

Stented versus Stentless Bioprostheses in Aortic Valve Stenosis: Effect on Left Ventricular Remodelling

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ABSTRACT

Background. Whether the use of stentless aortic bioprostheses improves hemodynamics more than stented bioprostheses in the small aortic root is still a matter of debate.

Methods. Early- and mid-term effects were compared between 2 different types of stentless bioprostheses and 1 type of stented bioprosthesis for left ventricular remodelling. The effects of the bioprostheses were studied by echocardiography in 68 patients (age, 74 ± 7 years) with aortic annulus diameter ≤ 23 mm who were undergoing prosthesis implantation due to aortic isolated stenosis. Stented bioprostheses (Carpentier-Edwards Perimount [CEP]) were implanted in 36 subjects and stentless bioprostheses (18 Toronto SPV and 14 Shelhigh Super Stentless) were implanted in 32 subjects.

Results. A progressive and similar decrease in left ventricular mass of 30% was observed in both stented and stentless bioprostheses at 12 months. A progressive increase in transprosthetic effective orifice area and a decrease in transprosthetic pressure gradient were observed at 3, 6, and 12 months in the Toronto group, but these variables showed improvement only at 3 months in the CEP and Shelhigh groups. No mortality occurred during surgery or during the 1-year follow-up period.

Conclusions. Our results confirmed good feasibility of aortic stented and stentless bioprostheses implantation in the elderly population. A 30% decrease in left ventricular mass occurred in the early- and mid-term (12 months) periods after surgery with all 3 types of bioprostheses. Advantages consisting of a progressive increase in transprosthetic effective orifice area and a decrease of the transprosthetic pressure gradient were observed in the Toronto group in comparison to the CEP and Shelhigh groups. These observations may help surgeons in choosing bioprostheses.

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INTRODUCTION

Aortic prosthesis implantation is becoming increasingly frequent because of critical aortic stenosis [Levinson 2000]. Bioprostheses have become increasingly frequent because elderly people with critical aortic obstruction due to degenerative fibrocalcification are likely candidates for this procedure. Bioprosthesis implantation does not require anticoagulant therapy, has better transprosthetic hemodynamics, and produces a lower number of thromboembolic events. After specific pretreatment, it has also proved to be more durable [Black 1976; Arom 1987].

However, conventional stented bioprostheses may lead to unsatisfactory hemodynamics and to a high residual transprosthetic pressure gradient (ΔP) among patients with a small aortic root [Westaby 2000; David 2001]. In this context, stentless bioprostheses are considered because they have advantages in hemodynamics and durability [Back 2000; David 2001; Jin 2002]. There has been a great deal of debate over this issue [Back 2000; Fries 2000; Cohen 2002; Jin 2002].

We designed a prospective study on early- and mid-term mortality and left ventricular remodelling after the implantation of one of 3 different bioprostheses for patients with isolated aortic stenosis with an aortic annulus diameter ≤ 23 mm. Conventional stented bioprostheses (Carpentier-Edwards Perimount [CEP]; Edwards Lifesciences, Irvine, CA, USA) and 2 types of stentless bioprostheses (Toronto SPV; St. Jude Medical, St. Paul, MN, USA, and Super Stentless, Shelhigh, Union, NJ, USA) were used.

PATIENTS AND METHODS

Patient Population

Over the course of 24 months (September 2002-2004), all patients with isolated critical aortic stenosis undergoing aortic valve prosthesis implantation were studied. Informed consent was obtained from all participating patients and the study protocol was approved by the ethics committee of Parma University. Inclusion criteria were: isolated critical aortic stenosis, aortic annulus diameter ≤ 23 mm, age ≥ 65 years, sinus rhythm, and optimal acoustic window. Exclusion criteria were: ischemic heart disease, severe hypertension, complex atrial and ventricular arrhythmias, pacemaker, other valvular

Table 1. Surgical Data of the Patient Population*

	CEP	Shelhigh	Toronto	P
Body surface area, m ²	1.7 ± 0.2	1.64 ± 0.2	1.7 ± 0.2	Not significant
Cardiopulmonary bypass, min	108.8 ± 26.9	114.0 ± 24.1	95.4 ± 19.1	Not significant
Aortic cross clamping, min	87.0 ± 20.5	88.4 ± 23.9	75.9 ± 16.8	Not significant

*All data are presented as mean ± standard deviation. CEP indicates Carpentier-Edwards Perimount.

involvement, endocarditis, and dilated cardiomyopathy with a left ventricular ejection fraction (LVEF) ≤40%.

