Long-term clinical results of mitral valvuloplasty using flexible and rigid rings: A prospective and randomized study

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Objectives: The Carpentier rigid ring and the Duran flexible ring have been used for mitral valve repair. The Carpentier ring reduces mitral insufficiency very effectively, but it causes minor systolic dysfunction. Meanwhile, the Duran ring interferes less with the normal movements of the mitral annulus during the cardiac cycle than the Carpentier ring.

Methods: From January 1995 through August 2005, 363 patients underwent mitral valvuloplasty with annuloplasty rings. We chose the ring with randomization for mitral valve repair, and the data were collected prospectively. Seven patients who had undergone re-repair or replacement because of failure of initial repair confirmed by means of intraoperative transesophageal echocardiography were excluded in this study, and 356 patients were enrolled (Carpentier ring group, $n = 186$; Duran ring group, $n = 170$). Mean age was 49.4 years and 50.3 years for the Carpentier and Duran ring groups, respectively. There were no significant differences in age, sex, body surface area, or cause of mitral regurgitation between the 2 groups.

Results: There were 4 (1.1%) operative mortalities. The patients were followed up for 3 to 126 months (mean, 46.6 months), and total follow-up was 1368.2 patient-years. The left ventricular end-diastolic diameter, left ventricular end-systolic diameter, and left atrial size were significantly decreased in both groups. However, there was no difference in the long-term echocardiographic results between the 2 groups. Overall actuarial survivals at 10 years were $85.9\% \pm 4.9\%$ in the Carpentier ring group and $75.7\% \pm 7.2\%$ in the Duran ring group, without a significant difference. Significant mitral regurgitation (grade ≥ 3) recurred in 23 patients (Carpentier ring group, 8; Duran ring group, 15). The 8-year freedom from recurrence of significant mitral regurgitation was $62.6\% \pm 19.0\%$ in the Carpentier ring group and $55.5\% \pm 14.1\%$ in the Duran ring group ($P = .172$). Independent prognostic factors for recurrence of mitral regurgitation in logistic regression analysis were preoperative tricuspid regurgitation of grade 3 or greater and residual mitral regurgitation of grade 2 or greater at the 5th ~ 7th postoperative days.

Conclusions: Mitral valvuloplasty favors the excellent surgical and long-term results in our prospective randomized study, regardless of the type of annuloplasty ring. There was no difference between the rigid and flexible rings in terms of left ventricular systolic function measured with echocardiography. It seems that timing of the operation before significant tricuspid regurgitation and precise mitral valve repair might prevent late recurrence of mitral regurgitation.

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Reconstruction of the valve for mitral regurgitation (MR) has been thought to be the treatment of choice, even in patients with mild or no symptoms. Numerous long-term studies have demonstrated excellent results in terms of being free from reoperation and valve-related complications after mitral valve reconstruction. However, there are still controversies in the selection of prosthetic materials for annuloplasty.

Basically, there are 2 types of prostheses: the rigid ring developed by Carpentier and colleagues,¹ which restores the mitral annulus to its normal size and shape, and the totally flexible ring developed by Duran and associates,² which also reduces the annular size but allows for it to continuously change during the cardiac cycle.³

Physiologically, the shape and area of the mitral annulus are changing during the cardiac cycles with ventricular motion.⁴ Experimental fixation of the mitral annulus with a rigid ring prosthesis impairs left ventricular systolic function.⁵ Also, the same group demonstrated that a flexible annuloplasty ring results in better left ventricular systolic function than a rigid annuloplasty ring 2 to 3 months after mitral valve reconstruction.⁶ The same results were also reported by Okada and coworkers³ using echocardiographic techniques 6 months after mitral valve reconstruction. However, there are contrary studies^{7,8} that report no harmful effects with a rigid ring. Also, there is a possibility of a high incidence of recurrence of MR with a rather round shape of flexible ring in patients with left ventricular dilatation. Thus the shape of the mitral annulus, in addition to reduction of its area after annuloplasty, might play an important role in preventing the recurrence of regurgitation. A prospective clinical study was undertaken in a randomized fashion to understand the roles of annuloplasty rings (the ellipsoidal rigid ring and the rather spherical flexible ring) on long-term results.

