Mechanical Assessment of Local Bone Quality to Predict Failure of Locked Plating in a Proximal Humerus Fracture Model

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abstract

The importance of osteoporosis in proximal humerus fractures is well recognized. However, the local distribution of bone quality in the humeral head may also have a significant effect because it remains unclear in what quality of bone screws of standard implants purchase. The goal of this study was to investigate whether the failure of proximal humerus locked plating can be predicted by the DensiProbe (ARI, Davos, Switzerland). A 2-part fracture with metaphyseal impaction was simulated in 12 fresh-frozen human cadaveric humeri. Using the DensiProbe, local bone quality was determined in the humeral head in the course of 6 proximal screws of a standard locking plate (Philos; Synthes GmbH, Solothurn, Switzerland). Cyclic mechanical testing with increasing axial loading until failure was performed. Bone mineral density (BMD) significantly correlated with cycles until failure.

Head migration significantly increased between 1000 and 2000 loading cycles and significantly correlated with BMD after 3000 cycles. DensiProbe peak torque in all screw positions and their respective mean torque correlated significantly with the BMD values. In 3 positions, the peak torque significantly correlated with cycles to failure; here BMD significantly influenced mechanical stability. The validity of the DensiProbe was proven by the correlation between its peak torque measurements and BMD. The correlation between the peak torque and cycles to failure revealed the potential of the DensiProbe to predict the failure of locked plating in vitro. This method provides information about local bone quality, potentially making it suitable for intraoperative use by allowing the surgeon to take measures to improve stability.

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Figure: Fluoroscopic radiographic image showing head migration during the cyclic test after 3000 cycles. Head migration was defined as the total translation in the coronal plane of the most medial aspect of the humeral head at the osteotomy level with respect to the shaft. Subsequently, a cranial cut-through of the fixed-angle screws can be observed.
The treatment of proximal humerus fractures, the third most common fracture in patients older than 65 years, is a challenge.\(^1\) Despite the development of better implants, the failure rate remains significant; in a study of 153 patients, Krappinger et al.\(^2\) reported a failure rate of 13.7%. One important reason for failure is the osteoporotic bone stock in elderly patients, which makes it difficult to obtain satisfactory implant purchase, resulting in limited primary stability.\(^3\) A direct relationship between bone mineral density (BMD) and mechanical stability has been shown in the proximal humerus.\(^4,6\) Moreover, these data suggest that a variation exists in the intra-individual distribution of local BMD within the humeral head. Tingart et al.\(^5\) reported that the proximal half of the humeral head has a significantly higher trabecular BMD than the distal head. Lill et al.\(^6\) reported that the proximal aspect and the medial and dorsal regions of the proximal humerus have the greatest BMD and strength. Therefore, it is likely that standard implants may not always reach the areas enabling the best bone purchase in the humeral head. This could be another reason for the significant failure rates, even when using locking plates and despite the fact that the superior mechanical stability of these devices has been proven.\(^7,8\)

To address this problem, the DensiProbe (ARI, Davos, Switzerland), a torque measurement tool designed for the intraoperative assessment of local bone quality, was developed.\(^9\) The DensiProbe method provides reproducible results, showing good in vitro correlation with high-resolution computed tomography (CT) scans in the same volume of interest.\(^9\) The purpose of the current study was to clarify whether the method allows prediction of mechanical failure of locked plating in a proximal humerus fracture model in vitro.

**Materials and Methods**

**Specimen Preparation and Instrumentation**

Twelve unpaired fresh-frozen (−20°C) human cadaveric humeri (8 left and 4 right bones; 4 female and 8 male donors; mean age, 70.7 years [range, 42-95 years]) dissected of all soft tissue were used. Anteroposterior radiographs were obtained to exclude possible pathology affecting the bone structure integrity. All specimens underwent high-resolution peripheral quantitative CT. Scans were performed at a resolution of 82 μm from the top of the humeral head to 10 mm distal to the lower margin of the anatomical neck. The volume of interest in the humeral head was defined as an area reaching from the lower margin of the anatomical neck 25 mm proximally. Bone tissue was segmented at a threshold of 122 mg HA/cm\(^3\), corresponding with 9% of the maximal gray value. All specimens were thawed overnight at 4°C in a refrigerator prior to instrumentation and mechanical testing and covered with a towel soaked with a saline solution during instrumentation to prevent dehydration.

