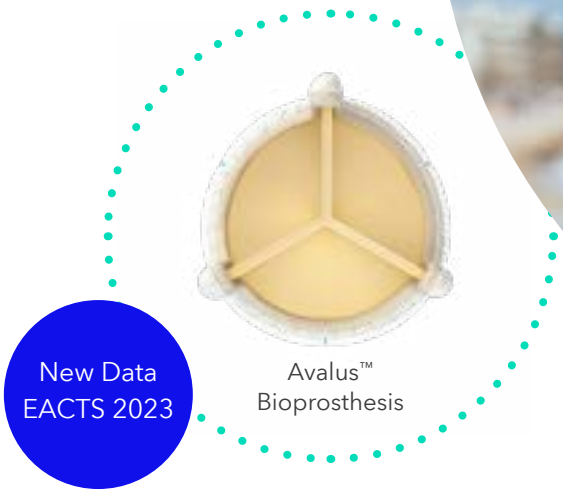
Medtronic



Surgical Aortic Valve Replacement

Quality data. Better heart decisions.

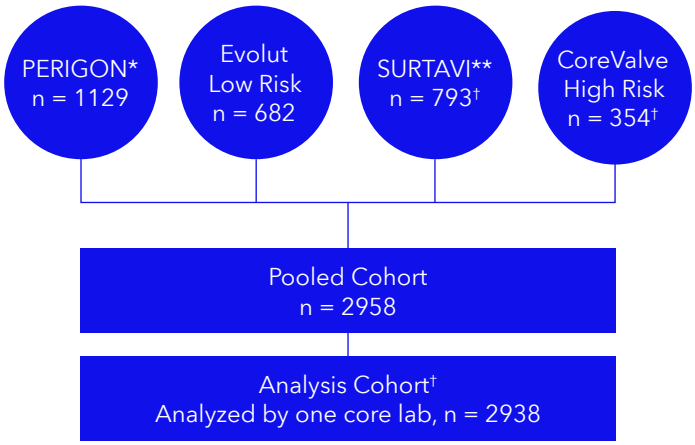
Discover the largest data set of contemporary surgical aortic valves, analyzed by a single core lab.[1] Using this data set, Medtronic created a tool for cardiac surgeons that is a novel, robust instrument for evaluating valve performance.

Discover the ultimate valve performance evaluation tool you've been waiting for.

Study design

Previous publications on hemodynamic performance of multiple surgical valves have been limited[2,3] by a small sample size, a lack of contemporary valves and a lack of the standardized echo technique of a single core lab.

Medtronic and Mayo Clinic partnered together to pool data from four large clinical trials of surgical aortic valve replacement (SAVR) and created **the largest surgical valve data set with echocardiograms evaluated by a single core lab to date.**[4-8]



