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First A. Author, Second B. Author, Jr., and Third C. Author, *Member, IEEE*

Abstract— **Rotary blood pumps which have contact-less suspension are small, durable and widely used for left ventricular assist devices (LVADs). In order to design a total artificial heart (TAH) with rotary blood pumps, two pumps one for each ventricle, are controlled independently. Some of the challenges for the development of a TAH includes the requirement of a small size and the anatomical fitting of inlets and outlets which should be arranged closely on the circumference in the same direction. And they should be combined into a unit. In this paper, a helical flow total artificial heart (HFTAH) combing two centrifugal pumps with helical inlet in face is proposed in order to achieve a smaller TAH. To examine the pump performance, a preliminary test model for left ventricle was built, the size of the pump was 69.0mm in diameter and 45.0mm height. The size of the impeller was 44.0mm in diameter and 23.0mm height including a 15.0mm-height hydrodynamic bearing. The pump was externally driven by a direct current motor. 5.0L/min flow rate against 100mmHg pressure difference was obtained, where the total power consumption was 5.0W, the system efficiency was 23% with a rotational speed of 2070rpm. In this system, maximum pressure head, flow rate and efficiency were 420mmHg, 15.0L/min and 26%, respectively. In acute animal experiments with three healthy adult goats, the total biventricular bypass assist system using the pumps was able to maintain the maximum aortic flow at approximately 5.0L/min, and the pulmonary arterial flow at approximately 4.6L/min, the mean aorta pressure was 105mmHg, and the mean pulmonary artery pressure was 51mmHg. The development of the control method is undergoing, and a driving system and the pump aiming at the chronic animal experiments will be developed.**

I. Introduction

THE clinical trials of several kinds of left ventricular assist devices (LVADs) for long-term use have begun and show excellent results. Rotary blood pumps (RBPs) with non-contact supports such as magnetic levitation [1] or hydrodynamic bearing [2] have long durability. However, there are many cases in which LVAD is not sufficient; in these cases, heart transplant is thought to be the best and ultimate treatment, although there are problems of donor shortage and ethical problems. Therefore, a right support must be added. Implantation of bi-ventricular assist device (BiVAD) and total artificial heart (TAH) are expected to become important therapeutic procedures.

It is desired to develop BiVAD and TAH which have small size, an ability to totally assist ventricular function and longer durability. Externally actuated TAHs that comprise two volume-displacement, pneumatically actuated pumps have been used for bridge to transplantations [3, 4]. However internally actuated TAHs [5] need hydraulic or mechanical actuators and compliance cambers therefore they are bulky and have limited durability. On the other hand, RBPs used for LVADs are smaller, more durable and have higher efficiency than volume-displacement blood pumps. However, in order to configure implantable BiVAD [6, 7] or TAH [8, 9] using RBPs, it is difficult to combine two pumps for left ventricle and right ventricle into one device because of their ports arrangement. In this paper, we propose a novel structure of centrifugal blood pump for helical flow TAH (HFTAH). Firstly, we carried out the animal experiments of total biventricular bypass to confirm characteristics of this pump in vivo.

II. Material and Method

A. Structure of the pump

In Fig. 1, an illustration of the implantation of the HFTAH which we have been developing is shown; it was designed to be easily implanted and satisfy anatomical fitting. As shown in Fig. 2, two novel centrifugal pumps which have helical inlet were combined in face, arranging two inlets closer and making the width smaller. Long durability can be achieved by using the hydrodynamic bearing as a support mechanism of the impeller. It was thought that hydrodynamic bearing was suitable for TAH because it cloud avoid complication and reduce total size and weight. The size of the TAH designed was 69.0mm in diameter and 63.0mm wide as shown in Fig. 3. The weight was 720g; also the mock-up of HFATH is shown in Fig. 4.

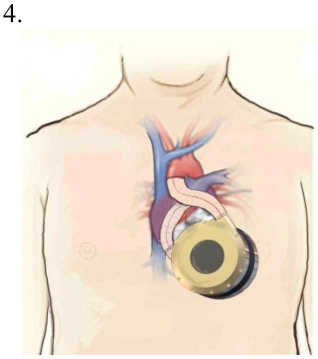

Fig.1. Implantation of the HFTAH

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H. Miura, Y. Shiraishi and T. Yambe are with the Institute of Development, Aging and Cancer, Tohoku University, Sendai, 9808575JPN (phone: 022-717-8517; fax: 022-717-8518; e-mail: h.miura@ idac.tohoku.ac.jp)

JX. Chen, TK. Sugai and T. Yambe are with Graduate school of biomedical engineering Tohoku University, Sendai, Japan.

