

# Prospective Study of Mitral Valve Repair with the CarboMedics AnnuloFlex™ Annuloplasty System: Effectiveness and Safety after One Year

Vibhu R. Kshetry<sup>1</sup>, Louis T. Kanda<sup>2</sup>

<sup>1</sup>Abbott Northwestern Hospital, Minneapolis Heart Institute, Minneapolis, Minnesota, <sup>2</sup>Washington Heart at the Washington Hospital Center, Washington DC, USA

**Background and aim of the study:** The CarboMedics AnnuloFlex™ annuloplasty system includes a flexible ring that may be implanted as a complete or partial ring to correct mitral annular dilatation by reinforcement of the entire annulus, or only the posterior portion of the annulus. The study aim was to evaluate clinical and functional results during the first year in patients receiving this flexible annuloplasty system.

**Methods:** Between February 2001 and August 2002, 69 patients (mean age 55 years; range: 27-81 years) underwent mitral valve repair that included implant of the AnnuloFlex annuloplasty ring. Mitral regurgitation (MR) was the predominant lesion, with 98.6% of patients exhibiting grade 3/4 insufficiency. Functional classification of valve pathology was normal leaflet motion (type I) in 4% of patients, leaflet prolapse (type II) in 93%, and restricted leaflet motion (type III) in 3%. Valve disease was degenerative in 90%, ischemic in 4%, infectious in 3%, and other in 3%.

**Results:** There was one hospital death. Late follow up

was obtained for 62 patients; cumulative follow up was 61 patient-years. One-year actuarial survival was 99%, freedom from thromboembolism was 94%, from endocarditis 98%, and from reoperation 98%. Echocardiographic evaluations performed at 3-6 months after repair (mean 4.7 months) showed MR to be grade 0/1+ in 90% of patients and grade 2+ in 8%. Mitral valve area was  $3.4 \pm 1.7 \text{ cm}^2$ , within normal limits (mitral valve area  $\geq 1.5 \text{ cm}^2$ ) in 95% of patients. Average peak and mean pressure gradients were  $5.9 \pm 3.0$  and  $2.8 \pm 1.7 \text{ mmHg}$ , respectively. Left ventricular end-diastolic diameter decreased postoperatively, which may reflect successful correction of MR after mitral valve repair.

**Conclusion:** These early results show that the AnnuloFlex annuloplasty system is safe and effective when used with other techniques for repair of MR, and preserves mitral annular flexibility and function at one-year follow up.

The Journal of Heart Valve Disease 2005;14:105-113

Surgical reconstruction of the mitral valve is widely accepted as an effective treatment for mitral regurgitation (MR). Patient outcome is better with mitral valve repair than replacement, mainly because left ventricular function is better maintained with subvalvular preservation (1-7). Mitral valve repair is also associated with low operative mortality, excellent long-term survival, low failure rate, and few long-term complications. Annuloplasty rings are generally used in mitral reconstruction to correct annular dilatation, increase leaflet coaptation, and prevent recurrent or progressive annular dilatation (8-10). The first annuloplasty

rings were rigid rings designed to remodel the annulus to its correct size and shape. Flexible rings were developed later to preserve annular motion and left ventricular function by remodeling of the mitral annulus without restricting physiological movement, thus achieving only correction of annulus dilatation. Previous studies have shown that the mitral annulus flexes during the cardiac cycle, and mitral annulus dilatation occurs along the attachment of the posterior leaflet, while the anterior portion of the annulus does not change significantly during systole (11). Therefore, annular dilatation may be corrected by reinforcement of the posterior annulus only by using a partial annuloplasty ring. However, in ischemic or dilated cardiomyopathy, dilatation of the mitral ring is proportional and does not exclusively affect the posterior annulus (12). These patients benefit from a complete ring. The study aim was to collect data on the

---

Address for correspondence:

Vibhu R. Kshetry MD, Abbott Northwestern Hospital, Minneapolis Heart Institute, 920 East 28th Street, Suite 610, Minneapolis, Minnesota, 55407 USA  
e-mail: Vibhu.Kshetry@aol.com

effectiveness and clinical outcome of the CarboMedics AnnuloFlex™ annuloplasty ring, that may be implanted as either a complete or partial ring to reinforce either the entire native annulus or only its posterior portion while retaining the native valve apparatus.

