

Transcatheter Aortic and Mitral Valve-in-Valve Implantation Using the Edwards Sapien 3 Heart Valve

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Valvular heart disease is a growing clinical problem with significant morbidity and mortality. Surgical valve replacement using mechanical or tissue prosthesis has remained the preferred therapy for several decades. In contrast to mechanical valves, the use of bioprosthetic valves to treat significant aortic valve stenosis (AS) or aortic valve regurgitation (AR) in the native aortic valve has continued to increase over time.^{1,2} Bioprosthetic valves are advantageous to patients as they negate the need for long-term anticoagulation therapy; however, they have limited durability and are expected to degenerate within 5 to 20 years.²⁻⁴ The current standard of care for patients with a degenerated bioprosthetic valve is surgical valve replacement; however, the morbidity and mortality for reoperation is significant because of the technical complexity of the re-do sternotomy, and also because most of these patients are elderly with multiple

comorbid conditions such as prior coronary artery bypass surgery, diabetes mellitus, and cerebrovascular disease.^{2,5,6}

Although transcatheter heart valves (THV) were initially designed to treat aortic stenosis, the design yields to its use for other indications. The first use of a THV device to treat a failing bioprosthetic heart valve in the aortic position was reported in 2007.⁷ Since then, valve-in-valve (VIV) has become a feasible alternative for treating patients who have degenerated bioprosthetic aortic valves and who are at increased risk of adverse perioperative events.^{2,5,6} VIV is also emerging as a treatment option for patients with failed bioprosthesis in the mitral position. Hundreds of patients with failed mitral bioprosthesis have been treated worldwide with the off-label use of aortic transcatheter heart valves.^{8,9}

The procedural success rate for aortic VIV transcatheter aortic valve replacement (TAVR) was 93.1% based on the preliminary data from the Valve-in-Valve International Data (VIVID) registry.⁶ In the VIVID registry, the overall 1-year survival was 83.2% in patients who underwent transcatheter VIV implantation for degenerated bioprosthetic aortic valves.⁶ The US Food and Drug Administration had approved an expanded indication for the use of the balloon-expandable Sapien, Sapien XT valves (Edwards Lifesciences), and the self-expanding CoreValve System (Medtronic Inc) for aortic VIV implantation. The Sapien 3 (S3) (Edwards Lifesciences) valve is the latest iteration of the US Food and Drug Administration–approved balloon-expandable THV, and it has unique characteristics compared with previous valves. The use of S3 THV was expanded by the US Food and Drug Administration on June 5, 2017 not only for VIV implantation inside a failed bioprosthetic aortic valve, but also for a failed bioprosthetic mitral valve; this is the first approval of any THV for both aortic and mitral VIV implantation.

Several new features of the S3 THV, especially its outer skirt and the ability to overexpand its stent frame,¹⁰ may have an impact for choosing the optimal size of S3 THV for aortic and mitral VIV implantation.

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Accompanying Tables S1 through S3 are available at <http://jaha.ahajournals.org/content/7/14/e007767/DC1/embed/inline-supplementary-material-1.pdf>

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In this article we evaluate existing methods with respect to utilization of the S3 valve in aortic and mitral VIV procedures, describe bioprosthetic valve sizing terminology (Figure 1), and discuss preprocedural sizing as well as relevant intraoperative factors and techniques used for a successful VIV implant.

Sizing and Deployment

In general terms, “under/oversizing” refers to the degree to which a THV is smaller/larger than the measured annulus or bioprosthesis internal diameter, respectively. A degree of oversizing is essential—particularly when implanting self-expanding valves—to ensure THV anchoring and stability after deployment. During native valve TAVR, excessive oversizing may increase the risk of heart block requiring permanent pacemaker implantation and annulus rupture. How much oversize is required to ensure adequate fixation and at the same time avoid incomplete device expansion of balloon-expandable THVs is unclear, and hence an oversize in the range of 2 to 3 mm is usually practiced.

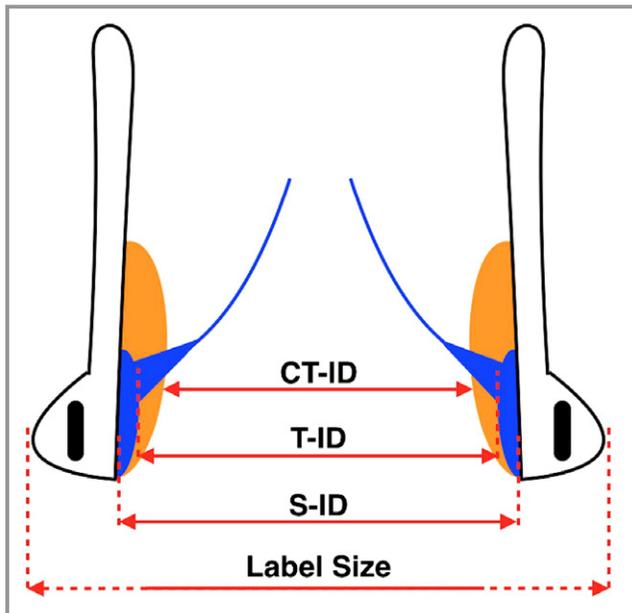


Figure 1. Surgical bioprosthesis sizing terms. A schematic representation of a cross-section through a failed bioprosthetic valve is shown. Valve size measurements may be defined in a number of ways. Manufacturer label size is variable and does not usually indicate the internal diameter of the valve. S-ID is used to indicate the inner diameter of the valve struts/frame, including overlying fabric. T-ID accounts for the leaflets and sutures (represented in blue) sewn within the stent frame, whereas CT-ID also includes any accumulated pannus or calcification (represented in orange) within the degenerated bioprosthesis. CT-ID indicates computed-tomography inner diameter; S-ID, stent inner diameter; T-ID, true inner diameter.

In this review, “under/overexpansion” refers specifically to the balloon filling volume strategy used to deploy the S3 THV, with reference to the nominal filling volume. For example, overexpansion of the 23-mm S3 THV, with an extra 2 mL of filling volume, results in a prosthesis diameter of ≈ 24 mm—mainly at the in- and outflow part of the valve frame—while preserving normal valve function.¹⁰ This under/overexpansion capability of the S3 means that the size of the implanted THV can be more precisely tailored to the dimensions of the bioprosthesis during VIV procedures, thus avoiding excessive oversizing. As a general principle during VIV procedures, we recommend implanting the *smallest* size S3 device that can be adequately deployed and anchored to achieve a minimum of 1 mm oversizing (Figure 2), within the constraints of the bioprosthesis and notwithstanding other anatomical considerations.

Foreshortening

Unlike preceding iterations of balloon-expandable THV, S3 foreshortening during deployment occurs almost exclusively from the inflow side of the device. This technical feature has implications when choosing the deployment height of the valve, particularly as deliberate under- or overexpansion will result in a lesser or greater degree of foreshortening, respectively.

Appropriate Valve Expansion

Appropriate S3 expansion is important to achieve an optimal hemodynamic outcome. An inadequately expanded THV may be at risk of elevated transvalvular gradient because of inadequate leaflet expansion and mobility, also potentially increasing the risk of accelerated leaflet degeneration.^{1,2,4,11}

Measure of VIV Success

The requirements for a successful VIV implantation are as follows: secure anchoring of the THV within the failed bioprosthesis, a good seal around the valve to eliminate intervalvular leak, patent coronary arteries (in aortic VIV) and left ventricular outflow tract (in mitral VIV), a low gradient across the newly implanted THV, and lack of central regurgitation. Selection of the appropriate size THV and preprocedural identification of potential complications are key to a successful VIV procedure.

