Carpentier-Edwards supra-annular aortic porcine bioprosthesis: Clinical performance over 20 years

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Objective: Experience with the Carpentier-Edwards supra-annular porcine bioprosthesis (Edwards Lifesciences, Irvine, Calif) has been evaluated longitudinally over 20 years. Clinical performance was evaluated by actuarial and actual analysis. Hemodynamic performance was evaluated by echocardiographic/Doppler assessment. Morphology of structural failure was evaluated from pathologic examinations.

Methods: From 1981 through 1999, 1823 patients (mean age, 68.9 ± 10.9 years; range, 19-89 years) underwent 1847 procedures. Concomitant coronary artery bypass was performed in 788 (42.7%) patients. Previous valve procedures were performed in 107 (5.8%) patients, and other cardiac procedures were performed in 87 (4.7%) patients.

Results: The overall valve-related complication rate was 4.36% per patient-year (630 patients), with a fatality rate of 0.96% per patient-year (139 patients). Patient survival at 18 years was $15.8\% \pm 1.6\%$. Overall late mortality rate was 6.3% per patient-year. Overall actual cumulative freedom at 18 years from reoperation was $85.0\% \pm 1.2\%$, valve-related mortality was $88.7\% \pm 1.1\%$, and valve-related residual morbidity was $96.3\% \pm 5.0\%$. Actual freedom from structural valve deterioration at 18 years was $86.4\% \pm 1.2\%$ overall, $90.5\% \pm 1.8\%$ for age 61 to 70 years, and $98.2\% \pm 0.6\%$ for age greater than 70 years. Structural valve deterioration presented with pathologic evidence consistent with stenosis in 27.6% and insufficiency in 72.4%. Hemodynamic performance at 1 year revealed normal effective orifice area indexes for sizes 23 to 27 mm and mild-to-moderate reduction for size 21 mm.

Conclusions: The Carpentier-Edwards supra-annular aortic porcine bioprosthesis continues to provide excellent freedom from structural valve deterioration and overall freedom from valve-related residual morbidity, mortality, and reoperation up to 18 years. Hemodynamic performance is satisfactory. The prosthesis remains recommended for patients older than 70 years and for patients 61 to 70 years of age, especially when comorbid risk factors are not anticipated to provide extended survival.

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The Carpentier-Edwards supra-annular (CE-SAV; Edwards Lifesciences, Irvine, Calif) aortic porcine bioprosthesis was introduced in 1981. This second-generation porcine bioprosthesis has the tissue fixed with glutaraldehyde at 2 mm Hg, is initially treated with polysorbate 80, and is subsequently

treated with the combination of polysorbate 80 and ethanol, calcium mitigation agents. The most extensive worldwide experience with this bioprosthesis has been documented from the University of British Columbia.^{1,2}

This report extends the experience with the CE-SAV in aortic valve replacement to 20 years. This documentation will facilitate future comparison with other second- and third-generation porcine and pericardial bioprostheses.

Patients and Methods

The CE-SAV was implanted in 1823 patients (1847 procedures) for aortic valve replacement from 1981 through 1999 at the affiliated teaching hospitals of the University of British Columbia, namely St Paul's Hospital, Vancouver General Hospital, and Royal Columbian Hospital. The mean age of the patient population was 68.9 ± 10.9 years (range, 19-89 years). Of the total population, 5.8% (107) had previous valve procedures, and 4.7% (87) had other cardiac procedures. Concomitant coronary artery bypass (CAB) was performed in 42.7% (788).

The patient population was evaluated as an overall patient cohort and by age distribution: 50 years or less, 133 procedures (7.2%); 51 to 60 years, 230 (12.5%); 61 to 70 years, 579 (31.3%); and more than 70 years, 905 (49.0%) procedures.

The total cumulative follow-up was 14,435.3 patient-years, with a mean $\pm$ SD of 7.82 ± 4.82 years. The follow-up by age categories was as follows: 50 years or less, 1377.6 patient-years; 51 to 60 years, 2217.5 patient-years; 61 to 70 years, 4989.2 patient-years; and more than 70 years, 5850.9 patient-years. The total follow-up was 97.4% complete during a 6-month closing interval in 2002.