## Clinical material and methods

### AnnuloFlex annuloplasty system

The AnnuloFlex System consists of a flexible silicone annuloplasty ring, a translucent template, and a holder. The silicone ring is enclosed with a knitted polyester fabric and impregnated with barium sulfate, which enables radiographic visualization. All materials are non-ferrous and do not present a significant risk during magnetic resonance imaging. The mitral annuloplasty ring has a kidney-shaped blue holder, the curved posterior segment of which corresponds to the native posterior leaflet. The straight anterior portion of the holder corresponds to the native anterior leaflet. Two suture cut points on the anterior segment allow for intraoperative selection of either a partial or complete annuloplasty ring. The AnnuloFlex annuloplasty ring is available (in increments of 2 mm) in sizes from 26 to 36 mm.

Table I: Preoperative patient characteristics (n = 69).

Parameter	Value
Age (years)*	55.8 (27-81)
Body surface area (m <sup>2</sup> )*	2.0 (1.4-2.4)
LVEF (%)*	57.3 (30-75)
Age at implant (years)	
20-29	1 (1.4)
30-39	4 (5.8)
40-49	19 (27.5)
50-59	17 (24.6)
60-69	16 (23.2)
70-79	11 (15.9)
80-89	1 (1.4)
Gender	
Male	47 (68.1)
Female	22 (31.9)
NYHA functional class	
I	23 (33.3)
II	34 (49.3)
III	10 (14.5)
IV	2 (2.9)
Sinus rhythm	58 (84.1)

\*Values are mean (range).

Values in parentheses are percentages.

LVEF: Left ventricular ejection fraction.

### Patient population

Between February 2001 and August 2002, 69 adult patients (47 men, 22 women; mean age 55.8 years; range: 27 to 81 years) with MR underwent mitral valve repair that included implant of the AnnuloFlex annuloplasty ring. Approval was obtained from the Institutional Review Board at each center before the start of the study. Before entering the study, each patient signed an informed consent and agreed to return for a follow up visit between three and six months after surgery.

Before mitral valve repair, 57 patients (83%) were in NYHA classes I/II, and 12 (17%) were in NYHA classes III/IV. The predominant cardiac conditions were left atrial enlargement (87%) and left ventricular dilatation (57%). Preoperative patient characteristics are listed in Table I.

### Valve disease and pathology

In each patient MR was the predominant lesion identified, with 98.6% of patients exhibiting grade 3/4 insufficiency. The cause of MR was degenerative disease in 89.9% of patients (Table II). Patients were classified into three groups according to the functional analysis of the mitral valve (Table II). Leaflet prolapse

Table II: Mitral valve disease etiology, functional classification and pathology.

Condition/pathology	No. of patients
<i>Mitral valve disease</i>	
Degenerative disease	62 (89.9)
Myxomatous	47 (68.1)
Fibroelastic deficiency	13 (18.8)
Barlow's disease	4 (5.8)
Ischemic	3 (4.3)
Endocarditis	2 (2.9)
Rheumatic	1 (1.4)
Congenital	1 (1.4)
<i>Functional classification</i>	
I. Normal leaflet motion	3 (4.3)
II. Leaflet prolapse	64 (92.8)
Anterior	3 (4.3)
Posterior	51 (73.9)
Anterior + posterior	10 (14.5)
III. Restricted leaflet motion	2 (2.9)
<i>Valve pathology</i>	
Leaflet prolapse	64 (92.8)
Chordal elongation	33 (47.8)
Dilated annulus	28 (40.6)
Chordal rupture	22 (31.9)
Perforated leaflets	1 (1.4)

Values in parentheses are percentages.

was the most common functional anomaly (92.8%).

