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Development and Animal Experiment of Moving-Actuator Type Electromechanical Total Artificial Heart[1]

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=Abstract=A new type of electromechanical total artificial heart(TAH) based on circular rolling-cylinder mechanism was developed to overcome critical problems in motor-driven heart such as large size and difficulties in fitting the heart to atrial remnants and arterial vessels. Its performance and reliability were evaluated in mock circulation and animal implant experiments. The total weight and volume of the pump are 650 g and 600 ml, respectively.

This new pump was implanted in a calf for total heart replacement, and it had been operated for 100 hours, with the animal in excellent physical condition. The whole system, including pump, controller, and control algorithm, has performed well to improve the prospect of clinical application of our TAH system.

Key words: ***Total artificial heart(TAH), Mock circulation test, Animal implantation***

INTRODUCTION

Compared to the conventional air-driven total artificial heart, the motor-driven artificial heart has several advantages, such as portable system, usage of small-diameter wire instead of large size percutaneous tubes, possibilities of accurate control and quiet operation. Also, the use of electricity as energy source for pumping is expected to lead us to the era of tether-free totally implantable artificial heart in the near future. The developments in microelectronics, permanent magnet material, rechargeable battery, and transcutaneous energy transmission-(TET) technique, make the permanent artificial heart more realistic goal (Pierce 1986).

The existing pusher-plate-type motor-driven heart system has two major disadvantages for clinical application compared to the pneumatic system: one is the fitting problem to the remnants of natural heart (Rosenberg *et al.* 1984), and the second is its relatively larger size and heavier weight. These critical problems are caused by the two facts of structural principles. First, the actuator is located in a fixed position between the right and left artificial ventricles-(Sacs of diaphragms) which makes the right and left inflow ports apart, while the natural atra are almost attached together with the septum in the middle. Second, since the rotational motion of the motor shaft is converted to a linear motion of pusher plates too produce contraction of the sacs, the electromechanical pump has the right and left outflow ports parallel to each other. This

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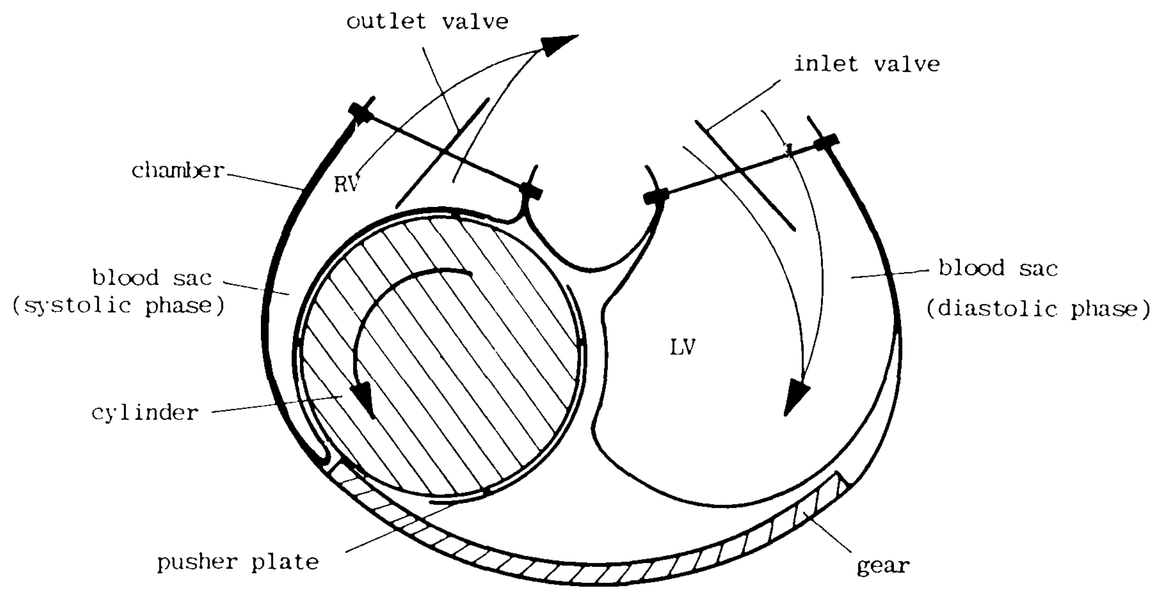


Fig. 1. Diagram of the circular-motion rolling cylinder blood pump.

straight orientation of aortic and pulmonary arterial grafts makes for a very poor orientation to fit to the natural vessels of pulmonary artery and aorta. Thus, it makes long connections inevitable, and vulnerable to kinking of the pulmonary graft.

Except for an electrohydraulic heart developed at University of Utah, where they solved these problems by utilizing the same heart as a pneumatic system with an energy converter using an extremely small motor(Jarvik 1981), almost all other motor-driven hearts face the same problems. In the Utah system, the very high speed operation of the motor (about 10,000 RPM) can be a major problem in reliability.

After succesfully achieving the linear rolling-cylinder mechanism which optimally utilizes the dead space between artificial ventricles, as reported in our previous paper (Min *et al.* 1988), we concentrated on solution of the above-mentioned to a fitting problems. In this new pump, we can diminish these poblems in considerable degree by rolling the cylinder on a circular track as shown in Fig. 1.

As a result of this modification, the distance between two inflow ports is consideraby reduced and the outflow's orientations cross each other for convenient fitting to arteries. This new heart with a circular rolling-cylinder has a round shape with an elliptical cross section which provides a compatible condition for the surrounding soft tissues. Also, we could reduce the total height of the heart, which has been known to be the most critical dimensional parameter for implantation. The outlook of the assembled heart is shown in Fig. 2.

