Project number 64

Modification of vascular prosthesis surface for interactive remodelling process design

［1］**Research group**
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Expenditure report of research funds :
Consumables 100,000YEN

［2］**Research setup**

Active prevention design of thrombogenesis or hemolysis on the surface of polyester vascular prosthesis is inevitable. Interaction of blood chemistry and physiological complications as well as the promotion of remodelling via interventional treatment of vascular diseases are to be understood. We will conduct several material modification approaches to prevent clot formation and thrombosis, as below, and compare the efficiency of each:

1) Coating surface of polyester vascular prosthesis to enhance biocompatibility
2) Nanoparticle-infused coatings for anti-fouling vascular devices
3) Hydrogel-based interfaces for improved tissue compatibility in implantable devices
4) Antimicrobial coatings for implantable devices: Reducing infection risks in long-term use
5) Surface modification to reduce protein fouling on vascular prosthesis

The modification procedures will be carried out in an aqueous environment to avoid any organic reagent residues after chemical reactions. Meanwhile, the materials used to modify the surface are derived from natural sources to ensure biocompatibility.

We planned to use in vitro and in vivo models with polyester vascular prostheses, and the plan includes in vitro vascular prosthesis surface modification under the blood coagulation as well as in vivo evaluation in goat experiments with bypassed graft installation in the aorta.

The coating materials for vascular devices have been developed, and primary investigation from the blood chemist and applied biomaterial point of view. The coated material will be surgically installed into the animal model in the IDAC laboratory, and the characteristics of the acute response and chronic physiological tissue remodelling as well as anti-fouling properties are to be derived. The procedures may be also applied to the consideration of revision ISO 7198 (Cardiovascular implants and extracorporeal systems – vascular prostheses – tubular vascular grafts and vascular patches).

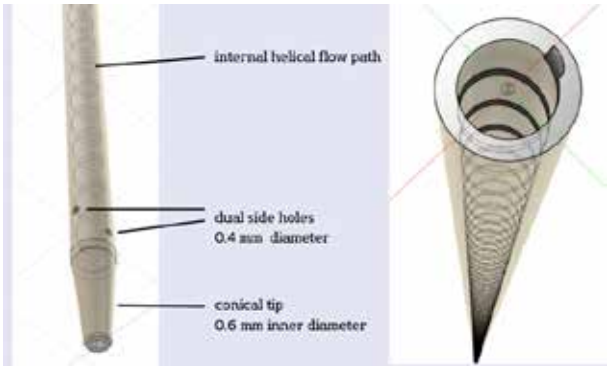

Fig. 1 An example for the use of blood-infusion contamination with delivery catheter under the different shear stress on the blood contacting surface.

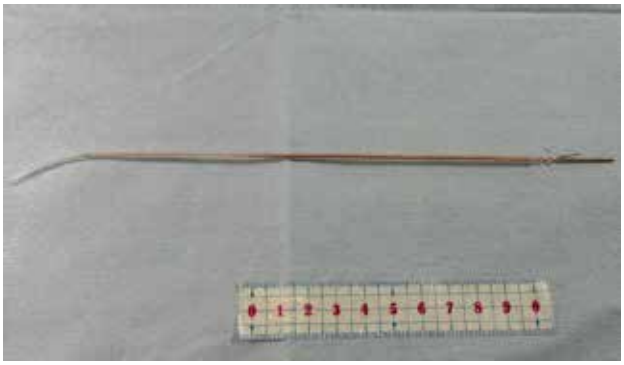

Fig. 2. An originally designed tubing mould with transparent silicone rubber material to test the low Reynolds number helical flow

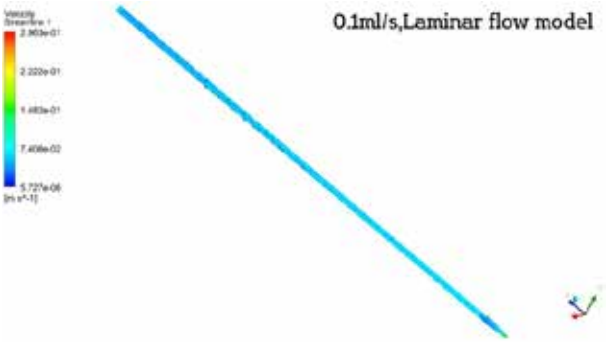

Fig. 3　Simulation image of the laminar flow tubing for primary coating with surface modification. The primary concern of the internal surface is that it could be effective for blood-infusion mixing, but the wall shear increased remarkably by around 5-6 times higher stress evaluated.

［3］Research outcomes

（3－1）Results

We designed a helical flow with high shear stress flow chamber with low Reynolds number condition as shown in Fig. 1.

The primary investigation of the tubing in silico showed that the shear stress at the distal portion by the internal shear could be around 6 times higher than the values at the centre of the catheter. The additional side holes on the wall of tubing may induce more complicated non linear helical flow in the laminar conditions. The coated material might be examined under the practical and critical shear on the non-linear flow under slow flow conditions to examine more efficiently in vitro and in vivo for the sophisticated protein-platelet or cell interactions on the vascular walls by the hydrophilic material to be investigated for the material coating.

（3－2）Future perspectives

Our team has started the discussion on the collaboration for preclinical and clinical evaluation of biomedical devices, particularly vascular implants, with Dr. Yasuyuki Shiraishi, since September 2024 in Taiwan. In 2025, we plan to start the lab member exchange as the summer internship program based on the institutional academic exchange agreement between the labs in the Tohoku University IDAC and in Chang Gung University. All the animal experiment is to be performed according to the international standard of humane care for laboratory animals. The animal experiment plan on the vascular prostheses evaluation at Tohoku University has already been approved (2022AcA-009-01).

The methods and expected results from the collaboration research is to be applied for clinical devices based on the medical device regulation of each country. The project focuses on sharing the Asia-Pacific biomaterial therapeutic research and development protocols and regulatory sciences for medical device harmonization with aged population societies in Taiwan and Japan.

The output from the project will be presented as collaboration research results, and moreover, the mutual understanding of biomaterial investigational methods accredited in countries will be proposed.

［4］List of Papers

In preparation.