Single-center experience using the Freedom SOLO aortic bioprosthesis

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Objective: This study reviews a single institution experience with the Freedom SOLO (Sorin Group, Saluggia, Italy) aortic bioprosthesis.

Methods: Between October 2006 and February 2010, 128 patients (64 men, 64 women; mean age, 75.8 ± 5.1 years) underwent aortic valve replacement using the Freedom SOLO stentless aortic valve. The follow-up time was 36.7 ± 1.2 months and 100% complete.

Results: Concomitant procedures were performed in 77 patients (60%). The mean standard European System for Cardiac Operative Risk Evaluation was 9 ± 2.7 . Grade 3 aortic stenosis was present in 73% of patients, mixed aortic stenosis and regurgitation were present in 40% of patients, and mitral regurgitation was present in 46% of patients. The mean crossclamp time was 53 ± 12 minutes for isolated Freedom SOLO aortic valve implantation and 80 ± 28 minutes for concomitant procedures, and the mean cardiopulmonary bypass time was 103 ± 31 minutes. The mean implanted valve size was 22.6 ± 1.4 mm. The mean intensive care unit and hospital stays were 2.4 ± 1.1 days and 8.8 ± 2.6 days, respectively. Three patients underwent reoperation for bleeding. The 15-day, 30-day, and perioperative mortality were all 4.6%. The 36-month survival was $95.4\% \pm 1.6\%$ for the cohort with a low European System for Cardiac Operative Risk Evaluation (<9) and $88.6\% \pm 1.7\%$ for the cohort with a high European System for Cardiac Operative Risk Evaluation (>9). Echocardiographic data preoperatively, immediately postoperatively, and at 3, 6, and 12 months postoperatively showed peak transvalvular gradients of 75 ± 23 , 17 ± 6 , 18 ± 6.5 , 16 ± 6 , and 16 ± 9 mm Hg, respectively ($P < .001$), and a mean left ventricular end-diastolic diameter of 51 ± 7 , 50 ± 6 , 48 ± 8 , 47 ± 6 , and 46.5 ± 7.5 mm, respectively ($P < .05$). There were only 3 cases of early mild aortic regurgitation (grade 1), which remained stable at 12 months.

Conclusions: The Freedom SOLO stentless aortic valve has excellent early and intermediate-term results. (J Thorac Cardiovasc Surg 2013;146:96-102)

Aortic valve replacement (AVR) using a stentless bioprostheses usually requires 2 separate suture lines for correct and exact fixation in the aortic root. As a result, increased crossclamp time is required compared with that required for stented bioprostheses. The Freedom SOLO (Sorin Group, Saluggia, Italy) (Figure 1) aortic valve is a stentless pericardial valve prosthesis that is made of 2 sheets of pericardium with no fabric reinforcement and that requires only 1 suture line.¹ As are all stentless bioprostheses, the Freedom SOLO aortic valve is designed to provide superior

hemodynamics, improved transvalvular gradients, left ventricular reverse remodeling, increased orifice areas, and possibly better survival compared with other earlier generations of stented pericardial bioprostheses.²⁻⁵ This is important, especially in sicker patients with reduced left ventricular function and various types of comorbidities. Since the Freedom SOLO was introduced in 2004, it has been increasingly used, but still little is known of the intermediate-term results. This single-center study reports our experience with the Freedom SOLO aortic valve to assess the early and intermediate-term results of a consecutive series of 128 patients.

MATERIALS AND METHODS

Study Population

From October 2006 to February 2010, 128 consecutive patients underwent AVR with the Freedom SOLO aortic valve. The indication for surgery was aortic valve stenosis or regurgitation or mixed lesions. Implantation of the Freedom SOLO valve was carried out by the same experienced surgeon for the whole series. Aortic valve pathology is listed in Table 1. The study population had a mean age of 75.8 ± 5.1 years (range, 55-86 years), and 50% (64 patients) were male. The mean body surface area was 1.7 ± 0.2 , mean standard European System for Cardiac Operative Risk

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Abbreviations and Acronyms

AVR	= aortic valve replacement
CPB	= cardiopulmonary bypass
euroSCORE	= European System for Cardiac Operative Risk Evaluation
IVS	= interventricular septum
LVEDD	= left ventricular end-diastolic diameter
LVESD	= left ventricular end-systolic diameter
NYHA	= New York Heart Association
PW	= posterior wall

