TRI-LEAFLET VALVE WITH A PURGE FLOW FOR CARDIAC ASSIST DEVICES

T. Timmel*, L. Goubergrits* and K. Affeld*

* Biofluidmechanics Lab, Charité - Universitätsmedizin Berlin, Berlin, Germany

tobias.timmel@charite.de

Abstract: Purpose of this study is the optimization of an improved valve for cardiac assist systems. Clinical applications of these systems still suffer from thromboembolic complications. The problem often originates from thrombus formation behind the valve's leaflets. A thrombus is likely to form wherever the blood flow is stagnant. Especially in the sinuses of the valves stagnation areas are found. The valve design of the study presented here avoids the formation of the stagnation zone behind the leaflets by a purge flow during systole. This purge flow is separated from the valve's main flow by a flow divider directing a part of the main flow into the sinus behind the leaflet. The optimization in the present study was performed on a tri-leaflet valve. Two approaches were shown depending on whether the valve ships with a housing or not. In the latter case the housing and the flow divider can be designed freely. With a housing included, the flow divider's design is bound to the housing's geometry. The optimization was carried out numerically and experimentally. The results show that a sinus purge flow increases fluid exchange and thus minimizes stagnation areas in the sinus.

Introduction

Clinical applications of ventricular assist devices (VAD) continue to display one severe problem, that of thrombo-embolic complications. Thrombus formation often originates from the valves [1]. The thrombi normally develop in the sinus - the space between the leaflet and the housing. The housing is made of polymeric material or metal, for which a fast blood flow is required if it is to remain free of thrombi. However, the flow in the sinus is slow and partially stagnant. Wherever the flow is stagnant a thrombus is likely to form, as Virchow recognized in the 19th century [2]. Till to date there is no valve known which avoids this problem. Normally the flow design of heart valves is aimed to avoid flow separation and stagnation. The idea behind the new principle is to accept flow separation but to purge the regions periodically to avoid stagnant flow and to reduce the residence time of thrombo-active substances in the sinus. Thus thrombo-active substances that may have accumulated in the sinus are carried away. The wash-out process is generated by a purge flow that is diverted from the main flow during systole. Figure 1 demonstrates the principle of the new valve design. Because of its simple geometry a mono-leaflet valve is shown in figure 1; above the leaflet 3 is closed and below it is opened. The flow divider 1 is a protrusion of the wall into the duct 2. It directs the purge flow 5 (a part of the main flow 4) into the sinus 6. The purge flow turns around at the root of the leaflet 7 where the leaflet is attached to the wall and there it joins the main flow.

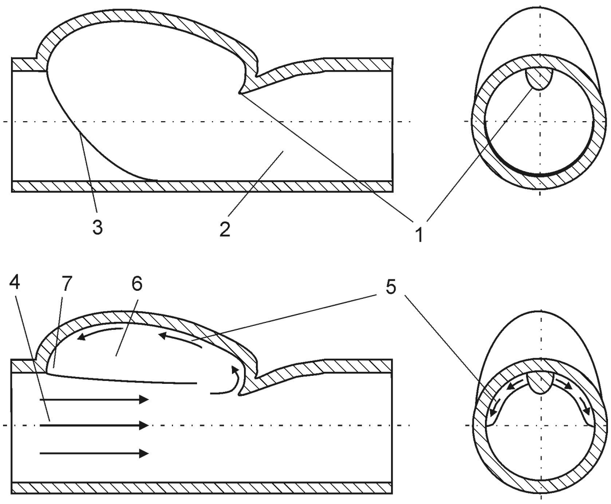

Figure 1: Principle of the purge flow shown on a mono-leaflet valve.

The principle of purge flow was investigated with experimental and numerical methods on a mono-leaflet valve [3]. It was shown that a flow divider can effectively generate a flow in the sinus region of leaflet valves, and thus may avoid stagnant blood flow behind the sinus. Objective of this paper is the application of the purge flow principle to the more often used and clinically relevant tri-leaflet valve. Investigation and optimization was exemplified on a commercially available stented bioprosthesis. For cardiac assist valves that are delivered with a rigid housing another approach is shown. The goal is an optimized heart valve for the use in VAD.

