Implantable physiologic controller for left ventricular assist devices with telemetry capability

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Objective: Rotary type left ventricular assist devices have mitigated the problem of durability associated with earlier pulsatile pumps and demonstrated improved survival. However, the compromise is the loss of pulsatility due to continuous flow and retained percutaneous driveline leading to increased mortality and morbidity. Lack of pulsatility is implicated in increased gastrointestinal bleeding, aortic incompetence, and diastolic hypertension. We present a novel, wirelessly powered, ultra-compact, implantable physiologic controller capable of running a left ventricular assist device in a pulsatile mode with wireless power delivery.

Methods: The schematic of our system was laid out on a circuit board to wirelessly receive power and run a left ventricular assist device with required safety and backup measures. We have embedded an antenna and wireless network for telemetry. Multiple signal processing steps and controlling algorithm were incorporated. The controller was tested in in vitro and in vivo experiments.

Results: The controller drove left ventricular assist devices continuously for 2 weeks in an in vitro setup and in vivo without any failure. Our controller is more power efficient than the current Food and Drug Administration–approved left ventricular assist device controllers. When used with electrocardiography synchronization, the controller allowed on-demand customization of operation with instantaneous flow and revolutions per minute changes, resulting in a pulsatile flow with adjustable pulse pressure.

Conclusions: Our test results prove the system to be remarkably safe, accurate, and efficient. The unique combination of wireless powering and small footprint makes this system an ideal totally implantable physiologic left ventricular assist device system. (J Thorac Cardiovasc Surg 2014;147:192-202)

ACD

By 2030, it is anticipated that 10 million people in the United States will live with heart failure (1/33 people).[1,2] However, the available donor hearts remain stagnant at approximately 2000 per year.[3] In recent years, implantable left ventricular assist devices (LVADs) have offered another option to this ill population. Although showing a survival advantage, the earlier pneumatically driven positive displacement pumps showed high mechanical failure due to wear and tear associated with multiple moving parts and associated friction. The technologic improvement of rotary pumps with a single moving part has led to increased durability and patient survival compared with their earlier generations both as a bridge to transplant and as destination therapy. However, the improved durability of rotary blood pumps comes at the compromise of having a pulseless continuous blood flow.

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Despite the technologic advances to the pump body, the requirement of a transcutaneous driveline to conduct power (previously needed for shuttling air for pulsatile devices), controller algorithms, and data exchange between the pump and the extracorporeal controller remains unchanged. Despite the benefits of this technology, driveline-associated infections are a common and devastating complication[4,5] that causes a significant negative impact on a patient's quality of life and increased medical cost.[6] The presence of nonphysiologic pulseless blood flow in patients with long-term LVAD support has been implicated in increased gastrointestinal bleeding,[7-9] limited cardiac unloading,[10,11] vascular malformations,[12,13] and aortic incompetence.[14,15] Moreover, because successful LVAD explantation occurs less often with continuous-flow pumps, concerns have been raised regarding their use in patients with a potential for myocardial recovery.

We have previously demonstrated the efficacy of a Free-Range Resonant Electrical Energy Delivery (FREE-D) system that uses high-quality factor resonant coupling technology to wirelessly transfer energy to power an LVAD.[16] The FREE-D system uses magnetically coupled resonators to seamlessly supply energy without compromising mobility or requiring direct contact between the patient and the energy source,[17] thus freeing the patient from a driveline. Application of such technology also requires a small implantable controller with wireless communication.

Abbreviations and Acronyms

ECG	= electrocardiography
EMF	= electromotive force
FREE-D	= Free-Range Resonant Electrical Energy Delivery
LVAD	= left ventricular assist device
MCL	= mock circulation loop
rpm	= revolutions per minute
⊿RPM	= difference between systolic and diastolic pump speeds
UMC-Physio	= ultra-compact implantable physiologic controller

In the current study, we present an ultra-compact implantable physiologic controller (UMC-Physio) to entirely untether patients from the LVAD driveline, increase patients' quality of life, and significantly reduce complications associated with nonphysiologic continuous flow.

MATERIALS AND METHODS

Left Ventricular Assist Device Motor

Current-generation LVADs are based on brushless direct current motors, also known as electronically commutated motors that are powered by a direct current electric source (Appendix 1). An LVAD has 3 sets of coils positioned around its impeller. Once a coil is energized, it produces a magnetic field that causes the permanent magnet on the rotor to align with that magnetic field, which in turn rotates the impeller. However, the rotating action stops when the rotor is aligned with the magnetic field created by the energized coil. To keep the impeller in motion, the coils are energized in a particular sequence (120° out-of-phase from one another). The process of activating and deactivating the coils to keep the impeller spinning is termed ''commutating.''