Evaluation (euroSCORE) was 9 ± 2.7 , and mean logistic euroSCORE was 15.9 ± 12.8 . Sinus rhythm was present in 81.3% of patients, and atrial fibrillation was present in 15% of patients. Twenty-four patients (18.7%) were in New York Heart Association (NYHA) class I, 71 patients (55.4%) were in NYHA class II, 30 patients (23.4%) were in NYHA class III, and 3 patients (2.3%) were in NYHA class IV. Twenty-one patients (16.4%) had a low preoperative euroSCORE (defined as a standard euroSCORE <9), and 107 patients (83.6%) had a high euroSCORE (defined as a standard euroSCORE >9). Preoperative risk factors (Table 2) were coronary heart disease in 64.8% (83 patients), arterial hypertension in 93% (119 patients), diabetes mellitus in 35.9% (46 patients), renal dysfunction in 18.8% (24 patients), hypercholesterolemia in 68% (87 patients), and pulmonary hypertension in 14.8% (19 patients). Six patients (4.7%) had undergone prior cardiac surgery. Preoperative medications in the whole series consisted of beta-blockers in 46.9% of patients, angiotensin-converting enzyme inhibitors in 34.4% of patients, angiotensin inhibitors in 8.6% of patients, aldosterone antagonists in 7% of patients, diuretics in 41.7% of patients, digoxin in 10.2% of patients, calcium channel blockers in 35.2% of patients, statins in 48.4% of patients, platelet inhibitors in 64% of patients, and warfarin (Sintrom, Novartis, Greece) anticoagulants in 9.4% of patients. Preoperative echocardiographic left ventricular end-diastolic diameter (LVEDD) was 50.9 ± 7.2 mm, left ventricular end-systolic diameter (LVESD) was 33.7 ± 9.8 mm, ejection fraction was $53.8\% \pm 12.8\%$ (range, 25%-75%), fractional shortening was $33.4\% \pm 10\%$, posterior wall (PW) thickness was 11.8 ± 1.9 mm, interventricular septum (IVS) thickness was 12.3 ± 2 mm, right ventricular end-diastolic diameter was 26.3 ± 6.9 mm, left atrium was 43.2 ± 6 mm, and aortic root was 32.6 ± 5.1 mm. Preoperative pulmonary artery systolic pressure was 43.3 ± 12.8 mm Hg, peak flow velocity was 4.05 ± 1.09 ms, peak transaortic gradient was 75.3 ± 23.5 mm Hg, and mean transaortic gradient was 48.8 ± 15.8 mm Hg. The main outcome measures were early and late mortality, echocardiographic data in all patients immediately postoperatively (defined as 3 days after the operation) and 3, 6, and 12 months postoperatively, and incidence of complications.

Operative Technique

Isolated AVR was performed in 51 patients (39.8%), and concomitant procedures were performed in 77 patients (60.2%), which consisted of coronary artery bypass grafting in 72 patients (56.3%), mitral valve replacement in 8 patients (6.3%), tricuspid valve repair in 3 patients (1.5%), and pulmonary valve replacement in 1 patient (0.8%). Concomitant procedures were performed before valve implantation with the exception of proximal anastomosis of the saphenous vein or radial artery grafts, which were performed after the implantation and before aortic declamping. After induction of general anesthesia, a median sternotomy was performed and mild hypothermic (32°C) cardiopulmonary bypass (CPB) was instituted.

After aortic crossclamping, a transverse aortotomy was performed 0.5 to 1 cm above the sinotubular junction and intermittent cold cardioplegia was administered via the coronary ostia, followed by thorough resection of the leaflets and annular decalcification. The size of the implant was determined by measuring the diameter of the aortic annulus with the appropriate sizer provided by the manufacturer. Patients with annuloaortic ectasia were excluded from the study. Annuloaortic ectasia was defined as dilation of the aortic root and ascending aorta tapering to a normal caliber at the origin of the innominate artery. The Freedom SOLO aortic valve should not be used in cases of porcelain aorta due to native severe aortic calcification. Complete decalcification of the annulus is important before valve implantation, because a heavily calcified aortic root could impede the placement of the sutures.

