AVALUS™ BIOPROSTHESIS **IN SMALL SIZES**

Tadokoro N, Fukushima S, Shimahara Y, et al. Comparison of safety and haemodynamic performance between the Avalus™ stented aortic valve bioprosthesis and Magna™ valve in Japanese patients. *Gen Thorac Cardiovasc Surg*. Published online January 5, 2021.

STUDY DESCRIPTION

This study was a retrospective, single-center observational analysis comparing the feasibility, safety, and valve hemodynamics between Avalus and Magna™* valves in patients who underwent surgical aortic valve replacement: 87 patients with an Avalus bioprosthesis and 381 patients with a Magna valve were enrolled. Valve hemodynamics, adverse events, and outcomes were recorded up to one year postoperatively.

KEY TAKEAWAYS

GOOD AVALUS FUNCTIONALITY, SIMILAR MPG AND EOA WITH MAGNA, EVEN IN THE SMALLEST SIZES.

SUCCESSFUL IMPLANTATION OF AVALUS VALVE SMALL SIZES

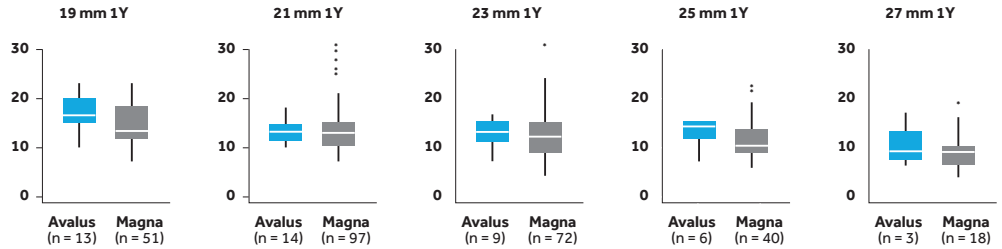
HEMODYNAMIC PERFORMANCE

MPG and EOA measures were not significantly different between the two valves, up to one year postoperatively.

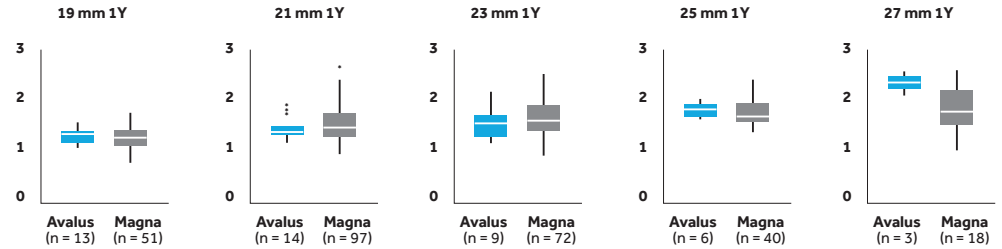
Small-size Avalus valves (19 or 21 mm) were **successfully implanted** with the same surgical procedure used for Magna.

In addition, these smaller valves produced an MPG and EOA similar to that of the Magna valves, achieving **good hemodynamic functionality** in patients with a small body size.

Mean Pressure Gradient (mm HG) at 1-year Follow-up



Effective Orifice Area (cm²) at 1-year Follow-up



CONCLUSION

Avalus bioprosthesis implantation resulted in **good hemodynamic** performance and **good in-hospital outcomes** similiar to those of Magna in this patient group of overall smaller body size — **including in those with smaller valve sizes** (19 and 21 mm) — which are typically more difficult to implant.

Medtronic

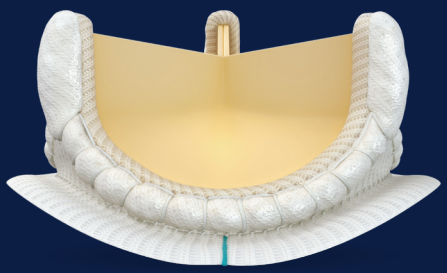
AVALUS BIOPROSTHESIS **IN SMALL SIZES**

As seen in this recent study, the Avalus patients had great hemodynamic results.

DESIGN BENEFITS

INTERNALLY MOUNTED LEAFLETS AND AOA™† TREATMENT FOR
LONG-TERM DURABILITY

POLYMER STENT FOR STRENGTH AND FLEXIBILITY, AND RESISTANCE TO PERMANENT DEFORMATION FOR
STABLE HEMODYNAMICS



LOW-PROFILE GEOMETRY AND RADIOPACITY FOR
LIFETIME PATIENT MANAGEMENT

LOW-PROFILE SOFT SEWING CUFF FOR
ENHANCED IMPLANT EXPERIENCE

†No clinical data is available which evaluates the long-term impact of AOA treatment in patients.

Avalus™ Bioprosthesis

Indications: The Avalus bioprosthesis is indicated for the replacement of diseased, damaged, or malfunctioning native or prosthetic aortic valves. **Contraindications:** None known. **Warnings/Precautions/Adverse Events:** Only physicians who have received proper training in valve replacement should use this device. Accelerated structural deterioration due to calcific degeneration of bioprosthesis may occur in: children, adolescents, young adults, and patients with altered calcium metabolism (e.g., chronic renal failure, or hyperparathyroidism). Adverse events can include: angina, cardiac dysrhythmias, endocarditis, heart failure, hemolysis, hemolytic anemia, hemorrhage, infection other than endocarditis, transvalvular or paravalvular leak, myocardial infarction, nonstructural valve dysfunction (leaflet entrapment/impingement, obstructive pannus ingrowth, suture dehiscence, inappropriate sizing or positioning, or other), pericardial effusion or tamponade, prosthesis regurgitation, prosthesis stenosis, prosthesis thrombosis, stroke, structural valve deterioration (calcification, leaflet tear or perforation, or other), thromboembolism, tissue dehiscence, and transient ischemic attack. These complications could lead to reoperation, explant of the bioprosthesis, permanent disability, or death.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use. For countries that use eIFUs, consult instructions for use at medtronic.com/manuals. Note: Manuals can be viewed using a current version of any major internet browser.

Medtronic

710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Tel: (763) 514-4000
Fax: (763) 514-4879
Toll-free: (800) 328-2518

medtronic.com/avalus