N91-23032

ADAPTATION OF NASA TECHNOLOGY FOR THE OPTIMIZATION OF ORTHOPEDIC KNEE IMPLANTS

by

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ABSTRACT

NASA technology originally developed for the optimization of composite structures (engine blades) is adapted and applied to the optimization of orthopedic knee implants. A method is developed enabling the tailoring of the implant for optimal interaction with the environment of the tibia. The shape of the implant components are optimized, such that the stresses in the bone are favorably controlled to minimize bone degradation and prevent failures. A pilot tailoring system is developed and the feasibility of the concept is evaluated. The optimization system is expected to provide the means for improving knee prosthesis and individual implant tailoring for each patient.

INTRODUCTION

The history of design of orthopedic implants represents an extended iterative process of design improvements. Particularly for total hip replacement (THR) and total knee replacement (TKR) implants (Fig. 1), designs have improved to the point where probabilities for good long-term survival rates and functional restoration are quite high. Nonetheless, higher long term success rates and longer potential useful lives are clearly desirable goals.

The problem of optimizing joint prosthesis design is most commonly defined in terms of structural mechanics. Although unacceptable clinical results can occur without structural failure, the predominant modes of implant failure may be described in terms of structural mechanics. Huiskes [1] has noted five possible design optimization objectives, all of which relate to possible structural failures in either the interface between component and adjacent bone, the adjacent bone itself, or the implant component.

Given that the prosthetic joint will satisfactorily reproduce gross joint dynamics, the goal of design optimization becomes one of optimizing the shape and the material characteristics of the implant components to control stresses or other related quantities in the structure. The satisfactory definition of the optimization criteria can be a formidable task. However, once this is accomplished, the remainder of the design optimization process then becomes the laborious process of searching for the best corresponding choices for implant geometry and materials. The

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use of numerical nonlinear programming techniques for this purpose has proven to be an extremely useful tool to the designer. Coupled with advanced structural analysis techniques, especially the finite element method (FEM), they have been used extensively with considerable success in structural design [2].

Among the many contributions in the field, we selectively mention some of the work performed at NASA-Lewis on the multi-objective and multi-disciplinary optimization of layered composite structures [3, 4], as it is related to the research described herein. Applications of analogous optimal design methodologies in biomechanical design have been relatively few and limited in scope [1, 5-7]. In the present paper, we report on some recent work which has been conducted by applying the previously mentioned composite mechanics and structural optimization techniques to the design of the tibial component of TKR. The long-term goals are to develop some broadly applicable methodologies for optimizing the design of orthopedic implants. The first efforts have been concentrated on examining the capabilities and limitations of these methods in application to shape optimization procedures in optimizing total knee prosthetic component shapes.

The methodology and the computer code are adapted from those used for the multi-disciplinary structural tailoring of composite structures [3, 4]. While there are many obvious differences in the applications, the combination of essential features, namely the composite mechanics, the FEM models, the stress analysis, and the structural optimization techniques remains the same.

As a starting place, a pilot tailoring system is developed for the optimal design of the tibial component of the TKR. Specifically, we have considered the metal backed component with a central post or stem, and have examined the shape tailoring of the post and the thickness sizing of the metal backing or tray. In our approach, we assume, as have others [1, 5-7], that the basic criterion for design optimization is the stress state in the bone/implant composite structure. For the tibial component, the most likely mode of failure is aseptic loosening, which involves the resorption of the bone adjacent to the implant. This is presumably due in many cases to the stress-induced adaptation. Thus, the optimal design goal becomes the minimization of undesirable bone atrophy of the adjacent bone. In this paper, we report the basic features of the methodology and its evaluation of the shape tailoring of a tibial prosthesis using this approach.