Sixty-eight patients (38 women and 30 men; mean age at the time of valve implantation, 74.1 ± 6.6 years) were suitable for aortic bioprosthesis implantation. Three types of bioprostheses were used. Thirty-six patients (17 men and 19 women, aged 70.9 ± 6.9 years) were implanted with a stented bioprosthesis (CEP, 43% with n° 23 and 57% with n° 21). In 18 patients (7 men and 11 women, aged 74.3 ± 6.6 years) a Toronto stentless bioprosthesis was implanted (39% with n° 23, 55.5% with n° 21, and 5.5% with n° 19). In 14 patients (5 men and 9 women, aged 77.8 ± 3.2) a Shelhigh Super Stentless bioprosthesis (43% with n° 23 and 57% with n° 21) was implanted.

The selection of a stented or stentless bioprosthesis was made on a case-by-case basis by the operating surgeon.

The Shelhigh bioprosthesis is an easy-to-implant aortic stentless bioprosthesis that is only mildly distorted by the hemodynamic load because it has a soft stent inside and is totally constructed with biological material. It thus has a lower probability of insufficiency as well as low receptivity to infective endocarditis.

Echocardiography

All patients underwent a comprehensive echocardiography Doppler (echo-Doppler) evaluation with a Vingmed System 5 ultrasound (Horten, Norway) 24 hours before implantation. A multiarray 3.5 MHz transthoracic probe was used. Patients were imaged in the left lateral supine position. Data were acquired on VHS videotape by an expert medical examiner, and the sweep was set at 100 mm/s. To minimize calculating errors, all echo-Doppler parameters were performed in zoom imaging, and the range of left ventricular outflow tract pulsed wave flow and transvalvular and transprosthetic continuous wave flow velocities were adjusted as needed to achieve an optimal spectral display.

Left ventricular mass (LVM) was calculated using Devereux's method [Devereux 1977], and left ventricular volumes and LVEF were calculated using Simpson's method [Schiller 1989]. The maximal instantaneous ΔP and mean ΔP across the aortic valve and prostheses were calculated with the modified Bernoulli equation. The aortic valve and the prosthetic effective orifice area (EOA) were calculated from the continuity equation by using the left ventricular outflow diameter and velocity.

These echo-Doppler parameters were obtained from the 4-chamber apical view, except for the left ventricular M-mode dimensions, wall thickness, and B-mode left

ventricular outflow diameter, which were obtained from the left parasternal long-axis view as recommended by the American Society of Echocardiography. Echo-Doppler evaluation was carried out after a 10-minute stabilization period at rest. All parameters were averaged from 5 consecutive cardiac cycles.

Surgery

All patients underwent median sternotomy. Cardiopulmonary bypass was performed with ascending aortic arterial return and insertion of a 2-stage venous cannula into the right atrium. We utilized antegrade warm blood cardioplegia for myocardial protection. Extracorporeal circulation was carried out at a temperature ranging from 34°C to 37°C. The surgical approach to the aortic valve was achieved with a transversal incision of the aortic root, 4 cm beyond the aortic valvular plane; the native valve was excised, the annulus debrided, and the valve was then sized. CEP were inserted by means of U-shaped stitches with 2.0 interlaced polyester threads enforced with Teflon pledgets. Toronto and Shelhigh prostheses were anchored to the native annulus by simple stitches without pledgets; afterwards, they were sewn onto the aortic wall to minimize distortion due to their stentless configuration. Shelhigh prostheses were sewn to the aortic wall with 3 single prolene stitches at each commissure level because the upper portion of this prosthesis includes 3 triangular commissure terminations. After prosthesis placement, the aortic wall was sutured with prolene 4.0.

