Durability of tissue valves: Only time will tell?

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Disclosures: Author has nothing to disclose with regard to commercial support.

Received for publication May 31, 2017; accepted for publication June 5, 2017; available ahead of print June 29, 2017.

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J Thorac Cardiovasc Surg 2017;154:1243-4

0022-5223/\$36.00

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<http://dx.doi.org/10.1016/j.jtcvs.2017.06.007>

Durability has been one of the 2 most important cornerstones for widespread acceptance of a tissue valve. The other one is hemodynamic performance. Newer-generation tissue valves have been associated with improved durability,¹ a perception that has contributed to the ever-growing use of tissue valves for aortic valve replacement independently of age, with the use of mechanical valves becoming almost negligible.² Thus, mechanisms of tissue valve failure should be important.

However, current practice often counteracts current evidence. For instance, transcatheter tissue valves increasingly are implanted in patients with lower risk (and therefore longer life expectancy).³ Their long-term durability is currently unknown. The increasing use of tissue valves for conventional aortic valve replacement is accompanied by growing evidence for the superiority of mechanical valves regarding hemodynamics and survival.⁴ The often quoted valve-in-valve option, which also has been used by Kalra and colleagues⁵ in this issue of the *Journal*, to treat 2 Trifecta (St Jude Medical, Saint Paul, Minn) failures may not be the answer to all durability questions, at least in 2017.⁶ Finally, valves with the best documented durability may not be the newest ones.⁷

Because optimal hemodynamics may be associated with better results (possibly including survival and durability), the Trifecta filled a gap for tissue valves, because its new design and sizing strategy resulted in superior hemodynamics in almost all published reports.^{8,9} In addition, durability in in vitro accelerated wear testings has been remarkable (<https://www.sjm.com/~media/galaxy/hcp/featured-products/structural-heart/trifecta-gt/ide10cvd1858en1-trifecta-white-paper-a4-ous.pdf>). Thus, reports such as the one by Kalra and colleagues,⁵ demonstrating a new and early failure mechanism, should raise significant attention in the community, despite the discrepancy of evidence and practice.

Kalra and colleagues⁵ demonstrate that 8 of approximately 700 Trifecta valves failed within a mean of 32 months as the result of pannus formation on the inside of the

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Central Message

Durability is key for tissue valves. Internal pannus formation is rare but an early mechanism for Trifecta (St Jude Medical, Saint Paul, Minn) failure. However, true relevance assessment requires long-term follow-up.

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prostheses and leaflet calcification around the posts. This specific mechanism is unusual because pannus formation has been considered a characteristic mechanism for late failures of pericardial valves.¹⁰ It also cannot be addressed easily by valve modifications because the cause is not clear. For other reported mechanisms (ie, leaflet tears, possibly the result of mechanical stress during implantation) and reasons, the company modified the design and valve holder for the new Trifecta GT model (<https://www.sjm.com/~media/galaxy/hcp/featured-products/structural-heart/trifecta-gt/ide10cvd1858en1-trifecta-white-paper-a4-ous.pdf>).

Currently, the number of failures in the study by Kalra and colleagues⁵ still seems acceptably small, with approximately 1% of all implants (although the number may be higher for lack of complete echocardiographic follow-up). All other reports have presented excellent rates for freedom from structural valve deterioration,^{8,9} thus far. Therefore, it seems safe to continue using the Trifecta (specifically for its hemodynamic properties). However, careful follow-up of all tissue valves seems to be a “must.” In the end, one (possibly unpleasant) principle applies to the durability of all new tissue valves (conventional or transcatheter): “Only time will tell.”

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