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Hydrodynamic Effects of the Partial Opening of a Trileaflet Valve

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***Abstract*- Manufacturing process of medical grade silicon rubber trileaflet valves for VADs could propitiate important leaflet thickness variations which could result in partial opening of the valve and affect its hydrodynamic performance. The leaflets of a total of 10 valves were measured to assess its thickness variability. Two experiments were performed to asses the impact of the leaflets thickness variation under hypothetical situations. The first experiment was divided into three hypothetical cases. In each case either none, one or two leaflets of different valves were mechanically blocked, resembling possible critical working circumstances. The second experiment was intended to know how the variation on the leaflets thickness affects the hydrodynamic performance of the valves. The results demonstrated a significant variation on the leaflets thickness was found. As for the first experiment, a small variation on the hydrodynamic performance was found above 4 L/min flow rates and a slightly higher energy loss was found in one of the cases. As for the second experiment, the results showed that the variation of the leaflet thickness does not affect the general hydrodynamic performance of the valves. No relationship between the thickness variability and the hydrostatic performance of the valves was found.**

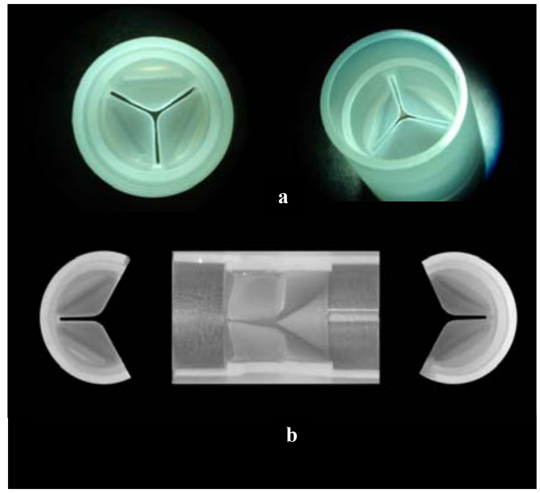

Fig. 1. Pictures of the valves and the detail of the leaflets. In a) an upper picture shows the whole valve. In b), one leaflet was cut and removed.

I. INTRODUCTION

The use of Ventricular Assist Devices (VADs) is becoming an important alternative in acute heart failure, cardiogenic shock, cardiac surgery and rehabilitation [1-5].

Performance and hemodynamic efficiency of VADs rely, in an important extent, on the parameter-based refinement of valve design. Development of different valve designs for cardiac support systems can be evidenced in the literature [6-15]. Variations on design and materials influence valve performance. Regurgitation, flow rate and hemolysis are exemplar valve-dependant hydrodynamic VAD design parameters [6, 14-16].

In a recent publication, our group reported the hydrostatic performance comparison of two new silicon rubber valves [17], as part of the complete design of a pneumatic VAD [18]. The conclusions of the study dictated the preference for a trileaflet valve design for the VAD developed by Sacristan et al. However, after manufacturing the first lot of this valve design, we noticed that sometimes, under preliminary rough tests using air, and for some valves, only one leaflet opened. We tested several valves under different transvalvular pressure gradients and we observed that occasionally one leaflet opened, and other times two or all three leaflets opened. This behavior was not consistent for all valves, so we supposed that it could be due to a variation on the leaflets thickness. The manufacturing process used for the fabrication of trileaflet valve design is appropriate for biocompatibility purposes, but does not allow an optimal control of mechanical tolerances. The variability on the leaflet thickness, due to the manufacturing process leads to important questions about the hydrodynamic valve performance. When a leaflet is much thinner than the other two leaflets, just the first one is likely to open when a pressure gradient is applied. A similar situation occurs when a leaflet is considerably thicker than the other two. Just two leaflets are likely to open. This fact does not mean that in a real situation only one or two leaflets will open. One will fully open and probable one or two more will partially open. To evaluate the possible hydrodynamic effects of the partial opening of the valve leaflets, this study considered three possible scenarios: the opening of one, two and three leaflets. These cases enclose the possible leaflet partial opening combinations.

The aim of this study was to assess the leaflet thickness variation of a sample from a lot of manufactured trileaflet silicon rubber valves, and to evaluate how this fact could affect the hydrodynamic performance of the valve.

