Development of Extracorporeal Maglev Blood Pumps

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Abstract- In centrifugal blood pumps, contactless support of the impeller and a sufficient fluid gap in the pump head have been identified as features that have the potential to keep blood damage to a minimum and enhance the durability of the blood pump. We have developed three types of cost-effective magnetic bearings and contactless torque transmission mechanisms for disposable centrifugal blood pumps which can be used for extracorporeal circulation. In this paper, we introduce prototype maglev centrifugal blood pumps that utilize these mechanisms and we present both the experimental results and the results of simulations carried out on them.

INTRODUCTION

For bridge to implant of a donor heart or expensive implantable ventricular assist device, a cost-effective, highly durable extracorporeal blood pump system that does not cause thrombus formation and hemolysis is required. We have developed three types of magnetic bearing and contactless torque transmission mechanisms for centrifugal blood pump systems that have disposable simply structured magneticallylevitated impeller-rotors.

First, in this paper, we introduce these three types of magnetic bearing and contactless torque transmission mechanisms [1]-[5]. Then, the designs and prototypes of three types of disposable maglev centrifugal blood pump that use these mechanisms are described. Finally, the mechanical performance of all three pumps in mock circulatory systems is described. Details of biocompatibility of Types 1 and 2 pump heads evaluated using animal tests [6]-[9] are given. Furthermore, the possibility of blood damage in Types 1 and 3 pump heads is discussed based on CFD simulation results.

MAGNETIC BEARING AND TORQUE TRANSIMISSION MECHANISMS FOR EXRTACORPOREAL MAGLEV PUMPS

Figures 1(1), (2) and (3) show the proposed magnetic bearing and contactless torque transmission mechanisms. The stators in each case are placed on the outer side of the disposable rotors. The radial motion of the rotor is actively controlled by the electromagnets in the stator. The axial and tilt motion of the rotor is passively supported by the magnetic coupling between the rotor and the core of the electromagnet. In Type 1, the rotor consists of a rare earth magnet ring sandwiched between two slotted-iron rings. In Types 2 and 3, in order to reduce the cost of the permanent magnets, the disposable rotor consists of slotted iron parts only.



 Outer magnetic bearing and inner torque transmission mechanism using a rare earth magnet ring in a disposable rotor (Type 1)



(2) Outer magnetic bearing and inner torque transmission mechanism using no permanent magnet ring in a disposable rotor (Type 2)



(3) Outer magnetic bearing and outer torque transmission mechanism using no permanent magnet ring in a disposable rotor (Type 3)

Figure 1. Proposed magnetic bearing and noncontact torque transmission mechanisms for disposable centrifugal blood pumps.

To rotate the rotor, three types of torque transmission mechanism are proposed. In Types 1 and 2, the magnetic couplings are placed on the inner side of the disposable rotor. The motor torque is transmitted to the rotor using the magnetic coupling between the rotor and a coupling disk, which is directly driven by a motor.

Type 3 also uses magnetic coupling mechanism to transmit the motor torque, but the coupling disk is placed on the outer side of the disposable rotor. Compared with Types 1 and 2, the configuration of Type 3 has high design flexibility for the impeller-rotor and smooth secondary flow can be generated under the impeller-rotor in the pump head as shown in Figure 2. The smooth secondary flow is expected to reduce blood damage.

DESIGN AND FABRICATION OF THE MAGLEV CENTRIFUGAL PUMPS

Three types of maglev centrifugal blood pump were designed and fabricated as shown in Figures 3 (1), (2) and (3). Figure 4 shows a photograph of the preclinical maglev centrifugal blood pump system including the magnetic bearing and motor drivers, the monitor for the Type 1 blood pump and an artificial lung.

All the pumps consist of a pump head, a two-degree-of freedom controlled magnetic bearing, a magnetic coupling disk and noncontact displacement sensors and a motor. The pump head consists of disposable top and bottom housings and an impeller-rotor. The external dimensions of the impeller used for these pumps are almost the same. The impeller has six straight vanes and its diameter is 50mm. The radial and axial minimum fluid gaps between the rotor and the bottom housing is set to be 300µm and 1mm, respectively.

These magnetic bearings were designed to have the same magnetic gaps and almost the same passive stiffness in the axial and tilt directions. Furthermore, the designed maximum transmittable torque using the magnetic coupling is almost the same.

EVALUATION OF PUMP PERFORMANCE AND BIOCOMPATIBILITY

In the development of blood pumps, not only pump performance but also evaluation of the biocompatibility is important. All the maglev pumps achieved contactless levitation and rotation at speeds of more than 3,250rpm. The rotational accuracy of the impeller-rotor was measured. The radial vibration of the three types of pump during pumping was approximately within $\pm 50\mu$ m which is much smaller than the fluid gap of 300 μ m.

Figure 5 shows the measured H-Q characteristics of the Type 2 blood pump in a 40 per cent glycerol–water solution. The other H-Q characteristics of Types 1 and 3 blood pumps

are the same. This performance satisfies the requirements for both left ventricular assist and heart-lung support.



Figure 2. Magnetic bearing and magnetic coupling configurations and the secondary flow channel design in the pump heads.



(1) Outer magnetic bearing and inner torque transmission mechanism using a rare earth magnet ring in a disposable rotor (Type 1)



(2) Outer magnetic bearing and inner torque transmission mechanism using no rare earth magnet ring in a disposable rotor (Type 2)



(3) Outer magnetic bearing and outer torque transmission mechanism using no rare earth magnet ring in a disposable rotor (Type 3)

Figure 3. Designed and fabricated maglev centrifugal blood pumps.

