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The development of a physiological hip prosthesis: the influence of design and materials

J. VANDER SLOTEN*, L. LABEY, R. VAN AUDEKERCKE, J. HELSEN‡, G. VAN DER PERRE
*Department of Mechanical Engineering, Division of Biomechanics and Engineering Design, and ‡Department of Metallurgy and Materials Engineering, Orthopaedic and Dental Implants Research Group, K.U.Leuven, Celestijnenlaan 200 A. B-3001 Heverlee, Belgium, * and also Belgian National Fund for Scientific Research*

A wooden femur model was used together with matched cementless experimental implants to investigate the influence of some design concepts on the stress distributions within the proximal femur model, with emphasis on the longitudinal stresses on the outer bone surface, because the longitudinal stresses are believed to be the most important stresses in view of the laws of bone remodelling. In addition to the integration of alternative geometrical design concepts in a hip prosthesis design, the effect of using alternative materials upon bone stresses was also investigated. Stress evaluation was made by a combination of two-dimensional finite element analysis and strain-gauge measurements. The results and conclusions drawn from these experiments have led to a prototype of a so-called "physiological" hip prosthesis, in which are integrated a properly oriented collar, a hinge between stem and neck part, and a flexible stem.

1. Introduction

Hip arthroplasty has become a current surgical intervention with high success rates. The average life time of a hip prosthesis (time before revision arthroplasty) is now at least 10 years [1]. Clinical results with the current types of hip prostheses are good but, especially in younger patients, there is a need to at least double the lifetime of a hip prosthesis.

The development of a hip prosthesis that replaces optimally the natural, degenerated hip joint is a challenging task. This implant should meet the following specifications:

1. It must restore the function of the natural joint: this refers to the mobility of the joint and the load transfer across the joint.
2. The implant must be stable in both the short and the long term.
3. Taking into account Wolff's Law of optimal use of bone material in the skeleton, stress distributions in the bone after surgical intervention must be as close as possible to the normal stress distribution for all loads that will be transferred across the joint.
4. These stress distributions must be predictable and must be as surgeon-independent as possible.
5. The implant must have adequate strength and special attention must be paid to fatigue resistance in aggressive circumstances.
6. The materials used must not be toxic or harmful to the human body.
7. The implant should be implantable and explantable.

This paper focuses on the third and fourth requirements: we investigated which design characteristics must be present in a prosthesis in order to create normal, "physiological" stresses in the surrounding bone. The axial (longitudinal) stresses are important in view of Wolff's Law and this research was concentrated on these stresses. Hip implants that are aimed at physiological stress distributions in bone have already been designed by various authors, e.g. Mathys and Mathys [2] and Engelhardt *et al.* [3]. They demonstrated by various stress analysis techniques, that their designs created stresses in the bone that were closer to normal than with conventional implants.

We describe here how a number of design concepts were integrated in test designs which were evaluated by means of two-dimensional finite element analysis and strain-gauge measurements on an idealized geometry for the proximal femur.

2. Materials and methods

2.1. Basic concepts and test designs

Some concepts in the design of a hip prosthesis were judged worthy of further evaluation.

1. A. "tailor made" medullary stem fills the entire proximal medullary cavity and is over its entire surface in contact with the bone [4, 5]. This concept ensures stability against rotational and antero-posterior forces and eliminates the use of bone cement.

2. A properly oriented collar was thought to raise compressive stresses in the calcar region. Care has to be taken that under all circumstances the collar makes contact with the underlying bone.

3. An antero-posterior groove in the distal part of the stem makes the stem more flexible and at the same time allows the prosthesis to sink into the medullary cavity such that the collar can find a new support if necessary.

4. A hinge between stem and neck which allows rotation in the medio-lateral plane ensures that there is always contact between a collar and the calcar. This concept is also implemented in the Engelhardt prosthesis [3].

5. Material selection for the stem must be optimized.

Concept 1 was implemented in all designs tested. Concepts 2–4 were tested in three different designs: models 1, 2 and 3, respectively. Concept 5 was tested separately (model 4).

2.2. The models for femur and prosthesis

Because this research was aimed at a qualitative understanding of the influence of the design characteristics that are summed up above, it was decided to use a wooden model for the proximal femur (Fig. 1). The dimensions are average values for the length and cross-sectional dimensions as they are observed in the upper part of the femur [6]. Furthermore, a greater trochanter was simulated to allow the attachment of the abductor muscles and the proximal end was cut in the same way as the femur during hip surgery. Beech wood (transversely isotropic, $E = 16$ GPa in longitudinal direction) was used as a model for cortical bone as it has comparable mechanical properties.