Follow-up

All patients underwent echo-Doppler follow-up at 3, 6, and 12 months postoperatively. At the same time, clinical and laboratory evaluations were performed. All patients completed each follow-up.

Statistics

One-way analysis of variance with pair-wise comparisons by adjusted *t* test were used to compare age, body surface area, extracorporeal circulation, and aortic clamping times. Changes over time of echo-Doppler variables were evaluated by analysis of variance according to a Split-plot 3.4 factorial model. Factors considered were the type of prosthesis and time period.

The significance level was set at .05. An SPSS 12.0 statistical package (Chicago, IL, USA) was used for calculation. In 34 of 68 patients, echo-Doppler parameters were analyzed by 2 independent observers; variability of the mean examined values between the observers was <4%.

Table 2. Echocardiographic Data at Basal and Follow-up Periods*

	Baseline	3 mo	6 mo	12 mo	P	
					Time	Between Prostheses
IVSd, mm						
CEP	16.42 ± 2.46	15.39 ± 2.38	14.47 ± 2.24	13.94 ± 2.00	.001	ns
Shelhigh	16.00 ± 2.34	14.77 ± 2.20	13.69 ± 1.97	13.38 ± 2.18		
Toronto	17.44 ± 2.87	15.17 ± 2.83	14.39 ± 2.75	13.78 ± 3.15		
IVSs, mm						
CEP	20.39 ± 3.10	19.64 ± 2.89	18.83 ± 2.29	18.81 ± 3.01	.001	ns
Shelhigh	20.15 ± 3.87	18.46 ± 3.07	18.46 ± 2.60	17.85 ± 1.86		
Toronto	20.39 ± 3.53	19.67 ± 3.45	19.78 ± 3.89	17.89 ± 2.17		
LVPWd, mm						
CEP	13.75 ± 2.00	12.58 ± 1.50	12.03 ± 1.34	11.64 ± 1.31	.001	ns
Shelhigh	12.77 ± 1.64	12.31 ± 1.18	11.69 ± 0.95	11.07 ± 1.04		
Toronto	14.72 ± 2.65	12.89 ± 1.64	12.50 ± 1.58	12.17 ± 1.10		
LVPWs, mm						
CEP	19.89 ± 3.20	17.33 ± 2.44	17.00 ± 2.14	16.44 ± 2.05	.001	ns
Shelhigh	17.46 ± 3.02	16.31 ± 1.80	16.38 ± 2.02	16.77 ± 2.20		
Toronto	21.17 ± 3.23	18.67 ± 1.91	18.22 ± 3.02	17.06 ± 2.48		
LVEDD, mm						
CEP	46.64 ± 6.67	44.56 ± 6.32	44.44 ± 6.00	43.92 ± 4.99	.05	.05
Shelhigh	45.77 ± 6.47	42.15 ± 5.96	41.85 ± 5.22	42.85 ± 3.94	.05	
Toronto	43.83 ± 6.14	44.28 ± 4.51	44.61 ± 4.68	43.89 ± 5.69	ns	
LVESD, mm						
CEP	28.86 ± 7.22	30.03 ± 5.69	29.22 ± 5.67	28.81 ± 6.40	ns	ns
Shelhigh	28.46 ± 6.13	28.00 ± 6.88	27.38 ± 4.57	29.08 ± 4.21		
Toronto	28.35 ± 6.63	29.33 ± 4.50	28.39 ± 4.42	29.22 ± 4.66		
LVM, g						
CEP	367.4 ± 118.7	302.4 ± 94.8	284.6 ± 82.0	263.8 ± 66.8	.001	ns
Shelhigh	322.5 ± 74.2	267.9 ± 58.5	242.5 ± 45.6	223.4 ± 56.6		
Toronto	361.1 ± 84.4	308.9 ± 77.9	298.8 ± 84.4	259.7 ± 75.5		
LVMi, g/m ²						
CEP	207.1 ± 57.1	173.4 ± 44.6	160.8 ± 39.4	146.1 ± 32.6	.001	ns
Shelhigh	194.1 ± 46.2	163.1 ± 36.8	145.3 ± 27.2	138.3 ± 30.9		
Toronto	210.4 ± 52.1	180.2 ± 39.8	167.1 ± 42.1	151.6 ± 35.7		
LVEDV, mL						
CEP	111.36 ± 33.07	101.00 ± 28.70	97.11 ± 23.81	93.53 ± 20.72	.001	ns
Shelhigh	95.92 ± 22.23	82.77 ± 16.14	81.42 ± 15.36	80.62 ± 13.35		
Toronto	97.50 ± 21.06	89.17 ± 12.68	88.00 ± 14.28	85.83 ± 13.94		
LVESV, mL						
CEP	42.47 ± 24.67	34.61 ± 21.22	32.64 ± 14.94	29.89 ± 11.56	.001	ns
Shelhigh	39.92 ± 22.98	31.46 ± 15.82	27.50 ± 12.72	24.77 ± 10.07		
Toronto	34.28 ± 17.09	29.06 ± 8.06	27.61 ± 8.47	26.50 ± 8.57		
LVEF, %						
CEP	63.58 ± 10.87	67.17 ± 10.35	67.44 ± 7.72	68.97 ± 7.19	.001	ns
Shelhigh	59.50 ± 15.56	63.69 ± 10.57	67.25 ± 10.21	69.46 ± 8.07		
Toronto	65.94 ± 9.68	67.83 ± 6.13	68.61 ± 6.13	70.00 ± 6.54		

