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EDITORIAL COMMENTARY

Coning down on the effects of an left ventricular assist device engineering enhancement

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Left ventricular assist devices (LVADs) represent one of the quintessential engineering accomplishments that have improved the quantity and quality of life for patients with end-stage heart failure. Although the primary function of LVADs is to augment or replace native cardiac output, they also have strict engineering requirements related to minimization of size, ease of implantability, and interaction with the hematologic system. These challenges have been continuously addressed during the relatively short history of the various LVADs available for clinical use.

In this issue of the *Journal*, a study by Tarzia and colleagues¹ highlights the midterm clinical effects of a design change in the Jarvik 2000 LVAD (Jarvik Heart, Inc, New York, NY). The iterative improvement of this axial-flow device is centered on the bearing design: the first generation used a pin and sleeve configuration, whereas the newer generation device uses a cone and seat design. In this retrospective study, the investigators used the Italian registry to identify 99 cases of patients who received the Jarvik 2000 LVAD in a 5-year period. Because the study time frame

straddled the change in bearing design, 2 distinct groups of patients, derived from the era of implantation, were compared. The 2 groups had similar baseline characteristics. By applying various statistical methods, Tarzia and colleagues¹ found that the group of patients who had received the device with the newer cone bearing design had significantly lower rates of cardiovascular-related death,

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Central Message

Iterative engineering improvements in left ventricular assist device design do affect clinical outcomes.

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hemorrhagic complications, stroke, and right ventricular failure. Two major strengths of the study deserve mention here. First, Tarzia and colleagues¹ have analyzed the largest cohort of patients with the Jarvik 2000 device published to date. Second, this is a study of a rare scenario of a specific iterative change in a particular LVAD design. A weakness of this study is that it was not a prospective comparison of the 2 versions of the LVAD, but one can argue that such an undertaking would have raised ethical questions in light of the favorable findings of the cone bearing design in preclinical studies.

What spurred the evolution of the current generation of the Jarvik 2000 LVAD? The development of the bearing enhancement first occurred in the Jarvik 2000 pediatric device (a scaled-down version of the adult device and one of several pediatric devices that had their development supported by the US National Heart, Lung and Blood Institute's Pediatric Circulatory Support program²). In vivo animal studies of the pediatric device demonstrated that the pin bearings were the site of significant thrombus formation.³ An early clinical study of the older generation of the adult device did not demonstrate this as an issue, perhaps because the length of support was much shorter than in the Italian registry study,⁴ although a more recent case report has described a severe thrombotic complication in the first-generation adult device.⁵ Iterative enhancement of the pediatric device resulted in the cone and seat design, which was subsequently shown to avoid thrombus formation in vivo in addition to demonstrating significantly improved hydrodynamic efficiency in vitro.^{6,7} This bearing design improvement was then implemented in the adult device.

Mechanical circulatory support devices seek to emulate the human heart, one of the most efficient mechanical

pumps. Here we have seen that the more efficient version of the Jarvik 2000 pump yields superior clinical outcomes. Perhaps pump hydrodynamic efficiency should be further evaluated as a predictor of clinical outcomes, because pump inefficiency may be related to turbulent flow, activation of the thrombotic system, and damage to blood components. Finally, a lesson to be learned from this story of bearing improvement in the Jarvik 2000 is that pediatric device development and enhancement can impart considerable benefit with respect to larger adult devices, and this should provide impetus for device companies and the US National Institutes of Health to continue pediatric device development. Certainly, with respect to the Jarvik 2000 LVAD, coning down on the bearing design in the pediatric device has led to improvements in the adult device and in clinical outcomes.

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