II. VALVE DESIGN

The design is one-piece trileaflet type of supple and elastic low-durometer medical grade silicon rubber. The material allows the valves to stretch and deform under pressure gradients reducing the risk of blood components damage. The valve is hinge-less and the leaflets are flexible and elastic, simulating the action of natural heart valves, improving their reliability and durability. The valves are injection molded and were designed as evolution from a

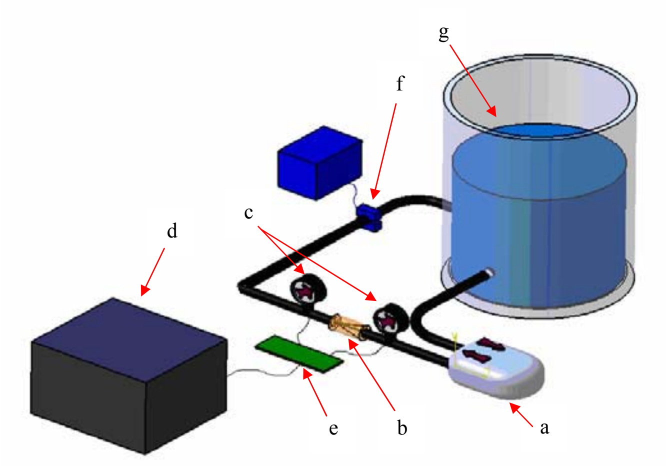

Fig. 2. Experimental Set up, where a) is the constant rate puma, b) the testing zone, c) the pressure sensors, d) the PC, e) the data acquisition card, f) flow probe, and g) the reservoir.

bileaflet valve design reported previously [17, 18]. The non-attached part of each leaflet was designed as planes that start from the valve rib corner and converge in the middle of the leaflet on a normal plane to the valve axis, having an offset from the starting point and allowing the leaflets to completely close the center of the valve. Although some parts of the leaflets experience stretching during their open configuration they also fold down, having non-stretching zones. CAD models for the design of the valves were made by using *Inventor*™ software.

III. Materials and Methods

Leaflet Thickness Variability

We believe the silicon rubber trileaflet valve is optimal for the application it was designed for. However, the involved manufacturing process is not the ideal for the scale design of the trileaflet valves involved in this study. Nevertheless, it is suitable for the future medical application of the valves and convenient from a cost-benefit point of view. Better tolerances and probably less variation in the leaflet thickness could be achieved at a higher cost. For this reason, the aim of this study was to find if the variation of the leaflets allowed by the used manufacturing process is significant and if affects, significantly, the hydrodynamic performance of the valve.

To assess the leaflet thickness variation, a digital camera (Kodak, Germany) and a stereoscopic microscope (Zeigen, Germany) were used. The leaflet thickness of 10 valves was measured at the apex of the leaflets using CAD software.

Experimental Set Up for Hydrostatic Experiments

A Mock Loop was shortcut to acquire an optimal hydraulic resistance configuration for the experiment. The set up consisted of a centrifugal constant flow rate pump (Lifestream Centrifugal Pump System 2100CM, USA), a testing zone and a reservoir, all connected by rigid and soft polymer tubing (Fig. 2). The testing zone consisted of rigid tubing having the testing valve inside, two pressure sensors coupled to two monitoring kit TruWave disposable pressure transducers (Edwards Lifesciences, USA). The three different cases of the study were achieved by the mechanical blockage of one, two and none leaflets of different trileaflet valves. Pressure signals were recorded in a personal computer by using a Data Acquisition System CIO-DAS08/Jr (Measuring Computing, USA). The flow rate was measured with a Transonic flow probe 16A540 connected to a T-106 Transonic flow-meter (Transonic, USA) which was calibrated by using a standard flow measuring method. A 65% saline and 35% glycerin (in volume) solution at room temperature was used to mimic the properties of blood at 37°C as referred by Sturm et al. [19].

Hydrostatic Experiments

For the hydrodynamic performance evaluation, two different experiments, using the same experimental set up, were considered.

In the first experiment, a theoretical, ideal experiment was designed. This experiment contemplated three cases. In the first case, two leaflets of a valve were mechanically blocked by filling their concave space with epoxy resin (ITW PolyMex S.A de C.V, Mexico), leaving the thinnest leaflet free. This configuration simulated the extreme case when just one leaflet, probably the thinnest one, would open. For the second case, the thickest leaflet of a valve was blocked. This case simulated when a leaflet in a valve in found to be considerably thicker than the other two, or when two leaflets were considerably thinner than the other one, having just one leaflet able to open. The hydrodynamic performance of the cases was assessed by calculating the Pressure Gradient Drop under flow rates varying from 1 to 20 L/min at 1 L/min steps and the Effective Orifice Area Index (EOA Index) reported by Yoganathan et al. [20] according to the following equation:

$$EOA(\text{cm}^2) = \frac{Q_{rms}}{51.6\sqrt{\Delta p}}, \tag{1}$$

where Q_{rms} is the root mean square systolic/diastolic flow rate (cm^3/s) and Δp is the mean systolic/diastolic pressure drop (mm Hg).

