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Design of A Human Model of the Moving-Actuator Type Total Artificial Heart

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= Abstract =

A human version of Korean total artificial heart(TAH) was designed based on the magnetic resonance imaging(MRI) data. To obtain accurate measurements of human thoracic structure including the valvular sites, we analyzed the dimensions of the natural heart of healthy persons and cardiomyopathy(CM) patients. The MRI findings were analyzed to measure the volume of the thoracic cavity that would be occupied by the TAH. The design upgrade of the mechanical parts was also performed with the computer aided design(CAD) system to develop a new version of Korean TAH.

Key words : Total artificial heart, Anatomical fitting, Magnetic resonance imaging, Orthotopic implantation

INTRODUCTION

Accurate anatomical fitting is a critical problem for the use of the total artificial heart(TAH) in humans. Anatomical fitting failure is mostly due to geometrical mismatches such as, large size of blood pump compared to the human chest cavity, especially in Oriental, and incorrect heart valve sites and direction in recipients[1-3]. Our previous animal model TAH has a large volume compared with human chest size.

The "moving-actuator" type energy converter was used in the Korean TAH to eliminate the space occupied by the fixed-actuator in the conventional electromechanical TAHs, and an integrated variable volume space(VVS) was provided inside the pump, compared with the external volume compensation chamber (VCC) in other pumps. These advantages enable the Korean TAH to be fitted for permanent human use [3].

Accurate and detailed dimensional criteria of the space to be occupied by the TAH in the human thoracic cavity are necessary for the design of new-type TAH. To obtain accurate measurements we analyzed the dimensions of the natural heart of healthy persons and cardiomyopathy(CM) patients. Magnetic resonance imaging(MRI) findings were analyzed to measure the volume of the space that would be occupied by a TAH in a normal Oriental[4].

In this paper, we present a new TAH model for human implantation based on the dimensional analysis of MRI data. The design of the new version of Korean TAH was performed on the computer-aided design (CAD) system.

MATERIALS AND METHODS

1. MRI Analysis

The MRI findings of three healthy persons(weight 59-75kg) and three CM patients(weight 50-67kg) were examined. The images were taken at the end-diastolic phase of the heart cycle.

From MRI, the following dimensions were acquired: (1) the distance between the sternum and the ventral

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Table 1. Dimensions obtained from magnetic resonance imaging findings

	i) [mm]	ii) [mm]	iii) [deg]	iv) [mm]	v) [deg]	vi) [mm]	vii) [mm]	viii) [mm]
CM patients	55～68	85～114	40～45	105～121	15～32	55～65	43～56	57～77
healthy persons	40～52	75～94	38～46	90～103	18～29	48～53	40～49	52～60

i) the distance between the sternum and ventral edge of strial septum, ii) maximum diameter of atrioventricular ring, iii) the angle between the maximum diameter plane of atrioventricular ring and vertical section plane at axial section plan, iv) the longitudinal thoracic length from the atrioventricular ring to the apex, v) the angle between apex direction and sagittal plan at longitudinal section MRI, vi) the distance between the centers of the tricuspid and the mitral valve, vii) the distance between the centers of the mitral and the aortic valve and viii) the distance between the centers of the tricspid and the pulmonary valve

