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Computer-assisted Methods for Design Optimization of Cardiac Bioprosthetic Valves

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Excessive mechanical stresses on valvular leaflets are considered an important factor in the degeneration of cardiac porcine bioprosthetic valves. This study describes a computer-assisted numerical model of a bioprosthetic valve which estimates the magnitude and distribution of leaflet stresses. The study also describes our initial attempts to determine the influence of stent height upon leaflet stresses. Whereas lowering stent heights has been suggested to improve hemodynamics in the bioprosthetic valve region, results indicate that an increase in leaflet stresses can accompany reductions of stent height.

In spite of marked improvements in recent years in the design of bioprosthetic valves, spontaneous degeneration after several years of implantation remains a clinical problem. Degeneration of tissue valves has been attributed to several factors including static and fluid dynamic stresses as well as hematological and immunological processes. Although some of these factors may be tested experimentally, assessing the static structural stresses is a difficult problem (1). One approach to the determination of the magnitude and distribution of stresses on bioprosthetic leaflets is the use of computer-assisted numerical methods. In our laboratory (2), as well as in others (3,4), the finite element method, a powerful computer-based numerical tool for the solution of complex problems in the field of structural mechanics, has been employed to predict bioprosthetic leaflet stresses. When a numerical model is developed, multiple design interventions may be introduced to examine their impact upon the magnitude and distribution of stresses for various physiological pressure-loading conditions. The present study describes the development of a minicomputer-based numerical model to assess the stresses in bioprosthetic valve leaflets. In addition, the model is used to predict the influence of stent height on leaflet stresses.

Methods

The finite element method

The finite element method breaks the structure to be studied into small portions called "elements" and establishes the governing mathematical relations for the elements by invoking appropriate physical principles. By considering small segments (elements) of the structure under study separately rather than the structure as a whole, one can incorporate the nonuniformity of material characteristics which can vary from one location to another. This approach continuously updates the geometry and the nonlinear properties of the material under consideration.

For each element, evaluation of the structural governing equilibrium equation is based upon principles of minimum potential energy or virtual displacement. Subsequently, the individual governing equations for each element are assembled (just as all the elements are assembled to form the original structure), resulting in a set of simultaneous algebraic equations that can be solved using computer-assisted methods. The algebraic equations are of the form:

$$[K] = \{u\} = \{p\}$$

where [K] is the structural stiffness matrix, {u} is the displacement vector that results from the application of the load (pressure) vector {p}.

This numerical approach to determine structural stresses may involve the solution of hundreds of equations of the form shown (1). The number of equations to be solved depends directly upon the number of structural elements and associated number of nodes which connect the elements. Traditionally, the solution of large numbers of equations requires the use of large computer memory, usually available in mainframe computer systems. For the present application, however, specific software was developed which allowed the use of a minicomputer with limited memory.

The computer system and software

The minicomputer available in this laboratory and used in this study is a Hewlett-Packard 21 MX multiple user

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system. The computer operates on an RTE IVB system with 160K word of total memory of which a 20K word memory partition is available to the user at any time. Data storage capabilities include a 5 megabyte permanent disc, a 10 megabyte removable disc, a 0.5 megabyte floppy disk drive, and a 0.5 inch 1600 BPI magnetic tape drive. The system peripherals include a 600 line/min printer, a digital pen plotter, and two cathode ray tubes, one of which incorporates two digital tape cartridge drives, each capable of storing 128K bytes. The cartridges are used primarily to store images from the graphics terminal.

In the present application, the computer code was based on segmentation techniques which allow the user to divide a large program into small portions that can be handled easily by a limited memory space. The basic program flow diagram is shown in Fig. 1. It consists of three major segments: the preprocessor, the analysis segment, and the postprocessor. Within each of these major segments, the program contains multiple subsegments. The preprocessor contains two subsegments, one for the mesh generation (data preparation) and the other for plotting the mesh. The analysis procedure has two options which depend on the strategy to be used for the solution of the finite element equations. The program could select either the band solver or the frontal solver (5). Both solution techniques are based on Gaussian elimination*, and they use an out-of-core solution procedure. Minimum memory requirements to solve finite element equations were achieved by efficient bookkeeping and optimal storage of equations in active memory. In the band solver, equations were eliminated in sequential order up to the last one, followed by the back substitution procedure. On the other hand, in frontal solver, the element equations were assembled one by one. Any completely assembled nodal equations were eliminated before the assembly of further elements. This approach optimized the memory requirements and computation time. The postprocessor contains two subsegments. One subsegment evaluates the stresses based upon the computed displacements obtained in the analysis processor, and the other plots the stress distribution.