In the second experiment, flow rate values were varied from 2 to 20 L/min in steps of 2 L/min by adjusting the centrifugal pump. The transvalvular pressure of the 10 valves used for the leaflet thickness measurement was calculated and plotted for each flow rate. This second experiment was used for two purposes: to evaluate the variation of pressure drop between the valves of the lot sample; and to prove whether the variation of the leaflet thickness has a significant effect on the valve performance or not.

Prior the experiments, the reservoir was set to a hydrostatic pressure of 10 mmHg, and the pressure transducers calibrated.

V. Results and Discussion

Leaflet Thickness Variability

As mentioned before, the variation on leaflet valve thickness was supposed to have important consequences in

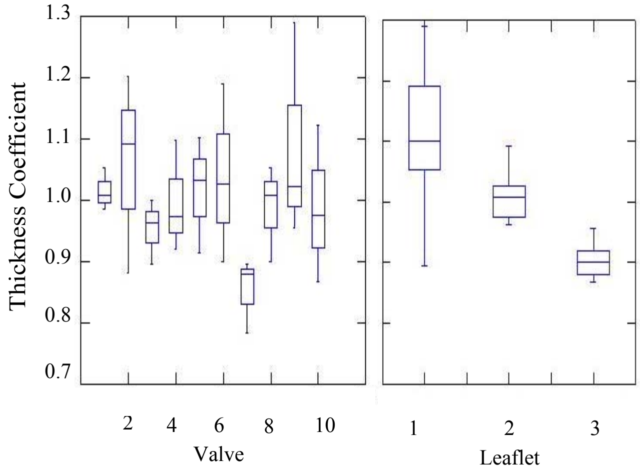

Fig. 3. Variability on leaflets thickness for each group.

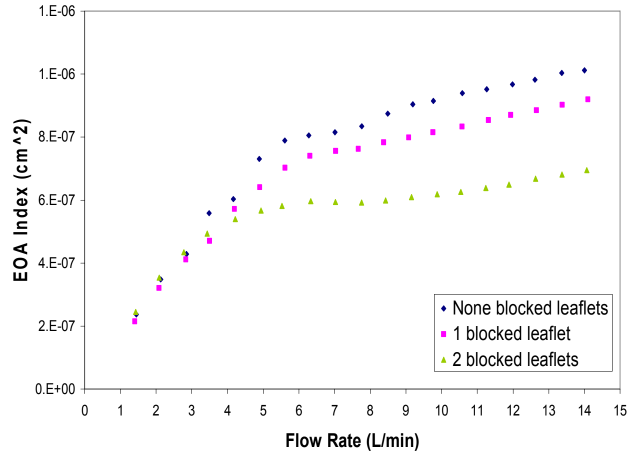

Fig. 4. Effective Orifice Area Index of the three cases.

terms of valve hydrodynamic performance. For this reason, the thickness variability measurement among leaflets of the same valve and among leaflets of different valves was desirable to obtain. A sample of 10 valves was taken out from a lot of 50. Every valve leaflet from the sample was numbered. A number 1 was given to the thickest and a number 3 to the thinnest leaflets. The basic descriptive statistics for the measurements is shown in Table 1 for n = 30. Thickness measurements were divided over the overall mean thickness to obtain a coefficient as shown in Fig. 3. It can be observed that the variation between leaflet groups is considerably high. Actually, within group 1, which corresponds to the thickest leaflet of each valve, the variation is high. For groups 2 and 3, outliers can be observed. In Table 1, a standard deviation equivalent to 11.2% of the mean thickness coefficient is observed. Moreover, 28 out of 30 values lied outside the confidence limits. All the previous facts, demonstrated a significant variation on the leaflet thickness of the valves. Therefore, the following step was to test the valves, hydrostatically with the previously mentioned experiments.

