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Artificial Heart Control

엄경식* · 안재목** · 조영호*** · 박용님*** · 조한상****
김욱은* · 김원곤***** · 노준량***** · 원태희****** · 김희찬*** · 민병구***

*서울대학교 공과대학 의용생체공학 협동과정
**한림대학교 정보전자공과대학 전자공학부 의용생체 신자공학,
서울대학교 의과대학 의공학교실, *(주)바이오메드랩,
*****서울대학교 의과대학 흉부외과학교실, ******이화여자대학교 의과대학 흉부외과학교실
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K.S. Om*, J.M. Ahn**, Y.H. Jo***, Y.N. Park***, W.E. Kim*, H.S. Cho****,
W.G. Kim*****, J.R. Roh*****, T.H. Won******, H.C. Kim***, and B.G. Min***

*Dept. of Biomedical Engineering, College of Engineering, Seoul National University
**Dept. of Electronics Engineering - Biomedical Electronics,
College of Information and Electronics Engineering, Hanlym University
***Dept. of Biomedical Engineering, College of Medicine, Seoul National University
****Biomedlab Co.
*****Dept. of Thoracic and Cardiovascular Surgery, College of Medicine, Seoul National University
******Dept. of Thoracic and Cardiovascular Surgery, College of Medicine, Ewha Women's University
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요 약 : 심장은 생명의 가장 중요한 장기 중 하나이며, 이 중요성은 인공 심장의 연구를 불러일으켰다. 본고에서는 전세계적으로 연구되는 인공 심장 제어의 방법론, 추세, 그리고 현 상황을 비교 분석하였다. 인공 심장 개발에 있어서 중요한 연구 분야 중 하나인 인공 심장 제어는 자연 심장의 역할을 최대한 모방하여야 하는데 현실적으로 각종 생리적 제어 인자를 얻기에는 센서 기술의 한계가 있다. 따라서 인공 심장을 위한 많은 입력 제어 변수가 연구되었으나 단지 몇가지만 실제로 적용되는 상태이다. 본고에서는 왜 다른 요인들이 제외되었으며 무엇이 현재 제어 방식의 선택 기준으로 고려되었는지를 설명한다. 이것을 설명하기 위하여 인공 심장의 제어에 앞서서 자연 심장의 제어를 쉽게 설명하였고, 5개의 대표적인 인공 심장 제어 연구 조직을 선정하여 소개와 정리를 하였다.

Abstract Heart is one of most important vital organs, and this inspire the research of artificial heart. This paper describes, compared, and analyzed the methodologies, trends and current status of the artificial heart control researches which are studied over the world. Artificial heart control which is one of most important research area in the development of artificial heart system must imitate the role of native heart. For this various physiological control parameters have the hindrance of practical application in the perspective of sensor's reliability. So, there have been many candidates as input control parameters for the artificial heart, but only a few have remained. This paper explains why other candidates have been abandoned and what are considered for the selection of present control mechanisms. For this, the mechanism of the native heart control

통신저자 : 민병구, (110-744) 서울시 종로구 연건동 28번지
서울대학교의공학과
Tel. (02)760-2509, 3128 Fax. (02)745-7870

is slightly stated before artificial heart control, and five representative artificial heart control research groups were introduced and summarized.

Key words : Heart control, Artificial heart, TAH

INTRODUCTION

The control mechanism of native heart is well stated in numerous popular physiology books [1][2]. And there are a lot of articles which have related with the control of native and artificial heart. But most of them have focused only a few points and the control mechanisms depend heavily on their own systems. This article focuses on the control of totally implantable artificial heart (TAH) with various points and the differences and similarities of the each control mechanisms. Also the present trends and current status of the artificial heart control researches which are studied over the world were stated.

The purpose of the TAH control can be said to imitate the native heart control. So it is important to know the mechanism of the native heart control. For the native heart control, the mechanisms were well studied and known even if there are some issues on debate. It is generally accepted that there are two mechanisms which occupy the activity of native heart. One is known as the Frank-Starling mechanism which belongs to the intrinsic regulation, and the other is the extrinsic regulation, i.e., the native heart is controlled by the humoral and neural mechanisms. Clearly, the natural heart balances left and right flows mainly through the Frank Starling mechanism. To respond fully to changes in metabolic demand, however, particularly during exercise, the natural heart requires guidance from central command and other neutrally-mediated signals. To respond reasonably, at least some sensitivity to the chemical milieu (hormones and metabolic by products) is needed. It is therefore a lofty goal to attempt to achieve both left right balance and variation in systemic flow in a TAH through sensitivity to atrial pressure alone even if preload (atrium) sensitive and afterload (aorta) insensitive controls are the popular artificial heart control [3]. So, there have been many candidates as input control parameters for the artificial heart, but only a few have remained. This paper represents why other candidates have been abandoned and what are considered for the selection of present control mechanisms. Firstly, native heart control is slightly stated before artificial heart control. After this, five representative artificial heart control research groups are introduced and summarized.

