Abbott

CLINICAL INSIGHTS

MASTERS SERIES MITRAL MECHANICAL HEART VALVES

Key Mitral MHV selection considerations: durability, size range, hemodynamics, and implantability[1]

The Masters Series Mitral Valves Demonstrate Excellent 30-Year Clinical Outcomes

- DURABILITY: Masters Series mechanical Heart valves demonstrate long-term durability based on experience of more than 3 million implants[2] over several decades
- SIZE RANGE & HEMODYNAMICS: Wide range of sizes (15 to 33 mm) allows for individualizing valve implantation for enhanced hemodynamic performance
- IMPLANTABILITY: Lower profile reduces protrusion into the left ventricle

TITLE

Thirty-year experience with a bileaflet mechanical valve prosthesis[1]

AUTHORS

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BACKGROUND

Valves in the Masters Series are bileaflet pyrolytic carbon valves available for use in both mitral and aortic positions. In addition to their low profile, Masters valves delivers small transvalvular gradients, low rates of thrombotic events, and few mechanical failures.[1]

OBJECTIVE

The objective of this study was to evaluate the long-term outcomes of mitral valve replacement with a Masters Series mechanical valve prosthesis.

METHODS

From January 1979 to December 2014, all patients undergoing mechanical mitral valve replacement (N=439) were prospectively entered into a computer database. Patient questionnaires, telephone call, and in-person interviews were used to collect adverse event and mortality data. Follow-up was 95% complete with 4735 total patient years for the MVR cohort.

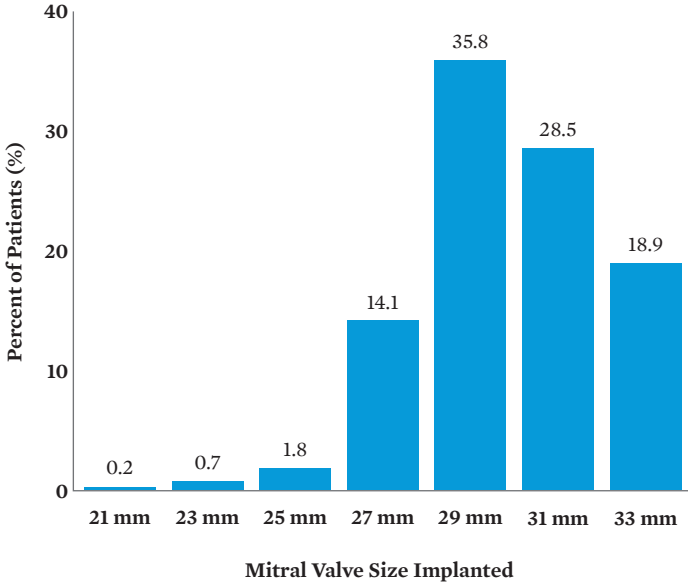
RESULTS

Between 1979 and 2014, 439 patients underwent mitral valve replacement with a Masters Series valve. In patients undergoing MVR, late actuarial survival was 64%, 28%, and 14% at 10, 20, and 30 years, respectively. Analysis quantified thirty-year freedom from reoperation (85%), thromboembolism (55%), valve thrombosis (99%), bleeding (57%), and endocarditis (95%). Incidence of bleeding was 2.0% per patient-year and incidence of thromboembolism was 2.9% per patient-year.

CONCLUSION

The Masters Series of valves continues to demonstrate high reliability after decades of study.[1] Structural failures and reoperation due to device malfunction are rare. These factors combine to make the Masters Series an excellent valve choice for a wide variety of patients.

Figure 4. Over 90% of patients in the 30-year study cohort had a size 27 or larger valve implanted during mitral valve replacement.



See Important Safety Information referenced within.

