Aortic valve replacement with the Sorin Pericarbon Freedom stentless prosthesis: 7 years' experience in 130 patients

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Objectives: Aortic stentless pericardial valves were introduced into clinical practice to combine properties of both stentless and pericardial prostheses. The aim of this single-center retrospective study was to assess midterm clinical and hemodynamic results of aortic valve replacement with the Sorin Pericarbon Freedom stentless bioprosthesis.

Methods: From July 1999 through November 2005, 130 consecutive patients (73 [56.1%] male patients) underwent aortic valve replacement with the Sorin Pericarbon Freedom bioprosthesis at our institution. Mean age was 76 ± 5 years (range, 42-86 years), and associated procedures were performed in 50 (38.4%) patients; of these, 41 were coronary artery bypass grafts. Surgical intervention under urgent/emergency conditions and reoperations were performed in 18 (13.8%) and 7 (5.3%) patients, respectively. Mean crossclamp and cardiopulmonary bypass times were 82 ± 24 and 125 ± 40 minutes, respectively. All patients underwent clinical and echocardiographic follow-up (100% complete), and the total cumulative follow-up was 324 patient/years (mean, 2.5 ± 1.8; range, 6 months–7 years).

Results: Overall hospital mortality was 8.4%. Overall patient survival was 63% ± 6% and 50% ± 10% at 5 and 7 years, respectively. Late deaths occurred in 23 patients, and 6 of them were valve related (1.8% patient/years). Freedom from valve-related death and reoperation was 91% ± 4% and 94% ± 4%, respectively, at 7 years. No structural valve deterioration was observed. Endocarditis, thromboembolism, and hemorrhagic complications occurred in 2 (0.6% patient/years), 1 (0.3% patient/years), and 1 (0.3% patient/years) patients, respectively. Mean transprosthetic gradients for valve sizes 23, 25, and 27 were 12.1 ± 3.8, 10.8 ± 3.8, and 9 ± 3.1 mm Hg, respectively.

Conclusions: The Sorin Pericarbon Freedom stentless bioprosthesis provides good early and midterm results in terms of hemodynamic performance, survival, and freedom from valve-related complications.

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Stentless aortic bioprostheses appear to provide improved transvalvular gradients and increased orifice areas and survival rates compared with stented valves.[1] Furthermore, pericardial aortic stented valves have demonstrated excellent durability, freedom from primary tissue failure, and freedom from prosthetic endocarditis.[2,3]

The Sorin Pericarbon Freedom (SPF; Sorin Biomedica, Saluggia, Italy) is a stentless pericardial valve prosthesis made of two sheets of pericardium sutured together without any fabric reinforcement and prepared with a postfixation treatment with homocysteic acid, which neutralizes residues of unbound aldehyde groups left after the fixation process. This peculiar design, the anticalcification treatment, and the absence of any synthetic material except for sutures should provide good results

Abbreviations and Acronyms
AVR = aortic valve replacement
SPF = Sorin Pericarbon Freedom

in terms of hemodynamics, freedom from structural valve deterioration, and freedom from prosthetic valve endocarditis. The aim of this retrospective and single-center study was to assess early and midterm results of aortic valve replacement (AVR) with the SPF bioprosthesis.

Materials and Methods

Study Population

From July 1999 through December 2005, 130 consecutive patients underwent AVR with the SPF bioprosthesis at our institution. Demographic and clinical preoperative data of the study population are listed in Table 1.

Selection criteria for the implantation of the SPF bioprosthesis were as follows: age older than 65 years, contraindication to oral anticoagulant therapy, request for a biologic valve by the patient, small aortic annulus, and surgeon's preferences. Furthermore, SPF bioprostheses were intentionally implanted in patients with abscesses of the aortoventricular junction. The contraindications for the implantation of the SPF were severe calcification of the aortic annulus and aortic root aneurysm.

