

Cardiomyoplasty in 26 Patients with up to Six Years Follow-Up

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Abstract

Cardiomyoplasty was performed in 26 patients with dilated cardiomyopathy, 53.8% of them with idiopathic cardiomyopathy, 26.9% chagas, 11.5% hypertensive, 3.8% viral cardiomyopathy and 3.8% peripartum cardiomyopathy, who were in New York Heart Association (NYHA) class III(10) or IV(16). The early and late mortality rates were 11.5% and 17.5%, respectively. The average follow-up period was 14.5 ± 12.9 months. The linearized rate of the fatal complication was 10.8% of congestive cardiac failure (CCF)/patient-year and 3.6% of ventricular fibrillation (VF)/patient-year. The non-fatal complication rate was 10.7% CCF/patient-year. The actuarial survival rates were 84% at 1 year, 74.2% at 2 years and 58.7% from 3 to six years. Considering just non-chagas patients, the survival rate was 90% at 1 year and was maintained unaltered through 5 years of follow-up. Furthermore, 13 of the 19 surviving patients improved to NYHA class I and six to class II. Doppler echocardiography demonstrated that ejection fraction increased from $37.8 \pm 10.2\%$ to $54.4 \pm 4.9\%$ ($p < 0.001$) and segmental shortening from $15.9 \pm 4.9\%$ to $25.3 \pm 5.8\%$ ($p < 0.001$). The systolic and diastolic diameters were reduced from 61 ± 6.8 mm to 52.9 ± 9.3 mm ($p = 0.04$) and from 72.7 ± 7 to 68.3 ± 10.4 mm ($p < 0.05$), respectively, by 18 months. Cardiomyoplasty is indicated for dilated cardiomyopathy. The future success of cardiomyoplasty will depend on the survival of these patients after surgery compared with matched medically treated patients.

Key words: cardiomyoplasty, cardiomyopathy, surgery.

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Approximately two million North Americans develop cardiac failure [15] every year. In South America, the incidence of this disease is also high. Chagas cardiomyopathy [4, 37] is present in seven million people, among them 28% develop major cardiomyopathy, for which no therapeutic alternative exists [8].

The mortality in the first year after the diagnosis of cardiomyopathy varies from 20 to 50% [14, 37, 39]. Angiotensin converting enzyme inhibitors for treatment of cardiac failure have prolonged life in 15 to 25% [31]. However, the duration of this benefit is still unknown.

Dilated cardiomyopathy is responsible for more than 30% of the candidates needing cardiac transplantation, and it is a significant cause of death. Although cardiac transplantation is used for the treatment of cardiopathies [17,

26], its utilization is limited due to restrictions and difficulties with donors, effects of immunosuppressive agents, [17, 29], and the social economical problems of various countries.

Mechanical assist devices require external batteries that limit the activity and life-style of the patient, and expose the patient to infection and thromboembolism risk. Therefore, this approach is used only as a temporary support to cardiac transplantation. The use of autologous skeletal muscle is another option [34, 35].

Cardiomyoplasty was originally introduced by Kantrowitz and Hume [19, 20], in the 50's and subsequently used in humans by Carpentier and Chachques [5]. This procedure avoids the direct contact of the muscle with the blood eliminating the risk of thromboembolism, it reinforces the

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sometimes thin ventricular wall providing better cardiac function with its own muscular contraction, in addition to being a relatively easy technique to perform.

Several authors [6, 11, 18, 23, 28, 29, 30] have demonstrated that cardiac performance increased after cardiomyoplasty. Our experience has been similar [36]. Our surgical technique for cardiomyoplasty and results are presented in this study.

Materials and Methods

Selection of Patients

The 26 patients who were selected for cardiomyoplasty were high risk for dying in a period of a year, after recognition of their severe myocardial dysfunction. Four of those patients (cases 20, 21, 23, 24) were operated on

by the same team in other cardiovascular surgery centers in Brazil. Five patients were female with ages of 25 to 57 years (average of 41 ± 13.3 years). Twenty-one patients were male 22 to 72 years with an average of 45.1 ± 12.0 years. The dilated cardiomyopathy, observed in the patients was of undetermined cause in 53.8%, Chagas origin in 26.9%, hypertension in 11.5%, virus in 3.8% and peripartum in 3.8% (Table I).

The pre-operative evaluation consisted of:

a) Clinical and laboratory exam enabled the diagnosis and functional classification of the patients, who presented NYHA functional classes III (10) and IV (16) (Table I). Patients in NYHA class IV with ejection fractions lower than 30% by Doppler echocardiography were submitted to

Table I. Patients submitted to cardiomyoplasty, etiology, NYHA class in the pre and postoperative period, mortality and follow-up.

PAT.	SEX	AGE	ETIOLOGY	NYHA CLASS		FOLLOW-UP	DEATH
				PRE	POST		
1.	m	30	MCP.MG+	IV	-	21 Months	CCF late
2.	m	44	MCP.MG+	IV	-	4 Months	CCF late
3.	m	52	MCP.MG+	IV	-	9 Days	Pulm.Emb. Hosp.
4.	m	31	MCP.Idiop.	IV	-	6 Months	CCF late
5.	m	55	MCP.Idiop.	IV	II	46 Months	-
6.	m	22	MCP.MG+	III	-	12 Months	VT and VF late
7.	m	50	MCP.MG+	III	I	40 Months	-
8.	f	51	MCP.Idiop.	III	I	39 Months	-
9.	m	72	MCP.Idiop.	III	-	16 Days	VF Hosp.
10.	m	35	MCP.Viral	III	I	23 Months	-
11.	f	25	MCP.Peripartum	IV	I	23 Months	-
12.	m	39	MCP.Idiop.	IV	I	22 Months	-
13.	m	27	MCP.Idiop.	III	I	18 Months	-
14.	m	42	MCP.Idiop.	III	I	15 Months	-
15.	f	57	MCP.Idiop.	III	II	15 Months	-
16.	m	58	MCP.Idiop.	IV	II	14 Months	-
17.	f	31	MCP.Idiop.	IV	I	10 Months	-
18.	m	45	MCP.MG+	IV	-	5 Days	VF Hosp.
19.	m	49	MCP.Idiop.	IV	I	7 Months	-
20.	m	57	MCP.Idiop.	IV	II	5 Months	-
21.	m	32	MCP.MG+	IV	I	4 Months	-
22.	m	52	MCP.Idiop.	IV	I	3 Months	-
23.	m	55	MCP.Idiop.	III	II	3 Months	-
24.	m	48	MCP.Idiop.	IV	II	2 Months	-
25.	m	52	MCP.Idiop.	IV	I	2 Months	-
26.	f	51	MCP.Idiop.	III	I	1 Month	-

MCP = Myocardiopathy

MG+ = Chagasic

HYP. = Hypertensive

CCF = Congestive Cardiac Failure

VT = Ventricular Tachycardia

VF = Ventricular Fibrillation

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an intensive clinical treatment, with rest, so that at surgery, the severity of their heart failure was less.

b) Psychologists and social workers evaluated the patients for their likelihood of adherence to the protocol as well as acceptance of a new therapeutic approach, still on a trial basis.

c) Thoracic radiography in PA and lateral, to evaluate the area of heart and lungs. When necessary, the computed tomography of the thorax was done in order to detect pulmonary or pleural diseases.

d) Pulmonary function test.

e) Simple and dynamic electrocardiogram to exclude severe arrhythmias which could indicate that the procedure was counterindicated. The cineangiocardiology enabled the evaluation of the morphology and condition of the ventricle function, as well as coronary arteries and cardiac valves.

f) Echocardiogram was used to evaluate the heart valves, as well as the cardiac function through the ejection fraction, segmental shortening and cardiac output speed.

Preoperative parameters are recorded in figures 1 to 4 with a variation of 53 to 80 mm ($M = 61.0 \pm 6.8$) for the systolic diameter and of 60 to 90 mm ($M = 72.7 \pm 7.0$) for the diastolic diameter, of 18 to 56% ($M = 37.8 \pm 10.2$) for ejection fraction and 8 to 25% ($M = 5.9 \pm 4.9$) for shortening fraction.

