

The Liotta-BioImplant LPB

6 year follow-up

Flexible stent

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One of the major achievements in cardiac surgery over the past 20 years has been the replacement of severely diseased heart valves with prostheses. Mechanical and tissue valves prostheses were developed almost simultaneously. Although no single prosthesis type has proven to be ideal for valve replacement, both types have proven palliative for a great number of patients.

In general, mechanical valves have a tendency to produce thromboembolic complications, therefore requiring an anticoagulant treatment for indefinite periods of time. However, the durability of this valve substitute, while less than ideal, does seem to be acceptable.

Tissue valves, on the other hand, are generally less prone to thromboembolism and do not require permanent anticoagulant therapy. However, questions on durability persist, and although most recent types have shown better results, the length of their clinical evaluation is still too short to produce more than tentative answers. The major problem of the biological valves has been the failure resulting from tissue alterations. The tanning of porcine aortic valves with glutaraldehyde has resulted in improved late results.

Extensive, independent studies of the functional anatomy of the porcine aortic valve were carried out in our Hospital. These studies demonstrated that the porcine commissures do not rise as high as they appear to do when bioprostheses are mounted on long struts.

On the basis of these observations, a method for supporting the porcine valve was devised to approximate more closely the normal porcine anatomy. This mounting technique resulted in a low profile valve with a greater valve orifice and lower transvalvular gradient than other porcine bioprostheses. As a result of the anatomic simulation, we reasoned that stress on the bioprostheses would be lessened and long term durability improved.

Initially, stents were made of metal, but since 1978, they have been made of a highly flexible acetalic resin (Delrin). The external and internal surfaces are covered with a tubular seamless piece of high porosity medical grade Dacron fabric. Only valves mounted on flexible stent are considered in this study.

Late follow-up

This late follow-up study (6-72 months, to December 1984) includes 297 valves implanted in 279 pts (178 men, 101 women) operated from November 1978 through December 1983; mean age was 53.8 years (range: 17-76 years); aortic valve replacements (AVR) 132; mitral valve replacements (MVR) 129; double valve replacements (DVR) 18 (Table 1).

Actuarial curve revealed at 72 months a late patient survival of $78.48\% \pm 5.68\%$ for AVR, $86.27\% \pm 4.3\%$ for MVR and $77.78\% \pm 12.2\%$ for DVR (fig. 1); 93.6% of AVR pts and 81% of MVR pts remain in NYHA class I postoperatively (fig. 2).

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TABLE 1

CLINICAL DATA

NBR OF PATIENTS	279
-MALE	178
FEMALE	101
MEAN AGE	53.8 YEARS (17-76)
NUMBER OF VALVES IMPLANTED	297
AORTIC VALVE REPLACEMENTS	132
MITRAL VALVE REPLACEMENTS	129
DOUBLE VALVE REPLACEMENTS	18

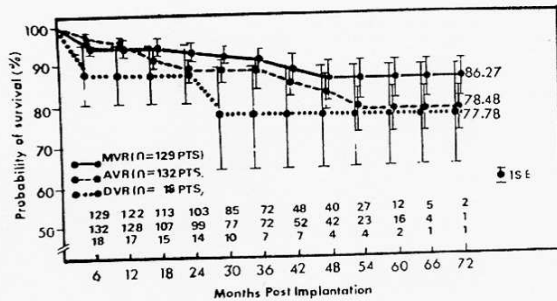


FIG. 1: Liotta-BioImplant LPB. Late mortality

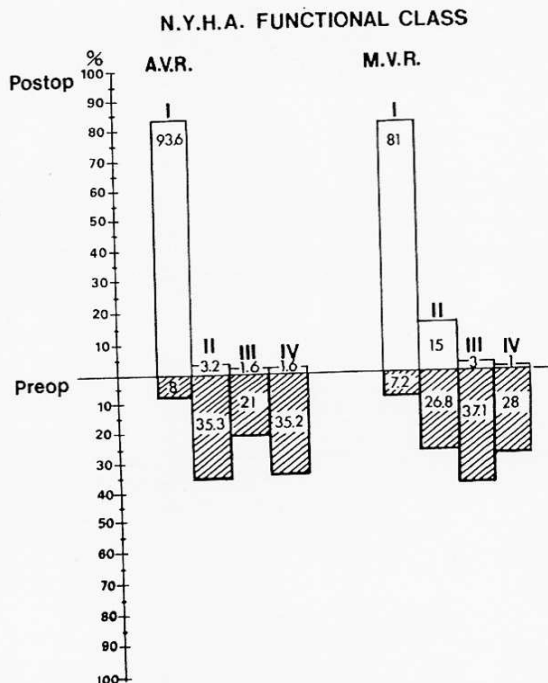


FIG. 2: Preoperative and postoperative New York Heart Association classifications

Endocarditis

At 72 months the actuarial probability of freedom from endocarditis is:

AVR = 97.06% ± 2.0%; MVR = 96.03% ± 3.0%; DVR = 100%

Two patients with AVR suffered from prosthetic endocarditis between the 2nd and the 7th follow-up semester: 1 patient underwent reoperation but the 2 pts died. Two out of the 129 pts with MVR suffered endocarditis (1 died after reoperation). There was no endocarditis out of the 18 pts with DVR (Figure 3).

