Preclinical Testing of Total Hip Stems

The Effects of Coating Placement

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The long-term fixation endurance of noncemented hip stems in total hip arthroplasty is subject to incompatible design goals. To reduce stress shielding and periprosthetic bone loss, proximal fixation and load transfer are indicated. However, to prevent interface motion and promote interface-bonding security, fixation preferably should be maximized over the entire stem surface. In this study, the authors questioned whether hydroxyapatite coatings could be applied in patterns that reduce bone resorption, while maintaining safe interface stress levels. For that purpose, strain-adaptive bone-remodeling theory was applied in 3-dimensional finite element models, to simulate the long-term postoperative bone resorption process. During the process, the adaptation of interface stresses was monitored, and its effects on interface failure probability evaluated. This analysis was done for a fully coated stem, a ½ proximally coated stem, a smooth uncoated, press-fitted stem, and a stem with 5 proximal patches of circumferential stripes. The uncoated stem reduced bone loss dramatically, but promoted interface motions and distal pedestal formation. In all cases, the gradual bone-remodeling process increased the interface security of the coated stems. Bone loss and interface failure probability were not very different for the fully and ½-coated stems. Stripe coating reduced bone resorption considerably, while increasing long-term interface failure probability only slightly. The investigators concluded that the initial stability and the ingrowth potential of such a stem design are likely to be inadequate.

Components for total hip arthroplasty are subject to incompatible design goals. Obvious examples are optimal fit, which is served by modularity, whereas fretting and wear, conversely, are minimized with monoblocks. The reason for such unfortunate design complications is that the endurance of a reconstruction is threatened by a variety of failure scenarios. The culture of orthopaedic implant innovation has been 1 of trial and error. Typically, a particular problem is identified, a design solution is introduced that presumably solves it, and the innovative product is tested in a clinical trial. Unfortunately, although the innovative feature of the design may hold 1 failure scenario at bay, it may promote another. One cannot escape the necessity of testing a device for safety and efficacy in clinical trials. But laboratory and computer simulation analyses can be useful to establish adequate compromises for conflicting goals in the design stage, to confirm the presumed positive
effects of innovative design features, and to test preclinically the safety of devices relative to failure scenarios that are well defined. This article presents a demonstration of such tests with respect to the location of ingrowth coatings on noncemented hip stems, relative to the probability of long-term interface loosening and periprosthetic bone loss.

Optimal compromises in design features are not trivial and difficult to assess without sophisticated design-analysis tools. A notorious design-goal incompatibility for noncemented hip stems is produced by conflicting requirements for optimal interface mechanics and those for optimal bone mechanics. To maintain periprosthetic mass, bones should be stressed to normal physiologic levels and stress shielding must be minimized, which is achieved with stems that transfer load proximally. Such stems ought to be flexible, short, and bond proximally. To reduce the probability for noningrowth and loosening, interface stress and micromotions must be minimized, and bonding strength maximized; such stems ought to be rigid, long, and bond over their entire lengths. Evidently, a good stem design balances these features relative to the failure scenarios of excessive periprosthetic bone loss on the 1 hand, and interface loosening on the other.

The purpose of this study was to establish if fortuitous compromises in stem-coating geometry could accomplish, conceptually, that balance. In particular, the investigators hypothesized a priori that interrupted, so-called striped coatings would significantly reduce stress shielding, while maintaining safe interface-stress levels. To test this hypothesis, strain-adaptive bone-remodeling theory was used in combination with 3-dimensional finite element models.

MATERIALS AND METHODS

The Finite Element Models

The development of the bone model was described earlier. A proximal right femur was selected from a stock of 160 embalmed specimens. This specimen was considered average in shape and bone density, as confirmed by external dimensional measurements and visual radiographic inspection. The bone was scanned on a computed tomographic (CT) scanner in slices of 4-mm thickness at 27 locations. The CT data were transferred to a graphics computer program. Based on the geometry of the bone contours, a 3-dimensional finite element mesh of the intact femur was constructed, using 2106 8-node isoparametric brick elements (Fig 1). A finite element model of the Osteonics Omniflex Number 9 implant (Osteonics, Allendale, NJ) with a 16-mm-diameter distal tip was developed and fitted in the femoral model (Fig 1). The surface of the finite element mesh was smooth and did not represent the detailed proximal anterior and posterior surface structures of the stem.