Hemolytic characteristics of Types 1 and 2 blood pumps were evaluated by in-vitro tests using fresh porcine blood. The normalized index of hemolysis (NIH) is half of that generated by a conventional centrifugal blood pump using a contact bearing (BioPump BPX-80, Medtronic).

In the Tokyo Medical and Dental University, Types 1 and 2 blood pumps were implanted into young Holstein calves for ventricular assist tests for up to two months as shown in Figure 6 and for cardiopulmonary bypass tests for up to three weeks as shown in Figure 7. After the improvements of manufacturing process of the pump heads, no problems occurred during the animal tests and the disposable pump heads did not need to be changed. Both types of blood pump achieved high durability and high biocompatibility.



Figure 4. Preclinical maglev centrifugal blood pump system using Type 1 magnetic bearing and magnetic coupling mechanisms



Figure 5. Experimental HQ characteristics in a 40 per cent glycerol-water solution (Type 2 blood pump).



Figure 6. Left ventricular assist test using a centrifugal blood pump of Type 1 blood pump.

In order to evaluate the effectiveness of using a Type 3 pump head on blood damage, streak-lines in the secondary flow in Types 1 and 3 pump heads were simulated and compared using the CFD models shown in Figure 8. The pump head profile of Type 1 is the same as that of Type 2. Assuming a flow rate of 5L/min at 2,000rpm, the transit time and the length of the trajectory of each particle passing through the area between the impeller and bottom housing were calculated and the results are summarized in Figure 9.

The transit time and length of trajectory of the particle passing through the Type 3 pump head are smaller than those for Type 1 pump head. It is concluded that the secondary flow pass in the Type 3 pump head is much smoother and the damage to blood cells is expected to be less compared with Types 1 and 2 pump heads.



Figure 7. Cardiopulmonary bypass test using a centrifugal blood pump of



Inlet for analytical space Entrance Pump inlet egion Outlet Pump outlet regio Outlet for analytical spa

(8-2) Pump head model of Type 3





CONCLUSION

In this paper, three types of disposable centrifugal blood pump using cost-effective maglev impeller-rotors were introduced and the pump performances and biocompatibilities reported. In future work, we plane to carry out in-vitro and in vivo tests using a Type 3 blood pump and to develop a more compact bearingless motor using disposable rotor-impeller without a permanent magnet.

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REFERENCES

- W. Hijikata, T. Shinshi, J. Asama, L. Li, H. Hoshi, S. Takatani, A. Shimokohbe, "A MagLev Centrifugal Blood Pump with a Simple-Structured Disposable Pump Head, "Artificial Organs, vol. 32, no. 7, pp. 351-540, 2008.
- [2] W. Hijikata, H. Sobajima, T. Shinshi, Y. Nagamine, S. Wada, S. Takatani, A. Shimokohbe, "Disposable MagLev Centrifugal Blood Pump Utilizing a Cone-Shaped Impeller," Artificial Organs, vol. 34, no. 8, pp. 669-676, 2010.
- [3] W Hijikata, T Mamiya, T Shinshi, S Takatani, "A cost-effective extracorporeal magnetically-levitated centrifugal blood pump employing a disposable magnet-free impeller," Proc. IMechE, J. Engineering in Medicine, vol. 225, pp. 1149-1157, 2011.
- [4] T. Mamiya, W. Hijikata, T. Shinshi, "A Disposable Magnetic Bearing System for an Extracorporeal Centrifugal Blood Pump," Proceedings of The 13th International Symposium on Mgnetic Bearings, Washignton, USA, 2012.
- [5] K. Momose, T. Mamiya, W. Hijikata, T. Shinshi, "An Extracorporeal Maglev Centrifugal-type Blood Pump Employing a Permanent Magnetfree Disposable Pump Head and an Outer Magnetic Coupling Mechanism, " Journal of the Japan Society for Precision Engineering, vol. 80, no. 2, pp. 81-88. 2014. (in Japanese)
- [6] T. Someya, M. Kobayashi, S. Waguri, T. Ushiyama, E. Nagaoka, W. Hijikata, T. Shinshi, H. Arai, S. Takatani, "Development of a Disposable Mag-Lev Centrifugal Blood Pump (MedTech Dispo) Intended for One Month Support in Bridge-to-Bridge Applications In Vitro and Initial In Vivo Evaluations," Artificial Organs, vol. 33, no.9, pp.704-713, 2009.
- [7] E. Nagaoka, T. Someya, T. Kitao, T. Kimura, T. Ushiyama, W. Hijikata, T. Shinshi, H. Arai, S. Takatani, "Development of a Disposable Mgnetically Levitated Centrifugal Blood Pump (MedTech Dispo) Intended for Bridge-to-Bridge Applications Two-Week In Vivo Evaluation s, "Artificial Organs, vol. 34, no. 9, pp. 778-783, 2010.
- [8] T. Fujiwara, E. Nagaoka, T. Watanabe, N. Miyagi, T. Kitao, D. Takota, T. Mamiya, T. Shinshi, H. Arai, S. Takatani, "New Generation Extracorporeal Membrane Oxygenation With MedTech Mag-Lev, a Single-Use, Magnetically Levitated, Centrifugal Blood Pump: Preclinical Evaluation in Calves," Artificial Organs, vol. 37, no. 5, pp. 447-456, 2013.
- [9] E. Nagaoka, T. Fujiwara, D. Sakota, T. Shinshi, H. Arai, S. Takatani, "MedTech Mag-Lev, Single-use, Extracorporeal Magnetically Levitated Centrifugal Blood Pump for Mid-term Circulatory Suppor, "ASAIO Journal, vol. 59, no.3, pp. 246-252, 2013.



Figure 9. Analysis of streak-lines in the secondary flow of Type 1 and Type 3 pump heads