AN IMPLANTABLE VENTRICULAR ASSIST SYSTEM EMPLOYING A RADIALLY CONTROLLED MAGLEV CENTRIFUGAL BLOOD PUMP WITH CAPABILITY TO MEASURE BLOOD FLOW RATE WITHOUT ADDITIONAL SENSORS

Chi Nan Pai, chinan.pai@ufabc.edu.br
Universidade Federal do ABC, Rua Santa Adélia, 166, Bloco A, Torre 1, sala 652, Santo André, São Paulo, 09210-170, Brazil

Tadahiko Shinshi, shinshi.t.ab@m.titech.ac.jp
Tokyo Institute of Technology, R2-38, 4259 Nagatsuta, Midori-ku, Yokohama, 226-8503, Japan

Abstract. *In order to solve the problems of lack of heart donors for transplant, implantable ventricular assist systems (VAS) have been developed to assist the failing heart ventricle. One of the components of a VAS is a blood pump that connects the left ventricle to the aorta. Therefore, the pump flow rate is influenced by the cardio-vascular system. To control the flow rate through the blood pump, real-time measurement of flow rate is required. However, the use of conventional flow sensors is not desirable due to issues of compactness and durability. In a magnetically levitated (maglev) rotary blood pump, the radial thrust acting on the maglev impeller depends on the pump flow rate. In this study, we present a centrifugal blood pump (CBP), incorporating a radial-controlled magnetic bearing (MB) and a brushless DC motor to be used in an implantable VAS. We also present a method for estimating average pump flow rate during ventricular assistance, based on the radial thrust estimated by a disturbance force observer of the MB. The magnetic bearing of the CBP is composed of two pairs of electromagnets located in the stator and a sandwich of two iron rings and a permanent magnet (PM) ring embedded in the impeller. To design the observer, parameters of the dynamic model of a maglev impeller were identified under different flow conditions, assuming the density and viscosity of water to be constant. The disturbance force observers were designed based on linear models that were obtained for a given rotational speed. The relationship between pump flow rate and radial thrust was first identified experimentally under continous flow conditions. Then, using this relationship and the measured radial thrust, the pump average flow rate was estimated under pulsatile flow conditions. The maglev CBP is 69.0 mm in diameter, 28.5 mm in height, 50.0 mm in impeller's diameter and the pump priming volume is 20 ml. The pump mass is 370 g, while the impeller mass is 98 g. Under rotational speed of 1700 rpm, the operating point (5 L/min, 100 mmHg) can be achieved. Using the proposed estimation method, the pump average flow rate estimation error was less than 11% (0.4L/min).*

Keywords*: Centrifugal blood pump, magnetic bearing, sensorless measurement, flow rate, implantable ventricular assist device*

1. INTRODUCTION

Heart transplant is the only treatment for patients with severe heart failure. However, there is a lack of heart donors and a long waiting list, and not all patients are able to have a transplant. For these patients, implantable ventricular assist systems have been used either as a bridge to transplant, or a bridge to recovery, or even a destination therapy, with good clinical results and improvements in the heart ventricle function and in the quality of life (Miller *et al.*, 2007). An implantable ventricular assist system, as shown in Fig. 1, is composed of a blood pump, which is connected to the ventricle in order to assist its pumping function, a flow sensor that measures the blood flow rate for the control of the pump, portable controllers and power sources. The blood pump and the flow sensor are implanted inside the body, while the controllers and power sources are placed outside the body. Power and signal cables passing through the skin are responsible for the connection between both sub-systems.

In order to be implantable, the blood pump should be compact and biocompatible, should cause little hemolysis and no thrombosis, and should have high durability and low power consumption. Rotary pumps have advantage over pulsatile pumps in that they are more compact and more durable. Among the rotary pumps, magnetically levitated (maglev) rotary blood pumps have been shown to be a good choice as an implantable device because of the non-contact support of the impeller, which decreases the hemolysis and the risk for thrombosis, and increases the pump durability (Hoshi *et al.*, 2006b).

When the rotary pump is connected to the heart ventricle, the pump flow is influenced by the cardio-vascular system. Therefore, to control the flow rate of the rotary pumps, measurement of the flow rate is required. However, conventional flow sensors for medical use are not compact, and requires more space inside the body. Hoshi *et al.* (2006a) have proposed using the radial displacement of the maglev impeller in a centrifugal blood pump (CBP) to estimate the flow rate. The radial displacement of the maglev impeller is caused by the radial thrust, which depends on the flow rate and the head pressure. Therefore, understanding the radial thrust acting on the maglev impeller provides a means to estimating the pump flow rate.

