in-vitro Assessment of Expanded-Polytetrafluoroethylene Stentless Tri-leaflet Valve Prosthesis for Aortic Valve Replacement

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Abstract: Truly stentless polymeric valve prosthesis can be a viable alternative for aortic valve replacement (AVR). In the present paper, the dynamic and hemodynamic performance of a novel designed expanded-polytetrafluoroethylene (ePTFE) stentless tri-leaflet valve was assessed experimentally. The *in-vitro* tests were performed under time-varying physiological pressure by using the Vivitro pulse duplicator. A high-speed camera, a flow meter, and pressure transducers were utilized to evaluate the dynamic leaflet behaviours and coaptation parameters. The maximum effective orifice area, mean pressure gradient, regurgitant volume, leakage volume and energy loss of the stentless ePTFE tri-leaflet valve are 2.86 cm^2, 9.89 mmHg, 7.09 ml/beat, 2.81 ml/beat and 129.03 mJ, respectively. The results of the current study may provide a viable option for the future clinical application.

1 INTRODUCTION

The Ross procedure is a widely accepted surgical option for the treating of the aortic valve failure (Ross 1967; Talwar et al. 2012; Brancaccio et al. 2014; Oury et al. 1998). However, for the patients with a diseased pulmonary valve or in a severe situation, the standard AVR thus became an alternative treatment method of the aortic valve failure.

The need for AVR is increasing for pediatric patients. And the quest for a perfect aortic valve substitute has been going on for more than fifty years (Lower et al. 1960). The selection of the ideal prosthesis for AVR is controversial (Mazzitelli et al. 1998). Multiple surgical options for AVR are available for these patients, including stented and stentless porcine valves, porcine valve conduits, bovine jugular vein conduits, mechanical valves and mechanical valve conduits. The prosthetic selection for AVR, however, is still debatable, and all choices have significant limitations.

The use of polymeric materials for valve leaflets has been more than 60 years (Roe & Moore 1958). Polymeric valves' long-term durability and no need of permanent anticoagulation combined the advantages of mechanical valves and bioprosthetic valves (Sachweh & Daebritz 2006). Among the polymeric materials, ePTFE valves have shown good performance in the recent clinical trials in pulmonary sites(Miyazaki et al. 2011; Miyazaki et al. 2007).

However, there is a lack of information about the application of ePTFE valves in aortic site. To expand the current understanding of the performance of the ePTFE valves in the aortic site, the dynamic and hemodynamic performance of an ePTFE tri-leaflet aortic valve prosthesis was assessed in this paper.

2 METHODS

2.1 Preparation of Physical Model

The design parameters of the tri-leaflet valve were listed in Table 1.

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Table 1: Design parameters of the conventional tri-leaflet valve.

Design Parameters	Value
d_b (mm)	25
d_c (mm)	25
H_s (mm)	4
H (mm)	21.9
A (mm^2)	561.3

A set of resin mold based on the geometry was fabricated by using 3D printing technology (Figure 1).

Figure 1: 3D Printed Resin Mold.

The valve leaflets were prepared by placing the ePTFE membrane in-between the mold and cutting along the edge. The aortic root was constructed by using the silicon polymer (VTV, MCP-HEK Tooling GmbH, Kaarst, Germany). Guiding lines were cast inside the silicon conduits to guarantee the leaflets can be properly sutured (Figure 2).

Figure 2: Silicon Conduit.

The commissures of the leaflets were sutured to the aortic root with one running 4-0 polypropylene suture following the guide line in the conduit (Figure 3).

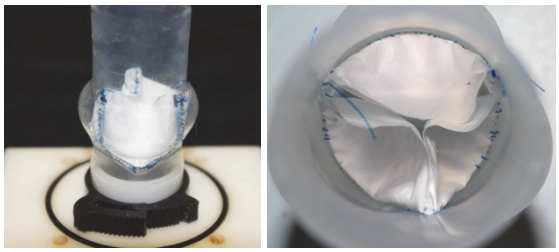


Figure 3: Valved Conduit.

2.2 Experimental Set-up and Flow Conditions

The Vivitro pulse duplicator (Vivitro Systems Inc., Victoria, BC, Canada) was used to generate the physiological pressure and flow in the left ventricle and aorta.

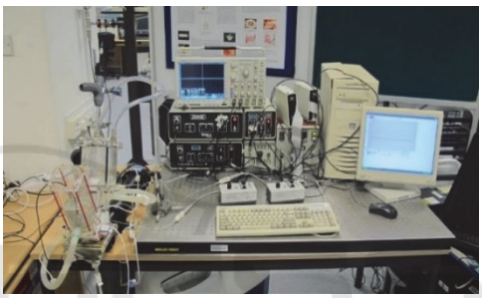


Figure 4: Experimental Setup.

The physiological pressure applied in the *in-vitro* investigation was shown in Figure 5. The ventricular and aortic pressures were measured at the exit of the left ventricle and the exit of the aorta model by pressure transducers (SPC 330A, Millar Instruments, Inc., Houston, TX, USA), respectively. The pressures were controlled by adjusting the resistor and piston movement magnitude. The systolic and diastolic pressure in the aorta is 120 mmHg and 80 mmHg, respectively.

