

Chronic Animal Experiment with Magnetically Suspended Centrifugal Pump

Tomoyuki Yamada, Kazunobu Nishimura, Chang-Hee Park, Satoshi Kono,
Sadatoshi Yuasa, *Tomonori Tsukiya, *Teruaki Akamatsu, Katsuhiko Matsuda, and
Toshihiko Ban

*Department of Cardiovascular Surgery and *Department of Mechanical Engineering, Kyoto University, Kyoto, Japan*

Abstract: We have been developing a new type of centrifugal pump for long-term use. The magnetically suspended centrifugal pump (MSCP) contains no shaft and seal so that long life expectancy is predicted. Paracorporeal left ventricular (LV) assist circulation between the left atrium and the descending aorta was instituted using sheep. The flow rates ranged from 2.5–5.5 L/min. The sheep that lived the longest (46 days) died of an embolism as a result of the thrombus in the pump. No thrombus formation was observed in other pumps. Plasma free hemoglobin levels ranged from 9 to 18 mg/dl, which led to the

conclusion that the hemolysis level remained within an acceptable range. Two driving modes were compared. The slope of the pressure-flow relationship plot under a constant motor current mode was steeper than that under a constant rotational speed mode, and thus, the flow fluctuation decreased. In conclusion, the MSCP is durable for more than a month at the current stage of development and is a promising device for long-term ventricular assist.

Key Words: Magnetically suspended centrifugal pump—Long-term ventricular assist.

Centrifugal pumps currently available have a shaft and seal, which restrict the life expectancy because of problems such as blood leakage, thrombus formation, and friction. To overcome such problems, we have been developing a magnetically suspended centrifugal pump (MSCP), which does not contain the shaft and bearing and can be used for the long term. The impeller is suspended between the casing with magnetic forces produced by permanent magnets and electromagnets, and it rotates without contact. Therefore, it is expected to have long-term durability. We examined the *in vitro* pump performance, hemolysis test, and the preliminary animal experiment (1–5). The purpose of this study was to evaluate the pump performance, durability, influence on blood components, and antithrombogenicity, as well as the regulation of the pump in a chronic animal experiment using sheep.

PUMP STRUCTURE

Figure 1 shows the pump structure, which is composed of the following 3 parts: a motor unit, a pump casing, and a magnetic bearing. The motor unit contains a DC brushless motor and a rotor. The pump casing has an impeller inside that pumps the blood flow in and out. The magnetic bearing contains 3 electromagnets and 3 gap sensors. The rotor of the motor and the impeller have 24 pairs of permanent magnets, and these produce the magnetic attraction. On the other hand, the electromagnets produce repellent magnetic force against the permanent magnets, allowing the impeller to float inside the casing. Therefore, the impeller is suspended magnetically between the magnets and rotates synchronously with the motor. Three sensors control the gap between the impeller and pump casing by 0.2 mm. The regurgitant flow occurs through the gap, and avoids blood stasis and thrombus formation in the gap.

The pump casing is made of polycarbonate. The impeller is composed of 3 segments: the plate on the motor side that is made of polycarbonate with 24 samarium magnets embedded inside; the plate on

Received December 1996.

Address correspondence and reprint requests to Dr. Tomoyuki Yamada, Department of Cardiovascular Surgery, Kyoto University Faculty of Medicine, 54 Shougoin Kawara-cho, Sakyo-ku, Kyoto 606, Japan.



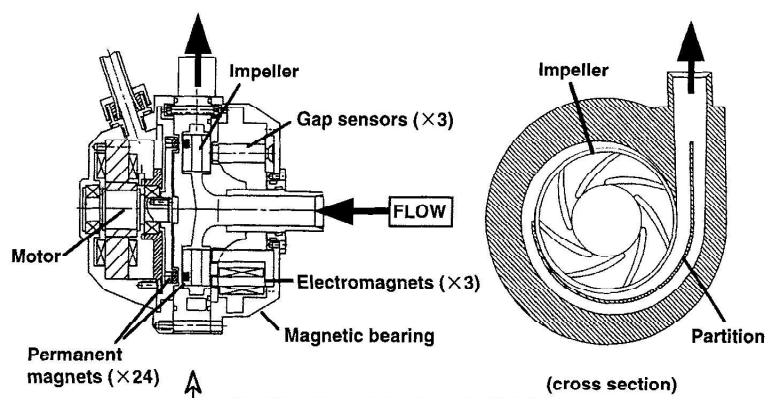


FIG. 1. The drawing shows the pump structure of the current prototype (size: 80 × 86 mm, weight: 670 g).

the electromagnet side made of ferrite stainless steel; and between the 2 plates, 7 vanes made of polycarbonate. The inner surface of the pump is coated with silicone or heparin; silicone was used in the first 6 pumps, and heparin (6) was used starting in the seventh pump.

