A synthetic fiber-reinforced stentless heart valve

G. Cacciola*, G.W.M. Peters, F.P.T. Baaijens

Department of Mechanical Engineering, Eindhoven University of Technology, P.O. Box 513, 5600 Eindhoven, The Netherlands

Accepted 23 December 1999

Abstract

There is strong evidence that failure of bioprosthetic and synthetic valves occurs as a consequence of high tensile and bending stresses, acting on the leaflets during opening and closing. In stented prostheses, whether synthetic or biological, the absence of contraction of the aortic base causes the leaflets to be subjected to an unphysiological degree of flexure, which is also related to calcification. However, a stentless synthetic valve, which has a flexible aorta base, can be a good alternative for stented synthetic valves. Moreover, fiber-reinforcement is assumed to lead to a decrease of tears and perforation as a result of reduced stresses in the weaker parts of the leaflets in their closed configuration. The manufacturing method for a stentless, fiber-reinforced, synthetic valve is presented. Prototypes are tested in a pulse duplicator system. The results show that the mean systolic pressure difference is very low, while the high regurgitation (up to 26%) is probably caused by a too small coaptation area of the leaflets.

Keywords: Heart valve prosthesis; Leaflet fiber-reinforcement; Synthetic heart valves; Stentless valve

1. Introduction

Three-leaflet synthetic valves are currently used only in ventricular assist devices and artificial hearts as bridges to transplant, because at this time such prostheses are not reliable for long-term applications.

In numerous studies it has been shown that failure of bioprosthetic and synthetic valves occurs as a consequence of high tensile and bending stresses, acting on the leaflets during opening and closing (Hilbert et al., 1987; Wiseman et al., 1982). The design of the valve which gives a stress reduced state of the leaflets is very likely to give improved performance in long-term applications.

Many researchers have tried to reduce the stresses acting on the leaflets by changing their design. Different manufacturing techniques (Leat and Fisher, 1995), leaflets shapes (Leat and Fisher, 1994; Jansen et al., 1991), and frame mounting methods (Leat et al., 1995) have been investigated over recent years. However, these efforts did not lead to a synthetic prosthesis suitable for implantation, as they still fail in long-term fatigue tests and in vivo experiments.

In Cacciola et al. (1996), we proposed that fiber reinforcement could improve fatigue and in vivo behavior of synthetic valves. The leaflets of the natural valve are reinforced with collagen and elastin fibers which act as a stress-reducing mechanism for the matrix material preventing tearing and, indirectly, calcification of the leaflet tissue. The fiber-reinforced structure combines a high degree of mobility during opening and closing with high strength and stiffness in the closed configuration. We developed a stented synthetic valve made of ethylene-propylene-diene-monomer rubber matrix (EPDM) reinforced with high-performance polyethylene (HP-PE) fibers.

In de Hart et al. (1998), the effect of fiber reinforcement on the stress distribution in the leaflets in this kind of valves was investigated with a finite element analysis. The results showed that the presence of fibers reduced stress peaks in the matrix material by up to 60% with respect to the same stented valve without fibers. Different fiber layouts and fiber contents were also investigated.

However, not only fibers can be used as a stress-reducing factor, but also flexible aortic base and leaflets attachment also seem to improve the performance and lifetime of a valve. In stented prostheses, whether synthetic or biological, the absence of contraction of the aortic base causes the leaflets to be subjected to an unphysiological degree of flexure, which is also related to
calcification. Moreover, the stent of biological or synthetic valves is a major cause of failure in accelerated fatigue tests. Stentless biological valves are a good alternative for stented biological valves. In some cases the entire aortic valve (sinuses and leaflets) is used as a replacement of the injured valve. In other cases three leaflets of three different valves are sewn together with a piece of biological tissue and the patients own sinuses are preserved. In all these cases no stent is needed. Stentless valves are considered to have superior hemodynamics, and this may be translated into improved durability and lower risks of thromboembolism (Westaby et al., 1995; Dossche et al., 1996). Moreover, mechanical characteristics of the porcine aortic root are similar to those of an aortic homograft. Stentless valves show larger orifice areas and lower mean pressure gradients in comparison with stented bioprostheses. Elimination of the stent thereby allows the insertion of a larger bioprosthesis for a given patient (Gross et al., 1995; Meloni and Ricchi, 1995). In the same way stentless synthetic valves could be a good alternative for stented synthetic valves.

