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Structural Design of a Newly Developed Pediatric Circulatory Assist Device for Fontan Circulation by Using Shape Memory Alloy Fiber

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Abstract—**Total cavopulmonary connection (TCPC) is commonly applied for the surgical treatment of congenital heart disease such as single ventricle in pediatric patients. Patients with no ventricle in pulmonary circulation are treated along with Fontan algorithm, in which the systemic venous return is diverted directly to the pulmonary artery without passing through subpulmonary ventricle. In order to promote the pulmonary circulation after Fontan procedure, we developed a newly designed pulmonary circulatory assist device by using shape memory alloy fibers. We developed a pulmonary circulatory assist device as a non-blood contacting mechanical support system in pediatric patients with TCPC. The device has been designed to be installed like a cuff around the ePTFE TCPC conduit, which can contract from outside. We employed a covalent type functional anisotropic shape memory alloy fiber (Biometal, Toki Corporation, Tokyo Japan) as a servo actuator of the pulmonary circulatory assist device. The diameter of this fiber was 100 microns, and its contractile frequency was 2-3 Hz. Heat generation with electric current contracts these fibers and the conduit. The maximum contraction ratio of this fiber is about 7% in length. In order to extend its contractile ratio, we fabricated and installed mechanical structural units to control the length of fibers. In this study, we examined basic contractile functions of the device in the mock system. As a result, the internal pressure of the conduit increased to 63 mmHg by the mechanical contraction under the condition of 400 msec-current supply in the mock examination with the overflow tank of 10mmHg loading.**

I. Introduction

A VARIETY of ventricular assist device have been applied as bridge to recovery of ventricular function or heart transplant in adult patients [1]–[3]. However, infants or small children who experience severe ventricular dysfunction with congenital heart disease have fewer options for mechanical circulatory assistance due to the limited size of thoracic cavity as well as a wide range of types of cardiac dysfunction. Pediatric patients with ventricular or pulmonary dysfunction are more likely to receive surgical reconstruction by Fontan procedure using total cavopulmonary connection (TCPC) [4]–[9]. Patients with no ventricle in pulmonary circulation are treated along with Fontan algorithm, in which the systemic venous return is diverted directly into the pulmonary artery by using expanded polytetrafluoroethylene (ePTFE) conduit without passing through subpulmonary ventricle.
The Fontan procedure by TCPC results in the ventricular blood pumping through the systemic and pulmonary circulation in series without an intervening right ventricular pumping stage.

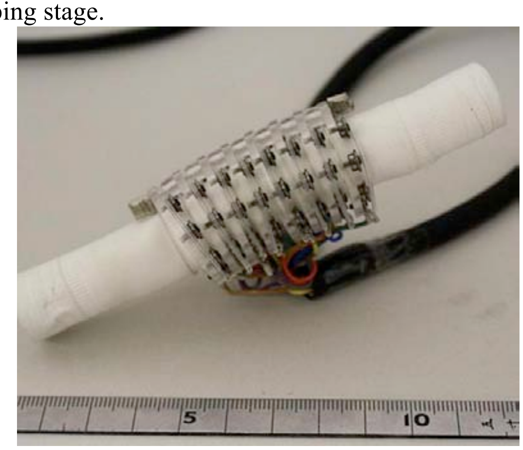

Fig. 1 A prototype of the pediatric mechanical circulatory support device developed in this study; the actuator is attached on the ePTFE conduit

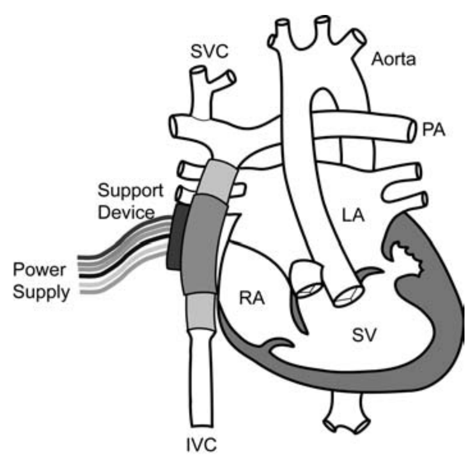

Fig. 2 Schematic illustration of the mechanical support system in Fontan circulation with TCPC; the device can be installed at the bypass portion from inferior vena cava (IVC) to pulmonary artery (PA). (LA: left atrium, RA: right atrium, SV: single ventricle, SVC: superior vena cava)

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Consequently this single ventricular pumping action induces elevated systemic venous and caval pressure and altered pulmonary artery hemodynamics with lower pulsatility and pulmonary hypertension as well as unequal hepatic blood distribution which may cause severe problems in the early postoperative stage. Therefore, the mechanical circulatory support during the palliative circulatory repair by TCPC can improve the pulmonary blood flow followed by the decrease of venous pressure and systemic load.

