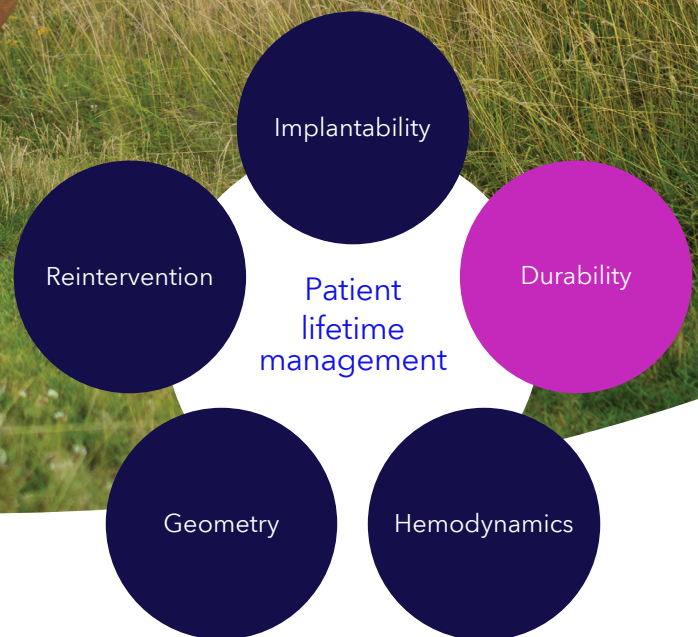


Medtronic



Mosaic™ Bioprosthesis

Unsurpassed
durability

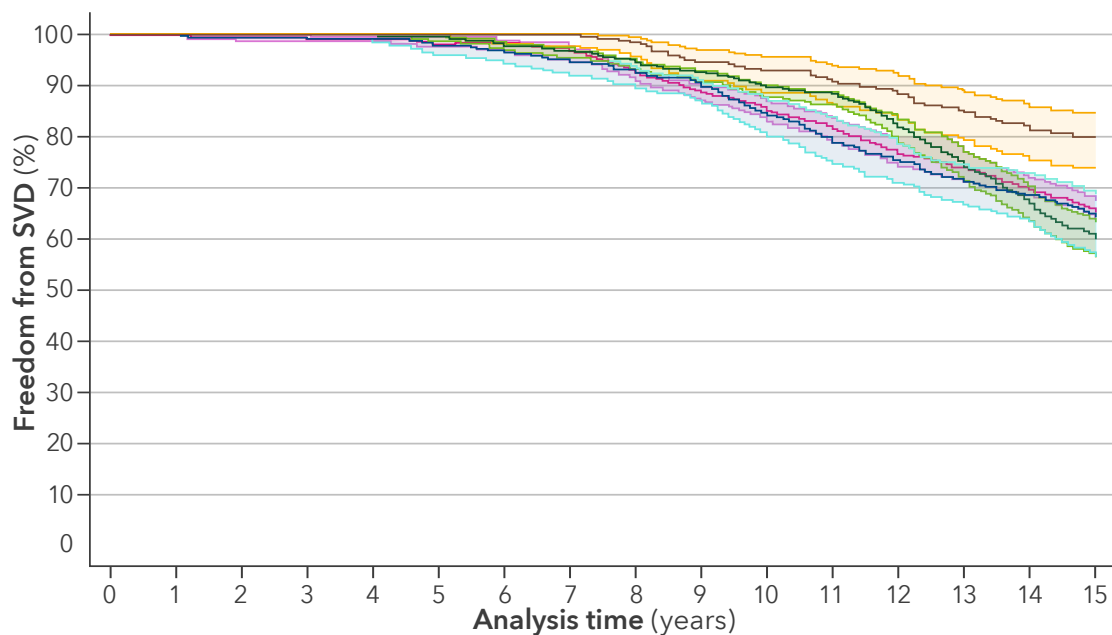
Durability of mitral bioprostheses: A meta-analysis of long-term follow-up studies

Methods

- This is a meta-analysis undertaken to compare SVD risk of porcine and pericardial valves in the mitral position.
 - 1,570 papers were identified and 40 were reviewed after criteria was applied.
 - More than 15,000 patients were included.
 - Four valve types with data after 1980 were selected for the analysis: Carpentier-Edwards™ (CE) porcine (1,361), Hancock™ II (424), Mosaic (940), and CE pericardial (1,143).
- The majority of studies defined SVD according to the STS/AATS guidelines.

