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Research Letter

Wireless Powered and Water-Proof Mechanical Circulatory Support Device for Ambulatory Class III Heart Failure

Despite advances in medical management, heart failure (HF) is typically a progressive disease and of the 3 million patients with the reduced ejection fraction form in the United States, 900,000 suffer with the advanced form, which is associated with multiple hospitalizations, high readmission rates with progressive decrease in survival with each subsequent admission, and poor quality of life. As such, patients with advanced HF have been a target population for mechanical circulatory support research for several decades. However, despite technological advances with large durable vascular assist devices, the high rates of serious adverse events including stroke, gastrointestinal bleeding,[1] and driveline infection have limited their use in this population. The solution will require totally wireless power in a device designed to eliminate these complications. Previous attempts at wireless power have used transcutaneous energy transfer that required surgical placement of a large inductive coil to receive external power from a large power source applied to the skin directly over the coil,[2] but this approach failed, and no solution has been pursued for over 25 years.

The Second Heart Assist device (Second Heart Inc) is a 13.5-F impeller-driven pump mounted on a driveshaft placed inside a stent cage delivered percutaneously into the descending aorta only 10 cm above the renal arteries, thereby eliminating the risk of stroke. It is the most efficient pump in the field, because it operates at only 7,500 revolutions/min and provides direct benefit to both the heart and kidneys. It improves cardiac output and reduces cardiac filling pressures due primarily to the afterload reduction created by activation of the impeller blades, which pull blood down through the pump, which can generate up to an additional 2.5 L of augmented pulsatile flow over native cardiac output to the kidneys and the rest of the body. The increase in renal blood flow of up to 50% over baseline can offset the intrarenal vasoconstriction associated with low cardiac output in HF, leading to increased urine output, improved kidney function, and faster decongestion. The catheter-based first-generation device can be inserted and the stent and impeller blades fully deployed in <2 minutes.[3] It is designed for 24 hours of support for patients admitted with acute decompensated HF who develop significant diuretic resistance. At the end of this support, the control handle can collapse the blades and stent for easy device removal of the stent and driveshaft.

The second-generation SHA Freedom device (Second Heart Inc) provides totally wireless power and eliminates the driveline without the need for a large sub-Q inductive coil, as the coil has been markedly miniaturized to fit on the distal tip of the catheter, along with the motor and battery, which are housed in a titanium case on the driveshaft. The stent and pump can be inserted and the driveshaft detached by demagnetizing a ball at the end of the driveshaft, leaving the device in close proximity to the kidneys (**Figure 1**). The power source is the size of a cell phone and is housed in a pocket inside a lightweight vest worn around the chest that is totally waterproof. The receiver coil can store enough power for the patient to electively remove the vest and take a shower with no attachments, because it is not providing life support, and allows patients to go in any body of water up to 30 m, which is a first in the field, and a big advance in patient quality of life. The risk of thrombosis is minimized by use of anticoagulation and antivibrational technology. The wireless device can provide 72 hours of uninterrupted power and is easily rechargeable, Bluetooth-enabled, and programmable to operate at as low as 2,000-3,000 revolutions/min as a partial support pump that can meet the individual patient's support needs. It is intended for a wide range of long-term support duration from weeks to

Editor's Note: To view the authors' full presentation at TCTMD Shark Tank, please visit https://www.jacc.org/journal/basic-translational/tht-2022-shark-tank

FIGURE 1 SHA Freedom Catheter Detached From Delivery

The SHA Freedom catheter is shown fully detached from delivery. The driveshaft is designed to remain in place in the descending aorta 10 cm above the renal arteries.

months or longer, such as during the vulnerable period after a HF hospitalization, as well as pretransplant support, or in patients with HF and chronic kidney disease, or for ventricular recovery. Removal of the stent only requires the ball at the tip of a driveshaft to be remagnetized to recapture and remove the stent, and another stent can be deployed if needed in the future.

In summary, a wirelessly powered mechanical circulatory support device has been developed that can provide significant support to both the heart and kidney of patients with advanced HF who are ambulatory and can provide unprecedented improvements in these patients' quality of life. The long-term goals of this device are to reduce hospitalizations, improve volume and diuretic management, and alter progression of native heart and kidney function, thereby also reducing cost of care.

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

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