

Transcatheter Aortic Valve Replacement With the SAPIEN 3

A New Balloon-Expandable Transcatheter Heart Valve

Ronald K. Binder, MD,* Josep Rodés-Cabau, MD,† David A. Wood, MD,*
Michael Mok, MD,† Jonathon Leipsic, MD,* Robert De Larochellière, MD,†
Stefan Toggweiler, MD,* Eric Dumont, MD,† Melanie Freeman, MBBS,*
Alexander B. Willson, MBBS,* John G. Webb, MD*

Vancouver, British Columbia, and Quebec City, Quebec, Canada

Objectives The aim of this study was to demonstrate the first-in-human feasibility and short-term clinical outcomes with a new balloon-expandable transcatheter heart valve (THV).

Background The SAPIEN 3 (S3) THV incorporates a paravalvular sealing system, an active 3-dimensional coaxial positioning catheter, and is compatible with a 14-F expandable sheath.

Methods The S3 THV was implanted in 15 patients with symptomatic severe aortic stenosis via femoral arterial access. Multidetector computed tomography before and after valve implantation allowed assessment of a novel annular area sizing algorithm. Clinical and echocardiographic data were obtained at baseline, discharge, and 30 days.

Results All 15 device implants were successful. Multidetector computed tomography estimated an aortic annular area of $4.9 \pm 0.4 \text{ cm}^2$, predicting $9.7 \pm 6.9\%$ THV oversizing. Post-transcatheter aortic valve replacement multidetector computed tomography showed consistently symmetrical and circular THVs. Aortic valve area increased from $0.7 \pm 0.2 \text{ cm}^2$ to $1.5 \pm 0.2 \text{ cm}^2$ ($p < 0.001$), and mean transaortic gradient decreased from $42.2 \pm 10.3 \text{ mm Hg}$ to $11.9 \pm 5.3 \text{ mm Hg}$ ($p < 0.001$). No patient had more than mild paravalvular aortic regurgitation. Hospital discharge occurred at a median of 3 (range 2 to 12) hospital days. At 30 days there were no deaths, strokes, vascular complications, bleeds, or transfusions, although 1 patient (6.7%) required a new pacemaker. All patients were in New York Heart Association functional class I or II.

Conclusions The S3 THV and delivery system might facilitate fully percutaneous implantation in a broader range of patients with the potential for more accurate positioning and less paravalvular regurgitation. (J Am Coll Cardiol Intv 2013;6:293–300) © 2013 by the American College of Cardiology Foundation

From the *St. Paul's Hospital, University of British Columbia, Vancouver, British Columbia, Canada; and the †Quebec Heart and Lung Institute, Laval University, Quebec City, Quebec, Canada. Drs. Binder, Dumont, Leipsic, Rodés-Cabau, Webb, and Wood are consultants to Edwards Lifesciences. Dr. Leipsic has served on the Speakers' Bureau for and received research support from Edwards Lifesciences. Drs. Binder and Toggweiler received unrestricted research grants from the Swiss National Foundation. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

Manuscript received September 4, 2012, accepted September 12, 2012.

Transcatheter aortic valve replacement (TAVR) has become a generally accepted option for symptomatic severe aortic stenosis in “inoperable” patients (1,2) and is noninferior to surgical aortic valve replacement in “high-risk operable” patients (3,4). After the first-in-human TAVR over 10 years ago (5), the procedure continues to be refined (6). Current efforts focus on minimizing access site complications, stroke risk, paravalvular regurgitation, and atrioventricular block while facilitating accurate positioning. To some extent these issues will be addressed by new transcatheter heart valves (THV) and delivery systems. We report the first-in-human experience with a new balloon-expandable THV, the SAPIEN 3 (S3) (Edwards Lifesciences, Inc., Irvine, California), which incorporates features intended to reduce vascular complications, increase paravalvular sealing, and enhance ease of positioning.

Methods

Abbreviations and Acronyms

CT = computed tomography

MDCT = multidetector computed tomography

PAR = paravalvular aortic regurgitation

TAVR = transcatheter aortic valve replacement

TEE = transesophageal echocardiography

THV = transcatheter heart valve

TTE = transthoracic echocardiography

Transcatheter aortic valve replacement with the S3 was performed in 15 patients with symptomatic, severe aortic stenosis at 2 centers (St. Paul’s Hospital, Vancouver, Canada and the Quebec Heart and Lung Institute, Quebec, Canada) between January and June 2012. Patients were considered at increased risk for surgery by a multidisciplinary team, including cardiac surgeons and cardiologists, because of age, frailty, comorbidities, or technical issues (e.g., porcelain aorta, adherent grafts). All patients gave written informed consent for prospective data acquisition approved by the local ethics committee. Short-term clinical outcomes were reported according to the Valve Academic Research Consortium guidelines (7). Patients underwent pre-procedural aortic root, coronary, and iliofemoral angiograms, transthoracic echocardiography (TTE), and multidetector computed tomography (MDCT). The THV sizing incorporated MDCT annular area assessment according to the Vancouver computed tomography sizing guidelines (Table 1). Annular area oversizing was calculated as: $(\text{THV nominal area}/\text{annular area} - 1) \times 100$. Patients underwent intra- and peri-procedural transesophageal echocardiography (TEE). TTE was performed in all patients before discharge.