### Surgical technique

Each patient underwent annular remodeling with the AnnuloFlex ring. The rings were inserted after completion of valve repair and restoration of leaflet coaptation. In order to select the correct ring size, the anterior leaflet of the mitral valve was unfurled and the ring sizer used to measure the height of the anterior leaflet. The intercommissural distance was then measured by placing the notches on the sizer at the commissures. The AnnuloFlex ring was sutured into place with horizontal mattress sutures using the implant template, which has marks indicating the location of the commissures and a suture placement guide. Sutures were then placed around the annulus, keeping the implant holder in place until the sutures were tied down. For the implantation of a partial ring, the sutures were placed from trigone to trigone, and upon placement of the anterior-most sutures the anterior portion of the ring was removed. As per standard practice at each site, patients underwent intraoperative transesophageal echocardiography (TEE) to determine the presence of residual MR and to assess the overall success of the mitral valve repair.

The repair techniques used on specific structures of the mitral valve are listed in Table III. In 91.3% of cases, a partial ring was used to reinforce only the posterior annulus. In addition to annular remodeling, the most common repair technique was posterior leaflet resection, usually in combination with the sliding leaflet procedure (13). The sizes of the ring implanted are listed in Table III. Concomitant procedures included coronary artery bypass grafting (18.8%) and patent foramen ovale closure (18.8%). Three patients also had concomitant tricuspid valve repair (two with DeVega annuloplasty, one patient with the AnnuloFlex ring).

Most patients were placed on anticoagulation or antiplatelet therapy for six to eight weeks after surgery, at which time the therapy was stopped if the patient was in sinus rhythm and did not have any other medical condition that required anticoagulation.

### Patient follow up

Patients returned to the hospital for a physical examination and echocardiographic evaluation at three to six months after surgery. Patients were later contacted by telephone at 12 months to assess their status and outcomes. If subsequent hospitalization, death or valve-related events had occurred, the patient's physician or appropriate hospital records department were contacted to document the events or hospitalization.

Of the 69 patients in the study, 62 survived hospitalization. In two patients the mitral repair failed to correct the MR; hence, the AnnuloFlex ring was removed

and the patients received a prosthetic valve, using the same procedure. These patients were not included in the analysis of postoperative results. One patient died from cardiac arrest nine days after surgery, but the cause of death was not related to the AnnuloFlex ring. Four patients withdrew from the study due to physical disabilities unrelated to their valve repair, which prevented them from returning for their scheduled follow up visit. None of the remaining patients was lost to follow up.

The data reported herein include patient follow ups obtained until July 2003. The current follow up was obtained for all 62 hospital survivors for a follow up rate of 100%. The mean follow up was 11.7 months (range: 6 to 13.4 months), and the cumulative follow up was 61 patient-years.

### Echocardiography measurements and calculations

All patients underwent echocardiography before

Table III: Mitral valve repair procedures.

Procedure	No. performed
Annulus remodeling	
Posterior	63 (91.3)
Entire	6 (8.7)
Annuloplasty size (mm)	
26	2 (2.9)
28	4 (5.8)
30	15 (21.7)
32	35 (50.7)
34	6 (8.7)
36	7 (10.1)
Posterior leaflet resection + sliding leaflet technique	58 (84.1) 55 (79.7)
Chordal reattachment	36 (52.2)
Chordal resection	15 (21.7)
Chordal transposition	8 (11.6)
Chordal replacement	3 (4.3)
Chordal shortening	1 (1.4)
Suture repair of commissures	19 (27.5)
Suture/patch repair of leaflets	15 (21.7)
Ligation of left atrial appendage	25 (36.2)
Annulus decalcification	4 (5.7)
Concomitant procedures	27 (39.1)
CABG	13 (18.8)
PFO closure	13 (18.8)
Tricuspid repair	3 (4.3)
Maze ablation	2 (2.9)
ASD closure	1 (1.4)

Values in parentheses are percentages.

ASD: Atrial septal defect; CABG: Coronary artery bypass grafting; PFO: Patent foramen ovale.

