LONG-TERM IN VIVO TESTING OF THE TOTALLY IMPLANTABLE ARTIFICIAL HEART SYSTEM WITH NEWLY ENERGY CONVERTER AT NATIONAL CARDIOVASCULAR CENTER

Akihiko Homma, Ph.D. (1), Eisuke Tatsumi, MD, PhD. (1), Yoshiyuki Taenaka, MD, PhD. (1), Tomohiro Nishinaka, MD, PhD. (1), Tomonori Tsukiya, PhD. (1), Yoshiaki Takewa, MD, PhD. (1), Yukihide Kakuta, MS. (1), Hisateru Takano, MD, PhD. (1), Kohji Koshiji, PhD. (2), Yasuhiro Fukui, PhD. (3), Katsuya Tsuchimoto, MS. (4), Kinji Tsukahara, MS.(4)

(1) Department of Artificial Organs,
National Cardiovascular Center Research Institute,
Suita, Osaka, Japan
(2) Electrical Engineering, Faculty of Science and Technology,
Science University of Tokyo,
Moda, Chiba, Japan
(3) Department of Electronic and computer Engineering, School of Science and Engineering,
Tokyo Denki University,
Hatoyama, Saitama, Japan
(4) Aisin Cosmos R&D Co., Ltd.
Kariya, Aichi, Japan

INTRODUCTION

We have been developing an electrohydrauric total artificial heart (EHTAH) system since 1987 [1]. The system has a unique feature in order to implant in average Asian patients. The energy converter is placed outside the pericardial space to minimize anatomic constraint in the pericardial space. The design of the energy converter was modified for minimization and better oil transfer performance. The EHTAH pumping unit with newly energy converter was evaluated by in vitro study and in vivo animal experiments. This paper describes the present status of development and the results of in vitro and in vivo evaluation of the EHTAH system.

MATERIAL AND METHODS

System configuration

The system consists of diaphragm blood pumps, a separately placed electrohydraulic energy converter with regenerative oil pump, an internal control unit, a transcutaneous energy transfer (TET) system, a transcutaneous optical telemetry (TOT) system, and internal and external batteries. System configuration of EHTAH system was shown in Figure 1. The pumping unit is composed of diaphragm type blood pumps and an electrohydraulic energy converter.

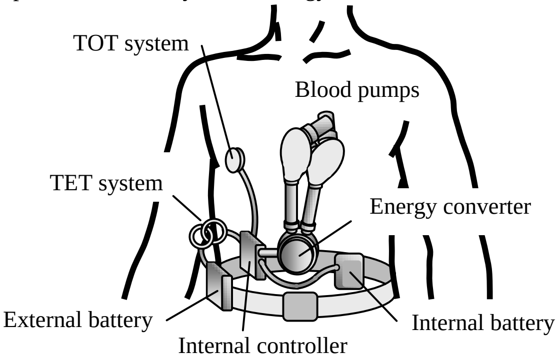

Figure 1. Schematic drawing of the EHTAH system.

Blood pumps

The EHTAH system uses polyurethane diaphragm-type ellipsoidal blood pumps. The blood pumps consist of a blood chamber, an oil chamber and a diaphragm. The total volume of the left and right pumps is 390 ml, and effective stroke volume of each pump is 75 to 80 ml to fit in patients weighing 50 to 60 kg. Housings of the blood pumps are formed by a vacuum injection molding method and made of polyurethane resin and polyurethane elastomer. Mechanical heart valves are set at the inlet and outlet ports of both pumps, respectively. A composite atrial cuff made of antithrombogenic polyurethane reinforced velour texture and aortic and pulmonary artery graft made of a woven Dacron graft.

Energy converter

The energy converter consists of a brushless DC motor （SPK0513-16A, Shinmeiwa Kogyo, Co., Kanagawa, Japan） and a regenerative oil pump. A pair of oil ports for the energy converter is connected to the left and right blood pumps with flexible oil conduits (Toughmic bellows, SUS316L, Valqua Seiki Ltd., Shinshiro, Japan). Silicone oil (SH200、kinematic viscosity: 1.5 [cSt], specific gravity: 0.853, Toray Silicone Co., Ltd., Tokyo, Japan) filled the oil conduits and oil chambers of blood pumps. The left and right blood pumps are alternately driven by the bidirectional rotation of a disk impeller in the energy converter.

The design of the energy converter was modified for minimization and better oil transfer performance. The diameter of the impeller was downsized from 69 to 67 mm. As the result, the diameter of the oil flow path and the external diameter of the energy converter are decreased from 75 to 73 mm and from 79 to 76 mm, respectively. The thickness and weight of the new energy converter are 47 mm and 720 g, respectively.

The angle of the pair of oil ports was changed in order to facilitate the flow of oil. One oil port meets the other oil port at an angle of 20°in the old energy converter. In the new energy converter, one oil port was arranged parallel to the other oil port.

The inner shape of the oil ports, which consist of the cylindrical part and conical part, was also modified. The conical part is formed to adjust the diameter of ports between oil pump and oil conduits. The conical part of new oil ports is shorter than the cylindrical part of it. In order to decrease hydraulic resistance, conical part was extended.

In vitro evaluation of the energy converter

The oil transfer function of the new energy converter was examined. HQ (head-flow) characteristics with unidirectional rotation of the oil pump impeller were evaluated. Head was calculated by the difference in pressure between outlet port and inlet port of the oil pump. Outlet and inlet pressure were measured by semiconductor pressure sensors, while the flow rate was measured by a propeller flow meter.