The MDCT was repeated post-implant. The THV geometry was assessed by measuring long- and short-axis diameters from cross-sectional images of the inflow, outflow, and midportion of the stent frame. Eccentricity was defined as $(1 - \text{short diameter}/\text{long diameter}) \times 100$, with

Table 1. CT Sizing Guidelines Demonstrating Valve Selection and Percentage of Aortic Annular Area Oversizing on the basis of CT Annular Area and Valve Size

Annular Area (mm ²)	Percent Oversizing
400	NR
410	29.5
420	26.4
430	23.5
440	20.7
450	18.0
460	15.4
470	13.0
480	10.6
490	8.4
500	6.2
510	4.1
520	2.1
530	0.2
540	NR

Percentage of annular oversizing calculated by nominal external valve area/annular area. The lower and upper limits for annular oversizing are 0% and 30%, respectively, where the upper limit would represent 0% oversizing with the anticipated next largest (29 mm) valve. The target amount of annular oversizing is 5% to 15%. If oversizing by 20% to 30% is anticipated, underfilling the deployment balloon by 1 to 3 ml or undersizing should be considered. Given the nominal deployment balloon volume of 22 ml for the 26-mm SAPIEN 3, this would translate into 5% to 15% balloon underfilling.

CT = computed tomography; NR = not recommended.

a THV considered circular when eccentricity was <10% (8). The THV area was assessed by tracing the external margins of the stent at the inflow, outflow, and midportion of the stent frame. Expansion was defined as $(\text{THV external area}/\text{nominal THV area}) \times 100$, with <90% expansion considered under-expanded.

Clinical and echocardiographic follow-up were obtained at 30 days. All data were prospectively collected in a dedicated database.

Device. The S3 THV (Fig. 1) incorporates a stent and leaflet design that allows for crimping to a reduced profile as compared with the predicate SAPIEN and SAPIEN XT devices (Table 2). As with these earlier devices, the inflow of the S3 is covered by an internal polyethylene terephthalate skirt. However, the S3 incorporates an additional outer polyethylene terephthalate cuff to enhance paravalvular sealing. This sealing cuff has no filling and functions like a parachute by bulging outward (Fig. 2). At the time of this study the S3 THV was available in a 26-mm (fully expanded diameter) version. The height of the crimped frame is 28 mm, shortening 8 mm to a height of 20 mm when deployed.

Delivery system. The delivery system (Commander) (Figs. 2 and 3) incorporates a nose cone tipped inner balloon catheter on which the prosthesis is crimped and an outer deflectable flex catheter. An attached handle (Fig. 2) incorporates a rotating wheel used to deflect the flex

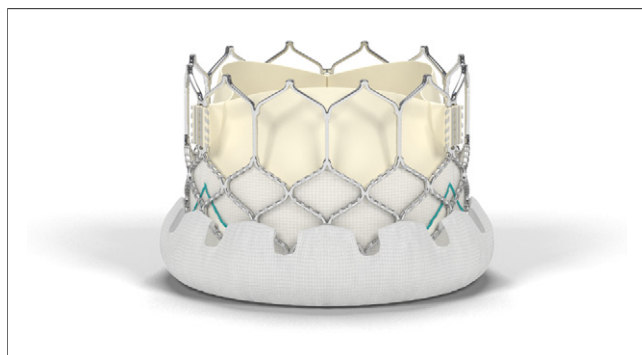


Figure 1. The SAPIEN 3 Valve

This transcatheter heart valve comprises a balloon-expandable, radio-opaque, cobalt chromium frame; a trileaflet bovine pericardial tissue valve; and polyethylene terephthalate fabric. The inflow of the valve is covered by an outer polyethylene terephthalate cuff, which enhances paravalvular sealing. The height of the 26-mm SAPIEN 3 (Edwards Lifesciences, Inc., Irvine, California) is expanded 20 mm and crimped 28 mm, shortening 8 mm during deployment. The nominal external area of the fully expanded 26-mm SAPIEN 3 stent is 5.31 cm².

catheter tip, a flex indicator that indicates the degree of tip articulation, a fine adjustment wheel for fine alignment of the THV during valve alignment, a balloon lock knob to secure the balloon catheter to the flex catheter, and a flush port. The balloon catheter contains radio-opaque valve alignment markers, defining the valve alignment position and working length of the balloon. A central radio-opaque marker in the balloon assists in valve positioning. The delivery system allows for advancing or retracting the valve several millimeters up or down within the annulus by rotating the fine alignment wheel.