Development of the model

Geometry of the bioprosthetic leaflet, like the natural aortic valve leaflet, is complex, and its response to loading conditions is nonlinear. Therefore, bioprosthetic valve modeling is exceptionally complex unless some assumptions are made which, in fact, may not be truly representative of the biological state.

The shape of the closed leaflet was modeled as an elliptic-paraboloid in accordance with observations by others (6). The following assumptions were made in the development of the computer model:

1. All three valve leaflets were assumed to be equal in size and symmetrical.
2. Deformation of the annular ring was considered negligible under loading.
3. The leaflet material was assumed to be nearly incompressible and isotropic with a Poisson's ratio of 0.45.
4. The thickness of the leaflet was assumed to be uniform (0.6 mm).
5. The stent was considered to be rigid.

Because of symmetry in geometry and loading, only one half of the leaflet was considered for the analysis. The finite element discretization is shown in Fig. 2. Triangular membrane shell elements were used. On the basis of observations by Swanson and Clark (7), the bending effects were neglected.

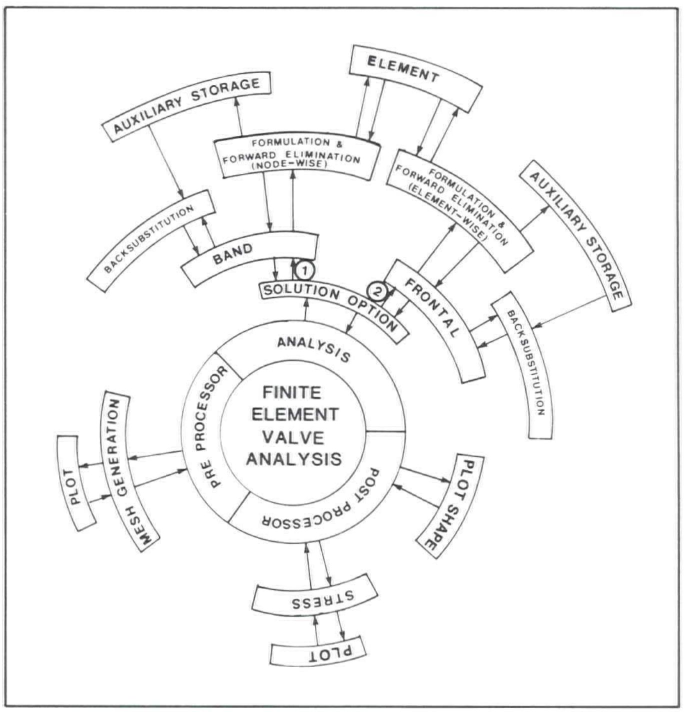

Fig. 1

Diagrammatic representation of the organization and procedure of the finite element program.

The leaflets were assumed to be firmly attached to the stent which was assumed to be rigid. This rigidity led to a zero displacement boundary condition along the attachment points. The boundary condition along the free margin, however, was not known a priori. As the pressure increased, the free margin deformed, contacting with the neighboring leaflet and forming the

*Ed. note: Gaussian elimination, named after the German mathematician Gauss, is a technique to obtain the solution of simultaneous equations.

coaptation surface. This contact boundary condition was achieved as the finite element solution proceeded. As a result of applying this boundary condition, the coapting points were allowed to move freely in a plane normal to the annulus of the valve, whereas motion in a plane normal to the coapting edge of the leaflets was restricted.

