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The helical flow total artificial heart: implantation in goats

Yusuke Abe, Kohei Ishii, Takashi Isoyama, Itsuro Saito, Yusuke Inoue, Masami Sato
Shintaro Hara, Kyohei Hosoda, Koki Ariyoshi, Hidemoto Nakagawa, Toshiya Ono
Kyoko Fukazawa, Kazuhiko Ishihara, Kou Imachi

Abstract—**To realize a total artificial heart (TAH) with high performance, high durability, good anatomical fitting, and good blood compatibility, the helical flow TAH (HFTAH) has been developed with two helical flow pumps having hydrodynamic levitation impeller. The HFTAH was implanted in goats to investigate its anatomical fitting, blood compatibility, mechanical stability, control stability, and so on. The size of the HFTAH was designed to be 80 mm in diameter and 84 mm wide. The maximum output was 19 L/min against 100 mmHg of pressure head. Eight adult female goats weighting from 45 to 56.3 kg (average 49.7 kg) were used. Under the extracorporeal circulation, natural heart was removed at the atrioventricular groove and the HFTAH was implanted. The HFTAH was driven with a pulsatile mode. The 1/R control was applied when the right atrial pressure recovered. The HFTAH could be implanted with good anatomical fitting in all goats. Two goats survived for more than a week. One goat is ongoing. Other goats did not survive for more than two days with various reasons. In the goats that survived for more than a week, the hydrodynamic bearing was worn and broken, which indicated that the bearing touched to the shaft. The cause was supposed to be the influence of the sucking effect. The potential of the HFTAH could be demonstrated with this study. The stability of the hydrodynamic bearing in a living body, especially the influence of the sucking effect, was considered to be very important and a further study should be necessary.**

I. Introduction

The total artificial heart (TAH) replaces the pump function of the heart totally. There are two TAHs available in clinical setting [1]. One is the Cardiowest temporary TAH (Syncardia, Tucson, AZ, USA) that is a pneumatically driven TAH for bridge to heart transplantation. The other one is the AbioCor implantable replacement heart (Abiomed, Danvers, MA, USA) that is an electrohydraulic-driven total-implantable TAH for destination therapy in patients with end-stage heart failure who were ineligible for heart transplantation. These TAHs adopts displacement pumps that generate physiological pulsatile flow. However, these TAHs are big in size for implantation to the patients with a small stature. Additionally, displacement pumps do not work for a very long time, limited by the durability of polymer diaphragm and/or mechanical parts.

Y Abe, K. Ishii, T. Isoyama, I. Saito, Y. Inoue, M. Sato, S. Hara, H. Nakagawa, T. Ono and K. Imachi are with the Department of Biomedical Engineering, Graduate School of Medicine, the University of Tokyo, Tokyo, 113-0033, Japan (corresponding author to provide phone: +81-3-5841-3562; fax: +81-3-3811-3693; e-mail: abe@bme.gr.jp).

K. Hosoda and K. Ariyoshi are with the Graduate School of Medical Science, Kitasato University, Sagamihara, 252-0373, Japan.

K. Fukazawa and K. Ishihara are with the Department of Material Engineering, School of Engineering, the University of Tokyo, Tokyo, 113-0033, Japan

To improve the problems of the conventional TAHs, TAHs using rotary blood pumps (RBPs) such as axial flow pumps or centrifugal pumps are expected with their small size and long-term durability. Frazier et al. developed a continuous flow total artificial heart (CFTAH) using two axial-flow pumps [2]. The Cleveland clinic group has been developing a unique one-piece CFTAH using the centrifugal pump with two impellers and one motor [3]. Greatrex et al. reported development of a similar one-piece CFTAH utilizing electromagnetic bearing [4].

However, axial flow pumps and centrifugal pumps present geometries that inflow and outflow ports open at different directions, while the natural heart presents geometry that inflow and outflow ports open at the same direction, which makes it difficult to construct a TAH with good anatomical fitting easily. Additionally, such pumps are not suited for generation of a pulsatile flow. While the physiological role of pulsatility has not been clarified yet, a pulsatile flow is ordinarily considered to be more ideal than a continuous flow [5].

