Eight-year results after aortic valve replacement with the CryoLife-O'Brien Stentless Aortic Porcine Bioprosthesis

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Objective: The long-term durability and hemodynamics of stentless valves are largely unknown. In this study we prospectively analyzed 8-year clinical results with the CryoLife-O'Brien Stentless Aortic Porcine Bioprosthesis (CryoLife Inc, Kennesaw, Ga) and assessed its hemodynamic performance by serial echocardiography.

Methods: A total of 206 patients with a mean age of 72.8 years were followed up prospectively after aortic valve replacement with the CryoLife-O'Brien stentless bioprosthesis. Patients have been followed up from 2 to 96 months for mean 56 months. Echocardiography was performed by a single echocardiographer preoperatively, intraoperatively, postoperatively at discharge, 3 to 6 months later, and annually thereafter.

Results: The 30-day operative mortality was 4.8%. Sixty-five percent of patients received a valve 25 mm in diameter or larger, and 37% underwent concomitant coronary bypass grafting. Twelve late deaths, none valve-related, have occurred. Severe aortic insufficiency caused by oversizing led to early reoperation in 3 patients. The peak and mean systolic gradients decreased significantly during the first 12 months after implantation ($P < .001$), and the effective valve areas increased significantly during this interval ($P < .001$). At 8 years, 2 patients have mild to moderate aortic insufficiency. The actuarial survival at 8 years was $82\% \pm 3\%$. The freedom from endocarditis was 100%, and the freedom from thromboembolic events was 93%.

Conclusion: Despite more demanding surgical technique than with conventional bioprostheses, the CryoLife-O'Brien bioprosthesis can be implanted safely in a population predominantly older than 70 years at the time of the operation, with excellent measures of hemodynamics, clinical outcomes, prosthesis durability, and survival through 8 years.

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Because several models of stentless xenografts have been introduced gradually in clinical practice, any beneficial effect of these valves needs to be verified for every xenograft model. The objective of the CryoLife-O'Brien Stentless Aortic Porcine Bioprosthesis (CryoLife Inc, Kennesaw, Ga) composite design was to optimize hemodynamic performance and durability of bioprosthetic valves. Three noncoronary leaflets are prepared by low-pressure glutaraldehyde fixation process of less than 2 mm Hg. The scalloped design and the absence of xenograft tissue below the leaflet hinge allow implantation with a single suture line. Because there are no synthetic materials other than the suture, the risk of endocarditis is expected to be reduced. Previously published reports confirm excellent hemodynamics associated with this bioprosthesis.¹⁻³ However, some studies have suggested that this implant offers less satisfactory outcome than seen with standard stentless models.⁴ This work represents a detailed standardized study that prospectively evaluated the hemodynamic performance of the CryoLife-O'Brien biopros-

TABLE 1. Selected preoperative patient characteristics (n = 206)

Age (mean $\pm$ SD)	72.8 $\pm$ 3
Male (No.)	89 (43%)
Hypertension	134 (65%)
Coronary artery disease (No.)	92 (45%)
Myocardial infarction (No.)	36 (17%)
Congestive heart failure (No.)	99 (48%)
New York Heart Association functional class III or IV (No.)	168 (81%)
Diabetes mellitus (No.)	45 (22%)
Renal insufficiency (No.)	12 (6%)
Liver dysfunction (No.)	8 (4%)
Peripheral vascular disease (No.)	38 (18%)
Carotid atherosclerotic disease (No.)	25 (12%)
Stroke (No.)	37 (18%)
Smoking (No.)	56 (27%)
Chronic obstructive pulmonary disease (No.)	7 (18%)
Reoperation (No.)	15 (7%)
Pathology (No.)	
Pure stenosis	62 (30%)
Primarily stenosis with insufficiency	107 (52%)
Pure insufficiency	37 (18%)

thesis through serial echocardiography by a single echocardiographer and analyzed the clinical outcomes of 206 patients who underwent aortic valve replacement (AVR) in an 8-year experience of a single surgeon.

