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완전이식형 인공심장의 좌,우 심박출량 균형의 개선에 관한 연구

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A New Method for Enhancement of Right-Left Pump Output Balance in the Totally Implantable Artificial Heart

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요 약 : 이동형 작동기 방식의 완전이식형 인공심장을 대상으로 부가적인 체적보상실(compliance chamber)이 필요없는 새로운 균형적 심방압 유지방법을 개발하였다. 이동작동기의 비대칭 원주운동을 통하여 좌우심박출의 균형을 유지할 수 있었으며, 두 심실 사이의 공간에 존재하는 공기가 심박출량 차이를 보상하도록 고안되었다. 인공심장 표면의 가변적인 부분은 좌우 심박출량의 균형 보상을 도와주게 된다. 그러나 인공심장 표면의 가변성을 높일 경우, 전체 심박출량의 감소를 유발할 수 있다. 본 논문에서는 두 심실사의 공기량을 조절하여 좌우 심박출량의 균형 및 전체 심박량에 대하여 좋은 조건을 모의 순환 실험을 통하여 결정하였다. 새로운 인공심장은 63kg의 양에 이식하여 3일간 생존하였으며, 생존기간중 평균 심박출량은 4.2l/min 이었으며, 심방압은 15mmHg 이하로 유지되었다.

Abstract : A new balancing method of atrial pressures balancing for the moving actuator total artificial heart(TAH) without an extra compliance chamber was developed. The asymmetric operation of the pendulous moving actuator have made it possible to compensate the left and right pump output difference by utilizing the interventricular air space as an internal compliance chamber in a pump housing. Furthermore, the balancing performance between left and right pump outputs is increased through the improvement of the flexibility of part of the polyurethane housing. However, the increase of the flexibility of the pump housing causes a little loss of the cardiac output due to the reduction of active filling property. In this paper, a good condition between the balance and pump output performance is evaluated by adjusting the air volume in the interventricular space through a series of *in vitro* experiments. This new pump was implanted in a sheep weighing 63kg, and it survived for 3 days and the average cardiac output during postoperative days was about 4.2 L/min with the atrial pressures under 15 mmHg.
Key words : Pump output balance, Moving actuator TAH, Interventricular space, Active filling.

INTRODUCTION

Cardiac output of two ventricles in a totally implantable artificial heart should be controlled to maintain the balanced pump output as well as to provide sufficient pump output according to the physiologic demand[1]. In spite of many years of development and research on the artificial heart for the long-term clinical applications, these problems associated with the pump output balance are not yet clearly solved.

Especially, the imbalance problem is a considerable obsta-

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(a)

(b)

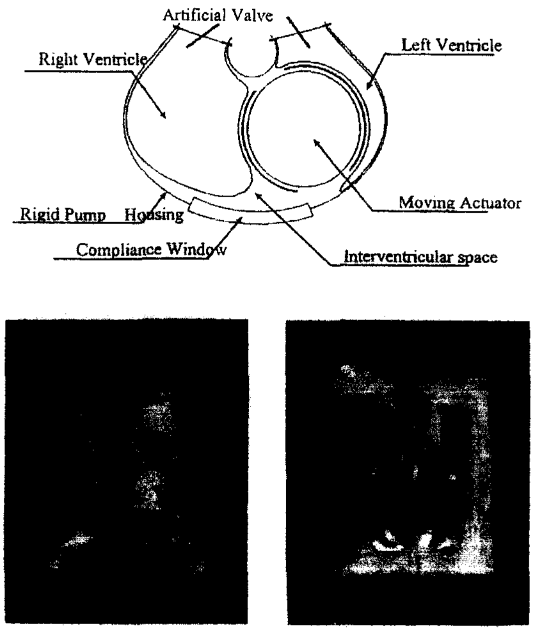


Fig. 1. A schematic diagram (a) and a photograph (b) of the moving actuator type electomechanical TAH

cle in the development of volumetric-coupled implantable electromechanical total artificial heart(TAH). Also, with the consideration of the variation of atmospheric pressures due to climatic or altitude changes, this compliance problem is more complicated[1].