STRUCTURAL ANALYSIS

The present section outlines the NASA technology which was used to model the quasi-static response of the upper tibia. The technology has been successfully applied in the analysis of composite laminates and structures [3, 8], but has seen limited application in the case of bone structures despite the profound similarities, namely, the capability to represent nonuniform material regions and out-of-plane bending/torsional deformations. Instead, most of the efforts have been focused either on two-plane finite element analysis based on thickness corrections to represent the nonhomogeneity of the implanted tibia or on more elaborate three-dimensional analyses of the continuum solid. The proposed laminate theory may be viewed as a compromise between these two extremes.

The analysis involves three stages. In the first stage (upward synthesis), the stiffness characteristics of the discrete bone layers are synthesized. Integration through the thickness (sagittal plane) provides the equivalent extensional and flexural stiffness properties, relating the average (generalized) laminate stresses to the average (generalized) laminate strains. In the second stage, the global static response is obtained with finite element analysis. The third and final stage involves the back-calculation of stress and strain at each layer from the global structural response.

OPTIMAL IMPLANT DESIGN

The objective of the proposed design procedure is to control the stress field in the cancellous and cortical bone of the implanted tibia by changing the shape and the dimensions of critical implant components. The original (unimplanted) tibia has a unique bone macro- and micro-morphology to efficiently carry the applied loads at the joint. It is generally accepted [9-13] that this particular bone morphology has been developed in response to an average stress/strain stimulus induced by the applied joint loads. The bone adapts its morphology reacting to this stress stimulus. The presence of the prosthesis alters both the mechanical characteristics and the load path in the implanted tibia, hence, it significantly perturbs the stress field creating the potential for changes in the bone, which may cause bone atrophy in the vicinity of the bone-implant boundaries. The latter phenomenon is undesirable in knee prosthesis since it is primarily responsible for the typical failure mode in this joint, that is, the loosening and subsequent failure of the tibial component.

Based on experimental results and clinical observations, phenomenological models have been developed to the point where one can attempt numerical predictions of bone remodeling histories [9, 10]. However, considerable work remains to validate the various models, and the appropriate parameters to be incorporated into these models are still to be determined experimentally. Hence, optimizing prosthesis design using time dependent remodeling is relatively impractical at the present time. The alternative approach, using a stress- or strain-related criterion, has a direct relationship to the anticipated remodeling behavior since they are typically the basis for the remodeling models [11-13]. The use of a stress-based criterion, although it does not follow the history of the remodeling process nor does it reflect the time dependent adaptation, is nevertheless sufficient for a first approach to the design of an optimal prosthetic implant.

It appears that the most important requirements are minimal interfacial movement and minimal bone stresses/strains near the bone/implant interfaces [12, 14]. The global stress field in the implanted tibia should be also maintained within normal physiological levels. In this way, global alterations in the bone tissue will be retained in minimal levels.

Other secondary modes of implant failures may be either bone fracture or mechanical failure of the implant components as a result of high stress concentrations in extreme loading conditions. Although preliminary FE analyses indicate that the stress level in the bone and the implant are too low for this mode of failure, suitable preventive mechanisms have been incorporated into the proposed methodology.

In view of the previous observations, candidate quantitative design criteria leading to favorable stress fields within the implanted tibia are: (1) minimization of the stress concentrations at the vicinity of the bone/implant interface, and (2) maintenance of the stress in the bone within the physiological levels of the original tibia. Some additional criteria involve the prevention of mechanical failures, bounds on the admissible shape for the tibial post, and minimal removal of bone tissue.

This constrained optimization problem was solved numerically with the modified feasible directions non-linear programing method [15]. The feasible directions method is a direct search algorithm performing direct search in the feasible design domain. The search direction is estimated from the gradients of the objective function and the active constraints. A line search along this search direction based on polynomial interpolation is then performed to complete each design move.

APPLICATION AND RESULTS

The present section includes evaluations demonstrating the applicability of the tailoring system on the shape optimization of a single-post tibial component (Fig. 1) subject to symmetric and unsymmetric loading in the frontal plane. The section also describes the geometry and material properties and the validation of the FEA model.