To realize a total artificial heart (TAH) with high performance, high durability, good anatomical fitting, and good blood compatibility, the helical flow pump (HFP) was invented at the University of Tokyo. The initial animal experiment of the HFP with a left ventricular bypass method showed a promising prospect of the pump with the result of 208 days survival in a goat [6]. Based on the results, the helical flow TAH (HFTAH) has been developed. The HFTAH was implanted in goats to investigate its anatomical fitting, blood compatibility, mechanical stability, control stability, and so on.

II. Materials and Methods

Device description

The HFTAH was designed to have two pump units, left HFP and right HFP. Each HFP includes own motor and works independently. The motor stator is positioned at the center of the pump so that the motor stator is cooled by a blood stream. The rotor magnets are set in the multi-vane impeller. The motor stator and rotor magnets form a DC brushless motor. Between the stator and impeller, hydrodynamic bearing is formed for levitation of the impeller. The impeller rotate around the stator with hydrodynamic levitation. The axial position of the impeller is suspended with magnetic repulsion with permanent magnets set in the impeller and pump housing.

The left HFP was designed to be 80 mm in diameter, which could meet the maximum size of the TAH for implantation in the body weighting 40 kg. The width of the

HFP was designed to be 40 mm. To fit the size to 80 mm in diameter, the impeller was designed to be 66 mm in diameter. The vane was designed to be 8 mm wide and 9.5 mm in height. The number of the vane was 24. The clearance between the impeller and the pump housing was designed to be 0.5 mm except the hydrodynamic bearing. The hydrodynamic bearing was designed to have three narrow gaps with the clearance of 30 μm and three grooves for blood passage. The size of the hydrodynamic bearing was designed to be 28 mm wide and approximately 37 mm in diameter.

The right HFP was designed to be 64 mm in diameter and 37 mm wide. The impeller was designed to be 66 mm in diameter. The vane was designed to be 7 mm wide and 7.5 mm in height. The number of the vane was 24. The clearance between the impeller and the pump housing was designed to be the same as that in the left HFP. The hydrodynamic bearing was designed to have the same shape and the same narrow gap clearance as these in the left HFP. The size of the hydrodynamic bearing was designed to be 21 mm wide and approximately 25 mm in diameter.

With the combination of the left and right HFPs, the total size of the HFTAH was designed to be 80 mm in diameter and 84 mm wide.

The pump housing and the impeller were made with epoxy resin. The shafts were made with titanium or zirconium dioxide. The bearings were made with titanium. Neodymium magnet was used for both the rotor magnets and the repulsion magnets. The stator was molded with epoxy resin to prevent water infiltration. At the stator coil, a temperature sensor was molded together. The drive unit for the undulation pump total artificial heart (UPTAH) [7] was modified and used for driving the HFTAH.

The surface of the shaft and bearing and the inner surface of the pump housing were coated with 2-methacryloyloxyethyl phosphorylcholine (MPC) polymer [8]. The impeller was not coated but was polished to have a smooth surface.

Figure 1 shows the developed HFTAH. The maximum continuous output was 19 L/min against 100 mmHg of pressure head, which was limited by the capacity of the drive unit.

Implantation

Animal experiments were conducted under the permission and the Guidelines of the animal experiment committee at the Graduate School of Medicine, the University of Tokyo.