After the long-term mock circulation tests for the evaluation of performance and reliability, the first animal implantation was performed with a female calf. She survived for 100 hours in good physical condition shown by voluntarily standing up and eating(Klain *et al.* 1971). Our control algorithm performed by manual adjustment worked well, as shown by the almost normal ranges of hemodynamic and laboratory data during the implant.

MATERIALS AND METHODS

Description of pump system

Except the changes from linear to circular shapes of rack, guiding rod, and actuator frame, the principle of the mechanism and the mechanical components are the same as the linear type heart of the previous design(Min *et al.* 1988). In the linear type actuator, rotational angle (ΘL) of the cylinder is directly proportional to the given stroke length (SL) by the following equation:

$$\Theta L = SL/Rc[rad] \quad (1)$$

where Rc is the radius of cylinder.

But, in circular type, the dimensional parameters are related each other as follows:

$$(\Theta L + \alpha) \times Rc = L \quad (2)$$

(a)

(b)

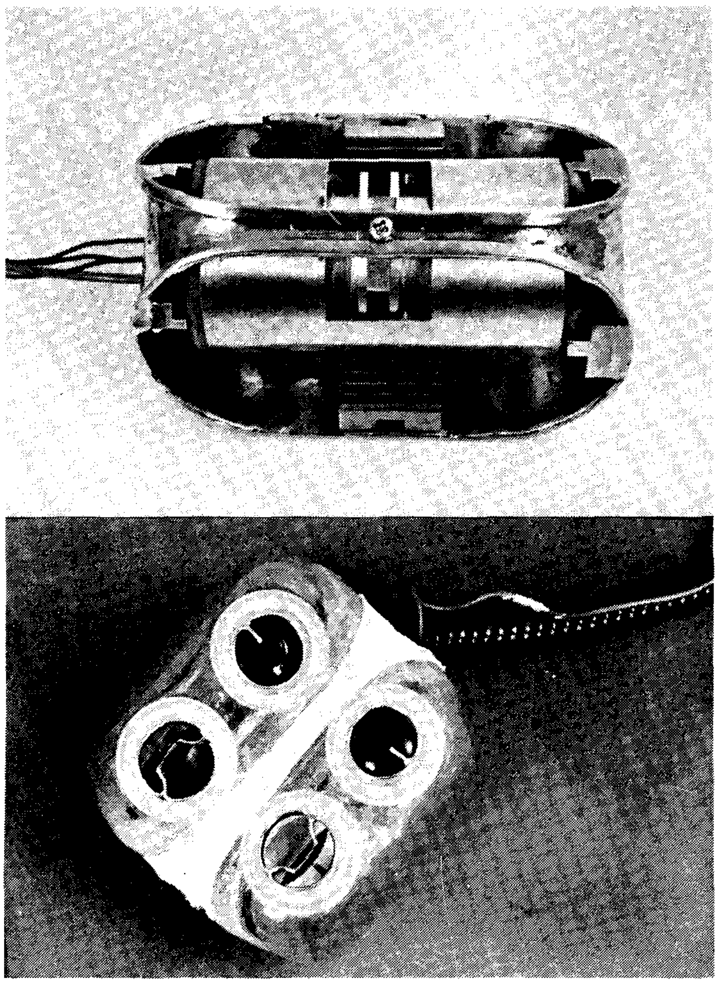


Fig. 2. Figure of the assembled circularly rolling-cylinder total artificial heart (a) actuator (b) pump.

$$L = SL \times \frac{2 \times Rc + \delta R}{Rc + \delta R} \tag{3}$$

From the equations of (2) and (3), the rotational angle is given by:

$$\Theta L = SL \times \frac{2 \times Rc + \delta R}{Rc \times (Rc + \delta R)} - \alpha \tag{4}$$

$$\simeq 2 \times \frac{SL}{Rc} - \alpha, \; Rc \gg \delta R \tag{5}$$

where α is the angle of arc and δR is as shown in Fig. 3.

The design parameters of stroke length (SL), radius of cylinder (Rc), and the angle of arc (α) were chosen to make the distance between inflow and outflow ports as short as possible. Then, the operating point of the motor was chosen to have higher speed and lower torque region where the efficiency of motor is higher using DC motor (S/M566-18) with small diameter and long length.

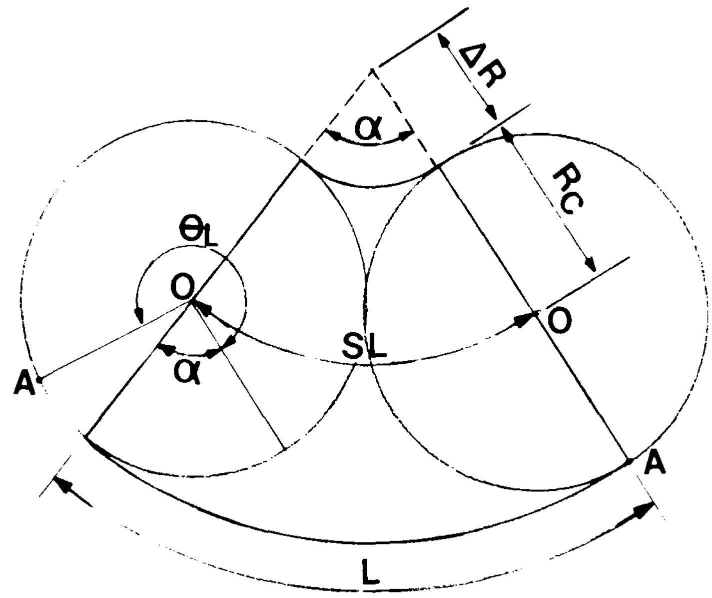


Fig. 3. Relationship of dimensional design parameters in circularly rolling-cylinder actuator.

