Determinants of Stress Shielding:

Design Versus Materials Versus Interface

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Experimental studies of cementless porous-coated total hip arthroplasty indicate that a critical design variable for femoral remodeling is stem stiffness. In the long term (two years) in the canine model, other variables, including the presence, type, and placement of the porous coating, did not significantly affect the pattern of bone remodeling when tested with metallic stems. The basic pattern of bone remodeling was characterized by proximal cortical atrophy, and distal cortical and medullary bone hypertrophy. In the short term (six months), the use of low-stiffness stems altered this pattern, leading to reduced proximal bone loss, increased proximal medullary bone hypertrophy, and no distal cortical hypertrophy, suggesting that stem stiffness had a profound effect on stress shielding.

Cementless total hip arthroplasty (THA) has experienced significant clinical success in the past few years. Short-term clinical experience indicates satisfactory clinical results with a low incidence of failure.[4,7,9,12,27] There are, however, a series of issues of concern regarding the long-term performance of these implants. One of these issues is that of cortical bone loss observed after implantation of cementless femoral stems.[5,6,12] Remodeling changes in cementless femoral stems appear to be more severe and appear to develop in a shorter period of time as compared to those seen in cemented femoral stems.[2,14,28] While the reasons for this phenomenon are many, the net effect of cortical bone loss can be serious and lead to failure of the arthroplasty. Cortical loss can lead to fracture of the bone, potential fracture of the implant, pain and disability, and, potentially, can present very difficult problems for future reconstruction. While the prevalence of these changes has not been well defined, they appear to be more severe with large stems.[5] Biologic and mechanical factors have been implicated in their appearance and development. These include the size of stem, the extent of porous coating, the age of the patient, and the presence of preexisting osteopenia. Long-term clinical studies are invaluable in establishing the importance of the different elements involved in the complex process of bone remodeling after cementless stem implantation. However, experimental studies are necessary to understand the mechanisms involved, to predict the effect of different variables, and to serve as a basis for eventual design and future development of prosthetic implants.

The basic theoretical consideration behind the experimental studies to be reviewed is that implantation of a prosthetic device changes the mechanical environment of the

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host bone and that the femur then remodels to adapt to this new situation.[11,22] Cortical atrophy of the proximal femur after cementless implantation is thought to occur because the stresses normally experienced by the femur are transferred to the distal part of the bone through the implant. Theoretically, the bone remodels to bring the stresses back to the original level. The actual mechanical signal to which bone cells respond is controversial. Thus, the relevant signal could be change in strain rather than change in stress.

The authors postulate that specific design features of the femoral stem can affect the bone remodeling patterns. These include among others: (1) the presence and type of the porous surface, (2) the extent of the porous surface, (3) the conformity of the component to the host cortical bone, (4) the component geometry, and (5) the material from which the component is made.

The various types of porous coatings have different pore geometries and mechanical properties. It is then possible that their bone interface mechanics vary. The pattern of bone ingrowth may differ for each one of these materials and, consequently, this may affect stress transfer mechanisms and in turn influence the bone remodeling processes.

The extent of stem coverage by the porous surface is another important variable. Extensive coatings may encourage distal fixation. This would promote transfer of load distally, which in turn, would tend to reduce strains in the proximal cortex and ultimately lead to a net loss of bone proximally. In an attempt to promote proximal stress transfer, many contemporary prosthetic devices incorporate the porous coating at the proximal level only. Several questions can be raised. Is the bone loss less severe with proximal coating and is fixation and stability of the stem adequate?

The conformity of the component to the host bone relates to the shape of the component and to its position in the medullary cavity. Close proximity to cortical bone probably results in a different biologic response than that of a cancellous bone envelope. There really is no choice in this matter. To provide stability, components have evolved into more anatomic shapes that by necessity conform to the cortical envelope.

