JOURNAL OF MATERIALS SCIENCE: MATERIALS IN MEDICINE **11** (2000) 443–448

Bone strains and anterior lift-off, measured with three alternative designs of tibial components of TKA

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Total knee replacement is a successful procedure with high clinical success rates. Problems are mostly initiated on the tibial side, and may be due to – amongst others – improper mechanical design of the tibial base plate. In this paper some new design concepts for the tibial component of a total knee prosthesis are presented. They are evaluated experimentally using a model for a proximal tibia, and strain gauge measurements and displacement measurements as experimental techniques. The designs are meant to yield a physiological load sharing between the trabecular and the cortical bone in the proximal tibia, and to minimize anterior lift-off of the tibial base plate. The optimal design required a metal backing of the plastic part and a thin continuous metallic rim in contact with the proximal tibial cortex. An optimal macro-composite structure within the plastic part was obtained by using thin steel wires in the transversal direction, connected to the metallic rim. With this optimal design, it was shown that the force required to close the anterior gap at simulated knee bending was smaller than 250 N, which can easily be applied clinically by an anteriorly placed clamp or bone screw.

1. Introduction

Total knee replacement is nowadays a widely performed surgical procedure with a very high success rate. The Swedish knee arthroplasty register has clearly indicated that revision rates of between only 5 and 10 per cent at 10 years post-operative are well possible [1]. The same publication also demonstrates a marked progress with time, due to improvements in patient selection, technical improvements such as better alignment tools, better cementing techniques and improved surgical experience. Clinical problems that arise post-operatively seem to concentrate most on the tibial part [2], and are due to a multitude of causes including aseptic loosening, malfunctioning of the restored joint, generation of wear particles, and poor surgical technique. Loosening of the tibial component may be initiated by inappropriate loading of the proximal tibial bone, causing adaptive bone remodeling, or by a lack of initial stability of fixation. For this reason we started a research project on the mechanical behavior of the tibial component of a total knee prosthesis. Studies dealing with the mechanics of total knee replacement concentrate either on contact stress analysis between femoral component and polyethylene [3, 4], on fatigue failure of the tibial plateau [5], or investigated the relationship between knee joint loading and tibial component loosening using roentgen stereophotogrammetry [6]. Both the bone strains in the proximal tibia and the relative motion between bone and implant are determined by the bone-implant structure which is created peroperatively, and which develops in the post-operative period. Influencing factors are the design of the implant itself, the nature of the bone-implant interface [7] but also the accuracy of the surgical intervention. The factor accuracy is a difficult topic since it depends upon the skills and the experience of the surgeon. A well-designed set of specialized instruments is a valuable tool to assure a very accurate placement of tibial, patellar and femoral components of a total knee replacement. Recently robot-assisted surgery is being introduced as a means to achieve higher precision during orthopaedic surgery [8].

The design of the tibial component has been the issue of only a small number of research projects. Vasu *et al.* [9] and Beaupré *et al.* [10] made two-dimensional finite element studies of the load transfer of a tibial component in the frontal plane and in the sagittal plane. The design objectives were minimal bone stress shielding and limited component tilting. A tibial component design whose interface geometry mimics the epiphyseal plate in both frontal and sagittal section yielded the most physiological stress distributions. Wevers *et al.* [11] presented a design of a prototype tibial base plate aimed at physiological load transfer to the subchondral trabecular bone and the epiphyseal cortex, and aimed at minimal micromotion in the bone-implant interface. They presented a flexible condylar tibial base plate, consisting of a medial and a lateral section, connected through a flexible bridge. Three-dimensional finite element analysis was applied to investigate the stresses in this base plate.

The research that is reported here was focused on the influence of the mechanical characteristics of three new types of tibial plateau upon the strain distribution in the proximal tibial bone and loosening at the anterior side of the tibial component, loaded by a femoro-tibial contact force. These three designs were based upon preliminary research in our laboratory [12] showing the potential of (1) anisotropic material properties in the posterior part of the tibial plateau, and (2) a perfect contact between the tibial component and the cortex of the proximal tibia.

2. Materials and methods

The designs are based upon a tibial plateau without medullary stem, because of the stress shielding that it causes and potential problems in the case of revision arthroplasty. Studs or short screws can be used to assure initial stability, but we neglect their influence on the load transfer from tibial plateau to proximal tibia. Studs and screws however have a positive influence upon relative motion between bone and implant. Therefore our research on a flat-bottomed tibial plateau represents a worst case, as far as loosening and relative motion is concerned.