Identification and Sizing of the Failed Bioprosthetic Valve

An important component of performing the VIV procedure starts with an in-depth understanding of the failed

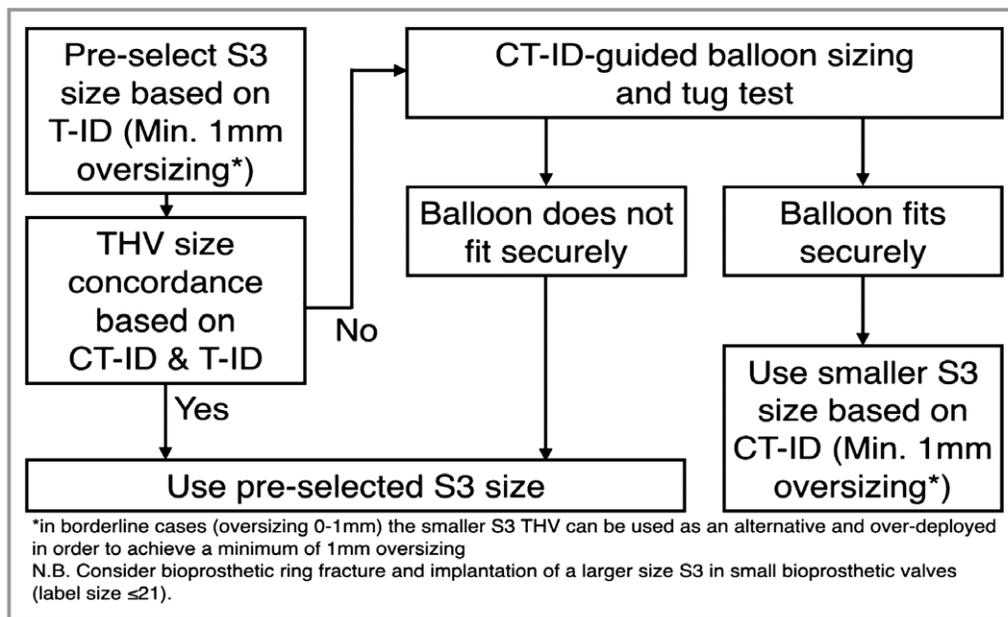


Figure 2. Algorithm for determining the choice of S3 THV size. This simplified flow chart can be used during VIV TAVR to facilitate selection of the S3 THV size, and guide when balloon sizing may be appropriate. A minimum of 1 mm oversizing is required in order to ensure adequate anchoring of the S3 THV within the bioprosthesis. Use of the smallest possible THV reduces the risk of excessive flaring of the outflow portion of the stent frame. N.B. In small bioprosthetic valves (label size ≤ 21), the risk of patient–prosthesis mismatch is high after VIV TAVR. High-pressure balloon postdilatation with bioprosthetic valve fracture may enable implantation of a larger size THV with improved transvalvular gradient. CT-ID indicates computed-tomography inner diameter; S3, Sapien 3; THV, transcatheter heart valve; T-ID, true inner diameter; VIV TAVR, valve-in-valve transcatheter aortic valve replacement.

bioprosthetic valve, which includes the following: the type of valve used (stented, stentless, sutureless, transcatheter valve), its structural elements, the technical details of the primary valve surgery (intra-annular versus supra-annular), and the cause of bioprosthetic valve failure (wear and tear, calcification, endocarditis, thrombosis, leaflet dysfunction, and pannus formation).^{1,2,4,5,12} Selection of the THV size for the aortic and mitral VIV implantation depends on many factors listed above.

Failed Bioprosthetic Valve Inner Diameter

The type of bioprosthesis and manufacturer-defined label size could be obtained from the operative report. When this information is not available, the type of implant may be identified by fluoroscopy, chest radiograph, and/or cardiac multidetector computed tomography (MDCT).⁵ The sizing and labeling of the surgical bioprosthetic valves are not standardized and vary widely based on the different manufacturers. The minimum internal diameter of the surgical bioprosthetic valve may vary markedly from the given labeled valve size^{1,2,4,5} (Figure 1); label size alone is therefore not suitable as a guide to THV size selection.

The “true” inner diameter (T-ID) of the surgical bioprosthesis is one of the most important pieces of information needed for selecting the size of the THV for the aortic or mitral VIV procedure.⁴ It is important to note that most bioprosthetic valves have a “stent” inner diameter, which consists of the frame/skeleton of the valve, including the overlying fabric, and the T-ID, which takes into account the leaflets sewn within the valve frame¹³ (Figure 1). The term “neo-annulus” has been used to describe the narrowest physical plane—determined in vitro by balloon inflation—of a surgical bioprosthesis, and it is this benchtop dimension that determines the T-ID. In most bioprosthesis types, this minimum diameter is located at the level of the sewing ring.¹⁴ Another crucial point to remember is that when we factor in the additional space taken up by degenerated leaflets and accumulated material in the failed bioprosthesis including pannus formation, the actual internal diameter of that valve is likely to be even less than the T-ID. In addition to providing information regarding the degree and distribution of calcific degeneration, accumulated material at the level of the sewing ring within a bioprosthesis can be assessed using contrast-enhanced MDCT. We propose using the definition “CT” inner diameter (CT-ID) to describe this minimum internal diameter in degenerated in vivo bioprosthetic valves

(Figure 1). Use of the CT-ID may indicate that a smaller S3 valve is preferable in order to achieve an optimal VIV result (Figures 3 and 4).

In order to facilitate suitable valve sizing, Bapat et al have developed a mobile app “ViV Aortic” and “ViV Mitral” in collaboration with the technology company UBQO.¹⁵ This app provides data that guide proper identification of all available surgical and transcatheter valves and rings, as well as an in vitro estimate of the valve T-ID, and sizing recommendation for the S3 THV.³ Although the ViV App (version 2.0) is invaluable, there are a few limitations of this App when using the Edwards S3 valve for VIV. The ViV App sizing recommendation may in some cases exceed the optimal THV size for a selected bioprosthesis. For example, the 21-mm Perimount valve (Edwards Lifesciences) has a 19-mm T-ID, and the App recommends selecting a 23-mm Sapien XT or S3 THV (Edwards Lifesciences).³ This may lead to inadequate expansion of the 23-mm valve within the bioprosthesis frame, leading to prosthesis–patient mismatch with possible higher transvalvular gradients and inadequate function of the valve leaflets, and hence a 20-mm Sapien 3 could be a better option with just 1-mm oversizing. In this situation, our preferred approach is to use high-pressure postdilatation after 20-mm S3 valve deployment to optimize expansion and stretching of

the bioprosthetic frame and sewing ring¹⁶ or consider implanting a supra-annular THV; however, if there is adequate space in the aortic root, then “cracking the ring” with high-pressure postdilatation technique (described below) can enable implantation of a 23-mm S3 THV (Figure 5).

Balloon-Sizing and Tug-Test

Balloon sizing is not routinely recommended in VIV procedures, as there is an increased risk of embolization or creating aortic insufficiency,^{1,2,4,6} which can result in acute hemodynamic instability. However, in addition to selecting the size of the THV based on the T-ID of the initially implanted bioprosthetic valve, balloon sizing can provide additional information and better understanding in selected cases such as when the CT-ID suggests a smaller size S3 may be suitable, borderline valve sizes, stentless bioprostheses, or valves with a high risk of coronary artery obstruction. In these situations, balloon sizing can be performed along with a tug-test (Figures 4 and 6). The tug-test involves applying negative tension to the fully inflated balloon within the bioprosthetic valve to help assess how well the balloon is anchored in the valve. This information can be used to guide the selection of the appropriate THV