Eight adult female goats weighting from 45 to 56.3 kg (average 49.7 kg) were used. 800 ml of blood was collected before surgery for autotransfusion. Before anesthesia, 2.5 mg of atropine sulfate was given intramuscularly or subcutaneously. General anesthesia was introduced with sevoflurane with slow induction method. After intubation, anesthesia was maintained under isoflurane. The chest was opened with left thoracotomy. 300 IU/kg of heparin was given. The systemic outflow cannula was anastomosed end-to-side with the descending aorta. The outflow canula for

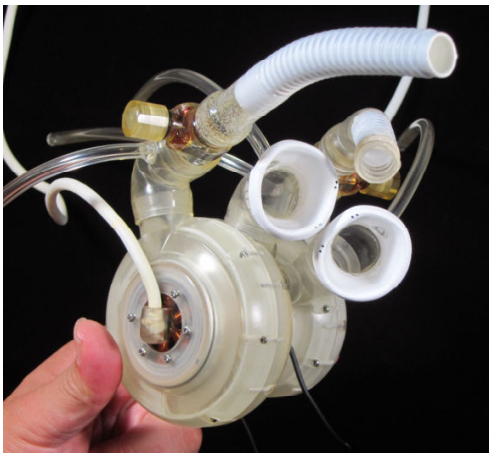

Fig. 1 Helical flow total artificial heart.

extra-corporal circulation (ECC) was inserted into the left carotid artery and tied. The inflow balloon canulae for ECC were inserted into the superior and inferior vena cava via right atrium. The ascending aorta was closed with an arterial clamp after ECC was introduced. The ventricles were removed at the atrio-ventricular groove. The appendage of the left atrium was ligated to prevent sucking of the atrium. The left and right atrial cuffs were sutured to the remnant left and right atria, respectively. The pulmonary outflow cannula was inserted into the pulmonary artery and tied. The HFTAH was then connected to the cannulae and cuffs inside the chest. After the HFTAH was activated, 20-30 mg of protamine sulfate was given to neutralize the heparin. After the extubation of inflow canulae for ECC, the appendage of right atrium was ligated to prevent sucking of atrium.

Postoperative management

After the wound closure, the goats were transferred to the animal care unit. The goats were initially provided with nasal oxygen at 5 L/min after recovering from anesthesia. The oxygen flow was then reduced as required to maintain the arterial blood pO2 above 80 mmHg. Nasal oxygen was continued until lung function recovered. The chest drainage tube was removed on postoperative day (POD) 3. Antibiotic medication (1-2 g/day of Ampicillin sodium) was given by doping it into the infusion bags for pressure lines through the period of experiment. Neither anti-coagulant nor anti-platelet medication was given systemically.

Measurements

The left and right pump outputs were measured with electromagnetic flow-probes (FT-130TB, Nihon koden, Tokyo, Japan) attached at the systemic and pulmonary outflow canulae. The aortic pressure (AoP), the pulmonary artery pressure (PAP), the left and right atrial pressures (LAP and RAP) were measured with pressure transducers (P23XL, Nihon koden, Tokyo, Japan) through the side tubes of the systemic and the pulmonary outflow canulae, and the left and right atrial cuffs, respectively. These pressure lines were perfused with heparinized saline to prevent occlusion using infusion bags. The pressure transducers were fixed to the cover set on the left chest wall. Vertical offsets of the pressure transducers accompanied by the postural change of

the animal were compensated using a custom-built postural sensor fixed on the back. Data were sampled with the sampling rate of 200 Hz.

Control protocol

After surgery, the left pump output was maintained at 100 ml/kg/min by controlling the right pump and the infusion rate until the animal recovered from post-operative hypovolemia due to ECC for several days. The left and right pumps were driven with a quasi-pulsatile mode in which some flow was maintained even at the diastolic phase, and the systolic high flow and diastolic low flow were alternately generated. The pulse rate was set to 100 bpm. To prevent pulmonary edema, left-right (L-R) balance control was performed automatically using the left pump for keeping the mean LAP within a fixed range of 5-10 mmHg depending on the condition of atrial sucking.

The 1/R control [9] that was modified for the UPTAH [10] was applied when the mean RAP was recovered to around 10 mmHg and the intravenous infusion became unnecessary. In the 1/R control, the L-R balance control was performed automatically with balancing LAP and RAP.

Through the control period, automatic sucking control to detect and release the atrial sucking was performed.