In Cacciola (1998), a finite element model of the stentless valve was developed. The effect of fiber reinforcement and flexible leaflet attachment was analyzed. The results showed that the stentless design reduces the stress peaks by up to 80% for a sinusoidal reinforcement with respect to a stented valve with the same reinforcement.

For these reasons we concluded that the optimal synthetic valve should be a fiber-reinforced stentless valve. In this paper, the manufacturing method of such a valve is presented in Section 2. The results of in vitro tests and visualization of the opening and closing behavior by means of high-speed video are presented in Section 3 and compared with those of stented prototypes. Section 4 contains the discussion and conclusions.

2. Methods

When a polymer matrix is combined with a strong, high modulus reinforcement, the resulting composite material has in general superior mechanical properties compared to the matrix material alone.

EPDM rubber, K520 (DSM), with a Young's modulus of 1.5 MPa, is reinforced with HP-PE fibers, which have a diameter of 0.06 mm and a Young's modulus of 30 GPa.

Various fiber layouts can be made. Two possible layouts, which are used in this study, are shown in Figs. 1 and 2, projected on a cylinder. The first one is a unidirectional fiber layout. Fibers run parallel to the circumferential direction, imitating the distribution of collagen fibers in the natural leaflet. Such a layout mostly influences the composite behavior in the circumferential direction.

The layout in Fig. 2, also called sinusoidal, is a kind of network. In this example the angle formed between the fibers and the axis of the cylinder is about 30°. This layout prevents propagation of cracks in the leaflets.

The most important mechanical properties of a composite material reinforced with these two layouts are summarized in Table 1, and compared with non-reinforced EPDM rubber.

When the composite of Fig. 1 is loaded in the axial direction, the fiber–matrix interface determines the strength of the composite. Indeed, in a tensile test in this direction the specimen breaks at the interface, at a stress lower than the stress required to break the EPDM rubber without fibers. For this reason, such a layout should be combined with some other type of reinforcement. The combination of the sinus layout and the unidirectional layout has proven to produce a composite too stiff for our purposes.
Chopped fibers could be used as second reinforcement. Short fibers are easily added to the rubber solution, avoiding the filament winding procedure needed for continuous fiber composites.

Nylon and polyethylene networks were also tried as reinforcement instead of continuous fibers. Knitted composites are in general easier to make than wound composites, because the networks are pre-made and they need only to be mounted on the mold. However, in this way the reinforcement would be uniform over the leaflets, so we lose the possibility to reinforce the structure locally.

For these reasons, our valve prototypes are reinforced with sinusoidal or unidirectional layout, the last one combined with a layer of PE chopped fibers, randomly oriented, to prevent cracks in the matrix material.

Table 1

<table>
<thead>
<tr>
<th>Sample</th>
<th>E (MPa)</th>
<th>SF (MPa)</th>
<th>EB (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EPDM non-reinf.</td>
<td>1.3</td>
<td>2</td>
<td>167</td>
</tr>
<tr>
<td>Sin-long.</td>
<td>2.1</td>
<td>30</td>
<td>148</td>
</tr>
<tr>
<td>Sin-tran</td>
<td>64</td>
<td>12</td>
<td>6</td>
</tr>
<tr>
<td>Uni-long</td>
<td>98</td>
<td>37</td>
<td>10</td>
</tr>
<tr>
<td>Uni-tran</td>
<td>2.5</td>
<td>1</td>
<td>65</td>
</tr>
<tr>
<td>Ch-long</td>
<td>23.6</td>
<td>8</td>
<td>46</td>
</tr>
<tr>
<td>Ch-tran</td>
<td>44.7</td>
<td>6</td>
<td>17</td>
</tr>
</tbody>
</table>

2.1. Valve construction

Valves are made on a steel mold. To prevent the rubber from sticking on the steel, the mold was covered with a polymeric coating (Frekote, Dexter). Such a coating does not influence the manufacturing procedure or the properties of the rubber.