NATIVE HEART CONTROL

The heart serves as a pump because of its ability to contract under an electrical stimulus. When an electrical triggering signal is received the heart will contract, starting in the atria, which undergo a shallow, ripple like contracting motion. A fraction of a second later the ventricles also begin to contract, from the bottom up, in a motion that resembles wringing out a dishrag or sponge. The ventricular contraction is known as systole. The ventricular relaxation is known as diastole The heart in a resting adult pumps approximately three to five liters of blood per minute (3~5 L/min). Figure 1 shows the human circulatory system in simplified form [4].

The heart must adapt its performance to widely varying needs of the body, in order that each organ will receive enough blood to support its metabolic requirements. The limit of adaptation range from the minimum work needs during sleep to the maximum demands while performing heavy exercise. The normal heart adjusts its work output to its load by utilizing any or all of a number of available mechanisms which enable it to augment or diminish its performance level. The heart can increase its work output by increasing the *rate* at which it contracts and by increasing the *force of contraction,* thereby ejecting more blood with each stroke. The force of contraction can be augmented by *humoral and neural mechanisms* which alter the metabolic state of the myocardium (extrinsic regulation) or by *stretching the myocardium to increase its resting length or tension* (intrinsic regulation, Frank-Starling mechanism) [1].

Pressure and flows in the uncontrolled circulation tend to be stabilized by the *Frank-Starling mechanism* which is plotted in Figure 2. (a); this may be shown by the partial recovery of cardiac output after a left ventricular infarction. However, the normal cardiovascular system has a more important stabilization mechanism as a result of *feedback control* acting through the *central nervous system.* This control depends on pressure signals that are converted to efferent nerve signals by the baroreceptors in the carotid arch. These nerve pathways are shown in Figure 2. (b). Studies of the baroreceptor control system have shown that

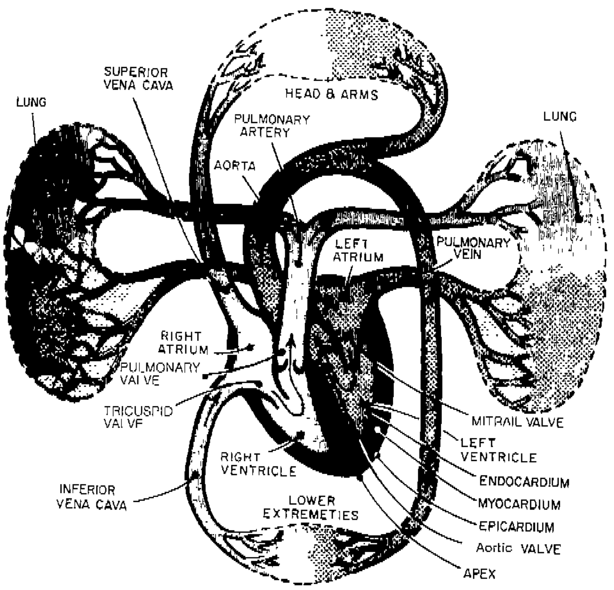


Fig. 1. The human circulatory system. (Hewlet- Packard.)

