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In Vitro Modelling for Bulging Sinus Effects of an Expanded Polytetrafluoroethylene Valved Conduit Based on High-Speed 3D Leaflet Evaluation*

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***Abstract*—The study aimed to develop a pulmonary circulatory system capable of high-speed 3D reconstruction of valve leaflets to elucidate the local hemodynamic characteristics in the valved conduits with bulging sinuses. Then a simultaneous measurement system for leaflet structure and pressure and flow characteristics was designed to obtain valve leaflet dynamic behaviour with different conduit structures. An image preprocessing method was established to obtain the three leaflets behaviour simultaneously for one sequence with two leaflets images from each pair of three high-speed cameras. Firstly, the multi-digital image correlation analyses were performed, and then the valve leaflet structure was measured under the static condition with fixed opening angles in the water-filled visualization chamber and the pulsatile flow tests simulating paediatric pulmonary flow conditions in the different types of conduit structures; with or without bulging sinuses. The results showed the maximum 3D reconstruction error to be around 0.06 mm. In the steady flow test, the evaluation of opening angles under the different flow rates conditions was achieved. In the pulsatile flow test, each leaflet's opening and closing behaviours were successfully reconstructed simultaneously at the high-frequency recording rate of 960fps. Therefore, the system developed in this study confirms the design evaluation method of an ePTFE valved conduit behaviour with leaflet structures interacting with local fluid dynamics in the vicinity of valves.**

***Clinical Relevance*— The system reveals the bulging sinus effects on ePTFE valve leaflet motion by the 3D reconstruction using multi-camera high-speed sequential imaging *in vitro*.**

I. Introduction

The handmade expanded polytetrafluoroethylene (ePTFE) valved conduits is one of the gold standards for the right ventricular outflow tract (RVOT) reconstruction. The fan-shaped three leaflets made of the 0.1-mm-thick ePTFE membrane are sutured in the conduit, and the size of valved conduits ranging from 6 to 24mm has been designed and supplied for clinical application. Their widespread use and their excellent long-term outcomes for congenital heart failure patients in Japan have been reported [1-3]. As their anatomically identical bulging sinus is shaped in the conduit, the valve leaflet motion is to be stabilized with vortices in the vicinity of leaflets [1, 4].

Although the mortality associated with heart failure after conduit implantation has been low and the freedom from conduit explantation was high (>86%, at 15 years), some conduit removed for conduit exchange represented multifocally mineralized to produce exophytic concrete region at the leaflet attachment portion after the long-term use, which might compromise valvular motion [2]. Thus implanted valved conduits over ten years of use with repeated closing stress may give reasons for concern of mineralization followed by high-pressure gradient and insufficiency of the leaflet dynamics.

We hypothesized the long-term cyclic stress on the leaflet membrane structural deformation related to the local blood flow velocity distribution would be associated with the material microstructural degeneration [5]. Then the study aimed to examine the valve membrane motion in reconstructed 3D shapes obtained by multi high-speed cameras synchronized with hemodynamic pressure and flow measurements. The evaluation focuses on the leaflet structure changes varied from the local flow distribution in the conduits with bulging sinuses. In this study, we developed a new 3D leaflet reconstruction system by using multi-digital image correlation with high-speed camera images in the pulmonary circulatory simulation system capable of paediatric pulmonary hemodynamics. Then we compared the valvular dynamics associated with bulging sinus conduit structure *in vitro*.

II. Materials and Methods

A. Preparation of Fan-Shaped Leaflets for Digital Image Correlation Calibration

Prior to the measurement, speckle patterns were transcripted on an ePTFE sheet which was extended by vacuum thermoforming producing 0.04-mm-thick sheet from 0.1-mm-thick materials. Pseudorandom speckle patterns were

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introduced by the Speckle generator (Correlated Solutions, SC, USA). Then the fan-shaped leaflets were cut out as shown in Fig. 1, and sutured on the valve seat by CV-8 suture (Gore-Tex, W. L. Gore & Associates, Inc., DE, USA).