A solution of EPDM rubber is prepared using 30 g of rubber diluted in 0.4 l xylene. In EPDM rubbers the crosslinks are provided by an external crosslinker, that is added to the solution and activated by temperature. These rubbers indeed need to be crosslinked in an oven or under UV rays. As crosslinker (1% w/w), dibenzoylperoxide was used.

The mold used to make the valves, shown in Fig. 3, consists of two parts. The first part (Fig. 3a) is used to make the leaflets, which are not completely open but in half-closed configuration. This is kept rotating and dipped in the rubber solution, at low speed, to avoid the formation of air bubbles. After xylene has evaporated, leaving a dry rubber layer, the dipping procedure is repeated.

When the second rubber layer is also dry, we proceed with the fiber winding, shown in Fig. 4. Before the fiber is put on the mold it is impregnated with rubber solution, to obtain a better adhesion between fibers and rubber. With a computer-controlled system, fibers can be laid down following the wanted layout. For a chosen fiber layout, a data file is generated containing the velocities of two motors. One motor keeps the mold rotating while the other motor moves the eye to the left and to the right. Some PE fiber ends are left free by the commissures for reasons that are going to be explained later in this section. When the winding procedure is completed, the dipping step can be repeated, in order to

Fig. 3. Second mold used for the manufacturing of the stentless valve.
create a symmetrical structure, where the fibers are kept between the rubber layers. The composite structure is shown in Fig. 5. Dipping four times, two times for the base layers, two times for the covering layers, we obtain leaflets with a thickness of about 0.2 mm, which was chosen as optimum value for our application because it gives a good compromise between bending stresses and stiffness.

The second part of the mold (Fig. 3b), representing the sinus cavities and a piece of the aorta, is dipped in the rubber solution, separately, in order to create a rubber layer on the outside. Next, it is mounted on the first part of the mold (Fig. 3c), and the fiber ends that were left free can be pressed on the second part of the mold, creating in this way a direct connection of the leaflet fibers with the sinuses and reinforcing the commissures.

Next, the mold is taken out and it is cured in an oven to crosslink the rubber, with the leaflets in the closed position. In fact, it has been observed that if the leaflets are cured in an open or half open configuration the regurgitation is higher. A curing time of 2 h at 120°C is enough to obtain a level of crosslinking suitable for our application. A picture of such a prototype is shown in Fig. 6.

3. Results

A pulse duplicator system is used to test the valves in vitro. A description of such a system and the test conditions can be found in Cacciola et al. (1996) and Cacciola (1998).

Two commercial valves, one mechanical and one biological (stented) and a stented fiber-reinforced prototype (Cacciola et al., 1996) are tested in the same way as our prototypes, in order to make a comparison.

The values tested are the following:

- **MEC**: Carbomedics pyrolitic carbon bileaflet valve.
- **BIO**: Carbomedics stented porcine valve.
- **SYNT**: Stented synthetic valve prototype, with sinus fiber layout. The valve is made in the open position and vulcanized in the closed position. The manufacturing of this type of valve is described in Cacciola et al. (1996) and Cacciola (1998).
- **SL**: Stentless synthetic valve prototype, with a sinus fiber layout.

The values of the mean systolic pressure difference of different valves (pressure drop while the valve is open) are summarized in Fig. 7, for cardiac outputs of 2, 4, 5 and 7 l/min, which are standard values varying from a rest to a moving state. The values were determined from an average over 10 cycles.
Fig. 7. Mean systolic pressure difference for different valves, for cardiac outputs of 2, 4, 5 and 7 l/min.

Fig. 8. Regurgitation given as percentage of the stroke volume, for cardiac outputs of 2, 4, 5 and 7 l/min. The contribution of closure and leakage volume are shown with dark and light gray, respectively.

Fig. 9. Motion of a stented (a) and stentless (b) prototype in the pulse duplicator system. Images are obtained with a high-speed camera.

Fig. 8 shows the regurgitation of different valves for cardiac outputs of 2, 4, 5 and 7 l/min. The two contributions of closure volume and leakage volume are separated. The regurgitation is given as percentage of the closure volume. The regurgitation of the SL goes up about 26% for a cardiac output of 2 l/min and reduces to 10% for a cardiac output of 7 l/min.

Visualization of the leaflet motion is made possible with the use of a high-speed camera (Kodak Ektapro HS 4540 motion analyzer, resolution of 256 × 256 pixels). An endoscope is inserted into the valve chamber in the aortic position. It is possible to select different recording speeds. We used a speed of 500 frames per second.