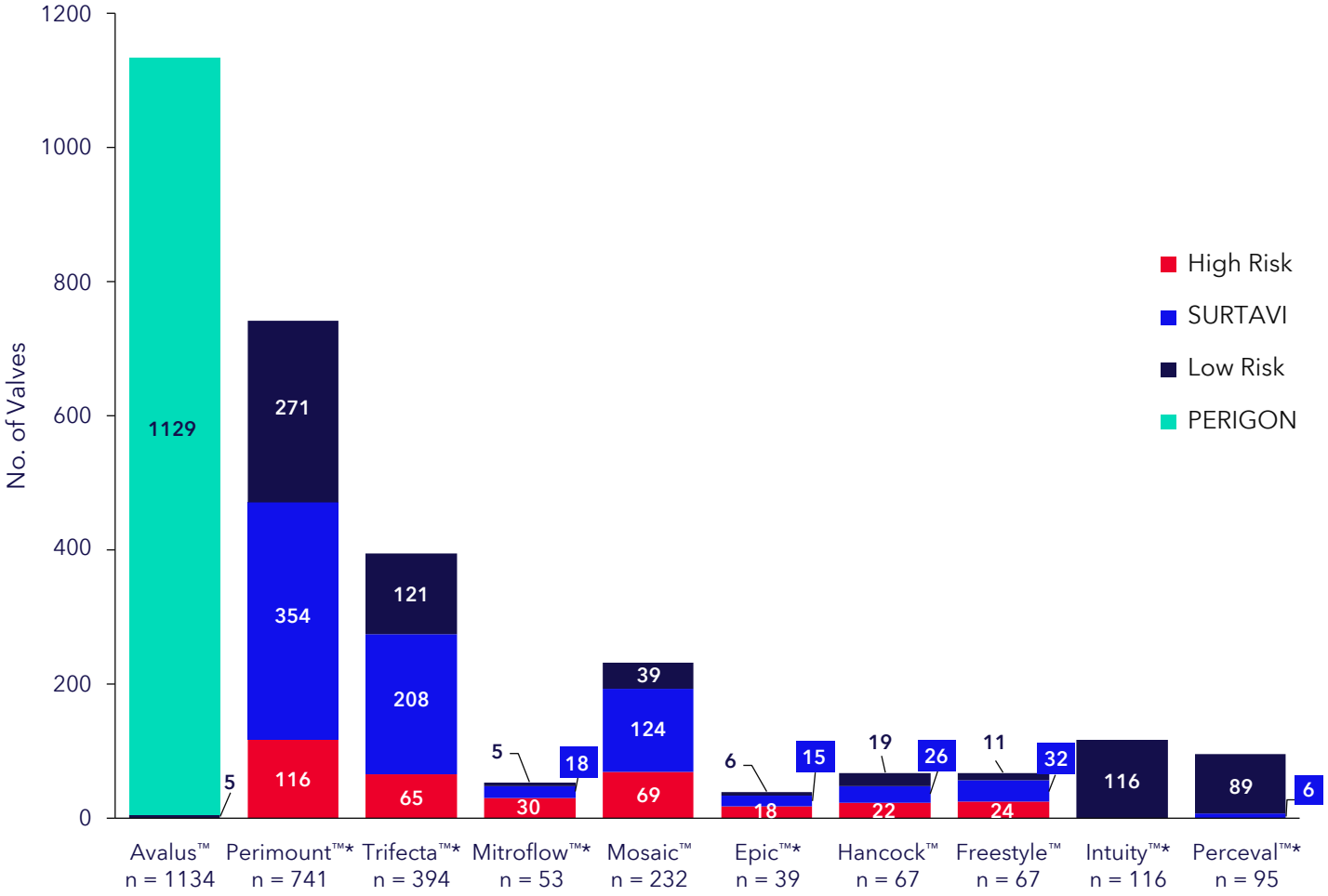
*PERIcardial SurGical AOrtic Valve ReplacemeNt (PERIGON) Pivotal Trial of the Avalus bioprosthesis.

**SUrgical Replacement and Transcatheter Aortic Valve Implantation (SURTAVI) trial.

†20 exclusions due to small sample size: 3F™* (8), Enable™*(2), Solo Smart™* (3), Carbomedics™* (2), Flex Cuff™* (1), Oxane-21™* (1), Regent™* (3).

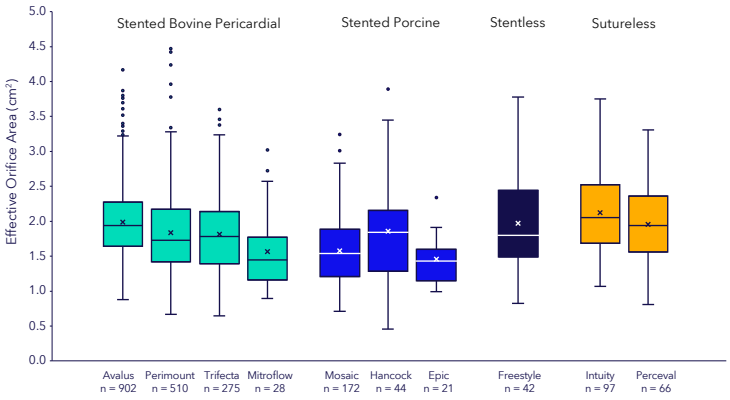
The standardized data acquisition and use of a single core lab **help ensure the consistency in echo assessment methods** needed for robust hemodynamic analysis.[9]

