Quality Assurance and Control for Human-type Korean Total Artificial Heart (TAH)

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In 1988, we first reported the development of electromechanical total artificial heart (TAH) based on the rolling cylinder mechanisms. A TAH having 100 ml pump ejection volume was built for 100 kg animal, and survival of 4 days in calf was achieved with hermetically sealed systems and paracorporeal electronics [1].

In 1990, we developed the 'pendulum motion' generating energy converter mechanisms and downsized the blood pump system to actuate 70 ml stroke volume pumps more suitable for clinical applications [1,2]. Implantable control electronics with transcutaneous energy transmission (TET) and telemetry were available in 1993 on a newly developed human-type TAH (KORTAH v.1.3). Using this KORTAH v.1.3, we could successfully achieve several purposes including good anatomical fit, easy and simple control, and good biocompatibility [8].

Since September of 1993, Seoul National University Hospital, Korea Gear Co. and Korea Lost-Wax Industry Co. have worked jointly on this heart project, which has been supported by a Ministry of the Science and Technology (MOST). Together we have made some modifications that were bench tested. Our data shows that this new, modified KORTAH v.1.3 has improved high performance, good anatomical fitting, and long-term endurance. We are preparing this pump for long-term *in vivo* testing [5].

In this paper, we focus on the long-term endurance test and quality assurance and control of KORTAH v.1.3. A new endurance test system was developed to estimate the influence of physiological load, heat generation by the TAH motor and gear train, and humidity condition of human body. We describe the basic concept of and preliminary results achieved with this test system and quality assurance.

MATERIALS AND METHODS

Energy Converter and Pumping Unit

A brushless DC motor (Sierracin/Magnedyne 566-18) was used to drive the KORTAH v.1.3. Rotational movement of the motor's rotor is transferred to the planetary gear train of the energy converter which has total systemic gear ratio of 1/60. With high reduction of rotational movement, large torque is transferred to the second cage plate and the pinion of the last hypocyclic gear train. Then the pinion, which travels together with energy converter, moves back and forth on the gear of hypocyclic gear train according to rotation of the motor shaft by action-reaction mechanism. Then the energy converter moves back and forth between two artificial ventricles. For the purpose of lubrication and heat dissipation, the rest space inside the pump chamber is filled partially with motor oil [2,8]. Figure 1 shows the perspective view of the KORTAH v.1.3.

Both of blood sacs have double membranes and outer membrane was attached to the energy converter for diastolic augmentation by active suction. Air volume between the outer and inner

membrane is adjusted to about 20 cc to prevent any excessive suction pressure inside the inner sac. Total volume of the left blood sac is larger than that of the right by 10 % to diminish the imbalance problem, which is produced by bronchial recirculation and valvular regurgitation. Block diagram of the implantable KORTAH v.1.3 in which there exists a brushless DC motor, gear trains including circulatory system is shown in Figure 2.

Endurance Testing

One of the major problems in the successful development of the artificial heart is the reliability problem of the long implantable artificial organs [3,4,7]. In order to evaluate the reliability of KORTAH v.1.3, we built a endurance test setups. Our goal in the reliability test of KORTAH v.1.3 is to demonstrate an 80 % reliability with 60 % confidence for 1 year operation of the entire system including electronics. 10 sets of the endurance test systems were provided and 10 TAHs are under construction. Figure 3 shows the endurance test system for KORTAH v.1.3. The flow rate of the TAH was monitored in real time and its failure condition was checked from the data of pump flow rate. The temperature of the test fluid was maintained as 37 °C and the TAH was submerged in the test fluid during test to mimic the 100 % humidity condition of human thoracic cage. One endurance test system is under operation from November of 1993.

Quality Assurance and Quality Control

Assurance of product quality is derived from careful attention to a number of factors including selection of the quality parts and materials. Due to the complexity of today's artificial organs such as artificial heart (AH) and left ventricular assist device (VAD), routine end-product testing alone is not sufficient to assure product quality for several reasons. Some end-product tests have limited sensitivity. In some cases destructive testing would be required to show the manufacturing process was adequate and in other situations end-product testing does not reveal all variations that may occur in the product that may impact on safety and effectiveness [6].

