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Loosening of the femoral component of the ICLH double cup hip prosthesis

A biomechanical investigation with reference to clinical results

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Abstract

The cancellous bone in the proximity of the rim of the ICLH femoral cup may not only be subjected to an axial stress that is about three times the value physiologically encountered, but the cup also tends to move transversally away from the medial bone margin in this area. Hence, fracture of the trabecular structure in this area can occur, accompanied by cleavage formation. Across the gap which thus forms between cement and bone, the mating surfaces that are now no longer joined, probably move relative to each other with every subsequent walking cycle. This relative motion leads to bone resorption and the development of a thick intermediate layer of fibrous connective tissue that spreads until eventually the whole cup becomes loosened. In the meantime the bone further proximal probably undergoes atrophy due to mechanical inactivity.

This presentation includes a biomechanical analysis which might explain the discouraging observations made in a series of forty-three implantations carried out between 1976 and 1979 in our clinic.

Key Words: Hip – Surface Replacement – Finite Elements – Stress Analysis

Introduction

The idea to replace natural joint surfaces that have become severely altered by osteoarthritic disorders, by means of resurfacing is by no means new (Clarke, 1977; Freeman, 1978a). Rather recent, however, are the several endeavours to attach a metal shell to the dressed head of the femur together with a high-density polyethylene (HDPE) cup within the acetabulum, both by means of acrylic cement. During the past decade, Trentani et al. (1978), Freeman et al. (1978b), Capello et al. (1978), Wagner (1978) and Amstutz et al. (1978) amongst others, have devoted much effort in developing this kind of prosthetic implant.

The apparent advantages of such surface replacements, such as the preservation of the femoral head, including the possibility to convert to a conventional prosthetic design or to effect an arthrodesis at a later date, make this prothesis particularly appealing for use in younger patients. We therefore decided to introduce the Freeman Double-Cup arthroplasty in our clinic and from July 1976 to December 1979, forty-three double cups were implanted in thirty-seven patients in the Department of Orthopaedic Surgery BALGRIST, in Zurich. At the moment, three to six years after implantation, only nineteen hips are free of pain and ten prostheses have had to be removed.

Already in 1979, Cserhati et al. and Schreiber et al. reported on histomorphological investigations of three cases of femoral cups that had loosened. These investigations led us to believe that probably adverse biomechanical conditions were responsible for the failures. As the number of failures increased, we decided to look into the biomechanical situation more closely and undertook a stress analysis of the bone stump within the metal shell, employing the finite element method.

The purpose of this presentation is to expose the results of the biomechanical investigation which confirms our earlier presumption that the living bone within the metal shell was probably being subjected to unphysiological loads, resulting in bone resorption and subsequent loosening of the device.

Materials and Methods

The first indication of adverse biomechanical conditions being responsible for the observed failures of the cup arthroplasty arose from previous histological investigations (Cserhati et al., 1979). We will briefly describe the characteristic findings of these investigations.

Histomorphological investigations.

Case 1 (S.A., 54-year-old male, P 138 984)

A reoperation was carried out only three months after implantation due to a loosened acetabular stocket. Even though the femoral cup was observed to be still firmly attached to the bone, it was removed simultaneously for histological investigation.

Fig. 1a shows the bisected preparation and Fig. 1b the histological section (paraffin section after decalcification). A band of 0.5 to 2 mm width is visible along the whole boundary between the cancellous bone and the cement. This band consists of tough connective tissue with collagen fibre bundles running parallel to the surface. The collagen fibre bundles are firmly anchored to the underlying bone trabeculae. The vascularisation is good and osteoblastic activity lively. The deep-lying interconnected bone trabeculae show a normal bone structure.

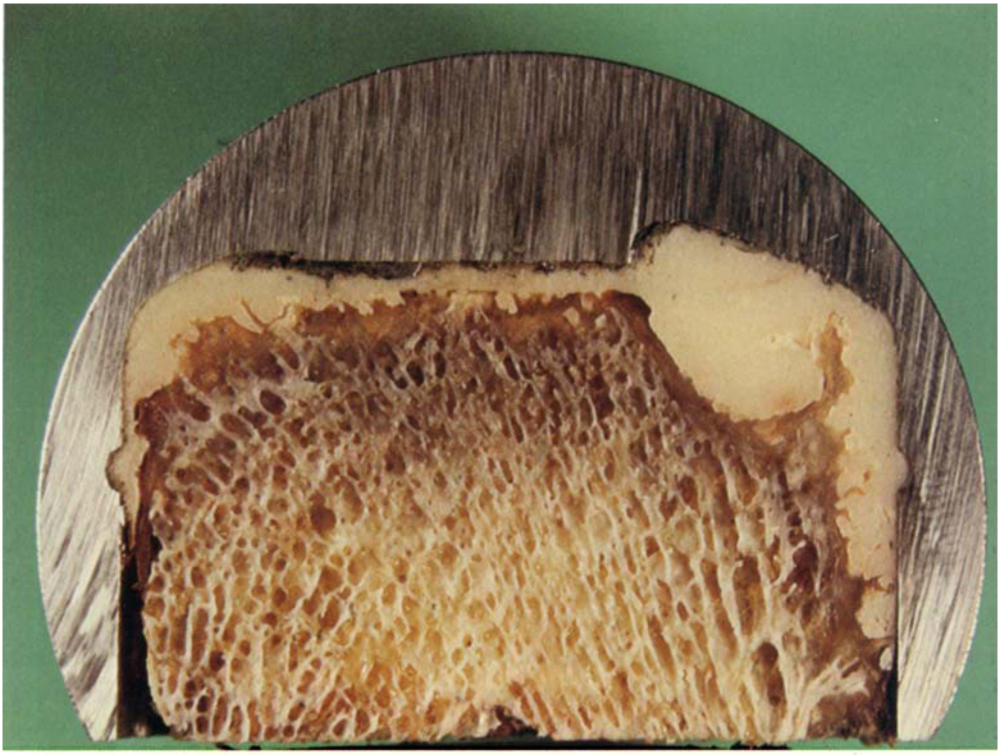

Fig. 1a: Case 1. Overview of the bisected Freeman femoral cup (in the frontal plane), twelve weeks after implantation.

Fig. 1b: The corresponding histological section showing the cancellous bone structure and the enclosing seam of fibrous connective tissue.

Case 2 (W.J., 53-year-old male, P 144 622)

This double cup was removed ten months after insertion because of an acute infection.

Fig. 2a shows the bisected preparation and Fig. 2b the histological section. A wide layer of soft tissue, in some places 5 to 6 mm thick, was present between the cement and bone substrate. The cancellous bone interspaces were filled with a slimy substance. The superficial cancellous bone has deteriorated all around, in places to a width of 8 mm. It has been replaced by a wide inflammatory pannus. The trabeculae have disintegrated to pointed, shapeless, partly fragmented rods. An undecalcified histological preparation shows, however, that despite extensive marrow necrosis and fibrosis of the bone trabeculae, an osteoid accumulation still takes place.

Fig. 2a: Case 2. The bisected femoral cup (in the frontal plane), removed ten months after insertion because of an acute infection.

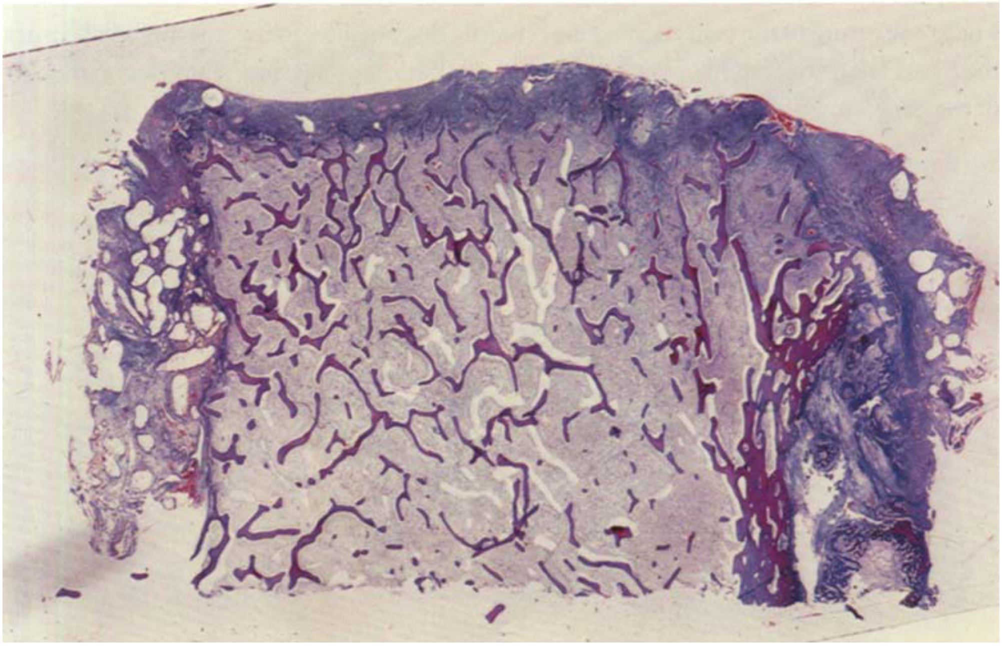

Fig. 2b: The corresponding histological sample showing the broad layer of connective tissue encapsulating the bone and the trabeculae that have undergone considerable disintegration.

