Three Years' Experience with the Sorin Pericarbon Stentless Prosthesis: Mid-Term Results with Three Different Implantation Techniques

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Background and aim of the study: **Sorin Pericarbon stentless pericardial valves were implanted using three different surgical techniques, and early and mid-term clinical and hemodynamic results were analyzed according to the method used.**
Methods: **Between January 2000 and December 2002, 102 Pericarbon stentless valves were implanted in 101 patients (55 females, 46 males; mean age 67.6 ± 7.1 years). Among these patients, 63 had isolated aortic valve replacement and 39 underwent a combined procedure. The inflow portion of a matching-size prosthesis was fixed to the aortic annulus either by semi-continuous Prolene suture (n = 48), interrupted simple Ethibond (n = 29) or interrupted Ethibond mattress stitches (n = 25). Valve sizes were not significantly different in the three subgroups. The aortic cross-clamp and cardiopulmonary bypass times were 145 ± 31 min and 171 ± 39 min, respectively, with interrupted stitches; these times were significantly longer than in the continuous suture group (115 ± 27 min and 143 ± 45 min) or with interrupted mattress stitches (111 ± 28 min and 137 ± 34 min).**
Results: **Early mortality was 6.8% (n = 7) for the entire patient group. None of the deaths was valve-related. Postoperatively, all patients were followed up (mean 26.6 ± 9.4 months). There were two late deaths (both non-valve-related). One patient developed early endocarditis, and the infected valve was re-replaced with another Pericarbon stentless valve. During the follow up period the mean and peak transvalvular gradient was decreased from 12.8 ± 8.5 mmHg to 9.1 ± 2.3 mmHg and from 22.5 ± 13.9 mmHg to 16.1 ± 4.3 mmHg respectively, and left ventricular wall thickness from 15.5 ± 2.1 mm to 12.8 ± 1.4 mm. Regurgitation was not more than trivial for any of the implanted valves. The implantation technique did not significantly affect the hemodynamic performance of the Pericarbon stentless valve.**
Conclusion: **The Sorin Pericarbon stentless pericardial prosthesis showed excellent hemodynamic performance, even if implanted in a matching-size aortic root. The implantation technique used had no significant influence on valve performance.**

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The idea of using a stentless porcine xenograft for aortic valve replacement (AVR) dates back to 1965 (1). However, in the pioneer era when myocardial protection was poorly developed, the ease of implantation of first-generation stented bioprostheses and mechanical valves put into disfavor the stentless valve concept. More than two decades later, when myocardial protection was more refined, David et al. reintroduced the stentless valve into clinical practice (2). During the past decade, several studies have demonstrated a superior hemodynamic performance, more complete left ventricular mass regression, and improved survival with stentless bioprostheses (3-6).

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Bovine pericardium was first used to construct an artificial heart valve in the early 1970s (7). The second generation of stented pericardial valves showed superior hemodynamic characteristics, and at least equal durability to that of standard porcine bioprostheses (8). After several years of favorable experience with the stented pericardial valve (9), the stentless version of the Sorin Pericarbon valve was launched in 1992.

The Sorin Pericarbon stentless pericardial valve was introduced in Hungary in December 1999. Since January 2000, all patients undergoing AVR with a stentless pericardial valve at the authors' institution were prospectively enrolled into the present study. The effect of three different implantation techniques on the early hemodynamic function and mid-term outcome was analyzed for the first three years' experience with the Sorin Pericarbon stentless pericardial valve.

Clinical material and methods

Patient population

Between January 2000 and December 2002, a total of 102 Sorin Pericarbon stentless pericardial bioprostheses was implanted in 101 patients (46 males, 55 females; mean age 67.6 ± 7.1 years; range: 36 to 82 years). All patients were prospectively enrolled into the study after having obtained their informed consent. The main diagnosis was aortic valve disease in all patients, though 26% of them had concomitant coronary artery disease and 8% also had mitral valve pathology. Sixteen patients were in NYHA functional class II, 67 in class III, and 19 in class IV.