Implanted valves by study and model, N

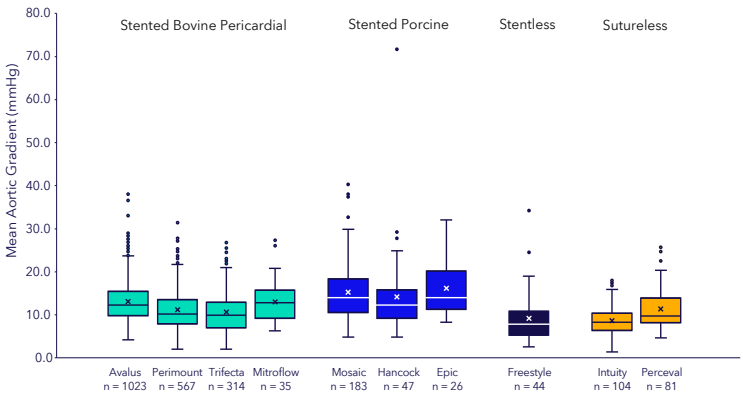


Results

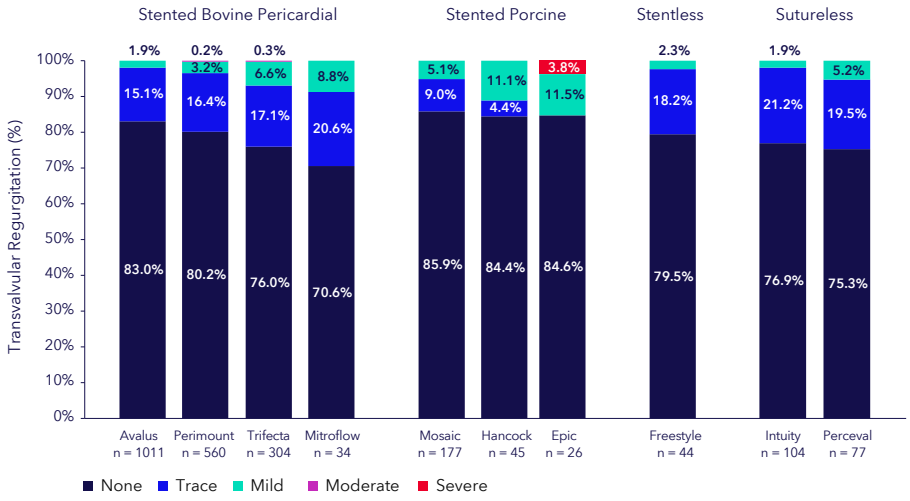
Effective orifice area (EOA) at one year



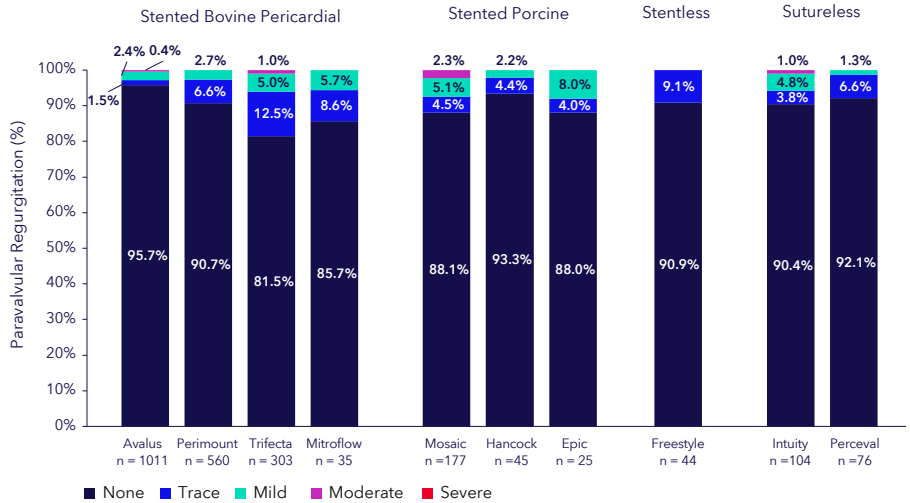
Mean pressure gradients (MPG) at one year