Sheath. The system uses a 14-F expandable sheath (eSheath, Edwards Lifesciences, Inc.). The low-profile sheath is intended to reduce the potential for arterial injury during introduction but can transiently expand to accommodate passage of the compressed valve and then return to its lower profile diameter. The working length of the sheath is 36 cm (Fig. 4, Table 3).

Procedure. The TAVR was performed under general anesthesia with fluoroscopic and TEE guidance (Fig. 5). Patients were pre-medicated with aspirin and clopidogrel. A 14-F eSheath was introduced into the common femoral

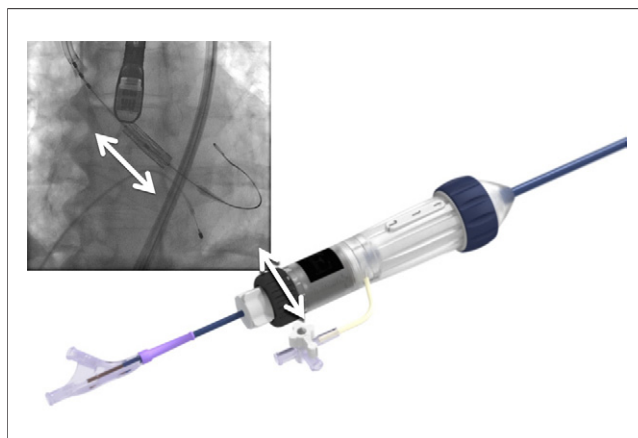


Figure 2. Features of the Delivery System

The handle contains a flexion indicator (rotating the **blue wheel** creates flexion), depicting to what degree or not the catheter is flexed, a fine adjustment wheel for fine adjustment of the transcatheter heart valve during valve alignment (**black wheel**), and a balloon lock knob (**white wheel**) to secure the balloon catheter to the flex catheter. Once the native valve is crossed, alignment of the crimped transcatheter valve in the aortic annulus is achieved by rotating the fine adjustment wheel at the back of the handle (**white arrows on black wheel**). Before deployment, the position of the valve can be precisely changed millimeter by millimeter more aortic or ventricular without having to push or pull the catheter. The radio-opaque marker in the center of the crimped valve indicates the middle of the deployment balloon. The valve is flanked by 2 small markers, which assist in aligning the valve on the balloon. The 3 radio-opaque markers (in a row) proximal to the valve indicate to where the flex catheter has to be pulled back to fully expose the deployment balloon.

artery. Balloon aortic valvuloplasty was performed under rapid ventricular pacing. The delivery catheter was advanced over an Amplatz extra stiff 0.035-inch guidewire (Cook, Inc., Bloomington, Indiana) into the left ventricle. Accurate positioning of the THV was ascertained by aortic root angiograms with a pigtail catheter and by TEE guidance. Final deployment was documented by aortic root angiogram and TEE. The femoral access site was closed as per local practice either percutaneously (Perclose ProGlide, Abbott, Inc., Abbott Park, Illinois) (10 Vancouver patients) or surgically (5 Quebec City patients). Patients were monitored for at least 48 h and discharged to continue on a regimen of low-dose aspirin (81 mg) and 3 months of daily

Table 2. Evolution of Balloon-Expandable Transcatheter Heart Valves

Features	SAPIEN Model 9000TFX (26 mm)	SAPIEN XT Model 9300TFX (26 mm)	SAPIEN 3 Model 9600TFX (26 mm)
Crimped profile	8.3 mm	8 mm	6.7 mm
Frame height (expanded)	16.1 mm	17.2 mm	20 mm
Frame height (crimped)	18.1 mm	20.1 mm	28 mm
Frame shortening (deployment)	2 mm	2.9 mm	8 mm
Delivery system	RetroFlex3	NovaFlex+	Commander
Sheath profile (internal diameter unexpanded)	24-F	18-F	14-F
Indicated vessel size	7 mm	6.5 mm	6.0 mm

