Original

Development of a Totally Implantable Artificial Heart

Saitama Medical School Type Total Artificial Heart: STAH

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A prototype of Saitama Medical School type Total Artificial Heart (STAH) was newly developed. STAH designing is to be installed totally inside the mediastinal cavity replacing the natural heart. Because of the sophisticated shape of the blood pump based on an anatomical view, as well as separation of the blood pump from the actuator, the whole system is resulted in good feasibility for anatomical fitting. The principle of drive mechanism is that two pusher plates eject the blood in the left and the right chambers of the blood pump alternately, by driving a simple cam with an electromechanical actuator. This prototype has proven to eject 4.6 L/min on a mock circulatory system. Although further efforts will be necessary for a practical application, the STAH pump may have a possibility to be one of the most promising devices as a total artificial heart.

Keywords: total artificial heart, electromechanical pump, cam system
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Introduction

Although heart-transplantation procedure is accepted as a common treatment of profound heart failure, lack of the donor heart has appeared to be one of major problems as well as immune-suppression therapy. Under this situation, an artificial heart, which is able to replace total pump function of the natural heart, is the only one practical answer at present for solving donor-shortage [1)]. Already some artificial hearts have been applied to the patients with profound heart failure and resulted in some successful results from the '60s, but are not still capable for common therapy [2-4)]. Even now, in spite of many trials [5-15)], none of the artificial heart has yet achieved any practical success to give a healthy life to the patient.

We have been researching mechanical circulatory system as well as investigating a totally implantable artificial heart according to the Saitama Medical School Artificial Heart Project for these twenty years. As one of the results of the project, a prototype of the Saitama Medical School type total artificial heart has been developed, currently named STAH, has a unique mechanism that allows good capacity for anatomical fitting and easy manufacturing. This paper describes STAH in its details, and discusses future possibility for clinical application.

1. Materials and Methods

1.1 Total concept of designing

A whole system is divided into two major parts, the blood pump, and the driving unit. A blood pump part is consisted of a pump housing, a pair of diaphragm with pusher-plate, and a cam. Two spaces made by pump housing and each diaphragm are called left and right blood chambers working as the left and right pump reservoir, respectively. Inside the blood pump a cam system is incorporated between the pusher plates. One way rotational motion supplied from the driving unit is converted to linear action by the cam, giving alternate movement to the two diaphragms attached to the left and the right blood chamber cavities, respectively. Thus the blood is pushed out from the each blood chambers alternately. The pump housing, that means outer cell structure of the blood pump, is designed to simulate the natural heart shape being suitable for the

residual pericardial cavity with minimizing unpleased compression against the organ structures aside.

A driving unit consists of a connector, a connecting wire, a coupler, an actuator and controller and power supply. To allow easy implantation and good stability in the humane body, the connecting wire is made flexible by introducing a connector, flexible wire, and coupler. All of the components are to be installed inside the humane body. But since a leading aim of the STAH prototype is to prove the primary practicality of the system only, designing of the driving unit receives no restrictions for the anatomical and physiological fitting to the natural body. So a controller is able only to regulate the rotation ratio of the actuator and is located outside of the actuator. Electrical power is supplied from conventional AC power. In the final stage the source of power will be controlled by DC only. A whole system configuration is illustrated in Fig. 1.

1.2. Principle of displacement of the diaphragm

The rotating cam is placed center of the left and the right blood chambers, being sandwiched between the diaphragms of each chambers. When the cam starts to rotate from zero degree at the top of the hypothetical circle, the cam top starts to push one diaphragm surface gradually according to displacement of the cam head. The initial quarter rotation gives one systolic motion as of a natural heart. The next quarter rotation of the cam relief the pushing power against the diaphragm, that means diastolic phase of the blood chamber. Thus a half rotation of the cam gives one single systolic and diastolic cycle for the one blood chamber. Subsequently the cam starts to push the other diaphragm. Finally one cycle of cam rotation results in alternate linear motion of two diaphragms.