The "Guidelines for Reporting Morbidity and Mortality After Cardiac Valvular Operations" was used to define valve-related complications and served as a basis for our methodology.³ Multivariate proportional hazard regression analysis was used to assess risk factors (age [continuous and age categories ≤ 50 , 51-60, 61-70, and >70 years], sex, rhythm, previous CAB, previous valve procedure, concomitant CAB, and valve size) as independent predictors of structural valve deterioration (SVD), prosthetic valve endocarditis (PVE), nonstructural dysfunction (NSD), valve-related reoperation, valve-related residual morbidity (permanent functional or neurologic impairment), and valve-related mortality. The composites of valve-related complications are inclusive of SVD, NSD, thromboembolism, hemorrhage (antithromboembolic-related hemorrhage [ATH]), and PVE.

Patient survival was assessed by Kaplan-Meier actuarial methods. SVD and composites of valve-related complications were evaluated by both actuarial and actual (cumulative incidence) methods. The actual cumulative incidence and risk probabilities were determined by an analog of the Kaplan-Meier method.

The overall longitudinal evaluation, conducted periodically, incorporated a prospective hemodynamic study commencing in 1990 and a retrospective study in 1999. The studies included a transthoracic echocardiographic/Doppler assessment at approximately 1 year postoperatively. The echocardiographic examinations documented the following variables: mean pressure gradient, peak pressure gradient, effective orifice area (calculated by the continuity equation), effective orifice area index (effective orifice

area divided by body surface area), cardiac output, cardiac index (cardiac output divided by body surface area), and presence and degree of regurgitation.

The operative and pathologic reports were evaluated to summarize the morphology of the structural failure of the documented failed prostheses. The reports facilitated classification as calcification without leaflet tears, calcification with leaflet tears, primary tears, and stent post dehiscence. The sites of the primary tears were classified as commissural, middle and belly of the leaflet, basal portion of the leaflet, and free margin of the leaflet.

This article has been formulated from the University of British Columbia Cardiac Valve Database, and the investigators have maintained University of British Columbia Clinical Research Ethics Board approval throughout the years, which is currently effective to January 2006. The approval incorporates an informed consent process.

Results

The early mortality was 5.0% (93/1847 procedures). The early mortality with CAB was 5.6% (44/791 procedures) and without CAB was 4.6% (49/1056 procedures). The late mortality was 6.3% per patient-year. The overall survival at 15 years was $28.8\% \pm 1.5\%$, at 18 years was $15.8\% \pm 1.6\%$, and at 20 years was $6.8\% \pm 2.0\%$.

The linearized occurrence rates of valve-related complications was 4.36% per patient-year (630), whereas the fatality rate was 0.96% per patient-year (139 patients). The linearized occurrence rates for valve-related complications were as follows: PVE, 0.36% per patient-year (52); NSD, 0.24% per patient-year (34); ATH, 0.53% per patient-year (76); overall thromboembolism, 2.33% per patient-year (336); and major thromboembolism, 1.27% per patient-year (183). Composites of valve-related complications were as follows: valve-related reoperation, 1.12% per patient-year (161); valve-related residual morbidity, 0.40% per patient-year (58); and valve-related mortality, 0.96% per patient-year (139).

The freedoms from SVD, both actuarial and actual, are designated in [Figures 1](#) and [2](#). There were 132 events for the overall cohort. Actuarial and actual freedom at 18 years was $64.0\% \pm 3.6\%$ and $86.4\% \pm 1.2\%$, respectively. For the 61- to 70-year age group, the actuarial and actual freedom from SVD was $77.6\% \pm 4.9\%$ and $90.5\% \pm 1.8\%$, respectively, and for the greater than 70-years age group, it was $94.6\% \pm 2.3\%$ and $98.2\% \pm 0.6\%$, respectively. The number of events of age categories is detailed by age groups in [Table 1](#), documenting linearized rates and related fatalities and reoperations. There were a total of 132 events with 26 fatalities and 109 reoperations with 6 fatalities (5.5%). There were 23 documented events that did not have reoperations, with 22 fatalities, 20 attributed primarily to SVD. The fatalities were contributed to by congestive heart failure, myocardial infarction, cardiac arrest, cancer, left ventricular dysfunction and mitral regurgitation, renal failure,

Figure 1. Actuarial freedom from SVD overall and by age groups.

chronic obstructive pulmonary disease, gastrointestinal hemorrhage, and nonvalve-related cerebrovascular accident.

The actuarial freedom at 18 years from other valve-related complications was as follows: PVE, 92.1% ± 2.4% (actual, 96.3% ± 0.6%); NSD, 88.6% ± 5.6% (actual, 96.7% ± 0.8%); ATH, 88.9% ± 1.9% (actual, 94.1% ± 0.7%); overall thromboembolism, 66.0% ± 5.1% (actual, 80.7% ± 1.3%); and major thromboembolism, 85.2% ± 1.4% (actual, 90.0% ± 0.8%).