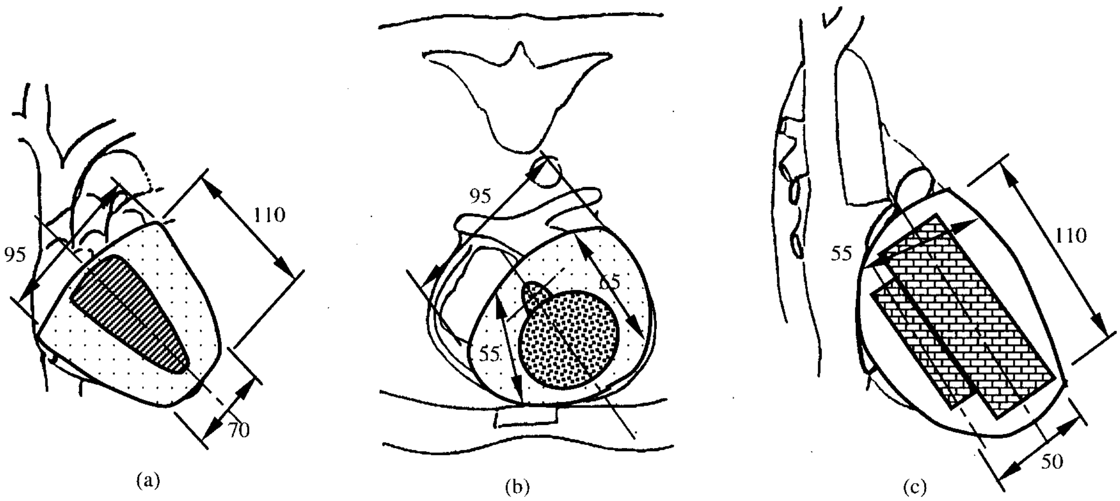

Fig. 1. TAH for human use, (a) front view, (b) axial section view and (c) right side view. All measurements in Figures are in mm

edge of the atrial septum, (2) the maximum diameter of the atrioventricular ring, (3) the angle between the maximum diameter plane of the atrioventricular (AV) ring and the vertical section plane at the axial section plane, (4) the longitudinal thoracic length from the atrioventricular ring to the apex, (5) the angle between the apex direction and the axis of the sagittal plane of the MRI, (6) the distance between the center of the tricuspid valve and that of the mitral valve, (7) the distance between the center of the mitral valve and that of the aortic valve and (8) the distance between the center of the tricuspid valve and that of the pulmonary valve. Dimensions (1), (2), and (4) are needed for determining the shape and size of implantable pump, (3) and (5) are needed for determining the size and arrangement of the actuator, and the last three dimensions are needed for selecting the location of valvular sites and direction.

An axial plane image at the height of the center of the tricuspid valve was used to measure dimensions (1), (2), and (3). The dimensions of (4) and (5) were measured on a sagittal plane image and the last three dimensions, of valve sites, were measured on a 3-D MRI reconstruction image.

The dimensions for the thoracic cavity and the anatomical structures around the heart are summarized in Table 1. The available space within the thoracic cavity was less than 600 cc for normal persons and about 800 cc for CM patients.

2. Conceptual Design of Korean TAH

The design of the new type of Korean TAH was based on the MRI dimensions; the dimensional criteria and actuator arrangement are shown in Table 2 and Figure 1, respectively. The height of the right

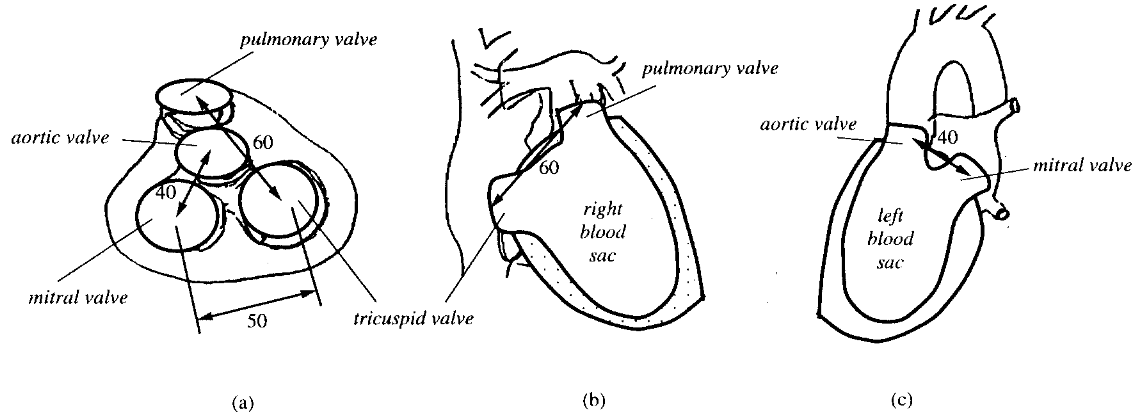

Fig. 2. Valve sites and direction in TAH for human use, (a) distance between valves, (b) right blood sac and (c) left blood sac

