Biomechanical and histomorphological investigations on an isoelastic hip prosthesis after an eight month implantation period

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1. Introduction

Late aseptic loosening is the most frequent long-term complication of cemented total hip arthroplasty. Theoretical and experimental studies have shown that stiff cemented stems significantly alter the stress distribution of the femur, including reduced proximal stresses and strains [1–3]. This led to further developments on how to produce a more physiological load transfer from prostheses to bone without using cement. The development of a hip stem based on a compound structure using a lower elastic moduli material offers the possibility of reducing the implant stiffness, thereby creating a more 'physiological' strain distribution in the proximal femur.

The goal of this study was to compare strain distributions and micromotions under three different conditions:

(a) intact femur without prosthesis;
(b) femur with implant directly after implantation;
(c) femur with implant after an 8-month implantation period.

2. Materials and methods

This study was performed on a pair of femurs from a 67-year-old patient who died secondary to an accident 8 months after the implantation of a RM-isoelastic hip prosthesis [4] made of polyacetal resin and reinforced by a metallic stainless steel core. Deep indentations are in the polyacetal stems to enhance stability. A large collar enables the support of the stem at the resection plane and the fixation of the prosthesis to the lateral cortex by means of two lag screws.

After the soft tissue had been removed, the intact right femur and the left femur containing the 8-month implant were prepared with four triaxial strain-gauge rosettes (Type 6/120 RY 11, HBM, Darmstadt, FRG) on both the medial (SG1–SG4) and lateral (SG5–SG8) surface of the femoral cortex using cyanoacrylic adhesive (Fig. 1). Gauge 5 was located 5 mm below the level of the lesser trochanter and gauges 3 and 7 on the level of the tip of the prostheses. The micromotion (i.e. the relative displacement between the hip prostheses and the bone) was measured three-dimensionally with a laser measuring system [5] (six degrees of freedom, resolution 0.02 mm, 0.1°) and four LVDTs (resolution 0.01 mm) two lateral and two ventral (1–4, Fig. 1). The LVDTs were fixed at the bone, their anchors were elongated with rods (1 mm diameter) which were connected to the surface of the prostheses through drill-holes in the cortex (1.2 mm diameter). The distal femoral diaphysis of each specimen was potted in methylacrylate after removing the femoral condyles. Then the femora were fixed in a material testing machine (ZWICK 1454) with an inclination angle of 8° by means of an acetabular cup and a ball joint at the level of the knee centre (Fig. 1). The femurs were loaded up

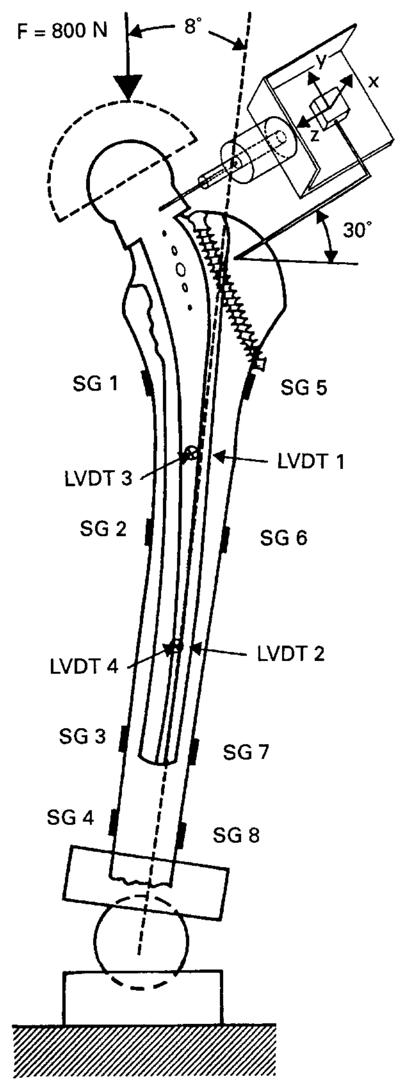

Figure 1 Schematic diagram of the loading condition and location of strain gauges (SG1–SG8), displacement transducers (LVDTs) and the laser system used in this *in vitro* study.

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to 800 N and strains were recorded (UPM 60, Hottinger Baldwin Meßtechnik, Darmstadt, FRG).

First the 8-month specimen was tested. Then the intact femur without prosthesis was investigated. After that the same type of isoelastic hip prosthesis was implanted by the same surgeon who carried out the original implantation. The same biomechanical procedure was repeated.

Following the biomechanical investigation the bones with the prosthesis were cut in cross and longitudinal sections for undecalcified bone histology.

3. Results

3.1. Strain patterns

All bones showed highest strain values in a longitudinal direction oriented close to the vertical. They were tensile strains on the lateral side (SG5–SG8) and compressive strains on the medial side (SG1–SG4), see Fig 2. The longitudinal strains exhibited about three to four times higher values than hoop strains oriented close to the horizontal, which had the opposite sign, i.e. compressive strains at lateral and tensile strains on the medial side. The orientations of principle strains of the three bones did not show any significant differences. The exception was the 8-month specimen at the proximal medial strain gauge (SG1) with an inclination of 20° to dorsal.