We set an exchangeable valved conduit sinuses as shown in Fig. 2. Each valved component was installed into the valve chamber with compliance. The valve leaflet dynamics were recorded by three sets of in-water cameras (RX0, Sony, Tokyo, Japan) with wide conversion lens adaptors (UCL-G165, Inon, Kamakura, Japan) as shown in Fig. 3.

B. Pulmonary Circulatory System

A natural pulmonary circulatory model for the valve dynamics evaluation has been developed as shown in Fig. 4. The system consisted of a valved chamber with compliance, a view chamber filled with water to place the cameras installed in, a right ventricular (RV) chamber, and overflow tanks as an afterload and a preload. A flow resistance unit was connected at the outflow tubing of the pulmlonary compliance chamber. A mechanical bileaflet valve with the polymer leaflet was installed at the tricuspid valve position. The RV chamber was connected to a originally designed pulse duplicator with the stepping linear actuator (PWA-100, Oriental Motor, Co. Ltd, Tokyo, Japan) and its stroke volume and pump rate were controlled by the original pulse generator implemented in the Arduino (DUE R3-E, Arduino S.R.L., MB, Italy).

C. Calibration of Camera Images and Leaflet Reconstruction in Steady Flow Test

Prior to the image analyses, a tetrahedral pyramid-shaped calibrator was made to calibrate the coordinate in the multi-camera view in the system. Three cameras were installed on the alignment table with sliders to arrange the distance and elevation angle in the water chamber to eliminate the refract differences. They were wirelessly synchronised via Wifi, at which the underwater antenna was attached to expand the Wifi transmission in the water chamber. The pairs from three cameras were individually calibrated after the angular preprocessing of images by Mathematica (Wolfram Research Inc., IL, USA) and processed by Matlab (2019a, MathWorks, MA, USA) with the MultiDIC toolbox[6]. Room temperature water was used in the tester. We also calculated the 3-D structural point clouds by the DIC analyses based on the calibrated spatial distribution.

High-speed sequential images were recorded at 960 fps by remotely accessed to the cameras. Then the valve leaflet structural reconstruction was performed and examined in the fixed opening angles as a static validation in the water-filled visualisation chamber.

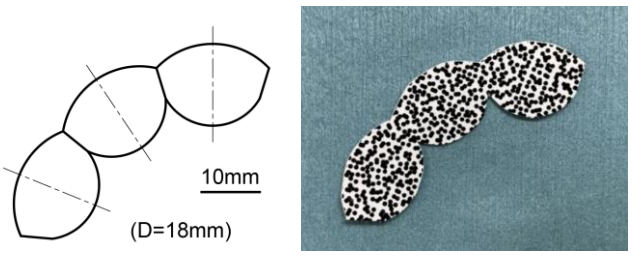

Figure 1. Schematic illustration of the fan-shaped leaflet for the 18-mm-diameter ePTFE valved conduit (left) and the valve leaflet membrane with speckle pattern transcribed for digital image correlation.

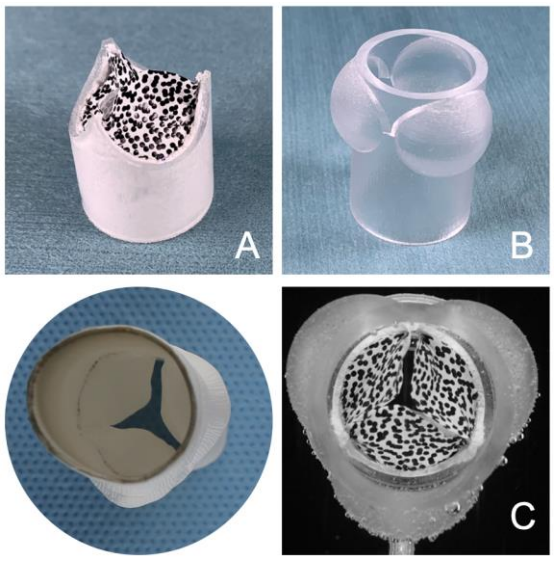

Figure 2. A valve leaflet model in the hard-shell valve seat (A), and a bulging sinus conduit (B) representing the clinical valved conduit design (in the circle). The valve seat (A) was inserted in the conduit (B), and then the valved conduit with bulging sinuses was presented (C).

