The Sorin freedom stentless pericardial valve: clinical and echocardiographic performance at 10 years

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ABSTRACT

Objective: *The Sorin Pericarbon Freedom (SPF) is a stentless valve made of pericardium clinically available in 1990. We report the clinical and hemodynamic performance of the SPF at 10 years.*

Methods: *From April 2000 to December 2005, 85 patients with a mean age of 75 ± 6 years (range 57-86), underwent aortic valve replacement (AVR) with an SPF. Mean left ventricular ejection fraction was 58 ± 10% (range 29-86%) and mean peak transvalvular gradient (PG) 86 ± 24 mm Hg. Clinical evaluation was performed at 3, 6, 12 months, and yearly thereafter.*

Results: *There were 2 operative deaths (2.4%). Follow-up ranged from 2 to 135 months (mean 78 ± 32 months) and was 99% complete. There were 35 late deaths, 7 of which were valve-related, with an actuarial survival of 45 ± 8% at 10 years. Structural SPF deterioration occurred in 2 patients, with an actuarial freedom of 96 ± 3%. A total of 4 patients were re-operated, 2 because of structural deterioration, 1 because of endocarditis, and 1 because of sinotubular junction dilatation; freedom from reoperation was 93 ± 4% at 10 years. At last clinical control, 41 patients (89%) were in NYHA class I or II. Mean SPF effective orifice area varied from 1.55 ± 0.66 cm^2 for size 21 mm to 2.33 ± 0.86 cm^2 for size 27 mm; PG varied from 19 ± 10 mm Hg for size 21 mm to 11 ± 6 mm Hg for size 27 mm. Left ventricular mass index decreased from 213 ± 51 gm/m^2 to 157 ± 436 gm/m^2 ($p<0.001$).*

Conclusions: *The SPF has demonstrated overall good results in terms of valve durability and freedom from valve-related complications up to 10 years, with excellent hemodynamic performance.*

KEY WORDS: *Aortic valve replacement, Long-term follow-up, Stentless bioprostheses*

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INTRODUCTION

Stentless bioprostheses have proven to be a valid alternative to traditional stented tissue valves, particularly owing to their superior hemodynamic performance which allows an earlier and more complete regression of left ventricular hypertrophy and increased survival following aortic valve replacement (AVR) (1-4). Despite this, stentless valves have not gained worldwide acceptance mainly because the complexity of implantation techniques; moreover, recent reports have indicated that the durability of some of the currently available models may be limited (5). To address the issue of ease of implantability and prolonged durability a new generation of stentless valves has been manufactured. Among these, there is the Sorin Pericarbon Freedom (SPF; Sorin Biomedica, Saluggia, Italy) a stentless valve made entirely of pericardium, which has been available for clinical use since 1990. After more than two decades, however, clinical data on the performance of this device are extremely limited. The purpose of this report is to present a long-term clinical follow-up on the SPF in a series of patients undergoing AVR.

MATERIALS AND METHODS

After obtaining approval from the Ethics Committee of both hospitals, a retrospective study was carried out on patients having AVR with an SPF at the departments of cardiac surgery of the university hospitals of Verona and Pisa, Italy. A total of 85 patients, operated on from April 2000 to December 2005, form the basis of this report.

Clinical data

Preoperative clinical data are summarized in Table I. Preoperative mean functional class, according to the New York Heart Association (NYHA) classification, was 2.5 ± 0.7, peak transvalvular gradient (PG) was 86 ± 24 mm Hg, mean gradient (MG) 57 ± 14 mm Hg, aortic valve area 0.62 ± 0.20 cm^2, indexed aortic valve area 0.38 ± 011 cm^2/m^2 (mean body surface area of 1.73 ± 0.16 m^2), mean left ventricular (LV) ejection fraction was 58 ± 10% (range 29-86%), and mean LV mass index 213 ± 51 gm/m^2.

SPF characteristics

The SPF is a stentless bioprosthesis made of 2 sheets of bovine peiricardium sutured together with no fabric reinforcement. The pericardium is treated with glutaraldehyde and then submitted to a detoxification process with homocysteic acid to neutralize the residues of unbound aldehyde groups left after the fixation process. The valve is then stored in a aldehyde-free solution without the need for rinsing prior to implant (6).