In every case, the Freedom SOLO aortic valve was implanted using 3 continuous single sutures (4-0 polypropylene) in the supra-annular position, starting at the deepest point of each sinus of Valsalva just above the top of the corresponding commissures and placed 3 to 4 mm apart from the annulus. On completion, the 3 suture lines were tied outside the aortic wall, with no need for reinforcement. Valve sizes 21, 23, 25, and 27 mm were implanted in 47 patients (36.7%), 57 patients (44.5%), 23 patients (18%), and 1 patient (0.8%), respectively. The mean implanted valve size was 22.65 ± 1.48 mm. The median implanted valve size was 23 mm. After aortotomy closure, de-airing, and release of the crossclamp, the patient was weaned from CPB. Intraoperative transesophageal echocardiographic evaluation of the correct opening of the valve leaflets and confirmation of absence of paravalvular leak and aortic regurgitation greater than trivial were performed before CPB weaning and transfer to the intensive care unit. Routine anticoagulation after chest tube removal was applied only in patients with postoperative atrial fibrillation, because oral anticoagulation is not the routine for bioprostheses at Athens Medical Center. All patients received subcutaneous low-molecular-weight heparin until hospital discharge. All patients received lifelong antiplatelet therapy with aspirin (100 mg/d).

Statistical Analysis

Data are expressed as percentages, means $\pm$ standard deviations, or medians with ranges as appropriate. One-way repeated-measures analysis of variance with the Bonferroni multiple comparison test was used to assess the influence of time on cardiac dimensions and transvalvular gradients and velocities. The α value for the Bonferroni test was set at 0.05. Overall survival was determined using Kaplan–Meier curve analysis. SPSS software (17.0 for Windows, SPSS Inc, Chicago, Ill) was used.

RESULTS

Operative Data, Mortality and Morbidity, and Survival

The mean crossclamp time was 52.7 ± 11.9 minutes for isolated Freedom SOLO aortic valve implantation and 80.4 ± 28.3 minutes for concomitant procedures, and the mean CBP time was 103.2 ± 31.2 minutes. Mean intensive care unit and hospital stays were 2.4 ± 1.1 days and 8.8 ± 2.6 days, respectively. Three patients required reoperation for bleeding.

All patients survived the operation. The 30-day mortality was 4.6% ($n = 6$). None of these deaths were related to valve complications or dysfunction. Two patients died of cardiogenic shock, 2 patients died of multiorgan failure, and 2 patients died of hemorrhage. All of them had a high standard euroSCORE (>9). The 2 patients who died of bleeding had undergone early reoperation for possible

FIGURE 1. Survival of patients with low versus high euroSCORE who underwent Freedom SOLO (Sorin Group, Saluggia, Italy) AVR. euroSCORE, European System for Cardiac Operative Risk Evaluation; SE, standard error; ES, euroSCORE.

surgical correction, but no potential source could be identified. On return to the cardiac intensive care unit, every possible effort was undertaken to reverse coagulopathy with transfusion of fresh-frozen plasma and fibrinogen, but without success, and the patients died. Patient follow-up was 100% complete for a mean of 36.7 ± 1.2 months. There were 4 late deaths in our series (3.2%), 2 due to heart failure and 2 due to non-valve-related cerebrovascular accident. There were no cases of reoperation for endocarditis, valve thrombosis, or structural valve degeneration. None of our patients required a pacemaker implant. The actuarial survival was $92.9\% \pm 1.2\%$ at 24 months and $91.4\% \pm 2.3\%$ at 36 months for the entire series. After comparing survival in patients with low versus high euroSCORE, the survivals were $95.4\% \pm 1.6\%$ at 24 months in the low euroSCORE subgroup, which remained stable at 36 months, and $91.3\% \pm 1.8\%$ at 24 months and $88.6\% \pm 1.7\%$ at 36 months in the high euroSCORE cohort. Early and

intermediate-term survival of the 2 cohorts is shown in Figure 1. There were no statistically significant differences in the survivals between the 2 groups ($P = \text{not significant}$).