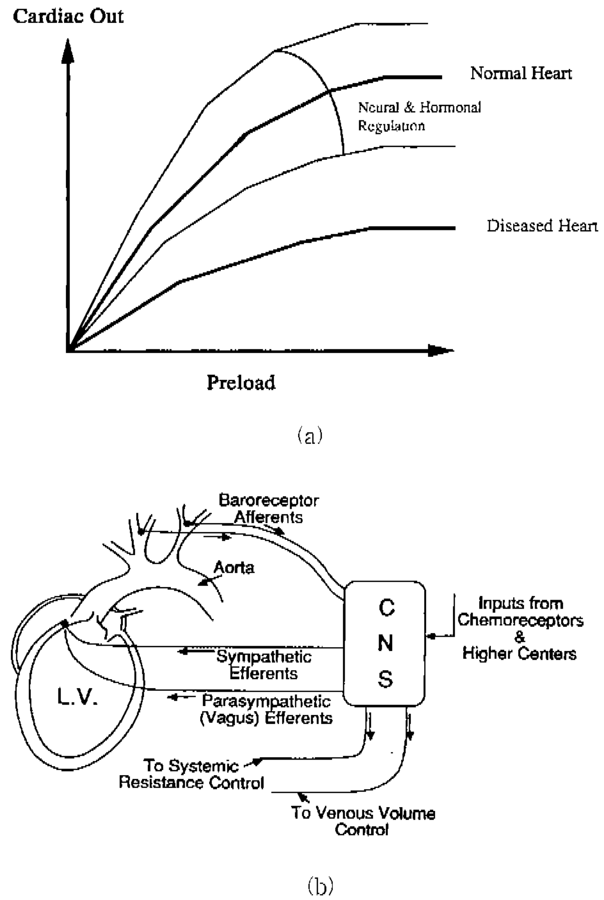


Fig. 2. (a) The curve between the preload and cardiac output, (b) nerve pathways [5].

the signals returned to the heart tend to reduce both heart rate and strength of contraction in response to increased pressure in the carotid arteries and to increase both if there is decreased pressure in the carotids. In addition, other signals lead to an increase in peripheral systemic resistance and decreased venous volume with decreasing carotid pressure, and vice versa. It is interesting to add elementary negative feedback regulation, corresponding to the baro-receptor system, to the cardiovascular system [5].

The efferent innervation of the heart is controlled by both the sympathetic and the parasympathetic systems. *Afferent* fibers accompany the *efferents* of both systems. The *sympathetic fibers* have positive chronotropic (rate-increasing) and positive inotropic (force increasing effects). The *para·sympathetics* have a negative chronotropic effect and may be somewhat negatively inotropic, but the latter effect is, at most, small and is masked, in the intact circulatory system, by the increased filling which occurs when the diastolic filling time is increased [1]. The hormone in the blood can directly control the contraction and extension of the heart. And the hormone vary the cardiac output by adjusting the resistance of vessel [2].

TAH CONTROL

It would be generally agreed that a TAH should be controlled in a noninvasive fashion. Traditionally, the term noninvasive is applied to systems lacking indwelling catheters or transducers [3]. A control algorithm for a TAH should meet the following requirements: 1) simple and reliable; 2) smallest physical package to meet anatomic constraints; and 3) adequate responses to all possible hemodynamic demands [6]. A tradeoff between sensitivity and complexity must be achieved to produce a TAH input control parameters that maintains metabolic homeostasis and an acceptable level of component reliability [7].

There are two elements of Starlings work that are critical to TAH control theory: 1) the vascular resistance to ejection (afterload) must have a negligible effect on CO; and 2) the volume of blood pumped by the heart is the rate of entry of blood in the heart primarily governed by the volume of blood present at end-diastole (preload) [7]. The most important requirements of a TAH system are to provide a physiologic flow rate while maintaining a safe left atrial pressure (LAP) [8].

The automatic control of TAH must ensure sufficient cardiac output (CO), adaptive regulation to the organisms actual need and must save the pulmonary circuit from overhydration (edema) by left/right balance. The choice of control mode depends on the TAH system used and the available control parameters. Full-to empty work without diaphragm standstill and full stroke is favourable with regard to anatomical fit and wash-out [9].

Left and right atrial pressures are the most widely used parameters for the control of TAH function. However, there are limitations in using atrial pressure for assessing card iovascular function. Atrial pressures are influenced by multiple factors and they are not a direct measure of metabolic demand. Furthermore, temporary changes in TAH puming or device position may cause atrial collapse and erroneous atrial pressure measurements. Atrial remnant fibrosis develops in long-term TAH recipients, causing decreased compliance and artificially increased atrial pressures. Renal sympathetic nerve activity [10], aortic nerve activity [11], hemoglobin concentration, oxygen saturation, tissue perfusion, central neurologic signals, neurohumoral input, the electrical output of the atria (P wave), pH, respiration, central venous temperature, and physical activity have all been considered as potential TAH input control parameters but these are not expected to be long-term usage in the perspective of sensor stability, reliability, and durability [7].

Failure to match right and left TAH ventricular flow with their respective vascular flow demands is termed *balance mismatching,* a situation causing venous congestion in the lagging circulation. TAH balance mismatching has plagued nonpneumatic TAH research and clinical performance. It has been established that the net left ventricular CO exceeds the right ventricular CO by approximately 10% or more. Alth ough the explanation remains a subject of debate, it is generally agreed that flow through the bronchial arteries and left sided valvular regurgitation are the primary factors in this flow discrepancy between right and left ventricles [7].