Surgical technique

All patients were operated through a standard sternotomic incision, with moderate systemic hypothermia. Antegrade cold blood cardioplegia was administered in the aortic root or into the coronary ostia in case of aortic valve incompetence. Topical cooling with iced saline was used throughout each procedure. Associated procedures such as distal coronary anastomoses in case of myocardial revascularization were performed prior to AVR. The aortic valve was approached through a transverse aortotomy approximately 2 to 3 cm above the coronary ostia. It was excised and the annulus was carefully debrided of calcium infiltrates, when needed, paying attention not to cause any annular disruption. The annulus was then sized and the largest size that would fit the annulus was chosen. According to the preference of each surgeon, the SPF were implanted either with interrupted 4/0 sutures of Ethibond (Ethicon Inc., St-Stevens-Woluwe, Belgium) or with 3 continuous sutures of 3/0 polypropylene to secure the inflow pericardial rim, after the valve had been inverted into the LV. The valve was then pulled out and the outflow pericardial rim was always

TABLE I - SUMMARY OF PATIENT CHARACTERISTICS AND STUDY DATA

Gender	
Male	23 (27%)
Female	62 (73%)
Age (years)	
Mean (± SD)	76 ± 6
>80	22 (12%)
Rhythm	
Sinus	72 (85%)
AF	10 (11.5%)
PM	3 (3.5%)
NYHA class	
I	6 (7%)
II	37 (44%)
III	24 (28%)
IV	18 (21%)
Valvular lesion	
Pure or prevalent stenosis	79 (93%)
Pure or prevalent incompetence	6 (7%)
Etiology	
Calcific degeneration	79 (82%)
Valve prolapse	4 (5%)
Rheumatic	2 (3%)
Prosthesis size	
21 mm	15 (18%)
23 mm	43 (51%)
25 mm	16 (19%)
27 mm	3 (3%)
Associated procedures	
CABG	11 (13%)
Ascending aorta replacement	1 (1%)
Enlargement of aortic annulus	1(1%)
Other	3 (3.5%)

AVR = aortic valve replacement; AF = atrial fibrillation; CABG = coronary artery bypass grafting; NYHA = New York Heart Association; PM = pacemaker.

sutured in the supraannular position with 3 continuous sutures of 4/0 polypropylene (7-10). Care was always taken to avoid prosthesis distortion in the event of unequal sinuses of Valsalva (11). Associated surgical procedures were performed in 17 patients (20%): of these, 11 patients had concomitant myocardial revascularization, 1 replacement of the ascending aorta, and 1 enlargement of the aortic annulus. Mean duration of cardiopulmonary bypass was 110 ± 26 minutes and mean duration of aortic cross clamp time was 89 ± 23 minutes. Prosthetic sizes implanted were as follows: 21 mm in 15 patients (18%), 23 mm in 43 (51%), 25 mm in 16 (19%), 27 mm in 8 (9%) and 29 mm in 3 (3%).

Postoperative management

Following AVR, all patients were given subcutaneous heparin followed by oral anticoagulants on postoperative day 1 or after extubation. Heparin was suspended when a target INR of 2.0 to 3.0 was reached. Oral anticoagulants were usually suspended after the first 3 postoperative months and replaced with antiplatelet drugs. Anticoagulation was maintained only in the presence of risk factors for thromboembolic complications such as chronic AF. After discharge, all patients were entered in a follow-up program for heart valve recipients, which includes control visits at 1, 3, 6, and 12 months, and yearly thereafter. A control transthoracic 2D echo-Doppler study was obtained at discharge and further controls then planned every 6 or 12 months. Clinical and echocardiographic follow-up aimed to verify patient status, occurrence of postoperative complications, and to assess SPF and LV performance. For patients who failed to come to the outpatient clinic, information was gathered from relatives or referring physicians. Incidence and types of postoperative complications were evaluated in compliance with recently revised guidelines (12). Follow-up ranged from 2 to 135 months (mean follow-up of 78 ± 32 months) with a cumulative duration of 6698 patient/years (pt/yrs). One patient could not be traced, yielding a 99% complete follow-up.