Many attempts to overcome the imbalance problem have been tried. One of the most popular methods is to utilize a separate flexible air-compliance-chamber filled with appropriate volume[2]. Other trials include usage of a leaky valve at the pulmonary arterial site[3], a two phase fluid [4], a compliant fluid chamber around the left atrial cuff to bypass a part of the hydraulic fluid[5], and an inter-atrial shunt[6]. Each methods, however, has both advantages and disadvantages and none has been clearly proven by long-term performance.

To cope with the imbalance situation, we have developed a method for atrial balancing based on the control of the moving actuator without an extra compliance chamber[7]. In the author's laboratory, the larger left stroke volume than the right one was achieved by making left blood sac a little bigger by 10 % than the right one and controlling the left systolic stroke angle of the moving actuator larger than the right[8]. And, in order to compensate the pressure change due to the left-right stroke volume difference, the air enclosed inside a polyurathane pump housing is compressed or expanded. In other words, the interventricular space(IVS) inside the rigid pump housing is utilized for a compliance chamber instead of an external one.

In this paper, a new method for enhancement of the pump output balance performance by making a flexible window in part of the rigid pump housing is proposed and a quantitative analysis of the improved balance performance is also presented. Besides, the suboptimal air volume inside the interventricular space for atrial balance and cardiac output is determined through a series of mock circulatory experiment. We determined, however, the suboptimal condition instead of the optimal amount of air since it is difficult to experimentally find the optimal point between balancing and cardiac output criteria.

Further, this new pump was implanted in a sheep weighing 63kg who survived for 3 days and the average cardiac output during postoperative days was about 4.2 L/min with the atrial pressures under 15 mmHg.

MATERIAL AND METHODS

1. Description of blood pump

The blood pump is composed of the moving actuator as an energy converter, the right and left ventricles, and the interventricular volume space enclosed by a rigid polyurethane housing. Figure 1 shows a schematic diagram of the moving actuator type blood pump. The actuator uses a brushless DC motor (S/M 566-18, Sierracin/ Magnedyne Carlsbad, CA), and pumps out blood with the pendulous motion by an epicyclical gear train[9].

Each ventricle consists of extremely smooth, seam free, segmented polyurethane (Pellethane 2363-80AE; Dow Chemical Co., Midland, MI) double sacs which are contained within the mesh-reinforced polyurethane housing. The maximum static stroke volumes of left and right sac are 50cc and 45cc, respectively.

The interventricular space between the two ventricles and moving actuator acts as a variable volume space. It has an important role to compensate the difference of left and right pump output.

2. Description of active filling mechanism

The interventricular space of the TAH is filled with 100cc of lubrication oil and 50cc of air. Since two ventricles and the moving actuator are enclosed within the rigid pump housing, the two ventricles are volumetrically coupled