The basic principles of quality assurance have as their goal the product of articles that are fit for their intended use. These principles may be stated as follows: (1) quality, safety, and effectiveness must be designed and built into the product; (2) quality cannot be inspected or tested into the finished product; and, (3) each step of the manufacturing process must be controlled to maximize the probability that the finished product meets all quality and design specifications.

The main purpose of quality assurance is to developing a program for assessing the reliability, safety and the effectiveness of the KORTAH and achieving the high reliability of the KORTAH under the condition of the minimum overall costs of it, trade-off against cost and performance.

RESULTS AND DISCUSSION

Mechanical design of implantable blood pump was analyzed for the quality assurance and quality control. All mechanical parts were approved in the points of the stability, weight, shape and assembly of the part, performance of the system, and the cost of fabrication and maintenance. Table 1 shows the one example of the quality control engineering for the outer case of blood pump. Other parts were also approved to have the maximized quality assurance and quality control.

In the endurance tester filled with 37 °C distilled water, the KORTAH v.1.3 is running continuously for 150 days, almost 5 months. No mechanical or electrical troubles were observed during almost 22 million cycles of pumping. The power consumption of KORTAH v.1.3 with TET maintained constant, indicating stable and reliable performance, and the system's efficiency was satisfactory (data are not shown).

All device accident in our KORTAH system were registered and analyzed for the Failure Mode Analysis (FMA). Table 2 shows the failure of the polymeric part in KORTAH system. The polyurethane blood sac of the TAH is considered as the unendurable part throughout FMA. The durability of the polyurethane blood sac and the folding pattern analysis will be tested independently with the endurance test of KORTAH system. We will estimate the reliability

of our TAH system with the Weibull time-to-failure distribution model and the date of the endurance test which will be obtained from next one year [6].

The endurance test system is suitable to validate long term durability of implantable cardiac protheses, such as total artificial heart.

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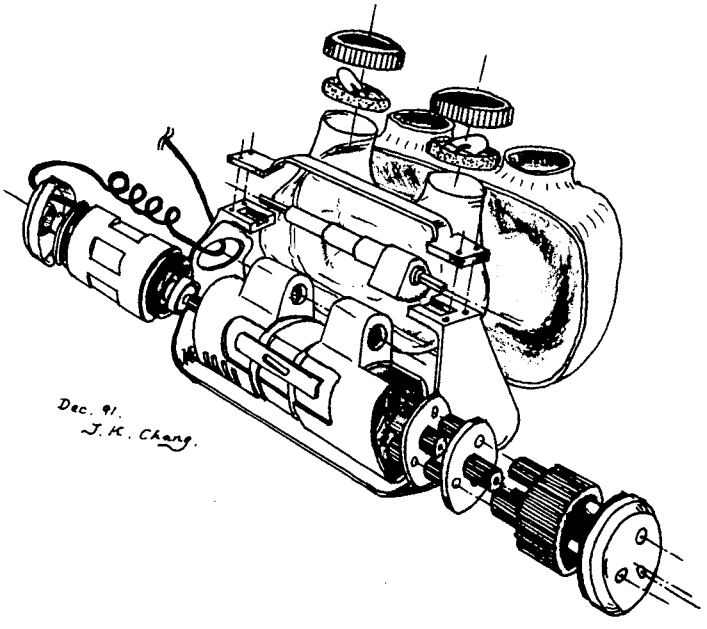

Figure 1. Perspective view of the KORTAH v.1.3. Right blood sac and right side pump chamber weren't be seen in this assembly.