The stems of the implants referred to as models 1, 2 and 3 were in aluminium ($E = 70$ GPa) and the other parts in stainless steel ($E = 210$ GPa). Aluminium was chosen as stem material because of its moderate stiffness, comparable with a titanium alloy ($E = 110$ GPa). In this way the ratio of the Young's moduli of titanium to bone is similar to that for aluminium to wood. All stems were assumed to fill the medullary cavity completely and have a circular cross-section. A hollow cylinder to 30 mm length remains underneath the stem tip to prevent the implant from resting upon the solid section and to model the diaphyseal bone. These three types of prosthesis are shown in Fig. 2a–c. A collarless stem design (model 4, Fig. 2d) was used to study the influence of the materials choice for the stem.

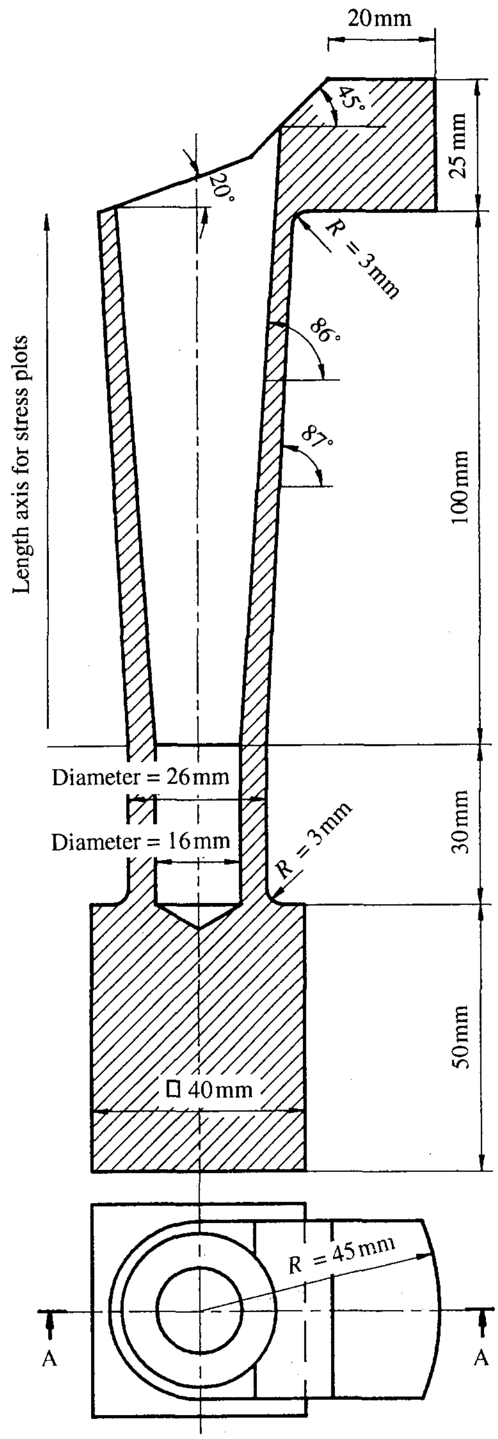

Figure 1 The idealized model for the reamed proximal femur.

2.2.1. Model 1

Fig. 2a shows the prosthesis with properly oriented collar, perpendicular to the mean direction of the load on the femoral head in one-legged stance. It was assumed that this direction was 20° from vertical. The experimental apparatus allowed the direction of the joint force to be changed to 0°, 10°, 20° and 30° from vertical, which is a physiological range. With a joint force vector running at 20° from vertical, and a collar perpendicular to this direction. mainly compressive stresses exist in the cortical bone under the collar, at least in the case of one-legged stance which is a frequent high-load condition for the hip joint [7]. The compressive stresses are due to the normal force and to bending on the shaft of the femur.

2.2.2. Model 2

Fig. 2b shows a prosthesis with collar plus a groove in the distal stem part. The advantage may be two-fold: first, the stem is more flexible and second, it can sink in the cavity such that the collar finds a firm support on

