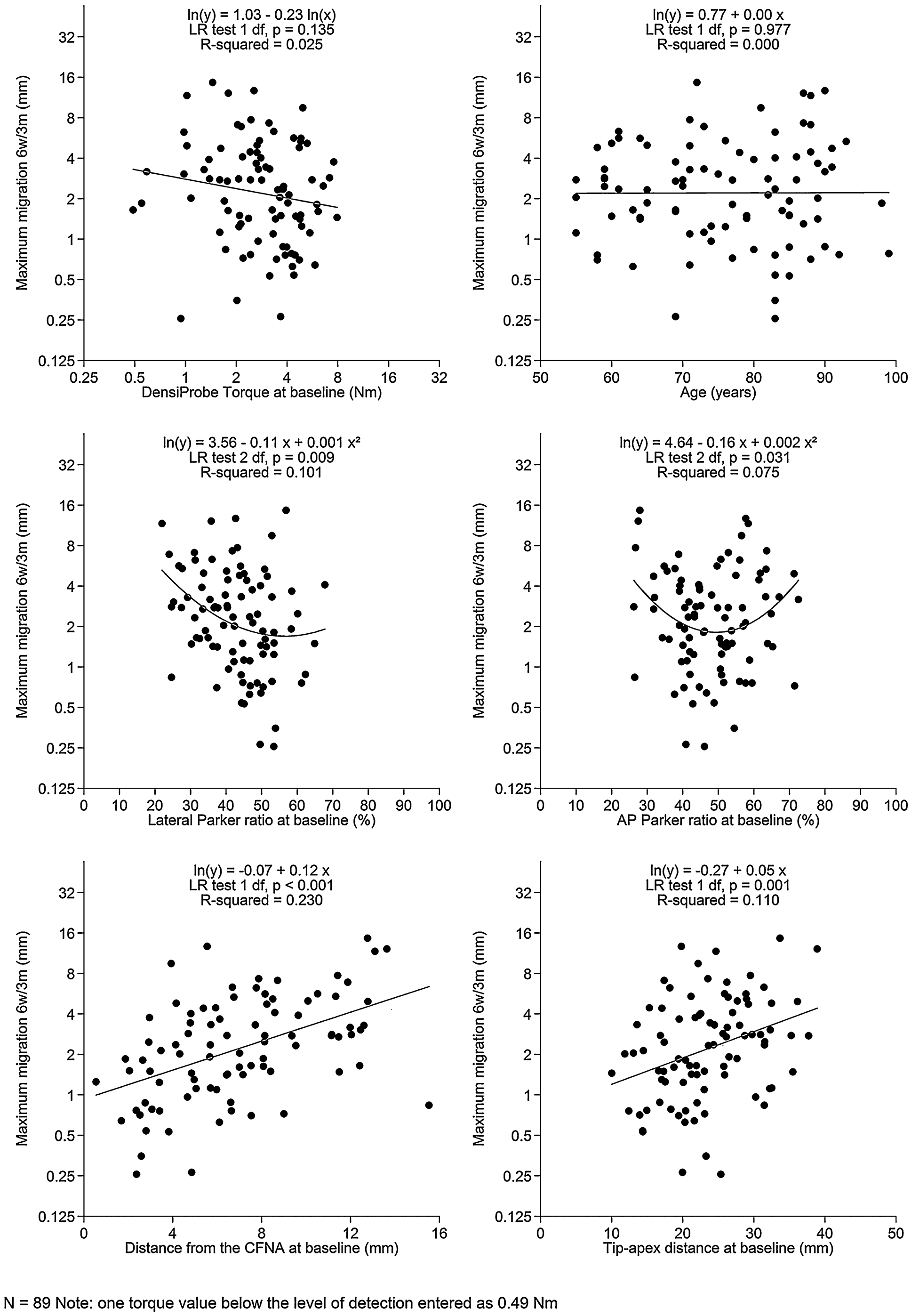

Figure 3. Scatter plots of continuous DHSM values against DensiProbe™ Hip torque, age, and each of the primary implant position measures including the results of regression analysis.

fixation. Surgeons may therefore not rely on areal BMD as a predictor of hip fracture fixation failure.