Thirty-four patients presented with pure aortic stenosis, eight with aortic regurgitation, and 59 with mixed aortic valve disease. One patient developed prosthetic valve dysfunction secondary to endocarditis following AVR with the Sorin Pericarbon stentless valve. The peak and mean transvalvular gradients were 78 ± 29.7 mmHg and 50 ± 20.6 mmHg, respectively. The left ventricular function was good in 72% of patients, moderately impaired in 26%, and poor in 2%.

Surgical procedures

Sixty-three patients underwent isolated AVR, and 26 also required myocardial revascularization, with an average of 1.5 grafts per patient. In six cases the mitral valve, and in two other cases the mitral and tricuspid valves, were repaired. In three cases the dilated ascending aorta was either plicated (n = 2) or replaced (n = 1), and in two other cases the hypertrophied septal muscle was also resected to relieve left ventricular outflow tract (LVOT) obstruction. The cardiopulmonary bypass (CPB) and aortic cross-clamp times were 134 ± 28.5 min and 114 ± 25.5 min, respectively, for isolated AVR, and 175 ± 50.7 min and 139 ± 35.1 min for combined procedures.

Implantation technique

All operations were performed via a median sternotomy using extracorporeal circulation with mild hypothermia (32°C). Cardiopulmonary bypass was established using ascending aortic cannulation with the venous return from the right atrium via a two-stage venous cannula. The heart was arrested with cold antegrade crystalloid cardioplegia repeated every 20 min. Following a transverse aortotomy, the aortic valve was excised and the annulus completely decalcified, when necessary. The annulus size was measured using an obturator, and a valve of the size of the largest obturator passed through the annulus was chosen for implantation in all cases. Any additional procedures were then performed on the mitral valve, coronary arteries or LVOT. The Sorin Pericarbon stentless pericardial prostheses were implanted in the subcoronary position in all cases. Three different implantation techniques were used at the proximal suture-line, with particular attention being paid to valve orientation: (i) 4-0 Prolene running suture interrupted at each commissure utilizing the valve inversion technique (n = 48); (ii) 3-0 Ethibond single stitches (n = 29); and (iii) 3-0 Ethibond mattress stitches without pledgets (n = 25). The remnant tissue below the coronary ostia was then excised from the skirt of the prosthesis, and three separate 5-0 Prolene commissural stitches were placed through the aortic wall to achieve perfect alignment of the prosthesis. The distal suture-line was then completed with the three 5-0 Prolene sutures. The aortotomy was closed with 4-0 Prolene suture in one or two layers, depending on the aortic wall structure. Cardiopulmonary bypass was then discontinued and the chest closed in routine fashion.

There was no significant difference between the sizes of valves implanted with the different surgical techniques. However the CPB and aortic cross-clamp times were significantly longer with simple stitches than with mattress stitches ($p = 0.0008$ and $p = 0.00005$, respectively) or with continuous suture ($p = 0.003$ and $p = 0.00001$, respectively). No difference was found between the mattress stitches and continuous suture with regard to CPB and cross-clamp times ($p = 0.3$ and $p = 0.29$, respectively) (see Table III).

Postoperative care

All patients were administered prophylactic subcutaneous calcium-heparin injections (2 × 7,500 U/day) until complete mobilization. Only patients with chronic atrial fibrillation were anticoagulated with warfarin; all others were commenced on aspirin (75 mg/day) on the day after operation. The duration of intensive care unit (ICU) and hospital stays was recorded. Transthoracic echocardiography was performed in all patients before hospital discharge.

Follow up

The follow up was 100% complete; the mean period was 26.6 ± 9.4 months (range: 15 to 51 months). Postoperative valve-related events were determined as mortality, reoperation, prosthetic valve endocarditis, thromboembolism, anticoagulant-related complication, structural deterioration and valve dysfunction. Transthoracic echocardiographic assessment of the valve was performed by the same cardiologist (A.B.) in all cases. Flow velocity in the LVOT and across the stentless prosthesis was measured from the apical four-chamber view. Mean and peak transvalvular pressure drops were calculated. Valvular regurgitation was semi-quantified using a scale of 0 to 4 according to the width of the regurgitant jet. End-diastolic and end-systolic

dimensions, and septal and posterior wall thickness were measured from M-mode echocardiograms. The left ventricular ejection fraction was also calculated.