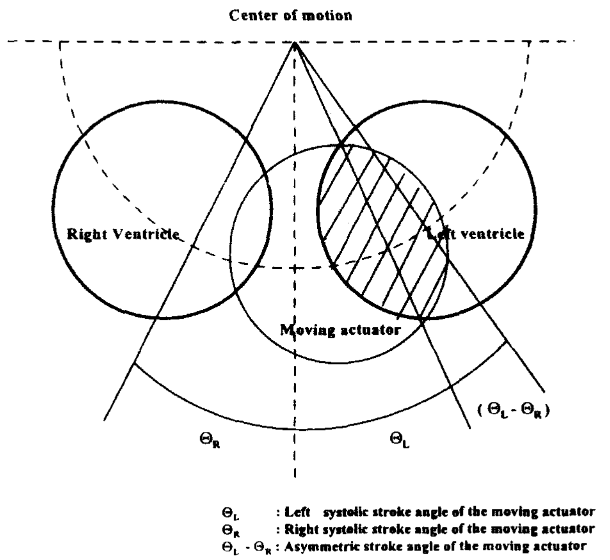


Fig. 2. Description of the asymmetric operation of the moving actuator

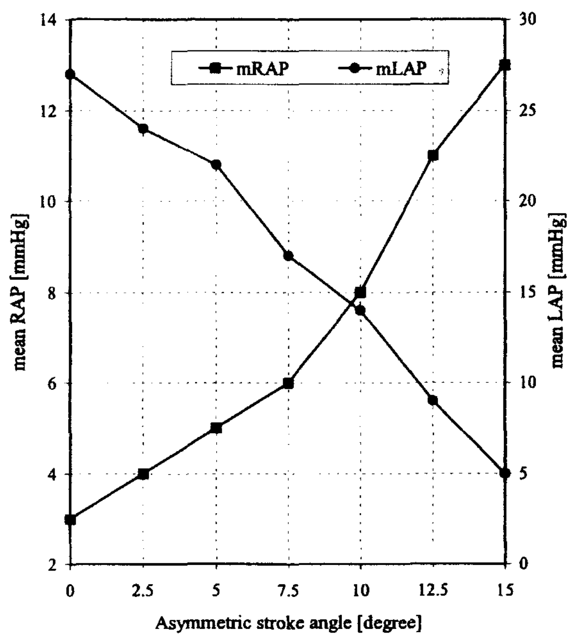


Fig. 3. *In vitro* atrial pressure response to the change of asymmetry control

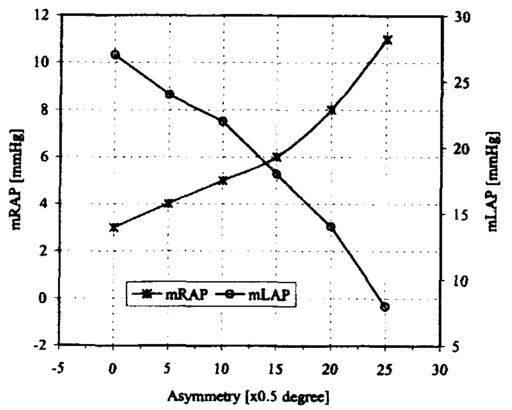
in the moving actuator. In other words, when the moving actuator pumps out blood from one ventricle, the circulating blood fills the other ventricle from the atrial remnant. During each systolic phases, thus, the total volume of the IVS is increased and in the sequel, the pressure in the interventricular space is in the negative range. Therefore, the pendulous motion of the moving actuator generates the negative pressure in the IVS and leads to active filling of blood from the atrium to a certain extent. Therefore, the more rigid is pump housing, the greater is active filling property and vice versa. With an assumption of the sufficient inflow to the TAH, cardiac output is proportional to the active filling performance.

3. Balancing atrial pressures without an extra compliance chamber

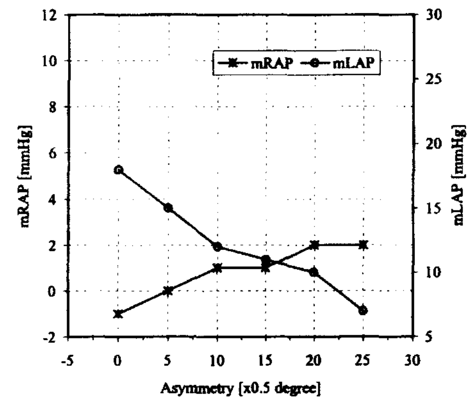
The imbalance situation of the atrial pressures due to the bronchial circulation and valvular regurgitation has to be circumvented by providing larger left pump output than the right one. This larger left stroke volume was achieved by making the left sac larger than the right one and controlling a larger left-side stroke angle defined as *asymmetry* in this paper. Figure 2 depicts a mechanism of the asymmetry stroke angle and Figure 3 shows a controlled left and right atrial pressure, which is reflected by the left and right stroke volume, as the asymmetry stroke angle is adjusted. According to the increase of the asymmetry value, the left stroke volume increases and the left atrial pressure is almost linearly diminished.