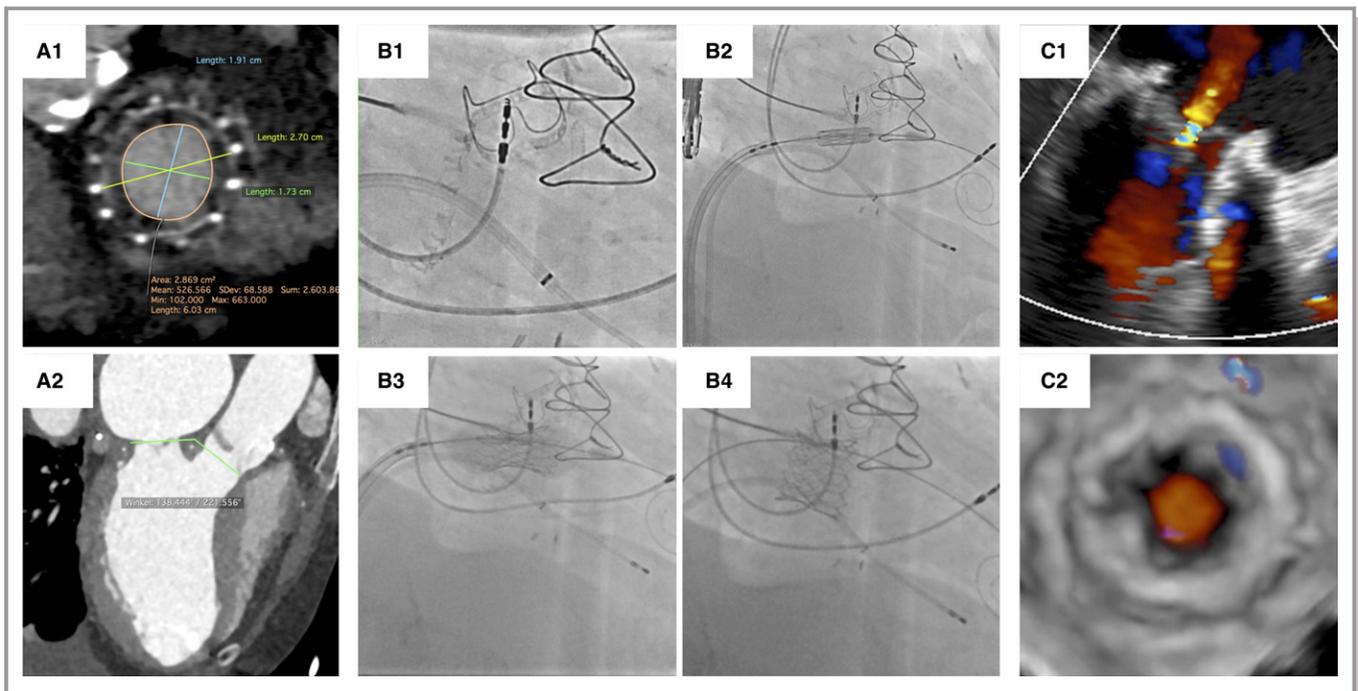


Figure 3. Central regurgitation after extensive oversizing of a 26-mm S3 THV within a St. Jude Epic 27-mm bioprosthesis in the mitral position. Although the T-ID of the 27-mm St. Jude Epic is 22.5 mm, a mean preoperative CT-ID of 18.2 mm was measured in this degenerated bioprosthesis (Panel A1). The VIV app recommends use of a 26-mm S3 THV; however, deployment resulted in underexpansion of the device within the bioprosthesis and extensive flaring of the outflow portion of the frame (Panels B1 to B4), associated with central regurgitation (Panels C1 and C2). CT-ID indicates computed-tomography inner diameter; S3, Sapien 3; THV, transcatheter heart valve; T-ID, true inner diameter; VIV, valve-in-valve.

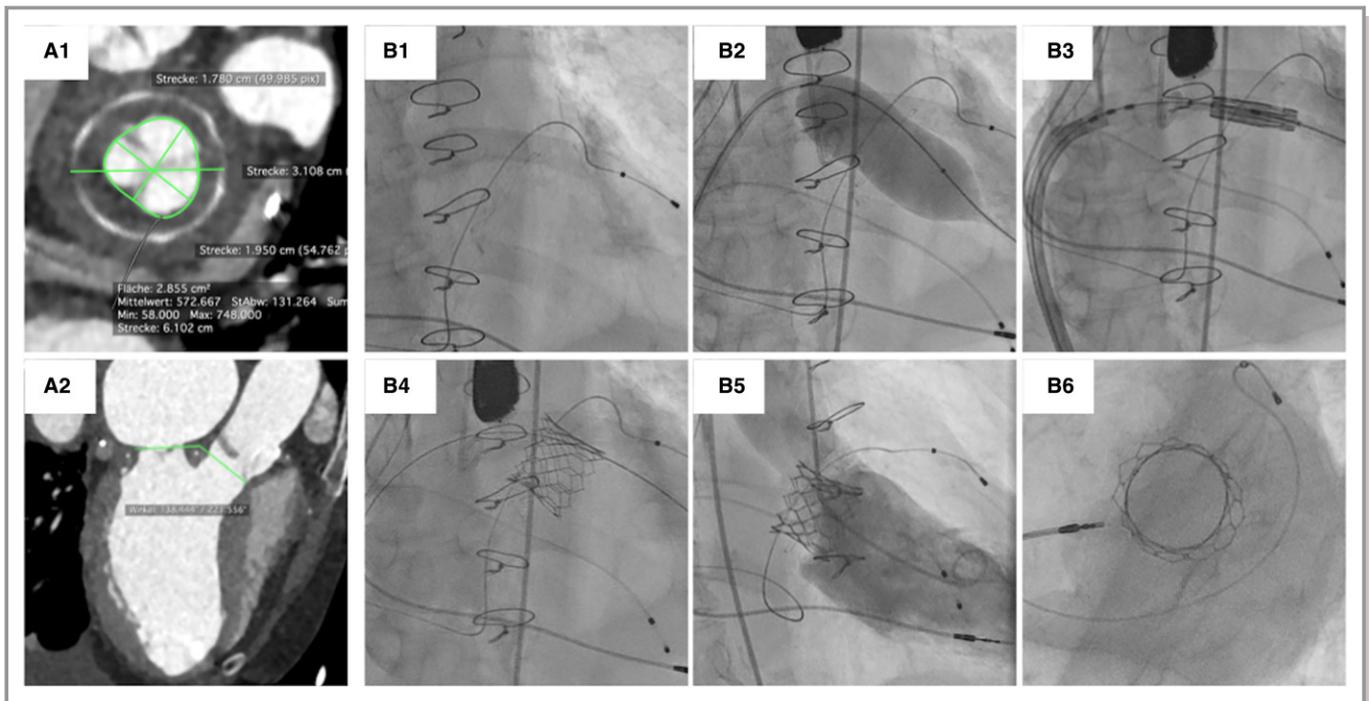


Figure 4. Mitral VIV. S3 valve choice based on CT-ID, balloon-sizing, and tug-test. Case of S3 26-mm valve inside an Epic 31 mm (St. Jude Medical) with a T-ID of 26.5 mm. The VIV Mitral App recommends implanting a S3 29-mm valve. Based on the CT-ID of 18.7 mm and balloon-sizing and tug-test with a 25-mm Edwards balloon, the decision was to deploy a 26-mm S3 valve with nominal filling volume. A1. Epic 31-mm (St. Jude Medical) valve: CT-ID was measured at 18.7 mm. A2. Aorto-mitral angle: 138 degrees. B1. Coplanar view of the mitral valve. B2. Balloon-sizing and tug-test with a 25-mm Edwards balloon. B3. S3 26-mm positioning towards left ventricle because of expected underdeployment. B4. S3 26-mm implantation result with a flared frame on the ventricular side. B5. Left ventricular angiography to assess for MV regurgitation. B6. S3 26-mm “round” deployment. CT-ID indicates computed-tomography inner diameter; MV, mitral valve; S3, Sapien 3; T-ID, true inner diameter; VIV, valve-in-valve.

size and to assess the solidity of any material that may be accumulated within the bioprosthesis.

