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INITIAL CLINICAL EXPERIENCE OF TOTAL CARDIAC REPLACEMENT WITH DUAL HEARTMATE-II® AXIAL FLOW PUMPS FOR SEVERE BIVENTRICULAR HEART FAILURE

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Introduction

Continuous flow pumps are commonly used to support patients with acute cardiogenic shock and are increasingly used for chronic support in heart failure patients. In the past, pulsatile long-term left ventricular assist devices (LVADs), such as the Novacor and HeartMate-I, provided adequate cardiac support yet they were subject to complications including eventual device failure and infections. With improvements in technology and migration towards axial or continuous flow devices, device miniaturization has become possible, thereby leading to improved anatomical fitting, less vibration and driving noise, and more efficient power consumption. Furthermore, device durability, anti-thrombogenicity, and physiological adaptation to continuous flow pumps appear to be clinically feasible not only for bridge-to-transplant but also for extended longer-term support, namely "destination therapy."[1, 2]

In cases of severe biventricular heart failure, right heart support may be required in addition to left heart support. Using a biventricular assist device (BiVAD) to treat biventricular heart failure is one reasonable option;[3] however, its clinical feasibility remains controversial.[4] Another acceptable option for treating biventricular heart failure is total cardiac replacement with a total artificial heart (TAH).[5] According to clinical results reported by the INTERMACS Study group, the Syncardia pulsatile TAH (Syncardia Systems, Inc., Tucson, AZ, USA) whose implantation resulted in lower postoperative complications and better bridge-to-transplant rates compared to conventional BiVAD implants.[6]

As a similar technology transition from pulsatile to nonpulsatile LVAD, nonpulsatile mechanical circulatory support may be applicable for total cardiac replacement as well, i.e., continuous flow TAH. Unlike the conventional pulsatile TAH driven by pneumatic compression, a continuous flow total artificial heart (CFTAH) would generate absolutely no pulsatility at all. To bring CFTAH into the clinical arena, flow control including the right and left flow balance, inflow suction prevention, and overall physiological adaptation are still remaining issues to be solved.[7] Dr. O.H. Frazier (Texas Heart Institute, Houston, TX) reported the first animal study experiences using a CFTAH implant as a total heart replacement — with two HeartMate II® axial flow LVADs — in 2009, which followed a study using dual Jarvik 2000 pumps in 2005.[8, 9] The animals implanted with the CFTAH in these studies maintained normal physiological parameters for up to seven weeks following device implant. These earlier results were encouraging and suggested the potential future role of a CFTAH for treating biventricular heart failure.

This case report describes our initial clinical experience of total cardiac replacement (complete resection of the heart) with dual HeartMate II® (HM II) axial flow pumps (Thoratec Corporation, Pleasanton, CA, USA) for treating severe biventricular heart failure.

Case Report

Clinical course

The patient was a 25-year-old male, originally diagnosed with nonischemic dilated cardiomyopathy, and was 4-year status post orthotopic heart transplant following chronic HM II LVAD support.[10] He was the first patient supported with the HM II, which is currently the most widely used LVAD. He had the pump implanted at the Texas Heart Institute at St. Luke's Episcopal Hospital in Houston by Dr. Frazier in November 2003 and was supported for 749 days. Following his heart transplant, the patient developed end-stage renal disease and was maintained on chronic hemodialysis in addition to chronic LVAD support. He was electively admitted for dialysis access surgery, during which he suddenly developed cardiogenic shock with cardiac arrest during the operative procedure. He was urgently resuscitated and placed on femoral arteriovenous extracorporeal membrane oxygenation (ECMO) support. Transthoracic echocardiogram showed severely impaired biventricular function with ejection fraction less than 10%. Over the next 24 hours, he continued to be stabilized on full ECMO support and mechanical ventilation. The patient's general condition, along with his hemodynamic parameters, gradually improved on ECMO support, however profound biventricular heart failure and multi-organ dysfunction remained as life-threatening conditions. His case was discussed at the transplant review board, and he was deemed to be too high-risk for urgent heart transplant; therefore, further mechanical support options were proposed. After discussions with the Institutional Review Board at The Methodist Hospital, the use of dual HM II devices was granted as a compassionate application for severe biventricular heart failure status post-orthotopic heart transplantation in this critically ill patient.

