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# Restrictive Mitral Valve Annuloplasty for Chronic Ischemic Mitral Regurgitation: A 5-Year Clinical Experience with the Physio Ring

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## ABSTRACT

**Background:** This study investigated the results of restrictive mitral annuloplasty with the semirigid Carpentier-Edwards Physio ring in patients with moderately severe to severe chronic ischemic mitral regurgitation (IMR) and advanced ischemic cardiomyopathy (ICM).

**Methods:** From 2003 to 2007, 100 consecutive patients (mean age ± SD, 69 ± 10 years) with chronic IMR of grades 3 to 4 (3.6 ± 0.5) and a left ventricular ejection fraction (LVEF) of 31% ± 9% (range, 12%-45%) underwent standardized restrictive prosthetic ring annuloplasty (ie, downsizing of 2.7 ± 1.0 [range, 2-4] ring sizes) and concomitant coronary artery bypass grafting. All surviving patients were restudied 8 ± 1 days, 3 ± 1 months, and 2.5 ± 1.0 years after surgery to assess survival, residual MR, New York Heart Association (NYHA) class, and LV function (end-systolic and end-diastolic dimension/volume indices and LVEF). Data were analyzed exploratatively.

**Results:** Survival rates at the postoperative reexamination times were 98%, 97%, and 94%, respectively (1 noncardiac and 5 cardiac deaths). NYHA class improved from 3.5 ± 0.5 to 1.4 ± 0.5 ($P < .0005$). The residual MR grades at discharge, early follow-up, and late follow-up were 0.4 ± 0.5, 0.5 ± 0.5, and 0.4 ± 0.6, respectively ($P < .0005$). Postoperative recurrence of significant IMR (>grade 2) was absent in all patients. The leaflet coaptation height was 8 ± 1 mm and did not decrease significantly over time. All LV dimension and volume indices and the LVEF (41% ± 9% at 2.5 years) improved significantly after surgery ($P < .0005$), even in patients with initially severely reduced myocardial function and a preoperative LVEF of <30% (n = 42; LVEF, 22% ± 5% versus 33% ± 6% at late follow-up; $P < .0005$).

**Conclusion:** Restrictive mitral valve annuloplasty using the semirigid Physio ring corrected chronic IMR in ICM patients with very low mortality and improved contractility. Surgery also prevented recurrence of significant IMR in parallel with the phenomenon of postoperative continuous reverse myocardial remodeling.

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## INTRODUCTION

The effects of surgery on myocardial and valvular function are still incompletely understood in patients with both advanced ischemic cardiomyopathy (ICM) or dilated cardiomyopathy (DCM) and chronic mitral regurgitation (MR). Whenever severe left ventricular (LV) dysfunction is etiogenic for chronic MR, mitral valve (MV) annuloplasty in a "restrictive" (ie, undersized/"downsized") fashion has been proposed as a reliable approach for efficiently correcting MR [Bolling 1995; Bax 2004; Geidel 2005]. However, some of the difficulty in assessing the results of this strategy may lie in the variety of surgical techniques applied (eg, regarding the type of ring material used for annuloplasty), and some other difficulties may lie in the different characteristics of valvular and myocardial pathology. At present, it is still unclear why some patients experience progressive deterioration of myocardial function and secondary recurrent MR consequent to a process of continuous myocardial remodeling, even if an "established" surgical strategy of MV repair has been applied. Our study investigates the early and late results of using a standardized approach of downsizing the MV annulus by 2 to 4 ring sizes with the Carpentier-Edwards Physio ring (Edwards Lifesciences, Irvine, CA, USA), which is a semirigid 2-dimensional ring-shaped device for correcting myocardial function in patients with advanced ICM and moderately severe to severe chronic ischemic MR (IMR) (grades 3-4). We describe a 5-year clinical experience in surgery and relevant postoperative changes with respect to myocardial and valvular function for 100 consecutive patients. We also provide a detailed presentation of the clinical follow-up data.

