First HeartWare[®] Ventricular Assist System Implantation in Switzerland

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The first HeartWare Ventricular Assist System implantation in Switzerland was performed in late May 2010 by a team from the Inselspital in Bern together with Prof. Wieselthaler from Vienna. The 59-year-old female patient suffered from end-stage heart failure, and the system was implanted to support the patient's cardiac function while waiting at home for cardiac transplantation [1]. Since then, a second implantation was performed in a 72 yr-old patient with dilated cardiomyopathy.

Background

The HeartWare Ventricular Assist System features the HVAD pump, centrifugal flow а ventricular assist device with an external Controller and power source [2]. The HVAD is typically implanted in a left-ventricular configuration, and reports were recently published which describe 2 HVADs implanted in a biventricular configuration for support of both the left and right ventricle [3,4]. A touch-screen tablet computer Monitor facilitates transmission of information to and from the Controller during implantation and post-operatively. Several modes of power sources are available, which provide increased versatility and mobility for the patient. After recovery from the initial implanta-

tion, patients are discharged home after receiving in-depth education regarding equipment management, dressing changes to the driveline exit site, and anticoagulation regime manage-Patients ment. attend an outpatient clinic after discharge for follow-up. Twenty-four hour support is provided by the clinic for any issues that arise while the patient is on the device, and the device manufacturer offers round-the-clock support to the clinic for technical problems.

The Pump

The small size of the HVAD pump allows implantation in the pericardial space, without the need for creating a pump pocket. The displacement pump has а volume of 50 ml and weighs 140 g. An integrated inflow cannula allows for flexibility in positioning the pump in the ventricular apex. The 10 mm outflow graft is composed of gel-impregnated graft material and is partially covered by an interlocking strain relief to prevent kinking of the outflow graft. The percutaneous driveline cable contains inner cables made of a wear-resistant alloy and connects the pump to the Controller. The pump itself is completely wear-free due to the passive magnetic and hydrodynamic thrust bearings contained within the pump. This suspension allows the wide-blade impeller to rotate without contacting the outer housing of the pump or any internal components. Estimated pump flow is deby the following termined variables: power consumption in watts, pump set speed in rpm, and the patient's blood viscosity based on hematocrit.

The Peripherals

The Controller manages pump operating parameters, provides information regarding which power source is being used, remaining battery capacity available, alarm diagnostic information, and stores pump data for 30 days. A two-line liguid crystal display shows information such as pump speed, flow, power consumption, in addition to alarm messages and the appropriate action to be taken. A button on the Controller allows for alarm silencing in minor alarm situations. A cascading series of indicator lights inform the user as to the severity of the alarm.

Three variations of power source are possible: 2 Batteries, 1 Battery and an AC adapter, or 1 Battery and a DC adapter for use in automobiles. The Batteries are lithium-ion, weigh 0.47 kg each, and, depending on pump parameters, have a combined capacity of approximately 12 hours.

Physiologic Algorithms

There are 2 operator-enabled algorithms designed for physiologic enhancement. The Suction Detection Alarm algorithm generates an alarm during abrupt low-flow conditions. The Lavare Cycle causes periodic pump speed fluctuations, which facilitate pump washout.

Brief Overview of Implantation Procedure



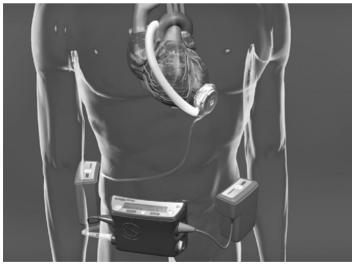
The HVAD pump is implanted in the beating heart using cardiopulmonary bypass (CPB) via a median sternotomy [5]. Left ventricular cannulation consists of a Sewing Ring sewn on the apex of the ventricle, an Apical Coring Tool to excise the myocardium within the Sewing Ring, and the prepared HVAD is then

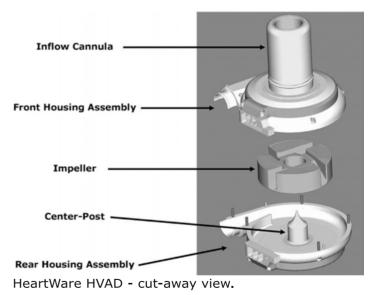


The Inselspital team in Bern, CH

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Implanted HeartWare HVAD and portable components

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inserted inside the hole within the Sewing Ring. The outflow graft is trimmed according to the patient's anatomy and sewn endto side to the aorta. The driveline tunnel is fashioned with a Tunneler, and the pump is started after securing all connections and performing a de-airing procedure. CPB is weaned, and the HVAD pump speed is simultaneously increased until full HVAD pump support is reached.

Conclusion

The HeartWare Ventricular Assist System with the HVAD pump is a small, reliable, and portable device, making it an important addition to the current armamentarium of ventricular assist device therapies.