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A MINI-CENTRIFUGAL BLOOD PUMP USING A 2-DOF CONTROLLED MAGNETIC BEARING

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ABSTRACT

A mini-centrifugal blood pump (CBP) employing a two-degrees-of-freedom (2-DOF) controlled MB has been developed as a ventricular assist device. In this pump, a magnetically suspended impeller is driven by an internal brushless DC motor. The developed maglev CBP (55 mm in diameter, 25 mm in height, 59 ml in total volume and 16 ml in priming volume) is more compact than conventional maglev CBPs (cf. one third of the total volume of 'DuraHeart') and it offers the necessary pump performance to provide implantable cardiac assistance to adults.

INTRODUCTION

Ventricular assist devices (VADs) have been used as bridges to transplantation and to recovery, and are currently being employed in final-destination therapy for heart-failure patients who are not eligible for heart transplantation. In Japan, the chance of a heart transplant operation being carried out (10 cases in 2007) is far less than in Europe (380 cases in France and 162 cases in UK, both in 2006) and the United States (2,224 cases in 2006), so the development of more compact and more durable VADs to correspond with the transplant situation in Japan is a pressing issue [1].

Many types of magnetically levitated (maglev) centrifugal blood pumps (CBPs) have been developed because they offer the potential for long-term use and cause little blood damage, due to the absence of any mechanical contact. Maglev CBPs must be small in size in order to provide implantable cardiac assistance to patients of all ages, from small children to adults.

'DuraHeart', which was developed by Terumo Corp., Japan, is an implantable CBP (72 mm in diameter, 45 mm in height and 180 mm in total volume) which incorporates a maglev impeller and also includes a three-degrees-of-freedom (three-DOF) controlled magnetic bearing (MB) [2][3].The impeller is actively controlled in the axial and angular directions, and is passively supported in the radial direction. Rotational torque is transmitted from a brushless motor to the impeller via a magnetic coupling. DuraHeart achieved the CE Mark in Europe in 2007, and received conditional approval from the FDA to begin enrollment in US Pivotal Trials in 2008. Thus, it is now proceeding towards practical utilization as a maglev implantable CBP.

'HeartMate III', which is being developed by Thoratec Corp and Levitronix GmbH., is also a compact maglev CBP (69mm in diameter and 30mm in height). The motor and the magnetic levitation functions are achieved in a single integrated unit. Preclinical in-vivo testing has been performed in calves [4].

The authors have previously developed a compact two-degrees-of-freedom (2-DOF) controlled MB which exhibited high passive stiffness in the uncontrolled directions and low power consumption due to the inclusion of a magnetic coupling (MC) induced by a permanent magnet (PM)[5]. Using this MB, a prototype maglev CBP (65 mm in diameter, 40 mm in hight) was fabricated [6].

In this article, we report on the design and fabrication of a mini-CBP using a 2-DOF controlled MB, which has a cardiac output of 0 to 8 L/min and which can be used by both pediatric and adult patients. The target total volume for the mini-CBP pump is 60 ml, which is less than one-third of that of DuraHeart. For this prototype mini-CBP, the pressure-flow (HQ) curve, the power consumption and the rotational accuracy of the impeller across the operating range have been evaluated as the first stage towards realizing a practical implantable mini-CBP.

DESIGN AND FABRICATION OF THE CBP

Configuration of MB and Brushless DC Motor

Figure 1 shows a cross-sectional view of the 2-DOF controlled radial MB, without any motor parts. The stator of the MB consists of four sets of U-shaped iron cores and coils surrounding the rotor. The rotor consists of a ring-shaped PM sandwiched between iron rings. The magnetic flux bias from the PM ring produces a MC between the rotor and the electromagnetic cores.

In this MB, a radial feedback control system is necessary to avoid contact with the rotor due to negative stiffness in the radial directions. When the rotor moves in the radial direction, a restoring force is necessary to return the rotor to its initial position. In order to produce this restoring force, an electromagnetic flux (shown by the dotted line in the iron rings and iron cores) is generated by controlling the current through a pair of coils. On the right-hand side in Fig. 1, the bias flux in the gap is weakened by the magnetic flux generated by the electromagnet. On the opposite side, the bias flux is strengthened. A restoring force is then generated toward the left-hand direction due to this unbalance in the flux.

As shown in Fig. 2, the axial and tilt motions are passively suspended by the MCs using a combination of radial feedback controls. Thus, the rotor can be levitated without any mechanical contact. Because an MC that uses a closed magnetic flux generates a high restoring force and high torque, the rotor can exhibit high passive stiffness in both the axial and tilt directions.

