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Peristaltic Hemodynamics of a New Pediatric Circulatory Assist System for Fontan Circulation using Shape Memory Alloy Fibers

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Abstract— **Fontan procedure is one of the common surgical treatments of congenital heart diseases. Patients with Fontan circulation have single ventricle in the systemic circulation with the total cavopulmonary connection. We have been developing a pulmonary circulatory assist device using shape memory alloy fibers for Fontan circulation with total cavopulmonary connection. It consisted of the shape memory alloy fibers, the diameter of which are 100 µm. The fibers could wrap the ePTFE conduit for Fontan TCPC connection from the outside. We designed the sequential motion control system for sophisticated pulmonary hemodynamics by the pulsatile flow generation. In order to achieve pulsatile flow assistance in pulmonary arterial system, we fabricated a mechanical structure by sequential contraction of shape memory alloy fibers. Then, we developed a sequential contraction controller for the assist system, which could reproduce the wall contractile velocity at 6.0 to 20.0 cm/sec. We examined hemodynamic characteristic of its function using a mock circulatory system, which consisted of two overflow tanks representing venous and pulmonary arterial pressures in Fontan circulation. As a result, the pulmonary circulation assist device with sequential contraction could achieve effective promotion of the pulsatility in pulmonary arterial flow.**

I. INTRODUCTION

Fontan procedure is one of the surgical procedures for the pediatric patients with congenital heart disease such as single ventricle or hypoplastic left heart syndrome [1]–[7]. Superior vena cava (SVC) is anastomosed to a pulmonary artery (PA), and inferior vena cava (IVC) is directly connected to a pulmonary artery using an expanded polytetrafluoroethylene (ePTFE) vascular prostheses. The serial connection between the pulmonary circulation and systemic circulation, in which there is no ventricle in the pulmonary circulation, results in a non-physiological circulatory system. Fig. 1 shows schematic illustrations of structural difference for the restoration of pulmonary hemodynamics by using the extra-cardiac conduit.

The Fontan procedure is commonly applied in the treatment of 2–3 year-old pediatric patients. Thus, it is anticipated that supporting blood flow in the pulmonary circulation followed by encouraging the growing lung functions are might be important. Promoting of pulsatile flow would be necessary to maintain the pulmonary flow conditions. In the Fontan circulation, the lack of pulsatility may induce localized lung ischemia, and it may impair the development of pulmonary peripheral endothelial cells [8].

A variety of ventricular assist device has been applied for adult heart failure patients [9]–[10]. However, the small and light-weight devices, which can generate pulsatile flow for infants or a small child with congenital heart disease, are not clinically applied. We have been developing a pulmonary circulation support device for temporary-use. The system can promote pulmonary flow pulsatility in the pediatric patients after Fontan procedure as shown in Fig. 2 [11]. We used the shape memory alloy fibers as the actuator of this device, the diameter of which was 100 μm (BMF100, Toki Corporation).

In this paper, we focused on the additional pulsatility in the pulmonary circulation for the pulmonary arterial flow support for congenital heart failure patients. In order to promote the pulsatility in the flow that infuses the lungs, we implemented an original control system which promotes flow pulsatility by a mechanical contraction. Then we developed a circulatory support device with the function of peristaltic contraction for the promotion of an efficient assistance for Fontan circulation. And we examined its basic hemodynamic function in the steady flow test for the evaluation of pulsatile function which could be generated by the system developed in this study.

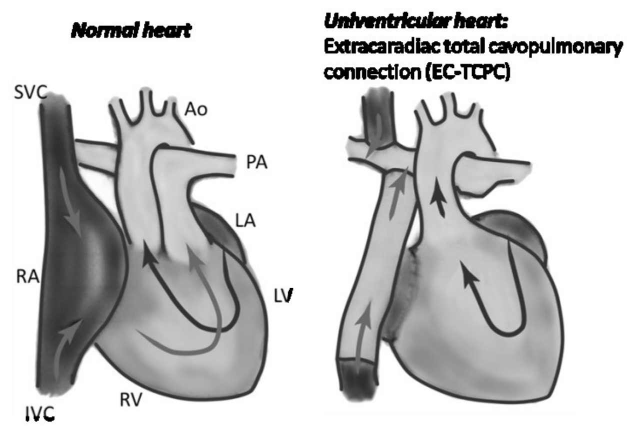

Figure 1. Schematic illustrations of the changes in hemodynamics of the normal heart and the univentricular heart (Fontan circulation). (SVC: superior vena cava, IVC: inferior vena cava, RA: right atrium, RV: right ventricle, LA: left atrium, LV: left ventricle, PA: pulmonary artery, Ao: aorta)

