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ORIGINAL PRE-CLINICAL SCIENCE

Extended in vivo evaluation of a miniaturized axial flow pump with a novel inflow cannula for a minimal invasive implantation procedure

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BACKGROUND: Minimally invasive techniques are desirable to minimize surgical trauma during left ventricular assist device (LVAD) implantation. This is particularly challenging for full-flow support. In this study, a minimally invasive implantation technique was developed for a microaxial rotary pump. The system was evaluated in a chronic sheep model.

METHODS: A HeartWare MVAD (HeartWare, Miami Lakes, FL) pump (length, 50 mm; diameter, 21 mm; maximum flow, 7–8 liters/min) was combined with a novel inflow cannula, including a new flow-optimized tip. The device was implanted into sheep (range, 60–80 kg, mean, 71.6 ± 6.8 kg) through a right-sided minithoracotomy. The inflow cannula was inserted through the superior pulmonary vein, passing through the left atrium into the left ventricle. Scheduled implant period was 30 days for 8 sheep and 100 days for 3 sheep. Mean support flow was set to half of the nominal cardiac output.

RESULTS: Six of 8 sheep finished the scheduled 30-day investigation period (one failed due to early non-pump-related post-operative bleeding and one due to prototype controller failure). The 3 sheep scheduled for 100 days reached the study end point. Peak pump flows of up to 6.9 liters/min were achieved. At necropsy, no signs of mitral valve lesions or thrombus formation around the cannula, the tip, or the insertion site were observed, except for valve leaflet erosion in 1 animal, where the cannula had been entangled in the sub-valvular chords due to lack of ultrasound monitoring.

CONCLUSIONS: The minimally invasive implantation technique using the HeartWare MVAD pump, together with a new cannula, provided excellent results in a chronic animal model.

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The use of a left ventricular assist device (LVAD) as temporary as well as permanent support is a well-established therapy option for patients with end-stage heart failure. The introduction of miniaturized rotary blood pumps has dramatically improved overall clinical outcomes, due not only to their enhanced durability but also to the reduced size of the pump.[1–4] In addition, smaller-sized pumps have led to reduced surgical trauma because large pump pockets or even an intra-abdominal implantation can be avoided.[5] Zimpfer and Schmitto (unpublished data) and Cheung et al[6] have

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demonstrated that placing pumps using a left-sided thoracotomy instead of through a median sternotomy can further reduce surgical trauma during implantations, specifically in patients who have undergone previous heart operations. Off-pump implantation without the use of extracorporeal circulatory support has also been performed to minimize the activation of cytokines and consecutive inflammatory responses.[7]

For further reduction of surgical trauma, minimally invasive access has to be pursued. In a first step, small pumps for partial support for minimally invasive implantation have been developed and are already in clinical use.[8,9]

For end-stage New York Heart Association class IV heart failure patients, however, full support is often required. We therefore developed a minimally invasive off-pump implantation technique using a full-support miniaturized pump and a specially designed inflow cannula. Initial animal experiments were performed to prove that this VAD configuration could provide pump flows of >6 liters/min. We report the in vivo testing of this pump concept in a medium-term (MT) and long-term (LT) sheep model. (Figure 1)

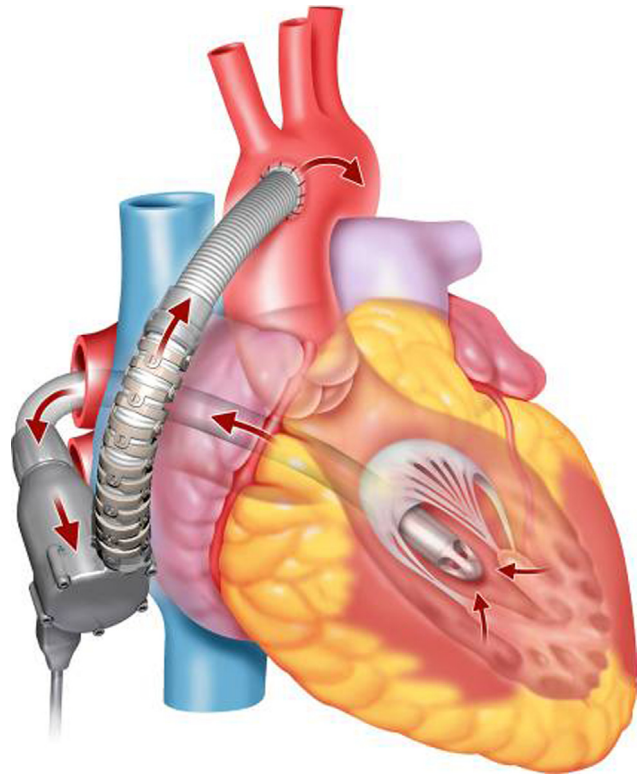

Figure 1 Schematic situs of the transatrial cannulation for ventricular unloading with a left ventricular assist device.