Statistical analysis

Data are presented as mean ± standard deviation and as simple percentages. Overall survival and freedom from valve-related complications were determined by Kaplan-Meier actuarial analysis and expressed as percentage of patients who were event free ± standard error. The linearized rate of postoperative complications was expressed as %pt/yrs ± standard error. Student's *t* test or Wilcoxon test for continuous data and X^2 or Fisher's test for discrete variables were used, as appropriate. Statistical analyses were performed using SPSS version 16.0.1 (SPSS Inc, Chicago, IL, USA).

RESULTS

Mortality and survival

There were 2 hospital deaths with a 2.4% mortality. One patient died of low output syndrome and multiorgan failure, and 1 of perioperative myocardial infarction. There were 35 late deaths (42%) because of neoplasms in 13 patients, stroke in 4, senectus in 6, respiratory failure in 3, myocardial infarction in 2, endocarditis in 2, pulmonary embolism in 1, trauma in 1, bowel ischemia in 1, and rupture of an abdominal aneurysm in 1, while 1 died of unknown causes; 19 of the late deaths (54%) occurred in patients >80 years of age. Seven late deaths were considered to be valve-related with a linearized incidence of 0.10 ± 0.04 %pt/yrs; they were due to stroke in 4, endocarditis in 2 and unknown causes in 1. At 10 years actuarial survival is 45 ± 8% (Fig. 1) and actuarial freedom from valve-related deaths is 90 ± 4% (Fig. 2). Out of 46 current survivors 40 (87%) are in NYHA class I or II, while 5 are in class III with a mean NYHA class of 1.7 ± 0.7.

Postoperative complications (Tab. II)

Thromboembolic episodes occurred in 5 patients with a linearized incidence of 0.07 ± 0.03 %pt/yrs; of these 4 were fatal while 1 patient sustained a major cerebral embolism. All embolic episodes occurred in patients >85 years of age; 2 of them were on oral anticoagulants because of AF, 3 were in sinus rhythm, but 1 of them had had a transient ischemic attack preoperatively. Actuarial freedom from thromboembolism is 92 ± 4% at 10 years (Fig. 3).

Hemorrhagic complications were observed in 3 patients with an incidence of 0.04 ± 0.03 %pt/yrs. Two patients on anticoagulants because of AF had minor episodes treated medically; one had a hemorrhagic pericardial effusion after 3 months requiring pericardial drainage; actuarial freedom from hemorrhages at 10 years is 96 ± 2%.

Prosthetic endocarditis occurred in 4 patients, with an incidence of 0.06 ± 0.03 %pt/yrs; 2 patients were successfully treated medically, 1 died at reoperation, and 1 died without reoperation due to sepsis and cardiac failure. Actuarial freedom from endocarditis is 95 ± 2% at 10 years.