In the circular type system, a full 2.9 cm stroke of the pusher plate motion is produced by 6.1 revolutions of the motor in one direction through the 28:1 reduction gears. Since the cross sectional area of rolling-cylinder is 35 cm^2, the expected maximal stroke volume is 100 ml. Total weight and volume of the integrated pump system are 650 g and 600 ml, respectively.

Each ventricular sac is basically the same as the one used for the linear type heart, which is a smooth, seamless, elliptical polyurethane (SPU: Pellathane,® General Polymer) blood sac, but has slightly different dimensions and is specially designed to avoid touching with any metal part of the actuator. Also, it was made to make two inflow ports located closer together and two outflow arterial ports cross each other with sufficient angle to decrease the length of vascular grafts and to prevent any kinkings in the grafts.

To increase the efficiency of pump by decreasing the frictional loss, a special engineering plastic material was used for the component of contacting area between cylinder and guiding rod.

In-vitro and in-vivo test

A long-term in-vitro test was performed on a Donovan mock circulation system with the controller to evaluate the performance and reliability of new circular type heart(Lioi *et al.* 1988). After achieving reliable results in in-vitro tests, we performed animal implantation experiments.

After trials of our pump on two sheep as an extracoporeal biventricular assist device, a chronic animal implantation was performed in June, 1988 with a female calf, "Shim Chung", 4 months old, and approximately 100 Kg. The operative procedure was as follows: from the previous morning, NPO was kept, and KM 2.0 g with 150 ml water was given for intestinal disinfection. One hour before induction, the area of right chest wall and neck were thoroughly clipped and gave a shower bath. Sampling 50 ml of blood, anesthesia was induced with thiopental sodium (Pentotal) 1250 mg and atropine and maintained with Halothane(1 vol %) $-N_2O$(50 vol %) gas. After inserting pressure monitoring lines in the left saphenous vein, the right jugular vein and carotid artery were exposed. Excising the fifth rib, a right throacotomy was performed. SVC, IVC, and azygous vein were dissected on which tourniquets were placed. Just after successive opening the pleural sac containing the intermediate lobe of the lung and pericardium, two arterial grafts and two atrial cuffs were preclotted with 60 ml unheparinized blood. A subscutaneous tunnel for placement of chest tubes and drive lines and heparinized standard dose of 3 mg/Kg were prepared. After placement of bypass lines with arterial lines in carotid only, very slow partial bypass was started, not more than 0.5 L/min. After at least 3 min to get adequate mixture of blood and priming solution, total bypass was performed maintaining PEEP 5cm H_2O on lungs, and hemazygous vein was ligated and ventricles were excised. After the arterial grafts and atrial cuffs were sutured, artificial heart was connected and pumping was slowly started, and then bypass was stopped. After chest closing, and repairing juglar vein and carotid artery, the animal was placed in the cage and recovery procedure of normothermia and lung ventilation as dictated by blood gases was initiated. The same surgical equipments and techniques as developed in University of Utah, were used, and the screw type quick connectors, also fabricated in Utah, were used to connect Dacron atrial cuffs and arterial grafts to the circular type pump. Four Bjork-Shiely tilting disc valves(two 29 mm for inlet and two 27 mm for outlet) were located inside the quick connectors.

To continuously monitor the changes of the aortic pressure(AOP), pulmonary arterial pressure(PAP), four polyurethane monitoring catheters were attached to the side walls of cuffs and grafts.

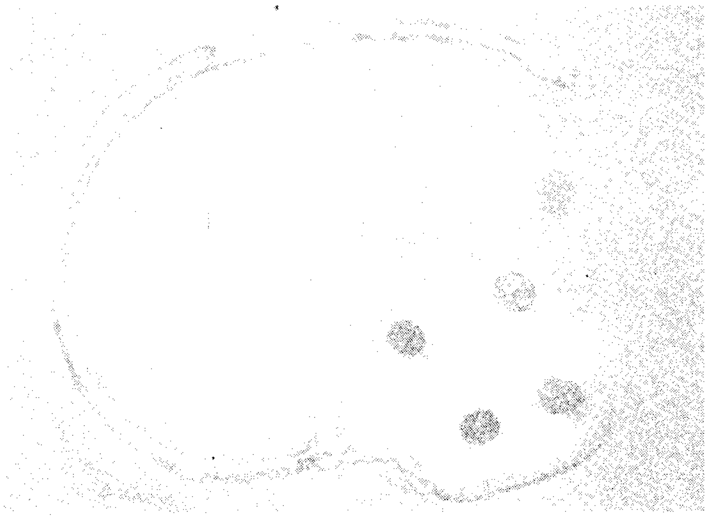


Fig. 4. Figure of the circular type pump implanted in a calf.

Eight electrical wires for motor drive and hall effect sensors are located inside 3/8″ Tygon tube, which penetrates the skin through a subcutaneous button. The purpose of using a tube is not only to protect the electrical wires inside the body form body fluids, but also to provide a way to given suction pressure into variable volume between two sacs to help diastolic filling of blood, when it is required.