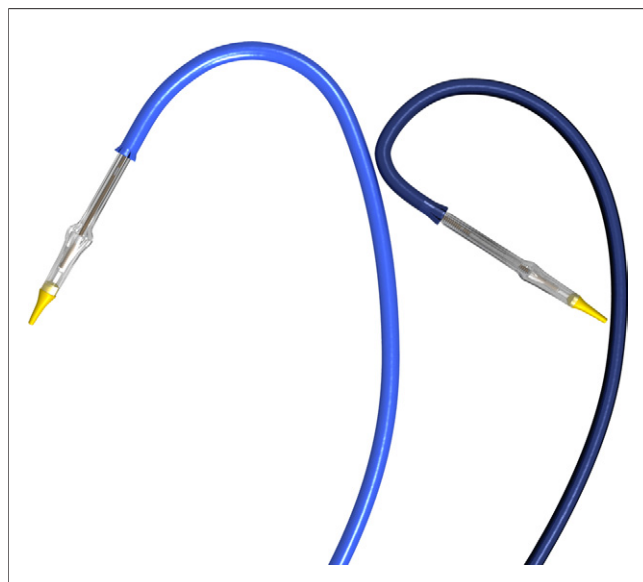


Figure 3. Flexibility of the New and Previous Delivery Catheters

The flexibility of the Commander (**dark blue**) is higher than the NovaFlex+ (**light blue**), which assist in coaxial alignment of the transcatheter heart valve. The delivery systems include a short tapered tip at the distal end of the delivery system to facilitate crossing the native valve and the balloon catheter for deployment of the transcatheter heart valve.

clopidogrel (75 mg). If oral anticoagulation was indicated, it was continued as monotherapy.

Statistical analysis. All analyses were performed with SPSS software (version 17, SPSS, Inc., Chicago, Illinois). Continuous variables are expressed as mean values \pm SD. Categorical variables are described by frequencies and percentages. Comparisons of continuous variables were performed by the *t* test. All statistical tests were 2-tailed, and a value of $p < 0.05$ was considered statistically significant.

Results

Patients. Baseline clinical characteristics are outlined in Table 4.

Clinical outcomes. All patients underwent successful device implantation. There were no minor or major vascular complications and no minor or major bleeds. Post-dilation was not necessary, and no patient required implantation of a second THV. In 1 patient with very tortuous iliac arteries the 14-F eSheath kinked, and the procedure was subsequently performed with a 16-F eSheath. New left bundle branch block developed in 3 patients, becoming permanent in 1 (6.7%). A pacemaker was implanted in 1 patient (6.7%) due to persistent second-degree atrioventricular block. All patients were discharged home after a median of 3 (range 2 to 12) hospital days.

At 30-day follow-up there were no myocardial infarctions, minor or major strokes, transient ischemic attacks, minor or major bleeds, minor or major vascular complica-

tions, repeat valve procedures, hospital readmissions, or deaths, although the Society of Thoracic Surgeons Predicted Risk of Mortality was $5.4 \pm 3.2\%$. All patients were in New York Heart Association functional class I or II.

Echocardiogram. Mean transaortic gradient was reduced from 42.2 ± 10.3 mm Hg to 13.0 ± 5.1 mm Hg at discharge ($p < 0.001$) and 11.9 ± 5.3 mm Hg at 30 days. Aortic valve area increased from 0.7 ± 0.2 cm² to 1.5 ± 0.2 cm² at discharge ($p < 0.001$) and 1.5 ± 0.3 cm² at 30 days. Paravalvular aortic regurgitation (PAR) as assessed by TTE at discharge was none in 2 (13%), trivial in 9 (60%), and mild in 4 (27%) patients. No patient had more than mild PAR assessed by intra-procedural TEE, pre-discharge TTE, or 30-day follow-up TTE.

MDCT annulus evaluation. The aortic annular diameter measured 23.1 ± 1.5 mm on TTE, 23.1 ± 0.8 mm on TEE, and 24.2 ± 1.7 mm on MDCT (mean of the MDCT short and long axis). Baseline aortic annulus dimensions are shown in Table 3.

The MDCT estimated an aortic annular area of 4.9 ± 0.4 cm² with the THV oversized $9.7 \pm 6.9\%$ by area. However, 2 of these THVs were actually smaller than the MDCT estimated annular area in the patients, 1 of whom had a very eccentric bicuspid valve (1 of 15 patients had a bicuspid valve). Despite modest undersizing (4.8% and 1.7%), both had only trivial leaks after THV implantation.

Post-TAVR MDCT showed that THVs were consistently symmetrical and circular (Fig. 6). Mean THV eccentricity was $2.9 \pm 2.1\%$, $2.3 \pm 2.5\%$, and $2.6 \pm 1.7\%$ at the inflow, midportion, and outflow, respectively. The outflow of the S3 stent frame was located 0.8 ± 2.2 mm below the left main, and the inflow extended 4.9 ± 2.5 mm below the aortic annulus. All valves but 1 were fully expanded (mean THV area expansion was $102 \pm 7\%$, $101 \pm 6\%$, and $106 \pm 6\%$ at the inflow, midportion, and outflow, respectively). The “underexpanded” THV was expanded 89%, 84%, and 91% at the inflow, midportion, and outflow, respectively (failing to meet the $>90\%$ expansion threshold for “complete” expansion). It had been implanted into the smallest