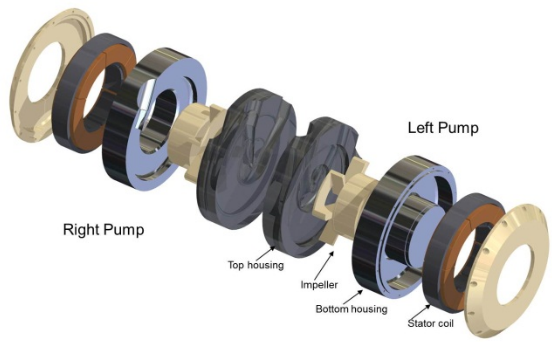

Fig.2. Scheme of parts consist of the rotary HFTAH

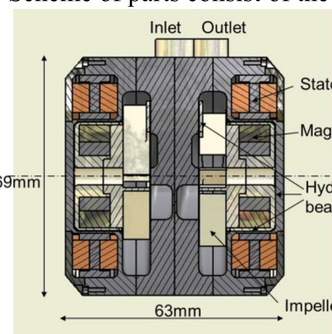

Fig.3. Scheme of the rotary HFTAH

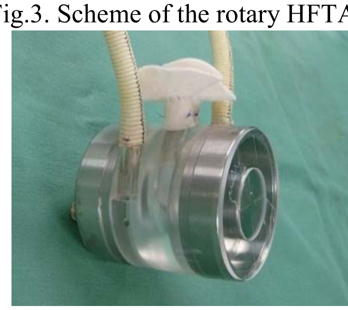
Fig.4. Cross section of the HFTAH

B. Pressure-flow characteristics

The prototype pump for the left ventricle of HFTAH was developed as shown in Fig. 5. In order to measure the pressure-flow characteristics and examine the hydrodynamic bearings of the pump distinctly, the motor which consists of the magnets and the stator coil was not embedded. The size of the pump was 69.0mm in diameter and 45.0mm height. The size of the impeller was 44.0mm in diameter and 23.0mm height including 15mm height hydrodynamic bearing part. The hydrodynamic bearings were composed on the top surface, the bottom surface, and the side of the impeller. The impeller, the top and the bottom housings were made from duralumin, acrylic resin and stainless steel (SUS304), respectively. A shaft was attached to the impeller and was connected to brushless direct current (DC) motor (EC-45, Maxon Co., Switzerland) via flexible coupling. In this means the impeller is suspended only by the hydrodynamic bearings. The motor was driven with sensor-less motor driver (AECS35/3, Maxon Co., Switzerland). The operational fluid was 0.9%NaCl, 33% glycerin solution, and the temperature of fluid was controlled to 37 degrees Celsius. Pressure was measured with the diaphragm type pressure sensor on the inlet and the outlet of the pump. Moreover, flow rate was measured by using the electromagnetic flow meter（Nihon Koden corp. Tokyo, Japan).

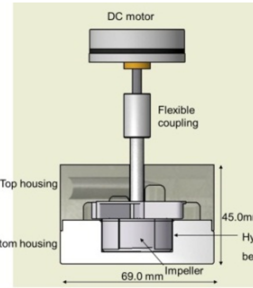

Fig.5. Cross section of the test pump for hydraulic performance

C. Animal experiment ure

Animal experiments were performed after approval by the Research Animal Resource Committee Guidelines of the Institute of Experimental Animals, School of Medicine, Tohoku University (Japan). Three female goats (Saanen) used weighed 47-63kg.The goats were kept fasting for a day before experiments. The goats were anesthetized by halothane inhalation. After intubation by tracheotomy, they were placed on a respirator. Electrodes for electrocardiography (ECG) were attached to the body. The left pleural cavity was opened via left fourth rib resection. The right atrial pressure (RAP) and the left atrial pressures (LAP) were monitored continuously with catheters inserted into each atrium. The pulmonary arterial pressure (PAP) and the aortic pressure (AoP) were monitored in the outlets of the pumps. To monitor flow rates, ultrasonic flow meters (Transonic Systems Inc. Ithaca, NY, USA) were attached to each outlet of the pumps. For pump connection, polyvinyl-chloride (PVC) inflow cannulae were inserted into each atrium through the auricles, and they were secured with ligatures. Right and left outflow cannulae were sutured to the pulmonary artery and to the descending aorta, respectively, as shown in Fig. 6.