Materials and Methods

From August 1995 through August 2005, a total of 363 patients underwent mitral valve reconstruction by one surgeon (BCC) for MR at Severance Hospital, Yonsei University College of Medicine. In all patients, a classical Carpentier mitral annuloplasty ring (Edwards Lifesciences LLC, Irvine, Calif) or a flexible Duran annuloplasty ring (Medtronic, Inc, Minneapolis, Minn) was assigned according to a table of random numbers at the time of the operation. Seven patients (5 patients with the Duran ring and 2 with the Carpentier ring) were excluded from the study for long-term results because of valve replacement (n = 5) or re-repair (n = 2) just after initial reconstruction because of significant MR in 6 patients or left ventricular outflow stenosis in 1 patient (confirmed by means of intraoperative transesophageal echocardiography).

Of the 356 patients, a Carpentier ring was used in 186 patients, and a Duran ring was used in 170 patients. The mean age of the patients was 49.9 years (range, 17-83 years). There were no differences in sex, age, preoperative New York Heart Association

Abbreviations and Acronyms

CI = confidence interval

HR = hazard ratio

MR = mitral regurgitation

functional class, incidence of atrial fibrillation, or cause of regurgitation (Table 1).

The distribution of the cause of mitral valve disease is listed in Table 1. The main cause of MR was degenerative disease in 236 (66.3%) patients. Other causes were rheumatic in 40 (11.2%) patients, endocarditis in 17 (4.8%) patients, congenital in 24 (6.7%) patients, annular dilatation or dilated cardiomyopathy in 37 (10.4%) patients, and trauma in 2 (0.6%) patients. There was no statistically significant difference in the causes of MR between the Carpentier group and the Duran group.

Surgical Techniques

Transesophageal echocardiography was performed in all patients after the induction of anesthesia to evaluate valvular and ventricular function during surgical intervention. All operations were performed by one surgeon, and surgical techniques remained substantially unchanged during the study period. Cardiopulmonary bypass was performed after achievement of mild systemic hypothermia (30°C-34°C) by using a membrane oxygenator. Myocardial protection was accomplished with a cold blood cardioplegic solution. The size of the Carpentier annuloplasty ring was selected according to the size of the anterior leaflet; the size of the Duran ring was based on the intertrigonal distance. The valve reconstruction was the same in all patients using the French technique developed by Carpentier.⁹ Mitral annuloplasty rings were implanted with 2-0 Ethibond (Ethicon, United Kingdom) interrupted horizontal mattress sutures.

Another operative technique that has been used recently is neochoardae formation with a Gore-Tex suture (W. L. Gore & Associates, Inc, Flagstaff, Ariz); this is decided according to the underlying pathology. After weaning from cardiopulmonary bypass, MR was re-evaluated by using transesophageal echocardiography. MR greater than grade 2 was considered significant, and the valve was re-repaired (n = 2) or replaced (n = 5).

The techniques of mitral valve repair and concomitant operations are shown in Tables 2 and 3.

Patient Follow-up

Three hundred forty-six (97.5%) patients were re-evaluated with transthoracic echocardiography on postoperative days 5 through 7 before discharge from the hospital. Three hundred fifty-two patients were discharged and followed up periodically by either the cardiologists, surgeons, or referring physicians. Follow-up was accomplished by patient visit, mailing, or telephone contact with the patient or patient's family. All patients (100%) were followed up. Follow-up echocardiography was performed 1 year after the operation and every third year thereafter. Three hundred thirty-one (94.0%) of the 352 discharged survivors underwent follow-up echocardiography. The mean duration from the operation to follow-up echocardiography was 26.7 ± 24.1 months.

