

Aortic Valve Replacement with New-Generation Stentless Pericardial Valves: Short-Term Clinical and Hemodynamic Results

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Background and aim of the study: Aortic valve replacement (AVR) with stentless bioprostheses offers superior hemodynamics. In order to overcome the disadvantages of older, stentless valves, a new generation of pericardial stentless prostheses has been developed. Herein, the hemodynamic and clinical results of these substitutes have been evaluated. **Methods:** Between March 2002 and May 2004, 85 patients (59 females, 26 males; mean age 73.6 ± 6.1 years) who underwent AVR received either a bovine (Sorin Pericarbon Freedom®; SPF; $n = 50$) or an equine (3F Aortic Bioprosthesis®; 3F; $n = 35$) pericardial stentless valve. Patients were followed up prospectively at six months after surgery by clinical and echocardiographic examination. The mean follow up period was 5.6 ± 0.8 months, and was 96.4% complete.

Results: Mortality was 2.4% at 30 days (two SPF patients; one died at reoperation for suspected valve thrombosis and one was a non-valve-related death) and 2.5% at follow up (two SPF patients; both non-valve-related). Neither structural valve failure nor

endocarditis were observed. Preoperatively, there were no differences in baseline data, functional status and hemodynamics between SPF and 3F patients. The aortic cross-clamp time was similar in both groups (51.7 ± 11.2 min for SPF; 51.6 ± 8.2 min for 3F). NYHA functional status improvement was similar in each group (1.8 ± 0.5 for SPF; 1.7 ± 0.6 for 3F). The mean transaortic pressure gradient (Δp_{mean}) was reduced in all patients during follow up. With SPF, a lower Δp_{mean} was found for smaller aortic roots (indexed annular diameter (IAD) <14 mm/m²) as well as in larger (IAD ≥ 14 mm/m²) aortic roots: 8.0 ± 4.5 mmHg versus 13.2 ± 7.2 mmHg ($p < 0.05$) and 6.8 ± 3.0 mmHg versus 12.8 ± 4.8 mmHg ($p < 0.05$), respectively.

Conclusion: New-generation pericardial stentless aortic valves are very pliable, which facilitates their implantation. Clinical and hemodynamic results with these prostheses are promising. The SPF prosthesis demonstrates excellent performance, and may be superior when implanted in small aortic roots.

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Following the introduction of stentless porcine bioprosthesis for aortic valve replacement (AVR) in 1988, superior hemodynamic performance and increased regression of left ventricular hypertrophy have been demonstrated (1-3). In order to overcome any disadvantages of this first-generation stentless aortic xenografts, these substitutes have undergone remarkable modifications during the past decade. By focusing on the ease of implantation and increased durability,

full pericardial constructs together with different anti-calcification treatments have been developed (4-6). These valves are free of the compromises of the porcine aortic root, and early clinical experiences have shown encouraging results (7-12).

The aim of the present study was to investigate the implantation technique, hemodynamic characteristics and clinical outcome of two new-generation pericardial stentless aortic valves, the Sorin Pericarbon Freedom® and the 3F Aortic Bioprosthesis®. The focal point of the study was a detailed comparison of transvalvular flow characteristics.

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Clinical material and methods

Patients

Patients who had undergone AVR with either a Sorin

Pericarbon Freedom (SPF) prosthesis (Sorin Biomedica, Saluggia, Italy) or a 3F Aortic Bioprosthesis (3F) valve (3F Therapeutics, Lake Forest, CA, USA) were prospectively studied. Each patient group formed part of a multicenter trial evaluating clinical and hemodynamic results. Approval for the study was granted by the local ethics committee on 28th January 2002. Patients aged ≥ 65 years and requiring AVR, even in association with mitral valve repair, coronary artery bypass grafting (CABG) and other procedures, were enrolled. The exclusion criteria were double valve replacement, active endocarditis, disorders of calcium metabolism, autoimmune disease, intravenous drug abuse, severe calcification of the aortic sinuses or abnormal insertion of the coronary ostia. Informed consent was acquired from each individual included in the study.

Stentless pericardial prostheses

The SPF (Fig. 1A) is constructed from two sheets of bovine pericardium without any prosthetic material (4). After glutaraldehyde fixation, the valve is treated with homocysteic acid, thereby protecting calcification by the elimination of aldehyde residues (5). This detoxification treatment renders the valve ready to use without any need for rinsing.