Figure 3 shows a combination of an internal brushless direct current (DC) motor and the MB described above. Fan-shaped pieces of PM in multiples of four are embedded inside the rotor and are periodically magnetized (as shown by the white arrows) to generate several poles in the inward radial direction only. This is known as a 'Halbach array'[7]. The motor stator has a laminated core and three-phase windings. A wire is wound continuously around each tooth to form a coil. The rotor is driven directly by the internal brushless DC motor. With this design, consisting of a combination of the 2-DOF controlled MB and the internal brushless DC motor, the MB and the driving mechanism can be simpler than that used in Duraheart, and this has advantages in terms of miniaturization.

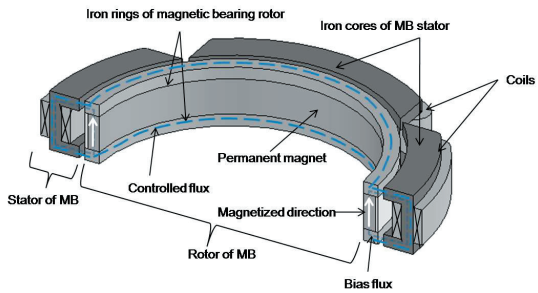


FIGURE 1:Configuration of 2-DOF controlled MB

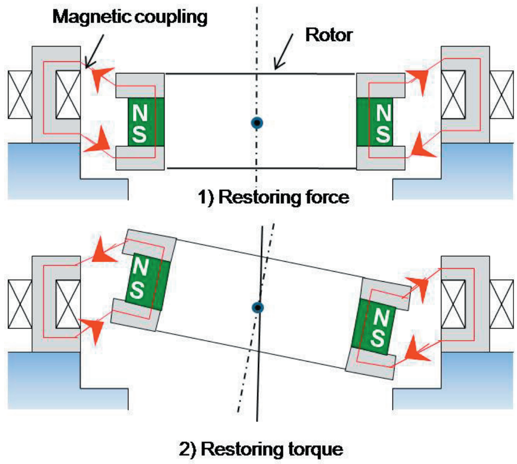


FIGURE 2:Principle of passive stabilization in axial and tilt directions

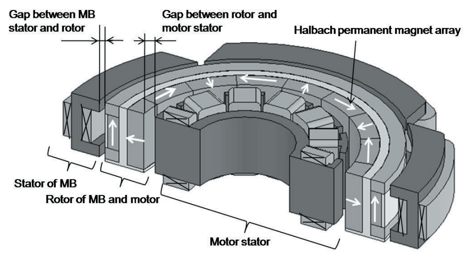


FIGURE 3:Combination of the 2-DOF controlled MB and the brushless DC motor

MB and Motor Design

In order to satisfy our target volume of 60 ml, the outer diameter and height of the pump housing and the rotor diameter were initially set at 55 mm, 25 mm and 40 mm, respectively. Furthermore, from the viewpoints of shear-stress that might be applied to the blood and also limitation of pump fabrication, the magnetic gaps in the MB and the brushless DC motor were set at 0.8 and 1.05 mm, respectively.

Using these design conditions, the dimensions of the MB and the brushless DC motor were surveyed using a three-dimensional electromagnetic field FEM package (Maxwell 3D, Ansoft Corp., U.S.A.) to realize higher passive stiffness in the axial and tilt directions, acceptable touch-up current (4A) for the coil (100 turns), and larger current-torque constant of the motor as shown in Fig. 4. The height of the electromagnet is greater than that of the rotor in order to permit a large coil space and to decrease the coil current at start-up.

The simulated stiffnesses of the MB in the axial, radial and tilt directions are 8.5N/m, -65N/m and 1.7Nm/rad, respectively. The current-torque constant of the motor, which has six slots in the stator and eight poles in the rotor, is 4.9 X 10^{-4} Nm/A turns. Each tooth of the stator has a concentrated winding of 100 turns.