Case 3 (J.B., 38-year-old female, P 195 712)

Despite an uncomplicated post-operative course, the patient continued to experience pain, so that finally, fourteen months after insertion, without clear or radiological evidence of loosening, the double cup had to be removed. Intraoperatively, the suspicion arose that movement between the femoral neck and the metal cup might have taken place.

Fig. 3a shows the bisected preparation and Fig. 3b the histological section. The bone fragment was movable within its bed but could not be dislodged. A space of 0.2 to 2.6 mm width separated the cement from the bone. This space is partially occupied by tough connective tissue that adjoins a thin, easily recognizable, almost completely uninterrupted bone laminate, a kind of thin cortical layer that encases the cancellous bone. The architecture of the cancellous bone is hardly discernable. In the inferomedial corner the tissue is brownish and opens into a wide subcortical cavity. In the predominant part of the preparation the spongiosa trabeculae lie far apart and are slim.

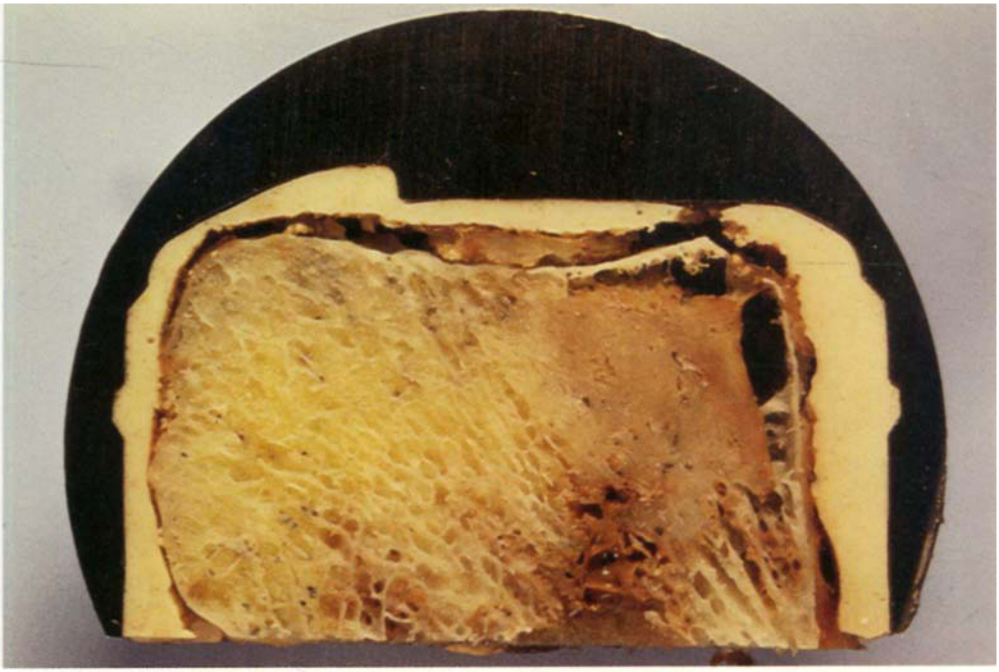

Fig. 3a: Case 3. The bisected femoral cup (in the frontal plane), fourteen months after implantation.

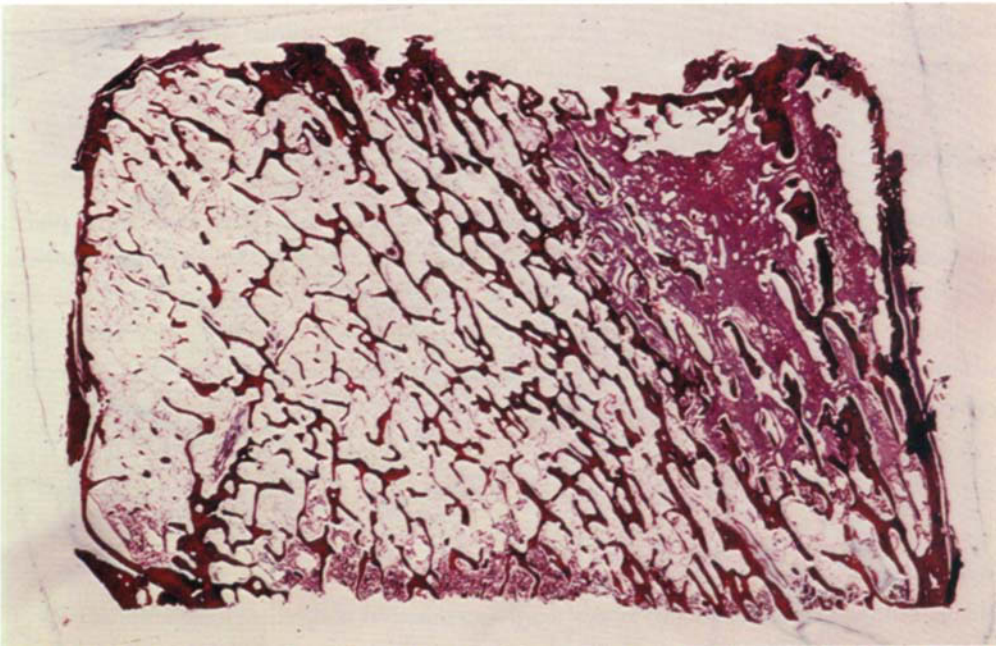

Fig. 3b: The histological section (case 3) showing deterioration of the trabecular structure and the presence of a brownish coloured tissue mass in the infero-medial corner of the sample.

Case 4 (B.E., 56-year-old female, P 202 741)

After a trouble-free period of twenty-two months, following implantation of a double cup prosthesis, the patient – who continued to be an ardent gymnast – complained of severe starting pains. A radiograph showed signs of slight migration of the femoral cup in a caudal direction. Two months later the pain increased and the femoral cup was observed to have adopted a relatively strong varus position.

Fig 4a shows a section in the frontal plane through the femoral head. In the cranial area, a connective tissue layer of up to 3 mm width is present while well preserved cortical bone can be seen in the caudal region, in apposition, however, with a thick layer of connective tissue.

Fig. 4b shows that the femoral head is covered by a fibrous layer of connective tissue, the thickness of which varies between 2 and 5 mm. The cranial area exhibits severe destruction and atrophy of the cancellous bone.

These cases illustrate that bone turn-over with osteoblastic activity was taking place, also that a thick layer of fibrous connective tissue was interposed between the cement and living bone, and further that the density and structure of the cancellous bone was undergoing alteration within the cup. These observations drew our attention to the possibility of adverse biomechanical factors that might be responsible for the loosening process (Schreiber et al., 1980).

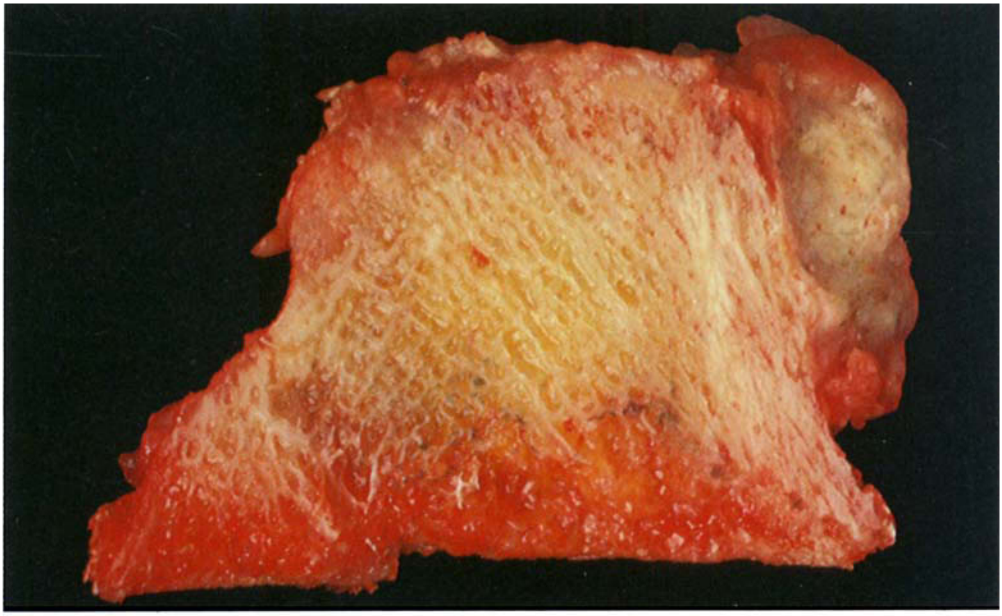

Fig. 4a: Case 4. A section in the frontal plane through the bone stump loosely contained within the cup; twenty-four months after insertion.