Anaesthetic approach

All the patients were monitored with a continuous electrocardiogram, pulse oximeter, rectal and esophageal tem-

perature probe. Two venous accesses and flow-directed balloon-tipped pulmonary artery catheter were utilized for hemodynamic calculations. The right radial artery was catheterized to monitor arterial pressure. The anaesthesia was induced with etomidate (0.3 mg/kg), and alfentanil (75 µg/kg). Atracurium (0.4 mg/kg) was used for neuromuscular blockade. A double lumen endotracheal tube was used to perform one lung ventilation during the rib resection (2nd rib) and introduction of the *latissimus dorsi* muscle into the thoracic cavity. The volume controlled ventilation with a tidal volume of 10 to 15 ml/kg, FiO_2 of 0.5 and PEEP of 3-5 cm H_2O , was readjusted accordingly to the $PaCO_2$, PaO_2 , SpO_2 and the measured cardiac output. The anaesthetic maintenance was done with continuous alfentanil (0.75 - 1.0 µg/kg/min), and isoflurane at 1% minimal alveolar concentration (MAC) and subsequent doses of atracurium. This neuromuscular blocking agent infusion was interrupted 20-30 minutes before testing and neuromuscular blocking maintained at 10% twitch depression to prevent failures in the electrophysiologic tests [3]. All patient received dopamine (3-5 µg/kg) during the entire procedure. When systolic blood pressure was < 90 mmHg dobutamine was also used (5 mg/kg/min).

Surgical Technique

The technique was that fundamentally described by Carpentier and Chachques [17] with minor variations. The use of extracorporeal circulation was avoided in order to decrease the chance of bleeding from the muscle graft. In addition, the heart was manipulated carefully so that the hemodynamics were maintained.

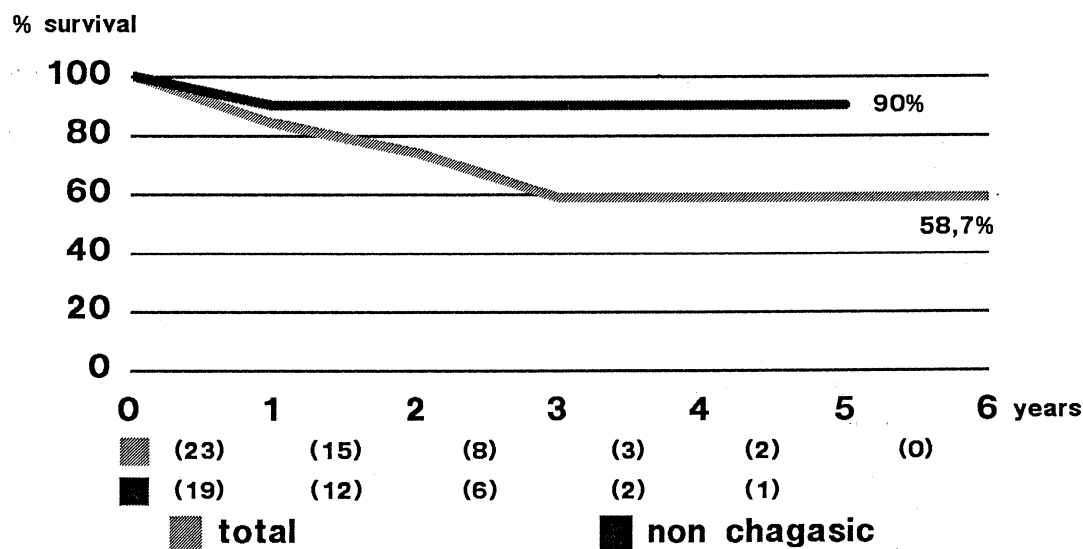


Figure 1. Survival actuarial rates of total and non chagasic patients submitted to cardiomyoplasty in six years of follow-up.

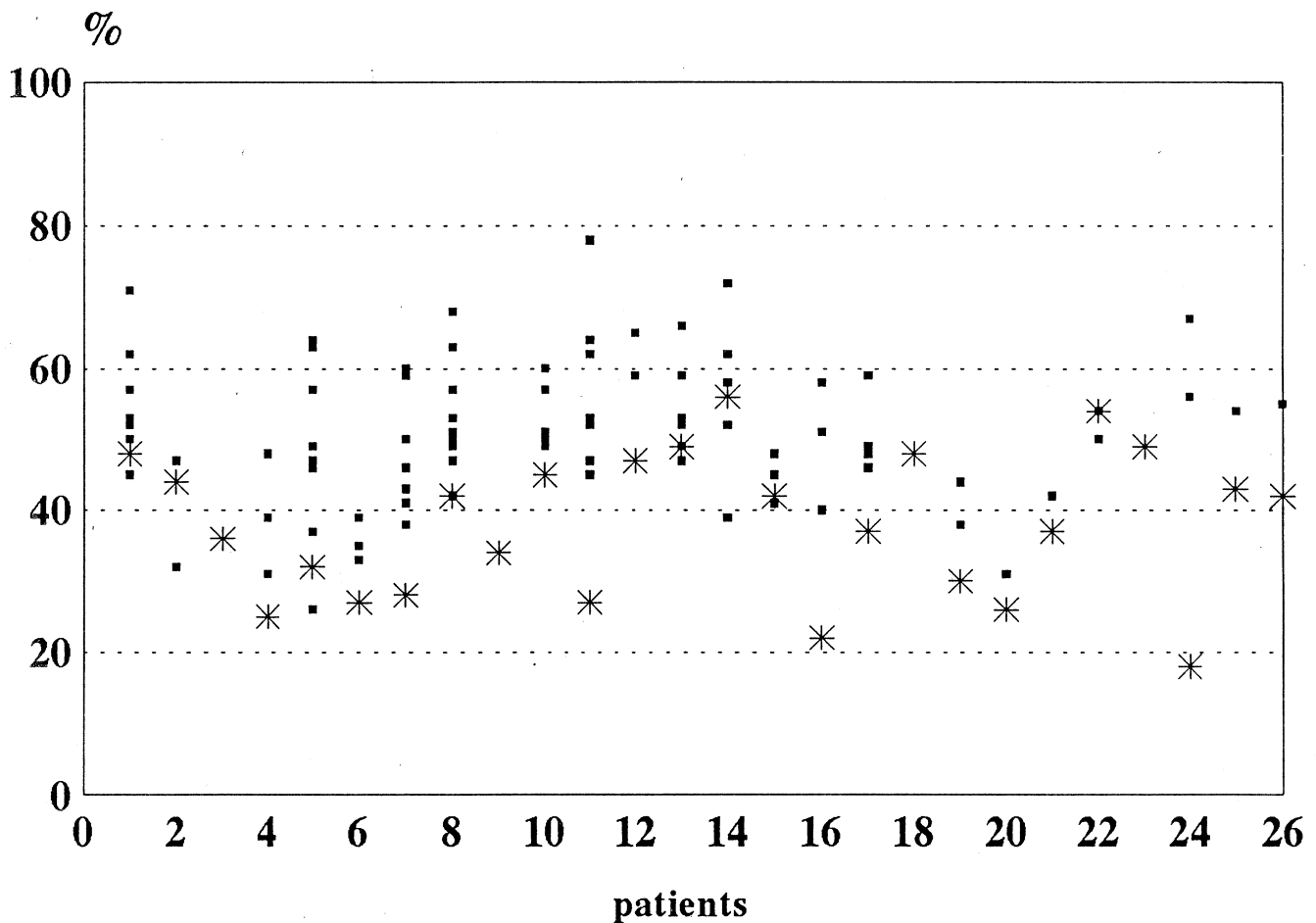


Figure 2. Fraction ejection indexes in the pre (*) and postoperative (■) of patients submitted to cardiomyoplasty with follow-up from 1 to 44 months.

Surgical technique for dissection of muscle flap.