Patients and Methods

From September 1996 through September 2004, a total of 206 consecutive patients underwent AVR with the CryoLife-O'Brien model 300 Stentless Aortic Porcine Bioprosthesis. The mean age was 72.8 ± 3 years, with a range of 65 to 84 years. All these replacements were performed by the same surgeon. During the last 8 years, 1426 aortic prostheses were implanted, excepting double-valve replacements. In 690 patients a mechanical valve was used, and in 736, a tissue valve was used. A total of 402 stentless aortic tissue valves were implanted by two surgeons. Stentless valves accounted for approximately 58% of all tissue valves. Medtronic Freestyle stentless bioprostheses (Medtronic, Inc, Minneapolis, Minn) and St Jude Medical Toronto stentless porcine valve bioprostheses (St Jude Medical Canada, Mississauga, Ontario, Canada) were also implanted. There were no special indications for selection of each bioprosthesis, except for 20 patients who had a disease of the ascending aorta in addition or were undergoing reoperation because of endocarditis or valve degeneration; in those cases, the Medtronic Freestyle prosthesis in full-root technique was implanted. The contraindications for the implantation of the CryoLife-O'Brien bioprosthesis were excessive calcification of the aortic root and aortic root aneurysm. Patients have been followed up from 2 to 96 months, mean 56 months. Patients were contacted once a year.

Echocardiography was performed by the same echocardiographer preoperatively, intraoperatively, postoperatively at discharge, 3 to 6 months later, and annually thereafter. Mean values for each

TABLE 2. Pertinent surgical parameters

Cardiopulmonary bypass time (min, mean $\pm$ SD)	92 $\pm$ 16
AVR	76 $\pm$ 7
AVR plus coronary artery bypass grafting	112 $\pm$ 9
Aortic crossclamp time (min, mean $\pm$ SD)	62 $\pm$ 9
AVR	51 $\pm$ 8
AVR plus coronary artery bypass grafting	76 $\pm$ 12
Coronary artery bypass grafting (No.)	76 (37%)
Valve size (mm)	
21 (No.)	12 (6%)
23 (No.)	59 (29%)
25 (No.)	87 (42%)
27 (No.)	48 (23%)
Intra-aortic balloon pump support (No.)	16 (8%)

AVR, Aortic valve replacement.

echocardiographic measurement were derived from three consecutive heartbeats in patients with sinus rhythmus and from five beats in those in atrial fibrillation or a ventricular inhibited pacemaker.

The effective orifice area (EOA) of the aortic valve was calculated by the continuity equation, and the mean transvalvular gradient at rest was derived from a simplified Bernoulli equation accounting for the flow velocity across the left ventricular outflow tract.⁵ Echocardiographic classification of aortic insufficiency was in accordance with the criteria described by Perry and colleagues.⁶ The left ventricular mass (LVM) was calculated by the formula introduced by Devereux and Reichek and was indexed for body surface area to obtain the LVM index (LVMI).⁷ Selected preoperative patient characteristics are summarized in Table 1. The surgical procedure consisted of a subcoronary supra-annular single suture line technique, as has been described previously,⁸ and remained constant throughout the study period without any modifications.

The design of the CryoLife-O'Brien stentless bioprosthesis allows the valve to be implanted in effective position such that a prosthesis larger than the measured host annulus diameter can be installed, independent of the indicated size. Oversizing by one size (2 mm) was used in most patients; oversizing by two sizes was used in 16 patients. Surgical intraoperative variables, including aortic crossclamp time, cardiopulmonary bypass time, and valve sizes, are listed in Table 2. Morbid and fatal valve-related events were categorized as structural valve deterioration, nonstructural valve dysfunction, thromboembolism, anticoagulant-related bleeding events, prosthetic valve endocarditis, reoperation, valve-related mortality, and all valve-related morbidity and mortality, according to the framework devised by the Society for Thoracic Surgeons and The American Association for Thoracic Surgery ad hoc committee.⁹

Statistical Analysis

Data from individual patients were expressed as mean $\pm$ SD, and important ratios were expressed with 70% confidence limits. Comparisons between continuous variables were performed by repeated-measures analysis of variance to detect any significant changes (in mean transvalvular gradient across the aortic valve prosthesis,

EOA with time), followed, if statistically significant, by a 2-tailed paired Student *t* test with Bonferroni correction. The actuarial estimates were used to describe the time-related event-free rates for death and other valve-related complications, and the variability of these estimates is indicated by SEM.