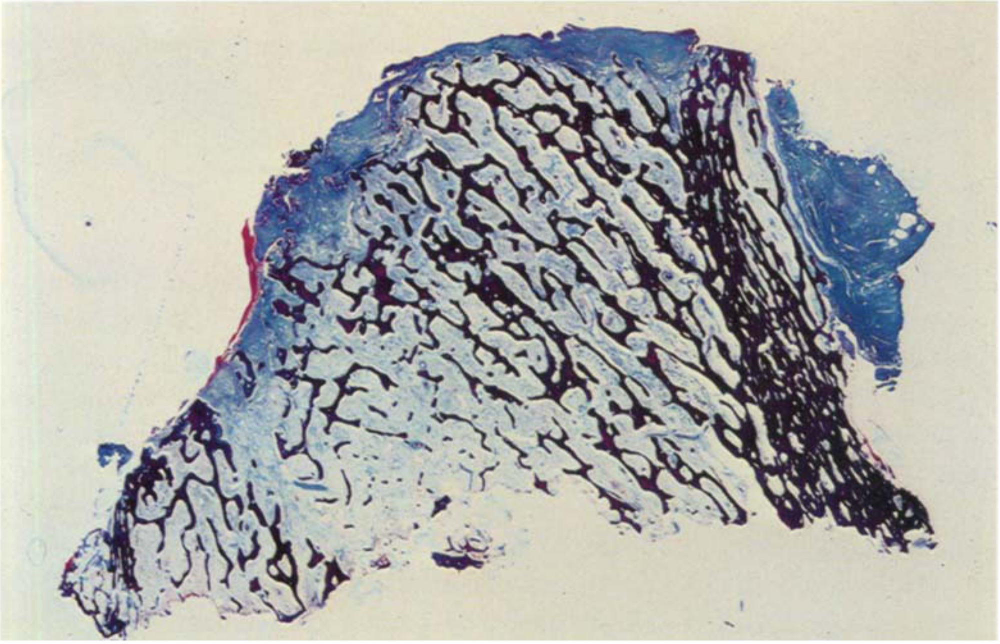

Fig. 4b: The histological preparation indicating clearly the layer of connective tissue encapsulating the bone and the extent to which the cup had drifted in a caudal direction. Apposition of bone in the region of the calcar femoralis and the thick layer of fibrous connective tissue immediately adjacent to it can also be seen.

An hypothesis of the loosening mechanism.

The Freeman femoral cup is fixed to the cylindrically-dressed cancellous bone stump by means of bone cement. Through some extent of cement penetration into the intertrabecular spaces along the exposed surfaces of the bone stump, mechanical interlocking of the latter with the encasing metal shell is achieved – at least for some time following implantation. Assuming this linkage between bone and cup can resist loading of the hip joint, it might be expected that the force transmission from cup to bone would occur over a small area immediately proximate to the rim of the cup. This, because the cup is a rigid shell preventing most of the elastic mass of bone which it encloses from being strained – and therefore stressed. Hence, while some regions of the cancellous bone stump become prone to excessive, unphysiological stresses, other regions become mechanically inactive. The photoelastic experiment depicted in Fig. 5 illustrates this qualitatively. If the trabeculae in the area of force transmission cannot bear the load imposed they will fracture, and the area of force transmission is then removed to a more proximal zone, hitherto relatively unloaded. Across the gap which forms between cement and bone, the mating surfaces that are now no longer firmly joined together would move relative to each other with every successive loading cycle.

In this space, where micromovements occur, a layer of fibrous connective tissue will form between bone and cement (Perren et al., 1975), concomitant with increased loosening of the cup. At the same time alteration in the architecture of the bone takes place.

To verify this hypothesis we undertook a stress analysis of the bone within the metal cup using the «finite element method».

The "Finite Element Method" of stress analysis.

The finite element method is a numerical method for engineering analysis that has found extensive application during the past twenty years (Desai, 1972, Scholten, 1975, Andriacchi et al., 1976, Huiskes, 1979, and Rohlmann, 1981). In the present paper only those details of the procedure which might clarify or support the conclusions drawn, will be mentioned. The method consists of dividing the structure to be analyzed into small elements of rhombic prisms, tetrahedrons, struts, plates, etc. Each single element can be allotted individual material characteristics like the Young's modulus, Poisson's ratio, etc., even directionally dependant in some special cases. Neighbouring elements are attached to each other at nodes through which normal forces, shearing forces and turning moments could be transferred. In this manner it is possible to determine the deformation of the whole structure, or parts of it, caused by the action of external forces on it, while considering the mutual dependancy of each of the individual, discrete elements of the structure. At the same time the forces acting on each element can be determined and hence the local stresses obtained.

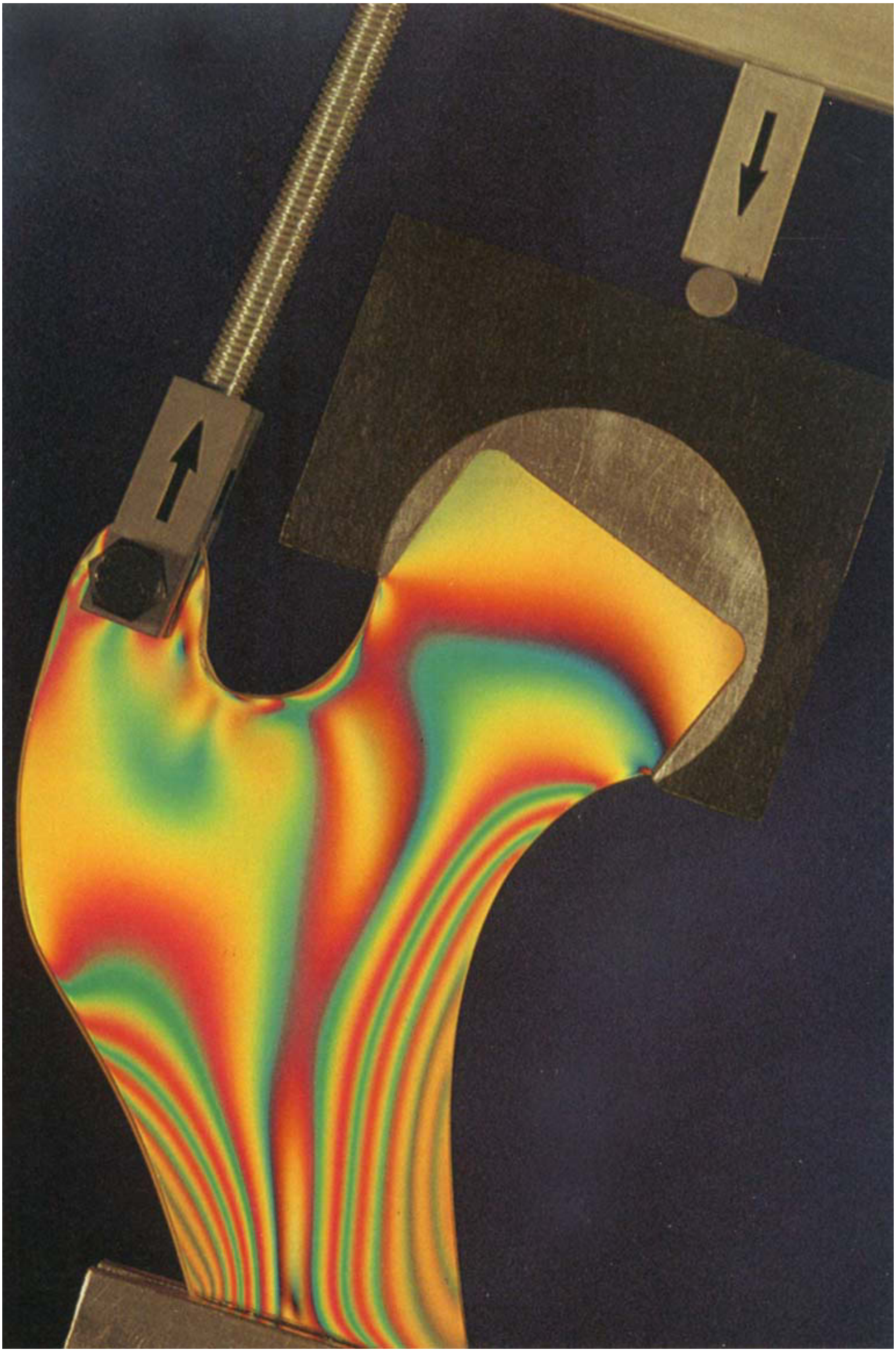

Fig. 5: A photoelastic model, qualitatively indicating the stress situation within the bone.