Hematologic Data

Minimum postoperative hematocrit, hemoglobin, platelet, and red blood cell counts were $27.6\% \pm 3\%$, 8.9 ± 1 g/dL, 71.6 ± 41.7 mL, and $3.1 \times 10^6 \pm 403.8 \times 10^4/\mu\text{L}$, respectively, the high euroSCORE cohort versus $38.1\% \pm 5.1\%$, 12.4 ± 1.8 g/dL, 229.9 ± 74.5 mL, and $4.3 \times 10^6 \pm 713.9 \times 10^4/\mu\text{L}$, respectively, in the low euroSCORE cohort (all $P < .01$). Only 1 of our patients had severe thrombocytopenia with a platelet number less than $30,000/\mu\text{L}$. Minimum platelet number was observed 3.51 ± 1.17 days (median day, 3) after the operation. Mean autologous red blood cell transfusion units and fresh-frozen plasma units were 3.5 ± 2.2 units and 5.6 ± 3.2 units, respectively. None of our patients required platelet transfusion, including the 3 patients who underwent reoperation for bleeding.

TABLE 1. Frequency of different aortic valve pathologies in 128 patients undergoing aortic valve replacement with the Freedom SOLO (Sorin Group, Saluggia, Italy) valve

Aortic valve pathology	N	%
Aortic stenosis		
• Mild	6	4.7
• Moderate	15	11.7
• Severe	93	72.7
Aortic regurgitation		
• Mild	31	24.2
• Moderate	27	21.1
• Severe	8	6.3
Mixed aortic pathology	51	39.8
Bicuspid aortic valve	3	2.3

TABLE 2. Preoperative risk factors for the entire cohort of 128 patients

	N	%
Coronary heart disease	83	64.8
Arterial hypertension	119	93
Diabetes mellitus	46	35.9
Renal dysfunction	24	18.8
Hypercholesterolemia	87	68
Pulmonary hypertension	19	14.8
Prior cardiac surgery	6	4.7
Urgent cases	30	23.5
Elective cases	98	76.5

Hemodynamic Data

Left ventricular ejection fraction was $53.8\% \pm 12.8\%$, $59.3\% \pm 15.1\%$, $55.7\% \pm 10.2\%$, $56.2\% \pm 10.7\%$, and $53.9\% \pm 11.1\%$ preoperatively, at discharge, and at 3, 6, and 12 months postoperatively, respectively, in the entire cohort after AVR.

The LVEDD, LVESD, IVS thickness, and PW thickness preoperatively, postoperatively, and at 3-, 6-, and 12-month follow-ups are shown in Table 3. LVEDD reduction was significant during the follow-up ($F = 2.93$, $P < .05$); the Bonferroni test showed a significant difference between postoperatively and 12 months ($P < .05$). Reduction of IVS was significant during follow-up ($F = 2.77$, $P < .05$); the Bonferroni test showed a significant difference between postoperative IVS and IVS at both 6 and 12 months ($P < .05$).

LVESD changes and PW reduction during the follow-up could be due to chance, and no significant differences between the follow-up intervals were found on the Bonferroni test.

Peak and mean gradients postoperatively and at 3-, 6-, and 12-month follow-ups are shown in Table 3. Peak and mean gradient reduction during follow-up was significant ($F = 3.50$, $P < .001$ and $F = 3.21$, $P < .05$, respectively); the Bonferroni test showed a significant difference between postoperatively and 3, 6, and 12 months ($P < .05$). Values of peak velocity as depicted in Table 2 showed a significant reduction during follow-up ($F = 2.17$, $P < .001$); the Bonferroni test showed a significant difference between early postoperatively and 6 months ($P < .001$).

LVEDD, LVESD, IVS thickness, PW thickness, and peak and mean gradients per valve size are shown in Table 4 in regard to preoperative, postoperative, and 3-, 6-, and 12-month follow-up values. In 21-, 23-, and 25-mm valves, LVEDD reduction was significant during follow-up ($F = 3.89$, $P < .05$; $F = 4.54$, $P < .05$; and $F = 3.01$, $P < .05$, respectively). The Bonferroni test showed a significant difference between immediately postoperatively and 12 months in all of these valve sizes ($P < .05$). For the 27-mm valve, statistical analysis was not applicable because of a single value.

LVESD reduction was not significant for 21- and 25-mm valves, but it was significant for the 23-mm valve ($F = 5.01$, $P < .05$). The Bonferroni test showed a significant difference between postoperatively and 12 months ($P < .05$). For the 27-mm valve, statistical analysis was not applicable because of a single value.

PW reduction was not significant for 23- and 25-mm valve sizes, but it reached statistical significance in the 21-mm size ($F = 3.99$, $P < .05$). The Bonferroni test showed a significant difference between postoperatively and both 6 and 12 months of follow-up ($P < .05$). For the 27-mm valve, statistical analysis was not applicable because of a single value.