In order to compensate the pump output difference, the most commonly used method is a separate compliance chamber that absorbs and releases an appropriate volume of air from and to the extra compliance chamber. However, the extra compliance chamber may be an obstacle to completely implant the total artificial heart system, especially in the small chest cavity of an oriental person. Also, the air leakage through the very thin flexible membranes of the compliance chamber is required to refill every two weeks [10]. The TAH based on the moving actuator mechanism uses an interventricular space as a compliance chamber instead of the extra air bag. In other words, the volume difference of pump output is compensated by expansion and compression of the air inside the rigid pump housing.

In addition, since the performance of compensating the stroke volume difference can be improved by the higher flexibility of the pump housing. We changed, therefore, some part of rigid pump housing to have a flexible window, for the purpose of improving the balance performance without the air leakage. In this case, the air volume inside the pump housing is an important variable to affect the balance performance, that is, the greater is air volume, the better is

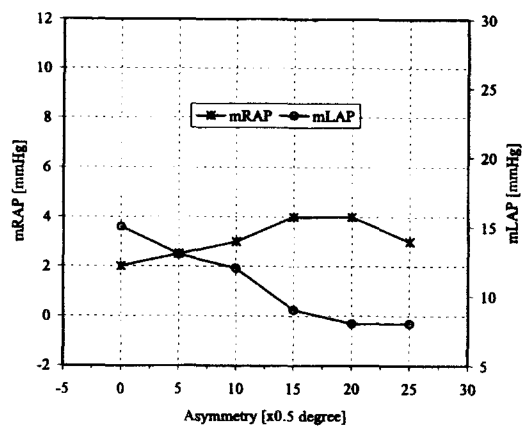


(a)



(b)

mRAP, mLAP : mean right and left atrial pressure respectively



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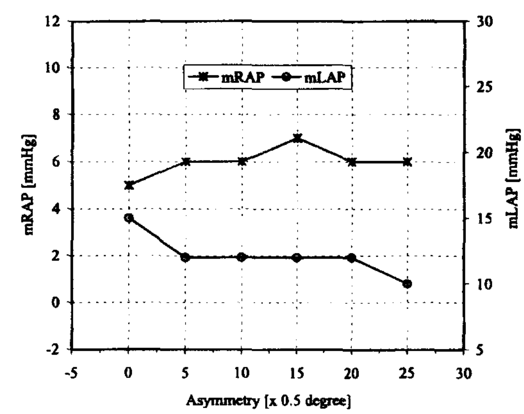

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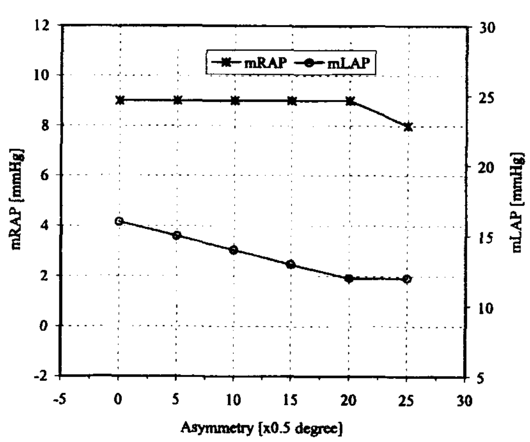

(e)

Fig. 4. Characteristic changes of the atrial balance with various air volumes: additional air volume is (a) 0 ml, (b) 5 ml, (c) 10 ml, (d) 15 ml, and (e) 20 ml.

balance performance. However, this flexible window deteriorates the performance of active filling of the TAH and lessens cardiac output after all. Thus, we have to determine how much air volume is suboptimal in terms of both balance performance and cardiac output criterion. As the air volume determination is not based on the mathematical analysis, the optimality is not guaranteed, but the suboptimality is adopted through an experimental approach. The criterion of the suboptimality is that left atrial pressure must be maintained below 15 mmHg with zero asymmetry and cardiac output loss due to deterioration of active filling performance has to be less than 10 % of the cardiac output.