The element stiffness description was chosen in accordance with the assumed strain formulation. Using this method, the elements are known to provide more accurate results in bending mode. The accuracy of this approach was confirmed in a convergence test for a bonded total hip arthroplasty configuration with an unbonded distal stem-tip, relative to a model in which the 8-node brick elements were converted to quadratic 20-node elements.

Fig 1. Finite element mesh of the femur (posterior and medial views) and the prosthesis with distal tip. Each of the 3 loading cases was made up of 3 muscle forces (F, indicated) and a hip joint force, for which the successive values (in Newtons) and orientations (in degrees) are shown.
The average apparent density $\rho$ (g/cm$^3$) in each element was determined from the CT density values. The maximal CT-density value of all slices was identified and assumed equal to an apparent density value of $\rho = 1.9$ g/cm$^3$. Using linear interpolation between the lowest and this maximal value, the CT density distribution in the slices could be transformed to a corresponding apparent density distribution. The apparent density distribution in the 4-mm slices were extrapolated to the element layers concerned, which were approximately 10 mm thick. The maximal density value in the finite element model was normalized at 1.73 (g/cm$^3$). The elastic moduli per element $E$ (MPa) were determined from the apparent densities using

$$E = cp^3$$

where $c = 3790$ (MPa/(g/cm$^3$)). In the model with the prosthesis implanted, the elements at the lateral proximal side of the stem and around its distal part were given a low apparent density of 0.01 g/cm$^3$ to represent the reamed medullary canal, in accordance with the surgical technique recommended by the manufacturer. The elastic moduli for implant materials were 110 Gpa for the titanium stem and 210 Gpa for the cobalt chrome alloyed distal tip.

Three loading cases of a daily loading cycle were considered (Fig 1). The hip joint forces in the first and second cases represented those during the walking cycle at 35° flexion (heel strike of stance) and at 0° flexion (45% of walking cycle), according to in vivo measurements by Bergmann et al. The hip joint force in the third loading case represents the 1 during stair ascent at 70° flexion, according to in vivo measurements by Kotzar et al. Three muscle forces (gluteus minimus, medius, and maximus), acting on the greater trochanter, were included in each loading case. The magnitudes of these forces were estimated from the work of Crowninshield and Brand. The directions in which the muscle forces acted for the different flexion angles were determined from the points of attachment of the muscles, as described by Dostal and Andrews. The loads were identical in the pre- and postoperative femoral models.

Four stem-coating configurations were considered: a full coating over the whole length of the stem, a proximal coating extending to just below the metaphysis, a stripe coating of 5 stripes on the proximal half of the stem, and a stem with no coating, representing a smooth press-fitted design. All coatings extended around the full circumference of the stem. Interface conditions in the model were prescribed depending on the presence of stem coating. At the coated areas, full bonding between bone and implant was assumed. At the uncoated areas, including the distal tip, no bonding and no friction were assumed. In addition, a 10-µm gap width was interpositioned in these areas to represent a thin fibrous interface. For this purpose, special nonlinear interface elements were used, allowing local slip and tensile separation to occur.

**Interface Stress Assessment**

The algorithm used to determine the interface stresses at the bone and implant interface was based on nodal forces rather than on stress extrapolation, which guarantees better accuracy. At each interface node $i$, an interface-normal direction ($n_i$) and an interface area associated with this node ($A_i$) were calculated. The nodal force vector was decomposed into a normal component ($F_{ni}$), perpendicular to the surface, and a resultant shear component ($F_{Si}$), tangential to the surface. The interface stresses were determined by dividing the nodal interface force by the interface area associated with the node. Hence, for the interface normal (tensile or compressive) stress, $\sigma_{ni} = F_{ni}/A_i$, and for the interface shear stress, $\sigma_{si} = F_{si}/A_i$.