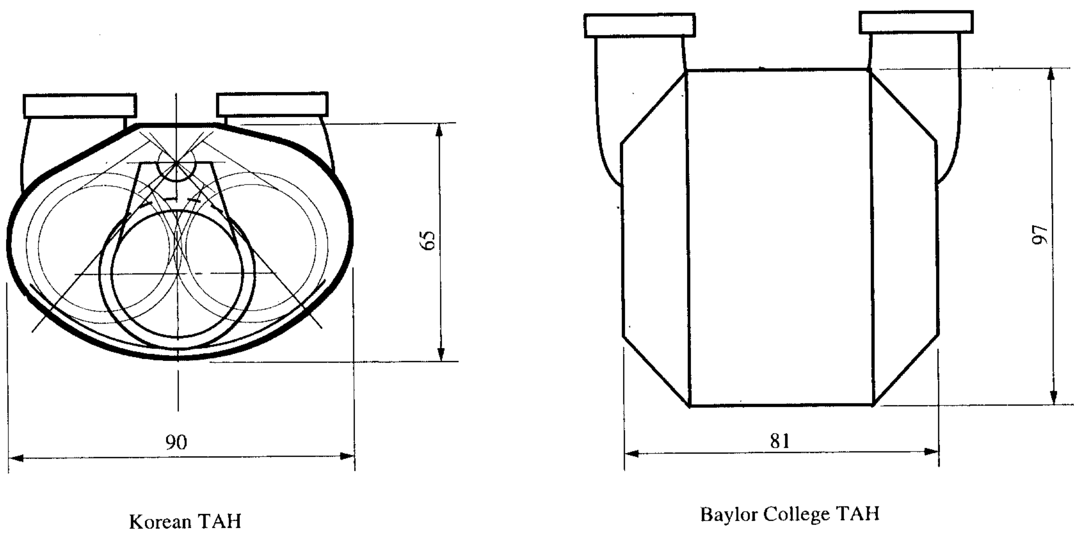

Fig. 3. Comparison of the human version of the Korean TAH and Baylor College TAH

ventricle corresponding to the distance from the tricuspid valve to the sternum was the most critical dimension throughout the pervious animal experiments with the old-type Korean TAH. To minimize these dimensions and to have a smaller stroke volume of the right than for the left ventricle, a non-symmetrical blood pump is required(Figure 1 (b)). The apex of the TAH can contact smoothly to the diaphragm due to its round edges(Figure 1 (a),(b)).

From the dimensions for (6), (7), and (8), four valvular rings were located in good anatomical sites. To have low inflow resistance and a good anatomical fit, atrioventricular valves should be larger than outlet valves. The directions of the four valves are shown in Figure 2[3].

Figure 3 shows a comparison of the external dimensions of our model and those of the Baylor College model. The Baylor model has been evaluated extensively in transplantation patients in intraoperative fitting trials, and has been found to have a good fit in orthotopic heart transplant recipients with average body weights of 70 Kg[1,3,5].