Intra-operative findings and surgical procedures

On May 3, 2010, the patient was taken to the operating room; upon entering the chest by redo sternotomy, there were noted to be numerous adhesions around the right ventricle. The ascending aorta was not recognizable and dense adhesions also surrounded it. During the dissection, a short period of hypothermic circulatory arrest (femoral cannulation) was performed to control surgical bleeding. The heart was observed to be diffusely enlarged and exhibited signs of severe biventricular failure. The cardiac tissue was extremely friable and the ventricular tissue would have not held any suture material. Therefore, both ventricles were completely excised and two HM II axial flow pumps were placed in order to achieve full hemodynamic support as a total cardiac replacement therapy. Both ventricles were excised and the atrial cuffs were then trimmed in order to prepare them for anastomosis (Figure 1). Prior to sewing ring and pump placement, two 20-mm Hemashield grafts (MAQUET, Inc., Wayne, NJ, USA) were anastomosed to the pulmonary artery and the ascending aorta using a 5-0 Prolene running suture (Figure 2). Next, the left atrial cuff was then "buttressed" to the sewing ring by using interrupted 2-0 Ti-Cron pledgeted sutures (Figure 3). Following the left sewing ring placement, another sewing ring was secured to a 38-mm Hemashield graft extension that had also been sewn to the right atrial cuff (Figure 4). To avoid collapse of the right inflow graft chamber by possible inflow suction, BioGlue® surgical adhesive (CryoLife, Inc., Kennesaw, GA, USA) was used by applying it to the outside walls of the Hemashield graft. The previously placed vascular graft "extensions" to the aorta and pulmonary artery were then sewn to the 16-mm right and left pump outflow grafts included in the HM II LVAD package. Finally, the inflow cannulas for the HM II pumps were positioned into each sewing ring, and the previously placed outflow grafts were attached (Figure 5). Final orientation of both pumps is depicted in Figures 6 and 7. The patient tolerated weaning from cardiopulmonary bypass, and both pumps

Figure 1. Schematic of the heart resection and atrial trimming for sewing ring placement. CPB was established by using the femoral ECMO venous cannula with another cannula directly inserted into the SVC through the right atrium. The previously placed femoral arterial cannula was used as the arterial return for the bypass circuit.

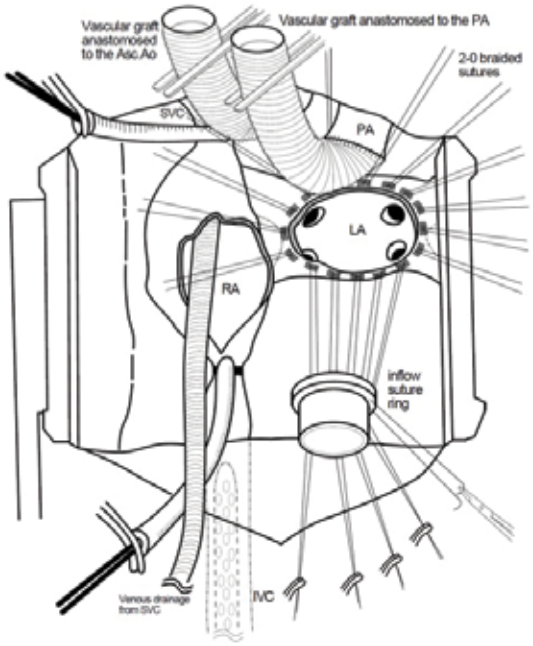

Figure 2. Schematic of vascular graft "extensions" and preparation for the left atrial sewing ring attachment. 20-mm vascular grafts were sewn end-to-end and anastomosed to the ascending aorta and the pulmonary artery. Ti-Cron sutures with pledgets were placed around the circumference of the left atrial cuff.