The patient was placed on the right side with the left arm stretched over the head. The incision was initiated in left underarm in an italic s-shape reaching the anterior and superior iliac spine. The initial portion of the incision passing through the medium underarm line, towards the back parallel to the backbone, finally returning to the front end in the anterior superior iliac spine. This incision of the skin and of subcutaneous tissue helped the muscle dissection on its anterior surface with detaching the skin and subcutaneous tissue. Next, the muscle was released from the insertions with all other muscles and with the bone structures. The dissection of the subcutaneous tissue went towards the vertebral column until it was reached. The anterior edge of the muscle was lifted, starting the dissection of its posterior surface in contact with the ribs. This dissection requires a lot of effort because there are quite a few vessels which penetrate into the muscle from the deep levels. The dissection should reach the posterior surface of muscle at the vertebral column mid-line. Once the muscle has been detached all the way to the vertebral column, its

insertion is cut in the same region. The dissection extends toward the iliac region through the anterior and posterior edge of the muscle, until the muscle tendons and insertions present in its farthest portion are identified and cut. Once released from its farthest part, the muscle is dissected in a cranial direction. The dissection is carried towards the pedicle, releasing it from the anterior and posterior skeletal muscle insertions. Its insertion along with the humerus tuberosity is cut and the pedicle carefully dissected to avoid injury of the nerve, artery or vein.

The anterior arch of the second or third rib (whichever looks more favourable) is identified and removed within about 8 cm, in such a way that through the window the muscle can reach the left pleural cavity. The *latissimus dorsi* muscle is lifted in a cranial direction. The pedicle is identified with its trunk and branches. Biotronik electrodes model CMB3 with universal pacemaker connectors, and titanium oxide wires are implanted. The body of each electrode is protected by a silicone cover, which slides over itself and allows for the exposure of the desired electrode length.

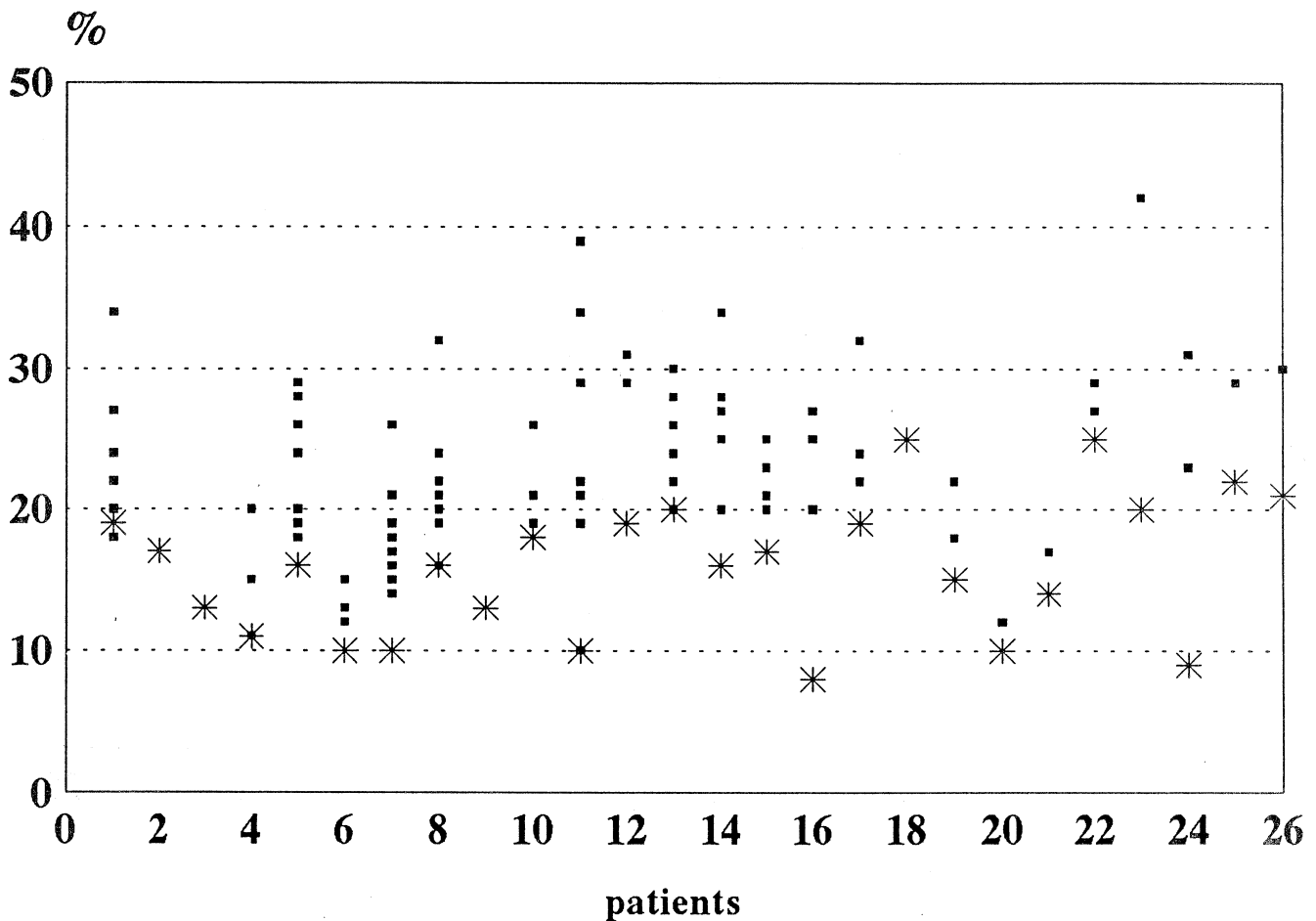


Figure 3. Segmental shortening indexes in the pre (*) and postoperative (■) of patients submitted to cardiomyoplasty with follow-up from 1 to 44 months.

Each electrode is implanted in the muscle, in such a way that the negative pole remains in the proximal part and the positive pole in the more distal portion of the muscle pedicle. The wires are passed through the musculature with the help of its own surgical needle, passing near the nerve branches, but without harming them. Once the electrodes have been passed, they are isolated with silicone protectors. The polypropylene suture is fixed to the muscle and the silicone protectors are fixed to the muscle with continuous 4-0 polypropylene suture. The silicone cover which runs along the electrodes is adjusted and fixed to the muscle in such a way that no other part of the electrode is exposed. Otherwise, the contact with structures other than the *latissimus dorsi* muscle would lead to a great loss of energy. At this point, the threshold of muscle stimulation and resistance is measured.

Once the electrodes are implanted and fixed, the muscle is introduced into the left thoracic cavity through the window previously made. The muscle is then fixed to the edges of this opening, so that it has a supporting point and, at the same time, there is no air leak from the pleura to the

latissimus dorsi muscle dissection area. A drainage tube is placed in the left pleural cavity. The lateral anterior and posterior part of the subcutaneous tissue is drained using negative pressure suction to avoid dead space and seroma. The superficial and deep layers are sutured, avoiding potential space.

Surgical technique for muscle wrap

Once the *latissimus dorsi* muscle has been dissected, the patient is placed on his back. A midline sternotomy is done as usual, and the left pleura widely opened. The pericardium is released and opened close to the left phrenic nerve, then an inverted T-shape incision is made to expose the heart. An epicardial electrode Biotronik model DMS 50 is implanted in the left ventricle and will be used for cardio-synchronizer synchronization.

The *latissimus dorsi* muscle is carefully inspected for hemostasis. New threshold measurements for stability and resistance are checked at this point with the muscle warmed up and, thus, in better physiological condition. Lidocaine hydrochloride (5 ml) without adrenaline is