To relate interface stresses to the probability of mechanical failure (interface disruption), a criterion as described by Hoffman was defined. At each interface nodal point, a Hoffman number was determined from the normal and shear stresses, and the interface–bone density, using

$$H = \frac{1}{S_i} \sigma_{ni}^2 + \left(\frac{1}{S_v} - \frac{1}{S_c}\right) \sigma_{ni} + \frac{1}{S_v} \sigma_{si}^2$$

(2)

where $S_i$ and $S_c$ being the uniaxial interface tensile and compressive strengths, respectively, and $S_v$ the interface shear strength, depending on the density of the interface bone. The relationship between strength and apparent density was determined according to the formulas of Stone et al. and Kaplan et al.

$$S_i = 14.5p^{0.71}, S_c = 32.4p^{0.85}, S_v = 21.6p^{0.65}$$

(3)

The above formula transforms the local interface stress state to a value termed Hoffman num-
ber, or $H$, representing the probability of interface disruption, using experimental data on strength of the bond between hydroxyapatite and bone. For $H < 1$, no interface failure is expected; for $H \geq 1$, failure is expected. The value $1/H$ can be considered a safety factor against interface failure. During the remodeling simulation, the interface stresses change continuously, because of the adaptation of density. But the strength of the interface bone changes as well for the same reason. The Hoffman number effectively interrelates the roles of the different stress components (tension, compression, shear) in the initiation of failure, their gradually changing values and the density-dependent strength variations, into 1 measure for interface-bonding security. It does not account for hydroxyapatite resorption or gradual changes in the bonding strength between hydroxyapatite and metal.

**Bone Remodeling Simulation**

The prediction of long-term periprosthetic bone remodeling was based on strain-adaptive bone-remodeling theory, used in conjunction with the finite element models, in iterative computer simulation procedures. In the theory, it is assumed that bone cells react to local deviations in elastic strain energy, produced by a representative loading cycle, as provoked by the prosthesis relative to the normal situation. In the mathematical procedure, the bone-remodeling signal $S$ is determined in each element-integration point as the average strain energy per unit of mass (strain-energy density divided by density) produced by the series of 3 load cases described above. In each time step of the simulation procedure, these values are equated to the strain energies in the (preoperative) intact bone $S_{\text{ref}}$ at identical locations. The rates of bone density adaptations then are determined, in each element integration point, from the remodeling stimuli $S - S_{\text{ref}}$ according to the relationship shown in Figure 2. Where locally the stimulus is positive, bone is formed, and where it is negative, bone is lost. There is a threshold level, $s = 0.75S_{\text{ref}}$, assumed under which no reaction occurs (a dead zone, or a window). Thus, the apparent bone-density distribution in the postoperative bone is regulated between 0.01 (the assumed lower boundary) and 1.73 g/cm$^3$ (the normal density of cortical bone), until it is adapted fully to the mechanical changes produced by the implant. A schematic of the computer simulation procedure is shown in Figure 3. The procedure was almost identical to the presented by Huiskes et al; the only difference was that additional iterative procedures were required for the nonlinear interface conditions, because the earlier analyses were restricted to fully bonded prostheses only.
RESULTS

The long-term periprosthetic bone-remodeling patterns predicted for the fully coated stem reflected its design characteristics, as compared with an earlier study of another prosthesis. Bone loss was most pronounced in the proximal-medial and anterior regions (fully coated in Fig 4). The calcar was rounded off, while the density of the trabecular bone near the stem interface increased around the whole proximal stem (fully coated, or Fe, in Fig 5). The increase in bone density at the lateral isthmus was typical, caused by a preremodeling density concentration, which acts as a stress riser. Below the isthmus, few changes occurred, which implies that load effectively was transferred proximally, because of the sliding tip and the slender, flexible distal stem, which has no effective contact with the endosteal cortex. This proximal load-transfer mechanism was seen by the normal (compressive or tensile) and shear stress patterns at the interface, which are most pronounced for the most strenuous loading Case 1. In the early, preremodeling configuration, shear-stress transfer (FC in Fig 6) was limited to the proximal half of the stem and concentrated medially and laterally in particular. Notable is the shear-stress concentration on the lower lateral side, near the isthmus. Normal stress transfer (FC in Fig 7) also was limited to mostly the proximal region, with the highest compression near the calcar and moderate tensile stress further down. At this latter site, high shear stresses occurred as well. The combination of shear and tension is particularly hazardous for interface debonding, much more so than a combination of shear and compression. After long-term adaptive remodeling, the interface stresses changed as well, because of the adapted bone density. Interface shear became even more concen-