Materials and Methods

Exemplary application of the purge flow to a bioprosthesis. To investigate the purge flow principle on a tri-leaflet valve the commercially available stented bioprosthesis from InCor/Fisics (Brazil) was chosen. The bioprosthesis was scanned with a 3D scanner (resolution: $100\,\mu$m) to adapt the valve's housing to the leaflet's spe-

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cific geometry. The scan was done by GfaI e.V. (Germany). Resulting from the scan a 3D-CAD model of the stented valve was generated using the 3D-CAD system SolidWorks™ (SolidWorks Corp., USA) (see Figure 2).

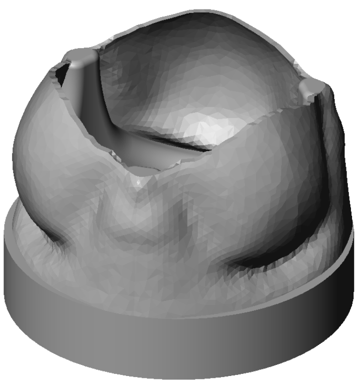

Figure 2: Model of the stented valve generated from a 3D scan

The geometries of housing and flow divider were designed considering the results from previous investigations carried out on the mono-leaflet valve [3]. The following geometric parameters were systematically varied: size and shape of the sinus and of the flow divider and the flow divider's position. Figure 3 shows the parameters on a 3D model in detail.

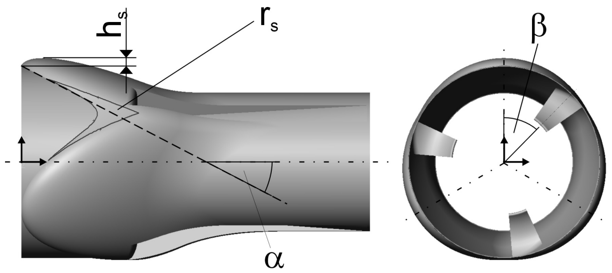

Figure 3: Varied geometric parameters (h_s: height of sinus cavity; r_s: transitional radius between sinus cavities; α: angle of construction plane for sinus dome; β: angle of flow divider's position relative to symmetric plane).

A total of 5 parameters with 3 levels each was varied. Thus the number of all possible parametric combinations would have led us to investigate 3^5 different geometric variations. This approach is known as full factorial design. Using a special technique from quality management - the Taguchi Method [4] - the number of models in question could be reduced to 9. This method is a partial fractional design that is used to produce the best parameters with the least number of experiments or designs. To permit direct estimation of the effect of the purge flow, the same 9 geometries but without flow divider were designed. The CAD model of one geometry with flow divider including the bioprosthesis is shown in a longitudinal section in Figure 4.

The flow investigation has been performing in two steps. First, the flow was calculated using methods of computational fluid dynamics (CFD). The tetrahedral unstructured meshes were generated using the preprocessors Gambit™ and TGrid™ (Fluent, Inc., USA). The leaflet was in systolic position i.e. the fully open position to assess the run of the purge flow. The computation of the Navier-Stokes equations for stationary flows was performed by the CFD solver Fluent™ (Fluent, Inc., USA). A standard k-ε turbulence model with standard wall functions was applied; turbulence was assumed to be 5 %. The inflow condition was constant, with a plug flow profile of $v = 1\,\mathrm{m/s}$. The blood was modeled as a Newtonian fluid with a kinematic viscosity of $\nu = 3.5 \cdot 10^{-6}\,\mathrm{m^2/s}$. Studies [5] show that at shear rates higher than $100\,\mathrm{s^{-1}}$ blood can be considered as a Newtonian fluid. With a valve's diameter of 0.02 m the Reynolds number is $Re = 5714$.

Table 1: Varied geometric parameters and their levels. The flow divider's position $\beta = 0°$ (symmetric) was not investigated due to the results from the mono-leaflet valve.

Parameter	**Levels**
h_s	1 mm 2 mm 3 mm
α	26° 33° 40°
r_s	– small big
Size of flow divider	small medium big
β	15° 30° 45°

The estimation of the wash-out process was carried out based on cumulative areas of low wall shear stress. Low wall shear stress indicates stagnation and thus promotes thrombus formation. Two ranges of low wall shear stress were defined: smaller than 0.5 Pa and smaller than 1.0 Pa.