A short locking plate (Philos; Synthes GmbH, Solothurn, Switzerland) (length, 90 mm; 3 shaft holes) was fixed to each sample with 6 proximal and 3 distal 3.5-mm locking screws. The plates were instrumented according to the manufacturer’s guidelines using standard surgical tools. The locking screws were inserted and locked with a recommended torque of 1.5 Nm using a torque limiter (PB 8320 A 15 Nm DigiTorque1; PB Swiss Tools, Bern, Switzerland). The surgical procedure, including drawings, implant fixation, and osteotomy, was performed by experienced surgeons (G.R., A.S.) according to the following steps.

The planned osteotomy lines were marked on the bone surface using a skin marker. The Philos locking plate was fixed to the bone, and a humeral surgical neck osteotomy was created with a medially ascending fracture gap of 10 mm to simulate comminution or an OTA type I1-A2 proximal humerus fracture and to prevent impaction by cortical contact of the fragments using a microsagittal saw with a blade 0.4-mm thick.\(^10\) The shaft length was standardized for biomechanical testing, cutting the shaft perpendicular to its axis 70 mm distally to the most distal locking screw and embedding the specimen’s diaphysis in polymethylmethacrylate (PMMA) perpendicular to the ground in a cylindrical stainless steel base plate up to 30 mm proximally to its distal end. One radiopaque marker was attached to the humeral shaft and 1 to the head as local reference points for radiological assessment (Figure 1).\(^11\)

**Local Bone Quality Assessment**

The main part of the DensiProbe torque measurement tool for the proximal humerus is a 316L medical stainless steel, 115-mm long, solid cylinder with a 2.8-mm-diameter and a 25-mm long gauging tip. The gauging tip consists of 3
V-shaped depressions 120° apart. The solid cylinder runs through a polycapetal copolymer holder that allows for rotation of the solid cylinder with negligible friction. At the opposite end of the gauging tip, a bush allows the connection of a torque sensor (Figures 2, 3). After gently hammering the probe into the bone, the sensor is rotated while keeping the probe through the polycapsetal copolymer holder and measuring the local resistance to breakaway offered by the cancellous bone.

To apply the DensiProbe through the proximal holes of the Philos plate, the aiming device for the proximal head screws was first mounted to the plate (Figure 3). Next, the standard centering and drill sleeves were connected. A caliper was introduced in the sleeves, and the distance between the flat surface of the drill sleeve and the humeral head surface was measured and recorded. A second custom-made measuring device was used to fix stoppers on the drill and on the torque measurement tool at predetermined distances. Thus, the V-shaped depression of the 25-mm probe gauging tip was fully in contact with undrilled cancellous bone 3 mm from the humeral head surface (Figure 3). A 10-Nm range torque measuring device (Mecmesin Torque Sensor; Mecmesin, West Sussex, United Kingdom) with an accuracy of ±0.032 Nm at 1 Nm was connected to the torque measurement tool and rotated 120° clockwise. The torque was recorded during the whole measurement, and its maximum value was documented as an indicator for bone resistance to determine the local bone quality in the course of the six proximal screws. Screw positions for the sample were adjusted to a right-sided specimen so screws 1, 3, and 6 aimed at the posterior (1, superior; 3, inferior; 6, medial) and 2, 4, and 5 at the anterior (2, superior; 4, inferior; 5, medial) region of the humeral head.9