*All data are presented as mean ± standard deviation. IVSd indicates ventricular septal diastolic thickness; CEP, Carpentier-Edwards Perimount; ns, not significant; IVSs, ventricular septal systolic thickness; LVPWd, left ventricular posterior wall diastolic thickness; LVPWs, left ventricular posterior wall systolic thickness; LVEDD, left ventricular end-diastolic dimension; LVESD, left ventricular end-systolic dimension; LVM, left ventricular mass; LVMi, left ventricular mass index; LVEDV, left ventricular end-diastolic volume; LVESV, left ventricular end-systolic volume; LVEF, left ventricular ejection fraction.

Table 3. Echocardiography Doppler Data at Basal and Follow-up Periods*

	Baseline	3 mo	6 mo	12 mo	P	
					Time	Between Prostheses
ΔP maximum, mmHg						
CEP	81.67 $\pm$ 19.63	21.36 $\pm$ 5.48	21.64 $\pm$ 6.33	21.11 $\pm$ 6.66	.001	.001
Shelhigh	85.31 $\pm$ 26.70	25.46 $\pm$ 7.93	25.69 $\pm$ 9.13	25.15 $\pm$ 8.53		
Toronto	99.83 $\pm$ 28.99	21.39 $\pm$ 9.27	20.33 $\pm$ 10.00	18.56 $\pm$ 8.32		
ΔP mean, mmHg						
CEP	54.81 $\pm$ 14.55	12.75 $\pm$ 3.57	12.78 $\pm$ 3.39	12.22 $\pm$ 4.22	.001	.01
Shelhigh	57.31 $\pm$ 18.77	14.85 $\pm$ 5.81	14.92 $\pm$ 5.54	15.00 $\pm$ 5.70		
Toronto	65.50 $\pm$ 20.98	11.94 $\pm$ 4.93	11.00 $\pm$ 4.89	10.33 $\pm$ 4.20		
EOA, cm ²						
CEP	0.71 $\pm$ 0.18	1.89 $\pm$ 0.56	1.92 $\pm$ 0.47	1.93 $\pm$ 0.49	.001	.05
Shelhigh	0.69 $\pm$ 0.14	1.78 $\pm$ 0.46	1.75 $\pm$ 0.40	1.75 $\pm$ 0.38		
Toronto	0.64 $\pm$ 0.15	2.00 $\pm$ 0.81	2.17 $\pm$ 0.74	2.24 $\pm$ 0.84		
EOAi, cm ² /m ²						
CEP	0.40 $\pm$ 0.11	1.07 $\pm$ 0.27	1.11 $\pm$ 0.27	1.07 $\pm$ 0.24	.001	.05
Shelhigh	0.40 $\pm$ 0.08	1.08 $\pm$ 0.27	1.05 $\pm$ 0.18	1.05 $\pm$ 0.21		
Toronto	0.37 $\pm$ 0.11	1.17 $\pm$ 0.44	1.27 $\pm$ 0.38	1.35 $\pm$ 0.43		