The absolute strain values for the longitudinal as well as for the hoop strain were highest for the intact femur. They were reduced by the implantation of an isoelastic prosthesis. In tendancy the stain was lowest for the 8-month specimen, e.g. at strain-gauge 1 the medial compressive strain was 76% for the freshly implanted one compared to 63% for the 8-month implanted one. This effect was even more evident on the lateral side, particularly around the tip of the prostheses, with only 40% of the normal tensile strain compared to 65% directly after implantation. Similar results were found for the hoop strains.

3.2. Micromotions

A significant relative motion between prostheses and bone could only be measured in the 8-month specimen (Fig. 3). The displacements and rotations were reversible after removing the loads. The main relative motion at the bone-prostheses interface was 0.14 mm medialward in the proximal region and 0.2 mm lateralward in the middle region. In the distal region above the distal tip of the prostheses there was a lower value by 0.14 mm lateralward. The interface motion in the longitudinal direction was about 0.1 mm. In the anterior–posterior direction there was a small displacement of 0.01 mm proximal and 0.04 mm distal. After removing the lateral screws there was only a small increase in the medial–lateral motion: in the proximal area the prosthesis moved 0.16 mm medialward and in the distal area 0.15 lateralward.

In the freshly implanted device the measured micromotion was less than the resolution of the measuring system (< 0.01 mm).

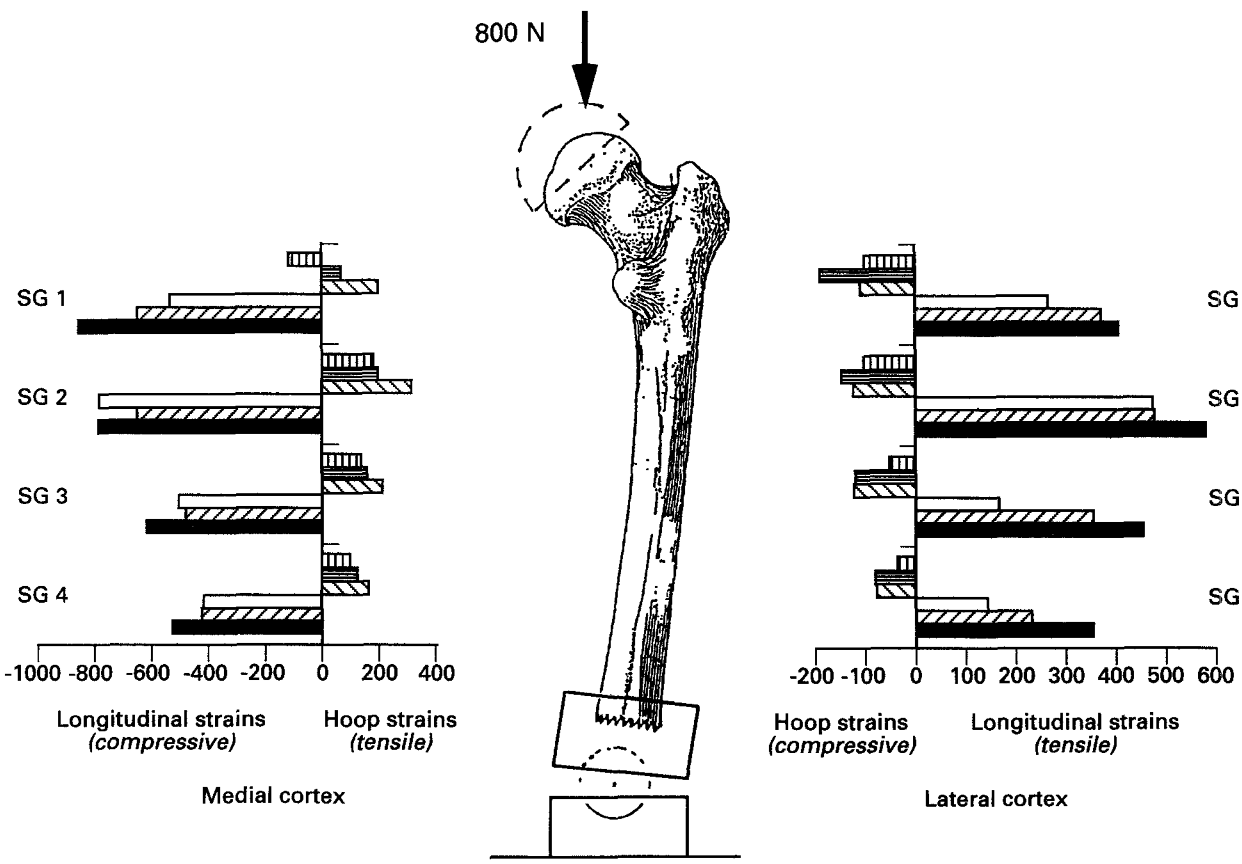

Figure 2 Strain distribution (longitudinal and hoop strains) in the proximal femur under a load of 800 N for natural bone, with implant directly postoperative and after an 8-month implantation time (longitudinal strains: □ 8-month, ▨ post-implant, ■ natural femur; hoopstrains: ▥ 8-month, ▤ post-implant, ▧ natural femur).