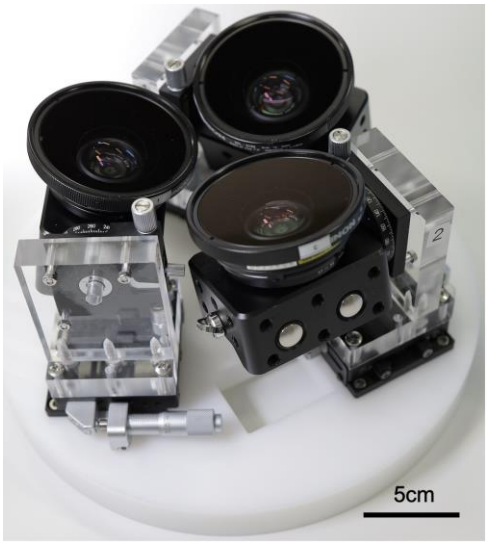

Figure 3. Three high-speed cameras for sequential image recording developed in the study; one sequence with two leaflets images from each pair of three cameras. The set of cameras was installed in the water-filled visualisation chamber. Images were monitored and synchronised via Wifi transmission.

C. Pulsatile Flow Tests

Transvalvular flow rate and pressure waveforms were measured and recorded by a PowerLab data acquisition system (8/32, ADInstruments, NSW, Australia). Simulated cardiac output was 16.7 mL to represent infant scale of pulmonary circulation at 100 bpm. Mean pulmonary arterial pressure was maintained to 12 mmHg through the study under the systolic fraction of 35% at the pulse duplicator. The displacement of the pulse duplicator was controlled by an open-loop sequence with a stepping actuator at microseconds pulse durations. Fig. 6 showed an example of the displacement of the pulse

duplicator cylinder to reproduce flow waveforms and the flow and pressure waveforms obtained at the pulmonary arterial model in the tester.

III. Results

A. 3-D Coordinate Calibration and Static Images of Leaflets

Maximum reconstruction errors were calculated using the pyramid-shaped calibrator to be around 0.06 mm. Fig. 7 showed reconstructed leaflet surfaces (right) from the images obtained at the cameras simultaneously (left). The height and width of each leaflet were compared, and they represented the similar structure of ePTFE leaflets.

B. Comparison of Leaflet Motion in Two Types of Conduits

Fig. 8 showed an example of the changes in the leaflet obtained in the bulging sinus and the straight conduit under the pulsatile flow condition at the closing phase of the valve motion. Fig. 9 showed a comparison of the changes in the leaflet shapes reconstructed at the closing phase of each leaflet. Each timing from the start of RV model contraction was compared in the valves with bulging sinuses and with the straight conduit. The end of valve closure of the bulging sinus was at 316 millisec while that of the straight model was 322 millisec.

IV. Discussion

The simultaneous recording of trileaflet valved conduit formed 3-D surfaces by using one sequence with two valve leaflet images as the region of interest from each pair of three high-speed cameras. The three-camera systems were useful for reducing the view chamber and effective to focus inside the narrow conduits with complicated structures such as bulging sinuses.

As shown in Fig. 9, the bulging sinus structure promoted the dynamic closure of the leaflet. Therefore, the visualisation system developed in this study is useful for the design evaluation of the paediatric pulmonary heart valves by 3-D reconstruction via digital correlation methods.

In clinical applications, as the conduits are made of elastic ePTFE materials, the flow velocity profiles might vary from the results in this study using rigid plastic materials. Although the 3-D reconstruction was practical to analyse the shape of leaflets, the edge of valvular cusps and suture lines could not be applied due to the limitation of multi-camera visualisation inside the small-sized conduits.

The strain field of each leaflet is to be calculated and considered to investigate the alternative parameters associated with durability for more long term use in clinical applications.