![Fig 4. Long-term periprosthetic bone resorption (−) and formation (+) predicted by the remodeling simulations of the 4 coating configurations. The numbers are shown for 4 or 5 regions in 4 longitudinal sections; the upside is anterior, and the downside posterior.](image-url)
Fig 5. Pre- and postremodeling bone-density patterns, shown in mid-frontal cut-away sections of the models in posterior view. (FC = fully coated, PC = proximal coated, SC = stripe coated, PF = press fit.)

The amount of bone loss in the proximal region (fully coated in Fig 4, Region 4) varied between -14.4% and -59.3%, depending on periprosthetic location, with the highest numbers medial anteriorly. Further distally (Fig 4, Regions 1–3), little bone loss, or gain, was seen. This was notably less than that found in the earlier study of fully bonded stems,16 again because of the proximal load-transferring capacity of the present design. The maximal interface Hoffman number for the fully coated configuration, calculated from the interface stresses, amounted to approximately 0.64 in the initial stage and decreased to 0.40 in the long term (Fig 8). This implies an interface safety factor of approximately 1.6, increasing to approximately 2.5, against static (not fatigue) interface failure initiation. So the probability of failure of hydroxyapatite-bone bond decreases with time. The gradual reduction in the maximal Hoffman number after bone remodeling was not caused by a reduction in maximal interface stresses (which increased considerably, by factors of ≥2), but by the increase in interface–bone density. The interface bone adapted its mass and became stronger to resist the higher mechanical demands. It must be noted that the Hoffman criterion was defined relative to the holding power of the
Fig 6. Pre- and postremodeling shear stresses at the stem–bone interface for 3 coatings, shown as shades on the stem surface. The stresses are those for the most strenuous loading Case 1. The press fit stem is not shown, because its frictionless surface does not transmit shear stress. High stresses are black; 0 stress is a medium grey shade. (FC = fully coated, PC = proximal coated, SC = stripe coated.)

bone. The bonding strength of the hydroxyapatite coating did not adapt, so disruption of the coating from the metal does become more likely with time.

The remodeling patterns around the proximally coated stem confirmed that stem shape and dimensions, in conjunction with canal reaming and a sliding tip, inherently promote proximal load transfer. Reducing stem bonding to that region then barely affects the stress and resorption patterns, which were similar to those in the fully coated configuration (PC versus FC in Figs 5–7). Bone loss was slightly higher in this case, from -56.2% to -60.2% in Region 4 (Fig 4). This is attributable to the stress-rising effect of the lateral isthmus, further enhanced by the edge of the coating, which produced an additional stress riser (compare FC and PC in Fig 6). The distal coating edge gradually enhanced local load transfer, which produced slightly more
stress shielding proximally. The densification near the distal coating edge is a well-known phenomenon, often seen on radiographs. The interface shear stresses tended to be slightly higher in the proximal coating case, as compared with the full-coating configuration, and the compressive and tensile stresses somewhat lower. The maximal Hoffman number was slightly higher initially and somewhat lower after remodeling (Fig 8).

