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Stemmed femoral knee prostheses

Effects of prosthetic design and fixation on bone loss

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ABSTRACT – Although the revision rates for modern knee prostheses have decreased drastically, the total number of revisions a year is increasing because many more primary knee replacements are being done. At the time of revision, bone loss is common, which compromises prosthetic stability. To improve stability, intramedullary stems are often used. The aim of this study was to estimate the effects of a stem, its diameter and the interface bonding conditions on patterns of the bone remodeling in the distal femur.

We created finite element models of the distal half of a femur in which 4 types of knee prostheses were placed. The bone remodeling process was simulated using a strain-adaptive bone remodeling theory. The amount of such remodeling was determined by calculating the changes in bone mineral density in 9 regions of interest from simulated DEXA scans.

The computer simulation model showed that revision prostheses tend to cause more bone resorption than primary ones, especially in the most distal regions. Predicted long-term bone loss due to a revision prosthesis with a thin stem equalled that around a prosthesis with an intercondylar box. However, strong regional differences were found— the stemmed prostheses having more bone loss in the most distal areas and some bone gain in the more proximal ones. A prosthesis with a thick stem led to an increase in bone loss. When the prosthesis-cement interface was bonded, more bone loss was predicted than with an unbonded interface. These results suggest that a stem which increases stability initially may reduce stability in the long term. This is due to an increase in stress shielding and bone resorption.

■

The cumulative revision rate of knee prostheses in the Swedish Knee Arthroplasty Register is 17% at 10 years, and 28% after 19 years (Robertsson et al. 1999). Similar revision rates have been reported by Rand and Ilstrup (1991) in a study of 9,200 total knee replacements. Although the revision rates for modern knee prostheses, using better implantation techniques, have decreased drastically (Knutson et al. 1994, Robertsson et al. 2001), the total number of revisions a year is increasing worldwide because of the great increase in the number of primary knee replacements (Haas et al. 1995). The main reason for revision is aseptic loosening (Knutson et al. 1994, Lonner et al. 1999), which may be due to their design (Schai et al. 1998). At the time of revision, bone loss is commonly found behind the anterior flange of the femoral component (van Loon et al. 1999), which weakens the support for a revision component. It has been shown that these typical bone loss patterns are due to stress shielding, a process in which the prosthesis carries part of the load which was formerly carried by the bone alone (Tissakht et al. 1996, van Lenthe et al. 1997). This stress-shielding phenomenon is affected by the bonding characteristics and design of the implant (van Lenthe et al. 1997).

In revision surgery of failed knee prostheses, large bone defects are usually filled with metal augmentation or by bone grafting (Engh and Ammeen 1999, an Loon et al. 1999). To improve prosthetic stability, cemented or press-fitted intramedullary stems are commonly used (Whiteside 1993, Murray et al. 1994). The stem is intended to transfer the load to the diaphyseal part of the

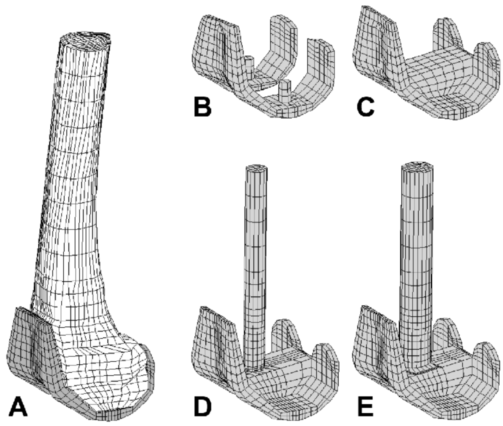

Figure 1.
A. Finite element model of the distal femur with 1 of the 4 implanted knee prostheses, B-E. The 4 prostheses studied.
B. Primary prosthesis.
C. Prosthesis with an intercondylar box.
D. Revision prosthesis with a thin stem.
E. Revision prosthesis with a thick stem.

bone and improve stability (Engh and Ammeen, 1999). However, these stems may cause even more bone loss due to an increase in stress shielding. The cumulative revision rates for revision knee prostheses are higher than those for primary ones (Ritter et al. 1991, Scuderi and Insall 1993, Haas 1995), although the rates differ considerably in the various studies (Haas et al. 1995). Accurate measurements of bone loss using dual-energy X-ray absorptiometry (DEXA) have not been reported for revision prostheses and the results of revision surgery have not been evaluated concerning the extent of bone loss (Engh and Ammeen 1999). Therefore, questions as to whether a stem is needed, or the stem should be cemented can not be answered on the basis of the current clinical literature.