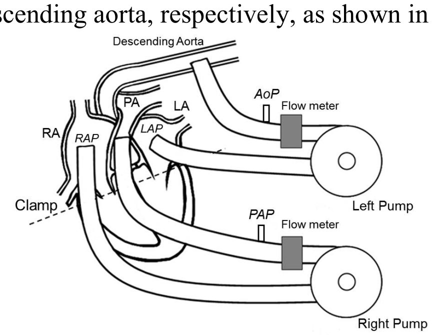

Fig.6. Connection of the pumps in the animal experiment

At first the pumps were operated as a BiVAD, and then the ventricles were clamped by a forceps below the bicuspid and tricuspid valves. In these acute animal experiments, pumps were not implanted into the thoracic cavity. In chronic experiments, we are considering resection of the ventricles and placing the pumps instead of the ventricles. The pumps were driven by brushless DC motors (EC-45, Maxon Co., Switzerland) with sensor-less motor drivers (AECS35/3, Maxon Co., Switzerland). The outputs of the pumps were controlled to maintain appropriate circulation by manually changing of the input voltage of the drivers.

III. RESULTS

The pressure-flow characteristics are shown in Fig. 7, the power consumption is shown in Fig. 8, and the system efficiency including the pump, the motor and its driver is shown in Fig. 9. An output of 5.0L/min against 100mmHg, which is the typical operating condition of LVAD was obtained by 2070 rpm with a power consumption of 5.0W and with an efficiency of 22% .The motor has the rated power and rotational speed of 30W and 4000rpm, within this condition; the maximum output pressure, flow rate and system efficiency were 420mmHg, 15.0L/min and 26% respectively. In the hydrodynamic bearings, wear was not seen except in the running-in period. Acute animal experiments with healthy adult goats were performed. As shown in Fig.10 the developed pumps were successfully attached in the means of total biventricular bypass and were able to maintain the circulation. In Fig. 11, P wave in ECG and a pulsatility which was synchronized to the P wave in LAP were observed. The maximum aortic flow rate in the animal experiments was approximately 5.0L/min, approximately 4.6L/min for the pulmonary arterial flow rate were obtained, the aortic pressure was approximately 105mmHg, and the pulmonary artery pressure was approximately 51mmHg, as shown in Fig. 12. Sometimes, occlusions by a suction at atria occurred, the pump outputs were reduced by changing of the input voltage of the driver to release the suction.

