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EFFECTIVE ORIFICE AREA OF A NEWLY DEVELOPED POLYURETHANE AORTIC VALVE: MANUFACTURING AND EVALUATION

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Key words: polyurethane (PU) aortic valve, molding technique, effective orifice area (EOA).

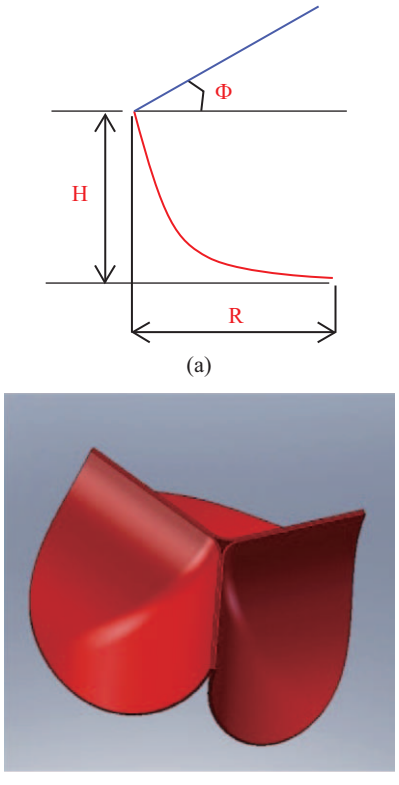
ABSTRACT

An optimal design for a polyurethane (PU) aortic valve was developed in a previous study. The current study investigated an approach for manufacturing PU aortic valves, evaluating the effective orifice areas (EOAs) of the prototypes. Two manufacturing approaches, assembly and single-piece forming methods, were developed. In the assembly method, support frames and valve leaflets were manufactured separately and then glued together by using an adhesive substance. By contrast, in the single-piece forming method, two main components of the valve were fabricated simultaneously by using a molding technique. This study established an experimental loop that mimics natural circulation from the left ventricle through the aortic valve to the aorta to observe the opening and closing behaviors of the valve. In addition, a testing loop was developed for measuring the EOAs of the manufactured valves. The approach developed in this study can be a procedure for efficiently developing a quick fabrication and testing method for PU heart valves, thereby reducing the cost of fabricating these devices in the future.

I. INTRODUCTION

Polyurethane (PU) prosthetic valves imitate the geometry of native valves, thereby providing high hemocompatibility and favorable biomechanics.

The shape of these valves varies widely, ranging from hemicylindrical cusps [11] to leaflets in a half-open position [5, 6], from variable-curvatures [7] to elliptical and hyperbolic shapes [8], and from a conical base with a spherical upper part [1] to high-profile cusps [3, 9]. A comprehensive study has never been conducted on the effect of design parameters on the biomechanics of PU valves.



(a)

(b)

Fig. 1. (a) Valve leaflet design parameters, (b) valve leaflet model.

The present study simplified the design of PU aortic valves according to five main parameters, namely the valve radius (R), valve height (H), angle of the free edge (Φ), leaflet thickness, and fundamental curve (red curve in Fig. 1(a)). Vu [10] thoroughly described these five design parameters and the optimization process for determining such parameters. The

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optimal design parameters were a height of 17.5 mm, free edge angle of 0°, thickness of 0.3 mm, and fundamental curve of a logarithm for a valve radius of 11.75 mm [10].

This study focused on manufacturing and evaluating the effective orifice area (EOA) of the PU valve design. Two fabrication approaches that involve using a molding technique were developed, and a testing loop was established for evaluating the EOA performance of the valves.

II. METHODOLOGY

1. Fabrication Approach

1) Assembly Approach

In the assembly approach, the support frame and leaflets of the PU aortic valve were manufactured separately. The support frame was created from a PU cylinder that was processed on a mini computer numeric control machine (mini-CNC). However, the fabrication process of the PU valve leaflet was more complex. In this process, a PU layer with an appropriate thickness was first developed. This PU layer can be custom fabricated by a materials laboratory or company. A plastic mold was manufactured using the mini-CNC to shape the layer according to the designed geometry. Finally, the PU support frame and PU leaflets were glued together by using epoxy glue. Through this method, different types of PUs can be applied to the support frame or leaflets according to particular stiffness or flexibility requirements.

