Changes in proximal femoral strain after insertion of uncemented standard and customised femoral stems

AN EXPERIMENTAL STUDY IN HUMAN FEMORA

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We have compared the changes in the pattern of the principal strains in the proximal femur after insertion of eight uncemented anatomical stems and eight customised stems in human cadaver femora. During testing we aimed to reproduce the physiological loads on the proximal femur and to simulate single-leg stance and stair-climbing.

The strains in the intact femora were measured and there were no significant differences in principal tensile and compressive strains in the left and right femora of each pair. The two types of femoral stem were then inserted randomly into the left or right femora and the cortical strains were again measured. Both induced significant stress shielding in the proximal part of the metaphysis, but the deviation from the physiological strains was most pronounced after insertion of the anatomical stems.

The principal compressive strain at the calcar was reduced by 90% for the anatomical stems and 67% for the customised stems. Medially, at the level of the lesser trochanter, the corresponding figures were 59% and 21%. The anatomical stems induced more stress concentration on the anterior aspect of the femur than did the customised stems. They also increased the hoop strains in the proximomedial femur. Our study shows a consistently more physiological pattern of strain in the proximal femur after insertion of customised stems compared with standard, anatomical stems.

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Insertion of an implant into the femoral canal induces an alteration of the pattern of physiological strain and this phenomenon has been called stress shielding. The clinical significance of stress shielding is still unclear, but it is followed by dynamic remodelling of the bone, which is a biological process leading to changes in the density and geometry of it. The potential adverse effect of this adaptive remodelling may be failure of the interface between the bone and implant, giving rise to loosening of the prosthesis.¹ The prevailing principle for the design of uncemented femoral stems is, among several others, to aim at proximal implant-bone fit and proximal load transfer. The stiffness of the implant has been considered as the dominant factor for producing stress shielding of the proximal femur.^{2,3} Recently, however, it has been shown that the relationship between the stiffness of the implant and stress shielding is more complex and that large and stiff implants do not consistently produce more stress shielding than smaller prostheses.^{4,5} Furthermore, the use of more compliant and flexible stems may increase the interface shear strains and secondarily generate interface micromovements which are incompatible with osseointegration.⁶⁻⁹ There are experimental and clinical data which show that geometrical conformity between the stem and the endocortical femoral canal has a considerable effect on the load transfer to the proximal femur.¹⁰⁻¹⁴ Because of the great variability of the anatomy of the femoral canal¹⁵ an optimal fit between a standard uncemented stem and the endosteal surface cannot be expected. In an attempt to improve these limitations of standard implants custom-made femoral stems are used and it has been shown that these achieve more physiological load transfer and better mechanical stability.^{10,12,16}

Our aim in this study was to compare the changes in the pattern of principal cortical strains after insertion of uncemented anatomical stems and of uncemented custom-made stems in human cadaveric femora.

Materials and Methods

Design of the femoral stem. The two femoral components which we used were an uncemented, anatomical stem (Profile; DePuy, Leeds, UK) (Fig. 1) and a custom-made stem (SCP as., Trondheim, Norway) (Fig. 2). Their similarities included an identical composition (Ti 6Al4V), prox-

Fig. 1a

Fig. 1b

Photographs of the Profile anatomical stem showing a) anterior and b) medial views.

Fig. 2a

Fig. 2b

Photographs of the customised stem showing a) anterior and b) medial views.

imal HA coating, no collar and a modular femoral head. The design of the customised femoral component was based on cross-sectional CT scans of the proximal femur. Using an interactive design algorithm, closed contours were generated along the corticocancellous interface of the femoral canal. It has been shown that a CT density of 600 Hounsfield Units (HU) represents this interface.¹⁷ The stems were designed to fit closely to the inner cortical surface in the metaphyseal region in order to obtain maximum mechanical stability and optimal load transfer. We then created a three-dimensional computer model of the stem which could be inserted through an osteotomy of the femoral neck. The final prostheses were manufactured on a four-axis computer-controlled numerical milling machine. All the femoral stems of both types were inserted by one experienced orthopaedic surgeon (PB).

