Reply to the Editor:

We are gratified by Dr Anderson's solid endorsement of our editorial, helping to clarify this rather confused and confusing situation surrounding the use of the word "actual" in the assessment of intrinsic valve performances. We fully agree with him regarding the importance of the concept of competing risks environment. His proposals on reporting long-term experiences with replacement heart valves are excellent, and we recommend that future authors follow his advice.

The letter by Grunkemeier, Takkenberg, and Jamieson incorrectly summarizes in its first paragraph the content of our editorial and therefore adds unnecessary confusion. Dr Bodnar was probably the first to introduce competing risks to cardiac surgery; Dr Blackstone and colleagues have used competing risks analyses extensively in multiple settings of adult and, particularly, congenital heart disease, and both will continue to do so to answer questions that methodology was designed to answer. The method is not the problem! The problem is its inappropriate use in answering questions related to intrinsic properties of heart valve substitutes, such as comparative durability. From its beginning, our editorial was clear about the specific, focused context of our remarks. Rather than restate the entire editorial to make 1 point clear, perhaps an analogy would be helpful.

Pretend we wish to compare durability (tread life) of 3 brands of tire. (We understand that, just like structural valve deterioration [SVD], this is a continuous process and not an event; for simplicity, however, we will estimate durability by the time to change tires because of excessive tread wear, just as we may estimate SVD by time to valve replacement.) Likely there are specific risk factors for tire durability, but let us imagine that miles traveled is the strongest (just as young age is the strongest correlate of SVD). Now, let us say that our study of tire durability for brand A is dominated by a fleet of cars operated by traveling salespersons, study of brand B by commuters living within 5 miles of work, and study of brand C by mothers with children involved in many after-school activities. After a stated period, most salespersons have had to change tires, a number of mothers have, but few short-distance commuters have. Should we conclude that

A and C tires wear out too fast, and we should switch to brand B? If we instead compare the tires in a distance-specific fashion using time-to-event (actuarially based) analysis methods, we would be getting closer to a fair comparison of brands A, B, and C by isolating tire properties from the driving specifics of their owners. In the case of SVD, the only universally found risk factor is age of patient at implant, so age-specific durability provides a reasonable comparison of bioprosthetic device durability. As with the tires, estimates of durability are properly made by time-to-event-type analyses.

You may then ask: What tire should we recommend for the driving habits of a given person? The answer may well depend on how long different people intend to keep their cars. A person who leases a new car every 3 years no matter how little he or she drives may never need to change tires. Trading in a car, like death of a patient, is a competing risk. For someone who drives little, there is no reason to pay a premium for a tire of superior durability if at trade-in there is unlikely to be much tread wear! However, it is important to understand that the car-trading habits of owners do not themselves affect intrinsic properties of the tires. So, interesting as competing risks analysis is for answering some questions such as those posed, for simply comparing intrinsic durability of tires, these trading habits are extraneous and should not be allowed to confound the comparison.

Choice of a prosthesis for a given patient, like choice of a tire, may well depend on a number of factors, such as the patient's expected longevity, which itself has many correlations that are unrelated to intrinsic properties of the device. These are appropriately evaluated by competing risks analyses. However, longevity of the person, like car-trading habits, is a far more complex matter than the intrinsic properties of the prostheses. Estimates of whether or not a patient will live to experience SVD of their prosthesis will be different for every patient, despite the prosthesis retaining its unchanged intrinsic durability.

It is important to recognize that in *both* time-to-event and competing risks methods, time to SVD and time to death are assumed to be completely independent of one another. Thus, the fundamental "actuarial" calculation for each component of a

competing risks analysis can be performed independently of one another, after which a mathematical combination is made. Thus, actuarial estimates are fundamental and unchanging, whereas competing risk estimates will vary, depending on what set of events is considered competing or ignored. (You may protest that it is irrational to think there is no linkage between SVD and death, and you are probably right. However, that is the assumption that both "actuarial" and competing risks methods assume. Methods for dealing with linked events, called methods for "informative censoring," are still not well developed.)

In conclusion, we suggest that Drs Grunkemeier, Takkenberg, Jamieson, and Miller need to realize the magnitude of the mistake they make. Actuarial analysis and cumulative incidence assessment are not *competing* but *complementary* methods. One is apple, the other orange, and oranges should not be blamed for not being apples. The question is not which is better—the question is which should be used for what purpose. Cumulative incidence cannot be used to assess let alone compare intrinsic valve properties. We were not advocating that articles employing competing risks analysis appropriately be "banned" from our journals but that research focused on long-term intrinsic performance of replacement heart valves and their comparison not be published with inappropriate analyses of competing risks.

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doi:10.1016/j.jtcvs.2006.03.070

Reporting "actual freedom" should not be banned

To the Editor:

The life of a bioprosthetic heart valve usually ends as a result of structural valve deterioration (SVD) or death of the patient. In this competing risks situation, the probability of SVD is estimated by the cumulative incidence function, sometimes referred to as "actual" analysis.

The editorial by Bodnar and Blackstone published in the January 2006 issue of the *Journal*¹ criticized this method and recommended its prohibition. Specifically,