The relative stiffness of the stem compared to the femur is another important variable. This relationship depends on the cross-sectional geometry and the material properties of the stem and femur, as well as the location of the stem within the femur. If everything else is constant, as stem stiffness increases, the proximal femur will experience less stress and less strain. The amount and location of bone tissue will be altered to return strain levels to normal. Net bone resorption would be expected, a condition that is clinically called stress shielding. With very stiff prostheses, a theoretical analysis predicted that the bone eventually may resorb completely.[11]

The material used to make the component represents an important design feature with canal-filling stems. These stems are inherently stiff because of their large cross sections. Significant net bone resorption should be expected particularly with very large, very stiff metallic stems. Unfortunately, these stems are required for the patient population at risk with bone deficient femurs.

An interesting development in this area has been the introduction of fiber reinforced composites. Composites can have excellent strength and fatigue properties while at the same time reduce the mismatch in stiffness between the component and the femur. A cemented femoral component represents a composite device whereby the overall stiffness is reduced by the combination of a stiff metallic alloy and the more deformable polymethylmethacrylate.

To study the effects of particular implant design features, clinical studies are not really appropriate, although stem size and degree of canal filling and by implication stress shielding have been identified clinically as important risk factors in cortical atrophy.[5] Conversely, animal models offer the opportunity of testing the role of particular design features on bone remodeling. Stress-shielding effects, in theory, can be modulated by altering the bone implant interface or by changing the stiffness of the implant.

EXPERIMENTAL STUDIES

To look at these issues, the authors have developed an experimental total hip canine model.[26] Before discussing particular studies and the principles derived, it is useful to review some of the features of this model system. The dog is an appropriate model for bone-remodeling studies because the anatomy of its femur and its bone microstructure are similar to that of humans.[18] Bone remodeling in the canine has been studied considerably so that there is information of normal values for remodeling dynamics and data on the effect of various types of treatments. The major difference is that the canine has relatively thin cortices as compared to the human and this implies that the use of equally canal-filling stems in humans and canines would lead to greater stress shielding in the canine.[17] In fact, this geometric difference may partially explain why the canine appears to offer an accentuated model of bone remodeling.

The authors perform unilateral THAs and normalize the data to the unoperated (control) limb. It is then possible to compare two or more variants of a given design by comparing normalized data. This requires the assumption of bilateral symmetry.[19]

Sample size is an important issue. A sample size of at least seven animals in the experimental group in the later studies was chosen based on the normal left-right variability in the canine femur and the anticipated variability in the response to the prosthesis.[19] In the authors' studies, three time periods were chosen: one month, six months, and 24 months. The 24-month period was chosen as a reasonable reflection of long-term effects.

One of the important factors that may cloud the relationship between the design feature and bone remodeling is the degree to which the animal uses the operated limb. Ideally, direct measurements of load during gait would allow for an objective study of the functional performance of the operated limb. Determinations of tibial bone mineral content of the operated limb and control side have been used as a reflection of the degree of usage of the affected limb by the animal.[8]

Each animal was implanted with a cemented ultra-high molecular-weight polyethylene acetabular component and a cementless experimental femoral prosthesis. The dimensions and shape of the femoral prosthesis were identical regardless of the type of porous coating or material from which the stems were manufactured.[20,21,23–26] The stems were either made from Ti6A14V alloy or from a reinforced composite. At surgery, the stems were impacted into cavities that were slightly smaller than the outer dimensions of the implant to achieve an initial interference fit.

Three types of porous coating were tested: beads, plasma spray, and fiber metal (all made from unalloyed titanium). The stems were coated along their length. In additional groups, the fiber metal was applied only to the proximal one-third part of the stem. Finally, the same stems were tested without any porous coating.

At the completion of the experiment, the femurs were oriented in a standard position in a jig, roentgenographed, and sectioned serially, perpendicular to their long axis. Sections were prepared for light microscopy, for scanning electron microscopy, and for measurements of cross-sectional geometry. The light microscope was used to quantitate bone ingrowth and to evaluate qualitatively the bone–implant interface and bone remodeling at the different surfaces. Sections were stained with fuchsin and toluidine blue. The scanning electron microscope and a video-based image analysis system were used to measure medullary bone density and cortical bone porosity and, more recently, bone ingrowth.[16]

Cross-sectional geometry was studied in photographically enlarged contact roentgenographs. Subperiosteal, endosteal, and implant perimeters were digitized and analyzed to calculate the cortical area, the total subperiosteal area, and the area occupied by the medullary canal. All of the values were compared to the control nonoperative side.