2.1. Designs of the three tibial plateaus

An idealized model of the proximal tibia was used in all the experiments. It had a rectangular cross-section with rounded corners in the transverse plane and a posterior slope of approximately 12°. The upper end was flat, to simulate a perfect cut as it should be obtained during surgery. The materials used were balsa wood, to simulate the trabecular bone, and a 1 mm layer of fiber-reinforced epoxy-resin to simulate the thin cortex in the proximal tibia. The use of one standard model for the tibia allows us to exclude variations in geometry and material properties in the interpretation of the results.

We designed three novel tibial plateaus with a geometry such that the contact between the ''cortex'' and the outer rim of the plateaus was as perfect as possible, i.e. the outer rim of the tibial component was an exact copy of the near-rectangular geometry of the proximal tibia model. The additional features, which were integrated in the designs, were thought to be able to yield either a better distribution of the load towards the cortices, or minimize the problem of anterior loosening.

Model A (Fig. 1a)

Component A featured no continuous metal backing, but had a 2 mm thick frame that covered the cortex and part of the trabecular bone next to the cortex. The frame was filled with a resin (Technovit 4000) that simulated a plastic insert. In part of the experiment the influence of reinforcement of the posterior part of the plastic by four 1.8 mm diameter steel wires, aligned in the medio-lateral direction, was investigated.

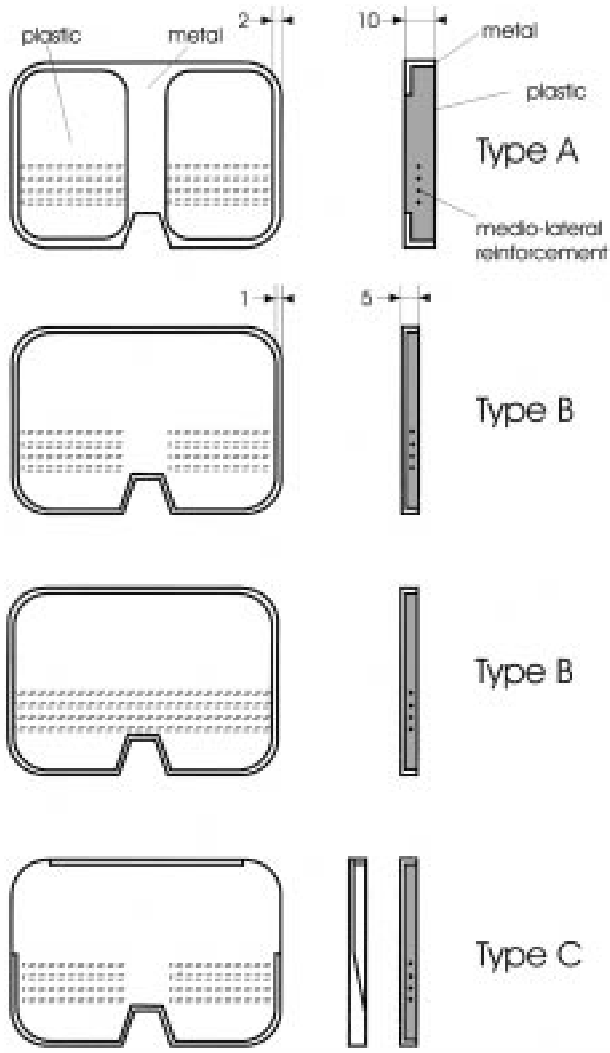

Figure 1 Three novel designs for the tibial component of a total knee prosthesis.

Model B (Fig. 1b)

A complete 1 mm thick metal backing was present in tibial plateau B. A thin rim (1 mm thick) followed the contours of the cortex. The influence of two kinds of reinforcement was also investigated in this plateau: four 1.8 mm steel wires along the medio-lateral direction in the posterior part of each condyle; four 0.8 mm steel wires along the medio-lateral direction in the posterior part of the plateau, glued to the medial and lateral vertical rim.

Model C (Fig. 1c)

Component C was identical to model B, with the exception that the rim was not continuous along the entire cortex. The medial and lateral anterior parts of this rim were omitted to enhance the flexibility of the plateau in the anterior region in an attempt to minimize anterior loosening.

