A randomized comparison of the Cryolife O'Brien and Toronto stentless replacement aortic valves

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Objective: A composite stentless valve might be less obstructive than a preparation incorporating the porcine right coronary muscle bar. The aim of this study was to compare early hemodynamic function in a prospective series of 78 patients randomized to receive either a Toronto or Cryolife O'Brien stentless valve.

Methods: Echocardiography was performed early after surgery, between 3 and 6 months, and at 1 year after surgery.

Results: The groups were matched demographically. The Cryolife O'Brien valve was significantly less obstructive in terms of effective orifice area (1.81 vs 1.30 cm²; $P < .0001$), mean pressure difference (7.1 vs 11.7 mm Hg; $P < .0001$), and peak velocity (1.7 vs 2.2 m/s) assessed at 1 year ($P = .001$). Bypass time was 91 (SD 22) minutes for the Cryolife O'Brien compared with 125 (SD 22) minutes ($P < .0001$) for the Toronto. There was a higher incidence of paraprosthetic regurgitation in the Cryolife O'Brien valve (16.7% vs 3.2%). Mortality and clinical events were similar.

Conclusion: The composite valve was less obstructive than the porcine valve, suggesting that stentless valves cannot be considered as a homogeneous class.

All replacement valves are obstructive compared with normal native valves,¹ but the orifice area available for flow is expected to be larger with a stentless than a stented valve. Although this was confirmed in early studies,^{2,3} larger randomized studies⁴⁻⁷ show conflicting results. It is possible that apparent discrepancies are partly caused by differences in the comparator stented valve, as there is some evidence that pericardial valves are hemodynamically superior to porcine valves.⁸ However, it is also possible that a stentless valve manufactured from a whole porcine aortic root is more obstructive than a composite stentless valve lacking the muscle bar at the base of the right coronary cusp.

The aim of this study was therefore to compare hemodynamic function in patients prospectively randomized to either the Toronto (St Jude Medical Inc, Minneapolis MN) porcine stentless valve or the Cryolife O'Brien (Cryolife O'Brien International, NW Kennesaw, GA) tricomposite stentless valve.

Materials and Methods

Patients

A total of 80 consecutive patients scheduled to have single bioprosthetic valve replacement in the aortic position were recruited. The population sizes were calculated to detect a difference in mean effective orifice area of 0.2 cm² and standard deviation of 0.3 cm² with 80% power. A random number sequence with a block of 16 was applied at the time of listing for surgery. However, 2 patients randomized to receive a Toronto required a stented biologic valve because of dilatation of the aortic root. The study group, therefore, comprised 78 patients. The mean age was 73 (range 55-88) years and 39 (50%) were men. Demographic details are given in Table 1. The study was accepted by the Local Committee on Ethical Practice, and all patients gave written consent.

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Abbreviations and Acronyms

ANOVA	= analysis of variance
CSA	= left ventricular outflow cross-sectional area
ΔP	= pressure difference
EOA	= effective orifice area
LV	= left ventricular
LVDD	= left ventricular diastolic diameter
NYHA	= New York Heart Association
v_1	= subaortic peak velocity
v_2	= transaortic peak velocity
VTI_1	= subaortic velocity integral
VTI_2	= aortic velocity integral

Surgery

The Toronto valve was chosen as the porcine stentless replacement. It consists of a preparation of porcine aortic root sculpted to accommodate the coronary ostia and lined externally with Dacron. The valves were implanted using a subcoronary technique with interrupted sutures for the lower suture line at the level of the annulus joining the lower midpoints of previous cuspal attachment and passing across the intercommissural triangles. The porcine commissures were suspended independently, and a running polypropylene suture was used for the upper suture line. The Cryolife O'Brien model 300 valve was chosen as the composite stentless valve. It is composed of 3 individual noncoronary porcine cusps and has no Dacron lining. The profile is lower than for the Toronto, and it is sewn using a single continuous suture to the aortic wall just above the annulus.⁹