METHODS

Paracorporeal left ventricular (LV) assist circulation between the left atrium and the descending aorta was established using the magnetically suspended centrifugal pump (MSCP) in 7 adult sheep (40–57 kg). The sheep were anesthetized with thiopental sodium and intubated. The anesthesia was maintained with halothane. A left thoracotomy and fifth rib resection were performed. A prosthetic vascular graft (12 mm or 14 mm) for an outflow cannula was sutured to the descending aorta, and a drainage cannula was inserted into the left atrium. Heparin (1 mg/kg) was administered at the cannulation. The MSCP was positioned externally on the back of the sheep. Except for the first 2 experiments, the whole circuit, including the cannulas and connectors, was coated with silicone or heparin to avoid thrombus

formation in the circuit. Anticoagulation treatment was performed with a combination of warfarin and ticlopidine. Prothrombin time was averaged from 15–20 s.

In the first 2 experiments, a constant rotational speed mode (a conventional method) was applied, but the pump flow fluctuated greatly as the afterload changed. To reduce the flow fluctuation, we examined another driving mode, a constant motor current mode. The differences in hemodynamics created when the afterload was changed by occluding the outflow tube were recorded.

Constant motor current mode

The characteristics of the constant motor current mode are explained in Fig. 2. The rotational speed directly correlates with the pressure head under a constant motor current. The rotational speed increases linearly as the pressure head rises (Fig. 2a). Also, the rotational speed increases consistently as the flow rate decreases (Fig. 2b). Therefore, the changes in the pump flow and the pressure head can be detected by monitoring the rotational speed under a given motor current. Moreover, the flow rate and the pressure head can be calculated by means of the rotational speed and the motor current when the

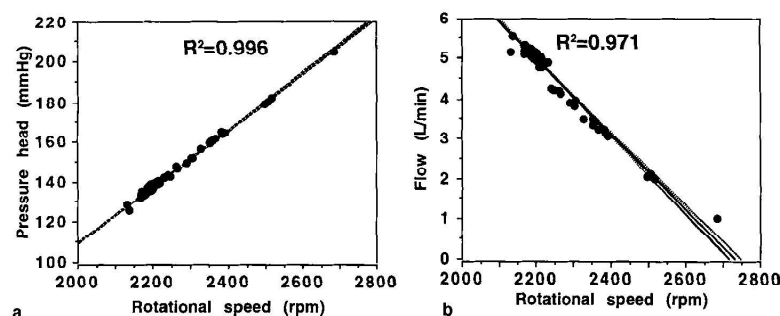


FIG. 2. The graphs show characteristics of the constant motor current mode in terms of the relationship between the pressure head and the rotational speed (a) and the relationship between the flow rate and the rotational speed (b) for Sheep 4, motor current: 0.7 A.

blood viscosity is obtained (7). This driving mode was applied beginning with the third experiment.

The motor current and the rotational speed were constantly monitored. The following 3 parameters were usually measured: the pump flow, the inflow pressure, and the outflow pressure. A Swan-Ganz catheter was used to obtain the total blood flow in 4 of the 7 experiments.

RESULTS

The assist conditions and hemodynamics are shown in Table 1. The flow rates ranged from 2.5–5.5 L/min. The pressure head ranged from 100–160 mm Hg. The total systemic flow measured by a Swan-Ganz catheter averaged from 5.0 to 7.0 L/min, and the assist rates to the systemic flow were around 50–70%. The sheep were healthy under the hemodynamics of diminished pulse. The pulsatility was almost none when they were sitting or sleeping and ranged from 10–30 mm Hg when they were standing or moving. The results are summarized in Table 2. Thrombus formation often developed in the circuit, particularly around the connections, despite the coating and the anticoagulation. It caused embolisms, which was the main reason for the termination of the experiments. Thrombus formation located in the pump was seen only in Sheep 4, which survived the longest (46 days) (Fig. 3), and was observed in the gap between the impeller and the casing on the motor unit side because of cracks in the polycarbonate. The chloroform treatment used to smooth the surface might have been responsible for the cracks because no thrombus was observed in the opposite gap on the magnetic bearing side where the surface was treated with ethylene chloride. Therefore, the treatment method was changed, treating every surface with ethylene chloride, and no further thrombus formation was observed in the pumps. Plasma free hemoglobin levels ranged from 9 to 18 mg/dl. No reduction in the counts of red blood cells or platelets was observed.