The 3F prosthesis (Fig. 1B) is a glutaraldehyde-fixed equine pericardial valve which resembles a more tubular shape of an earlier developmental stage in utero (6). Three leaflets have been assembled with locking sutures. Three polyester-reinforced tabs have been placed at the outflow side; these simulate commissures and allow fixation at the aortic wall. A polyester ring is incorporated at the inflow side for suturing the valve to the bottom of the aortic sinus.

Surgery

All operations were performed via a median sternotomy and using standard normothermic extracorporeal circulation with cardioplegic arrest by warm blood cardioplegia. After excision of the diseased aortic valve and complete decalcification, the diameter of the aortic annulus and sinotubular junction were measured using standard ball sizers. The size of the prosthesis was chosen according to the diameter of the annulus (3F) or the sinotubular junction (SPF). The choice of valve was left to the discretion of the surgeon. For further comparison, the indexed annulus diameter (IAD) was determined by dividing the annulus diameter by body surface area. The implantation of SPF prostheses was performed with the usual subcoronary technique requiring two suture rows: either single stitches

Table I: Baseline data and clinical characteristics.

Parameter	All patients	3F valve	SPF valve	p-value
No. of patients	85	35	50	
Age (years)*	73.6 \pm 6.12	73.8 \pm 6.61	73.4 \pm 5.82	NS
Gender				
Female (n)	49 (69.4)	23 (65.7)	26 (52.0)	NS
Male (n)	36 (30.6)	12 (34.3)	24 (48.0)	NS
Body surface area (m ²)*	1.8 \pm 0.18	1.8 \pm 0.18	1.8 \pm 0.18	NS
Aortic valve lesion				
Stenosis (n)	73 (85.9)	31 (88.6)	42 (84.0)	NS
Mixed lesion (n)	12 (14.1)	4 (11.4)	8 (16.0)	NS
Cardiac rhythm				
Sinus rhythm (n)	68 (80.0)	28 (80.0)	40 (80.0)	NS
Atrial fibrillation (n)	15 (17.6)	6 (17.1)	9 (18.0)	NS
Other (n)	2 (2.4)	1 (2.8)	1 (2.0)	NS
Concomitant disease				
Coronary artery disease (n)	42 (49.4)	17 (48.6)	25 (50.0)	NS
Arterial hypertension (n)	54 (63.5)	23 (65.7)	31 (62.0)	NS
Pulmonary hypertension (n)	8 (9.4)	3 (8.6)	5 (10.0)	NS
Renal dysfunction (n)	20 (23.5)	8 (22.9)	12 (24.0)	NS
Pulmonary disease (n)	10 (11.8)	5 (14.3)	5 (10.0)	NS
Diabetes (n)	27 (31.8)	11 (31.4)	16 (32.0)	NS
Obesity (n)	15 (17.6)	8 (22.9)	7 (14.0)	NS
NYHA class*	2.9 \pm 0.40	2.8 \pm 0.60	3.0 \pm 0.25	NS
EuroScore*	6.4 \pm 2.07	6.3 \pm 2.50	6.6 \pm 1.64	NS

*Values are mean \pm SD.

Values in parentheses are percentages.

NS: Not significant.

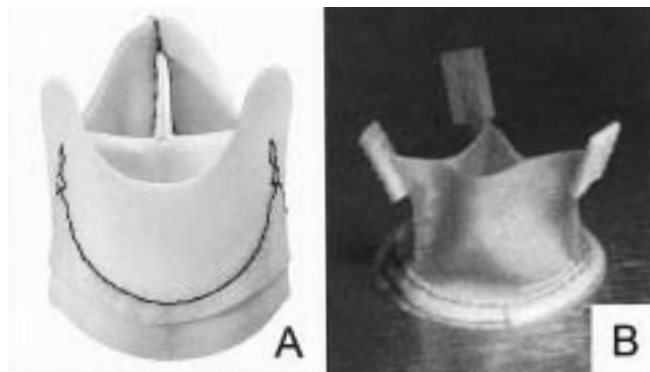


Figure 1: New-generation stentless pericardial valves. A) The Sorin Pericarbon Freedom® valve is constructed from bovine pericardium without prosthetic material. B) The 3F Aortic Bioprosthesis® is an equine pericardial valve with a polyester ring at the inflow side and polyester reinforced tabs at the outflow side.