TABLE 1. Patient profile

	All	Carpentier ring	Duran ring	P value
No. of patients	356	186	170	
Sex				
Male	197 (55.3%)	104 (55.9%)	93 (54.7%)	
Female	159 (44.7%)	82 (44.1%)	77 (45.3%)	.819
Age	49.9 ± 16.0 (17-83)	49.4 ± 1.53 (18-81)	50.3 ± 16.0 (17-83)	.458
Mean NYHA functional class	2.63 ± 0.76	2.62 ± 0.74	2.64 ± 0.78	.649
NYHA ≥3	223 (62.6%)	115 (61.8%)	107 (62.9%)	.894
Ejection fraction <40%	22 (6.2%)	11 (5.9%)	11 (6.5%)	.828
BSA	1.66 ± 0.17	1.65 ± 0.17	1.67 ± 0.17	.503
Tricuspid regurgitation ≥3	46 (12.9%)	21 (11.2%)	25 (14.7%)	.328
Aortic valve disease	30 (8.4%)	24 (12.8%)	6 (3.5%)	.02
CAOD	32 (9.0%)	20 (10.7%)	12 (7.1%)	.23
Heart rhythm				
Normal sinus	236 (66.3%)	125 (67.2%)	111 (65.3%)	
Atrial fibrillation	118 (33.1%)	60 (32.3%)	58 (34.1%)	
Atrial flutter	2 (0.6%)	1 (0.5%)	1 (0.6%)	.765
Cause				
Degenerative	236 (66.3%)	129 (69.4%)	107 (62.9%)	
Rheumatic	40 (11.2%)	17 (9.1%)	23 (13.5%)	
Endocarditis	17 (4.8%)	10 (5.4%)	7 (4.1%)	
Congenital	24 (6.7%)	8 (4.3%)	16 (9.4%)	
Annular dilation/DCMP	37 (10.4%)	21 (11.3%)	16 (9.4%)	
Trauma	2 (0.6%)	1 (0.5%)	1 (0.6%)	.258

NYHA, New York Heart Association; BSA, body surface area; CAOD, coronary artery obstructive disease; DCMP, dilated cardiomyopathy.

The mean follow-up period was 46.6 ± 32.6 months (43.0 ± 31.5 months for the Carpentier ring and 50.6 ± 33.4 months for the Duran ring), and the cumulative follow-up was 1368.2 patient-years (663.7 patient-years for the Carpentier ring and 704.5 patient-years for the Duran ring).

Statistical Analysis

Valve-related complications were defined in accordance with the guidelines established by the American Association for Thoracic Surgery and the Society of Thoracic Surgeons. All data are presented as the mean ± standard deviation. The variables of the 2 groups were compared by using the unpaired *t* test. In the analysis of serially checked echocardiographic parameters, the Wilcoxon signed-rank test and the repeated-measures analysis of variance test were applied. Estimates of survival and event-free survival for

reoperation and the recurrence of significant MR were calculated by using the Kaplan–Meier method and are reported with 95% confidence limits. Patients were censored (ie, withdrawn from the study at the time of reoperation or at the time of death). The SAS software package (SAS 8.0; SAS Institute, Inc, Cary, NC) was used for the statistical power analysis of these results.

Estimates are reported with their standard errors. Comparisons of the curves were established by using the log-rank test for long-term results. To analyze risk factors affecting late mortality, we reviewed preoperative and intraoperative variables (listed in Tables 1 and 2); multivariable Cox proportional hazards regression models were used to calculate hazard ratios (HRs) after adjustments were made for preoperative factors. Model selection was performed with a backward stepwise method. HRs and 95% confidence intervals

TABLE 2. Techniques of mitral valve repair

	Carpentier ring	Duran ring	P value
Ring annuloplasty	187 (100%)	170 (100%)	
Segmental resection of leaflet	154 (82.4%)	129 (80.6%)	
New chordae formation with PTFE sutures	43 (23.0%)	40 (23.5%)	
Chordae shortening	12 (6.4%)	9 (5.3%)	
Chordae transfer	2 (1.1%)	1 (0.6%)	
Commissurotomy	6 (3.2%)	3 (1.8%)	.743

PTFE, Polytetrafluoroethylene.

TABLE 3. Concomitant operations

	Carpentier ring	Duran ring	P value
Tricuspid annuloplasty	24 (12.8%)	30 (17.6%)	
Coronary artery bypass grafting	20 (10.7%)	12 (7.1%)	
Aortic valve replacement	20 (10.7%)	5 (2.9%)	
Repair of atrial septal defect	4 (2.1%)	4 (2.4%)	
Maze procedure for atrial fibrillation	6 (3.2%)	4 (2.4%)	
Graft interposition of aorta	2 (1.1%)	0	
Bentall procedure	2 (1.1%)	1 (0.6%)	.065

TABLE 4. Echocardiographic results

	Carpentier ring			Duran ring		
	Preop	Postop	Last f/u	Preop	Postop	Last f/u
LVEF (%)*	62.5 ± 11.8	55.9 ± 13	59.0 ± 12.3	63.2 ± 11.9	56.5 ± 14.1	60.2 ± 11.5
LVESD (mm)*	46.2 ± 11.7	42.1 ± 10.1	37.1 ± 9.3	45.8 ± 11.9	41.2 ± 10.5	37.1 ± 8.2
LVEDD (mm)*	58.3 ± 12.3	48.6 ± 10.3	48.8 ± 8.3	59.4 ± 11.7	50.6 ± 9.1	50.4 ± 8.2
LAD (mm)*	51.1 ± 9.1	44 ± 8.6	43.8 ± 9.5	52.8 ± 11.2	45.3 ± 9.4	45.9 ± 10