Surgical Intervention

Surgical intervention was performed during moderate hypothermia in all patients. Myocardial protection was obtained by using retrograde and selective antegrade cardioplegia. The SPF bioprosthesis was implanted with 3 continuous 4-0 polypropylene sutures both for the inflow and the outflow rim.

Valve sizes 21, 23, 25, and 27 were implanted in 1 (0.8%), 57 (43.8%), 54 (41.6%), and 18 (13.8%) patients, respectively.

Fifty-one associated procedures were performed in 50 (38.4%) patients: 41 coronary artery bypass graftings, 4 mitral valve repairs, 2 mitral valve replacements, 3 replacements of the ascending aorta, and 1 patent foramen ovale closure. Mean aortic crossclamp times were 82 ± 24 and 79 ± 18 minutes for the whole population and for isolated AVR, respectively. Mean cardiopulmonary bypass times were 125 ± 40 and 122 ± 36 minutes for the whole population and for isolated AVR, respectively. Indications for AVR were as follows: calcific aortic stenosis in 99 (76.2%), aortic regurgitation in 10 (7.7%), endocarditis in 8 (6.2%), rheumatic disease in 5 (3.8%), prosthesis malfunction in 6 (4.6%), and congenital bicuspid valve in 2 (1.5%) patients.

After implantation, oral anticoagulant therapy was prescribed in all patients and discontinued 3 months later; this is the routine anticoagulation protocol for all bioprostheses at our institution. Acetylsalicylic acid, 100 mg daily, or ticlopidine, 250 mg daily, were then used as antiplatelet agents. Permanent anticoagulant therapy in a dose adjusted to achieve a target international normalized ratio of 2.0 to 3.0 was prescribed in 6 (5%) patients with chronic atrial arrhythmias.

TABLE 1. Preoperative patient characteristics

	n	%
Age (y)	76 ± 5 (range, 42-86)	
Sex	Male: 73	56
	Female: 57	44
History of smoking	44	34
Hypertension	101	78
Hypercholesterolemia	61	47
Diabetes	30	23
History of CVA	12	9
Chronic renal failure	8	6
Bacterial endocarditis	8	6
Severe COPD	15	12
Previous surgical intervention	7	5
Atrial fibrillation	21	16
EF (%)	58 ± 14	
Urgent/emergency	18	14
NYHA class	I: 6	5
	II: 23	18
	III: 81	62
	IV: 20	15
Additive EUROscore	9.2 ± 2.2	

CVA, Cerebrovascular accident; *COPD*, chronic obstructive pulmonary disease; *EF*, ejection fraction; *NYHA*, New York Heart Association.

Follow-up

All patients underwent scheduled visits at our outpatient clinic 1, 6, and 12 months after the operation and on a yearly basis thereafter. Clinical follow-up was 100% complete. Mean clinical follow-up time was 2.5 ± 1.8 years (range, 6 months-7 years), and total cumulative follow-up was 324 patient/years.

From January through September 2006, all of the 96 survivors (74% of the initial study population) were purposely asked to undergo an echocardiographic evaluation. Echocardiography was performed at our institution by the same physician in 70 (72.9%) patients. Twenty-six (27.1%) patients underwent evaluation at different outside laboratories. Echocardiograms from outside laboratories were sent to us by patients or by the patients' referring cardiologists.

Mean echocardiographic follow-up time was 37.1 ± 20 months (range, 9.4-82.2 months). Echocardiography was performed with an iE 33 cardiac ultrasound scanner (Royal Philips Electronics, Amsterdam, The Netherlands) according to the American Society of Echocardiography guidelines. Peak and mean transvalvular pressure gradients were derived by using the modified Bernoulli equation, and the effective orifice area was calculated with the continuity equation.

Morbidity and fatal valve-related events were categorized as resulting from structural valve deterioration, nonstructural valve dysfunction, thromboembolism, prosthetic valve endocarditis, hemorrhagic complication, reoperation, valve-related mortality, or cardiac-related mortality according to the Society of Thoracic Surgeons and American Association for Thoracic Surgery guidelines for reporting morbidity and mortality after cardiac valvular operations.[4]