Geometry and Material Properties

Typical dimensions and bone morphology representing the upper tibia of an average adult male were assumed in this study. For simplicity, symmetry was assumed in both frontal and sagittal planes, as well as, elliptical cross-sections. Nevertheless, the developed pilot tailoring system entails the capacity to handle more complicated bone geometries and morphologies. The variation in bone material properties was approximated by discrete laminated material regions and properties as shown in Fig. 2. As seen in Fig. 2, the discretized bone morphology consists of cortical bone surrounding different densities of cancellous bone.

The tibial component of the prosthetic knee implant, which was used both as a reference and an initial design, is a simple but valid representation of ones found to be in common use today and therefore it is a suitable start for the optimization process. The reference design incorporates a 15 mm thick ultra-high molecular-weight polyethylene (UHMWPE) plateau supported by a 3 mm thick titanium backing tray. A 15 by 15 mm square by 30 mm long titanium stem or post protrudes from the bottom center of the tray. The polyethylene plateau and the titanium backing tray are both 70 mm wide and 45 mm deep and they match exactly the geometry of the corresponding tibial cross-section.

Loading Conditions

Two different loading conditions were considered in this paper (Fig. 3):

(1) Symmetric, in-plane, vertical forces parabolically distributed over each condylar surface area totaling 2000 N. The load magnitude of 2000 N represents a resultant joint reaction force equivalent to three times the body weight, which is typical during normal, level walking [16, 17].

(2) Unsymmetric, in-plane, vertical forces totalling 1333 N and 667 N (2:1 ratio) respectively, parabolically distributed over their corresponding condylar surface. Unsymmetric loads are considered to be a more realistic representation of the actual loading conditions within the knee joint.

Validation of the FEA Model

The validity and limitations of the finite element model incorporated in the tailoring system were illustrated by comparisons with more detailed three-dimensional continuum finite element models of the same implanted tibia. The comparisons made are for the reference prosthesis design and involved the same symmetric and unsymmetric in-plane loading conditions as described earlier. There is good agreement between the two models, which is evident when comparing the stresses in each model for the cortical bone and cancellous bone regions as well as the tray and post configuration. While the stresses at every element are not exactly identical, the trends of the stresses in each model are comparable. That is, the general behavior of the stress contours in the three-dimensional model are adequately reproduced in the two-dimensional case for both symmetric and unsymmetric loading conditions.

Results

Corresponding to the requirement for maintenance of the bone/implant interface, we have chosen the objective function to be minimization of the maximum stress at the bone/implant interface regions.

The design variable sets for the optimization cases presented here involved combinations of post and tray geometry parameters including: the post length (-15% to +20%), width tapering along the length of the post (-25% to +25%), and tray thickness (-3% to +10%). The values in parenthesis indicate the lower and upper bounds imposed as a percent of the respective reference implant design value.

In-Plane Loading, Symmetric. Shape optimization of the post only resulted in a 28% reduction in the maximum stress which occurs at the outermost elements in the tray/bone interface. For this design case, the post width has been tapered and its length increased.

Combined optimization of the post and tray resulted in a 30% reduction in the maximum stress and results in nearly the same stress distribution as in Case 1. The tray was thickened considerably illustrating that thicker trays provide improved immobilization at the tray/bone interface. The current trend of using metallic backing trays as opposed to the less successful all-plastic tibial implant configuration reinforces the obtained results. The combined optimization did not produce significant additional reductions in the maximum stress.

Thus, the results for optimization in a symmetric loading scenario indicate the need for a design that includes a thicker holding tray with a wider but tapered post of slightly longer length as compared to the initial design case. Such a design transfers the maximum stress from the outer portions of the tray/bone interface region to regions below the bottom of the post within the cortical shell (Fig. 4).

In-Plane Loading, Unsymmetric. Optimization of the post resulted in a 12% decrease in the maximum stress within the bone/implant interface, and the maximum stress has now been transferred to elements in the bone which are below the lower end of the post. The post has been slightly shortened and widened as well as tapered.

Optimization of the post and the tray resulted in a 18% reduction in the maximum stress within the bone/implant interface. In this case, the post has been shortened and tapered while the tray has been made thicker.