Fig. 2 shows schematic drawing to explain cam and diaphragm relationship at various rotation angles in one chamber. Thus the left and the right blood chambers are driven alternately. The alternate motion gives the filling time for one blood chamber as diastolic phase when the other ejects blood as systolic phase at the same time. The pusher-plates made from the aluminum metal attached to each diaphragm are introduced to accept the cam motion and to transfer the power against the soft diaphragms with stable condition.

1.3. Blood chamber

The blood chamber is designed small enough for easy installation in the pericardial space of the human body simulating the natural heart as possible. The width of the whole body is 76 mm, the height from the left atrial port end to top of the body is 95 mm, and the interval of each atrial port is 48 mm in center as described in Fig. 3. The pump housing of the left and right blood chambers have different shapes because inlet and outlet port shape are modified as being fitted to anatomical location of the left atrium, the aorta, the right atrium, and the pulmonary artery. Main material used for fabrication of the blood chamber shell is industrial grade silicon (Shinetsu Chemical, Japan). Classical dipping method was employed using the metal mold based on the clay model certified in calf fitting study. The diaphragm was made also from the silicon by dipping method. An aluminum plate was attached to the diaphragm in a series of fabrication of the diaphragm at the same time. The inside of the silicon blood chamber received surface treatment with re-coating of the silicon over the

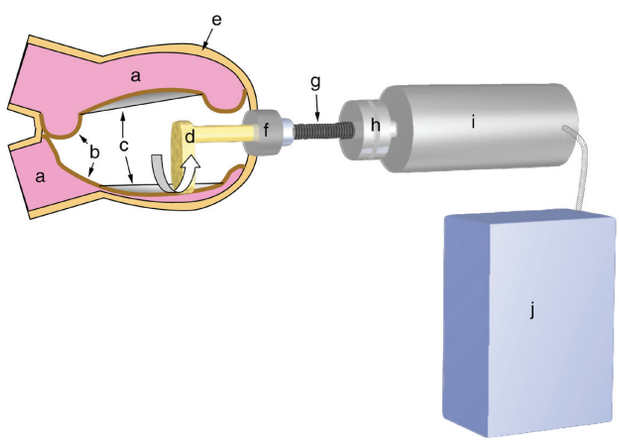

Fig. 1. Basic concept of the STAH system. Each character in the figure. indicate system parts as follows; a: left or right blood chamber, b: left or right diaphragm, c: left or right pusher plate, d: cam, e: pump housing, f: connector, g: connecting wire, h: coupler, I: actuator, j: controller and power supply. A unit of the blood pump is consisted from a to f, and a unit of driving unit is from g to j, respectively. A big blank arrow shows an ideal direction of cam rotation.

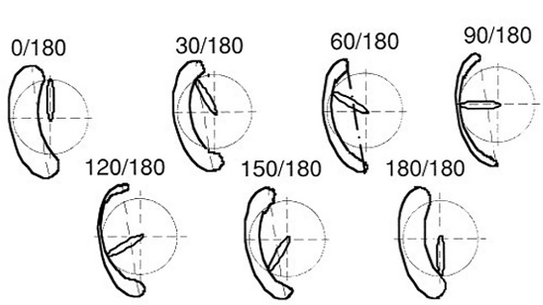

Fig. 2. Schematic drawing of relationship between the cam and pump diaphragm at each angle of the cam. Angles are shown by each degree per 180 degrees.

initial silicon layer, when the diaphragm was assembled to the chamber. This process gives seamless inner surface of the blood chamber.

Four mechanical artificial valves (Medtronic Hall valve, 25 mm in diameter, Medtronic, U.S.A.) were installed to the inlet and outlet of each blood chamber, respectively. The capacity of the left and the right chamber volume in static condition were 60 and 55 ml, respectively.

1.4. Cam

A cam is an assembled unit consisted of eight bearings and metal plate. Four pairs of the bearing were attached to the one side of metal plate (shown in Fig. 4), which is shaved to produce an adequate linear motion to the diaphragm of the blood pump. When the plate rotates, four pairs of bearings push the pusher plate in succession. The cam was fixed into a supporting frame made from epoxy-resin.

