The Liotta-BioImplant
Low profile bioprosthesis (LPB)
For mitral valve replacement

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Since their introduction in the early 70's, several new bioprostheses have been developed in order to provide better long term durability and to minimize calcifications.

Among the bioprostheses that were developed in recent years, the Liotta-BioImplant LPB (Low Profile Bioprosthesis) seems to meet most of the requirements for a satisfactory cardiac valve substitute.

This prosthesis presents two main features:

1) Low profile, obtained through a reduced height of the stent, a wavy shape at the inlet side and a wavy conformation of the sewing ring (Fig. 1).

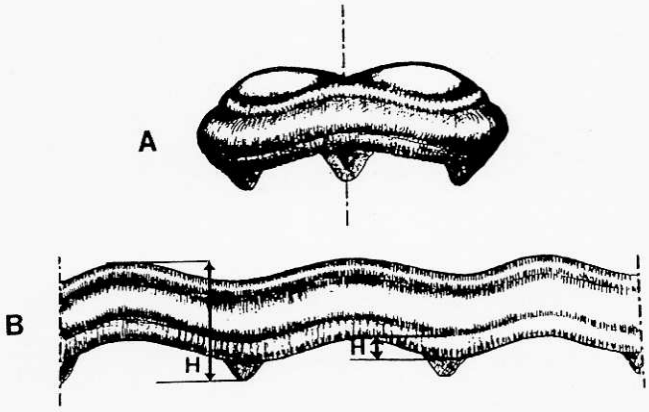

FIG. 1: Low profile bioprosthesis: note the wavy shape of the sewing ring
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2) A highly flexible stent (Delrin) with scalloped outline which transmits the functional motion of the natural annulus to the commissures of the implanted prosthesis reducing the fatique and chance of rupture at this level. The reduction of the height of the struts make these prostheses more compatible with the implantation in small ventricles in mitral position avoiding the injuries to the left ventricular wall and reducing the risk of outflow obstruction (1-2) (Fig. 2).

We present our 3-4 years experience with a series of patients receiving a Liotta-BioImplant LPB as a mitral valve replacement.

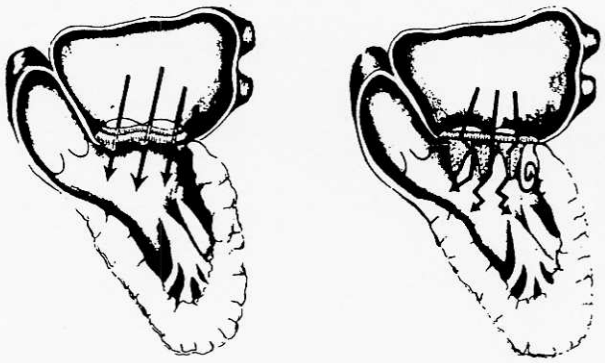

FIG. 2: Comparison between a Low Profile Bioprosthesis (LPB) and a conventional bioprosthesis. Reprinted from: J.A. Navia et Coll., European Heart Journal (1984) 5 (Suppl. D) 95-100

Patients and results

Between January 1980 and October 1981, 41 patients underwent mitral valve replacement with LPB at our institution. Pre-operative clinical data are listed in Table 1.

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TABLE 1. PRE-OPERATIVE CLINICAL DATA

NBR OF PATIENTS	41
- MALE	11
- FEMALE	30
AVERAGE AGE	52.61 (22-73)
NYHA CLASS II	6
III	22
IV	13
RHEUMATIC FEVER	33
DEGENERATIVE DISEASE	4
ISCHEMIC HEART DISEASE	2
INFECTIVE ENDOCARDITIS	2
SINUS RHYTHM	11
CHRONIC ATRIAL FIBRILLATION	30
MEAN CTR	0.59 + 0.59 (0.38 - 0.78)

NYHA: New York Heart Association
CTR: Cardio thoracic ratio

The anatomic lesions encountered are listed in Table 2.

TABLE 2. ANATOMIC LESIONS

PURE MITRAL STENOSIS	13
PURE MITRAL REGURGITATION	10
PREDOMINANT MITRAL STENOSIS	14
PREDOMINANT MITRAL REGURGITATION	4
	41

Associated lesions were present in 17 patients as aortice valve disease or tricuspid disease. Eight of these patients presented a triple valvular involvement.

Two-dimensional echocardiography performed in 31 patients showed a moderate to massive enlargement of the left atrium. (Mean diameter 53 ± 1.5 mm: range 30-80 millimeters)

Thirty-nine patients underwent preoperative right and left cardiac catheterization. Mean cardiac index (CI) was 2.04 ± 0.6 l/min/m^2. All were operated on with moderate hypotermia (25°C - 28°C) and cold potassium cardioplegic solution delivered into the aortic root (or coronary sinus in patients with aortic regurgitation).

Interrupted mattress sutures or running sutures were employed indifferently.