Balloon sizing can be useful when the pre-existing valve is supra-annular with external leaflets, such as the Mitroflow (Sorin) and Trifecta (Abbott), and there is a short distance to the coronary ostia, thereby increasing the risk of coronary artery obstruction.^{2,4–6} Furthermore, balloon sizing may be useful to assess for height of the prosthetic valve neo-annulus and to assess for unanticipated expansion of a stentless bioprosthesis, a technical issue that can lead to THV embolization.¹⁷

Prosthesis–Patient Mismatch

Prosthesis–patient mismatch (PPM) is the phenomenon when the implanted prosthetic valve has a lower effective orifice area (EOA) than a normal human valve.¹⁸ Calculations based on patients’ body surface area, direct measurements of the aortic root during surgery, and echocardiographic parameters such as transvalvular gradient and EOA are calculated to assess PPM. In general, an echocardiographically derived prosthetic EOA, indexed to body surface area (indexed EOA), of ≤ 0.60 cm^2/m^2 is considered severe, of 0.60 to 0.85 cm^2/m^2 is moderate, and

≥ 0.85 cm^2/m^2 is considered nonsignificant.^{19–21} Based on the surgical literature, severe PPM following aortic valve replacement is associated with worse clinical outcomes, less reduction in left ventricular mass, and lower long-term survival.^{22,23} Likewise, severe PPM following surgical mitral valve replacement is also associated with lower long-term survival.²⁴

Aortic VIV procedures are associated with a higher rate of PPM than native valve TAVR,^{6,25} particularly in surgical valves with a manufacturer size of ≤ 21 mm.²⁵ Results from the VIVID registry revealed an elevated postprocedural mean aortic transvalvular gradient of ≥ 20 mm Hg in 28% of patients.

When considering a VIV procedure, it is important to determine whether a high gradient across a surgical valve is because of degeneration of the valve or simply as a result of postoperative PPM.²⁶ A VIV procedure will not correct a stable elevated transvalvular gradient caused by surgical PPM unless an adjunctive technique—such as bioprosthetic ring fracture—can be used.

Treatment of small bioprosthetic valves (label size ≤ 21 mm) remains a challenging problem during aortic VIV procedures because of the risk of high postprocedural transvalvular gradient with new, or persistent, PPM.⁶ As a result, a preprocedural evaluation of the EOA may be particularly

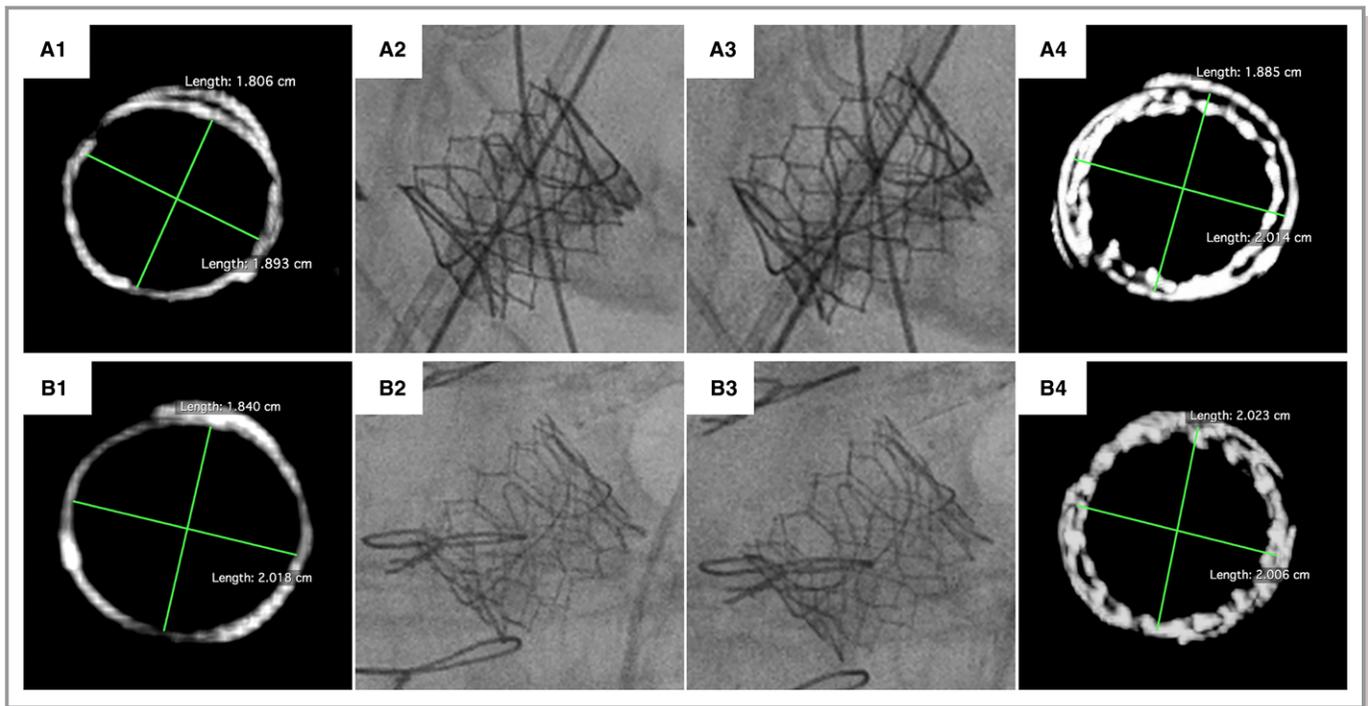


Figure 5. Examples of using high-pressure postdilatation to optimize THV deployment in small bioprosthetic valves. Contrast and brightness are adjusted to minimize blooming artifact. A. Edwards S3 20-mm THV inside a Perimount 21 valve (true inner diameter 19 mm). A1. Stent inner diameter of the Perimount sewing ring measured on the baseline CT—18.1×18.9 mm. A2. Twenty-mm S3 angiographic appearance after deployment. Note the waist appearance at the level of the sewing ring. A3. Angiographic appearance of the 20-mm S3 after postdilatation with a 20-mm True Dilatation balloon (Bard) to 16 atmospheres showing improved device expansion within the bioprosthesis. A4. Stent inner diameter of the Perimount sewing ring on CT after high-pressure postdilatation showing increased dimensions of 18.9×20.1 mm. A residual transvalvular mean gradient of 12 mm Hg was observed on echocardiography. B. Edwards S3 23-mm THV inside a Perimount 21 valve (true inner diameter 19 mm). B1. Stent inner diameter of the Perimount sewing ring measured on the baseline CT—18.4×20.2 mm. B2. Twenty-three-mm S3 angiographic appearance after deployment. Note the mild waist appearance at the level of the sewing ring. B3. Angiographic appearance of the 23-mm S3 after postdilatation with a 22-mm Atlas Gold balloon (Bard) to 20 atmospheres showing improved device expansion within the bioprosthesis. B4. Stent inner diameter of the Perimount sewing ring on CT after high-pressure postdilatation showing increased dimensions of 20.2×20.1 mm. A residual transvalvular mean gradient of 18 mm Hg was observed on echocardiography. CT indicates computed tomography; S3, Sapien 3; THV, transcatheter heart valve.

important to determine appropriate clinical management and THV implantation strategy; however, in selected cases the benefit of acute gradient reduction and hemodynamic improvement in highly symptomatic patients at prohibitive risk of re-do surgery may, nevertheless, outweigh the risk of PPM that can occur after a VIV procedure. More recently, deliberate bioprosthetic sewing ring fracture (discussed below) using high-pressure balloon dilatation (“cracking-the-ring”) has emerged as a promising adjunct for aortic VIV in a small bioprosthesis in order to facilitate implantation of a larger THV size and effectively reduce postprocedural gradients.^{27,28}

Balloon-Inflatable Versus Self-Expanding THVs in VIV Procedures

Registry and in vitro data suggest that supra-annular THVs are associated with lower gradients after aortic VIV procedures; however, technical factors, such as future access to the

coronary vessels, concerns about THV recoil associated with self-expanding devices, or use of deliberate bioprosthetic ring fracture, may prompt selection of a balloon-expandable intra-annular THV.^{11,16,29–32} While randomized comparisons of the transvalvular gradient after S3 versus supra-annular THV implantation in surgical bioprostheses have not been performed, accurate sizing, positioning, and deployment of the S3 is clearly essential in order to achieve a good functional outcome with low transvalvular gradients.