Experimental procedure. For biomechanical testing we used 16 femora from eight human cadavers, four male and four female, with a mean age of 63 years (55 to 71). The specimens were removed from the cadavers within 24 hours, packed in saline-soaked towels and stored at -20°C. Standardised radiographs in two projections were obtained to rule out any pathology and, by using templates, to estimate the size of the standard prostheses to be inserted and tested.

Before testing, each femur was thawed at room temperature and the remaining soft tissue removed. It was then placed on a horizontal surface resting on the posterior condyles and the posterior aspect of the greater trochanter and this was defined as the frontal plane of the femur.

Before resection of the condyles the angle between the frontal plane and the anterior head-trochanter tangent was determined for later guidance in the orientation of the femur in the frontal and sagittal planes. The condyles were then resected and the distal part of the diaphysis cemented into a steel cylinder. The cementing was performed in a jig which ensured that the vertical axis through the fossa piriformis coincided with the central axis of the cylinder. The distance from the tip of the greater trochanter to the upper end of the cylinder was 25 cm, regardless of the original length of the femur.

To simulate the hip abductor muscles a nylon strap 40 mm wide was attached to the lateral aspect of the greater trochanter using epoxy glue and small cortical screws. It was attached to the femur with a load axis parallel to a plane through the centre of the femoral head, the fossa piriformis and the central axis of the cylinder, attempting to avoid torsional forces acting on the femoral head when the trochanter strap was loaded. After preparation the femur was placed in a jig, which was mounted in a materials testing system (Lloyd LR10K; Lloyd Instruments Ltd, Hampshire, UK) (Fig. 3). Distally, the femur rotated around its longitudinal axis and also tilted along the mediolateral axis. In this way, unphysiological bending moments of the femur were eliminated. For the remainder, loading characteristics were used according to data published by McLeish and Charnley.¹⁸ The femur was tilted into 12° of valgus, which corresponds to the physiological inclination during single-leg stance. Load was applied to the femoral head by a lever arm connected to the cross-head of the testing

Fig. 3

Photograph of the testing machine and the apparatus for strain measurements.

machine (Fig. 4). The centre of the cup containing the femoral head was positioned 110 mm lateral to the load axis and the trochanter strap formed an angle of 75° to the lever arm which simulates the pelvis. The trochanter strap was adjustable both in length and position on the lever arm, which was horizontal when maximum axial load was applied to the femoral head. In addition to the application of axial load through the Lloyd cross-head, torsional load was applied to the femur by a weight-and-pulley system acting on transverse cross-bars mounted to the rotating cylinder containing the specimen. Thus, the torsional load was applied to the distal femur and the moments were transmitted to the trochanter strap and the acetabular cup, which prevented the femur from rotating. A load cell was fitted to the cup so that the torsional forces acting on the head could be monitored. The trochanter strap and the torsional loading system were also fitted with load-cells to allow continuous monitoring of the forces.

For measurement of strain 12 45° rosettes (RY 91 3/120; Hottinger Baldwin Messtechnik GmbH, Darmstadt, Germany) were bonded to the proximal femur at four levels (A to D), 15, 35 and 80 mm distal to the most caudal part of the femoral head and at a level corresponding to the tip of the prosthesis to be inserted later (Fig. 5). At level A one rosette was bonded medially at the calcar, at levels B and C they were attached to the medial, anterior, lateral and posterior aspects, and at level D at the medial, anterior and lateral aspects. By using the distance from the distal part of

Fig. 4

Illustration of the apparatus for applying the load to the hip, the abductor load and the torsional load to the femur.

Fig. 5

Diagram showing the sites for placement of strain-gauge rosettes on the proximal femur. Inset: close-up view of one rosette with the three 45° grids on the polyamide carrier.

the femoral head as well as the posterior condylar plane as references, we were able to reproduce and to recover the exact localisation and orientation of the rosettes on the femur.