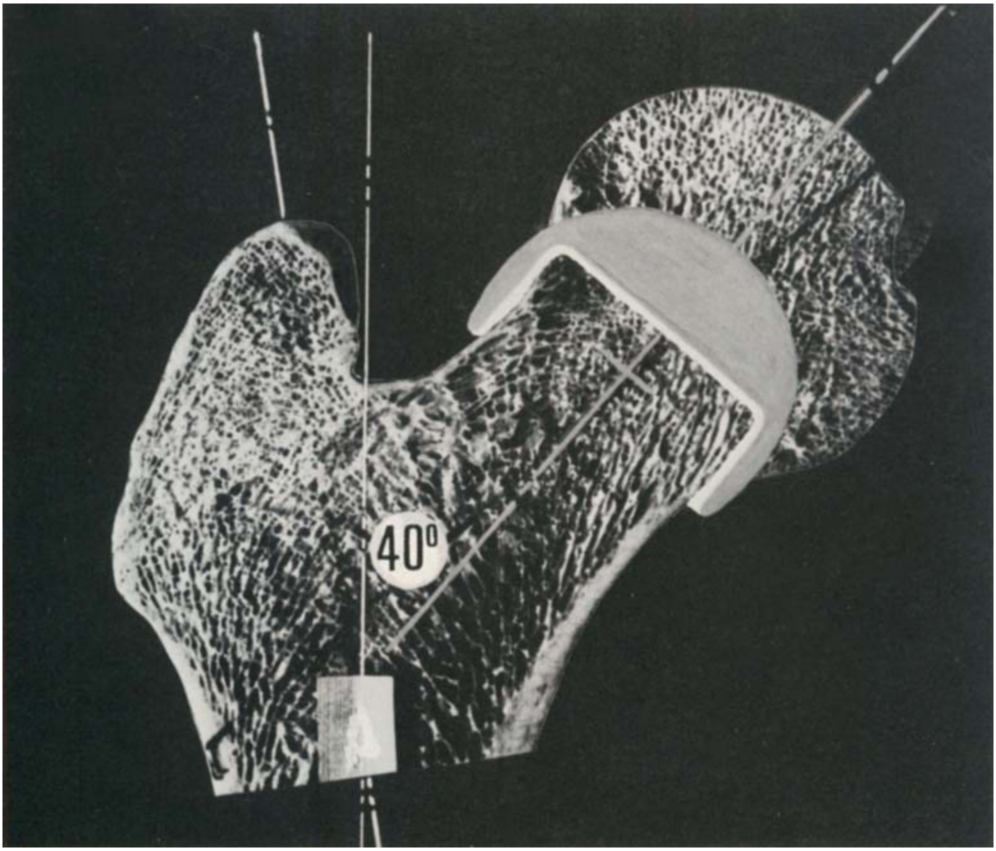

Fig. 6: The best possible fit of a femoral cup in a given case, but still deviating considerably from the recommendations of Freeman.

Parts of a structure in which steep stress gradients are expected, that is, areas within which the value of stress changes rapidly from point to point, must be divided into a sufficiently large number of elements if the true peak stress values are to be determined. Otherwise, the calculated stress values will turn out deceptively low. A considerable part of the total effort in analyzing a structure is dedicated to this, since this influences the results to a high degree.

The model.

Freeman (1978c) pointed out the load-bearing significance of the medial trabecular system within the femoral head and therefore recommends positioning the cup in 20° of valgus. This condition can rarely be fulfilled when at the same time the rim of the cup should reach over the cortical layer of bone at the base of the femoral head, as recommended by Freeman (1978c). Fig. 6 shows the best possible location of the cup on a given femur specimen. Notice the position occupied by the cortical bone within the cup.

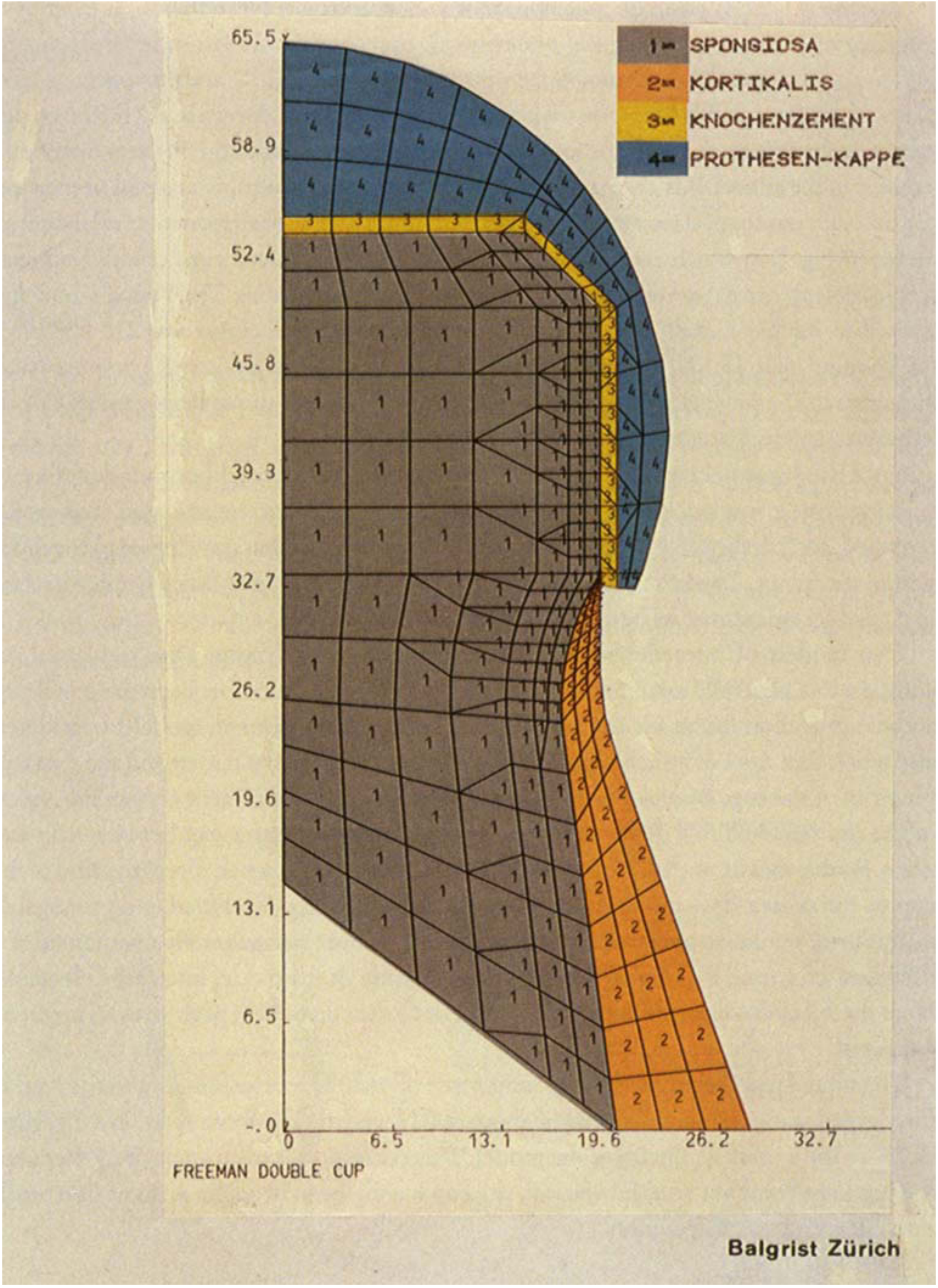

Fig. 7: The model employed, showing subdivision into finite elements.

1. Cancellous bone.	3. Bone cement (PMMA)
2. Cortical bone	4. Co-Cr alloy

Cancellous bone is basically inhomogenous and anisotropic. Nevertheless, it exhibits a strikingly orthotropic (orthogonally symmetrical) characteristic due to its inherent nature (90° lattice) that makes it well suitable for substitution by an isotropic and homogenous substance, within reasonable limits, for the purpose of stress analysis. Brown et al. (1980a) on determining the principal stress field for an adult proximal femur, confirm that very minor differences in the stress fields are manifest for anisotropic versus isotropic material properties. For this, and economical reasons too, we decided to use a rotationally symmetrical model as shown in Fig. 7 in which each of the component structures (metal cup, cancellous bone, acrylic cement, cortex) are assumed to be isotropic and homogenous. The Young's modulus allotted to the metal shell, acrylic cement, cancellous bone and cortex was 210 kN/mm^2, 1.2 kN/mm^2 and 15 kN/mm^2 respectively, whilst a Poisson's ratio of 0.3 was assumed throughout. The finite element programme that was chosen for the analysis was ANSYS of Swanson Analysis Systems, USA.

Since the stress field within the bone only in the immediate neighbourhood of the cup is of interest, it was not necessary to consider details of force transmission at areas far removed, such as the force acting at the greater trochanter or that transferred to the distal part of the femur. Therefore, the model in Fig. 7 was considered as being firmly attached to a rigid foundation at its base.

Two models of interconnection between metal cup and bone were simulated. In addition to a generally assumed slip-free mechanical connection between the metal cup and the cancellous bone, via the intermediate layer of bone cement, model 1 considered also a belt-like zone of attachment just 1 mm broad between the cortex and the overlapping rim of the cup. Model 2 had the interconnecting layer of cement only in the region of the rim removed to a depth of 4 mm, thus providing a narrow gap between cup and bone. By this means, the state of stress in the cancellous bone, when direct fixation of the cup to the cortex does not exist, or when an interspace has developed and propagated in this area, could be observed. The acrylic cement layer was generally maintained at a thickness of 1 mm. Fig. 7 also shows the subdivision of the model into finite elements. Note the subdivision in the area close to the rim of the cup, where peak stresses might be expected.

The model was loaded with a hip joint force of 1680 N, corresponding to the load in one-legged stance of an individual of about 600 N weight. The force acted in a direction of 23° to the axis of symmetry of the model. This corresponds to an angle of 15° between the hip joint resultant and the vertical, the cup having been brought as far as practically possible into a valgus position.