## MATERIALS AND METHODS

The population of this prospective study consisted of 100 patients with chronic moderately severe to severe MR (grades 3-4) and ICM (LV ejection fraction [LVEF], 31% ± 9%; range, 12%-45%). These patients were scheduled to undergo MV surgery between 2003 and 2007 in our institution

(Table 1). Chronic IMR was defined as MR caused by ischemic heart disease with a normal leaflet morphology and an absence of organic MV disease. This definition also included advanced ICM and a reduced LV function (LVEF of ≤45% and no previous myocardial infarction within 2 weeks before surgery). Our indication for concomitant coronary artery bypass grafting (CABG) was significant coronary artery disease with ≥70% stenosis of at least one significant coronary branch (all 100 cases). Patients were managed medically before and after surgery with standard heart failure medication, including diuretics, angiotensin-converting enzyme inhibitors, and β-blockers. At the time of surgery, 88 patients were in stable sinus rhythm, and 12 patients had permanent atrial fibrillation. Forty other procedures were performed concomitantly in 30 cases, and 12 cases were reoperations (Table 2).

Table 1. Characteristics of 100 Cases of Ischemic Cardiomyopathy and Chronic Ischemic Mitral Regurgitation of Grades 3 to 4*

| | |
|---|---|
| Age, y | 69 ± 10 (45-86) |
| M/F sex, n | 66/34 |
| EuroScore | 9 ± 2 (4-14) |
| NYHA class | 3.5 ± 0.5 (2-4) |
| LVEF, % | 31 ± 9 (12-45) |
| MR grade, n | |
| 3 | 42 |
| 4 | 58 |
| Leaflet tethering, n | |
| Apical-symmetric (central jet) | 65 |
| Posterior-asymmetric (eccentric jet) | 35 |
| Coronary vessel disease, no. of vessels | 2.6 ± 0.7 (1-3) |
| Previous CABG, n | 12 |
| Previous PTCA, n | 66 |
| History of previous MI, n | 90 |
| Location of MI, n | |
| Anterior | 20 |
| Posterior/lateral | 42 |
| Combined | 28 |
| Time of MI, n | |
| 2-6 wk | 10 |
| 6 wk | 52 |
| Combined | 28 |
| Concomitant cardiac disease (in 30 cases), n | 40 |
| AV stenosis | 6 |
| TV regurgitation | 20 |
| ASD | 2 |
| Permanent AF | 12 |

*Data are presented as the mean ± SD (range) where indicated. EuroScore is a score established to evaluate the predicted risk of cardiac operations (low risk, 1-2 points; moderate risk, 3-5 points; high risk, ≥6 points). NYHA indicates New York Heart Association; LVEF, left ventricular ejection fraction; MR, mitral regurgitation; CABG, coronary artery bypass grafting; PTCA, percutaneous transluminal coronary angioplasty; MI, myocardial infarction; AV, aortic valve; TV, tricuspid valve; ASD, atrial septal defect; AF, atrial fibrillation.

Table 2. Surgical Data and Early Postoperative Outcomes for 100 Cases of Ischemic Cardiomyopathy and Chronic Ischemic Mitral Regurgitation of Grades 3 to 4*

| | |
|---|---|
| Downsizing of Physio ring size | 2.7 ± 1.0 (2-4) |
| Prosthetic Physio ring size | 28 ± 2 (24-32) |
| Reoperation, n | 12 |
| Associated procedures (in 30 patients), n | 40 |
| AV replacement | 6 |
| TV repair | 20 |
| ASD closure | 2 |
| Permanent AF RF ablation surgery | 12 |
| No. of grafts | 2.4 ± 0.7 (1-3)† |
| ACC time, min | 88 ± 14 (52-175) |
| CPB time, min | 115 ± 17 (75-199) |
| Operation time, min | 189 ± 23 (125-297) |
| Perioperative IABP, n | 12 |
| Reoperation for bleeding, n | 0 |
| Perioperative MI, n | 2 |
| Pneumonia, n | 7 |
| Cerebrovascular events, n | 7 |
| Wound infection, n | 2 |
| ICU stay, d | 6 ± 5 (2-29) |
| Hospital stay, d | 13 ± 6 (6-32) |
| 30-d mortality, n | 2 |
| Cardiac death | 2 |
| Noncardiac death | 0 |

*Data are presented as the mean ± SD (range) where indicated. AV indicates aortic valve; TV, tricuspid valve; ASD, atrial septal defect; AF, atrial fibrillation; RF, radiofrequency; ACC, aortic cross-clamping; CPB, cardiopulmonary bypass; IABP, intra-aortic balloon pump; MI, myocardial infarction; ICU, intensive/intermediate care unit.