Using metallic porous-coated stems, a consistent pattern of bone remodeling and secondary bone loss emerged. The general characteristics of this phenomenon will be described using data from a two-year study[20] and some unpublished data as well. There was a 15% reduction in cortical bone area adjacent to the porous-coated regions of the stem (Fig. 1). Proximally, most of the bone loss was caused by subperiosteal bone resorption. At the middistal stem level, bone was lost because of cancellization of the endosteal surface of the cortex. There were some increases in cortical porosity. The areas of the cortex that were in closest proximity to the porous surface of the implant showed the largest increases in porosity. In these areas, which were the most proximal, the amount of the porosity nearly doubled. However, this change in microstructure accounted only for a minor fraction of the bone loss. At the stem tip, the cortical area increased mainly because of addition of bone at the subperiosteal surface. Within the medullary canal, there were increases in the density of the cancellous bone proximally and, particularly, distally. The increase in proximal medullary bone density offset to some extent the loss of bone experienced in the cortex. It resulted effectively in the redistribution of the available bone mass. Thus, cortical bone was removed proximally and added distally. If one assumes that this pattern of bone remodeling reflects the pattern of stress distribution from the prosthetic device through the cancellous bone to the surrounding cortex, then it can be postulated that it reflects a preferential pattern of stress transfer through the distal portion of the stem.

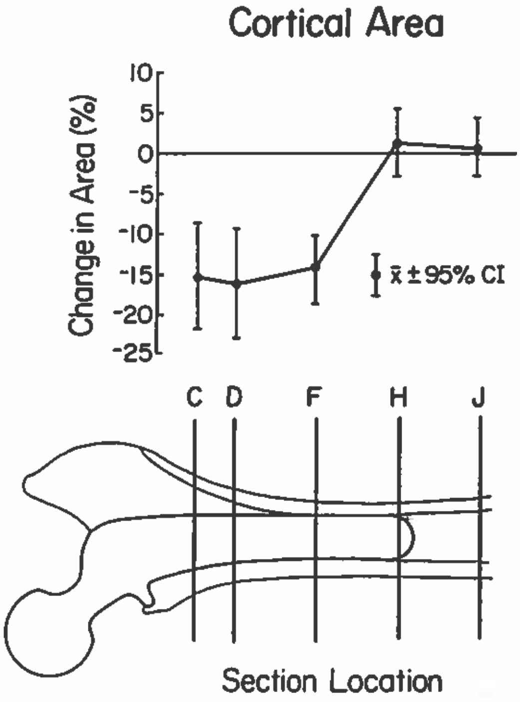

FIG. 1. Change in cortical area at two years in the canine model. The Ti6Al4V stems were porous coated along their length with either fiber metal, bead, or plasma spray surfaces. Porous-coating type had no effect on the bone-remodeling response. A characteristic pattern of proximal cortical atrophy and distal cortical hypertrophy was observed in all of the experimental groups.[22]

Tibial bone mineral content was determined to evaluate the functional performance of the affected limb.[8] There were no differences between the operated and contralateral (control) limbs at six months. At two years, tibial bone mineral content was actually reduced by about 5% compared to the control limb. Despite these findings, the animals clinically appeared to be fully weight bearing. The degree of left-right asymmetry in tibial bone mineral content did not correlate, though, with the left-right asymmetry in femoral cortical area, indicating that changes in the femur were probably local changes caused by the presence of the stem and not manifestations of generalized limb disuse.

Having defined the characteristic features of the remodeling process, a series of variables are looked at that may have a possible effect on it. These include bone implant interface design variables and stiffness of the stem. The major bone implant interface design variables for which experimental data exist include (1) the type of porous coating, (2) the location of the porous coating, and (3) press-fit versus bone ingrowth fixation.

The first variable is the type of coating. There were three different coatings evaluated: beads, fiber metal, and plasma sprayed.[20,26] The geometry of the coatings was different in terms of the size of the pores, nature of the interconnecting channels, and structure of the coating. However, despite these major differences in the nature of the bone–prosthesis interface and related potential differences in interface mechanics, there were no differences in the cortical response. The extent and distribution of cortical bone loss was the same for all coatings. The type of porous coating had no effect on the cortical bone remodeling process. In all three groups, cortical bone was lost proximally and medullary bone density increased distally.

