A Single-Use, Centrifugal Type Assist Heart with Excellent Durability and Biocompatibility

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IN JAPAN, A LAW governing organ procurement from brain death patients was approved in 1997, followed by the second heart transplantation in 1999. Since then, over ten years have passed, but because of a shortage of donor hearts the heart transplantation rate in Japan has been limited to about ten cases per year. The end-stage heart failure patients who need heart transplantation must wait over two years before transplantation. During this long waiting time, maintaining circulation relies on mechanical circulatory support devices (MCSD).

Currently three types of MCSD are available for clinical use in Japan. The first is the blood pump used in the cardio-pulmonary bypass for several hours during open heart surgery, the second is the percutaneous cardio-pulmonary support (PCPS) pump used for emergency treatment for approximately one week, and the third is an implantable blood pump which can be used for two years or longer, bridging to heart transplantation. However, we do not have an appropriate MCSD that can be used from one week to one month to safely support circulation for patients who are awaiting transplantation. Such devices not only sustain life, but also allow a diagnosis of how well the heart function can recover and whether or not the patients actually need a heart transplant, enabling better decisions on how to proceed with treatment.

Magnetically Levitated Centrifugal Blood Pump

To meet the requirements for a one-month blood pump, we have designed and evaluated the durability and biocompatibility of a magnetically levitated centrifugal blood pump, MedTech Mag-Lev, in calves. Fig.1 shows the overall design of such a system. A simple, X- and Y-axis active control that uses electromagnets, combined with passive control that uses permanent magnets, and a radial magnetic coupling drive mechanism were employed to implement a single-use magnetic levitation mechanism of a centrifugal pump. The pump head consists of top and bottom housings and an impeller-rotor. It has a priming volume of 23 mL and incorporates a secondary flow path of 0.3 mm width, allowing a better wash-out effect and anti-thrombogenecity. The pump can provide a flow of 4-5 L/min against 100 mmHg after load at 2000 rpm. The nominal peak-to-peak vibration of the impeller-rotor at 2000 rpm is around 20-30 micron with a power consumption of around 10-15 watts. The prototype system has been successfully tested in calves in the left ventricular assistance mode to demonstrate stable operation for duration of 60 days. Five calves survived to 60 days with normal hemodynamics and without any adverse effects on major organ function. In addition, the plasma-free hemoglobin level remained below 5 mg/dL. Autopsy findings revealed that there were no thrombi inside the explanted pump head and no signs of infarction in the major organs.

Clinical Applications

The MedTech Mag-Lev pump can be used in the area of cardio-pulmonary bypass during open heart surgery, percutaneous cardio-pulmonary bypass for the duration of three weeks, one-week to one-month circulatory support bridging to implantable assist hearts or heart transplantation. The MedTech Mag-Lev can contribute to extracorporeally and safely maintain circulation of heart failure patients for one-month or during the time in which the next treatment options can be explored and decided upon.

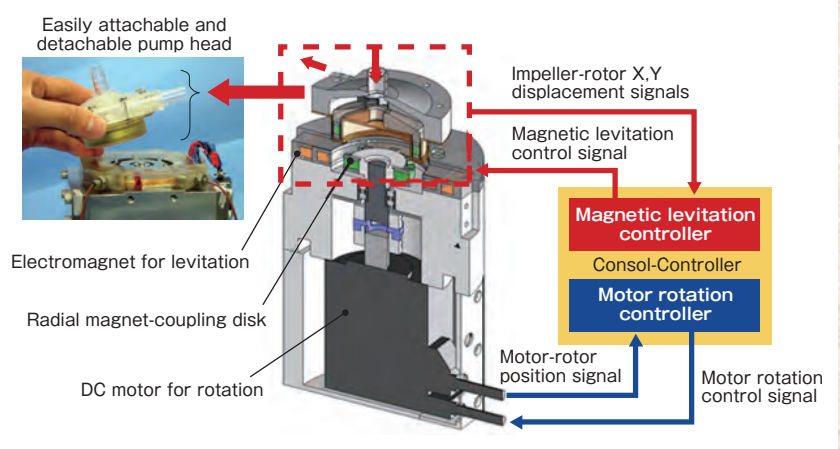

Fig.1: Schematic diagram of a single-use, magnetically-levitated centrifugal blood pump.

Fig.2: Newly assembled clinical console and motor-driver.