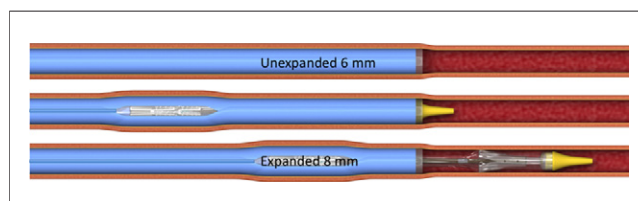


Figure 4. The Principle of an Expandable Sheath

The expandable sheath temporarily enlarges by unfolding to allow entry of the device (expanded outer diameter 8 mm for the SAPIEN 3 26-mm valve) and subsequently recoils to its reduced profile as the transcatheter heart valve passes. This expansion minimizes the force required to insert and pass the delivery system and transcatheter heart valve through the sheath, while maintaining a reduced profile in comparison with standard, non-expandable introducer sheaths.

		14-F eSheath	16-F eSheath	18-F eSheath	20-F eSheath
Recommended valve		SAPIEN 3 26 mm	SAPIEN XT 20 mm 23 mm	SAPIEN XT 26 mm	SAPIEN XT 29 mm
Sheath ID	Unexpanded	4.7 mm	5.3 mm	6 mm	6.7 mm
Sheath OD	Unexpanded	6 mm	6.7 mm	7.2 mm	8 mm
	Expanded with valve	8 mm	8.9 mm	8.9 mm	9.9 mm
Recommended minimum artery diameter		6 mm	6 mm	6.5 mm	7 mm
Sheath OD/vessel ID (SFAR)	Unexpanded	1.0	1.12	1.11	1.14
	Expanded with valve	1.33	1.48	1.37	1.41

eSheath (Edwards Lifesciences, Inc., Irvine, California).
 ID = internal diameter; OD = outer diameter; SFAR = sheath to femoral artery ratio on the basis of recommended minimum artery diameter.

annulus of the cohort (21% oversizing of the native annulus area 4.4 cm² with 30% eccentricity); however, the valve area on TTE was 1.4 cm² (mean gradient 13 mm Hg), and the THV was circular on MDCT (eccentricity 7%, 4%, and 5% at the inflow, midportion, and outflow, respectively).

Discussion

We report the first-in-human experience with a new low-profile, balloon-expandable valve. Transcatheter aortic valve replacement was successful in all patients. At 30-day follow-up, there were no deaths, repeat hospital stays, myocardial infarctions, strokes, or vascular or bleeding complications. Clinical and hemodynamic outcomes were excellent. The advantages of the S3—compared with the Cribier Edwards,

SAPIEN (currently approved for clinical use in the United States), and SAPIEN XT THVs—are its lower profile (Table 1), facilitated positioning, and the paravalvular sealing cuff. Clinical trials of the S3 device and delivery system are anticipated to begin later this year.

Vascular complications. Vascular complications have been a major cause of morbidity and mortality after TAVR (1,9). A strong predictor of vascular complications is the ratio of the outer diameter of the sheath to the minimal lumen diameter of the access artery (10). The ability to introduce the S3 THV through a 14-F expandable sheath is likely to translate into better outcomes and might facilitate transfemoral TAVR in patients previously considered unsuitable for femoral access (10). The absence of vascular complications