2.2. Loading of the models

A loading apparatus was designed and built that allowed variance of the magnitude of the resultant femoro-tibial contact force, its orientation and its point of application. Two small cylinders, simulating a medial and lateral condyle of a femoral component, were used to apply the femoro-tibial force. A patellar tendon force could be applied or omitted by means of a cable and pulley system. The magnitude of the femoro-tibial contact force was equal to 1000 N in all measurements, and the patellar tendon force was equal to 300 N.

2.3. Measurements

Fourteen strain gauges (11 single gauges and three rosette gauges, Micro-measurements, types CEa-06-125Un-120 and CEa-06-125Ur-120) were glued on the entire proximal circumference of the tibia model. They were connected to an amplifying and signal-conditioning unit that was capable of measuring eight gauges simultaneously. Dummy gauges were used for temperature compensation and the excitation voltage of the Wheatstone bridge was kept low (4 V) to minimize heating of the gauges and the substrate.

An extensometer (HBM-DD1) was placed anteriorly across the interface between the tibial plateau and the proximal cortex and measured the relative vertical displacement between both parts. We will call this phenomenon ''anterior loosening''. The loading apparatus could be modified to measure the force required to close the anterior gap between bone and plateau.

3. Results

3.1. Strain gauge measurements

All strain gauge measurements showed that the strains in the proximal cortex are extremely sensitive to the flatness of the proximal tibia and the position of the plateau on the bone. As an example, the cortex is loaded in tension if the contact between cortex and plateau is not perfect, i.e. if the plateau is supported by the trabecular bone just next to the cortex, but not by the cortex itself. This phenomenon was investigated by a finite element analysis of a structure, consisting of a cortex and trabecular bone adjacent to it and loaded with a vertical force, at various positions ranging from the cortex to the trabecular bone. The result from this two-dimensional analysis is shown in Fig. 2, together with the experimental results: if the load is applied to the cortex, compressive strains appear on the cortex, but if the load shifts to the trabecular bone, tensile strains appear on the cortex.

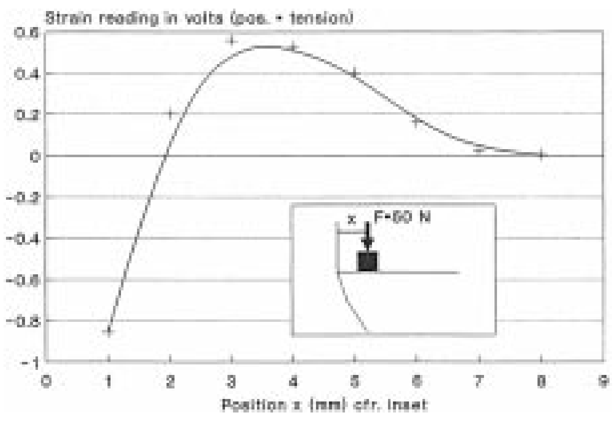

Figure 2 Strain in the anterior cortex as a function of the position of the load application; ($-$: finite element analysis, $+$: strain gauge measurements).

The results of the strain gauge measurements are presented graphically by means of vectors along the circumference of the tibial plateau. A small legend and a scale marker are included in the following illustrations. A strain vector above the reference line indicates compression, a vector underneath the reference line represents tension at the cortical surface.

The experiments with component type A indicated that the absence of a metal backing was reflected in small cortical bone strains. Due to the local flexibility of this plateau type, most of the femoro-tibial contact force is transferred locally to the underlying trabecular bone and not to the cortex. There is only a minor increase in the straining of the cortex due to medio-lateral reinforcement of the plastic with tibial plateau type A (Fig. 3a).