III. Results

The HFTAH could be implanted with good anatomical fitting in all goats. Table 1 shows the results of implantation in the goat up to date. ECC time was from 132 to 203 min (average 154 min). Two goats, 1107 and 1207, survived for more than a week. Two goats, 1201 and 1203, did not survive with the surgical complication. In 1205, a cerebral infarction was occurred in a day after surgery. In 1207, the hydrodynamic bearing of right pump was locked and the pump was stopped at 3.3 h after surgery. In 1211, the right motor stopped with a short circuit in the motor cable on the next day of surgery. The short circuit was occurred at the position where the cable was bended with steep right angle. In 1301, the experiment is ongoing.

In 1107, implantation was performed without major surgical complication. Figure 2 shows the picture of the goat. The pumps were driven with a pulsatile mode in which the drive condition was changed in systolic and diastolic phases.

Table 1 Results of implantation

No.	BW (kg)	ECC (min)	Survived time (days)	Cause of termination
1107	53.2	132	8	Left bearing broken
1201	46.5	152	0.2	Encephalopathy
1203	45	143	0.1	Lung edema
1205	48	145	1	Cerebral infarction
1207	54.5	139	12	Right bearing broken
1208	48.5	203	0.1	Right pump stopped
1211	45.7	171	1.3	Cable short circuit
1301	56.3	148	3 (ongoing)	

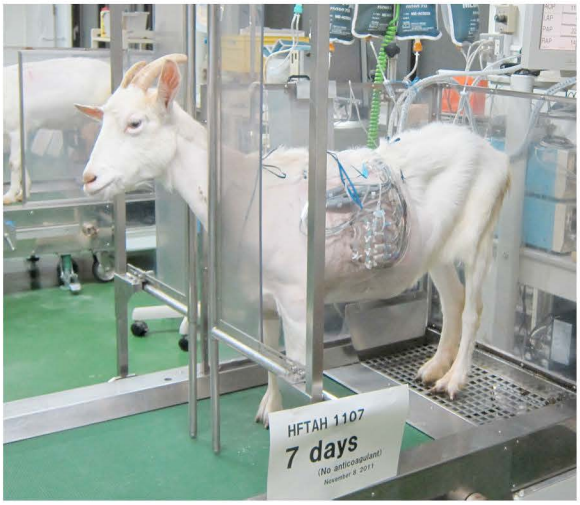

Fig. 2 HFTAH implanted goat.

The 1/R control was applied on postoperative day (POD) two and was performed with good condition after then. However, the sucking of atrium, in which the atrium was sucked to the inlet of the pump and the output decreased, sometimes occurred in both pumps. On POD 8, the left pump stopped without any intervention and restarted automatically. After several times of stop and restart, the left pump could not restart any longer and the experiment was terminated. In the autopsy, the shaft of left pump was worn indicating that the hydrodynamic bearing touched to the shaft and was broken. There was no thrombus formation in both pumps.

In 1205, implantation was performed without major surgical complication. The pumps were driven with pulsatile mode. The 1/R control was applied on the next day of the implantation and was performed with good condition after then. However, the sucking of atrium also sometimes occurred in both pumps. On POD 11, the mechanical noise began to occur from the device. On POD 12, the right pump stopped without any intervention and restarted automatically. Since the bearing was considered to be broken, the experiment was terminated. In the autopsy, the shaft of right pump was worn indicating that the hydrodynamic bearing touched to the shaft and was broken. There found fibrin deposits on the impeller of right pump.

Figure 3 shows the waveform of the hemodynamic parameters of 1107. The pulsatile flow where some flow was maintained in the diastolic phase is shown in both pumps. Figure 4 shows the hemodynamic changes of 1205 over the course. The pump output was changed from 90 to 120 ml/kg/min depending on the condition of the goat. The mean aortic pressure was around 100 mmHg. The left and right atrial pressures remained within the physiological level.

IV. Discussion

For the development of the total artificial heart, animal study is necessary to detect the problems to occur in in-vivo condition. An anatomical fitting is one of the major subjects. In this study, the HFTAH could be implanted in the goat's chest with good anatomical fitting in all goats.