The native aortic valve was completely excised with aggressive debridement of all calcium to leave a smooth tissue annulus. Both valve types were sized from the sinotubular junction as discussed by David and colleagues¹⁰ using a cylindrical independent sizer. This had been confirmed to correspond to the sizers provided by the 2 manufacturers. The patient tissue annulus was also measured using the independent sizer to exclude oversizing. In most cases, a valve of 1 label size larger than the patient tissue annulus diameter was selected,¹¹ but in the presence of a large sinotubular junction, a valve of 2 label sizes larger was occasionally used. However, if the sinotubular diameter was more than 2 sizes larger than the patient tissue annulus diameter, a stented valve was implanted instead and the patient was excluded. This occurred on 2 occasions. Aortoplasty or enlargement of the sinotubular junction was not required. Standard operative procedures were used with a median sternotomy, cardiopulmonary bypass, cooling to 32°C, and cold blood cardioplegia for myocardial preservation.

Echocardiography

Studies were performed immediately before discharge, at the first postoperative visit at 6 weeks, then between 3 and 6 months, and again at 1 year. Five patients refused echocardiography at 3 to 6 months and 1 was in hospital elsewhere, and 3 patients refused restudy at 1 year. Measurements were made as recommended by the American Society of Echocardiography¹² over 3 cycles in sinus rhythm or over 6 cycles in atrial fibrillation. Left ventricular (LV) outflow diameter was measured from inner to inner edge just

TABLE 1. Demographic comparison of patients receiving Toronto or Perimount valves (mean $\pm$ standard deviation)

	Cryolife O'Brien (n = 40)	Toronto (n = 38)
Age (y), mean (range)	73 (55-86)	73 (57-88)
Male:female	21:18	18:21
BSA (kg/m ²)	1.76 $\pm$ 0.20	1.77 $\pm$ 0.19
LV outflow diameter (mm)	20.5 (1.7)	19.8 $\pm$ 1.4
Etiology		
Aortic stenosis	33	33
Aortic regurgitation	3	4
Mixed AS and AR	3	2
Previous AVR	0	0
Previous CABG	1	0
Associated procedures		
Combined CABG	15	16
Aortic root replacement	0	1
Mitral valve repair	0	1
Preoperative NYHA class		
I	3	4
II	16	11
III	17	20
IV	1	1
Preoperative LVEF < 35%	4	3
Functionally bicuspid valve	5	1

AR, Aortic regurgitation; AS, aortic stenosis; AVR, aortic valve replacement; BSA, body surface area; CABG, coronary artery bypass grafting; LV, left ventricular; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association.

below the replacement aortic valve in a parasternal long-axis view frozen in systole. The largest of 3 measurements was used. Regurgitant jets were localized, then graded by a combination of the jet height and the density, and pressure half-time of the aortic regurgitant signal on continuous wave Doppler. Moderate regurgitation was defined by a jet height between 25% and 65% of the outflow diameter with a pressure half-time longer than 300 ms. Mild regurgitation was defined by a jet height less than 25% of the outflow diameter and a complete, low-intensity continuous waveform with pressure half-time longer than 500 ms. Trivial regurgitation was defined by a thin, low-momentum jet ending close to the valve with an incomplete continuous waveform. No jet in this study was found to be severe.

Calculations

The following calculations were performed: (1) effective orifice area (EOA) by the continuity equation ($EOA \text{ in cm}^2 = CSA \times VTI_1/VTI_2$ where CSA is LV outflow cross-sectional area (cm²) calculated from the diameter assuming circular cross section, VTI_1 is subaortic velocity integral (cm), and VTI_2 is aortic velocity integral (cm)); (2) peak pressure difference across the aortic valve ($\text{peak } \Delta P \text{ in mm Hg} = 4(v_2^2 - v_1^2)$ where v_2 is transaortic peak velocity (m/s) and v_1 is subaortic peak velocity (m/s)); (3) mean pressure difference across the aortic valve ($\text{mean } \Delta P \text{ in mm Hg} = \text{aortic mean } \Delta P - \text{subaortic mean } \Delta P$); (4) LV mass (g) = 0.83 (left ventricular diastolic diameter [LVDD] + septal thickness + pos-

Figure 1. LV outflow tract diameter (mean and 95% confidence interval) for each label size by valve type. LV, left ventricular.

terior wall thickness)³ – (LVDD)³. LV mass and EOA were indexed to body surface area.