TABLE I

LEAFLET THICKNESS DESCRIPTIVE STATISTICS

Mean	1.000
Minimum	0.783
Maximum	1.289
Median	0.993
95% CI Upper	1.042
95% CI Lower	0.958
Standard Dev	0.112

Hydrostatic Experiments

Two experiments were carried out. The first experiment was used to have a theoretical energy loss approach under extreme situations. The second experiment was to test the variation of the pressure drop between the valves used to assess the leaflet thickness variability discussed in the previous section.

For the first experiment, three cases were considered as mentioned in section IV. For these cases, measurements of prevalvular and postvalvular pressures were acquired via a data acquisition system and a personal computer. Pressure difference and flow rates were used to calculate and plot the Effective Orifice Area Index, according to equation (1), shown in Fig. 4. In his work, Yoganathan et al. explain the Effective Orifice Area (EOA) Index in terms of energy. The larger EOA Index, the smaller energy loss due to a transvalvular pressure gradient. In Fig. 4, the Indexes of the three cases are shown for a spectrum of 20 L/min flow rate, with 1 L/min steps. A better index for the cases when one or none leaflets were blocked was obviously expected. However, the importance on the information lied in the evaluation of the difference between the cases. As observed, the difference between the three cases is not equivalent. A smaller difference between the first and the second cases was found, as compared to the difference between the second and the third cases. When only one leaflet is blocked, or its equivalent hydraulic area due to a combination of the leaflets is obtained, the hydrodynamic performance is about the same as when none of the leaflets are blocked. Actually, for low flow rates, the difference is null. In the case of when two leaflets are blocked, the difference becomes more

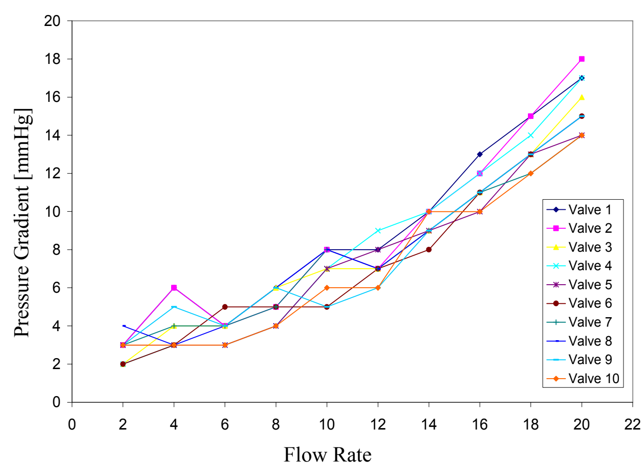

Fig. 5. Pressure Gradient under different Flow Rates.

important for flow rates higher than 5 L/min. In general, this first experiment showed us a theoretical EOA Index spectrum of the valves: from a critical situation, having two very thicker leaflets, to a regular working condition, having all three leaflets free to open. All possible combinations of partial opened leaflets will rest inside this range.

For the second experiment, the pressure gradient under different flow rates was measured for each of the 10 valves, as shown in Fig. 5. It can be observed that the variations between valves do not correspond to any specific thickness-related trend. We could expect a higher hydraulic resistance in valves 2, 6 and 9, that correspond to the three valves that have thickest leaflets in average (Fig. 3). However, in Fig. 5 they do not show a significant difference as compared to the rest of the valves.

VII. Conclusions

Leaflet thickness of the valves used in this study, were found to have significant variation due, presumably, to the manufacturing process. The variation was found between leaflets of the same valve and between leaflets of different valves.

For the first experiment conducted in this study, energy loss due to the block of one leaflet, or its equivalent hydraulic area, is small, as the slightly offset of the EOA index proves. In contrast, when two leaflets do not open, the offset is as large as four times, compared to the previous case. As a general conclusion, we can suggest that, as long as the equivalent hydraulic area equals the surface of two leaflets together, the hydrostatic performance of the valve will be acceptable for hypothetical or the critical cases presented in this work. Although these cases are not likely to happen, they are useful for knowing the performance limits of a valve during a possible critical situation. Moreover, this experiment demonstrated that there is no hydrodynamic performance difference between the cases, at flow rates below 4 L/min.

For the second experiment, we can conclude that under real working conditions, the variation of the leaflet thickness does not affect the general hydrodynamic performance of the silicon rubber trileaflet valve presented in this study. Therefore, we conclude that for future applications, the manufacturing process used for the fabrication of the studied valves of this work is good enough, and that the thickness variation of the leaflets in the valves will not affect in an important manner, the VAD performance. No relationship between the thickness variability and the hydrostatic performance of the valves, under the realistic scenario of this second experiment, was found.

Acknowledgment

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