

Aortic Valve Replacement With a Cryolife O'Brien Stentless Bioprosthesis

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Introduction and objectives. The Cryolife O'Brien xenograft is a stentless bioprosthesis constructed from noncoronary leaflets from three porcine aortic valves. The aim of this study was to investigate short-term results after aortic valve replacement with this composite xenograft.

Methods. Since October 1993, Cryolife O'Brien bioprostheses have been implanted in 210 patients. The patients' mean age was 70.9 (7.5) years (range, 23-83 years). The indication was aortic stenosis in 132 cases, aortic insufficiency in 25 cases, and both lesions in 53 cases. Valve function was studied by echocardiography preoperatively, at discharge, and 6 and 12 months postoperatively.

Results. The 30-day mortality rate was 5.2% (11/210). Over time, the mean gradients decreased and the effective area index increased. In addition, the left ventricular mass index, wall thickness, and septum thickness also decreased shortly after surgery.

Conclusions. Use of the Cryolife O'Brien stentless bioprosthesis demonstrated satisfactory results at 1-year follow-up. Additional follow-up is required to assess the performance of this bioprosthesis over the long term.

Key words: Surgery. Echocardiography. Stentless bioprosthesis.

Reemplazo valvular aórtico con bioprótesis no soportada de Cryolife O'Brien

Introducción y objetivos. El xenoinjerto de Cryolife O'Brien es una bioprótesis no soportada, construida por valvas no coronarias de 3 válvulas aórticas porcinas. El objetivo de este estudio es investigar los resultados precoces después del reemplazo valvular aórtico con este xenoinjerto compuesto.

Métodos. Desde octubre de 1993, la bioprótesis Cryolife O'Brien ha sido implantada en 210 pacientes. La edad media fue de 70,9 \pm 7,5 años (intervalo, 23 y 83 años). La indicación fue estenosis aórtica en 132 casos, insuficiencia aórtica en 25 casos y doble lesión en 53 casos. Se ha estudiado la función valvular, mediante ecocardiografía preoperatoria, en el momento del alta y a los 6 y 12 meses del postoperatorio.

Resultados. La mortalidad a 30 días fue del 5,2% (11/210). Los gradientes medios se reducen y el índice de área efectiva aórtica aumenta con el tiempo. El índice de masa ventricular izquierda, el grosor de la pared y el espesor del septo también se reducen de forma precoz en el postoperatorio.

Conclusiones. El uso de la bioprótesis no soportada de Cryolife O'Brien ha mostrado unos resultados satisfactorios en el seguimiento a un año. Será necesario realizar seguimientos futuros para analizar el comportamiento de esta bioprótesis a largo plazo.

Palabras clave: Cirugía. Ecocardiografía. Bioprótesis no soportada.

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INTRODUCTION

A stented bioprostheses in the aortic position has the disadvantage of presenting high transvalvular gradients as well as incomplete regression of left ventricular hypertrophy.¹ The stent can cause non-physiological mechanical stress, with valvular calcification and consequent dysfunction.² In contrast, the presence of a

rigid stent produces a residual obstruction in transaortic flow, reducing effective area, and impeding complete resolution of left ventricular hypertrophy.³ This has been shown to have a negative effect on ventricular function following aortic valve replacement⁴ and, therefore, on long-term survival.⁵

Homografts have been demonstrated to have excellent hemodynamic performance⁶ but their clinical use is restricted due to the limited number of donors.

When compared with stented prostheses,⁷ stentless prostheses have been credited with better hemodynamic performance, earlier and more complete regression of left ventricular hypertrophy,^{8,9} and improved ventricular function in patients with aortic insufficiency and left

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TABLE 1. Perioperative Data*

Characteristics	Number	%
Diagnosis		
Aortic stenosis	132	59.5
Aortic insufficiency	25	11.3
Both lesions	53	23.9
Etiology		
Degenerative	166	74.8
Rheumatic	27	12.2
Congenital bicuspid	9	4.1
Native valve endocarditis	6	2.7
Active	2	0.9
Treated	4	1.8
Prosthetic endocarditis	1	0.5
Associated heart disease	58	27.6
Coronary heart disease	47	22.4
Mitral valve disease	12	5.7
Aneurysm of the ascending aorta	5	2.3
Surgical procedure		
AVR	167	79.5
AVR+CR	32	14.4
AVR+AAR	5	2.3
AVR+MVR	5	2.3
AVR+MVP	1	0.5

*MVP indicates mitral valve plasty; CR, coronary revascularization; AAR, ascending aorta replacement; AVR, aortic valve replacement; MVR, mitral valve replacement.

ventricular dysfunction,¹⁰ leading to better quality of life and improved survival rates among recipients.