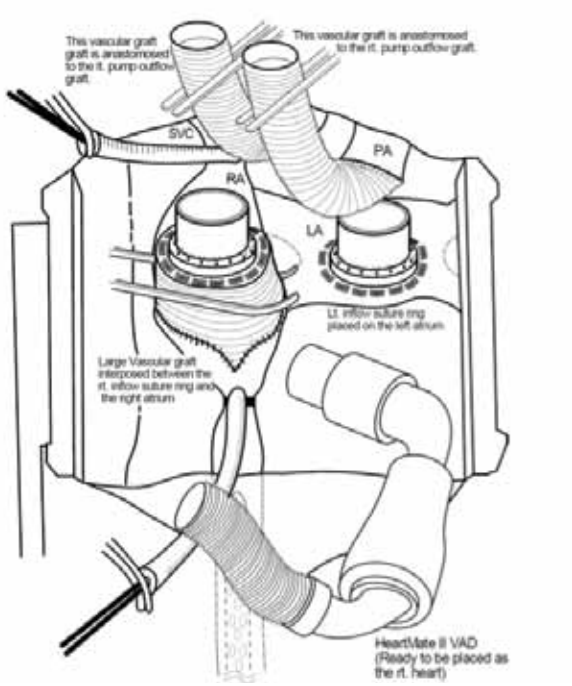

Figure 3. Schematic of the atrial sewing ring positions. The left inflow sewing ring was directly sewn to the left atrial cuff. A 38-mm vascular graft was interposed between the right inflow sewing ring and the right atrium to form a reservoir for venous return (neo-atrium).

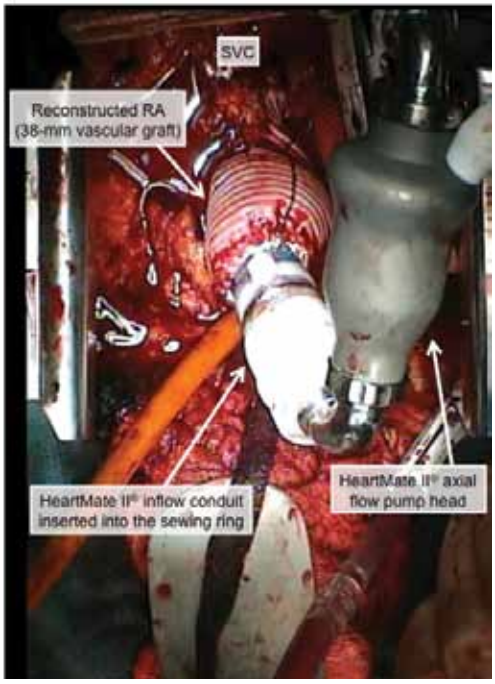

Figure 4. Surgical view of the reconstructed right atrium and HeartMate II® placement for the right heart. A 38-mm vascular graft was sewn to the right atrial cuff and the other graft end was anastomosed to the sewing ring. The inflow conduit of the HeartMate II® axial flow pump was inserted into the sewing ring and secured with tie bands..

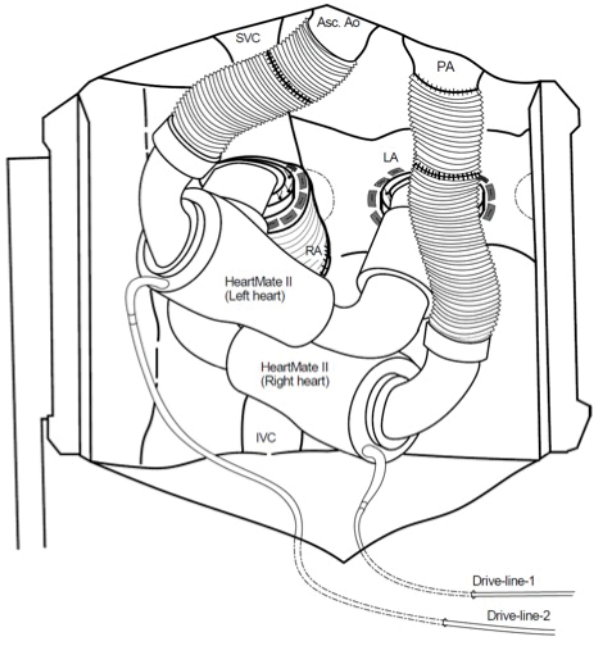

Figure 5. Schematic of the dual HeartMate II® axial flow pump placement for total cardiac replacement. Two pumps were placed in the mediastinum and each outflow graft was sewn to the ascending aorta and pulmonary artery as previously described.