*All data are presented as mean $\pm$ standard deviation. ΔP indicates pressure gradient; CEP, Carpentier-Edwards Perimount; ns, not significant; EOA, effective orifice area; EOAi, effective orifice area index.

RESULTS

Mean age was significantly higher in the Shelhigh group with respect to the Toronto or CEP groups ($P < .001$). No differences in body surface area, cardiopulmonary bypass, or aortic cross clamping times were observed between the 3 groups (Table 1). No deaths occurred during the operative and follow-up periods.

Echo-Doppler measurements of the morphological and functional state of the left ventricle and the anatomical and hemodynamic state of the aortic valve and prostheses preoperatively and during follow-up periods are reported in Tables 2 and 3. Ventricular septal diastolic thickness decreased significantly and progressively after implantation throughout the follow-up period. Left ventricular posterior wall diastolic thickness decreased up to 6 months in all groups. Left ventricular end-diastolic dimension decreased significantly at 3 months in the patients implanted with Shelhigh and CEP bio-prostheses, but remained unchanged in the Toronto group.

Left ventricular volumes were reduced significantly, progressively, and similarly during the follow-up period in all 3 groups. A significant and progressive decrease in absolute LVM and left ventricular indexed mass of about 30% was also observed postoperatively during the follow-up period in all groups (Table 2, Figure 1). LVEF slightly but significantly increased postoperatively in all patients (Table 2). The data reported in Table 3 show differences between prostheses over time (type of prosthesis, time period). As expected, the prosthetic EOA significantly increased in all 3 groups at 3 months. In the Toronto group, a further progressive and significant increase of EOA was observed up to 12 months (Table 3, Figure 2).

Consequently, transprosthetic maximum ΔP and mean ΔP decreased significantly at 3 months in all groups, but a continuous and progressive reduction of transprosthetic gradients through all follow-up steps was observed only in the Toronto group (Table 3, Figure 3). The significance reported in Table 3 and in the Figures is relative to differences between bioprostheses.

DISCUSSION

Implantation of an aortic valvular prosthesis was essentially aimed at achieving the lowest and most clinically irrelevant transaortic gradient and a larger aortic valve area [Westaby 2000; Cohen 2002]. This should have the effect of remodeling the left ventricle by decreasing its hypertrophy caused

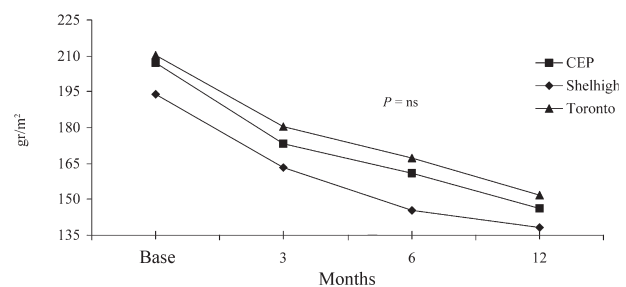


Figure 1. Left ventricular mass index assessed by echocardiography between prostheses at each time point; significant differences between the groups are not highlighted. P was not significant among the groups. CEP indicates Carpentier-Edwards Perimount.