A supporting frame works not only to fix the cam but also to couple the left and right blood chambers at angle of twenty degrees. Angled placement of the left and right blood chambers allows shortening of the length between the left and right atrial port enough for optimal anatomical fitting. At the center of the bottom of the frame, the connector was implanted for insertion of connecting wire.

Fig. 4 shows assembled cam into supporting frame, which was ready to be sandwiched by the left and the right blood chambers.

1.5. Connecting wire, coupler, actuator, controller and power supply

The connecting wire and coupler work as delivery of the rotational power from the actuator to the cam. A connector was screwed in to an Oldham coupler by the flexible connecting wire (6 mm in diameter), and was tunneled through a flexible tube made of aluminum.

An actuator was consisted of commercially available planetary gear and coreless DC servomotor, and taco generator (TORMAX TC-3264XXG 17W, 24V, Chibaprecision Co., Ltd, Japan). These parts were assembled lineally and placed into cylindrical acrylic acid resin case as described in Fig. 5. Rotation was controlled by a controller and power supply, which was consisted of current control board and AC-DC converter. Electrical power was supplied from conventional AC 100V electric power source. The driving unit allowed revolution change up to 150 rpm by changing current under unloaded condition.

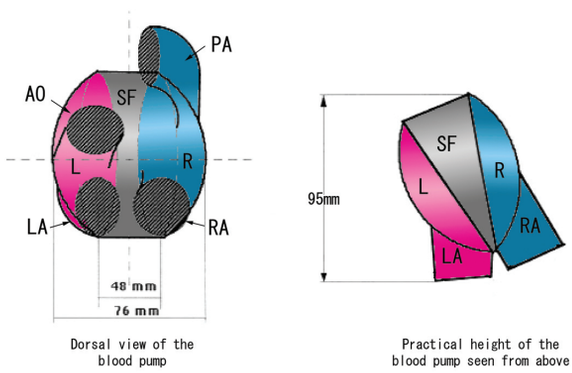

Fig. 3. Ideal measurement made on a design specification of the blood pump is shown. Practical margin of error is not considered which may appears in a course of fabrication. Characters in the figure indicate each pump sites as follows: AO: aortic port, LA: left atrial port, PA: pulmonary arterial port, RA: right atrial port, L: left blood chamber housing, R: right blood chamber housing, SF: supporting frame.

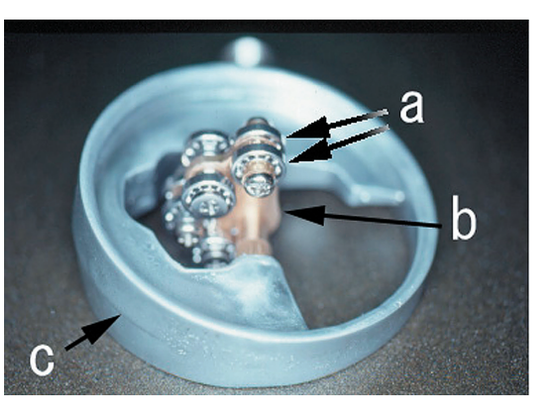

Fig. 4. A supporting frame and the assembled cam are shown in ready-to-go condition. Character “a” indicates bearings assembled into cam plate (b). Character “c” indicates supporting frame.

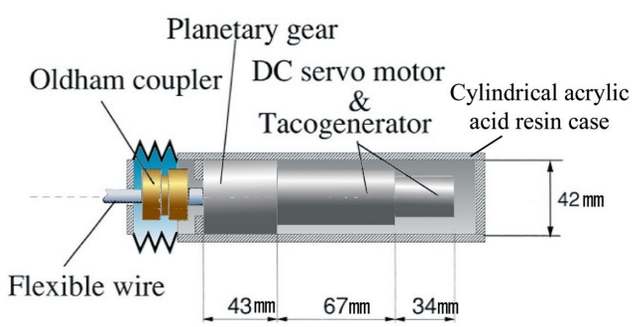

Fig. 5. Mechanical configuration of the actuator. Planetary gear, DC servomotor, and taco generator are coupled in production process. Each height is 43, 67, and 34mm, respectively as shown in the figure. Planetary gear brings maximum diameter by 42mm. These units are installed into a cylindrical acrylic acid resin case with 2mm thickness.

