# A Decade of Experience With Continuous-Flow Left Ventricular Assist Devices

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The use of continuous-flow left ventricular assist devices (CF-LVADs) has revolutionized the landscape of mechanical circulatory support for patients with heart failure. Clinical trials are already testing the next generation of CF-LVADs. In this study, our objective was to review our long-term experience with the current generation of CF-LVADs, specifically, the HeartMate (HM) II (Thoratec Corp, Pleasanton, CA). In this single-center retrospective analysis, we evaluated the records of 278 consecutive patients who underwent a total of 302 HM II placements from June 2005 through June 2014. We excluded 11 patients from our final study group, who had previously undergone placement of a HM XVE that failed. We divided the remaining 267 patients into 3 equal groups of 89 patients each, by time period: group 1, June 2005 through May 2009; group 2, June 2009 through January 2012; and group 3, February 2012 through June 2014. To examine differences in survival between our 3 groups, we used time-to-event analysis, including the Kaplan-Meier method. To examine secondary outcomes (including stroke, hemolysis, gastrointestinal bleeding, pump thrombus, and transplant), we used one-way analysis of variance. For our final study group of 267 patients, the total follow-up time was 479.01 patient-years (median, 469 days). The mean age of patients was 57 years; 81.4% were male. In all, 209 (78.9%) patients underwent HM II placement as a bridge to transplant; 58 (21.1%), as destination therapy (DT). The overall survival rate was 94% at 30 days, 77% at 1 year, 65% at 2 years, 60% at 3 years, 50% at 4 years, and 48% at 5 years. In bridge to transplant patients, the survival rate was 78% at 1 year and 66% at 2 years; in DT patients, 70% and 60%. In group 1 patients, the survival rate was 94% at 30 days, 64% at 1 year, and 48% at 2 years; in group 2, 93%, 88%, and 76%; and in group 3, 94%, 77%, and 73% ($P = 0.003$). In the later years of our study period, from June 2009 onwards (ie, in groups 2 and 3), we noted a statistically significant increase in HM II placement as DT, a reduction of driveline infections, increasing pump exchange, increasing hemolysis, a reduced frequency of transplants, and an improved survival rate (as compared with the earlier group 1). The HM II has favorably influenced the outcomes of patients with end-stage heart failure, yet major complications still limit their survival. Improving compatibility between the pump and the individual host patient, enhancing anticoagulation strategies, and developing a totally implantable pump might further reduce complications thereby improving survival times and allowing CF-LVAD placement to be a true long-term alternative to a heart transplant.

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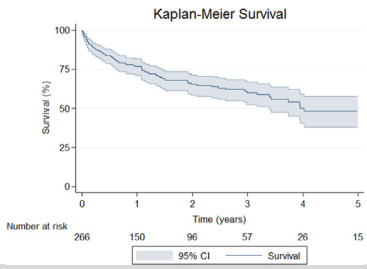


Survival for entire cohort (77% at 1 year, 60% at 3 years, and 48% at 5 years).

**Central Message**

The HM II has favorably influenced the outcomes of patients with end-stage heart failure.

**Perspective**

The HM II has favorably influenced the outcomes of patients with end-stage heart failure, yet major complications still limit their survival. Improving compatibility between the pump and the individual host patient, enhancing anticoagulation strategies, might further reduce complications, and allowing CF-LVAD placement to be a true long-term alternative to a heart transplant.

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## INTRODUCTION

Increasing number of patients are being successfully bridged to a heart transplant (BTT) with a left ventricular assist device (LVAD), with a smaller proportion undergoing LVAD placement as destination therapy (DT). A heart transplant remains the gold standard of therapy for patients with end-stage heart failure; however, a stable cardiac donor pool and persistent morbidity posttransplant limit the wider use of this therapy.

The initial successes in BTT patients in the United States occurred with pulsatile, volume-displacement devices such as the HeartMate (HM) XVE (Thoratec Corp, Pleasanton, CA).[1] Those devices provide excellent hemodynamic support and did improve patient survival rates, but they have significant constraints, including the need for extensive surgical dissection, the requirement for the patient to have a large body habitus, the need for a large-diameter percutaneous lead, and the audible nature of their pump operation. Importantly, their long-term mechanical durability is limited, frequently resulting in reoperations for pump exchange.

Over the last decade, tremendous progress has been made with the use of the newer continuous-flow LVADs (CF-LVADs) such as the HM II (Thoratec Corp) and the HeartWare (Framingham, MA) device; they incorporate CF rotary pump technology.[2-8] Those devices have demonstrated enhanced durability and have provided improved quality of life for extended periods of support. A major advantage is their small size, thereby extending therapy to underserved patient populations including women and even some children. Results have consistently improved over time, but several questions remain with regard to timing of placement, patient selection, patient care, and timing of transplant. Concerns have also been raised regarding the deleterious effects of partial pulsatility, as well as the possibly negative effects in patients who later undergo a heart transplant and thus return to full pulsatility.[9] Despite those concerns, CF-LVADs have rapidly become the standard of care for virtually almost all patients with heart failure who require mechanical circulatory support; thus far, excellent outcomes have been reported.[2-7,10]

Despite the awareness of previously unknown risks of pump thrombus and gastrointestinal (GI) bleeding, the use of CF-LVADs has revolutionized the landscape of mechanical circulatory support for patients with heart failure.[11] Clinical trials are already testing the next generation of CF-LVADs that address some of the limitations of current CF-LVADs such as decreased pulsatility and aortic valve opening. In this study, our objective was to review our long-term experience with the current generation of CF-LVADs. Previously, we published our preliminary experience with HM II placement as a BTT in a smaller number of patients.[12,13] But for our current study, we reviewed our collective experience over a 10-year period involving more than 300 HM II placements: we analyzed patient survival, adverse events, outcomes, and trends in 3 different eras. We hope to use the lessons learned from this large single-center experience to improve outcomes in future LVAD patients by focusing on patient selection and clinical care issues.

## METHODS

### Patients

In this single-center retrospective analysis conducted at our large academic quaternary care hospital, we compiled our clinical outcomes database to include the records of patients who underwent HM II placement. Our 10-year study period was from June 1, 2005 through June 30, 2014. We evaluated all patients, preoperatively and postoperatively, in a multidisciplinary manner, collaborating with the cardiothoracic surgery service and the heart failure cardiology service. Our database and study were approved by the University of Minnesota institutional review board, which waived the need for consent from individual patients.

### HeartMate II

The HM II consists of an internal axial-flow blood pump with a percutaneous lead that connects the pump to an external system driver and power source (as previously described). Details of HM II function and the placement technique have also been previously described.[2,3]

### Patient Care

Per our local practice at the University of Minnesota, we set the speed of the HM II to provide adequate cardiac output and achieve optimal left ventricular decompression, while maintaining a pulsatility index >3.5-4.0. In addition, we usually adjusted the fixed-rate speed of the HM II to maximize left ventricular decompression and to improve cardiac output, simultaneously attempting to allow for at least a 1:3 ratio of aortic valve opening. We