

Newly Designed Eccentric Roller Type Total Artificial Heart

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ABSTRACT

We have produced an eccentric roller type total artificial heart (ERTAH). As the first step in the development of this ERTAH, we conducted simulations such as a numerical simulation, a mock test, and an acute animal experiment using DeBakey roller pumps to analyze the left-right balance during its operation. The next step was redesigning the blood chambers to improve energy efficiency and implanting the ERTAH with an interatrial shunt into an animal for evaluation of the *in vivo* performance of the device. In the simulations, shunt flow through the bronchial arteries was approximately 500–600ml/min, and the interatrial resistance was varied from 2.9–7.7 mmHg·min/liter. Redesigning the blood chambers resulted in the mock test in a 20% increase in energy efficiency, about a two-fold increase in cardiac output and improved durability compared to the previous type in the mock test. In the animal experiment the ERTAH operated with a left flow rate of 6.0 liters/min and a right flow rate of 5.4 liters/min. The interatrial shunt flow rate was 250–400ml/min. Creating an interatrial shunt is a useful method for balancing the blood flow between the left and right heart of the ERTAH. A decrease in friction resistance and the prevention of backward flow resulted in an increase in energy efficiency, cardiac output, and improved durability, in spite of downsizing the blood chambers.

Key words: Total artificial heart, Roller pump, Interatrial shunt, Left-right balance

A variety of motor-driven artificial heart systems have been developed by many institutions throughout the world, with the aim of realizing a totally implantable artificial heart^{3,6,13,18)}. Many of these artificial hearts are pulsatile with blood pumps requiring artificial valves. On the other hand, research work on developing a rotary blood pump without an artificial valve has been frequently published¹³⁾. We have developed various prototypes of a totally implantable total artificial heart (TAH) at Hiroshima University School of Medicine^{4,5,8,10,11,16)}, and we continue in our effort to improve the TAH for several reasons: a satisfactory cardiac output has not yet been obtained; the energy efficiency was low; and there remains the problem of antithrombogenicity. Among recent prototypes of electric motor-driven TAH studied, the latest to be developed is an ERTAH in which right and left silicone blood chambers output blood alternately by being compressed by alternate rotations of eccentric rollers^{8,15,17)}. The advantages of this artificial heart are that no valves are mounted, it is one of the most compact devices in the world (8 × 10 cm), and a pulsatile-like flow waveform can be obtained although it is a roller pump. On the other hand, the disadvantages are that the left-right output balance of the device is fixed, its

output volume is relatively low and its energy efficiency and durability are unsatisfactory. Like the DeBakey roller pump, its right and left output volumes are determined to be constant by the chamber volumes and rolling rates of the rollers because of an active filling mechanism. In physiological conditions, however, the volume of circulating blood in the left side is larger than in the right side due to blood circulation through the bronchial artery (left to left shunting). Furthermore, the left pump afterload and workload are larger than those of the right pump. In the current ERTAH, the left-right balance of the artificial heart is maintained by differences in the size of the left and right chambers^{15,17)}. However, this technology was thought to have a limitation in that it could not accommodate physiological fluctuations because the left-right output ratios were constant. For these reasons we conducted simulations for LL (left to left) shunting under the ERTAH operation, and redesigned the blood chambers to improve its basic performance.

MATERIALS AND METHODS

1. Animals, surgical procedures, and instrumentation.

A mock test using the Donovan mock circulatory

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Table 1. Basic equations, constants and variables

Basic Equations	$AOP \cdot CAO + RAP \cdot CRA + PAP \cdot CPA + LAP \cdot CLA = V_0$	(1)
	$AOP - RAP = RS \cdot QS$	(2)
	$PAP - LAP = RLL \cdot QP$	(3)
	$AOP - LAP = RLL \cdot QLL$	(4)
	$LAP - RAP = RAA \cdot QALR$	(5)
	$FL = QS + QLL$	(6)
	$FR = QS + QALR$	(7)
	$FR = QP$	(8)
	$QP + QLL = FL + QALR$	(9)
Constants	FL=6 (liters/min)	
	CLA=5 (liters/mmHg) @ 4 (mmHg)	
	CAO=1 (liter/mmHg) @ 100 (mmHg)	
	CRA=10 (liters/mmHg) @ 0 (mmHg)	
	CPA=1 (liter/mmHg) @ 15(mmHg)	
	RS=16 (liters/mmHg)	
	RP=2.5 (mmHg·min/liter)	
	RLL=160 (mmHg·min/liter)	
Variables	V ₀ = 135 (mL), Total blood bolume in compliance (CAO, CRA, CPA, CLA)	
	FR=5-6 (liters/min) RAA=0-500 (mmHg·min/liter)	