The maglev impeller is levitated without contact inside the pump. Therefore, conventional methods to measure the radial thrust, such as use of load cells, cannot be used. Observers are algorithms used to estimate state variables from measurements of the output variables, based on system models, and disturbance force observers have been proposed by Mizuno and Higuchi (1988) to estimate the unbalance forces in a MB system. Therefore, another option is the use of disturbance force observers to estimate the radial thrust acting on a maglev impeller.

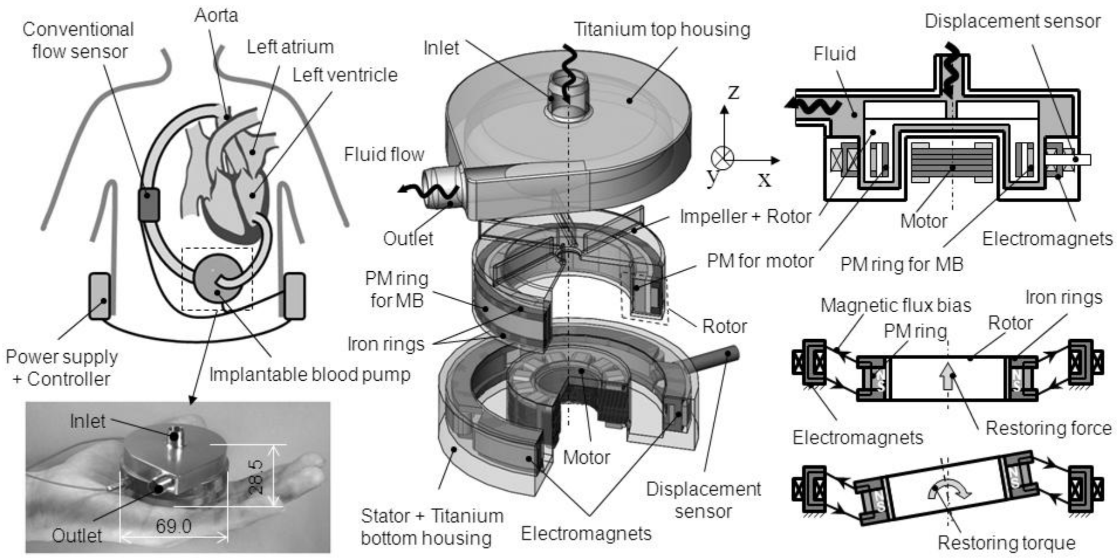

Figure 1. Ventricular assist system, photograph and configuration of the implantable maglev CBP, and passive stability of the rotor of the maglev CBP

In this study, a two-degrees-of-freedom radial controlled maglev CBP to be used in an implantable VAS is presented. Using a radial disturbance force observer of the magnetic bearing (MB) of the CBP, a blood flow rate estimation method without additional sensors is also presented.

2. MATERIAL AND METHODS

2.1. Maglev centrifugal blood pump

The two-degrees-of-freedom radial controlled MB system is composed of two pairs of electromagnets (EMs) located in the stator and a sandwich of two iron rings and a permanent magnet (PM) ring embedded in the rotor. This PM ring, which is magnetized axially, provides closed magnetic circuits between the rotor and the EMs. In this way, the axial and the angular motions are passively supported, as shown in Fig. 1. Two displacement sensors are placed between the EMs to measure the radial displacement of the rotor, for the feedback control of the MBs. Movements in the radial X and Y directions are controlled independently, without interference between each direction.

A brushless DC motor, located at the center of the CBP, is responsible for the rotation of the rotor. The motor stator has twelve teeth and three-phase winding, and the motor rotor consists of an eight-pole Halbach PM array embedded in the impeller.

In order to be biocompatible, the maglev CBP has a titanium housing isolating the blood from the mechanical parts of the pump. The configuration of the proposed maglev CBP is shown in Fig. 1.

The pump characteristic curve (HQ curve) and its power consumption were obtained with the pump set in a mock circulatory loop, which is composed of two pressure sensors (KL76, Nagano Keiki Co., Japan), one connected to the inlet and the other to the outlet of the pump to measure the head pressure (H), an ultrasonic flow sensor for medical use (HT-320, Transonic System Inc., USA) to measure the flow rate (Q), a screw clamp to provide variable flow resistance and a reservoir, with water used as the working fluid.

