

## ARTICLE IN REVIEW:

# Aortic Valve Allografts Demonstrate Long-Term Performance and Durability

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**TITLE:** Performance and Durability of Cryopreserved Allograft Aortic Valve Replacements

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**STUDY DESIGN:** Retrospective, 2,042 patients, 2,110 aortic allografts

**SUMMARY:** This retrospective study evaluates the long-term durability and performance of aortic valve allografts. Clinical data from January 1987 to January 2017 was collected from the Cleveland Clinic Cardiovascular Information Registry which provided data on 2,042 patients (mean age 54±15) who received 2,110 aortic allograft root replacements. Indications included infective endocarditis (47%), native valve degradation (21%), prosthetic valve dysfunction (12%), and others. At 3 years, 77% of patients had no or only mild regurgitation, while only 23% had worse than mild. The rate of severe regurgitation was 0% at discharge and 14%, 25%, and 35% at 5, 10, and 15 years, respectively. Allograft valve mean gradient at discharge was 6mmHg which increased to 9, 13, and 15 mmHg at 5, 10, and 15 years, respectively. By the end of follow-up, 405 allografts were explanted due to structural failure, 67 for endocarditis, and 10 for non-structural dysfunction or unknown reasons. Younger patient age was a consistent risk factor for durability and loss of performance. Donor-related risk factors included increased donor age and larger valve sizes for mean valve gradient and structural failures. The 15-year actuarial risk of structural failure in the study (34%) was comparable to other studies using allograft valves (16-53%)<sup>1-4</sup> and was not increased by the indication for implant, including endocarditis. From a patient perspective, over 20 years and 17,283 patient-years of data, less than one-third of the allografts were explanted, and surviving allografts were associated with good long-term durability and performance.

## Long-term durability:

Over 20 years and more than 17,000 patient-years, less than one-third of allografts were explanted for structural failure at 15-years postoperative, which was lower than the actuarial risk of structural failure at the time of study completion.

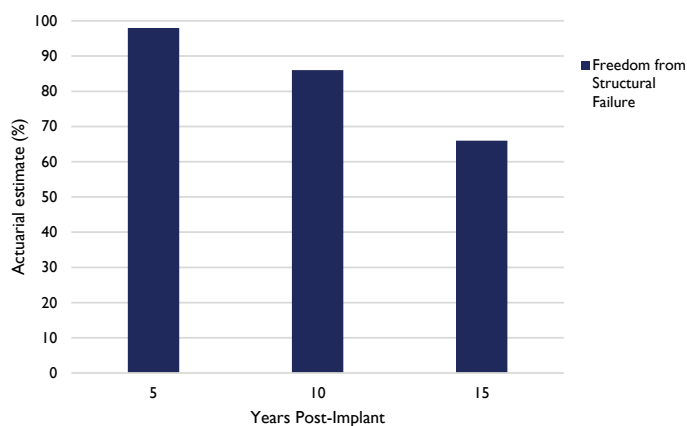
## Long-term hemodynamic performance:

At discharge, none of the patients had severe regurgitation, which increased to only 14%, 25%, and 35% at 5, 10, and 15 years, respectively. Allograft valve mean gradient at discharge was 6 mmHg and generally remained low throughout follow-up, increasing only to 9, 13, and 15 mmHg at 5, 10, and 15 years, respectively.

## Consistent with previous studies:

The rate of structural failure in other allograft studies ranged from 16% to 53%<sup>1-4</sup>, placing the results of this study in alignment with previous reports.

## Long-Term Durability of Aortic Valve Allografts



The estimated freedom from structural failure based on the actuarial risk assessment performed was 98%, 86%, and 66% at 5, 10, and 15 years respectively, demonstrating that aortic valve allografts have long-term durability. Adapted and modified from Figure 3B. Copyright, The Annals of Thoracic Surgery, 2020.

## Reference:

1. Solari S, Mastrobuoni S, De Kerchove L, et al. Over 20 years experience with aortic homograft in aortic valve replacement during acute infective endocarditis. *Eur J Cardiothorac Surg* 2016;50:1158-64.
2. Nappi F, Nenna A, Petitti T, et al. Long-term outcome of cryopreserved allograft for aortic valve replacement. *J Thorac Cardiovasc Surg* 2018;156:1357-65 e6.
3. Fukushima S, Tesar PJ, Pearse B, et al. Long-term clinical outcomes after aortic valve replacement using cryopreserved aortic allograft. *J Thorac Cardiovasc Surg.* 2014;148(1):65-72.e2. doi:10.1016/j.jtcvs.2013.07.038
4. Mokhles MM, Rajeswaran J, Bekkers JA, et al. Capturing echocardiographic allograft valve function over time after allograft aortic valve or root replacement. *J Thorac Cardiovasc Surg.* 2014;148(5):1921-1928.e3. doi:10.1016/j.jtcvs.2014.04.023

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