Another type of DC servomotor (100W, 24V. TOYU TECHNICA Co., Ltd, Japan) was also prepared for back up. This motor provided stronger power to the system. This servomotor was consequentially employed because of power shortage.

1.6. Assembly of the whole system

The left and the right blood chamber were assembled with the supporting frame that incorporated the cam. For easy understanding of outer shape of pump housing, the artificial grafts were attached to the aortic and the pulmonary arterial ports, the suturing cuff, temporarily made from polyether-polyurethane, to the left and the right atrial ports, respectively, as shown in Fig. 6. For in-vitro study, solid tubes were inserted to the inlets and outlets instead of grafts and cuffs.

The blood pump, connecting wire and driving unit are finally assembled into one system as shown in Fig. 7.

1.7. Anatomical fitting study of the blood pump

To examine anatomical fit in the chest cavity, chest cavity model supplied by Uyama et al., National Cardiovascular Center Research Institute, Japan,[16] was employed.

1.8. In-vitro evaluation

A simple over flow type mock circuit was employed to evaluate in-vitro pump function. As a simulation of the physiological systemic circulation against the left side of the blood pump, the mock circuit supplies variable afterload by changing height of the water level with 20 mmHg of fixed preload. As a simulation of the pulmonary circulation for the right side of the pump, 40 mmHg as afterload and 20 mmHg as preload were fixed in the mock circuit, respectively. The circuit was filled up with tap water enough to supply the scheduled condition.

Using the mock circuit, pump flow, arterial pressure, and motor current were constantly monitored. Since pump rate was controlled manually, accurate pump rate was calculated manually on the recorded paper after termination of the study.

Evaluation of the system was performed in two steps. The first step was performed to evaluate the primary whole system performance. Based on the primary result, the second step evaluation was done to find out pure blood pump performance using larger 100W DC-servomotor because the motor employed in the first step study was evaluated not enough to prove the actual performance of the blood pump.

2. Result

2.1. Potency for anatomical suitability

The blood pump was easily installed into the pericardial space of the human chest cavity model. No unnatural folding of the left and right outlet conduits or mechanical pressure coming out from the blood pump body were observed toward the chest wall or the vertebral bones as seen in Fig. 8.

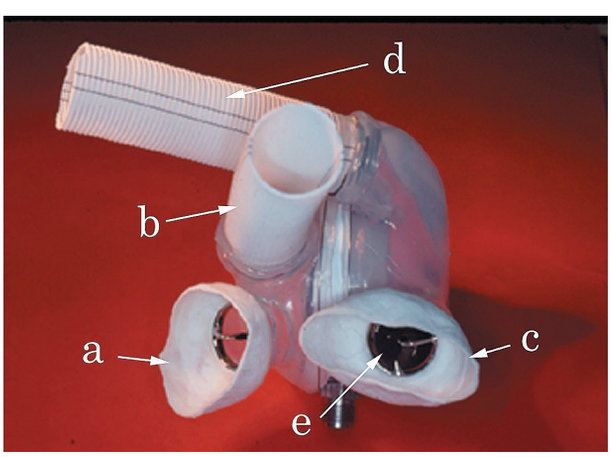

Fig. 6. Photograph of backside view of the assembled blood pump. Dacron grafts are attached to the aortic port (b) and the pulmonary arterial port (d) for easy understanding. A pair of atrial cuff is coupled to the left (a) and right atrial port (c). Four mechanical valves are also installed into left atrial port, aortic port, right atrial port, and pulmonary arterial port, respectively. Character “e” indicates the mechanical valve assembled to the right atrial port as an example. Locations of the right atrium, the left atrium, the aorta, and the pulmonary artery are similar to the natural hear as initially designed.