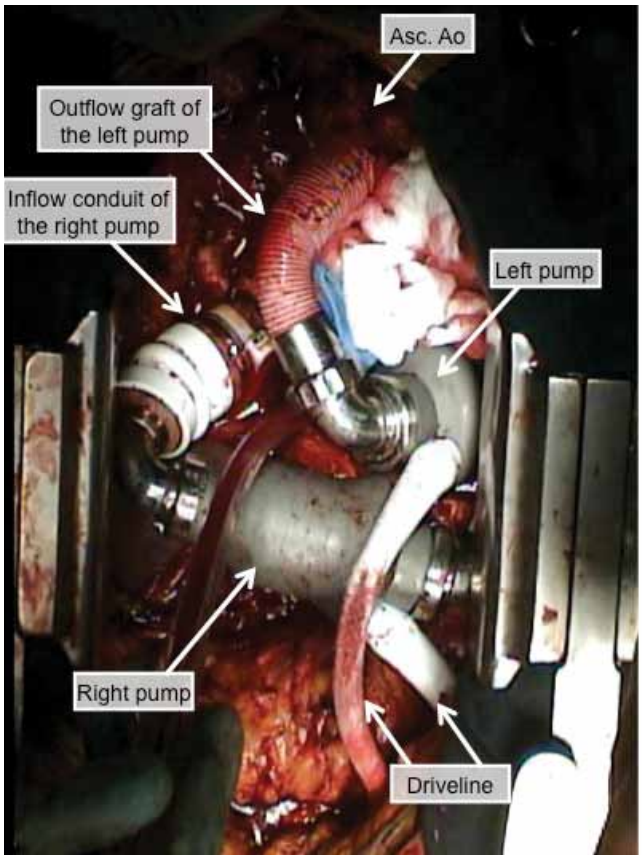

Figure 6. Surgical view of dual HeartMatell® axial flow pump placement. The outflow graft of the right pump and the inflow conduit of the left pump are hidden behind the chest retractor.

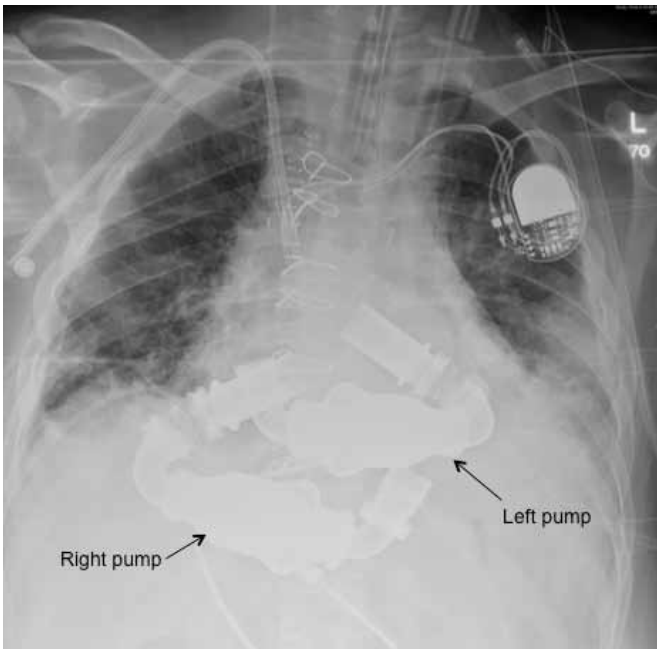

Figure 7. Chest X-ray (A-P view) after total cardiac replacement with Dual HeartMate II® devices.