The second group of experiments investigated the effect of location of the porous coating. With stems porous coated along their length, the authors have compared bone remodeling in dogs in which the porous coating was restricted to anterior and posterior stem faces and in dogs in which the porous coating was applied circumferentially.[20,26] In the long term (two years), no difference in cortical bone remodeling was found between these two configurations.

Proximally coated stems are used clinically in an attempt to decrease the severity of the cortical loss. Bobyn *et al.*[3] looked at the effect of restricting the porous coating to the proximal portion of the stem in a canine model in which cobalt-chromium alloy stems were used. There was no consistent difference in proximal cortical bone resorption between dogs receiving proximally and fully coated stems. However, the cancellous bone at the distal most extent of the porous coating was hypertrophied in both groups suggesting that the pattern of stress transfer from the implant to the host bone may have been different.

The authors have also tested the effect of restriction of the porous coating to the proximal stem.[21,24] The porous coatings were located on the anterior and posterior surfaces, either along the length of the stem or restricted to the proximal part of the stem. These stems were manufactured from Ti6A14V alloy. The pattern of cortical bone loss was similar in the two groups at two years. Thus, restriction of the porous coating to the proximal stem not only did not decrease cortical resorption proximally but also had only a negligible effect distally. Both groups had distal cortical hypertrophy, suggesting that a considerable fraction of the load was transferred distally. In three of the nine dogs with proximally coated stems, there were occasional areas of fibrocartilage at the distal bone implant interface, suggesting that significant distal motion occurred even though the devices were well fixed proximally by bone ingrowth. This is an issue of concern in terms of potential clinical performance as to whether limiting the area of ingrowth proximally might limit further the effectiveness of fixation and, hence, present the problem of extensive distal micromotion.

The severity of cortical resorption in proximally coated stems was time dependent. In animals studies at six months, the extent of bone loss in the proximally coated stems was limited and significantly less then that observed in fully coated stems.[24] However, at two years, there was no difference between the two groups.[21] In contrast, the process of proximal cortical loss was well established by six months in the fully coated stems. The presence of extensive porous coating thus resulted in a faster rate of bone loss.

Two additional conclusions can be derived from this finding. The first one is that short-term experiments are not adequate for studies of bone remodeling. If the authors had terminated their experiments at six months, they would have concluded that the extent of bone loss was minimal in the proximally coated stems. Studies of bone remodeling in the dog should probably be performed at a minimum of two years.

The second conclusion is that it is not known when and if the bone remodeling process reached a steady state. Longer-term studies are required. If one extrapolates to the human patient, it appears that most of the changes in humans are observed within the first two years.[5,12] The changes observed between two and four years after implantation are very subtle. The process, however, may progress slowly for many years and it may take perhaps a decade or longer to ascertain its true severity.

In the following experiment, the authors compared press fit with bone-ingrowth fixation.[20,23] Bone remodeling was compared in the canine model after use of porous coated and uncoated Ti6A14V stems of the same geometry. At six months and two years, the porous-coated stems were fixed by bone ingrowth, while the uncoated stems had a fibrous membrane in most areas. Distally, however, in these stems, there were sites of intimate contact between the host bone and the implant. At six months, the authors observed a 15% reduction in proximal cortical area in dogs with the porous-coated stems and little change in cortical area in the dogs with uncoated stems. However, at two years, the amount of cortical bone loss was equivalent in the two groups.

The finding of similar severity of long-term bone loss in all of the metallic stems, regardless of porous-coating type, location, or presence indicates that other factors beside interface mechanics may play an important role in influencing the bone-remodeling process. One of the potential factors is stem stiffness. The amount of stress shielding imparted by the prosthesis depends on (1) the elastic modulus of the stem material, (2) the geometry of the stem, (3) the placement of the stem within the femur, and (4) the geometry and elastic modulus of the host femur.

