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EDITORIAL COMMENT

Does Orientation Matter?*

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From a surgical perspective, the orientation of bioprosthetic aortic valves was never much of a question. Under direct visualization, the valve can be placed quite easily in an anatomic orientation. When the coronary ostia are located in their normal positions, separated by 120°, such orientation allows the surgeon to achieve the greatest distance between ostia and valve posts. Offsetting the valve orientation from normal makes sense only when the coronary ostia have aberrant origins, such as an 180° separation, in cases in which normal positioning of the valve would cause 1 post to lie in front of 1 of the coronary ostia.

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For transcatheter valves, similar orientation becomes more difficult and is the subject of the study by Fuchs et al. (1) in this issue of *JACC: Cardiovascular Interventions*. The authors asked 2 questions: 1) how often are surgical and transcatheter aortic valve replacement (TAVR) valves placed in alignment with native aortic valve commissures; and 2) does the alignment matter? Using a structured approach to compare orientation of the commissures of native and prosthetic valves, they defined alignment as normal (0° to 15° deviation), mild (15° to 30° deviation), moderate (30° to 45° deviation), and severe (45° to 60° deviation). The answer to the first question is not surprising. All surgical valves but 1 were aligned normally. However, the alignment of transcatheter valves was distributed randomly among the various orientations. The answer to question 2 is more interesting. If orientation is really important then random distribution of orientations is problematic. The degree of alignment did not affect transvalvular gradient, coronary flow (in a computational fluid dynamics simulation), leaflet thickening, or paravalvular leak. However, more central aortic regurgitation was observed among valves with moderate or greater misalignment versus those with less (6.3% vs. 1.0%). Why this should be is less clear. Does commissural malalignment itself cause asymmetric distortion of the valve frame and subsequent misaligned closure of the prosthetic leaflets, or does heavy calcification cause both malalignment and frame distortion? All in all, the orientation of the TAVR valve did not appear to have significant clinical impact on the early outcomes.

If these findings are not important in the short term should we care? In theory, at least, we should, as stress on the valve leaflets may limit their durability. TAVR valves rarely assume the shape with which they were designed to function optimally with minimally stressed leaflets. In a canine model, the radius of the base of the aortic valve decreases during systole, while that of the commissures increases, causing the open valve to assume a cylindrical configuration (2). In patients with aortic stenosis, though, the valve annulus is usually eccentric and deformed by calcium deposits. In as many as one-fifth of patients undergoing TAVR, the ratio between major and minor axes (the eccentricity index) actually exceeds 20% (2), and in most cases the expansion of TAVR valves is incomplete and asymmetric, forming an imperfect cylinder (3,4). Modeled data suggest that the von Mises stress (a predictor of the likelihood of a material yielding when subjected to complex loads) on the leaflets of TAVR valves, increases as the degree of malalignment increases from 0° to 60°, and then decreases again (5). Two randomized trials have shown intermediate term noninferiority of TAVR to open valve replacement in the intermediate-risk

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population (6,7). Additionally, 2 randomized trials have completed enrollment and are likely to present data in 2019. Hence, we will likely continue the move to younger and lower-risk patients, whose expected survival is longer than the population heretofore undergoing TAVR. The issues of valve durability and the long-term importance of mild aortic regurgitation will assume increasing importance.

It is important to recognize some of the limitations of the current study. The observations were taken from the SAVORY (Subclinical Aortic Valve Bioprosthesis Thrombosis Associated With 4-Dimensional Computed Tomography) and RESOLVE (Assessment of Transcatheter and Surgical Aortic Bioprosthetic Valve Thrombosis, And Its Treatment with Anticoagulation) registries. Published together in 2016, these registries included a total of 1,205 patients who underwent 4-dimensional computed tomography (CT) scanning after aortic valve implantation (8). In the current study, only 212 patients undergoing TAVR were included, leading one to wonder whether CT scans were technically adequate to determine valve orientation in the majority of patients. Additionally, assuming that the valves are placed at appropriate depths, central aortic regurgitation is a feature that has been observed largely in annular (currently balloon-expandable and mechanically expandable) rather than supra-annular (self-expanding) valves, as the prosthetic annulus is located well above the basal annular place in the latter valve types. The majority (59%) of valves within this study were annular rather than supra-annular. As central aortic regurgitation is a low-frequency event, one wonders whether this observation is driven by the relative paucity of supra-annular valves. The observations will have a chance to be replicated, as several pivotal trials of TAVR valves now contain nested substudies in which patients undergo post-implant CT angiography.

Assuming that these findings are reproducible, and that the relation between alignment and mild central aortic regurgitation is clinically meaningful, the observations of Fuchs et al. (1) provide fodder for a number of considerations for further development of the TAVR procedure and of the valves themselves. First, assuring anatomic orientation of TAVR valves is a technical challenge. It is difficult to know exactly where the commissures of the native valve are located and it is equally challenging to know where the commissures of the TAVR valve are located. Implanting markers on the frame of the TAVR valve, corresponding to commissural location would seem to be fairly easy, whereas locating the patient's native commissures is more of a challenge. Improved co-registration between CT angiography and fluoroscopy would seem to be the answer to this approach. Several such software packages currently exist. Alternatively, increased use of intraprocedural 3-dimensional transesophageal echocardiography might serve this function well. The other challenge would be to assure that the commissures of the TAVR valve in fact landed on the appropriate place selected landing zones at the time of implantation and to assure that the anatomy of the aorta and annulus did not cause autorotation of the valve. The development of guides or orienting clips on the TAVR valve may help in this regard. As the field of TAVR progresses, the ability to implant TAVR valves in an anatomic position may well be beneficial. The observations of Fuchs et al. (1) provide some early data to help us understand why this approach might be necessary. Now we need to look mechanisms to make the approach feasible.

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