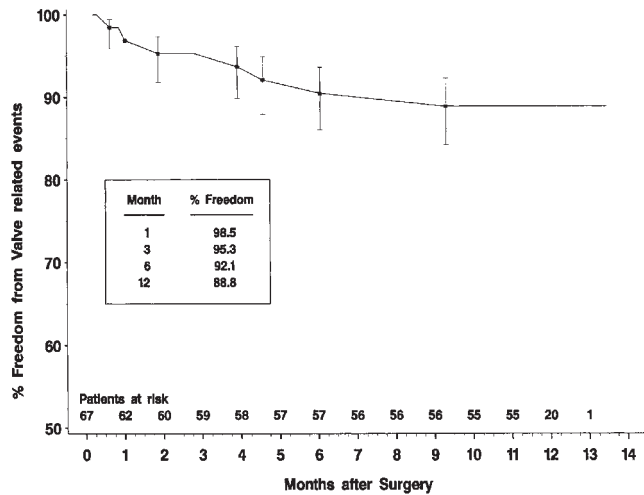


Figure 1: Kaplan-Meier actuarial freedom from all valve-related adverse events. Vertical bars represent asymmetric confidence limits equivalent to one standard error.

their mitral valve repair, and each hospital survivor underwent transthoracic echocardiography between three and six months after surgery. Two-dimensional/M-mode echocardiography was used to assess mitral valve structure and function, as well as left ventricular (LV) diastolic and systolic dimensions and volume. LV measurements were made according to the recommendations of the American Society of Echocardiography (leading edge to leading edge) (14). Pulsed-wave (PW) Doppler recordings were made from the apical window to assess forward transvalvular flow. The PW transvalvular velocity was used to calculate transvalvular peak pressure gradient and the time velocity integral (TVI). The severity of MR was graded from 0 to 4+ (none to very severe) by color-flow and PW Doppler studies of the spatial distribution of the regurgitant jet from multiple imaging planes (15,16). Grade 3/4 MR was considered to be hemodynamically significant. The mitral valve area, peak and mean pressure gradients and LV mass were measured postoperatively (see Appendix I).

**Data analysis**

All data were presented as the mean ± SD, or as a percentage of the patient cohort. Results were reported according to recommendations of the STS/AATS Ad Hoc Liaison Committee (17). The collection of preoperative and postoperative data on most patients allowed for a paired analysis of each of the end-points. Echocardiography variables were analyzed using a paired *t*-test, and categorical data were analyzed as contingency tables using a chi-squared test. The differences between preoperative and postoperative values were considered significant at a *p*-value <0.05. Actuarial freedom from death and valve-related com-

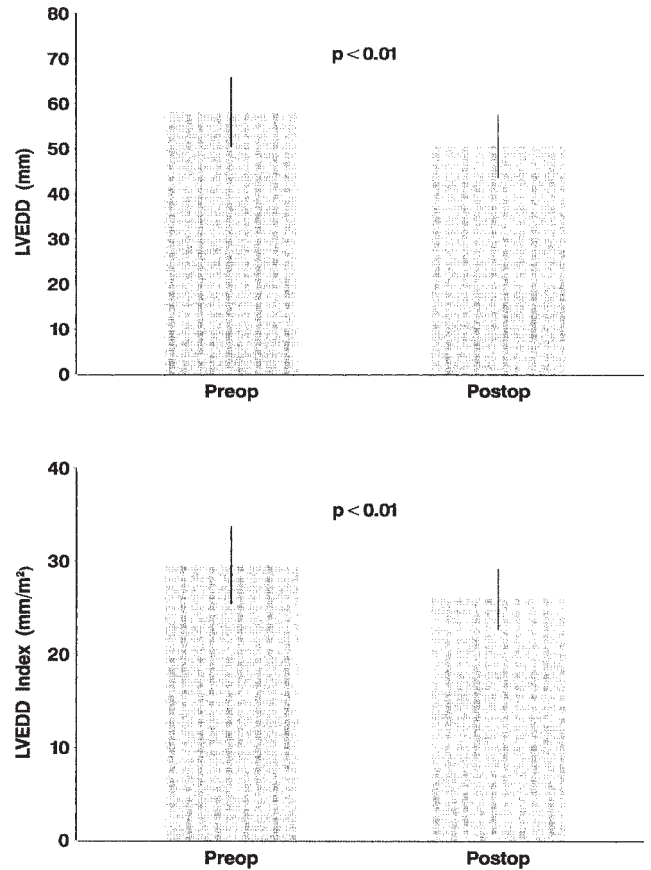


Figure 2: Changes in left ventricular end-diastolic diameter (LVEDD) and LVEDD indexed to body surface area after mitral valve repair with the AnnuloFlex annuloplasty ring (n = 49).