There were 139 mortalities from valve-related complications and 161 reoperations with 8 fatalities. Of the total 139 valve-related mortalities, 26 were due to SVD, 21 were due

to PVE, 3 were due to NSD, 23 were due to ATH, and 66 were due to thromboembolism, with no cases of thrombosis. Of the valve-related reoperations, there were 109 due to SVD, 18 due to PVE, and 30 due to NSD, with 6, 1, and 1 fatalities, respectively.

The freedoms from valve-related composites (reoperation, mortality, and residual morbidity) by age categories are summarized at 18 years and designated time intervals in Table 2.

The predictors of SVD were age (hazard ratio [HR], 0.96; $P < .001$), male sex (HR, 1.75; $P = .0255$), and concomitant CAB (HR, 0.58; $P = .0256$). Age (HR, 0.97;

Figure 2. Actual freedom from SVD overall and by age groups.

TABLE 1. Structural valve deterioration documented overall and by age groups by linearized rates, events, events alive and fatal, and reoperation and no reoperation, alive and fatal

Age groups	Rates (%/pt-y)	Total events	Events		Reoperation	No reoperation
			Alive	Fatal		
≤50	3.7	51	46	5	47 (1)*	4 (4)*
51-60	1.94	43	38	5	39 (1)	4 (4)
61-70	0.56	28	16	12	18 (4)	10 (8) [1]
>70	0.17	10	6	4	5 (0)	5 (4) [1]
Total	0.91	132	106	26	109 (6)	23 (20) [2]

pt-y, Patient-years. *SVD fatalities are shown in parentheses, non-SVD fatalities in brackets.

$P = .001$) was the only predictor of PVE. The predictors of NSD were age (HR, 0.96; $P = .01$) and male sex (HR, 1.29; $P < .001$). The predictors of valve-related reoperation were age (HR, 0.95; $P < .001$) and concomitant CAB (HR, 0.48; $P = .0022$). The only predictor of valve-related mortality was age (HR, 1.04; $P < .001$). The predictors of valve-related residual morbidity were age (HR, 1.05; $P = .003$) and cardiac rhythm (atrial fibrillation or paced; HR, 2.1; $P = .0442$).

The mean time from implantation to reoperation for SVD was not different ($P = .278$) by age categories: 50 years or less, 11.8 ± 3.1 years (47); 51 to 60 years, 11.2 ± 3.4 years (39); 61 to 70 years, 11.5 ± 3.8 years (18); and more than 70 years, 8.8 ± 2.9 years (5).

The pathology of the 132 cases of SVD was reviewed. Of the 132 cases of SVD, 109 came to reoperation, 18 others were noted at autopsy, and 5 were confirmed by echocardiography. The pathology of 127 SVDs, 109 reoperations and 18 autopsies, revealed the following findings: calcification with leaflet tear, 78 (61.4%); calcification without accompanying leaflet tear, 29 (22.8%); primary tears, 19 (15.0%); and stent post dehiscence, 1 (0.78%). Of the primary tears, the location of the lesions were commissural (11), free margin (7), basal (1), and unknown (4), and there was often more than one tear per valve. The degree of calcification was graded as mild in 22, mild to moderate in 30, moderate to severe in 29, and unknown in 27, for a total of 108 valves with calcification as a component. The location of the calcification was at the commissures in 44,

middle-belly in 12, free margins in 33, as known in 66 patients, with often more than one location affected. The pathologic lesions created stenosis in 35 (27.6%) and aortic insufficiency in 92 (72.4%).

The distribution of the SVD lesions changed throughout the age groups: 50 years or less, 46; 51 to 60 years, 44; 61 to 70 years, 28; and greater than 70 years, 9. This broke down as follows: calcification with tears, 78%, 59%, 50%, and 22%, respectively; calcification without tears, 13%, 23%, 32%, and 44%, respectively; and primary tears, 9%, 18%, 14%, and 33%, respectively. The one case of stent post dehiscence occurred in the 61- to 70-years age group (4%).

Of the 5 SVDs diagnosed on the basis of clinical parameters and echocardiography, echocardiograms showed 3 calcifications without tears with severe stenosis and 2 primary tears showing mild and moderate degrees of stenosis and moderate and severe degrees of insufficiency.