The stripe-coated stem has more of these stress risers associated with coating edges (spot welding), which enhance local trabecular-bone density. The overall remodeling patterns were morphologically similar to those of the full and proximal-coated stems, but with notably reduced loss of bone. In the proximal region between -4.71% and -46.9% bone was lost, again depending on periprosthetic location (stripe coating in Fig 4). The reduction in bone loss was caused mainly by an increase in trabecular-bone density; osteopenia of the cortex was not very different from the other cases (SC in Fig 5). In Region 3 (upper middle) (Fig 4), a net gain in bone was seen, principally caused by the spot welding effects. As in the other 2 cases, no net remodeling effects were seen in the lower regions. The interface stress patterns illustrate this spot welding effect (SC in Figs 6, 7); they were concentrated much more locally than in the other configurations. However, the maximal stresses were not higher, because the anterior and posterior stem surfaces became more prominent in load transfer. The tensile interface stresses on the medial–posterior side in the lower proximal half of the stem also occurred in the other 2 cases. In this case, they were extended to the lateral region after long-term remodeling (SC in Fig 7). Associated with shear stress concentrations (SC in Fig 6), this may promote interface debonding. Only 4 of the 5 stripes contributed to load transfer. The fifth stripe was not in contact with bone that was dense enough for significant load transfer. The maximal Hoffman number for the stripe-coated stem was almost twice that of the other coating configurations and reached the critical value of 1 in the initial situation. After long-term remodeling, it decreased, but was still somewhat higher than in the other 2 cases (Fig 8). This implies that interface failure during the long term is slightly more likely with a stripe-coated stem than with a continuously coated stem, but that there definitely is a higher probability for early loosening, so it might compromise early stability. Considering the distribution of Hoffman numbers over the interface more closely showed that the maximal values occurred at anterior and posterior sites, where the bone was relatively porous. Because the stem was carried largely by the medial and lateral contours, one may question whether local failure at these sites would seriously threaten its overall stability.

The results for the uncoated (unbonded) stem confirmed the conceptual advantages of proximal press fitting for bone maintenance. Because the stem could slide downward when loaded, it stressed the bone interface in compression (PF in Fig 7), producing tensile hoop stresses in the bone. Although cortical resorption occurred also in this case (PF in Fig 5), there were pronounced density increases in the periprosthetic trabecular bone. There was no net bone loss in the proximal region, but a
net gain in the upper middle region (press fit in Fig 4). Whereas little occurred in the lower middle region, bone mass gained between 2.56% and 4.25% in the distal part (Fig 4). This occurred as an effect of the compression exerted by the distal tip on the underlying trabecular bone, while it subsided under load. This phenomenon is similar to the pedestal formation one sees around noncemented stem tips (PF in Fig 5). The proximal compressive interface stresses were high initially (PF in Fig 7), but reduced considerably in the course of time, because of the increasing contribution of the distal pedestal to the resistance of the axial force component. The maximal Hoffman number reached about 8.5 initially and reduced to approximately 2.8 after remodeling, again because of the ensuing contribution of the pedestal. This implies that compaction of the interface bone is highly likely in this case. Some friction occurs in reality, even if fibrous interposition presides along the whole interface, which reduces compression and the Hoffman number. So these results represent an exaggerated situation, but they do serve to illustrate the trends of the subsiding mechanism.

Proximal trabecular densification associated with cortical resorption also was found in canine experiments with press-fitted stems,24 which could be explained by adaptive remodeling simulations.26 The gradual development of bone mass adaptations was similar to that canine study, and very different from what occurred around the coated stems (Fig 9). Whereas the coated stems provoked monotonous proximal bone loss in the course of time, with an exponentially reducing rate, around the proximal press-fitted stem bone mass first increased, but then reduced again. The initial increase is attributable to the high proximal interface stresses, which densify the trabecular bone. The later decrease is a combined effect of calcar (cortical) resorption, which develops slower than the trabecular densification, and the development of the distal pedestal, which releases proximal interface compression.

**DISCUSSION**

The effectiveness of an experiment depends on closeness to reality on the 1 hand, and experimental control on the other. A clinical experiment is real, but provides little control over experimental conditions. With animal and laboratory models as intermediates on these scales, computer models are remote from reality, but offer virtually complete control over experimental conditions. The assets and limitations of this study must be considered in that light. The computer model allowed the authors to vary interface bonding conditions, while all other relevant parameters remained the same. These included the series of loads considered, the geometry and initial density distribution of the bone, and the shape, materials, and placement of the implant. Conclusions can be drawn exclusively about the effects of bonding. However, the results are limited to the 1 configuration and set of loads selected for the study.
Care must be taken in extrapolating the results to other configurations.

The finite element models, as descriptions of a given reality, are believed to be adequate to answer the questions posed, but they are limited as well. These models are state of the art, fully 3-dimensional, and anatomic, and use experimentally determined data for the initial bone density distributions and the loads. Mesh density, in conjunction with the assumed strain solution method, was adequate in a convergence test. A 10-µm soft tissue interface was assumed between stem and bone where no coating was present. This is thought to be realistic, because it was found consistently in canine experiments in association with smooth metal surfaces. The investigators assumed that this fibrous layer created frictionless sliding conditions. Although some friction is bound to occur in reality, it will be relatively low.