Results

Model 1

Figs. 8, 9a and 9b show the determined stresses in the frontal plane under the action of a hip resultant of 1680 N. Note the stress concentration in the cortex on the caudo-medial side. The peak stress in the *y* direction in this area reaches a value of about –26 N/mm^2 (the negative sign denoting compressive stress). It is interesting to also note that the cortical bone just outside the rim of the cup is still loaded to an extent of over –26 N/mm^2. The cancellous bone in this vicinity is loaded to a level of approximately –2 N/mm^2 in the *y* direction, whereas in the *x* direction even tensile stresses of a magnitude of about 1 N/mm^2 appear! The cancellous bone far within the metal cup is stressed to a maximum of only –0.4 N/mm^2.

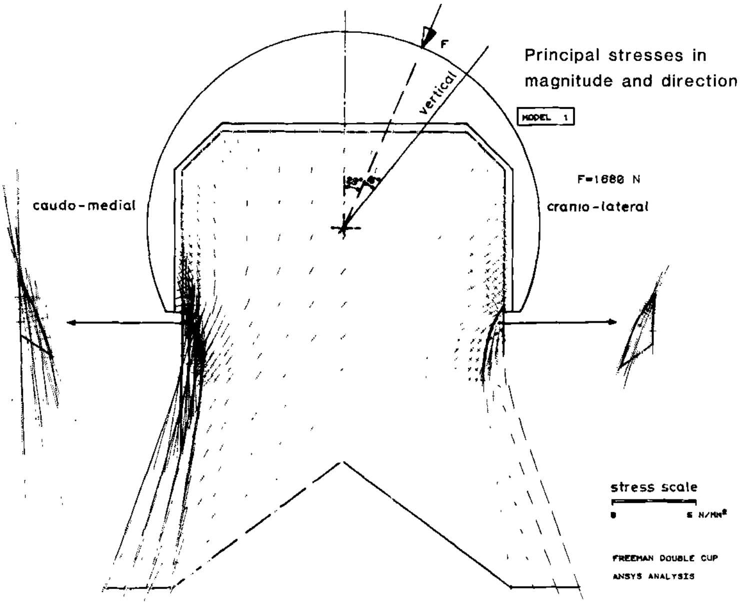

Fig. 8: Results with Model 1 (metal shell slightly overlapping the cortex), showing the direction and magnitude of the principal stresses in the frontal plane
-------- compressive stress
——— tensile stress

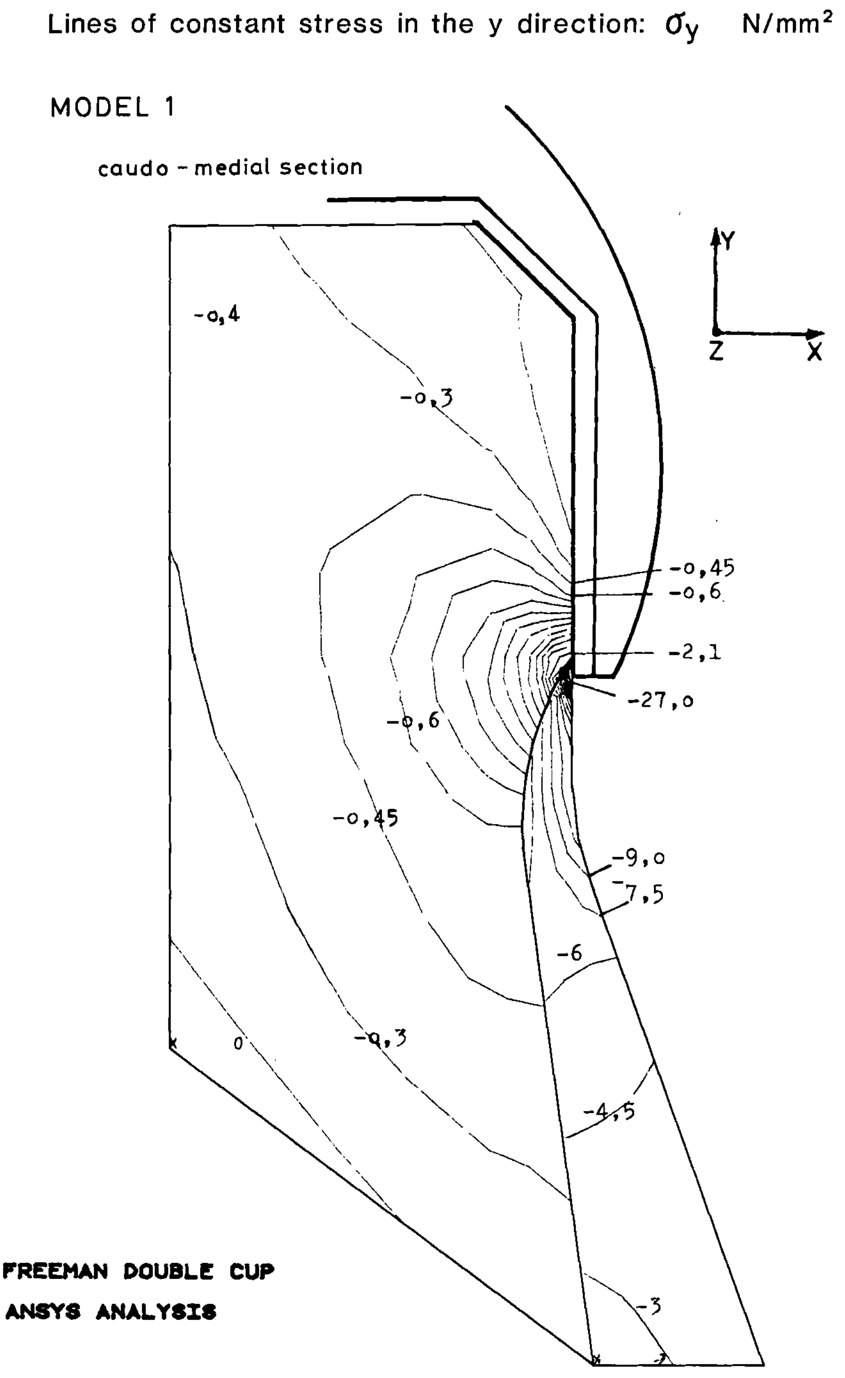

Fig. 9a: Results with Model 1 (metal shell slightly overlapping the cortex), showing lines of constant stress in the *y* direction in the caudo-medial area of the bone.

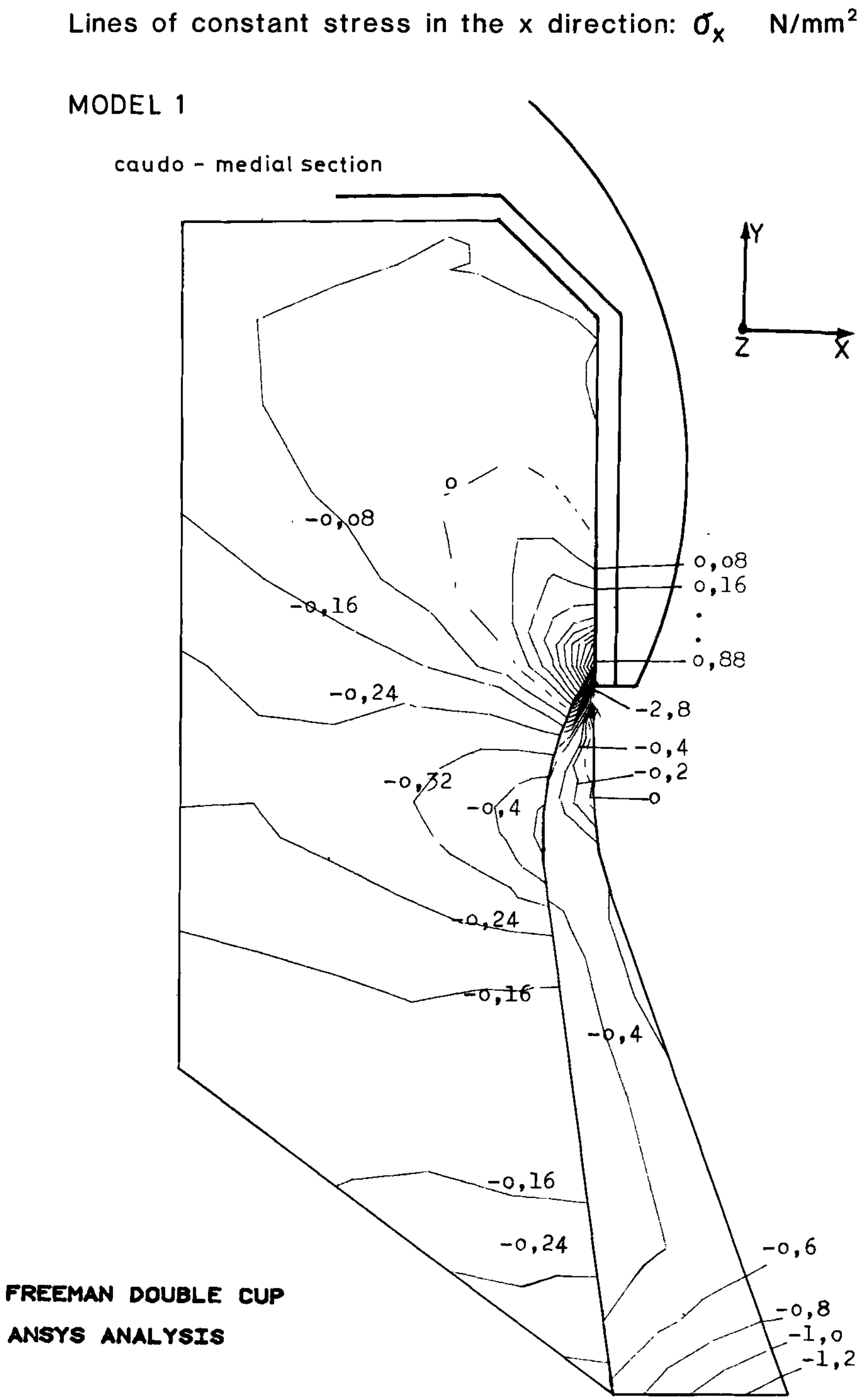

Fig. 9b: Results with Model 1 (metal shell slightly overlapping the cortex), showing lines of constant stress in the *x* direction in the caudo-medial area of the bone.