(Ethibond) or continuous sutures (Prolene) proximal and a continuous subcoronary suture (Prolene). 3F prostheses were implanted with only one running proximal suture (Prolene). The tips of the commissures were attached to the aortic wall by three single stitches.

Echocardiography

Preoperatively, before discharge and at follow up, all patients underwent transthoracic echocardiography (TTE) using a HP Sonos 5500 (Hewlett Packard, Andover, MA, USA); all investigations were performed by two experienced echocardiographers. On standard views, left ventricular morphology and function were assessed by B- and M-mode and transvalvular hemodynamics using Doppler and color Doppler. The left ventricular ejection fraction was determined using the Simpson method. All hemodynamic measurements were performed with the patients in a stable condition. Mean values for each measurement were derived from three beats in patients in sinus rhythm, and from five beats in those in non-sinus rhythm. Transaortic flow velocities were assessed by continuous-wave Doppler. Transvalvular pressure gradients were calculated using the Bernoulli equation with correction for left ventricular outflow tract velocities. The aortic valve effective orifice area was determined using the continuity equation, and indexed by body surface area.

Intraoperatively, transesophageal echocardiography (TEE) was used in all patients to control prosthesis and ventricular function following implantation.

Follow up

The prospective follow up was performed at six months postoperatively. All patients were interviewed

and underwent clinical, electrocardiographic and echocardiographic examinations. In a few patients (those unable to visit the clinic), the interviews were conducted by telephone, and echocardiographic data were obtained from the referring cardiologist.

Data analysis

Valve-related morbidity and mortality were evaluated according to standard guidelines (13). The results of continuous variables were provided as mean \pm SD. In order to examine differences between groups, paired and unpaired Student's *t*-tests were used respectively after testing for normal distribution. For discontinuous variables, absolute and relative frequencies were given. For inter-group comparison, a chi-squared test was applied. A *p*-value <0.05 was considered to be statistically significant.

Results

Between March 2002 and May 2004, a total of 85 patients (59 females, 26 males; mean age 73.6 ± 6.12 years) who underwent AVR (predominantly for stenosis) each received a stentless pericardial bioprosthesis. SPF prostheses were implanted in 50 patients, and 3F prostheses in 35. No patients were excluded due to calcification of the aortic root or abnormal origins of the coronary arteries. There were no significant differences in baseline data and functional status in SPF and 3F patients, nor in the entire study population (Table I). Preoperative echocardiographic data were comparable in the SPF and 3F groups with regard to left ventricular ejection fraction ($56.8 \pm 12.0\%$ versus $60.8 \pm 8.8\%$, *p* = NS), left ventricular end-diastolic diameter (50.7 ± 9.9 mm versus 46.8 ± 9.0 mm, *p* = NS), diastolic left ventricular posterior wall thickness (12.3 ± 2.8 mm versus 12.1 ± 1.9 mm, *p* = NS), and transaortic peak (82.9 ± 27.0 mmHg versus 86.2 ± 24.3 mmHg, *p* = NS) as well as mean gradient (53.5 ± 20.4 mmHg versus 62.3 ± 16.3 mmHg, *p* = NS).

Operative data

After decalcification, the mean annulus diameter was 25.7 ± 2.28 mm (range: 20 to 29 mm); consequently, the IAD was 14.2 ± 1.46 mm/m² (range: 11.5 to 17.9 mm/m²). Although the different valve sizes were implanted with similar frequency in the SPF and 3F patients (Table II), SPF prostheses were approximately one size larger than the annulus of the patient due to the sizing strategy described above. In valves of size 21, 23, 25, 27 and 29 mm, the mean annulus diameter was 20, 21.5, 24, 25.9 and 28.3 mm in the SPF group, and 21, 23, 25, 27 and 29 mm in the 3F group. The mean aortic cross-clamp time was 58.0 ± 15.63 min (range: 31 to 98 min). Slightly more associated procedures were