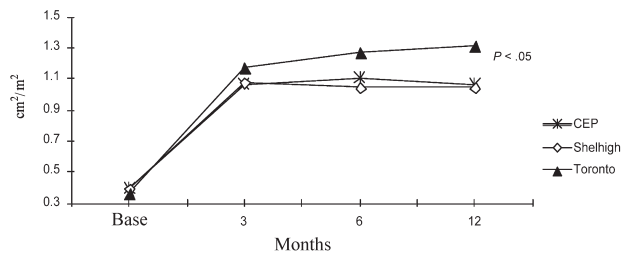


Figure 2. Effective orifice area index assessed by echocardiography between prostheses at each time point. A significant difference between the Toronto versus the Shelhigh and the Carpentier-Edwards Perimount (CEP) prostheses is highlighted. $P < .05$ among the groups.

by stenosis [Levinson 2000]. In spite of surgical success in aortic valve implantation with low a perioperative mortality, follow-up at 10 years from surgery has shown unsatisfactory results, with survival rates between 50% and 66% [Czer 1990; Hammermeister 2000; David 2001].

This relatively high mortality rate has been attributed to a partial regression of left ventricular hypertrophy due to residual transprosthetic gradient. Aortic prostheses did not completely relieve the transprosthetic gradient and in fact constituted further obstacles to flow because of annular calcifications and rigid structural components of the prostheses [Re 1995; De Paulis 1998].

Many researchers consider left ventricular hypertrophy a high risk factor for cardiovascular morbidity and mortality [Levy 1989; Cohen 2002]. After aortic prosthesis implantation, mid- and long-term deaths have been described either as sudden deaths or as consequences of arrhythmias or cardiac failure, likely to be associated with left ventricular hypertrophy [Levy 1989]. Regression of the LVM after aortic prosthesis implantation might represent an important and underestimated prognostic factor [Christakis 1996]. Echocardiography certainly represents the most feasible technique to monitor LVM regression [Salcedo 1989; Levinson 2000].

Degree and times of LVM regression are controversial. Many researchers have observed the greatest reduction of LVM within the first month and further moderate regressions at one year [Jin 1999; Walther 1999], although some believe that LVM regression may continue up to 5 years after surgery [Del Rizzo 1996; Jin 1999; Walther 1999].

For this reason, we studied left ventricular remodelling up to one year using echocardiography after aortic prosthesis implantation in patients with critical isolated aortic stenosis. A significant, progressive, and similar decrease (30%) in LVM was observed one year after surgery in the 3 different groups (stented and stentless) even though the mean values remained higher than normal.

Left ventricular end-diastolic diameter was not associated with an early significant reduction in the Toronto group as it was in the other 2 groups. An explanation for this could be the greater reduction in wall thickness subsequent to the regression of the wall stress after surgery on ventricles with higher preoperative transvalvular gradients. However, the

most interesting finding was a significant progressive increase of prosthetic EOA and a consequent decrease of the residual transprosthetic gradient at 3, 6, and 12 months from surgery for the stentless Toronto bioprosthesis. It fell from 0.4 cm/m² and 66 mmHg before surgery to 1.2, 1.3, and 1.4 cm/m² and 12, 11, and 10 mmHg at 3, 6, and 12 months, respectively. But for CEP and Shelhigh, EOA increase and transprosthetic gradient reduction was observed only at 3 months after surgery (Table 3, Figures 2 and 3).

In discussing the relative merits of stentless versus stented aortic bioprostheses in patients with isolated aortic stenosis, this report supports the use of stentless bioprostheses when the aortic annulus diameter is ≤ 23 mm.

The absence of a rigid ring in the Toronto prosthesis yields several advantages: a larger bioprosthesis can be implanted on the aortic ring, which is very useful when the ring is narrow, [Walther 1999]; the native ring is still dynamic and can be stretched [Jin 1999]; and outflow of the aortic tract can be remodelled with preservation of sinus-tubular junction integrity [Black 1976].