†At least one arterial graft (predominantly the left internal mammary artery) was used in 79% of the patients.

### *Surgery*

Following sternotomy, distal CABG anastomoses were performed with the patient on cardiopulmonary bypass (CPB) under the protection of antegrade Bretschneider cardioplegia. The left atrium (LA) was opened by a standard left atriotomy, and etiologic, functional, and segmental MV analyses were performed according to the technique of Carpentier [Carpentier 1983]. Intraoperative transesophageal echocardiography (TEE) examinations confirmed in all cases chronic IMR (Carpentier type I/IIIb) without associated organic MV disease (combined annular dilatation, displacement of the papillary muscles, and more or less intense tethering of the mitral leaflets due to myocardial dysfunction). Next, we performed permanent atrial fibrillation radiofrequency-ablation surgery in 12 patients by means of the Cobra® device (Boston Scientific Corporation, San Jose, CA, USA). Then, sizing was carried out for prosthetic ring annuloplasty: The ring sizers for the Physio ring were compared with the commissural distance and the surface of the anterior leaflet to evaluate the "normal" size. A ring was identified to have a normal size when the commissural distance coincided with the sizer and precisely covered the anterior leaflet. Next, restrictive

MV annuloplasty was performed in a dynamic fashion over 2 to 4 sizes, depending on the patient's LV function (for LVEFs of >30%, 20%-30%, and <20%, the prosthetic rings were downsized 2, 3, and 4 ring sizes, respectively), and an undersized (semirigid) Carpentier-Edwards Physio ring (sizes, 24-32; mean ± SD, 28 ± 2) was implanted with 12 to 15 single 2x0 Ethibond sutures (Ethicon, Somerville, NJ, USA). Preservation of valve symmetry and proper leaflet coaptation was precisely evaluated by filling the ventricle with saline solution. All other concomitant procedures and proximal CABG anastomoses were performed after LA closure.

### *Echocardiography and Protocol Design*

Functional status was assessed according to New York Heart Association (NYHA) criteria within 1 week before surgery. Transthoracic echocardiography (TTE) and TEE were performed within 3 days before surgery with a VingMed Vivid 5 system (GE Heathcare, Fairfield, CT, USA). LV and LA dimensions were determined from parasternal M-mode acquisitions. MR severity was graded from color-flow Doppler in the parasternal long axis and from apical 4-chamber images. MR was quantified by the vena contracta and the maximal jet area/left atrial area. MR was characterized as mild, moderate, moderately severe, and severe (grades 1, 2, 3, and 4) according to vena contracta (4-5, 6-7, and >7 mm) and jet area/left atrial area (<10%, 10%-20%, 21%-45%, and >45%). A mean of 3 cardiac cycles was taken for MR measurements. When MR severity was less than grade 3, a standard provocative test was performed. The tethering of both leaflets was described to be predominantly apical-symmetric or posterior-asymmetric with either the central or the eccentric jet in the LA. After CPB, TEE was performed with a VingMed Vivid 3 system (GE Healthcare) to assess residual MR, the MV area, and the leaflet coaptation height (LCH), a parameter that is used to assess sufficient mitral leaflet coaptation. A residual MR grade of ≤1, an MV area >2.2 $cm^2$, and an LCH of ≤5 mm were assessed as a good result for MV repair. Clinical follow-up and serial TTE studies were performed (before discharge at 8 ± 1 days, 3 ± 1 months [ie, early follow-up; range, 2-4 months], and at 2.5 ± 1.0 years [ie, late follow-up; range, 0.5-4.5 years]) to assess survival, NYHA class, MR, LCH, LA and LV dimensions (LA diameter, LV end-diastolic dimension [LVEDD], and LV end-systolic dimension [LVESD]), and fractional shortening (FS = [LVEDD – LVESD]/LVEDD × 100%). LV volumes (LV end-diastolic volume [LVEDV] and LV end-systolic volume [LVESV]), the LV end-diastolic volume index, and the LV end-systolic volume index were calculated with the biplane Simpson method from the apical 4- and 2-chamber views [Grigioni 2001]. The LVEF was evaluated as follows: LVEF = (LVEDV – LVESV)/LVEDV × 100%. All postoperative TTE investigations were analyzed at random with a VingMed Vivid 5 system by experienced cardiologists who were blinded to TTE timing and the precise clinical and surgical data (eg, annuloplasty ring size, previous LA and LV dimensions/volumes, and functional status). Aortic cross-clamping time, CPB time, and total operation time were documented according to the protocol. We noted further pre- and postoperative cardiac rhythm studies, the need for an intra-aortic balloon pump, intensive/intermediate care unit stays, and the following complications: cardiac and noncardiac death, reoperation for bleeding, perioperative myocardial infarction, cerebrovascular events, pneumonia, and wound infection. We noted the following events at follow-up: cardiac and noncardiac death, reoperation for recurrent MR, endocarditis, and myocardial infarction.