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II. MATERIALS AND METHODS

A. Development of the Circulatory Assist Device

We used a shape memory alloy fiber for the actuator of the pulmonary circulation assist device (BMF100, Toki Corporation, Japan) [11]–[14]. The diameter of fiber was 100μm. The fibers could contract by Joule heating, and the conduit was forced to shrink circumferentially. The maximum contraction ratio of the fiber was about 7% in length. We designed an original structure for the effective contraction and for promoting more pulmonary flow. The extra cardiac conduit made of an ePTFE graft could be functioning as an actuator for the pulmonary circulation assist system (Fig. 3).

We made a new structure with a rigid support sheath to achieve bigger contraction on the surface of the conduit. The fibers inserted into the elastic tubing, the 20% of which was covered with the low-compliant sheath. The length of each contractile portion covered with elastic silicone tubing was 50mm, which could encircle the ePTFE conduit circumferentially, as shown in Fig. 3. Then we could achieve bigger fiber contraction on the surface of the graft by up to around 20 mm in each unit. We mounted 16 units in parallel as a circulatory assist system attached on the surface of the ePTFE graft. As we could supply electric current for each fibered unit individually, the wall contraction velocity for radial direction could be varied.

We also developed a single chip driver by using a PIC microcomputer (Microchip Technology, USA) as shown in Fig. 4. We could control the radial wall contraction velocity by adjusting the intervals of the driving pulse in each fiber. The velocity change could be controlled sequentially at the range of 6.0 to 20.0cm/sec.

B. Examination of the Contractile Function in the Mock System.

We examined the basic function of the device in the overflow tank mock circulatory system as shown in Fig. 5, which consisted of two overflow tanks representing venous and pulmonary arterial pressures in Fontan circulation. The mock circulatory system of the preload was set to 20mmHg, an afterload was15mmHg. Under the condition with the static preload head of 20mmHg, the flow rate was 1.5L/min, which could represent in native pulmonary conditions in Fontan circulation. The device actuator consisted of sixteen units, and its contraction was controlled by the originally programmed PIC with the variable contraction velocity (6.0–20.0cm/sec). We also measured pressure waveforms at the graft as well as the flow waveform.

III. RESULTS

A. Contraction Force and Flow Waveform

Fig. 6 shows the pressure and flow waveform measured when the velocity of the peristaltic contractions was set to 20 and 7.0cm/sec, respectively. Under the faster contractile velocity condition, the flow waveforms exhibited the fluctuations from 1.2 to 1.8L/min, whereas the flow rate of the slower contraction velocity increased from 1.3 to 1.5L/min. Pressure increased to 13–20mmHg of the peristaltic velocity at 7.0cm/sec.

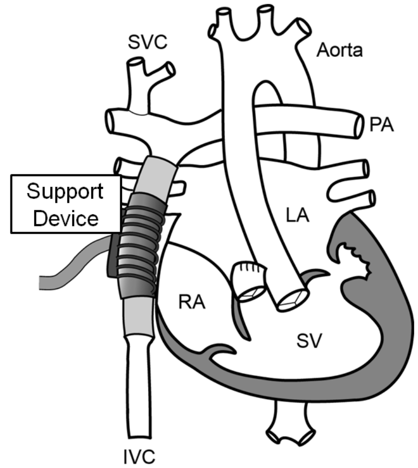

Figure 2. Schematic illustration of an implantable Fontan circulation support device; this device can be installed at the bypass portionfrom inferior vena cava (IVC) to pulmonary artery (PA).