The appearence of the assembled heart used in animal implanatation is shown in Fig. 4.

The postoperative procedures include administration of anticoagulants (Heparin 2,000 IU/day and Persantin 40 mg/day) and antibiotics-(Cefamezine 4 g/day, Gentamicine 320 mg/day), and controller parameter adjustment to maintain AOP and LAP within physiological range with vasodilator injection.

Four pressure changes of AOP, PAP, LAP, and RAP were continuously monitored and recorded using HP 8890B CATH LAB system 8 channel monitor and Gould 4 channel paper recorder.

After death, a detailed autopsy was performed to check the conditions of the animals and the implanted heart system.

RESULTS

Through a series of mock circulation tests, we could confirm that the performance and reliability of this new circular type heart are comparable to our previous linear type one. A typical tracing of

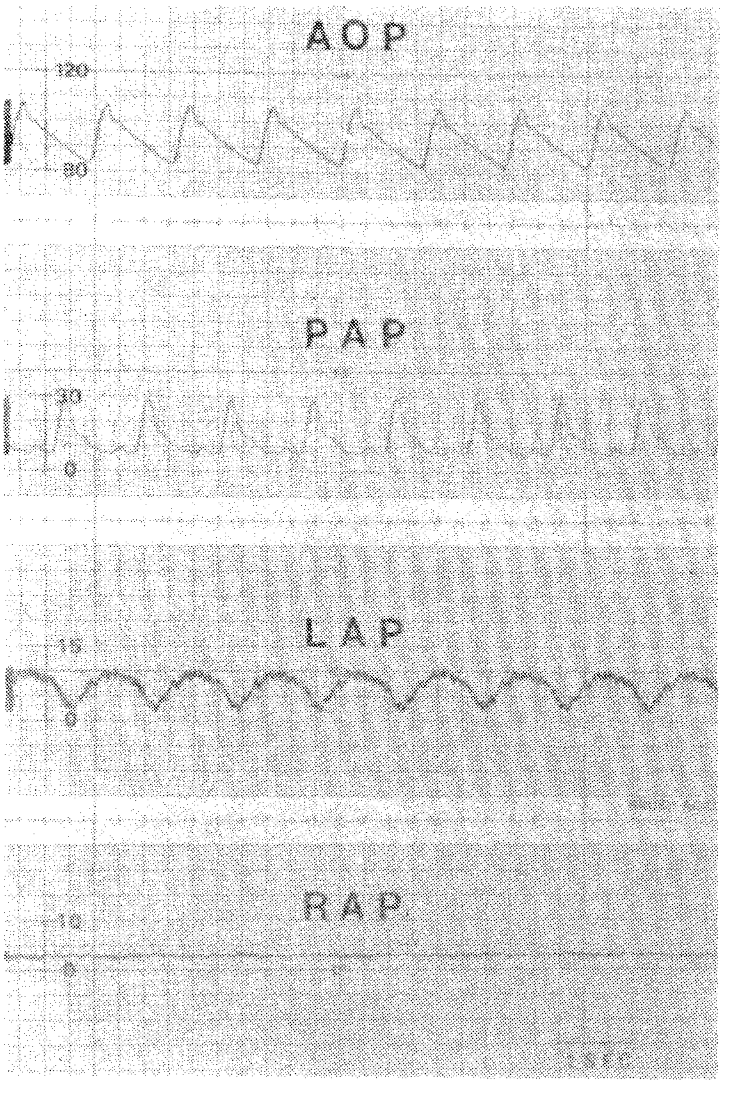


Fig. 5. Typical waveforms of the results of mock circulation experiments.

AOP, PAP, RAP, and LAP waveforms in the mock circulation system is shown in Fig. 5. To simulate long-term chronic implantation, a continuous operation test was performed and the results were satisfactory for stable operation.

In-vivo test as an extracoporeal biventricular assist device on two sheep gave us another confirmation of the possibility of chronic animal implantation. In animal implantation, "Shim Chung" recovered after surgery to the degree of voluntarily standing and eating, and survived for 100 hours in excellent physical condition(Fig. 6)

On the fourth post-operative day, sudden artificial heart failure occurred in animal's standing posture. After about 30 ml of fluid was drained from the tube connecting controller and pump, the cause of this accident was found as an electrical short circuit formation between the intermediate connector pins. This accidental artificial heart failure was thought to bring accute

Fig. 6. "Shim Chung", female calf, 4 months old, approximately 100 kg who received a circular type artificial heart for 100 hours.

severe pulmonary edema and cerebral ischemic damage, and the sacrifice of animal was confirmed by no light refelxes on her eyes. After death, a detailed autopsy was performed to check the conditions of the animals and the implanted heart system.

All laboratory data were summarized in Tab. 1.

The variation of hemodynamic parameters of AOP, PAP, RAP, LAP, and heart rate are shown in Fig. 7 for the survival period. A typical waveform is shown in Fig. 8. Higher RAP and LAP, as shown in Fig. 7, may be caused by the posture of animal, where the animal's weight pressed down the atrial cuffs to produce unbalanced pressures inside the atrial cuffs. But while standing, a normal, well-balanced condition between LAP and RAP was restored as marked in the same figure.

Parameter adjustment on the controller system was required frequently only on the first day after surgery, and in this case, the heart rate was adjusted to maintain LAP within physiological limits. A negative pressure was provided into the variable volume inside pump to help diastolic filling of the blood sac, when the LAP was higher than 30 mmHg. Constant negative pressure of -10 mmHg was maintained using a vacuum connected through a water column.