The question whether stemmed knee prostheses may increase bone resorption, which would explain the increase in revision rates of revision prostheses, was studied here. In this paper, we assess the effect of a stem, its diameter and interface bonding conditions, on the patterns of bone remodeling in the distal femur.

Methods

In previous studies, we examined the amount of bone loss induced by stress shielding due to a hip prosthesis, using a strain-adaptive bone remodeling theory (Huiskes et al. 1987, 1992) in conjunction with a finite element (FE) model. In this study, an FE model of the distal half of a male femur was created. It was based on 28 cross-sectional CT-scans, separated 4 mm distally to a maximum of 16 mm more proximally, to cover a total length of 232 mm. This model was similar to that described by van Lenthe et al. (1997), although the density distribution of the femur was slightly changed. The density of our model was based on CT-scans together with DEXA-scans.

Finite element models of 4 knee prostheses (PFC, Johnson & Johnson, Bracknell, UK) were created (Figure 1). For the revision prosthesis, 2 stem diameters were simulated: a canal-filling stem (18 mm) and a thinner one (12 mm), the latter surrounded by relatively soft bone. The canal-filling stem is that used most often; the thinner stem must be used in conjunction with impaction bone grafting and may be of value in reducing stress shielding. To study the effects of the stem accurately, we made a finite element model of a prosthesis with an intercondylar box, but without a stem. However, since this type of prosthesis is rarely used, we also designed a model of a primary prosthesis, to compare the effects of the stem in relation to those of primary prostheses.

The prosthetic models were all connected to the FE model of the intact femur, after removing the appropriate bone cuts. Elements representing the cement layer were added between the prosthesis and the bone. The stems were not cemented. This type of 'hybrid' fixation is the commonest (Engh and Ammeen 1999); it is meant to form a bonded prosthesis-cement interface and an unbonded, press-fit, stem-bone interface. At the bonded interface, no micromotion can occur in the model, while tensile, shear and compressive forces can be transmitted; tensile forces can not occur at the unbonded interfaces. In revision operations, the prosthesis-cement interface has frequently been found to be unbonded (van Loon et al. 1999). This can markedly change the bone-remodeling patterns (van Lenthe et al. 1997), and we therefore studied its effects by also evaluating bone loss in an unbonded prosthesis-cement interface. The unbonded interfaces were regarded as frictionless.

All materials were assumed to be linear and isotropic in the FE analyses. The elastic modulus of the prostheses (CoCr alloy) and the bone cement (PMMA) were 210 GPa and 2.1 GPa, respectively; the Poisson ratios 0.3 and 0.4, respectively. Young's modulus of the bone elements was estimated from their apparent bone densities (ρ_{app}) as (Carter and Hayes, 1977):

$$E = 3790\ \rho^3_{app} (\mathrm{MPa}) \qquad (1)$$

with ρ_{app} in g/cm^3. The Poisson ratio was 0.3 for all bone elements.

In the FE analyses, no displacements were allowed for the upper part of the femur model. The model was loaded at the knee, using 3 loading conditions representing functions of normal daily living. Each loading represented the patello-femoral and tibio-femoral joint forces. These forces were the same as those described elsewhere (van Lenthe et al. 1997).

Long-term prediction of apparent bone density was based on a strain-adaptive bone remodeling theory (Huiskes et al. 1987, 1992, van Lenthe et al, 1997). According to this theory, bone in the treated femur strives to normalize its stress-strain patterns locally to the same values as in the intact femur, under the same loading conditions. This process is regulated by the strain energy per unit of mass (Carter 1987), which is determined as

$$S = 1/2\ \sigma\varepsilon \cdot \rho_{app}^{-1} \qquad (2)$$

in which S is the strain energy per unit of mass, σ and ε are the stress and strain tensors, respectively, and ρ_{app} is the apparent density. In each iterative step of the finite element simulation, the apparent bone density of each element was adapted on the basis of the local difference between S and S_{ref}, where S_{ref} is the strain energy per unit of mass in the intact femur. We used a threshold level of 75% of the physiological strain energy per unit of mass, below which no bone adaptation occurs (S_{ref}). This value produced realistic results in simulations of bone remodeling around human total hip replacements (Huiskes et al. 1992, Huiskes and van Rietbergen 1995). The minimal and maximal apparent densities of each element were set at 0.01 g/cm^3 and 1.73 g/cm^3, respectively. The simulations stopped when the operated bone had adapted to the mechanical changes produced by the implant.