From an engineering perspective, *alternate pumping* is preferable with regard to both design and size consider · ations. Left and right master alternate (LMA, RMA) control modes are version of variable rate control in which one pump serves as the master and the other as the slave. RMA control leads to comparatively lower left sided output, with an associated increase in left atrial pressure (LAP); the resultant pulmonary congestion can cause compromised oxygen transfer and hypoxemia. Although less sensitive to systemic venous return, the LMA control mode effectively protects the lungs from fluid overload [7].

For the alternate pumping mode, a few aspects still remained to be investigated: 1) long term effects of the alternate pumping mode; 2) how to protect the lung circulation against any possible sudden hemodynamic changes; and 3) the possible requirements for built-in stroke volume differences between two ventricles. The in vivo experiments suggest that there were no significant effects of different control modes on the calves survival, daily activity, and/or major organ functions. Hematologic and biochemical data obtained from chronic animal studies suggested that the LMA mode is as effective and safe as the independent (IND) mode. IND mode has the best overall sensitivity to physiologic flow needs, followed by LMA and then RMA. The LAP changes during these exercise tests indicated that the lungs were better protected by the LMA and IND modes than the RMA mode, which tended to elevate the LAP further in the equal stroke volume system. The LMA mode makes the left side sensitive to the pulmonary venous return but the right side relatively insensitive to the systemic venous return. In the RMA mode, on the other hand, the right side is sensitive to systemic venous return, but the left side is insensitive to the LAP. Because of the presence of this flow difference, when the system is run in RMA mode with the left side rate following that of the right, the left pump cannot respond to the increase in LAP. Therefore, to compensate for the flow difference, the right side stroke must be kept lower than that of the left. This is the reason for the inferior performance of the RMA mode shown in the exercise tests and also explains the better performance of the unequal stroke volume system in RMA. In theory, the LMA mode is superior to the RMA mode from the point of view of lung protection. This is clearly shown in this study by the lower LAP elevation with the LMA mode. Theoretically the IND is best, since each side of the TAH produces an optimal flow depending on its own preload and afterload. The flow difference can thus be compensated for automatically. Three points can be considered as the per formance scores of each modes: 1) long-term blood chemistry results; 2) flow sensitivity to demand; and 3) the influence of equal versus unequal stroke volume on various control modes. The following conclusions were drawn from this study: 1) With the LMA mode, TAH recipients can be maintained in a physiologically normal state for long periods. 2) In the progressive exercise tests, TAH recipients demonstrated good flow response, good lung protection, and good exercise tolerance in the LMA mode. 3) The stroke volume difference between left and right pumps of the TAH system may not be necessary in regard to the LMA mode, as long as the right pump is operated at partial stroke. 4) Overall, the LMA mode is the preferable control mode for a alternate pumping TAH system [6][12][13].

The findings in the LMA mode with equal ventricles and in RMA mode with the bigger left ventricle were comparable to the IND mode without problems in left/right matching. One solution is to control with different heart rates (HR), another is to change maximum stroke volume by means of stroke length variation by end-position trigger for pusher plate system. In consideration of a maximum 5% left-to-left shunt and about 10% less efficiency of the left ventricle, maximum designed stroke volume should be right ventricle > 90% left ventricle for LMA and right ventricle < 85% left ventricle for RMA mode. The regurgitation flow for the left ventricle is about 0.9, because of greater regurgitation with Bjork-Shiley mechanical valves. This is in accordance with the experience of other groups [9][14][15][16][17].

A TAH control system that links right and left ventricular performance can address the flow imbalance in several ways: a reduced right ventricular stroke volume with compliance window (Seoul group) [18], a regurgitant mechanical pulmonary valve, or a air volume displacement chamber (VVC, Penn State group). To eliminate the VVC and thus minimize the overall volume of the device to be implantable, the Utah group initially proposed to use leaky valves in the right outflow, but the current approach employs a so-called interatrial shunt (IAS) in the inflow cuffs [19]. Other control schemes attempt to resolve the mismatch, either by allowing independent left and right ventricular pumping modes, or by designing one side as the pacemaker or master for both systems [7].

The belows are the deep illustrations of the control methods of representative TAH research groups all over the world. And each systems have their peculiar structural characteristics.

Penn State University TAH control (U.S.A.)