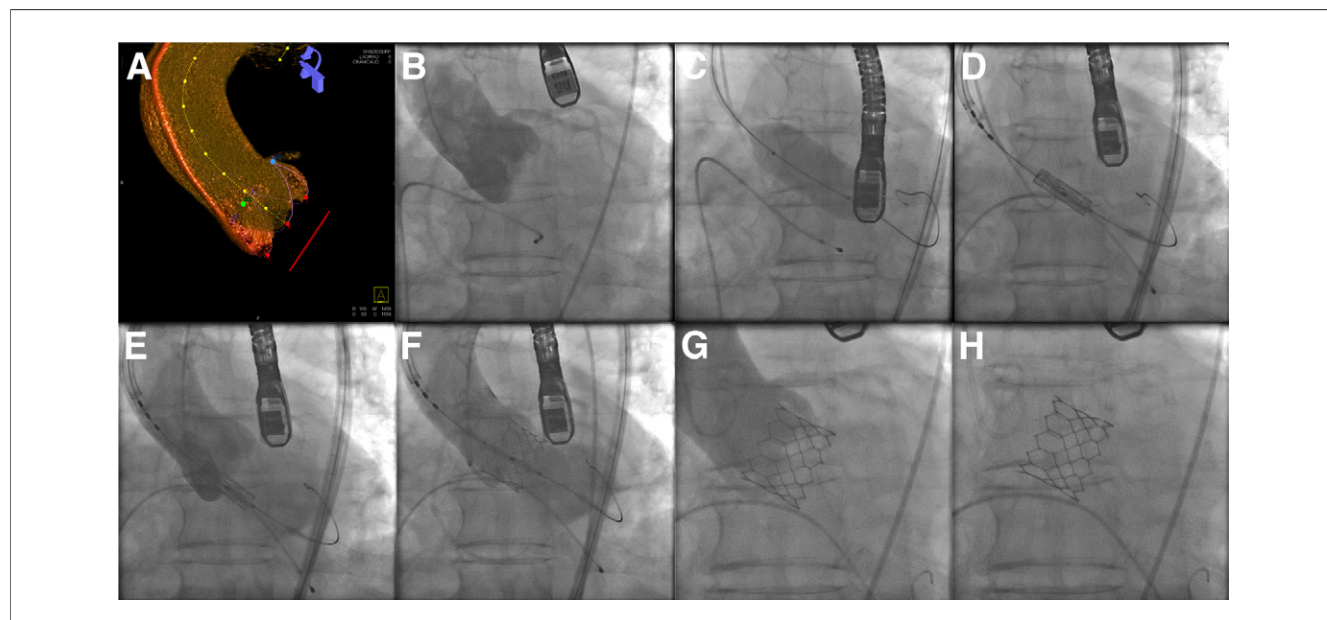


Figure 5. Implantation Sequence

To determine the optimal, perpendicular implant angle, where all 3 cusps are separately depicted in 1 line, a 3-dimensional aortic root reconstruction was performed from a rotational C-arm angiogram (A). The implant angle was confirmed by a conventional angiogram (B). A balloon aortic valvuloplasty was performed (C), after crossing the valve. The alignment of the transcatheter heart valve in the aortic annulus (D) was confirmed by an angiogram (E). The SAPIEN 3 was deployed under rapid ventricular pacing (F). Paravalvular sealing (G) and final position (H) were assessed.

Table 4. Baseline Characteristics (N=15)

Age (yrs)	80.3 ± 11.2
Male	15 (100%)
Diabetes	3 (20%)
Height (cm)	174.1 ± 5.7
Weight (kg)	79.3 ± 13.6
Prior CABG	6 (40%)
COPD	5 (33%)
Prior pacemaker	2 (13%)
Porcelain aorta	1 (7%)
STS PROM score (%)	5.4 ± 3.2
NYHA pre-TAVR	
I	0 (0%)
II	5 (33%)
III	9 (60%)
IV	1 (7%)
GFR (ml/min.)	59.6 ± 24.0
Hemodialysis	1 (7%)
TEE aortic annulus diameter (mm)	23.1 ± 0.8
TTE aortic annulus diameter (mm)	23.1 ± 1.5
MDCT aortic annulus diameter (mm)	24.2 ± 1.7
MDCT aortic annulus area (cm ²)	4.9 ± 0.4
AVA (cm ²)	0.7 ± 0.2
Transaortic gradient (mm Hg)	42.2 ± 10.3
LVEF (%)	55.3 ± 9.3
Mitral regurgitation (moderately severe to severe)	1 (7%)

Values are mean ± SD or n(%).
 AVA = aortic valve area; CABG = coronary artery bypass graft; COPD = chronic obstructive pulmonary disease; GFR = glomerular filtration rate; LVEF = left ventricular ejection fraction; MDCT = multidetector computed tomography; NYHA = New York Heart Association functional class; STS PROM = Society of Thoracic Surgeons predicted risk of mortality; TAVR = transcatheter aortic valve replacement; TEE = transesophageal echocardiography; TTE = transthoracic echocardiography.

in this feasibility study is consistent with the possibility of a reduction in vascular complications, improved outcomes in general, and potential application in a broader spectrum of patients.

PAR. Paravalvular aortic regurgitation after TAVR has been associated with increased mortality (11). Although an association of mild PAR with mortality was found in the 2-year analysis of the PARTNER (Placement of Aortic Transcatheter Valves) 1A trial (2), a cause-and-effect relationship was not established. In the PARTNER 1A and 1B trials core laboratory analysis reported moderate or severe PAR at 30 days in 12.2% and 11.8%, respectively (1,3). In the present study no patient had moderate or severe PAR. Paravalvular aortic regurgitation was absent or trivial in 73% of patients and mild in the remainder. Possible reasons for this low PAR rate include: 1) the outer polyethylene terephthalate sealing cuff, which enhances paravalvular sealing; 2) more accurate positioning; and 3) improved sizing with adjunctive MDCT.

Sizing recommendations. It is known that undersizing THVs is a potential cause for PAR and device embolization; however, this knowledge is balanced by an appreciation that

aggressive oversizing might contribute to annular rupture, coronary obstruction, atrioventricular block, peri-aortic hematoma, ventricular septal rupture, or anterior mitral leaflet injury. Traditional sizing criteria on the basis of single-plane 2-dimensional measurements do not appreciate the consistently oval-shaped anatomy of the aortic annulus (12) (Fig. 7). Recently, 3-dimensional annular assessments by MDCT and annulus area-based sizing have been shown to predict PAR and potentially contribute to appropriate valve sizing (8).