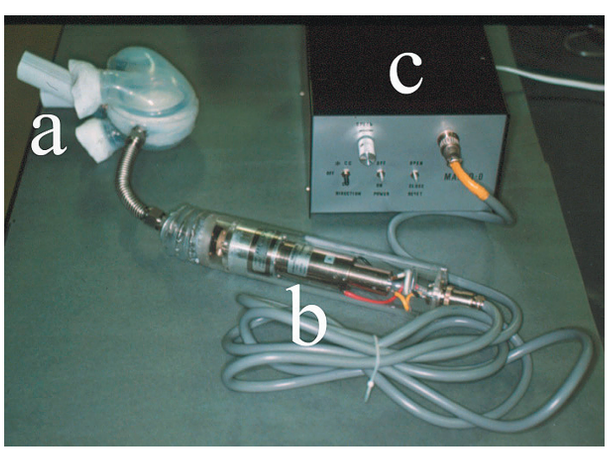

Fig. 7. A whole view of the assembled system. Character “a”, ”b”, ”c” indicate blood pump, actuator, and controller and power supply, respectively. The blood pump is coupled with actuator with connecting wire and connector. The actuator is also hooked up to the controller and power supply via a shield line.

2.2. Pump performance

In the first evaluation aiming to evaluate initial performance of the whole system, strong twist of the connecting wire beyond expectation was observed under condition at afterload of over 100 mmHg. So the system was evaluated incapable to endure over 100 mmHg of the afterload. Because of unpredicted weakness of the connecting system, the afterload was fixed at 80 mmHg for further evaluation including the second step. The maximum output of the left blood pump was 4.3 L/min under the condition of 20 mmHg of the preload and 70 mmHg of the afterload, and systemic efficiency was two percent.

The second step of evaluation using larger servomotor showed that the blood pump had enough potential performance for practical use. The left output increased gradually as the pump rate raised. The maximum output was 4.9 L/min at 95 RPM. Stroke volume was kept constant by 50ml(Fig. 9). The right output varied from4.3 L/min to 7.4 L/min, and its behavior was unstable. The stroke volume of the right output was not depending on pumping cycle and remained unstable (Fig. 10).

The flow pattern of the left output showed flutter in the systolic phase. The flow trace was consisted of four small waves, which were considered being derived from four pairs of bearings. The right output showed smooth waveform like the natural heart output. Major regurgitation observed in the right waveform was supposed to be mainly produced by malfunction of the artificial valve (Fig. 11).

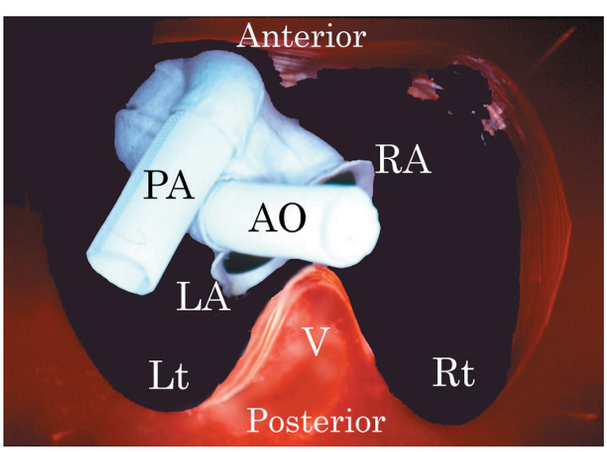

Fig. 8. The blood pump installed in the chest cavity model. AO: aortic port, LA: left atrial port, PA: pulmonary arterial port, RA: right atrial port, Lt: left chest cavity, Rt: right chest cavity, Anterior: Ventral side of the humane body, Posterior: Dorsal side of the humane body, V: Vertebra.

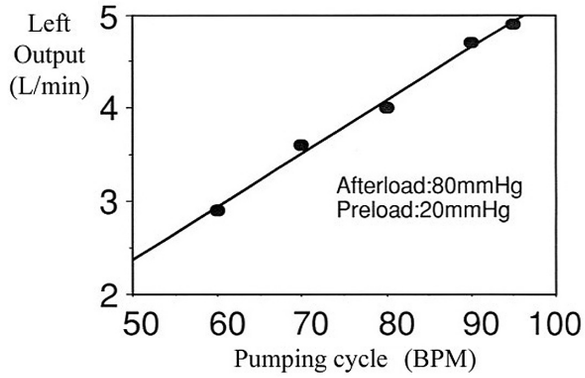

Fig. 9. Performance of the left pump in the second step of the study using DC actuator (100W, 24V). Stroke volume is 52 ml. Calculated diaphragm displacement is 12mm.