In the second step later on, the models with the best numerical results will be investigated with a computer controlled valve tester. Physiological parameters will be measured and the washout of a dye filled in the sinus will be observed, recorded and and digitally quantified. The second step is still in process and not presented in this paper.

Application of the purge flow to a cardiac assist valve with housing. Valves intended for use in cardiac assist devices often ship with a rigid housing. Therefore the above mentioned way of adapting the valve's housing including

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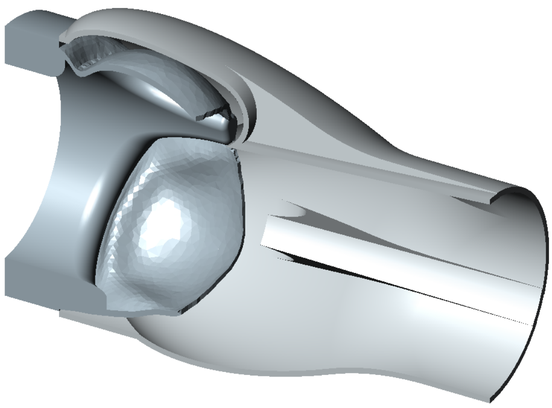

Figure 4: CAD model of a purge flow valve containing the digitized bioprosthesis in open position and the generated housing in a longitudinal section.

the flow divider is not applicable. A proper approach is to simply put a flow divider into the outflow duct of the valve.

To investigate the feasibility of this approach a simple star-shaped flow divider was put into the outflow duct of tri-leaflet polyurethan valve from Medos AG (Germany). Figure 5 shows the principle of this configuration.

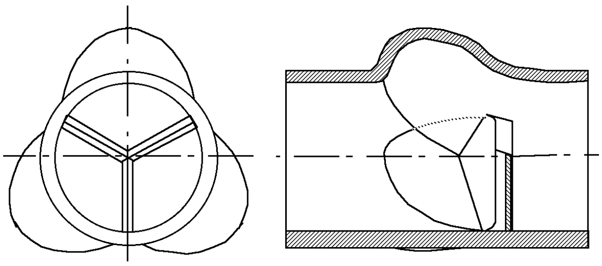

Figure 5: Possible application of the purge flow principle to cardiac assist valves shipped with a rigid housing: a star-shaped flow divider was put in the outflow duct of the valve.

The effect of the purge flow was investigated experimentally in a computer controlled valve tester. The proven wash-out method was used. A dye (black ink) was filled into the sinus and the wash-out process was observed and digitally recorded.

Results

Exemplary application of the purge flow to a bioprosthesis. Comparing the numerical results nearly all models with flow divider show a reduction of low wall shear stress areas. Figure 6 shows the cumulated areas of wall shear stress (WSS) smaller than 0.5 Pa and 1.0 Pa of all models. The direct comparison of geometries with and without flow divider indicates a general reduction of areas of low wall shear stress due to the flow divider. In model no. 3 the flow divider reduces areas of low walls shear stress especially effective. On the other hand the flow divider can even increase areas of low wall shear stress (e.g. model no. 1 and 6).

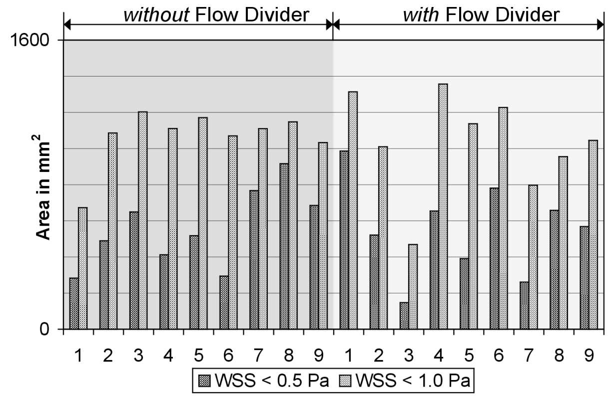

Figure 6: Result of numerical investigation: Cumulated areas of wall shear stress (WSS) smaller than 0.5 Pa and 1.0 Pa of all models. Except for three models the flow dividers reduces the formation of these areas.