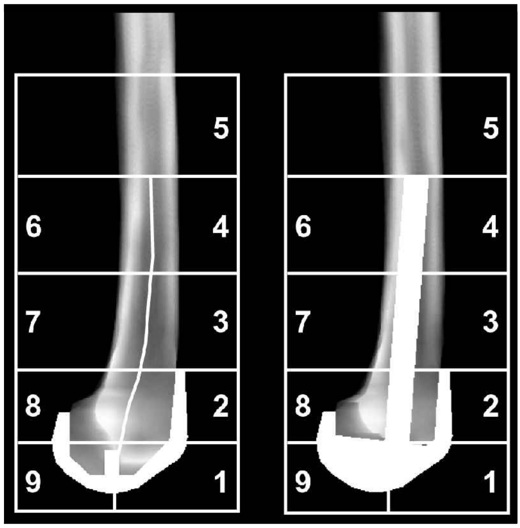

Figure 2. Simulated DEXA scans, depicting the 9 regions of interest (ROIs) for which the bone mineral density was determined. Both a primary and a revision prosthesis are shown to indicate clearly the location of the 6 ROIs.

The amount of bone remodeling was determined by calculating the gradual changes in bone mineral density (BMD) in 9 regions of interest (ROIs; Figure 2) from simulated DEXA scans. This also allows for (future) comparisons with clinical data on bone resorption. In the DEXA simulation program, a 2D projection was made of the bone mineral in the model. The bone mineral density per element was calculated as

$$\rho_{ash} = 0.533\rho_{app} - 0.0028 \qquad (3)$$

in which the ash density (ρ_{ash}) and the wet apparent density (ρ_{app}) are both in g/cm^3. Eq. 3 was obtained from the relationship between ash density and apparent density of dried bone (Keller 1994) and the relationship between the apparent densities of hydrated and dried trabecular bone (Keyak et al. 1994). In the DEXA simulating process, we could choose whether or not to project the prostheses on the DEXA scan. This allowed us to analyze bone areas (ROIs 1 and 9) which can not be seen on clinical DEXA scans.

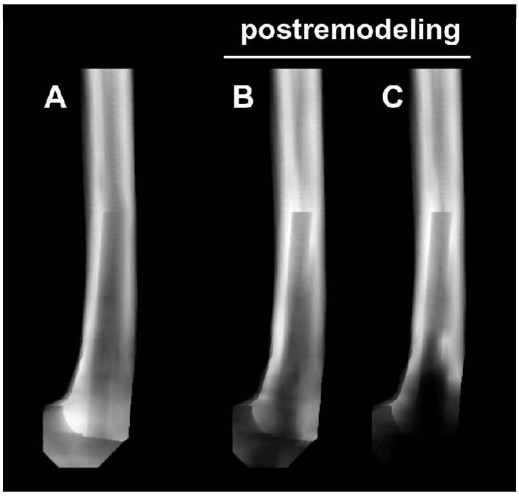

Figure 3. Simulated DEXA scans of the model with the thin-stemmed revision prosthesis. The prosthesis was removed before the DEXA simulation was done to show clearly the bone loss in the distal femur.
A. Immediately after surgery.
B. Predicted long-term bone density in the unbonded prosthesis.
C. Predicted long-term bone density in the bonded prosthesis.

Results

Removal of bone during the operation caused an immediate loss of bone. In the thick-stemmed revision-prosthesis, 31 grams of bone (16% of initial mass) had to be removed (Table). The placement of the primary part accounted for 62% of the 31 grams of bone loss, the intercondylar box and the thin stem accounted for 12% and 7%, respectively. Replacement of the thin stem by a thick stem accounted for the remaining 19%.

After surgery, the stresses and strains in the distal femur were much lower than in the intact femur. The bone remodeling theory predicts that this stress-shielding effect causes bone resorption. This can be seen clearly on the simulated DEXA scans of the model with the thin-stemmed prosthesis (Figure 3). These simulated scans also show that the bonding conditions greatly influence the predicted bone loss. Bone loss in the distal part of the femur is severer in the bonded prosthesis. Proximal to the stem and along its upper half, stresses and strains were higher than in the intact situation, and increased the bone density. We found that bone resorption and bone gain were fast initially, but gradually decreased to zero, so that BMD reached equilibrium. This was found for all prostheses and both interface bonding conditions.

These conditions markedly affected the predicted bone loss. First, the results of the bonded analyses are given. These had a bonded prosthesis-cement interface, but when a stem was present, it was unbonded. The long-term bone loss induced by the remodeling process was 14% to 16% of the initial bone mass (Table). Although the predicted total bone loss did not differ very much in the 4 designs, the presence of a stem resulted in markedly different patterns of bone remodeling. Both the thin and thick stems showed that more bone was lost distally (ROIs 2 and 8), but more bone was gained proximally (ROIs 3–6) (Figure 4). The patterns of bone remodeling due to the thick stem were nearly the same as in the thin stem. The box itself also affected bone loss, as shown by the 15% more bone resorption in ROIs 2, 8 and 9 than in the primary prosthesis.