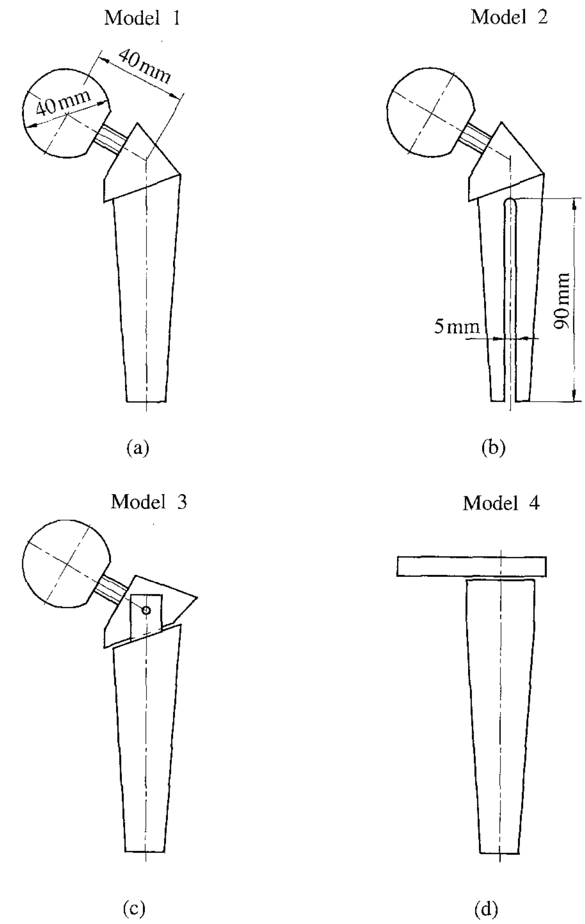

Figure 2 The test models: (a) collared model, (b) model with groove, (c) hinged model, (d) collarless model for stem material testing.

the calcar region without excessively high hoop stresses in the cortical bone, provided the stem surface is smooth. This model was also used to study whether the medial part of this stem could be omitted without altering the load transfer.

2.2.3. Model 3

Fig. 2c shows the prosthesis with hinge. The hinge connects the aluminium stem and the steel neck-collar part, giving rotation around the antero-posterior axis. The integration of a hinge in a hip implant should ensure firstly that the contact between collar and bone is permanent and secondly that the load on the femoral head is transferred mainly to the cortex and the trabeculae in the calcar.

The orientation of the collar is critical and therefore the range of motion (rotation around the hinge) is limited. The objective of the integration of a hinge is to ensure that, in the frontal plane no bending moment can be transferred from the neck-collar part to the stem.

2.2.4. Model 4

The collarless stem design is shown in Fig. 2d and was used to compare the following materials:

(a) a wooden stem (iso-elastic material);

(b) a stem, made of a raw Mathys-prosthesis stem (polyacetal with thin metal core);

(c) a stem with a steel core and a 2 mm thick rubber layer (polyphosphazene) on the outside. The rubber layer was expected not only to make the stem more flexible, but also to maximize the contact surface between stem and bone and to take up relative motion by shear deformation of the rubber layer;

(d) an aluminium stem.

2.3. Method 1: strain-gauge measurements

The prostheses were tested in the wooden femur. Strain gauges were mounted on it as is shown in Fig. 3. The distal part was clamped in a vice and loading applied simulating one- and two-legged stance. This was done by a lever arm ensuring physiological ratios between forces on the prosthetic head and the trochanter.

The direction of the load on the head could be changed between 10°, 20° and 30° from the vertical by means of a wedge. A weight of 9.066 kg (chosen for practical reasons) represented body weight and precautions were taken to minimize the friction at the contact point. The structure was assumed to be linearly elastic so extrapolation to realistic load values was allowed. The loading corresponding with two-legged stance assumed that there was no force on the greater trochanter.

Table I shows the loads that acted on the head and on the greater trochanter as a function of the angle of the wedge that was used to vary the direction of the load on the head. Because the same load was used in all load cases, the ratio between the forces of one- and

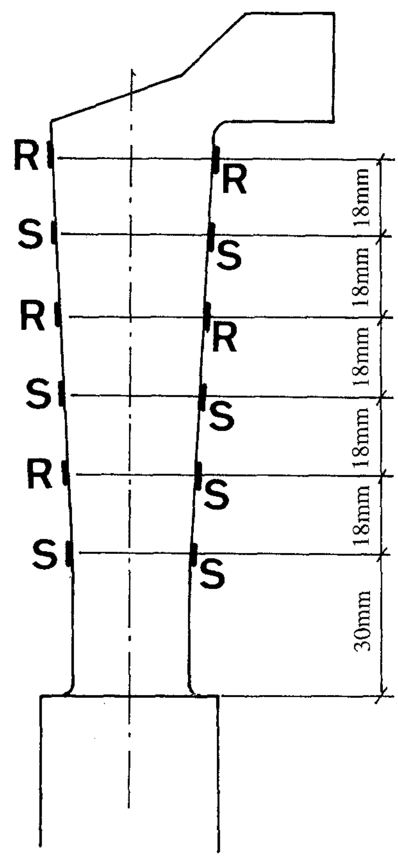

Figure 3 Location of the strain gauges: R, rosette gauge; S, single gauge.

TABLE I The loads acting on the prosthesis head and on the greater trochanter as a function of wedge angle

Wedge angle (deg)	Load (N)	
	Head	Trochanter
0	286	0
10	290	207
20	304	226
30	330	260

two-legged stance is not realistic. However, this was considered to be permissible because we were dealing with a parametric analysis.