There were no significant differences between the 2 rings in each parameter (repeated-measures analysis of variance). *Preop*, Preoperative; *Postop*, postoperative (immediate); *f/u*, follow-up; *LVEF*, left ventricular ejection fraction; *LVESD*, left ventricular end-systolic dimension; *LVEDD*, left ventricular end-diastolic dimension; *LAD*, left atrial dimension. *All parameters were changed significantly ($P < .001$), except left atrial dimension between postoperative and last follow-up at serial examination by means of echocardiography.

(95% CIs) were calculated. Results were calculated by using the statistical software package SPSS 12.0 (SPSS, Chicago, Ill).

Results

There were 4 operative deaths among the 356 patients (mortality, 1.1%), all of which occurred in the Duran ring group. The cause of death was heart failure in 2 patients, upper gastrointestinal bleeding in 1 patient, and sudden ventricular fibrillation in 1 patient. Two patients underwent reoperation in the early postoperative period for significant MR caused by valve perforation (Carpentier ring, 1) or hemolysis (Duran ring, 1).

The transthoracic echocardiogram performed on the seventh postoperative days revealed that 20 (5.6%) patients had greater than grade 2 MR (grade 2, 14 patients; grade 3 or 4, 5 patients). Among them, 1 patient died postoperatively, 2 patients underwent mitral valve replacement later, and the others are under observation.

Changes in Left Ventricular Function

Preoperative and postoperative left ventricular ejection fractions, left ventricular dimensions, and left atrial dimensions are shown in Table 4. All parameters except left atrial dimensions from the immediate postoperative period to the last follow-up at serial echocardiographic examination had changed significantly ($P < .001$). The ejection fraction was decreased in the immediate postoperative period; in the late follow-up period, it was increased significantly. The left ventricular dimensions were significantly decreased at the time of serial echocardiography. The left atrial dimension was decreased in the immediate postoperative period, but there was no change at late follow-up. There was no significant difference between the 2 rings in the tendency of changes of each parameter (repeated-measures analysis of variance).

Late Death and Patient Survival

Of the 352 patients discharged from the hospital, 21 patients died during the follow-up period (late mortality, 5.8%). Of the 21 deaths, 11 were in the Carpentier ring group (late mortality, 5.9%), and 10 were in the Duran ring group (late

mortality, 6.0%). The 2 most common causes of late death were heart failure ($n = 6$) and malignancy ($n = 5$). There were 4 unknown causes of late death. Other causes of late death were intracranial hemorrhage in 2 patients, acute myocardial infarction in 1 patient, ventricular arrhythmia in 1 patient, chronic renal failure in 1 patient, and motor vehicle accident in 1 patient. There was no significant difference between the 2 groups.

The Kaplan–Meier survival in all patients was 93.3% ± 1.7% at 5 years (Carpentier ring, 95.6% ± 1.7%; Duran ring, 91.4% ± 2.8%) and 77.4% ± 8.0% at 10 years (Carpentier ring, 85.9% ± 4.9%; Duran ring, 75.7% ± 7.2%; Figure 1). There were no statistical differences in the survival rates between the Carpentier ring group and the Duran ring group ($P = .74$).

The Cox regression hazard model identified age and an ejection fraction of less than 40% as risk factors for late death (Table 5).

Figure 1. Actuarial survival. *C ring*, Carpentier ring group; *D ring*, Duran ring group.

TABLE 5. Cox regression analysis

	<i>P</i> value	Hazard ratio	95% CI
Late death			
Age	.001	1.09	1.04-1.14
LVEF <40%	.030	5.37	1.17-24.54
Reoperation			
Postop MR ≥2	.003	20.67	2.72-156.8
Recurrence of mitral regurgitation			
Preop TR ≥3	.03	6.18	1.44-33.4
Postop MR ≥2	<.001	12.26	3.21-46.83

CI, Confidence interval; LVEF, left ventricular ejection fraction; Postop, postoperative; Preop, preoperative.

Three hundred ten patients had 50% or greater than 50% ejection fraction preoperatively. The actuarial survival of the patients was identical to that of the general population matched by age and sex, but it is lower when the operation was performed in patients with an ejection fraction of less than 50% (Figure 2).