Before mounting the rosettes the bone surface was smoothed with sandpaper (#100-240), degreased with acetone and dried in a N_2 -gas stream. An etchant (Multipurpose Etch-

ant; 3M, Minneapolis, Minnesota) was applied to the site of the gauge for 15 seconds, then rinsed off with saline. After renewed drying the surface was primed (Multipurpose Primer; 3M) and the rosette was bonded using a two-component PMMA adhesive (X-60; Hottinger Baldwin Messtechnik). The leads of the gauges were soldered to terminals fixed to the bone immediately adjacent to the rosettes and connected to a signal amplifier (UPM 100; Hottinger Baldwin Messtechnik) by means of a wire cable. Finally, the rosette and solder terminal were covered with a waterproof sealing (Vitremex; 3M).

One rosette consists of three strain gauges mounted at an angle of 45° to the polyamide carrier (Fig. 5) and gauge *a* is always positioned perpendicular to the longitudinal axis of the femur. In addition to the direct strain readings from the three gauges, the magnitude and direction of the principal strains were computed.¹⁹ During application of an axial load to the femoral head, the proximal femur was subjected

to bending. Thus, the longitudinal deformation was compressive on the medial side of the femur and tensile on the lateral side. On the anterior and posterior aspects of the femur the deformation was more complex. To simplify the presentation of the data and to emphasise the most interesting findings, we have chosen to present only the principal compressive strains from the rosettes on the medial side of the femur. For all the other rosettes only the principal tensile strains are presented. During statistical analysis we have combined the two types of strain measurement. This is a reasonable approach because we consider the amount of bone deformation to be equivalent, being either compression or tension.

After mounting the specimen in the jig inside the materials testing machine the femur was preloaded with an axial force of 600 N, then unloaded and the strain gauges were set to zero. Thereafter, an axial load of 600 N was applied to the horizontal lever arm to simulate the single-leg stance

Fig. 6

Axial load. Changes in principal compressive strain (medial) and principal tensile strain (lateral, anterior and posterior) in the proximal femur after insertion of a femoral stem. The measurements are normalised to the principal strain values in the intact specimens. The error bars indicate the 95% CI.

of a subject weighing 70 kg. The resultant joint force was approximately 1450 N, but this could vary between the specimens because of differences in the medial offset of the femoral head. During the second loading, simulating stair-climbing, an additional internal torsional moment of 10 Nm was applied to the femoral head. At the plateau phase of both loadings three outputs (1 Hz frequency) from the strain gauges were recorded and the mean strain at all gauge sites was computed.

A femoral stem was then implanted by an experienced orthopaedic surgeon (PB) using the operative technique and instruments recommended by the supplier of the prosthesis. The specimen was wrapped in moist towels and care was taken not to damage the strain-gauge rosettes. We measured the medial position of the centre of the femoral head on the intact femur before performing the osteotomy of the neck. Then, by selecting a ball head with the appropriate length of neck, we were able to reproduce the medial position of the anatomical centre of the femoral head within ± 1.25 mm. In this way the moments acting on the intact and prosthetic femoral heads were similar. The loading sequences were then repeated as previously described.

Statistical analysis. To reduce variation from bone to bone which may have merely reflected the variable size and physical properties of the individual bones the changes in strains measured by the strain gauges were expressed as a percentage of the intact bone.

A three-way ANOVA test was applied to test the entire data set regarding the effects of the design of the prosthesis (factor 1), the level of the rosette (factor 2), and the location around the circumference of the femur (factor 3). An interaction term factor 1 $\times$ factor 2 was included to evaluate if there was a larger variation from level to level in one prosthetic design *versus* the other. If the ANOVA detected statistical differences ($p \leq 0.05$) the computation was pursued by applying *post-hoc* multiple comparison tests (Fisher's least significant difference test).

A two-way ANOVA was applied to test the results for each level A to D as an *a priori* test regarding the design of the prosthesis (factor 1) and location around the circumference of the femur (factor 2).

Finally, the mean strain changes in corresponding locations were compared using a *post-hoc* test (Fisher's least significant difference test) which allows any number of comparisons between pairs means.