The predicted bone loss was less severe at the fully unbonded interfaces, with about half the loss as compared to the bonded analyses (Table). The long-term bone loss ranged from 7% to 9% of

Bone loss as a percentage of initial bone mass. A distinction is made regarding the bone loss as a result of bone removal during the operation and the predicted long-term bone loss in the fully unbonded and the bonded interfaces

	Bone loss due to operation	Predicted long-term bone loss induced by bone remodeling	
		Unbonded	Bonded
Primary prosthesis	–10	–8	–14
Prosthesis with box	–12	–8	–16
Revision prosthesis, thin stem	–13	–7	–15
Revision prosthesis, thick stem	–16	–9	–16

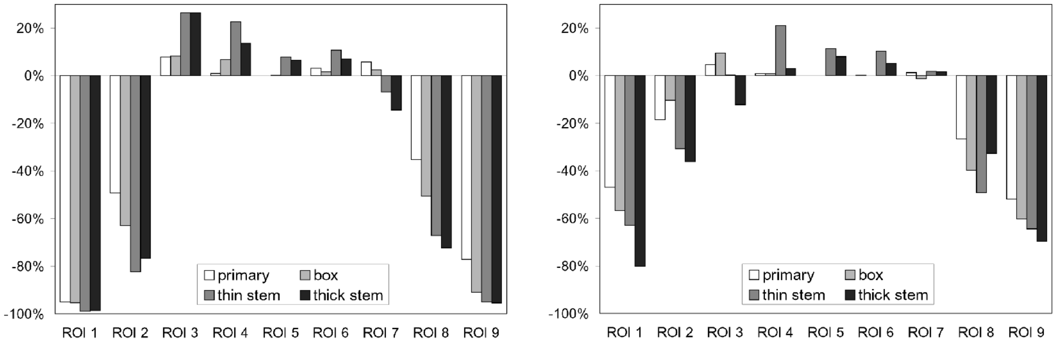

Figure 4. Long-term bone remodeling patterns in 4 different prosthesis designs and 2 interface conditions: a bonded prosthesis-cement interface (left) and an unbonded interface (right); when present, the stem-bone interface was unbonded. Bone loss (-) and bone gain (+) are given in each region of interest and in each prosthesis design; they are expressed as a percentage of the immediate postoperative value.

the initial bone mass. In ROIs 1–3, the thin stem caused 5% to 17% less bone loss than the thick stem, and 18% more bone gain in ROI 4 (Figure 4). However, on the posterior side, bone loss was increased by 16% in ROI 8. As in the bonded analyses, we found that the stem markedly affected the unbonded analyses. Again, large differences were predicted as regards the regional bone losses, but not so much in the total amount of bone loss (Table). In comparing the prosthesis with a thin stem to the prosthesis with the box, we found 6% and 21% more bone loss, and 10% less bone gain, in ROIs 1, 2 and 3, respectively. However, 10% to 20% more bone gain was found in ROIs 4–6. These increases were such that, in total, slightly less bone was lost with the thin stem design. The box itself also affected the patterns of bone remodeling, as shown by more bone loss distally than with the primary prosthesis.

Discussion

The aim of this study was to estimate the effects of a revision stem, its diameter and bonding conditions on long-term bone density in the distal femur. We found that the stemmed revision prostheses would cause more bone resorption than the primary ones. It was predicted that long-term bone loss due to the revision prosthesis with a thin stem would be about the same as that due to the prosthesis with an intercondylar box. However, there were strong regional differences—i.e., the revision prosthesis lost more bone distally, but some bone was gained more proximally. On the other hand, it was predicted that the thick stem would significantly increase the loss of bone, mainly because more bone would be removed during the operation. Bonding conditions strongly affected the bone loss predicted—i.e., bonded prostheses caused about 15 grams (7% of initial mass) more resorption than prostheses which were entirely unbonded.

