An in vitro study of the strain distribution in human femora with anatomical and customised femoral stems

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Hydroxyapatite-coated standard anatomical and customised femoral stems are designed to transmit load to the metaphyseal part of the proximal femur in order to avoid stress shielding and to reduce resorption of bone. In a randomised in vitro study, we compared the changes in the pattern of cortical strain after the insertion of hydroxyapatite-coated standard anatomical and customised stems in 12 pairs of human cadaver femora. A hip simulator reproduced the physiological loads on the proximal femur in single-leg stance and stair-climbing. The cortical strains were measured before and after the insertion of the stems.

Significantly higher strain shielding was seen in Gruen zones 7, 6, 5, 3 and 2 after the insertion of the anatomical stem compared with the customised stem. For the anatomical stem, the hoop strains on the femur also indicated that the load was transferred to the cortical bone at the lower metaphyseal or upper diaphyseal part of the proximal femur.

The customised stem induced a strain pattern more similar to that of the intact femur than the standard, anatomical stem.

The relationship between mechanical load and adaptive remodelling of bone is described by Wolff’s Law.1,2 The insertion of an implant into the femoral canal alters the load distribution in the proximal femur. The femoral stem should be designed to maintain the distribution of the physiological load in the femur to avoid stress shielding, which produces negative bone remodelling with progressive resorption of bone in the proximal periprosthetic part of the femur and hypertrophy around the distal part of the stem. Several in vitro methods have been used to study the stress-shielding phenomenon including strain-gauge analysis,3-5 a photoelastic-coating technique6,7 and finite-element analysis.8,9

The geometrical conformity between the stem and the medullary canal of the femur is one of fit and fill. An optimal fit of the stem into the metaphyseal part of the femur is important to achieve proximal load transfer.6,10-12 A tight diaphyseal fit enhances proximal stress shielding.12,13

Uncemented stems with an anatomical shape were designed to achieve proximal load transfer by proximal press-fit. Compared with the first-generation uncemented stems with less proximal fit, the anatomical stems caused less proximal stress shielding,14,15 but a proximal bone loss of 20% to 25% two years after hip replacement has still been described. One design of anatomical stem with a long-term follow-up is the Anatomique Benoit Girard stem (ABG-I). Radiological and dual-energy x-ray absorptiometry (DXA) studies have shown proximal stress shielding and bone resorption in a large number of patients.16-19 Several studies have measured the filling of the medullary canal in vivo by the ABG-I stem on post-operative radiography and related this to later radiological signs of bone remodelling, with different conclusions as to the correlation between stem fit and remodelling.10,20,21

Customised femoral stems are designed to have a better fit to the endocortical surface of the proximal femur compared with a standard stem. If proximal load transfer to the femur is correlated with proximal fit and fill of the stem, the customised stem should give a more physiological strain distribution.

In this study we addressed two questions: first, did insertion of the ABG-I stem cause stress shielding which could explain the bone loss observed in clinical studies and, secondly, to what extent would an optimal proximal fit
of the stem improve the strain distribution in the femur? We investigated the alternation in the pattern of cortical strain in the proximal femur in vitro after insertion of a standard uncemented anatomical and a custom-made stem.

Materials and Methods

Implant systems. The two systems used were the uncemented, anatomical ABG-I (Stryker-Howmedica, Allendale, New Jersey) and the Unique customised femoral stem (SCP, Trondheim, Norway) (Fig. 1). Both prostheses are made of titanium alloy. They have modular femoral heads and no collar. In order to achieve proximal load transfer the proximal part of the ABG stem has an anatomical shape and this part of the stem also has a macro-relief of the surface. Its proximal third of the stem is coated with a 50 μm layer of hydroxyapatite (HA). It is not polished distally. The size of the ABG stem and the level of the osteotomy of the femoral neck are decided pre- and intra-operatively by the surgeon. The femoral canal is prepared by diaphyseal overreaming to 1 mm wider than the diameter of the tip of the selected stem, and by progressive broaching.