Figure 3 shows the schematic drawing of the Penn State University TAH system. A control algorithm developed at Penn State University adjusts the pump rate (PR) in response to the changing hemodynamic state of the recipient. All sensing of the hemodynamic state is done through the left pump (LMA), which is readily estimated from motor speed and voltage and which provides information regarding the critical balance between left and right pump outputs. In small steps, the controller decreases right diastolic time until a decreasing left end-diastolic volume (EDV) is observed, indicating that right pump output has fallen and the pulmonary venous pressure is low. The controller than increases right diastolic time until left EDV is restored, and then repeats the cycle. At equilibrium, the right diastolic time permits just enough right pump filling to obtain matched left and right pump flows. Left EDV remains at about 90% of maximum over most of the working control range. As right atrial pressure rises, shorter right diastolic times are required to maintain this balance. The pump rate therefore rises with right atrial pressure (RAP), similar in function to a Starling cardiac output response [8].

As right diastolic time is decreased, left diastolic time can be programmed to decrease as well, yielding an amplified rate response (sensitive Starling response); to remain constant, yielding a modest rate response; or to increase, yielding little or no rate response. The latter mode permits the implementation of an afterload-based cardiac output control in which cardiac output is responsive to systemic vascular resistance. Afterload control has been used in studies with the Penn State pneumatic TAH in calves and in patients, and with a 100 cc stroke volume electric TAH system in calves. The more limited cardiac output of the 70 ml TAH system limits our ability to test the afterload control mode in calves, and we presently use a sensitive-response Starling mode. LAP was shown to remain lower than RAP in all test conditions and less than 15 mmHg for flows up to 7.5 L/min. A safe LAP was maintained even at low PAP, where right pump volumetric efficiency is highest. The blood sacs are not attached to the pusher plates, allowing the pumps to fill passively. This prevents atrial suction and allows the control system to actively adjust left and right stroke volumes. An intrathoracic compliance chamber maintains near atmospheric pressure in the pump chamber. Periodic refills of gas are required every 4-6 weeks through a subcutaneous infusion port. Penn State University TAH control uses three techniques to bias the system closer to equal left and right outputs. 1) Less efficient valves were used, within the normal manufacturing tolerance range, in the right pump. 2) The right pump has a slightly smaller pusher plate than the left. 3) Finally, the control system inserts a short diastasis period at the end of left diastole, so that, with equal speed in left and right ejection motions in the alternately ejecting pump, the left pump has a slightly longer filling time than the right.

The control system therefore adjusts automatically over a range of hemodynamic conditions such as changes in cardiac output, venous return, and pulmonary and systemic vascular resistance. The operating range can be adjusted by changing control system parameters via telemetry, which may be desirable to accommodate operating extremes in some

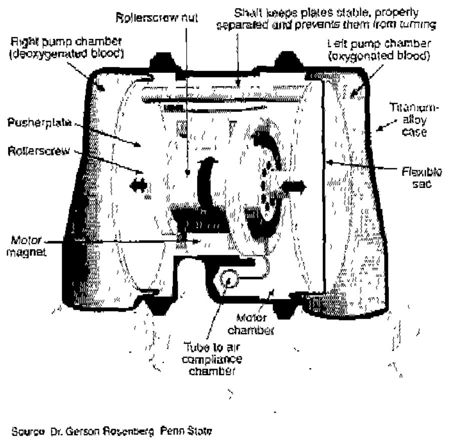


Fig. 3. Schematic drawing of the Penn State University TAH.

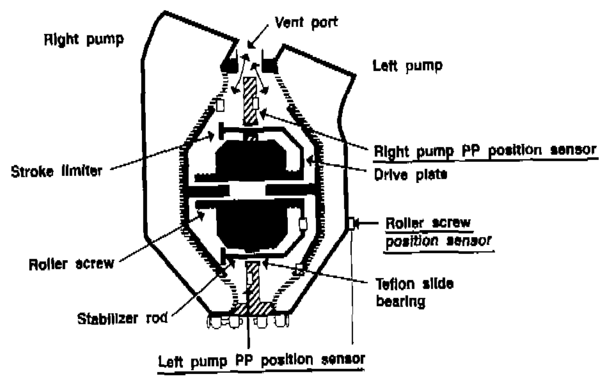


Fig. 4. Schematic drawing of the Baylor College TAH [21].

patients [8].