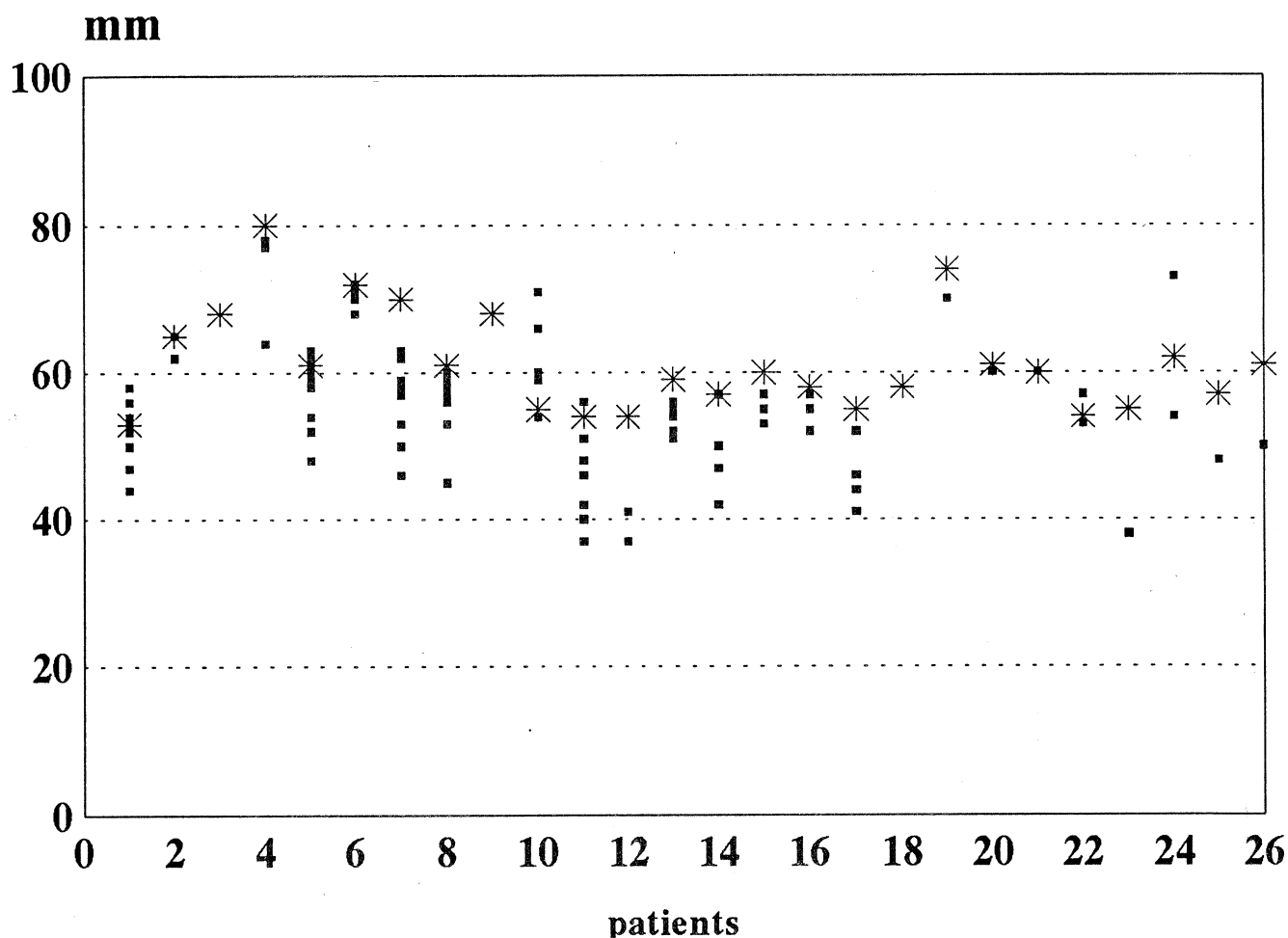


Figure 4. Systolic diameter indexes in the pre (*) and postoperative (■) of patients submitted to cardiomyoplasty with follow-up from 1 to 44 months.

placed in the pericardial sack to avoid arrhythmias during cardiac manipulation.

The heart is carefully dislocated, always observing the hemodynamic conditions. The manoeuvres are done slowly and progressively, which enables the mobilization of the heart without major functional alterations.

A point is chosen in the left atrioventricular sulcus underneath the left atrium, and marked with a polypropylene 4-0 suture. The edge of the *latissimus dorsi* muscle that was inserted into the vertebral column is then sutured on to the posterior heart surface in the previously marked point, in such a way that the pedicle will not be under tension, and so it will be possible to utilize the complete extension of the skeletal muscle to wrap the ventricle. The point is marked with a polypropylene 4-0 suture. Separated mersilene 2-0 sutures are then passed with pledgets along the left atrioventricular sulcus starting in the previously marked place. The stitches are spaced 1.5 to 2 cm apart to avoid harming the marginal branches of the circumflex arteries. Normally 4 to 5 stitches are used in the heart's posterior surface. Then these stitches are passed on the posterior edge of the muscle graft. The first suture is implanted in the heart in the previously marked point and

the others in sequence, keeping the same distance that is kept in relation to the heart. The stitches are tied in such a way that the *latissimus dorsi* muscle surface which is in contact with the vertebral column will be opposite the posterior aspect of the heart.

The graft is adjusted into position and sutures tied between the atrioventricular sulcus and the right ventricle. Then the muscle is sutured on itself, starting at the portion along the cardiac apex and continuing towards the base of the heart. Generally, it was possible to close the loop always suturing muscle to muscle. When this was not possible, a bovine pericardium patch treated in glutaraldehyde was utilized, to fill the defect.

Finally, the part of the muscle that related to the cardiac surface was adjusted avoiding dead space in this area. Thus, the *latissimus dorsi* muscle was wrapped around the heart counter-clockwise, covering both ventricles. Benzathine penicillin 1.200.000 Ui was injected in the cardiac skeletal muscle interface to provide better adherences. The right side of the pericardium edge was fixed on the muscle closing the mediastinum completely.

A pocket was made in the left subclavicular region in the anterior thoracic position sufficient in size to contain the

cardiomyostimulator. The electrodes for muscular stimulation were passed into the subcutaneous pocket. The sternotomy was closed as usual.

After the suture of skin, the electrodes were connected to the cardiomyostimulator Myos-Biotronik, and put in the previously prepared pocket.

The cardiomyostimulator was turned off. The electrocautery was not used after pacemaker implantation. Mediastinum chest tubes were not used, since the left thoracic cavity was in communication with the mediastinum and had already been drained.

The operation, due to the extensive dissection is very painful. The extubation can be done as soon as the patient is awake. Usually gastric drainage is necessary.

Muscle Stimulation Protocol

The stimulation protocol was modified from Carpentier and Chachques [5] and follows the sequence below.

1 to 2 weeks after the cardiomyoplasty: no stimulation. This phase is necessary for the collateral blood vessel formation in the muscle graft and adherence between the muscle and the myocardium, in addition to the regression of graft edema and maturation.

3 to 4 weeks: the electrostimulation with single pulses 2:1, in synchronism with the aortic valve opening.

5 to 6 weeks: number of impulses increased to two, with stimulation 2:1.

7 to 8 weeks: increase of impulses to three, with stimulation 2:1. The ideal number of stimuli in the burst at the completion of two months after the surgery is 6 to 8, with a frequency of 30 Hz. This is according to the parameters evaluated by echocardiography.

The precise synchronization between the muscle contraction and the ventricle systole takes into consideration the opening of the aortic valve and always checking the timing of the opening and closing of the pulmonary valve. The patients are followed up at 2 to 4 month intervals depending on their underlying cardiac disease and clinical condition.

Programming of Myos

The cardiomyostimulator Myos is controlled by a dual-chamber circuit (Physios). Myocardial detection and stimulation is performed by the atrial channel of this circuit. The signal from the ventricle delivered after the AV-delay triggers a burst to stimulate the skeletal muscle. The number of stimuli in the burst and the synchronization ratio from myocardial rate to the rate of burst delivery is adjustable by magnet placement as described below. The dual-chamber circuit (Physios) can be programmed using the PMS 600 (or PMS 1000) programmer.

1. Select the desired parameter values for the dual-chamber pacemaker circuit.

1.1. Select the mode DDDc (or DOO), a ventricular amplitude of 4.8V, a ventricular pulse width of 0.5 ms and a ventricular refractor period of 300 ms. These values are needed by the burst circuit and must not be altered.

1.2. Select the desired synchronization intervals between the myocardial event (sense or pace) and the start of burst stimulation by adjusting the AV-delay sensing and AV-delay stimulation, respectively. Note: the resulting synchronization interval (delay between myocardial event and start of burst) is AV-delay + 30 ms.

2. Skeletal muscle stimulation is turned on and off by briefly placing the magnet over the implanted pulse generator.

3. Selection of the number of pulses per burst and of the synchronization ratio.

3.1 Place the magnet over the implanted pulse generator. The time the magnet is left over the implanted stimulator defines the program of myostimulation in the stimulator. The number of pulses and the synchronization ratio can be adjusted. When the desired program is reached, the magnet is removed. The stimulator then continues to pace with this program.

Note: The AV-delay is 100 ms during magnet placement independent of the selected values in the program of the dual-chamber circuit.

* With every second basic interval the number of burst pulses is increased by one pulse. This is done up to 8 pulses.