Pump performance of the modified new energy converter was also examined in a mock circulation. The EHTAH system was driven with an afterload of 100 mm Hg for the left pump, an afterload of 20 mm Hg for the right pump, and a preload 10 mm Hg for both pumps. The efficiency of the pumping unit was calculated by input power and output work of EHTAH obtained by multiplying mean head and cardiac output. The input power into the EHTAH was measured by a power meter. Head was calculated by subtracting preload from afterload, and cardiac output was determined by measuring the amount of water overflow from the overflow tanks for a constant period.

In vivo evaluation of the EHTAH pumping unit

The EHTAH pumping units using modified energy converter were implanted in 5 Holstein calves weighing from 61-75 kg to examine the performance in vivo experiments. Anatomic compatibility, pumping function in vivo, and heat generation level on the energy converter were evaluated. The pumping units were driven by an external controller through a percutaneous lead. Both the blood pumps were implanted in the pericardial space and the energy converter was placed in the subcutaneous pocket in the right thoracic region. An interatrial shunt (IAS) was used in the EHTAH system to compensate for the left-right output imbalance. The IAS was formed by punching 5 mm diameter hole on orifice at the site of the fossa ovalis in the native atrial seprum.

RESULT

In vitro evaluation of the energy converter

The New and old energy converters were evaluated with unidirectional rotation of the oil pump impeller. Rotation speeds of the impeller were adjusted to 1000 rpm, 1200 rpm and 1600 rpm. As a result, HQ characteristics of new energy converter were inferior to old energy converter. However, the efficiencies of new energy converter were better than old energy converter at the each flow rate and the maximum efficiency increased from 23.3 to 26.1 %.

Figure 2 and Figure 3 show the EHTAH pump performance. The flow rate of left pump was saturated at 130 bpm in the old EHTAH pump. However, in the case of new EHTAH pump, the flow rate of left pump increased up to 140 bpm linearly.

The efficiencies of new EHTAH pump were better than old EHTAH pump through the whole pumping rate and the maximum efficiency increased from 12.5 to 14.4 %. The efficiency of the previous EHTAH pump and the modified one at 5 l/min of a cardiac output were 12.1 % and 13.6 %, respectively.

In vivo evaluation of the EHTAH pumping unit

The blood pumps could be implanted easily in the pericardial space of all calves and demonstrated good anatomic fit. Four of 5 calves survived for more than a week. The longest survivor lived for over 12 weeks (87 days). Major causes of termination were thromboembolism and device failure. Last 2 animals, which survive longer than other ones, exhibit rapid recovery from surgery and remain in good general condition until termination due to breakdown oil conduits.

In the longest-surviving animal, the pumping unit was driven at 120 bpm throughout mostly experimental period. The average values of mean right atrial pressure, mean left atrial pressure and mean arterial pressure in the standing position were maintained at 2 ± 5 mm Hg, 1 ± 7 mm Hg, and 71 ± 10 mm Hg, respectively, with energy consumption of 14 ± 3 mm Hg. The cardiac output was estimated to be about 6-8 l/min. The temperature on the surface of the energy converter and the oil conduit were 40 ± 1 ℃ and 40 ± 1 ℃, respectively.

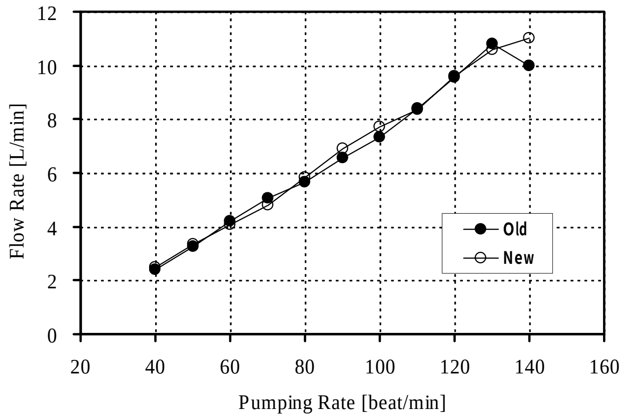

Figure 2. Flow Rate plot of the EHTAH system.

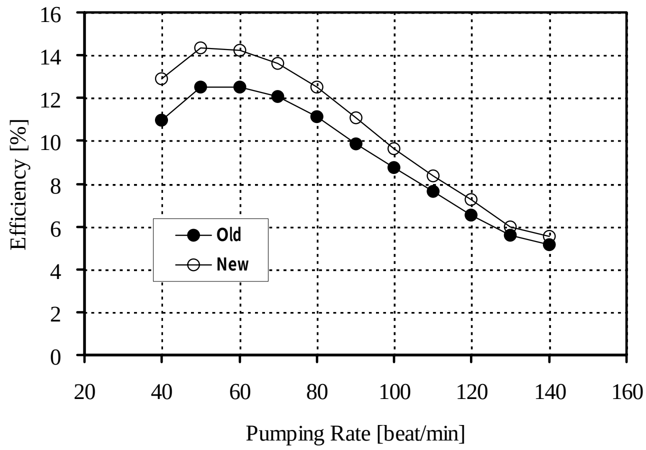

Figure 3. Efficiency plot of the EHTAH system.

CONCLUSION

The energy converter was redesigned to improve oil transfer performance. The maximum cardiac output and the efficiency of the EHTAH pumping unit were improved to 11 L/min and 14.4 %, respectively. The durability of the EHTAH system was confirmed in vivo animal experiments. These results indicate that the EHTAH has the potential to be a totally implantable cardiac replacement.

REFERENCES

1. Tatsumi E. Taenaka Y. Uesho K. Homma A. et al: Long-term in vivo testing of the National Cardiovascular Center electrohydraulic total artificial heart. Journal of Congestive Heart Failure and Circulatory Support 1(4): 153-160, 2001.