The cross section of the stem can be changed to decrease its structural rigidity. In the clinical use of a cementless stem, however, a change in cross-sectional geometry is not very practical. Cementless stems must be canal filling so that the shape and dimensions are mandated by the constraints imposed by the shape and dimensions of the host femur. A variety of strategies have been proposed to overcome these limitations. These include splitting the distal end of the stem, providing deep peripheral grooves, or using a hollow stem. However, the structural integrity of the stem is always significantly compromised by these measures, particularly when a porous coating needs to be added for the purpose of fixation. In the experiments reviewed here, stem composition rather than external stem geometry has been varied as a means of altering stem stiffness.

Low modulus femoral components have been used in the past with mixed clinical results.[1,15] One of the potential problems of such stems is that of increased relative motion at the interface between the prosthesis and bone with resulting abrasion of the polymeric surface and the occurrence of undesirable tissue reactions. For that reason the authors believe that adequate biologic bonding between the prosthetic device and bone is an important design parameter. One approach is to extensively coat the composite stem with a porous material to allow fixation by the process of bone ingrowth.

The authors recently compared dogs implanted unilaterally for a period of six months with either composite stems or Ti6A14V stems.[25] The stems were identical in geometry and had a porous coating from commercially pure titanium fiber metal applied to the anterior and posterior stem faces. The device stiffness of the composite in bending was less than 20% of that of the Ti6A14V stems. The reduction in proximal subperiosteal stress was calculated to be approximately 50% with the metal stems and 20% with the composite stems.

The composite stems had more bone ingrowth than the Ti6A14V stems. In addition, the patterns of bone ingrowth were different. Specifically, in the metal stems the most bone ingrowth was found proximally and distally, but in the composite stems the most bone ingrowth was found at the midproximal part of the stem. In addition, although the cancellous bone increased in density proximally and distally adjacent to both types of stems, the proximal hypertrophy was considerably more marked in the dogs with composite stems. There was 50% less reduction in the proximal cortical area after implantation with the composite stems compared with the metallic stems (Fig. 2). In addition, with the composite stems, there was no evidence of distal cortical hypertrophy. These findings imply that the pattern of stress transfer from

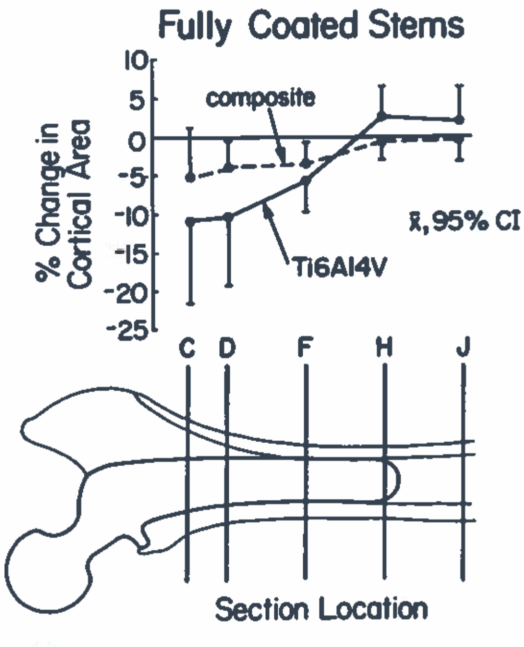

FIG. 2. Change in cortical area at six months in the canine model. Full-length porous-coated Ti6Al4V stems and similarly coated composite stems were implanted in two groups of animals. There was less, proximal cortical atrophy and no distal cortical hypertrophy in the animals with the less-stiff composite stems, suggesting that the pattern of load transfer from the implant to the host bone varies as a function of stem stiffness.[22]

the prosthesis to the host bone varied as a result of stem-stiffness differences and that large reductions in stem stiffness mitigate against proximal cortical atrophy.

THEORETICAL STUDIES

The experimental studies reviewed here indicate that of the variables investigated to date in animal models of THA, only reduced stem stiffness leads to reduced proximal cortical atrophy. These studies, while encouraging, involved substantial reductions in stem stiffness. Clinically, it may not be practical to reduce stem stiffness to this degree because of fatigue strength limitations of these types of stems.