Thromboembolism and Anticoagulation-related Hemorrhage

There were no thromboembolic complications during follow-up. Two patients experienced major hemorrhage during anticoagulation therapy. Freedom from major bleeding caused by anticoagulation at 10 years was 99.1% ± 0.7% overall, 100% for patients in the Carpentier ring group, and 98.2% ± 1.3% for patients in the Duran ring group (*P* = .16).

Figure 2. Actuarial survival according to preoperative left ventricular ejection fraction (gray line, actuarial survival of general population matched by age and sex). EF, Ejection fraction.

Infective Endocarditis

Three patients had infective endocarditis, and 1 patient died. Two patients were treated with antibiotics alone. Freedom from infective endocarditis at 10 years was 98.6% ± 0.9% for all patients, 98.7% ± 0.9% for patients in the Carpentier ring group, and 98.6% ± 1.4% for patients in the Duran ring group (*P* = .56).

Reoperation

Reoperation was required in 8 patients. The causes of reoperation were progression of MR in 5 patients (Carpentier ring, 1; Duran ring, 4), hemolysis in 2 patients with a Duran ring, and endocarditis in 1 patient with a Carpentier ring. The mitral valves were replaced in all 6 patients who had undergone valve repair with a Duran ring. The mitral valves were re-repaired in 2 patients with a Carpentier ring (1 with a chordae rupture and 1 with endocarditis).

Kaplan-Meier analysis for freedom from reoperation in all patients was 99.3% ± 1.7% at 5 years (Carpentier ring, 99.5% ± 0.5%; Duran ring, 95.7% ± 2.3%) and 77.4% ± 8.0% at 10 years (Carpentier ring, 95.5% ± 3.9%; Duran ring, 86.1% ± 7.9%; Figure 3). There were no statistical differences in survival rates between the Carpentier ring group and the Duran ring group (*P* = .174).

In regard to the causes of MR, freedom from reoperation was 98.2% ± 1.4% in degenerative MR, 92.3% ± 7.4% in rheumatic MR, and 76.9% ± 17.5% in MR caused by cardiomyopathy at 7 years (degenerative vs rheumatic, *P* = .45; degenerative vs cardiomyopathy, *P* = .0005; rheumatic vs cardiomyopathy, *P* = .07), and 10-year freedom from reoperation in degenerative MR was 87.6% ± 8.1%.

Figure 3. Freedom from reoperation. C ring, Carpentier ring group; D ring, Duran ring group.

Figure 4. Freedom from recurrence of significant mitral regurgitation (MR, grade ≥ 3). C ring, Carpentier ring group; D ring, Duran ring group.

The Cox proportional hazard model identified MR equal to or greater than grade 2 at the early postoperative period as a risk factor for reoperation (Table 5).

Recurrence of Significant MR

Recurrence of significant MR equal to or greater than grade 3 during the follow-up period occurred in 23 patients (Carpentier ring, 8; Duran ring, 15). Among them, 5 patients required reoperation.

Freedom from significant MR was $92.7\% \pm 2.2\%$ at 4 years (Carpentier ring, $95.0\% \pm 2.3\%$; Duran ring, $90.8\% \pm 3.7\%$) and $59.1\% \pm 11.5\%$ at 8 years (Carpentier ring, $62.6\% \pm 19.0\%$; Duran ring, $55.5\% \pm 14.1\%$; Figure 4). There were no statistical differences in the recurrence of significant MR between the Carpentier ring group and the Duran ring group ($P = .172$). The statistical power (β) of survival analysis in terms of the recurrence of MR was performed to determine whether there was enough power in this model, and it was .751.

In patients with degenerative disease, we analyzed freedom from recurrence of significant MR for the evaluation of the disease progression. Freedom from the recurrence of significant MR in patients with degenerative disease was $95.5\% \pm 2.2\%$ at 4 years and $53.8\% \pm 17.8\%$ at 8 years. Freedom from the recurrence of significant MR according to the presence of early residual MR (residual MR ≤ 1 vs residual MR ≥ 2) was analyzed and found to be $97.6\% \pm 1.7\%$ in the group with residual MR of grade 1 or less and $50.0\% \pm 25.0\%$ in the group with residual MR of grade 2

or greater at 4 years and $55.4\% \pm 23.1\%$ in the group with residual MR of grade 1 or less and $25.0\% \pm 21.7\%$ in the group with residual MR of grade 2 or greater at 8 years ($P < .01$).

