Project number 61

Simulation for Enhanced Clinical Decision Making in the Treatment of Congenital Pulmonary Arterial Stenosis

［1］**Research group**

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Expenditure report of research funds :

Consumables 100,000YEN

［2］**Research setup**

This project aims to investigate and model the maladaptive remodelling of the congenital pulmonary artery and the right heart in response to obstructions of the right ventricle outflow tract, namely pulmonary arterial stenosis as well as the remodelled expanded pulmonary artery by the use of baremetal stent. A zero-dimensional, lumped parameter hydroelectric analogue of the human circulation will be modified and tuned to recreate healthy and diseased heart states. From the diseased heart state, feedback systems will be added to represent the remodelling of the heart, attempting to recreate outputs seen in patients conditions as found in vivo/in vitro experiments conducted in the IDAC.

To achieve this aim, the following specific objectives have been outlined:

- Tune model to produce healthy outputs, achieving pressure and volume waveforms in physiological ranges, and perform sensitivity analysis of different variables.

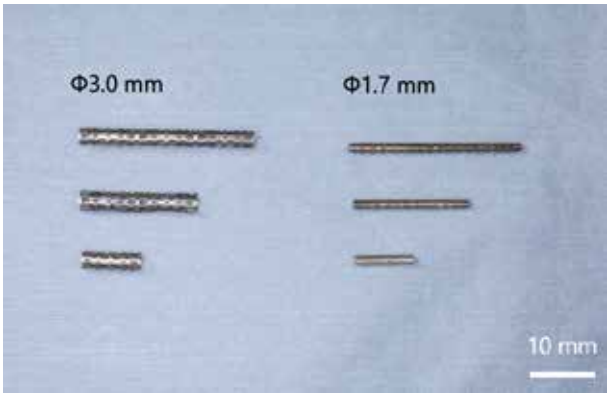

Fig. 1 Development of prototype models of bare-metal stent for congenital arterial stenosis; laser-cut balloon expandable model made by 0.35 mm-thickness metal pipe of 3-mm and 1.7-mm in diameter

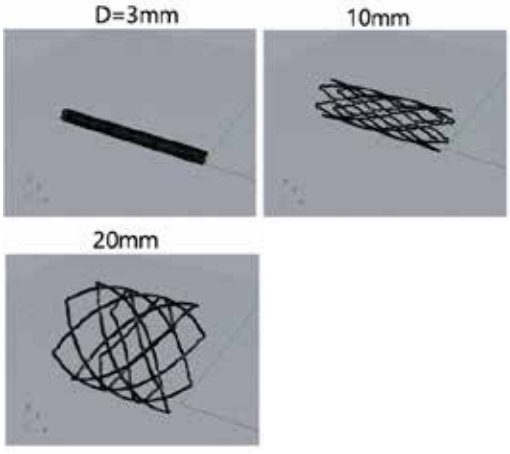

Fig. 2. Simulation images of expanded bare-metal stent prototype (3.0-mm) up to 20 mm in diameter with multiple expansions according to the size growth in each patient

- Change stenotic equation in model to simulate degrees of stenosis and flow propagation, plot different degrees of disease over time, including pressure volume loops associated pre or post vascular intervention with stent.
- Simulate compensatory contractility and remodelling over time, by introducing feedback loops that influence the elastance equation.

The procedure will be in parallel with the design and prototype modelling of a novel expandable paediatric vascular stent, which is capable of multiple intervention according to the growth of the body and vascular size from the age of 1 to 10-yr congenital cardiovascular disease. The data will be also applied to establish the examination standardized procedures for the investigational and clinical application analyses from the regulatory scientific point of view.

［3］Research outcomes

（3－1）Results

Fig.1 and 2 show the prototype bare-metal balloon expandable design. The variations of the size were set to 3.0 and 1.7 mm to apply to a wide range of stenotic lesions with anatomical structure, including surrounding organs in the thoracic cavity.

Features of the design are wide expandability up to around 8-fold diameter, and selective two types of primary size: one for coronary stent intervention balloon application (1.7 mm), and a full-expanded shape to fit adult vascular size (3.0 mm for primary intervention).

Through the project, we performed the acute test for a stenotic pulmonary branch flow model in vivo.

（3－2）Future perspectives

The project will generate novel computational approaches to analyse congenital cardiovascular diseases and interventional therapeutics using baremetal stents, closely integrated with experimental validation techniques. Standardised protocol of the interventional treatment for pulmonary arterial stenotic disease has not been established, and the outcome from the study may lead the international examination procedures of these congenital disease restoration by artificial internal organs. 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.

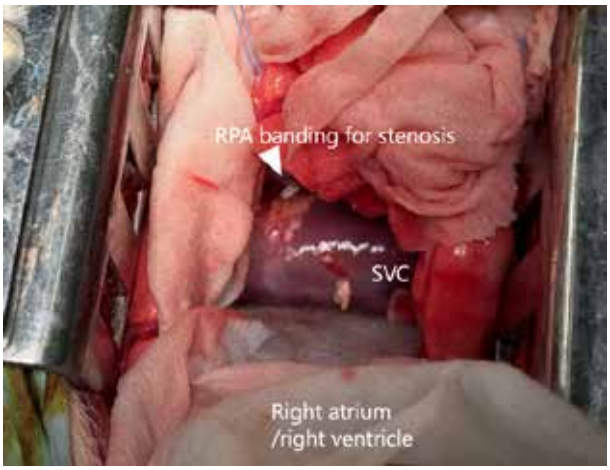

Fig. 3. An example of the results from the acute study on the right pulmonary arterial branch stenosis model.

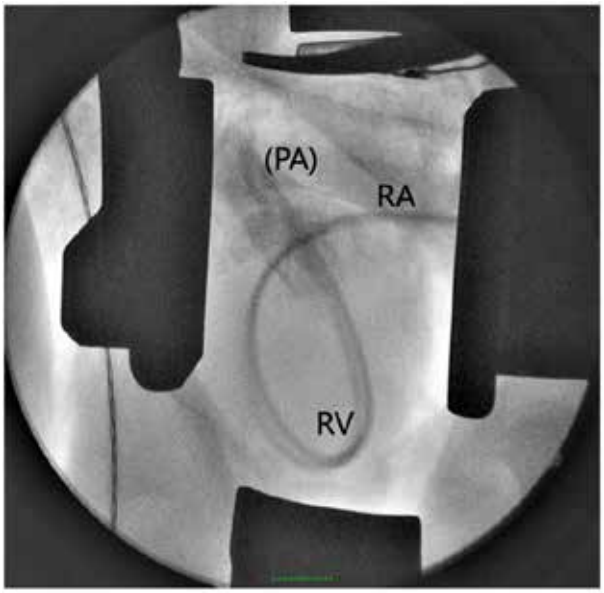

Fig. 4 An example of angiogram examination of flow distribution in the pulmonary arterial stenosis

［4］List of Papers

In preparation.