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研 究 論 文
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Development of the Rolling-cylinder Type Motor-driven Total Artificial Heart System

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=Abstract=

A new type of motor-driven total artificial heart system with a rolloing- cylinder mechanism has been developed. The prototype system consists of a brushless DC motor inside of a rolling-cylinder, two arc shaped pusher-plates, and two ventricles of smooth, seamless polyurethane sacs.

The motor-driven pump has the advantages of being portable and quiet compared to the present air-driven pump. It can also be controlled more accurately. This rolling-cylinder type electromechanical pump has several structural advantages including small size and weight, as compared to other research groups' motor-driven pumps.

The results of mock circulation tests confirm sufficient pump output capacity(cardiac output : 9 L/min, at aortic pressure : 120mmHg, with heart rate : 120 BPM) for animal implantation of our prototype system.

1. Introduction

There have been twenty recipients of artificial hearts since it was first implanted in a human in Feb. 1982 through Nov. 1986. The artificial heart has been used as a permament substitute and as a bridge to transplant. Experience in clinical and experimental use of artificial heart has been encouraging during its initial development stage and the possibility of long-term survival is expected within ten years.

The present pneumatic artificial heart has significant problems due to its bulky external power unit and percutaneous tubes. These large bore-size tubes pose a significant problem of infection, and have been an impetus to develop a totally implantable artificial heart.

The development of implantable heart using an elecric motor is, being pursued by serveral research groups. Up to the present time, no implantable system is available. Our research group has investigated a new type of motor-driven total artificial heart system with a rolling-cylinder mechanism since 1984.

This motor-driven artificial heart has the following advantages compared to the air-driven type.

First, the motor will require only a battery as an energy source and a compact electronic control system rather than a large air compressor. The size of the total system will be reduced to a portable and implantable one.

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Seond, in this system only small bore wires will be exiting the patient's skin. Futhermore, if one use power transmission by inductive coupling, a wireless system would be possible.

Third, the pumping state of the artificial heart can be adapted to the patient's physiological state through fine control of the motor operation.

Forth, the pump's operation is relatively quiet and gentle.

Our rolling-cylinder mechanism has structural advantages over other motor type pumps.

First, the pump size is reduced. The pump size is a very critical parameter for clinical implantation, especially for women and orientals who have smal thoracic cavities. Since the driving motor itself moves as an actuator in the rolling-cylinder mechanism and the contraction of each ventricle occurs alternately as shown in Fig. 1, it requires only one ventricular diastolic space and the motor space at one moment, since the pusher plates attach directly to the cylinder. In the fixed motor type of pump, one needs approximately two ventricular diastolic space plus motor space. Therefore, the fixed motor type has a dead space of a full stroke length between the motor and the pusher plate during systole.

Second, the usage of the arc-shaped pusher plate rather than flat type enables the shape of the housing to the elliptical with round corners, which is necessary for smooth blood flow dynamics during the contraction period.