Thus, the prosthesis optimization under unsymmetric loading indicates the need for a design that includes a thicker holding tray with a wider but tapered post of slightly shorter length as compared to the initial design case. Such a design results in the higher stresses appearing in regions that are below the bottom of the post (Fig. 5).

SUMMARY

A method is developed for the optimization of orthopedic knee implants by adapting NASA technology originally developed for the analysis and optimization of composite structures. The present paper is focused on the optimal design of the tibial implant components. The shape of the implant is tailored for improved bone growth near the boundaries of the implant. A research pilot code was developed to demonstrate the feasibility of the concept.

Evaluations of the pilot tailoring system were performed on the shape optimization of tibial implants subject to symmetric and unsymmetric distributed loads applied on the epiphyseal plate. The results illustrated that optimization of the implant shape can indeed reduce the maximum stress in the bone at the vicinity of the implant, therefore, shape optimization techniques can be successfully applied in designing durable and customized knee implants. The applications also demonstrated the dependence of the resultant optimal designs to the loads, suggesting the need for optimization under multiple loading conditions. The material properties of the implant were also proved important. Optimization of the material properties will be best accomplished with tailored composite implants, and work in this subject is currently in progress.

Acknowledgements -- The authors wish to express their thanks to Dr. Christos C. Chamis of the NASA Lewis Research Center for his direction and advisement. This work is supported by the technology utilization office at the NASA Lewis Research Center, Cleveland, OH under NASA Grant NAG 3-1027.

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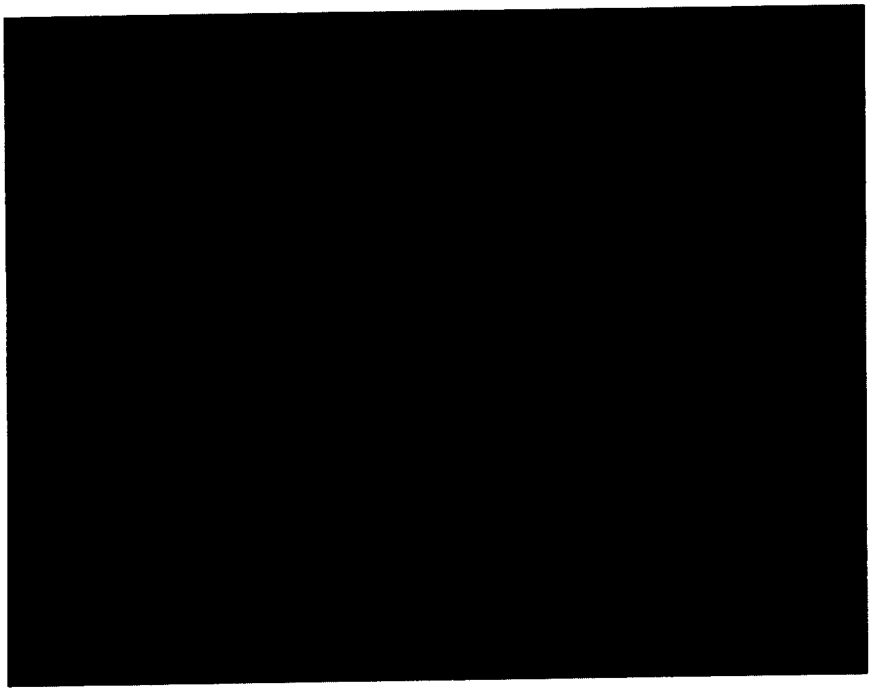
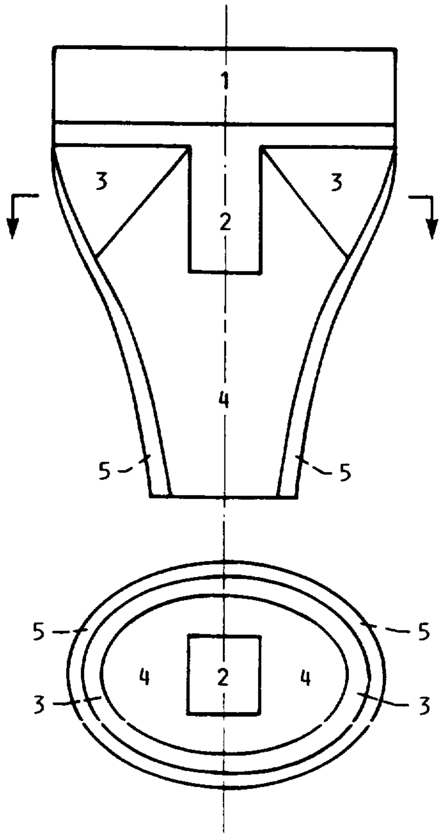