The hemodynamic evaluation was performed in 2 structured studies in 1990 (39 patients) and 1999 (19 patients) at the 1-year interval. Complete echocardiographic data is detailed on 45 of the 56 patients in Table 3. The number of evaluations were as follows: 19 mm, 5; 21 mm, 11; 23 mm, 17; 25 mm, 16; 27 mm, 6; and 29 mm, 1. The reliability of the 19-mm parameters to clinical practice might not be appropriate: mean gradient, 17.3 ± 2.6 mm Hg; peak gradient, 29.7 ± 15.8 mm Hg; effective orifice area, 0.75 cm^2 ; effective orifice area index, $0.47 \text{ cm}^2/\text{m}^2$; cardiac output, 3.9 L/min; and cardiac index, 2.4 L/min/m^2 . The echocardi-

TABLE 2. Freedom from valve-related composites of complications (actuarial and actual) by age groups at 18 years

Age groups	VR-REOP		VR-MORB		VR-MORT	
	Actuarial	Actual	Actuarial	Actual	Actuarial	Actual
Total	62.3 ± 3.5	85.0 ± 1.2	94.6 ± 8.2	96.3 ± 5.0	78.4 ± 2.9	88.7 ± 1.1
≤50	27.9 ± 5.7	44.8 ± 4.9	—	—	86.0 ± 4.7	88.3 ± 3.8
51-60	43.7 ± 6.4	64.2 ± 3.9	97.3 ± 1.2	97.6 ± 1.1	91.8 ± 2.7	93.9 ± 1.9
61-70	79.8 ± 4.7	91.1 ± 1.7	94.5 ± 1.3	95.9 ± 0.9	76.6 ± 5.6	88.1 ± 2.0
>70	96.6 ± 1.3	98.4 ± 5.1	91.4 ± 2.2	95.5 ± 0.8	67.6 ± 8.6	87.5 ± 1.5

VR-REOP, Valve-related reoperation; VR-MORB, valve-related residual morbidity; VR-MORT, valve-related mortality.

TABLE 3. Hemodynamic evaluation at the 1-year interval

Variable	21 mm (8)*	23 mm (15)	25 mm (16)	27 mm (6)
Mean gradient (mm Hg)	14.2 ± 5.3	14.9 ± 7.0	13.9 ± 5.2	8.5 ± 2.6
Peak gradient (mm Hg)	26.6 ± 13.4	28.6 ± 12.3	27.9 ± 9.7	16.7 ± 4.7
EOA (cm ² /cm ²)	1.46 ± 0.57	1.48 ± 0.52	1.37 ± 0.41	1.91 ± 0.72
EOA index (cm ² /m ²)	0.85 ± 0.34	0.83 ± 0.39	0.70 ± 0.21	0.98 ± 0.41
Cardiac output (L/min)	5.0 ± 1.9	5.3 ± 1.8	5.0 ± 1.6	4.7 ± 2.2
Cardiac index (L/min/m ²)	2.9 ± 1.0	3.0 ± 1.3	2.6 ± 0.8	2.4 ± 1.2

EOA, Effective orifice area. *Number of patients is shown in parentheses.

graphic evaluations at 1 year revealed 10.7% (6) with trivial-mild regurgitation, 1.7% (1) with moderate regurgitation, and the remaining 80.4% (45) with no regurgitation. In 7.1% (4) regurgitation was not reported.

Discussion

The Carpentier-Edwards SAV porcine bioprosthesis is the longest-standing bioprosthesis of the current second- and third-generation porcine and pericardial bioprostheses. The CE-SAV was introduced in the early 1980s with advanced tissue preservation and calcium mitigation therapy to reduce the incidence of SVD. The CE-SAV was designed for supra-annular implantation to optimize hemodynamics over that of the first-generation intra-annular bioprostheses. The CE-SAV is formulated with tissue fixed with glutaraldehyde at a pressure of approximately 2 mm Hg. The antimicrobialization treatment of the CE-SAV bioprosthesis encompasses the detergent agent polysorbate 80 and the addition of ethanol into the XenoLogiX treatment (Edwards Lifesciences). These treatments were commenced in the early 1980s.

The use of bioprostheses for aortic valve replacement has been considerably extended in the past 5 years, with improved stented bioprostheses and the introduction of stentless bioprostheses. This trend from the use of mechanical prostheses has been fostered by the knowledge of advanced age being protective from SVD, as well as the advancing age of the population with degenerative aortic valve disease.