2) Single-Piece Forming Approach

For the single-piece forming approach, the support frame and leaflet were manufactured simultaneously using a set of male and female molds. The manufacturing process was similar to that of compression molding. Both the male and female molds were created from silicone, which can ease the process of removing the prototype of the PU valve from the mold after shaping. The distance between the two molds was precisely designed to control the thickness of the valve leaflet.

A debubbling process was performed in a vacuum degasser, and the PU was poured into the female mold; the male mold was subsequently pressed onto the female mold. After the drying process, the prototype was removed from the mold.

2. Testing Loop

This study assessed the opening and closing behaviors of PU aortic valves and measured the EOA of the valves. Two testing loops were established for evaluating the performance of the valves.

1) Opening and Closing Observation Loop

The testing loop (Fig. 2) was established for detecting the opening and closing behaviors of the PU valve prototypes. The loop comprises four key components, namely a waveform generator, pneumatic pump, transparent tube, and high-speed camera.

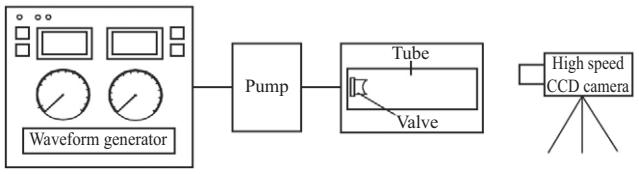


Fig. 2. Opening and closing observation loop.

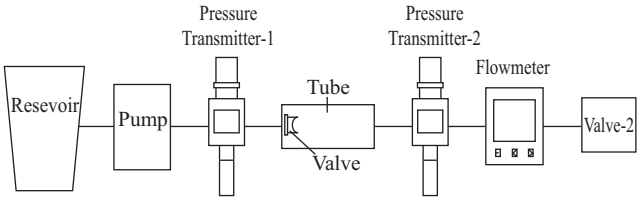


Fig. 3. EOA measurement loop.

The waveform generator is used to generate a pulsatile air stream for controlling the output of the pneumatic pump. An air compressor serves as the air supplier for the waveform generator. An output that mimics pulsatile flow in a natural heart flows through the tube and is ejected through the testing valve. The tube, which serves as a sinus model, is transparent to ensure that a light source can affect the quality of the picture captured by the high-speed camera. The high-speed camera can operate at a speed exceeding 400 frames per second, and is thus used to capture the movement of the valve leaflet at short time intervals.

2) Effective Orifice Area Measurement Loop

The EOA can be computed in square centimeters as follows [2]:

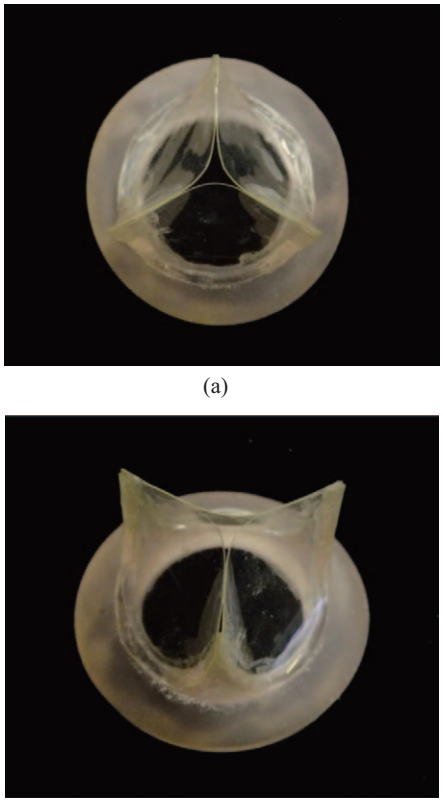
$$\mathrm{EOA}(\mathrm{cm}^2) = \frac{Q_{rms}}{C\sqrt{\Delta p}} \tag{1}$$

where Q_{rms} is the root-mean-square (rms) flow rate (mL/s) during the forward flow through the valve, and Δp is the mean pressure drop (mmHg) across the valve. The constant C (51.6) [4] is based on the discharge coefficient used for the aortic valve.