RESULTS

To implant our moving-actuator type TAH inside

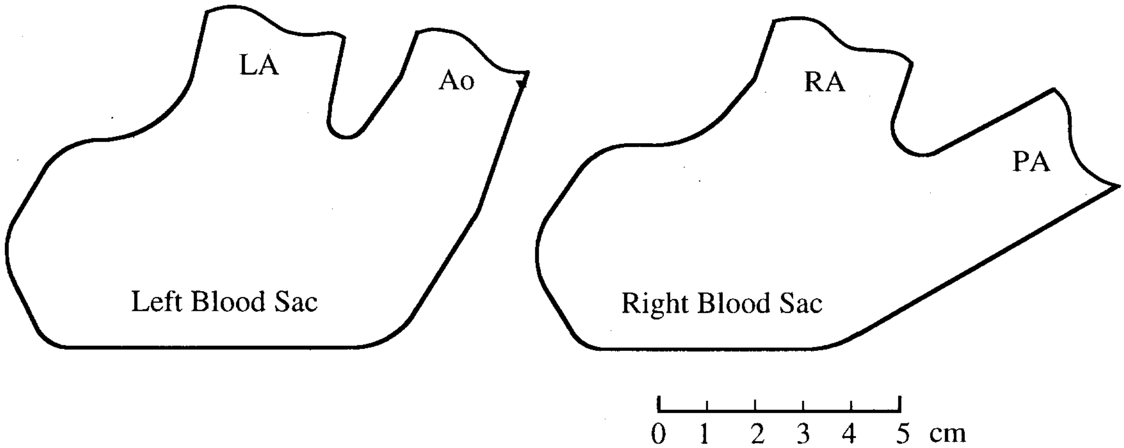

Fig. 4. Blood sac for human use. LA, left atrium; RA, right atrium; PA, pulmonary artery; Ao, aorta

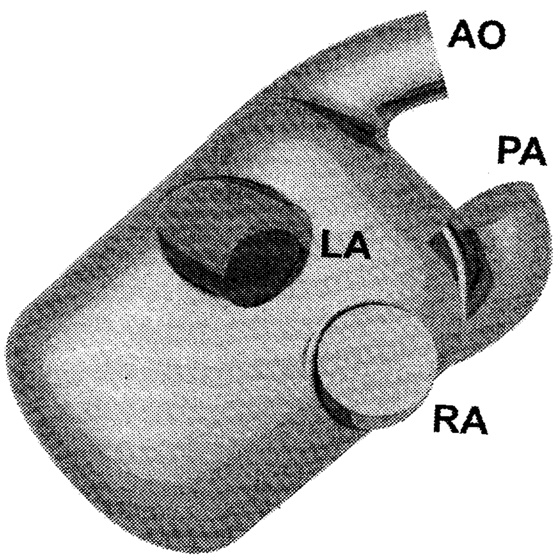

Fig. 5. External appearance of Korean TAH human version

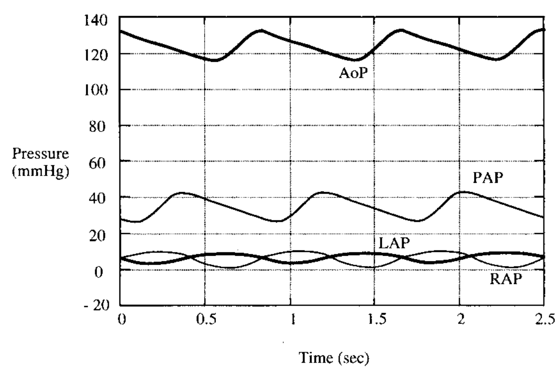

Fig. 6. Pressure changes in the compartment of the cardiovascular system. AoP, aortic pressure; LAP, left atrial pressure; RAP, right atrial pressure; PAP, pulmonary arterial pressure

the thoracic cavity of Orientals, several design modifications were made : (1) The position of the outflow ports(aorta[Ao] and pulmonary artery[PA]) was changed toward the upward direction compared to that of the current model. Thus the pump is connected to the Ao and the PA in an upright position in a recipient. This change reduces the pump height at the outlet sides to save the small space between the natural vessels, the atrium remnants, and the sternum. (2) The direction of the inflow ports(left atrium[LA] and right atrium[RA]) was bent toward the outlet ports. The inlet and outlet valve planes were located on the atrioventricular ring plane for improved fit in human implantation. The problem of kinking in the RA side in old animal models may be diminished with this outlet direction[6]. Figure 4 shows the new blood sac designed for human use. The stroke volume of the new blood pump is about 77 cc for systemic circulation and 60 cc for pulmonary circulation under the normal operations of the energy converter. This new blood sac has an ejection fraction of more than 80 %[7,8].