Model 2

Figs. 10, 11a and 11b show the stresses determined in the frontal plane when only cancellous bone is left attached to the cup. Here too, the hip joint force applied was 1680 N. The peak stresses in the cancellous bone on the caudo-medial side attain values of about –6 N/mm^2 (compression) in the y direction, while in the x direction, tensile stresses of about 1 N/mm^2 persist. The highest stress in the cortical bone is about –11 N/mm^2. The proximal end of the cancellous bone plug is loaded to an extent of –0.7 N/mm^2 within the cup in this case.

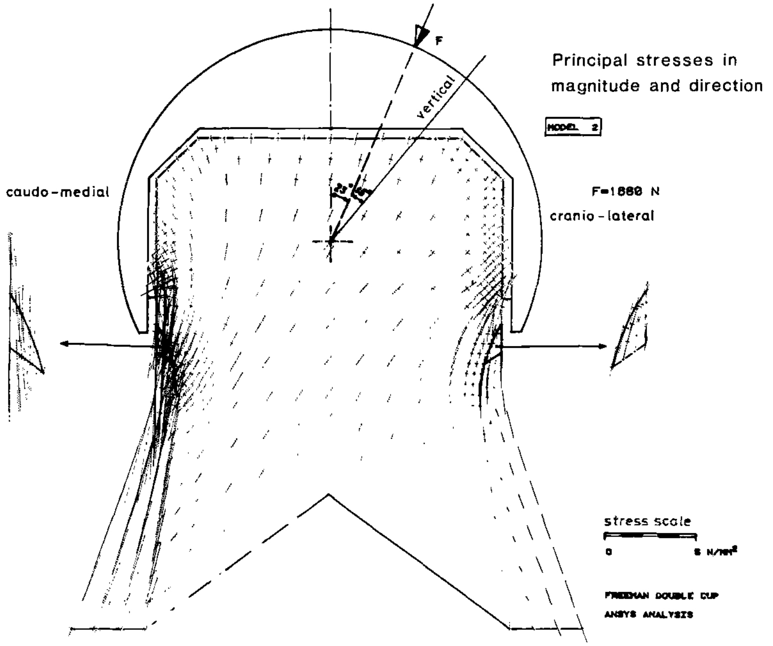

Fig. 10: Results with Model 2 (metal shell in contact with cancellous bone only), showing the direction and magnitude of the principal stresses in the frontal plane

------- compressive stress

——— tensile stress

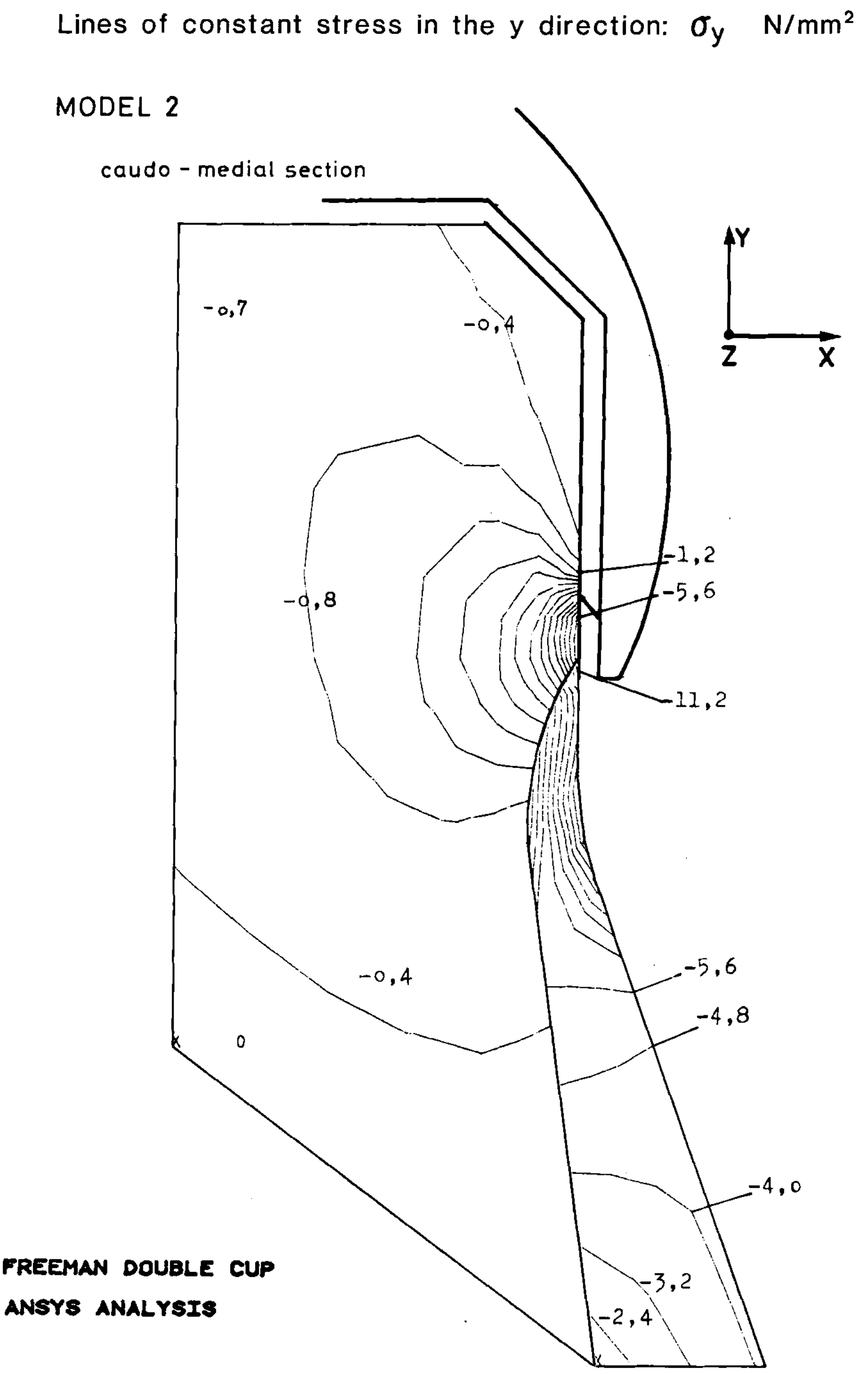

Fig. 11a: Results with Model 2 (metal shell in contact with cancellous bone only), showing lines of constant stress in the *y* direction in the caudo-medial area of the bone.

