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Pulsatile Driving of the Helical Flow Pump

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***Abstract*—The helical flow pump (HFP) is newly developed blood pomp for total artificial heart (TAH). HFP can work with lower rotational speed than axial and centrifugal blood pump. It can be seen reasonable feature to generate pulsatile flow because high response performance can be realized. In this article, pulsatility of HFP was evaluated using mock circulation loop. Pulsatile flow was generated by modulating the rotational speed in various amplitude and heart rate. In the experiment, relationship between Pump flow, pump head, rotational speed amplitude, heart rate and power consumption is evaluated. As the result, complete pulsatile flow with mean flow rate of 5 L/min and mean pressure head of 100 mmHg can be obtained at ±500rpm with mean rotational speed of 1378 to 1398rpm in hart rate from 60 to 120. Flow profiles which are non-pulsatile, quasi-pulsatile or complete flow can be adjusted arbitrarily. Therefore, HFP has excellent pulsatility and control flexibility of flow profile.**

I. Introduction

Total artificial heart for severe congestive heart failure has researched for years. To date, two TAHs, CardioWest[1-3] and AbioCor[4]were reached to the stage of clinical use. However, durability is limited and size of pump isn't small enough for a patient of small body, due to a diaphragm pump. Thus, still many challenges are awaiting to be conquered. After TAH implantation, stable systemic and pulmonary blood circulation must be achieved. However suction phenomenon which is sudden inflow port occlusion by arterial wall triggers pump flow drop suddenly. Especially sever suction in left pump inlet causes sudden lung edema and aortic pressure drop. Thus, the suction of atrium is huge problem in continuous flow rotary blood pump. One of the ways to prevent them is to keep inlet pressure high [5]. However, it's not physiological and the risk of lung edema is still remaining. While, pulsatile flow generation by modulating the rotational speed of blood pump is one of the powerful candidates to avoid severe suction and to release suction early stages [6]. Since introducing the pulsatile flow can release suction periodically. Therefore the risk to fall into sever suction can be reduced and also inlet pressure can be kept in physiological level. Highly sophisticated blood pumps for LVAD are centrifugal flow pump or axial flow pump [7-9]. Especially centrifugal pumps can obtain passively-created pulsatile flow which is induced by native heart beat. But it is difficult to create the pulsatile flow actively which is required in the TAH to prevent suction. The HFP which is a novel rotary blood pump designed for the helical flow total artificial heart (HFTAH)[9]. It is a rotary blood pump with hydrodynamically suspended impeller. In the HFP, with a combination of a multi-vane impeller and a double-volute pump housing generates a helical flow inside the pump. In this article, pulsatility of HFP is evaluated through in vitro test.

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II. Materials and Methods

Device description

HFP is novel blood pomp designed for total artificial heart. Figure.1 is the HFP working as left pump of HFTAH. The HFP can perfuse 19l/min against 100 mmHg at 2500rpm. In the HFP, mainstream passes helical passage that consists of helical inlet volute, impeller and helical outlet volute. A part of blood flows through the hydrodynamic bearing to levitate impeller and to cool the motor stator which besides the hydrodynamic bearing. Helical volutes are double volute structure to keep pressure distribution symmetry and make levitated impeller stable. Inlet and outlet port of HFP are located in side-by-side, unlike axial pump and centrifugal pump. When assembled as TAH, the ports of left and right pump can be located in same direction adjoiningly. The layout is similar to native heart, so that anatomically acceptable implantation can be realized.

The diameter of HFP is 80 mm, the width is 40 mm, and the weight is 370 g. HFP consists of three major parts, impeller, stator and a couple of housing. Impeller is levitated by hydrodynamic bearing (Figure.2). Hydrodynamic bearing is three-lobe hydrodynamic bearing. Gap between hydrodynamic bearing and true circle shaft is 30um at the minimum position, 80um at the maximum position. Diameter of shaft is 37.1 mm, width is 29 mm. Three blood channels are located in the bearing. Width of the blood channel is 0.6 mm depth is 0.5 mm. 24 radial vanes are arranged on the outside of impeller, and hydrodynamic bearing is set on the inside of impeller for radial support. Rotor magnet is embedded in impeller. Stator is placed core of HFP, inner side of impeller. The stator directly actuates the magnet embedded impeller. Since gap of the hydrodynamic bearing covers the stator cylindrically, generated thermal energy in the stator is taken away by blood stream that flows through the hydrodynamic bearing. Each of housing has helical volute. Repulsion magnets embodied in housing and impeller, are used for thrust support.