left side, and a varying pump speed for the right side. Vascular grafts were sutured to the left atrium, the pulmonary artery, and the descending aorta (inner diameters, 19, 12, and 12mm, respectively). An exsanguination catheter (inner diameter 12mm) was inserted into the inferior vena cava through the jugular vein. With 3 grafts and a line connected, extra corporeal circulation was established using a roller pump, the roller pump was driven, and the hemodynamic parameters were measured.

3. Modification of the ERTAH.

3-1. Redesign of the blood chambers.

The pump system basically has the same configuration as that previously reported in which right

and left silicone blood chambers output blood alternately by compressing them with alternate rotations of eccentric rollers (Fig. 2). The newer system has smaller blood chambers (right side volume, 35 ml; left, 40 ml) than those of the previous ERTAH (right side volume, 53 ml; left, 60 ml), which had been designed to have as large a stroke volume as possible (Fig. 3). In addition, the designs of the input and output ports were modified to prevent backward flow. It is expected that these modifications will improve energy efficiency and durability, and increase output volume through a possible reduction of the friction resistance generated between the blood chambers and casing, although the previous pulsatile-like wave form will not be obtained.

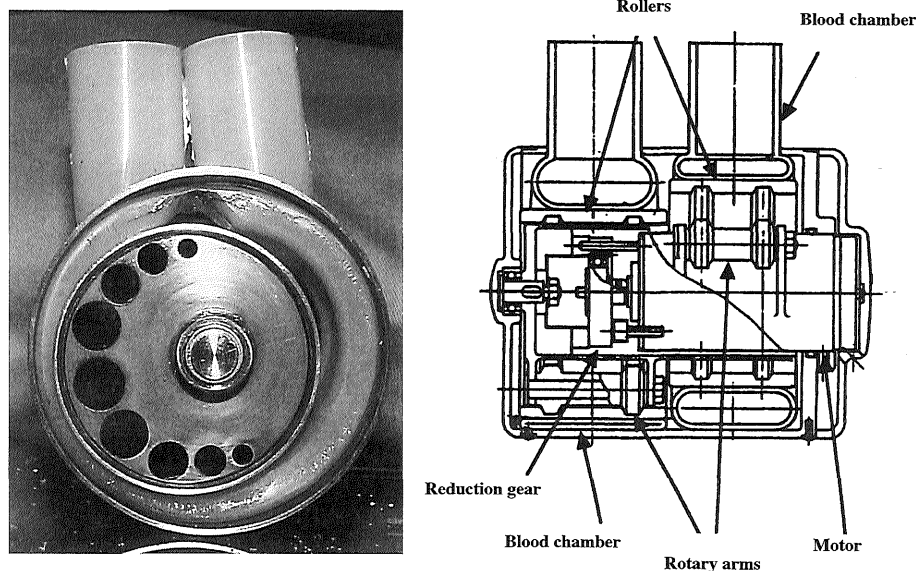


Fig. 2. Principle and structure of the eccentric roller type total artificial heart.

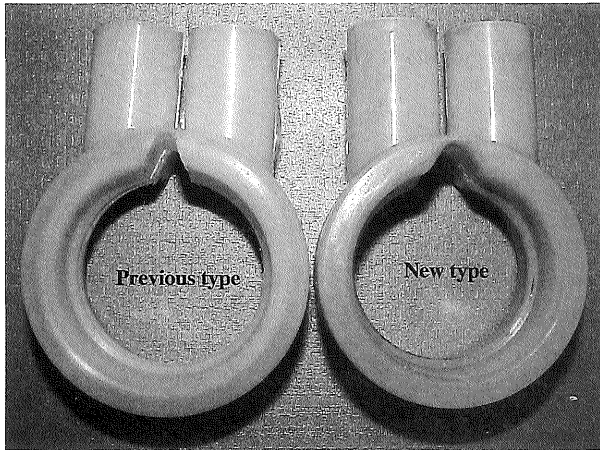


Fig. 3. Left blood chambers. Left: previous type. Right: new type blood chamber. Size and shape are different. Left blood chamber volume was changed from 60ml to 40ml. Right blood chamber volume was changed from 53ml to 35ml. The form between inlet and outlet ports is modified to prevent backward flow.