TABLE 1. Driving condition and hemodynamics

No.	Driving mode	Speed (rpm)	Current (A)	Pressure head (mm Hg)	Flow (L/min)
1	N	2,200–2,400	0.62–0.85	100–140	3.0–4.0
2	N	2,200	0.68–0.78		3.5–5.0
3	I	2,100–2,300	0.90	110–150	4.0–5.0
4	I	2,000–2,200	0.60–0.70	100–140	2.5–5.0
5	I	2,300–2,350	0.95	140–160	3.0–4.0
6	I	2,150–2,400	0.95–1.10	145–160	3.0–5.0
7	I	2,000–2,200	0.90–1.00	110–140	2.5–5.5

N: constant rotational speed mode, I: constant motor current mode.

TABLE 2. Results of experiments with respect to coating methods

No.	Duration (days)	Coating		Thrombus		Cause of termination
		Pump	Circuit	Pump	Circuit	
1	14	S	–	–	+	Infection
2	15	S	–	–	++	Embolism
3	27	S	S	–	±	Intestinal impairment
4	46	S	S	+	+	Embolism
5	14	S	S	–	++	Embolism
6	15	S	H	–	±	Respiratory failure
7	37	H	H	–	+	Embolism

The internal surface of the pump and circuit were coated with silicone or heparin (S: silicone; H: heparin; –: no coating).

Thrombus formation (+: observed; -: not observed; ±: trivial).

Comparison of the driving modes

The pressure flow (P-Q) relationship is shown in Fig. 4. The P-Q slope under a constant current mode became steeper than that under a constant rotational speed mode. Therefore, steadier pump flow should have been obtained under the constant current mode. In fact, the flow fluctuation under the constant current mode was less than that under the constant rotational speed mode.

DISCUSSION

A centrifugal pump has been developed for long-term use with the following advantages over a pulsatile pump. First, it has high efficiency. Second, it does not need a prosthetic valve, and the cost may be lower. Third, it is small and can be designed to become smaller. Its driver is also compact, which is advantageous both for its implantation and its use for long-term assist.

The MSCP is expected to have long-term durability because it contains no shaft and seal, and it operates as a bearingless pump. After preliminary experiments, we evaluated the MSCP in a chronic animal experiment using sheep. Pump performance was sufficient for left ventricular assist. Hemolysis levels remained within an acceptable range (under 20 mg/dl). However, the pump flow depended on the afterload, particularly under a constant rotational speed. We were concerned that a momentary low flow could cause thrombus formation in the pump. Therefore, we examined the constant motor current mode to make the pump flow steadier. Under a constant motor current, the P-Q slope became steeper, and the actual flow fluctuation decreased. Therefore, the constant current mode is useful for ventricular assist.

Avoiding thrombus formation in the use of an artificial heart is mandatory. The thrombus located in

Artif Organs, Vol. 21, No. 7, 1997

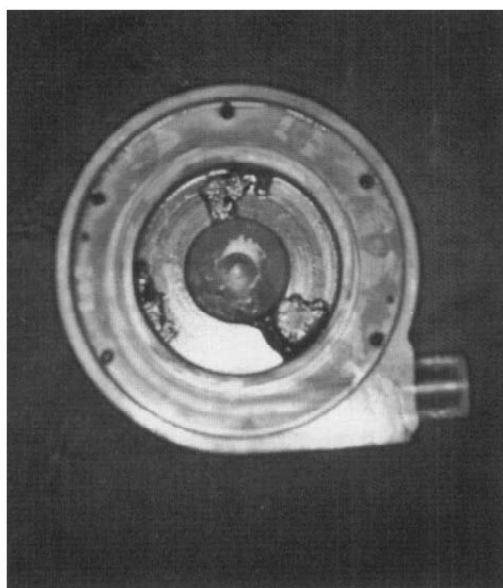


FIG. 3. The photograph shows thrombus formation in the pump for Sheep 4. The thrombus formed in the gap between the impeller and the casing on the motor unit side.