Fig. 3 illustrates the measurement loop that was used for evaluating the EOA according to the pressure drop and flow rate across the valve when it fully opened. The pump pushed the water from the reservoir through the PU valve prototype mounted on a transparent tube. Pressure Transmitter 1 and Pressure Transmitter 2 measured the pressure drop across the valve, and a flow meter detected the flow rate through the valve. Within the limitations of the experimental conditions, the opening and closing processes were computed by adjusting Valve 2 manually.

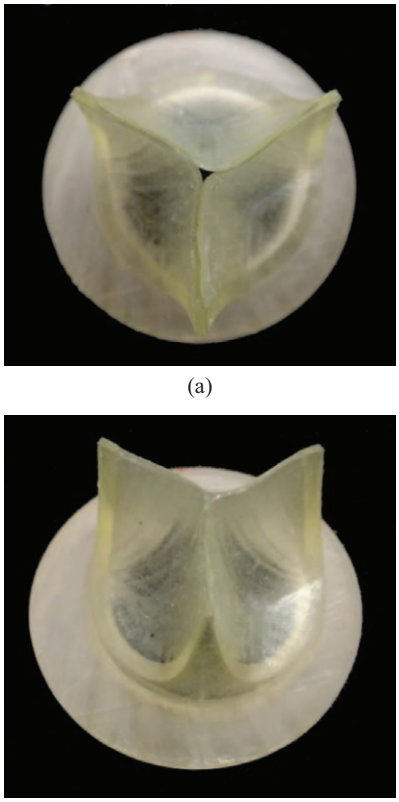
III. RESULTS AND DISCUSSION

As stated in the Introduction, the optimal design was a PU



(a) (b)

Fig. 4. Assembly valve prototype: (a) top view, (b) front view.



(a) (b)

Fig. 5. Single-piece forming valve prototype: (a) top view, (b) front view.

aortic valve with a height of 17.5 mm, free edge angle of 0°, thickness of 0.3 mm, and fundamental curve of a logarithm for a valve radius of 11.75 mm. This design satisfied all proposed criteria, such as an efficient opening and closing time and a substantial opening level. In practice, a PU valve model consists of two main components, a support frame and leaflets.

1. Assembly Prototype of Polyurethane Aortic Valve

Fig. 4 shows a prototype of the PU aortic valve manufactured using the assembly approach. The advantage of the assembly approach is that various PU can be used to fabricate the support frame and valve leaflets according to particular flexibility or stiffness demands. In this study, the support frame was fabricated from a PU cylinder, whereas the leaflets were fabricated from a PU layer purchased from a materials company. Because this study focused on the leaflets, the material properties of only the PU layer were measured. The tensile test revealed that the Young's modulus of the PU sample was 1.67 MPa.

The layer was shaped according to the leaflet geometry, and the leaflets were glued onto the support frame manually. Although the shaping process was performed using a plastic mold, the accuracy of the leaflet geometry was substantially dependent on the manual gluing outcome. This disadvantage may have affected the accuracy of the dimensions, thereby affecting the accuracy of the experimental results. Moreover, this approach cannot be used if many prototypes must be fabricated in a short period.

2. Single-Piece Prototype of Polyurethane Aortic Valve

The prototype of the PU aortic valve manufactured using the single-piece approach achieved a substantial accuracy rate. Furthermore, the single-piece approach afforded an option for manufacturing many samples without losing accuracy. As previously mentioned, the leaflet thickness was determined according to the clearance between the internal wall of the female mold and external wall of the male mold. The PU fluid sometimes filled the gap incompletely, thus causing errors, such as tears on leaflet surfaces and a nonuniform thickness in the sample.

