Medium term results of the Liotta-BioImplant low profile Bioprosthesis


The use of bioprostheses to replace diseased valves has become more prevalent in recent years. Problems that occurred with first generation replacements have, in recent years, given rise to models with improved characteristics.

The Liotta-BioImplant low profile valve is the culmination of such a research effort.

The evaluation of a new valvular substitute necessarily includes a short term study to investigate the handling properties and the expected theoretical advantages of the valve. This work has been previously reported. The second stage in the evaluation of a valvular substitute is a medium term study to assess its hemodynamic properties and clinical performance. These results for the Liotta-BioImplant are presented here.

Materials & methods

From February 1981 to December 1983, 207 Liotta-BioImplant low profile heterografts were implanted in 193 patients at Hôpital de la Pitié.

Sixty-two patients received an aortic valve replacement (AVR), one hundred and two a mitral valve replacement (MVR), twenty-two a double mitral-aortic replacement (DVR), and seven a tricuspid replacement (TVR).

The mean ages were: fifty-two years for both the AVR and MVR patient populations, fifty-one years for the DVR patients, and thirty-six years for the TVR patients.

There were no hospital deaths for the AVR and TVR operations. Nine deaths occurred during the MVR operations and one during the DVR operations, thus representing an overall surgical mortality rate of 5.2%.

Clinical follow-up

Post-operatively, patients were reexamined either by one of the authors or through the use of a bi-annual questionnaire filled out by the doctor or cardiologist treating the patient.

Thus, 183 patients were followed for periods ranging from 3 to 36 months, with a mean of 13.5 months, for a total of 2464 patient-months follow-up.

For the AVR cases, 62 patients were followed during 803 patient-months (mean follow-up: 13 months). For the MVR, 93 patients were followed during 1373 patient-months (mean follow-up: 14 months).

Late mortality

There were eight late deaths (4.37%); three with an AVR (4.83%), three with a MVR (3.22%), one with a DVR, and one with a TVR. The causes of death are summarized in Table 1.

<table>
<thead>
<tr>
<th>TABLE 1. LATE MORTALITIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>AGE</td>
</tr>
<tr>
<td>-----</td>
</tr>
<tr>
<td>AORTIC</td>
</tr>
<tr>
<td>70</td>
</tr>
<tr>
<td>49</td>
</tr>
<tr>
<td>72</td>
</tr>
<tr>
<td>MITRAL</td>
</tr>
<tr>
<td>70</td>
</tr>
<tr>
<td>71</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>65</td>
</tr>
<tr>
<td>MITRO</td>
</tr>
<tr>
<td>65</td>
</tr>
<tr>
<td>AORTIC</td>
</tr>
<tr>
<td>49</td>
</tr>
</tbody>
</table>

The actuarial survival rate of all follow-up patients is 94.33% ± 2.1 at 3 years (Figure 1).

It is 94.89% ± 2.88 at 3 years for the AVR patients (Figure 2) and 95.36% ± 2.27 for the MVR patients (Figure 3).

FIG. 1: Probability of survival for all patients (excluding surgical mortalities)
Thromboembolism

All patients were treated with anticoagulants for three months post-operatively, which was subsequently discontinued except where circumstances called for anticoagulant therapy: complete arrhythmia, giant left atrium history of thrombosis, etc...

To date 38% of the AVR patients and 46% of the MVR patients are under anticoagulant treatment.

Three cases of regressive thromboembolism have been observed, one at six months and two at ten months post-operatively (1.4 cases per 100 patient-years).

No valve trombosis was detected and no thromboembolic incidents were encountered with the AVR. Conversely, a regressive cerebral vascular accident occurred ten months post-operatively with an MVR in a 60 years old woman with complete arrhythmia and under anticoagulation treatment. Examination showed no thrombosis in the valve and confirmed the proper functioning of the prosthesis. The two other cases of regressive cerebral vascular thromboembolism occurred at six and ten months post-operatively in patients with a DVR aged 65 and 66 years respectively. Only one of these was under anticoagulation therapy.

Actuarial analyses show that 97.43% ± 1.39 of patients at 36 months were free of any of thromboembolic incidents (Figure 4).

Endocarditis

Three cases of prosthetic endocarditis were observed in this study (1.63%).

- One occurred in a 38 year old male patient with an AVR initially operated for rheumatic aortic insufficiency, but who also showed evidence of a streptococcus infection in systematic valve cultures. A para-valvular leak occurring at the fifth month post-operatively required the reconstruction of the aortic annulus using our technique (4) and the insertion of a Björk valve. A recurrence of the infection at the second month post-operatively necessitated reintervention to place a Björk valve in the supra-coronary position and to perform an aortocoronary bypass. Results have been favourable thus far at one year.