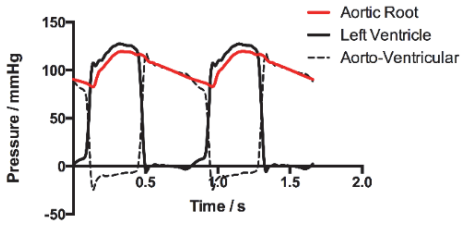


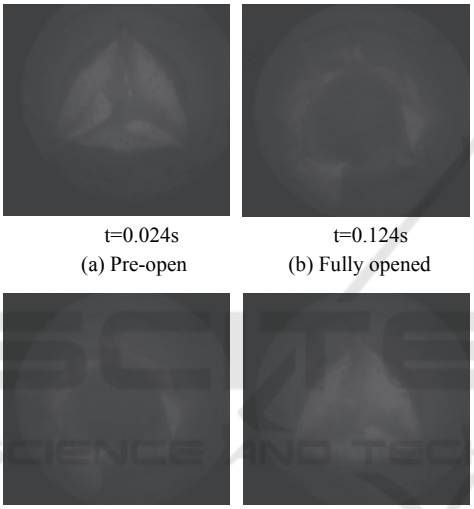
Figure 5: Time-varying pressure loadings measured in *in-vitro* experiment.

All tests were conducted at a stroke volume of 75 ml (5.4L/min) and a heart rate of 72 beats/min. An aqueous solution of glycerol (42% by weight) was

used as the working fluid to mimics blood. The dynamic viscosity and density of the working fluid is 3.52 mPa·s and 1038 kg/m^3, respectively.

3 RESULTS

To analyze the structural dynamics, key frames from the film that recorded by the high-speed camera were extracted (Figure 6). The start point of the record was defined as t = 0. The opening of the leaflets begins at t = 0.024s. The opening stage, fully open stage, closing stage of the valve are 0.12s, 0.132s, and 0.136s, respectively. The leaflets of the valve closed fully at 0.38s.



t=0.024s (a) Pre-open; t=0.124s (b) Fully opened

t=0.244s (c) Pre-close; t=0.380s (d) Fully closed

Figure 6: Dynamic deformation of the valve leaflets.

The mean trans-valvular pressure of the proposed valve during the systolic phase is 9.89 mmHg. The trans-valvular pressure and the aortic flow of the valves are shown in Figure 7.

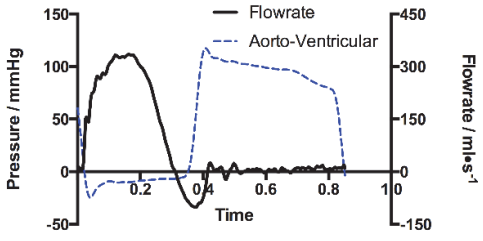


Figure 7: Aortic flow rates over one cardiac cycle.

The regurgitant volume (V_R) and leakage volume (V_L) was 7.09 ml and 2.81 ml per cycle, respectively. Thus the regurgitant fraction (RF) can be calculated by using the Equation 1:

$$RF = (V_R + V_L)/V_F \times 100\% \quad (1)$$

Where V_R is the regurgitant volume, V_L is the leakage volume and V_F is the forward volume.

The equation from ISO: 5840:2005 (ISO: 5840:2005) was applied to evaluate the maximum EOA (Equation 2):

$$A_{EO} = \frac{Q_{RMS}}{51.6\sqrt{\Delta P / \rho}} \quad (2)$$

Where A_{EO} is the orifice area of the valve (cm^2), ΔP is the mean systolic transvalvular pressure gradient (TPG) in mmHg, ρ is the working fluid density (g/cm^3), and Q_{RMS} is the root mean square volumetric flow rate (ml/s) (Equation 3).

$$Q_{RMS} = \sqrt{\frac{\int_{t_1}^{t_2} Q^2(t)\,dt}{t_2 - t_1}} \quad (3)$$

Derived from Bernoulli equation, the energy loss of the left ventricular that associated with the valve prosthesis was calculated by integrating the aorto-ventricular pressure times flow rate with respect to the time (Bernacca et al. 2002; Claiborne et al. 2013; Burriesci et al. 2010) (Equation 4):

$$E_L = 0.1333 \int_{t_0}^{t_1} \Delta p(t) \cdot Q(t) dt \quad (4)$$

Where E_L is the energy loss (mJ), t_0 to t_1 be the range of a cardiac cycle, Δp is the aorto-ventricular pressure difference (mmHg) and $Q(t)$ (ml/s) is the volume flow. The calculated parameters are listed in Table 2.

Table 2: *In-vitro* results of the hemodynamic parameters.

Parameters	Values
RF (%)	14.37
TPG (mmHg)	9.89
E_L (mJ)	129.03
Q_{RMS} (ml/s)	456.0
EVOA (cm^2)	2.86

4 DISCUSSION AND CONCLUSIONS

The current study was aimed to assess the performance of the ePTFE tri-leaflet valve. The dynamic and hemodynamic performance of the valve were *in-vitro* evaluated under *in-vitro* conditions.

As the well-accepted industry standard, ISO 5480:2055 provides a full set of criterions for evaluating a valve design (ISO 5480:2055). The criterions that related with the current study were listed in Table 3.

Table 3: Minimum performance requirements for aortic valve prosthesis.

Valve size (TAD, mm)	25
A_{EO} (cm^2)	≥1.20
RF (%)	≤15

The EOA and RF of the valve that tested in this study are all satisfied the criterions of the standard. This validated that the proposed ePTFE valve design could be a viable choice for AVR operations.

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