As with any passively filling device, the rate at which blood enters a pump is determined primarily by the atrial pressure and the forward-flow characteristic of the inlet valve. Secondary effects are ascribable to the mechanical characteristics of the atrium and the flexibility of the blood sac. At a stable point, the left CO will be the right pump flow plus the bronchial flow, and the LAP will be that necessary for the left pump to provide the CO. The actual CO and LAP will depend upon inlet valve characteristics, the relative competence of left and right pumps valves, and the magnitude of the bronchial flow. They could control the relationship between LAP and RAP by our choice of the relative left and right ejection speeds [3]. Bidirectional telemetry is used to monitor the device and to download parameter adjustments and software changes [8].

Baylor College TAH control (U.S.A.)

Baylor college TAH system is very similar to that of Penn state. Figure 4 shows the schematic drawing of the Baylor college TAH system. The pusher plates are shaped conically to accommodate an actuator in the space between them. When the TAH was run in the LMA fill-empty or variable rate mode, the left fill signal was used to turn on the motor power and to start the cycle. In this mode, the pump rate varied depending on the left fill rate. The LMA ejection mode was easily implemented utilizing the Hall effect stroke signal with the right pump operated in the fill-limited mode. The left pump fill trigger level was adjusted to run the right pump at 80% of the full stroke. In this way, increase in the RAP results in increase of the right pump stroke volume, increase in the LAP, and consequent increase in the pumping rate. The stroke volume of the right pump was made smaller than the left by 10% 15%. The built-in play length of the left pump stroke allowed this adjustment without affecting the left stroke volume [20].

When the preload is above 10 mmHg, there are two possible approaches to regulate the LAP level. One is to reduce the right output by decreasing the right end-eject level. It would not be wise to physically limit the right stroke length to less than the left because this would limit the maximum capability of the device. The second approach is more aggressive. The pump rate is increased by further reducing the left effective stroke volume. Since a small play length is incorporated in the right side, the reduction in the left end-eject level does not interfere with the end-fill level of the right pump. Reducing the left end-eject level of the roller screw enables the actuator to run at the higher pump rate. This will force more flow from the right side to elevate the left atrial pressure, which in turn further increases the pump rate and consequently the pump rate. The pump rate is computed continuously from the roller-screw position signal, and when the pump rate falls below 30 bpm (beats per minute), the control is automatically switched to the internal fixed rate mode. Since the right pump is more efficient than the left, the left pump must pump (approximately 10-15%) more than the right in order to regulate left atrial pressure. The VVC is connected to the actuator chamber, and the difference in volume displacement of the two ventricles is supplied from this chamber [21].

Helmholtz Institute TAH control (Germany)

This team made an unique idea to enhance the pump

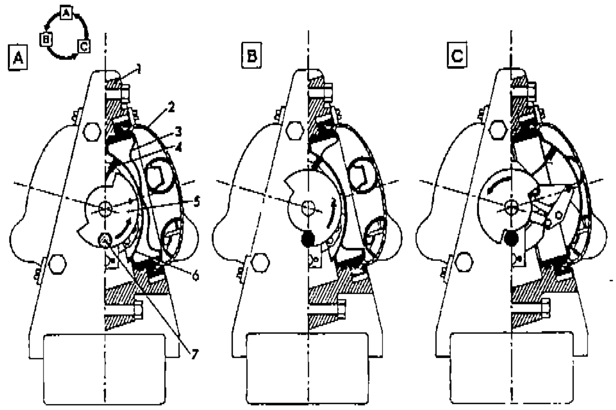


Fig. 5. Schematic drawing of the Helmholtz Institute TAH [24].

efficiency by transforming the unidirectional constant rotational movement of a sensorless commutated brushless d.c. motor with internal rotor into translatory pusher plate movements. This figure permits the elimination of rotor position sensors and rotational switches which decrease the general reliability. Figure 5 shows the schematic drawing of the Helmholtz Institute TAH system. The contact time of the diaphragm of the artificial ventricle to the pusher plate is detected by a diaphragm contact sensor which is located at the pusher plate. This contact time is a function of filling velocity and the respective atrial pressure. But the recent direction has been changed from the usage of contact sensor to motor current [22][23].

