A three-dimensional analysis of a fibre-reinforced aortic valve prosthesis

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Abstract

Failure of synthetic heart valves is usually caused by tearing and calcification of the leaflets. It is postulated that leaflet fibre-reinforcement leads to a decrease of tears and perforations as a result of reduced stresses in the weaker parts of the leaflets. A three-dimensional finite element model of a reinforced three-leaflet valve prosthesis was developed to analyse the stress reduction. Different fibre reinforcements were investigated and the model responses were analysed for stresses that are expected to contribute to failure of fibre-reinforced valve prostheses. Results of these simulations show that, in peak stress areas of reinforced models, up to 60% of the maximum principal stresses is taken over by fibres and that, in some cases of reinforcement, a more homogeneous stress distribution is obtained.

Keywords: Heart valve prosthesis; Leaflet fibre-reinforcement: 3-D Finite element model; Peak stresses and stress distributions

1. Introduction

Disfunctioning heart valves are increasingly replaced by heart valve prostheses. Commercially available prostheses are, up to now, either mechanical or biological. However, major problems with trombo-embolic complications and leaflet failure are still existing with these prostheses. Attempts to make functional, fully synthetic leaflet prostheses have not been very successful either. It is thought that the use of flexible leaflets attached to a stent, which can be more or less flexible, gives a better performance of the prosthesis. However, at this time such prostheses are not reliable for long-term applications but are used in short-term applications such as artificial blood pumps, heart assist devices and artificial hearts.

Rousseau (1985), Wheatley et al. (1987) and, more recently, Bernacca et al. (1995) investigated the calcification and fatigue failure in bioprosthetic and synthetic polyurethane heart valves. The failure of leaflets due to tearing and calcification reported with synthetic valves are similar to those reported with bioprosthetic valves. Regions of high bending and shear stresses in the leaflets of the valves during opening and closing have been suggested to cause the degeneration (tearing) of the leaflet material, leading to calcification and failure. A design of the valve which gives a stress reduced state of the leaflets is very likely to give an improved performance.

The leaflets of the natural valve are reinforced with collagen and elastin fibres as a stress-reducing mechanism to prevent tearing and, indirectly, calcification of the leaflet tissue. The fibre-reinforced structure combines a high degree of mobility during opening and closing with high strength and stiffness in the closed configuration. Cacciola et al. (1996) used these understandings to develop a synthetic valve with fibre-reinforced leaflets of high-performance polyethylene (HP-PE) fibres embedded in an ethylene–propylene–diene–monomer rubber matrix (EPDM).

In this paper, the effect of fibre reinforcements on stress distribution over the leaflets in the EPDM synthetic valve is investigated with a finite element analysis. A three-dimensional finite element model is presented using shell elements to take into account the bending stiffness of the leaflets. The initial geometry of the model is an open cylindrical state of the leaflets corresponding to the original geometry of the synthetic prosthesis. Fibre reinforcements were projected on the leaflet surface...
giving the leaflet material a composite structure with lamina of pure rubber matrix and lamina of fibre-reinforced rubber. In this study, a quasi-static approach was used to analyse the deformation of the model from a stress-free open cylindrical position to a fully closed configuration applying a uniform pressure at the aortic side of the leaflet. The numerical problems caused by the mechanical instabilities as a result of the ‘snap-through’ behaviour of the model were solved using path-following solution algorithms. Different fibre-reinforced structures were analysed for stresses that are likely to contribute to the failure of fibre-reinforced prostheses. Moreover, peak stress areas of the reinforced models and a non-reinforced model are compared to peak stress areas previously reported in studies on synthetic prostheses and bioprostheses.

2. The model

The dimensions of a prototype fibre-reinforced valve developed in our laboratory (Cacciola et al., 1997, in press) were used to define the geometry of the finite element model. This prototype valve has a rigid stent. A photograph of this valve and a schematic drawing of its geometry are given in Figs. 1 and 2, respectively. The leaflets show a cylindrical shape (diameter \( D \)) in the stress-free open position and have a uniform thickness (\( t \)). The stent of the valve was modelled as a rigid body. The leaflets are fixed to the stent along a circular curvature (\( CBC \)). Towards the middle of the free edge the leaflets show a semilunar shape giving the leaflets a maximum height (\( H + h \)) in the middle and a minimum height (\( H \)) at the commissures (\( C \)). Taking advantage of the symmetry, only one half of a leaflet (as indicated by the hatching) was used in the analysis.

