Project number 89

Preclinical validation of a revised ePTFE paediatric heart valve for congenital heart failure

［１］Research group

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Consumables 90,000YEN

［２］Research setup

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 haemodynamics. Then we compared the valvular dynamics associated with bulging sinus conduit structure in vitro and focusing on future application in silico.

We joined the project and perform the in vitro/in vivo experimental part using valve testers based at IDAC and the University of Sheffield from the hydrodynamic or haemodyamic experimental point of view.

［３］Research outcomes

（３－１）Results

(1) New approach for leaflet 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 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. 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. 2.

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.

(2) High-speed structural observation of leaflets

Maximum reconstruction errors were calculated using the pyramid-shaped calibrator to be around 0.06 mm. Fig. 4 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.

（3－2）Future perspectives

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. 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.

［4］List of Papers

(1) Shiraishi Y, Narracott AJ, Yamada A, Fukaya A, Sahara G, Yambe T, Nagano Y, Yamagishi M. In Vitro Modelling for Bulging Sinus Effects of an Expanded Polytetrafluoroethylene Valved Conduit Based on High-Speed 3D Leaflet Evaluation. Annu Int Conf IEEE Eng Med Biol Soc. 2022 (in press)

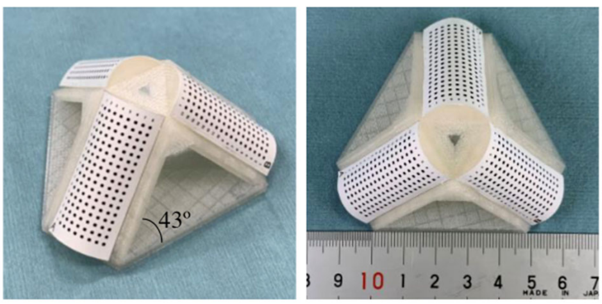

Figure 3. A tetrahedral pyramid-shaped calibrator for the coordinate calibration for the high-speed multi-camera system designed in the study; from the top (left) and the isometric view (right).

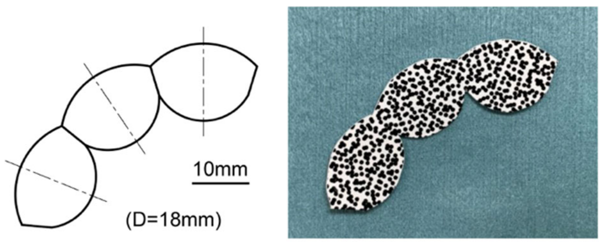

Figure 1. Schematic illustration of the fan-shaped leaflet for the 18-mm-diameter ePTFE valved conduit (left) and the valve leaflet membrane with speckle pattern transcribed for digital image correlation.

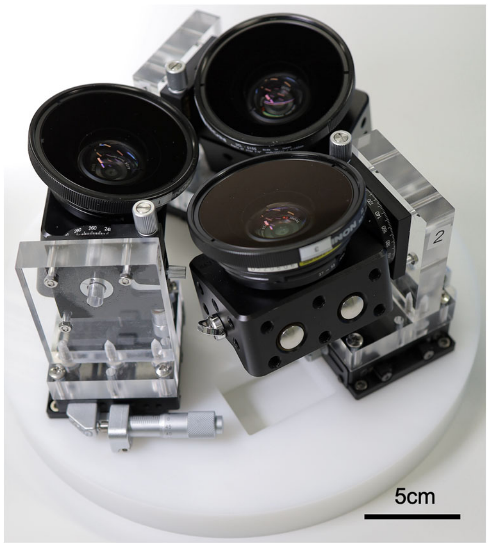

Figure 2. Three high-speed cameras for sequential image recording developed in the study; one sequence with two leaflets images from each pair of three cameras. The set of cameras was installed in the water-filled visualisation chamber. Images were monitored and synchronised via Wifi transmission.

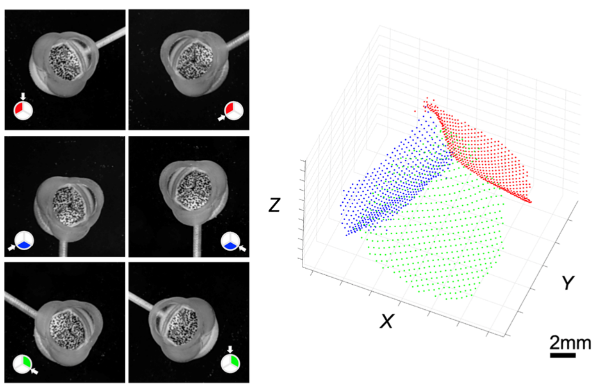

Figure 4. Processed images obtained by the three cameras (left) and the reconstructed leaflet images (right)