Statistical analysis

Demographic and clinical data were expressed as mean ± SD. Statistical analysis was performed using Student's *t*-test. Time-related events (death and valve-related complications) were analyzed using the Kaplan-Meier estimation method. A p-value <0.05 was considered to be statistically significant. Statistical analysis was performed using SPSS version 10 for Windows statistical software (SPSS, Inc.).

Results

Early clinical outcome

Seven patients died during the early postoperative period (mortality 6.8%), but none of the deaths was valve-related. Five of these patients had undergone a combined procedure (four with concomitant coronary surgery and one a reduction of the ascending aorta; mortality 12.8%), and only two had simple AVR (3.2%). The causes of death were multiorgan failure (n = 4), myocardial infarction (n = 1), bowel ischemia (n = 1) and sepsis (n = 1).

Four patients required resternotomy for bleeding (3.9%), and three required permanent pacemaker implantation during the early postoperative period (two for complete heart block, one for bradycardic atrial fibrillation). Eighteen patients developed paroxysmal tachycardic atrial fibrillation (17.6%), but all of them left the hospital in sinus rhythm. The average duration of ICU stay was 38.1 ± 71.4 h, and the mean hospital stay was 10.3 ± 3.5 days.

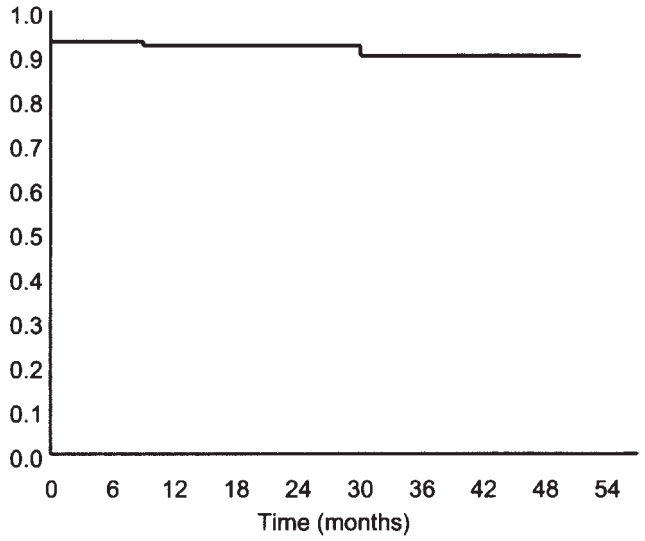

Figure 1: Survival analysis (Kaplan-Meier) of patients receiving the Sorin Pericarbon stentless pericardial prosthesis.

Late clinical outcome

There were two late deaths during follow up, none of which was valve-related. One patient had a sudden cardiac arrest at 30 months after surgery, but he had normal valve function just three months before his death. The other patient suffered a fatal pulmonary embolism following a major orthopedic operation. The actuarial survival rate is shown in Figure 1.

There were no valve-related thromboembolic or bleeding complications. One patient developed early prosthetic valve endocarditis at two months postoperatively. He was returned to the operating theater following a course of antibiotics. The inflow portion of the Pericarbon valve had become detached from the annulus and the valve was distorted. The prosthesis was removed and replaced with another Sorin Pericarbon

Table I: Clinical and echocardiographic data of patients with Sorin Pericarbon stentless bioprosthesis before surgery, at discharge, and at follow up.

Parameter	Preoperative	Discharge	Follow up	p-value
Rhythm				
Sinus rhythm	88 (86)	83 (87)	83 (90)	-
Atrial fibrillation	13 (13)	8 (9)	5 (6)	-
Pacemaker	1 (1)	4 (4)	4 (4)	-
NYHA class*	3.1 ± 0.6	-	1.6 ± 0.7	2.3E-33
Ejection fraction (%)*	54 ± 9.5	-	57 ± 5.8	0.007
>50%	73 (72)	-	83 (90)	-
<50%	29 (28)	-	9 (10)	-
Peak gradient (mmHg)*	-	22.5 ± 13.9	16.1 ± 4.3	2.2E-05
Mean gradient (mmHg)*	-	12.8 ± 8.5	9.1 ± 2.3	4.6E-05
LV wall thickness (mm)*	15.5 ± 2.1	-	12.8 ± 1.4	4.3E-19

*Values are mean ± SD.
Values in parentheses are percentages.