The accuracy of the simulation models depends on that of the finite element models and on the accuracy of the remodeling algorithm. The strength of FE analyses is that the more refined the mesh, the more accurate the outcome. The effect of mesh density was studied in our laboratory for stress distributions around hip prostheses. We found that a mesh density similar to that used in our models was adequate for accurate stresses (Stolk et al. 1998, 2001). The way in which micromotions at the prosthesis-bone interface affect the formation of a fibrous tissue layer and how this influences the precise bonding conditions and stress transfer between prosthesis and bone are less well understood. Although relevant to the unbonded analyses, where micromotions can occur at the prosthesis-cement interface and at the stem-bone interface and lead to the formation of fibrous tissue, their effect on bone loss around the prosthesis stem was not analyzed. It was expected that the associated bone loss would be much less than that seen in the distal femur. In these simplified cases, we analyzed a fully bonded and a fully unbonded prosthesis, the latter without friction at its interfaces which represented a very loose implant.

Quantitative validation of the remodeling algorithm used in this study was done by comparing the predictions of the computer simulations of bone loss around hip prostheses with results obtained in vivo. In a study on dogs, a good agreement was found between the predictions made with the computer model and resorption after 6 months and 2 years (Weinans et al. 1993, van Rietbergen et al. 1993). The agreement was also good for bone loss patterns in patients with hip replacements (Kerner et al. 1999), although the amount of long-term bone loss was slightly overestimated.

A quantitative validation of the remodeling routines for predicting resorption patterns around knee prostheses is not possible, because no accurate data of bone loss around revision knee prostheses are available. Some measurements of bone density have been made in the distal femur after primary knee replacement, using dual photon absorptiometry (Petersen et al. 1995, 1996) or dual energy X-ray absorptiometry (Liu et al. 1995, Spittlehouse et al. 1999, van Loon et al. 2001). However, the use of these data for validating the model is limited because there is no agreement on the definition of the regions of interest; various ROIs have been used in each study. Furthermore, due to the relatively small areas of the ROIs, accurate placement of these regions is of the utmost importance. In a preliminary study, we found large differences in BMD when a small ROI was only slightly malpositioned. This indicates that a comparison between published data and the results obtained here can only be qualitative. To allow for future comparison with clinical data, we defined ROIs in a way similar to the Gruen zones (Gruen et al. 1979), which are commonly used for examining bone loss around hip replacements. The definition of the ROIs is based on easily identifiable landmarks—i.e., the most distal and proximal parts of the anterior flange and the tip of the stem. We made the height of the ROIs 3–7 the same. A line divides the anterior and posterior regions to make both areas equal.

We used the same density distribution for the femur model in all analyses. This permitted accurate evaluation of the effects of a stem. However, it does not resemble the situation which would occur in a patient since a stemmed prosthesis is used only when the bone in the distal femur is too weak to support a primary prosthesis. Hence, in the patient, the initial density distribution of the femurs would be different, which could lead to a different remodeling process.

Although we regarded the density distribution as equal in all analyses, the finite element representation of the femur differed in the 4 models. This could have introduced changes in the stress and strain distributions in the femur; hence, it could have affected the bone remodeling process. However, the element distribution was refined so that the models were accurate as regards geometry and mass distribution and provided accurate stresses (Stolk et al. 1998). Therefore, the effects on local stresses and strains were small and the effects on the bone remodeling process, if any, were negligible.

A relatively large amount of bone was removed from the model before the stems could be placed, especially the thick stem. Although the stem size was chosen by an orthopedic surgeon, the bone loss indicates that this thick stem might be a little too large for the femur analyzed in this study. However, the present study showed that the bonding conditions affect bone loss more than stem size. A slightly larger or smaller stem will not change the outcomes drastically.

Advice on the use of a stem must be based on factors other than stress shielding alone, like stability. Intramedullary stems are intended to increase the stability and, in case of bone grafting, protect the graft from high stresses. This stabilizing factor has been shown in an in vitro study (van Loon et al. 2000). Here, we did not evaluate stability because it is not clear how much protection a stem should give and for which forces, in particular, it should be fail-safe. Furthermore, stability strongly depends on the interface between prosthesis and bone and/or cement. These interfaces were assumed to be perfect in this study, which makes stability analyses inaccurate.

In summary, predicted long-term bone loss due to a revision prosthesis with a thin stem was equal to bone loss for the prosthesis with an intercondylar box. However, marked regional differences were found as regards the stemmed prostheses, more resorption in the most distal areas, but some bone gain in the more proximal ones. A prosthesis with a thick stem increased the bone loss. When the prosthesis-cement interface was bonded, more bone resorption was predicted than with a fully unbonded interface. This amount of bone loss was the same in primary and revision prostheses. These findings suggest that a stem which increases stability initially may reduce stability later because of increased stress shielding and bone resorption. This is a classical dilemma in implant fixation: for bone to remain healthy and strong, it requires loading. However, to increase interface stability, stress transfer must be limited.

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