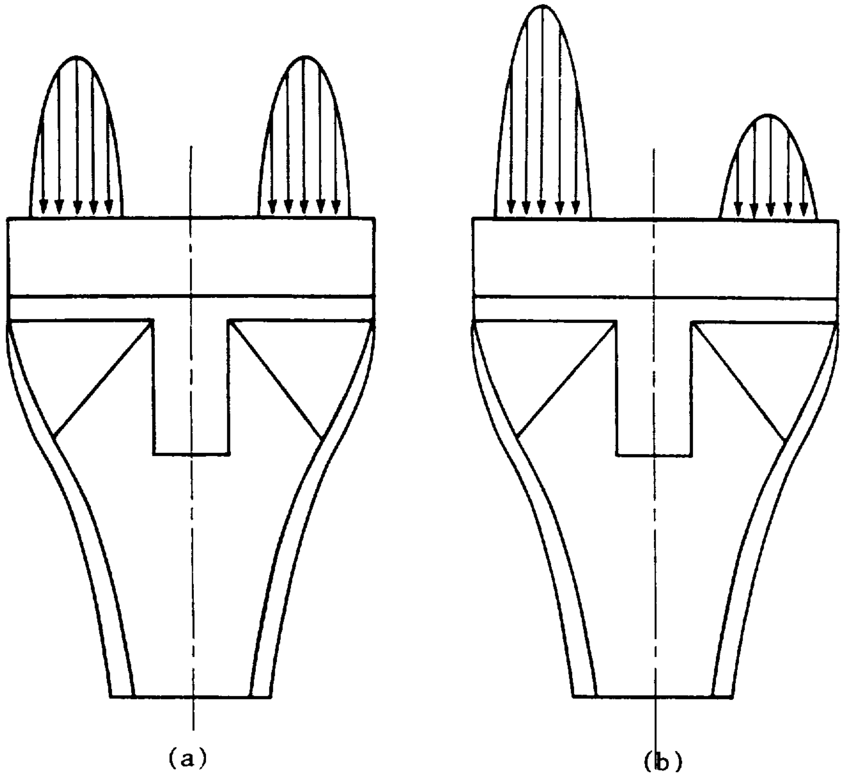
Fig. 1 Typical components of knee implants (from left to right): (a) Femoral component; (b) Patellar component; (c) Tibial component.



MATERIAL PROPERTIES FOR CORRESPONDING MATERIAL REGIONS

MATERIAL	DESCRIPTION	YOUNG'S.	MODULUS.	POISON'S
		MPa	Mpsi	RATIO
1	POLYETHYLENE	500	0.08	0.40
2	TITANIUM	113 764	16.50	0.30
3	CANCELLOUS HD	400	0.06	0.20
4	CANCELLOUS LD	200	0.03	0.20
5	CORTICAL SHELL	15 169	2.20	0.32

Fig. 2 Morphology and material regions for typical adult male tibia with prosthesis.


(a)

(b)

Fig. 3 Loading scenarios: (a) In-plane, symmetric; (b) In-plane, unsymmetric.