After death, a detailed autopsy was performed; at the skin incision site, cutting the suture and subcutaneous tissue the fifth intercostal space was opened. Small amount (50-80 ml) of blood was in the pleural cavity and there was

Table 1. Summary of laboratory data

1. LFT

Date	Time	Cholesterol (mg/dl)	protein (mg/dl)	Albumin (mg/dl)	Total Bilirubin (mg/dl)	Alk. Phos (U/L)	SGOT (U/L)	SGPT (U/L)	CPK (U/L)	LDH (U/L)
14	07 : 00	54	7.1	3.6	0.9	136	24	7	61	844
	23 : 00	34	4.4	2.6	0.6	131	120	11	2,955	1,375
15	08 : 00	24	5.1	2.9	0.2	299	224	16	4,925	2,955
	20 : 00	32	4.8	2.9	0.5	134	195	17	6,300	2,455
16	08 : 00	22	4.7	2.8	0.2	98	226	8	627	2,360
17	08 : 00	26	5.1	2.8	0.4	92	184	9	627	2,360
Normal range		20-147	4.9-7.7	2.4-5.2	0-8.0	18-97	9-67	1-48	0-17	357-756

2. Blood Gas

Date	Time	ABGA : A VBGA : V	pH	P-CO_2 (mmHg)	P-O_2 (mmHg)	HCO_3 (mmol/L)	Oxygen(%) Saturation)	Comments
14	13 : 50	.A.	7.55	35	99	31	98	Pump start
	14 : 30	.A.	7.42	42	198	27	99	Heart-lung mach. off
	15 : 20	.A.	7.44	41	320	27	99	After position change
	16 : 50	.A.	7.42	41	249	26	99	Ventilator off
	17 : 25	.A.	7.45	39	87	27	97	
	18 : 30	.A.	7.46	38	98	27	0	
	19 : 40	.A.	7.42	48	141	30	0	Extubation:O_2 10L/min
	21 : 20	.A.	7.48	42	70	31	95	
	23 : 20	.A.	7.46	46	130	33	0	Milk 200 ml intake
15	07 : 20	.A.	7.45	40	80	28	0	Milk 1l intake
	13 : 00	.A.	7.45	42	173	29	99	
	13 : 00	.A.	7.42	42	33	27	64	
	18 : 00	.V.	7.46	46	34	32	68	
	18 : 00	.A.	7.55	37	132	32	99	
	23 : 00	.A.	7.46	40	135	28	0	After Stand up
	23 : 00	.V.	7.40	46	28	29	0	
16	07 : 00	.A.	7.47	43	129	32	99	
	07 : 00	.V.	7.43	48	32	32	62	
	18 : 50	.A.	7.47	42	125	30	0	Vac. 10 mmHg at 13 : 00
	18 : 50	.V.	7.43	44	33	30	0	
17	09 : 00	.A.	7.51	40	77	31	96	Nasal Prong Removal
	09 : 00	.V.	7.46	45	29	32	59	
	20 : 00	.A.	7.49	39	75	30	91	C-tube Remov. 18 : 00
	20 : 00	.V.	7.44	46	28	31	53	
18	07 : 00	.A.	7.52	37	73	30	96	
	12 : 00	.A.	6.75	123	55	17	55	Pump off.

3. Microbiology

Date	time	Type	Report	Comment
14	07 : 00	BL	G(+)ROD,Anaerobe	Contammination
15	08 : 00	BL	No	
16	08 : 00	BL	No	
17	08 : 00	BL	COAG(−) STAPH	Contammination
18	08 : 00	BL	No	

4. Coagulation Lab.

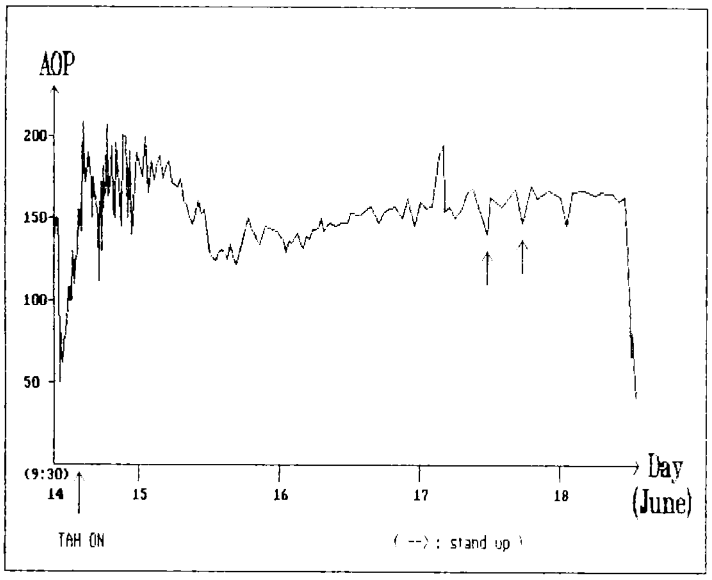
Date	Time	PT (sec)	APTT (sec)	Fibrinogen (mg/dl)	Factor Assay (VIII)	FDPTest (Neg: <10 ug/ml)	PLT Agg. Test
14	07 : 00	17.9	120	252	200% 37sec	1 : 5(−)	Negative
	12 : 00	25.3	120	0	>200%	1 : 5(−)	Negative
	23 : 00	26.2	120	0	190% 41sec	1 : 5(−)	Negative
15	08 : 00	27.6	120	0	160% 42sec	1 : 5(−)	Negative
16	08 : 00	27.5	120	255	160% 42sec	1 : 5(−)	Negative
17	08 : 00	28.0	120	357		1 : 5(−)	Negative
18	08 : 00	20.2	81	0			