The objective of the present study is to examine initial results of using the Cryolife O'Brien stentless prosthesis in aortic valve replacement, thru a prospective cohort study.

METHODS

From October 1993 to October 2004, 210 patients received a Cryolife O'Brien prosthesis in the aortic position in our service. Mean age was 70.9 (7.5) years (range 23-83); 185 patients (88.1%) were >65 years; 110 (52.4%) were men; 100 (47.6%) were women; 128 (60.9%) were in New York Heart Association (NYHA) functional class III-IV.

Perioperative data on patients appear in Table 1.

Sinotubular dilation, extensive calcification of the aortic root, and the unfavorable position of coronary ostia, were exclusion criteria for implantation of the prosthesis.

Implanted valve sizes were: 21 mm in 20 patients (9.5%); 23 mm in 61 (29%); 25 mm in 58 (27.6%); 27 mm in 56 (26.7%); and 29 mm in 15 (7.1%). In 129 patients (61.4%), valve size was ≥25 mm.

Mean extracorporeal circulation time was 83.68 (22) min for all series; 77 (16.7) min for isolated aortic valve replacement; and 109.5 (21.9) min for valve replacement combined with other procedures.

Mean aortic clamping time was 64.5 (18.4) min for all series; 58.2 (11.4) min for isolated valve replacement; and 89.1 (19.7) min for valve replacement combined with other procedures.

Valves Under Study

The Cryolife O'Brien stentless porcine xenograft (Cryolife International, Marietta, GA, USA) is a composite prosthesis, constructed from 3 noncoronary valves obtained from 3 porcine valves, fixed in glutaraldehyde under low or near-zero pressure. Valves are adjusted for size and symmetry to ensure synchronic opening and maximum coaptation. Once adjusted, the 3 valves are sewn together along the free edge of the aortic wall to the commissures. The base of the valve is sewn with a continuous suture to ensure its integrity. A significant difference by comparison with other stentless valves is the absence of any other type of artificial material.

In all cases, the prosthesis was implanted in supra-annular position, using continuous suture, as described elsewhere.¹¹ The size chosen was one size larger than that found when measuring the annulus with a Hegar dilator.

Echocardiography

Transthoracic echocardiography (TTE) was performed preoperatively, at discharge, at 6 months and at 12 months. Preoperatively and at discharge, studies were performed in the same hospital, but at 6- and 12 months they were not. These follow-up studies took place in patients' referring hospitals and the validity, and reliability of the measurements were determined by calculating the inter-class correlation coefficient for each parameter.

Left ventricular systolic and diastolic diameters, posterior wall in diastole, and interventricular wall in diastole were measured.

Left ventricular ejection fraction (LVEF) was calculated using the Teichholz formula. Peak and mean gradients were calculated with the modified Bernoulli equation. Effective area was calculated with the continuity equation.

Left ventricular mass (LVM), in grams, was calculated from measurements of interventricular wall (IVW) in diastole, posterior wall thickness (PW) in diastole, and left ventricular diastolic diameter (LVdD), all in centimeters, using The American Society of Echocardiography¹² modified cube method, as follow:

$$\text{LVM (g)} = 0.8 \{ 1.04 [(IVT + PW + LVdd)^3 - (LVdD)^3] \} + 0.6$$

Effective area and left ventricular mass values were indexed by body surface area in m².

Follow-Up

Follow-up required patients to attend outpatient clinics and, at the time of writing, 168 patients have attended

all check-ups; 16 (7.6%) have yet to complete 1 year of follow-up; and 4 (1.9%) have been lost to the study. Mean follow-up is 301.4 (8.4) days.

Following Edmunds et al,¹³ we collected data on morbidity and mortality after cardiac valve operations for subsequent publication.