Analysis

The mean and standard deviation values were calculated for variables that were approximately normally distributed and the median and range for those that were skewed. Comparisons were made between valve types using the unpaired *t* test or nonparametric Mann–Whitney *U* test as appropriate. The hemodynamic results were compared over the 4 postoperative visits using 1-way analysis of variance (ANOVA). The incidence of regurgitation was compared using Fisher exact test as the numbers in some categories were expected to be small. Standard definitions of clinical events were used.¹³ Sizing was compared by plotting the LV outflow diameter measured by echocardiography against the label

size for each valve design. Analyses were performed using the statistical package social sciences version 11.5.1.

Results

The groups were similar with respect to demographic characteristics (Table 1). The mean label size was 25.05 (standard deviation 2.62) for the Cryolife O’Brien and 24.80 (2.62; *P* = .66) for the Toronto valves. LV outflow tract diameter was similar for both valve types for label sizes 21 through 25, and approximately 2 mm smaller for the Toronto at label size 27 and 29 (Figure 1). Crossclamp time for the Cryolife O’Brien group was 67 (SD 12) minutes, which was statistically shorter than for the Toronto group at 102 (SD 21) minutes (*P* < .0001). Total bypass time for the Cryolife O’Brien group was 91 (SD 22) minutes compared with 125 (SD 22) minutes for the Toronto group (*P* < .0001). Two patients died in the early postoperative period (2.6%), 1 in each group. There were 6 deaths between 30 days and 1 year, 4 in the Toronto group and 2 in the Cryolife O’Brien group. One patient developed endocarditis in each group, which was fatal for the patient in the Cryolife O’Brien group but not fatal for the patient in the Toronto group. There were no thromboembolic events and no valve thromboses.

There were minor changes in results over time (Table 2), but these did not attain statistical significance within each group. At 1 year, the effective orifice area was 1.81 (0.50) cm² for the Cryolife O’Brien and 1.30 (0.42) cm² for the Toronto group (*P* < .0001; Table 2). Patient–prosthesis mismatch defined by indexed effective orifice area < 0.8 cm²/m² occurred in 16 patients in the Toronto group and 4 patients in the Cryolife group (*P* < .0001). The peak transaortic velocity was 1.7 (0.4) m/s for the Cryolife O’Brien group and 2.2 (0.5) m/s for the Toronto group (*P* < .0001), and the mean gradient for the Cryolife O’Brien group was 7.1 (3.7) mm Hg compared with 11.6 (5.7) mm Hg (*P* = .001) for the Toronto group. For comparison with

TABLE 2. Hemodynamic results for whole Cryolife O’Brien group and whole Toronto group (mean ± standard deviation)

Variable	Preop	Postop	6 wk	3-6 mo	1 y
Cryolife O’Brien group					
EOA (cm ²)	0.80 ± 0.47	1.61 ± 0.50	1.83 ± 0.48	1.82 ± 0.51	1.81 ± 0.50
VTI ₁ (cm)	20.9 ± 5.6	16.5 ± 4.01	19.3 ± 4.5	19.7 ± 4.9	19.4 ± 4.1
Vmax (m/s)	4.1 ± 1.0	2.1 ± 0.6	1.9 ± 0.5	1.8 ± 0.5	1.7 ± 0.4
Mean ΔP (mm Hg)	43.3 ± 19.1	9.9 ± 6.5	8.4 ± 4.8	7.6 ± 4.4	7.1 ± 3.7
Toronto group					
EOA (cm ²)	0.76 ± 0.50	1.31 ± 0.54	1.42 ± 0.41	1.47 ± 0.46	1.30 ± 0.42
VTI ₁ (cm)	19.9 ± 5.9	15.1 ± 4.0	18.3 ± 3.5	19.4 ± 4.1	19.5 ± 4.1
Vmax (m/s)	4.1 ± 1.1	2.5 ± 0.7	2.2 ± 0.5	2.1 ± 0.5	2.2 ± 0.5
Mean ΔP (mm Hg)	44.3 ± 22.5	15.29 ± 8.8	11.4 ± 4.9	10.9 ± 5.2	11.6 ± 5.7