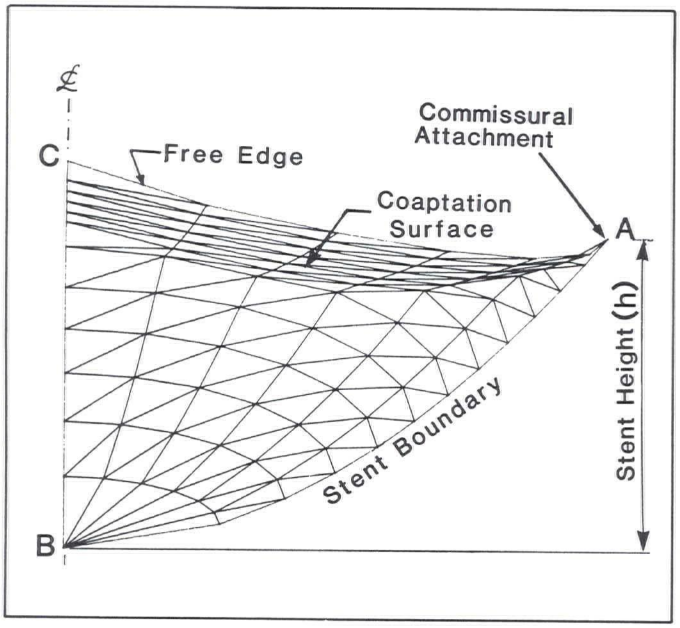

Fig. 2
Finite element discretization of one half of the leaflet using triangular elements. The height of the stent (h) is indicated. A indicates the site of commissural attachment. B indicates the site of attachment to the stent at the center of the leaflet. C represents the site of the corpus arantii, center of the leaflet along the free margin.

Analysis

In the current application, the band solver was employed. The solution of the finite element equations was obtained by increasing the pressure incrementally from 0 mm Hg to 200 mm Hg. The pressure load increments were applied to the outflow surface of the leaflet while the inflow surface was assumed to be free from any applied pressure. The stress strain curve for porcine bioprosthetic leaflets employed in this study was based upon experiments by others (8).

Three different stent heights were studied while a fixed annular diameter of 27.8 mm and a constant leaflet surface area of 5.8 cm^2 was maintained. The selected stent heights were 22, 19, and 14.6 mm (Fig. 2). The stent was not incorporated into the model because of assumed rigidity.

Results and Discussion

The magnitude and distribution of bioprosthetic leaflet stresses predicted from our model using a minicomputer system were similar to those reported by others who used mainframe computer systems (4).

This model predicted greater leaflet stresses with lower stent heights. At a diastolic pressure of 100 mm Hg, typically encountered by a bioprosthetic valve in the aortic position, maximal principal normal stresses occurred near the leaflet commissural attachment and increased by 43% as the stent height was reduced by 33%. At a systolic pressure of 120 mm Hg, typically encountered by the closed bioprosthetic valve in the mitral position, maximal principal normal stresses occurred at the same site and increased 36% as the stent height was reduced by 33%. To our knowledge, this work represents a first attempt at defining the influence of the stent height of bioprosthetic valves on leaflet stresses.

Carpentier, et al (9) suggested several attractive features which may result from reducing the stent height of bioprosthetic valves. Reducing the stent height would certainly minimize protrusion of the struts into the left ventricular outflow tract in the case of the mitral valve and into the aorta in the case of the aortic valve. Furthermore, reduction of the stent height, within the limits of preserving the normal configuration of the valvular orifice, was thought to be an important consideration in reducing turbulence. The latter is considered to be a factor leading to increased risk of thromboembolism and calcification as well as accelerating the development of fatigue lesions (9). Although a reduction of the stent height may have these advantages, our analysis indicates that reducing the stent height also results in increased leaflet stresses.

Our observation of maximal stresses near the leaflet commissural attachment may also be important in understanding some aspects of the degeneration process of bioprosthetic valves. Among 37 dysfunctioning porcine bioprosthetic valves removed during surgery at this hospital, 15 of 26 (58%) showed tears at or near the site of leaflet commissural attachment. It is possible, therefore, that the presence of a stress concentration at that site, as predicted by this model, explains this high, localized incidence of leaflet failure.

The use of computer-assisted numerical methods described in this study can be a valuable tool in the design optimization of cardiac bioprosthetic valves. Because of inherent assumptions, however, extrapolation to the true biological state should be exercised with care. The model can be further refined to assess the influence of other structural factors such as stent flexibility and tissue stiffness on leaflet stresses.

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