### *Statistical Analysis of the Data*

Continuous data were described as the mean ± SD or as the median (25th/75th percentiles), as appropriate. Qualitative data were presented as absolute frequencies and compared by means of the Fisher exact chi-square test. Changes in repeatedly measured functional parameters and echocardiographic values were investigated within groups by means of the Friedman test (Monte Carlo method; upper bound of 99% confidence interval given). Relative changes from the first postoperative week to the 3-month and 2.5-year follow-ups were calculated and compared by means of the Mann-Whitney *U* test. An exploratory data analysis was performed for data assessment. All *P* values were 2-tailed and interpreted nominally, ie, not adjusted further for multiple comparisons on the data set; *P* values <.05 were considered statistically significant. Statistical analyses were performed with SPSS for Windows (version 11.5.2.1; SPSS, Chicago, IL, USA).

## RESULTS

Relevant surgical data and early postoperative results are given in Table 2, and survival, functional status, and echocardiography data are summarized in Table 3. No case of myocardial infarction, endocarditis, or reoperation due to recurrent MR occurred during the follow-up period.

### *Survival*

The 30-day mortality rate was 2.0% (2 early cardiac deaths). The survival rates at 3 months and 2.5 years were 97% and 94%, respectively (3 cardiac and 1 noncardiac late deaths). A comparison of the data for the 5 patients with early or late cardiac death with the data for all of the other patients demonstrated increased preoperative end-diastolic values (LVEDV and LVEDD) and decreased LVEF values in the death cases. Death occurred in 9% (2/13) of the patients with LVEDV values >200 mL before surgery, in 13% (2/15) of the patients with LVEDD values >70 mm, and in 12% (3/25) of the patients with LVEF values of <25%.

### *Functional Class*

The NYHA class improved significantly from 3.5 ± 0.5 before surgery to 1.4 ± 0.5 at the late follow-up ($P < .0005$). Eighty-nine percent (86/97) and 98% (92/94) of the patients had reached NYHA class I or II by the 3-month and 2.5-year follow-ups, respectively. The NYHA class of patients with a severely reduced LV function preoperatively (n = 42; LVEFs, 12%-29%) was worse than that of patients with a better preoperative myocardial function, both before

Table 3. Survival, Functional Status, and Echocardiographic Results for 100 Cases of Ischemic Cardiomyopathy and Chronic Ischemic Mitral Regurgitation of Grades 3 to 4 after Restrictive Mitral Valve Annuloplasty with the Physio ring*

