

M. Umezu, K. Iwasaki, Y. Qian, T. Yagi, K. Yamazaki. *Is there any possibility that heart transplantation can be replaced by an artificial heart?* Gerontechnology 2008; 7(2):228. EVAHEART is a Japanese-made implantable ventricular assist device (VAD) that has been produced in a multi-institutional project¹. The pilot study of clinical implantation started in May, 2005 and satisfactory performance has been exhibited in three initial cases, which have been running for over 2.5 years. Prior to the clinical application, in-vitro tests (hemodynamic, durability, and biocompatibility) and animal experiments were performed in parallel, because break-through technologies are included in the EVAHEART system, such as a cool seal circulatory system. After several improvements, the final clinical design was set (Figure 1). **Methods and results** The pump flow performance was represented as head-flow (H-Q) relations, demonstrating that a blood pump flow of 8 L/min can be achieved at 100 mmHg at a pump speed of 2400 rpm. This performance is sufficient as a clinical LVAD (left ventricular assist device) under most practical conditions.

An in-vitro durability test was performed with both the total system and its individual components. The results show sufficient durability and reliability. Biocompatibility with the blood contacting surface proved favourable in a series of animal experiments, which included eight long-term evaluations (90-180 days) in calves. In recent cases no serious problems such as thrombus formation or mechanical problems were encountered. Various tests with risk conditions have also been conducted. One of these tests is the hemolysis test with simulated seal defect conditions. The first out of three clinical implantations of EVAHEART has been conducted at Tokyo Women's Medical University in May, 2005 (Figure 2). Up to now, all three patients are in satisfactory health conditions (Table 1). **Conclusion** The EVAHEART system has exhibited good performance. Although the artificial heart is recognized as an expensive device, the first patient has been able to find and maintain a full-time job. Moreover, safety is confirmed, showing the possibility of replacing cardiac transplantation with EVAHEART implantation in the near future.

Reference

1. Umezu M, Yamazaki K, Yamazaki S, Iwasaki K, Miyakoshi T, Kitano T, Tokuno T. Biocybernetics and Biomedical Engineering, 2007;27:111-119

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Table 1 Summary of the ongoing pilot study with 3 patients with dilated cardiomyopathy; TWMU=Tokyo Women's Medical University, Tokyo; NCVC= National Cardiovascular centre, Osaka; Time period is given in days until February 1, 2008

No	Age/sex	Institute	Time period
1	46/M	TWMU	994+
2	29/M	TWMU	958+
3	40/F	NCVC	934+



Figure 1 The EVAHEART system



Figure 2 The first patient with the EVAHEART: He has a full-time job