Applying Taguchi's analysis one can derive the first order effect of every parameter on the formation of low shear regions. Therefore the cumulated areas of low wall shear stress of those models, having one parameter with the specific level in question, are added up and averaged. This procedure is done with all parameters and their settings. Hence the effect of a parameter is the difference of its level with the biggest value and its level with the smallest value. Besides, the parametric level with the smallest value of cumulated areas of low wall shear stress is the best setting of this parameter. As the chart in Figure 7 shows, the greatest effects have the transition between the sinus cavities and the position of the flow divider.

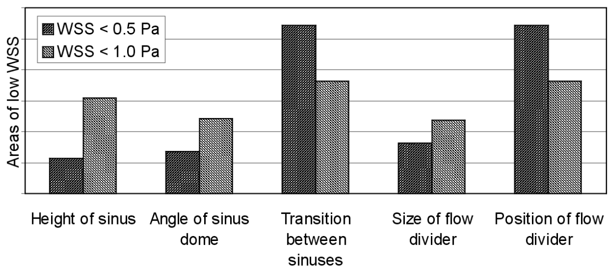

Figure 7: Result of numerical investigation: First order effects of parameters on formation of low wall shear stress (WSS) regions. The areas of low WSS represent the difference of the cumulated maximum and minimum.

Application of the purge flow to a cardiac assist valve with housing. Figure 8 shows a sequence of the recorded wash-out process for both, the valve without flow divider (upper row) and the valve with star-shaped flow divider (lower row). The shots are taken at four different moments. The graph below in Figure 8 contains the corresponding time-line of the flow. It is clearly visible, that already after two cycles the flow divider provides a better wash-out of the valve.

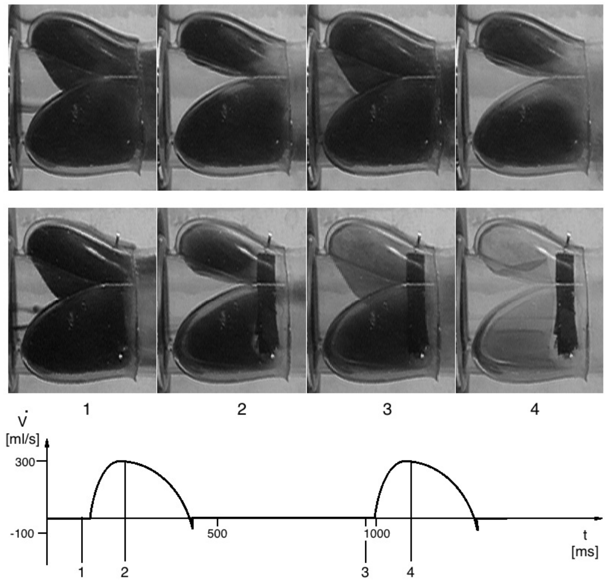

Figure 8: Result of experimental investigation: Sequence of the dye wash-out. The shots in the lower row show the valve containing the star-shaped flow divider. The moments when the shots were taken are visible in the corresponding time-line below.

Discussion

From the numerical analysis with Taguchi's method follows that the best parametric combination has a medium sized sinus cavity, an asymmetric position of a medium or large sized flow divider and no transition between the sinus cavities. This parametric combination already exists with model no. 3. As shown in Figure 6 this model produces the smallest areas of low wall shear stress in the sinus region. This confirms the results from Taguchi's method.

The experimental results show a faster wash-out of the model with flow-divider. Although the star-shaped flow divider is of a very simple geometry and was not optimized, the stagnation in the sinus cavities could markedly reduced. A detailed quantitative analysis and optimization process was abandoned. The experimental study shall just demonstrate the feasibility of the concept.

Conclusions

Two different approaches depending on the type of valve were introduced. For cardiac assist valves that ship with a rigid housing the proof of concept was experimentally shown. Design improvements and detailed investigation and optimization to decrease pressure loss and flow resistance would probably further improve the wash-out process. For valves that are available without housing, another approach with custom adaption of housing and flow divider to the valve's geometry was shown using quality management techniques and CFD. In the next step an experimental investigation will be carried out to validate the CFD and to further optimize the geometry.

The results of the numerical and experimental investigation show that a sinus purge flow increases fluid exchange and thus markedly reduces the stagnation areas in the sinus. The effect is likely to decrease the danger of thrombus formation.

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