Results

Clinical Outcomes

Sixty-five percent of patients received a valve 25 mm in diameter or larger. Operative mortality rate at the time of surgery was 0.5%. Rethoracotomy for bleeding had to be performed in a total of 4 cases. None of the patients had mediastinitis develop. The 30-day mortality was $4.8\% \pm 2\%$. In the last consecutive 178 patients, the 30-day mortality rate 2.2%. Among the first 28 patients, there were 6 in-hospital deaths (21.4%), with no deaths directly valve related. Postmortem examination was performed in all 6 cases, and no technical or valve failure was demonstrated. Three of these patients had undergone concomitant coronary artery bypass grafting, and another 3 patients also had associated morbidity. Causes of death were respiratory failure necessitating prolonged mechanical ventilation and subsequent pneumonia in 2 patients, perioperative stroke with severe neurologic deficit in 1 patient being readied for hospital discharge, and prolonged intensive care stay because of low output syndrome after myocardial infarction complicated by multiple organ failure in 3 patients with concomitant coronary artery bypass grafting. Causes of late deaths are shown in Table 3. Freedoms from death at 1 and 8 years after AVR were $95\% \pm 2\%$ and $83\% \pm 3\%$, respectively (Figure 1). Freedoms from cardiac mortality at 1 and 8 years, when noncardiac deaths were excluded, were

TABLE 3. Causes of late deaths

	No.
Metastatic carcinoma	6
Myocardial infarction	3
Renal failure	1
Trauma	1
Sudden death	1

$97\% \pm 2\%$ and $92\% \pm 2\%$, respectively (Figure 2). At last follow-up, 96% of patients were in New York Heart Association functional class I or II, with a mean class of 1.09 ± 0.32 (vs 3.11 ± 0.5 preoperatively, $P < .001$).

Valve-Related Complications

Freedom from structural valve deterioration at 8 years was 100%, and freedom from reoperation at 8 years was $98\% \pm 1\%$. Severe aortic insufficiency led to early reoperation because of technical reasons in 3 patients. All reoperated valves were well positioned, but 2 of them with large disparity between sinotubular and annular diameters had central valvular incompetence. The third patient had para-valvular incompetence, and torn suture was found intraoperatively at the site where the aortic annulus had significant calcification. This valve was refixedated, and the other 2 were replaced with same model but one diameter number smaller. Freedom from endocarditis at 8 years was 100%, whereas freedom from thromboembolic complications at 8 years was $93\% \pm 3\%$ (Figure 3). After implantation, permanent anticoagulation with warfarin was prescribed only if additional atrial arrhythmia was present. Aspirin was routinely used

Figure 1. Freedom from death after AVR. Open circles represent estimated survival for 73-year olds in Germany in 2001. Data are from National Statistics Bureau (Statistisches Bundesamt) Wiesbaden, 2004. Vertical line represents 95% confidence interval of survival for patients with CryoLife-O'Brien valves; *n* indicates number of patients at risk for each interval.

Figure 2. Freedom from cardiac death; *n* indicates number of patients at risk for each interval.

only in patients undergoing concomitant coronary artery bypass grafting. There were 11 documented thromboembolic events. There were 3 late strokes and 5 late transient ischemic attacks, none of which were fatal. The mean age of these 8 patients was 81.5 years. Five had atrial arrhythmia develop close to the time of the events, and hemodynamically significant internal carotid stenosis was diagnosed in 4. Another 9 patients had late atrial arrhythmias develop; in 6 of them, warfarin therapy was initiated. None of patients had clinically important anticoagulant-related bleeding events.

Hemodynamic Outcomes

Table E1 summarizes the changes in mean aortic transvalvular gradient as a function of time for all patients preoperatively, at discharge, at 6 months, and annually thereafter. Table E2 summarizes the changes in EOA as a function of

time for all patients preoperatively, at discharge, at 6 months, and annually thereafter. There were consistent decreases in mean aortic gradient as a function of time to 1-year follow-up. Thereafter, the values appeared to plateau. There was a significant increase in EOA in the postoperative series and again at 3 to 6 months. Analysis of variance showed significantly larger EOA in larger valves, which also was consistent throughout the follow-up period.