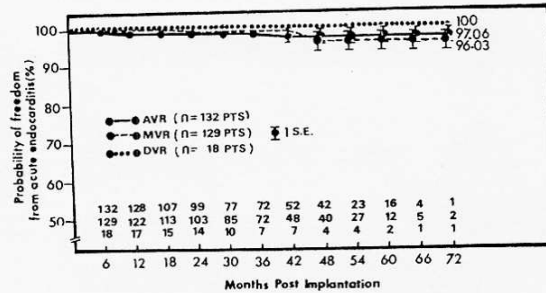


FIG. 3: Freedom from endocarditis

Thromboembolism

Since there is no clear-cut standard in the literature concerning the definition of thromboembolism after heart valve replacement, we have applied the following criteria to our statistical analysis: All new episodes of focal neurologic deficit, either transient or permanent as well as all peripheral arterial emboli were considered to be thromboembolic complications related to the prosthesis. Furthermore, patients who awoke with a focal neurological deficit, following valve replacement, were considered to have a prosthetic related thromboembolic episode (Figure 4).

Freedom from thromboembolism at 72 months was:

AVR = 97.52% ± 1.38%; MVR = 94.11% ± 2.97%; DVR = 100%

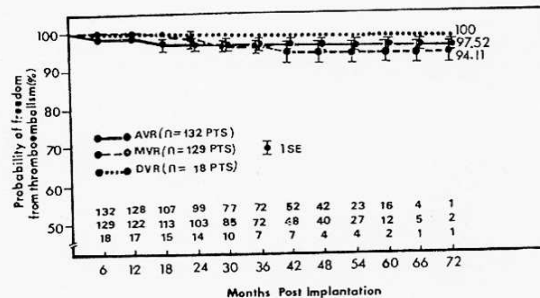


FIG. 4: Freedom from thromboembolism

Four patients with MVR suffered from embolic episodes, the 4 were on anticoagulants during the acute episode. Three of them had atrial

fibrillation and one was in normal sinus rhythm. The events occurred on the 3rd, 4th, 5th and 7th semester, the four patients survived.

Three patients with AVR suffered from embolic episodes, one during the 1st semester of follow-up. All of them had aortic insufficiency preoperatively with enlarged left ventricles and cardiothoracic indexes of 0.56 - 0.60. Two of them were receiving treatment when the embolic complications occurred.

One patient was in atrial fibrillation preoperatively, he remained in atrial fibrillation when discharged from the hospital, and developed a central vascular accident. He died later of bacterial endocarditis.

No embolic complications were reported in patients with DVR (18 pts).

Primary tissue failure

Patients are considered to have spontaneous degeneration of the bioprosthesis (primary tissue failure) when valve incompetence or stenosis was demonstrated by clinical examination or cardiac catheterization. The degenerative changes were confirmed on gross or histologic examination of the explanted valve.

Excluded from this study are:

- The postoperative development of new regurgitant murmurs, confirmed by left ventricular angiography and revealed during surgery to be a periprosthetic leak.
- Patients with clinical, bacteriological or histological evidence of endocarditis.
- Asymptomatic patients showing some calcification or deterioration of the porcine valve, suspected by periodic echocardiographic evaluation.

Actuarial curves for primary tissue failure were basically constructed according to surgical pathologic findings and examination of the explanted valve.

In the total group (279 pts) freedom from primary valve degeneration at 72 months was: AVR = 93.70% ± 3.6%; MVR = 100%; DVR = 100% (Fig. 5).

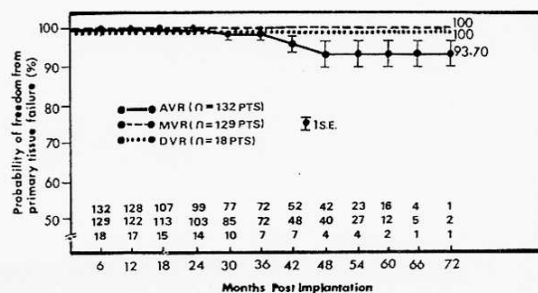


FIG. 5: Freedom from primary tissue failure

Only three aortic pts developed tissue degeneration (calcification, valve rupture). One 26 years old patient, had calcification and prosthetic insufficiency on the 8th semester of follow-up; 2 pts, 61 and 62 years old, showed primary tissue degeneration on the 5th and 7th semester. The last one is undergoing calcium metabolism tests to study this extremely unusual prosthesis calcification (for his age group).

