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Transcutaneous Energy Transmission: Can we do it now?

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Abstract

The percutaneous driveline used in contemporary LVADs presents a continuous risk of infection for the duration of support. Minimizing infection in durable mechanical circulatory support systems requires total implantation of all components and energy transfer by means other than percutaneous drivelines. A novel coplanar energy transfer (CET) system, similar to the original transcutaneous energy transfer (TET) design, is unique by incorporating two large rings with coil-within-the-coil topology to ensure strong resonance power. The CET system consists of an internal integrated controller, a battery coupled with an internal thoracic coil ring, and the LVAD pump. External equipment includes a power transmission belt with an external controller, a battery, and wristwatch monitor. The CET system is adaptable to multiple LVAD designs, though the Jarvik 2000 (Jarvik Heart, Inc., New York, NY) with postauricular power cable was used in the initial clinical cases. Two male patients, ages 51 years and 24 years, underwent implantation of the CET/Jarvik 2000 system for the bridge to transplant indication. One patient experienced a stroke and device thrombosis which led to termination of LVAD support while the patient waited for transplantation. The second patient underwent successful transplant after two months of support. The CET functioned as intended in both patients. Larger, multicenter, controlled clinical trials are necessary to determine the long-term safety and efficacy of the CET technology.

Introduction

Infection following left ventricular assist device (LVAD) implantation is a leading cause of morbidity, mortality, hospital readmission, and high cost of care.1,2 The required percutaneous driveline for contemporary LVADs presents a continuous risk of infection for the duration of support. Minimizing infection in durable mechanical circulatory support systems requires total implantation of all components and energy transfer by means other than percutaneous drivelines. Elimination of the percutaneous driveline by integration of transcutaneous energy transfer (TET) has been performed successfully in earlier designs of the LVAD and total artificial heart,3,4 but is not currently incorporated into the widely used LVAD systems today.

A novel coplanar energy transfer (CET) system, similar to the original TET design, is unique by incorporating two large rings with coil-within-the-coil topology to ensure strong resonance power. The CET system (Leviticus Cardio, Ltd., Petach Tikva, Israel) is designed for total implantation of an LVAD with wireless power and control with no percutaneous driveline. The system is designed to be adaptable for use in multiple blood pump systems. An internal battery can provide greater than 8 hours of continuous untethered operation. The initial clinical implants have been performed at the National Research Cardiac Surgery Center, Astana, Kazakhstan.5 In this report, we provide a description of the CET system and the clinical status of the first patients implanted with the system.

Methods

CET system description

The CET system consists of an internal integrated controller, a battery coupled with an internal thoracic coil ring, and the LVAD pump (Figure 1A). External equipment includes a power transmission belt with an external controller, a battery, and wristwatch monitor (Figure 1B). The integrated controller and battery are coupled with an internal thoracic coil ring. The CET system allows a greater distance between transmitter and receiver coils and can reach power levels of up to 30 Watts with 75% efficiency. The coil ring is placed around the lung and fixed to the chest wall. Power is received by the coil ring from the external power transmission belt. The internal controller and battery control the power circuits, activate the LVAD's brushless DC motor, communicate with the external controller, and control the battery charging circuits. The battery provides power backup and enables several hours of operation without the external transmission belt. The user watch provides status and alarm information for the patient. The power transmission belt transmits power to the internal receiver coil by magnetic coupling. The external controller runs the power transmission control algorithm, communicates with the pump, and pushes power to the belt, using special power driver circuits. The external battery provides the main power source to the implanted pump. A tablet is used mainly for patient-specific configuration during device startup.