| | Before Surgery | End of CPB | 8 ± 1 Days | 3 ± 1 Months | 2.5 ± 1.0 Years | *P* |
|---|---|---|---|---|---|---|
| Total deaths, n | – | – | 2 | 3 | 6 | – |
| Total survivors, n | 100 | 100 | 98 | 97 | 94 | – |
| NYHA class | 3.5 ± 0.5 | – | – | 1.8 ± 0.6 | 1.4 ± 0.5 | <.0005 |
| MR grade† | 3.6 ± 0.5 | 0.4 ± 0.4 | 0.4 ± 0.5 | 0.5 ± 0.5 | 0.4 ± 0.6 | <.0005 |
| LCH, mm | – | 8 ± 1 | 8 ± 1 | 7 ± 1 | 7 ± 1 | – |
| MVA, $cm^2$ | – | 2.9 ± 0.5 | 2.9 ± 0.5 | 2.9 ± 0.6 | 2.9 ± 0.6 | – |
| LVEDD, mm | 63 ± 8 | – | 59 ± 8 | 58 ± 7 | 57 ± 7 | <.0005 |
| LVESD, mm | 50 ± 9 | – | 46 ± 10 | 43 ± 11 | 40 ± 10 | <.0005 |
| FS, % | 20 ± 8 | – | 23 ± 8 | 25 ± 7 | 26 ± 7 | <.0005 |
| LA, mm | 52 ± 6 | – | 48 ± 6 | 46 ± 5 | 44 ± 4 | <.0005 |
| LVEDVI, $mL/m^2$ | 105 ± 17 | – | 99 ± 16 | 96 ± 15 | 93 ± 13 | <.0005 |
| LVESVI, $mL/m^2$ | 73 ± 20 | – | 65 ± 18 | 60 ± 17 | 55 ± 15 | <.0005 |
| LVEDV, $mL/m^2$ | 194 ± 32 | – | 182 ± 30 | 178 ± 27 | 173 ± 25 | <.0005 |
| LVESV, $mL/m^2$ | 134 ± 38 | – | 119 ± 34 | 111 ± 32 | 104 ± 29 | <.0005 |
| LVEF, % | 31 ± 9 | – | 35 ± 10 | 38 ± 10 | 41 ± 9 | <.0005 |

*Data are presented as the mean ± SD. CPB indicates cardiopulmonary bypass; NYHA, New York Heart Association; MR, mitral regurgitation; LCH, leaflet coaptation height; MVA, mitral valve area; LVEDD, left ventricular end-diastolic dimension; LVESD, left ventricular end-systolic dimension; FS, fractional shortening; LA, left atrium; LVEDVI, left ventricular end-diastolic volume index; LVESVI, left ventricular end-systolic volume index; LVEDV, left ventricular end-diastolic volume; LVESV, left ventricular end-systolic volume; LVEF, left ventricular ejection fraction.

†MR: 59% grade 0 (n = 55), 38% grade 1 (n = 36), and 3% grade 2 (n = 3). Median MR grade (25th/75th percentiles): before surgery, 4.00 (3.00/4.00); end of cardiopulmonary bypass, 0.00 (0.00/1.00); at 8 days, 0.00 (0.00/1.00); at 3 months, 1.00 (0.00/1.00); and at 2.5 years, 0.00 (0.00/1.00).

surgery (3.8 ± 0.4 versus 3.2 ± 0.5; $P = .025$) and at the late follow-up (1.7 ± 0.5 versus 1.2 ± 0.5; $P = .031$).

### *Mitral Regurgitation*

Intraoperative TEE evaluations demonstrated successful MV repair in all cases. The relevant MR (>grade 2) was absent at discharge in all 98 patients (MR grade 0, 57 patients; grade 1, 41 patients; grade ≥2, 0 patients). At the 2.5-year follow-up, the residual MR was grade 0.4 ± 0.6: grade 0, 59% (n = 55); grade 1, 38% (n = 36); and grade 2, 3% (n = 3). The MV area was 2.9 ± 0.5 $cm^2$ after surgery, and the LCH was 8 ± 1 mm at 1 week and 7 ± 1 mm at the 3-month and 2.5-year follow-ups. Patients with a severely reduced LV function preoperatively (LVEF, 12%-29%; n = 42) were not significantly different from the other patients with respect to MR grade, both before surgery (3.6 ± 0.5 and 3.5 ± 0.5, respectively; $P = .976$) and at the late follow-up (0.6 ± 0.6 and 0.4 ± 0.6, respectively; $P = .854$).