ΔP, Transaortic pressure difference; EOA, effective orifice area by the continuity equation; Preop, preoperative; Postop, postoperative; Vmax, peak transaortic velocity; VTI₁, subaortic velocity time integral.

TABLE 3. Hemodynamic results at 3-6 and 12 months displayed for convenience by label size* (mean $\pm$ standard deviation)

	Toronto	Cryolife O'Brien	P
3-6 mo (n)	34	35	
21 mm (n)	6	3	
EOA (cm ²)	0.87 $\pm$ 0.11	1.16 $\pm$ 0.17	.082
Vmax (m/s)	2.6 $\pm$ 0.5	2.5 $\pm$ 1	.903
Mean Δ P (mm Hg)	17.2 $\pm$ 4.4	16.8 $\pm$ 7.7	.942
23 mm (n)	9	12	
EOA (cm ²)	1.4 $\pm$ 0.3	1.6 $\pm$ 0.3	.293
Vmax (m/s)	2.2 $\pm$ 0.5	2.0 $\pm$.37	.336
Mean Δ P (mm Hg)	12.1 $\pm$ 5.3	8.6 $\pm$ 3.2	.101
25 mm (n)	9	9	
EOA (cm ²)	1.7 $\pm$ 0.5	2.0 $\pm$ 0.4	.361
Vmax (m/s)	2.0 $\pm$ 0.4	1.7 $\pm$ 0.4	.05*
Mean Δ P (mm Hg)	9.1 $\pm$ 2.9	6.1 $\pm$ 2.5	.03*
27 mm (n)	4	3	
EOA (cm ²)	1.6 $\pm$ 0.4	2.2 $\pm$ 0.5	.159
Vmax (m/s)	2.1 $\pm$ 0.6	1.5 $\pm$ 0.2	.110
Mean Δ P (mm Hg)	9.7 $\pm$ 5	5.0 $\pm$ 0.7	.156
29 mm (n)	6	8	
EOA (cm ²)	1.8 $\pm$ 0.3	2.2 $\pm$ 0.4	.088
Vmax (m/s)	1.7 $\pm$ 0.2	1.6 $\pm$ 0.3	.445
Mean Δ P (mm Hg)	6.4 $\pm$ 1.7	5.3 $\pm$ 1.3	.192
12 mo (n)	31	36	
21 mm (n)	6	3	
EOA (cm ²)	1.0 $\pm$ 0.1	1.1 $\pm$ 0.3	.392
Vmax (m/s)	2.7 $\pm$ 0.3	2.0 $\pm$ 0.5	.122
Mean Δ P (mm Hg)	16.7 $\pm$ 3.2	13.1 $\pm$ 5.1	.353
23 mm (n)	6	13	
EOA (cm ²)	1.3 $\pm$ 0.3	1.6 $\pm$ 0.4	.082
Vmax (m/s)	2.4 $\pm$ 0.6	1.8 $\pm$ 0.5	.063
Mean Δ P (mm Hg)	14.4 $\pm$ 8.6	7.3 $\pm$ 4.3	.143
25 mm (n)	9	9	
EOA (cm ²)	1.4 $\pm$ 0.3	1.9 $\pm$ 0.4	.005*
Vmax (m/s)	2.1 $\pm$ 0.4	1.7 $\pm$ 0.3	.043*
Mean Δ P (mm Hg)	10.0 $\pm$ 4.2	6.2 $\pm$ 2.3	.034*
27 mm (n)	4	4	
EOA (cm ²)	1.6 $\pm$ 0.3	2.0 $\pm$ 0.2	.04*
Vmax (m/s)	2.0 $\pm$ 0.4	1.8 $\pm$ 0.2	.454
Mean Δ P (mm Hg)	9.6 $\pm$ 4.1	7.2 $\pm$ 1.2	.328
29 mm (n)	6	7	
EOA (cm ²)	2.1 $\pm$ 0.7	2.2 $\pm$ 0.5	.662
Vmax (m/s)	1.7 $\pm$ 0.3	1.6 $\pm$ 0.3	.437
Mean Δ P (mm Hg)	7.0 $\pm$ 2.6	5.2 $\pm$ 2.0	.237