Fourty-one mitral Liotta-BioImplant LPB were implanted. The most common size was 30 mm. Associated lesions were treated as follows: 12 patients received an aortic prosthesis (mechanical in 7, biologic in 5).

Tricuspid regurgitation was corrected in 9 patients by various techniques of annuloplasty. Only one patient required a tricuspid valve replacement because of a severe organic disease.

There were 3 hospital deaths (7.3%) and 3 late deaths (7.9%) in the first year after valve replacement.

The causes of deaths are exposed in Table 3. The first of the two patients who died of low cardiac output had had a previous mitral commissurotomy 13 years before, and presented an involvement of aortic and tricuspid valves. The second, with calcified mitral and aortic stenosis had been operated in emergency because of severe cardiac failure.

TABLE 3: HOSPITAL AND LATE MORTALITY

HOSPITAL DEATHS:		
INFECTIVE PNEUMOPATHY	1	
LOW OUTPUT SYNDROME	2	
LATE DEATHS:		
CEREBRAL HEMORRAGE	1	6 MONTHS LATER
CARDIAC FAILURE	1	12 MONTHS LATER
AV BLOCK	1	13 MONTHS LATER

We deplored 3 late deaths: 1 due to an anticoagulant accident in a patient with chronic atrial fibrillation; 1 due to a severe and evolutive cardiac failure in a patient who was in NYHA class IV preoperatively and the third in a patient who presented several episodes of paroxystic AV block.

Follow-up

The thirty-five surviving patients were followed up for periods going from 38 to 59 months (mean 44.6) by personal interview, letter or letter to the cardiologist.

Twenty-five are in NYHA class I; 10 in NYHA class II.

Fourteen patients accepted to undergo complete heart catheterization 1 month after valve replacement. Hemodynamic data obtained were compared with the preoperative and analyzed with the Wilcozon signed rank test (Table 4) which showed a non significative difference between mean pulmonary artery pressures and mean pulmonary capillary pressures.

The cardiac index was significantly different in the two groups.

TABLE 4: COMPARISON OF PRE AND POST-OPERATIVE PAP, PCP AND CI

	PREOPERATIVE	POSTOPERATIVE
PAP	27.17 + 10.52 (14 - 50)	20.96 + 7.64 (5.5 - 34) n.s.
PCP	16.28 + 6.55 (7.0 - 30)	12.42 + 4.65 (3.5 - 20) n.s.
CI	1.88 + 0.55 (1.2 - 3.3)	2.37 + 0.36 (1.8 - 2.8) p<0.01

PAP: mean pulmonary artery pressue (mm Hg)

PCP: mean pulmonary capillary pressure (mm Hg)

CI: mean cardiac index (liters/min per m^2)

Thromboembolism

We considered as thromboembolic complications all new focal neurologic deficit either transient or permanent, unless they were proven to be of other origin, as well as peripheral arterial emboli.

Following the above criteria, none of our patients suffered from thromboembolic complications in spite of the fact that the majority of the patients were in chronic atrial fibrillation and four had a giant left atrium.

Anticoagulation policy

The 15 patients in sinus rhythm received oral anticoagulants for 3 months after surgery. The others received anticoagulants for period going from 1 to 2 years after valve replacement.

Longer periods of anticoagulation are unnecessary because the probability of thromboembolic accidents decreases significantly beyond the first year after valve replacement (3).

Patients with mechanical prosthesis in aortic position receive anticoagulants on a long term basis. We deplored two hemorragic accidents due to anticoagulants.

The first one was lethal and the patient died of cerebral hemorrage, the second was a minor gastrointestinal bleeding.

Reoperations

Follow up of the patients was completed with two-dimensional echocardiography which did not show any sign of valve failure, none of the surviving patients had to be reoperated.

Conclusions

Our results are similar to those of other authors implanting this device (4) and compare favorably with those obtained with other bioprostheses.

We would like to emphasize some of the advantages of this prosthesis: low profile, highly flexible stent, low thrombogenicity due to the reduced contact of blood elements with non biologic tissue.

The highly flexible stent results in a very low incidence of valve failure and degeneration. In our series no patient showed sign of valve degeneration four years after valve replacement. We do not have long term experience but, according to the data published in the literature, the probability of degeneration of this prosthesis is expected to be lower than that of bioprosthesis mounted on rigid supports (4,5,6).

The hemodynamic performance of this prosthesis is very satisfactory and compare favorably with the one obtained from other bioprosthesis (4).

These features are of particular interest in the choice of a bioprosthesis for mitral valve replacement. In small left ventricles mechanical complications are minimized and intrinsic stenosis due to inward stent post deformation of long strut bioprostheses is avoided (1,2,6).

The good clinical and hemodynamic results and the low incidence of thromboembolic complications obtained with this and with other series make the Liotta-BioImplant LPB a reliable cardiac valve substitute particularly in mitral position.

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