In all other locations, a firm bond between (coated) metal and bone was assumed, and maintained throughout the simulation. An initial period of gradual ingrowth was neglected, as were the potential effects of imperfect fit. This is not entirely realistic, because gaps are bound to be present initially and the process of osseous integration takes time. However, this is a study of conceptual design features, meant to assess the trends of effects. Similar computer simulations of canine experiments have shown that reasonable predictions of long-term bone morphology could be obtained, notwithstanding the above assumptions. The results of the present study and others show that incomplete fit and ingrowth do affect bone remodeling, and particularly interface stress, when it is not distributed regularly over the interface or occurs in mechanically strategic locations. The implant model was placed in the bone model in accordance with the guidelines of the manufacturer, which implies that the distal half of the stem was fitted loosely in the medullary canal and not effectively in contact with firm endosteal bone. The distal tip was fitted perfectly in the canal, with frictionless sliding contact in the axial direction; again, this was the intent of the designers. There was no collar on the stem. These are the conditions to which the results apply.

The bone-remodeling simulation procedure was validated earlier relative to animal-experiment results and those of human retrievals. The remodeling rule uses a trilinear relationship between the stimuli (the differences in strain energies provoked by the stem) and the rates of bone formation and resorption, with threshold levels of 75% of the natural, physiologic strain energy. This level produced realistic predictions of bone loss relative to long-term clinical results. In simulations of canine studies of long-term remodeling around hip stems, a threshold level of 35% provided the best results. The difference probably reflects the faster bone metabolism in the animal. When using this same threshold level for the human case, the amounts of bone loss predicted reached unrealistic levels. Investigators have proposed that the threshold levels vary considerably in a patient population, which could produce a significant intraindividual variation in the extent of bone loss. However, the adaptive theory predicted an extensive variability because of differences in preoperative periprosthetic bone density. Engh et al. reported excellent correlations between preoperative mineral content and postoperative bone loss from their retrieval studies. It is likely that the variability in remodeling threshold levels, if they exist, have insignificant effects relative to those of the variability in preoperative bone densities. The latter effects must be considered when interpreting the present results, because the variation of bonding characteristics was studied here for 1 particular bone only, and 1 threshold level.

The Hoffman failure criterion, used in this article to evaluate the probability of interface failure, has less support in experimental validation. It works reasonably well for trabecular bone, but has not been tested for bonds between hydroxyapatite and bone. However, it does account for the different roles of ten-
sion, compression, and shear in failure initiation, and also the gradually changing interface bone density and strength. The Hoffman number can provide only for qualitative estimates on a relative basis. If the interface fails, it will be attributable to fatigue, not static overload. In addition, the bond between hydroxyapatite and metal may be the weak link, rather than the bond between hydroxyapatite and bone. Possible resorption of hydroxyapatite is not considered.

Coating extent and location also have important effects on preingrowth, early postoperative relative motions, and stability, not considered in this study. Keaveny and Bartel\textsuperscript{20} showed that high coefficients of friction, provided by porous (and evidently hydroxyapatite)-coated surfaces, hold the implant secure in the initial stage. The extent of the coating reduced the amount of relative motions, particularly when no collar was present, which contributes to ingrowth. Although this study concerned an Anatomic Medullary Locking stem (DePuy, Warsaw, IN), which is canal-filling over its entire length, its results still plead against stripe coating, in view of its reduced overall friction.