In the current study, a PU valve prototype was manufactured using ordinary PU (Fig. 5). However, the properties of this sample and the uniformity of the leaflet thickness could not be measured because the necessary equipment was unavailable. Furthermore, the PU generated adhesiveness between the commissure of the leaflets; the reason for this was not clearly understood. These disadvantages may have affected the accuracy of the experimental results.

3. Opening and Closing Behaviors

The simulation and testing results regarding the opening and closing behaviors of the PU aortic valves at selected

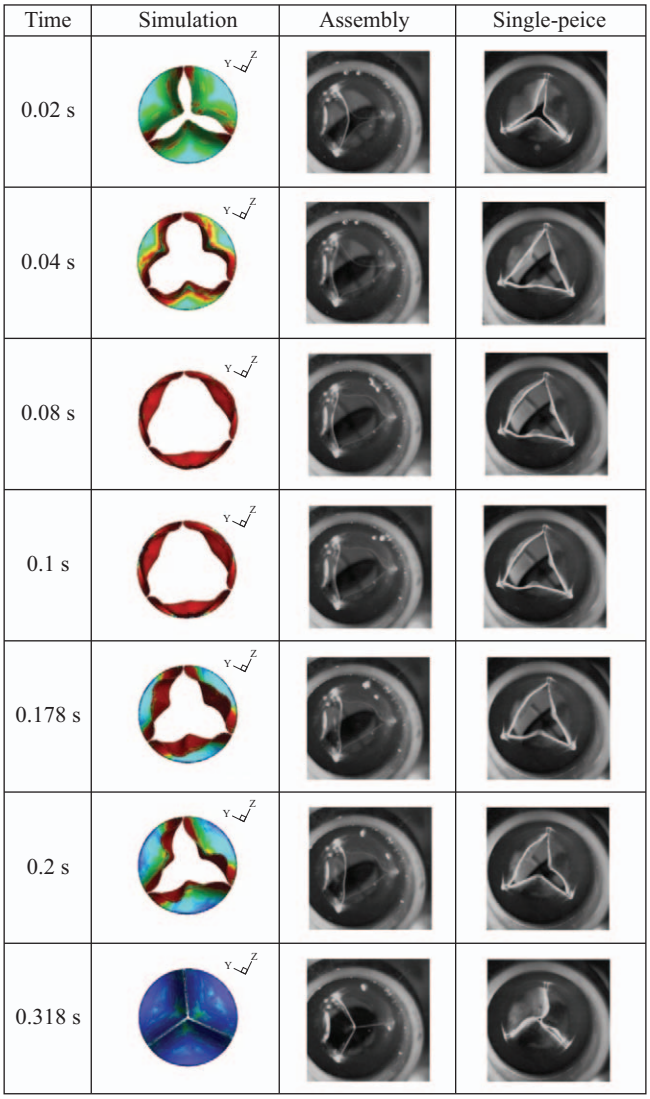


Fig. 6. Opening and closing behaviors: simulation versus testing.

moments during systole were compared; Fig. 6 illustrates the comparison results (see Vu [10] for a detailed description of the numerical simulation model). Valve opening and closing during systole involves a strong interaction between blood and the surrounding tissue. The fluid-structure interaction (FSI) in the aortic valve involves a coupling of the fluid (blood) domain with immersed structures (the valve leaflets) and bounding structures (the aortic root and wall). The coupling approach was based on a weak theory that assumes that flow simulation occurs first, followed by structure simulation, which was based on variables from the flow simulation. Flow simulation can typically be used to determine fluid variables, such as pressure and velocity (related to the surface and volume), of the simulated object. After the aforementioned variables were applied, structure simulation was used to determine the displacement (deformation) and von Mises stress. The updated geometry was imported to conduct another flow simulation.