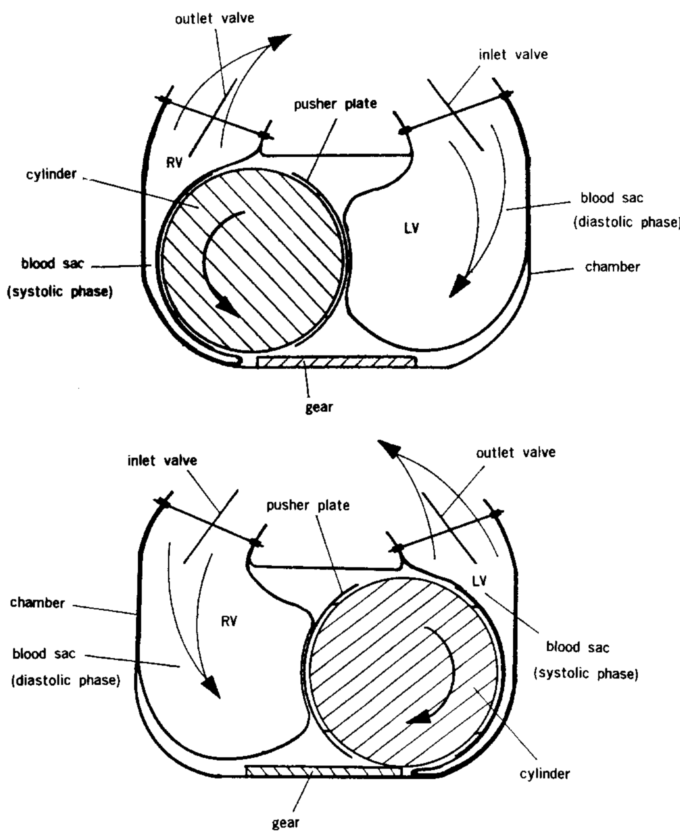

Fig. 1. Diagram of the linear-motion rolling-cylinder blood pump

2. Materials and methods

2-1. Description of pump system

The prototype pump system consists of three major parts ; right and left ventricles, and actutor including a rolling cylinder as shown in Fig. 2. Each ventricle consists of a smooth, seamless, elliptical segmented polyurethane (SPU ; Pellathane, General polymers) and a blood sac attached to a rigid mesh reinforced polyurethane housing. In orther to balance the left-right pump output, the volume of the left blood sac'is slightly larger than right one by 10 ml to compensate for the difference due to bronchial circulation and valvular regurgitation. This difference is supplemented by air flow through the compliance chamber attached to the cylinder frame.

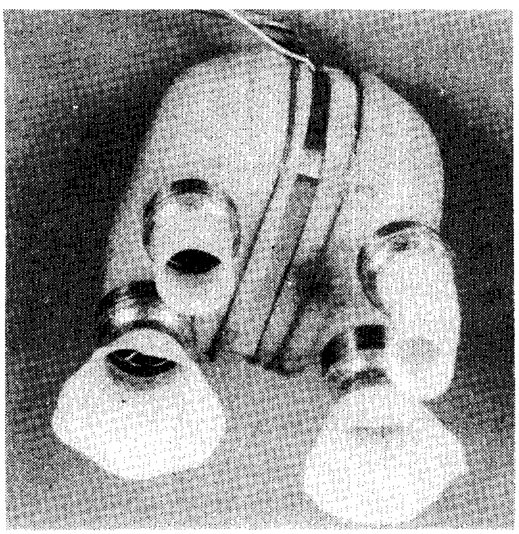

Fig. 2. Figure of the assembled rolling cylinder total artificial heart system

The actuator consits of a rolling cylinder, cylinder frame, and arc shaped pusher plates, positioned between ventricles as shown in Fgi. 3. The energy converter is a small brushless DC motor inside the middle part of the rolling

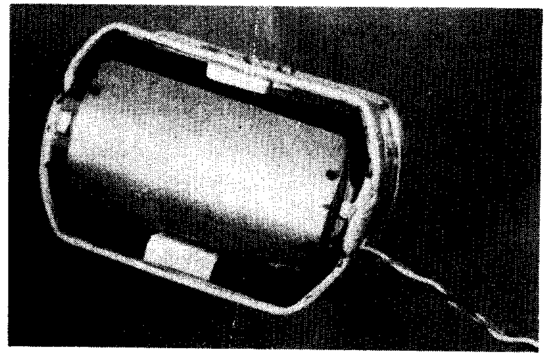

Fig. 3. Figure of the assembled actuator : rolling-cylinder, cylinder hosing, and pusher plates

cylinder. The cylinder rolls back and forth for full stroke length in connection with the motor through the two stages of planetary gears with a 1 : 30 speed reduction.

To ensure the steady motion of the rolling cylinder, the external housing holds the cylinder by the two guiding rods and a bottom rack. A gear attached to the bottom of the cylinder surface and a rack fixed to the cylinder housing produce a reliable rolling motion of the cylinder. Both side parts of the cylinder are separated from the middle part during motion and maintain a contact with the housing through the two guiding rods. Thus, these parts of the cylinder provide the linear motion as the middle part rolls on the rack.