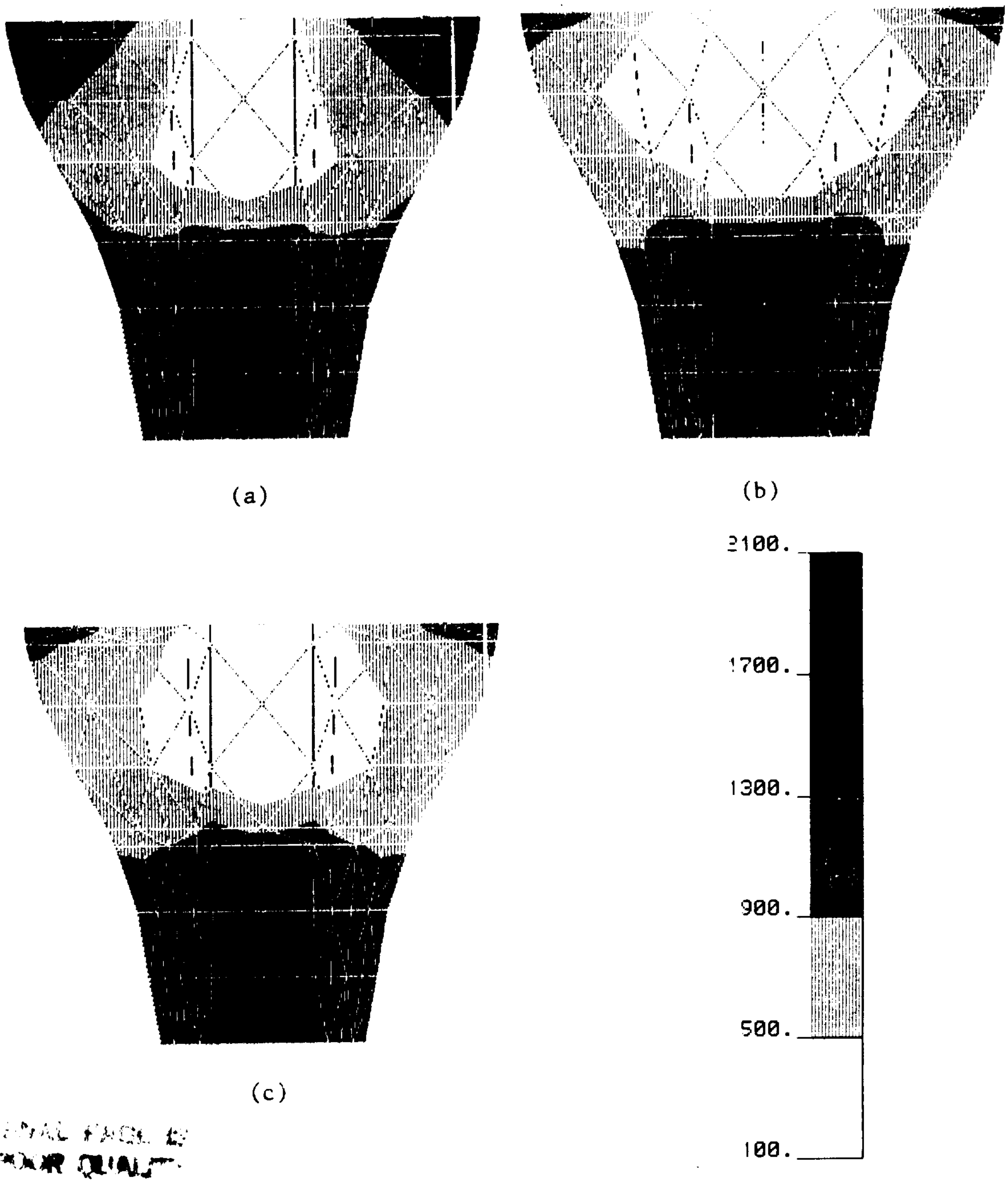


Fig. 4 Equivalent stress distributions in the cortical bone for symmetric loads: (a) Reference design; (b) Optimized post only; (c) Optimized tray and post.