- A 71 year old male with an MVR using a 28mm Liotta-BioImplant valve initially operated for dystrophic mitral insufficiency. A para-valvular leak due to Escherichiacoli infection was detected six weeks post-operatively. At reintervention, the extent of the lesions in the mitral annulus prevented a standard implantation of a mitral valve and necessitated the use of an intra-atrial Liotta-Gandjbakhch (3) valve in the supra-annular position. Unfortunately, the patient died 25 days post-operatively.

- A 13 year old female with a para-valvular leak in a Starr valve which was replaced by a 28 mm Liotta-BioImplant valve. A new leak developed 30 days post-operatively requiring further surgery. Two more interventions were subsequently necessary to obtain stable healing to date at 2 years post-operatively.
A total of 98.18% ± 1.04 of the patients have been free of infections at 3 years (Figure 5).

![Graph showing probability of freedom from prosthetic infection.](image)

**FIG. 5:** Probability of freedom from prosthetic infection.

**Surgical reintervention**

Five patients have been reoperated, three due to endocarditis (discussed above) and two due to para-valvular leaking of the Liotta-BioImplant mitral valve.

The first patient, 49 years old, underwent DVR with a double aorto-coronary bypass in March of '81. A reoperation was required 7 months post-operatively due to a mitral para-valvular leak. The leak originated in the region of the posterior mitral leaflet.

The Liotta-BioImplant valve showed no deterioration and was replaced by another 28mm Liotta-BioImplant valve.

The second patient, 58 years old, underwent AVR in November of '82. Immediately post-operatively, an intense systolic murmur was heard indicating para-valvular leaking. Reoperation was necessary on the 30th day post-operatively, and a St. Jude valve was implanted.

In total, 97.43% ± 1.28 of the patients did not require any reoperation at 3 years post-operatively (Figure 6).

![Graph showing probability of freedom from reoperation.](image)

**FIG. 6:** Probability of freedom from reoperation.

**Primary tissue failure**

To date, no deterioration in valve function has been recorded with the Liotta-BioImplant bioprosthesis.

**Clinical results**

Table II shows the pre and post-operative functional status of the patient population. Pre-operatively the majority of the patients were in NYHA class III and IV, while post-operatively most were in NYHA class I or II. Post-operatively 98% of the AVR patients (Table IIa) and 89.2% of the MVR patients (Table IIb) were in classes I and II.

<table>
<thead>
<tr>
<th>Class</th>
<th>Pre</th>
<th>Post</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>5.8%</td>
<td>49%</td>
</tr>
<tr>
<td>II</td>
<td>33.4</td>
<td>49</td>
</tr>
<tr>
<td>IIIa</td>
<td>31.4</td>
<td>2</td>
</tr>
<tr>
<td>IIIb</td>
<td>21.6</td>
<td>0</td>
</tr>
<tr>
<td>IV</td>
<td>7.8</td>
<td>0</td>
</tr>
</tbody>
</table>

**TABLE IIa:** Patient status pre and post-operatively according to the NYHA classification scheme for patients with an aortic valve replacement (AVR).

<table>
<thead>
<tr>
<th>Class</th>
<th>Pre</th>
<th>Post</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>0</td>
<td>43.9%</td>
</tr>
<tr>
<td>II</td>
<td>11%</td>
<td>45.3</td>
</tr>
<tr>
<td>IIIa</td>
<td>46.6</td>
<td>10.8</td>
</tr>
<tr>
<td>IIIb</td>
<td>35.6</td>
<td>0</td>
</tr>
<tr>
<td>IV</td>
<td>6.8</td>
<td>0</td>
</tr>
</tbody>
</table>

**TABLE IIb:** Patient status pre and post-operatively according to the NYHA classification scheme for patients with a mitral valve replacement (MVR).

**Hemodynamic studies**

Post-operatively at one month and at one year, thirty-eight patients were catheterized.

After surgery both pulmonary capillary pressure and left ventricular volume were significantly decreased. Ejection volume substantially increased at one year, confirming the beneficial effects of surgery.

Twenty AVR patients were thus examined, and the average transvalvular aortic gradient was consistently found to be the same at one month and one year after surgery. It was found to be 12.4 mmHg ± 4.8 at rest and 17 mmHg ± 6.1 during exercise (Figure 7a). The increase in gradient between rest and exercise were found
both in the early and late catheterizations. Similarly the average aortic effective orifice area at rest (Figure 7b) was 1.6 cm² ± 0.3 while during exercise it increased to 2.0 cm² ± 0.3. This data remained constant at one month and at one year.