The Cox regression hazard model identified preoperative tricuspid regurgitation of grade 3 or greater and MR of grade 2 or greater in the immediate postoperative period as risk factors for the recurrence of significant MR (Table 5). We reanalyzed the late failure of MR repair, excluding the early postoperative residual MR (grade ≥ 2) because residual MR so strongly related to late MR. The preoperative and intraoperative independent predictors for the recurrence of significant MR included dilated cardiomyopathy (HR, 24.5; 95% CI, 5.7~104.5), chordae shortening technique (HR, 7.5; 95% CI, 2.0~27.9), new chordae formation technique (HR, 5.0; 95% CI, 1.4~18.1), male sex (HR, 2.7; 95% CI, 1.0~7.4), and age by increment of 1 year (HR, 1.05; 95% CI, 1.01~1.09).

Discussion

Lillehei and associates¹⁰ introduced the concept of annuloplasty in 1957; subsequent suture annuloplasty techniques were developed by Reed and coworkers¹¹ and Kay and Egerton.¹² An improved approach that began to address the more complex leaflet pathology was pioneered by Carpentier and colleagues.¹³ As Carpentier's results were duplicated, studies began to demonstrate numerous advantages of valve repair over valve replacement. These advantages included improved maintenance of left ventricular function, lower risk of thromboembolism and anticoagulant-related complications, reduced risk of endocarditis, and increased freedom from all valve-related complications. Subsequently, the long-term durability of valve repair became firmly established, and the various advantages of repair over replacement led to an acceptance of valve repair as the preferred treatment of mitral insufficiency.¹⁴

This study was designed to compare the long-term results between rigid and flexible rings. Freedom from reoperation and recurrence of MR were somewhat lower in the Duran ring group, but this difference did not reach statistical significance. Among 8 patients who required reoperation, the cause of recurrence of MR in 2 patients was the elongation of the anterior-posterior diameter of the mitral annulus because of the morphologic deformation of the Duran ring, which resulted in the inability to achieve annular fixation; however, it is unclear why the recurrence and reoperation rate is higher in the Duran ring group. More long-term data might be required to make a conclusion on the longevity of different annuloplasty ring types.

Although flexible annuloplasty devices preserve the normal annular motion and orifice area during the cardiac cycle, this benefit might be offset by their decreased ability to geometrically remodel the annulus, which could have a

negative effect on late repair durability. David and associates⁶ showed that patients with flexible ring annuloplasty have better left ventricular systolic function 2 to 3 months postoperatively, but this difference disappears after 1 year. Meanwhile, van Rijk-Zwikker and coworkers⁸ demonstrated that there were minimal differences of mural leaflet motion and diastolic filling of the basal part of the left ventricle between the rigid and flexible rings in an animal study. These kinds of data were also identified by the Stanford group.⁷ They demonstrated no significant differences between rigid and flexible rings in terms of left ventricular systolic performance and energetics 1 and 6 weeks after the operation. According to our late follow-up echocardiographic data, mitral valve repair with an annuloplasty ring improved the left ventricular ejection fraction and reduced left ventricular dimension, but there were no statistical differences between the degrees of change of these parameters between the 2 groups.

Recently, minimally invasive surgery for functional MR after myocardial infarction or idiopathic dilated cardiomyopathy focused on mitral annular shape.¹⁵ The tethering effect of the posterior mitral leaflet with enlargement of the left ventricular cavity in ischemic or idiopathic dilated cardiomyopathy results in MR. The fundamental surgical concept of dilated cardiomyopathy was to reduce the mitral annulus,^{16,17} especially the anterior-posterior diameter of the mitral annulus, with coaptation of the anterior and posterior leaflet. In this point of view, mitral annulus shape, as well as size, is thought to be very important to long-term outcome. In this series we could not find any significant differences in Kaplan-Meier survival, freedom from reoperation, and recurrence of significant MR. However, there was less incidence of recurrence of significant MR in the Carpentier group without significance ($P = .172$). Therefore it seemed that annuloplasty with a rigid ring might prevent the recurrence of MR with prevention of elongation of the anterior-posterior diameter of the mitral valve.