Methods

Pump

The study was performed using prototypes of the new MVAD pump developed by HeartWare, Inc (Miami Lakes, FL).[10] This miniaturized pump allows full cardiac support with a size of only 50 mm in length and a housing diameter of only 21 mm. In this configuration it was used with a spiral centrifugal outlet (Figure 2).

The MVAD impeller and its hybrid suspension system were designed to eliminate the upstream and downstream support structures, which leads to a wear-less axial-flow pump. The axial constraint of the rotor is provided by strong magnetic coupling between a conventional stator within the housing and a magnetized impeller. For radial constraint, the impeller contains large surface areas on each impeller blade as hydrodynamic thrust bearings. The rotor was made from biocompatible, abrasion-resistant metal alloy, whereas the inner tubing was made from ceramics, which reduces the eddy current losses, provides a thin and durable structural wall, and allows high precision on inner diameter for good thrust bearing performance. The pump operated at a speed of 12,000 to 20,000 rpm, producing flows of up to 7 to 8 liters/min. Pump operation was controlled by an early prototype controller/monitoring system.

Inflow cannula

A special inflow cannula was developed for the transatrial access to the LV cavity and for stagnation-free inflow of the blood: wire-reinforced tubing (internal diameter, 8.1 mm; outer diameter, 9.3 mm; length, 110–130 mm, depending on the size of the animal) was equipped with a specifically designed tip. This tip had been optimized by the use of computational fluid dynamics, using a shear-stress transport (SST)-kw model with 340.000 polyhedral cells (Fluent 6.3; Fluent Inc, Lebanon, NH), to allow suction-free inflow of the blood from the ventricular cavity. On this tip, 3 large lateral inflow orifices provide stagnation-free flow patterns

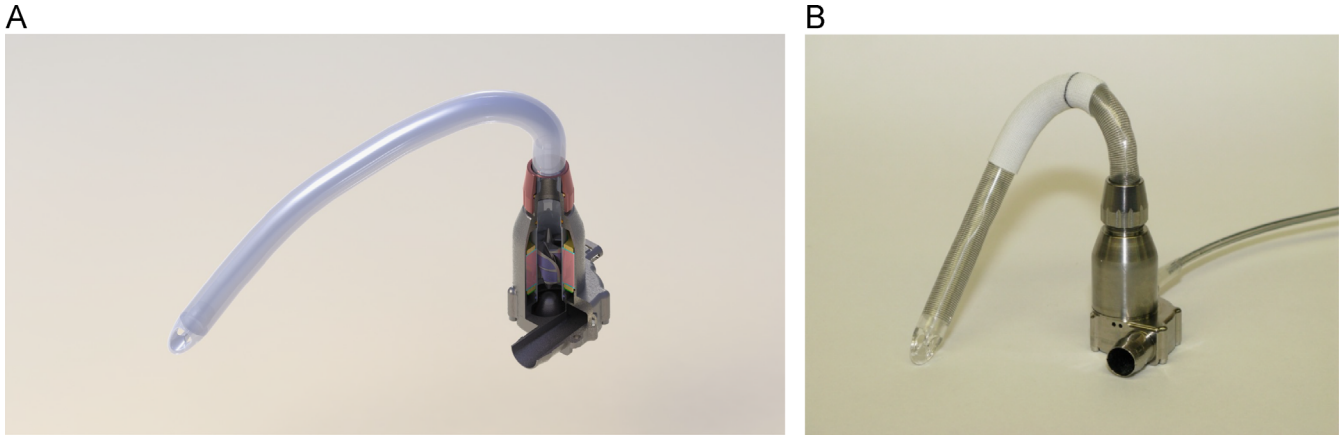

Figure 2 HeartWare MVAD pump (HeartWare, Miami Lakes, FL) with a transatrial cannula is seen in a (A) schematic drawing (human design) and in a (B) photograph (sheep design).