3-2. Mock test for evaluation of basic performance of the ERTAH.

A mock test was performed using a Donovan type mock circulatory system. In the test the newer ERTAH without an interatrial shunt was connected to a mock circulatory system and the basic performance of the device as a blood pump system was evaluated.

3-3. Animal experiment design for implantation.

An animal experiment involving an adult goat of 40kg was performed under general anesthesia with a cardiopulmonary bypass. A 24-Fr exsanguination catheter was inserted into the inferior vena cava through the jugular vein. After place-

ment of a tube for the blood supply into the descending aorta, a cardiopulmonary bypass (CPB) was established. After induction of ventricular fibrillation using a fibrillator in the cardiopulmonary bypass condition, inflow cannulas for TAH with an inner diameter of 12 mm were inserted into the left and right atriums via the left and right apices of the heart, respectively, and a blood supply tube with an inner diameter of 8 mm was inserted into the aorta and the pulmonary artery, respectively. The central side of the aorta and the pulmonary artery were ligated after vascular cannulations were completed. The blood flow into the CPB was gradually reduced and the blood flow into the TAH was increased correspondingly. Finally a transition from CPB to TAH was achieved after weaning from CPB. A shunt circuit with an inner diameter of 10 mm and a length of 5 cm was created between the left and right exsanguination tubes (Fig. 4). Blood flows at the outlet ports of the right and left sides of TAH and that in the interatrial shunt were measured using electromagnetic flowmeters.

RESULTS

1. Simulations of the left-right balance of the ERTAH.

1-1. numerical simulation.

Numerical simulation was performed under conditions where the flow of the FL was fixed at 6 liters/min, the flow of the FR was varied from 4.8 liters/min to 6 liters/min, and the RAA was 0 and 20 mmHg·min/liter. The relationship between QALR and output of the left and right artificial hearts was balanced when the FR was 5.45 liters/min (FR-FL=0.55 liters/min). Regarding the relationships between the pressure data (RAP, LAP, PAP, and AOP) and the interatrial shunt,

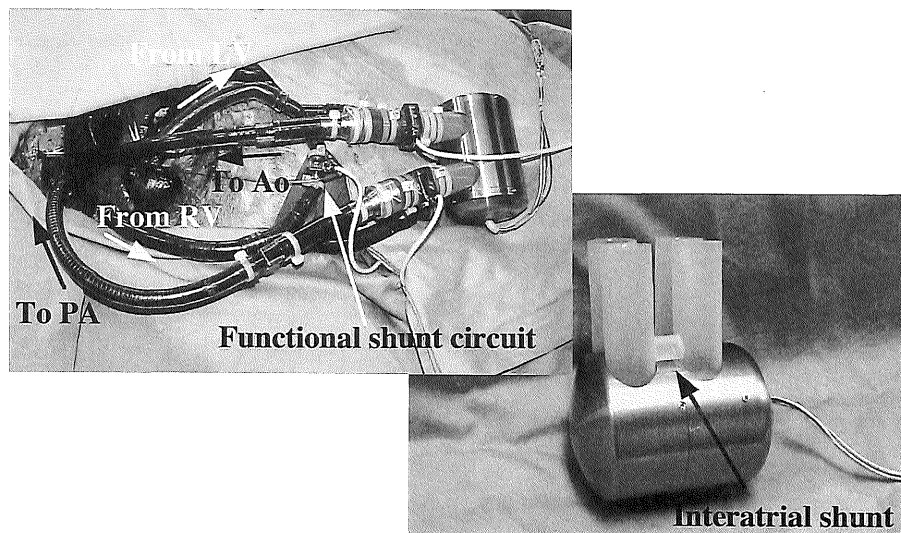


Fig. 4. Acute animal experiment involving an adult goat. Left: Functional shunt circuit with an inner diameter of 10 mm. A length of 5 cm was created between the left and right exsanguination tubes. Right: ERTAH creating interatrial shunt.

