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Sizing Strategy and Implant Considerations for the Avalus Valve

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Hemodynamic performance of the Avalus valve through 3 years after implant is comparable to that of contemporary surgical bioprostheses. Many variables affect hemodynamic outcomes, including surgical technique. This article describes our experience with the Avalus bioprosthesis and strategies to achieve optimal hemodynamic performance.

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The Pericardial Surgical Aortic Valve Replacement (PERIGON) Pivotal Trial (NCT02088554) is a prospective investigation of the Avalus bioprosthesis (Medtronic, Minneapolis, MN). The stent of the valve is composed of a nondeformable base frame and a superimposed frame with flexible posts.[1] The leaflets, made of bovine pericardial tissue treated with α-amino oleic acid, are mounted within the stent. The valve is commercially available in several countries in sizes of 19 to 27 mm.

Previous analyses through 3 years of follow-up demonstrated hemodynamic performance and clinical outcomes comparable to those of other surgical valves.[1-3] Although multiple patient factors influence hemodynamic performance after valve implantation, surgical technique is important to consider. This article describes our experience with the Avalus bioprosthesis and the sizing strategy and implant technique to achieve optimal hemodynamic outcomes.

Technique

Valve Implantation

The valve can be implanted through a full sternotomy, partial or ministernotomy, or right anterior thoracotomy. A hockey stick–type incision, angling for the midportion of the noncoronary sinus, is optimal. If the sinotubular junction (STJ) needs to be divided to facilitate valve placement, extend the aortotomy into and through the junction above the level of the noncoronary sinus and open the STJ directly (Figure 1A). In routine cases, the aortotomy does not need to extend deep into the noncoronary sinus. If the aortic root is dilated and the ascending aorta requires replacement with a tube graft, a transverse aortotomy may be more appropriate. In patients with a narrow STJ and a small annulus, enlarge the STJ and annulus with a prosthetic patch. Aortic valve replacement is facilitated by retracting the distal ascending aorta with a traction suture and placing 3 stay sutures in the top of the commissural pillars to support and stabilize the aortic root. After debridement of the root and annulus, size the annulus to select a valve size.

Use only the Avalus sizer with the Avalus valve (Figure 1B). The barrel end approximates the valve's internal diameter and indicates the maximum size that may fit. The replica end represents the true valve size in the implanted position (Figure 1B). The replica is the most accurate predictor of the size that corresponds to the patient's annulus and root and should always be used to select the valve size. The replica should fit relatively easily

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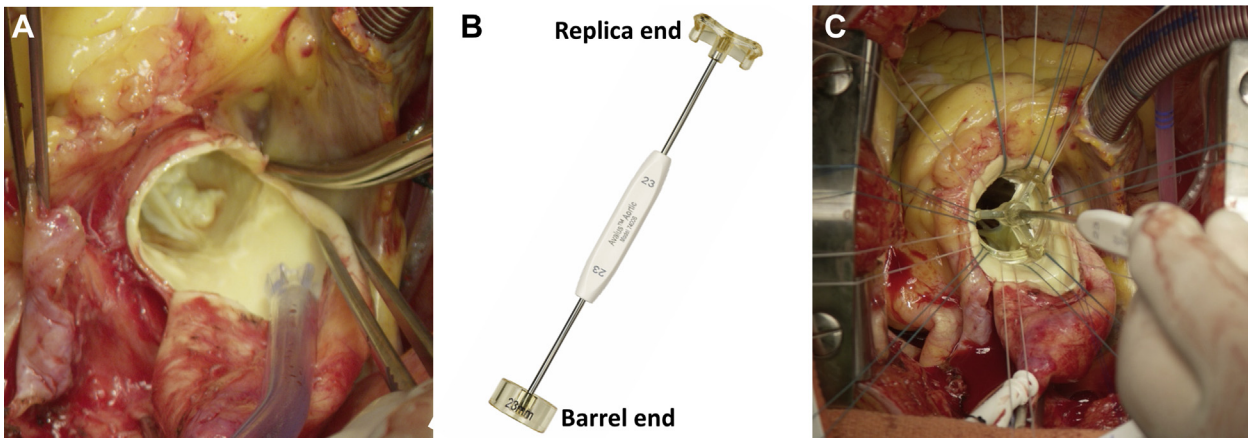
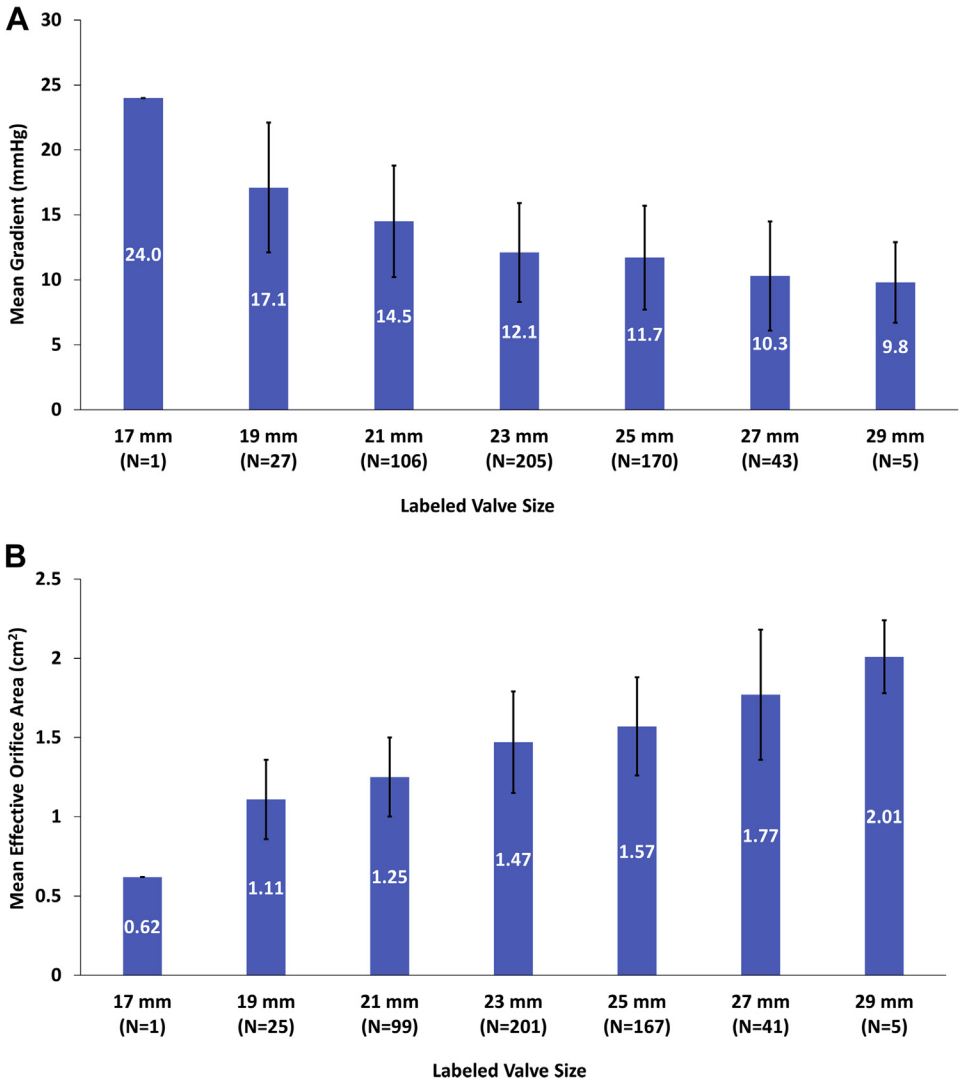