It should be noted that because of anatomical constraints, balloon-expandable valves are currently mandated in mitral VIV procedures.

Anticipating Complications During VIV Procedures

The risk of potential complications can often be determined by rigorous evaluation of preprocedural investigations. The

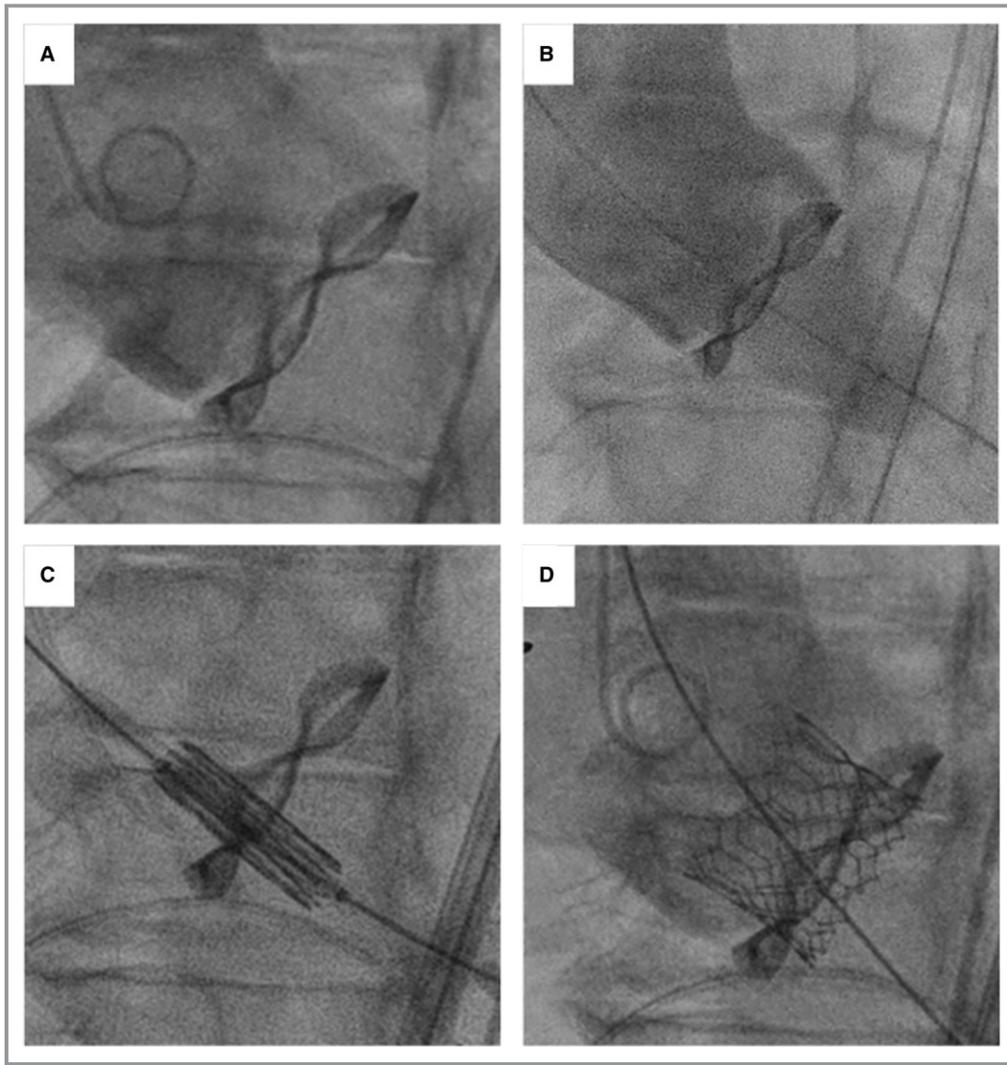


Figure 6. Balloon-sizing, tug-test, and S3 overdeployment. Case of S3 23-mm valve inside a Mitroflow 27-mm valve with a T-ID of 23 mm. The VIV Aortic App recommends implanting a S3 26-mm valve in this circumstance. Planned overdeployment of a S3 23-mm (+2 mL in deployment-balloon) THV after balloon-sizing and tug-test with a 23-mm balloon. A. Coplanar View. B. Balloon sizing and the tug-test show that the coronary arteries are not obstructed, and the balloon is fixed in the bioprosthetic surgical valve. C. Placement of the S3 23-mm middle marker is at the bottom of the suture ring of the bioprosthetic surgical valve (“low position”). D. Implantation result shows no aortic insufficiency with a peak-to-peak gradient of 5 mm Hg across this valve. S3 indicates Sapien 3; THV, transcatheter heart valve; T-ID, true inner diameter; VIV, valve-in-valve.

MDCT data, in particular, provide valuable information when assessing the risk of severe intraprocedural complications.

During aortic VIV procedures, coronary artery occlusion may occur because of impingement of displaced surgical leaflets and/or bulky degenerative material on the coronary ostia, especially in stentless valves and valves with leaflet attachment outside the frame, such as the Mitroflow (Sorin Group) and the Trifecta (Abbott) valves. In this regard, MDCT enables accurate assessment of the height of the coronary ostia in relation to the surgical bioprosthesis and the width of the aortic sinus. Low coronary height (<12 mm) and/or small

sinus of Valsalva diameter (<30 mm) will increase the risk for coronary artery obstruction during native valve TAVR,³³ and aortic VIV procedures are associated with a higher risk.²⁹ Unfavorable anatomy identified on MDCT may prompt avoidance of a VIV procedure altogether; it may also direct the implanter to use balloon sizing, or use a risk-minimization strategy, such as less aggressive valve oversizing and deeper valve implantation, to avoid coronary artery occlusion. A recently described first-in-humans procedure involving intentional laceration of the bioprosthetic leaflet scallop before valve implantation (BASILICA) may enable a successful aortic

VIV procedure despite a high risk of coronary occlusion (unpublished data—TCT 2017).

Mitral VIV poses a unique set of challenges to the operator. Closing pressure is higher across bioprosthetic valves in the mitral position when compared with those in the aortic position; this is because of exposure to left ventricular systolic, rather than aortic diastolic, pressure. For this reason, secure anchoring of a VIV THV may be more important in the mitral position than the aortic. The principles of MDCT-based valve sizing also apply to mitral VIV.

Mitral VIV also carries with it a risk of left ventricular outflow tract (LVOT) obstruction because of displacement of the bioprosthetic leaflets and coverage of the open part of the THV frame. Mitral VIV-induced LVOT obstruction with hemodynamic compromise is a serious complication with limited treatment options and can be fatal; therefore, it should be avoided whenever possible. Bioprostheses with bovine pericardial leaflets are at particular risk of creating a LVOT obstruction because the leaflets are positioned higher up the stent frame, thus resulting in greater THV frame coverage in the LVOT. Assessing the LVOT tract anatomical morphology with MDCT can be helpful to identify patients at high risk of this complication.³⁴ Prominent septal hypertrophy and a narrow aorto-mitral angle increase the risk of subsequent LVOT obstruction. The aorto-mitral-annular angle—defined as the angle formed at the intersection of lines running through the intercommissural diameter of the mitral annulus and the center of the aortic annulus—is readily determined from preprocedural MDCT images. Acute angles <115 degrees may increase the risk of LVOT obstruction after deployment of a balloon-expandable valve³⁵ (Figure 4). Preprocedural virtual valve implantation, performed using commercially available 3-dimensional reconstruction software, and calculation of the neo-LVOT area can assist preemptive identification of this complication (Figure 7). Preliminary studies suggest that a neo-LVOT area of 250 mm² or larger is associated with a low risk of LVOT obstruction.^{36,37}