In aortic patients over 35 years old, freedom from tissue degeneration is 96.21% ± 2.7% at 72 months. In patients under 35 years old only one event was observed out of 7 patients, bearing no statistical significance (freedom from tissue failure under 35 years old: 77.78% ± 19%) (Fig. 6).

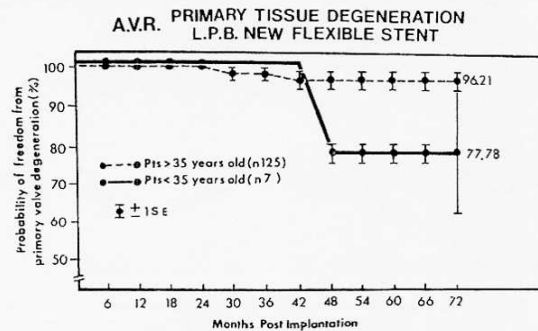


FIG. 6: Freedom from primary tissue failure in AVR. Age factor.

In mitral and double valve replacement there are no recorded events for primary tissue degeneration.

Discussion

The low profile Liotta-Bioimplant bioprosthesis for cardiac valve replacement consists of a highly flexible plastic stent supporting a porcine aortic cardiac valve, fixed with glutaraldehyde. The low profile support of this bioprosthesis was designed in accordance with anatomical findings of the normal porcine aortic valves (1). Based on this anatomical findings, a unique support was designed with three main features: 1) low profile (reduced height in relation to the frame diameter); 2) wavy shape at the inlet opening and 3) a wavy conformation of the sewing ring. The wavy shape of the sewing ring includes highly flexible commissural struts and allows the commissures of the bioprosthesis to be sewn directly into the annulus of the patient. The functional motion of the patient's annulus during the cardiac cycle is thereby transmitted to the implanted commissures. Low struts also avoid protruding components of the bioprosthesis, either into the left ventricular cavity or into the ascending aorta. Such myocardial-

bioprosthetic disproportion is currently seen when long strut bioprostheses are employed. It can be easily demonstrated during double valve replacement.

From the outset, we have been aware that many variables can be introduced during the preparation of a valve, especially by the manufacturer. For this reason, the manufacturers of the Liotta-BioImplant LPB have been carefully supervised by surgeons. The time from removal of the valve until it is sterilized and fixed has been controlled by the manufacturer to between 4 and 6 hours. Carpentier and Angell have recently reported their experience regarding the variables of valve preparation (2-3).

The hemodynamic data obtained from 40 patients demonstrate that gradients are quite similar to other series (4).

It is reasonable to suppose that when the volume of the prosthetic components are reduced from both the left ventricular cavity and the ascending aorta, the risk of thromboembolic complications would be decreased (5). Furthermore, in the mounting technique of Liotta-BioImplant LPB, the porcine aortic ring is directly sutured to the stent inlet opening contributing to a decreased exposure of prosthetic surfaces to the blood stream.

It is well established that an enlarged left atrium with atrial fibrillation increases the risk of thromboembolic complications.

In our institution warfarin anticoagulation therapy is indicated in the absence of specific contraindications during 3-6 months following MVR: approximately 40% of the patients with atrial fibrillation remained on anticoagulation therapy after one year.

During the same period of time (1978-1984), mechanical prosthesis were implanted in 35% of MVR patients and 45% of the AVR patients. However, adequate anticoagulation is not always possible. It must be recognized that the specific risks associated with anticoagulants interfere with the patient's quality of life. Furthermore, the serious danger of warfarin or heparin embriopathy (6) in young females cannot be neglected.

We continue to use the porcine bioprosthesis Liotta-BioImplant LPB as our first choice in cardiac valve replacement. Bioprosthetic dysfunction can be monitored well clinically and, in fact, can be predicted with echocardiography. In our experience, catastrophic events do not occur when bioprosthetic dysfunction ensues. Reoperation can be accomplished safely and

with a low mortality.

At present time, we considered the stent design (rigid or flexible) plays an important role in tissue stress. Good stent flexibility and design yields a lower incidence of tissue degeneration. On the other hand, the age factor is also very important. According to our experience and the literature (7-8), LPB is indicated only in pts over 35 years old. However, young females, under 35, should be considered for LPB implantation if pregnancy is possible.

In conclusion, the actuarial curves for endocarditis, thromboembolism and primary tissue degeneration show a low incidence of those events.

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