This underscores the need for a better understanding of the relationship between stem stiffness and bone remodeling. Because, as described above, bone remodeling after THA is thought to be driven by change in bone stresses or strains, it is first essential to understand the relationship between stem stiffness and alteration of the bone's mechanical environment.[10,13] This relationship is, itself, dependent on the particular geometries and material properties of the femoral component and femur. For the canine model described in this paper, beam-theory calculations for the proximal medial subperiosteal surface indicate a nonlinear relationship between the reduction in predicted bending and torsional subperiosteal bone stresses and stem stiffness (Fig. 3). A nonlinear relationship was also predicted for the human femur in a three-dimensional finite element model.[13]

The next critical relationship to understand is that between cortical atrophy and the reduction in bone stress (or strain). Based on the authors' previous experimental studies, three models can be posited (Fig. 4). Two of these models are nonlinear while one is linear. Currently, the experimental data are inadequate to support one of these models in preference to the others. If the data from the two previous figures are combined, then the potential relationships between stem stiffness

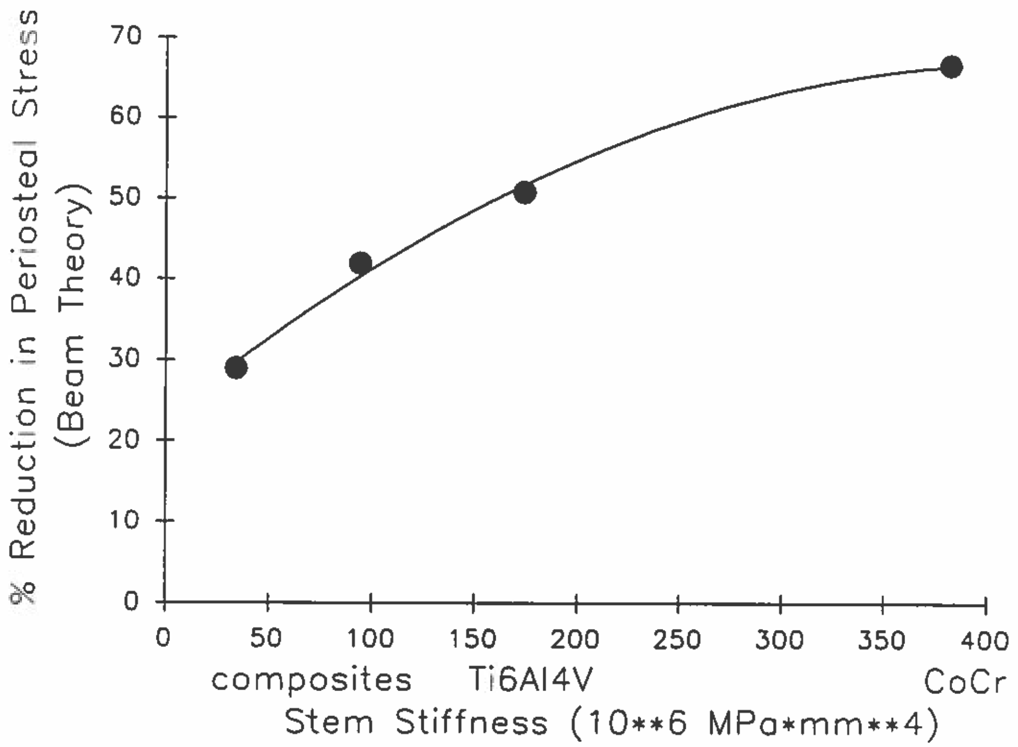

FIG. 3. Stem stiffness versus stress reduction in the canine model. This graph shows that the relationship between stem stiffness and reduction in proximal-medial subperiosteal bone stress is nonlinear. The graph was made by using beam theory to calculate normal stresses for the intact bone and the bone immediately after placement of the stem, from which the reduction in stress was determined. The graph depicts the relationship for torsional stiffness. The bending stiffness graphs were similar.

and cortical atrophy can be explicitly stated. As can be seen from Figure 5, the predicted relationships between stem stiffness and bone remodeling varies widely depending on which model is used. These differences have important clinical implications. If Model 1 is correct, then one would expect to observe more than twice as much proximal cortical atrophy with a CoCr stem than with a Ti6A14V stem of the same geometry. However, if Models 2 or 3 are correct, then the difference in bone remodeling would be much less. Clinically, this is an important issue because CoCr stems are the most commonly used cementless prostheses and there are no follow-up studies of comparable TI6Al4V and CoCr stems that address this issue. In practice, because of differences in stem geometry, it may never be possible to make these comparisons except in an animal model. The curves in Figure 5 also suggest that substantial reductions in stem stiffness may be required to mitigate against proximal cortical atrophy. However, until additional experimental data become available, these models only serve as theoretical guidelines.