Left Ventricular Mass Index

LVMI with time is shown in Table E3. LVMI decreased significantly early after AVR for all valve sizes. Between 2 and 6 years, there was a small but statistically not significant increase in LVMI. The reason for this is probably multifactorial, but it may partially be related other coexisting morbidities, such as hypertension (65% of patients).

Figure 3. Freedom from valve-related events of endocarditis (filled circles) and thromboembolic events (open diamonds); *n* indicates number of patients at risk for each interval.

Aortic Regurgitation

At 1 year of follow-up 92% of patients (179/195) had no aortic regurgitation, 5% (10/195) had trivial regurgitation, and 3% (6/195) had mild regurgitation. At 3 years, 85% (141/166) had no aortic regurgitation, 12% (20/166) had trivial regurgitation, and 3% (6/166) mild to moderate regurgitation. At 5 years, 80% (100/125), 16% (20/125), and 4% (5/125) had no, trivial, and mild aortic regurgitation, respectively. The last group represents the same patients that had progression from trivial to mild regurgitation with time and remained stable. Three of them were among the 12 patients with oversizing by two sizes, and that could be a possible cause of aortic regurgitation. At 7 years of follow-up, 88% of patients (45/51) had no aortic regurgitation, 8% (4/54) had trivial regurgitation, and 5% (3/54) had mild to moderate regurgitation. The aortic valve remained pliable in all patients, and the leaflets did not change in thickness or show evidence of calcification as assessed by echocardiography.

Discussion

Clinical reports have demonstrated that the residual transprosthetic pressure gradient after AVR for aortic stenosis is a major risk factor for impaired left ventricular diastolic dysfunction and incomplete postoperative regression of left ventricular hypertrophy.¹⁰⁻¹² Through elimination of a rigid sewing ring, the dynamic nature of the aortic root may be maintained after AVR with this device.¹³ Maintenance of normal aortic root function may at least in part be responsible for the excellent hemodynamic performances of both stentless valves, as well as aortic homografts.¹⁴ Stentless aortic bioprostheses were reintroduced nearly 12 years ago to overcome the limited durability observed after AVR with stented bioprostheses.^{15,16} Long-term follow-up data now suggest that durabilities of stentless valves are comparable to those of stented bioprostheses. Recently, Desai and coworkers¹⁷ have reported on about 200 patients with excellent early clinical results after AVR with St Jude Medical Toronto stentless porcine valve bioprostheses but with significant increase in hazard for structural valve deterioration in late follow-up. Actuarial freedom from structural valve deterioration was 98.8% at 5 years but declined to 77.9% at 10 years. Luciani and colleagues⁴ have suggested unsatisfactory early outcomes with the CryoLife-O'Brien stentless bioprosthesis relative to two other stentless xenografts, although midterm survivals after stentless AVR were good with all three xenografts.

In our series, CryoLife-O'Brien stentless bioprostheses were implanted in a large number of patients, mostly older than 70 years (85%) and were not implanted in patients younger than 65 years. Follow-up has extended beyond 8 years for some. There are sufficient data on patients at 8-year follow-up to allow some inferences with regard to

