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# Commentary: Is a novel bioprosthetic valve durable? Time will tell

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**CENTRAL MESSAGE**

Only time will tell whether early favorable outcomes of Cingular bioprosthetic valves will translate into excellent late survival, durability and functional outcomes.

The use of bioprosthetic valves for aortic and mitral valve replacement is becoming increasingly popular.[1,2] Given the projected dramatic increase in the elderly population in the near future, there is an increasing need for durable bioprosthetic valves. The ideal bioprosthetic valve should have excellent hemodynamic performance, a minimal risk of structural valve deterioration, excellent functional outcomes, and low valve-related morbidity and mortality. Creating such a valve requires well-designed in vitro hydrodynamic performance studies, in vivo preclinical animal studies, and high-quality first-in-human clinical studies.[3]

In this issue of the *Journal*, Chen and colleagues,[4] under the auspices of Cingular Biotech, present premarket clinical outcomes of their new bioprosthetic valve, a modification of the Carpentier–Edwards PERIMOUNT valve designed to achieve a large effective orifice area (EOA). The early clinical trial of this novel Cingular valve included 197 patients who received 148 aortic valves, 36 mitral valves, and 13 double valve replacements. The 1-year outcomes were excellent, with a very low rate of valve-related complications (0.5%) and excellent EOA, associated with only 1 episode of moderate patient–prosthetic mismatch (PPM) in an aortic valve replacement.[4] Notably, the indexed EOA, especially for the 19-mm and 21-mm valve sizes, is significantly larger than that of other currently available bioprosthetic valves. The same group of cardiovascular surgeons and research engineers developed the concept of this novel valve, manufactured the valves, and performed the preclinical animal studies[5] and the premarket clinical trials.[4-6] The authors should be congratulated on their dedicated work in developing this novel Cingular valve that has yielded promising 1-year outcomes.

However, several issues remain to be addressed to further determine the safety and efficacy of Cingular valves. First, the inclusion of aortic, mitral, and double valve replacements together makes it difficult to interpret the outcomes. The 2010 US Food and Drug Administration (FDA) guidelines state that "pooling the data from the aortic and mitral valve position should be avoided" when evaluating new heart valve prostheses.[3] These guidelines also specify that the sample size for safety and efficacy evaluation should be a minimum of 400 valve-years for each valve position and 800 valve-years for double valve replacements.[3] Unfortunately, however, the sample size of this study of the novel Cingular valve was limited to 148 valve-years, 36 valve-years, and 13 valve-years for aortic, mitral, and double valve replacement, respectively, owing to the limited observational period of this study.[4] Although the target age range of the study protocol was 60 to 85 years, the patients in this cohort were relatively young (mean age, 66.9 years) and represented very low-risk patient groups (mean Society for Thoracic Surgeons–predicted mortality of 1.6%). This may have contributed to the reported excellent 1-year outcomes of the Cingular bioprosthetic valve.

Obviously, further long-term study is warranted, and studies should include patients with a wide range of age and preoperative risks. Long-term durability also needs to be tested in terms of various important metrics, including structural valve deterioration, development of PPM, as

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well as other indices proposed as new objective performance criteria.[3] Only time will tell whether the Cingular valve is one step closer to the ideal bioprosthetic valve.

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