The analysis were done with the MARC K6.2 (MARC Analysis Research Corporation, 1996) finite element package using four-node shell elements to take into account the bending stiffness of the leaflets. The surface of half of a leaflet was converted to a mesh of 319 elements as shown in Fig. 3. Along the circular curved edge of the surface, the nodes were restricted from moving and rotating in any direction to model the leaflet fixation to the stent. Appropriate boundary conditions were used at the plane of symmetry. Contact facilities are essential to

![Fig. 1. Prototype of a three-leaflet valve prosthesis with sinusoidal fibre reinforcement; (a) open position and (b) nearly closed position from top view.](image1)

![Fig. 2. Schematic presentation of the valve geometry from two different viewpoints. Half of one leaflet used in the FE model is indicated by the hatching.](image2)
model the coaptation of two leaflets. A fixed rigid contact body was placed where two adjacent leaflets come in contact during closing to model this coaptation area. Deformation of the model was realised by applying a uniform pressure \( P \) at the aortic surface of the leaflet to simulate the diastolic pressure load on the leaflet. From a physiological point of view, it is incorrect to realise deformation of the model with such a uniform pressure load. Movement of the leaflets is primarily caused by the complex fluid flow which causes non-uniform pressures and shear stresses on both sides of the leaflets. A model with fully coupled fluid–solid interactions is not available yet. However, using the simplified boundary conditions, a realistic deformation of the model was obtained for all analysed fibre reinforcements.

Computer-designed fibre reinforcements were projected on the leaflet surface as shown in Fig. 4. Fibreless elements in the mesh were modelled with a nearly incompressible isotropic linear elastic material behaviour according to Hooke’s law defined by the Young’s modulus \( E_m \) and the Poisson’s ratio \( \nu_m \). Elements containing at least one fibre were modelled as a composite. For each fibre crossing the element, a homogenous orthotropic linear elastic layer was defined with layer properties equal to the fibre-in-matrix properties using the Halpin–Tsai rule of mixtures (Fig. 5). The thickness of each of these equivalent layers was taken conform with the PE fibre diameter \( d_f \) in the prosthesis. Only the longitudinal Young’s modulus \( E_l \), longitudinal shear modulus \( G_l \) and Poisson’s ratio \( \nu_l \) of the transversal isotropic fibre properties were relevant in this case. Isotropic rubber layers enclosed the homogeneous orthotropic layer(s) of the elements giving the leaflet a uniform thickness. The implementation of fibre-reinforced structures in the model resulted in a complex composite structure of the leaflet. With this material modelling approach, different computer designed fibre layouts can easily be implemented within the leaflet structure without changing the model of the valve.
Geometric non-linearities were present because of the large deformations of the model, whereas the coaptation area led to non-linear boundary conditions. A full Newton–Raphson iterative procedure was used to solve the system of non-linear equations. However, the deformation of the open cylindrical model to a closed configuration using a uniform pressure led to a mechanically unstable snap-through behaviour of the structure. Hence, path-following solution algorithms were used to pass local unstable (bifurcation) points. Basically, the total load step was subdivided into incremental steps with a partial load of the total load step determined by the path-following algorithm using the arc-length method (Kouhia et al., 1989).

The complexity of the numerical model as sketched above is such that some of the numerical values of the dimensions and properties of the valve are limited due to convergence problems. This means that not all of the valve designs could be used in the model. This concerns the thickness of the leaflet (lower limit, i.e. leaflet stiffness not too low), the ratio between the fibre and matrix modulus (upper limit, i.e. fibre stiffness not too high), and the maximum pressure load (upper limit). Improvement of the algorithms that are used to solve the numerical model should erase these problems in the near future.

3. Results

Four fibre-reinforced models, which can be considered as basic designs, were investigated for their responses to the uniform pressure load applied at the aortic side of the leaflet. Two models with a unidirectional, circumferential fibre reinforcement of 10 and 20 fibres were analysed (uni-10 and uni-20, respectively), as well as two models with a sinusoidal fibre reinforcement of 10 and 20 fibres (sin-10 and sin-20, respectively). The unidirectional and sinusoidal fibre layouts are shown in Fig. 6. The numerical values of all relevant dimensions and properties of the models are given in Table 1. The real values are also given to show the modifications that were needed to get convergence. Numerical experiments showed that these modifications did not affect the stress distributions over the leaflet and thus comparison between different designs is still possible. However, absolute stress values should be interpreted carefully.
The deforming behaviour of the models was compared to the motion of the prototype valves, which were tested in an experimental set-up that simulates the natural blood circulation (a pulse duplicator). Here, only the result for a sinusoidal reinforcement of 10 fibres is shown as the closing/opening behaviour of the valves was nearly the same for all analysed models. A high-speed camera (KODAK HS Ektapro model 4540) was used to record the valve’s motion from the aortic side and the video images were digitised. Four stages of deformation are shown in Fig. 7 with matching deformed configurations of the corresponding numerical model. Deformation of the leaflets in the heart and in the testing machine is mainly caused by the fluid motion around the valve. However, as the finite element model does not include the fluid motion, a difference is observed in the open position of the model valve and the prototype valve. The model shows its initial cylindrical configuration in the open position. The space between two adjacent leaflets in the coaptation area of the finite element model in the closed configuration is a result of the contact facilities in MARC and is assumed to have no consequences for model responses. The maximum principal stress distribution in the ventricular rubber layer of the leaflets is shown on the right side of Fig. 7. The influence of the fibre reinforcement on this stress distribution becomes clear with closure of the valve as the implemented sinusoidal fibre reinforcement can more or less be recognised in the stress distribution. Since the closing behaviour is nearly the same for all fibre layouts under investigation and since the highest stresses are found for a fully closed valve, the presented results are restricted to the closed configuration.