Surgical complications were also the problems to perform animal experiments. Two goats did not survive with surgical complications. 1201 suffered an encephalopathy possibly caused by the ECC. 1205 did not survive with a lung edema caused by the misbalancing of the left and right pumps.

The cause of the cerebral infarction in 1205 was not clear. We think that there was a possibility of air embolism caused by the unexpected occurrence of cavitation that was generated in the left pump with severe sucking of left atrium.

In three goats, the stability of the bearing was the main cause of termination. In 1207, the hydrodynamic bearing of right pump was locked within short time after surgery. The cause was supposed to be the low viscosity in the blood owing to the hypoplotainemia and low hematocrit level caused by the ECC, which spoiled the function of the hydrodynamic bearing and disabled the hydrodynamic levitation of the impeller. In 1107 and 1205, the hydrodynamic bearing was worn and broken, which obviously indicated that the bearing touched to the shaft. The cause was supposed to be the influence of the sucking effect because the hydrodynamic bearing did not touch to the shaft in in-vitro condition when the pump was driven with a pulsatile mode. To improve the problem in the hydrodynamic bearing, further studies to detect the influence of sucking effect in detail, to develop the control program to prevent the serious sucking and to increase the levitation force in the hydrodynamic bearing.

Concerning the control stability, the 1/R control that was modified for the UPTAH could work with the HFTAH without any excursion for a short period of 8 and 12 days in this experiment. Development of the control method of the HFTAH requires long-term animal experiments and which is the next subject.

Despite that a further study should be necessary, the potential of the HFTAH could be demonstrated with this study

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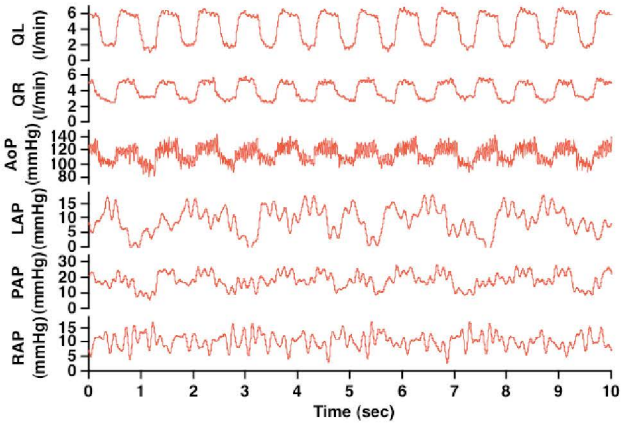

Fig. 3 Waveform of the hemodynamic parameters of 1107. QL:left pump flow, QR:right pump flow, AoP:aortic pressure, LAP:left atrial pressure, PAP:pulmonary artery pressure, RAP:right atrial pressure.

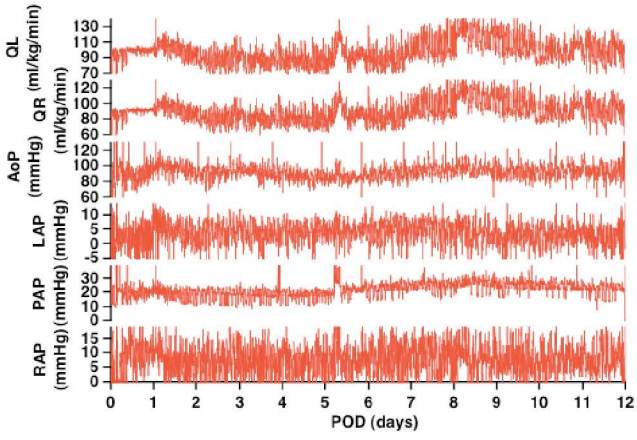

Fig. 4 Hemodynamic changes of 1205. QL:left pump flow, QR:right pump flow, AoP:aortic pressure, LAP:left atrial pressure, PAP:pulmonary artery pressure, RAP:right atrial pressure.