SIZE RANGE - THE IMPORTANCE OF ORIFICE AREA

Individualizing Care for Patients Undergoing MVR

Masters Series valves offer a choice of sizes with relational internal diameters and lower risk of protrusion. Other commercially available valves may offer smaller orifice areas, especially in larger sizes, that may have an impact on hemodynamics. For example, the On-X‡ valve for the mitral position is only manufactured with two carbon sizes, 23 mm and 25 mm, with only the later available in the U.S. Patients with larger mitral tissue annuli receive the same sized carbon with bigger versions of a supra-annular flange style cuff or a tapered intra annular cuffs. The result is a smaller effective orifice area than is possible given the size of the patient's natural anatomy.[3,4]

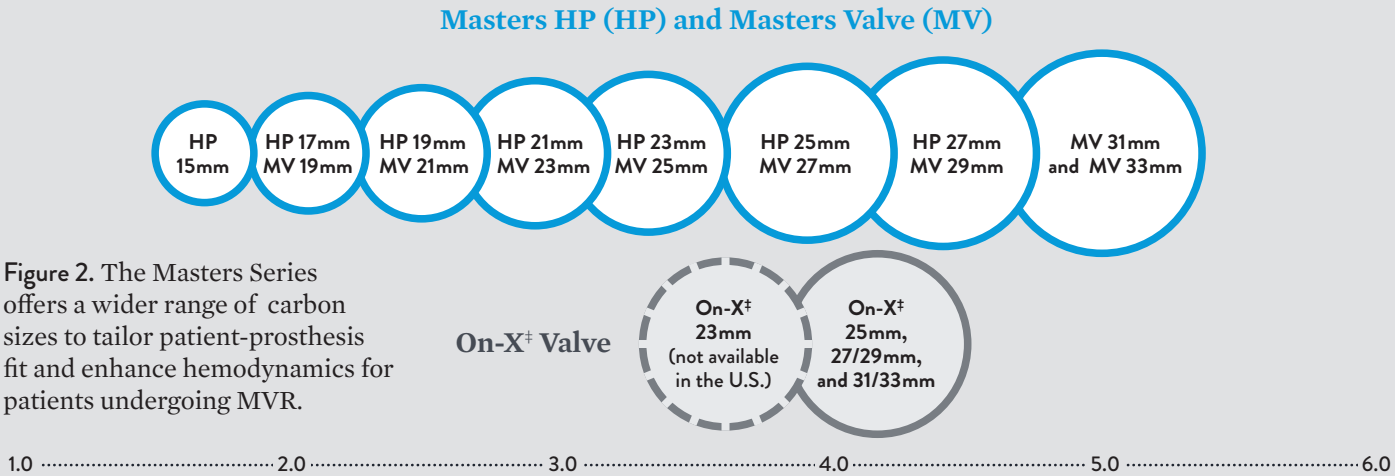


Figure 2. The Masters Series offers a wider range of carbon sizes to tailor patient-prosthesis fit and enhance hemodynamics for patients undergoing MVR.

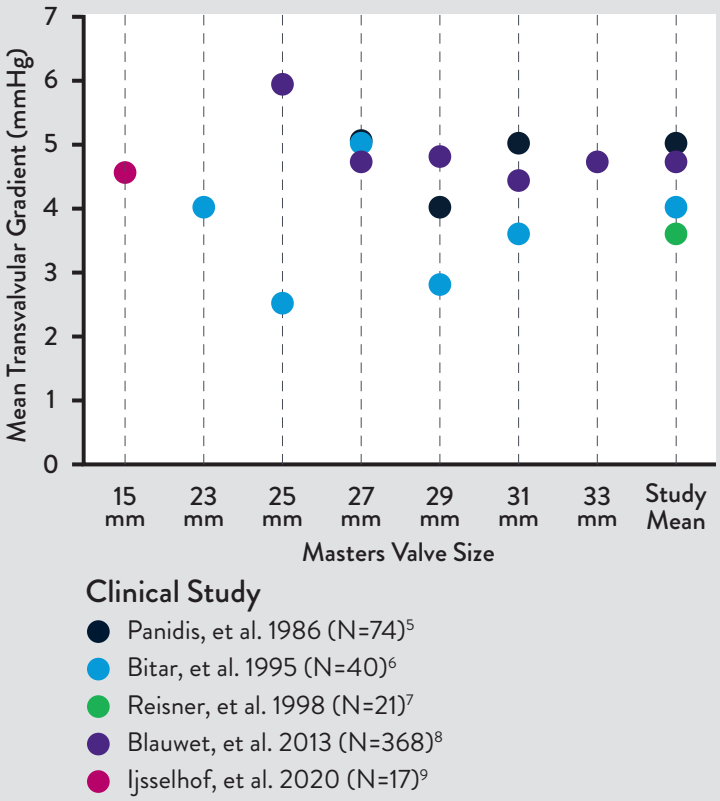
HEMODYNAMICS - MASTERS VALVE: CONSISTENTLY LOW GRADIENTS ACROSS A WIDE RANGE OF SIZES

The Masters Series has been studied in the mitral position for decades and consistently delivers low gradients across sizes to optimize care based on the patient anatomy (see Figure 3).