Pump housing and impeller was made with epoxy resin. True circle shaft was made with Ti-6Al-4V or ZrO2 ceramic. Hydrodynamic bearing was made with Ti-6Al-4V. Blood contact surfaces in housing, shaft, hydrodynamic bearing was coated by 2-methacryloyloxyethyl phosphorylcholine（MPC）polymer.

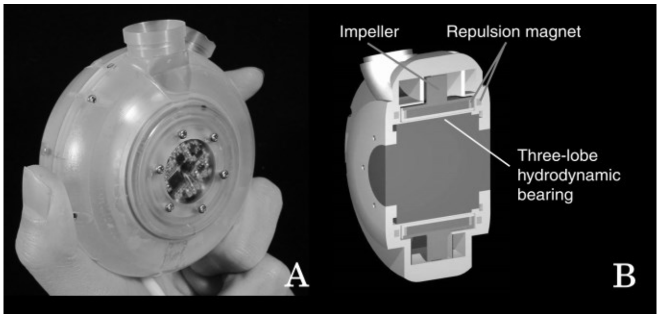

Figure.1 Helical flow pump

A: the helical flow pump used for experiment. B:cross-section view of the helical flow pump

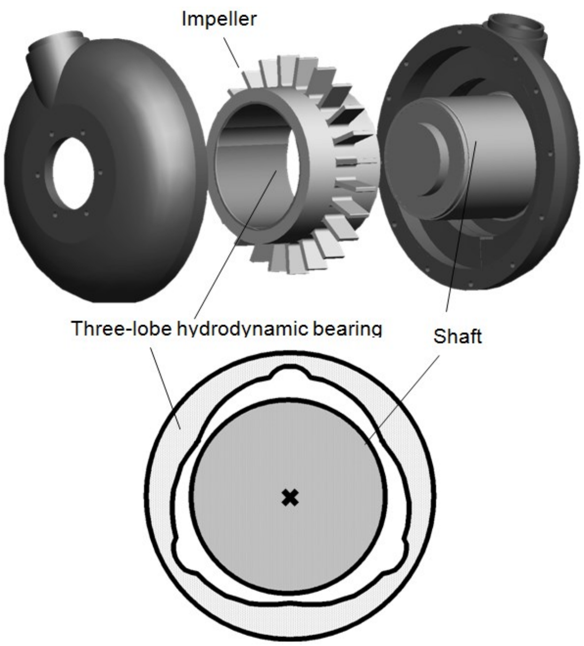

Figure.2 Three-lobe hydrodynamic bearing

Generation of pulsatile flow

Pulsatile flow was generated by cyclic modulation of rotational speed of the HFP. Driving voltage was controlled to modulate the rotational speed. Pulse-width modulation was used to control the driving voltage. The source voltage was divided into 256 steps, and then the driving voltage was adjusted between 0 and 255, 255 indicated full power (duty ratio: 1). Pulsatile flow was generated by switching different duty ratio. Base wave form was rectangular, and it was modified to trapezoid to make eccentric force of impeller milder.

Pulsatility evaluation

A donovan type mock circulatory loop was used (Figure.3). It was composed of HFP, connecting tube, water reservoir, systemic compliance camber and systemic resistor. These parts were connected sequentially. To simulate systemic circulation, compliance was set at 1.5 ml/mmHg by adjusting air volume in the camber. The resistor was adjusted to obtain targeted flow rate in average value. Working fluid was glycerol solution of 33%. Temperature was regulated at 37 degrees celsius by a heater.