Table II: Transvalvular gradients measured by transthoracic echocardiography on the different-sized Sorin Pericarbon stentless bioprostheses.

Valve size (mm)	No. implanted	Peak gradient (mmHg)*	Mean gradient (mmHg)*
21	17	19 ± 3.6	11 ± 2.1
23	32	16 ± 3.9	9 ± 2.2
25	26	15 ± 3.4	9 ± 1.6
27	16	14 ± 3.9	8 ± 2.0
29	2	12 ± 5.6	5 ± 1.4

*Values are mean ± SD.

stentless valve, without difficulties. The actuarial freedom from valve-related complications is shown in Figure 2.

Preoperatively, 13% of the patients were in chronic atrial fibrillation, whilst postoperatively more than 90% were in sinus rhythm. The functional status of the patients was improved significantly (Table I).

Echocardiographic results

Doppler echocardiography showed there to be no regurgitation in 82 patients (89%), and only trivial (grade 1) regurgitation in 10 (11%). The peak and mean transvalvular pressure gradients were significantly decreased during the follow up period, and a very significant reduction was seen in terms of left ventricular wall thickness. Left ventricular function was also improved postoperatively as compared to preoperative performance. Postoperatively, a greater percentage of patients had good left ventricular function than preoperatively, and this contributed to their improved general condition (Table I). All valve sizes showed excellent hemodynamic performance at follow up (Table II).

No significant difference was found in valvular performance (transvalvular gradient, regurgitation) in relation to the three different implantation techniques utilized (Table III).

Table III: Comparison of cardiopulmonary bypass details and prosthesis performance of the Sorin Pericarbon stentless valve implanted using three different techniques.

Parameter	Single (n = 29)	Mattress (n = 25)	Continuous (n = 48)	p-value
CPB time (min)*	171 ± 39	137 ± 34	143 ± 45	$p^1 = 0.0008$ $p^2 = 0.003$ $p^3 = 0.3$
ACC time (min)*	145 ± 31	111 ± 28	115 ± 27	$p^1 = 0.00005$ $p^2 = 0.00001$ $p^3 = 0.29$
Prosthesis size (mm)*	23.6 ± 1.9	23.9 ± 2.0	24.4 ± 2.1	$p^1 = 0.26$ $p^2 = 0.06$ $p^3 = 0.21$
Peak gradient (mmHg)*	16.6 ± 4.2	16.2 ± 4.4	15.5 ± 3.8	$p^1 = 0.37$ $p^2 = 0.12$ $p^3 = 0.24$
Mean gradient (mmHg)*	8.8 ± 2.1	9.5 ± 2.7	9.0 ± 2.2	$p^1 = 0.16$ $p^2 = 0.33$ $p^3 = 0.23$

*Values are mean ± SD.
ACC: Aortic cross-clamp; CPB: cardiopulmonary bypass.
p^1: *t*-test between single and mattress stitches.
p^2: *t*-test between single stitches and continuous suture.
p^3: *t*-test between mattress stitches and continuous suture.

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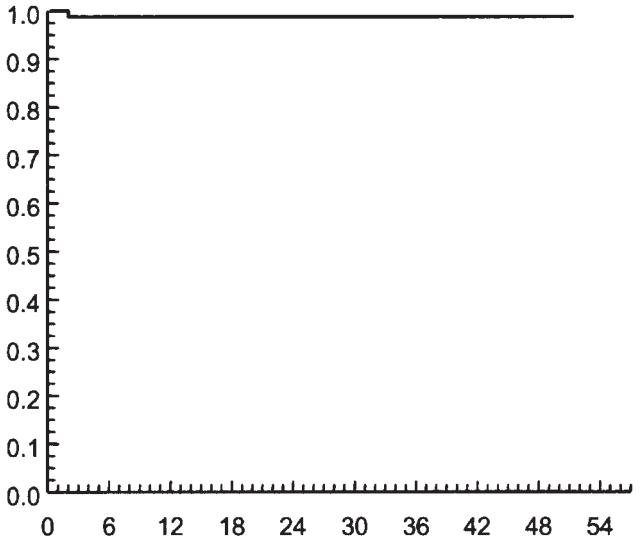

Figure 2: Freedom from valve-related complications (Kaplan-Meier) of patients receiving the Sorin Pericarbon stentless pericardial prosthesis.