Our S3 THV Sizing Recommendation for VIV Implantation

When using the S3 THV for VIV, we recommend a minimum oversizing of 1 mm in relation to the T-ID. However, when the measured CT-ID suggests that a smaller size THV could be selected, we would recommend balloon sizing and tug testing to confirm adequate anchoring before implanting the smaller size. A simple algorithm for choosing the S3 THV size is provided in Figure 2. In borderline cases between 2 S3 THV sizes (oversizing range of 0–1 mm based on T-ID or CT-ID), the smaller S3 valve can be safely overexpanded in order to optimize valve leaflet function and ensure anchoring¹⁰ (Figure 6). Furthermore, overexpansion by overfilling of the deployment balloon with additional volume results in further

flaring, mainly of the in- and outflow segments of the S3 valve¹⁰; this may also play a role in better fixation of the S3 THV within bioprosthetic surgical valves. During mitral VIV procedures in particular, some degree of flaring of the ventricular portion of the S3 is recommended to avoid late atrial dislodgement.³⁴

Surgical Bioprosthetic Sizing Charts

Tables S1 and S2 show the published T-ID, available in the Aortic VIV and Mitral VIV apps, for selected stented bioprosthetic valves, in the aortic and mitral positions, respectively. We recommend ≥ 1 mm oversizing when implanting a S3 THV within a stented bioprosthesis. Based on this recommendation, a smaller S3 could be utilized in a number of cases compared with the VIV app recommendation. For example, the 27-mm Mitroflow valve (Sorin) has a T-ID of 23 mm and the VIV Aortic App recommends selecting a 26-mm S3 valve.³ However, an overdeployed 23-mm S3 valve achieved an excellent final result (Figure 6).

Stentless and Sutureless Surgical Bioprosthetic Valves

The surgical technique used for implantation of stentless and sutureless bioprosthetic valves could vary the T-ID of these valves. Walther et al described implantation of oversized stentless surgical valves in patients with a small aortic root using controlled oversizing and adjusting the valve size to the sinotubular junction diameter.³⁸ They were able to achieve a gain of 2 to 4 mm in prosthesis size with improved hemodynamics based on this controlled oversizing.³⁸ Thus, for stentless and sutureless surgical valves (Table S3) we recommend MDCT-based sizing. Measurement of the CT-ID, which matches with the internal diameter of the sewing ring (“neo-annulus”), and assessment of the amount of degenerative material, such as pannus or calcification in and around the valve, is important and should be taken into consideration.

Valve in THV

Because of the recent popularity of TAVR, failed THVs are likely to account for an increasing proportion of VIV procedures. Because of the common practice of oversizing self-expanding transcatheter valves, and the variability in final internal diameter, CT measurements of the size of the native annulus should be taken into consideration. In the majority of patients with a prior Sapien, Sapien XT, or S3 valve, the same size S3 THV can be implanted. For example, if a patient has a failed 23-mm Sapien XT valve, then we would recommend implanting a 23-mm S3 THV inside this failed THV.

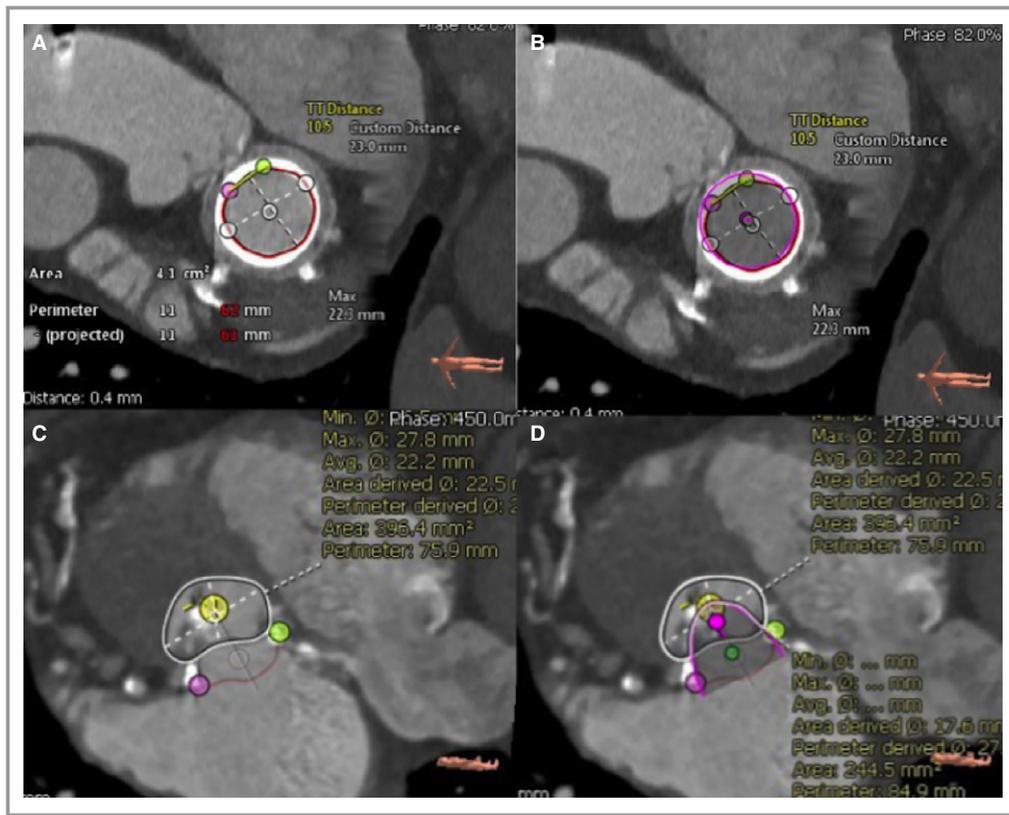


Figure 7. Mitral annular area and neo-LVOT area measurements. A, Cardiac computed tomography–based measurement of the mitral internal annular area using 3Mensio Structural Heart Mitral Workflow version 8.1 (Pie Medical Imaging, Maastricht, the Netherlands). B, Short-axis view of the mitral bioprosthesis with a 23-mm virtual valve in place (pink circle). C, Measurement of the LVOT tract area in systole in short-axis (white circle) view using 3Mensio Structural Heart Mitral Workflow version 8.1 (Pie Medical Imaging, Maastricht, the Netherlands). D, Measurement of the remaining LVOT area in short axis (white circle) after placement of the virtual transcatheter heart valve (pink). The remaining space in the LVOT after placement of the virtual valve is the neo-LVOT. A neo-LVOT area of 250 mm² or larger is associated with a low risk of LVOT obstruction. LVOT indicates left ventricular outflow tract.

Intraprocedural Considerations: Aortic VIV

To facilitate accurate THV landing zone evaluation, stented surgical valves should be aligned fluoroscopically so that the basal ring and struts form a single plane perpendicular to the imaging beam. This coplanar view can usually be achieved by aligning the stent strut tips, the suture ring of stented valves, or the nadir points of stentless valves³⁹ (Figure 8).

To ensure an optimal valve deployment with safe anchoring and good sealing, the skirt of the S3 valve should be implanted at the height of the “neo-annulus” of the surgical bioprosthetic valve. The neo-annulus is almost always located at the level of the surgical valve sewing ring; however, fluoroscopic identification of the location of the sewing ring can vary depending on the valve type.¹⁴

In stented valves, the base of the S3 central radiopaque marker should be placed 3 to 5 mm above the suture ring when using nominal deployment volumes. In case of the

Mosaic valve (Medtronic), where the top markers of the outflow struts are the only fluoroscopically visible markers, the aortic edge of the crimped S3 stent frame should be placed 2 mm above the aortic edge of the markers in nominally deployed valves.