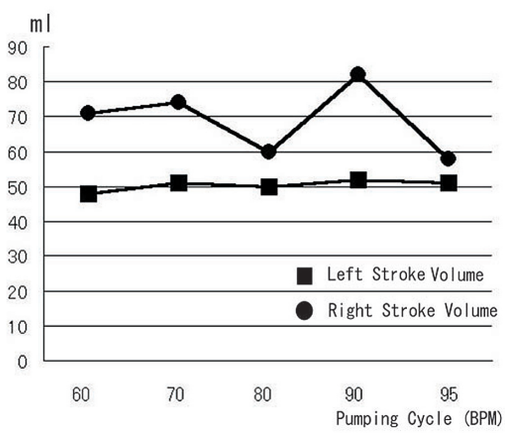

Fig. 10. The changes of the left and the right stroke volumes by various pumping cycles in the second step of the study are drafted. While the left heart stroke volume (shown by closed square) remains stable, the right heart stroke volume (shown by closed circle) varies unstable.

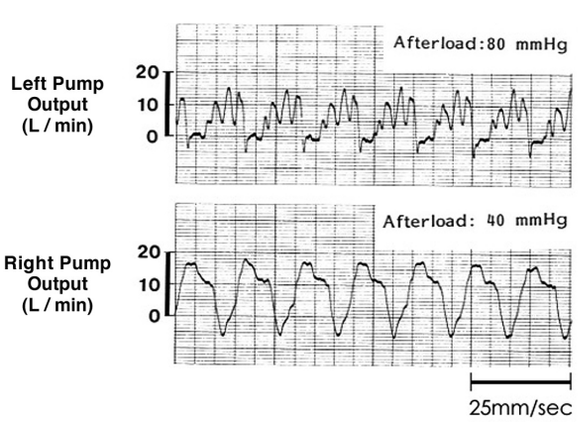

Fig. 11. Traces of the left and right flow. Systolic duration per cycle is calculated 68% during the measurement. Flutter phenomena is seen in the left output.

3. Discussion

3.1. Generic requirements for TAH design and STAH

Since Akutsu et al. reported the first successful experimental implantation of a total artificial heart (TAH) in 1958[1], various types of TAH have been developed. Only Liotta, Akutsu and Jarvik among the researchers made success in clinical application of their air driven devices[2-4]. Especially Jarvik's prosthesis has been widely accepted as the Cardiowest pump as a bridge to transplantation still now[10]. But all these products require a big air-supply console outside of the human body. For further benefit to the patient, various trials have been made to implant whole system including the blood pump, driving unit, and battery system inside the human body[5-10]. Instead of long history of development, space availability of the human body has not allowed all these trials in successful application. Recently only the AbiCor pump has become successful to put all parts into a humane body in the experimental clinical trial[11].

The difficulty of designing artificial heart surely exists in space limitation of the human body. Compared to the natural heart that blood chamber wall which acts as a power unit as well as blood holding cell at the same time, the artificial heart must have two independent parts; the blood chamber and driving unit. It has been and still is hard to implant these two parts into humane pericardial space as one unit. In this study we solved this problem by departing the blood pump and driving unit. To introduce this concept, designing of the blood pump becomes easier and more flexible for anatomical fitting.

Thrombus formation caused by activation of blood coagulation is another big problem for artificial heart as well as the anatomical property. But material and surface treatment to reduce thrombus formation in this study are considered little because fundamental mechanical property must be first object to be solved. This problem remains as a future settlement in the next stage of development.

