Factors affecting the stability of screws in human cortical osteoporotic bone

A CADEVER STUDY

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We investigated several factors which affect the stability of cortical screws in osteoporotic bone using 18 femora from cadavers of women aged between 45 and 96 years (mean 76). We performed bone densitometry to measure the bone mineral density of the cortical and cancellous bone of the shaft and head of the femur, respectively. The thickness and overall bone mass of the cortical layer of the shaft of the femur were measured using a microCT scanner. The force required to pull-out a 3.5 mm titanium cortical bone screw was determined after standardised insertion into specimens of the cortex of the femoral shaft.

A significant correlation was found between the pull-out strength and the overall bone mass of the cortical layer ($r^2 = 0.867$, $p < 0.01$) and also between its thickness ($r^2 = 0.826$, $p < 0.01$) and bone mineral density ($r^2 = 0.861$, $p < 0.01$). There was no statistically significant correlation between the age of the donor and the pull-out force ($p = 0.246$), the cortical thickness ($p = 0.199$), the bone mineral density ($p = 0.697$) or the level of osteoporosis ($p = 0.378$).

We conclude that the overall bone mass, the thickness and the bone mineral density of the cortical layer, are the main factors which affect the stability of a screw in human female osteoporotic cortical bone.

Osteoporosis is a widespread metabolic disorder which has a serious socio-economic impact on national health-care systems. It is estimated that every second Caucasian woman will suffer from a fracture because of osteoporosis once in her lifetime. For a woman, the risk of death from a fracture of the hip due to osteoporosis is equal to that of dying from breast cancer. Failure of the fixation of these fractures as a result of the loosening of the implant is a well-known problem. After the menopause an exponential decrease in bone mineral density (BMD) results in a higher risk of osteoporosis in elderly women. More complex types of fracture occur more often in patients with osteoporosis, and are associated with failure of fixation. The main factors contributing to the stability of the implant are the mechanical properties of the cortical bone. The relationship between different properties, such as the BMD, the thickness of the cortical shell, the porosity, the density of microcracks and the shrinkage temperature of bone collagen, and bone stiffness, strength and toughness has been studied intensively. However, clinically the interface between the screws and the bone is the most relevant factor. We have therefore studied the strength of fixation of a screw in osteoporotic cortical bone.

Materials and Methods
We used 18 human femora from women aged between 45 and 96 years (mean 76). Permission to use organs for scientific purposes had been provided either by the subjects or their relatives. Their age, weight and height were recorded. We applied a subjective classification of osteoporosis on a scale of 0 to 3. The classification was undertaken by a pathologist in a blinded manner at post-mortem. At level 0 there were no clinical or macroscopic signs of osteoporosis. Level 1 included patients who were considered to have macroscopically weaker cancellous bone texture in the vertebrae of the spine. In level 2 the vertebral cancellous bone was easy to crush by finger pressure. Level 3 comprised patients with fractured vertebrae. Patients were excluded who, except for osteoporosis had a known history of a disease related to bone.

Standard radiographs of the femora were taken to exclude unidentified fractures or tumours. An anteroposterior view of the proximal femur orthogonal to the femoral neck was used to measure the caput-collum-
The diaphyseal angle. The BMD of the cortical bone was measured on the lateral aspect of the femur.

Three standardised sites were used, namely the mid-point between the top of the greater trochanter and the surface of the lateral femoral condyle, and points 6 mm proximally and distally from this.

All the peripheral quantitative CT scans were performed using a Densiscan 1000 (SCANCO Medical AG, Bassersdorf, Switzerland) bone densitometer. The BMD of the cancellous bone at the widest diameter of the femoral head was also measured over a distance of 1 mm.

After the densitometric studies, cylindrical samples of cortical bone with a diameter of 15 mm were harvested from the same three positions in each femoral shaft. These specimens were analysed in a microCT 40 scanner (SCANCO Medical AG) with a resolution of 9 µm to evaluate the thickness and the overall bone mass of the cortical layer. In the absence of published data we defined the threshold for discrimination between cancellous and cortical bone as the ratio of the bone volume to the total volume of the particular specimen. Bone with a ratio of less than 50% was considered to be cancellous, while that with higher than 50% was judged to be cortical bone.

The strength of fixation of the screw was studied using the 15 mm samples. A MS-TTS-10 torque-controlled insertion apparatus (Rischag AG Messtechnik, Liestal, Switzerland) was used to make standardised 3 mm drill holes for insertion of an AO 3.5 mm titanium screw (Synthes GmbH, Oberdorf, Switzerland). This machine generated a speed of 30 revolutions per minute, an axial force of 30 N, and an axial velocity of 12 mm per min during tapping and insertion of the screw with 300 revolutions per minute for the initial drilling. The screw was inserted perpendicular to the former axis of the femur. The bone samples were secured in the insertion apparatus at a constant position for all specimens.

