High Pressure-type Rotary Blood Pump with a New Principle

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Abstract An extracorporeal membrane oxygenator (ECMO) is used for the management of severe heart or respiratory failure. In the conventional ECMO system, centrifugal blood pumps are commonly used in recent years. However, a relatively high rotational speed is required to perfuse against the high hydrodynamic resistance of the system circuit. High rotational speed causes high shear stress. To provide a blood pump that can be operated at a lower rotational speed than conventional centrifugal blood pumps, we propose a novel high-pressure type rotary blood pump named the toroidal convolution pump (TCP). In the TCP, fluid that acquires centrifugal force from rotation of the impeller is returned to the impeller through the flow path and again acquires centrifugal force. With repetition of this cycle, fluid is accelerated to generate high pressure. We investigated the performance and basic property of the TCP using an experimental model and computational fluid dynamic (CFD) analysis. The TCP generated pump output of 5 L/min against a pressure head of 350 mmHg at a rotational speed of 2450 rpm. This rotational speed is much lower than that of conventional centrifugal blood pumps, which is usually higher than 3000 rpm. The efficiency of the TCP including the motor was approximately 4.2% at that setting. CFD analysis showed symmetrical pressure distribution about the central pivot bearing. The pressure difference between inlet and outlet ports was approximately 40% higher than that of the experimental model. We found no excessive negative pressure that would cause hemolysis. Although we identified areas of high shear stress, hemolysis is estimated to be low because of the short exposure time to the high shear stress. We found no stagnant area that would cause thrombus formation.

Keywords: ECMO, blood pump, toroidal convolution pump.

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1. Introduction
An extracorporeal membrane oxygenator (ECMO) is used for the management of severe heart or respiratory failure [1–3]. In the ECMO system, centrifugal blood pumps are conventionally used in recent years. Centrifugal blood pumps usually have the characteristic of generating high flow with low pressure. Therefore, when using a centrifugal pump in the ECMO system, a relatively high rotational speed is required to perfuse against the high hydrodynamic resistance of the system circuit. High rotational speed causes high shear stress. High shear stress could cause hemolysis and destruction of high molecular weight von Willebrand factor multimers, and stimulates platelet and fibrinogen to cause thrombus formation [4–7].

To provide a blood pump that can be operated at a lower rotational speed than conventional centrifugal blood pumps, we propose a novel high-pressure type rotary blood pump named the toroidal convolution pump (TCP). In this study, we investigated the performance and basic properties of the TCP using an experimental model and computational fluid dynamic (CFD) analysis.

2. Materials and methods

2.1 Structure and principle of the TCP
The TCP is composed of an impeller with upper and lower housings (Fig. 1A). The TCP has a pair of pump elements with a single impeller. Each pump element has its own inlet and outlet volutes. The upper housing consists of an inlet port, a gallery, and pairs of inlet volutes, outlet ports, outlet volutes and flow paths (Fig. 1B). The inlet port is connected to a pair of inlet volutes through the gallery. The outlet volute is connected to each outlet port. The two pump elements are located symmetrically about the pivot bearing, so that the lateral force is balanced at the pivot bearing. The impeller is driven by a magnet coupling mechanism, in which permanent magnets built in the impeller are coupled with the outer permanent magnets connected to the motor (Fig. 1C).
rotation of the impeller is returned to the impeller through the flow path and again acquires centrifugal force. With repetition of this cycle, fluid is accelerated to generate high pressure (Fig. 2). Thus, the principle of the TCP is similar to that of cascade pumps.

2.2 Development of the experimental model
To perfuse the ECMO system having high circuit resistance, the TCP is assumed to be capable of generating pump output of 5 L/min against a pressure head of 350 mmHg. To achieve this performance, the impeller with 20 vanes was designed to be 60 mm in diameter. The vane was designed to be 10 mm high and 20 mm long. A closed impeller was used. The clearance between the impeller and pump housing was designed to be 1 mm. All the parts were made of acrylic resin by machining process. The mono-pivot bearing with a diameter of 4 mm was made of stainless steel. The experimental model was made with acrylic resin using 3DCAM software (Creo2.0, PTC, Needham, USA) and a milling machine (MDX 50, Roland DG corporation, Hamamatsu, Japan).

2.3 Measurement of pump performance
Pump performance was measured using a mock circulation system. A fluid with the same viscosity as blood (2.8 Pa·s) was prepared by diluting glycerin to 33% in salty water. Specific gravity of the fluid was 1.08. Temperature of the fluid was maintained at 37°C. Pump flow was measured with an electromagnetic flow probe (FT-160T, Nihon Koden, Tokyo, Japan) attached to the outflow tube. The pressure head of the pump, which is the differential pressure between the outlet and inlet ports, was measured with pressure transducers (DX-300, Nihon Koden) attached to the outflow and inflow tubes.