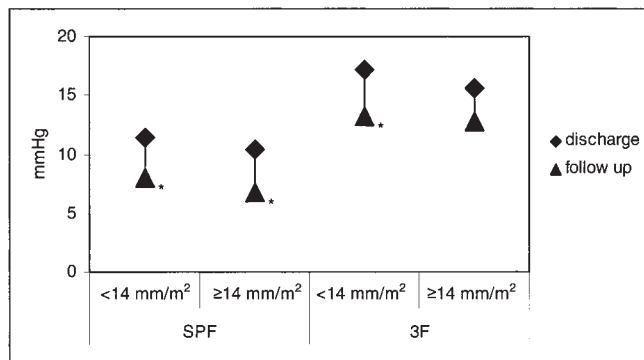


Figure 2: Influence of valve type (SPF versus 3F), indexed annular diameter (<14 versus ≥14 mm/m²) and time (discharge versus follow up) on mean transaortic gradient. **p* < 0.05, paired Student's *t*-test for postoperative and follow up data.

performed in the SPF group; these were mainly CABG and ablation for atrial fibrillation, but the inter-group difference was not statistically significant. In patients without associated procedures (n = 34 for SPF valves; n = 27 for 3F valves), the aortic cross-clamp time was comparable between groups (Table II).

Perioperative course

Overall, re-exploration for bleeding was required in three patients (in two after SPF implantation and in one patient after 3F; *p* = NS). All of these patients had an uneventful recovery. One SPF patient developed

new-onset atrioventricular block requiring pacemaker implantation. In one 3F patient, pulmonary artery embolism occurred due to heparin-induced thrombocytopenia, but this was successfully treated by anticoagulation. A transient ischemic attack occurred in one SPF patient on postoperative day 5. However, this patient suffered from chronic atrial fibrillation, and echocardiography excluded the aortic valve prosthesis as a source of thrombi. Transient confusion was observed in three patients (one after SPF; two after 3F; *p* = NS). Mortality at 30 days was 2.4% (n = 2, both after SPF). One of these patients died as a result of a bleeding complication at reoperation on postoperative day 28 to remove thrombosis from the aortic valve prosthesis. The second death was not valve-related, but resulted from sepsis due to sternal infection with mediastinitis complicated by multiple organ failure. No hemorrhagic events, endocarditis or permanent valve-related impairment were observed.

Follow up

The mean follow up period was 5.6 ± 0.8 months (range: 3 to 8 months), and was 96.4% complete. In total, three patients were lost to follow up (two after SPF, one after 3F; *p* = NS). The mortality rate during follow up was 2.5% (n = 2, both after SPF; *p* = NS). None of the deaths was valve-related; one patient died from pneumonia and one due to pulmonary embolism after deep-vein thrombosis. Neither structural valve failure nor endocarditis were observed. No thromboembolic or hemorrhagic events occurred. On the

Table II: Operative data.

Parameter	3F valves	SPF valves	p-value
Valve size (mm)			
21 (n)	1 (2.8)	1 (2.0)	NS
23 (n)	3 (8.6)	4 (8.0)	NS
25 (n)	11 (31.4)	19 (38.0)	NS
27 (n)	11 (31.4)	16 (32.0)	NS
29 (n)	9 (25.7)	10 (20.0)	NS
Associated procedures			
Patients (n)	8 (22.8)	16 (32.0)	NS
Myectomy (n)	2 (5.7)	2 (4.0)	NS
AML debridement (n)	1 (2.8)	1 (2.0)	NS
MV repair (n)	1 (2.8)	-	-
Ablation (n)	1 (2.8)	5 (10.0)	NS
CABG (n)	5 (14.3)	11 (22.0)	NS
CPB time (min)* ⁺	68.4 ± 9.9	70.7 ± 15.9	NS
Aortic cross-clamp time (min)* ⁺	51.6 ± 8.2	51.7 ± 11.2	NS

*Values are mean ± SD.

⁺Patients with associated procedures (n = 34 in SPF group; n = 27 in 3F group) were excluded.

Values in parentheses are percentages.

AML: Anterior mitral leaflet; CABG: Coronary artery bypass grafting; CPB: Cardiopulmonary bypass; MV: Mitral valve; NS: Not significant.

basis of NYHA class, the functional status was improved to a similar degree in both groups (1.8 ± 0.5 in SPF patients and 1.7 ± 0.6 in 3F patients; $p = \text{NS}$).