3.2. Anatomical suitability of the STAH

Various studies have been done to estimate practical humane pericardial cavity in order to make a design of the artificial heart using magnetic resonance imaging or direct measurement of the human body performed in the consecutive orthotopic cardiac recipients[17-20]. According these results, the permissible space prepared for the artificial heart may stays in 10 cm sphere. The blood pump size of the STAH completely fulfilled this condition of the pericardial cavity. Practical trial using Uyama's chest cavity model based on the magnetic resonance imaging proved suitability of the pump.

In this study we introduced a method to separate the artificial heart to the blood pump unit and the driving unit. This unique technique is also employed by the National Cardiovascular Center group[9]. The pump is driven by hydrodynamic actuator located in the abdominal cavity, and requires fairly big two conduits to flow the silicon oil tunneled through the diaphragm. Compared to their pump, the STAH is smaller in pump size and has a single thin cable against their two big oil conduits.

From the surgical point of view, distance between the left and right inlet is also an important factor. The previous total artificial hearts had wide distance between the left and right atrial port derived from mechanical construction. If it is possible to reduce the distance, implantation of the blood pump becomes easier. A unique design employed to the STAH that the two blood chambers are not placed in a parallel alignment, made possible to shorten the width between the left and right port. The design that is the first and only one technique ever used, except Helmholtz Total Artificial Heart[15] appeared after the first presentation of the STAH in American Society of Artificial Internal Organs meeting in 1992.

Thus design of the STAH was proved to overcome some of the problems in anatomical suitability.

3.3. In vivo study

In vivo study also proved potency of the STAH in practical performance. Due to energy loss, that means low mechanical efficiency, the small power unit used in the first step of evaluation could not ideally drive the system. The reason of low efficiency was apparently attributed to unsophisticated manufacture of the cam. But generic cam mechanism itself is already established in engineering field. It is surely not difficult to improve efficiency of the cam system adopted in the STAH.

According to Suga et al.[21], requirement of the work to the natural heart to drive the systemic blood is said one to 10 W. So if system efficiency is improved up to 10%, a conventional and commercially available DC servomotor just like employed in the STAH becomes a promising candidate for the system without major mechanical modification.

In the experiment the reason why the right output was unstable and went over the expected volume by up to 50% is unclear, while the left output remained within

calculated range. One fact that outer shell of the blood pump was fabricated fairly soft and had some expansion characteristics, might affect practical stroke of the right blood chamber. Another suspected reason may be instability of the diaphragm motion under low afterload condition. Since the soft silicon membrane suspends the diaphragm, the diaphragm must have swayed around the counter area of the cam tip. But these possibilities do not look fatal because the system itself is simple and easy enough for accepting further reinforcement of the chamber shell and improvement of manufacturing process.

The flutter seen in the left flow may not be a fatal problem in a physiological point of view, because, as far as the output is maintained, the flow is going smoothen by compliance of the vessels. But of course this turbulence must be eliminated from engineering point, and it is easy when the cam system is improved. In the next stage of development the bearings will be taken out from the system by smoothing the cam and plate surface.

Regurgitation observed at the right pump flow was considered mainly due to the mechanical artificial valve employed in the prototype. The slight backflow is generally seen when the mechanical artificial valve is closed. As far as total performance is maintained, small back flow is not a major problem. If there exists some need to solve this problem, best answer is to adopt the biomechanical valve. But the high height of the biomechanical valve has refused to be incorporated into the total artificial heart ever.

Confined air inside the pump might affect stability of the pump efficiency. The inside space of the STAH is airtight and not opened to the air. When the one side of the diaphragm moves, the air is expanded and the negative pressure is produced. The negative force pulls the other diaphragm and consequently sucks the blood into the blood chamber. Generally the air compliance chamber is adopted as another unit to stabilize the performance of a mechanical pump like Honda et al. reported[8]. Compared to their pump that has less loose cavity for the air because of mechanically tight design, the STAH has fairly big space for cam rotation. Thus the STAH resulted in elimination of the air-compliance chamber.