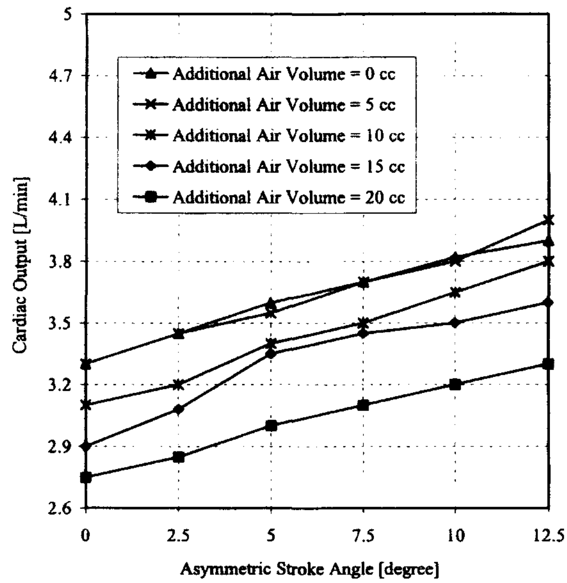

Fig. 5. Cardiac output variation according to the change of air volume in the interventricular apace

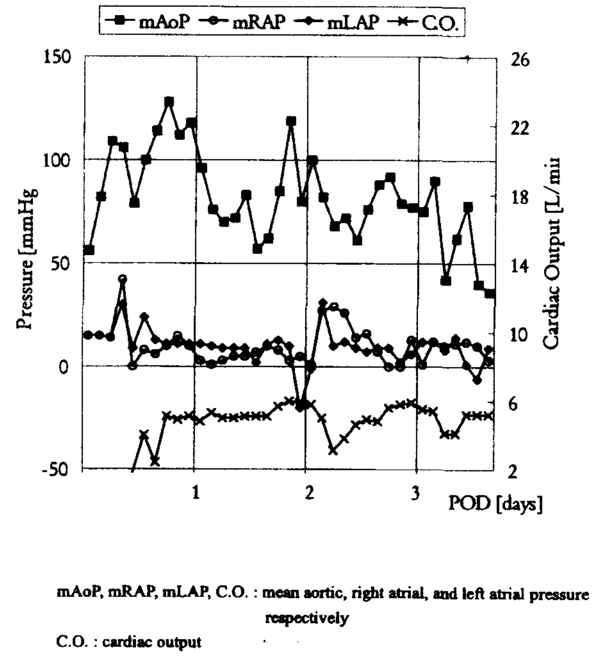

Fig. 6. Hemodynamic changes in animal experiment

4. Mock circulatory system

The suboptimal air volume was determined through a series of in vitro test in a Donovan type mock circulatory system. Fig. 2 shows the schematic diagram of the mock circulatory system with necessary measurement equipments.

In this study, the circulatory fluid is water instead of blood. When the left ventricle of the TAH is contracted by the moving actuator, the circulatory fluid is ejected to the aortic chamber and concurrently, water in the right atrial reservoir connected to the systemic venous chamber is guided into the right ventricle of the TAH and vice versa at the right systolic phase. The compliance of the systemic circulation is manipulated by the adjustment of the air amount in the aortic chamber. Besides, the mean aortic pressure is able to be fixed on an arbitrary value by the adjustment of the systemic resistance using a cock valve between systemic venous and aortic chamber as shown in Fig. 2.