The overall sizes of the implant blood pump are : 12cm in length, 6.5cm in height, and 9cm in width.

Table 2. Dimensions of total artificial heart for human use

• maximum height of right ventricle side	55mm
• maximum height of left ventricle side	65mm
• maximum length to apex direction	110mm
• maximum width by AV ring diameter	95mm
• approximate volume of TAH	600cc

With this size, we expect this TAH will have a suitable fit inside the Oriental chest, based upon our MRI findings and on the indirect comparison with the findings for the Baylor model in vivo human fitting trials. The external appearance of the human version of the Korean TAH, which was generated on the Unigraphics CAD system, is shown in Figure 5.

The design of the Korean TAH was also changed to improve the stability and efficiency of the TAH system : (1) A new gear train mechanism was adopted, which means, a two-step planetary gear train and a one-step hypocyclic gear train with a small gear module to reduce the vibration and noise. (2) Light materials were used to reduce the weight of the moving parts in the energy converter system. This will reduce the inertia loss of the moving mass of TAH system. (3) Wire fatigue problems due to the moving-actuator mechanism were improved by using a specially designed S-shaped wiring system made with the flat wire[3].

DISCUSSION

A human version of Korean TAH was designed based on the MRI data. As these data were acquired from the human chest, they are closer to the actual in vivo dimensions than those from conventional cadaver fitting trials. In cadaver fitting trial, the available volume to be occupied by a TAH is likely to be overestimated, due to the collapse of the lungs and deformation of the great vessels.

A computer simulation study was performed to estimate the stroke volume and the pressure changes in the Korean TAH and cardiovascular system model. The VVS in our pump can be considered to be the residual volume between the two sacs inside the pump housing chamber, after excluding the actuator and its lubricants[9]. The size of the VVS in our pump is about 150cm^3; this can be used to compensate for the difference in left and right cardiac output. The simulation results are shown in Figure 6. In this case, the amplitude of the fluctuating volume in the VVS is about 23cm^3 during one heart cycle, with a mean of 150cm^3; this volume change causes pressure fluctuation in the VVS within the range of $\pm$ 30mmHg. With a moderate degree of the active suction inside the sacs, the filling of the sac was shown to be assisted by the diastolic augmentation, even at low atrial pressure level, in the simulation and mock circulation test. The suction condition in the low venous return state can be detected by increases in the motor current, and the velocity of the moving actuator can be lowered to reduce the cardiac output to the level of the venous return. In the computer simulation of the cardiovascular system and the TAH, the left atrial pressure and the right atrial pressure were estimated to be maintained at below 15mmHg with the full-fill operation of both sacs without any external compliance chamber, as shown in Figure 6.

In conclusion, the human type Korean TAH was designed with CAD system and evaluated in a simulation study. The changed gear train mechanism, fixture method, and wiring system increased the reliability of Korean TAH.

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=국문초록=

핵자기공명영상장치에서 얻은 심장과 흉곽의 칫수를 바탕으로 하여 한국형 인공심장을 설계하였다. 인공심장을 수혜받을 사람의 흉곽의 정확한 구조와 판막의 위치에 대한 정보를 획득하기 위하여, 정상인과 심장질환이 있는 환자의 핵자기공명영상을 분석하였다. 획득한 핵자기공명영상의 자료로 부터 인공심장이 이식될 수 있는 흉곽내의 공간에 대한 분석을 수행하였다. 이를 바탕으로 작동기의 기계요소의 설계개선을 포함하는 한국형 인공심장의 설계를 전산기원용설계기법으로 실현하였다.