* After that, the synchronization ratio is changed from 1:1 to 1:2, etc., a burst is delivered only every other myocardial event (sense or pace). The number of pulses is reduced to one again.

* With further magnet application the number of pulses per burst increases again up to 8 pulses with every second basic interval expiring.

* After that the synchronization ratio is changed from 2:1 to 3:1, i.e., a burst is delivered only every third myocardial event (sense or pace). The number of pulses is reduced to one again.

* This continues until the initial state is reached again and the procedure begins anew.

Note: To facilitate the program selection, interrupt the procedure from time to time by magnet removal and check the progress in setting the myostimulation parameters. Applying the magnet again makes the system start at the point where it was stopped.

Echocardiography

The function of the left ventricle was evaluated by the echocardiographic study in mode M, bidimensional and Doppler (echo-Doppler SIM 7000 CFM by ESAOTE Biomedica) evaluating the left ventricle function through the ejection fraction, segmental shortening and systolic and diastolic diameters in postoperative months 1, 3, 6, 9, 12, 15, 18, 21, 30, 36 and 44 after the surgery.

Statistical Analysis

The results of the evaluated parameters by Doppler echocardiography of the left ventricle in the pre- and postoperative periods are presented as mean and standard deviation. The Student's T-test was used to compare data obtained from these periods. The differences were identified by confidence interval, with significance level for $p < 0.005$.

The survival rates were obtained considering the total number of patients that were discharged. The non-Chagas patients were also evaluated separately [2, 12, 21].

Results

Immediate preoperative

There have been no intraoperative deaths. Vasoactive drugs (sodium nitroprusside, dobutamine, dopamine) were used to maintain the hemodynamic state early after surgery. Three patients (11.5%) died within a month after surgery. One patient with dilated Chagas myocardiopathy had pulmonary embolus on the 9th postoperative day and the two others with dilated cardiomyopathy (Chagas and idiopathic etiologies), developed ventricle fibrillation on the 5th and 16th days. The other patients had a satisfactory training period for their muscle grafts.

Late postoperative

The 23 patients who were discharged from the hospital were followed from 1 to 46 months, with a total of 336 months, (average of 14.4 ± 12.9 months). Late mortality occurred in 17.4% (4/23) of the patients. Three were Chagas patients, two died of congestive cardiac failure (CCF) and one ventricle fibrillation (VF) after 4, 12 and 21

months, respectively. The other late death was in a patient with hypertensive dilated myocardiopathy, who died of CCF after 6 months. The linearized study of fatal complications revealed an incidence of 10.8% CCF/patient-year and 3.6% of VF/patient-year. The actuarial survival was 84% in the first year, 74.2% the second year and 58.7% the third to the sixth year. On the other hand, when the Chagas etiology patients were excluded the survival rate increased to 90% for the first year and did not change for the next 5 years of follow-up (Figure 5).

Among those 19 patients who remained alive, two (10.5%) had Chagas disease (cases 7 and 21), two (10.5%) had idiopathic hypertensive myocardiopathy (cases 20 and 22) 13 (68.4%) had idiopathic myocardiopathy (cases 5, 8, 12, 13, 14, 15, 16, 17, 19, 23, 24, 25 and 26), one (5.3%) had a viral myocardiopathy (case 10) and one (5.3%) had peripartum myocardiopathy (case 11). Patient information, the etiology of the disease, follow-up, as well as the causes of death are shown in Table I.

Of the 19 patients preoperative NYHA class III and IV, 13 (68.4%) became class I and six (31.6%) class II. Of the 13 patients in functional class I, 10 decreased their medication intake. Among the others, one needed hospitalization twice and the other two once, all for CCF. The

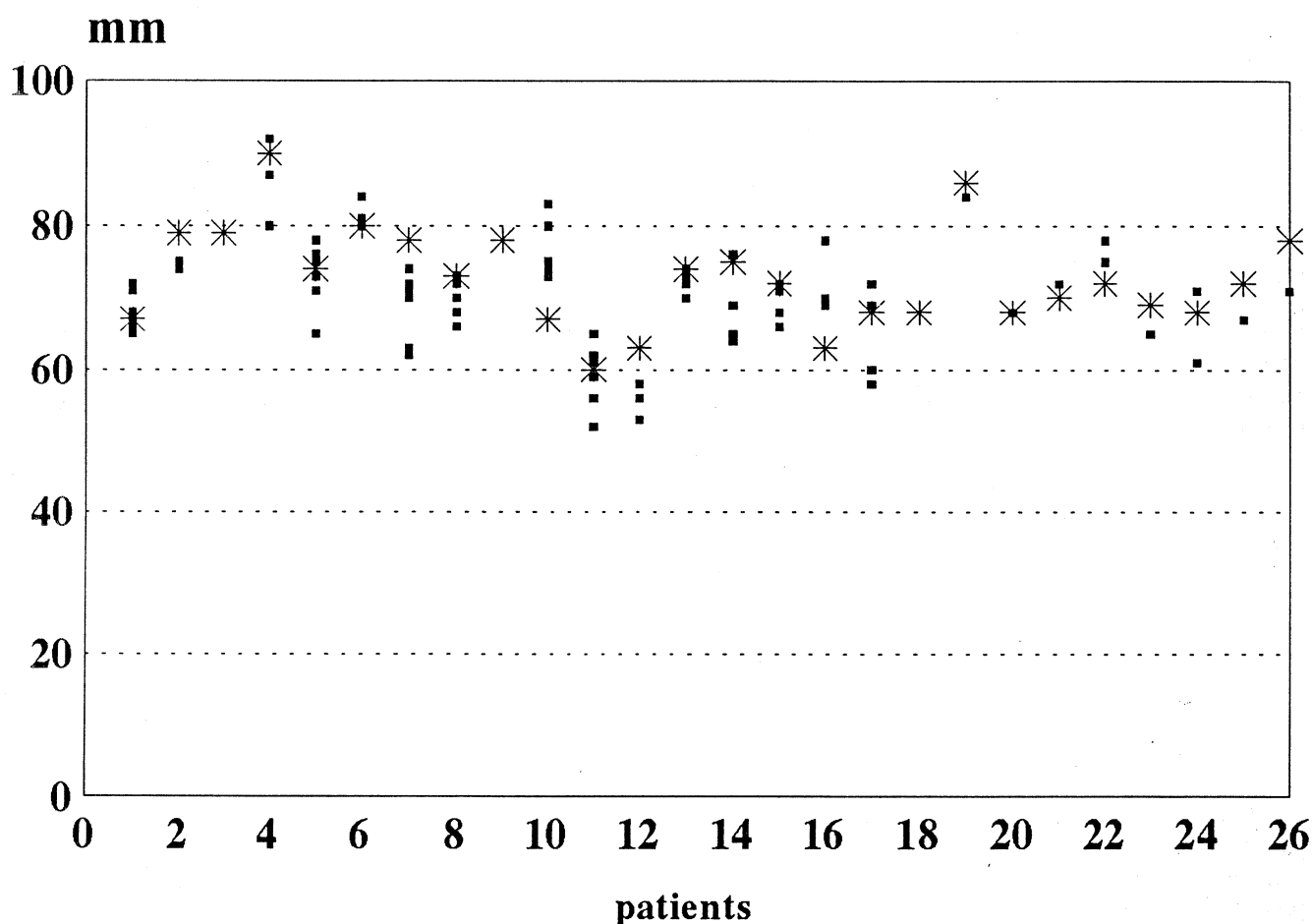


Figure 5. Diastolic diameter indexes in the pre (*) and postoperative (■) of patients submitted to cardiomyoplasty with follow-up from 1 to 44 months.

incidence of this non-fatal complications was 10.7 events %/patient-year. All patients seemed to tolerate the chronic stimulation of the *latissimus dorsi*. Arrhythmias, pain and discomfort during the training were not noted.