Even though the causes of MR were heterogeneous, it seems that the causes of MR have little influence on the results. The most common cause of MR was degenerative disease. Mitral valve repair is most applicable to patients with degenerative mitral valve disease, with successful valvuloplasty possible in 95% of such patients.¹⁸ Furthermore, mitral valve repair in these patients has its greatest durability. Deloche and colleagues¹⁹ found that the 15-year freedom from reoperation after mitral valve repair was 93% in patients with degenerative disease; this is similar to our results. The second most common cause of MR was rheumatic disease. The appropriateness of valve repair for patients with rheumatic mitral valve disease (even when repair appears to be technically feasible) is controversial.²⁰ However, Yau and associates²¹ reported that 10-year freedom from reoperation was 87%, and rheumatic mitral valves

should be repaired when technically feasible, accepting a risk of reoperation to maximize survival and reduce morbidity. Even though only a few rheumatic patients (11.2%) were included in this study, there were no late reoperations in patients with rheumatic disease. Most patients with rheumatic mitral stenosis underwent mitral valve replacement because of advanced stage with severe calcification in our hospital. However, mitral valve repair has been recommended in cases of significant MR, even with severe fibrosis. We think that precise preoperative evaluation of the valvular apparatus and careful decision making considering the feasibility of mitral valve repair in these patients led to such a good result.

The Cox regression hazard model revealed that the most potent risk factor for recurrence of significant MR after mitral repair was residual MR observed at the fifth to seventh postoperative days. Flameng and coworkers²² reported that when recurrence of any degree of regurgitation, be it minor, moderate, or severe, is considered, only about 50% of patients remain free from more than trivial mitral incompetence at 7 years after repair. These findings strongly suggest a progression of the disease process with time that results in an increasing degree of valve incompetence.

Even though this study was designed as a prospective and randomized study, the number of patients in both groups was somewhat different. The reason is that 7 patients included initially in this study were excluded later because they underwent reoperation because of residual MR demonstrated by means of intraoperative transesophageal echocardiography. However, during the analysis, the patients were excluded because of removal of bias of long-term results. Including the 7 patients who were excluded from this study, freedom from significant MR was $57.9\% \pm 11.2\%$ at 8 years (Carpentier ring, $61.8\% \pm 18.8\%$; Duran ring, $53.7\% \pm 13.7\%$). Also, there were no statistical differences in the recurrence of significant MR between the Carpentier ring group and the Duran ring group ($P = .072$). However, there was a trend toward difference with time between the groups. There might be a possibility of a significant difference in recurrence of significant MR between 2 groups with longer follow-up.

In patients with rheumatic MR, the long-term results were better than others. There might be a selection bias for mitral valve repair. Most patients with rheumatic MR combined with stenosis underwent mitral valve replacement. Therefore the long-term results might be excellent. There was no significant difference between the 2 types of prosthetic rings in early and long-term results. In this study the number of patients with cardiomyopathy was too small for statistical analysis, and further study should be necessary.

In conclusion, in this prospective and randomized study, we compared the effects of 2 different annuloplasty rings on early and long-term clinical results in patients with MR.

Mitral valve annuloplasty with both rings showed good long-term clinical results. There were no statistical clinical differences between the Carpentier ring and the Duran ring, and follow-up echocardiography demonstrated that both early and late postoperative left ventricular dimensions were significantly reduced and that left ventricular function was significantly improved in both groups. More long-term data might be required to determine the superiority of either of the rings. Meticulous operative skills and intraoperative transesophageal echocardiographic evaluation are mandatory to prevent the late recurrence of MR.

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Discussion

Dr Aubrey C. Galloway, Jr (New York, NY). This was a very nice presentation, and I congratulate you on doing a randomized trial, which we have too often been unable to do in this country. I do have some comments and questions.

The first comment is that this study includes a mixed group of patients, which limits your ability to draw conclusions. Although 66% of the patients had degenerative disease, 10% were rheumatic, and 10% had ischemic or dilated cardiomyopathy. The latter group really has a different mechanism for insufficiency than the degenerative patients, and they consequently have a different mechanism for late repair failure. These 2 groups really need to be evaluated separately.

For example, the patients with ischemic or dilated cardiomyopathy and functional MR had roughly a 25% failure rate for reoperation at 5 to 8 years. Did you see a difference in the rigid versus flexible rings in that group? Others have found that patients with ischemic or dilated cardiomyopathy have better results when rigid or semirigid devices are used.

Second, even when you looked at the overall freedom from reoperation and included all of the patients, there was roughly a 10% difference favoring the rigid group. Likewise, when you looked at freedom from recurrent 3 or 4+ MR, there was a difference favoring the rigid ring group, yet these differences were not statistically significant. Unfortunately, the study is underpowered to detect small or even moderate differences.