DISCUSSION

Bone loss and a reorganization of the intrinsic geometry of the bony femur are responses associated with implantation of a cementless porous-coated stem in the experimental animal. The characteristic pattern is one of proximal cortical bone loss and distal cortical hypertrophy. Several variables evalu-

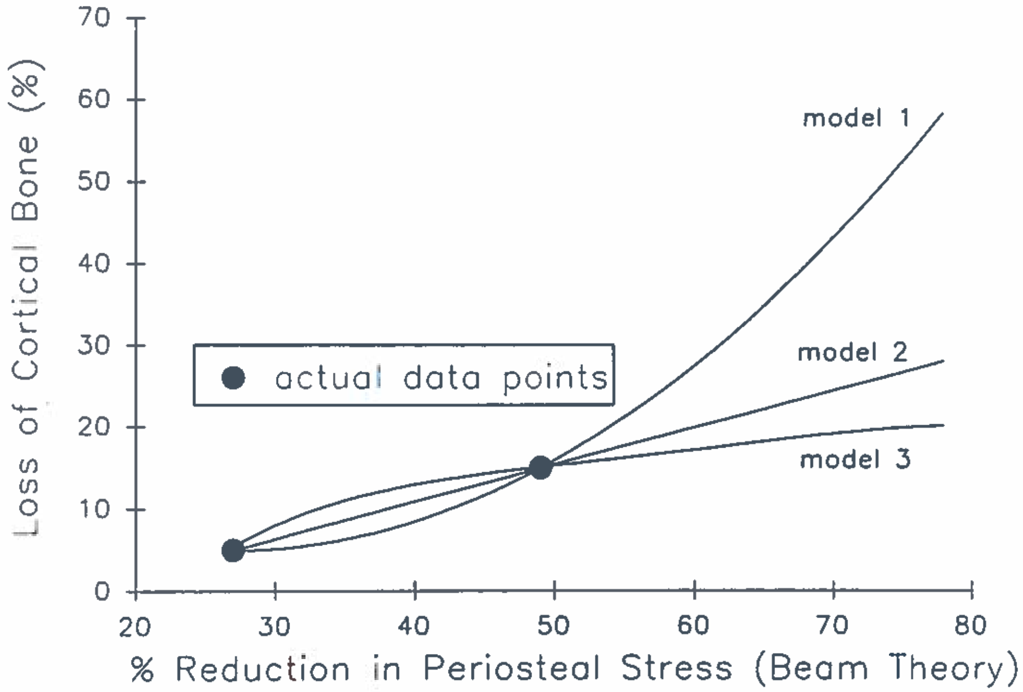

FIG. 4. Hypothetical relationships between reduction in stress and loss of cortical bone. The models are based on actual data points from the studies reviewed in this paper. With currently available data, the authors do not know if these points are related linearly (Model 2) or nonlinearly (Models 1 and 3).

ated in this study are relevant to this process: the extent of porous coating, the time of implantation, and the stiffness of the stem instability may create a completely different set of problems. The potential advantage of this approach, however, includes the ease of revision, a factor that must be taken into account when using THA in younger patients.

Restricting the porous coating to the proximal region of the stem represents one approach used in clinical practice today to limit the extent of bone loss. This approach does not fully accomplish its goals. Proximal bone loss still occurs and can be remarkable. In addition, inadequate fixation, potential micromotion and distal stem

The role of porous-coating location to cortical bone loss after cementless THA may be dependent on other design features (such as stem shape, stem flexibility, and the presence or absence of a collar) that were not included in our experiments. Strictly speaking, one must be cautious about extrapolating from a particular canine model. However, the currently available experimental data from this laboratory[21,24,25] and elsewhere[3] suggest that design features other than porous-coating location may be more important for reducing proximal stress-shielding related bone loss.