Statistical Analysis

Statistical analysis was with SPSS 11.0 (Statistical Package for the Social Sciences, Chicago IL, USA). Continuous variables are presented as mean (SD) and categorical variables as percentages.

Continuous variables were analyzed with Student *t* test and χ^2 test, and discrete variables with Fisher exact test.

To detect significant changes in echocardiographic data over time we used Student *t* test for paired data in related samples.

Stepwise backward logistic regression was used to analyze predictors of in-hospital mortality. We analyzed the following variables: gender, age, chronic obstructive pulmonary disease (COPD), kidney failure, coronary heart disease, diabetes, high blood pressure, previous stroke, pulmonary artery hypertension (PAHT), preoperative atrial fibrillation, weight, height, body surface area, body mass index, extracorporeal circulation time, and aortic clamping time.

The percentage of complication-free patients at 1 year was calculated according to Kaplan-Meier.

In all cases, a *P* value less than .05 was considered significant.

RESULTS

In-hospital mortality at 30 days was 5.2% (11 of 210) for all series and 4.2% (7 of 167) for isolated aortic valve replacement. Six patients died of multiorgan failure, 1 of sepsis, 1 of hemorrhage, 1 of pulmonary embolism, 1 of respiratory insufficiency, and 1 of mesenteric ischemia.

Logistical regression analysis found in-hospital mortality was predicted by: extracorporeal circulation time >90 min; aortic clamping time >75 min; and preoperative atrial fibrillation. Presence of coronary heart disease was associated with increased mortality but was not statistically significant (Table 2).

Of 199 patients who survived surgery, 2 presented peripheral embolisms during the first year (1%): 1 in the humeral artery and 1 in the popliteal artery, at 2 days, and 5 months, respectively. These were non-anticoagulated patients who had presented atrial fibrillation. The episodes were resolved by embolectomy. At >1 year, 98.47% (0.88%) of patients were free of thromboembolic complications.

Three patients presented early prosthetic endocarditis (2%) at 2, 3, and 5 months, respectively, without prosthetic

TABLE 2. Factors Predicting in-Hospital Mortality*

Risk Factor	OR	95% CI	<i>P</i>	β
ECC >90 min	2.07	1.26-3.39	.002	.57
Aortic clamping >75 min	2.71	1.48-4.97	.007	.186
Preoperative AF	2.58	1.10-6.07	.045	.138
Coronary heart disease	2.15	1.06-4.34	.059	.130

*ECC indicates extracorporeal circulation; AF, atrial fibrillation; CI, confidence interval; OR, odds ratio.

dysfunction. These patients were reoperated, 2 for aortic annular abscess and 1 for sepsis not responding to antibiotic treatment. All 3 died following reoperation. At 1 year, 98.38% (0.93%) of patients were free of endocarditis.

Five patients have been reoperated (2.5%). Three of these (described above) were operated for prosthetic endocarditis; 1 had prosthetic stenosis due to defective implantation technique; 1 had mild periprosthetic insufficiency, and hemolytic anemia with substantial clinical repercussions. After 1 year, 97.22% (1.23%) of patients were free from reoperation.

During the first year, 9 patients (4.5%) died: 3 patients with prosthetic endocarditis died following reoperation; 1 sudden death; 1 had acute myocardial infarction; 1 had congestive heart failure; 1 had kidney failure; 1 had respiratory insufficiency; and 1 had a tumor. Survival at 1 year was 94.65% (1.65%).

Comparison of preoperative functional class with functional class at 12 months shows improvement in all 168 patients who have completed 1-year follow-up: 161 (95.8%) are in functional class I and 7 (4.1%) in functional class II.

At 1 year, aortic insufficiency was not present in 113 patients (67.3%), and was only trivial in 40 (23.8%) and mild in 15 (8.9%). Echocardiographic data are in Table 3.

Comparison of left ventricular diastolic diameter measurements showed significant reduction at discharge ($P<.001$) versus preoperatively. However, measurements at 6 and 12 months did not vary significantly by comparison with data collected at discharge.

Left ventricular systolic diameter measurements reduced significantly at discharge ($P=.008$) versus preoperatively. Data at 12-months showed further significant reduction versus data collected at discharge ($P=.049$).