The average values for ejection fraction, segmental shortening and systolic and diastolic diameters during the pre- and postoperative periods evaluated by Doppler echocardiography are represented by graphs in Figures 1 to 4. The comparative study between the mean values of the parameters of pre- and postoperative periods, that were significant at $p < 0.05$ are: reduction of the systolic diameter at 1 ($p = 0.01$), 6 ($p = 0.04$), 9 ($p = 0.007$), 12 ($p = 0.05$), 15 ($p = 0.01$) 18 ($p = 0.04$) and 21 ($p = 0.05$) months after surgery. The ejection fraction increased significantly at 1, 3, 6, 9, 12, 15, 18, and 21 (all $p < 0.001$) and 30 ($p = 0.01$) months after surgery as well as the segmental shortening at 1, 3, 9, 15 (all $p < 0.001$), 6 ($p = 0.002$), 12 ($p = 0.02$), 18 ($p = 0.01$), 24 ($p = 0.04$) and 30 ($p = 0.05$) months after surgery.

The patients showed decrease of systolic diameter from 2% to 31% (mean 14%) in the first month ($p < 0.001$) and maintained similar decreases to 18 months ($p = 0.04$) (Figure 6). The ejection fraction increased from 8% to 18.8% (average 50%) at 6 months ($p < 0.001$) (Figure 7).

The segmental shortening also showed significant improvement ($p < 0.001$) already in the first month postoperatively with increased values from 6% to 212% (average 57.4%); 18% to 290% (average 77%) ($p < 0.001$) at 6 months and 15% to 240% (average 75%) ($p = 0.001$) at 18 months. At 24 months there was a small but significant difference between pre- and postoperative values ($p = 0.004$) (Figure 8). The diastolic diameter, even in the absence of significant difference between the pre- and postoperative average values, showed decreased rates at 3 months (2% to 11% - average 7%) and at 18 months (16% to 19% - average 18%).

Discussion

The cardiomyoplasty procedure does not require cardiopulmonary bypass. Our results are satisfactory when compared to other clinical treatments where mortality rates can be up to 60% [29]. Early mortality rate of 18.2% [11] and late mortality rates from 9.1% to 31.2% [11, 18, 29] have been reported. Our early mortality was 5.3% and 5.6% late mortality when excluding the Chagas patients. The intraoperative mortality is related to the patients preoperative condition. Grandjean has reported a 33% early

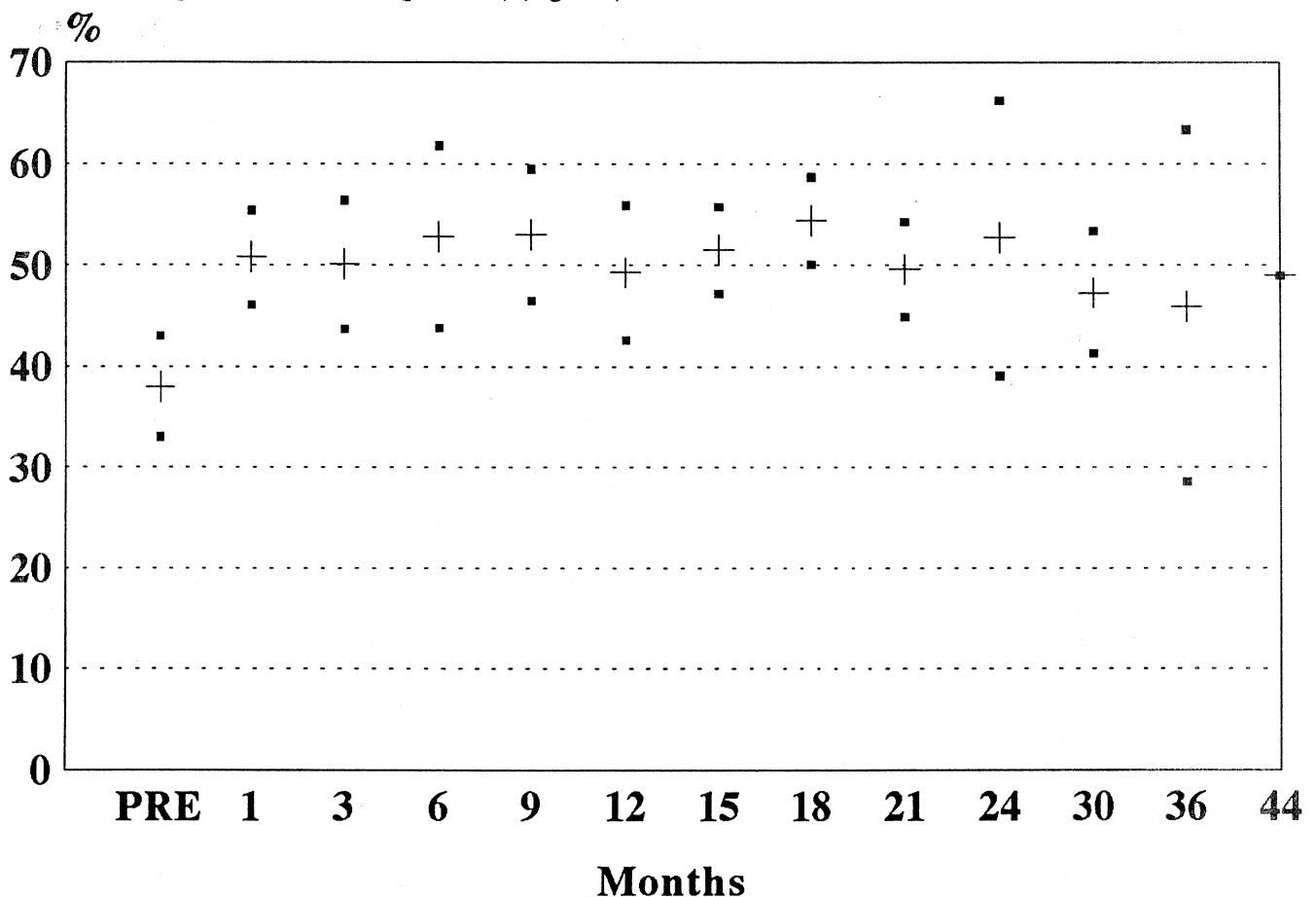


Figure 6. Fraction ejection medium estimates (+) with 95% of respective confidence interval (■) in the pre and postoperative of patients submitted to cardiomyoplasty with follow-up from 1 to 44 months.

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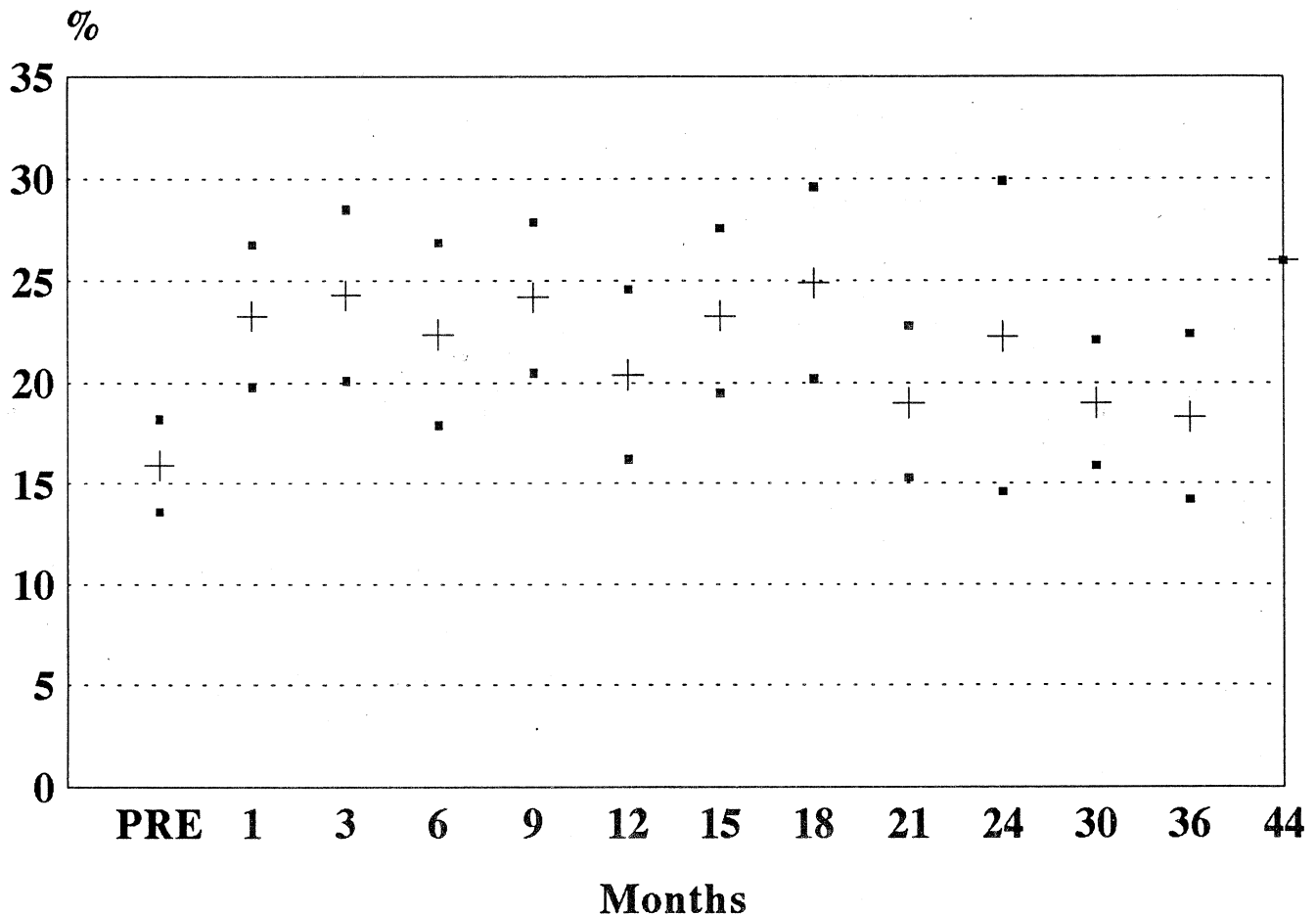