Δ P, Transaortic pressure difference; EOA, effective orifice area by the continuity equation; Vmax, peak transaortic velocity. *Valves of the same label size are not biologically comparable.

the literature, hemodynamic results by label size are given for 3-6 months and 1 year in Table 3.

There was no change in the incidence or degree of regurgitation during the short study period. At 1 year there was mild regurgitation through the valve in 2 (6.5%) pa-

tients in the Toronto group and 2 (5.6%) patients in the Cryolife O'Brien group. None had moderate or severe regurgitation. There was mild paraprothetic regurgitation in 6 (16.7%) patients in the Cryolife O'Brien group but none in the Toronto group, while there was moderate paraprothetic regurgitation in 1 (3.2%) patient in the Toronto group and none in the Cryolife O'Brien group. Of the 5 patients with functionally bicuspid native valves who received a Cryolife O'Brien valve, only 1 had mild paraprothetic regurgitation, and the single patient receiving a Toronto valve had no regurgitation. There was no significant difference in the incidence of regurgitation using Fisher exact test. There was no significant difference in LV mass index or indices of systolic function between the 2 valve types at any point after surgery (Table 4). New York Heart Association (NYHA) class was similar in the 2 groups at 1 year, with 30 of 37 (81%) patients in the Cryolife group and 27 of 31 (87%) patients in the Toronto group in NYHA I, 6 (16%) and 3 (10%) patients, respectively, in NYHA II, 1 patient in each group in NYHA III, and none in NYHA IV.

Discussion

Stentless xenograft replacement valves are usually considered as a homogeneous class. This study suggests that differences within the class may be important as the Cryolife O'Brien valve was hemodynamically superior to the Toronto valve.

This is likely to be related predominantly to the difference in design and implantation site. The Toronto valve is prepared from a whole porcine aortic root with the possibility of a reduction in the compliance of the annulus and increased stiffness of the paracommissural parts of the cusps caused by the retained muscle bar at the base of the right coronary cusp and the use of a Dacron lining. By comparison, the Cryolife O'Brien valve has no Dacron lining and is composed of 3 noncoronary cusps and therefore has no muscle bar. Furthermore, the Toronto valve is sewn with the lower sutures at the annulus, and the Cryolife O'Brien valve is sited just above the annulus. Similar results were shown in a comparison of the cryopreserved homograft and Prima,¹⁴ (Edwards Lifesciences, Irvine, Calif) which is a porcine preparation with the septal muscle shelf removed but with a Dacron-covered annulus. The mean pressure drop was 5 mm Hg in the homograft group compared with 12 mm Hg in the Prima group. By contrast, another study¹⁵ found a similar pressure drop in homografts and the Toronto stentless valve, but this was measured only a few hours after surgery using a regression equation to calculate pressure difference. In the present study, there were small differences in the size of the aorta in favor of the Cryolife valve. The mean label size, which reflects sinotubular junction diameter, differed by only 0.2 mm. However, the LV outflow diameter on echocardiography, which reflects patient tissue

TABLE 4. Measures of LV structure and function (mean $\pm$ standard deviation)