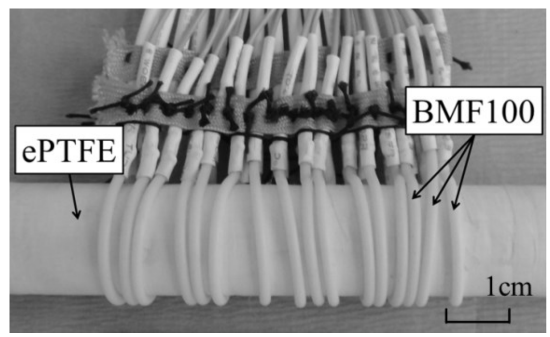

Figure 3. Contraction portion of the prototype model of the newly developed Fontan circulation support device which was covered with elastic silicone rubber tubing.

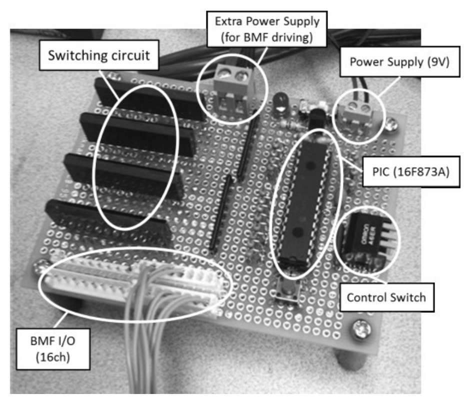

Figure 4. Control unit designed for the pulmonary assist device.

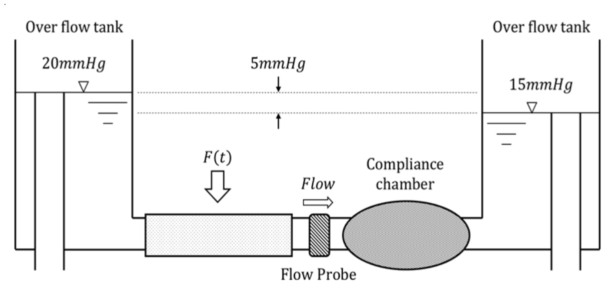

Figure 5. Schematic illustration of the mock circulatory system for the hydrodynamic test of the support device developed.

B. *Relationship between Pulsatility and Contractile Velocity*

Fig. 7 shows the result of comparison between the changes in flow pulsatility and contractile velocity, which was calculated from peak-to-peak flow under each contractile condition. When the contraction velocity was elevated, flow velocity fluctuation increased. Mean flow velocity in the ePTFE conduit was measured to be 12.5 cm/sec under the unassisted condition without the radial device contraction in the steady flow mock test. The increase of radial contraction speed enhanced the pulsatility of the flow in the conduit as shown in Fig. 7. The effect by the radial contractile function at the speed of 20 cm/sec on the amplitude of flow fluctuation showed higher velocity than the flow rate under the unassisted condition. We also calculated the power spectral density of the flow measured under the condition with the radial contraction speed at 20 cm/sec (Fig. 8). The spectral peaks could be recognized at the basic and harmonic frequencies of the device input.

IV. Discussion

We developed the pulmonary assist device using the shape memory alloy fibers. The device could generate higher pulsatility with an increase in peristaltic contraction velocity. The fundamental design of the surgical application was to install the system encircling the TCPC grafting in the Fontan procedure. To determine the optimized assistive condition by the sequential or individual contraction by the fibered unit, we examined the pulsatility effects of the device on the flow fluctuations in the steady flow test.

Our experiments indicated that the adjustment of radial contraction speed might increase the forward pulsatile flow velocity from outside of the TCPC conduit. As there is a risk of pulmonary hypertension in the patients with the Fontan circulation due to the long-term steady flow stress exposure in the pulmonary circulation, the efficient pulsatility might be profitable as well as the promotion of immature pulmonary systems.

In this study, we fabricated a combined structure for the elevation of the fiber contraction ratio by using the low-compliant and elastic plastic tubing, and we regulated the radial contraction speed on the wall of the ePTFE conduit from 6 to 20 cm/sec. We found the effective contribution of the wall contractile speed on the pulsatility in the conduit for the TCPC. And from the frequency analyses, it was suggested that these mechanical wall motion could generate pulsatility under the steady flow conditions representing a congenital heart failure Fontan circulation. The advantage of our device is the feasibility of the attachment on the conventional Fontan procedure without another mechanical apparatus installation, such as heart valves.