2.4. Method 2: finite element investigations

Only two-dimensional finite element models were analysed, based upon equivalence of bending stiffness in the frontal plane and equivalence of medio-lateral compression stiffness of the diaphyseal bone of the femur. A non-linear spring element was used to model the bone-prosthesis interface [8, 9].

The reamed "femur" was simulated by 252 quadratic plane stress elements with 6 or 8 nodes (Fig. 4). The prosthesis models 1, 2 and 3, as well as a collarless design (model 4, stem in aluminium) were also modelled by quadratic elements. Their finite element meshes are shown in Fig. 5.

Material properties were as described in Section 2.2 and the boundary conditions (clamping at the distal end) reflected the clamping of the experimental apparatus. In the finite element calculations, both cortical bone and wood were assumed to be isotropic. This simplification can be justified because the highest stresses are observed in the length direction of the material (direction of the fibres), so the elastic properties in perpendicular directions do not have much influence on the resulting stresses and strains.

Three loading conditions were analysed for each prosthesis: one- and two-legged stance for a human of 56 kg (arbitrarily chosen weight, taking into account the moderate dimensions of our femoral model) and the same loading as in the experimental apparatus (also both one- and two-legged stance). The resultant forces on the head and the trochanter for each of these loading conditions are summarized in Table II. For the 56 kg human, forces are calculated, based upon static equilibrium of the pelvis and transferred to a reference system, with the y-axis coincident with the long axis of the femur.

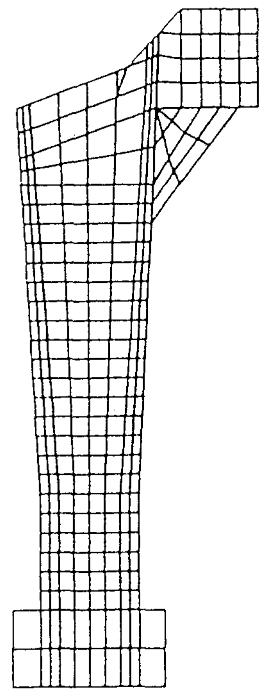

Figure 4 The finite element mesh of the reamed femur.

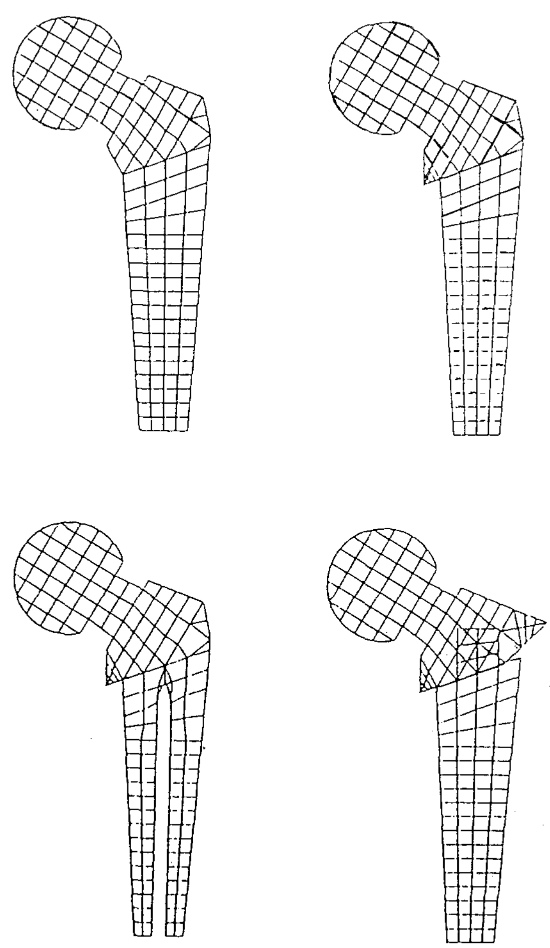

Figure 5 The meshes of the prosthesis models.

3. Results

3.1. Agreement between the experimental and the numerical stress analysis techniques

On the medial side there was generally a good agreement between the results of the strain-gauge measurements and the finite element analysis. Strains were measured during four independent sessions to include the effect of the positioning of the implant upon the resulting strain distribution. The agreement between experimental and numerical results indicates that the finite element analysis is capable of predicting the average stress distribution on the medial periosteal surface that can be expected after implantation of a hip prosthesis. One particular result is shown and

TABLE II The loads used in the finite element analyses (x-axis from medial to lateral, y-axis from distal to proximal)

	Head		Trochanter	
	Fx(N)	Fy(N)	Fx(N)	Fy(N)
One-legged (56 kg)	708	− 1558	− 635	1100
Two-legged (56 kg)	16	− 186	0	0
One-legged (9 kg)	104	− 286	− 104	201
Two-legged (9 kg)	0	− 286	0	0