The important concerns of aortic bioprostheses are the extent of durability and the hemodynamic capability to avoid detrimental patient-prosthesis mismatch. This evaluation of the CE-SAV bioprosthesis has addressed both these issues. The second issue of patient-prosthesis mismatch and its prevention has been extensively evaluated by Pibarot and Dumesnil.⁴

This second-generation aortic porcine bioprosthesis (CE-SAV) has been evaluated periodically since the commencement of its use in late 1981.^{1,2} This report has provided the opportunity to evaluate performance to predominantly 18 years. The actual freedom from SVD for patients more than 70 years of age was 98% (actuarial, 95%), and for patients 61 to 70 years of age, actual freedom from SVD was 91% (actuarial, 78%). The diagnosis of SVD was made at the

time of reoperation or autopsy or echocardiographically in patients with reducing functional class. Of the 132 failed prostheses in 1823 patients, 109 prostheses were explanted for SVD; 18 were identified at autopsy, and 5 were identified on the basis of clinical and echocardiographic parameters.

The remaining currently marketed aortic bioprostheses of the second and third generations have commencement of use and reporting of shorter duration. These prostheses are the following: Carpentier-Edwards PERIMOUNT, Sorin Pericarbon pericardial, Hancock II, St Jude Medical Epic (formerly Biocor), and Medtronic Mosaic porcine bioprosthesis, as well as the new stentless configurations, namely St Jude Medical Toronto SPV, Medtronic Freestyle, Edwards Prima Plus, and Sorin Freedom. The published durability of the stented bioprostheses is summarized in Table 4.⁵⁻¹⁴ The identification of SVD does vary between studies from diagnosis at explantation for the Carpentier-Edwards PERIMOUNT pericardial bioprosthesis by Frater and associates¹⁰ and Banbury and colleagues¹¹ to the current study on the Carpentier-Edwards SAV porcine bioprosthesis by explantation, autopsy, and clinical assessment confirmed by echocardiography. Follow-up of the stentless porcine bioprostheses is now only nearing the time interval when structural failure was identified with the stented bioprostheses.

A comparison of the aortic CE-SAV and the CE-PERIMOUNT was conducted by Jamieson and colleagues.¹⁵ Actual freedom from SVD at 15 years was 99.6% and 98% for patients more than 70 years of age for the CE-PERIMOUNT and the CE-SAV, respectively; 99% and 93% for patients 66 to 70 years of age, respectively; and 86% and 92% for patients 61 to 65 years of age, respectively. The freedom from SVD for the 61- to 70-year age group was 93% for both the CE-SAV and the CE-PERIMOUNT. The diagnosis of SVD with the CE-SAV at the University of British Columbia is documented above, whereas the Francois Rabelais University diagnosis was with stenotic or regurgitant symptoms or asymptomatic with a mean gradient of greater than 40 mm Hg or insufficiency of grade III-IV. These reports of the CE-PERIMOUNT documented that calcification stenosis was the predominant mode of failure. This study has revealed that the mode of

TABLE 4. Summary of reported freedom from structural valve deterioration of predominant marketed porcine and pericardial bioprostheses