Leaflet motion of a stented valve (SYNT) is shown in Fig. 9a, for comparison. The behavior of the stentless valve (SL), shown in Fig. 9b, is rather different.

4. Discussion and conclusions

A flexible aortic base and leaflets attachment seems very important to improve the performance and lifetime of a valve. In stented prostheses, whether synthetic or biological, the absence of contraction of the aortic base causes the leaflets to be subjected to an unphysiological degree of flexure, which also is related to calcification.

Our stented prototype shows the typical buckling of the leaflets during opening and closing (see Fig. 9a).

Stentless biological valves are a good alternative to stented biological valves. They are considered to have superior hemodynamics, and this may be translated into improved durability and lower risks of thromboembolism (Westaby et al., 1995; Dossche et al., 1996; Gross et al., 1995; Meloni et al., 1995). The behavior of the stentless valve (SL), shown in Fig. 9b, is very different from the behavior of the stented prototype (SYNT). During opening the commissures move outwards keeping the leaflets straight. The typical opening orifice is triangular, like in the natural valve.

Similar to the biological valves, a stentless synthetic fiber-reinforced valve could be a better solution than a stented fiber-reinforced (Cacciola et al., 1996; Cacciola, 1998). However, the manufacturing procedure to make a stentless valve is slightly complicated due to the irregular shape of the mold which does not allow the use of a pressing cylinder (Cacciola et al., 1996), to keep the fiber in place during the winding procedure. The fiber must be kept in place manually.
Our synthetic prototypes are reinforced with fibers following two types of layout. The unidirectional layout reinforces the material in the circumferential direction and it should be combined with another layout that reinforces the leaflet in the axial direction. A possible solution is the use of chopped PE fibers, which are easily added to the rubber solution and applied on the mold during dipping.

On the other hand, the behavior of very short fiber composites is dominated by end effects (Mathews and Rawling, 1987). Regions toward the ends of fibers do not carry the full load. The fiber length should be considered in relation to a critical length, below which the end effects become important and the average stress in a short fiber is lower than that in a continuous fiber subjected to the same external loading. Further investigation is required to find the critical length and control the reinforcement efficiency of this kind of reinforcement.

The other layout used is the sinusoidal one, which reinforces the leaflets in both the circumferential and axial directions.

Computer simulations (de Hart et al., 1998; Cacciola, 1998, 2000) show that the unidirectional fiber layout lead to a major reduction of stresses in the rubber layers.

However, it is possible to change the mechanical properties of the rubber reinforced with the sinusoidal layout by changing the angle between fibers and the axis of the cylinder, which is now about 30°. If this angle is 45°, for instance, the properties will be the same in the axial and circumferential directions. For a higher angle the material will be stiffer in the circumferential direction and more compliant in the axial direction, simulating better the material properties of the natural leaflet.

Both stented and stentless valves have been tested in a pulse duplicator system and compared with a biological stented and a mechanical valve. From the results we can conclude that the mean systolic pressure difference is not a critical parameter in our design. In fact, our prototypes offer a low resistance to forward flow, for all cardiac outputs. The higher values for the stentless valves are probably due to stiffer leaflets. These can be lowered using less rubber layers or less fibers (see Cacciola, 1998). This parameter increases with increasing cardiac output, except for SYNT, where the first three values are slightly decreasing.

On the other hand, the regurgitation is a critical parameter. This parameter reaches a value of about 26% for the SL for a cardiac output of 2 l/min, although from Fig. 9b it looks like the valve closes perfectly. Probably, the leaflets must be larger to ensure a larger coaptation area. In the future the leaflet design will be slightly adjusted to solve this problem. Moreover, long-term fatigue tests will be performed. It is known from literature (Hilbert et al., 1987; Wiseman et al., 1982), that failure of biological and synthetic valves is related to the high stresses acting in the leaflets. In Cacciola (1998) and Cacciola et al. (2000) we showed that a finite element analysis of such a stentless, fiber-reinforced valve confirms that stresses are reduced by up to 80% with respect to the same valve without fiber reinforcement. Thus, we expect the fiber-reinforced prototypes to have a longer lifetime.

References