We found a significant improvement ($P=.003$) in ejection fraction at 1-year versus preoperatively and at discharge ($P=.001$).

Interventricular wall in diastole showed significant reduction ($P<.001$) at 6 months versus preoperatively and at discharge ($P=.007$). Subsequent measurements did not vary significantly.

Posterior wall in diastole measurements reduced significantly ($P=.015$) at 6 months versus preoperatively.

TABLE 3. Echocardiographic Data*

	Preoperative (n=210)	At Discharge (n=199)	6 Months (n=188)	2 Months (n= 68)	P§	ICC
LVdD, mm	51 (9.4)	47.1 (10)†	47.5 (7.7)†	47.2 (7.3)†	<.0001	0.83
LVsD, mm	33 (9.6)	32.3 (10.3)†	31.1 (7.8)†	30 (7)†,‡	<.0001	0.85
EF, %	61.1 (14.2)	59.7 (14.9)	63 (12.6)	63.9 (11.7)†,‡	.003	0.76
IVWd, mm	15.1 (3.5)	15.1 (3.3)	13.7 (3.3)†,‡	13.2 (2.8)†,‡	<.0001	0.80
PWd, mm	13 (2.6)	13.2 (2.5)	12.2 (2.5)†	11.8 (2.4)†,‡	<.0001	0.75
LVM, g	307 (102)	282 (105)†	253 (97)†,‡	237 (78)†,‡	<.0001	0.79
LVMI, g/m ²	176 (58)	160 (60)†	143 (52)†,‡	136 (43)†,‡	<.0001	0.77

*ICC indicates inter-class correlation coefficient; LVdD, left ventricular diastolic diameter; LVsD, left ventricular systolic diameter; EF, ejection fraction; LVMI, left ventricular mass index by body surface area; LVM, left ventricular mass; PWd, posterior wall in diastole; IVWd, interventricular wall in diastole.

†Statistically significant versus preoperative data.

‡Statistically significant versus data at discharge.

§1-year follow-up versus preoperative data.

Data are presented as mean (SD).

We found further significant reduction at 1 year versus preoperatively ($P<.001$) and at discharge ($P=.026$).

Left ventricular mass reduced significantly at discharge ($P<.001$) versus preoperatively; and at 1 year versus discharge ($P=.007$).

Similarly, left ventricular mass index per m² of body surface area reduced significantly ($P<.001$), and reduction at 6 months was significant versus discharge ($P=.02$), although subsequent variation was not significant.

Mean transvalvular aortic gradient (Table 4) reduced significantly at discharge following valve replacement ($P<.001$); at 6 months this reduction continued ($P<.001$) versus discharge; and at 12 months, versus 6 months ($P=.007$).

Effective aortic area ($P<.001$) and effective aortic area index versus body surface area ($P<.001$) also improved significantly versus preoperatively; variation during the first year was not significant. Values of area and area index were optimal and were >0.8 cm²/m² in all patients.

DISCUSSION

Stentless aortic valve implantation was first reported in 1965, by Binet et al,^{1,4} and in 1966, by O'Brien and Clareborough.¹⁵ With the development of tissue fixing using glutaraldehyde and the relatively simple implantation of mounted prostheses, interest in stentless valves fell away; however, stented bioprostheses in the aortic position have the disadvantage that mechanical stress appears in the valve, which is associated with the stent and restrictive hemodynamic performance with relatively high residual gradients in small sized valves.¹⁶

To avoid these inconveniences of stented bioprostheses, a growing number of surgeons began to use aortic homografts. Independently, Ross¹⁷ in 1962 and Barrat-Boyes¹⁸ in 1964 started to implant homografts using the technique described previously by Duran and Gunning.¹⁹

However, the availability of homografts is limited by the scarcity of donors. In 1988, David et al²⁰ reintroduced the use of stentless porcine bioprostheses fixed in glutaraldehyde. The composite porcine valve reported by O'Brien and Clareborough¹⁵ in 1966, was reintroduced in 1991 with glutaraldehyde used for preservation.²¹

Aortic valve replacement with stentless bioprostheses is associated with excellent hemodynamic performance and clinical course,^{22,23} despite the greater technical complexity. The presence of residual gradient elevation continues to be the most important factor in the persistence of left ventricular hypertrophy after aortic valve replacement. Absence of the stent and greater effective areas ensure low residual obstruction, as shown by low postoperative gradients and rapid regression of left ventricular hypertrophy, even in patients with small aortic annulus.