Discussion

The results of in-vitro studies have shown that the biomechanical properties of the bovine pericardium are suited to its use as leaflet material for bioprosthetic valves (10,11). At present, the Sorin Pericarbon is the only stentless pericardial valve available. It is constructed from two separate sheets of glutaraldehyde-treated bovine pericardium, and does not contain any prosthetic material other than the stitches holding the two sheets together. The whole valve is very thin, soft and pliable, and this facilitates implantation regardless of the surgical technique used.

The sizing protocol for the present study was very simple: the annulus size was measured with a series of metal valve sizers and the maximum size which could pass through the annulus was chosen as the prosthesis size. It was shown in previous in-vitro studies that porcine stentless valves had the best hydrodynamic function and least leaflet deformation if slightly undersized (12,13). Although most surgeons advise oversizing the porcine stentless valves by at least one size (1-2 mm) (14) and the pericardial stentless valve by two sizes (3-4 mm) (15), the present size-for-size implantation approach did not result in more than trivial aortic valve regurgitation in any of the patients. The hemodynamic performance of the Sorin Pericarbon stentless valves at mid-term follow up was excellent, and slightly inferior to the results of Westaby et al. (15,16), but comparable to those of Bonacchi et al. (17).

The technique of implantation was the surgeon's choice. Four surgeons, who implant stentless valves at the authors' department, use three different techniques. The duration of valve replacement was longest with the originally recommended simple stitches. The flexibility of the Pericarbon stentless valve makes it suitable for the inversion technique, which was employed in all cases with semi-continuous suture. No difference was found in the early and mid-term hemodynamic and clinical results between the different implantation techniques.

The mortality rate in the present series was similar to that of other reports with the Sorin Pericarbon valve (17,18). There was no higher occurrence of complete atrioventricular block after stentless than after stented AVR among the patients, as was reported earlier by Casabona et al. (18). Neither was any correlation found between surgical technique and the development of complete heart block (one case in the simple stitch, and one in the semi-continuous suture group).

Previous randomized controlled studies demonstrated an improved late survival in patients with stentless valves compared with patients undergoing conventional bioprosthetic AVR (5,6). The mid-term outcome in the present series was excellent, and neither of the two deaths was valve-related. The only valve-related late complication was an early prosthetic valve endocarditis (0.4% per patient-year), and this was similar in other reported series (19). However, treatment of the infection was straightforward, since the patient responded to antibiotic treatment well and, by the time of redo surgery, the valve was free from active infection. Explantation of the infected valve was not challenging technically, and interrupted Ethibond mattress stitches were used for the re-replacement.

The biggest attraction of stentless valves is most likely their superior hemodynamic performance, especially during exercise (20). After implanting a stentless valve, regression of left ventricular hypertrophy was quicker and more complete than with any other conventional valve substitute (21). In the present series there was a very significant reduction in left ventricular wall thickness during the follow up period. The regression of left ventricular hypertrophy also helps to prevent potential complications such as congestive heart failure, stroke, coronary artery disease and sudden cardiac death (22).

A significant improvement was also found in the performance of the Sorin Pericarbon valve during the follow up period. Several previous investigators identified the same phenomenon with other stentless valves as a result of the improving left ventricular function and resolution of perivalvular hematoma (17,23). Interestingly, in the patient cohort of Westaby et al., when the Pericarbon valve was oversized by 3-4 mm, the hemodynamic parameters of the valve did not improve in time (15).

Study limitations

An initial limitation was that the patients were non-randomized to different implantation techniques, as it

was the surgeon's priority to decide on the surgical technique used. Moreover, in the pioneer series only those patients were selected whose aortic root anatomy was ideal for stentless valve implantation. Nonetheless, the indication for stentless valve implantation is expanding.

In conclusion, the Sorin Pericarbon stentless pericardial valve is a soft, pliable and easy-to-use bioprosthesis. The early and mid-term clinical and echocardiographic results were satisfactory, and the valve performance and left ventricular mass regression were comparable with results obtained with other stentless bioprostheses. However, the long-term results with this prosthesis remain to be determined.

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