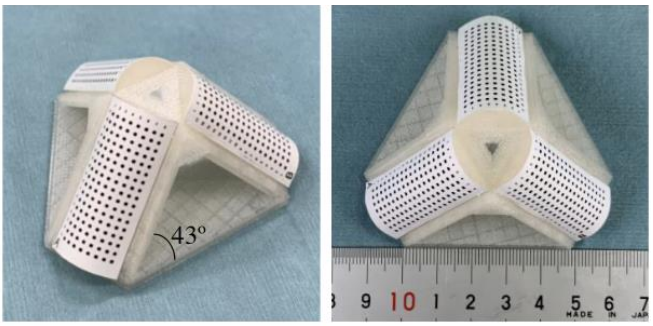

Figure 4. A tetrahedral pyramid-shaped calibrator for the coordinate calibration for the high-speed multi-camera system designed in the study; from the top (left) and the isometric view (right).

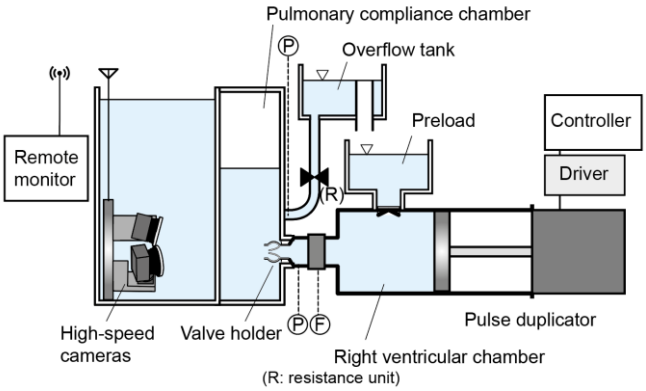

Figure 5. Schematic illustration of the mechanical circulatory system for the simulation of paediatric pulmonary circulation to evaluate valve leaflet behaviour with high-speed cameras used in the study.

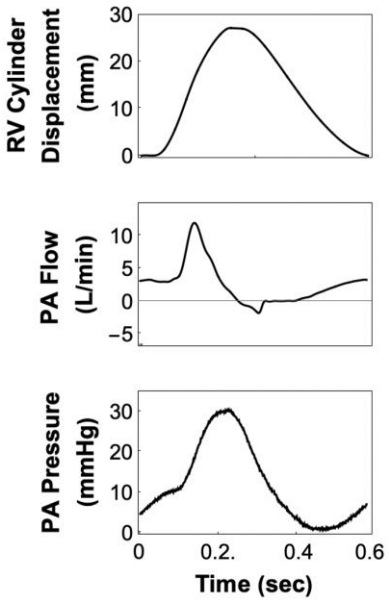

Figure 6. An example of synchronous single-beat measurement of waveforms of the displacement of the pulse duplicator for the right ventricular (RV) model (top), pulmonary arterial (PA) flow (middle) and pressure waveforms (bottom) obtained in the tester. There was no discernible difference in every cyclic waveform showing high reproducibility.

V. Conclusion

We designed the first new high-speed camera digital correlation system for 3-D reconstruction of ePTFE leaflets in valved conduits. Three cameras were used for the total reconstruction of trileaflet valves simultaneously. Pressure and flow waveforms and valve leaflets dynamics were successfully obtained in the pulmonary circulatory system simulating a natural paediatric circulation. Two types of conduit shapes were evaluated, and the pressure and flow distribution in the vicinity of the leaflet under the pulsatile flow could be examined for long-term durability by the high-speed fluid and structural analyses. The system developed in this study confirms the design evaluation method of an ePTFE valved conduit behaviour with leaflet structures interacting with local fluid dynamics in the vicinity of valves.