In stentless and sutureless aortic bioprosthesis, the “neo-annulus” should be angiographically aligned and the base of the S3 central marker should be placed at the height of the “neo-annulus.” If possible, the frame of the S3 should cover the neo-annulus and the leaflet of the bioprosthesis. A pigtail can be positioned in the aortic root to assist accurate alignment with the annulus.

When treating failed supra-annular and intra-annular TAVR devices, the S3 should, if possible, be deployed so that its frame covers the native aortic valve annulus and the leaflets of the first device.

During deployment of the S3 THV, it should be kept in mind that the foreshortening of the valve occurs predominantly

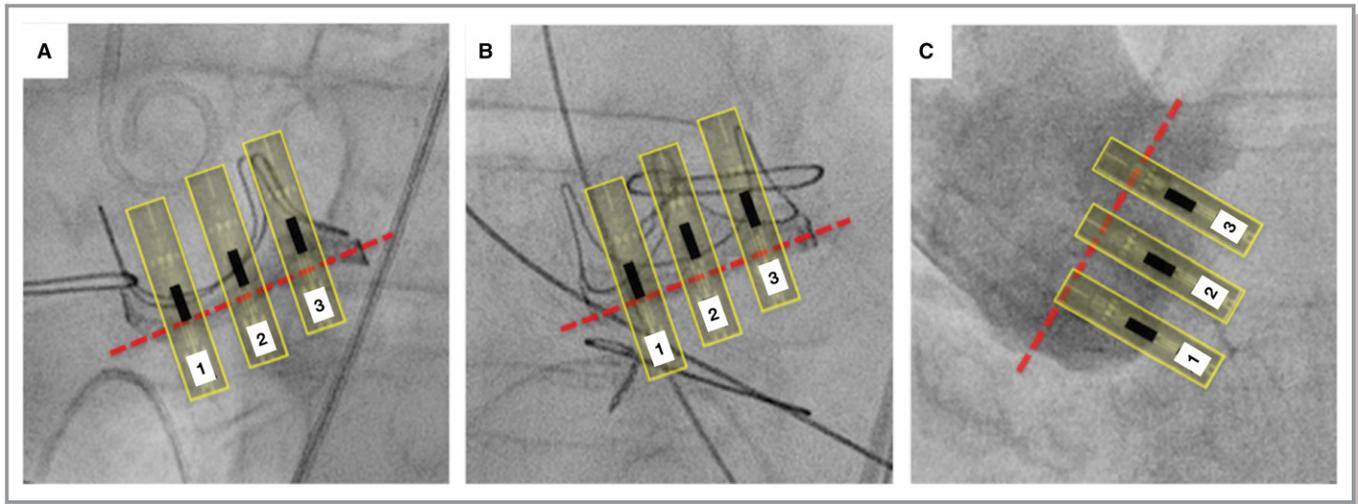


Figure 8. Coplanar alignment of stented surgical bioprosthetic valves. Varying alignment of the coplanar view: A. Overlap of struts, B. Struts in 1 line, C. Stent top markers in 1 line. Stented surgical valves can be aligned based on the top markers/struts of the valve, the suture ring, or angiographically at the nadir of the cusps of the leaflets. The dotted red line represents the suture ring or the stent strut tips of the surgical valve. The length of the middle marker is 3 mm on the S3 THV. The figure depicts the accurate placement of the S3 THV along the dotted red line: 1, Predetermined overexpansion (“low position”); 2, Predetermined nominal deployment (3–5 mm above the suture ring); 3, Predetermined underexpansion (“high position”). S3 indicates Sapien 3; THV, transcatheter heart valve.

from the inflow side of the valve during the late stage of valve expansion. For this reason, the deployment height of the S3 during VIV procedures should be adjusted to compensate for this foreshortening. Figure 8 shows an example of various coplanar views of surgical bioprosthetic valves, and where to position the 3-mm-long central marker of the S3 valve in relation to the suture ring of the aligned surgical valve based on the predetermined nominal deployment, overexpansion, or underexpansion THV strategy.

Intraprocedural Considerations: Mitral VIV

The fluoroscopic alignment of the initially implanted mitral bioprosthesis is performed in a similar manner to Ao VIV procedures. Based on analysis using the Sapien XT valve, a THV deployment position that is too far into the ventricle may be associated with an increased risk of LVOT obstruction.³⁵ For a given valve size, the frame height of the S3 THV is at least 3 mm greater than the Sapien XT.³⁵ In contrast to the Sapien XT, foreshortening of the S3 occurs from the atrial side and the extent is dependent on whether the valve is under-, over-, or nominally deployed. For this reason, we recommend that during nominal valve deployment the initial alignment of the S3 be performed by positioning the ventricular edge of the frame with the ventricular edge of the bioprosthesis. If an underexpansion strategy is chosen, then a more ventricular initial alignment may be necessary to avoid an excessively atrial implantation; conversely, more atrial alignment may be useful during planned valve overexpansion in order to avoid an

overly ventricular final position. If the anticipated risk of LVOT obstruction is not excessive, flaring of the ventricular portion of the S3 frame with the deployment balloon (nominal filling volume +1–2 mL) during valve implantation, or postdilatation, may be considered to reduce the risk of atrial embolization.

Intraprocedural Considerations: Bioprosthetic Valve Fracture and High-Pressure Balloon Postdilatation

Small bioprosthetic valves (label size ≤ 21) treated with VIV TAVR are at high risk of elevated postprocedural gradient and patient–prosthesis mismatch. Controlled cracking of the polyester loop within the valve sewing ring using high-pressure balloons has been described in vitro and in a small number of in vivo cases for surgical valves implanted in the pulmonary position⁴⁰ with meaningful reductions in postprocedural gradient. In vitro, the frames of the Mitroflow, Magna, Magna Ease, and Mosaic,²⁷ plus the Biocor Epic and Perimount⁴⁰ bioprosthetic surgical valves have been successfully fractured using high-pressure True Dilatation and Atlas Gold balloons (Bard Peripheral Vascular). Balloon-rated burst pressure was exceeded in all cases and fracture of valves with metal sewing rings was not possible. Chhatiwalla et al subsequently reported successful in vivo bioprosthetic valve fracture—in patients with bioprosthetic valves \leq label size 21 in the aortic position—with a reduction in mean transvalvular gradient and an increase in valve EOA in 20 consecutive clinical cases; valve fracture was performed either before or

after the VIV TAVR.²⁸ More recently, high-pressure postdilatation has been shown to improve transvalvular gradients in small bioprostheses even if sewing ring fracture is not achieved.¹⁶

Bioprosthetic valve fracture may allow satisfactory deployment of a larger THV than would otherwise be feasible, thus potentially correcting pre-existing PPM when treating small bioprosthetic valves (Figure 5). Care should be taken to ensure that there is adequate space within the aortic root anatomy to allow safe implantation of a larger THV.

High-pressure balloon dilatation can be performed before or after valve implantation. The former strategy may enable more reliable fracture of the bioprosthetic ring with the potential disadvantages of inducing hemodynamically unstable severe aortic regurgitation, and an increased risk of annulus rupture. The latter approach reduces the risk of acute valvular insufficiency but may increase the difficulty in achieving ring fracture and the risk of injuring the THV leaflets. In most cases our preference is to perform high-pressure balloon dilatation after implantation of the THV; however, this novel technique may also be associated with an elevated risk of embolization of degenerated valve material, rupture of the aortic root, coronary obstruction, and heart block.^{27,28}

Conclusion

VIV implantation is a feasible alternative to reoperation for a failed initial bioprosthetic valve. The use of the S3 THV for VIV implantation in a failed aortic and mitral bioprosthesis has recently received US Food and Drug Administration approval; the outer skirt of the S3 valve and the ability to overexpand its frame make it a suitable device for the VIV procedure. The selection of the S3 size should be based on the T-ID of the initially implanted bioprosthetic valve; however, CT imaging and determination of the CT-ID may influence the choice of S3 THV size in VIV procedures.