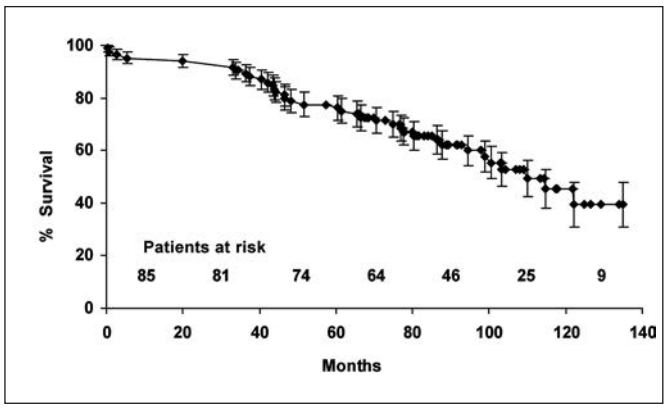

Fig. 1 - *Actuarial survival at 10 years.*

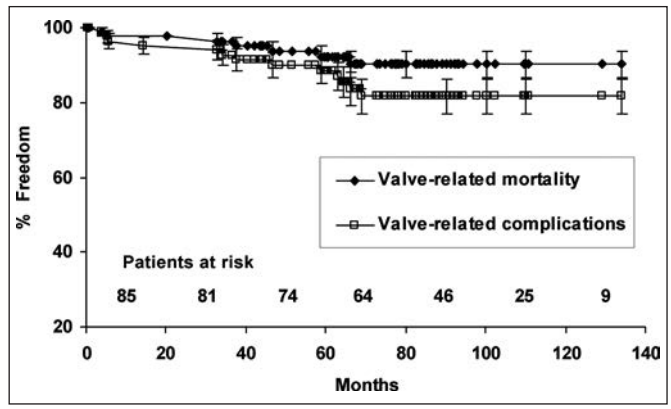

Fig. 2 - *Actuarial freedom from valve-related mortality and valve-related complications.*

TABLE II - ACTUARIAL AND LINEARIZED RATES OF MAJOR POSTOPERATIVE COMPLICATIONS

Complication	No.	Linearized incidence (%pt/yrs)	Actuarial freedom % ± SE	
			5 years	10 years
Late deaths	35	-	76 ± 5	45 ± 8
Prosthesis-related deaths	7	0.10 ± 0.04	92 ± 3	90 ± 4
Thromboembolism	5	0.07 ± 0.03	96 ± 2	92 ± 4
- major	1	0.01 ± 0.01	-	-
- fatal	4	0.06 ± 0.03	-	-
Hemorrhages	3	0.04 ± 0.03	99 ± 1	96 ± 2
Endocarditis	4	0.06 ± 0.03	95 ± 2	95 ± 2
Structural failure	2	0.03 ± 0.02	100	96 ± 3
Reoperation	4	0.06 ± 0.03	97 ± 2	93 ± 4
Prosthesis-related complications	15	0.19 ± 0.05	86 ± 4	82 ± 5

%pt/yrs = Percent per patient years; SE = standard error.

Structural deterioration of the SPF was observed in 2 patients, with a linearized incidence of 0.03 ± 0.02 %pt/yrs. An 82-year-old female was re-operated 6 years after AVR because of SPF incompetence due to a commissural tear with minimal calcification. A 74-year-old female was re-operated after 5 years at another hospital because of SPF dysfunction; although details of the operative findings are not available, it is known that both patients survived reoperation. Actuarial freedom from structural valve deterioration is 96 ± 3% at 10 years (Fig. 4).

Four patients required reoperation: 2 were reoperated due to structural valve deterioration, 1 due to endocarditis, and 1 due to non-structural valve deterioration. All patients underwent successful reoperation except the one with endocarditis. Actuarial freedom from reoperation is 93 ± 4% at 10 years.

Including late deaths, valve-related events occurred in 13 patients: thromboembolism in 5, reoperation in 4, endocarditis in 3, and death for unknown causes in 1, with a linearized incidence of 0.19 ± 0.05 pt/yrs and an actuarial freedom at 10 years of 82 ± 5% (Fig. 2).

Echocardiographic data

At last follow-up, echocardiographic controls showed a PG of 18 ± 9 mm Hg, an MG of 9 ± 6 mm Hg, an effective

