Project number 75

Optimisation of Flow Dynamics by Numerical Therapeutic Approach for Arterial Aneurysms with Stent Intervention Based on Animal Experiments

［1］Research group
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Consumables 150,000YEN

［2］Research setup

The purpose of the joint research was to establish numerical approach with the optimization of haemodynamics for the sophisticated design and development of a newly designed aortic bare-metal stent for the treatment of elderly patients with aortic dissection. The original analysis method developed in Macquarie University on the vascular lesions, such as aneurysms and dissections, was applied for the evaluation of animal dissection models presented and performed in IDAC Tohoku University.

The primary plans were as follows for numerical analysis approach with blood flow in the aortic dissection:

- Flow dynamics and pressure gradient in aortic dissection model with computational fluid dynamics (CFD)
- Blood velocity and shear stress distribution mapping associated with the acquired hematologic diseases
- Optimisation of stent deployment in the lesion of the aorta with the interactive validation by the animal experiment/patients data
- Design proposal of stent structure and intervention from the blood flow
- Qualifications of biomedical limitations of the baremetal stent intervention for aortic aneurysm

These approaches were performed associated with the animal experimental data analysis in IDAC with the reconstruction of experimental aortic dissection model. Haemodynamic data were measured and used for validation of numerical modelling process and output as well as the hybrid or combination analysis for future analysis with non-linear wave propagation in the dissected lumens.

Frequent discussions and meetings were held among the researchers in the joint research group for the modelling and data processing as well as haemodynamic examinations in vitro.

［3］Research outcomes

（3－1）Results

Three major achievements were presented as the project outcome and we are preparing to present research papers:

a) Dynamic volume examination during systole and diastole

Short axis images from ultrasonic echocardiogram were obtained along the longitudinal aorta for the detection of image slices. The sequential images of cross sectional dissected aorta was recorded with the electrocardiogram in the animal experiments (Figure A). The short-axes surface sizes of the false and the true lumens were calculated as a parameter of volumetric changes during pulsatile blood flow changes. Longitudinal Doppler images showed the synchronised flow entrance at the proximal entry of the aortic lesions. The changes of the cross-sectional area of the false lumen exhibited the

asynchonisation and dissynchronisation phenomenon against the changes in the true lumen area, which was synchronised with the cardiac contraction phases. The complex synchronisation between the false and the true dissection regions affects the additional expansion of dissected volume due to the increase of the pressure during end-diastole. Therefore, the volumetric reduction at dissected lesion may induce the reducing of dissynchronisation by the stent intervention at the enlarged false lumen.

b) Rigid modelling for in vitro examination
A transparent 3D prototyping with a polymer shell was carried out using optical modelling by the series of cross sectional aortic dissected images (Figure B,C). The 0.3-mm thick elastic membrane was used between the false and the true lumens. The changes of the false lumen volume and the membrane displacement under the steady flow condition at 5-10 L/min in the mock circulatory system using the 3D dissected prototyping models. The changes of the displacement of the membrane for enlarging the false lumen were observed under the high flow rate test conditions. The result indicated that the management of flow profiles in the dissected false lumen by the stenting, which was to be stabilise the dissected vascular wall, was to be one of the key as well as the reconstruction of the true lumen diameter by the intervention of stents. The visualisation technology will be applied to evaluate the expanding stent characteristics using the stent applicator through interventional therapeutics.

c) CFD analysis in parallel with in vitro modellings
An animal dissection model based CFD was performed using the reconstructed 3D model from the sequence images of the cross sectional short axes in the dissection of aorta. The preliminary result under the steady flow condition indicated the increase of wall pressure in the false lumen by the occurrence of complex turbulent flow. Pressure difference between the false and the true luminal walls was ~5mmHg under the normal flow conditions. As the structural variations of the morphological and pathophysiological dissection lesions correlate clinical outcome after the stent interventions, the application of CFD analysis with diseased spatial features is useful for estimating the device application (Figure D).

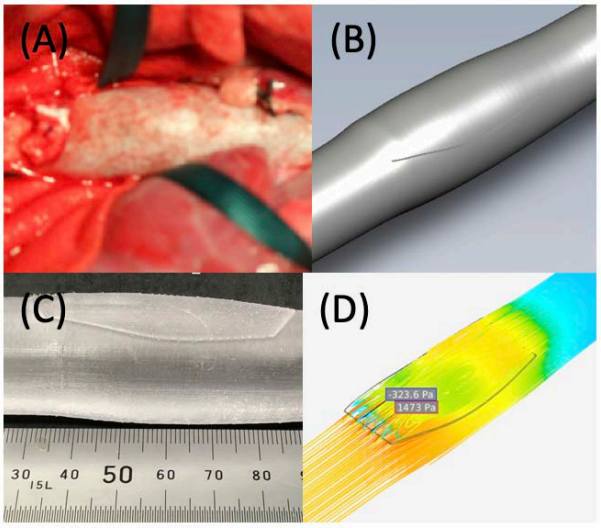

Fig 1 Four modalities for the biomedical assessment of aortic dissection derived in the project; (A) animal dissection model, (B) 3D solid/surface model, (C) optical prototyping, and (D) numerical analysis

（3－2）Future perspectives
Preclinical studies for medical device approval regulations are needed for global use of newly developed implantable device therapeutics. The numerical analysis, computational fluid dynamics (CFD) technology, which is capable of providing biomedical quantitative information and for promoting advancement of clinical therapeutics is highly needed in the preclinical research and development field especially for new medical devices. Through the use of computational hemodynamic technology, vascular properties and interventional procedures with artificial therapeutic devices were investigated. However, due to the complexity of vascular geometry and flow conditions, the cardiovascular flow simulation continues to be a challenging project.

Based on these discussions through joint research project themes, new stents for treatment of aortic dissection will be prepared for Japanese clinical device applications. As regulatory science supported by CFD analysis is now so global and repeatable, the collaborative joint research experience on the stent for aortic dissection intervention will advance to the second stage for clinical applications, including postoperative evaluation.

［4］List of Papers/Presentations
(1) Genda, et al. 人工臓器, 47(2), S-154, 2018.
(2) Morita, et al. 人工臓器, 47(2), S-162, 2018.