In the short-term (six months) the authors' data indicate that stiffness of the femoral stem is a very important issue. Given the time-dependency of the remodeling response caused by the presence and location of the porous coating, one must allow for a similar possibility based on stem stiffness. However the authors believe that the different patterns of bone ingrowth, medullary bone desification, and cortical remodeling in the short term with the use of relatively flexible composite stems compared to the relatively stiff

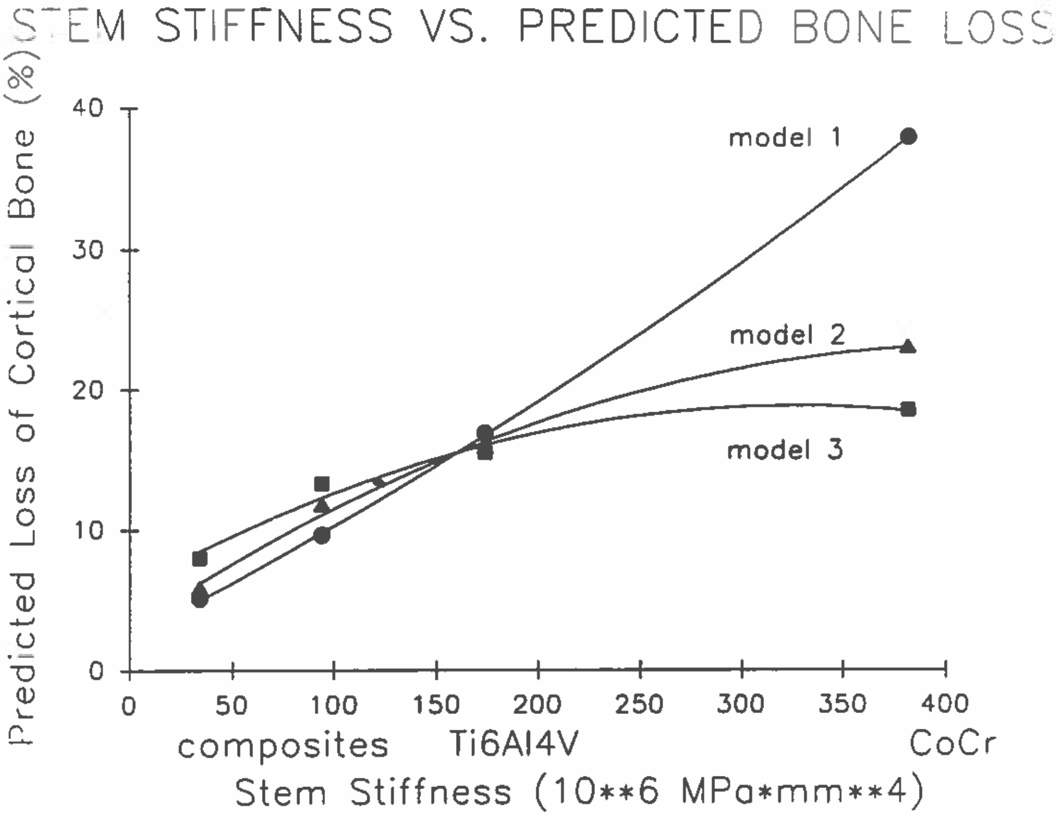

FIG. 5. Predicted loss of cortical bone as a function of stem stiffness. This figure uses the data from the two previous figures to show three possible relationships between stem stiffness and loss of proximal cortical bone. The nature of the relationship is dependent on which model from Figure 4 is used. If Model 1 is correct, then one would expect to observe more than twice as much proximal cortical atrophy with a CoCr stem than with a Ti6Al4V stem. However, with Models 2 and 3, the difference between the two stems would be much less. In addition, bone loss with low modulus stems would be less if Model 1 is correct than if Model 3 is correct. Currently, the experimental data are inadequate for discriminating between the three models.

metallic stems indicates that a long-term difference in the remodeling response will also be apparent. Thus, our current working hypothesis is that stem stiffness profoundly affects the stress distribution in the femur and is probably responsible for most of the long term remodeling changes observed.

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