The show must go on

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The article in this issue of the *Journal* by Goldman and colleagues¹ documents the “midterm” outcomes with the Trifecta bovine pericardial valve (St Jude Medical, Inc, St Paul, Minn) for aortic valve replacement. “Midterm” is in quotes, because only 157 of 710 patients were followed up to 6 years, with a median patient follow-up of 5 years. This report is a subset of the original prospective premarket approval study of this bioprosthesis published by Bavaria and associates,² in which 710 patients of the original 1014 at 11 of 21 enrollment centers composed the current cohort of longer term follow-up according to the original protocol. The outcomes in terms of valve-related events are within expected objective performance criteria, and the prosthesis is an effective replacement device at this stage of follow-up. This being said, several points need to be raised.

First, freedom from all hemorrhage at 6 years is only 83.7%, versus 91.7% at 1 year. One would expect freedom from hemorrhage to increase with time as patients are have their postoperative warfarin regimen discontinued after center-specific 3- to 6-month administration, which is the advantage of a bioprosthesis. These results may be biased negatively in that inclusion criteria allowed patients who were receiving preoperative anticoagulation to be enrolled in the trial.

Second, structural valve degeneration occurred early in 11 patients as a result of leaflet calcification (N = 10) and a leaflet tear (mean age, 64.1 ± 11.8 years). Although the mean age in the study group was 72.4 years, this finding may also be negatively biased in that patients as young as 49 years, one of whom required early reoperation, were enrolled under the inclusion criteria. Valve-in-valve therapy of failed bioprostheses may only be a pipe dream, because 72% of study patients had valve size 23 mm or less, and Azadani and colleagues,³ on the basis of pulse duplicator studies, indicate that such patients would not be effectively treated by this means.

Finally, and most importantly, it is common knowledge that at 12 to 15 years the downward curve of structural degeneration for US Food and Drug Administration–

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Central Message

The test of time is still required.

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approved biologic valves steepens, despite anticalcification treatment. In the series of reoperative prosthetic valve replacements of Potter and associates,⁴ the mean age of biologic prosthesis replacement was 8.6 years. In this report of Goldman and colleagues,¹ the effective orifice area and effective orifice area index decreased by small but significant increments from 1 to 3 to 6 years, and the mean gradients increased similarly (see that article's Figure 2 and Table E1). Whether these data portend earlier structural valve degeneration remains to be recorded. Continued follow-up of this cohort of patients is therefore mandatory.

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