Results

Forces on the intact and prosthetic femoral heads. The mean internal torsional force on the femoral head before and after insertion of the prosthesis was comparable for both prostheses, 166 N and 183 N ($p = 0.4$, paired *t*-test). The mean force in the abductor strap was 1108 N when testing the intact femur whereas it was 1160 N after insertion of the stem ($p = 0.24$, paired *t*-test). Table I shows the mean and 95% confidence interval (CI) for the differ-

ence in pre- and postinsertion forces on the femoral head. These measurements show that the total forces on the intact and prosthetic femoral heads were not significantly different.

Strain measurements during axial load. Figure 6 illustrates the distances between the preimplantation and postimplantation values of the principal tensile (ϵ_1) and principal compressive strain (ϵ_2) during axial load. In the intact femora there was no statistically significant difference in the strain pattern between the left and right specimens of each pair ($p > 0.5$).

The three-way ANOVA showed that there was significantly less change in strain around the customised prosthesis than around the standard design ($p = 0.014$). There were also differences from level to level ($p < 0.0001$) and from location to location ($p < 0.0001$). The *post-hoc* test of the interaction showed that the customised design caused less reduction in strain at level B compared with the anatomical design. No significant differences were detected for the other interaction term using the three-way ANOVA. The *a priori* two-way ANOVA showed that the levels A and B had significantly less change in strain in the customised prosthesis than in the anatomical type, while there were no differences in levels C and D. The *post-hoc* multiple comparison test verified that the readings from the calcar area differed between the two designs (level A), and that the customised stem caused less change in strain in all locations at level B, but only anteriorly and posteriorly at level C, and in no location at level D.

Table II shows the mean and 95% CI for the difference in strain between the types of prosthesis averaged over the rosettes that were used to measure compressive and tensile strain, respectively. The analysis indicates that there was an overall difference in compressive strains in the proximal femur containing either type of prosthesis, but a corresponding difference could not be demonstrated for the overall tensile strains.

Strain measurements during combined axial and torsional loads. Figure 7 shows the distances between the pre- and postimplantation principal strains when an internal

Table I. Mean and 95% CI for the difference in pre- and postinsertion forces on the femoral head

Force (N)	Abduction	Torsion
Mean	-52	-17
95% CI	+85	+40

Table II. Mean and 95% CI for the difference in strain between the types of prosthesis averaged over the rosettes which measured compressive and tensile strain, respectively

Strain ($\mu\text{m/m}$)	Compressive	Tensile
Mean	-296	79
95% CI	+211	+116

Fig. 7

Combined axial and torsional load. Changes in principal compressive strain (medial) and principal tensile strain (lateral, anterior and posterior) in the proximal femur after insertion of a femoral stem. The measurements are normalised to the principal strain values in the intact specimens. The error bars indicate the 95% CI.

torsional moment of 10 Nm was added to the axial joint force of about 1450 N. The results parallel those from the axial loading with a difference between the design ($p = 0.0016$), between levels ($p < 0.0001$) and between locations ($p < 0.0001$). In addition, the interaction term was significant ($p = 0.0019$) indicating that the change in strain around the two designs of stem was multiplicative instead of additive. The *a priori* two-way ANOVA showed that the levels A ($p = 0.00028$), B ($p = 0.000001$) and C ($p = 0.0067$) had significantly less change in strain in the customised group than in the anatomical group, while there were no differences at level D ($p = 0.194$). The *post-hoc* multiple-comparison test verified that the readings from the calcar area differed between the two designs (level A), and that the customised stem caused less change in strain in all locations at level B, but only anteriorly at level C, and in no location at level D. Figures 8 and 9 show the deviation of the principal strains ϵ_1 and ϵ_2 from the values in the intact specimens after insertion of the two different types of stem. At all sites along the proximal femur the customised stem restored the cortical strains closer to the physiological

strains better than did the standard stem. This was most apparent for the principal tensile strains.

