「様式３－B」

Project number　85

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

［1］Research group

Principal Investigator (PI)：
Andrew James Narracott
(Department of Infection, Immunity & Cardiovascular Disease
Faculty of Medicine, Dentistry & Health, University of Sheffield)
Host researcher at IDAC：
Yasuyuki Shiraishi
(IDAC Tohoku University)

Expenditure report of research funds：
Consumables 150,000YEN

［2］Research setup

Artificial ePTFE valves have been applied for congenital heart failure patients. This project provides a preclinical assessment for the modification of design of the valve leaflet as well as its anatomically identical shapes.
The purpose of this project is to develop combined numerical and experimental approaches to the study of valve function using a range of computational techniques to consider the impact of valve leaflet deformations on the local local blood flow (fluid). Numerical analyses will be informed by in vitro / in vivo experimental measurement and visualisation techniques. In vivo imaging of pulmonary valve leaflet dynamic behaviour will be used to inform understanding of the pathophysiological effects observed in patients undergoing pulmonary heart valve replacement procedures. Experimental in vitro studies will integrate the natural (in vivo) valve characteristics in highly sophisticated mock circulatory systems to replicate the mechanisms of low pressure valvular dynamics in the pulmonary arteries.
The sensitivity of valve function to parameters associated with valve geometry (local valvular stenosis and valve sinus geometry) and material properties (vein or arterial wall and valve leaflets) will be investigated in silico based on the in vitro/in vivo examinations at IDAC labs to determine target parameters for optimisation during valve-related surgical interventions.
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） Primary valve motion experimental setup

We designed the ePTFE heart valve motion tester to simulate paediatric pulmonary circulation (Figure 1). The trileaflet ePTFE valve was installed at the outflow portion of the right ventricular model in the circuit, with the numerically randomized dot pattern printed on each leaflet as shown Figure 2. The multi digital image correlation (DIC) was used for the calculation of leaflet 3D structure and deformation from the synchronized images obtained by a couple of high speed camera sets. We placed three cameras synchronized wirelessly in the water bath which could eliminate refractive index in the transparent medium in the circulatory system. The pulsatile flow was generated by the pneumatically driven right ventricle to represent the healthy or the heart failure conditions of paediatric pulmonary circulation at the flow range of 1-2 L/min with the systolic pressure around 15-25 mmHg. The pair of images obtained at the cameras were analysed and the leaflet deformation as well as the lealet membrane structural stress concentration, which was to be affected by the circulatory flow in vicinity of leaflet tip coaptation zone.

（3－2）Fundamental analysis for complicated flow distribution

As the pulmonary heart valve conduit energy consumption was related to the location in the major pulmonary trunk, the effects of the outflow condition of the valve leaflet on blood flow velocity were numerically investigated. The projection of natural bifurcation of pulmonary artery was presented at the outflow of valve conduit, and the flow acceleration through the valve was investigated. As a primary result which could be combined with the pulsatile flow experiments, the velocity of the recirculating flow across the pulmonary artery geometries using the several junction model of pulmonary bifurcated wall models (Figure 3). Consequently, the junction structure had a influence on the pressure at the bifurcation that might lead wave reflection changes at the leaflet position of the ePTFE membrane.

（3－2）Future perspectives

The project will generate novel computational approaches to analyse valve dynamics, closely integrated with experimental validation techniques. This combined computational and experimental approach will provide a strong platform for the assessment of novel approaches to interventional treatments for valvular disease, ultimately delivering improved patient outcomes including the future clinical analyses with the computational fluid structure interaction calculations in the dynamic characteristic of artificial internal organs. The evaluation method will contribute the novel medical device regulatory assessment as preclinical or clinical investigation. Moreover, the method will be applicable for fluid dynamic behaviour understanding in the vicinity of elastic membrane in the blood flow of cardiovascular systems.

［4］List of Papers

(1) Shiraishi Y, Yambe T, Narracott AJ, Yamada A, Morita R, Qian Y, Hanzawa K. Modeling Approach for An Aortic Dissection with Endovascular Stenting. Annu Int Conf IEEE Eng Med Biol Soc. 2020 Jul;2020:5008-5011. doi: 10.1109/EMBC44109.2020.9176423. PMID: 33019111

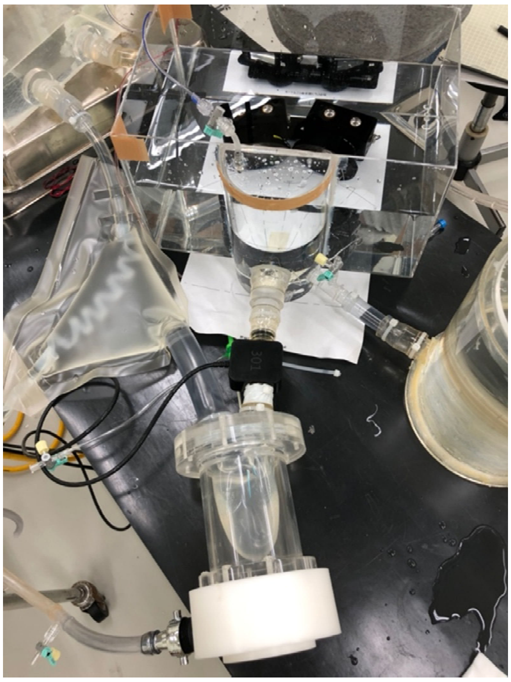

Figure 1. Whole view of the pulmonary arterial circulatory model. The high speed multi-angle images of the leaflets were synchronously obtained from the outflow position of the valve.

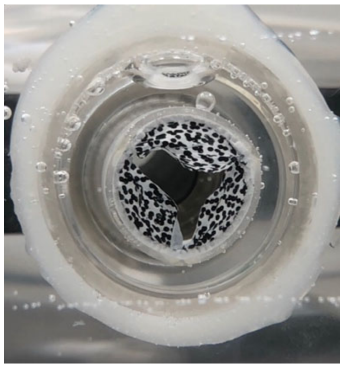

Figure 2. An example of the valve motion presented in the experimental setup. The randomised dotted pattern were printed onto the ePTFE valve leaflet for three dimensional reconstruction with digital image correlation.

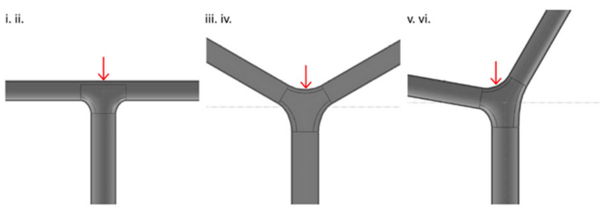

Figure 3. The types of main trunk of pulmonary arterial bifurcated models used for computational fluid dynamics analyses.