The vertical force required to pull-out the screw was measured by an Instron Type 4302 testing system (Instron Ltd, High Wycombe, United Kingdom). The pull-out force was defined as the highest point in the force-time diagram before the first failure occurred. The pull-out rate was set at 1 mm per min.

**Statistical analysis.** The pull-out force, cortical thickness, cortical and cancellous BMD, the overall cortical bone mass, the degree of osteoporosis and details of age, height and weight were analysed by Pearson’s correlation coefficient using SPSS software (SPSS Inc., Chicago, Illinois).13 The normal distribution of the data was tested using the Kolmogorov-Smirnov and Shapiro-Wilk tests.13 The level of significance was set at p < 0.05.

**Results**

The mean values, ranges and standard deviations of the measured data are listed in Table 1. The degree of osteoporosis of the patients was evenly distributed, with five donors showing no clinical signs of osteoporosis, three being classified as having level-1 osteoporosis and five each as having level 2 and level 3.
The mean cortical thickness of the specimens was 4.9 mm (2.74 to 6.57). The femora of donors without osteoporosis had a mean cortical thickness of 5.22 mm (5.13 to 5.61) compared with 3.27 mm (2.88 to 4.89) in those with level 3 osteoporosis. The femora without osteoporosis showed a mean ultimate pull-out force for the screw of 2577 N (2227 to 2796). This value decreased to a mean of 1185 N (513 to 1780) in specimens with level-3 osteoporosis (Fig. 1). The pull-out force shared significant linear correlation with the overall bone mass ($r^2 = 0.867$), the BMD ($r^2 = 0.861$) and the thickness of the cortical layer ($r^2 = 0.826$) (Fig. 2). The linear correlation between the pull-out force and the cancellous BMD in the femoral head was lower, but still significant ($r^2 = 0.561$). A higher degree of osteoporosis of the patients correlated with a lower pull-out force at the femur ($r^2 = 0.758$). The level of osteoporosis correlated significantly with the cortical BMD ($r^2 = 0.879$), the cancellous BMD ($r^2 = 0.718$), the overall bone mass ($r^2 = 0.667$), and the thickness of the cortical layer ($r^2 = 0.591$) of the femur (Table II).

The BMD of the cancellous bone in the femoral head showed a minor but significant correlation with the BMD of the cortical layers ($r^2 = 0.574$) as did the correlations between the cancellous BMD and the other cortical parameters such as the overall bone mass and thickness.

The cortical BMD accounted for 86.1% of the variance and the cortical thickness for 82.6% of the variability of the pull-out force. The highest correlation with the pull-out force was found for the overall bone mass of the cortical bone layer and was responsible for more than 87.6% of the variance.

There was no significant correlation between the age of the donors and the height ($p = 0.790$), weight ($p = 0.122$), BMI ($p = 0.131$), caput-collum-diaphyseal angle ($p = 0.413$), level of osteoporosis ($p = 0.378$), cancellous BMD ($p = 0.252$), cortical BMD ($p = 0.697$), cortical thickness ($p = 0.199$), overall cortical bone mass ($p = 0.279$) and pull-out force ($p = 0.246$).

We did not find a significant correlation between the height of the donors and the thickness of the cortical layers ($r^2 = 0.136$, $p = 0.637$). Similarly, the weight of the donors and the thickness of the cortical bone did not correlate significantly ($r^2 = 0.441$, $p = 0.100$).

**Discussion**

Our aim was to investigate the importance of relevant factors affecting the fixation of a screw in the cortical bone of femora from osteoporotic patients. Testing the stability of an implant by measuring the axial pull-out force of a screw has been an established technique since the late 1950s. Nevertheless, this only partially represents the clinical situation. The main forces operating on an implanted screw are shear stress which is likely to be the main cause of potential loosening of the screw and consequent failure of the implant. The absolute value of the pull-out forces measured in our study are therefore not comparable with that in the clinical situation.

Our definition of the threshold between the cortical and the cancellous bone in the microCT measurements as 50% of the ratio of bone volume to total volume was produced in the absence of any published data on the subject. In other studies which differentiated cortical from cancellous bone the thickness was estimated macroscopically and a threshold was not mentioned. Routine classification of the degree of osteoporosis was performed during autopsy by a pathologist. It is a subjective method of classifying the level from 0 to 3. We report this method of classification for the first time here; it has not previously been cited in a research paper.