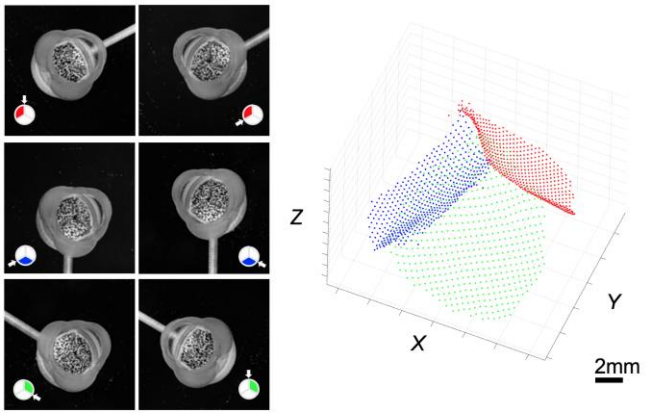

Figure 7. Processed images obtained by the three cameras (left) and the reconstructed leaflet images (right); the colours of leaflet position in the speckle pattern images (left) indicated each leaflet in the reconstructed point clouds (right). The white arrows in the left figures indicated the visual direction to each leaflet.

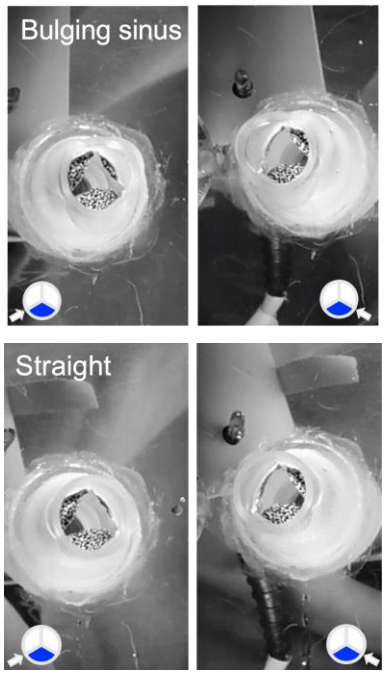

Figure 8. An example of the high-speed multi-angle images obtained by the valved conduit with bulging sinuses (top) and with straight-shaped model (bottom).

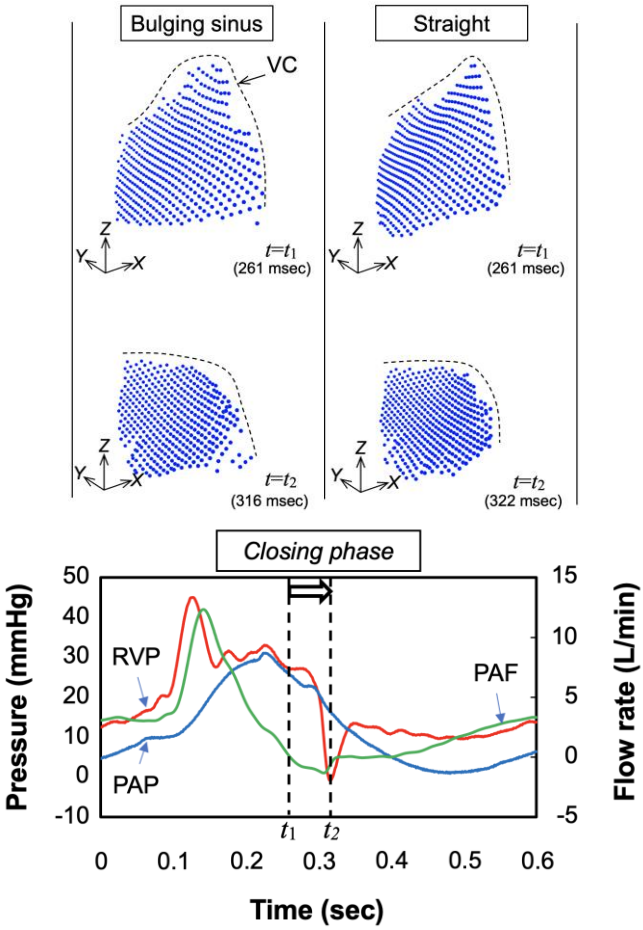

Figure 9. An example of comparison of high-speed valve leaflet images (top) obtained at the closing phase from the end systole at zero flow (t1) and at the peak negative pressure (t2); the timing from the start of the RV contraction. RVP, right ventricular pressure; PAP, pulmonary arterial pressure; PAF, pulmonary arterial flow.

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