The progressive increase in the EOA, which might continue for more than one year after surgery, tends to decrease the incidence of patient-prosthesis mismatch. Patient-prosthesis mismatch negatively influences LVM regression and thus prognosis [Del Rizzo 1996] and can result in persistent left ventricular outflow tract obstruction and higher postoperative transvalvular gradients. This residual obstruction may prevent the regression of LVM index. It has been suggested that earlier regression of left ventricular hypertrophy improves long-term survival after surgery, but patient-prosthesis mismatch results in significantly higher early and late mortality rates after bioprosthetic aortic valve replacement. For this reason, careful prosthesis-patient matching and careful selection of bioprostheses may prevent residual left

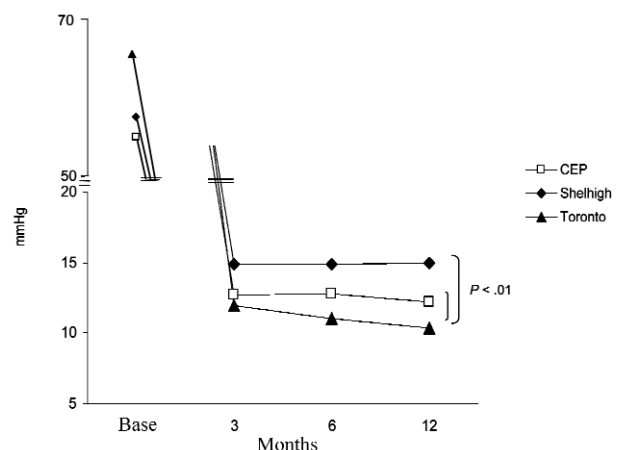


Figure 3. Mean transaortic pressure gradient assessed by echocardiography between prostheses at each time point (modified). A significant difference between the Toronto versus the Shelhigh and the Carpentier-Edwards Perimount (CEP) prostheses is highlighted. $P < .01$ among the groups.

ventricular outflow tract obstruction and thus persistent transvalvular gradients. It therefore improves both early and late survival after surgery [Rao 2000]. In spite of these favorable mid- and long-term effects, stentless prostheses are underused because of a reported higher operative mortality rate due to prolonged extracorporeal circulation and a lengthier and more complicated implanting procedure. However, these latter complications after stentless implantation were not confirmed by our results.

The Shelhigh aortic bioprosthesis has recently been introduced in surgical practice as an intermediate solution between stented and stentless prostheses because of its easier implantation procedure. We observed that the use of the Shelhigh bioprosthesis is associated with a tendency toward left ventricular volume reduction at 3 and 6 months (Table 2). If confirmed, this observation would point toward its feasibility for use in larger ventricles.

In conclusion, evaluation of prognosis and left ventricular remodelling at 3, 6, and 12 months after implantation of 3 different types of aortic bioprostheses (stented CEP, stentless Toronto, and stentless Shelhigh) because of critical isolated aortic stenosis with annulus diameter ≤ 23 mm has shown:

- (1) Absence of mortality;
- (2) A clear 30% decrease in LVM at one year in all patients;
- (3) An increase in the prosthetic area and consequently a progressive reduction in transprosthetic gradient at 3, 6 and 12 months after implantation of stentless Toronto bioprostheses.

This last effect was observed only at 3 months, without further variation in patients who received stented (CEP) and hybrid stentless (Shelhigh) bioprostheses. These findings seem to confirm the advantages of using stentless bioprostheses in older patients with critical aortic stenosis and a mid- to small-sized aortic root. Similar results were reported by Perez de Arenaza et al [2005] in a larger but less carefully selected group of patients.

Finally, further tests are needed to support the use of Shelhigh bioprostheses in larger ventricles in patients with isolated aortic stenosis and left ventricular systolic dysfunction or in patients with combined stenosis and aortic regurgitation leading to a relative volumetric overload.

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