Discussion

The common design rationale for anatomical uncemented femoral stems is to achieve a close fit of the prosthesis within the femoral canal, to restore the strains in the proximal femur and to obtain maximum mechanical stability of the implant. It is, however, necessary for the prostheses to become ingrown into bone in order to produce strain equilibrium in the proximal femur. Lack of bonding between the bone and the implant will subsequently lead to progressive stress shielding, bone remodelling, development of a fibrous membrane at the interfaces and finally to an unstable prosthesis.²⁰

Because of the large variability in the femoral geometry close-fitting of femoral components cannot consistently be achieved with standard implants.¹⁵ In order to overcome this geometrical mismatch between the femoral canal and cementless implants, customised femoral stems have been

Fig. 8

Principal tensile strain (ϵ_1). The bars indicate the deviation (%) of the value of the principal tensile strain after insertion of the stem compared with the strain value in the intact femur. 100% denotes the strain value in the intact specimens. Bars above the 100% line indicate increased strain after insertion of the stem. The figures along the x-axis indicate the 12 different locations of the strain gauge from which the measurements derive.

Fig. 9

Principal compressive strain (ϵ_2). The bars indicate the deviation (%) of the value of the principal compressive strain after insertion of the stem compared with the strain value in the intact femur. 100% denotes the strain value in the intact specimens. Bars above the 100% line indicate increased strain after insertion of the stem. The figures along the x-axis indicate the 12 different locations of the strain gauge from which the measurements derive.

developed. In this study we have compared the acute stress shielding observed in human cadaver femora after insertion of a standard, anatomical femoral stem and a customised stem. Except for the differences in the three-dimensional geometry, other variables such as the composition of the material, surface structure and modularity were similar. Our aim with the test protocol which we used has been to reproduce the physiological loads on the femur and to reduce the experimental variability of the testing. According to the recommendations of Cristofolini¹ our loading system in vitro consisted of an axial force applied to the femoral head as well as an abduction force simulating the gluteal muscles. This configuration of the loading of the proximal femur is simplified and the contribution of muscular forces other than the glutei is not considered in this model. Cristofolini et al²¹ found that the three glutei were the principal muscles determining the vertical strains in the femur, and that the increase in the strains on the lateral femur provoked by the glutei was as high as 500% compared with those measured with a single vertical load on the femoral head. Others^{22,23} have also emphasised the effect of the iliotibial tract, which acts as a lateral tension band and reduces the bending of the femur in the frontal plane. Finlay et al²² and Aamodt et al²⁴ found a decrease of 45% to 50% in the lateral tensile strain on the femur when comparing the effect of the iliotibial band with that of the gluteal muscles. Combining the forces in these two groups of muscles reduced the lateral tensile strain by 27%.²⁴ Previously, we also measured the strains in vivo at the proximolateral aspect of the human femur²⁵ and the magnitude and directions of these strains were comparable to

those observed in the present measurements in vitro. Ideally, experimental strain studies should include simulation of the forces in all muscles across the limb segment under consideration,²³ but for most muscles the magnitude and direction of the forces are not known and a more controlled and reproducible configuration of the loading is recommended.¹ Another potential source of experimental error is to maintain the geometrical position of the femoral head relative to the femur after insertion of the stem.²⁶ According to our protocol we measured the medial position of the intact femoral head and by using modular prosthetic heads we could reproduce the medial position within ± 1.25 mm, but we could not reliably reproduce the vertical position. Also, a change in anteversion of the neck could contribute to unintended torsional forces on the femoral head when the abductor strap was loaded. Monitoring of the forces in the abductor strap and the torsional force on the femoral head, however, showed no significant differences in these parameters when testing the intact and the operated femora. Thus, we conclude that small changes in the geometry of the testing system contribute very little to the changes in cortical strain.

We have used paired femora for testing to reduce the interfemoral variability in the pattern of strain. Although there may be slight differences between femora from one pair, studies have shown a high degree of symmetry of the strains of contralateral femora.²⁷ This is in agreement with our study in which we did not find any significant difference in the pattern of strain in intact left and right femora. During the application of the strain-gauge rosettes we also used a well-defined reference system for their positioning

on the femur. This reference system consisted of the longitudinal femoral axis, the posterior condylar plane and the distance from the distal aspect of the intact femoral head. Previous studies from our laboratory²⁸ have shown a coefficient of variation of the mean principal strains to be less than 1.1% after repeated dismantling and reassembling of the test jig and the measuring circuits. Thus, this step in the test procedure also accounts for very little of the variability of the strain measurements.

