

Advances in LVAD Design:

Improving Reliability and Minimizing Risk of Stroke and Thrombosis



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Left ventricular assist devices (LVADs) have become an established treatment for patients with advanced heart failure either as a bridge-to-transplantation (BTT) or as a long-term option for those who do not qualify for cardiac transplantation (destination therapy or DT). The addressable population is growing: nearly 100,000 people in the United States alone are currently estimated to be potential VAD candidates, although only a tiny fraction of that number have received them. The HeartMate II is Thoratec's first-line continuous flow chronic LVAD. It was approved as a BTT therapy in the United States in April 2008 and as a DT for patients ineligible for transplantation in January 2010. The device is also approved and being distributed in Europe, Asia, Australia, and Canada.

While early LVADs were large pulsatile volume-displacement devices, we have seen a recent dramatic switch to miniaturized continuous flow devices, with 98% of LVADs implanted between January 2010 and June 2010 being of the latter design.¹ Continuous flow devices are not only smaller, but also more reliable, offer better long-term survival, and present a better adverse event profile.² HeartMate II, the most widely used continuous flow LVAD, embodies unique and elegant design features that offer efficacy, safety, and reliability while minimizing the risk of complications.

Open pathways, smooth flow

The HeartMate II has only one moving part: the rotor that spins on blood-immersed ruby bearings located at either end of the assembly. Blood enters the pump from the apex of the left ventricle via an inflow conduit; the spinning rotor moves the blood through the pump to an outflow graft and ultimately back to the native circulation via the



ascending aorta. The pump is axially configured, with blood flowing past the rotor parallel to the axis of rotation, allowing for a smaller size and weight compared to earlier devices and eliminating the need for a blood reservoir. Open-flow paths also help to maximize washing of the pump and conduits, contributing to the lowest published stroke and thrombosis rates among continuous flow LVADs.³

In the HeartMate II, large channels passing through the inlet stator, rotor, and outlet stator work synergistically to provide a smooth flow path, minimizing shear stress and turbulence. By maintaining low shear stress and shear exposure time, the risk of damage to cellular components of the blood is reduced. With shear stress controlled appropriately and the inner walls of the LVAD continually washed, platelet aggregation is avoided and thrombosis risk is also reduced. In a recent study of patients who received the HeartMate II as destination therapy, plasma-free hemoglobin values remained low 12 months postimplantation, an indicator of low rates of shear and hemolysis.⁴

Textured surfaces

Many LVADs have been designed with smooth interior surfaces to minimize sites for thrombus nucleation. Despite this, the incidence of thromboembolic complications associated with some LVADs has been reported to be as high as 29%.⁵ More than 20 years ago, Thoratec began experimenting with textured surfaces in the wider, open-flow areas of their LVADs. This novel approach to minimizing thromboembolism was quickly found to reduce the risk of complications in HeartMate® recipients⁵ and has been refined and customized further for inclusion in the HeartMate II. A sintered titanium

surface is applied to the wide bore areas to stimulate the growth of a pseudoneointima,⁶ eliminating direct interface between the prosthetic material and blood elements and reducing coagulation needs over time. Some continuous flow devices that have not adopted this process have been found to have higher rates of pump thrombosis.⁷ The efficacy of this biologic layer is supported by the low rates of thromboembolic complications seen with the HeartMate II.

Flexible inflow conduit accommodates LV movement and reverse remodeling

There is significant evidence that LVAD unloading can cause reverse cardiac remodeling and myocardial function to recover.^{8,9} In 4.0% to 9.3% of cases, the benefit is sufficiently marked to allow for device explantation,^{10,11} although in a very recently published study,¹² the combination of LVAD support and intensive medical therapy in 19 individuals with nonischemic dilated cardiomyopathy led to an explantation rate of 63.2%. Before device removal, at low flow for 15 minutes, the mean ejection fraction was 70%.

The inflow conduit of the HeartMate II includes a flexible section consisting of a woven polyester graft that is reinforced and covered with a flexible silicone sleeve. This section allows for relative movement between the native left ventricle and the LVAD in response to reverse remodeling of the heart over time, while simultaneously maintaining cannula position inside the left ventricle.

The flexible section can also prevent potential inflow misalignment and impingement against the ventricular wall, as might occur during a “suckdown” event, which is an extreme case wherein insufficient volume entering the ventricle results in the left ventricle wall being pulled towards the VAD’s inflow conduit. To further reduce suckdown risk, the HeartMate II has a speed control algorithm that reduces the pump speed to accommodate a sudden drop in blood volume delivered to the device or in the event of any interference across the inlet cannula. The speed change allows the ventricular volume to recover and the device resumes normal operation after hemodynamics normalize.

Low stroke and thrombosis risk

As with all medical therapies, clinical outcomes are paramount. The HeartMate II offers the lowest published rates of stroke and pump thrombosis during long-term outpatient support^{8,13} (Table 1). Importantly, Boyle and colleagues determined that the HeartMate II could be run at lower levels of anticoagulation than predicted without elevated risk of thromboembolism or pump thrombosis. In response to these findings, INR recommendations for patients implanted with a HeartMate II have been reduced to between 1.5 and 2.5 to minimize hemorrhagic risk.

Table 1.

Events After Discharge	All events (220 PYs)		
	Pts (%)	Events	Events/PY
Thrombotic Events			
Ischemic Stroke	8 (2.4)	9	0.041
Pump Thrombosis	3 (0.9)	3	0.014
Hemorrhagic Events			
Hemorrhagic Stroke	7 (2.1)	7	0.032
Bleeding Requiring Surgery	4 (1.2)	4	0.018

The published outcomes are supported by HeartMate II’s market leading position, with more than 8,000 implants[†] worldwide and its standing as the only continuous flow device with an FDA bridge-to-transplantation or destination-therapy indication.

In summary, the HeartMate II LVAD is an elegant, precision-engineered device: it has only one moving part and offers uninhibited blood inflow from the left ventricle and outflow to the ascending aorta. Captured within that design elegance are decades of technological advancement—the highly customized textured surfaces that minimize embolic complications, the ability to accommodate reverse remodeling with a flexible inflow conduit, and reliability that assumes support for more than a decade. The advantages of this engineering design are apparent in the HeartMate II’s excellent safety record, resulting in its being the most used chronic LVAD in history.

⁸Based on published data from multicenter experience and separate studies, which may involve different patient populations and other variables. Please refer to the HeartMate II Instructions for Use about indications, contraindications, adverse events, warnings, and precautions (<http://www.thoratec.com/medical-professionals/resource-library/ifus-manuals/heartmate-ii-lvad.aspx#levelFour>).

[†]As of September 8, 2011. Robert W. Baird & Co. 2011 Health Care Conference Investor Presentation.

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