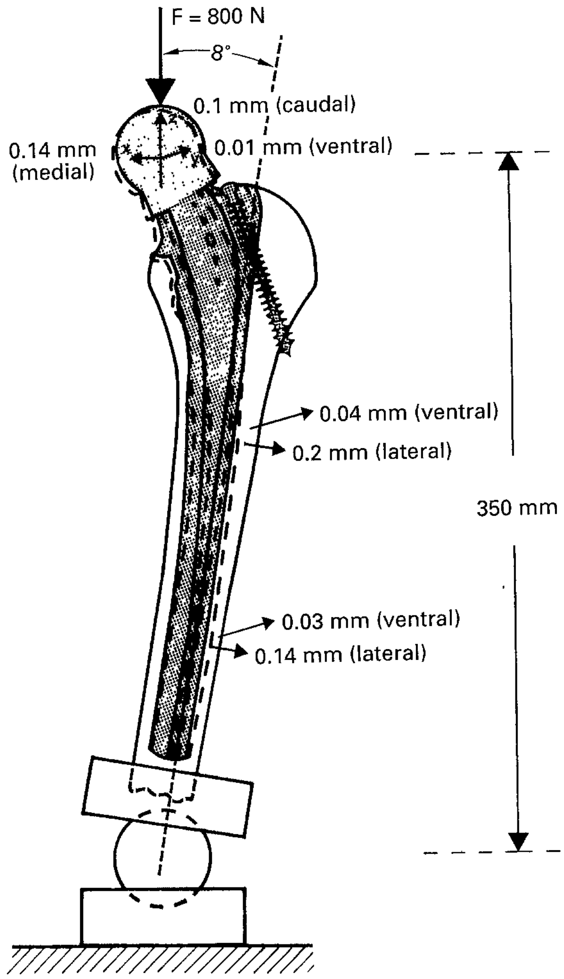

Figure 3 Results of the micromotion between bone and prosthesis for the 8-month specimen.

3.3. Histology

All cross-sections showed an encapsulation of connective tissue over the entire prosthesis. The thickness of this connective tissue layer was about 0.4 mm in the proximal medial area and about 0.15 mm on the lateral side. In the distal area there was a greater difference in the thickness between medial and lateral. The grooves and indentations of the prosthesis were filled by connective tissue, not with bone. Around the distal tip of the prosthesis new trabeculae could be found. A decreased bone mass by an increased porosity could be found.

The greater trochanter maintained its trabecular structure. In the thread between bone and screws no connective tissue could be found.

4. Discussion

Good initial fixation is one of the prerequisites for the long-term success of non-cemented hip implants. It is proposed that a reasonable stem design of non-cemented prostheses, whether press-fit or porous ingrowth, should transfer most of the axial load from the stem to the bone in the proximal region [6]. The lower part of the stem is used for stabilizing and minimizing micromotion. With these goals, the proximal bone should not be seriously stress-shielded compared with normal [6]. In this study we tested the RM-isoelastic hip prostheses directly after implantation and after an 8-month implantation time.

The strain behaviour of the 8-month implanted prosthesis demonstrated no substantial difference to the freshly implanted one. Only a tendency towards decreased strains compared to postoperative conditions could be found.

The micromotions directly after implantation were lower than reported data by other authors. Gebauer *et al.* [7] tested 30 cementless prostheses after implantation and measured micromotions between 50 and 190 μm under 2000 N axial loading. Burke *et al.* [8] found values of about 30 μm from seven prostheses at 520 N loadings.

After an implantation time of 8 months we found a significantly increased interfacial micromotion compared to our primary stability. The micromotion data were repeatable, and the motions returned closely to zero on unloading (i.e. elastic). Unfortunately these values can not be compared to studies in the literature as we could not find any references to micromotions of uncemented hip prostheses after certain implantation times. Our maximum value in the proximal area was 200 μm. Pilliar *et al.* [9] found that bone ingrowth is assured when relative motion is less than 28 μm; more than 150 μm prevents ingrowth of bone.

The histology demonstrated a complete membrane with no direct contact between bone and implant, which could be caused by these micromotions.

As no connective tissue in the thread between bone and lateral screws could be found, we concluded that these screws provided stable anchorage in that region. Thus the prosthesis seems to tilt medialwards in the proximal region and lateralward in the distal region with the centre of rotation in the proximal region at this level of the screws.

Two main limitations should be considered carefully. The experiment is a case report and the loading conditions were without using muscle forces: therefore the results should not be generalized. This study proved that the measured micromotion correlated with the connective tissue found close to the prosthesis. However, we cannot say whether the micromotion is a cause or an effect of the membrane.

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