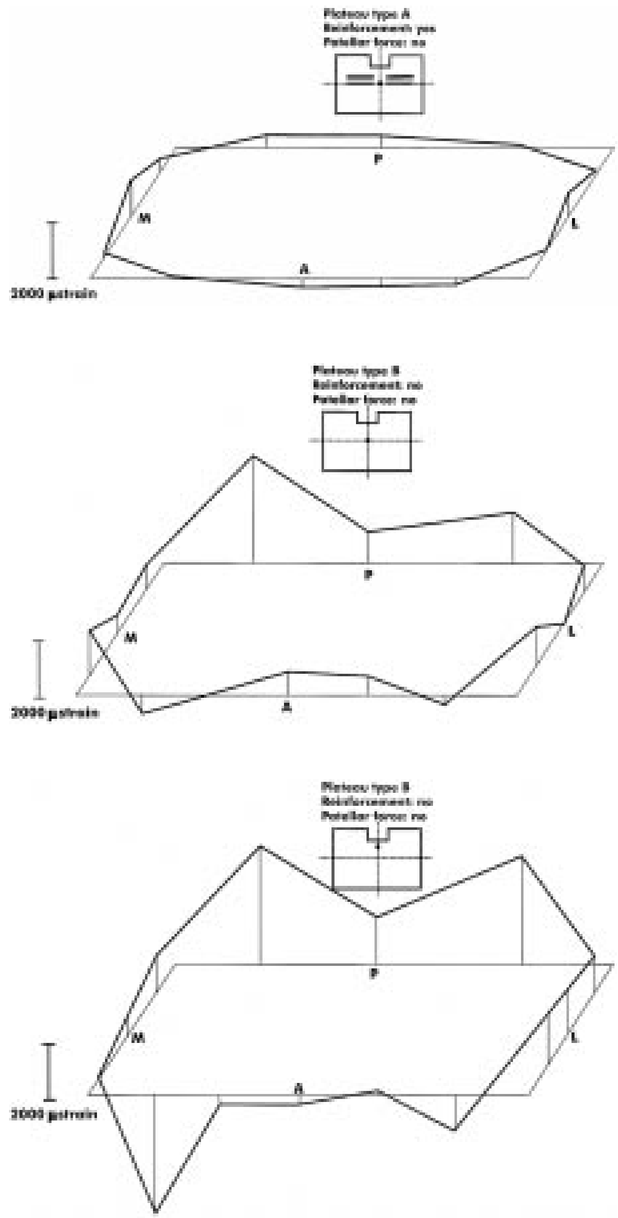

Figure 3 Strain distribution in the cortex for the three design alternatives.

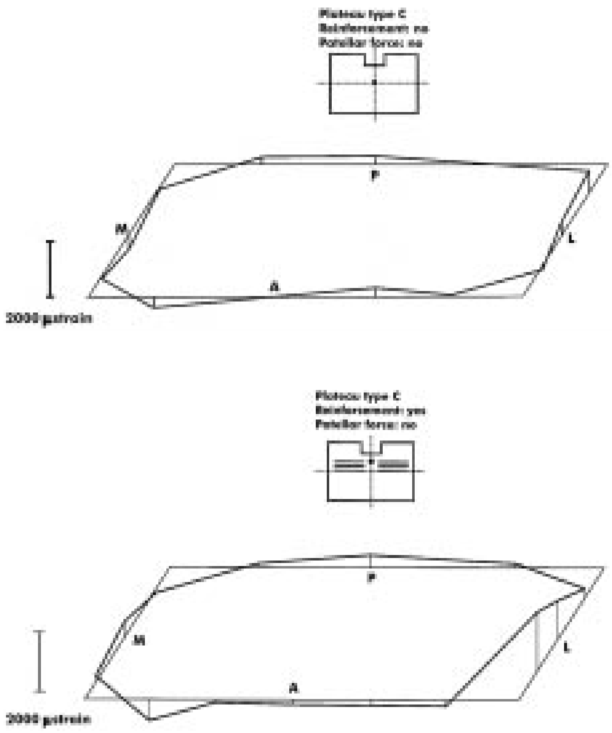

Figure 3. (Continued)

The metal backing and the metallic rim that are present in design B are responsible for the higher loading of the cortex in this case (Fig. 3b). Fig. 3c illustrates the effect of the simulation of knee flexion: the posterior femorotibial contact force causes a bending moment on the proximal tibia, which is reflected in higher compressive strains in the posterior cortex and tensile strains in the anterior cortex.

The load transfer with plateau type C is similar to the result of plateau type A (Fig. 3d): limited loading of the cortex due to the absence of the metallic rim medially and laterally which makes plateau C rather flexible. Medio-lateral stiffening of this plateau increases the compressive strains in the medial and lateral cortex (Fig. 3e, eccentric force application).