The new general information that can be obtained from the present study relates to the time-dependent interface and bone mechanics of a slender, exclusively proximally bonded stem, providing some lever-arm bending resistance from a distal tip. Such a stem provokes roughly 40\% less overall bone loss than a stem made of the same material, placed in the same bone, but with a thicker, canal-filling and fully bonded distal stem as studied earlier.\textsuperscript{16} The bone that does resorb around the present stem disappears mostly from the upper 1/4 of the periprosthetic length. Around the canal-filling stem, bone also resorbed further down. Similar patterns also were reported for the canal-filling Anatomic Medullary Locking stem from retrieval studies.\textsuperscript{6} In a bone-remodeling simulation study of another canal-filling stem, using 2-dimensional finite element models, the authors evaluated the effects of coating extent in a similar way.\textsuperscript{27} Although 2-dimensional, the trends found in that study are confirmed by the present sophisticated model. The reduction in bone resorption occurring as an effect of distal overreaming was indicated there, as were the beneficial effects of limiting bonding area to the proximal part of the stem. Interface stresses and security were not considered at that time. Skinner et al\textsuperscript{22} did a finite element analysis of the Anatomic Medullary Locking stem and reported pre- versus postoperative bone stresses, depending on coating extent. Although these cannot be coupled directly to long-term bone loss, because adaptive remodeling is a nonlinear process, they do give an indication. They showed that more loss of bone is to be expected for a longer coating area. Earlier, Engh and Bobyn\textsuperscript{5} reported the clinical and radiographic results of Anatomic Medullary Locking stems with variable coating lengths. They found more extensive bone loss around the longer coatings, but more loosening and clinical problems from the shorter-coated stems.

This brings us back to the problems of interface versus bone mechanics, where the goals of minimal bone loss and maximal interface security are incompatible. The present results show that interface stress peaks are likely to increase significantly (as much as 2-fold) in the course of time, because of remodeling, but that the probability of disruption from the bone reduces, owing to the same process, because the interface bone becomes stronger. It is uncertain whether hydroxyapatite-coated stems profit from this in interface security, because the bond between hydroxyapatite and metal does not strengthen in time.

However, the answer to the general question posed in the introduction is affirmative. Fortuitous compromises in stem-coating geometry can reduce, conceptually, the effects of the stress-shielding failure scenario, while not dramatically increasing the probability of interface failure. Stripe coating does reduce the loss of bone, by as much as 20\% to 25\% in the proximal region, relative to the continuously fully and proximally coated stems. At the same time, the maximal interface stresses
are not higher and the long-term probability of interface failure, as measured by the Hoffman number, is only slightly higher than in the cases of continuous coatings. These results illustrate that total hip prosthetic stems tend to be over-engineered in their load-transferring surface areas, relative to the amount of load to be transferred. This implies that these areas usually can be reduced considerably, without significant increases in interface stress. The problem is, that the designer cannot preselect the amount of area available for load transfer nor its precise location, because bone usually does not grow in over the whole coating. Over-dimensioning is important to provide for a fail-safe feature against incomplete osseous integration.

This fail-safe feature is precisely why the authors would advise against stripe coating on this particular stem. The hypothesis was confirmed by the results, but only for conditions of ideal proximal fit. As long as this cannot be realized in practice, the prospects for well-bonded areas are cut in half by the stripe coating. In theory, contact might occur only where no coating is present; in reality, some contact will occur where coating is present, and some where it is not. If osseous integration does not occur, or is lost eventually by interface disruption, the results can be dramatic, as shown by the present analysis of the uncoated stem. A likely scenario for that situation includes proximal face-bone compaction, gradual subsidence, and eventual distal pedestal formation. This could create a stress bypass, promoting proximal adaptive resorption in the long term. In another scenario, excessive cyclic distal tip motions could produce peripheral endosteal bone resorption and fibrous interposition, thereby potentially losing its lever-arm contribution to resistance of the bending moment. If stripe coating were introduced, a patient series should be followed up radiographically for a number of years to monitor these failure scenarios.

This study illustrates the possibilities and limitations of preclinically testing prosthetic designs using computer simulation models. The test only concerns the concept of the design, assuming that the goals of adequate fit and ingrowth are realized, and that the design features work as intended. Important failure scenarios such as wear and particulate reactions were not considered. The question of whether this prosthesis will provide for high survival rates cannot be answered. On the positive side, the tests provide documentation of the load-transfer mechanism that can be used as a reference for clinical performance and radiographic followup. The test supports the safety of the design for failure scenarios related to bone resorption and interface loosening, and specifies how it could be compromised by adverse bone-interface reactions. It discourages use of innovative features that are likely to promote failure. It is the cheapest way of design confirmation that can be used in the preproduction stage, and does not put patients at risk.

References

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