We routinely used 3-dimensional MDCT annular area measurements. Sizing guidelines were developed to assure that THVs were moderately but not excessively oversized relative to the annular area as assessed by MDCT. A reduction in PAR was anticipated with the improved accuracy of positioning and the improved external sealing cuff with this device. Consequently, it was decided that relatively modest 5% to 15% area oversizing would be adequate. In addition it was anticipated that avoiding area oversizing >20%, by slightly under-filling the deployment balloon, might reduce the risk of annular injury (Table 1). With this approach PAR burden was minimal, and annular injury was not encountered. Specific recommendations with respect to balloon under-filling will have to await further evaluation of effects on function and durability.

Positioning. The expanded length of the S3 THV is slightly greater than the currently available SAPIEN and SAPIEN XT THVs (Table 2). Although differences are small, this increase seems to greatly facilitate optimal positioning within the native aortic valve and annulus. The longer stent frame also decreases the likelihood of native leaflet tissue prolapse. In addition the delivery system has several char-

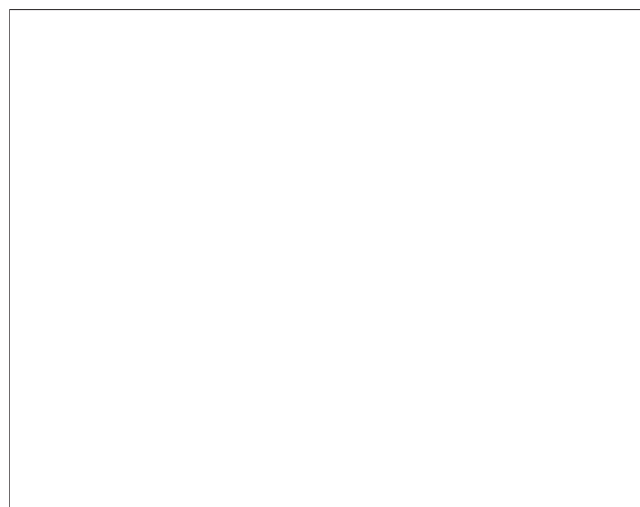


Figure 6. 3-Dimensional Reconstructions of the Transcatheter Heart Valve

Sagittal oblique maximum intensity projection (left) and double oblique transverse (parallel to the plane of the aortic root) images at the inflow, mid, and outflow show the circular, full expansion of the SAPIEN 3 (Online Video 1).

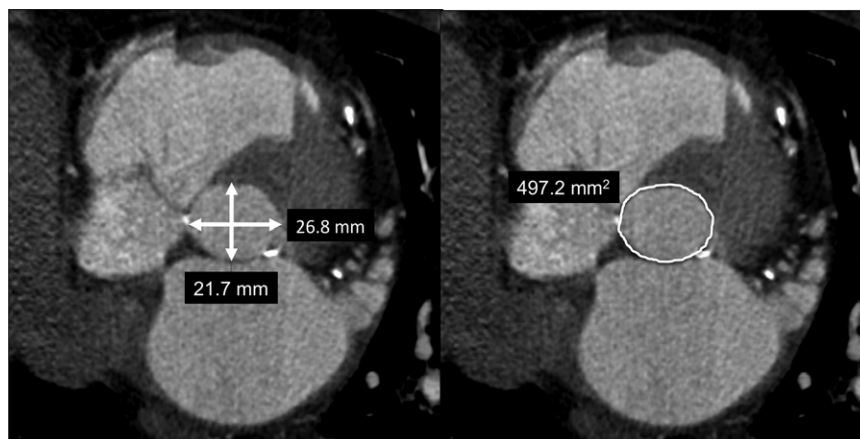


Figure 7. Appreciation of the Aortic Annulus by Multidetector Computed Tomography

Double oblique transverse (parallel to the plane of the aortic root) images from a multidetector computed tomography angiogram in a 78-year-old patient with severe aortic stenosis. The annulus is markedly eccentric with significant difference in the short- and long-axis dimensions. The eccentricity would have been underappreciated with traditional 2-dimensional imaging. The aortic annular area is measured in a planimetric fashion along the margins of the annulus during systole at maximum valve opening.

acteristics intended to facilitate accurate positioning. Increased flexion capabilities facilitate supporting the catheter within the transverse aorta while engaging the native valve in a coaxial manner (Fig. 3). From this fixed platform minor adjustments in the height of the implant can be obtained by using the fine alignment mechanism (Fig. 2).