Additional *in vitro* testing of Master Series and On-X‡ valves by Evin et al. in 2017, demonstrated lower gradients and larger EOAs with Masters valves than comparably sized On-X‡ devices.[10] For example, in the 29 mm label size, Masters valve delivered a mean transvalvular pressure gradient of 0.9 ± 0.1 mmHg with an EOA of 3.22 ± 0.32 cm², compared to On-X‡ size 27-29/31-33 with 1.3 ± 0.1 mmHg and 2.53 ± 0.34 cm².

*NOTE: Data not from head-to-head studies. Data differences depicted between these trials may not be directly comparable, statistically significant, or clinically meaningful due to differences in trial protocols, endpoints, and/or patient populations. Data provided for informational purposes only.

Figure 3. Mean Valve Gradient for MVR with Masters Series by Size*



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IMPLANTABILITY - THE POTENTIAL IMPACT OF HEIGHT ON PROTRUSION

Maximize Hemodynamics While Reducing the Risk of Obstruction

In the mitral position sub-annular valve protrusion can increase the risk of leaflet interference from the sub-valvular anatomy and increase risk of LVOT obstruction. The Masters Series mitral valve's outflow profile is between 2.9 mm and 8.2 mm (depending on size), with the occluding leaflets effectively pulled up-stream by the pivot guards. This upstream pivot location reduces sub annular mitral leaflet protrusion.

In contrast, the On-X‡ valve has a tall, flared, tube-like orifice structure, with the occluding leaflets located in the mid-line. Depending on the cuff and patient's mitral annular size, the On-X‡ sub-annular protrusion or outflow profile, can be as large as 7 mm to 11 mm, resulting in significantly more apparatus in the ventricle.

Additionally, since On-X‡ valves for sizes 25 mm and larger share the same profile height,[4] there may be significantly more protrusion relative to the native anatomy in smaller patients. This may complicate implantation and impact the performance of the valve depending on its alignment.

In the commonly used 29 mm mitral size Masters valve can have 20% less sub-annular protrusion.

Figure 4. The design and placement of the Masters Series mitral valve results in shorter overall height, can yield less protrusion, and may reduce the risk of entanglement.

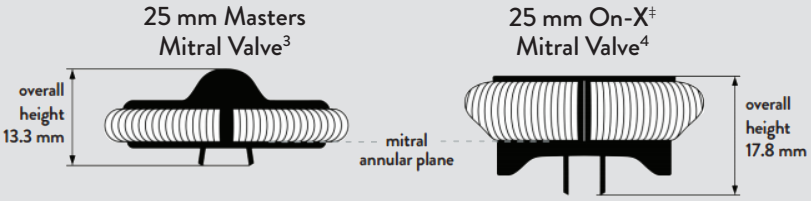
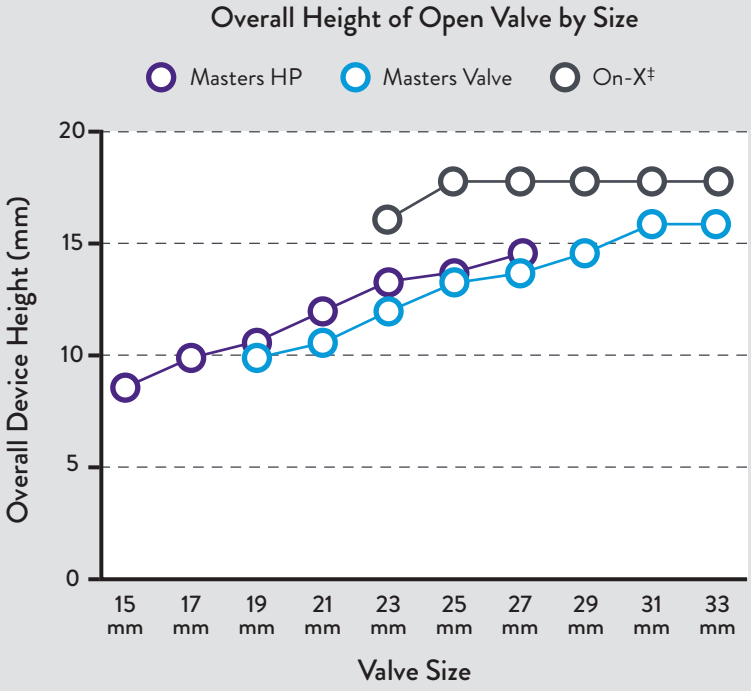


Figure 5. While the Masters Series valve height varies by size and is short, the On-X‡ device requires significant clearances regardless of the patient's annulus dimensions.