Two arc-shaped pusher plates are fixed to these linearly moving parts through four flat-top screws. When the cylinder moves to the left and contracts the left ventricle, the right ventricle inflates, and vice versa. Hence the chamber volume is composed of one ventricle and motor space only.

In the prototype system, a full 2.5㎝ stroke of the pusher plate motion is produced by 3.7 revolution of the motor in one direction. Since the cross sectional area of the rolling-cylinder is $40cm^2$, the maximum expected stroke volume is 100ml. The total weight and volume of the integrated pump system are 700g and 600ml, respectively.

2-2. Description of control system

To provide the position commutation for the brushless DC motor, three Hall effect switches (UGN 3020T, SPRAGUE) with bias magnets are used and activated by the side flux of the stator magnet. Hall effect switches produce sequences of pulses at a rate of 4]pulses/rev which are $\pi/3$ apart from each other. These pulses are then used for the position and speed control of the motor as well as the position commutation.

The position control unit combines and counts every output pulse of the Hall effect switches. When the output of the counter reaches to the preset value, the rotational direction of the motor is changed and the counter is reset. This position control scheme allows easy control of the stroke length by changing the preset value.

These pulses are also used as input to the frequency-voltage converter for the purpose of velocity measurements. The measured velocity signal is compared with the specificed velocity profile in the controller to achieve the optimal velocity performance.

A trapezoidal velocity profile is used and the total 64 set of profiles are stored in the two EPROMs. To control the stroke velocity on a beat by beat base, we select the higher addresses of the EPROMs according to the control scheme. To balance the diastolic filling period of both ventricles, the left and right diastasis(waiting) time control unit is also provided. These two control parameters, velocity profile selection and left and right dia stasis time, can be adjusted by manual or automatic control.

The power control unit adapted the pulse width modulation method and is operated by the three-phase, full bridge MOSFET(IRF540, I & R) inveter. A voltage drop across the sensing resistor is measured for the current limiting as well as aortic pressure estimation as the load of the motor.

The dual processor sytem monitors the operating state of the pump instantaneously and displays the following parameters : Heart rate, left to right diastolic filling period ratio, estimated right atrial pressure(RaP), left atrial pressure(LaP), aortic pressure(AoP), and cardiac output. For the eatimation of RaP, LaP, and C. O., the pairs of magnet and linear Hall effect sensor(UGN 3501, SPRAGUE) are attached to the outer wall of the two blood sacs and ventricular housings. The output voltage levels of these sensors are digitized to give the instantaneous dimensional change of a blood sac, and used as basic data for the estimation of inflow and outflow volume of the blood sac. From the inflow volume changes and the filling time, the inflow rate is calculated and then RaP and LaP are estimated based on this inflow rate using a functional relationship between the pressure and volume. Also, cardiac output is calulated as the product of outflow volume and heart rate.

3. Results

We have performed a series of mock circulation experiments with manual changes of several operating parameters. Each ventricle was connected to a Donovan mock circulation circuit, where water was pumped with known inflow pressures and outflow resistances. Additionally, a turbin flowmeter provided an accurate measurement of the cardiac output. The typical pressure waveforms with motor current and rotational direction signal are shown in Fig. 4.

Mock circulation tests have verified a Frank-Starling type response in outflow to prelad, and, also, showed outflow to be inde-

