The CryoLife-O’Brien Composite Stentless Porcine Aortic Xenograft Valve in 118 Patients

R. Bruce Garlick, FRACS; Mark F. O’Brien, FRCS, FRACS

The CryoLife-O’Brien stentless valve is a composite trileaflet porcine aortic valve. It is assembled from 3 non-coronary leaflets and has no foreign material support. It is therefore truly stentless. From December 1992 to January 1996, 118 patients with aortic valve replacement had a CryoLife-O’Brien stentless valve inserted at the Prince Charles Hospital, Brisbane. The mean age was 73 years (range 59–89) and 54% were men. Most patients had aortic stenosis secondary to a calcific degenerative valve. Follow-up is 100% with hematological and echocardiographic studies before discharge, at 6 months, and at 12–18 months. Five deaths (2 early and 3 late) have occurred and morbidity includes 3 strokes, 1 peripheral embolism, 3 perivalvular leaks, and 1 patient with late endocarditis. Valve performance has been good, with low transvalvular gradients and only a trace or no regurgitation in over 95% of patients after 18 months. No structural deterioration or hemolysis has occurred. Echocardiographic surveillance confirms a very effective central orifice. Short-term results show that the overall performance of the CryoLife-O’Brien stentless valve has been very satisfactory, with low mortality and morbidity in this elderly group of patients. The benefits include the absence of prosthetic material, wide leaflet coaptation, and a quick and easy insertion. Long-term anticoagulation is not necessary. It is particularly suitable for elderly patients with a symmetrical aortic root.

Key Words: Aortic valve replacement; Stentless porcine xenograft

The CryoLife-O’Brien (CryoLife International, Marietta, GA) stentless porcine aortic valve xenograft is a composite graft constructed from the noncoronary leaflets of 3 porcine aortic valves. This design arose from experience in the use of porcine xenografts in the mid-1960s when the muscle-based right coronary leaflet of the whole porcine xenograft valve was found to cause valve distortion, leading to postoperative incompetence. Although subsequent degeneration of these early composite valves occurred as a result of inadequate preservation with formaldehyde, important observations included the absence of leaflet dehiscence from the sutured commissure and no separation from the host wall using the single continuous supra-annular implantation technique. Subsequent studies showed that the durability of stentless valves was greater than that of stented valves.

Now, following a return to this composite valve in 1991, leaflets are excised from valves fixed in 0.35% glutaraldehyde under 2–3 mmHg pressure. They are matched for size and symmetry to ensure maximum leaflet coaptation and then sutured together along the free outer edges of the aortic wall at the back of the leaflet commissure (Fig 1).

As there is no Dacron or artificial support, foreign body reaction and the potential for infection are minimized. The xenograft aortic wall is used for suture fixation and is therefore minimized in breadth. The maximum effective orifice area is obtained, especially with supra-annular implantation.

Implantation Technique

At operation, after instituting cardiopulmonary bypass and cardioplegic arrest with antegrade and retrograde blood or crystalloid cardioplegia, the aortic valves are completely excised leaving no annular ridge. A valve 1 size larger (ie, 2 mm) than the host valve annular diameter is used. For example, for a 23-mm host valve annulus measurement, a 25-mm stentless graft is selected and washed for 6 min. This larger size of valve ensures maximal leaflet coaptation. It is implanted in the supra-annular position to obtain

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Department of Cardiac Surgery, The Prince Charles Hospital, Brisbane, Australia
Mailing address: Mark F. O’Brien, Cardiac Surgeon-in-charge, The Prince Charles Hospital, Rode Road, Chermside QLD 4032, Australia

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maximum valve orifice and to ensure streamlined flow from ventricle to aorta.

As the valve is constructed to have only supravalvular aortic tissue, a single suture line has proved to be feasible and sufficient. Three equidistant polypropylene sutures are placed in a supra-annular position at the midpoint of each sinus and through the corresponding points of the xenograft aortic wall. The valve is lowered into position and the sutures are tied, allowing equal lengths of suture for continuous fixation (Fig 2). To avoid leaflet damage the suture needle is passed from within out, ie, through first xenograft and then host aortic wall, proceeding to the top of the commissures (Fig 3). Virtually the full width of the xenograft aortic wall is taken in each suture in order to prevent any tissue projecting into the ventricular cavity. The sutures are then tied on the outside of the aorta. If the sinotubular junction is small, direct closure of the aortotomy may draw the anterior and posterior commissures together, causing leaflet distortion. A fresh autologous pericardial patch enlargement aortoplasty will prevent this? Recent experience has shown that a transverse aortotomy completely abolishes the need for an aortic pericardial patch.