Table 2. Numerical simulation

a) RAA=0mmHg·min/liter												
FR	liters/min	5.00	5.10	5.20	5.30	5.40	5.50	5.60	5.70	5.80	5.90	6.00
AOP	mmHg	89.34	89.33	89.32	89.30	89.29	89.27	89.26	89.24	89.23	89.21	89.20
RAP	mmHg	2.07	2.06	2.04	2.03	2.01	2.00	1.98	1.97	1.95	1.94	1.93
PAP	mmHg	14.57	14.81	15.01	15.28	15.51	15.75	15.98	16.22	16.45	16.69	16.93
LAP	mmHg	2.07	2.06	2.04	2.03	2.01	2.00	1.98	1.97	1.95	1.94	1.93
QS	liters/min	5.45	5.45	5.45	5.45	5.45	5.45	5.45	5.45	5.45	5.45	5.45
QP	liters/min	5.00	5.10	5.20	5.30	5.40	5.50	5.60	5.70	5.80	5.90	6.00
QLL	liters/min	0.55	0.55	0.55	0.55	0.55	0.55	0.55	0.55	0.55	0.55	0.55
QALR	liters/min	0.45	-0.35	-0.25	-0.15	-0.05	0.05	0.15	0.25	0.35	0.45	0.55
b) RAA=20mmHg·min/liter												
FR	liters/min	5.00	5.10	5.20	5.30	5.40	5.50	5.60	5.70	5.80	5.90	6.00
QALR	mmHg	91.53	91.03	90.54	90.04	89.55	89.05	88.56	88.06	87.57	87.07	86.58
RAP	mmHg	5.00	4.34	3.68	3.02	2.36	1.71	1.05	0.39	-0.27	-0.93	-1.58
PAP	mmHg	9.33	10.72	12.11	13.50	14.88	16.27	17.66	19.05	20.44	21.82	23.21
LAP	mmHg	-3.17	-2.03	-0.89	0.25	1.38	2.52	3.66	4.80	5.94	7.07	8.21
QS	liters/min	5.41	5.42	5.43	5.44	5.45	5.46	5.47	5.48	5.49	5.50	5.51
QP	liters/min	5.00	5.10	5.20	5.30	5.40	5.50	5.60	5.70	5.80	5.90	6.00
QLL	liters/min	0.59	0.58	0.57	0.56	0.55	0.54	0.53	0.52	0.51	0.50	0.49
QALR	liters/min	-0.41	-0.32	-0.23	-0.14	-0.05	0.04	0.13	0.22	0.31	0.40	0.49

Table 3. Mock test using DeBakey roller pumps for simulation of the left-right balance of the ERTAH

Shunt size inner diameter (mm)	Interatrial shunt flow rate (liters/min)	Interatrial pressure gradient (mmHg)	Resistance of interatrial shunt (mmHg·min/liter)
6	-1.2 to 1.2	-10 to 9.1	7.1 to 8.3 (mean 7.7)
8	-1.2 to 1.2	-5.5 to 5.4	3.5 to 4.6 (mean 4.3)
10	-1.2 to 1.2	-3.3 to 2.8	2.6 to 3.8 (mean 2.9)

there were no changes in RAP, LAP, PAP, and AOP when RAA was zero. LAP and PAP increased and RAP and AOP decreased as RAA increased (Table 2).

1-2. Mock test using DeBakey roller pumps for simulation of the left-right balance of the ERTAH.

In the mock test, LAP increased and RAP decreased with the increase in left to right shunting, as shown in the numerical simulation (Table 2). Furthermore, when the diameter of the interatrial shunt became smaller and shunt resistance was increased, the absolute left to right atrial pressure difference was increased. When the interatrial shunt flow rate was zero, the pressure difference was also zero. Because there was no LL shunt in this mock system, the flow difference between left and right roller pumps (FR-FL) was zero when the QALR was zero. The RAA of the mock system was varied from 7.1 to 8.3 (mean, 7.7) mmHg·min/liter, 3.5 to 4.6 (mean, 4.3) mmHg·min/liter and 2.6 to 3.8 (mean, 2.9) mmHg·min/liter when the inner diameter of the interatrial shunt was 6 mm, 8 mm, and 10 mm, respectively (Table 3).

1-3. Acute animal experiment using DeBakey roller pumps for simulation of the left-right balance under the ERTAH operation.

