「様式３－B」

Project number 63

Feasibility approach for right ventricular outflow tract reconstruction in silico/ in vitro

［1］Research group

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Expenditure report of research funds：
Consumables 130,000YEN

［2］Research setup

This project provides a preclinical assessment for the right ventricular outflow tract reconstruction in congenital heart failure patients in silico/in vitro. The selection process as well as the developmental procedure for cardiovascular prostheses is still reliant on re-intervention rate data for generalized patients. However, some in silico or in vitro modelling has been implemented into the clinical application by operative planning as well as regulatory consideration. Factors that increase the risk of implant valve degradation are highly dependent on the haemodynamic response. Variations in patient cardiovascular anatomy could influence the haemodynamic response to right ventricular outflow tract reconstruction, including valve function.

There currently exists no standard practice for in silico assessment using CFD. This project covers a multi-scale in silico modelling which is capable of anatomically identical representation combining 3D-CFD simulations through pulmonary valve anatomy with lumped parameter modelling of the whole cardiovascular system.

We held an in-person research meeting at the University of Sheffield to improve data sharing. Additionally, we carried out monthly progress meetings via conference calls to enhance each local project.

Fig.1 Development of preliminary CAD drawings to obtain the fluid domain of the geometry for the evaluation of pulmonary circulatory intervention with outflow tract reconstruction.

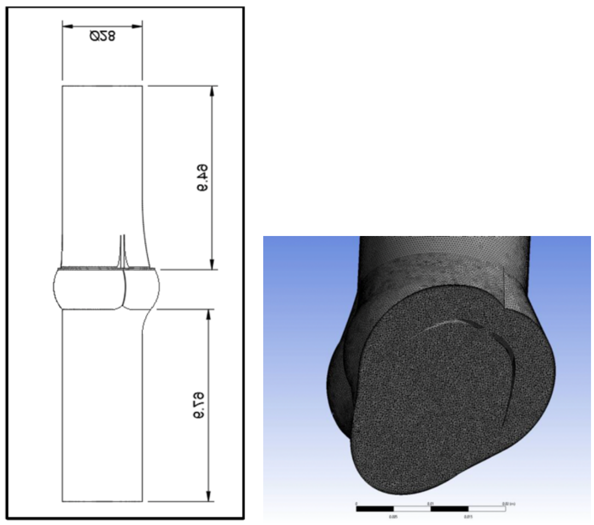

Fig. 2. 2D sketch dimensions for the straight artery with valve leaflets (left), and final mesh for the model in vicinity of valve region.

［3］Research outcomes

（3－1）Results

The 3D dimensions of the pulmonary artery were determined with varying diameters for different age groups. Figure 1 shows an example of pulmonary arterial bifurcation for 3D fluid analysis model. Prior to the CFD calculation, the pulmonary artery with valve leaflets was examined for different age groups to achieve mesh convergence for the arched structure of the vessels.

Figure 3 shows an example of the mesh convergence with varying dimensions. Final mesh for the body is 0.4mm with a sphere of influence at the bifurcation set to 0.37mm. Ten inflation layers are applied to the wall.

Figure 4 shows the model geometry for steady flow analyses in a complex structure applied to the variation in anatomy due to age. Consequently, the pressure drop across the age groups, a trend in decrease in average pressure can be observed with age, using the models.

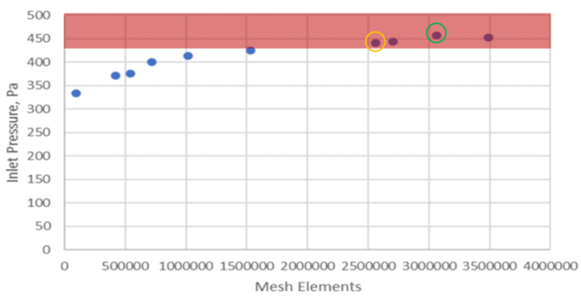

Fig. 3. An example of the results from the mesh convergence study for the arched artery with varying dimensions.

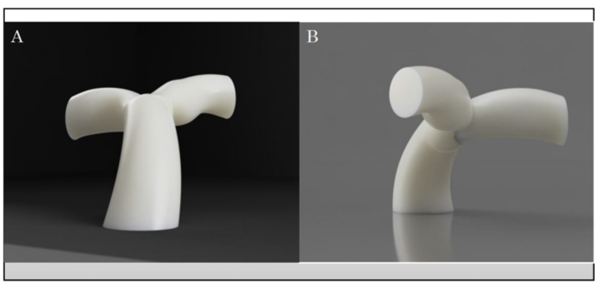

Fig. 4. Rendered images of the geometry used for the variation in anatomy due to age.

（3－2）Future perspectives

This project outcome provides a feasibility assessment by the CFD and CAD design. As an example of the evaluation of divergence of the diseased pulmonary structural variations, the mesh sensitivity with the straight pulmonary arterial tract was examined. The strength of the combination between in silico and in vitro evaluation lies in its ability to establish more accurate estimation of flow dynamics after the outflow tract reconstruction, as well as the modification of conventional pulmonary valvular interventions. The geometry of the CAD design could be a robust framework for simulating complex haemodynamics with the effects of anatomical changes due to age and with the deteriorating stenotic dynamics in patients. The potential of this modelling approach will be examined for more accurate representation of ameliorating haemodynamic properties after the right ventricular outflow tract reconstructions. The simulation carried out by the models can be taken as a preliminary validation for the treatment, and the wide range of modelled situations makes their versatility for more precise preclinical applications.

The project will generate novel computational approaches to analyse congenital right ventricular outflow tract reconstruction including artificial 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, as well as one of the new regulatory sciences for the preclinical research for medical devices.

Preclinical data are increasingly shared on a global harmonization scheme and analysed using standardized methodologies. The impact of the project lies in the fact that the biomedical science and engineering approach can be used for regulatory purposes by utilising the joint research data.

［4］List of Papers

In preparation.