Echocardiography

Intraoperative TEE demonstrated regular function of all aortic valve prostheses implanted. Postoperative TTE performed before discharge on days 4 to 7 revealed normal function of the aortic valve prosthesis in all patients. In the patient who underwent reoperation, early-stage valve thrombosis was not apparent on TTE at discharge. Transaortic hemodynamic parameters showed excellent flow characteristics, with a mean transaortic flow velocity of 1.5 ± 0.44 m/s and a low mean transaortic gradient of 13.2 ± 6.72 mmHg, that fell to 1.4 ± 0.42 m/s and 9.3 ± 5.32 mmHg, respectively, at follow up. The majority of patients had no more than trivial aortic regurgitation at discharge. Grade 1+ aortic regurgitation was seen in one SPF patient, but this did not progress during follow up.

The analysis of echocardiographic data with respect to different annulus sizes is summarized in Table III. At discharge and at follow up, the transaortic hemodynamics tended to be better with SPF valves than with 3F valves, and in general this difference was sta-

tistically significant. In particular, superior hemodynamics were demonstrated with the SPF prosthesis in smaller aortic roots. At follow up there was a tendency towards reduced transaortic flow velocities and gradients in both groups in comparison with values at discharge (Table III; Fig. 2).

Discussion

Whilst previous clinical experience with the SPF and 3F valves has demonstrated favorable results (7-12), there have been no reports of any detailed prospective comparison with a focus on transvalvular flow characteristics of these new-generation stentless prostheses.

Implantation technique

It would appear that pericardial stentless aortic valves are the most user-friendly of all stentless prostheses, as their extreme pliability allows inversion of the prosthesis into the left ventricle, thus facilitating implantation. In addition, by using continuous sutures, a relatively short aortic cross-clamp time could be achieved. Thus, even among the growing number of patients who require combined AVR and CABG, these valves can be used without any excessive

Table III: Echocardiographic results.

IAD/Parameter	Postoperative		p-value	Follow up		p-value
	3F valves	SPF valves		3F valves	SPF valves	
<i><14 mm/m²</i>						
Patients (n)	15 (42.9)	28 (56.0)	NS	15 (44.1)	23 (53.5)	NS
LVEF (%)	58.7 ± 10.5	56.5 ± 9.9	NS	57.5 ± 19.3	61.3 ± 10.5	NS
Mean transaortic flow velocity (m/s)	2.0 ± 0.6	1.5 ± 0.5	0.048	1.9 ± 0.4	1.2 ± 0.2	<0.001
Peak transaortic flow velocity (m/s)	2.6 ± 0.4	2.2 ± 0.6	0.030	2.4 ± 0.5	$1.9 \pm 0.4^{\dagger}$	0.007
Mean transaortic gradient (mmHg)	17.2 ± 7.6	11.4 ± 6.7	0.015	$13.2 \pm 7.2^{\dagger}$	$8.0 \pm 4.5^{\dagger}$	0.014
Peak transaortic gradient (mmHg)	29.0 ± 11.2	20.1 ± 10.9	0.016	24.3 ± 11.0	$14.7 \pm 7.2^{\dagger}$	0.005
EAOI (cm ² /m ²)	1.0 ± 0.5	1.2 ± 0.4	NS	1.0 ± 0.2	1.4 ± 0.4	NS
LVPWDI (mm/m ²)	5.6 ± 1.8	6.9 ± 1.5	NS	5.1 ± 3.8	7.1 ± 1.6	0.044
<i>≥14 mm/m²</i>						
Patients (n)	20 (57.1)	22 (44.0)	NS	19 (55.9)	20 (46.5)	NS
LVEF (%)	53.8 ± 13.5	55.4 ± 12.8	NS	56.5 ± 14.7	53.2 ± 13.2	NS
Mean transaortic flow velocity (m/s)	1.6 ± 0.3	1.5 ± 0.3	NS	1.6 ± 0.4	$1.2 \pm 0.3^{\dagger}$	0.002
Peak transaortic flow velocity (m/s)	2.4 ± 0.5	2.1 ± 0.5	0.085	2.3 ± 0.3	$1.8 \pm 0.3^{\dagger}$	0.002
Mean transaortic gradient (mmHg)	15.6 ± 5.9	10.4 ± 4.8	0.003	12.8 ± 4.8	$6.8 \pm 3.0^{\dagger}$	0.0005
Peak transaortic gradient (mmHg)	24.0 ± 8.2	19.2 ± 8.2	0.065	20.5 ± 7.4	$13.6 \pm 4.9^{\dagger}$	0.006
EOAI (cm ² /m ²)	1.1 ± 0.3	1.3 ± 0.5	NS	1.1 ± 0.5	1.3 ± 0.4	NS
LVPWDI (mm/m ²)	7.2 ± 1.4	6.5 ± 1.4	NS	6.8 ± 1.8	6.6 ± 1.5	NS

Values are mean \pm SD.