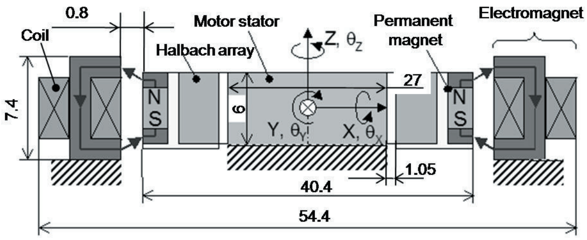


FIGURE 4: Dimensions of the MB and Motor

CBP Design and Fabrication

CBP Design. As shown in Fig. 5, the structure of the maglev CBP essentially consists of a top housing, an impeller-rotor and a bottom housing. The impeller-rotor and the bottom housing include the MB and the brushless DC motor mechanism. Two eddy-current-type displacement sensors for measuring the radial motion of the rotor are placed in the gaps between the electromagnets, as shown in Fig. 6 [1].

The impeller has six straight vanes, with an inlet vane angle of 40 degrees and a washout hole of 6 mm in diameter. The washout hole generates a secondary flow from the outer gap to the inner gap to prevent blood stagnation and to decrease the thrust force to the impeller.

CBP Fabrication. The impeller and the rotor cover are machined as a unit from a duralumin cylinder. The electrically conductive rotor cover also works as a sensor target. The permanent magnet ring and the Halbach array that are incorporated into the impeller are made of NdFeB, with a residual flux density of 1.2 T. The electromagnetic core is machined from soft iron, because the arc-shape is difficult to manufacture with laminated steel plates. The motor stator is made of a laminated silicon steel core with 6 teeth and has a three-phase winding.

The top housing is made from an acrylic resin, while the bottom housing is made from engineering plastic. The electromagnets for the magnetic bearing are embedded in the bottom housing using an epoxy resin, which serves as a coating to prevent the leakage of fluid, rusting of the cores, and undesired electrical conduction.

The inner-part of the epoxy coating is machined and polished smooth to decrease the effects of shear stress to the blood. The outer gap between the rotor and the inner surface of the bottom housing is 0.25 mm, which is designed to enable the magnetic levitation to be touched-up, and also to obtain sufficient passive stability of the bearing and to prevent hemolysis due to shear stress, which could occur with a narrower gap. The stator of the motor is also embedded in the bottom housing using an acrylic resin, and also contains the Hall sensors. The inner gap between the rotor and the stator is 0.5 mm, which is larger than the outer gap of 0.25 mm in order to allow a sufficient cross-sectional area for the flow path and to achieve a smooth flow.

The overall dimensions of the pump are 55 mm in diameter and 25 mm in height, which is more compact than any other conventional maglev CBPs. The total volume of the pump and the priming volume are 59 mL

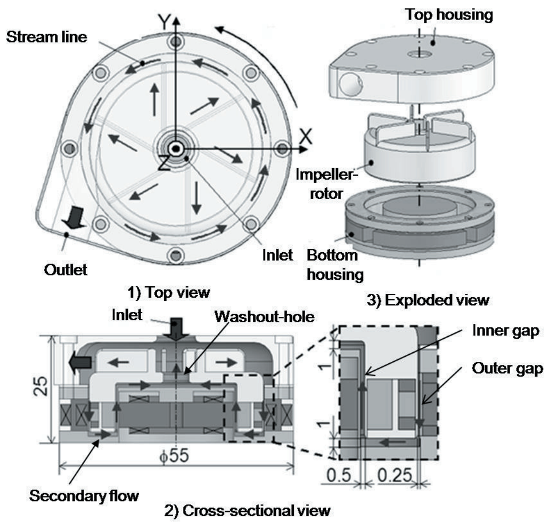


FIGURE 5: CBP design

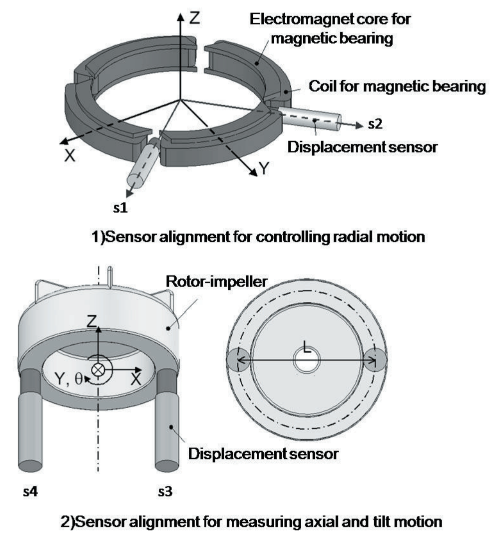
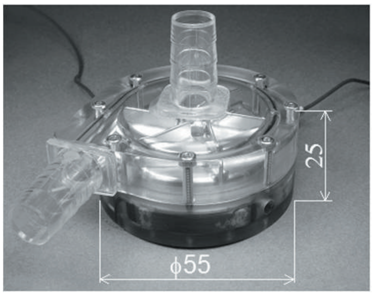
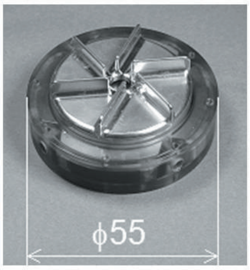