IVS reduction was significant for the 21-, 23-, and 25-mm valves ($F = 2.87$, $P < .05$; $F = 3.62$, $P < .05$; and $F = 4.21$, $P < .05$). The Bonferroni test showed a statistically significant difference between postoperatively and both 6 and 12 months for the 21- and 23-mm valves but only between postoperatively and 12 months for the 25-mm valves. For the 27-mm valve, statistical analysis was not applicable because of a single value.

The mean gradient reduction during follow-up was significant for the 21-, 23-, and 35-mm valves ($F = 7.34$, $P < .05$; $F = 5.21$, $P < .05$; and $F = 3.39$, $P < .05$, respectively). The Bonferroni test showed a statistically significant difference between postoperatively and 3, 6, and 12 months ($P < .05$). For the 27-mm valve, statistical analysis was not applicable because of a single value.

Peak gradient reduction during follow-up was significant for valve sizes 21, 23, and 35 mm ($F = 3.19$, $P < .001$; $F = 4.72$, $P < .001$; and $F = 5.56$, $P < .001$, respectively). The Bonferroni test showed a statistically significant difference between postoperatively and 3, 6, and 12 months ($P < .05$). For the 27-mm valve, statistical analysis was not applicable because of a single value.

Thromboembolism, Endocarditis, Reoperation, and Structural Valve Dysfunction

There were no episodes of thromboembolism, endocarditis, valve reoperation, or structural valve dysfunction during the follow-up time.

TABLE 3. Comparison of echocardiographic data postoperatively and at 3, 6, and 12-month follow-ups by means of repeated-measures analysis of variance

	Preoperative	Postoperative	3 mo	6 mo	12 mo	P value
LVEDD (mm)	50.9 $\pm$ 7.2	49.6 $\pm$ 6.2	48.4 $\pm$ 8.3	47.2 $\pm$ 5.7	46.5 $\pm$ 7.5	<.05
LVESD (mm)	33.7 $\pm$ 9.8	33 $\pm$ 7.9	32 $\pm$ 7.7	31.3 $\pm$ 6.1	31.1 $\pm$ 9.3	NS
IVS (mm)	12.3 $\pm$ 2	12.3 $\pm$ 2	11.4 $\pm$ 1.6	11 $\pm$ 1.6	10.8 $\pm$ 1.3	<.05
PW (mm)	11.8 $\pm$ 1.9	10.8 $\pm$ 1.8	10.6 $\pm$ 1	10.3 $\pm$ 1	10.2 $\pm$ 1.4	NS
Peak gradient (mm Hg)	75.3 $\pm$ 23.5	16.8 $\pm$ 5.6	16.1 $\pm$ 6.5	16 $\pm$ 6.3	15.9 $\pm$ 9.1	<.001
Mean gradient (mm Hg)	48.8 $\pm$ 15.8	10.6 $\pm$ 3.6	10.2 $\pm$ 1.6	10.1 $\pm$ 1	10 $\pm$ 2.9	<.05
Peak velocity (cm/sec)	4.1 $\pm$ 1.2	1.8 $\pm$ 0.4		1.8 $\pm$ 0.2		<.001

LVEDD, Left ventricular end-diastolic diameter; LVESD, left ventricular end-systolic diameter; IVS, interventricular septum; PW, posterior wall; NS, not significant.

TABLE 4. Comparison of echocardiographic data postoperatively and at 3-, 6-, and 12-month follow-ups by means of repeated-measures analysis of variance stratified by valve size