The outputs of both roller pumps (FR and FL),

the interatrial shunt flow rate (QALR), AOP, PAP, RAP, and LAP were measured under conditions where the speed of the roller pump used for the left side bypass was fixed at 60 rpm and that for right side bypass was varied. The right to left and left to right shunt flows were presented as positive and negative blood flows, respectively. The flow of the left pump was almost constant (4.7 liters/min). The FR was approximately 4.1 liters/min when the QALR was zero, allowing consideration that the LL shunt flow in this goat's heart was approximately 0.6 liters/min (Fig. 5). Regarding the relationships between pressure data (RAP, LAP, PAP, and AOP) and QALR, an increase in left to right shunting was associated with increases in LAP, PAP, and AOP, and a decrease in RAP (Fig. 6).

2. Modification of the ERTAH

2-1. Mock test for evaluation of basic performance of the ERTAH.

The results of the mock test using a Donovan type mock circulatory system are shown in Table 4. When the pump speed increased, the AoP and pump output increased. The ERTAH operated at a driving rate of 68–166 rpm with a left cardiac output ranging from 2.5–6.3 liters/min and a right cardiac output ranging from 2.4–5.8 liters/min. Input power ranged from 19–36 W, output power ranged from 0.5–2.3 W, varying according to the driving rate. The overall efficiency of the ERTAH

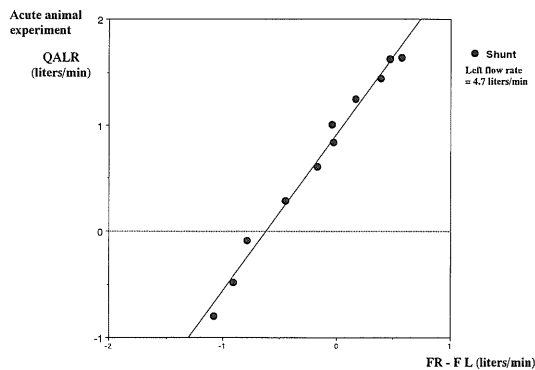


Fig. 5. The graph shows the interatrial shunt flow rate (QALR) vs. Right to left balance (FR-FL) in the acute animal experiment using DeBaakey roller pumps for simulation of the left-right balance of the ERTAH. The flow of the left pump was almost constant (4.7 liters/min). The flow of the right pump (FR) was approximately 4.1 liters/min when the QALR was zero, allowing consideration that the LL shunt flow in the goat's heart was approximately 0.6 liters/min.

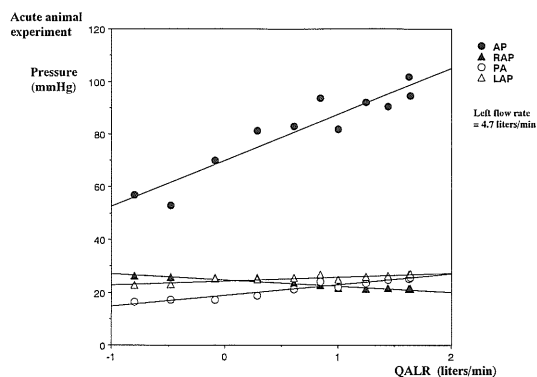


Fig. 6. Pressure data (RAP, LAP, PAP and AOP) vs. interatrial shunt flow rate (QALR). An increase in left-to-right shunting was associated with increases in LAP, PAP, and AOP and a decrease in RAP.

Table 4. Mock test for evaluation of basic performance of the ERTAH

Driving Rate (rpm)	68	88	141	166
AoP (mmHg)	82	107	112	138
PAP (mmHg)	17	18	21	25
Left CO (liters/min)	2.5	3.4	5.7	6.3
Right CO (liters/min)	2.4	3.0	5.0	5.8
Input Power (W)	19	24	34	36
Output Power (W)	0.5	0.9	1.7	2.3
Overall Efficiency (%)	2.6	3.8	5.0	6.4
Left SV (ml)	37	39	40	38
Right SV (ml)	35	34	35	35

AoP: aortic pressure, PAP: pulmonary arterial pressure, CO: output of the ERTAH, SV: stroke volume of the ERTAH.

was 2.6–6.4 %. Cardiac output increased to about twice as much as in the old type blood chambers, in spite of the smaller blood chambers. The overall

efficiency of the ERTAH was improved about 20 % in comparison with the old type blood chambers¹⁵. We deduced that the improvement was mainly dependent on the prevention of backward flow by modification of the form between the inlet and outlet ports. Moreover, its flow pattern changed to an entirely nonpulsatile flow from a pulsatile-like flow.