Results

- The Mosaic valve showed the lowest rate of SVD.
 - At 15 years, freedom from SVD was highest for Mosaic, followed by Hancock II, CE porcine, then CE pericardial.
 - Across similarly aged patients, freedom from SVD was higher in porcine valves compared to bovine pericardial valves.
 - CE bovine pericardial valve demonstrated significantly higher risk of SVD compared to the CE porcine valve, which is no longer distributed.



Hancock II	424	424	424	424	424	414	410	402	393	383	353	337	320	304	291	276
CE porcine	1,361	1,361	1,356	1,353	1,350	1,341	1,334	1,322	1,265	1,208	1,165	1,113	1,036	922	871	819
CE pericardial	1,143	1,143	1,143	1,143	1,143	1,138	1,120	1,104	1,083	1,056	1,024	847	526	481	433	388
Mosaic	940	940	940	940	940	940	232	232	228	219	215	211	206	197	190	185

Source:

Malvindi PG, Mastro F, Kowalewski M, et al. Durability of Mitral Valve Bioprostheses: A Meta-Analysis of Long-Term Follow-Up Studies. *Ann Thorac Surg*. February 2020;109(2):603-611.

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Long-term outcomes of Mosaic vs. Perimount^{TM*} mitral replacements

17-year follow-up of 940 implants

Methods

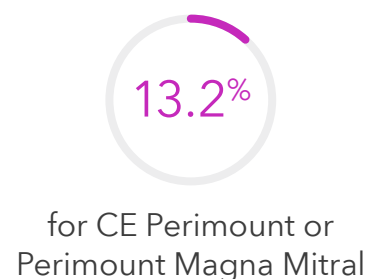
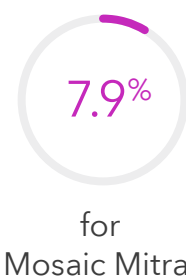
This retrospective study compared the long-term outcomes of Mosaic porcine mitral valves to Carpentier-Edwards bovine pericardial mitral valves.

- Study design:
 - Retrospective, observational, single-center study
 - 463 Mosaic mitral porcine bioprosthesis
 - 477 CE mitral pericardial bioprosthesis (majority Perimount Magna mitral)
 - 401 of each valve were propensity matched
- Patient characteristics:
 - Average age for Mosaic = 68.6 years
 - Average age for Perimount = 67.7
- STS and AATS jointly defined SVD as dysfunction or deterioration involving the operated valve, exclusive of infection or thrombosis, as determined by reoperation, autopsy, or clinical investigation.

Results

- 37% of Mosaic valves failed by stenosis and 63% for regurgitation versus 96% of pericardial valves failed by stenosis.
- None of the reoperative patients required emergent reintervention.

Cumulative incidence of reoperation at 15 years ($P < 0.001$):



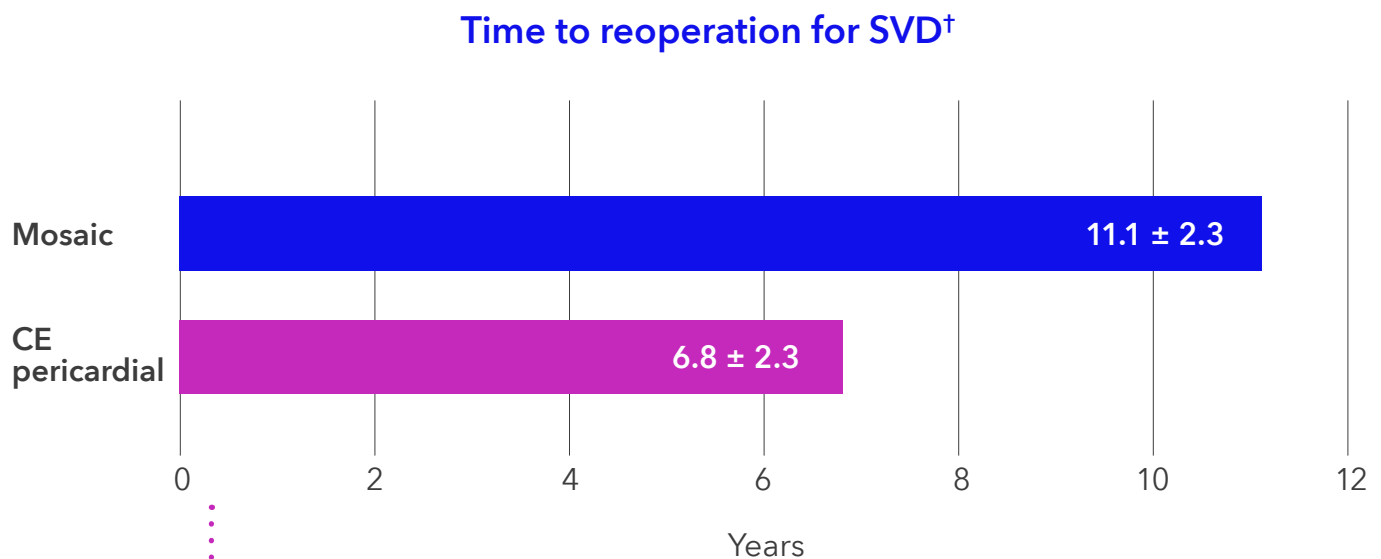
Source:

Beute TJ, Goehler M, Parker J, et al. Long-Term Outcomes of Mosaic versus PERIMOUNT Mitral Replacements: 17-Year Follow-Up of 940 Implants. *Ann Thorac Surg.* August 2020;110(2):508-515.

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Long-term outcomes of Mosaic versus Perimount mitral replacements

17-year follow-up of 940 implants (cont'd.)



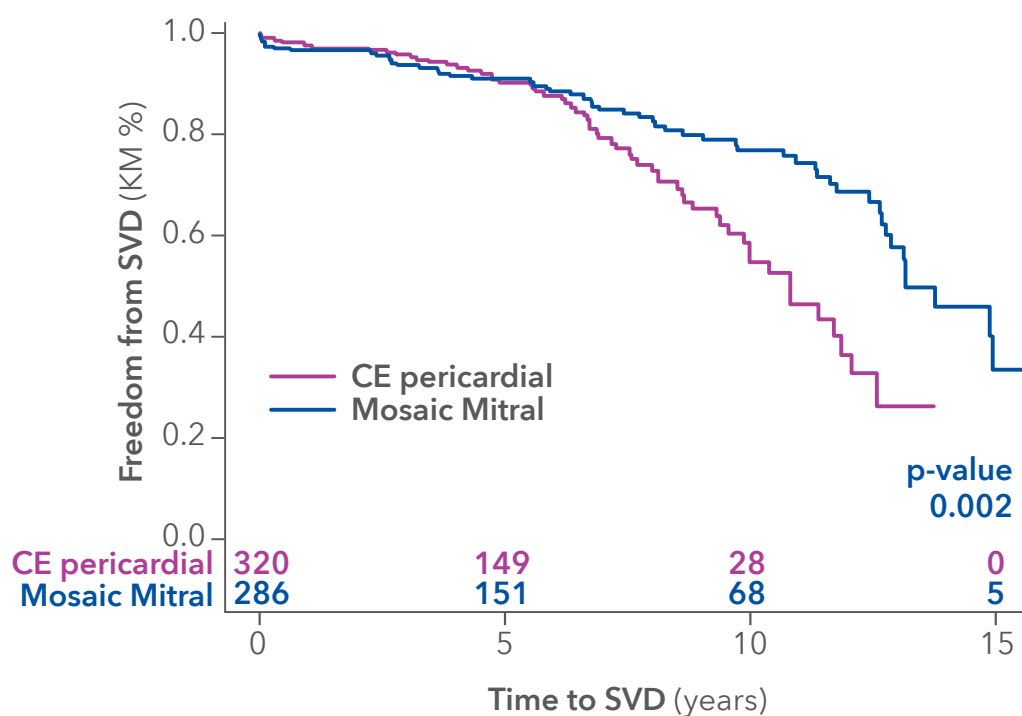
On average, the time before reoperation for SVD was 4.3 years longer with Mosaic porcine valves than Edwards pericardial valves.