The power consumption of the maglev CBP was due to consumption by the motor (P_{motor}) and the MB (P_{mb}), not including that of the amplifiers, power supplies, sensor transducers and control electronics. P_{motor} was measured by power meters (WT210, Yokogawa Electric Corp., Japan) and P_{mb} was calculated from the voltage and current applied to the MB.

The hemolytic performance was tested with the maglev CBP connected to the mock loop described before. The experiment was performed using flesh porcine blood, according to the protocol of ASTM (2005) for the assessment of hemolysis in continuous flow blood pumps. The hemolytic levels, defined by the Normalized Index of Hemolysis (NIH), were compared to those of Bio-Pump BPX-80, under same experimental conditions. This is because the Bio-Pump is a CBP with contact bearing and it has a clinically acceptable hemolytic level. The NIH was calculated as in Eq. (1)

$$NIH = \Delta freeHb \times V \frac{100 - Ht}{100} \frac{100}{QT} \tag{1}$$

where $\Delta freeHb$ is the increase in the plasma free hemoglobin concentration (g/L) over sampling time interval T (min), V is the circuit volume (L) , Q is the flow rate (L/min) and Ht is the hematocrit (%).

2.2. Radial disturbance force observer

Flow conditions, such as the working fluid, the rotational speed and the flow resistance, influence the dynamic characteristics of a maglev impeller (Asama *et al.*, 2007). To evaluate the radial dynamic characteristics of the maglev impeller and to design a radial disturbance force observer, a dynamic model of the maglev system was constructed, taking into consideration the effects of the fluid, the rotational speed, and the flow resistance, and variable parameters, such as additional mass, additional damping, and additional stiffness, were identified experimentally.

For experimental simplicity, water was used instead of blood. The density and the viscosity of water were assumed to be constant, and the variable parameters of the model were identified by comparing the measured frequency responses of displacement of the maglev impeller to current of the electromagnets in the maglev system with simulated values under different rotational speeds and flow resistances. We observed that the additional mass of the impeller is independent of the rotational speed and flow resistance, while the additional damping and stiffness are only dependent on the rotational speed. Based on the linear models obtained for a given rotational speed, disturbance force observers were designed (Mizuno and Higuchi, 1988).

Based on the assumption of no interference between the movements in the radial X and Y directions, two disturbance force observers were implemented, one in each radial X and Y direction, and the resultant force obtained by the Eq. (2), where F_d is the resultant disturbance force, and F_{dx} and F_{dy} are disturbance forces in X and Y directions, respectively.

$$F_d = \sqrt{{F_{dx}}^2 + {F_{dy}}^2} \tag{2}$$

In a maglev CBP, the radial disturbance forces (F_d) are composed of the magnetic unbalance pull (F_{mag}) caused by the difference between the magnetic center and the geometric center of the impeller; the rotating unbalance force (F_{rot}) generated by the difference between the rotational and inertial centers of the impeller; the weight of the impeller (F_w) when the CBP is used in a non-horizontal position; the fluid-induced rotordynamic force (F_{rdf}) caused by the wedge effect generated by the whirling motion of the impeller (as in the hydrodynamic bearings); and the radial thrust (F_{rt}) caused by the fluid flow, which is related to the rotational speed of the impeller and the pulsatile condition of the heart ventricle.

When the pump outlet is totally closed, there is no pump flow, and therefore no generation of radial thrust. So, by measuring the radial disturbance forces with the outlet of the pump open (F_{d_open}) and totally closed (F_{d_closed}), and then subtracting F_{d_closed} from F_{d_open}, the radial thrust can be obtained, as in Eq. (3).

$$\begin{aligned} F_{d\_open} &= F_{mag} + F_{rot} + F_w + F_{rdf} + F_{rt} \\ F_{d\_closed} &= F_{mag} + F_{rot} + F_w + F_{rdf} \\ F_{rt} &= F_{d\_open} - F_{d\_closed} \end{aligned} \tag{3}$$

2.3. Relationship between the flow rate and radial thrust

The relationship between the flow rate and radial thrust was identified under continuous flow condition, with the maglev CBP set in the mock loop described before. The conventional ultrasonic flow sensor used in this study has a measurement accuracy of 4%, a resolution of 50 mL/min and a bandwidth of 10 Hz. It is widely used in research involving blood pumps and flows in cardio-vascular systems. Therefore, it is used as reference to identify the relationship between the radial thrust and the flow rate. The identification process was performed for rotational speeds of the maglev CBP varying from 1300 to 1700 rotations per minute (rpm) in 100 rpm increments.