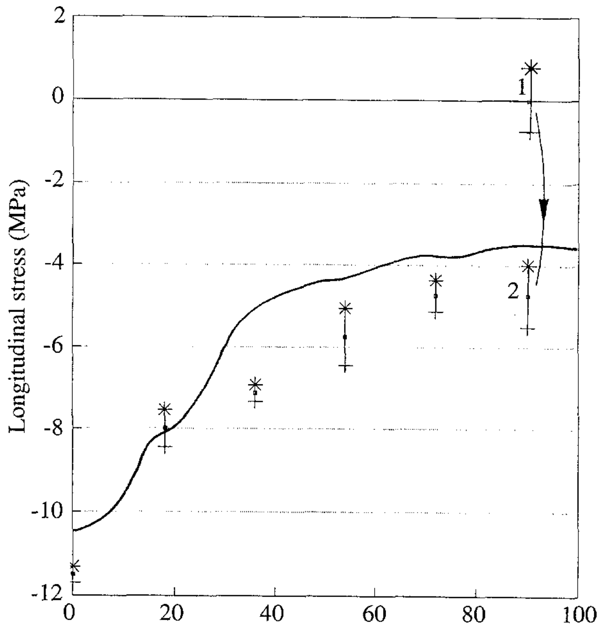

Figure 6 The medial longitudinal stresses for the hinge prosthesis: (——) results of the finite element analysis, (· · ·) results of the strain-gauge measurements (error bars $\pm 3\sigma$). Measurement 1 refers to the first measurement, measurement 2 refers to a measurement after correct positioning of the collar.

discussed here in more detail to illustrate the sensitivity of the strains upon the positioning of the implant.

The initial results of the hinge prosthesis were very disappointing. Fig. 6 shows the absence of compressive stressed in the calcar region immediately underneath the collar (measurement 1). An explanation was found by considering the other strains that were measured by the rosette strain gauge at that location. The directions of principal strains were 57.4° and − 32.6° from the vertical (positive is defined as clockwise, seen from the medial), indicating that this region was not primarily loaded by compressive strains in the vertical direction. This became clear by examining the contact under the collar which was not uniform, but located in one point, eccentric to the medial line. The stress increased to − 4.8 MPa, when the collar was centred properly (measurement 2). On the lateral side the tendencies found by the experimental and analytical methods agreed in the distal part. Fig. 7 shows a representative example obtained with the prosthesis with a collar. More proximally, owing to the difference in the connection of the greater trochanter to the femur in the wooden model (Fig. 1) and in the finite element model (Fig. 4), the measured strains were significantly higher than the calculated strains.

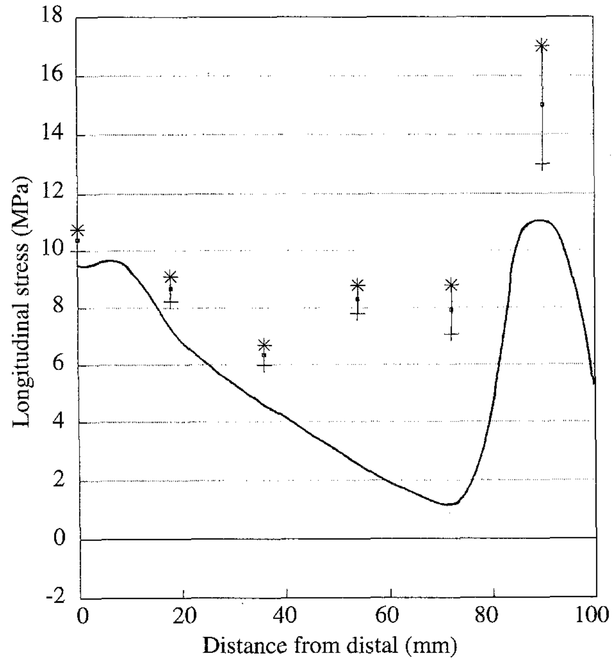

Figure 7 The lateral longitudinal stresses for the prosthesis with collar (cf. caption of Fig. 6).

3.2. Summary of the results of the finite element analysis

It appeared from the results that the two-dimensional finite element models, as used, were a valid tool for the analysis of the influence of some design parameters of hip prostheses upon bone stresses. This is especially true for the medial periosteal stresses. Therefore, the discussion will be based upon the results of the finite element calculations, with loads corresponding to a body weight of 56 kg and primarily the one-legged stance loading condition (Fig. 8 and 9). Fig. 8 shows the longitudinal stresses medially for all models and Fig. 9 shows these stresses at the lateral side.

The results of the two-legged stance loading condition do not offer new information. The appearance of the stress curves is comparable with those of the one-legged stance, but numerical values are an order of magnitude lower because of the smaller forces and bending moment on the structure. The same conclusions can be drawn from these results and therefore they are not shown here.