The third comment and question has to do with the way you analyzed the degenerative patients. We suspect that degenerative patients would be less likely to have a difference in durability based on the type of annuloplasty because late repair failure in these patients is more often thought to be due to surgical technique or leaflet pathology, such as repair of anterior versus posterior leaflet pathology or rheumatic versus degenerative status. I did not see repair of anterior leaflet pathology mentioned. Did you look at both repair techniques and pathology in your analysis?

Finally, because you used early postoperative residual MR as a variable for your late failure analysis, I think this might have skewed your results because the variable of early postoperative insufficiency might have overwhelmed any other factors that might have been significant. Obviously, patients who had significant early residual MR would be more likely to fail late. Did you analyze the degenerative group in terms of looking at only the preoperative or intraoperative variables, such as technique or pa-

thology, as predictors of failure? It might have been more helpful not to include early postoperative MR in the analysis.

Again, congratulations on a nice trial and the overall good results achieved.

Dr Chang. Thank you very much for your excellent questions and comments. For the first question, we suspected that there were some differences between the rigid ring and the flexible ring in the cohort with dilated cardiomyopathy compared with in the cohorts of idiopathic or ischemic origin. However, as you commented, there were only 40 patients with cardiomyopathy. We had analyzed the differences in the cardiomyopathy group with other groups, and we could not find any significant differences. However, the rigid ring favored the long-term results in recurrence of significant MR. We need more studies with more patients.

For the second question, we found that there were no differences in the long-term results between the anterior mitral leaflet problems and the posterior mitral leaflet problems. Since the late 1990s, we have used Gore-Tex sutures for new chordae formation. We could not find any differences between the anterior and posterior mitral leaflet pathology in terms of long-term results.

Dr Alain F. Carpentier (*Paris, France*). I rise to congratulate you on this sort of study, which is very necessary, a randomized study, very well done, and I think it is the first, as far as I know, concerning the comparison between a flexible and rigid ring. Now there is no surprise that both rings provided a pretty good result because they are based on the same concept of circular annuloplasty as opposed to posterior support. However, based on new data, it is remarkable that we see a trend in favor of rigid remodeling annuloplasty, and this difference might increase with time, as shown by your curves, and might be also improved by using a Physio ring, which is more or less a ring that had 2 advantages of certainly flexibility but a remodeling concept. Therefore my only question, after having congratulated you, is whether you have used or whether you plan to use a Physio ring to see whether there is a difference with these 2 well-known rings.

Again, congratulations, and thank you very much.

Dr Chang. Thank you very much, Professor Carpentier. It was a great comment for me. We actually wanted to use the Physio ring at the time of it being commercially available. However, we suspected that there were minor problems of recurrence of MR with some elongation of the annulus. Although we attempted to coapt the anterior leaflet to the posterior leaflet, we might suspect that the annulus dilates a little bit more than expected during diastole, and we suspected there might be some recurrence of MR. Thus we have used the classical rigid Carpentier rings. I think the rigid ring might have better results in cases of dilated cardiomyopathy, idiopathic as well as ischemic. Thank you very much, sir.

Dr Carlos Duran (*Missoula, Mont*). I rise to comment on this article, primarily because I knew that there were going to be a lot of people, and if they saw my face, they would expect I would have to say something. Basically, what I think is that there is not that much difference. And there is a tendency, a lot of it made by industry, of getting a new type of ring or band every few months. I do not know how many there are now available worldwide; there must be right around 30 to 40 types of rings. I think we are fussing too much about the ring and forgetting that the ring is the final thing of repair, and if your repair is bad, do not expect that the ring, whatever type of ring, is going to compensate for your incompetence or my incompetence. Therefore every time that someone comes along with a new ring, I say, that is fine, go ahead. The scientific basis behind this in 90% of the cases is completely absent. There is no reason except a picture or a fashion; you suddenly discover the mitral valve has the shape of a saddle, so you make a saddle shape. If tomorrow there is another great advance in the knowledge of the mitral valve, and it turns out that in a particular pathology one area is much higher than another, just change the ring. But do not forget that the ring does not solve a bad repair.

I congratulate the authors. This type of work is absolutely essential, and I hope you continue doing it and add other types of rings into the study. Thank you very much.

Dr Chang. Thank you, sir.