Transverse CT scans with a slice distance/thickness of 5/ mm were obtained for the individual design of the custom-made stem. The radiodensity used to evaluate the CT scans was measured in Hounsfield units (HU), defining the radiodensity of water as zero HU and of air as -1000 HU. Bone has a density between +400 HU and +1000 HU. On each of the transverse CT scans of the proximal femur, a software algorithm was used to create closed contours along the corticocancellous interface of the medullary canal. By definition, these contours follow the pixels with a CT density of 600 HU and are describing the surface of the stem to be fitted to the corticocancellous interface of the femoral canal. Based on the two-dimensional transverse contours on the CT scan, a three-dimensional computer model of the prosthesis was constructed, ensuring that the stem could be inserted through the femoral neck after resection of the femoral head. Finally, the stem was manufactured using a computer numerical-controlled machining process. The proximal two-thirds were coated with a 50 μm layer of HA; the distal third was polished and downscaled to prevent contact with endocortical bone and bone ingrowth. A resection guide mounted on an intramedullary reamer was used to achieve the preplanned level of division of the femoral neck. The femoral canal was prepared using a combination of standard and custom-made rasps, without any diaphyseal reaming. The mean length of the Unique stem was 19 mm (11 to 27) which is shorter than that of the ABG stem.

Preparation of cadaver femora. We obtained 24 femora from 12 human cadavers (11 male) with a mean age of 51.9 years (27 to 68). For each pair of femora the two stems were randomly allocated to the right or left sides. Standardised radiographs in two projections (frontal and anteroposterior) were obtained to identify and to exclude specimens with any localised skeletal abnormalities and to estimate the size of the prosthesis in the anatomical group by using tem-
plates. The posterior femoral condyles and the posterior aspect of the greater trochanter defined the frontal plane of the femur. Anteversion of the femoral neck was measured and recorded for later orientation of the femur in the frontal and sagittal planes. The condyles were removed and the distal part of the diaphysis cemented into a steel cylinder with the vertical axis through the piriform fossa aligned with the centre axis of the cylinder. The distance from the tip of the greater trochanter to the top of the cylinder was 25 cm for all specimens.

In order to simulate the hip abductors a nylon strap 35 mm in length was attached to the lateral aspect of the greater trochanter. The strap was mounted in parallel to a plane defined by the centre axis of the cylinder and the centre of the femoral head in order to minimise the torsional forces acting on the femur during loading.

**Hip simulator.** After preparation the femur was placed in the hip jig and mounted in an MTS 858 MiniBionix II servohydraulic testing machine (MTS Systems Corporation, Eden Prairie, Minnesota) (Fig. 2). The loading characteristics were defined according to McLeish and Charnley.23 The femur could rotate freely about its longitudinal axis and tilt freely in the mediolateral plane to avoid unphysiological bending moments. Torsional load was applied to the distal part of the femur through a weight-and-pulley system acting on a transverse crossbar connected to the cylinder holding the specimen. The femur was prevented from rotating by the acetabular component and the trochanter strap. Load cells monitored the force acting on the femoral head in the anteroposterior direction and that acting on the trochanter strap.

**Strain measurement.** For measurement of the strains ten strain-gauge rosettes (3/120 RY 91; HBM, Darmstadt, Germany) were attached at four levels at the medial, lateral and anterior aspects of the proximal femur and positioned as described and evaluated by Aamodt et al3 (Fig. 3). At the sites of attachment to the bone, acetone, etchant (Multipurpose etchant; 3M, St. Paul, Minnesota) and primer (Multipurpose primer; 3M) were used before the rosettes were bonded using a two-component polymethylmethacrylate adhesive (X60; HBM). The rosettes were covered with waterproof sealing (Vitremer; 3M).

Each rosette, consisting of three gauges (a, b and c), was orientated parallel to the longitudinal axis of the femur. The outputs of the gauges were recorded by a measurement amplifier (UPM 100; HBM) and the principal tensile and compressive strains for each rosette were computed. Because of the physiological bending moment of the proximal femur during gait, the rosettes located on the medial side were chosen as the most representative value for the principal compressive strain, whereas the principal tensile strain was determined by the lateral rosettes. On the anterior side both the principal tensile and compressive strains were used for statistical analyses.