3.3. Effects of variations in the materials

From Fig. 10 one can see that the longitudinal stresses at the proximal medial side (measured by strain gauges) are low for the "macro-composite" stem and for the wooden (iso-elastic) stem. The Mathys-stem and the aluminium stem however, give rise to high stresses. On considering Fig. 11, showing the hoop stresses, the reason for this may be seen: the stems which produce high longitudinal stresses also produce high proximal hoop stresses. The rather low longitudinal stresses at the proximal side with the wooden and rubber-layer stem are explained by a slight misfit of these stems. Visual inspection revealed a gap between these stems and the wooden femur model of about 0.5 mm proximo-medially.

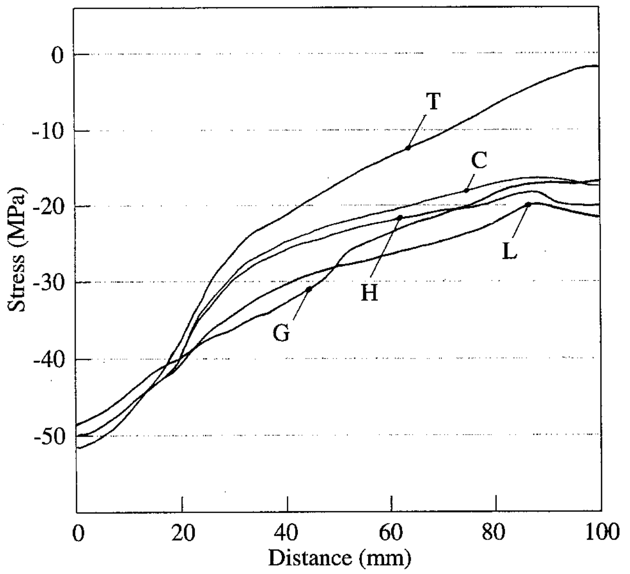

Figure 8 Comparison between the longitudinal stresses medially for all implant types (result of finite element analysis). T, Tailor-made prosthesis; C, prosthesis with collar; G, prosthesis with groove; H, prosthesis with hinge; L, hinge prosthesis with low-modulus stem.

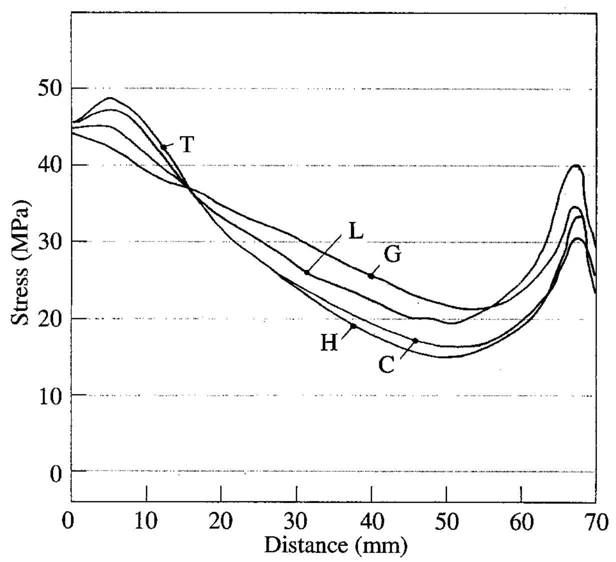

Figure 9 Comparison between the longitudinal stresses laterally for all implant types (result of finite element analysis). T, Tailor-made prosthesis; C, prosthesis with collar; G, prosthesis with groove; H, prosthesis with hinge; L, hinge prosthesis with low-modulus stem.

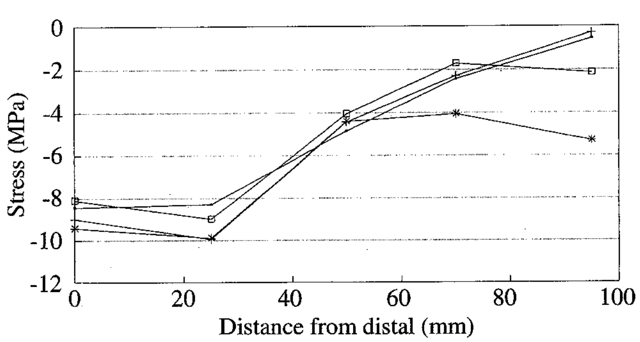

Figure 10 Longitudinal stresses measured medially by strain gauges for four different stem materials. (●) Wood, (+) rubber layered, (✱) Mathys type, (□) aluminium.