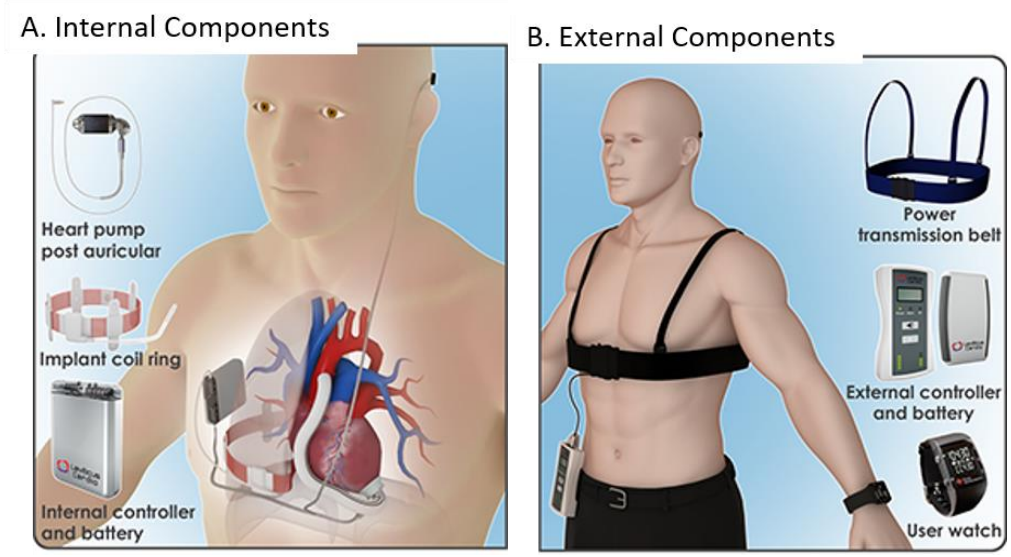

Figure 1. *The CET system internal components (A): Jarvik 2000 pump with postauricular power cable, coil ring, and controller/battery and external components (B): power transmission belt, controller and battery, and user wristwatch.*

The CET system is adaptable to multiple LVAD designs, though the Jarvik 2000 (Jarvik Heart, Inc., New York, NY) with postauricular power cable was used in the initial clinical cases.6 For safety in the initial clinical tests, employment of the Jarvik 2000 system with a retroauricular pedestal that connects to an external power source may be used as a backup in case of component failure of the CET system. The original Jarvik 2000 controller, battery, and monitor are replaced by the CET system controller.

Implantation

Implantation is accomplished through a median sternotomy approach. The power cable is tunneled from the thorax to the base of the skull, where it is attached to the skull pedestal. The lung is deflated, and the coil size is determined by sizers. The coil is positioned horizontally around the circumference of the lower portion of a pleural cavity. A pocket for the controller-battery is created between the serratus and latissimus dorsi muscles, along the lateral thoracic. Cardiopulmonary bypass is started, the pump is implanted into the left ventricle, and a parallel V-shaped driveline from the pump and internal coil are tunneled through an intercostal space to the controller. Both connectors are secured, the pump is started, and cardiopulmonary bypass is weaned.

Patients

Two male patients, ages 51 years (Patient A) and 24 years (Patient B), underwent implantation of the CET/Jarvik 2000 system for the bridge to transplant indication (Table 1). Both patients had NYHA class IV heart failure symptoms and were

classified as INTERMACS profile 3. Patient A experienced an ischemic stroke (modified Rankin Scale score >3) and required prolonged intensive care and rehabilitation. Computed tomography revealed pump thrombosis and occlusion of the outflow, consistent with high power requirements from the CET. A multidisciplinary team decided to terminate the LVAD and CET operation, and the patient was started on intravenous inotropic support. The patient remained stable with adequate organ function and was on the heart transplant waiting list. Implantation and recovery for Patient B was uneventful, and he was discharged from the hospital 30 days after implantation. After 3 days in the intensive care unit, Patient B became ambulatory and was without complications. He underwent successful heart transplant after 2 months of support. During outpatient support, the patient participated in common activities, including walking, shopping, and swimming.

Table 1. Patient Characteristics

	Patient A	Patient B
Age (years)	51	24
Gender	Male	Male
Body surface area (m^2)	2.02	1.89
Etiology	Ischemic	Non-ischemic
Left ventricular ejection fraction (%)	11	22
Cardiac index (L/m^2)	1.9	2.2
Pulmonary wedge pressure (mmHg)	24	20
Central venous pressure	6	5
NYHA class	IV	IV
INTERMACS profile	3	3

System performance

There were no malfunctions of the CET/Jarvik 2000 LVAD system. The CET system functioned as designed in both patients. Untethered operation was accomplished for 8.5 hours before the first alert for battery recharge. These alerts occur when 1 hour of power remains. Critical alarms occur at low battery levels for immediate recharge of the internal battery.

Discussion

These initial cases using the CET/Jarvik 2000 LVAD system demonstrate the feasibility of durable LVAD support without the need for a percutaneous driveline. This represents an important advancement for long-term mechanical circulatory support, as the continuous risk of device-related infections may be greatly reduced. Device-related infection, and in particular percutaneous driveline infection, is a long-standing problem that significantly contributes to morbidity and mortality.7-9 Elimination of the percutaneous driveline from durable mechanical circulatory support systems may enhance survival with less morbidity and overall cost of care in the future.

Concern for safety in a totally implanted LVAD system is paramount. In these initial studies, an externalized postauricular connector was employed as a backup in case of any failure of the CET system—it was not utilized in these cases. Also, the selected patients were transplant candidates, which offered a secondary bailout, if needed. The CET system did not reveal any negative effects on lung function, and chest x-rays and CT scans did not show signs of atelectasis or compression of the lung. The long-term effects of the CET implant on pulmonary function remains unknown.

The CET system was developed with the intent to be integrated with most durable mechanical circulatory support systems. Long-term animal studies have demonstrated feasibility for CET use with other available devices.5 Larger, multicenter, controlled clinical trials are necessary to determine the long-term safety and efficacy of the CET technology. At the time of this writing, no additional implants have been performed pending further technology and regulatory developments.

Discussion

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