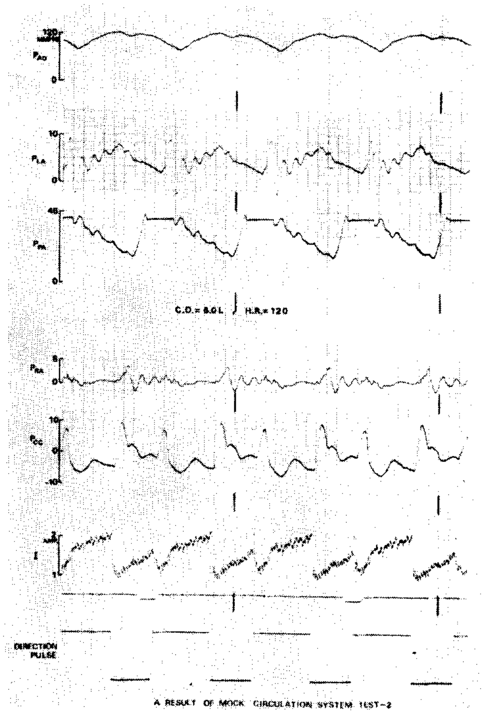

Fig. 4. Typical waveforms of the results of mock circulation experiments : aortic pressure, left atrial pressure, pulmonary aterial pressure, right atrial pressure, suction presure indside the chamber, motor current, and direction pulse(high for right diastolic and low for left diastolic period) from the top

pendent of afterload even without any automatic control algorithm. The cardiac output response of these physiologic variations is shown in Fig. 5, where cardiac output and LaP are both platted against RaP. With a rise in Rap from 0 to 6 mmHg, the cardiac output increases from a value of approximately 4 L/min up to maximum 9 L/min. Futhermore, as indicated in the same figure, as afterload was increased from 80 to 120 mmHg, the cardiac output response to varying RaP was only slightly decreased. This indicates that, in our prototype system, the filling charateristic are

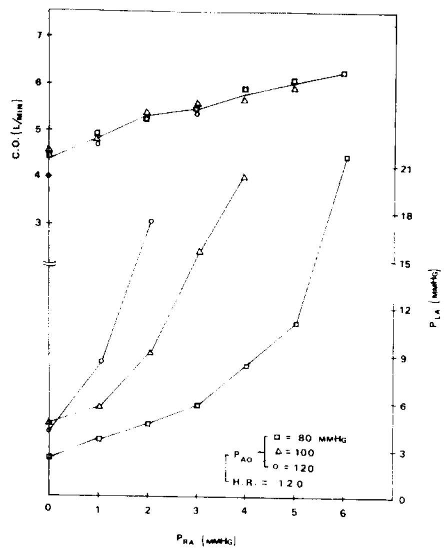

Fig. 5. Cardiac output response to preload and relationship of left atrial pressure and right atrial pressure without any control algorithm

more critical to cardiac output than any other parameters.

These in-vitro test results show the necessity to improve the heart's sensitivity to preload and its independence from afterload through automatic control. The results of mock circulation experiments also show that there exists a significant inbalance between outputs of two vetricles in this non-controlled case. Fig. 5 shows these discrepancies between RaP and LaP without any feedback control. Since there were different afterloads to the two ventricles, the motor speed was changed inversely propotional to each afterload.

Thus, these inbalance of RaP and Lap was natural results, since the right diastolic filling period was always longer than the left. But when the filling period of two ventricles was controlled, we could achieve a good balance between right and left artrial pressures as shown in Fig. 6. In this case, we used a more

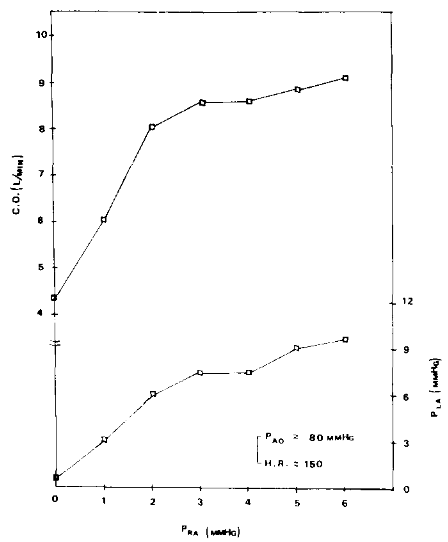

Fig. 6. Cardiac output response to preload and relationship of left atrial pressure and right atrial pressure with manual control

flexible compliance chamber and controlled the right diastolic filling period manually.

Table 1 summarizes the three hours of in-vitro blood test results during pumping to the mock circulation blood bag. The results are comparable to the other reported pump test using four mechanical prosthetic valves.