The higher correlation between the pull-out force and the overall bone mass in comparison with pull-out force and thickness implies that the more porous parts of the cortical structures in the transition between cancellous and cortical bone are important in the stability of the screw. This contradicts the finding from other studies, which were performed on vertebras and indicate that the cortical layer was exclusively responsible for stability. We have shown that the main factor in stability is the cortical layer, but that the cancellous structures are also important.

Seebeck et al. and Vangsness, Carter and Frankel found a linear correlation between the cortical thickness and pull-out forces of cortical screws in bovine and canine bones, respectively. We have shown that this is also true for human bone. The results of a study by Ansell and Scales showed no correlation between the cortical thickness of human femoral bone and the pull-out force, possibly because of their difficulty in defining the correct thickness of the cortical layer. Matter and Vangsness showed a broad variation in the pull-out forces of cortical screws in human tibiae, but the thickness was only estimated using a ruler. These findings contradict the results of our study which showed a strong correlation between pull-out force and cortical thickness ($r^2 = 0.826$, $p < 0.01$). This may be due to the more accurate method of measuring cortical thickness using the microCT.

### Table II. Details of the significant correlations found in the study

<table>
<thead>
<tr>
<th>FACTORS AFFECTING THE STABILITY OF SCREWS IN HUMAN CORTICAL OSTEOPOROTIC BONE</th>
<th>Overall cortical bone mass (g/mm²)</th>
<th>Cortical BMD (g/cm³)</th>
<th>Cortical thickness (mm)</th>
<th>Cancellous BMD (g/cm³)</th>
<th>Osteoporosis level (0 to 3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pull-out strength (N)</td>
<td>$r^2 = 0.867$, $p &lt; 0.01$</td>
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<td>$r^2 = 0.826$, $p &lt; 0.01$</td>
<td>$r^2 = 0.561$, $p &lt; 0.05$</td>
<td>$r^2 = 0.758$, $p &lt; 0.01$</td>
</tr>
<tr>
<td>Overall cortical bone mass (g/mm²)</td>
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<td>$r^2 = 0.667$, $p &lt; 0.01$</td>
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</tr>
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<td>Cancellous BMD (g/cm³)</td>
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</tr>
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* BMD: bone mineral density
densitometers. The pull-out forces in our study varied according to the level of osteoporosis. They also showed a significant linear correlation with the cortical BMD ($r^2 = 0.773$, $p < 0.01$).

A correlation between the cortical BMD and the mechanical properties of bone was demonstrated by Wachtet al. In their study, the specimens of human femora were too small to test screws and therefore the elasticity module ($r = 0.69$, $p < 0.05$) and shear stress ($r = 0.64$, $p < 0.05$) were analysed. Analogous to those results, our study also revealed a correlation between the cortical BMD and stability. This showed that the cortical BMD was also relevant for the fixation strength because the well-correlated bone mass was a function of the cortical BMD and cortical thickness.

Our study showed that the cancellous BMD of the femoral head was an unreliable parameter in regard to the stability of implants which are anchored in cortical bone, which is in accordance with the findings of Stromsoe et al who found a smaller correlation of pull-out force at the femoral shaft, but analysed fewer samples. There was no correlation between the cancellous BMD and cortical parameters such as the BMD, thickness and overall bone mass. In support of this Alho, Stromsoe and Hoiseth found that strong cancellous bone was not necessarily related to a strong cortical layer of bone. Whether an improvement in the mechanical properties of bone is caused by a larger BMD or geometrical adaptations of the bone structures to strain, remains to be elucidated.

The level of osteoporosis had a higher correlation with the cortical BMD than with the cancellous BMD. The cortical thickness did not correlate with the level of osteoporosis. This could be an indicator that the thickness of the cortical layer is more influenced by external factors such as mechanical loading and nutrition, and intrinsic factors such as genetic predisposition, than by osteoporosis. It again indicates that the quality of bone cannot be predicted at one site from measurements at another.

Our findings indicate that it is necessary to differentiate between age and osteoporosis. We could not show any correlation between age and osteoporosis, or between age and other factors measured. We suggest that age does not necessarily result in diminished thickness of the cortical layer or of the cortical BMD. These results are supported by a clinical trial involving 686 men in which no correlation between the cancellous BMD and age was established and by a study by Yeni, Brown and Norman who did not find a smaller correlation of pull-out force at the metaphysis.

The thickness of the cortical layer may be another factor related to a strong cortical layer of bone. Whether an improvement in the mechanical properties of bone is caused by a larger BMD or geometrical adaptations of the bone structures to strain, remains to be elucidated.

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References