2.4. Mock circulatory loop with a pulsatile pump

When the maglev CBP is connected to the natural heart, the pump flow is pulsatile flow. Therefore, a mock circulatory loop with a pulsatile pump was constructed to simulate the human circulatory system, in order to evaluate the proposed flow rate estimation method.

The new mock loop, as shown in Fig. 2, is composed of an open reservoir to simulate the left atrium, a pulsatile pump to simulate the left ventricle, a compliance tank to simulate the aorta and a screw clamp to simulate peripheral vascular resistances. The maglev CBP is connected to this simulator, receiving pulsatile flow from the ventricle simulator, and pumping it to the aorta simulator through the ultrasonic flow sensor connected at the outlet of the maglev CBP.

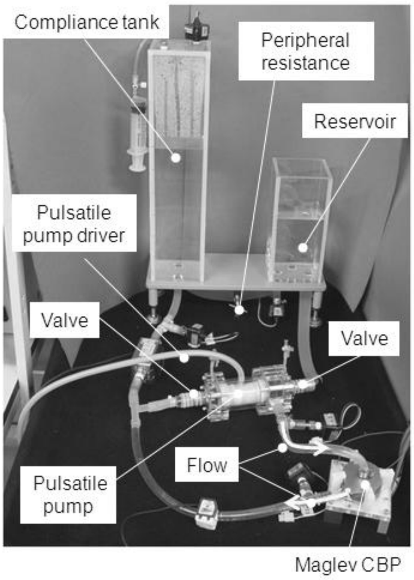

Figure 2. Mock circulatory loop with a pulsatile pump

The pulsatile pump was set at 60, 70 and 80 beats per minute (bpm), and the rotational speed of the maglev CBP was varied from 1300 to 1700 rpm in 100 rpm increments. The radial thrusts were estimated using the disturbance force observer, the flow rates were calculated using the relationship obtained under continuous conditions, and the estimated flow rates compared with the ones measured by the flow sensor.

In this study the average flow rate of the pulsatile flow was measured and compared with the estimated one.

3. RESULTS AND DISCUSSION

3.1. Maglev centrifugal blood pump

Figure 1 shows the configuration and photograph of the maglev CBP. The dimensions of the maglev CBP are 69.0 mm in diameter, 28.5 mm in height, with a weight of 370 g and a priming volume of 20 mL. The impeller is 51 mm in diameter and has six 5.5 mm high vanes. It has an outer lateral fluid gap of 0.25 mm between the impeller and the lateral surface of the bottom housing of the electromagnets, an inner lateral fluid gap of 0.5 mm between the impeller and the lateral surface of the bottom housing of the motor, and all of the axial fluid gaps are 1 mm. DuraHeart (TerumoHeart Inc., U.S.A.), which is a maglev CBP that is currently in clinical trial in the U.S.A., Europe and Japan, is 72.0 mm in diameter, 45.0 mm in height and 540 g in weight (Hoshi *et al.*, 2006b). Therefore, the developed maglev CBP is smaller and lighter than the available one.

Figure 3 shows the pump characteristic cruve of the maglev CBP. It was able to provide a flow rate of 5 L/min against a differential pressure of 100 mmHg, which is the pump operating point, when rotated at 1700 rpm. Under these conditions, the total power consumption was 5.5 W (P_{motor} = 4.0 W and P_{mb} = 1.5 W).

The measured mean NIH value and standard deviations of the maglev CBP and the Bio-Pump BPX-80 were 0.0022 ± 0.0006 g/100 L and 0.0039 ± 0.0022 g/100 L respectively. The hemolysis level of the developed maglev CBP is comparable to the one of the Bio-Pump BPX-80. Therefore it is clinically acceptable. After the experiments, no thrombus formation was observed inside the mock loop or the maglev CBP. Therefore, the maglev CBP is biocompatible from the point of view of hemolysis level and the thrombus formation.