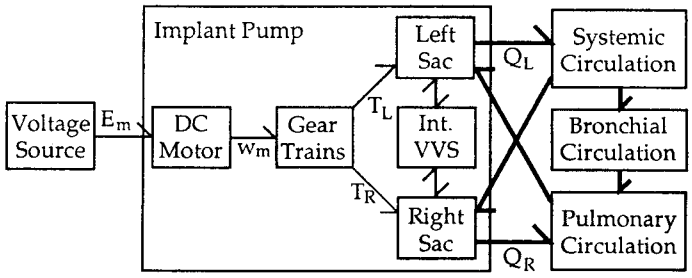

Figure 2. Block diagram of system configurations of KORTAH v.1.3

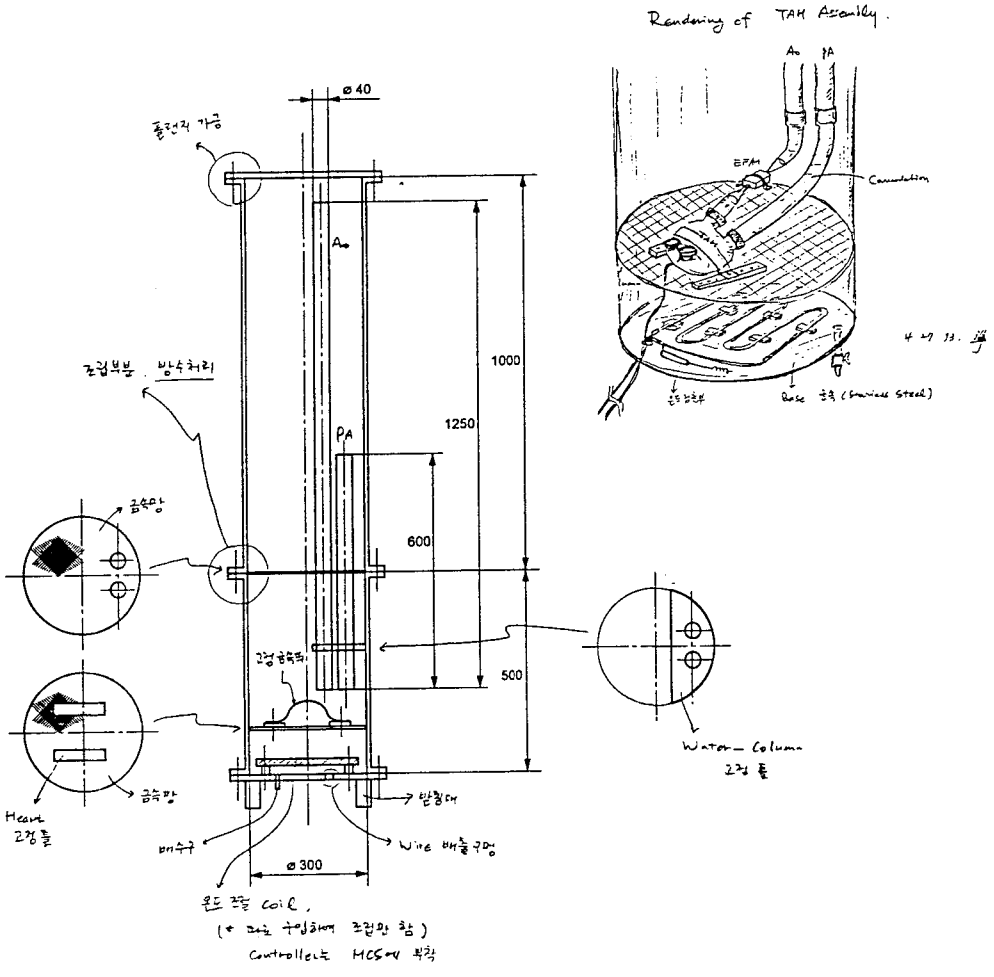

Figure 3. Endurance test system for reliability engineering

Table 1. The example of the design procedure for quality assurance and control

Item / Method / Weight	Stability	Perfor-mance	Size	Weight	Shape	Assembly	Fabrica-tion	Total	Cost	Solution
	15	20	10	10	10	15	20	100		
	0.15	0.20	0.10	0.10	0.10	0.15	0.20	1.00	1.00	
Engineering Plastic	10 / 0.10	15 / 0.15	10 / 0.10	8 / 0.08	8 / 0.08	13 / 0.13	5 / 0.05	(0.64) 0.69	0.25	0.94
Stainless Steel	10 / 0.10	10 / 0.10	5 / 0.05	3 / 0.03	5 / 0.05	5 / 0.05	15 / 0.15	(0.38) 0.53	0.75	1.28

Table 2. Summary of the polymeric part failure

Parts	**Major Reason of Failure**	**Failure Date**
Outer Sac	Friction between blood sac and actuator	Sep. 3, 1991
Outer Sac	Large enlongation by detachment of left blood sac	May, 1992
Sac (Valve Tester)	defolding in low temperature (5 °C)	Nov. 11, 1991