the MSCP was observed only in Sheep 4. Because the chloroform treatment applied to smooth the surface of polycarbonate may have been responsible for it, we treated every surface with ethylene chloride, and no further thrombus formation developed in the pumps. Because the gap between the impeller and the casing was narrow, thrombus might tend to develop in that area. A larger gap is advantageous in the avoidance of thrombus formation, but it results in lower pump efficiency because of an increase in

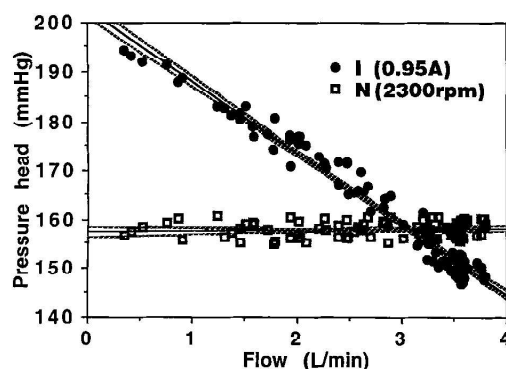


FIG. 4. The graph shows a comparison of the driving modes in terms of the relationship between the pressure head and the flow rate for Sheep 5: I: constant motor current mode (0.95 A), N: constant rotational speed mode (2,300 rpm).

Artif Organs, Vol. 21, No. 7, 1997

the regurgitant flow through the gap. In the current model, the gap was 0.2 mm, and the regurgitant flow ranged from 1–2 L/min. This gap was considered to be suitable because no further thrombus was observed and the pump performance was satisfactory. The majority of the experiments were halted because of thrombus formation in the circuits. As a result, we cannot yet confirm the antithrombogenicity of the MSCP when it has been in use for more than a month.

CONCLUSION

A new type of centrifugal pump has been developed for long-term use. The MSCP has a long life expectancy and can be used for ventricular assist because it contains no shaft and seal and operates as a bearingless pump. The constant motor current mode was useful for driving the MSCP because the P-Q slope became steep and steady pump flow was obtained. The pump flow can be estimated by means of the motor current and the rotational speed. The MSCP is durable for more than a month at the current stage of development and is a promising device for ventricular assist.

Acknowledgments: We thank M. Watanabe for the anesthesia, T. Ohnishi and Y. Wada for the support of the long-term sheep experiments, E. Hatanaka for preparation, T. Nakazeki for manufacturing the MSCP at NTN Corporation, and Dr. T. Nojiri for the heparin coating of the MSCP and circuits at Terumo Corporation.

REFERENCES

1. Akamatsu T, Nakazeki T, Itoh H. Centrifugal blood pump with a magnetically suspended impeller. *Artif Organs* 1992;16:305–8.
2. Akamatsu T, Nakazeki T. Recent development of a centrifugal blood pump with a magnetically suspended impeller. In: Akutsu T, Koyanagi H, eds. *Heart replacement-artificial heart* 4. Tokyo: Springer-Verlag, 1993:305–8.
3. Akamatsu T, Tsukiya T, Nishimura K, Park CH, Nakazeki T. Recent studies of the centrifugal blood pump with a magnetically suspended impeller. *Artif Organs* 1995;19:631–4.
4. Park CH, Nishimura K, Yamada T, Mizuhara H, Akamatsu T, Tsukiya T, Matsuda K, Ban T. A magnetically suspended centrifugal pump. In vitro and in vivo assessment. *ASAIO J* 1995;41:M345–50.
5. Nishimura K, Park CH, Akamatsu T, Yamada T, Ban T. Development of a magnetically suspended centrifugal pump as a cardiac assist device for long-term application. *ASAIO J* 1996;42:68–71.
6. Nojiri C, Hagiwara K, Yokoyama K, Kurbayashi E, Hidaka K, Ishida N, Horiuchi K, Oshiyama H, Nogawa A, Kido T, Kijima T, Akutsu T. Evaluation of a new heparin bonding process in prolonged extracorporeal membrane oxygenation. *ASAIO J* 1995;41:M561–7.
7. Tsukiya T, Akamatsu T, Nishimura K, Park CH. Indirect measurement of flow rate and pressure difference and operation mode of the centrifugal blood pump with magnetically suspended impeller. *Jpn J Artif Organs* 1996;25:249–54.