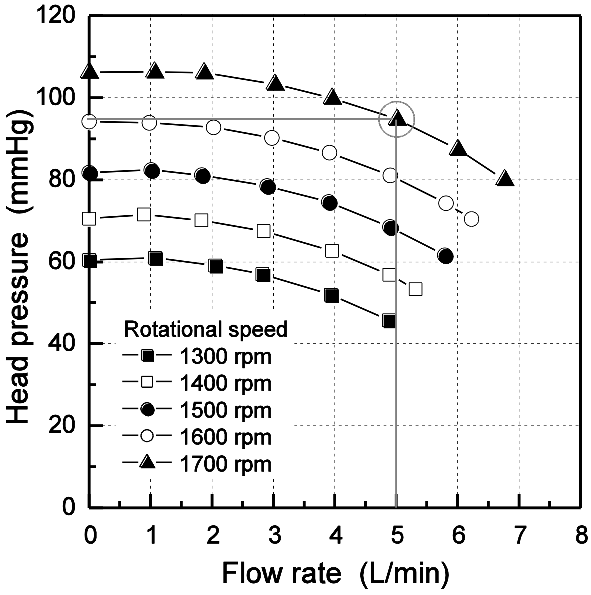

Figure 3. Pump characteristic curve of the maglev CBP

3.2. Radial thrust estimation

Figure 4 shows the estimated continuous forces, under different flow rates and rotational speeds. It can be observed that an increase in the flow rate was followed by an increase in the absolute value of the radial thrust, and the rotational speed had little influence on the radial thrust direction. At the pump operating point, the estimated radial thrust was 0.95 N.

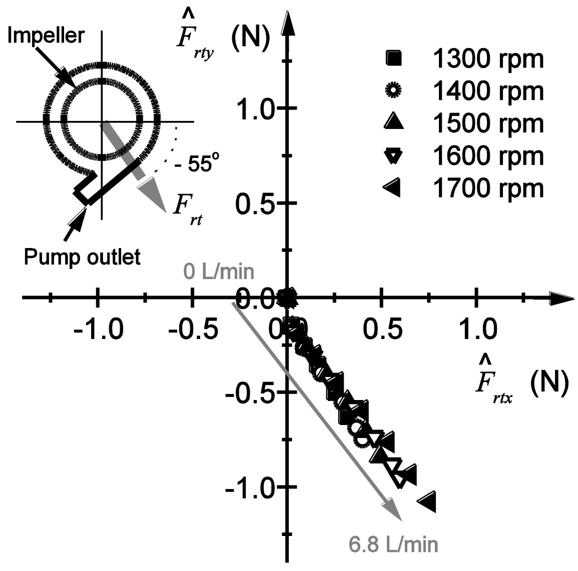

Figure 4. Variation of radial thrust inside the pump with respect to rotational speed and flow rate

3.3. Relationship between the flow rate and radial thrust

Figure 5 shows the relationship between the radial thrust and continuous flow rate for different rotational speeds, and an empirical relationship (Eq. 4) that relates the continuous radial thrust and the pump flow rate was obtained using the least squares method.

