

Not All Bioprosthetic Valves Are Created Equal



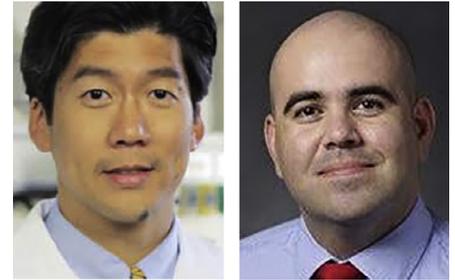
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In this study, Aasbjerg et al compared all cause risk of mortality in patients who had undergone aortic valve replacements with Mitroflow (Sorin, Milan, Italy) and Perimount (Edwards Lifesciences, Irvine, CA) bioprosthetic valves. They reviewed outcomes for 4453 patients representing 3 centers in Western Denmark. They found that implantation of the Mitroflow valve was associated with a 4.5% higher risk of death at 5 years than the Perimount bioprosthesis, a significant finding with even more significant implications. Unfortunately, the review's design does not allow us to infer causation. The study's results must be interpreted cautiously given its relatively short follow-up (5 years), study of valves that were no longer on the market (Mitroflow 12A and LXA), and the fact that none of the valves were treated with anticalcification treatment.

Indeed, not all bioprosthetic valves are created equal, both figuratively and literally. The Mitroflow's design features a single sheet of bovine pericardium mounted externally on a flexible, Dacron-covered stent with a small sewing cuff. This design allows for a favorable geometric orifice area to reduce patient prosthetic mismatch. Conversely, the C-E Perimount valve is constructed using 3 separate flaps of bovine pericardium sewn onto the stent, transferring all of the mechanical force to the stitching and not the leaflets themselves. Modes of failure for the Mitroflow valve have previously been reported, and primarily include para-stent post cusp tears, cusp thickening, and excessive early calcification.^{1,2} These failures have been attributed directly to valve design. Early structural valve degeneration (SVD) and limited durability have been reported with use of the Mitroflow valve as well.^{2–6} Senage et al found that SVD was approximately 8% at only 5 years after surgery and in patients that developed SVD, 16 patients (41%) died and SVD was considered the direct cause of death in the majority (12 patients).⁶ Similarly, Axtell et al found that valve-related mortality was significantly higher in patients who underwent Mitroflow implantation compared to those who received a C-E Magna Ease bioprosthesis (11% vs 1%, $P < 0.01$).³ Furthermore, Mitroflow valve type was found to be a significant and

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Central Message

In this study, implantation of Mitroflow versus Perimount bioprosthesis was associated with a higher risk of death at 5 years. The study adds to the mixed evidence on the durability of the Mitroflow valve and its clinical implications. We believe there is a small but important population that may benefit from its continued use.

independent predictor of mortality in their review. In spite of this evidence, the Mitroflow valve has been used widely with >100,000 implants worldwide and there are studies that show long-term durability.^{7,8}

The Mitroflow valve is not the only externally wrapped bioprosthetic valve to experience early SVD. The Ionescu-Shiley bioprosthetic valve is another notable innovation that showed promising early results but whose design, specifically the alignment stitch that was used to hold the valve cusps against the stents and align the cusps, was found to be source of cusp tears leading to early valve failure.^{9,10} Patients with failing bioprosthetic valves may benefit from replacement and the role of transcatheter valve-in-valve replacement is growing in high-risk populations. Surgical implantation technique (supra-annular), small aortic root size, and bioprosthetic valve design, specifically the externally wrapped pericardial valves, are important preoperative factors that must be considered. Externally wrapped pericardial valve design has been found to increase the risk of coronary occlusion given the bioprosthetic tissues' interaction with the coronary ostia and aortic wall.¹¹ Yet another important consideration while choosing this specific set of bioprosthetic valve implants.

We believe, as Mosquera et al⁷ showed, that the Mitroflow bioprosthetic valve in the aortic position is best suited for patients at high risk for patient-prosthetic mismatch, including

those with small aortic roots, severe aortic stenosis, a high degree of left ventricular hypertrophy, advanced age (>70 years old), and who avoiding an aortic root enlargement or replacement procedure are the top priority.

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