3.4. Expected improvements in future

We are planning to establish the next generation of the device. Improvement of the cam system must be the first target to raise system efficiency up. Some material, which has enough durability of fatigue strength, friction strength, and hard deformity, will be employed for cam plate and metal diaphragm plate. Bearings must be eliminated in order to give smooth motion of the diaphragm as well as to reduce structural friction. A metal plate-spring like moving arms will be applied to suspend the diaphragm plate to give steady motion and to eliminate flutter of the plate. For these trials, no new research is required because all of them have been already put into the practically industrial use.

For the practical model, battery and transcutaneous power transmitting system will be also incorporated into the system. To accomplish the development, cooperative work with the other fields of engineering is necessary. The final plan of the STAH-1 is illustrated in Fig. 12, which includes these attachment devices.

Biological adaptation will rise up as another factor to control the system. Looking back the past experiences, a role of the total/partial artificial heart is just to push out the blood without positive biological neural feedback, only depending on volume of the venous return. The reason why such simple mechanism is acceptable in the actual situation is that, as far as minimum requirement of the systemic flow is maintained, the peripheral resistance changes

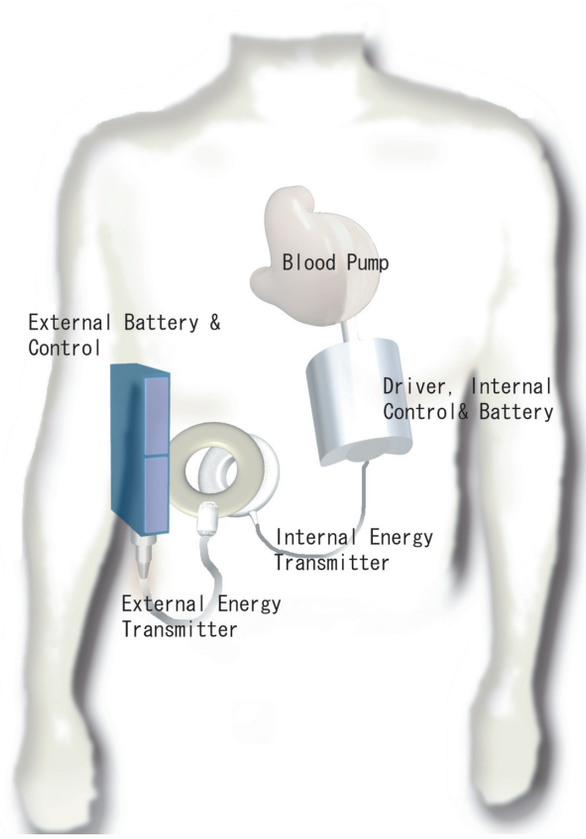

Fig. 12. Outline of the final system of the STAH.

automatically in order to supply optimum organ flow according to oxygen demand. If control of the pumping rate of the artificial heart becomes possible according to natural demand, the artificial heart will give further expansion of the social life activity to the patient. In the process of further improvement of the system, some method to detect natural feedback of the body must be introduced such as continuous measuring of mixed venous saturation[22, 23].

5. Conclusion

A prototype of the artificial heart(STAH) was developed aiming to be installed totally inside the human body. A simple cam system, and separation of the device into blood chamber and driving unit made the blood pump placed easily inside the natural pericardial cavity. Although further improvements must be required in the future, the STAH is a potential device for clinical applicatio

Acknowledgement

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埼玉医大方式完全埋め込み型人工心臓の開発

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埼玉医大方式完全植え込み型人工心臓（以下 STAH）の開発を目指し，その基礎モデルの開発と実効性を評価した．STAH は縦隔内に植え込まれる血液ポンプ部と腹腔内へ置かれる駆動部の 2 つによって構成される．血液ポンプ部は植え込みが容易な形状を持つプッシャープレートタイプであり，MRI データを基に再現された胸郭モデルでは良好な解剖学的適合性を示した．駆動は血液ポンプ部内に組み込まれたカムを外部の駆動部により柔軟性を持った駆動ワイヤーを介して行う．模擬循環回路では最大 4.6 L/min の流量を出す事が可能であった．実際の応用までには改善が必要であるが，本研究に置ける基礎モデルはこの STAH が充分に実用化に耐え得る考想であることを証明したと考える．

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