Figure 7. Segmental shortening medium estimates (+) with 95% of respective confidence interval (■) in the pre and postoperative of patients submitted to cardiomyoplasty with follow-up from 1 to 44 months.

mortality for patients in preoperative NYHA class IV, and 12% for those in NYHA class III [16].

These data are consistent with 50% intraoperative mortality for patients in class IV, reported by Carpentier's group. Their mortality has decreased to 10% with experience and rigorous selection of the patients [9].

The preoperative NYHA class is predictive of survival rate. This study showed that patient in NYHA class IV had a mortality rate of 31.2% while there was a 20% mortality for class III, with most of the deaths occurred during the first year postoperatively. The survival rate at one year was 84%. Among 16 patients in preoperative NYHA class IV 43.8% returned to class I and 25% to class II. Six of the 10 patients in NYHA class III preoperatively returned to class I and 2 to class II. This meant that 68.0% of the survivors returned to class I. These results compare favourably with the literature [10].

The cardiomyoplasty was effective in the left ventricular assistance, elevating the average value of ejection fraction from 37.8% to 54.4% ($p < 0.001$), the segmental shortening from 15.9% to 25.3% ($p = 0.001$) and reducing the systolic diameter from 61.0% to 52.9% ($p = 0.04$), 18 months after surgery. These rates are satisfactory compared to those of the literature, with increase of the ejection fraction from

22.9% to 30.5% ($p = 0.001$), of the segmental shortening from 12% to 16.4% ($p = 0.001$) and systolic diameter increases from 23.6% to 37.7% ($p = 0.006$) during this period [29].

The effects on the cardiac performance relates to the increase in ventricular function, which possibly occurs due to propulsating energy of the skeletal muscle. This contributes to the decrease of the ventricular wall tension, relieving the ventricle and, consequently allowing for a better contractile reserve. Ventricle dilation is avoided through the electric limits of the *latissimus dorsi* muscle and without causing restriction of ventricle compliance. Annular dilatation of the mitral and tricuspid valves is avoided. The muscle contraction provides for an increase of ventricle function, which is dependent on previous conditions of the heart. This includes the diameter of the heart. Cardiomyoplasty is not successful in patients with myocardiopathies in a very advanced phase, associated with severe mitral regurgitation [9, 28, 29, 30, 33].

The performance of *latissimus dorsi* muscle is proportional to the previous ventricular diameter, confirming the basic principle of the Laplace's law in which the tension is inversely proportional to the ratio [34, 35]. In this study, patient 4 with extremely enlarged systolic (80 mm) and

Cardiomyoplasty: six years follow-up

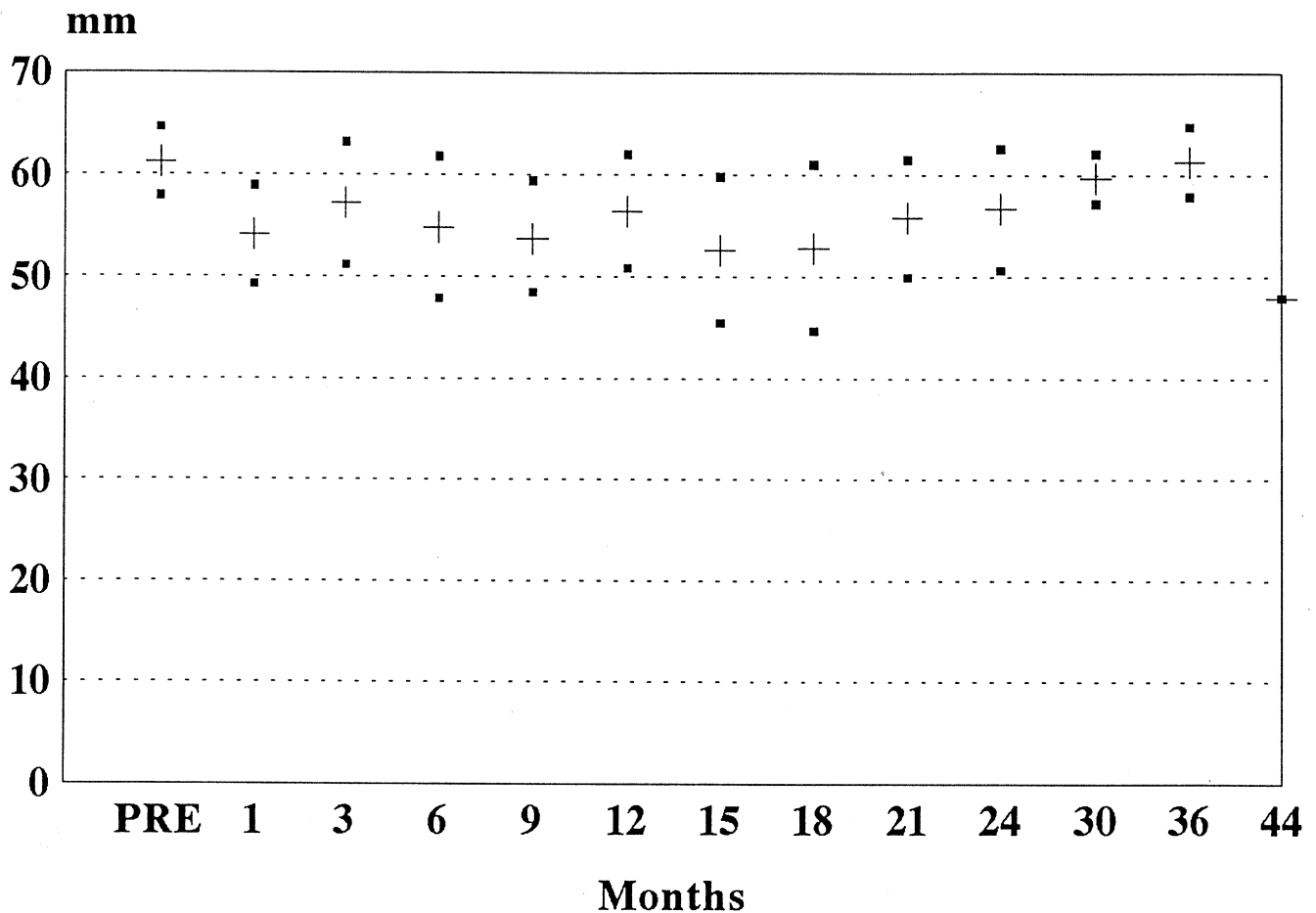


Figure 8. Systolic diameter medium estimates (+) with 95% of respective confidence interval (■) in the pre and postoperative of patients submitted to cardiomyoplasty with follow-up from 1 to 44 months.

diastolic (90 mm) diameters, had reduction of both diameters in the proportion of 3.8% and 3.3% postoperatively and elevation of the ejection fraction from 25% to 48% (92%) in the first month, 39% (56%) in the third, and 31% (24%) in the sixth when the patient died of CCF.