In this approach, FLUENT (CFD codes) begins computing and sends data (pressure or shear stress) to ABAQUS (FEA code), which then computes one step and sends data (node moving positions or face deformation) back to FLUENT for the next step. The data exchange is performed entirely by using commercial computer-aided design packages.

This study investigated the FSI in the aortic valve entirely by using commercial software with no complex calculations and programming. The deformed surfaces or volumes in ABAQUS (FEA codes) were delivered to FLUENT (CFD code) for fluid dynamics analysis by using Altair HyperMesh (for reading and recreating deformed surfaces) and SolidWorks (for regenerating the fluid working domain according to deformed valve leaflets). The coupling process corresponded to a serial algorithm in which, at each step, one code was running while another code waited for exchanging data. The simulation was simplified, and the entire deformation analysis in ABAQUS was operated independently by using predetermined loads (transvalvular pressure) and assuming that the valve was subjected to only this pressure during the systolic phase. The deformed valve leaflets in each step were then exported to FLUENT for flow analysis. The simplification revealed promising results that were adequately consistent with strong coupling solutions reported in a previous study [2]. Thus, the current study concluded that the simulation results were completely reliable, and that the proposed method can be used in future studies on FSI in the aortic valve. In the current study, the coupling process was performed manually, enabling users to control and alter the convergence of each computational step in both FLUENT and ABAQUS. This is an advantage of the proposed method; other commercial coupling software packages such as MpCCI operate by assuming that all analyses in both codes converge. However, the proposed method requires a substantial amount of time to complete and is almost impossible to apply when the step size is small. Therefore, the number of steps should be high. The authors are currently developing an interface for exchanging data between CFD and FEA codes more effectively.

As shown in Fig. 6, the behaviors of the assembly prototype were relatively similar to the simulation results, particularly during the ejection time (0.08-0.1 s) and closing time (0.17-0.318 s). The simulation results and testing results of the assembly prototype differed by 0.02-0.04 s.

As previously mentioned, the quality of the prototype manufactured using the assembly approach was highly dependent on manual skills, possibly leading to geometric discrepancies between the design and prototype. This discrepancy may have resulted in the difference between the simulation and testing results of the assembly prototype.

However, the results of the single-piece prototype contrasted with those of the assembly sample. During the opening time (0.02-0.04 s), the testing results were similar to those of the simulation results. However, during the rest of the cycle (0.08-0.3 s), the prototype of the single-piece valve behaved as a valve with two abnormally thick leaflets. The geometric

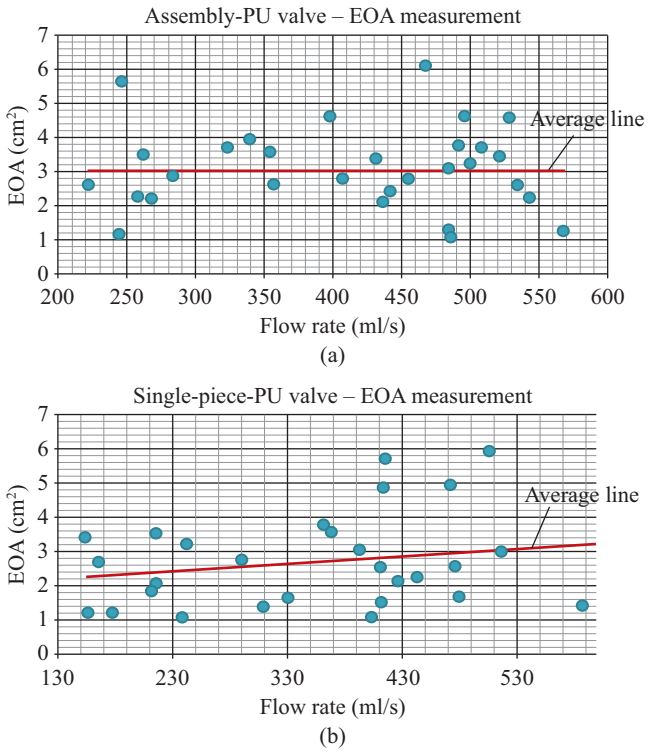


Fig. 7. (a) Assembly valve: EOA measurement; (b) Single-piece valve: EOA measurement.

accuracy of the prototype manufactured using the single-piece forming approach is presented in the preceding section. However, as mentioned previously, the fluid material sometimes did not completely fill the space between the female and male molds, thus leading to a nonuniform thickness of valve leaflets. Furthermore, adhesiveness was generated between the commissure of leaflets. These two disadvantages could have caused the valve to not open fully during the ejection time.