We have been developing a totally implantable pulmonary circulatory assist system which is capable of supporting blood flow with TCPC as shown in Figure 1 and 2. The device is to be attached on the TCPC conduit from the outside, and it can be actuated when it is needed according with physiological demand. In this study, we examined the structural design of a prototype and evaluated its dynamic function in the mock system simulating the hydrodynamic loading condition in natural hemodynamics.

II. Materials and Methods

A. Anisotropic Covalent Type Shape Memory Alloy Fiber

We used a sophisticated Ni-Ti alloy fiber (Biometal) as an actuator of the pulmonary circulatory assist device which was to be attached onto the external surface of ePTFE conduit [11]–[13]. The fiber material has the special features as follows by annealing process of the Ti-Ni-Cu (Cu: 6.5%) thin wire: a) stable two-way shape memory effect by approximately 5–7 % tensile strain, b) long operational life in the range of the strain less than 4% under the contractile frequency of 2–3 Hz, c) stable linear characteristics of electric resistance of approximately 20% against the changes in strain deformation of 5% in length. We employed fibers of 100 micron in diameter that can generate approximately 400gf as an exergy by the electric power supply of 0.5W in each fiber.

B. Structural Design of the Device and the Control Unit

The concept of our assist system is identified by a contractile TCPC conduit by using shape memory alloy fibers. As the graft implantation period in stable adult circulation is carried on for a long term, the TCPC conduit is chosen to be equal to the diameter of normal inferior vena cava from approximately 16 to 20 mm for preventing pulmonary impedance elevation with growth. These alterations and preparations of the conduit size influence the device design, and we selected the size of the actuator to be 18mm in internal diameter and 7cm in length. In order to extend the strain ratio of the fiber for the effective contraction from outside of the ePTFE conduit, we developed a horseshoe-type disc structure as shown in Figure 3.

The displacement of each fiber is duplicated by the disc. And each fiber of the device was electrically contracted by the driver unit, which consisted of a single chip PIC microcomputer (Microchip Technology, USA) (Figure 4).

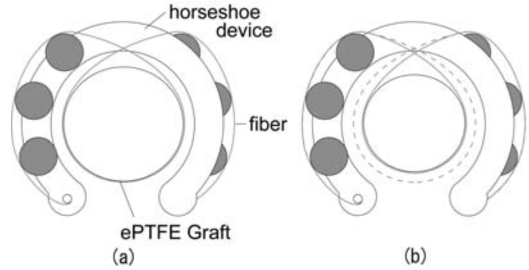

Fig. 3 Schematic illustration of the horseshoe structural design of the contraction unit with six rotatable pulleys, in diastolic phase (a) and in systolic phase (b); the displacement of the fiber is duplicated by is horseshoe-shape disc, and extend its contractile ratio.

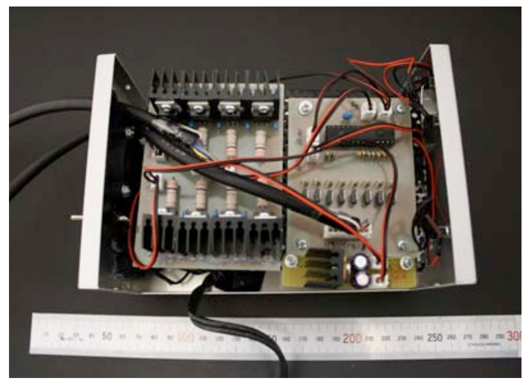

Fig. 4 Control unit developed for the pulmonary assist device

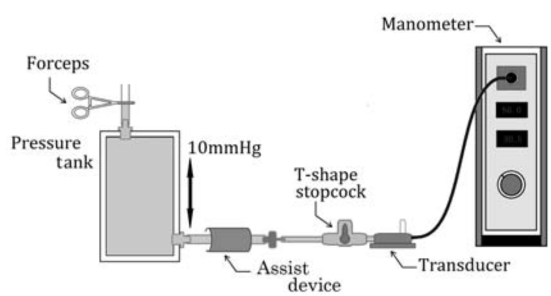

Fig. 5 Schematic drawing of the mock system representing the hydrodynamic loading condition in natural pulmonary hemodynamics; the pressure head of the preload tank was controlled to be 10mmHg, and the device was attached on the external surface of ePTFE conduit.