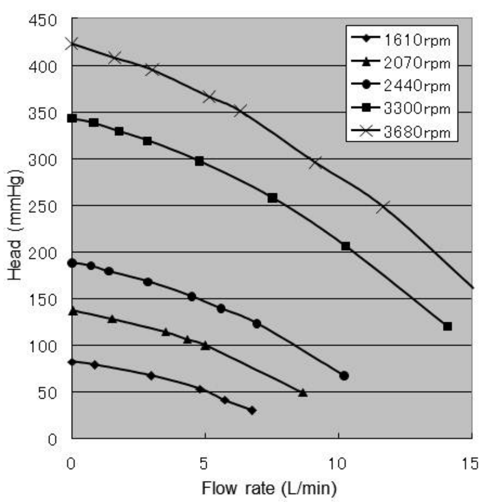

Fig.7 Characteristics of pressure-flow rate

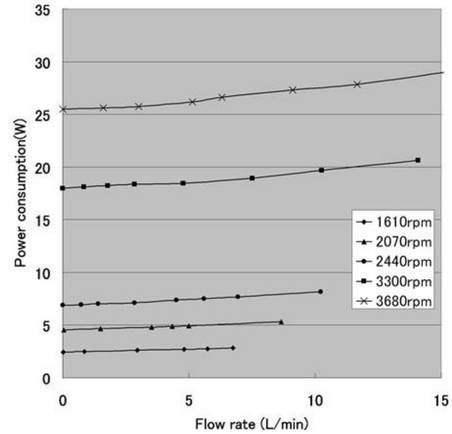

Fig. 8 Characteristics of power consumption vs. flow rate

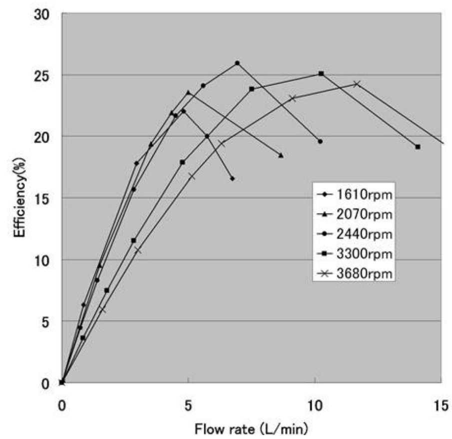

Fig.9. Characteristics of system efficiency vs. flow rate

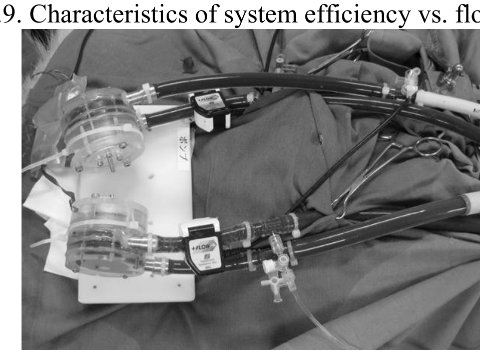

Fig.10. Picture of an animal experiment

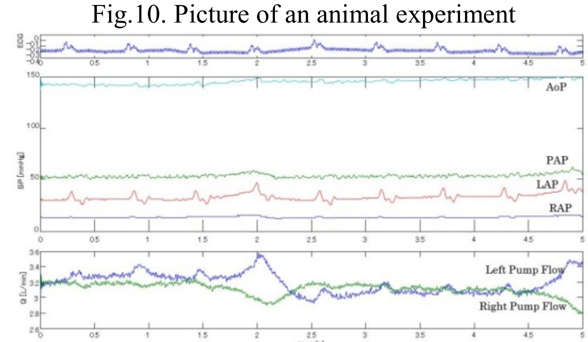

Fig. 11 Hemodynamic status; P wave and Pulsatility in LAP

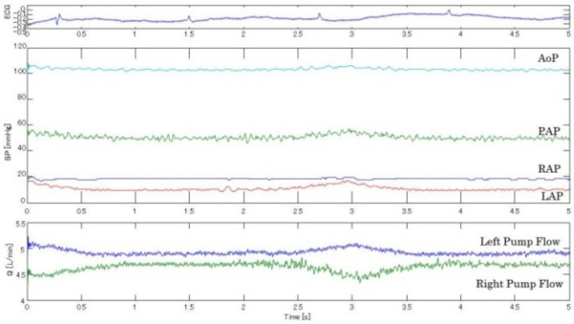

Fig. 12 Hemodynamic status; the maximum flow rate

IV. Discussion

The output performance of the prototype of the pump was enough to maintain the total circulation. The efficiency of the pump was almost the same level of present LVADs. It was thought the prototype pump could be driven by a small motor, which would result in smaller device. In acute animal experiments, the total artificial heart was able to maintain the circulation. The development of an implantable TAH with embedded motors is undergoing. The optimization of shape of the impeller, housing and bearing is necessary using a flow visualization and computational fluid dynamics. The total system will be constructed including the drive circuit and the control algorithm including sucking release control and left-right flow balance control. Some groups have begun challenges to develop continuous flow TAH (CFTAH) or BiVAD. BiVACOR[6, 7] and CFTAH under developed at Cleveland clinic include left and right vanes positioned on a shared rotating hub to form a magnetically and or hydrodynamically suspended centrifugal impeller. The left-right balance is achieved by the alteration of the clearance above the vanes. This means has a limitation in controllability. CFTAHs which are constructed from two axial flow pumps [8, 9], have complex cannulae system because of the port arrangement of the axial flow pumps. The proposed HFTAH has a possibility to overcome such kinds of shortage of CFTAHs. The total biventricular assist system was operated in continuous flow. By changing the rotational speed of motor, quasi-pulsatile flow is obtained in RBPs. Abe et al. figured out the importance of the pulsatility in the sucking release effect in the atria and the control method named 1/R was examined in the pulsatile and nonpulsatile mode with the same animal [10].The prototyped device was so heavy because heavy material of stainless steel was used. Weight should be reduced by changing materials and re-design. In this study we used easily available and processed material, however biocompatible materials should be used chronic animal experiment.

V. Conclusion

Helical Flow total artificial Heart (HFTAH) which combines two centrifugal pumps with helical inlet in face was proposed, the size and weight was designed to be 69.0 mm in diameter, 63.0 mm width and 720g. A preliminary test model for left ventricle was built, 5.0L/min flow rate against 100mmHg pressure difference was obtained, where the total power consumption was 5.0W, the system efficiency was 23% with a rotational speed of 2070rpm within the prototype. In acute animal experiments with three healthy adult goats, the total biventricular bypass assist system using the pumps was able to maintain the circulation within normal range. The development of the control method is undergoing, and a driving system and the pump aiming at the chronic animal experiments will be developed.

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