Failure of fibre-reinforced prostheses is most likely to be caused by longitudinal and/or transversal debonding between fibre and matrix (pull-out), and tearing and perforation of the matrix material. These failure mechanisms are the result of high stresses in critical areas of the leaflets and inhomogeneous stress distributions over the leaflets. Hence, in the fibre layers maximum longitudinal and transversal stresses with respect to the local fibre orientation are considered to be important. These stresses are denoted as MLS and MTS, respectively. In the outer rubber layers the maximum principal stresses are considered to be important. They are denoted as MPSA for the rubber layer at the aortic side and MPSV for the rubber layer at the ventricular side of the leaflet. The fully closed configuration at a pressure of 4 kPa was investigated for the fibre-reinforced models as well as for a non-reinforced model. The actual peak stress areas for the different fibre reinforcements are shown in Fig. 8 for a whole leaflet in the closed configuration. Each area is identified with a letter and the corresponding stress values are given in Table 2. In the remaining areas, lower stresses occur that are expected to have a minor contribution to the failure of fibre-reinforced prostheses.

Table 2 shows that for all fibre-reinforced models lower peak values exist in the outer rubber layers when compared to the peak stress value in the non-reinforced model. The unidirectional fibre reinforcements of 10 and 20 fibres show a significant reduction of ≈ 60% for the MPSA at the commissure in the aortic rubber layer (area A) when compared to the stress value of the non-reinforced model (≈ 1.81 MPa). This reduction is less strong (≈ 30%) for peak area B near the stent base at the middle of the leaflet (≈ 0.81 MPa for the non-reinforced case). The sinusoidal reinforcements of 10 and 20 fibres reduce stresses in these areas by ≈ 30 and ≈ 22%, respectively. In the ventricular rubber layer, peak stresses (MPSV) appear near the commissure along the free edge (area C). These stresses are reduced by ≈ 14 and ≈ 38% for the unidirectional reinforcement of 10 and 20 fibres, respectively, when compared to the non-reinforced model (≈ 0.46 MPa). The sinusoidal reinforcement reduces these stresses by ≈ 27 and ≈ 46% for 10 and 20 fibres, respectively. Maximum longitudinal stresses (MLS) appear in the reinforced layers at the commissure and along the free edge near the commissure (area D). High MLS of ≈ 16 MPa occur for the sinusoidal reinforcements, which are at least twice as high as the MLS of the unidirectional circumferential reinforcements. Moreover, a peak stress area is centred in the middle of the leaflet near the stent base (area E) for these sinusoidal reinforcements with a maximum stress of ≈ 7.15 MPa for 20 fibres. Maximum transversal stresses (MTS) in the reinforced layers occur in areas D and E with a value of ≈ 0.99 MPa for a sinusoidal reinforcement of 10 fibres in area D and ≈ 0.56 MPa in area E for all discussed reinforcements.
Fig. 7. Deformed configurations of a prosthesis under simulated physiological load and deformed configurations of a corresponding finite element model.
The effect of fibre reinforcement on the distribution of maximum principal stresses in the outer rubber layers of the closed leaflets is illustrated in Figs. 9 and 10. The stress distribution in the aortic rubber layer of the non-reinforced model (Figs. 9a and 10a) is compared to the stress distribution in the unidirectional reinforced models (Fig. 9c and e) and the sinusoidal reinforced models (Figs. 10c and e). The stress scales in these figures are fixed with a range of 0 to 1 MPa for comparison reasons. For all reinforced models more homogeneous stress distributions, i.e. smaller high stress areas, are obtained when compared to the non-reinforced model. Where little peak stress areas (area A and B of Fig. 8a) are found for the sinusoidal reinforced models these areas are reduced to high stress areas for the unidirectional reinforced models.