4. Effective Orifice Area Measurement

Fig. 7 shows the measurement results, obtained from the EOA measurement loop, of the assembly and single-piece PU valves. In this test, the flow through the valve was manually controlled by adjusting Valve 2 of the EOA measurement loop; manual control caused unstable flow rates (Fig. 7). However, the test results revealed high accuracy when most of the measured points were distributed around the average line.

The difference in the opening and closing behaviors between the assembly and single-piece valves was confirmed according to the results of EOA measurement. The advantages of the assembly valve were a high opening level during ejection time (0.08-0.1 s), an EOA of approximately 3.03 cm^2, and high stability of the output, resulting in a high distribution around the average line of the measured points. However, because the thickness of the leaflets was nonuniform, the EOA of the single-piece valve was nearly 2.70 cm^2. In addition, the measured points of the single-piece valve were scattered around the average line, reflecting an unstable output.

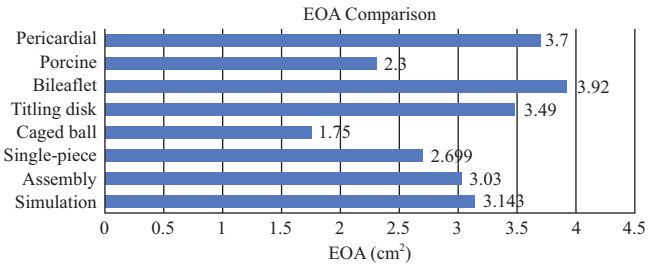


Fig. 8. EOA comparison.

The EOA measurement was conducted to compare the measured results with the simulation results of the PU aortic valve. The simulation and testing results were highly consistent with acceptable deviations (Fig. 8). The errors in the fabrication process and nonideal experimental conditions could account for these differences. This study concluded that the testing results were reliable.

The EOA of the designed PU aortic valve was also compared with that of existing products, such as a caged ball, a titling disk, a bileaflet, and porcine and pericardial valves, by using data provided by Chandran [2]. Although several drawbacks must still be improved, the developed PU valve exhibited a highly promising performance.

IV. CONCLUSION

This paper proposes two fabrication approaches, assembly and single-piece forming methods, for manufacturing PU prosthetic valves. In the assembly approach, different PU, or even different polymer materials, can be applied to the support frame and leaflets depending on particular flexibility or stiffness demands. However, most steps in this method are performed manually, and the geometric accuracy of the prototypes depends on the processing techniques. This method is almost impossible to apply when many samples must be produced in an extremely short period.

In the single-piece forming method, geometric errors can be considerably eliminated during manufacturing processes; this method is an appropriate option when many samples must be manufactured. In this study, the male and female molds were fabricated using silicone, which facilitated the process of removing the prototypes; however, this material is probably not ideal for fabricating molds in practice. This disadvantage may explain the nonuniform filling of the space between the male and female molds. The valve leaflets exhibited nonuniform thickness because this space was designed to form the thickness of the valve leaflets. To improve the quality of the valve prototype, other materials such as metal must be used to fabricate the molds and modify the structure of the molding system.

The valve with the optimal design parameters exhibited a highly promising performance compared with that of existing products; however, the fabrication process has shortcomings. This study used ordinary PU to manufacture the prototype

valve; biopolyurethane materials were not considered. Furthermore, fatigue testing of the prosthetic valves was not performed. These shortcomings must be addressed in future studies.

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