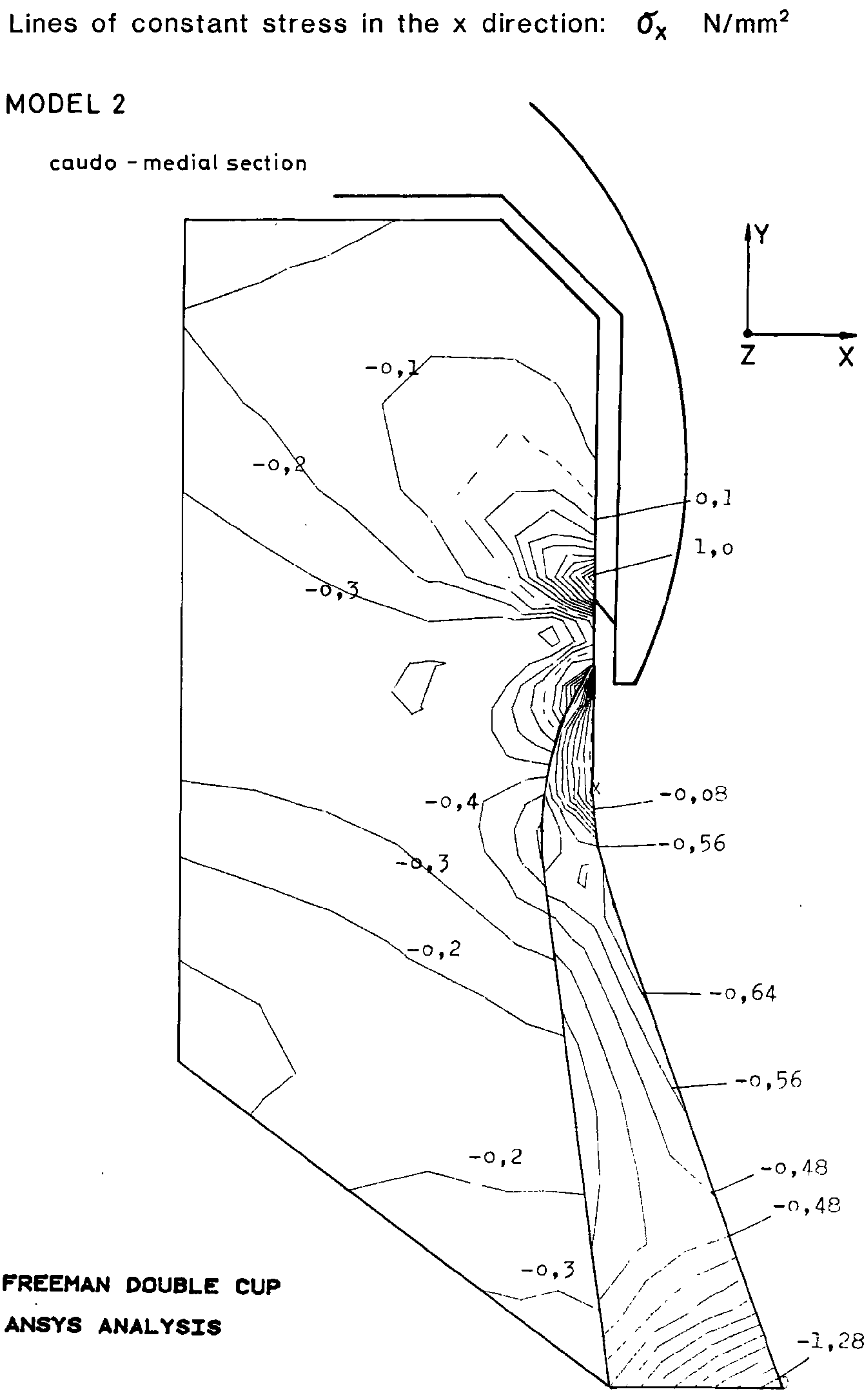

Fig. 11b: Results with Model 2 (metal shell in contact with cancellous bone only) showing lines of constant stress in the *x* direction in the caudo-medial area of the bone.

Discussion

A biomechanical investigation involving a finite element method of stress analysis of the bone within and in the immediate neighbourhood of the Freeman femoral cup has furnished details that might explain why the prosthesis loosens in a great many cases. Two models were examined. One, in which the cup was made to overlap the cortex with the acrylic cement firmly attached to the latter, and another in which attachment was only between the cancellous bone and the cup. In both cases a static hip joint load, acting at 15° to the vertical and of 1680 N magnitude, that would correspond to a body weight of about 600 N, was taken into account.

The results of the analysis of Model 1 show that because of the direct connection between the stiff metal cup and the cortex, through an intermediate layer of cement, the cancellous bone core within the cup is to a great extent relieved of stress while adequate loading of the cortex in the immediate vicinity of the rim of the cup occurs. Assuming that the acrylic cement is brought to interlock with the cortex of the femoral neck, the determined stresses of about -26 N/mm^2 should be well tolerated by the cortical bone (Fig. 12, described in detail by Jacob and Huggler, 1980). However, the cancellous bone contained within the cup will be stressed at a level as low as -0.4 N/mm^2, resulting in bone atrophy. Now, the question arises as to whether the assumption made, viz. that the acrylic cement would cling onto the cortical bone, could be maintained or not. Most certainly, the cortical bone surface presented to the cement after dressing with the milling cutter does not offer much purchase for the transmission of shear forces and even to a lesser extent for the transmission of tensile forces. If bone of sufficient load-carrying capacity is to be intimately joined to the cup, then it must form during the process of bone re-modelling, becoming interlocked with the surrounding layer of bone cement. This is of course only possible if the surface of the cement presented to the living bone is of adequate texture. Otherwise, the cancellous bone, which through nature of its trabecular structure is joined to the cup by means of the acrylic cement (at least immediately postoperatively), must alone transmit the forces imposed. This brings us to the configuration of Model 2.

Model 2 represents a case in which the cup is joined only to the cancellous bone, either from the beginning, or after cleavage has occurred between an initial attachment of the bone cement to the cortex. The stress field which presents itself under the same

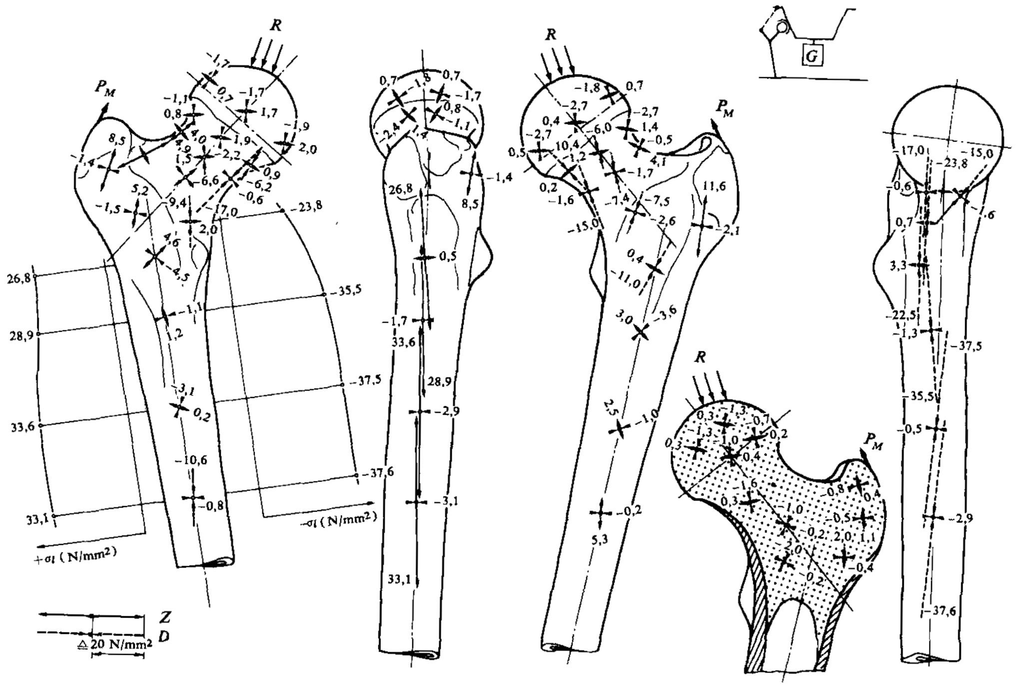

Fig. 12: Principal stresses in the femur when standing on one leg for a total body weight of 600 N. Principal stresses <5 N/mm² are not drawn to scale. σ_l Longitudinal stresses. *Z* Tensile Stresses (+). *D* Compressive stresses (−). *R* Hip joint force. P_M Muscle force. (Jacob and Huggler, 1980)

loading conditions as before, is that the cancellous bone near the rim of the cup is loaded up to about –6 N/mm² in the *y* direction (axially) while in the vicinity in the *x* direction (radially) tensile stresses of about 1 N/mm² come into play. The value of –6 N/mm² is very high for static loading of cancellous bone in one-legged stance where values of about –2 N/mm² might normally be expected under identical loading conditions, Fig. 12 (Jacob and Huggler, 1980).

At the same time the cancellous bone at the proximal end of the cup is loaded to an extent of about –0.7 N/mm², a more adequate condition as compared with the state of stress in Model 1. Nevertheless, the cancellous bone contained in the medial corner of the cup continues to remain mechanically quite inactive at a stress level of only about –0.4 N/mm². Now, would the cancellous bone in the highly stressed region in the vicinity of the rim of the cup cope with the loads imposed and re-model accordingly or would it break down completely? If it does break down by fracturing, cleavage will be supported by the presence of tensile stresses in the radial direction, with subsequent micromovements in this region and the still intact trabeculae immediately proximal to the area of failure that continue to join the cement to the living bone will now be exposed to the high stresses that previously caused fracture of the trabeculae just distal. A layer of fibrous connective tissue will now develop at the site of relative movement (Perren et al., 1975) and spread as fracturing continues. This process might thus proceed until the cup is completely loosened.

From the above, it becomes apparent that the finite element structural analysis has delivered information that can be of value in explaining the loosening of the cup only in combination with knowledge of the dynamic strength of bone. Virtually no quantitative information, however, is available on the behaviour of living bone to applied dynamic loads. One possibility to estimate the behaviour of bone under particular loading conditions is to compare the stress values with those determined under "physiological" conditions. This has already been attempted above, in referring to an experimental analysis performed earlier (Jacob and Huggler, 1980). Another possibility is to compare the stresses determined with the ultimate strength of bone, as follows:

Gaynor-Evans (1973) gives values for the ultimate compressive strength of cancellous bone of the femoral head between –5 and –39 N/mm^2. More recent investigations (Brown et al., 1980b) show an average value of about –19 N/mm^2 for the relevant area of the femoral head. Now, the maximum stress level determined in Model 2 was –6 N/mm^2. Taking into consideration that this stress is valid for static conditions of one-legged stance (hip joint force = 2.8 times body weight) and that the hip joint force could attain values of about 7.6 times body weight during fast walking (Paul, 1976) then a maximum stress of $-6 \times 7.6/2.8 = -16.2$ N/mm^2 could be expected. A stress of this level would correspond to about 84% of the ultimate compressive strength of –19 N/mm^2 mentioned above. Since the fatigue strength of living bone is certainly lower than the ultimate strength, we again arrive at the conclusion that the stresses determined in the vicinity of the rim of the cup are indeed very high and could well be responsible for fractures in the cancellous bone adjoining the cup.