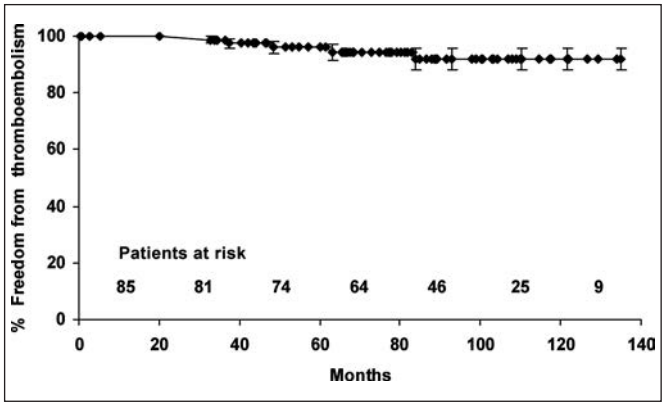

Fig. 3 - *Actuarial freedom from thromboembolic complications.*

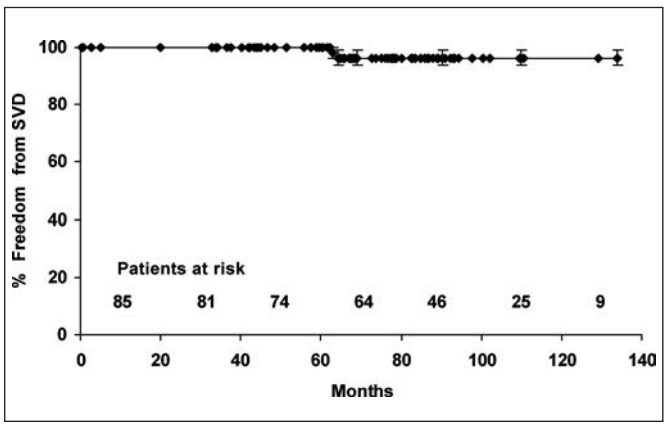

Fig. 4 - *Actuarial freedom from structural valve deterioration (SVD).*

orifice area (EOA) of 1.88 ± 0.63 cm^2, an indexed EOA of 1.02 ± 0.47 cm^2/m^2, a LV mass index of 157 ± 43 gm/m^2 ($p<0.001$ when compared to preoperative values) and an LV ejection fraction of 56 ± 15%. Trivial aortic regurgitation was present in 15 patients (3 with a 21 mm SPF, 8 with a 23 mm SPF, 3 with a 25 mm SPF and 1 with a 27 mm SPF) while moderate aortic regurgitation was found in 4 patients (3 with a 23 mm SPF and 1 with a 27 mm SPF). In terms of SPF sizes, echocardiographic data were available in 9 patients with a 21 mm SPF, 33 with a 23 mm SPF, 9 with a 25 mm SPF, and 6 with a 27 mm SPF (Tab. III).

DISCUSSION

The SPF has been in clinical use for more than 2 decades (13). Despite this history, information of the long-term clinical performance of this device is extremely limited. Nagy et al reported the mid-term results of a series of 101 patients receiving an SPF with a maximum follow-up of 51 months (14). Grubitzsch and associates compared 50 patients with the SPF with 35 patients receiving another stentless valve with a maximum follow-up of 8 months (15). More recently, in a series of 102 patients, Nyawo et al reported an 89% survival, 96% freedom from thromboembolism and no instances of structural failures at 5 years (16). The only long-term follow-up study on the SPF is by D'Onofrio et al, who reported their experience in 130 patients (10). At 7 years they

TABLE III - ECHOCARDIOGRAPHIC DATA

	21 mm		23 mm		25 mm		27 mm	
	Pre operative	Post operative	Pre operative	Post operative	Pre operative	Post operative	Pre operative	Post operative
LVEF (%)	64 ± 10	60 ± 8	58 ± 11	56 ± 12	61 ± 11	58 ± 10	55 ± 11	52 ± 14
Aortic PG (mm Hg)	94 ± 17	20 ± 10*	82 ± 18	19 ± 10*	84 ± 34	16 ± 8*	83 ± 31	11 ± 6*
Aortic MG (mm Hg)	63 ± 14	11 ± 7*	54 ± 14	10 ± 6*	55 ± 24	8 ± 6*	56 ± 27	8 ± 6*
EOAi (cm^2/m^2)	0.34 ± 0.10	0.94 ± 0.12*	0.37 ± 0.13	1.11 ± 0.25*	0.55 ± 0.26	1.20 ± 0.28*	0.41 ± 0.24	1.25 ± 0.20*
LVMI (g/m^2)	225 ± 42	191 ± 32*	209 ± 34	158 ± 27*	206 ± 49	135 ± 37*	208 ± 48	126 ± 26*

LVFE = left ventricular ejection fraction; Aortic PG = aortic peak gradient; Aortic MG = aortic mean gradient; EOAi = effective orifice area indexed; LVMI = left ventricular mass index ; * = $p<0.001$ pre-operative vs. post-operative values.

observed a 50% survival, 94% freedom from reoperation and 91% freedom from valve-related deaths. In addition, no cases of structural valve deterioration were observed in their study. Our paper thus appears to be the first long-term report on the clinical performance of the SPF with a maximum follow-up of over 11 years. Our results confirm the overall good performance of the SPF, particularly in terms of freedom from valve-related complications. In this respect, the safety of the SPF can also be confirmed by comparison with the rate of valve-related complications reported with other stentless and stented bioprostheses (5, 17-19). However, it is difficult to compare our results with those of previous reports due to the differences in follow-up intervals. Patient survival in our series was similar to that reported by others at 7 years (10). The high mean age of our patients at time of AVR and the fact that over 50% of late deaths occurred in patients 80 years of age or older must be stressed.