Four chamber pressures corresponding to the mean aortic pressure (mAoP), mean pulmonary arterial pressure (mPAP), mean left (mLAP) and right atrial pressure (mRAP) are monitored by pressure transducers (COBE, USA). And also, both systemic and pulmonary flow rates were measured by a 2-channel ultrasonic flowmeter (TRANSONIC T-201, Transonic systems Inc., USA) as shown in Fig. 2. All the measured signal are displayed and analyzed on a polygraph (Fukuda Denshi MCS-5000, Japan).

In order to simulate a limited volume of atrial reservoir, 150 cc flexible polymer chambers are connected between the inflow ports of the blood pump and the circulatory system. In addition, to simulate a bronchial circulation of a human circulatory system, the left atrial chamber is bypassed through a variable resistance to the aortic chamber.

5. Animal experiment

The new pump with a flexible window was implanted in a female sheep weighing 63kg for three days. After small cervical incision and transsternal bilateral thoracotomy, cardiopulmonary bypass was administered using membrane oxygenator (Univox-IC, Bentley). The circulating blood through superior and inferior vena cava were drained via cannulae placed in the right external jugular vein and the right atrial appendage, respectively. The arterial return cannula was inserted into the right common carotid artery. Almost all of the ventricular myocardium was excised down to the atrioventricular groove and the artificial heart was implanted.

RESULTS AND DISCUSSION

The optimal air volume is determined through a series of mock circulatory experiments. Figure 5 shows the variation of the balance performance of the atrial pressures according to the change of air volume with 100 mmHg of mean aortic pressure and no bronchial flow. In the figures, zero air volume means no added air volume to the initially set volume of 50 cc in the IVS. In the figure, it is represented that mean LAP without asymmetry control is decreased according to the increase of additional air volume. Comparing to the case without additional air volume, the pump output balancing performance of the blood pump improved through the addition of air volume by 10 ml to the IVS. However, when the asymmetry has a maximum value, the mean LAPs have have similar value without any additional volume chanber. In other words, it is a weak point that the sensitivity of the asymmetry control decreases to the increase of the additional air volume.

On the other hand, cardiac output responses to the asymmetry with respect to the change of air volume is represented in Figure 6. Cardiac output decreases little by little because of the loss of active filling performance according as the air volume is added. The loss of cardiac output is about 0.6 L/min by the change of air volume from zero to 20 cc. And the similar result occurred in the case with 0.5 L/min of bronchial flow. Such as the respect of the balance performance, cardiac output without asymmetry starts to down under about 3 L/min as the added air volume goes over 10 cc. Consequently, we determined 10 cc of air volume as the optimal value not only for the good balance performance but also for the guaranteed cardiac output.

We achieved three-day survival in a sheep weighing 63 kg with the new flexible window type TAH. Figure 6 shows a fluctuation of hemodynamic variables during postoperative days. At the first postoperative day, the sheep was successfully extubated. After extubation, the sheep walked around in a cage and fed herself. Several laboratory examinations and hemodynamic monitoring were executed during the postoperative days. Pulmonary disfunction was gradually developed, which was accompanied by oliguria. During the whole postoperative days, cardiac output was about 4.2 L/min and the left and right atrial pressure were maintained under 15 mmHg with well balanced conditions through the successful compensation of the new flexible window instead of using an extra compliance chamber.

CONCLUSION

A new atrial pressures balancing method for moving actuator total artificial heart(TAH) was developed without an extra compliance chamber. The pump output balance performance of the TAH has increased through the improvement of the flexibility of some part of the rigid polyurathane housing. The cardiac output of the new flexible window type TAH, however, is also varied according to the change of air volume inside the flexible window. In this paper, a suboptimal tradeoff between the atrial balance and cardiac output performance was proposed by adjusting the air volume in the interventricular space in *in vitro* experiment. The *in vivo* performance of the new pump with a flexible window was assessed through an animal experiment during three day. The average cardiac output during postoperative days was about 4.2 L/min with the atrial pressures under 15 mmHg.

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