the performance of this bioprosthesis for replacement of the aortic valve. Although most of the patients were elderly and almost half had concomitant coronary artery disease, an acceptable 30-day mortality of 4.8% was seen. For the age (28% octogenarians at follow-up) and associated morbidity of the patients with thromboembolic events, the thromboembolic rate for the CryoLife-O'Brien stentless bioprosthesis was low. Patients were not given warfarin sodium unless there was persistent atrial fibrillation or flutter. Early thromboembolism was noted in only 1.5% of patients. The freedom from endocarditis was 100% at 8-year follow-up. This indicates that the CryoLife-O'Brien stentless bioprosthesis is quite resistant to infection, possibly because this device has no synthetic materials other than suture, thereby reducing the possibility of foreign-body reaction and thus infection. Paravalvular leakage, not necessitating bioprosthesis explantation and responding well to refixation, was observed in 1 patient. Technical problems with oversizing in the initial phase, causing central transvalvular gradient and unacceptable hemodynamic performance, was the major cause of early reoperation, necessitating bioprosthesis explantation in 2 patients. According to our opinion, disparity is neither an absolute nor a relative contraindication for implantation. The absolute contraindications for the implantation of the CryoLife-O'Brien bioprosthesis were excessive calcification of the aortic root and aortic root aneurysm. In this study, structural deterioration was not observed. There was a remarkable improvement in functional capacity after the operation, with 95% of patients in New York Heart Association functional class I or II, even though 85% of the patients were in functional class III or IV before the operation. This remarkable improvement is likely related to the excellent hemodynamic performance of the bioprosthesis, probably because of its unique design. The selection of the three noncoronary leaflets removes the unfavorable muscle-based right coronary leaflet characteristics of the pig valve such the EOA is maximized. Because there is no need for external Dacron polyester fabric support or any additional material of biologic or synthetic origin at the annulus level of the xenograft, any unnecessary increase in the thickness of the xenograft and any artificially induced stiffness or stress on the tissue can be avoided.² This study shows that the low transvalvular gradients had reached their significantly decreased maximum at 3-year follow-up and were sustained at 4-year follow-up. EOA has been consistently good, even in small valves. The very small 5-mm to 6-mm cuff of xenograft aortic wall distal to the valve hinge and the absence of a proximal cuff of this composite valve enable a simple, rapid single suture line implantation technique. Because of this small aortic cuff, no problems have been encountered with low-lying host coronary ostia. Additional advantages of the supra-annular placement have included good exposure for the small aortic root, provision of an

effective central flow, and nonobstructive orifice with low transvalvular gradients mimicking those of the homograft valve.

Gelsomino and associates³ showed that left ventricular hypertrophy resolves rapidly after the aortic valve is replaced with this bioprosthesis. In our study, the preoperative values indicate minimal ventricular hypertrophy at the time of implantation. The normal male value is 130 g/m², and the normal female is 100 g/m². The preoperative values were within the normal range, and the postoperative values were considerably lower than normal throughout the 7-year evaluation. This is because LVM is indexed to body surface area to allow comparisons between subjects of different size. Estimation of LVM in obese subjects may therefore present a challenge, given that indexing to body surface area may normalize and thus incorrectly grossly underestimate LVM measurements, as in our group of 75% obese patients. By combining echocardiographic data with body composition measurements in 3107 adults, Bella and coworkers¹⁸ were able to demonstrate that LVM was more strongly related to fat-free mass than to adipose mass, waist/hip ratio, body mass index, or height-based surrogates for lean body weight. They concluded that that LVM/fat-free mass criteria could increase sensitivity to detect left ventricular hypertrophy.

Study Limitations

This was an observational assessment of outcomes. The patients were not randomly assigned to various therapies, and comparison between inherently dissimilar groups is problematic. Continued study will be necessary as patients reach time points during which prosthesis failure is more likely. Hemodynamic outcomes were measured only through 7 years because of limited data available thereafter.

Conclusions

The CryoLife-O'Brien bioprosthesis appears to be a reliable choice for a tissue valve in the aortic position, with very good associated hemodynamics maintained through 7 years. This valve has been implanted safely in a population predominantly older than 70 years, with excellent measures of clinical outcomes and prosthesis durability. Survival thus far is excellent and overlaps that of an age-matched population.

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TABLE E1. Changes in mean aortic transvalvular gradient according to valve size