Patients and Methods

From December 1992 to January 1996, 118 patients received the CryoLife-O'Brien porcine xenograft for aortic valve replacement. The mean age was 72.9 years, median age was 73 years (range 59–89 years) and 54% were men. Valve stenosis was the predominant lesion occurring in 107 patients. Ten patients had stenosis and incompetence and 1 patient had incompetence alone. The etiology was calcific degenerative trileaflet disease in 70 patients, congenital bicuspid disease in 43 and rheumatic valve disease in 4; 1 patient had a replacement of a Hancock xenograft.

Concomitant surgical procedures were carried out in 64 patients (54%); 56 patients had coronary artery bypass procedures (2 patients had a mitral valve annuloplasty as well), 5 patients had mitral valve surgery alone, and 4 patients had a left ventricular myectomy. The commonest implanted sizes of the
composite xenograft valve were 25 mm and 27 mm (range 21–29 mm).

Follow-up, clinically or by telephone, has been 100%. Echocardiographic data were obtained before discharge from hospital, at 6 months, and at 12–18 months, with measurements of peak and mean aortic gradients, degree of regurgitation, aortic valve area and the dimensionless severity index (DSI). The DSI is the ratio of left ventricular outflow tract velocity ($V_1$) to the peak velocity immediately above the aortic valve ($V_2$) (DSI=$V_1/V_2$). It is independent of cardiac output and left ventricular hypertrophy or muscle obstruction. It is more easily obtained than valve area and serves as a fingerprint for an individual’s prosthesis for future comparison. Hematological studies were obtained on the same occasions to exclude hemolysis.

Results

Mortality

The hospital survival was 98%. Two early deaths occurred. One patient died a few hours postoperatively from intra-abdominal bleeding following intra-aortic balloon pump insertion. The second patient died on the second postoperative day following ascending aortic dissection. There were no valve-related deaths.

Three late deaths have occurred. A 67-year-old man developed staphylococcal valve endocarditis on the xenograft valve 15 months after valve implantation. This was complicated by an aortic root abscess, and after replacement with a mechanical prosthesis he died of multiple organ failure secondary to continuing sepsis. One patient died following an acute myocardial infarction at 2 years and 1 patient, who had had pre- and perioperative strokes, died at 2 years after a further stroke.

Morbidity

Three patients required insertion of an intra-aortic balloon pump for low cardiac output syndrome. Two of these 3 patients survived without further morbidity. In retrospect these patients may have benefited from left ventricular myectomy to relieve possible muscular outflow impedance. Three patients required exploration for postoperative bleeding. Three patients had cerebrovascular accidents - perioperatively in 1 patient who had suffered 2 previous strokes, 1 on the fourth day post-operatively and in the other 6 weeks after operation. One patient had a femoral embolus at 3 weeks. All these patients with postoperative systemic embolism were in atrial fibrillation and not anticoagulated (the policy now is to recommend anticoagulation for 3 months).

Three patients have had paravalvular leaks. Two required reoperation. In 1 the suture had broken, probably as a result of calcium deep in the annulus (third month postoperatively) and in the other the cause was a loose suture (second week postoperatively). Both were successfully repaired. On each occasion at operation the valve appeared satisfactory and subsequent echocardiograms have shown abolition of the perivalvular leak.

There has as yet been no evidence of structural deterioration of a valve or hemolysis.

Valve Performance (Tables 1 and 2)

At 1 week the mean aortic valve gradient was 10
mmHg. This declined slightly (but not significantly) with time and at 18 months was 8.4 mmHg. The mean gradient for the 23-mm valve (21-mm host annulus) was 13.3 mmHg. Effective orifice areas were 1.8 cm² for the 23-mm valve (21-mm host annulus) and greater than 2 cm² for the larger valves. As expected, the effective orifice area did not change with time. The DSI was between 0.49 and 0.53 for all valves and did not change over the 18 months. At 1 week 95% of valves exhibited only a trace or no regurgitation. At 18 months no valve exhibited any significant regurgitation.