Mean flow rate and mean pump head was regulated at 5L/min and 100mmHg in all experiment. Profile of the rotational speed modulation was defined by rotational speed modulation amplitude and frequency that means heart rate. Three pulsatile modes using variations of rotational speed modulation amplitude which is ±100, ±200, ±300, ±400, ±500rpm were applied. Three conditions of heart rate were tested, 60, 90, 120bpm in each pulsatile modes. Additionally, nonpulsatile flow mode was applied and compared to the pulsatile modes. In the nonpulsatile flow mode, rotational speed was fixed at constant value.

Date measurement

For flow rate measurement, electromagnetic flow-probe (FT-160T, Nihon koden, Tokyo, Japan) was put in outlet tube. Pressure was monitored at inlet and outlet tube by transducers (DX-300, Nihon koden, Tokyo, Japan). Pump head was calculated by difference between the measured pressures. Power consumption was obtained by mean current and mean voltage in 30 second. Instantaneous value of current was output from driver board. Instantaneous value of voltage was calculated from source voltage and applied duty ratio.

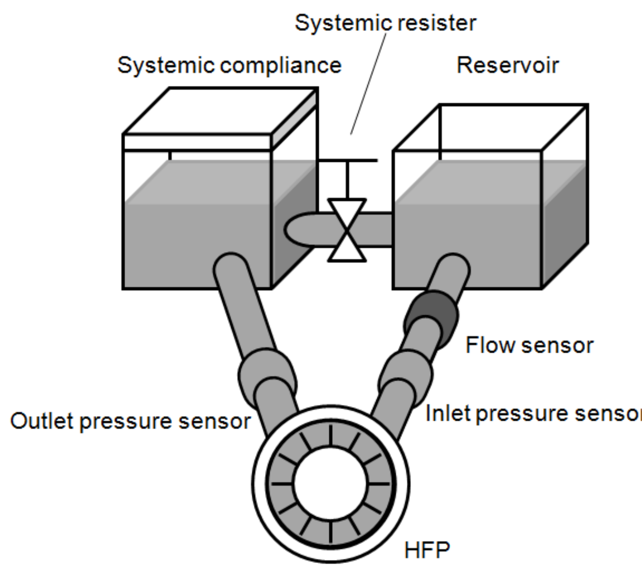

Figure.3 Mock circulation loop

III. Result

Rotational speed, Pump flow, pump head with different rotational speed amplitude at 90 bpm are shown in Figure.4. In each experiment, mean flow was kept at 5l/min and pump head was adjusted at 100mmHg. Mean rotational speed in the experiments were 1365 to 1391rpm. The magnitude of flow and pump head increased with increasing rotational speed amplitude. Nonpulsatile flow was obtained constant rotational speed of 1370rpm. Quasi-pulsatile flow is generated by rotational speed fluctuation of ±100rpm and ±300rpm. At the condition of rotational speed amplitude of ±100rpm, flow rate in systolic phase and diastolic phase are 6.09l/min and -4.02/min respectively. At the condition of rotational speed amplitude of ±300rpm, flow rate in systolic phase and diastolic phase are 7.8l/min and 1.62l/min respectively. In this mode, diastolic flow is not zero. Pump head is fluctuated in synchronization with rotational speed. Appling rotational speed amplitude modulation of ±500rpm, complete pulsatile flow is obtained. Flow rate in systolic phase and diastolic phase are 10.18l/min and -0.42l/min respectively. The maximum/minimum rotational speed was 1873/882rpm.

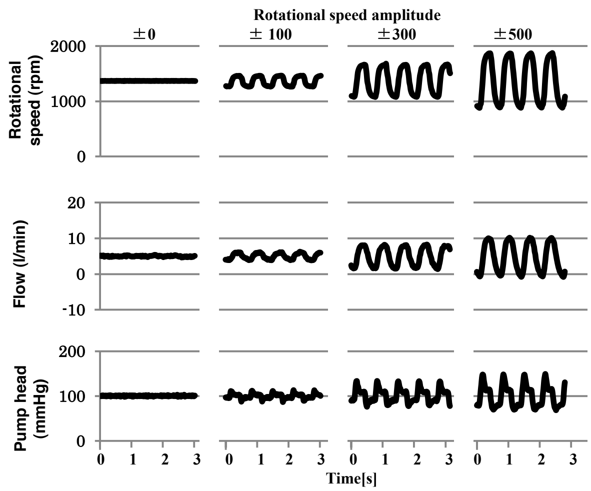

Figure.4 Rotational speed, Pump flow, and pump head with different rotational speed amplitude at 90BPM.