5. Plasma hemoglobin and complement

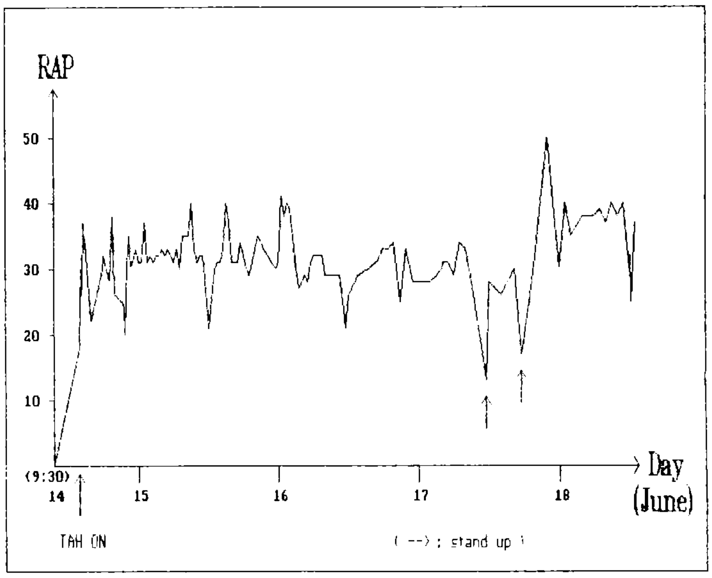
Date	Time	Plasma Hb (mg/dL)	C3 (mg/dL)	C4 (mg/dL)	CH50 (U/ml)
14	07 : 00	22.46	6.5	8.0	10.2
	12 : 00	16.30	5.8	8.0	10.2
	23 : 00	23.22	7.2	10.4	10.2
15	08 : 00	13.46	6.7	7.0	10.2
16	08 : 00	24.21	11.4	13.4	10.2
17	08 : 00	22.74	9.3	13.4	10.2
18	08 : 00	27.36			

6. CBC

Date	Tme	WBC (×10ˆ3)	RBC (×10ˆ6)	Hb (g/dl)	Hct (%)	PLT (×10ˆ3)
14	12 : 00	6.9	5.64	10.8	43.0	306
	16 : 00	7.4	6.99	11.5	30.5	0
	17 : 00	10.0	6.02	11.7	25.8	211
	18 : 30	9.8	6.40	9.8	28.1	0
	23 : 00	10.1	7.68	13.4	39.7	0
	23 : 00	11.8	5.05	10.3	21.8	224
15	07 : 00	10.6	5.91	9.9	26.6	0
	07 : 00	11.6	5.16	10.0	22.1	236
	13 : 00	11.0	5.05	9.6	30.1	112
	18 : 00	11.2	4.88	9.8	29.1	114
	23 : 00	14.6	5.15	9.9	30.6	10
16	07 : 00	13.4	5.26	10.6	31.3	0
	08 : 00	14.5	5.82	11.3	24.9	202
	19 : 00	13.6	5.51	10.6	32.5	0
17	08 : 00	9.7	5.25	9.7	22.8	171
	09 : 00	0.0	0.00	0.0	0.0	0
18	08 : 00	5.5	4.88	8.6	21.3	208
Normal Range		4-12	5-10	8-15	24-46	



(a)



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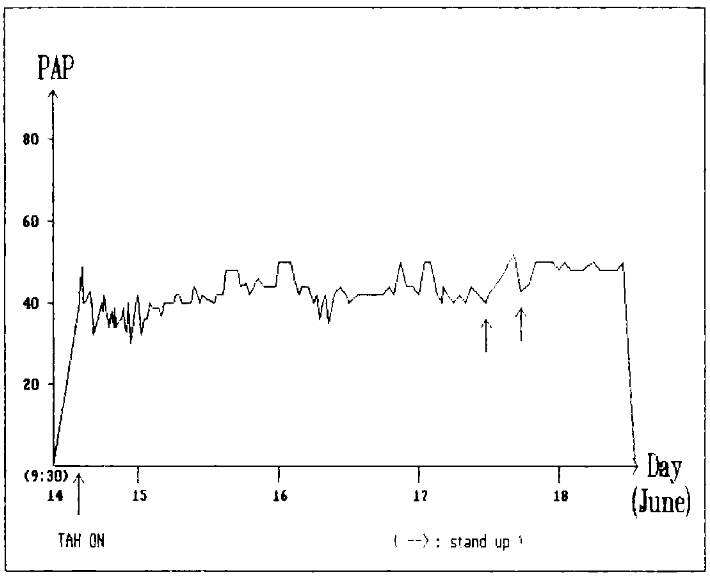