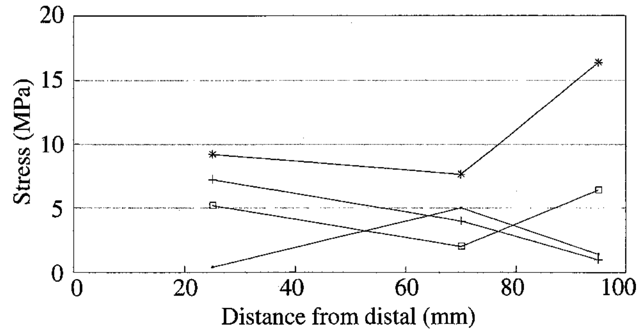

Figure 11 Hoop stresses measured medially for the different stem materials. For key, see Fig. 10.

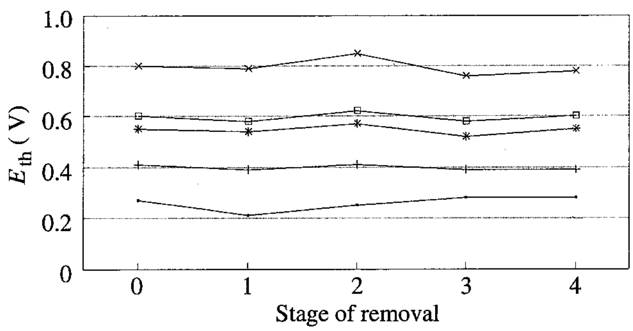

Figure 12 Longitudinal stresses measured medially for various stages of removal of the medial stem part (one-legged stance loading). Gauge: (●) 1, (+) 2, (✱) 3, (□) 4, (×) 5.

3.4. Omission of the medial stem part in the groove prosthesis

The medial stem part of the prosthesis with groove was removed gradually to study whether this affected the load transfer. A plot of the deformed geometry, calculated by the two-dimensional finite element analysis, suggested that this medial stem part moved away from the medial endosteum when the femur was loaded in bending. This would mean that it does not play a role in the load transfer. Fig. 12 shows the longitudinal stresses at the medial side for various stages of removal of the medial stem part. The effect is minimal, as was expected.

4. Discussion

4.1. Influence of the collar

The influence of the collar becomes clear by comparing the tailor-made prosthesis (T) with the prosthesis with a collar (C).

The collar indeed stresses the bone at the medial side underneath the collar. The influence is most pronounced proximo-medially and diminishes distally. The calcar bone is compressed by the collar if the collar continually bears on the calcar bone and if the stem does not act as a wedge, only supported at the distal part. In our concept of a physiological hip prosthesis, we wished to enhance the stress transfer in the proximo-medial region. Therefore, a collar, in combination with a stem that is covered entirely by a porous coating to allow for bone ingrowth, should be avoided, because this is intended to transfer the load uniformly along the entire surface of the stem. Only the most proximal part should be rough, the surface of the distal part should be as smooth as possible. The collar has no influence upon the stresses on the lateral side: the curves for both cases are identical.

4.2. Influence of a groove

A comparison of the prosthesis with collar (C) and the prosthesis with groove (G) provides information about the influence of the groove. The groove has reduced the stiffness of the stem, and this is reflected in the stress curves which show lower stress shielding of the diaphyseal bone in the mid-stem region. On the medial and lateral sides the stress concentration beneath the stem tip has disappeared. The mentioned stress concentration could have an influence on the callus formation, which is clinically frequently observed in this region.

Two groove lengths were analysed. It appeared that there was no noticeable difference between the results of a groove half the length of the stem and a groove of full stem length. The reduced bending stiffness is indeed only of advantage in regions were the bending load is predominant and this is in the distal region. The full length groove has the additional advantage that it allows the stem to sink into the cavity without generating excessive hoop stresses in the bone.

4.3. Influence of the hinge

Because the stem of the prosthesis with hinge was massive (without groove), the results of the prosthesis with hinge (H) are compared to the results of the prosthesis with collar (C).

Both types of prosthesis show comparable compressive stresses in the calcar region and relatively low stresses around the distal part of the stem (stress shielding). The effect of the hinge is not striking but its advantages should be situated in the fact that, due to the hinge, the contact between collar and calcar is optimal and will be maintained in the case of limited calcar resorption. The prosthesis with collar will, after resorption of the calcar, evolve to the situation of the tailor-made prosthesis.

The possibility of reducing the stress shielding in the diaphyseal region by a low-modulus intramedullary stem ($E = 12$ GPa) was investigated by a finite element analysis (curve L: hinge prosthesis with low-modulus stem). This raises the absolute value of the longitudinal bone stresses (mainly in the mid-stem region) by approximately 5 MPa.

4.4. Reference stresses

The evaluation of hip prostheses by considering how close to physiological the stresses which they generate are, requires knowledge of the reference stress distribution. Results reported in the literature from strain measurements as well as stress calculations on intact femurs, show an almost constant compressive stress at the medial cortex with only a slight decrease of the stress level in the calcar region [10–12]. Hence, we will select the concept that stresses the medial cortex the highest and the most constant as the most physiological concept.