FIGURE 6: Alignment of displacement sensors



1) With top housing including inlet and outlet



2) Without top housing

FIGURE 7: Prototype maglev CBP

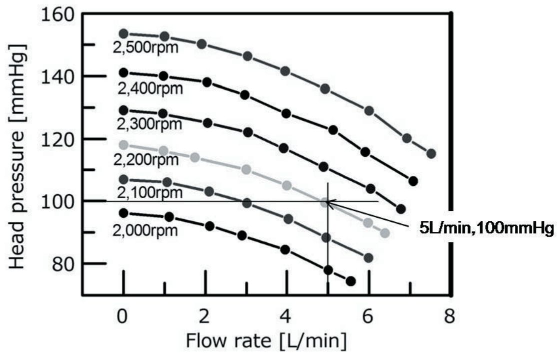


FIGURE 8: Pressure-flow characteristics (HQ curve)

and 16 mL, respectively. Figure 7 shows the prototype CBP with/without its top housing.

Controller for the MB and Brushless DC Motor

A zero-power controller [8] is employed to control the MB in this system. By regulating the radial position of the impeller to minimize the magnetic imbalance and by balancing the magnetic attraction induced by the magnetic flux-bias from the PM ring with external forces such as gravity and the radial thrust caused by uneven pressure distribution around the impeller, then steady power consumption in the MB can be eliminated.

In order to control the rotational speed of the brushless DC motor, a compact AC servo driver (UMXG-8, WACO GIKEN CO., LTD) is used. The rotational angle of the impeller is detected by the Hall elements, which are placed under the rotor and which measure the leakage flux from the Halbach array. The rotational angle, which is calculated from the output signals from the Hall elements, is used as a feedback signal to the servo driver.

EXPERIMENTAL RESULTS

HQ Curve and Power Consumption

A mock circulatory loop filled with water was used to examine the hydraulic performance of the maglev CBP. Its main constituents are the CBP, a reservoir tank, a flow meter, two pressure sensors placed before the inlet and after the outlet, and a resistance element.

The head-flow curves (HQ characteristics) were measured by manually regulating the resistance to change the head pressure and flow rate for a given rotational speed. The pump head and loop were filled with a 43 wt% glycerol-water solution, for which the viscosity at 25 °C was the same as that of blood.

The power consumption of the MB and the motor were measured at the same instant, but did not include the contributions from the digital signal processor that was used for the active control, the power supplies for the amplifiers and sensors, and any other electrical parts. In this study, the output power of the pump versus the total power consumption is defined as the pump efficiency.

The head flow curve of the maglev CBP at speeds between 2,000 and 2500 rpm is shown in Fig. 8. The maglev CBP rotated stably, without contact, and pumped up to 7.8 L/min. It also generated a flow of 5 L/min at 100 mm Hg at a speed of 2,200rpm, which is sufficient for implantable cardiac assistance to adults.

Figures 9 and 10 show the power consumption of the MB and the brushless DC motor, and also the efficiency of the pump. The power consumption of the MB and the motor in our maglev CBP at a flow rate of 5 L/min against a head pressure of 100 mm Hg were 4.9 and 1.8 W, respectively. The Terumo DuraHeart (an alternative maglev CBP) has been shown to consume 8–10 W of power for both the magnetic suspension and the impeller rotation in six animal experiments [2]. Our maglev pump is not only miniaturized, but is also required to perform sufficiently well to provide implantable cardiac assistance to adults, which means that there is a small margin in the magnetic circuit design, yet the power consumption of the MB and the brushless DC motor that it contains are the same as those of other maglev pumps that are currently available [9].