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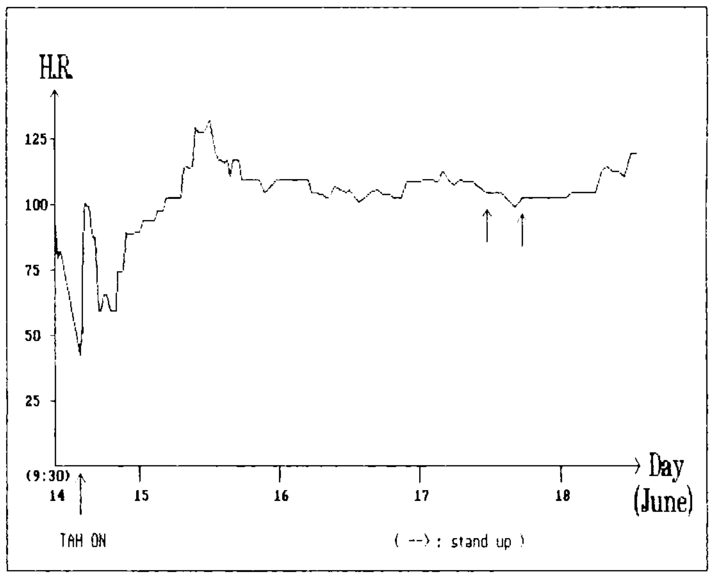

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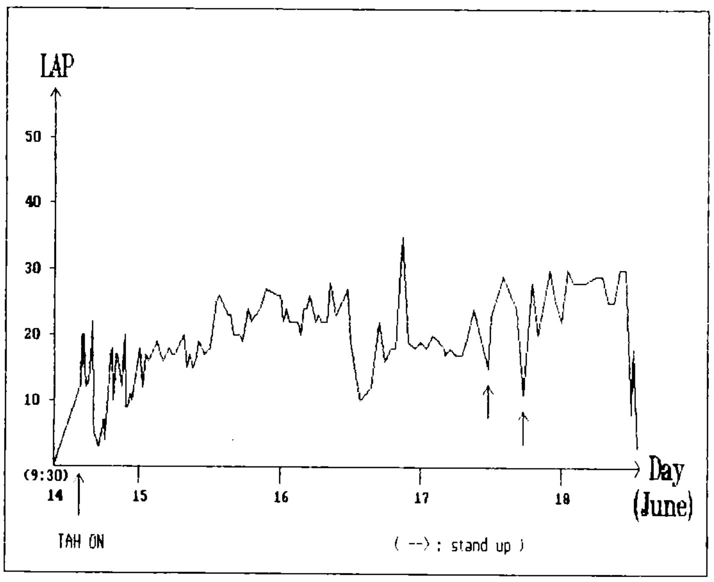

(c)

Fig. 7. Variations of the measured hemodynamic parameters of (a) aortic pressures, (b) pulmonary arterial pressure, (c) left atrial pressure, (d) right atrial pressure, and (e) heart rate.

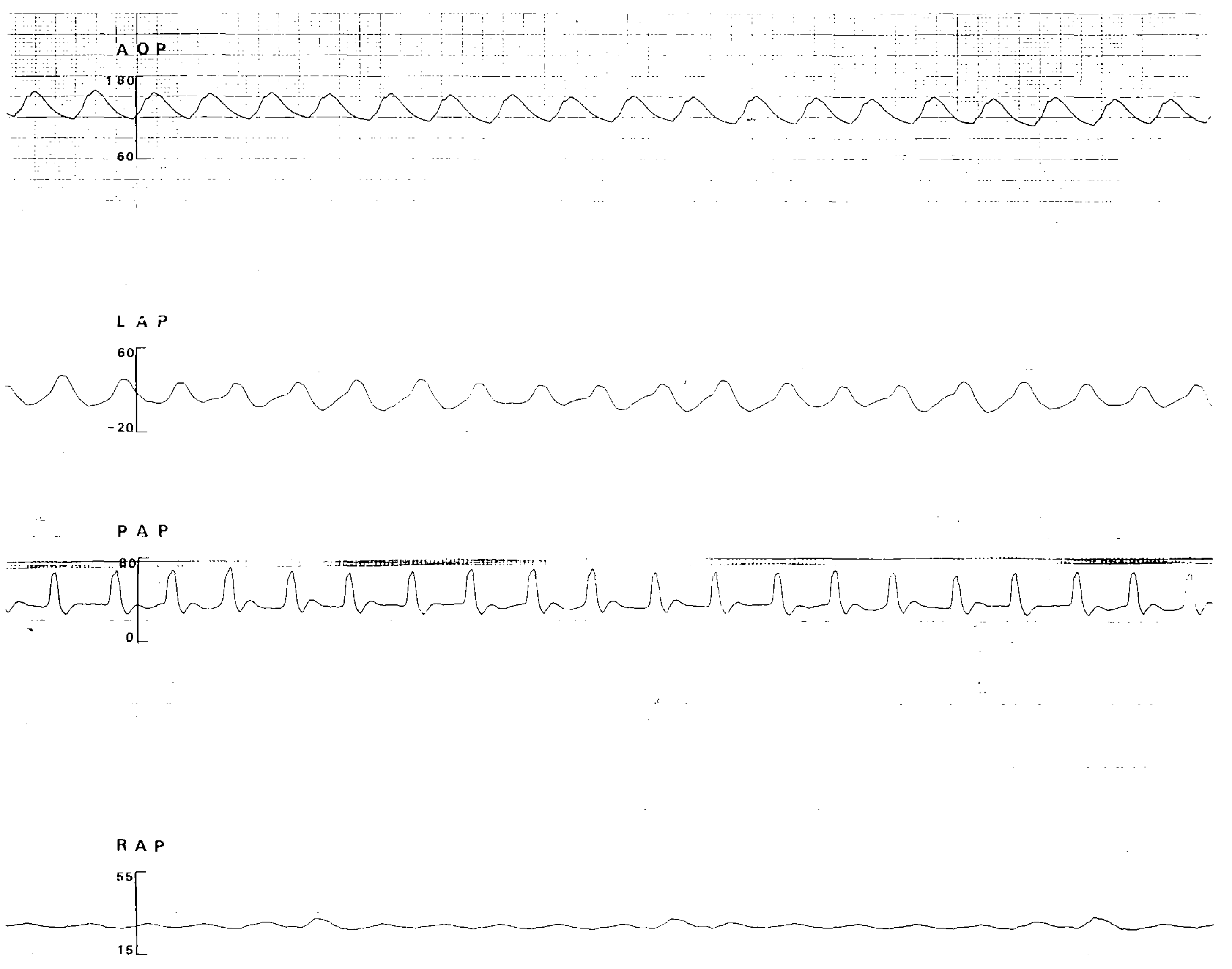

Fig. 8. Typical waveforms of results of animal experiment.