The specimen was mounted in the hip simulator and pre-loaded with an axial force of 600 N, then unloaded and all the strain gauges and load cells set to zero. A three-step testing sequence was used for the measurement of strain as follows: 1) an axial force of 600 N representing single-leg stance; 2) a combined axial force of 600 N and a torsional
moment of 15 Nm simulating stair-climbing; and 3) unloaded. This cycle was run three times with measurements taken at every stage and the mean values were chosen to represent the intact femur. An experienced orthopaedic surgeon (AA) then implanted the femoral stems, selecting a head with an appropriate neck length to reproduce the original medial offset. The specimen was again mounted in the simulator and the testing sequence was repeated for the implanted femur.

**Statistical analysis.** Strain measurements were expressed as a percentage of the strains in the intact femora to reduce the impact from variation in physical properties among the bones. Comparisons between the customised and the anatomical stems at each of the ten strain rosettes were performed using a paired $t$-test. In order to evaluate the overall differences between the two types of stem at all ten locations of measurement, we performed multivariate analysis of variance (MANOVA) to account for correlations between the different points of measurement. All the analyses were repeated on the log scale because of the relatively few number of observations ($p > 0.05$).

**Results.**

**Strain measurements during simulation of single-leg stance and stair-climbing.** The overall changes in cortical strains in the proximal femur were significantly lower after insertion of the custom-made stem compared with the anatomical stem for single-leg stance and for stair-climbing (MANOVA, $p < 0.05$). The difference was highly significant at sites A1, B1, C1 and B3 ($p < 0.001$) for both single-leg stance (Fig. 4) and stair-climbing (Fig. 5), and significant at site C3 ($p < 0.05$). Compared with the strain values of the intact femora, the customised and anatomical stems showed a significant reduction of cortical strain in Gruen zone 7 at site A1 with 44% and 87% for single-leg stance and 35% and 84% for stair-climbing, respectively. Insertion of the custom-made stems did not alter the cortical strain distribution at other sites, but insertion of the anatomical stems caused a significant reduction ($p < 0.05$) at sites B1, C1, B3 and C3 (Figs 4 and 5). The hoop tensile strain on the proximal femur was reduced after insertion of the anatomical stems, except at site B2, where it was significantly increased ($p < 0.05$) (Fig. 6). For the customised stems there were only small changes in hoop tensile strains compared with the intact femora.

**Forces on the proximal femur.** There was no significant difference in the pattern of strain in intact left and right femora. The difference in force on the femoral head before and after insertion of the stem was comparable for both prostheses. The mean internal torsional force on the femoral head was increased after the insertion of the prostheses, by 13.0% for anatomical stems and 14.7% for customised stems. However, there were no significant differences between the two groups ($p = 0.30$). The corresponding increase in the mean abduction force was 8.5% for the anatomical and 6.8% for the customised stems ($p = 0.16$). The mean resultant joint contact force after insertion of the prostheses was 1669 N (232% of body weight) for single-leg stance and 1755 N (244% of body weight) for stair-climbing.
In this *in vitro* study the insertion of a customised femoral implant resulted in a more physiological pattern of strain in the proximal femur than that of an anatomical stem. For the customised stem, strain shielding was mainly localised to an area corresponding to Gruen zone 7. For the anatomical stem there was significantly more strain shielding in Gruen zones 7, 6, 5, 3 and 2. The design of the customised stem allowed a more proximal load transfer to the femur.

Our aim was to reproduce the physical loads on the proximal femur and reduce the experimental variability of testing. We used a hip-simulating jig described by Aamodt et al. An axial force was applied to the femoral head, and an abduction force simulated the gluteal muscles, as recommended by Cristofolini. This loading configuration was controllable and reproducible. Our model did not include the iliotibial tract which could reduce mediolateral bending of the diaphysis, reducing lateral tensile strain. However, the loading configuration of the hip contact force and the abductor force seemed to reproduce adequately the load distribution in the proximal femur.

The force of internal torsion on the femoral head and the force in the abductor strap increased slightly but equally after the insertion of the two prostheses. This could have been a result of higher articular friction of the intact femoral head against a metal acetabulum compared with that of the replaced femoral head, which had a smaller diameter of the head and a smoother surface. A change in anteversion of the neck after insertion of the stem could also have affected the measured forces. The hip contact forces in our jig corresponded to those measured *in vivo* with instrumented implants.