Pump Speed

Because an LVAD does not have any sensor, the speed of the pump is measured from back electromotive force (EMF) generated by the motor's rotation. The amplitude of the back EMF is proportional to the angular velocity of the LVAD, but its shape will not change with speed and only depends on the pump characteristic. Our controller uses attenuation and filtering processing to sense this signal. The attenuation is required to bring the signal down to an allowable common mode range of the sensing circuit, and the low pass filtering is necessary for smoothing the high switching frequency noise.

When to Commutate and Power Efficiency

The challenge in controlling a brushless direct current motor is knowing when to commutate, because commutation must occur at precise points during rotation for the motor to have maximum torque and smooth operation. Because the implanted system must comply with the highest efficiency, we have incorporated a control algorithm that spins the motor more efficiently to reduce the overall power consumption by calculating when to commutate on the basis of the back EMF of the motor. To further reduce the power, we have introduced a sleep mode for our system that wakes the controller up at only certain point for a short amount of time (5 ms/s) to capture the sensor data and monitor the device operation.

Mode of Operation (Mimicking Physiologic Flow)

The purpose of an LVAD physiologic controller is to match the aortic pressure to a certain value derived from the patient activity. The UMC-Physio has 2 different modes of operation to mimic physiologic flow: continuous and pulsatile modes. In the continuous-flow mode, the user can set 1 speed. However, for the pulsatile mode, the user is required to define separate speeds during systole and diastole. Moreover, in case of a patient with potential myocardial recovery, the controller will have a higher speed during diastole and a lower speed during systole to decrease the preload of the heart. This allows the left ventricle to pump less blood during systole, which means less work for the left ventricle.[18] In the event when a higher pulse pressure is necessary, such as patients with gastrointestinal bleeding, the system uses a higher speed during systole and a lower speed during diastole to create a larger pulse. The difference between systolic and diastolic pump speeds is called ''⊿RPM.''

Signal Processing

The pulsatile algorithm in our controller needs to swiftly modulate the pump speed to be able to gate it with an electrocardiography (ECG) signal for co-pulsation, counterpulsation, or fixed operation modes. Thus, the response time of the system is of a unique interest to us, because heart rates up to 120 beats/min with 30% systolic duration would limit us with a window of 0.15 second for the period of systole. We have used amplifiers and signal processing and filtering methods to further analyze an ECG signal.

Communication

Many medically implanted devices use wired or wireless methods to communicate with their external circuitry. Furthermore, we have integrated an antenna, a transceiver unit (transmitter and receiver), and a wireless network algorithm to enable our UMC-Physio to establish a reliable telemetry communication with an extracorporeal platform, such as a smart phone, tablet, or personal computer. In our wireless networking, the amplitude and width of the data pulses are kept constant in the system. The position of each pulse is varied by instantaneous sampled value of the modulating wave. This method is called ''pulse position modulation.'' Our controller puts out a stream of pulses called ''sync pulses,'' which the external receiver recognizes with a circuitry called ''phase locked loop.'' To create synchronization, an oscillator in the phase locked loop generates pulses at the same frequency as the controller.

Backup and Safety

Because the system will be powered by using our FREE-D emitted electromagnetic fields, we had to consider the noise potential might influence the proper function of our electronic implant. To significantly reduce the EMF susceptibility of our controller, we have combined multiple filtering mechanisms, ground isolation, and ground decoupling in our design. Backup motor driver, overvoltage, and overcurrent protection circuits, thermal shutdown circuit, and independent pulse width modulation generator are among other safety issues that we have incorporated in our design. In addition, a suction event detection algorithm also was incorporated in the system for additional safety by detecting power consumption peaks that are abnormal.

Design and Development

The schematic of our system was laid out on a compact 4-layer printed circuit board using Altium Designer software (Altium, Australia) to run a rotary blood pump with required safety and backup measures. The control algorithms and graphical user interface were further developed in IAR System and LabVIEW software (both National Instruments, Austin, Tex) respectively. The final system was coupled with our alternating current to direct current converter and a receiver coil to wirelessly receive power (Figure 1, *A*).