Significant improvements of ventricular function in patients with dilated cardiomyopathy or Chagas disease have been sustained for as long as 12 and 18 months [18, 28-30]. This study presents three patients at 36 months and one with 46 months of follow-up. Although the number of patients is small and the values of the parameters analyzed are not significantly different from the preoperative, the rate of the ejection fraction and the segmental shortening increased up to 50% (average 34% and 32%) and the systolic diameter was reduced, at most, 10% (average 7.5%) in comparison to preoperative values.

Some of the Chagas patients in this study also had satisfactory clinical results. Cases 6 and 7, at 3 months, showed increased ejection fraction (increase from 30% to 114%) and segmental shortening (increase from 30% to 160%), persisting through 9 months with increases until 54% for the first parameter and 70% for the other. Cases 7 had a greater increase of these rates at 15 months. However, in this patient, the systolic diameter was gradually

increasing with a variation of 46 mm to 63 mm (37%) and diastolic diameter from 62 mm to 74 mm (38%) with reduction of the ejection fraction from 59% to and for segmental shortening 26% to 15% (42%) at 36 months of follow-up.

These results suggest that the residual intrinsic ventricle function improves with the cardiomyoplasty, which delays the underlying disease evolution but does not avoid its progression. This procedure should not be considered a substitute for cardiac transplantation, but may delay cardiac transplant in some patients.

The cardiomyoplasty is potentially important for patients with dilated myocardiopathy of Chagas etiology since the cardiac transplantation has resulted in high frequency of recurrence of infection by *T. Cruzi* [33]. The anatomopathologic study of Chagas patients showed that the skeletal muscle maintain its capacity of adaptation to fatigue, even in the presence of recurrence of Chagas myocarditis [36].

The contraction time is fundamental, occurring after the closure of the mitral valve and the opening of the aortic valve [36]. The echocardiogram in M mode is indispensable for the success in the synchronization of the pacemaker for ventricular assistance.

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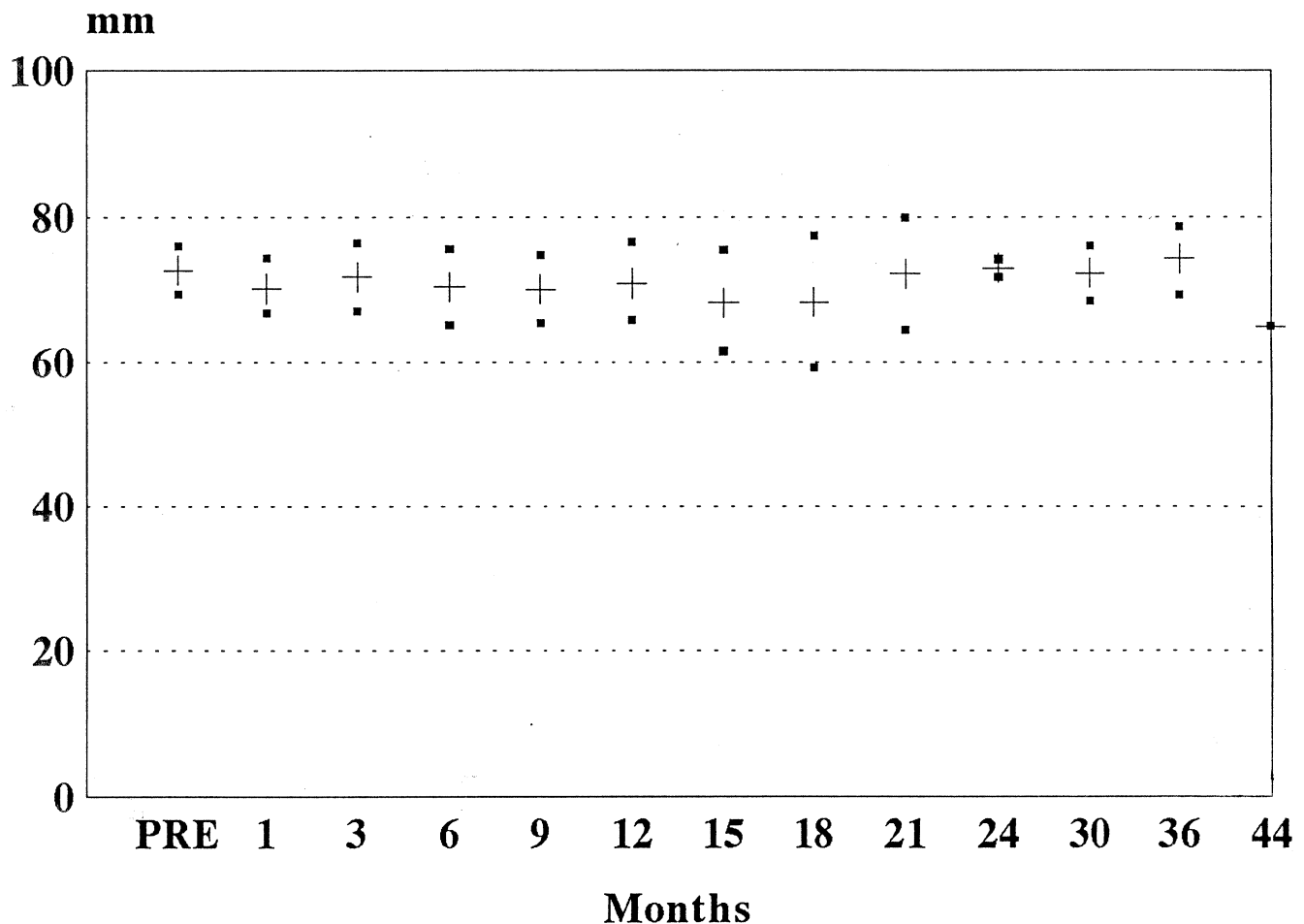


Figure 9. Diastolic diameter medium estimates (+) with 95% of respective confidence interval (■) in the pre and postoperative of patients submitted to cardiomyoplasty with follow-up from 1 to 44 months.

The object of the reference parameter is to concentrate the muscle graft's mechanical force to the most effective moment during ventricle ejection. This is during the first and second quarter of cardiac systole. The ideal number of pulses of the burst is determined by the time interval ranging between the aortic valve opening and the pulmonary valve closure. This interval is measured by means of echocardiography. The aortic valve is visualized in mode M and - after synchronization - it is shifted to the pulmonary valve visualization. At the moment of closure of the pulmonary valve the interval is measured. The reference of the pulmonary valve closure is utilized because at this moment little blood is being sent from the ventricles to the arteries. Therefore there is no need for further stimulation as the contraction of the skeletal muscle graft would be ineffective. Electrical energy for stimulation and muscle energy can be saved by determining precisely the time interval and calculating the number of pulses needed.

Considering that the patients are exposed to surgical trauma and they have to withstand the immediate postoperative period without the help of the contracting muscular graft, the choice of patient is key for a good surgical result in both the short and long term.

The experience acquired during this period makes it possible to define the patient best suited for cardiomyoplasty as follows:

1. Patients in NYHA class IV who have reverted back to class III or II, preferably.
2. Absence of malignant and uncontrollable arrhythmias.
3. Diastolic diameter by echocardiography less than 75 mm.
4. Patients with myocardiopathy that is mainly dilated, avoiding hypertrophy.
5. Right ventricular (RV) failure predicts a poor outcome with cardiomyoplasty. It has been reported that patients with significant RV failure present a worse prognosis than those patients with only LV involvement. The high mortality rate with RV failure is due to congestive cardiac failure and pulmonary embolus.
6. The myocardiopathy should not be done in cases during acute disease of the myocardium.
7. The patient must present in a good general condition, without failure in other organs. The skeletal musculature must be preserved and free from specific disease.
8. The pressure of the pulmonary artery and the pulmonary resistance must be in normal limits.
9. The patient must not be an addict to drugs or alcohol.

10. The socio-economical level of the patient must be considered.

Cardiomyoplasty represents an excellent alternative for the treatment of failure and is recommended in dilated cardiomyopathies. The future success of this approach will depend on improved life expectancy of these patients when compared with other forms of treatment.

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