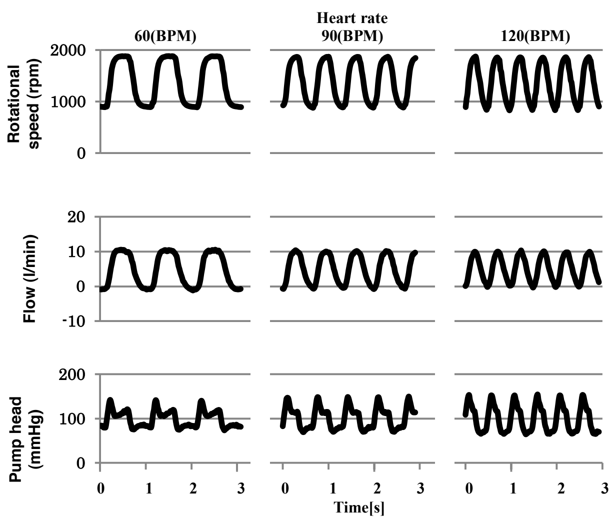

Figure.5 Pump flow and pump head response with different heart rate while keeping rotational speed amplitude at ±500rpm

Pump flow and pump head responses with different heart rate while keeping rotational speed amplitude at ±500rpm is shown in Figure.5. Three heart rates that were 60, 90 and 120bpm were tested. Mean flow was 5l/min and pump head was adjusted at 100mmHg in all experiments. Mean rotational speed in each experiment was 1378 to 1398rpm. Complete pulsatile flow was obtained in all conditions. Trapezoidal waveform was observed in 60bpm. Increasing the heart rate shortened plateau regions in systolic and diastolic phases. Flow fluctuation was slightly decreased in accordance with increase of heart rate. Systolic and diastolic flows were 10.4l/min and -0.96l/min respectively in 60BPM. In 120 BPM, Systolic and diastolic flows were 9.94l/min, -0.11l/min respectively.

Relationship between flow fluctuation, rotational speed amplitude and heart rate is depicted in Figure.6. Flow fluctuation was calculated from the difference between systolic and diastolic flow. Complete pulsatile flow was obtained by applying rotational speed amplitude of ±500rpm in any heart rate. Flow fluctuation was proportional to rotational speed amplitude. Changes of flow fluctuation were decreased slightly in accordance with the increase of heat rate at the same rotational speed amplitude, though it was 1l/min at the maximum.

The relationship between power consumption, rotational speed amplitude and heart rate is shown in Figure.7. Power consumption was correlated to rotational speed amplitude. Considering that the power consumption was 7.7W in continuous flow mode, Power consumption increased by 30% in rotational speed amplitude of ±500rpm in heart rate of 90. Heart rate slightly affects on power consumption.