In the durability test performed simultaneously, no problems were detected in the body of ERTAH or in the blood chambers at 18 hr. The results demonstrated an improvement in durability since a breakage of the sac had been detected at approximately 8 hr in the previous blood chambers¹⁵.

2-2. Animal experiment design for implantation.

The ERTAH operated at a driving rate of 160 rpm with a left cardiac output of 6.0 liters/min and a right cardiac output of 5.4 liters/min. The interatrial shunt flow rate was 250–400ml/min (Fig. 7). The animal experiment was terminated after 12 hr of ERTAH operation.

DISCUSSION

In the development process of totally implantable artificial hearts, left ventricular assist devices (LVAD) have been routinely applied, but no satisfying totally implantable total artificial heart (TAH) has been developed¹². Although there are many problems to be solved in developing the ERTAH, the advantages of this system are that it is simple and one of the most compact devices in the world (8 × 10 cm). The major problems encountered in developing ERTAH were mechanical problems including its low basic performance as a blood pump, and a fixed flow balance between the left and the right that was controlled by the principle of a roller pump. In the current version of ERTAH, the left-right flow bal-

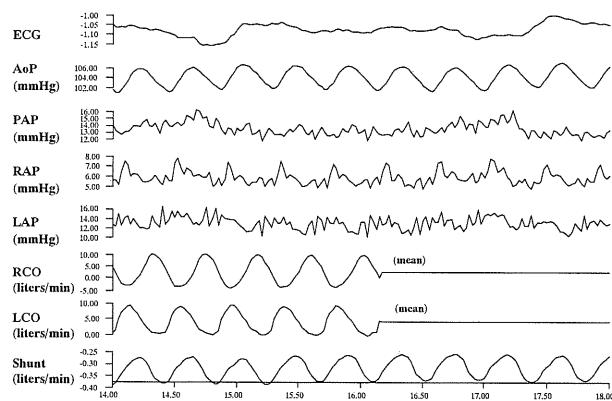


Fig. 7. Hemodynamic oscillogram of the animal experiment.

The ERTAH operated at a driving rate of 160 rpm with a left cardiac output of 6.0 liters/min and a right cardiac output of 5.4 liters/min. The interatrial shunt flow rate was 250–400ml/min

ance is maintained by controlling differences in the volumes between the left and right chambers, and the device was operated for several hours in acute experiments. However, it may be limited to balancing with this method alone when working toward a completely implantable total artificial heart^{15,17,20}. An interatrial shunt was designed for balancing the left and right sides of the electrohydraulic total artificial heart by the University of Utah^{1,7,9,14,19}. Therefore, our attention focused on a method whereby an interatrial shunt could be set at the inlet side to achieve a left-right balance. Prior to trial manufacture of an ERTAH with an interatrial shunt, the actual LL shunt flow and effectiveness of the interatrial shunt on left-right balance, when this artificial heart was operated in nonpulsatile and at regular flow, was evaluated by means of a numerical simulation test, a mock test using DeBaKey roller pumps and an acute animal experiment. In these simulations, the shunt flow through the bronchial arteries was approximately 500–600ml/min, and positioning an interatrial shunt between the inlet ports seems useful for balancing.

Regarding the basic performance of the pump, the two modifications—downsizing of the blood chambers (although the basic configuration of the pump was not modified), and redesigning the inlet and outlet ports to prevent regurgitation—resulted in a 20% increase of energy efficiency, about a two-fold increase in cardiac output and improved durability compared with the previous type. A completely non-pulsatile flow waveform could be obtained after the modifications, in contrast with the previous pulsatile-like waveform caused by a little of the blood flow being reversed. It is thought that the decrease of regurgitation primarily contributes to the improved basic performance. Although a maximal increase of energy efficiency of 6.4 % was achieved, the possibilities are endless. To achieve this goal, it is necessary to incorporate seven features into the system: small size, atraumatic features, antithrombogenic features, antiinfection features, a simple and durable design, and low energy requirement with easy controllability. In a discussion, the following may only be analyzed: size, design, energy requirement, and durability. In other respects, this device leaves much room for improvement and development. Especially in the atraumatic features, the increase of serum potassium level due to hemolysis, which is characteristic of roller pumps, has not been assessed and actually is not satisfactory at this stage. We are planning further improvements including employment of a different material for the sac, such as polyurethane, and a more effective motor. Furthermore, water-proofing of the system is to be realized for a totally implantable artificial heart.

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