While measurements of bone strength could not be significantly correlated with DHSM, multiple variable regression modeling showed that the primary screw position as described by the CFNAD was the predominant predictor of DHSM. The CFNAD as measured in this study may integrate various aspects determining the stability of an osteosynthesis: Previous experimental studies had detected highest bone density and strength around the CFNA.[21] In our study, peak torque was also shown to be inversely correlated with the CFNAD. These results suggest that a screw position close to the CFNA may be equated to appropriate strength of the surrounding trabecular bone to prevent DHSM best. Kuzyk et al.[22] demonstrated in an in vitro study that the screw position within the femoral head directly influences the load to failure of the femur-implant construct, irrespective of local bone strength. In this study, the load to failure was

Table 2. Multivariable Regression Model

Adjustment	R^2 for model	Adjusted R^2 for model
Full model	0.260	0.225
Minus (variable)		
Age	0.237	0.210
DensiProbe torque	0.247	0.220
Tip apex distance (TAD) at baseline	0.251	0.224
Distance from center according to Parker at baseline	0.124	0.093

TAD, Tip apex distance.

significantly lower if the screw was positioned in the anterior or posterior part of the femoral head as compared to the central position. The construct stiffness under axial compression was also significantly higher when the screw was placed centrally in the AP view. In summary, the CFNAD may indicate to surgeons both strength of the trabecular bone adjacent to the screw *and* the osteosynthesis' resistance to DHSM and ultimately cut out per se.

Nevertheless, in contrast to CFNAD, TAD was also not found to be an independent predictor of screw migration in multivariable analysis, which is perhaps contradictory to previous studies, demonstrating the ability of TAD to discriminate patients who are at risk for cut out. However, continuous DHSM was measured in our study rather than cut out with a mixed study population with stable and unstable fractures compared to previous studies including only unstable pertrochanteric fractures.[17] Nonetheless, in univariate analysis TAD showed a much closer correlation with DHSM for unstable factures than for stable fractures suggesting a much more predictive role of TAD in this subgroup.

We acknowledge several limitations of this study. The follow-up rate was at the lower acceptable limit of 79–80% which is mainly due to the elderly patient population with a generally impaired health status complicating the attendance at follow-up visits. In addition, DHSM but not cut out was chosen as a primary outcome of this study. The long term fate and clinical relevance of DHSM is unknown. However, cut out as an alternative outcome is a dichotomous parameter requiring large sample sizes for adequate study power. In this study, DHSM was only measured using AP radiographs although there is in fact a three dimensional movement within the femoral head. Therefore, the true degree of DHSM might have been underestimated by our method. Patients were only followed-up for 3 months although screw migrations may also occur later than at this time point. However, we did not observe any statistically significant difference between total cranial hip screw migrations measured at 6 weeks and 3 months postoperatively, which suggests that screw migration mainly occurs within the first 6 weeks after surgery.

In conclusion, bone strength measured by DensiProbe^{TM} Hip could not be identified as an independent predictor for postoperative DHSM in this prospective multicenter study. Conversely, multiple variable regression showed that the CFNAD is an independent predictive factor for screw migration. Therefore, for hip screws positioned next to the CFNA, surgeons may expect less DHSM compared to hip screws positioned in peripheral parts of the femoral neck, even in the presence of low bone strength.

AUTHORS' CONTRIBUTIONS

All authors have participated substantially in data acquisition and have read and approved the final submitted manuscript. Marc Andreas Müller and Norbert Suhm furthermore have made contributions to the study design, data analyses, data interpretation and manuscript drafting. Clemens Hengg was another contributor to the study design.

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Table 3. Areal Bone Mineral Density and Postoperative Dynamic Hip Screw Migration

Measurement Site	Mean BMD ± SD (g/cm^2)	Association (R^2) Between BMD and Peak Torque	Association (R^2) Between BMD and DHSM
Femoral neck	0.643 ± 0.147	0.142†	0.000‡
Ward's triangle	0.442 ± 0.150	0.059†	0.003‡
Femur-trochanter	0.577 ± 0.150	0.153*	0.005‡
Femur-intertrochanteric	0.837 ± 0.190	0.187*	0.001‡
Hip-total	0.722 ± 0.155	0.194*	0.003‡

BMD, bone mineral density; DHSM, dynamic hip screw migration. $^{*}p < 0.001$ $^{\dagger}0.001 \le p \le 0.05$ $^{\ddagger}p > 0.05$

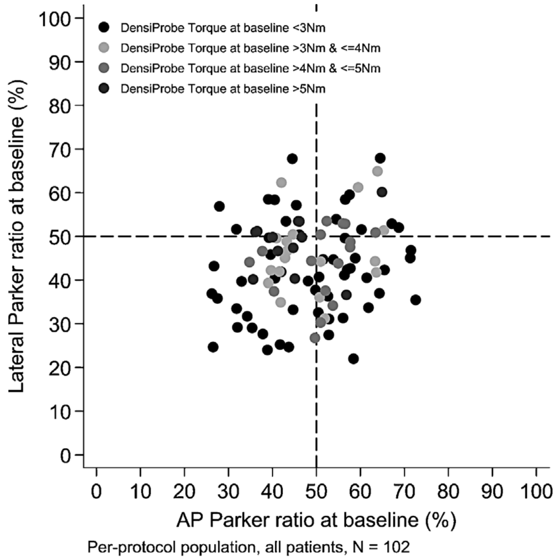

Figure 4. Individual DensiProbe^{TM} Hip torque measurements according to transverse primary screw position values as assessed on baseline AP and axial radiographs.

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