In this view, the combination of a hinge (to provide stable calcar support) and of a flexible stem (low modulus or groove) offers the best prospectives for our concept of a physiological hip prosthesis.

4.5. The effect of the stem material

The choice of lower modulus materials for the stem does not seem to be the appropriate way to raise the longitudinal stresses in the proximal femur. The use of a collar offers a more effective and physiological means to achieve this with lower hoop stresses. The rubber layer is not able to accommodate the imperfect fit of the stem in the cavity. Nevertheless, it might be interesting to use such materials locally to achieve good contact and to avoid micro-motions by allowing shear deformation within a rubber layer of adequate thickness.

4.6. The omission of the medial stem part

The medial part of a stem with groove can be omitted without altering the load transfer. The small stem that remains is mainly in contact with the lateral endosteal cortex and in the proximal region it is in contact with the entire endosteum. This stem does not play a major role in the load transfer, but it has mainly a stabilizing task. Stability against antero-posteriorly directed forces is ensured by the presence of a stem of a certain length as such, whilst stability against torsional moments can be ensured by a non-circular cross-section of the stem, especially in the proximal region. Tailor-manufacturing [5] can be used to achieve optimal stability.

5. Conclusions

This paper presented the systematic search towards design characteristics that have a favourable influence upon the stress distribution in the human femur taking into account the consequences of Wolff's Law. These design characteristics were implemented in four test models and all evaluated in one and the same femur model. Hence it ensured that we only measured the effect of the design characteristics we wanted to evaluate, without interference of bone-dependent influences.

Of course other demands, such as the optimization of the interface stresses or the limitation of the micromovements, must be taken into account in further stages of this research.

From our analysis the following points became clear:

1. The presence of a properly oriented collar is fundamental in augmenting stresses in the calcar region. Care must be taken that the collar bears on the calcar region on a large surface in order to avoid local overstressing of the bone and secondly care must also be taken that the collar continuously bear on the calcar, independent of some bone resorption underneath. The presence of a hinge, as proposed here, offers

good prospects in this view, provided the degree of calcar resorption is limited. The optimal orientation of the collar may also be patient dependent and the collar should therefore be a tailor-made part of the prosthesis. The transfer of joint loads to the bone as proximal as possible may also be enhanced by a porous coating on the proximal region of the stem.

2. The stem must be flexible in the medio-lateral plane. This can be achieved by a groove or by the use of low-modulus materials. The possibility of a composite material with anisotropic material properties should be investigated.

3. When a prosthesis with a groove is selected, the medial part of the stem can be omitted in the distal region.

4. Changes in the stem material properties alone are not sufficient to yield a "physiological" straining of the femoral bone.

In our view an optimal concept for the femoral part of a total hip prosthesis combines a hinged design and the use of a grooved stem with short medial part. The collar–neck part ensures load transfer to the medial cortex and the compression trabeculae, whilst the stem mainly ensures stability.

References

1. L. AHNFELT, P. HERBETS, H. MALCHAN and G. B. J. ANDERSSON, *Acta Orthop. Scand. Suppl.* 238 **61** (1990).
2. R. MATHYS and R. MATHYS Jr. in "Die zementlose Fixation von Hüft-endoprothesen" (Springer Verlag, Berlin, 1983).
3. A. ENGELHARDT, H. GRELL, W. HEIPERTZ and D. KOOKE, Acta Orthopaed. Belg. **42** (1976) 220.
4. B. HOORNAERT, J. PUTZEYS and E. SLEECKX, in "Proceeding of the Sixth European Congress on Biomaterials" (Elsevier, 1986)
5. J. C. MULIER, M. MULIER, L. P. BRADY, H. STEENHOUDT, Y. CAUWE, M. GOOSSENS and M. ELLOY, *Clin. Orthop. Rel. Res.* **249** (1989) 97.
6. E. SLEECKX, Internal Report, Division of Biomechanics, K. U. Leuven (1985)
7. V. T. INMAN, H. J. RALSTON and F. TOOD, "Human Walking" (Williams and Wilkins, Baltimore, 1981).
8. J. VANDER SLOTEN and G. VAN DER PERRE, in "Proceedings of the Institution of Mechanical Engineers" (1989) pp. 171–4.
9. J. VANDER SLOTEN, PhD thesis, Katholieke Universiteit Leuven (1990).
10. G. LORD, J.-H. MAROTTE, J.-P. BLANCHARD, J.-L. GUILLAMON and PH. BANCHEL, *Rev. Chir. Orthopéd.* **66** (1980) 141.
11. H. H. VICHNIN and S. C. BATTERMAN, *J. Biomech. Eng.* **108** (1986) 33.
12. H. A. C. JACOB and A. H. HUGGLER, *J. Biomech.* **13** (1980) 159.

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