**Biomechanical Testing**

Biomechanical testing was performed with a biaxial servohydraulic machine (Mini Bionix II 858; MTS, Eden Prairie, Minnesota) using a 4 kN/20 Nm load cell (Huppert 6; Huppert, Herrenberg, Germany). Each sample was mounted on the machine with a 25° lateral angulation according to the measurement range of Bergmann et al (Figure 1). The distal region of the embedded specimen was connected to a cardan joint, which restrained all sample displacements and the rotation around the shaft axis. Axial loading was applied to the humeral head using a custom-made PMMA cup prepared for each specimen. An even load distribution was provided via a cavity created in the PMMA cup as a negative of each humeral head, simulating the glenoid. Relative rotation between the cup and the humeral head was prevented by applying sandpaper strips on the part of the cup in contact with the sample. The PMMA cup was attached to the machine actuator using a custom-made flange transmitting only axial load to the sample. All specimens were tested according to the following loading protocol. The axial compression loading was ramped quasi-statically until 200 N at rate of 0.02 mm/s, followed by cyclic loading at a rate of 1 Hz until failure. The envelope of the load in each cycle was a filtered interpolation of the pattern recorded by Bergmann et al during flexion movement using an instrumented shoulder prosthesis. Starting from 200 N, the maximum (peak) of the compression load was cyclically increased at 0.05 N/cycle until specimen failure, whereas its minimum (valley) was kept constant at 50 N during the entire cyclic test.13-15 The test was automatically stopped when an actuator axial displacement of 15 mm was reached. At this stage, the wedge osteotomy should have been almost completely closed, and every fixation had clearly failed macroscopically.
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Data Acquisition

Axial load and axial displacement were recorded from the MTS controllers at a rate of 64 Hz. At the start of the test and at every 250 cycles until failure, the machine performed a 2-second pause in the unloaded (valley) condition (50 N axial load) to make a fluoroscopic assessment with a C-arm. The latter was performed with a focus on the identification of the failure mechanism to relate the loading history with the loss of fragment fixation. The trend of the relative position of the radiopaque reference points with respect to the implant (plate and screws) during the loading history of the cyclic test was recorded in each collected fluoroscopic image using the Matlab software package (MathWorks, Natick, Massachusetts) and was considered as an image of the fixation stability.

Parameters of Interest

The BMD (measured in mg HA/cm²) was defined as the cancellous portion of the humeral head and assessed from the CT scans. In addition, humeral cortical thickness was defined as the average thickness of the cortical shell measured in the entire humeral head. The peak torque during the measurements with the DensiProbe was defined as the maximum recorded value at each of the 6 proximal screw positions. The axial construct stiffness was calculated from the machine data recorded during the initial quasistatic axial compression ramp. Based on the machine data and the fluoroscopic radiographs during the cyclic test, head migration was defined as the total translation in the coronal plane of the head relative to the shaft in the unloaded condition (50 N valley axial load) (Figure 4). After matching the radiographs showing the first signs of failure with the machine data, a 2-mm head migration was defined as an arbitrary failure criterion. The number of cycles required to reach this failure criterion was defined as cycles to failure. Finally, the head migration after 1000, 2000, and 3000 cycles was determined.

Statistical Analysis

Statistical analysis was performed using SPSS version 19 software (SPSS, Inc, Chicago, Illinois). After testing for normal distribution using the Shapiro-Wilk test, the mean value and standard error of the mean (SEM) were calculated for each parameter of interest. Furthermore, the Levene test, the Pearson correlation test, and the general linear model repeated measures analysis of variance were performed using the BMD and age values as covariates. A P value of .05 was considered significant.

RESULTS

All parameters of interest were normally distributed. Bone mineral density (mean, 109.8±13.1 mg HA/cm²) significantly correlated with cycles to failure (mean, 5646±361) (P=.018). Similarly, cycles to failure significantly correlated with cortical thickness (mean, 0.98±0.14 mm) (P=.038). Bone mineral density as a covariate affected the head migration between 1000 and 3000 cycles with only a trend to significance (P=.078). No significant correlation existed between BMD or cortical thickness with head migration after 1000 and 2000 cycles. In contrast, during the test progression after 3000 cycles, a significant correlation existed between BMD and head migration (P=.037), as well as a trend to correlation between cortical thickness and head migration (P=.098).

Mean peak torque values calculated for the respective positions 1 to 6 were as follows: position 1, 0.52±0.10 Nm; position 2, 0.28±0.05 Nm; position 3, 0.40±0.09 Nm; position 4, 0.18±0.02 Nm; position 5, 0.18±0.03 Nm; position 6, 0.50±0.11 Nm (Figure 5). In addition, peak torque in positions 1, 3, and 6 (posterosuperior, posteroinferior, and posteromedial, respectively) was significantly higher (P≤.046) than in positions 4 and 5 (anteroinferior and anteromedial, respectively). The peak
torque in position 2 (anterosuperior) was significantly lower (P ≤ .042) than in positions 1 and 6 (posterolateral and posteromedial, respectively). As a covariate, age had no significant influence on these results. The peak torque in all 6 positions, as well as their respective mean torque, correlated significantly with BMD (P ≤ .012). In positions 4, 5, and 6, the peak torque correlated significantly with cycles to failure (P ≤ .039).