Figure 1. (A) Opening the sinotubular junction. (B) Avalus sizer. The replica end represents the valve in the final implanted position and should always be used for valve size selection. Reproduced with permission of Medtronic, Inc. (C) Appropriately sized Avalus valve. Minimal tissue is a good indicator that the valve size is appropriate.

Figure 2. (A) Mean aortic gradient and (B) effective orifice area 1 year after implant in the Pericardial Surgical Aortic Valve Replacement Pivotal Trial.[2]



through the STJ and into the root. If the replica moves too easily through the annulus, the valve is too small. If the replica fits tightly into the aortic root and there is significant protrusion of sinus tissue underneath the sizer, the valve is too large. A correctly sized valve fits firmly in the root with minimal to no sinus tissue protruding into the left ventricular outflow tract lumen (Figure 1C; Video). It is important to gauge the amount of visible annular tissue when looking through the sizer. Minimal tissue is a good indicator that the size is appropriate. Too much tissue indicates that the size is too large even though the replica may fit into the root. Avoid using indexed effective orifice area (EOA) charts for valve size selection because these have limited ability to predict prosthesis–patient mismatch.[4] Also, avoid oversizing to maximize hemodynamics and durability.

Noneverting pledgeted mattress sutures or simple interrupted sutures may be used. Place sutures with a generous bite into the cuff close to the stent to facilitate cuff folding and valve seating. The valve is designed to be implanted in the supra-annular position. We routinely place 9 to 12 noneverting pledgeted mattress sutures in a subannular position and lower the valve into position in the aortic root. Care should be taken when inserting the valve into a calcified or rigid aortic root.

Hand-tied knots or titanium auto-knotting devices may be used to secure sutures. Leaving the valve holder in place allows for safer manipulation of the valve while tying or using an auto-knotting device. Once all sutures are secured, the holder is removed. On rare occasions, the aortotomy may be too tight to close once the valve is seated. In these cases, an aortic root patch closure may be performed.

Comment

Sizing and surgical technique are critical to hemodynamic and durability outcomes after surgical aortic valve replacement.[5] Undersizing can result in implantation of a prosthesis that is too small for a patient's cardiac output requirements, producing patient–prosthesis mismatch, whereas oversizing may increase aortic pressure gradients, decrease EOAs, and diminish the effect of increased flow rates, causing premature prosthetic valve degeneration.[6] Use of the replica end of the sizer to select the valve size is critical.[5]

Adherence to these sizing considerations resulted in an overall mean gradient and EOA at 1 year after implant of 12.5 ± 4.4 mm Hg ($n = 518$) and 1.5 ± 0.4 cm^2 ($n = 394$), respectively, in the PERIGON Pivotal Trial (Figure 2),[2] outcomes that have remained stable through 3 years of follow-up[3] and are comparable to those from the contemporary COMMENCE (ProspeCtive, nOn-randoMized, MulticENter Clinical Evaluation of Edwards Pericardial Bioprostheses With a New Tissue Treatment Platform) study.[7]

An important consideration when choosing an aortic bioprosthesis is long-term durability, which is influenced by many factors, including valve design. The firm base frame of the Avalus valve will maintain its round shape, including in the elliptical bicuspid valve annulus. The flexible stent posts relieve mechanical stress on the leaflets, and in our experience, provide additional space for knot-tying. The valve has a low profile to reduce the risk of coronary obstruction. The leaflets are mounted internally within the stent, a construction associated with longer durability than externally mounted leaflets.[8]

The PERIGON Pivotal Trial has demonstrated favorable hemodynamic performance of the Avalus valve during up to 3 years of follow-up. As with any surgical valve replacement, valve sizing strategy and implant technique are important to achieve optimal hemodynamics and long-term durability. Use of the replica end of the sizer is critical to select the appropriate valve size, and oversizing should be avoided.

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