A fuzzy controller has been implemented for the adaptation of the pump rate to body perfusion demand by left pump chamber filling detection. The contact time between diaphragm and pusher plate is chosen as the first control input parameter because it is a reproducible measure of filling velocity and the respective atrial pressure. The second control input parameter is the pump rate because it is used for the pump output calculation and for the determination of energy converter efficiency and limits of performance. It is an adaptation of the left (and consequently of the right) pump rate to left preload or left filling velocity, respectively. Left and right afterload conditions can be derived easily from motor energy consumption. The uniform unidirectional motor rotation simplifies this task greatly. Finally, left-right pump output balancing may be achieved by monitoring right afterload and reciprocally switching between LMA and RMA. The present TAH control concept represents only one element of the mentioned superposed control strategy. It uses only the atrial pressure or filling velocity, respectively, at the left pump chamber and the pump rate itself as input parameters. In general, this concept follows the ideas of other groups which try to simulate Frank-Starling law: High venous returns cause an increase of cardiac output. The difference in TAH control compared with biological control is that the increasing ventricular stroke volume of the natural heart is replaced by pump rate acceleration of the artificial heart [24].

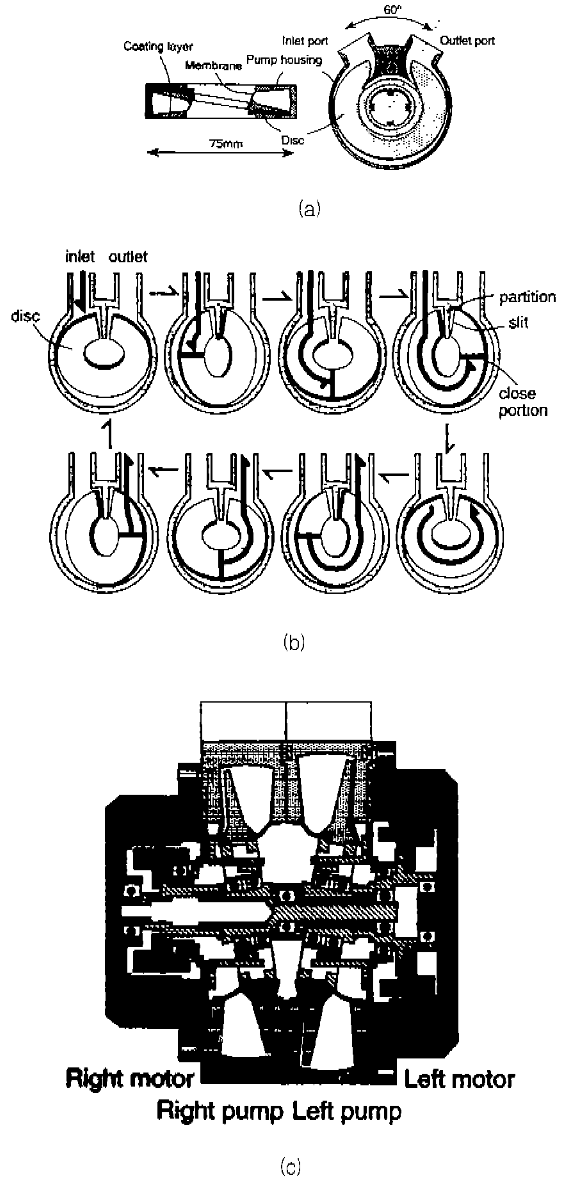


Fig. 6. Schematic drawing of the Tokyo University TAH. (a) the design of the undulation pump for the UPTAH, (b) the principle of the undulation pump, (c) structure of the UP-TAH2 [25]

Tokyo University TAH control (Japan)

Tokyo University team has developed two types of TAH. One is an undulation pump TAH (UP TAH) and the other

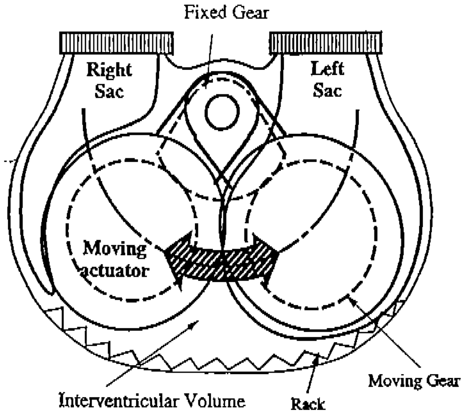
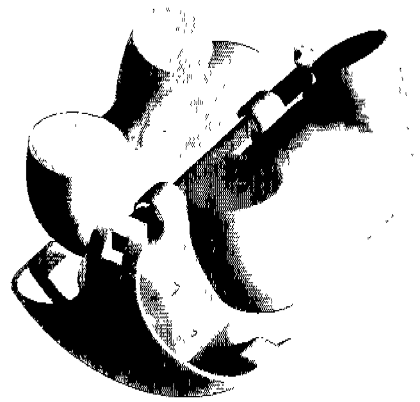


Fig. 7. Schematic drawing of the Seoul National University TAH



is a flow transformed pulsatile TAH (FTP-TAH). The undulation pump is a small-sized continuous flow displacement type blood pump. Figure 6. (a) and (b) show the principle of this unique pump. The new type of FTP-TAH is under a prototype study. And they have developed two types of UP-TAH, the UP-TAH alternate driven type (UP-TAH1) and the UP-TAH independent motor type (UP-TAH2). Because the UP-TAH1 did not have enough controllability, the UP-TAH2 was selected for an animal experiment. This UP-TAH2 was designed using two undulation pumps and two motors (Figure 6. (c)).