	Size (mm)				Total
	21	23	25	27	
Preoperative	58.6 ± 16.4	47.4 ± 16.1	43.8 ± 17.2	47.6 ± 18.8	48.8 ± 16.4
Discharge	16.3 ± 7.0	12.8 ± 3.8	10.4 ± 5.4	10.6 ± 5.2	12.8 ± 5.6*
3-6 mo	9.5 ± 4.2	7.6 ± 2.5	6.5 ± 2.6	4.9 ± 2.4	7.8 ± 3.8*†
1 y	9.2 ± 3.8	7.8 ± 3.6	6.8 ± 4.1	4.2 ± 2.2	7.2 ± 4*†
2 y	8.4 ± 3.8	6.0 ± 2.8	4.6 ± 2.1	4.2 ± 2.8	5. ± 3.2*†
3 y	6.4 ± 2.6	4.8 ± 2.4	3.6 ± 2.0	4.3 ± 3.1	4.9 ± 2*†
4 y	6.8 ± 2.8	2.7 ± 1	3.4 ± 2.1	4.8 ± 3.6	4.8 ± 3.2*†
5 y	7.1 ± 2	5.2 ± 2	4.6 ± 2	5.1 ± 2	4.6 ± 2*†
6 y	6.4 ± 2.6	4.7 ± 2.4	4.8 ± 2.4	4.9 ± 2.5	4.4 ± 2.4*†
7 y	7.2 ± 2	5.8 ± 2.3	3.8 ± 2.4	4.8 ± 2.4	5.2 ± 2.5*†

Values are in millimeters of mercury (mean ± SD). * $P < .05$ vs preoperative. † $P < .05$ vs discharge.

TABLE E2. Changes in EOA according to valve size

	Size (mm)				Total
	21	23	25	27	
Preoperative	0.54 ± 0.18	0.78 ± 0.25	0.88 ± 0.48	1.10 ± 0.681	0.76 ± 0.46
Discharge	1.32 ± 0.32	1.48 ± 0.28	1.78 ± 0.42	1.98 ± 0.54	1.58 ± 0.4*
3-6 mo	1.54 ± 0.36	1.74 ± 0.28	2.28 ± 0.58	2.60 ± 0.64	1.91 ± 0.5*†
1 y	1.48 ± 0.28	1.78 ± 0.33	2.34 ± 0.64	2.58 ± 0.65	1.94 ± 0.7*†
2 y	1.62 ± 0.36	1.86 ± 0.34	2.32 ± 0.44	2.76 ± 0.7	1.97 ± 0.7*†
3 y	1.61 ± 0.4	1.98 ± 0.3	2.3 ± 0.48	2.7 ± 0.68	2.2 ± 0.7*†
4 y	1.59 ± 0.34	2.24 ± 0.52	2.45 ± 1.16	2.74 ± 0.9	2.23 ± 0.8*†
5 y	1.5 ± 0.32	2.15 ± 0.42	2.4 ± 0.94	2.8 ± 1.12	2.3 ± 0.7*†
6 y	1.61 ± 0.4	2.06 ± 0.3	2.42 ± 1.04	2.73 ± 0.68	2.23 ± 0.7*†
7 y	1.41 ± 0.3	1.98 ± 0.3	2.3 ± 0.98	2.74 ± 0.64	2.24 ± 0.7*†

Values are in square centimeters (mean ± SD). * $P < .05$ vs preoperative. † $P < .05$ vs discharge.

TABLE E3. Changes in LVMI according to valve size

	Size (mm)				Total
	21	23	25	27	
Preoperative	104 ± 32	122 ± 31	126 ± 33	123 ± 32	121 ± 31
Discharge	96 ± 13	116 ± 28	116 ± 19	118 ± 32	111 ± 26*
3-6 mo	89 ± 28	101 ± 36	110 ± 29	98 ± 33	99 ± 30*
1 y	83 ± 18	99 ± 24	94 ± 31	82 ± 18	86 ± 26*†
2 y	82 ± 23	98 ± 27	97 ± 23	87 ± 14	92 ± 23*†
3 y	84 ± 20	87 ± 25	102 ± 58	90 ± 30	94 ± 33*
4 y	83 ± 36	88 ± 14	104 ± 30	92 ± 25	91 ± 25*
5 y	84 ± 23	90 ± 28	105 ± 26	94 ± 17	96 ± 24*†
6 y	87 ± 23	97 ± 28	104 ± 26	98 ± 17	97 ± 25*†
7 y	84 ± 23	94 ± 31	102 ± 58	96 ± 24	96 ± 25*†

Values are in grams per square meter (mean ± SD). * $P < .05$ vs preoperative. † $P < .05$ vs discharge.