	Toronto	Cryolife O'Brien	95% CI of the difference	P value
Preoperative LV mass index (g/m ²)	135 $\pm$ 48	134 $\pm$ 45	−0.23, 24	NS
LV mass index at 3-6 mo (g/m ²)	97 $\pm$ 32	101 $\pm$ 25	−18, 11	NS
LV mass index at 12 mo (g/m ²)	105 $\pm$ 46	106 $\pm$ 28	−21, 19	NS
Preoperative FS (%)	31 $\pm$ 12	33 $\pm$ 10	−7.6, 3.4	NS
FS at 3-6 mo (%)	38 $\pm$ 9	35 $\pm$ 9	−2.3, 7.2	NS
FS at 12 mo (%)	39 $\pm$ 15	33 $\pm$ 10	−2.6, 10.4	NS
Preoperative VTI (cm)	19.9 $\pm$ 6.0	20.9 $\pm$ 6.0	−3.6, 1.6	NS
VTI at 3-6 mo (cm)	19.3 $\pm$ 4.0	19.7 $\pm$ 4.9	−2.6, 1.9	NS
VTI at 12 mo (cm)	19.5 $\pm$ 4.1	19.2 $\pm$ 4.1	−1.7, 2.3	NS

CI, Confidence interval; FS, fractional shortening; LV, left ventricular; LVOT, left ventricular outflow tract; NS, not significant; VTI, velocity time integral.

annulus diameter, was approximately 2 mm smaller for the Toronto than for the Cryolife valves in the 27-mm and 29-mm sizes, although similar for the other sizes (Figure 1).

There are no significantly discrepant results compared with published information on the Cryolife O'Brien valve^{10,12,16-20} and for the Toronto valve.^{2,3,6,21,22} However, there is significant variation in the methodology and findings of previously published studies such that until our randomized comparison, it has not been possible to draw conclusions about the relative hemodynamic performance of the 2 valve types. We showed a fall in gradient between the postoperative study and 1 year for both valve types, as also shown by others.^{18,19} However, these changes were not significant on ANOVA. The hemodynamic differences were not associated with differences in NYHA class, LV mass regression, or clinical events.

The Cryolife O'Brien valve has a relatively large coaptation region. This avoids the tendency of valve prepared from a whole root to distort leading to regurgitation through the valve. We showed a low incidence of regurgitation through the valve in agreement with other authors,^{18,20} although this was no different from the regurgitation through the Toronto valve.²³ Previous work has shown a slightly higher incidence of regurgitation through the Toronto valve.²⁴⁻²⁷ The incidence of paraprosthetic regurgitation was higher for the Cryolife O'Brien valve than for the Toronto valve, although this difference did not attain statistical significance. The presence of regurgitation was not associated with native bicuspid valve disease, and in neither valve type was the regurgitation graded more than moderate.

Limitations

This study compared patients of similar body size and sinotubular junction diameter as measured by an independent sizer. The echocardiographic LV outflow diameters, reflecting tissue annulus diameters, were similar for the 21-mm through 25-mm valves but smaller for the Toronto than the Cryolife O'Brien for the 27- and 29-mm valves. This suggests a slight weighting in favor of the Cryolife

O'Brien but is insufficient to explain the overall better performance as results were better at the smaller as well as the larger sizes. The study was powered only to compare hemodynamic function, and the trend toward a higher incidence in paraprosthetic regurgitation in the Cryolife O'Brien valves might become significant with larger population sizes. This study was also concerned with early results and cannot exclude differences in durability or late events. Furthermore, the Toronto valves were implanted in a subcoronary position, and hemodynamic function is expected to be better with implantation as a total root replacement.

Conclusions

This study showed superior forward flow characteristics with a trend toward more paraprosthetic regurgitation for the Cryolife O'Brien valve compared with the Toronto stentless valve. This suggests that stentless valves should not be considered as a uniform class but must be subdivided according to design and implantation site. The Cryolife O'Brien valve is a tricomposite supra-annular valve, and the Toronto valve for this study was implanted in a subcoronary position.

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