[†]SVD was defined, according to STS, as dysfunction or deterioration involving the operated valve, exclusive of infection or thrombosis, as determined by reoperation, autopsy, or clinical investigation. Mean follow-up times were significantly different (Mosaic: 7.0 ± 4.8 versus Edwards: 6.0 ± 3.9, $p = 0.002$).

Source: Beute TJ, Goehler M, Parker J, et al. Long-Term Outcomes of Mosaic versus PERIMOUNT Mitral Replacements: 17-Year Follow-Up of 940 Implants. *Ann Thorac Surg*. August 2020;110(2):508-515.

17-year follow-up of 940 implants (cont'd.)




The rate of overall reoperation for pericardial valves is 1.89 (95% CI 1.13%–3.17%) times higher than that for porcine valves.

The rate of reoperation due to SVD is 2.32 (95% CI 1.31–4.11) times higher in the pericardial valves versus the porcine valves.

In the matched patient cohort, survival at 15 years was not significantly different between the two groups; nevertheless, the cumulative incidence of reoperation for structural valve deterioration was significantly lower in the Mosaic group. **For patients less than age 65 years, SVD at 15 years was 15.8% versus 30.2% for porcine and pericardial valves respectively (p = 0.009).**

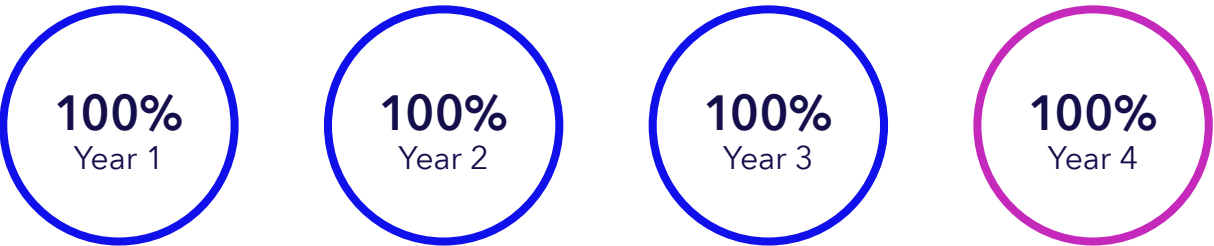
Take a closer look: Mosaic and Mitris™ IFU data

Mosaic IFU PMA trial

365 
Number of patients

68
Average age

Freedom from SVD:

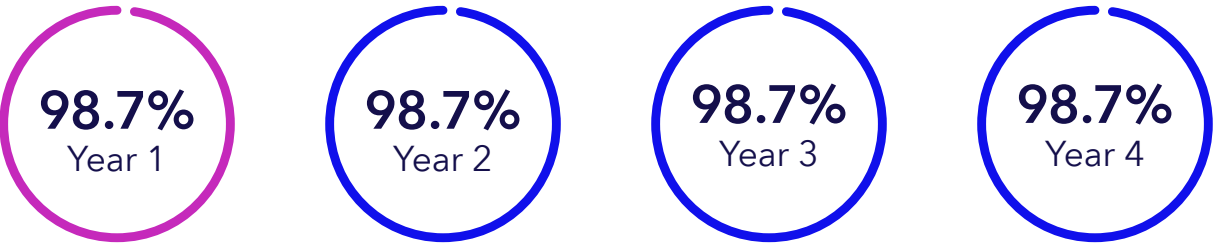


Mitris IFU PMA trial

82 
Number of patients

68
Average age

Freedom from SVD:



These charts are not intended to be a comparison of the two devices as there is no head-to-head clinical study, but rather are intended to illustrate the clinical results of two trials. Multiple factors contribute to clinical study outcomes and need to be considered in making any assessments across different studies.

Mosaic Porcine Bioprosthesis. Instructions for Use. Medtronic, Inc. 2013. 220016001 Rev. 1B.
EDWARDS Pericardial Mitral Bioprosthesis, Model 11400M. Instructions for Use. Edwards Lifesciences.
https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150048S012C.pdf.