The stress distribution in the ventricular rubber layer of the reinforced models (Fig. 9d, 9f and Fig. 10d, 10f) is also compared with a non-reinforced model (Figs. 9b and 10b). The stress scales in these figures are fixed with a range of 0–0.4 MPa. For the unidirectional fibre reinforcements the peak stress area C (Fig. 8b) is, with respect to the non-reinforced model, reduced to a high stress area. Moreover, high stress values in the middle of the leaflet of the non-reinforced model are decreased resulting in a larger low stress area. A more homogeneous stress distribution is thus obtained in the middle of the leaflet. The sinusoidal reinforced model of 10 fibres shows an irregular stress distribution with lower high stress values. On the other hand, the sinusoidal reinforcement of 20 fibres shows a much more homogeneous stress distribution when compared to all other analysed models. Very small high stress areas are observed for this reinforcement.

4. Discussion

A finite element analysis of the stress distribution over the leaflets of a three-leaflet fibre reinforced prosthetic heart valve is presented. Starting from an open stress-free position, deformation was realised by applying a uniform pressure load on the aortic side of the valve. The influence of different fibre reinforcements on the stress distribution in the aortic rubber layer of the closed models associated with the peak stress areas A to E. The ‘-’ in the table indicates that no relevant peak stresses are present in associated areas.

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Table 2

Fig. 8. Peak stress areas A to E of the closed leaflet; (a) aortic rubber layer; (b) ventricular rubber layer; (c) fibre-reinforced layers.
Fig. 9. Maximum principal stress distributions in the aortic and ventricular rubber layer of a non-reinforced model ((a) and (b), respectively) and a unidirectional, circumferential reinforced model with 10 fibres ((c) and (d), respectively) and 20 fibres ((e) and (f), respectively). Stresses are given in MPa and the scales are equalised for easy comparison.
Fig. 10. Maximum principal stress distributions in the aortic and ventricular rubber layer of a non-reinforced model ((a) and (b), respectively) and a sinusoidal reinforced model with 10 fibres ((c) and (d) respectively) and 20 fibres ((e) and (f), respectively). Stresses are given in MPa and the scales are equalised for easy comparison.
distribution has been shown. The results of this study can serve as a guide for design improvements of prosthetic heart valves.

From the results several conclusions can be drawn. Of most general importance is the decrease of stresses in the rubber parts of the leaflet, particularly in the regions where failure has been observed in other studies (Bernacca et al., 1995; Rousseau, 1983; Trowbridge et al., 1988; Wheatley et al., 1987). Regions of high stresses in the leaflets have been suggested as causing the degeneration of the leaflet material, leading to calcification and failure of the leaflets. Black et al. (1991) reported on high stress areas near the stent post at the commissures for a bi-leaflet bovine pericardium prosthesis. Chandran et al. (1991) and Krucinski et al. (1993) reported on high stress areas at the commissures for a three-leaflet polyurethane valve and a pericardial valve respectively. The (non-)reinforced models, described in this paper, showed similar high stress areas in the outer rubber layers of the leaflet structure on the aortic and ventricular sides of the valve. In some cases of fibre reinforcement, maximum stress values in these areas were reduced by \( \approx 60\% \) for the aortic rubber layer and \( \approx 30\% \) for the ventricular rubber layer. The fibre-reinforced structures partly took over the stresses in these areas, resulting in a decreased loading of the (weaker) rubber layers.

A more homogeneous stress distribution in the outer rubber layers was observed for the analysed unidirectional fibre structures when compared to a non-reinforced valve. The analysed sinusoidal reinforced structure of 10 fibres resulted in a rather irregular stress distribution in the ventricular rubber layer (Figs. 7 and 10d). However, an increase of the number of fibres resulted in a much more homogeneous stress distribution when compared to the other analysed models (Fig. 10f). Changes in stress distributions caused by these fibre reinforcements are more significant in the ventricular rubber layer than in the aortic rubber layer.

Longitudinal and transversal debonding of fibres and matrix material in peak stress areas is thought to be the most likely failure phenomenon of fibre reinforced leaflets. However, the influence of relevant stresses in the fibre layers of the leaflet on this failure behaviour still needs a closer investigation. Data on the fatigue behaviour of the leaflet material are not available at this time. Consequently, it has not been possible to make any direct comparison with the present analysis.

This work is thought to be a significant step towards a computer-based design for fibre reinforced valve prosthesis. However, there are still some limitations with respect to the parameters of the model, but a final model should be able to predict the levels of stresses in the leaflets for any design of fibre-reinforcement, leaflet dimensions, mechanical properties and loading. Design parameters that control the size, shape, and flexibility of the valve can then be investigated with respect to valve functioning. The influence of fluid interactions on the valve deformation and the use of flexible stents are currently under investigation. However, at this point it still can be concluded that the three dimensional finite element model that has been developed predicts high stress areas similar to those reported in other studies, and that fibre-reinforced structures reduce stresses in the leaflets and have a major influence on the stress distribution over the leaflets, particularly in regions where failure of the leaflets has been observed.

References


MARC Analysis Research Corporation, 1994, MARC K6.2.