* $p < 0.05$, paired Student's *t*-test for postoperative and follow up 3F data.

$\dagger p < 0.05$, paired *t*-test for postoperative and follow up SPF data.

Values in parentheses are percentages.

EAOI: Effective orifice area index; IAD: Indexed annulus diameter; LVEF: Left ventricular ejection fraction; LVPWDI: Left ventricular posterior wall diameter index; NS: not significant.

prolongation of ischemic time; for example, among the present patients the longest cross-clamp time was 98 min. Since only one running proximal suture is necessary, the implantation of 3F valves might be more straightforward (11). However, as shown in the present series, by sewing SPF prostheses (which do not require time-consuming rinsing for detoxification) with continuous sutures, the cross-clamp time is comparable with that for 3F valves.

Operative risk

A meta-analysis of 20 studies of stentless valves showed mortality rates to be less than those of the STS National Database average, while hospital mortality did not exceed 7.5% (14). Among the present patients, the 30-day mortality of 2.4% was remarkably different from the expected mortality as assessed by EuroScore (Table I). Death occurring at reoperation was due to severe bleeding complications, but these must be considered valve-related (13). Clearly, other factors such as age >80 years, female gender, severe left ventricular hypertrophy, obesity or simultaneous CABG, but not the valve substitute per se, determine operative mortality in AVR (15,16). In the present study, the operative morbidity was acceptably low, and there were no relevant differences between the SPF and 3F groups in terms of overall clinical outcome.

Hemodynamic performance

Since the sizing strategy differed between the SPF and 3F valves, comparison was justified by using the IAD of the patients as a reference for analyzing the hemodynamics. The need for complete decalcification and exact sizing of the patient's annulus has been demonstrated previously (17), and the importance of indexing the annulus diameter for body surface area has also been emphasized (3).

In the present study, due to the observed range in indexed annulus size, the mean value was used to separate patients into subgroups with smaller annuli (<14 mm/m²; n = 43) or larger annuli (≥14 mm/m²; n = 42) for further evaluation. The transvalvular flow characteristics of SPF prostheses were superior to those of 3F valves (Table III; Fig. 2), and because there was no difference in smaller or larger annuli within the SPF and 3F groups this performance appeared to be valve type-specific. Although the transaortic gradients declined in both groups during the six-month follow up, the difference in gradient between the valves persisted. The reduction in mean transaortic gradient (30-35%) was greater in the SPF group than in the 3F group (18-23%).

By preserving dynamic aortic root function, the pliability of stentless pericardial bioprostheses appears to be associated with a greater effective orifice area index (EOAI) at a given systolic flow (8). There was a ten-

dency towards larger EOAI values with SPF valves, but this did not reach statistical significance. Nonetheless, in the present study there was no patient-prosthesis mismatch observed which is considered to be an EOAI value of 0.85-0.90 cm²/m², and may result in higher morbidity and mortality (18).

In contrast to reports made by Walther et al. (3), significant left ventricular hypertrophic regression could not be demonstrated on the basis of an indexed left ventricular posterior wall diameter. In fact, the ventricles in Walther et al.'s patients were more severely hypertrophied. In order to detect hypertrophic regression in the present patients, a longer follow up period might be required.

In conclusion, the present study focused on hemodynamic and clinical outcome soon after the implantation of new-generation stentless pericardial aortic valves. Patients with similar demographic and clinical background were investigated prospectively and, although there was no randomization, comparable basic characteristics and consistent performance of the investigators should not have led to significant bias towards either prosthesis. In summary, these new-generation stentless pericardial aortic valves facilitate implantation due to their extreme pliability, and provide very satisfying clinical and hemodynamic results. In particular, the SPF valve is characterized by excellent performance, and may be superior when implanted in small aortic roots.

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