Limitations of the Study

Our study does have certain limitations. First, we have not compared this prosthesis with any other type of valvular replacement. The short follow-up period has prevented us from obtaining information about the durability of this type of prosthesis. Echocardiographic data corresponding to 6- and 12-month follow-up were obtained in 4 hospitals and, therefore, by different observers; consequently, we analyzed the reliability of these measurements by calculating the inter-class correlation coefficient for each parameter.

CONCLUSIONS

Both ventricular diameter and left ventricular mass show substantial early reduction, and these changes are significant in the echocardiographic study performed at discharge, some 5 to 7 days postoperation; this reduction continues consistently during the first year.

TABLE 4. Changes in Mean Aortic Transvalvular Gradient, Effective Aortic Area, and Body Surface Area Index*

	Preoperative (n=210)	At Discharge (n=199)	6 Months (n=188)	1 Year (n=168)	P§	ICC
mG, mm Hg	50.7 (21.9)	12.8 (9.2)†	9 (6)†,‡	7.8 (4.1)†,‡,§	<.0001	0.86
EAA, cm ²	0.67 (0.4)	1.93 (0.9)†	2.21 (0.8)†	2.14 (0.7)†	<.0001	0.75
EAAI, cm ² /m ²	0.38 (0.2)	1.11 (0.5)†	1.27 (0.4)†	1.32 (0.9)†	<.0001	0.75

*EAA indicates effective aortic area; EAAI, effective aortic area index by body surface area; ICC, inter-class correlation coefficient; mG, mean gradient.

†Statistically significant versus preoperative data.

‡Statistically significant versus data at discharge.

§Statistically significant versus data at 6 months.

||1-year follow-up versus preoperative data.

Data are presented as mean (SD).

Using the Cryolife O'Brien xenograft presents some specific advantages by comparison with other stentless prostheses. For example, implantation is simpler and faster due to the use of a single suture, resulting in only slightly longer extracorporeal circulation and aortic clamping time than in the conventional stented prosthesis. This benefits older patients, particularly if they receive other associated procedures.

Secondly, supraannular implantation permits the use of a larger size than could be deployed in a conventional bioprosthesis, with greater valvular orifices and lower residual gradients; this is also favored by absence of ventricular muscle in the base of the prosthesis. In our series, data on mean gradients and effective aortic area are similar to those reported elsewhere^{24,25} and better than published data on other types of third generation stented porcine prosthesis.²⁶

Even though the durability of these valves remains to be determined, they show excellent hemodynamic performance and are a good choice for aortic valve replacement in patients previously selected for bioprosthesis implantation, in particular for patients with a small aortic annulus, as found in degenerative aortic valve stenosis in the older patient.