**Discussion**

Osteoporosis is the main limiting factor in the surgical treatment of proximal humerus fractures. Impaired bone quality makes sufficient purchase of implants difficult and causes failure of the osteosynthesis. This can be explained by the direct relationship between BMD and mechanical strength. This association is confirmed by the results of the current study, which show a significant correlation between the BMD in the humeral head and the load cycles until failure. Locking plates have been successfully introduced in the treatment of proximal humerus fractures. However, failure rates of up to 14% highlight the fact that not all problems associated with the treatment of this demanding type of fracture have been fully solved. In addition to the general presence of osteoporosis, the local distribution of BMD within the humeral head may have a significant effect on the primary stability of an osteosynthesis because it remains unclear in what quality of bone stock within the humeral head the screws of a locking plate purchase and whether the areas with good bone quality are even reached by the screws. Thus, the intraoperative knowledge of local bone quality within the humeral head may be crucial.

The DensiProbe has been introduced as the only current method applying mechanical torque in real time for the in vitro assessment of local bone quality in the proximal humerus. The principle of this method for application in the proximal femur and spine has been described in previous studies. This method was shown to provide reproducible results for the proximal humerus, which highly correlated with CT scans of the same volume of interest in this specific anatomical region. The DensiProbe is applied using standard tools for the Philos plate instrumentation. From the technical point of view, this makes the method suitable for intraoperative use. The results of the current study show that it is possible to predict, to a certain extent, in vitro failure of locked plating in a proximal humerus fracture model. The correlation between bone quality assessment with the DensiProbe and load cycles until construct failure enhances the significance of the method in addition to its consistency with image-based methods. Moreover, it has been previously shown that a single measurement using the DensiProbe in a specific location has a high positive predictive value for BMD in the whole humeral head using CT. Based on these results, the method could potentially help the surgeon gain more individualized information about the local BMD in the humeral head and predict, to a certain degree, the primary stability of the osteosynthesis. Collectively, this may improve the clinical results of proximal humerus fracture treatment.

The reasons why a correlation existed only between the load cycles until failure and the DensiProbe measurements in 3 of 6 positions should be considered. One aspect is the 2-part fracture model used in this study. The lack of correlation can be interpreted such that the mechanical contribution of the cancellous bone is less important in 2-part fractures because of an intact cortical shell allowing joint loads to be evenly transmitted to the fixation device without excessively
stressing the cancellous bone adjacent to the screws. In contrast, in a 3-part fracture model, the disconnected cortical shell does not prevent humeral head displacement with respect to the greater tuberosity. Consequently, the mechanically stressed cancellous bone will fail earlier in comparison with a 2-part fracture model. This different mode of failure has a potential influence on the correlation between the cancellous bone quality (ie, the DensiProbe) and load cycles until failure. Therefore, a future study is necessary to further investigate the DensiProbe using a more unstable 3-part fracture model.

Another limiting factor of the current study is that the fracture model cannot fully simulate characteristics of an in vivo fracture such as cancellous impaction resulting in cavities within the humeral head. However, this is a characteristic limitation when in vitro results are transferred to the in vivo situation. Further investigations are necessary to identify a proper cutoff value that predicts the failure of an osteo-synthesis with high significance. This information could provide surgeons with the opportunity to select and properly apply techniques for further enhancement of the fixation stability, such as cement augmentation of the screws. Another alternative for this scenario could be the use of poly-axial implants to address areas with good bone quality or the implantation of a shoulder prosthesis when severely reduced bone quality is detected.

**Conclusion**

The general problem of osteoporosis is well recognized in the treatment of proximal humerus fractures. However, the local distribution of bone quality within the humeral head may have been underrepresented in this context in the past. This could be because only 1 method is available for the local assessment of humeral head bone quality by applying mechanical torque in real time (DensiProbe). The current study shows that the in vitro failure of proximal humerus locking plate osteosynthesis can be predicted to a certain extent with this method. The use of the DensiProbe could potentially allow the surgeon to intraoperatively address the problem of low bone quality and enhance the stability of an osteosynthesis.

**References**