It seems that, when deployed in a calcified aortic valve, the outflow of the stent contacts the native leaflet early, at which point the outflow of the stent frame is “fixed,” with the inflow moving up toward this point as the stent frame shortens. Therefore, we developed the strategy of aligning the top of the THV and the associated balloon marker with the tips of the native leaflets and the middle marker with the plane of the annulus (interpreted as the most basal attachments of the leaflets) (Fig. 6, Online Video 1). With this approach the THV often appeared too ventricular (in comparison with standard SAPIEN/SAPIEN XT positioning); however, early contact with the native leaflets during expansion seemed to assure a good final position.

Atrioventricular block. Heart block necessitating permanent pacemaker insertion is a concern after TAVR. The large observational UK TAVI (United Kingdom Transcatheter Aortic Valve Implantation) (13) and FRANCE 2 (French Aortic National CoreValve and Edwards) (14) registries, respectively, reported new pacemaker rates of 24.4% and 24.2% with the CoreValve (Medtronic, Minneapolis, Minnesota) device versus 7.4% and 11.5% with the SAPIEN/XT valves. In this present study only 1 patient (6.7%) required a new pacemaker. Whether the risk of atrioventricular block will be slightly increased by the greater length of the S3 valve (potentially extending the area of contact with the septum)

or slightly reduced by more accurate positioning and a lesser need for oversizing is speculative.

Conclusions

The low-profile S3 transcatheter valve and delivery system might facilitate fully percutaneous implantation in a broader range of patients with the potential for more accurate positioning and less paravalvular regurgitation.

Reprint requests and correspondence: Dr. John G. Webb, St. Paul’s Hospital, 1081 Burrard Street, Room 476A, Vancouver, British Columbia, V6Z 1Y6, Canada. E-mail: john.webb@vch.ca.

REFERENCES

1. Leon MB, Smith CR, Mack M, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med* 2010;363:1597–607.
2. Kodali SK, Williams MR, Smith CR, et al. Two-year outcomes after transcatheter or surgical aortic-valve replacement. *N Engl J Med* 2012;266:1686–95.
3. Smith CR, Leon MB, Mack MJ, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med* 2011;364:2187–98.
4. Kodali SK, Williams MR, Smith CR, et al. Two-year outcomes after transcatheter or surgical aortic-valve replacement. *N Engl J Med* 2012;388:1686–95.
5. Cribier A, Eltchaninoff H, Bash A, et al. Percutaneous transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis: first human case description. *Circulation* 2002;106:3006–8.
6. Webb JG, Chandavimol M, Thompson CR, et al. Percutaneous aortic valve implantation retrograde from the femoral artery. *Circulation* 2006;113:842–50.
7. Leon MB, Piazza N, Nikolsky E, et al. Standardized endpoint definitions for transcatheter aortic valve implantation clinical trials: a

- consensus report from the valve academic Research Consortium. *J Am Coll Cardiol* 2011;57:253-69.
8. Willson AB, Webb JG, Labounty TM, et al. 3-dimensional aortic annular assessment by multidetector computed tomography predicts moderate or severe paravalvular regurgitation after transcatheter aortic valve replacement: a multicenter retrospective analysis. *J Am Coll Cardiol* 2012;59:1287-94.
 9. Van Mieghem NM, Nuis RJ, Piazza N, et al. Vascular complications with transcatheter aortic valve implantation using the 18 Fr Medtronic CoreValve system: the Rotterdam experience. *EuroIntervention* 2010;5:673-9.
 10. Toggweiler S, Gurvitch R, Leipsic J, et al. Percutaneous aortic valve replacement: vascular outcomes with a fully percutaneous procedure. *J Am Coll Cardiol* 2012;59:113-8.
 11. Abdel-Wahab M, Zahn R, Horack M, et al. Aortic regurgitation after transcatheter aortic valve implantation: incidence and early outcome. Results from the German transcatheter aortic valve interventions registry. *Heart* 2011;97:899-906.
 12. Gurvitch R, Webb JG, Yuan R, et al. Aortic annulus diameter determination by multidetector computed tomography: reproducibility, applicability, and implications for transcatheter aortic valve implantation. *J Am Coll Cardiol Intv* 2011;4:1235-45.
 13. Moat NE, Ludman P, de Belder MA, et al. Long-term outcomes after transcatheter aortic valve implantation in high-risk patients with severe aortic stenosis: the UK Tavi (United Kingdom Transcatheter Aortic Valve Implantation) registry. *J Am Coll Cardiol* 2011;58:2130-8.
 14. Gilard M, Eltchaninoff H, Iung B, et al. Registry of transcatheter aortic-valve implantation in high-risk patients. *N Engl J Med* 2012;366:1705-15.
-
- Key Words:** balloon-expandable ■ SAPIEN 3 ■ transcatheter aortic valve replacement ■ transfemoral.