

Project number 98

In silico/vitro interactive modelling of a paediatric pulmonary valve reconstruction

[1] Research group

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Expenditure report of research funds :

Consumables 75,000YEN

[2] Research setup

This project provides an in vitro design evaluation and performance testing for a paediatric pulmonary heart valve. Artificial ePTFE valves have been applied for congenital heart failure as valved conduits for right ventricular outflow tract reconstruction. An anatomically identical trileaflet valves have been used for a long time, but some investigation indicated that the long time use, especially in young patients, might cause calcification followed by low performance of valve leaflets. In vitro design evaluation and performance testing includes design characterisation of the integrated structural components, such as leaflets, conduits, and individual subcomponents. As pre-clinical testing, the experimental flow characterisation by in silico/in vitro evaluation is performed to determine shear or turbulent flow regions in the valved conduit.

This project aims to establish a practical in silico/in vitro modelling approach to the valve design using high-speed 3D valve structural reconstruction techniques and fluid-structure interaction (FSI) analyses. FSI analyses will be informed by in vitro/in

vivo haemodynamics. High speed In vitro imaging of the valve leaflets will be used at IDAC labs to inform understanding of the pathophysiological effects observed in patients with chronic congenital heart valve disease. The pulmonary arterial structure as a conduit around the valve provides downstream characteristics in the main pulmonary artery geometry showing the significant influence of valve flow characteristics.

We performed the in vitro/in vivo experimental part using valve testers based at IDAC and the University of Sheffield from the hydrodynamic and haemodynamic experimental point of view. To achieve the project aim and to provide in silico/vitro interactive modelling, we had several web conferences and an in-person meeting in Sheffield. This work was also supported by two student projects to develop 3D CFD and 0D modelling techniques undertaken in Sheffield from October 2022 to May 2023.

[3] Research outcomes

(3 – 1) Results

A novel model for the presentation of paediatric pulmonary circulation has been designed to examine the ePTFE pulmonary heart valve haemodynamic characteristics in vitro/silico as shown in Figure 1.

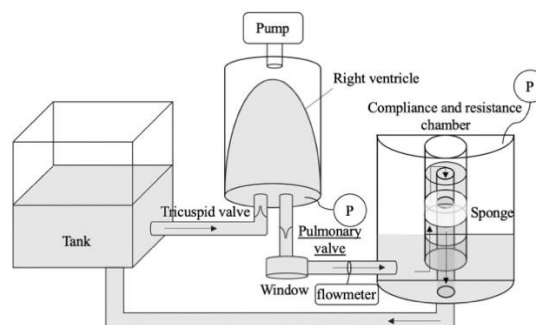


Fig. 1. Schematic illustration of a paediatric pulmonary circulatory system for the preclinical evaluation of heart valve in vitro.

The system provides the 3D visual valvular dynamic measurement under the highly simulated paediatric pulmonary circulatory conditions.

The special feature of the pulmonary model was the contraction of the pulmonary compliance chamber with the hydrodynamic damper and resistances which was to be simulating congenital heart failure patients. Figure 2 shows an example of pressure and flow waveform obtained at the pulmonary aorta in vitro, followed by the highly simulated natural pulmonary arterial input impedance with the use of an 18-mm diameter trileaflet ePTFE pulmonary heart valve conduit.

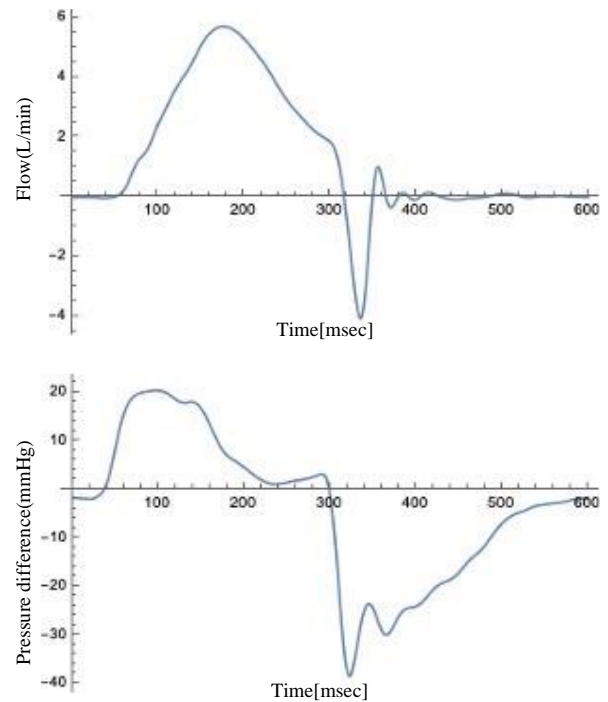
The preliminary results exhibited non-linear characteristics of the effective orifice area obtained under the different heart rate conditions at 60, 100, 160 bpm, which might indicate the optimal range of valvular leaflet motion under the natural haemodynamics in congenital heart failure patients from the infant to the grown adult patients.

(3 – 2) Future perspectives

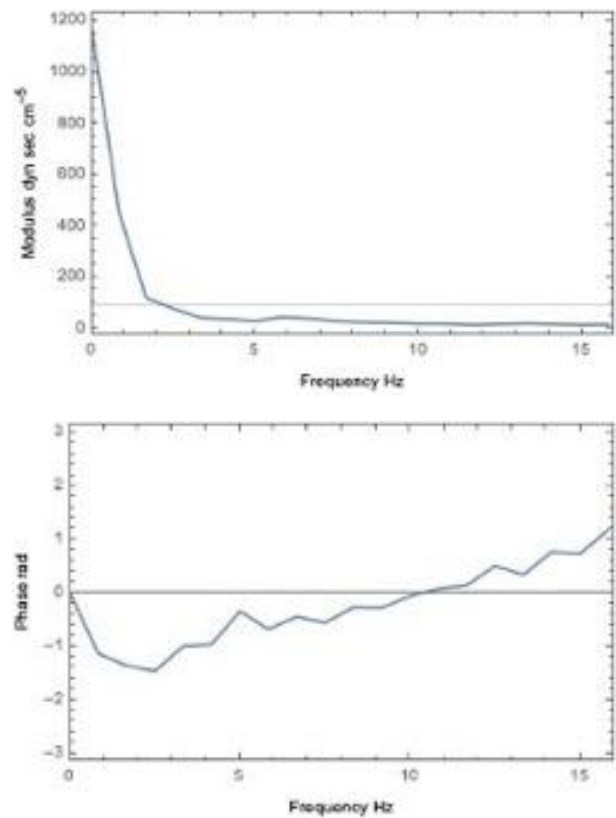
Based on our joint project outputs from mutual preclinical studies, the preliminary evaluation has been started in a working group on the preclinical evaluation methodology in Japan to establish domestic guidelines for use in paediatric patients. Since 2015, the need to evaluate the use of paediatric devices as an extension for adult patients has been presented. The part of the project outcomes contributes to supporting the limited evidence of paediatric use of medical devices examined by interactive, interdisciplinary scientific evidence bases.

[4] List of research achievements

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 Jul;2022:4001-4004. doi: 10.1109/EMBC48229.2022.9871676. PMID: 36086215.



(a) pressure and flow waveforms (in vitro)



(b) pulmonary impedance module and phase

Figure 2 Haemodynamic characteristics in vitro obtained in the paediatric pulmonary circulatory system developed in the project