Dimensional Design Criteria of the Korean Total Artificial Heart for Human Use

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Introduction

The dimension of implantable electromechanical total artificial heart (TAH), including the arrangement and the size of its actuator, is one of the most important factors for the optimal design to make successful long-term bridge transplantation or permanent artificial heart replacement.

During the development of TAH, accurate anatomical fitting is one of the serious problems for human use. Anatomical fitting failure is mostly caused from; i) large size of blood pump compared to human chest cavity especially in Orientals ii) inadequate heart valve sites and directions and iii) overestimation of healthy person's thoracic cavity from cardiomyopathy (CM) patients's data and cadaver fitting trials. With these defects, designed Korean TAH has a larger volume size than that of normal Oriental's for long-term or permanent use.

So, accurate and detailed dimensional criteria for TAH occupying space in human thoracic cavity are necessary for our new-type TAH in design for permanent human use. For accurate data, healthy person and CM patient's dimension data is needed. To satisfying this object, computed tomography (CT) of magnetic resonance imaging (MRI) is the most reasonable method to measure the volume of TAH occupying space.

Materials and Methods

CT of MRI of 3 healthy persons with weight of 59 ~ 75 Kg and 3 CM patients with weight of 50 ~ 67 Kg were examined systematically. Those images were taken at the end diastolic phase of the heart cycle.

From MRI, following data were acquired; i) the distance between the sternum and ventral edge of atrial 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 plane, iv) the longitudinal thoracic length from the atrioventricular ring to the apex, v) the angle between apex direction and the axis of the sagittal plane of MRI, vi) the distance between the center of the tricuspid valve and that of the mitral valve, vii) the distance between the center of the mitral valve and that of aortic valve and viii) the distance between the center of the tricuspid valve and that of pulmonary valve. Data i), ii), and iv) are needed for design of the shape and size of implantable pump design, iii) and v) are needed for design of the size and arrangement of actuator and last 3 data are needed for deciding the location of valvular sites and directions.

An axial plane image (Fig. 1) at the height of the center of the tricuspid valve was used to measure

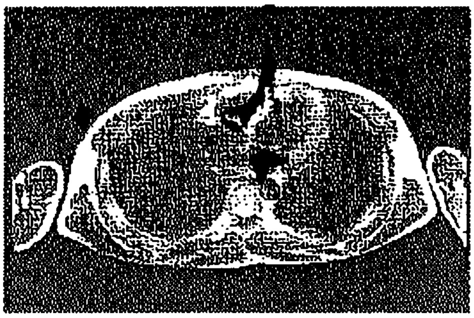

Fig. 1 *MRI of axial plane*
Data i),ii) and iii) are measured in this plane.

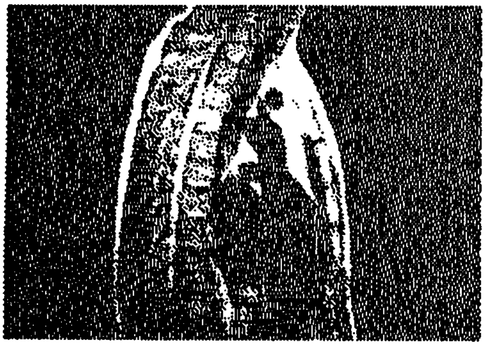

Fig.2 *MRI of sagittal plane*
Data iv) and v) are measured in this plane.

dimensions i), ii) and iii). Dimensions of iv) and v) were measured on a sagittal plane image (Fig. 2). And the last 3 data of valve sites were measured on the 3-D reconstruction image of CT of MRI.

Results & Discussion

The thoracic cavity and the anatomical structure around the heart were shown in Fig. 1 and 2 and its measured data were summarized in Table 1. With MRI, available thoracic cavity, heart valve's sites and arrangement are measured accurately. Acquired

Table 1. *summarized data from CT of MRI*

	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 atrial 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 plane, iv): the longitudinal thoracic length from the atrioventricular ring to the apex, v): the angle between apex direction and sagittal plane 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 tricuspid and the pulmonary valve