We also designed a new control system for the variable contraction speed control by a small chip-type microcomputer. Because of the availability of the absolute deformation changes by the electrical input in the shape memory fiber unit, we could achieve the small and lightweight pulmonary assist system for the use of the surgical treatment of congenital heart failure patients. The optimal condition of the sophisticated promotion of the TCPC conduit in the pulmonary circulation was not investigated in this study, we could analyze the pulsatility effect along with the radial wall contraction speed in the steady flow mock test.

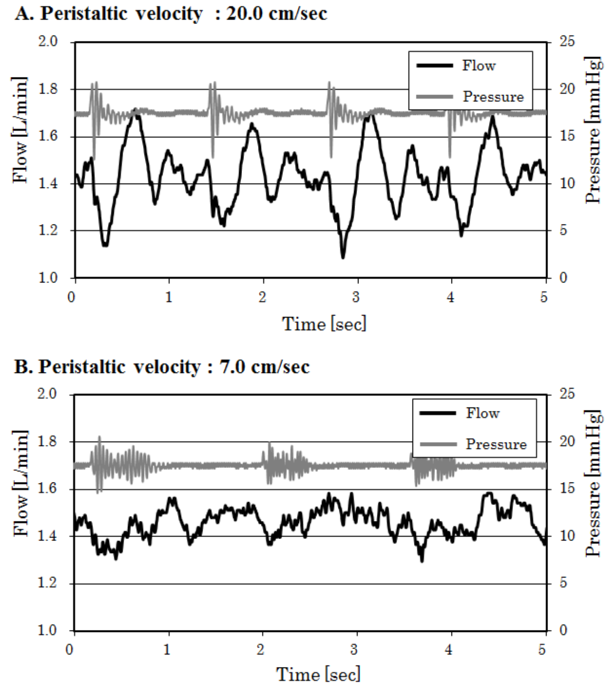

Figure 6. Flow and pressure waveforms measured in the mock test; A) the waveforms under the condition with the radial contraction speed at 20 cm/sec, and B) under the condition with the radial contraction speed at 7.0 cm/sec. Bigger pulsatility could be achieved under the condition with the radial contraction speed at 20 cm/sec.

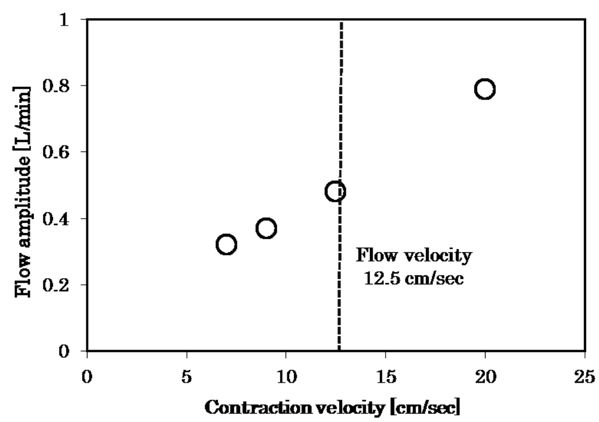

Figure 7. Relationship between the amplitude of flow fluctuation and the radial contractile velocity. The dotted line indicated the mean flow velocity under the unassisted condition without the device contraction (12.5 cm/sec).

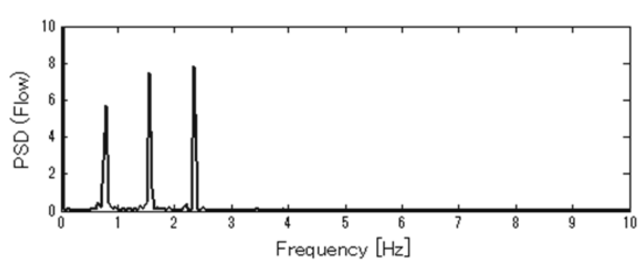

Figure 8. Power spectral density analysed from the flow waveforms obtained under the condition of radial contraction speed at 20cm/sec.

The mixed advancement by the improvement of the device structure and dynamic functional capabilities might be effective for more sophisticated support of the Fontan circulation.

V. Conclusion

A pulmonary circulation assist device that generates flow pulsatility through peristaltic contraction was developed employing shape memory alloy fiber. We examined the function of the device in the mock circulatory system. And it was indicated that the pulsatility by the device could be achieve by our method efficiency.

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