	Preoperative	Postoperative	3 mo	6 mo	12 mo	P value
21 mm (n = 47)						
LVEDD (mm)	47.9 ± 6.9	46.2 ± 6.1	45.2 ± 6.2	45 ± 3.8	45.1 ± 4.6	<.05
LVESD (mm)	30.4 ± 8.7	31.5 ± 7.6	30.9 ± 4.6	28.5 ± 6.1	30.1 ± 2.3	NS
IVS (mm)	12.6 ± 2.1	11.8 ± 1.5	11 ± 1.7	10.3 ± 1.5	10.8 ± 1.3	<.05
PW (mm)	12.1 ± 2.1	11.6 ± 1.4	10.5 ± 1.4	10.3 ± 1.1	10.2 ± 1.4	<.05
Peak gradient (mm Hg)	75.4 ± 21.8	20.5 ± 7.6	20.2 ± 5.9	16.9 ± 7.6	15.9 ± 8.3	<.001
Mean gradient (mm Hg)	46.3 ± 15.7	9.3 ± 2.2	9 ± 1.6	9.1 ± 1	9 ± 2.9	<.05
23 mm (n = 57)						
LVEDD (mm)	50.7 ± 11.1	50.1 ± 5.4	50.4 ± 5.9	49 ± 5	48.5 ± 7.9	<.05
LVESD (mm)	33 ± 9.1	32.2 ± 8.4	32.7 ± 5.9	33 ± 4.8	29.9 ± 5.6	<.05
IVS (mm)	12.3 ± 1.89	11.4 ± 1.8	11.4 ± 1.6	10.9 ± 1.1	10.8 ± 0.9	<.05
PW (mm)	11.8 ± 1.9	10.8 ± 1.9	10.9 ± 1.4	10.9 ± 1.3	10.9 ± 1	NS
Peak gradient (mm Hg)	74.9 ± 25.8	16.5 ± 6.3	16.4 ± 6.7	16.1 ± 5.6	13.4 ± 7.4	<.001
Mean gradient (mm Hg)	52.2 ± 16.1	10.1 ± 4.6	9.4 ± 2.1	9.2 ± 1.4	7.6 ± 5	<.05
25 mm (n = 23)						
LVEDD (mm)	57.4 ± 9.1	54.1 ± 6	54.2 ± 3.9	50 ± 7.1	45.8 ± 10.4	<.05
LVESD (mm)	33 ± 9.4	32.9 ± 6.9	32.2 ± 7.3	31.9 ± 5.3	31.5 ± 2.3	NS
IVS (mm)	11.7 ± 2.1	11.5 ± 1.8	10.9 ± 1.3	10.8 ± 1.2	10.5 ± 1.9	<.05
PW (mm)	11.2 ± 1.6	11.3 ± 0.7	11 ± 1	10.9 ± 1.1	10.9 ± 2.1	NS
Peak gradient (mm Hg)	74.2 ± 19.6	12.7 ± 2.5	12 ± 2	11.9 ± 4	11.4 ± 0.9	<.001
Mean gGradient (mm Hg)	38.4 ± 12.1	10 ± 2.9	9.4 ± 1.3	7 ± 4.5	5.1 ± 3.9	<.05
27 mm (n = 1)						
LVEDD (mm)	52	50	48	48	48	N/A
LVESD (mm)	N/A	N/A	N/A	N/A	N/A	N/A
IVS (mm)	11.5	11.4	11	11	11	N/A
PW (mm)	11.6	11.5	11	11	11	N/A
Peak gradient (mm Hg)	103	14	13	13	13	N/A
Mean gradient (mm Hg)	55	9	8	7	7	N/A

LVEDD, Left ventricular end-diastolic diameter; LVESD, left ventricular end-systolic diameter; IVS, interventricular septum; PW, posterior wall; N/A, not applicable.

Nonstructural Valve Disease

Early nonstructural valve dysfunction with mild (grade I) intravalvular aortic regurgitation was found in 3 patients, which remained stable during the follow-up time, and the patients were clinically asymptomatic. No clinically significant hemolysis was observed in the absence of valve dysfunction.

DISCUSSION

Stentless bioprostheses for AVR have been considered over the traditional stented bioprostheses because the stentless xenograft resembles and provides flow characteristics equivalent to an aortic homograft and similar to the normal human aortic valve.⁶ Both inflow and outflow sutures are excluded from the blood path, and by eliminating a rigid sewing ring in the annulus, the dynamic nature of the aortic root is preserved. The nonturbulent flow, with extremely low transvalvular gradients, mitigates thromboembolism or prosthetic valve endocarditis, and formal anticoagulation is unnecessary. This reduced propensity for valve-related events has been confirmed by clinical experience. As aortic valve prosthesis design has evolved, the

development of new stented valves has significantly reduced the hemodynamic differences between them and their stentless counterparts, except for patients with a small aortic annulus.^{7,8} This is of extreme importance when calcific aortic valve stenosis with a small annulus, which is prevalent in the elderly, is taken into consideration, because this population is at higher risk for patient–prosthesis mismatch. The Freedom SOLO bioprosthesis is a pericardial stentless valve with a design and implantation technique that make it an ideal choice for AVR in this population.

