One-Piece Bi-Ventricular Assist Device : AnyHeart

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I. INTRODUCTION

Approximately 10% to 15% of all patients implanted with ventricular assist devices (VADs) have required right heart support with another device.[1] And it is reluctant to patient with end-stage heart failure to remove his own heart. The necessity of aggressive bi-ventricular support was already supposed.[2] These situations drive the development of implantable bi-ventricular assist device (BVAD).

The small size and one-piece BVAD (the commercial name is 'AnyHeart') was developed by modifying the moving actuator type Korean artificial heart that has been developed in Seoul National University, Korea from 1984. The AnyHeart does not require the resection of natural heart of the patient, so we call this VAD as 'heart-saving BVAD'.

II. MATERIALS and METHODS

The AnyHeart is one-piece unit including all of the actuator and blood sacs. The actuator contains a brushless DC motor and reduction gear. Actuator rotates around a fixed shaft clockwise and counter-clockwise like a pendulum and ejects the blood sac. Both blood sacs are double layered smooth seam-free structures and made of segmented polyurethaneurea. 2cc of Silicone oil is injected between the layers of double sac to prevent sticking between both layers. All the compartments are contained within a rigid polyurethane chamber. 50cc of Fluor oil is added inside of chamber for gear lubrication and the heat dissipation of energy converter. 4 sets of custom-made polymer valves were adopted to control the direction of blood flow.

The contour of chamber was designed to fit with the silhouette of the pre-peritoneal space and tested in cadaver fitting study. The axes of 2 ports of each blood sac were lying on the same plane to minimize the dead space occupied by the parallel cannulae. The posterior to anterior (A-P) thickness was minimized to reduce the tension of skin covering the chamber.

The elapsed time from the start of a stroke to the first contact time of moving actuator with blood sac (we called this as 'proportional time before contact, PTBC') was different as the filling status. So we used this as the decision criteria of operating condition which met the Frank-Starling law. In order to monitor the status of the AnyHeart from everywhere and at any time, web-based remote monitoring system was constructed on the JAVA based program and tested in the animal experiments.

III. RESULTS and DISCUSSION

The main body of AnyHeart (version AH-350) was 106mm in length, 87mm in width, and 67mm in thickness. The weight and maximum cardiac output was 780g and 6L/min, respectively. The shape of the chamber satisfied the cadaver fitting tests. The inlet and outlet conduits of each blood sac of AnyHeart were connected with atrium and pulmonary artery or aorta, respectively.

The automatic control method using PTBC was composed in 3 modes; low, normal and high pump output. The amount of assist flow in each mode could be modified along the weight of animal and the purpose of the experiment. This method was tested in mock circulation system and functioned in animal experiments with good performance. The re-

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mote monitoring system had several functions such as data collecting, storing, and posting through internet and finished test successfully in *in-vivo* study.

IV. CONCLUSIONS

The compact one-piece BVAD was developed. This device does not remove the natural heart and can be cannullated in atrium or apex. Because the heart of the patient is alive and being assisted by AnyHeart, he can be treated with rigorous therapeutics and be anticipated to recover from cardiac failure. The fact that the natural heart is preserved would be helpful to make the patient comfort in the psychological aspect and also the recovered function of the natural heart could make the minimum flow in the rare case of device failure.

The AnyHeart can be adopted in other applications. This BVAD system could take over all the function of both ventricles like total artificial heart (TAH). And it could also be used as ventless implantable LVAD by replacing the cannulae of one of two artificial ventricles with mini-compliance chambers.

The next clinical model that has improved anatomical fitting characteristics with a shorter A-P dimension and larger stroke volume is under development.

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