4. Discussion

4-1. Pump capacity and efficiency

The mock circulation test results show that the output of the pump would be sufficient for clinical and animal experimental implantation. The size of the pump is also sufficiently small for the recipients of 60*kg* to 80*kg*. For the present, the pump efficiency is about 10 %, but it is also expected to be improved to over 25%. Pump efficiency is expressed as the product of the efficiencies of motor and mechanical parts. Our ultimate goal is to increase the efficiency of both parts to 50%.

The efficiency of motor is directly related to overheating problems. After three days of continuous operation, we measured the temperature distribution at the pump housing.

Table 1. Results of three hours of in-vitro blood test

	0	5	10	30	45	60	90	120	150	180 min
WBC(x10³)	8.8	8.8	8.8	8.6	8.5	8.7	8.7	8.6	8.7	8.7
RBC(x10⁶)	5.94	5.96	5.98	5.94	5.92	5.94	5.97	5.94	5.92	5.97
Hb(g/dl)	11.4	11.6	11.6	11.7	11.6	11.7	11.6	11.7	11.7	11.6
Hct(%)	31.5	31.5	31.9	31.7	31.4	31.6	31.9	31.5	31.6	31.7
MCV(fl)	53.0	52.9	53.4	53.4	53.1	53.2	53.4	53.0	53.3	53.1
MCH(pg)	19.2	19.5	19.4	19.7	19.6	19.7	19.4	19.7	19.8	19.4
MCHC(g/dl)	36.2	36.8	36.3	36.9	36.9	37.0	36.4	37.2	37.2	36.6
RDW(%)	19.1	19.1	19.1	19.0	18.8	19.1	19.0	18.7	18.7	19.1
PLT(x10³)	225	178	187	184	177	184	195	197	205	190
Pct(%)	.144	.112	.122	.118	.115	.120	.127	.128	.133	.122
MPV(fl)	6.4	6.3	6.5	6.4	6.5	6.5	6.5	6.5	6.5	6.4
PDW(%)	16.0	15.3	16.0	15.9	15.8	15.7	17.4	16.2	17.6	16.9
LDH(u/l)	1004.5	986.1	1005.3	998.0	1009.5	990.3	1001.4	996.5	1004.7	993.7
PT(sec)	19.0	19.5	20	17.5	18	18.5	18.5	18.5	17.5	19.5
APTT(sec)	58	63	63	75	57	53	43	62	72	74
Plasma Hb(mg/dl)	3.03	5.39	5.95	5.37	6.35	6.46	7.91	11.02	10.45	13.18