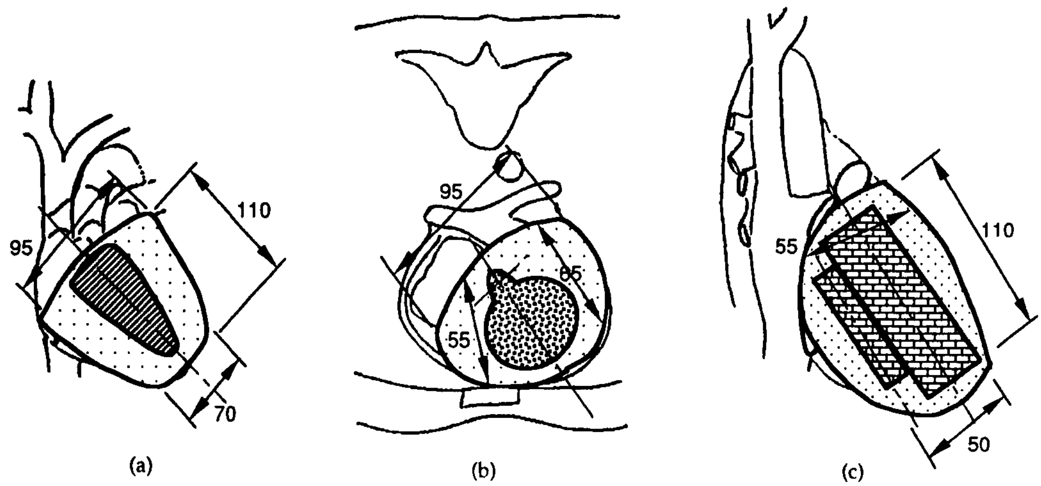

Fig. 3 *schematic diagram of TAH for human use: (a) front view, (b) axial section view and (c) right side view*

from a living body, these data have better physiological meaning than those from the conventional cadaver fitting trial. In the case of cadaver fitting trial, available volume size for TAH occupation is overestimated due to collapse of lung and deformation of great vessels. The available space within thoracic cavity is less than 600 cc for normal person and about 800 cc for CM patients.

New type of Korean TAH (pendulum #3) is in design with these MRI data. Korean TAH's dimensional criteria and actuator's arrangement are shown in Fig. 3 and Table 2. The shortness of the height of right ventricle is the most significant problem in the application of the present TAH (pendulum #2). To overcome this problem and compensate the bronchial circulation with small ejection volume of right ventricle , unsymmetrical shape of the actuator is required (Fig. 3-b). Trapezoidal shape of the modified pump will make smooth contact between the TAH apex and the diaphram. (Fig. 3-a,c)

From data of vi),vii) and viii), four valvular rings are located at good anatomical sites. For reducing the inflow resistance and having a good anatomical fitting, atrioventricular valves with larger size than outlet valves are needed. Four valvular directions are shown in Fig. 4.

Table 2. *dimensions of TAH for human use*

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

Conclusion

The realistic TAH for human use can be designed from the MRI data. Obtained data give very useful dimensional criteria. Although CM patient's data had larger dimensions than those of healthy person, healthy person's data must be adapted to TAH design for long-term implantation or permanent use of TAH.

Reference

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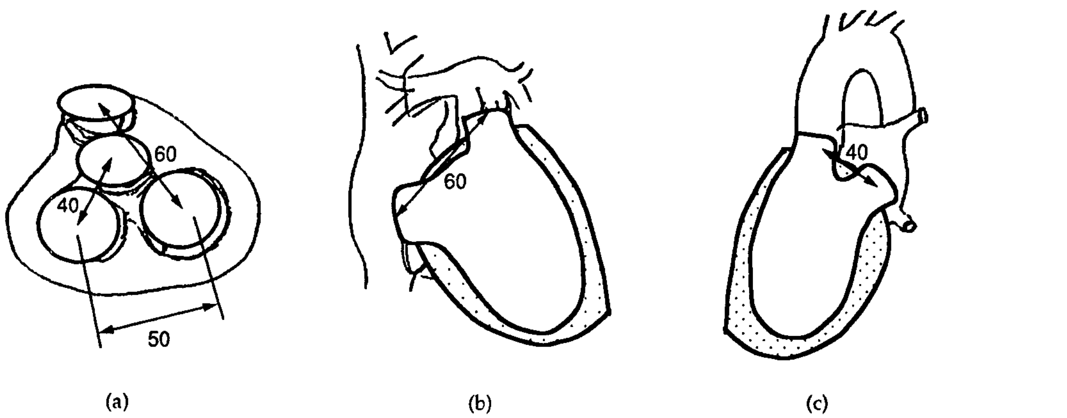

Fig. 4 *Valvular sites and directions in TAH for human use: (a) inter-distance between valves, (b) right blood sac and (c) left blood sac*