During the same period 18 MVR were examined. The average mitral transvalvular gradient was found to be low at rest, 5.9 mmHg ± 1.6. It increased significantly during exercise to 12 mmHg ± 1.3 (Figure 8a). The data was the same at one month and at one year post-operatively.
The average mitral effective orifice area was found to be 2.1 cm² ± 0.3 at rest and 2.9 cm² ± 0.5 during exercise (Figure 8b). Again, early and late results were similar. Average mitral effective orifice for 28mm valve area was 1.98 cm² (1.7 - 2.3) and 2.78 cm² (2.5 - 3.1) at rest and during exercise respectively. The same data for the 30mm valve was found to be 2.11 cm² (1.9 - 2.3) and 3.51 cm² (2.5 - 3.9) respectively.
Discussion

Analysis of clinical results of the Liotta-BioImplant low profile valve, both in the mitral and aortic positions confirms the expected theoretical advantages of this bioprosthesis.

The surgical mortality rate (5.2%) is comparable to results obtained using other valvular implants.

Surgical mortality rate though, is more dependent on the presurgical status of the patient rather than on valve type. Long term survival rate is a more significant indication.

In this serie the actuarial survival rate was 94.89% ± 2.88 and 95.36% ± 2.27 for the aortic and mitral replacements respectively.

These results compare favourably with those obtained with other biological and mechanical valves (1, 6, 11-14, 19).

During the follow-up period, there were 8 deaths unrelated to valve operation.

Low rates of thromboembolism with no need for anticoagulants is one of the principal advantages of a biological replacement over a mechanical one. In this study, approximately 7/9 of the patients were under no anticoagulation therapy at 3 months post-operatively.

Furthermore, a thromboembolic rate of 1.4 cases per 100 patient-years was found in this study, a rate comparable to that found with other bioprotheses (2, 5, 10, 18) and one significantly lower than with mechanical valves (2, 9, 11, 12).

No thromboembolism incidents occurred in patients with an AVR. Conversely, 3 cases occurred on patients under anticoagulant therapy.

Even though 50% of MVR patients had complete arrhythmias, the thromboembolism rate was relatively low. Three years post-operatively 97.43% ± 1.93 of all patients were free any thromboembolism.

There were three early cases of prosthetic endocarditis which were unrelated to valve design. The first was a case of recurring endocarditis, in the second case the infection was present in the diseased aortic leaflets of the patient, and in the third case early sepsis seemed to be caused by surgical contaminations. Nonetheless, 98.18% of the patients were free on infection three years after surgery.

A claimed disadvantage of biological valve replacement is their low durability. In this study no prosthetic deterioration or dysfunction of the Liotta-BioImplant bioprosthesis have yet been recorded. The implantation time to date though, is still insufficient to confirm that these results were due to the modifications done to the valve to improve its fatigue life.

Catheterization at one month and one year allowed the hemodynamic performance of the Liotta-BioImplant valve to be compared to those of other prostheses.

In the aortic position, the average transvalvular gradients were moderate at rest (12.4 mmHg ± 4.8) as well as during exercise (17 mmHg ± 6.1) and were independent of valve size. The average gradients were found to be lowest for the smallest valve (23mm), 13.5 mmHg (9 - 20) at rest and 20.3 mmHg (15 - 24) during exercise. The average aortic effective orifice area was found to be 1.6 cm² ± 0.3 at rest and 2.0 cm² ± 0.3 during exercise. This increase in functional surface area was the same at one month and one year post-operatively.

This data is comparable to that obtained with both porcine and pericardial valves (14, 15, 17, 20). The increase in effective orifice area with flow is an important property of the Liotta-BioImplant valve, which allows it to adapt to the increased cardiac output during exercise (15).

In the mitral position, there were similar encouraging results. A moderate transvalvular gradient at rest (5.9 mmHg ± 1.6) increased to 12 mmHg ± 1.3 during exercise. Furthermore, the effective flow area increased from 2.1 cm² ± 0.3 at rest to 2.9 cm² ± 0.5 during exercise. As in the aortic position, the effective orifice area of the valve increased during exercise, which allows it to adapt to exercise (15).

This data is comparable to that obtained with other biological substitutes thus confirming in-vitro hemodynamic studies (14, 16, 19, 20).

Conclusions

Medium term (3 years) results with the Liotta-BioImplant low profile implant are very encouraging, both in the aortic and mitral positions.

The thromboembolism rate is very low even without anticoagulation therapy.

The hemodynamic performance of this prosthesis is excellent both at rest and during exercise in the aortic or mitral position, even at small diameters.

The low rate of incidents related to the valve, as well as valve deterioration is encouraging for the long term prospects of this valve.
References


2) Edmunds L.H., Thromboembolic complications of current cardiac valvular prostheses. ANN. THORAC. SURG., 1982, 34, 96-106.