Both the standard anatomical and the customised stems were designed to avoid proximal stress shielding of the femur. Metaphyseal fit of the implant to the endocortical bone is important to maintain proximal load transfer. The wide individual variation in the shape and size of the proximal femoral medullary canal prevents perfect contact between a standard stem and the endosteal cortical bone. The HA-coated proximal two-thirds of the customised Unique stem is designed to fit the endosteal cortical bone. The HA-coated proximal third of the anatomical ABG-I stem is surrounded by more metaphyseal trabecular bone. Proximal wedging of press-fit stems could increase the hoop stresses, with a risk of periprosthetic fractures or secondary instability of the implant. Compared with the intact femora, the hoop tensile strains above the lesser trochanter were close to normal in the customised group, but significantly reduced in the anatomical group. In the anterior part of the femur, at the level of the lesser trochanter, the hoop strain for the anatomical stem was higher, indicating press-fit and wedging of this stem in this region.

The HA-coated part of the Unique stem, designed to give a better metaphyseal fit, is larger than that of the ABG stem. Adaptive bone remodelling is more apparent around larger and stiffer femoral prostheses. In experimental studies, composite components with a modulus of elasticity comparable with cortical bone (modulus < 20 GPa) favoured bone remodelling compared with rigid metal implants (modulus 80 GPa to 200 GPa). Both prostheses examined in our study were made of titanium alloy with a modulus (100 GPa) five to six times higher than that of cortical bone.

Tight distal fit and fill enhance proximal stress shielding. The ABG-I stem has a loose fit in the diaphysis, achieved by over-reaming. The distal third of the Unique stem is designed to avoid distal fit. Overall, the customised stems were approximately 20 mm shorter than the anatomical stems.
Proximal resorption of periprosthetic bone is commonly seen after the insertion of an uncemented stem, with a typical reduction in bone mineral density (BMD) during the first and second post-operative years, followed by a progressive recovery of density around fixed stems. A DXA study of the Unique stem showed a reduction in BMD of 22% in Gruen zone 1 and of 32% in zone 7 two years after hip replacement. DXA studies of the ABG-I stem showed a reduction of 16% and 17% in BMD three and five years, respectively, after hip replacement. Some of the initial bone loss could be a result of intra-operative rasping and reaming. The importance of the early resorption of bone within two years is not known, but according to the Norwegian arthroplasty register both the Unique and the ABG-I stems have a survival rate of more than 96% after ten years, using aseptic loosening as the endpoint. Our finding of excessive strain shielding in the metaphyseal part of the proximal femur after insertion of the anatomical stem, corresponds to that seen in radiological studies of the ABG-I stem, which showed progressive resorption of proximal bone in more than 50% of the patients seven to ten years after hip replacement. The percentage of patients with proximal bone resorption with loss of the density of trabecular bone, cortical softening or thinning, and distal bone formation increased between the follow-up study of five to seven years and that of seven to ten years. This consecutive proximal weakening of the femur could result in long-term aseptic loosening, periprosthetic fracture and more challenging revision. There are no medium- or long-term radiological or DXA studies of the Unique stem, but a randomised clinical and DXA study of the ABG-I and Unique stem is ongoing.

The design of the custom-made stem gives a more physiological pattern of strain in the proximal femur compared with that of the anatomical stem after insertion in human cadaver femora. This appears to be a result of better geometrical conformity between the endocortical bone and the custom-made femoral stem. The slightly shorter stem could also contribute to a more physiological distribution of strain by reducing the risk of distal locking. The more physiological pattern of strain in the proximal femur should give more successful bone remodelling, according to Wolff’s law, but the size of the customised stem could raise concern regarding the long-term bone remodelling in vivo.

Strain studies on cadaver femora are valuable to describe load transfer from the implant to bone with different designs of the femoral stem, but only reflect the immediate post-operative condition, and cannot be used uncritically to predict the performance in vivo of different prostheses. Our ongoing randomised, clinical and DXA study of the ABG-I and Unique prostheses will add information as to the clinical effects of the differences in femoral strain patterns in the two prostheses.

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