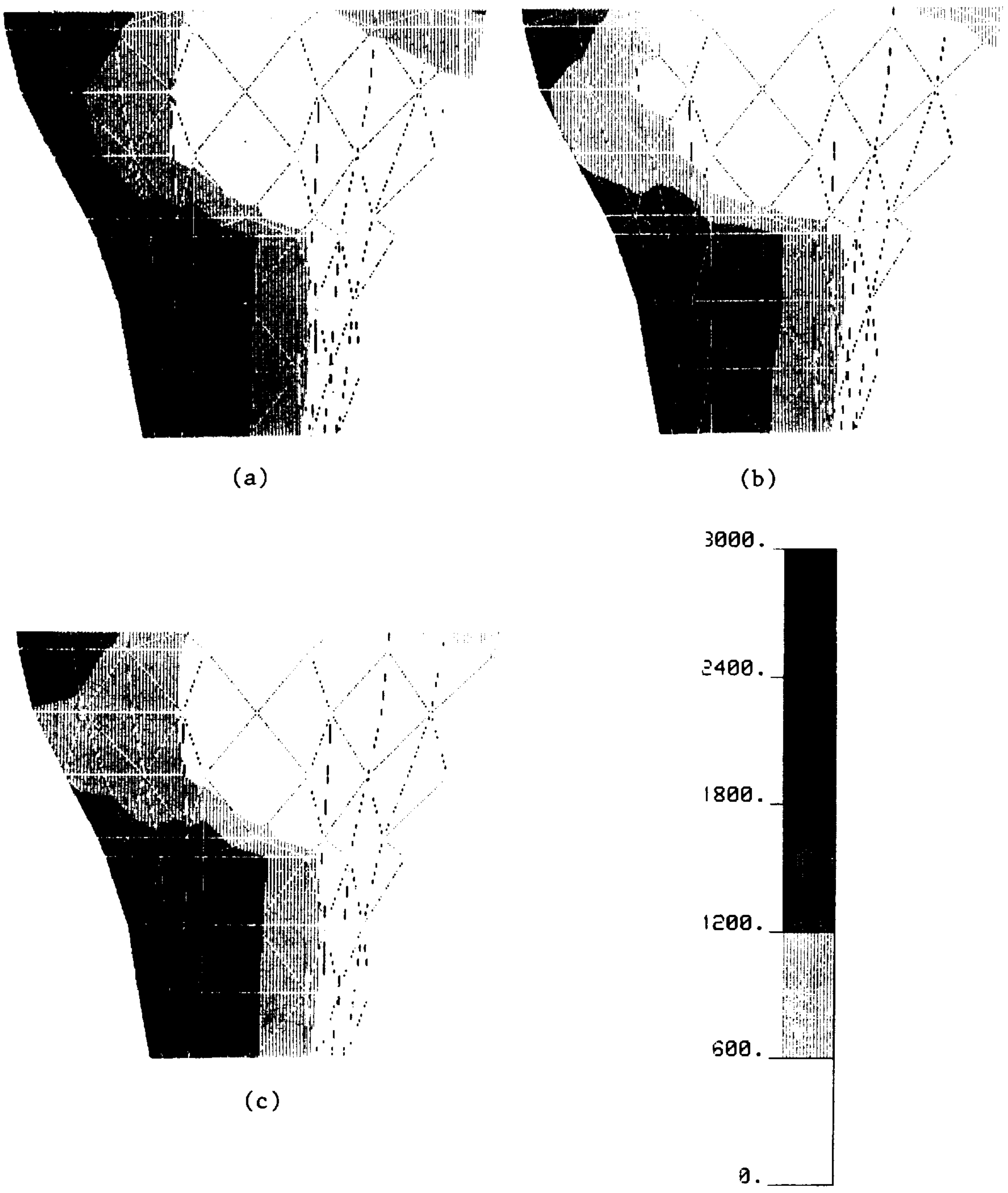

(a)
(b)
(c)

Fig. 5 Equivalent stress distributions in the cortical bone for unsymmetric loads: (a) Reference design; (b) Optimized post only; (c) Optimized tray and post.