Rotational Accuracy of the Impeller

The maglev CBP adopted a zero-power controller, so the equilibrium position of the impeller is shifted by unbalanced magnetic forces and fluid forces in the pump. Since the suction from the outlet increases in

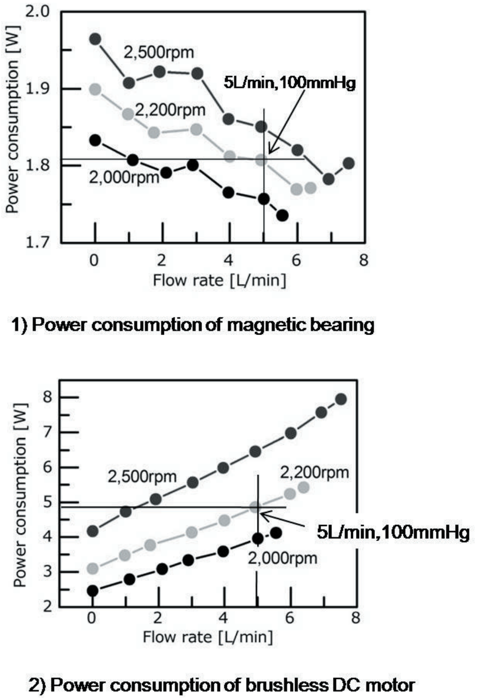


FIGURE 9: Power comsumption of the MB and motor

proportion to increases in flow rate, the impeller moves in the positive direction opposite the outlet in order to generate a magnetic force to balance the suction, as shown in Fig. 5.

As shown in Figure 11(1), the maximum displacement of the impeller in the X direction was less than 50 μm, which is much less than the designed outer gap of 250 μm. Even when the zero-power controller was used, since the negative stiffness of the magnetic bearing is large, the displacement of the impeller was suppressed by its tolerance level.

Figure 11(2) shows the axial position of the impeller from the bottom housing, which was measured by two displacement sensors tentatively placed under the rotor, as shown in Fig. 6(2). As the rotational speed of the impeller increased, the impeller moved upwards. However, the displacement of 0.2 mm is within the designed axial fluid gap of greater than 1 mm above and below the impeller. The axial stiffness of the magnetic bearing is sufficient to suppress the axial displacement induced by the thrust force.

Furthermore, the measured peak-peak amplitudes of the impeller vibration in the radial and axial directions were around 60 μm and 60-100 μm, respectively. These values are also within the tolerance level compared with the designed fluid gaps.

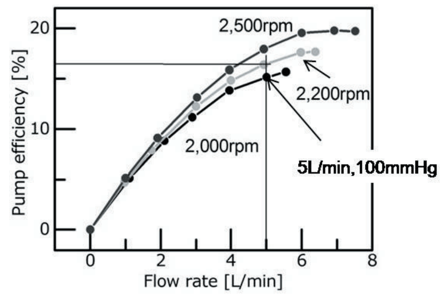


FIGURE 10: Pump efficiency

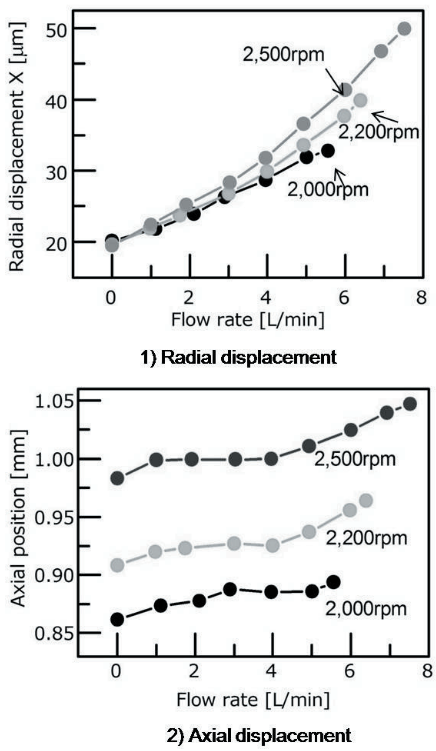


FIGURE 11: Shift of the equilibrium position

CONCLUSION

A maglev mini-CBP employing a two-DOF controlled MB has been developed. In this pump, a magnetically-suspended impeller is driven by an internal brushless DC motor. The developed maglev CBP (55 mm in diameter, 25 mm in hight, and 59 ml in total volume) is more compact than conventional maglev CBPs (cf. one third of the volume of DuraHeart) and it provides the pump performance that is required for implantable cardiac assistance to adults.

Although a resin was used for the pump housing and duralumin was used for the impeller cover in the case of the pump described here, a modified CBP using the same configuration with a titanium housing and cover, and which therefore has excellent biocompatibility, is also under development[9]. Furthermore, it is also necessary to examine the provision of an auxiliary bearing for backup at the time of failure of the MB.

ACKNOLEDGEMENT

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