There are not published control algorithm for the UP-TAH2. Even though the Tokyo University team showed long term survival record with their developed algorithm (conductance and arterial pressure based control or 1/R control), the algorithm is impractical in the perspective of the need of information of real hemodynamics and this algorithm is not testified with their TAH. They tested control algorithm in extracoporeal two VADs [25][26].

Seoul National University TAH control (Korea)

This team made an unique idea to exclude the dead space of actuator by moving actuator alternately. Figure 7 shows the schematic drawing of the Seoul National University TAH. As a noninvasive input control parameters, interventricular pressure (IVP) signal [27] and motor current were deeply studied. Motor current based preload sensitive and afterload sensitive control were established in [28][29]. In the sense of EDV, the motor current based volume state estimation is more favorite choice than the IVP because IVP reflects the dynamic inflow state not the EDV.

Other famous TAH researches are being done at the University of Utah and Natioanl Cardiovascular Center (NCVC). These teams developed electrohydraulic-type TAH. But, there is no published automatic control alrogithm for NCVC TAH [32][33]. And Utah TAH developed the automatic control algorithm based on the noninvasive pressure signal in the hydraulic fluid. Their automatic control algorithm find the physiological demand estimated from the oil pressure waveforms-diastolic filling pressure, and control the diastolic filling pressure to a set value [34].

CONCLUSIONS

The purpose of the TAH control can be said to imitate the native heart control. The nowadays control has been toward variable rate systems (speed control, Seoul TAH, Penn State University TAH, Baylor College TAH, Helmholtz Institute TAH). This mode of TAH function maximizes pump efficiency by providing the maximum stroke volume (full-fill governing principle) with each systolic phase and by varying heart rates to meet metabolic demands. A predetermined end diastolic volume acts as a trigger to initiate systole. Animal studies have concluded that blood flow in the range of 80 140 ml/min/kg is necessary to maintain aerobic metabolism [7].

The LMA mode triggered by the left pump fill can protect the lungs and can also respond to venous return change and therefore is a reliable control method for a one-piece TAH. One interesting phenomenon observed was the effect of respiration on the atrial pulsation. Since the left and right pumps are operated in the alternate ejection mode, inspiration and expiration result in a 180 out-of-phase effect. There is a delay of approximately 3-5 beats between the right and left ventricles. Thus, the feedback regulation of the motor speed should be based on the average pump performance of 5 previous beats or more. The question of whether an alternating or simultaneous ejection (systolic) phase is more effective remains a topic of debate [7]. In particular, since the most team's pump size has been reduced to obtain better anatomical fit, both pumps will be operated more often at full stroke volume. Although the pump rate can be increased to a higher range of 130-150 bpm, this may reduce the device durability. The physiological, pathological, and psychological consequences of using higher pump rates require further investigation [21].

Measurement of body acceleration can be accomplished easily by incorporating one or more accelerometers into the implanted TAH controller. Body acceleration has been shown to be sufficiently predictive of demand to be incorporated into commercial pacemakers and has been shown to correlate well with exercise intensity in calves [3][30]. Body acceleration does not necessarily increase monotonically as exercise intensity increases in humans, but a signal is available at the instant activity begins, making it potentially useful at least to augment other means of determining quantitative demand [3].

Relying solely on a Starling-like mechanisms, passive intrinsic TAH control may be adequate at rest and with mild to moderate exercise, but it requires the alteration of external control parameters during times of severe stress [7]. It is expected that patients will use the telemetry to check the implant status at routine intervals [8].

For clinical applications of the implantable artificial heart, not only physiologic controllability but also other points such as thrombosis, hemolysis, efficiency, durability, temperature, size, weight, battery, TET (transcutaneous energy transmission) system, telemetry, psychological effect, etc. must be considered simultaneously for clinical use.

The mechanical artificial heart control must be studied until the appearance of other type innovative artificial heart such as genetically engineered devices and techniques in around 2025 [31].

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