Transvalvular regurgitation (TVR) % at one year



Paravalvular regurgitation (PVR) % at one year



Data insights

- The data set provides valve normals, a useful tool for the evaluation of patients implanted with a specific valve model and size.
- The reference values reported in the data set can aid in evaluating whether an implanted valve is functioning normally after valve replacement.
- Data for 10 valve models of four surgical valve types are reported. Overall performance ranged from good to excellent for the individual tissue valve models and hemodynamic parameters.
- Hemodynamic performance at one year was good to excellent, with EOA ranging from 1.46±0.34 to 2.12±0.59 cm^2 and mean gradient ranging from 8.6±3.4 to 16.1±6.2 mmHg. Avalus and Freestyle valves demonstrated excellent performance with high EOAs and low MPGs at one year.
- For TVR, Avalus and Freestyle valves demonstrated outstanding performance at one year.
- For PVR, which is one of the key efficiency and safety end points, characterizing the quality of valve seating and sizing, Avalus valve showed superb performance: 97.2% with none/trace PVR.

Conclusion

This dataset overcomes shortcomings of previous surgical valve normals reports. The analysis demonstrates the hemodynamic performance that can generally be expected at one year with currently available valves. **This is the most robust SAVR valve normals analysis to date.*** Overall, performance ranged from good to excellent for the individual valve models, sizes, and hemodynamic parameters. The data from this analysis can serve as a benchmark for other studies and may be a useful resource to help guide patient management following SAVR.

Learn more about Avalus

*Although all echos in the dataset were read by a single core lab and these are the most robust SAVR valve normals to-date, limitations exist. There were differences in the patient population among individual studies, including PERIGON enrolled patients with bicuspid anatomy and regurgitant lesions. The PERIGON and Evolut Low Risk patients were generally healthier than patients in the CoreValve High Risk and SURTAVI studies. Number of each valve model varied. Perimount bovine pericardial specific models were not consistently collected. There were differences in how native annulus size was measured in the Randomized Controlled Trials (RCTs) and the observational study. Lastly, when using the valve normals as reference values, a measured hemodynamic valve worse than the reference value does not necessarily mean a valve is failing.

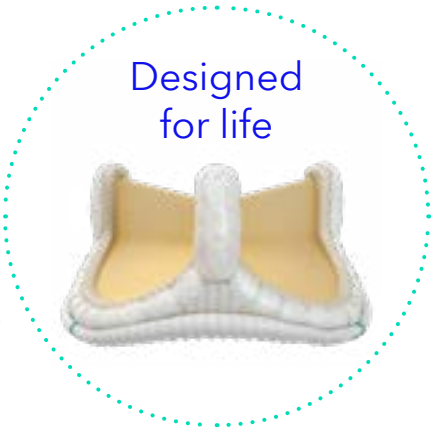
What does it mean for your valve choice?

The new data from this robust analysis provides **highly convincing clinical evidence of the safety and efficiency of the Avalus valve design.**

Durability

First implanted nearly 10 years ago, the Avalus valve is designed to last:

- Highly efficient AOA™ anti-calcification tissue treatment,* used on 500,000+ valves for over 30 years
- Internally mounted leaflet design, the gold standard for valve durability[10]



Circularity

Unique to the Avalus valve – and not available in other valves – its non-deformable polymer base combined with flexible stent post:

- Enables efficient blood flow
- Allows regular leaflet motion
- Increases valve durability

Hemodynamics

Designed for 100% coaptation, the Avalus valve provides:

- Large and stable EOAs, low and stable MPGs[1]
- Low rates of TVR and PVR[1]
- Low rates of PPM in both controlled and real-world studies[1, 11]

Lifetime management

Engineered in the modern era of TAVI, the Avalus valve provides:

- Cylindrical opening and circular base to accommodate TAVI landing
- Metal-free polymer frame, reducing risk of metal-on-metal corrosion

*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.

Learn more about the Avalus valve

References:

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[11]Verbelen T. et al. Real-world data on Avalus™ pericardial aortic valve 350+ patients results from prospective, multi-center registry. Poster presentation at HVS 2023.

See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential adverse events.
For further information, contact your local Medtronic representative and/or consult the Medtronic website at **cema.medtronic.com**.
For applicable products, consult instructions for use on **www.medtronic.com/manuals**.

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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