### *Myocardial Function*

LA and LV dimensions/volumes, the FS, and the LVEF improved significantly after surgery (Table 3). The relative median (25th/75th percentiles) changes in LVEF, LVEDV, and LVESV from the first week after surgery to the 2.5-year follow-up were +19% (+5%/+28%), –15% (–30%/–3%), and –20% (–50%/–8%), respectively. The phenomenon of continuous reverse myocardial remodeling was independent of the preoperative LVEF ($P = .290$), sex ($P = .310$), and age ($P = .200$). Continuous improvement in myocardial function was observed even in cases with severely reduced contractility (preoperative LVEF <30%, n = 42; LVEF, 22% ± 5% before surgery versus 33% ± 6% at the late follow-up; $P < .0005$). Patients with a severely reduced LV function preoperatively (ie, LVEF, 12%-29%) differed from patients with a better myocardial function with respect to the LV end-systolic/end-diastolic dimension and volume indices, both before surgery and at the late follow-up ($P < .0005$ for both comparisons).

## DISCUSSION

### *Strategies for Treating Chronic MR Caused by Reduced LV Function*

In ICM and DCM patients with chronic MR, analysis of the MV typically reveals normal leaflet morphology with a competent tensor apparatus but restricted leaflet motion, annular dilatation, and therefore a loss of leaflet coaptation (Carpentier type I/IIIb) [Carpentier 1983]. In this situation, several groups have demonstrated reproducible acceptable short-term results for MV repair but have reported varying degrees of mid- and long-term benefit [Dreyfus 2000; Suma 2000; Bitran 2001]. Some of the differences in these outcomes may lie in the variety of the repair techniques used, and some other differences may be due to the various reasons for LV dysfunction and secondary MV disease themselves. However, coronary artery disease has been implicated as the primary underlying problem in most MV cases with myocardial dysfunction [Trichon 2003a], and the concept of combined CABG and MV annuloplasty in a restricted or "undersized" fashion (downsizing by exactly 2 sizes) was introduced as a reliable surgical strategy [Bax 2004]. The implantation of undersized rings had initially been described by Bolling et al [1995] with the

intention of improving the prognosis for patients with MR and end-stage cardiomyopathy, because MR recurrence and progressive LV remodeling had been observed when "normal-sized" rings or bovine pericardial annuloplasty were used. However, several groups doubted an enduring benefit of surgery in cardiomyopathy patients with severe MR. Hung et al and the Cleveland Clinic group reported on MR recurrence after CABG and MV annuloplasty and concluded that the "myocardial remodeling problem" cannot be adequately interrupted by surgery [Hung 2004; McGee 2004]. Apart from this specific discussion, it is known that the prognosis of individual MV patients with a reduced LVEF depends predominantly on the severity of the symptoms, the degree of LV dysfunction, and the MR grade before surgery, and that the prognosis for ICM patients with conservative therapy or CABG alone is poor [Aklog 2001; Grigioni 2001; Trichon 2003b]. It is also widely accepted that MV repair with preservation of all the valvular structures with prosthetic ring material is generally superior to valve replacement in terms of short- and long-term survival prospects [Grossi 2001; Reece 2004]. Alternative efforts that focus on the problem of asymmetric or symmetric leaflet restriction are patch enlargement of the posterior leaflet with autologous or bovine pericardium, the implantation of specific 3-dimensional prosthetic rings, or LV-restoration procedures [Menicanti 2002; Isomura 2003]. Mid- or long-term data for these approaches are not available at present.

