

Clinical Summary

On-X[®] Mitral Heart Valve

Hemodynamic Data



ARTIVION™

On-X[®]
Mitral Heart Valve

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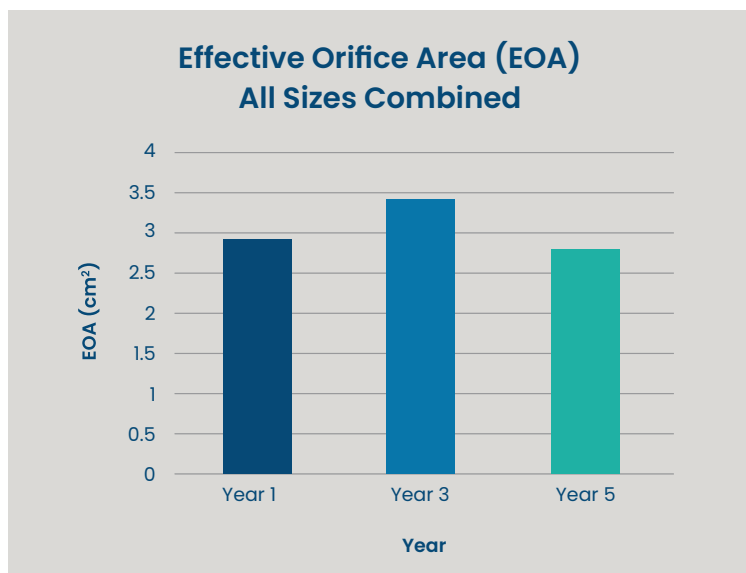
New Hemodynamic Data: The On-X Mitral Valve Demonstrates Optimal Performance in Large Landmark Study for Mechanical Mitral Valves

The Prospective Randomized On-X Anticoagulation Clinical Trial (PROACT) Mitral Trial¹ is one of the largest studies ever conducted with mechanical mitral valves involving 401 patients (mean age 55 y/o) at 44 North American centers.

PROACT Mitral represents the most contemporary evidence on performance and anticoagulation for any mechanical mitral valve. Due to its size and scope, a similar study is likely to never be repeated.

Key Takeaway

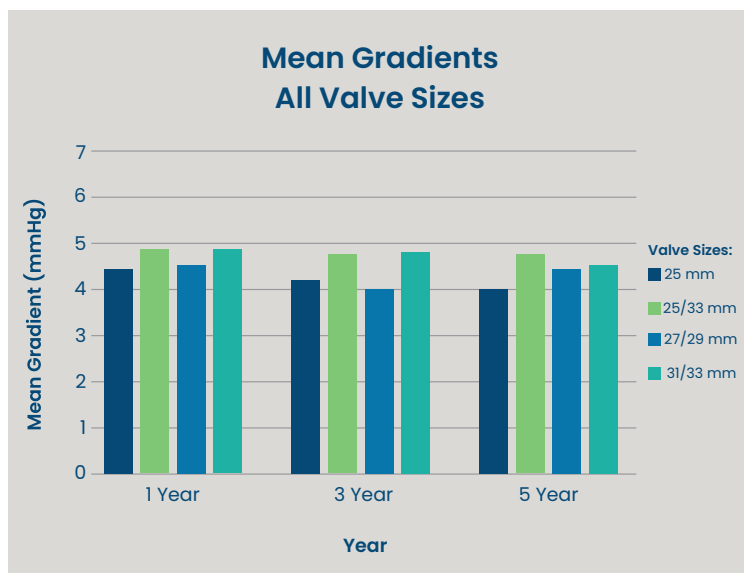
Figure 1



Echocardiographic data showed patients with the following EOAs across all On-X Mitral Valve sizes (Figure 1):

- 2.9 cm² at 1 year
- 3.4 cm² at 3 years
- 2.8 cm² at 5 years

Figure 2



Patients had exceptional mean gradients below 5mmHg across all On-X Mitral Heart Valves sizes, sustained out to 5 years. (Figure 2)

Conclusion

The On-X Mitral Heart Valve, which is engineered for exceptional clinical performance, now has the most robust body of evidence supporting its use as demonstrated by the excellent hemodynamic performance in PROACT Mitral.

On-X Mitral Heart Valves should be managed at current guideline recommendations of 2.5-3.5 INR.

References

1. Chu M.W.A., et al. (2023). Low-Dose Vs Standard Warfarin After Mechanical Mitral Valve Replacement: A Randomized Trial. *Ann Thorac Surg*, S0003-4975 (23)00005-X.

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