were allowed to flow while the outflow grafts were needle de-aired. The LVAD was eventually run at 9,200 rpm while the RVAD was run at 8,000 rpm. The initial flows were estimated by the device as 3.5 L/min on the right and 4.2 L/min on the left. During the rpm adjustment of the pumps in the operating room, it was noted that the RVAD had a tendency to "suction down" and partially collapse the right atrium/graft when the rpm was increased above 8,600 rpm. Therefore, the RVAD was only allowed to function at the lowest rpm settings (8,000-8,600) for the remainder of the patient's support.

Postoperative clinical course

After several trips back to the operating room for bleeding, the patient's hemodynamic parameters stabilized by post-op day 2. The LVAD was maintained at 9,200–9,400 rpm and RVAD flow was limited to 8,000–8,600 rpm, which resulted in estimated flows of 4.8 L/min on the left and 3.8 L/min on the right. The mean arterial pressure was maintained around 70 mm Hg, and the patient's end organ function slowly improved (i.e., improvement in liver function tests, arterial blood gas). Also of significance, the patient's pulmonary function remained stable throughout the duration of his support with normal blood gases and oxygen requirement of 40–50% on the ventilator. Serial chest X-rays also demonstrated clear lung fields without evidence of congestion or infiltrate (Figure 7).

Despite eventual hemodynamic stabilization, the patient developed severe brain injury and never regained consciousness, most likely secondary to his previous cardiac arrests. After one week of support with the dual HM II pumps, the patient was withdrawn from support because of irreversible neurologic injury. An autopsy was performed and confirmed the diffuse cerebral edema and brain injury. The pumps and outflow grafts were also analyzed and revealed no evidence of thrombus or any kinking of the grafts.

Discussion

The HM II axial flow LVAD is a FDA-approved continuous flow (nonpulsatile) mechanical circulatory assist device primarily designed for left ventricular assistance in classical bridge-to-heart transplant[10] and was also approved for destination therapy. In this case, our patient had severe biventricular heart failure and was dependent on ECMO support and high doses of vasopressors. Following placement of the devices, the vasopressor drips were weaned, liver tests improved, and pulmonary function remained stable. All aspects which indicate recovery of end organ function. This patient had total bilirubin levels over 40 mg/dL prior to

cardiac replacement, but following biventricular replacement, the total bilirubin levels fell to 13.1 mg/dL within 48 hrs of surgery.

One of the major issues we had was determining the optimal rpm for each pump, especially on the right side. As mentioned before, the HM II displayed flows are only an estimated flow and can be unreliable, especially in a dual configuration. During the implantation surgery, as previously described, we were very careful with the right-sided flows or the remaining right atrial cuff and Hemashield graft (neo-atrium) would partially collapse secondary to "suction" from the pump. This tendency for the right side to collapse was another problem we encountered during the initial operation; however, strictly keeping the rpm on the RVAD at a lower level and reinforcing the graft wall with Bioglue appeared to correct this problem, because the dual HM IIs did provide adequate hemodynamic support for almost eight days. Additional caution was maintained with RVAD flows due to concern over the possibility of pulmonary congestion from high continuous flows and potential alveolar damage; however, as previously mentioned, the arterial blood gases remained within normal limits. It would appear that continuous flow on the right side was well tolerated by this patient and most likely directly affected the left-sided flows as well. From Fraizer's experience with total cardiac replacement in calves, right-sided continuous flow support was well tolerated and in essence controlled the left-sided flows independent of the actual pump rpms.[8] These earlier studies and the current experience with our patient suggest that dual continuous flow pumps provide adequate and even "physiologic" support and automatically respond (by increasing or decreasing blood flow) to alterations in preload and afterload. In conclusion, the dual HM IIs did provide a continuous flow biventricular replacement strategy in this critically ill patient. Further refinements of this dual pump configuration, including optimization of the atrial cuffs, and determination of the optimal right-sided flows will be necessary before larger numbers of patients can be implanted in the setting of a clinical trial.

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