3.2. Loosening measurements

In those cases where medio-lateral reinforcement by 1.8 mm wires was applied, loosening is minimal for plateau type B (Fig. 4a). This was observed for all values of load eccentricity. The magnitude of the anterior gap in types A and C is comparable. The effect of reinforcement on anterior loosening in plateau type B becomes clear from Fig. 4b: minimal loosening is obtained when the plastic is reinforced by 0.8 mm stainless steel wires, fixed to the medial and lateral metallic rim. The difference is only noticeable, however, with a load eccentricity of more than 20 mm.

The magnitude of the force that must be applied to close the anterior gap as a function of load eccentricity is plotted in Fig. 5 for component type B without reinforcement. A force must be applied when load eccentricity is larger than 10 mm. It increases with increasing loading eccentricity, but always remains smaller than 250 N.

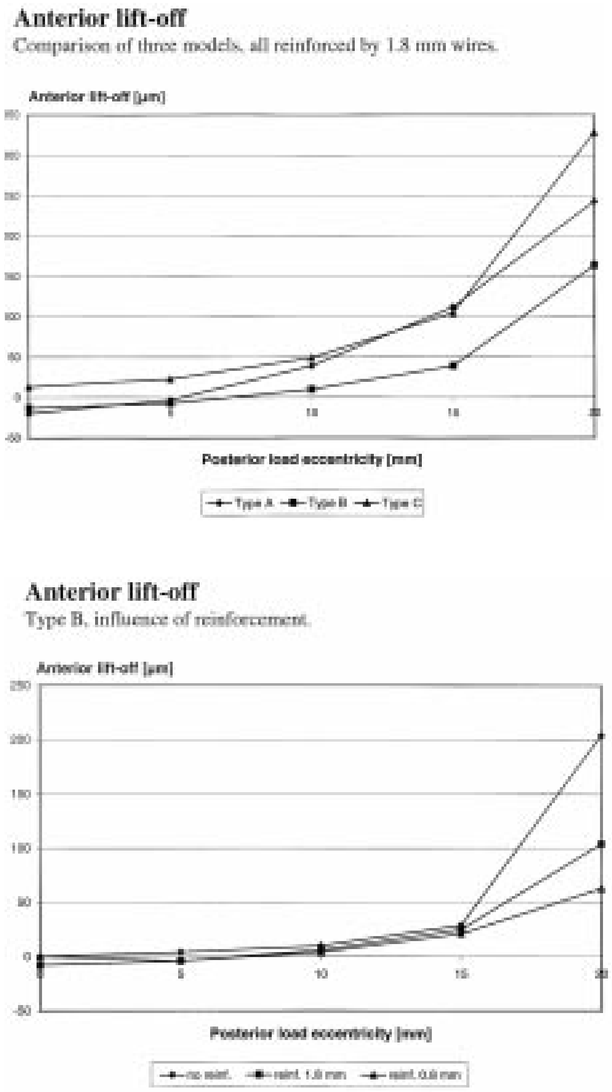

Figure 4 Anterior lift-off for the different plateau types.

The effect of a patellar tendon force was minimal: tensile strains at the anterior cortex lowered by only some 20 μ strain and also the amount of loosening lowered only slightly.

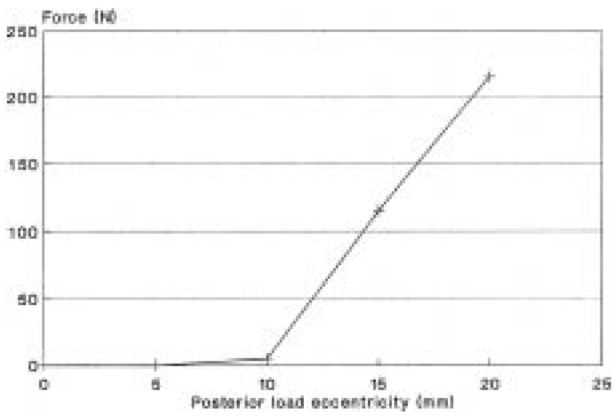

Figure 5 Magnitude of the load needed to close the anterior gap as a function of load eccentricity.

4. Discussion

A successful tibial component design has to solve, amongst others, the following biomechanical problems:

unnatural stress distributions in the proximal tibial trabecular bone. This may lead to local bone resorption due to local underloading of the bone or it can cause fatigue damage to the trabeculae in case of excessive local overloading; the tendency to anterior loosening (i.e. tilting of the plateau) under knee flexion. This compromises the bone-cement bonding in the case of a cemented implant or it compromises bone ingrowth when an uncemented plateau with porous coating is used.