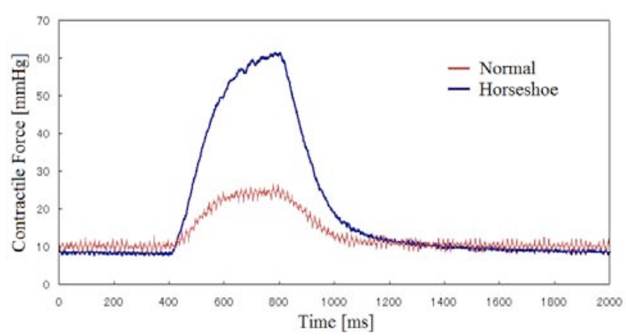

Fig. 6 Comparison of the changes in contractile hydraulic pressure waveforms obtained at the ePTFE conduit under the condition with 400 msec-current supply against 10mmHg loading condition at the preload water tank; Horseshoe design generates bigger hydraulic power than the device without the duplication structure, which is indicated by “Normal.”

C. Examination of Dynamic Characteristics of the Device

We examined its dynamic function in the mock system filled with room temperature water (Figure 5). The pressure head of the preload tank was controlled to be 10mmHg. The device was attached on the external surface of the ePTFE conduit (16mm in diameter). The device actuator consisted of eight horsehoe units, and its contraction was controlled by the originally programmed PIC with the variable contraction period, and contractile modes.

III. Results

A. Size of the Device and Effects of the Structure

As shown in Figure 1, the prototype of the pediatric pulmonary assist device was developed. The internal and external diameters of the actuator with the horseshoe structural discs are 16 and 26 mm, respectively. Each fiber was covered by silicone rubber tubing and fixed at the horseshoe edges. Total weight of the device was 20g with the structure. The duplication structure of the displacement by horseshoe shape disc was successfully achieved by using six rotatable pulleys, and its contraction ratio in internal diameter increased 15%, which was 6 times bigger than the contractile device without horseshoe design. Then the volumetric constriction in systolic phase could be achieved by 9% under the condition of the fiber strain change by 4%.

B. Comparison of Contractile Force Generated by the Structure

The changes in maximum hydraulic pressure were measured under the two different types of structural designs under the same electric power supply conditions with the horseshoe shape and without any duplication discs.

The maximum hydraulic pressure increased to be 63mmHg by using the device with horseshoe structure, whereas that obtained by the direct contraction was 27mmHg, as shown in Figure 6. Moreover, the positive hydraulic pressure incremental changes (dP/dt) obtained with and without discs were 302 and 94 mmHg/sec, respectively.

IV. Discussion

Results of this study indicate that the mechanical duplicable horseshoe structure offers promise as an effective design for the promotion of contractile support in the TCPC assistance using shape memory alloy fibers. We have shown that the dynamic compression from outside of the ePTFE conduit generates hydraulic pressure change followed by the conduit wall motion, and cause pulsatility in pulmonary circulation. The pressure waveform obtained by the device with the horseshoe shape discs demonstrates significant increase in dP/dt, and the incremental pressure was achieved to be more than 250 mmHg/sec which was measured in normal right ventricular function.

The application of the thin shape memory alloy fiber to the circulatory support device leads an advantage in order to reduce not only the device dimensions but also the size of whole system. As the material used in this study exhibits the linear electric resistance characteristics, the accurate displacement, contractile velocity, and acceleration as force can be arranged by using feedback systems. On the other hand, it is necessary to prepare optimal heating method with precise heat control for the accurate regulation of the motion of the pulmonary assistance. In conclusion, this study provides an alternative biomedical engineering approach for the pediatric circulatory assistance for the palliative surgical restoration on congenital heart disease.

V. Conclusion

This study demonstrated the possibility of a mechanical design of the newly developed pulmonary circulatory assist device by the small sized sophisticated actuator using shape memory alloy fiber. The presented prototype model examination simplifies a physiological loading condition that requires further in vitro validation studies and animal experiments.

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