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Mosaic: Built for a life

Younger patients are opting for tissue valves to avoid taking warfarin as needed with a mechanical heart valve. Traditionally, tissue valves fail earlier and more often in the younger patient population; so the following studies have evaluated the performance of the Mosaic Mitral valve in younger patients specifically:

- Riess¹: This study demonstrates acceptable long-term rates of death, reoperation, and explant due to SVD with the Mosaic bioprosthesis implanted in either the aortic or mitral position. Freedom from explant due to SVD was not significantly different between patients younger than 60 years or 60 years and older in the mitral cohort at 16 years.
- Beute²: In the series of bioprosthetic mitral valve replacements, rates of reoperation due to SVD were higher in patients < 65 years old compared to older patients both for Mosaic Mitral and CE Perimount. However, structural valve deterioration requiring reoperation occurred earlier and more frequently in the CE Perimount bovine pericardial valves than in the Medtronic Mosaic porcine valves when implanted in patients < 65 years old.
- Chiariello³: Mosaic mitral bioprosthetic implants showed acceptable results in younger patients. These results obtained in a younger patient population confirm that Mosaic is a reliable prosthesis even when employed in the < 65-year-old patients.



¹Riess FC, Fradet G, Lavoie A, Legget M. Long-term outcomes of the Mosaic bioprosthesis. *Ann Thorac Surg.* March 2018;105(3):763-769.

²Beute TJ, Goehler M, Parker J, et al. Long-Term Outcomes of Mosaic versus PERIMOUNT Mitral Replacements: 17-Year Follow-Up of 940 Implants. *Ann Thorac Surg.* August 2020;110(2):508-515.

³Chiariello GA, Beraud AS, Vahdat O, et al. Late results after mitral valve replacement with Mosaic bioprosthesis in patients aged 65 years or younger. *Interact Cardiovasc Thorac Surg.* July 26, 2021;33(2):181-187.

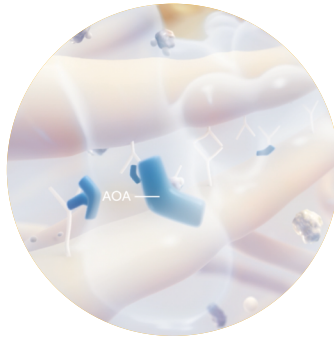
Time tested

The Medtronic-patented AOA™ tissue treatment that utilizes amino oleic acid is used across a suite of Medtronic devices to help drive durability, valve replacement and patient lifetime management. Clinical use with these devices encompasses more than half a million patients for over 30 years.[†]



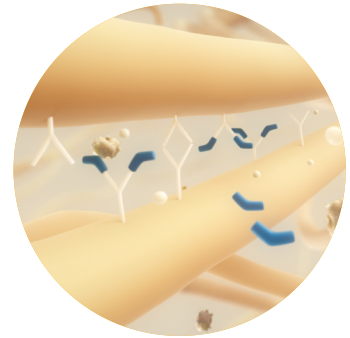
After fixation

- Free aldehydes present



After fixation

- AOA covalently bonds with free aldehydes
- Lipids are washed away
- Subsequent storage in glutaraldehyde allows any remaining free aldehydes to crosslink

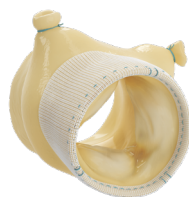


After treatment

- Large AOA molecules slow diffusion of calcium into tissue matrix



Mosaic™ Bioprosthesis
Aortic and Mitral[‡]



Freestyle™ Aortic
Bioprosthesis[‡]



Avalus™ Aortic
Bioprosthesis[‡]



CoreValve™
Evolut™ Platform[§]

[†] The benefits of AOA tissue treatment have been demonstrated through animal testing. No direct clinical evaluation of the benefits of AOA treatment in humans has been conducted.

[‡] Surgical valve replacement risks may include infection, surgical complications, stroke, endocarditis, and death.

[§] TAVR risks may include, but are not limited to, death, stroke, damage to the arteries, bleeding, and need for permanent pacemaker.

This material should not be considered the exclusive source of information, it does not replace or supersede information contained in the device manual(s).

Please note that the intended use of a product may vary depending on geographical approvals.

See the device manual(s) for detailed information regarding the intended use, the (implant) procedure, indications, contraindications, warnings, precautions, and potential adverse events.

For a MRI compatible device(s), consult the MRI information in the device manual(s) before performing a MRI.

If a device is eligible for eIFU usage, instructions for use can be found at Medtronic's website manuals.medtronic.com.

Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

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