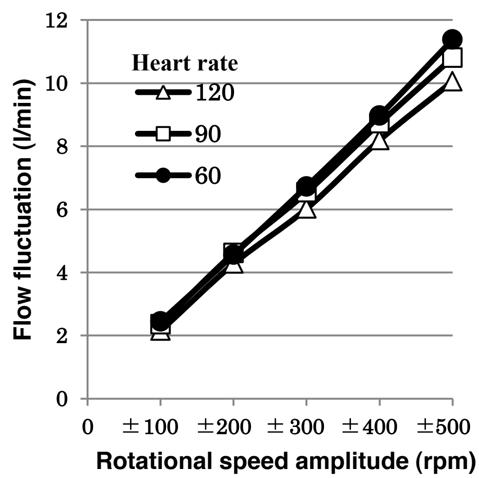

Figure.6 Flow fluctuation, rotational speed amplitude and heart

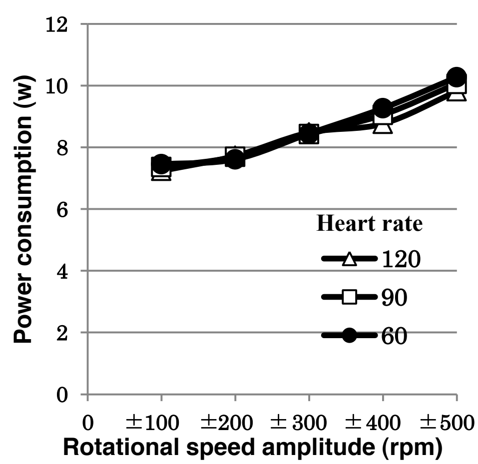

Figure.7 Power consumption, rotational speed amplitude and heart rate

IV. Discussion

One of the significant features of HFP is hydrodynamically levitated impeller that generates nonpulsatile flow and complete pulsatile flow. In the past decade, our group had developed undulation pump (UP) that can also generate pulsatile and nonpulsatile flow [10-12]. Undulation pump total artificial heart (UPTAH) that consists of two UPs was implanted to the goat, and the longest survival was 153 days. Comparing to commercially available TAH, Cardio west, AbioCor, the size of UPTAH is very small. In other point of view, favorable features, such as high hydraulic performance, anatomically suitable port configuration were realized in UPTAH. However mechanical wear of undulation shaft limited durability of UP, and the problem still remains. While, HFP eliminates mechanical wear in shaft and bearing, because impeller is supported with noncontact by hydrodynamic bearing. The approach enhances the durability of HFP. Thus, HFP overcomes weak point of UP.

In the case of pulsatile flow generation with hydrodynamically suspended impeller, special consideration is required to maintain stable operation for long-term. Levitation force is created by wedge effect between stationary surface and moving surface. That force is proportional to the difference of stationary part and moving part. There are possibilities to be too low rotational speed occurs to contact shaft with hydrodynamic bearing especially in diastolic period from the lack of levitation force. To prevent the problem, minimum rotational speed was defined and implemented. In the other point of view, switching between diastolic and systolic phase, eccentric force make impeller unstable. Thus square waveform was modified to trapezoid. In the future works, milder wave profile might be desirable to keep levitating impeller stable.

Suction in the inflow port is the huge problem in the TAH. Suction of left pump inflow rapidly leads decreasing of output flow. Subsequently aortic pressure drop and pulmonary arterial pressure rise were occurred. This reaction of pulmonary arterial pressure leads pulmonary edema. Abe et al. reported the problem and concluded that certain degree of pulsatile flow is necessary to maintain the stable circulation. Comparing to the nonpulsatile flow mode, sucking can be easily released in the pulsatile flow mode by changing outlet flow cyclically. In this paper it was confirmed that nonpulsatile flow, quasi-pulsatile flow and complete pulsatile flow in the heart rate of 60 to 120BPM can be created by HFP. Thus, HFP can be used to clarify the necessary and sufficient pulsatility to prevent severe suction. Additionally, quasi-pulsatile flow mode consumes less power than complete pulsatile flow mode. Maximum value of instantaneous flow and pressure comes to be lower as decreasing rotational speed amplitude. Then blood pump can be designed smaller size with appropriate performance. Therefore optimizing the pulsatility contributes to reduce power consumption and pump size. There were other factors on pulsatile flow to be researched. Ratio of systolic period and diastolic period is one of them. Difference of the ratio in constant heart rate, flow rate and pump head is affects to atrium volume at the beginning of systolic phase. Optimizations of the ratio have possibilities to reduce suction prevention.

In the past, consideration of microcirculation in short term period was attempted [13]. But it was difficult to research for long term because of limited durability of UP. HFP with hydrodynamic bearing can produce various flow profiles, flow fluctuation, and heart rate for long term. 19l/min against 100mmHg can be obtained at 2500rpm. Not only rest condition but also exercise condition can be reproduced by using HFP. Thus HFP can be used as desirable device to clarify the long-term effects come that from difference of nonpulsatile flow and pulsatile flow.