2.4 Computational model
The computational model for CFD analysis was created using preprocessing software included in the CFD package (CFX ver.15.0, ANSYS, Canonsburg, Pennsylvania, USA). The Frozen Rotor model that treated the flow from one component to the next by changing the frame of reference while maintaining the relative position of the components was applied. Figure 3 shows the computational model prepared for CFD analysis.

2.5 CFD analysis
CFD analysis was performed using a solver and a post-processor included in the CFD package (CFX ver.15.0, ANSYS). To adjust parameters of fluid to those of blood, density of fluid was set at 1060 kg/m³ and dynamic viscosity at 0.0036 Pa·s. The static analysis was performed using the k-ε turbulence model. The outlet port pressure was set at 0 mmHg. In this setting, the inlet port pressure was calculated to be negative. Mass flow rate was set at the inlet port. The hydrodynamic property was calculat-
ed from the rotational speed, flow rate, pressure head and torque of the impeller. To stabilize the calculation results, iteration count and timescale factor were set at 100–400 times and 1.0, respectively. The mesh size was from 0.1 to 1.0 mm. The node and element numbers were 893,854 and 4,259,922, respectively [8–12].

3. Results

3.1 Pump performance of the experimental model

Figure 4 shows a photograph of the developed TCP model. Figure 5A shows the performance of this model. The TCP generated pump output of 5 L/min against a pressure head of 350 mmHg at a rotational speed of 2450 rpm.

The H-Q (pressure head vs. output) curves of the TCP were relative steep. The efficiency of the TCP including the motor is shown in Fig. 5B. The efficiency at pump output of 5 L/min against a pressure head of 350 mmHg was approximately 4.2%.

3.2 CFD analysis

Figure 6 shows the pressure distribution in the impeller when the flow rate was set at 5 L/min and rotational speed at 2500 rpm. The pressure at the inlet port area was −490 mmHg. The pressure of −490 mmHg means that the pressure difference between the inlet and outlet ports is 490 mmHg, which is approximately 40% higher than that of the experimental model. We found no area where pressure was lower than that of the inlet port area.

Figure 7 shows the distribution of shear stress in the impeller when the flow rate was set at 5 L/min and rotational speed at 2450 rpm. Areas of high shear stress were observed. The maximum shear stress was approximately 400 Pa.

Figure 8 shows the flow velocity vector in the impeller when the flow rate was set at 5 L/min and rotational speed at 2450 rpm. The transit time of blood through the impeller was calculated to be shorter than 0.001 s. The exposure time of the blood to the shear stress of 400 Pa was much shorter than 0.001 s. No stagnant area was observed.
4. DISCUSSION

In this study, the TCP generated enough performance for the ECMO system. The rotational speed of 2450 rpm at the setting of pump output of 5 L/min against a pressure head of 350 mmHg is much lower than that of conventional centrifugal blood pumps, which is usually more than 3000 rpm [13–16]. Concerning efficiency, the inner shunt flow that would occur between the pump segments through the clearance between the circumference of the impeller and housing would deteriorate the pump efficiency. Therefore, the pump efficiency would be influenced by the inner shunt flow. In order to increase pump efficiency, this clearance should be reduced. Smaller clearance would also result in lower rotational speed of the impeller. However, small clearance have the possibility of causing some adverse effects to blood compatibility. Therefore, further study is necessary.

CFD analysis showed symmetrical pressure distribution about the central pivot bearing. The pressure difference between inlet and outlet ports is approximately 40% higher than that of the experimental model. The main causes of hemolysis are cavitation caused by excessive negative pressure and excessive shear stress. CFD analysis showed no excessive negative pressure. However, we observed some areas with high shear stress. The maximum shear stress was approximately 400 Pa. Under this shear stress, exposure time longer than 0.001 s would cause hemolysis [17]. In the TCP, hemolysis is estimated to be low because the exposure time to shear stress of 400 Pa was much shorter than 0.001 s. Regarding thrombus formation, there was no stagnant area in the pump. Other parameters such as surface roughness and materials that would affect blood compatibility should be investigated as a next step.

5. Conclusion

A novel high-pressure type rotary blood pump named the TCP was proposed. The TCP had enough performance despite having lower rotational speed than that of conventional centrifugal blood pumps for use in the ECMO system. CFD analysis showed low estimated risk of hemolysis and no stagnant area that would cause thrombus formation.

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