The current article reviews our first 128 consecutive cases with the Freedom SOLO bioprosthesis, and to the best of our knowledge, this is the first early and intermediate-term report of this type of prosthesis, especially in 2 euroSCORE groups (low vs high).

The simplified supra-annular subcoronary technique of implantation using a single running suture translates into a shorter mean crossclamp time and total CBP time. These times are comparable to those reported by Aymard and colleagues.⁹ This is a major benefit for our study population because the majority are high-risk patients with a standard euroSCORE greater than 9. Despite the recently reported

early dysfunction of a large Freedom SOLO valve,¹⁰ we did not encounter such a problem in our series. Despite the absence of an annular anchoring suture line or set of sutures that could have a detrimental impact on valve stability or motion, regular echocardiographic follow-up in our study did not demonstrate any structural valve degeneration. Moreover, no form of aneurysm developed in any of our patients in regular follow-up echocardiographic studies, which is a strong indicator that the outer ring abuts the aortic annulus well enough to prevent ejection of blood into the dead-end space below the coronet suture line. Because two thirds of our patients were aged 75 years or more, more than 75% had a standard euroSCORE greater than 9, and given the high risk nature of these patients, the incidence of complications was considered low.

In regard to the hemodynamics of the Freedom SOLO bioprosthesis, peak and mean transvalvular gradients and peak velocity have been shown to correlate as well as those of other bioprostheses.^{5,11-14} In our study population, 81.2% of patients had a prosthesis size of 21 or 23 mm. Fear of patient-prosthesis mismatch has been reported to be increased as the diameter of the aortic annulus decreases,¹⁵ and the Freedom SOLO valve seems to show excellent results in this group of patients.

The potential survival benefits of stentless valves may relate to the early regression of left ventricular hypertrophy and normalization of left ventricular function.^{16,17} Experience shows regression of left ventricular hypertrophy after valve replacement with most prosthesis types.¹⁸ However, comparative studies show that for mechanical valves and stented bioprostheses, the regression of left ventricular hypertrophy never reaches baseline levels.^{19,20} In contrast, aortic homografts and stentless xenografts allow rapid and complete resolution of left ventricular hypertrophy.^{16,21} In our series, LVEDD and IVS were reduced significantly between preoperative evaluation and follow-up. LVESD and PW also decreased, but this reduction was not statistically significant.

In 2008, a significant decrease in platelet count was reported in several cases in the early postoperative period after valve replacement with the Freedom SOLO prosthesis,²² which was also observed by other surgical teams.²³⁻²⁵ The data analyzed in our series showed a significant decrease in the platelet numbers compared with preoperative values, which occurred 3.5 ± 1.5 days (median day, 3) after the operation, as well as a decrease in hemoglobin, hematocrit, and red blood cell numbers. Nonetheless, in our study, only 1 patient experienced severe thrombocytopenia, and none of our patients required platelet transfusion.

Complete decalcification of the annulus is important before valve implantation, because a heavily calcified aortic root could impede the placement of the sutures. In patients in whom this is not technically feasible or severe

malformation of the annulus is present, it is preferable to avoid implantation of the Freedom SOLO bioprosthesis to avoid valve deformation and thus dysfunction. In our series, aneurysms of the suture line did not develop in any of our patients on follow-up echocardiographic evaluation.

Study Limitations

This is a single-center study that shares all the limitations of a retrospective study. Because life expectancy in those high-risk patients is low, survival decreases with time independently of valve-related events, which impedes follow-up. Moreover, echocardiographic evaluation was not performed by the same physician. Data from an appropriate control group of stented bioprostheses are currently being processed and will be reported in the future but were unavailable during this study. In addition, pulse-duplicator data for potential valve durability estimates are also unavailable.

CONCLUSIONS

The Freedom SOLO stentless bioprosthesis seems to be an adequate option for AVR, especially in older and critically ill patients with comorbidities. Early and intermediate-term hemodynamics assessed by echocardiography proved to be excellent even in patients with a small aortic annulus, which could make the Freedom SOLO bioprosthesis the best choice in this subgroup. Nevertheless, these data must be reconfirmed by other studies and supplemented by long-term data.

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