blood clot around the artificial heart surface. Pulmonary arterial graft was severely flexed by approximately 70(deg). there was no thrombus fomration inside PA graft and aortic graft showed good directional match. Right and left atrial cuffs were slightly folded which appeared to be pressed down by the animal's weight, and no thrombus inside them. Trachea was cut at the level of carina, and there was some water with air bubble inside tracheal lumen. Pulmonary artery was opened through the left main branch, and two thrombo-emboli, brownish white, 3 cm long, blocked the distal part of left PA. At the peripheral tissue of lung, there was small yellowish white dot-like fluid collection which seemed to be exudated congestion or pus. Right PA examination was performed. At the distal part of lung parenchyma, there was dark discolored part which might suggest the infarct area. Many small thrombo-emboli were found inside PA through the right main branch. Opening diaphragm, liver and kidney were examined. There was no severe congestion in liver tissue. Left kidney showed fetal lobulation and there were multiple discoloration due to central ischemic necrosis. Right and left ventricles of the artificial heart were dissected and 1.5 cm long linear--shaped thrombus was formed at 2 cm below the outflow opening in both ventricles. Lung, kidney, liver and embolus are examined microscopically. Lung shows large thrombotic emboli impacted in the pumonary artery. The emboli in the lung and separately embedded emboli show identical findings of laminated fibrinous and cellular layers. The lung parenchyme show diffuse congestion and fibrinous exudate in alveolar space. The kidney shows typical ischemic infarct with marginal hemorrhagic rim. The liver shows congestion aroung central vein.

DISCUSSION

To overcome the existing critical problems of a motor-driven total artificial heart, a new mechanism of a circularly rolling-cylinder was developed, and its performance was studied in in-vitro and in animal experiments.

The overall results of mock circulation tests and the first chronic animal implantation are very encouraging. Through these animal experiments we found several problems to be corrected before the next implantation.

The pumonary arterial outflow orientation should cross the aortic graft with a sharper angle to match smoothly with natural vessels. This can be easily changed in our circular type heart by a slight modification of the wax mold for the right blood sac.

The electrical wires and intermediate connector between controller and pump should be modified to resist any movement of body fluid and moisture into the pump.

An automatic control algorithm is necessary for long-term survival. For this purpose, the accurate pressure estimation of LAP, RAP, PAP and AOP without direct measurement by catheterization should be realized. For aortic and pulmonary arterial pressure, we can relate the motor current to these afterload pressures. Also, we are developing algorithm to estimate LAP and RAP using an implanted pressure transducer inside current to these afterload pressures. Also, we are developing algorithm to estimate LAP and RAP using an implanted pressure transducer insider variable volume(Blaylock *et al.* 1986). The pressure changes inside variable volume is shown to be related to the filling characteristic of tha sac, and our new algorithm is based upon the relative changes of pressure. In this case, the transducer is free from direct contact with blood and dirft effect in output signal level for long-term implantation experiments.

For future clinical application of our system, we are also studying the following problems.

To prepare the stage for a totally implantable system, a complete micro-processor based controller system is desirable(Fischetti 1983).

A TET(Transcutaneous Energy Transmission) system is also a necessity for a totally implantable system. The design of a high efficiency transmission coil is the most important aspect of the TET(Sherman *et al.* 1983). An interesting and important subject is the development of a motor controller based upon the back electromotive force(EMF) technique, which will eliminate the need for position sensors for commutation of a brushless DC motor(Orth *et al.* 1981). Using this method, the efficiency of motor operation can be increased by sensing the optimal commutation angle, and total reliability of the pump can be increased by reducing the number of electrical wires to three, in the case of a three phase motor.

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＝국문초록＝

이동작동기 원리를 이용한 인공심장의 개발 및 동물실험에 관한 연구

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새로운 형태의 전기기계식 인공심장을 개발하였는 바, 회전원통 원리를 사용하여 전동기 구동형 인공심장의 최대 단점인, 크기나 무게상의 제약과 이식시 생체에 남아있는 심방이나 동맥과 해부학적 접합상의 난점등을 해결하였다. 개발된 인공심장 시스템은 무게가 650g, 체적이 600 ml이었으며 성능과 신뢰성등을 실험하기 위해 장기간에 걸친 모의 순환 실험을 실시하였고, 동물실험도 시행하였다. 생후 4개월된 약 100 kg의 암송아지는 인공심장을 이식받은 후 100시간 동안 생존하였으며 스스로 일어서고 먹이를 먹을 정도로 양호한 상태를 유지하였다. 동물실험결과 펌프, 제어장치 및 제어알고리즘등의 동작이 우수한 것으로 판명되어 앞으로 임상응용의 가능성을 확인하였다.