$$Q = 5.81 F_{rt} \tag{4}$$

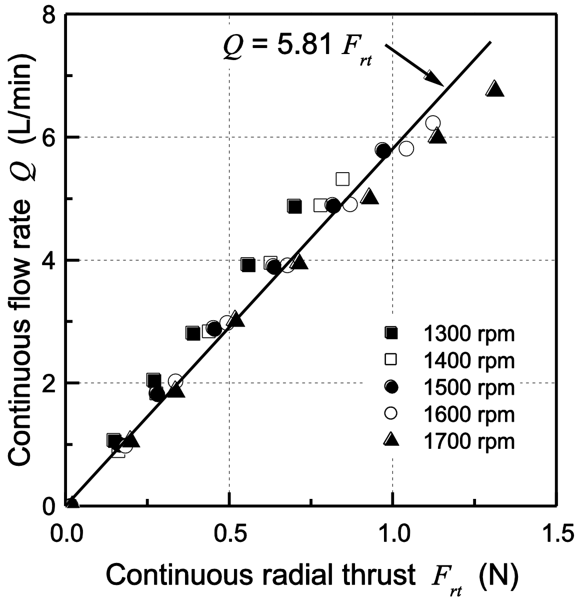

Figure 5. Relationship between the continuous flow rate and radial thrust

3.4. Estimation of the pump flow rate

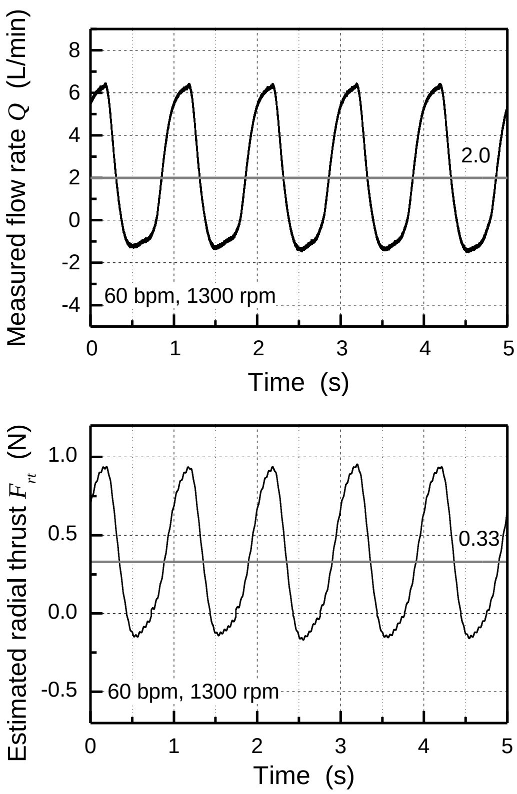

Figure 6. Measured pulsatile flow rate and estimated pulsatile radial thrust

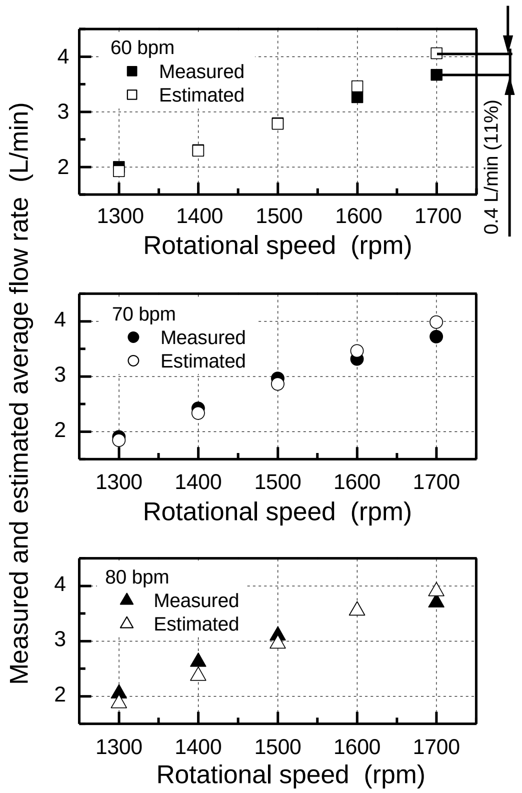

Figure 7. Accuracy of the estimate of the average flow rate

Figure 6 shows the measured pulsatile flow rate and the estimated radial thrust, with the pulsatile pump at 60 bpm and the maglev CBP at 1300 rpm. In this study, the flow rate as measured by the ultrasonic flow sensor was considered as correct, and the estimation error is defined as relative to the measured value.

Comparing the measured and estimated average flow rates, as shown in Fig. 7, the maximum estimation error was 0.4 L/min, which corresponds to 11 % of the measured pump flow rate.

Changes in blood density and viscosity may affect the estimation of the radial thrust. Consequently, the proposed flow rate estimation method may also be affected. Therefore, further investigations which take into account the effects of the viscosity and the density of blood are required.

4. CONCLUSION

A compact and biocompatible maglev centrifugal blood pump for use in an implantable VAS was developed. It presents low level of hemolysis, low power consumption and no risk for thrombus formation.

In order to estimate the pump flow rate, eliminating the requirement of an additional flow sensor in the implantable VAS, radial thrust was estimated using the disturbance force observers and a relationship between the radial thrust and pump flow rate was identified.

Disturbance force observers were developed using the radial controlled magnetic bearing of the maglev CBP to estimate the radial thrust inside the pump. In the design process, a dynamic model of the maglev system was constructed to analyse the dynamic characteristics of the radial motion of the maglev impeller, and the maglev system parameters were experimentally identified, and the disturbance force observers implemented.

The relationship between the radial thrust and the pump flow rate was obtained under continuous flow conditions. Using this relationship, and under pulsatile flow conditions, the average pulsatile flow rates were estimated and compared with the measured ones. The maximum error was 0.4 L/min, or 11%.

In future work, we plan to evaluate the influence of fluid density and viscosity on the estimates of the radial thrust of the maglev impeller and to perform acute and chronic animal experiments in order to better evaluate the estimation method.

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