REFERENCES

- Monrad ES, Hess OM, Murakami T, Nonogi H, Corin WJ, Krayenbuehl HP. Time regression of left ventricular hypertrophy after aortic valve replacement. *Circulation*. 1988;77:1345-55.
- Sidiropoulos A, Hotz H, Tschesnow J, Konertz W. Stentless porcine bioprostheses for all types of aortic root pathology. *Eur J Cardiothorac Surg*. 1997;11:917-21.
- Cohen G, Christakis GT, Butz KJ, Joyner CD, Morgan CD, Sever JY, et al. Early experience with stentless versus stented valves. *Circulation*. 1997;96 Suppl:76-82.
- Taniguchi KT, Nakano S, Kawashima Y, Sakai K, Kawamoto T, Sakaki S, et al. Left ventricular ejection performance, Wall stress and contractile state in aortic regurgitation before and after aortic valve replacement. *Circulation*. 1990;82:798-807.
- He GW, Grunkemeier GL, Gately HL, Furnary AP, Starr A. Up to 30-year survival after aortic valve replacement in the small aortic root. *Ann Thorac Surg*. 1995;59:1056-62.
- O'Brien MF, McGiffin DC, Stafford EG. Allograft aortic valve implantation: techniques for all types of aortic valve and root pathology. *Ann Thorac Surg*. 1989;48:600-9.
- Jin XY, Gibson DG, Yacoub MH, Pepper JR. Perioperative assessment of aortic homograft, Toronto stentless valve, and stented valve in the aortic position. *Ann Thorac Surg*. 1995;60 Suppl:395-401.
- Jin XY, Pillai R, Westaby S. Medium term determinants of left ventricular mass index after stentless aortic valve replacement. *Ann Thorac Surg*. 1999;67:411-6.
- Collinson J, Flather M, Coats AJ, Pepper JR, Heneim M. Influence of valve prosthesis type on the recovery of ventricular dysfunction and subendocardial ischaemia following valve replacement for aortic stenosis. *Int J Cardiol*. 2004;97:535-41.
- Collinson J, Flather M, Pepper JR, Heneim M. Effects of valve replacement on left ventricular function in patients with aortic regurgitation and severe ventricular disease. *J Heart Valve Dis*. 2004;13:722-8.
- O'Brien MF. The Cryolife O'Brien composite aortic stentless xenograft: surgical technique of implantation. *Ann Thorac Surg*. 1995;60:S410-3.
- Devereaux RB, Alonso DR, Lutas EM, Gottlieb GJ, Sachs I, Reichek N. Echocardiographic assessment of left ventricular hypertrophy: comparison to necropsy findings. *Am J Cardiol*. 1986;57:450-8.
- Edmunds LH, Clark RE, Cohn LH, Miller DC, Weisel RD. Guidelines for reporting morbidity and mortality after cardiac valvular operations. *J Thorac Cardiovasc Surg*. 1988;96:351-3.
- Binet JP, Duran CG, Carpentier A, Langlois J. Heterologous aortic valve transplantation. *Lancet*. 1965;2:1275.
- O'Brien MF, Clareborough JK. Heterograft aortic valve transplantation for human valve disease. *Med J Aust*. 1966;2:228-30.
- Johnson A, Thompson S, Vieweg WVR, Daily P, Oury J, Peterson K. Evaluation of the in vivo function of the Hancock porcine xenograft in the aortic position. *J Thorac Cardiovasc Surg*. 1978;76:599-605.
- Ross DN. Homograft replacement of the aortic valve. *Lancet*. 1962;2:487.
- Barrat-Boyes BG. Homograft aortic valve replacement in aortic valve incompetence and stenosis. *Thorax*. 1964;19:131-50.
- Duran CG, Gunning AJ. A method for placing a total homologous aortic valve in the subcoronary position. *Lancet*. 1962;2:488-9.
- David TE, Ropchan GC, Butany JW. Aortic valve replacement with stentless porcine bioprostheses. *J Cardiac Surg*. 1988;3:501-5.
- O'Brien M. Composite stentless xenograft for aortic valve replacement: clinical evaluation of function. *Ann Thorac Surg*. 1995;60:S406-9.
- Bach DS, Goldman B, Verrier E, Petrcek M, Wood J, Goldman S, et al. Eight-year hemodynamic follow-up after aortic valve

- replacement with the Toronto SPV stentless aortic valve. *Semin Thorac Cardiovasc Surg.* 2001;13 Suppl 1:173-9.
23. Westaby S, Horton M, Jin XY, Katsumata T, Ahmed O, Saito S, et al. Survival advantage of stentless aortic bioprostheses. *Ann Thorac Surg.* 2000;70:785-91.
24. Martinovic I, Everlien M, Farah I, Wittlinger T, Knez I, Greve H, et al. Midterm results after aortic valve replacement with a stentless bioprosthesis aortic valve. *Ann Thorac Surg.* 2005;80:198-203.
25. Gelsomino S, Frassani R, Porreca L, Morocutti G, Morelli A, Livi U. Early and midterm results of model 300 Cryolife O'Brien stentless porcine aortic bioprosthesis. *Ann Thorac Surg.* 2001;71 Suppl: 297-301.
26. Fradet GJ, Bleese N, Burgess J, Cartier PC. Mosaic Valve International Clinical Trial: early performance results. *Ann Thorac Surg.* 2001;71:S273-7.