If the fractures that thus develop are not given a chance to heal and if re-modelling of the structure to adapt itself to the new conditions of loading is interrupted by persisting heavy loads and relative movement of the separated parts, then the bone will resorb, leaving the gap to be filled by fibrous connective tissue, as always encountered in the observed cases. Simultaneously, the cancellous bone in highly stress-relieved areas would probably atrophise due to inactivity and the cup will proceed to tilt in a varus direction as the bone stump within the cup gradually gives way. Fig. 13 shows a case of a femoral cup which has migrated downwards by about 8 mm within a period of eleven months postoperatively. Fig. 14 shows the result of a follow-up X-ray study of eleven Freeman double cup implants, the radiographs of which could be exactly measured with certainty over a period of up to three years. In about 50% of all cases examined, a definite drift of the femoral cup into an increasingly varus position was observed, the average drift amounting to approximately 2 mm per year. But, as is also known, there are several cases in which the double cup functions satisfactorily. Probably these are cases in which the bone has been able to adapt itself without reaching the point where the loosening mechanism described before is triggered off.

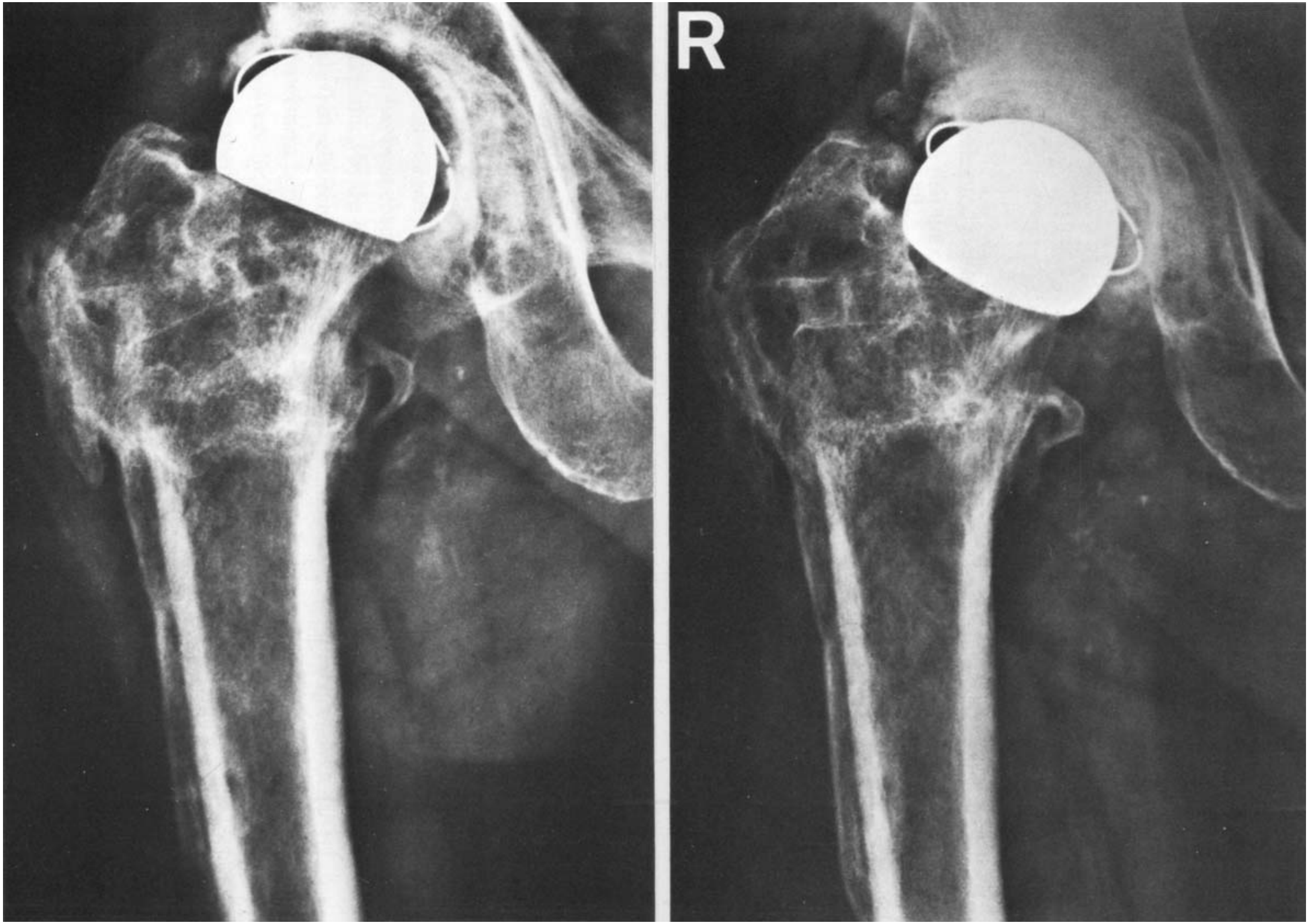

Fig. 13: A femoral cup which has migrated downwards by about 8 mm within eleven months postoperatively (K.A., P 178 214).

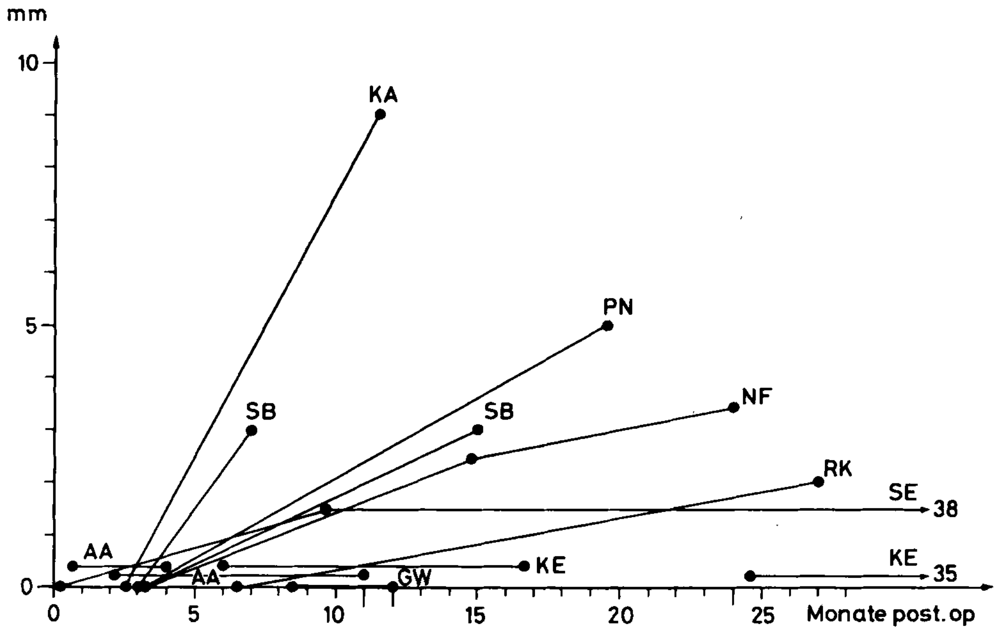

Fig. 14: Downward migration of the femoral cup in the course of time, as determined by measurement of radiographs.

Conclusions

A biomechanical investigation of the stress situation by means of a finite element analysis has shown that the cancellous bone in the immediate vicinity of the rim of the femoral cup could be very highly stressed. Compressive stresses in an axial direction of about 6 N/mm^2 and tensile radial stresses of about 1 N/mm^2 in magnitude have been determined in the caudo-medial area under static loading conditions during one-legged stance, for a body weight of 600 N. The cancellous bone of the femoral head is therefore hardly in a position to bear the corresponding dynamic stresses, that could amount to 2.7 times the determined value, unless adaptation to the new situation by bone remodelling takes place. During the remodelling phase, however, no relative movement between bone and cement can be tolerated as otherwise, a permanent rigid fixation will probably never be attained. This implies that on the one hand, the bone in the vicinity of the cup rim must be adequately stressed, so that the necessary remodelling can take place, but on the other hand, no cleavage between bone and cement should occur. Observation of a total number of forty-three double cups, three to six years after implantation, ten of which have had to be removed between three months and four years postoperatively and with only 44% of the total without pain, has shown that these conditions are difficult to meet. In eleven cases we were able to observe drifting of the cup into an increasingly varus position at a rate of about 2 mm per year which probably is a result of the bone atrophy that has been observed to take place deep within the cup and which is biomechanically explained by the extensive stress protection of the bone afforded by the enclosing metal shell of relatively high stiffness during the initial stage and subsequently due to relative movement between cup and bone combined with the tendency for the cup to migrate transversally, i.e., in a caudo-medial direction, simultaneously. Thus, the biomechanical investigation of the femoral cup – bone transition area under load, supported by histological evidence, offers an explanation for the clinical failures we have encountered and supports the recently published view of Freeman that "this procedure is still in evolution and therefore it should not yet be generally employed" (Freeman and Bradley, 1983).

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