### *Evaluation of Our Own Research Data and Perspectives for Improving on the Current Results*

In contrast to other research, our prospective investigation of 100 patients involved downsizing the MV by 2 to 4 sizes with the Carpentier-Edwards Physio ring. The degree of downsizing depended on the patient's cardiac function, and we obtained satisfactory outcomes after surgery: Early mortality was only 2.0%, and the 2.5-year survival rate was 94%, with almost all of the patients in NYHA class I or II at that time. It is remarkable that all of the survivors were nearly asymptomatic at the late follow-up without any evidence of relevant recurrent MR, as has been described by other investigators using other surgeries [Hung 2004; McGee 2004]. In contrast to other research, our data include a complete TTE series, including at the first week after surgery. These data demonstrate on the one hand that LV end-diastolic and end-systolic dimensions/volumes generally improve over time, that the MR was corrected with enduring sufficiency, and that the phenomenon of reverse myocardial remodeling was observed independently of the degree of LV function before surgery. On the other hand, most patients with early/late cardiac death notably had had highly increased LV end-diastolic dimensions and volume values before surgery. The data demonstrate a significant continuous reverse myocardial remodeling, an experience that is in line with the data of De Bonis et al, who studied 79 ICM and DCM patients with a follow-up of 2 years. These investigators found not only that an ischemic etiology was the main predictor of reverse remodeling but also that MR recurrence paralleled the absence of reverse remodeling [De Bonis 2006]; however, a limitation of this study is that the "double-orifice technique" was routinely used, with the result that almost 10% of the patients had MR of grades ≥3 at the 2-year follow-up. Furthermore, Di Giammarco et al [2006] recently reported on a series of 97 patients with ischemic/nonischemic cardiomyopathy and a follow-up of 4 years. These investigators concluded that the main predictor of MR recurrence was preoperative LV dilatation. The limitations of this investigation were that no restrictive annuloplasty was performed routinely (approximately 60% use of autologous pericardium or suture annuloplasty). In contrast to this experience, our data demonstrate that the "myocardial-remodeling problem" did *not* increase in ICM patients with severe chronic IMR after MV downsizing and that significant MR recurrence did *not* occur. According to the basic research of other groups, who have shown that the anterior MV leaflet trigone distance can enlarge over time [Timek 2005], our group stopped using flexible rings for MV repair in general in 2003, and we have used only semirigid ring material since that time. This strategy is supported by the recent data of Spoor et al [2006], who reported that patients with ischemic or nonischemic MR and ICM/DCM had a higher likelihood of developing recurrent MR requiring reoperation when a flexible ring was used. Interestingly, these authors reported that a flexible ring is unable to provide support over time to the posterior MV annulus, which tended to "fall outwards and downward secondary to ongoing LV wall changes." This finding represents the basis for the approach to the design of rings with a 3-dimensional shape, with the intention of optimizing LV geometry and supporting an adequate and stable zone of coaptation. However, surgery using these ring systems will have to demonstrate whether rings with a 3-dimensional shape are capable of improving on current results [Berdat 2007]. Furthermore, multimodal imaging techniques, including cardiac magnetic resonance imaging, may be of help in using virtual heart models to provide individually based planning of MV repair. In addition, preoperative imaging may be useful for identifying individual remodeling patterns. Perhaps an approach to reduce wall stress and myocyte overstretching from the outside through use of the Acorn CorCap Cardiac Support Device (Acorn Cardiovascular, St. Paul, MN, USA), a mesh-like device that is surgically positioned around the heart, could be a strategy for improving the prognosis for patients with limited reverse remodeling. Experimental studies suggest that the Acorn device can prevent or minimize maladaptive gene expression and phenotypic transformation and may be able to efficiently halt progressive remodeling by supporting the ventricle and reducing stress-mediated myocardial stretching. However, more randomized clinical trials are required to evaluate the long-term effects in patients with chronic severe MV disease and reduced myocardial function, even if the additional benefit recently described for the Acorn CorCap Cardiac Support Device can be achieved [Acker 2006]. The authors of this study reported a greater decrease in the LVEDV and LVESD at a median follow-up of almost

2 years in 91 patients who underwent both Acorn device implantation and MV surgery, compared with 102 patients who underwent MV surgery alone. At present, restrictive MV annuloplasty with the Physio ring can be regarded as a very reliable surgical approach in ICM patients with significant IMR.

## CONCLUSIONS

Restrictive MV annuloplasty with the Carpentier-Edwards Physio ring corrected chronic IMR of grades 3 to 4 in ICM patients, with very low mortality and improved myocardial and valvular function. Surgery prevented recurrence of significant IMR in parallel with satisfactory late survival and the phenomenon of postoperative continuous reverse myocardial remodeling, even in patients with initially severely reduced myocardial function. In summary, the surgical concept we have described can be strongly recommended for ICM patients with relevant chronic IMR.

### *Limitations*

Echocardiographic indices for evaluating global myocardial remodeling that other investigators have described were not evaluated in this study. The study was not designed for patients with ICM and chronic MR of less than grade 3. Even with the application of rigorous exclusion criteria, the study population remained inhomogeneous (40 concomitant surgical procedures had to be performed in 30 patients), and this fact may have influenced the results. The long-term prognosis of the patients is still unknown and should be the subject of further research.

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