### Discussion

Whereas the allograft is thought to be the ideal replacement for the aortic valve, its use is largely limited by its lack of availability. Over the last 6–7 years the stentless xenograft has emerged in a variety of forms with some of the attributes of the allograft. The effective orifice area of the stentless valve is greater than that of the stented bioprosthesis, thus improving the hemodynamic performance, especially when implanted in the small aortic root. Although longer durability is anticipated owing to better distribution of physical forces during leaflet movements of the stentless xenograft, this is yet to be proven.

The designs of the available stentless xenografts differ in the amount of retained xenograft aortic wall and the amount of Dacron support. In some valves support is found only around the base of the right coronary cusp (Edwards Prima and Medtronic Freestyle) and in others as a jacket around a scalloped valve (Toronto SPV). These differences dictate specific implantation techniques such as supra-annular subcoronary, intraluminal cylinder, or as a root replacement. A double suture line technique is generally required with these other valves.

The CryoLife-O’Brien valve is the only stentless xenograft with no Dacron support. The xenograft aortic wall above the valve is minimized and there is virtually no xenograft tissue beneath the leaflets. Thus, a single suture line is sufficient for implantation. This technique simplifies insertion, reducing cross-clamp and ischemic times. Hvass et al reported a cross-clamp time of 40 min for isolated aortic valve replacement (AVR) and 65 min for AVR/coronary artery bypass graft (CABG). It is important that the valve be placed in the supra-annular position to obtain maximum orifice area and to ensure streamlined flow from ventricle to aorta. Compared with stented xenografts, the stentless valve implanted into the supra-annular position may well be 2 sizes larger. For a host annulus of 25 mm, a stented xenograft of 23 mm would be inserted (or perhaps a 25-mm supra-annular Carpentier Edwards stented porcine valve), whereas a size 27 CryoLife-O’Brien stentless valve would be implanted.

Care must be taken when considering the use of stentless xenografts in young patients. There is no evidence as yet that these valves are as good or better than the allograft or mechanical valves. Nor is there any evidence that the poor performance of the stented bioprosthesis in the young will not be repeated with the stentless valve. We have used the CryoLife-O’Brien stentless valve only in the elderly (mean age
73 years), most of whom have acquired trileaflet degenerative calcific aortic stenosis. The aortic root in these patients is symmetrical, in contrast to the bicuspid valve in younger patients, in whom a deep noncoronary sinus may distort the stentless valve in the subcoronary position, leading to regurgitation. Although insertion of the valve as an intraluminal cylinder or complete root may partly or fully overcome this problem, the fate of the extra-aortic xenograft tissue in these younger patients is unknown. Significant calcification of the excessive xenograft tissue may develop, making reoperation a difficult procedure.

The large host aortic root (with an annular measurement >30 mm) is a specific contraindication to the use of the CryoLife-O'Brien valve. Extreme calcification of the aortic root and sinus wall around the coronary arteries may preclude the use of all stentless valves. Such calcification would certainly make implantation difficult.

This study confirms the good early results of the CryoLife-O'Brien valve and the results compare favourably with the results obtained with other stentless valves. The transvalvular gradients are universally low - the 23-mm valve in a 21-mm annulus has a mean gradient of 13.3 mmHg with an effective orifice area of 1.8 mm². More importantly however, the DSI has been measured for each valve for future comparison and so far there have been no changes. We believe that this is a more accurate measurement of a valve's performance as it is independent of cardiac output or left ventricular hypertrophy. By selecting a valve 2 mm larger than the host annulus and careful selection of patients avoiding the asymmetric root, aortic regurgitation has been no greater than mild in any patient. Two significant periprosthetic leaks have been the only technical problem with implantation. These occurred early in the series, and in both patients the leaks were repaired successfully.

**Conclusion**

The early results of the CryoLife-O'Brien valve have been most satisfactory. The good results in this series confirms the report by Hvass et al of 150 similar implants. Morbidity and mortality of valve implantation are low. The valve has been found to have excellent hemodynamic features with low gradients, minimal regurgitation, and an effective orifice area greater than 2 cm². It has most of the advantages of an allograft valve, including no need for permanent anticoagulation. The implantation technique is simple and quick. The elderly patient with calcific degenerative aortic valve stenosis - in whom the aortic root and valve annulus are generally asymmetrical - appears to be the ideal candidate. Although greater durability is anticipated, long-term (10–12 years) follow-up is required.

**References**