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Key Words: aortic valve implantation • aortic valve replacement • mitral valve • Sapien 3 • transcatheter aortic valve replacement • transcatheter mitral valve replacement • transcatheter valve implantation • valve-in-valve

SUPPLEMENTAL MATERIAL

Table S1. STENTED BIOPROSTHETIC SURGICAL AORTIC VALVES

Manufacturer valve size and internal diameter of selected commercially available stented surgical aortic valves are displayed. The published “true” internal diameter (T-ID) for each valve is shown. A **minimum of 1 mm oversizing based on T-ID** is recommended when selecting a S3 THV. Coronary height, aortic root width, and valve degeneration based on CT-sizing – with or without balloon sizing and tug-test – should also be taken into consideration. ID = internal diameter

STENTED SURGICAL AORTIC VALVES				
Valve Name	Valve Size	Height	Stent ID (S-ID)	True ID (T-ID)
Aspire (Vascutek)	20	16	18.2	16.5
	21	16	19	17.5
	23	17	21	19
	25	18	23	21
	27	18	25	22
Biocor / Epic (St. Jude Medical)	21	14	19	16.5
	23	15	21	18.5
	25	16	23	20.5
	27	17	25	22.5
	29	19	27	24.5

Biocor / Epic Supra (St. Jude Medical)	19	14	19	16.5
	21	15	21	18.5
	23	16	23	20.5
	25	17	25	22.5
	27	19	27	24.5
CE SAV (Edwards Lifesciences)	19	14	18	17
	21	15	20	19.5
	23	16	22	21
	25	17	24	22.5
	27	17	26	24
	29	18	28	25
	31	19	30	27
CE Standard (Edwards Lifesciences)	19	19	17	17
	21	19	19	19
	23	20	21	20
	25	21	23	21
	27	22	25	23
	29	22	27	25
	30	24	29	27
Dokimos	19	14	16	16

(Labcor)	21	15.5	18	18
	23	16.5	20	20
	25	17	22	22
	27	19	24	24
Hancock II (Medtronic Inc)	21	15	18.5	16.5
	23	16	20.5	18.5
	25	17.5	22.5	20.5
	27	18.5	24	22
	29	20	26	24
Intact (Medtronic Inc)	19	13.5	17.5	15.5
	21	15	18.5	16.5
	23	16	20.5	18.5
	25	17.5	22.5	20.5
	27	18.5	24	22
	29	20	26	24
Labcor Porcine (Labcor)	19	11	19	17
	21	11	21	19
	23	13	23	21
	25	14	25	23
	27	16	27	25

	29	16	29	27
Magna (Edwards Lifesciences)	19	14	18	17
	21	15	20	19
	23	16	22	21
	25	17	24	23
	27	18	26	25
	29	19	28	27
Magna Ease (Edwards Lifesciences)	19	13	18	17
	21	14	20	19
	23	15	22	21
	25	16	24	23
	27	17	26	25
	29	18	28	27
Mitroflow (Sorin)	19	11	15.4	15.5
	21	13	17.3	17
	23	14	19	19
	25	15	21	21
	27	16	22.9	23
	29	16	24.7	24.5

Mosaic (Medtronic Inc)	19	13.5	17.5	15.5
	21	15	18.5	16.5
	23	16	20.5	18.5
	25	17.5	22.5	20.5
	27	18.5	24	22
	29	20	26	24
Perimount (Edwards Lifesciences)	19	14	18	17
	21	15	20	19
	23	16	22	21
	25	17	24	23
	27	18	26	25
	29	19	28	27
Perimount 2700 (Edwards Lifesciences)	19	14	18	17
	21	15	20	19
	23	16	22	21
	25	17	24	23
	27	18	26	25
	29	19	28	27
Soprano (Sorin)	18	12	17.8	18
	20	14	19.8	20

	22	15	21.7	22
	24	16	23.7	23.5
	26	18	25.6	25.5
	28	19	27.6	27.5
Trifecta (St. Jude Medical)	19	15	17	16
	21	16	19	18
	23	17	21	20.5
	25	18	23	22
	27	19	25	24
	29	20	27	26

Table S2. STENTED BIOPROSTHETIC MITRAL VALVES

Manufacturer valve size and internal diameter of selected commercially available stented mitral valves are displayed. The published “true” internal diameter (T-ID) for each valve is shown. A minimum of **1 mm oversizing based on T-ID** is required when selecting a S3 THV. Aorto-mitral angulation and valve degeneration based on CT-sizing – with or without balloon sizing and tug-test – should also be taken into consideration. If the anticipated risk of LVOT obstruction is not excessive, flaring of the ventricular portion of the S3 frame with the deployment balloon (Nominal filling volume + 1-2ml of additional volume) during valve implantation, or post-dilatation, may be considered to reduce the risk of atrial embolization. ID = internal diameter

STENTED SURGICAL MITRAL VALVES

Valve Name	Valve Size	Height	Stent ID (S-ID)	True ID (T-ID)
Biocor / Epic (St. Jude Medical)	25	16	23	20.5
	27	17	25	22.5
	29	19	27	24.5
	31	20	29	26.5
	33	20	31	28.5
CE SAV (Edwards Lifesciences)	25	17	24	22.5
	27	17	26	24
	29	18	28	25
	31	20	30	27
	33	21	32	28
CE Standard (Edwards Lifesciences)	25	19	23	21
	27	21	25	23
	29	23	27	25
	31	24	29	27
	33	25	31	28
	35	26	33	30.5
Hancock II (Medtronic Inc)	25	18	22.5	20.5
	27	19	24	22

	29	20.5	26	24
	31	22	28	26
	33	23	30	28
Magna (Edwards Lifesciences)	25	16	25	24
	27	17	27	26
	29	18	29	28
	31	19	31	28.5
	33	19	31	28.5
Mosaic (Medtronic Inc)	25	18	22.5	20.5
	27	19	24	22
	29	20.5	26	24
	31	22	28	26
	33	23	30	28
Pericarbon More (Sorin)	19	12	15	15
	21	13	17	17
	23	14	19	19
	25	15	21	21
	27	17	23	23
	29	18	25	25
	31	19	27	27

	33	20	29	29
Perimount (Edwards Lifesciences)	25	17	25	23
	27	18	27	25
	29	19	29	27
	31	20	31	28.5
	33	20	31	28.5

Table S3. STENTLESS, SUTURELESS AND TRANSCATHETER BIOPROSTHETIC AORTIC VALVES

In stentless, sutureless and transcatheter bioprosthetic aortic valves, sizing based on “CT” internal diameter (CT-ID) is recommended. A **minimum of 1 mm oversizing based on CT-ID, or in the case of selfexpanding THVs based on CT measurement of the native aortic annulus,** is recommended when selecting a S3 THV. Coronary height, aortic root width, and valve degeneration – with or without balloon sizing and tug-test – should also be taken into consideration.

STENTLESS, SUTURELESS, TRANSCATHETER BIOPROSTHETIC AORTIC VALVES		
<i>Stentless</i>	<i>Sutureless</i>	<i>Transcatheter</i>
3F Valve (Medtronic Inc)	Enable (Medtronic Inc)	Accurate TA / Neo (Symetis)
Biovalsalva Porcine Conduit (Vascutec)	Intuity (Edwards Lifesciences)	CoreValve / Evolut (Medtronic Inc)
Cryolive O’Brien (Cryolife)	Perceval (Sorin)	JenaValve (JenaValve Technology)
Freedom Solo (Sorin)		Lotus / Lotus Edge (Boston Scientific)
Freestyle Root (Medtronic Inc)		Portico (St. Jude Medical)
Freestyle Valve (Medtronic Inc)		Sapien / Sapien XT / Sapien3 (Edwards Lifesciences)
Pericarbon Freedom (Sorin)		

Prima Root (Edwards Lifesciences)		
Toronto SPV Root (St. Jude Medical)		