V. CONCLUSION

Pulsatility of HFP is evaluated in vitro experiment. It is confirmed that the HFP with hydrodynamically suspended impeller can create nonpulsatile flow, quasi-pulsatile flow and complete pulsatile flow by modulating the rotational speed. The HFP is advantageous blood pump for total artificial heart, to clarify the necessary and sufficient pulsatile flow to prevent suction and to disclose the long-term effects induced by flow profile.

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REFERENCES

[1] Copeland JG, Smith RG, Arabia FA, et al: CardioWest Total Artificial Heart Investigators: cardiac replacement with a total artificial heart as a bridge to transplantation. N Engl J Med 351: 859–867, 2000.

[2] Slepian MJ, Smith RG, Copeland JG. The SynCardia CardioWeste Total Artificial Heart. :473–490.

[3] Leprince P. Bridge to transplantation with the Jarvik-7 (CardioWest) total artificial heart: a single-center 15-year experience. The Journal of Heart and Lung Transplantation. 2003;22(12):1296–1303.

[4] Dowling RD, Gray LA Jr, Etoch SW, et al: Initial experience with the AbioCor implantable replacement heart system. J Thorac Cardiovasc Surg 127: 131–141, 2004.

[5] Frazier OH, Tuzun E, Cohn WE, Conger JL, Kadipasaoglu KA. Total heart replacement using dual intracorporeal continuous-flow pumps in a chronic bovine model: a feasibility study. ASAIO J 2006;52:145–149

[6] Y. Abe et al., “A nonpulsatile total artificial heart with 1/R control.,” Journal of artificial organs: the official journal of the Japanese Society for Artificial Organs, vol. 11, no. 4, pp. 191-200, Jan. 2008.

[7] Chung MK, Zhang N, Tansley GD, Qian Y. Experimental determination of dynamic characteristics of the VentrAssist implantable rotary blood pump. Artif Organs 2004;28:1089–1094

[8] Nojiri C, Kijima T, Maekawa J, Horiuchi K, Kido T, Sugiyama T, Mori T, Sugiura N, Asada T, Umemura W, Ozaki T, Suzuki M, Akamatsu T, Westaby S, Katsumata T, Saito S. Development status of Terumo implantable left ventricular assist system. Artif Organs 2001;25:411–413

[9] Yamazaki K, Kihara S, Akimoto T, Tagusari O, Kawai A, Umezu M, Tomioka J, Kormos RL, Griffi th BP, Kurosawa H. EVAHEART an implantable centrifugal blood pump for long-term circulatory support. Jpn J Thorac Cardiovasc Surg 2002;50:461– 465

[10] Yusuke Abe, Kohei Ishii, Kou Imachi, et al. The helical flow pump with a hydrodynamic levitation impeller. Artificial Organs. 2012; DOI: 10.1007/s10047-012-0659-z. http://www.springerlink.com/content/v5l7m7tlj7151528/

[11] Abe Y, Chinzei T, Isoyama T, Ono T, Mochizuki S, Mabuchi K, Baba K, Matsuura H, Sun YP, Kouno K, Atsumi K, Fujimasa I, Imachi K. Development of the undulation pump total artifi cial heart. Artif Organs 1997;21:665–669

[12] Abe Y, Isoyama T, Saito I, Mochizuki S, Ono M, Nakagawa H, Taniguchi N, Mitsumune N, Sugino A, Mitsui M, Takiura K, Ono T, Kouno A, Chinzei T, Takamoto S, Imachi K. Development of mechanical circulatory support device at the university of Tokyo. J Artif Organs 2007;10:60–70

[13] P.Dobšák, J.Vaškuo, A.Baba, T.Isoyama, I.Saito, J.Siegelová, J.Jančík, H.Svačinová, K.Imachi . Microvessels of Bulbar Conjunctiva in UPTAH Goats. Artificial Organs. 2003; DOI: 10.1046/j.1525-1594. 2003.07189.x