The measurements of strain showed that both types of stem induced a dramatic reduction in axial strain in the bone adjacent to the proximal half of the prosthesis, but the changes in cortical strain were significantly less pronounced for the customised implants and these prostheses consistently achieved a more physiological pattern of strain in the proximal femur than did the anatomical stems. Therefore, by transmitting a more proximal load to the femur one of the goals of the design of the customised prosthesis has been achieved.

Customisation of the femoral stem is one of several features of an implant that can influence its biomechanical properties. For example, there is some indication that a collar, which rests on the calcar, can restore the proximal medial compressive strains.^{10,29} The effect, however, of the collar on proximal medial strains is unpredictable and also depends on the accuracy of the resection of the femoral neck and the reaming of the canal. After implanting an uncemented titanium stem with a collar, only 4% to 20% of the medial compressive strains were restored,^{9,30,31} which is comparable to or less than uncemented stems without a collar as shown in this and other studies.³²

The view is widely held, and has been shown in experimental studies,^{2,3,9} that the size and stiffness of the stem are dominant design features controlling bone remodelling after hip replacement. This seems to be well documented when metal implants (modulus > 100 GPa) are compared with low-modulus or composite implants (modulus < 20 GPa).^{7,9} When titanium-alloy prostheses were compared with those of stainless-steel of identical design, however, no difference could be detected in proximal stress shielding.⁹ This data suggests that flexibility of the stem, as a determinant for stress shielding, only has a role for prostheses with a modulus comparable to cortical bone and is less important for the differentiation of metal implants. Where the factors contributing to the restoration of femoral cortical strain are more complex.^{4,33} In particular, conformity of the implant to the host cortical bone in the proximal region seems to be important in order to maintain a physiological transfer of load.^{10,34} On the other side, it has been shown that proximal wedging of press-fit stems reduces the axial strains³⁵ and increases the hoop stresses,¹⁰ which may imply a risk for intra- or postoperative femoral fractures as well as secondary instability of the implant.

Both prostheses examined in our study were made of titanium alloy and had a similar surface structure and coating. Obviously, the customised stem fills the femoral

canal more extensively than the anatomical stem, yet the former produced less proximal stress shielding. Our experimental results therefore contradict some analytical studies³⁶ which predict extensive stress shielding around canal-filling implants. The customised stem used in our study is designed to fit the endosteal bone uniformly with a CT density of 600 HU. In some femora this can lead to a more time-consuming and elaborate broaching process when compared with standard procedures. In more than 40 experimental and 140 clinical implantations, however, we had only one case of an intraoperative fissure and none of fractures in the proximal femur. Thus, the conformity of the bone at the implant-bone interface and the extensive contact area may explain the more physiological pattern of strain observed for the customised stems. Also the hoop or tensile strains in the proximal medial region were close to normal in the customised group. For the anatomical stems the hoop strains in the calcar region were significantly reduced compared with those in intact femora, whereas the medial hoop strains at the level of the lesser trochanter were significantly higher than in the customised stems. These findings may indicate press-fit and wedging of the anatomical prosthesis in this region. Moreover, the hoop strains for the anatomical stems may be even higher than the strains actually measured in areas of contact between the 'corners' of the stem and the endosteal bone.

Studies of acute changes in the pattern of strain in cadaver femora after insertion of femoral stems are valuable in the assessment of the impact of different implant variables on the load transfer to the bone. Neither strain nor analytical studies, however, can be used uncritically to predict the performance in vivo of different prostheses. Engh et al³¹ compared the acute stress shielding and the strain pattern in contralateral remodelled specimens in vivo and found no obvious correlation. At least for the medullary locking prosthesis, there seems to be persistent strain shielding, which does not reach equilibrium and leads to ongoing bone loss around the prosthesis.³¹ Whether this is also the case for proximally ingrown prostheses is still unclear. In order to overcome the limitations of strain studies regarding clinical relevance, the remodelling around hip prostheses in vivo should also be closely monitored. For this purpose dual-energy x-ray absorptiometry seems to be a promising tool.

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