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See Important Safety Information referenced within.

SJM™ MASTERS SERIES MECHANICAL HEART VALVE

IMPORTANT SAFETY INFORMATION

℞ ONLY

INDICATIONS FOR USE

The SJM™ Masters Series Mechanical Heart Valve is intended for use as a replacement valve in patients with a diseased, damaged, or malfunctioning aortic or mitral heart valve. This device may also be used to replace a previously implanted prosthetic heart valve.

CONTRAINDICATIONS

The SJM™ Masters Series Mechanical Heart Valve is contraindicated for individuals unable to tolerate anticoagulation therapy.

WARNINGS

- For single use only. Attempts to reuse the valve may result in valve malfunction, inadequate sterilization, or patient harm.
- Do not use if:
  - The valve has been dropped, damaged, or mishandled in any way.
  - The expiration date has elapsed.
  - The tamper-evident container seal or inner/outer tray seals are damaged, broken or missing.
- Remove any residual tissue that may impair valve size selection, correct seating of the valve, rotation of the valve, or leaflet motion.
- Proper valve size selection is crucial. Do not oversize the valve. If the native annulus measurement falls between two SJM™ Masters Series Mechanical Heart Valve sizes, use the smaller size SJM™ Masters Series Mechanical Heart Valve.
- Use only St. Jude Medical™ mechanical heart valve sizers.
- The outer tray is not sterile, and should not be placed in the sterile field.
- To minimize direct handling of the valve during implantation, do not remove the holder/rotator until the valve has been seated in the annulus.
- Do not use hard or rigid instruments to test leaflet mobility, as this may result in structural damage to the valve or thromboembolic complications. Use a St. Jude Medical™ leaflet tester to gently test valve leaflet mobility.
- Place sutures in the outer half of the valve sewing cuff.
- Never apply force to the valve leaflets. Force may cause structural damage to the valve.
- Use only SJM™ Valve Holder/Rotators to perform valve rotation. Use of other instruments could result in structural damage. The valve holder/rotator is intended for single use only and should be discarded after surgery.
- The two retention sutures on the valve holder/rotator must be cut and removed before the SJM™ Masters Series Mechanical Heart Valve can be rotated.
- Do not pass catheters or other instruments through St. Jude Medical™ mechanical heart valves. This could result in scratched or damaged valve components, or leaflet fracture or dislodgment.
- Cut suture ends short, especially in the vicinity of the pivot guards, to prevent leaflet impingement.
- Three cases of impeded leaflet motion not satisfactorily explained were reported in a survey of 149 centers reporting on 4,934 patients implanted over a period of three (3) years. A number of other cases occurred early in the investigation of this prosthesis; however, the rates of occurrence are not statistically determinable.

PRECAUTIONS

- Do not touch the prosthetic valve unnecessarily, even with gloved hands. This may cause scratches or surface imperfections that may lead to thrombus formation.
- Be careful not to cut or tear the valve sewing cuff when removing the identification tag and the holder/rotator from the SJM™ Masters Series Mechanical Heart Valve.
- Before placing sutures in the valve sewing cuff, verify that the valve is mounted correctly on the valve holder/rotator.
- To avoid structural damage, the valve must be rotated in the fully closed position.
- To minimize rotational torque, verify that the valve holder/rotator is properly seated in the valve, and that the valve holder handle is perpendicular to the valve (Figures 15a and 15b).
- Remove any loose suture or thread, which may be a source of thrombus or thromboembolism.

POTENTIAL ADVERSE EVENTS

Complications associated with replacement mechanical heart valves include, but are not limited to:

hemolysis; infections; thrombus; or thromboembolism; valve dehiscence; unacceptable hemodynamic performance; hemorrhagic complications secondary to anticoagulation therapy; prosthetic failure; and heart failure or death.

Any of these complications may require reoperation or explantation of the device.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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