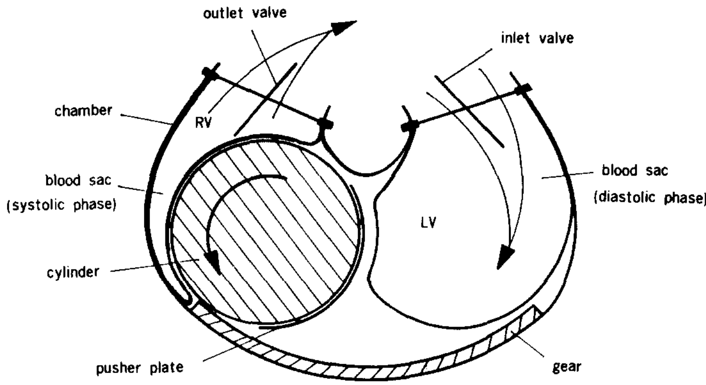

Diagram of rolling cylinder blood pump

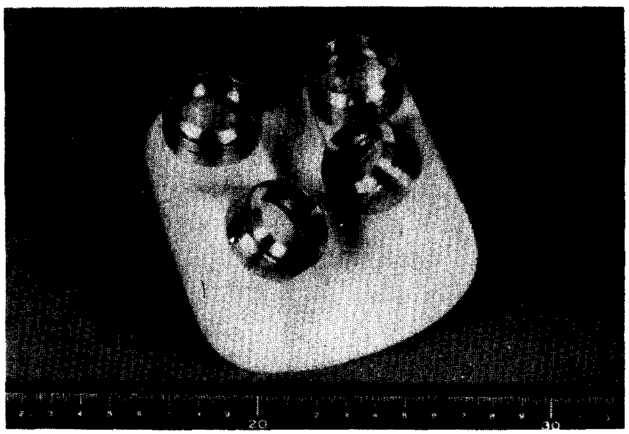

Fig. 7. Diagram of the circular-motion rolling-cylinder blood pump

A contacting region with the cylinder housing was hottest with 38 deg when water temperature was 24 deg. If we could increase the motor efficiency by changing the operating condition, especially motor speed, the temperature on the hot spot would also be decreased.

Presently, we are testing the reliability and stability of our pump system before animal implantation experiment.

All of the mechanical parts are designed and selected to have 5-year fail-safe operating time. Special attentions is given to the guiding rods of cylinder frame, planetary gear trains, blood sacs, and the motor and sensor wires. As motor and sensor wires, we are using biocompatible and ultraflexible wire with more than 200 million flexing cycle for 5 year of life expectancy at a heart rate of 100 BPM.

4-2. Pump dimension and shape

The pump is 6㎝ tall, 10㎝ long, and 10㎝ wide. Since the height is more critical than length and width, we chose a long cylinderical shape for the actuator. The orientation and positions of the inlet and outlet of most motor-driven pump are very poor for anatomosis.

In order to make the artificial heart easy to fit in the recipient's thoracic cavity, the pump should be round. The our valves, especially the inflow valves, should be positioned as close to each other as possible. Also, the orientations of the outflow valves should be such that the lengthes of the arterial grafts are as short as possible.

To accomplish these objects we are presently testing a circular type of pump as shown in Fig. 7. In this new type of pump, the rolling-cylinder moves circularly rather than the present pump's linear motion. Thus, the four inlet and outlet positions are located together to fit well to the natural vessels and atria. This circular motion is possible only in our moving actuator mechanism.

4-3. Automatic control

There are three basic control requirements in an artificial heart system ;

First, the heart should have a high sensitivity to preload following Starling's law, and pump output should be independent of afterload.

Second, it is important to deliver balanced ventricular cutputs. However, this is difficult in an alternately pumped, volumetrically coupled, motor-driven type artificial heart.

A new automatic control algorithm is now under development to support optimal control of the above basic control requirements. To become independent of afterload, we are utilizing a high performance feedback speed control loop with a PWM power control method.

The dimensional signal from a pair of linear Hall effect sensors and magnets, attatched to each side of a blood sac, gives the information about the preload. Then, the heart rate may be modulated in response to the amount of atrial inflow to provide a steeper Starling curve.

The difference between volumes of right and left blood sacs will also contribute to improve the balance between the right and left ventricular outputs. Also, by controlling the filling characteristics(period and suction) to adjust the right ventricular output, our automatic control algorithm can control ventricular outputs on a beat-to-beat basis.

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■ 국 문 초 록 ■

회전원통 원리를 이용한 모타 구동형 완전 인공심장의 개발

민병구 · 김희찬 · 천길정

회전원통(Rolling-cylinder)의 원리를 이용하여, 새로운 형태의 모타 구동형 완전이식형 인공심장을 개발하였다. 본 인공심장은 브러시가 없는 직류 전동기를 구동원으로 포함하는 회전원통에 구형의 밀판(Pusher Plate)을 붙인 구동자(Actuator)와 폴리우레탄으로 만든 혈액주머니인 좌우심실로 이루어졌다. 이와같은 모타구동형 인공심장은 현재 널리 사용되고 있는 공압식에 비해 소형이며, 작동이 부드럽고, 정밀하게 제어가 가능하다는 장점이 있다. 특히 회전원통형의 경우, 같은 모타구동형들 보다도 전체 펌프의 크기 및 중량을 줄일 수 있는 구조적인 장점을 갖고있다. 모의순환실험결과는 대동맥압 120mmHg, 박동수120BPM에서 심박출량 9L/min으로서 동물실험을 실시하기에 충분한 용량의 출력을 얻었다.

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