In this study a model for a proximal tibia was used, comprising the basic mechanical elements of a proximal tibia, namely a soft core surrounded by a stiff shell. Although there is always the danger that a model does not properly represent the complex mechanical behavior of a real proximal tibia, the use of a model eliminates the dangers related to generalization of results obtained with one particular cadaveric tibia. The loading device that was developed allowed applying a femoro-tibial contact force at various locations along the mid-sagittal line, hence simulating knee flexion. Three alternative designs for a tibial component of a total knee prosthesis were developed, aimed at maximizing load transfer to the cortices and minimizing the risk of anterior lift–off of the tibial component at knee flexion.

In the experiments it was shown that a full and uniform contact between the tibial base plate and the proximal tibial bone (trabecular as well as cortical bone) is necessary to obtain physiologic strains. Care was taken to realize such an ideal contact in the model. Undoubtedly, this is an idealized situation from a clinical point of view. However, with technological advances in medical image based, custom-manufacturing of prosthetic components [13], and advances in surgical techniques, it may well be possible to realize it also in clinical practice.

Comparison of the results from plateau types A, B and C show that a thin metal backing with a continuous rim is a very effective means to transfer the femoro-tibial contact force to the cortices and thus avoid overloading of the trabeculae. Medio-lateral reinforcement was initially integrated in the design to enhance load transfer to the medial and lateral cortex, but the results indicate that its effect on load transfer is limited except in the most flexible plateau (type C). Probably design C performs less well – considering both load transfer and loosening – because the omission of part of the metallic rim has made it too flexible.

Apparently, the bending stiffness of the plateau in the sagittal plane is an important parameter to control anterior loosening. If the plateau is too stiff, like in type A, it tends to tilt at higher load eccentricities. If the plateau is too flexible, which seems to be the case in type C, bending deformation in the sagittal plane leads to anterior loosening. In that case, an anterior gap appears, even when the load applies centrally. The plateau of type B features the right stiffness for this aspect of the mechanical behavior. For this plateau a further decrease of the anterior loosening with medio-lateral stiffening of the plastic was noted at large load-eccentricity.

Loosening can be counteracted by applying the forces that we have measured anteriorly between the tibial component and the bone. This can be achieved clinically by screws or clamps, made out of a metallic material or made from bioresorbable materials. The latter would allow use of these screws or clamps to obtain initial stability until there is a solid union between bone and e.g. a porous coating underneath the tibial plateau.

Literature [14] mentions the following initial values for bioresorbable materials (Polylactide-L, molecular weight 800 000): ultimate strength $\sigma_u = 100$ MPa and elastic modulus $E = 3000$ MPa. If two elements (screws or clamps) are used, each of them with a cross-section of $20\,\mathrm{mm}^2$, to deliver a force of 150 N. We can then calculate easily that each screw or clamp elongates 0.05 mm and that there is a safety factor of more than 10 as to the ultimate strength. These values demonstrate the usefulness of bioresorbable screws or clamps to assure initial fixation of the anterior side of the tibial component upon the tibia, provided that the rate of degradation of the material can be balanced with the bone growth process.

Our results indicate that optimal biomechanical behavior of a tibial plateau of a total knee prosthesis can be obtained with the combination of an optimal design and the use of an optimal macro-composite plastic part. The optimal design requires a metal backing of the plastic part and a thin continuous metallic rim in contact with the proximal tibial cortex. Both the need for proper flexibility of the tibial tray and the wish to integrate an anatomical shape and perimeter knife-edge, were also stressed in [11]. The first was meant to realize a proper load balance between trabecular, subchondral and cortical bone in the proximal tibia and the second to assure optimal fit and to contain micromotion. An optimal macro-composite structure within the plastic part was obtained by using thin steel wires in the transversal direction, connected to the metallic rim. This allowed minimizing anterior lift-off of the tibial tray. Modern custom made manufacturing techniques of orthopaedic implants allow the production of tibial components, designed to contact the cortex of the proximal tibia at its entire circumference, and based upon digital medical image data [13].

Acknowledgments

Parts of this work have been supported by the Fund for Scientific Research, Flanders, and by the Research Council of the Katholieke Universiteit Leuven.

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Received 20 October 1998
and accepted 17 November 1998