Author	Prosthesis	Mean age (y)	Age group (y)	Freedom from SVD		Time interval (y)
				Actuarial (%)	Actual (%)	
David and coworkers ⁵	Hancock II	65 ± 12	≥65	81 ± 5	100	15
			<65		76 ± 6	15
						15
Rizzoli and coworkers ⁶	Hancock II	67 ± 8	≥65	88.9 ± 6.2	92.4 ± 3.3	15
			<65		93.2 ± 4.8	15
					92 ± 4.5	15
Jamieson and coworkers ⁷	CE-SAV	67.6 ± 11.2	≥65	69.5 ± 3.1	85.7 ± 1.3	15
			>70	96.9 ± 1.5	98.8 ± 0.5	15
			66-70	87.0 ± 6.0	93.6 ± 2.3	15
			<65	54.2 ± 4.1	68.8 ± 2.8	15
			≥65	91.5 ± 2.9	96.4 ± 1.0	15
	Hancock II	65.2 ± 2.1	≥65	83.2 ± 4.8	88.1 ± 3.2	15
			>70	100	100	15
			66-70	100	100	15
			<65	75.1 ± 6.3	78.5 ± 5.4	15
			≥65	100	100	15
Myken and coworkers ⁸	SJM Biocor	69	≥65	76.0 ± 7		15
			61-70	83.0 ± 5		15
			71-80	99		15
			>80	100		15
						15
Jamieson and coworkers ⁹	MM	70.5 ± 10.7		99.7 ± 0.3	99.8 ± 0.2	6
Frater and coworkers ¹⁰	CE-P*	64.9 ± 11.8		85.1 ± 3.0	94.4	14
			>65	96.3 ± 2.1	98.7	14
			≤65	76.1 ± 5.0	88.2	14
Banbury and coworkers ¹¹	CE-P*	65 ± 12		77		15
Aupart and coworkers ¹²	CE-P	67.5 ± 11.2		96 ± 4		10
Neville and coworkers ¹³	CE-P	68.3 ± 10.8		94		12
			>60	98		12
			≤60	89		12
Dellgren and coworkers ¹⁴	CE-P	71.3 ± 8.8		86 ± 9	92 ± 6	12
Jamieson and coworkers (current study)	CE-SAV	68.9 ± 10.9		74.9 ± 2.3	88.9 ± 1.0	15
			>70	94.6 ± 2.3	98.2 ± 0.6	15
			61-70	85.7 ± 3.2	92.8 ± 1.5	15
			51-60	62.6 ± 5.4	75.4 ± 3.6	15
			≤50	44.0 ± 5.8	56.5 ± 4.9	15
				64.0 ± 3.6	86.4 ± 1.2	18
			>70	94.6 ± 2.3	98.2 ± 0.6	18
			61-70	77.6 ± 4.9	90.5 ± 1.8	18
			51-60	51.0 ± 7.0	70.6 ± 4.0	18
			≤50	31.9 ± 6.3	48.4 ± 5.3	18

CE-P, Carpentier-Edwards PERIMOUNT pericardial; MM, Medtronic Mosaic porcine; SJM, St Jude Medical Biocor (now Epic); CE-SAV, Carpentier-Edwards Supra-Annular porcine. *Diagnosed at explantation.

failure of the CE-SAV was 26% by calcific stenosis and 74% by insufficiency with or without calcification.

The documented studies identified that the CE-SAV and CE-PERIMOUNT aortic prostheses do not perform differently in contradistinction to the mitral prostheses. In 1999, the author reported a greater incidence of structural failure with the mitral CE-SAV.¹⁶ The actual freedom from SVD at

10 years was as follows: 41 to 50 years, 92% versus 70%; 51 to 60 years, 90% versus 80%; 61 to 70 years, 97% versus 88%; and older than 70 years, 100% versus 97%, respectively. It was considered that the low-profile configuration of the CE-SAV mitral prosthesis contributed to altered stress and the accelerated failure mode.¹⁵ This accelerated failure mode has not been evident with the CE-SAV aortic

configuration. The extended evaluation of the CE-PERIMOUNT mitral device by reporting colleagues in 2001 has confirmed the clinical performance of the prosthesis.¹⁷ The experience of the Carpentier-Edwards SAV mitral porcine bioprosthesis is worthy of further documentation.

The hemodynamic performance of aortic prostheses generally is recognized as being instrumental in regression of left ventricular mass and probably increasing survival. Pibarot and Dumesnil⁴ have researched the concept of patient-prosthesis mismatch, identifying that the normal effective orifice area index is 0.85 cm²/m² or greater. Severe obstructive features of a prosthesis correlate with an effective orifice area index of less than 0.65 cm²/m². The hemodynamic performance of the implanted aortic prostheses should be optimized by consideration of reference in vivo effective orifice area and the basal surface area to achieve the anticipated indexed effective orifice area to avoid detrimental patient-prosthesis mismatch.⁴ The CE-SAV bioprosthesis can provide satisfactory hemodynamics in all valve sizes, except possibly 19 mm, for which inadequate data are available. The suprastructure and fine sewing cuff of the prosthesis together with the supra-annular noneverting implantation technique should provide optimization of hemodynamics. The new extended supra-annular bioprosthesis configurations, namely the Carpentier-Edwards PERIMOUNT Magna, Sorin Soprano, and Mitroflow, are likely to play a significant role in the small aortic root to prevent unacceptable patient-prosthesis mismatch.

The CE-SAV porcine bioprosthesis has excellent durability approaching 20 years and is recommended for patients older than 70 years, as well as for 61- to 70-year-old patients, especially if comorbidity is likely to compromise anticipated life expectancy. The CE-SAV can be considered the gold standard to which other second- and third-generation bioprostheses can be compared.

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