There were 5 major thromboembolic episodes, all occurring in patients >85 years of age; however, considering the possibility of concomitant cerebral vascular disease in this very old patient subset, these episodes might have been overestimated since some of the cerebral ischemic events were probably not strictly valve-related. No cases of SPF structural valve deterioration have been so far reported in short- and medium-term studies (10, 14-16). Only one case of SPF failure had been documented previously (20): an 84-year-old female underwent replacement of a severely calcified SPF 6 years after AVR. At reoperation, excision of the SPF cusps left a rigid and diminutive aortic annulus which required an annular enlargement procedure to insert a prosthesis of adequate size (20). In the present series 2 patients underwent reoperation because of SPF failure. In 1 of them, severe valve incompetence was caused by a commissural tear with mild calcification, while in the other, operative details are lacking since reoperation was performed at another hospital. These results seem to confirm that durability of the SPF is satisfactory at 10 years; however, they also indicate that occasionally the SPF can undergo structural changes with a failure mode similar to that reported with traditional porcine or pericardial bioprostheses (21-23).

The SPF has demonstrated excellent hemodynamic performance in our experience as well, confirming results reported by others (7, 8, 10, 24). In our series low gradients and large valvular areas were recorded even in the small sizes. The hemodynamic benefit of the SFS is particularly evident in patients with aortic stenosis in whom significant reduction of LV hypertrophy is demonstrated over time. Interestingly, hemodynamic performance of the SPF does not seem to be influenced by different implantation techniques (8, 14).

Recently, Sorin Biomedica began manufacturing another pericardial stentless valve, the Freedom Solo, which is directly derived from the SPF. The Fredom Solo has the same manufacturing process and tissue treatment, but differs from the SPF in that the external pericardial support has been eliminated, allowing it to be implanted with a single suture line in complete supra-annular position. Early clinical and hemodynamic results with the Solo stentless valve are gratifying but long-term data are not currently available (25). Particularly owing to its ease of implantability, the Solo valve will probably render the SPF obsolete in a short time. However, we believe that continuous and extended follow-up information on the SPF may be helpful to verify durability of this new device.

The Freedom Solo bioprosthesis has been associated with the occurrence of postoperative thrombocytopenia in recent reports (26-28). This problem has never been investigated in patients with an SPF (10, 14-16). Due to the retrospective nature of this paper we were unable to verify occurrence of platelet count reduction in all our patients. In a small subset, too limited to gain statistical significance, however, we were able to confirm that postoperative thrombocytopenia is present in SPF patients, with a behavior similar to that in patients with the Freedom Solo bioprosthesis (27). Reduction of platelets, to values <150,000/μl, occurs on the first postoperative day, continues throughout the postoperative period, and does not completely normalize at discharge. These observations seem to support the theory that the peculiar tissue treatment of the Solo and the SPF might play an important role in causing thrombocytopenia after AVR (26, 28).

The major limitations of our study are its retrospective design and the limited number of patients. Echocardiographic evaluation of LV mass in retrospective studies may be another limitation, since analysis is performed by different operators. Nevertheless, we believe that an accurate follow-up, which was 99% complete, has provided meaningful data for assessing the long-term performance of the SPF. Furthermore, we are also confident that the information provided by this study can be used as a valid reference point for comparison with the new generation of pericardial stentless devices used for AVR, either with standard tech-

niques or through transfemoral or transapical approaches. In conclusion, a 10-year follow-up of patients receiving an SPF indicates that this bioprosthesis has satisfactory clinical results with an overall low rate of major complications. Based on its excellent hemodynamic performance, we can confirm that the SPF may be especially indicated in elderly patients requiring AVR for severe aortic stenosis.

Conflict of Interest Statement: None to declare.

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