plications were estimated using the Kaplan-Meier method (18). Asymmetric confidence limits (CL) equivalent to one standard error (70% CL) were calculated with the Kaplan-Meier estimates. All analyses were performed using SAS version 6.12 software (SAS Institute Inc., Cary, NC, USA).

Table IV: Early postoperative (≤30 days) cardiac events (n = 67).

Complication	No. of events
Atrial fibrillation	10 (14.9)
Bleeding	5 (7.5)
Arrhythmia	4 (6.0)
Pleural effusion	4 (6.0)
Cardiac arrest	1 (1.5)
Congestive heart failure	1 (1.5)
Death	1 (1.5)

Values in parentheses are percentages.

## Results

### Early morbidity and mortality

The incidences of early postoperative cardiac events and complications are presented in Table IV. One patient died due to cardiac arrest nine days after surgery; thus, the 30-day mortality rate was 1.5%. This patient, an 81-year-old woman, had previously undergone reoperation for post-surgical bleeding. However, there was no indication that her death was related to the AnnuloFlex ring.

In two patients the mitral repair failed to correct the MR, and the AnnuloFlex ring was subsequently removed during the initial surgery. The first patient, a 50-year-old man, underwent the annuloplasty procedure to repair severe (4+) MR due to annular dilatation arising from ischemic disease. The second patient was a 63-year-old woman who received an annuloplasty ring to treat severe (3+) MR resulting from congenital deformation of the mitral annulus. Neither patient had leaflet prolapse nor additional repair procedures performed. In each case, intraoperative TEE revealed persistent MR after implantation of the AnnuloFlex ring, and therefore the annuloplasty ring and native valve were replaced with a prosthetic valve. Each of these patients survived their valve surgery and was discharged from the hospital; however, they were excluded from any analysis of the postoperative results.

### Late mortality and valve-related complications

A total of seven valve-related adverse events (three transient ischemic attacks, two major anticoagulant-

related bleeds, one endocarditis, and one recurrent MR requiring reoperation) were reported in seven patients. There were no late deaths and no device-related mortality in this series of patients. The actuarial freedom from all valve-related events was 88.8% (CL, 84.2-92.2%) at 12 months (Fig. 1). Survival at 12 months after surgery was 98.5% (CL 96-99.4%).

According to the postoperative Doppler echocardiography studies, clinically significant MR recurred in one patient due to progression of the native valve disease. This patient required reoperation for grade 3+ MR at six months after surgery, during which the AnnuloFlex ring was removed and the patient received a prosthetic valve. The actuarial freedom from explant due to recurrent MR was 98.4% (CL 95.7-99.4%) at 12 months.

Three patients experienced a transient ischemic attack, for an actuarial freedom of 95.2% (CL 91.6-97.3%) at 12 months. Each of these events resolved without residual effects. One patient underwent reoperation for endocarditis almost four months after surgery. The actuarial freedom from endocarditis at 12 months in this series was 98.4% (CL 95.7-99.4%). There were two cases of major anticoagulant-related bleeding, each occurring less than two months after repair surgery. The actuarial freedom from major anticoagulant-related bleeding at 12 months was 96.9% (CL 93.8-98.5%). There were no cases of LV outflow tract (LVOT) obstruction due to systolic anterior motion, no structural failure of the AnnuloFlex ring, and no cases of ring dehiscence or hemolysis were reported.

Table V: Postoperative echocardiography parameters measured 3-6 months after mitral valve repair.

Parameter	No. of patients	Value*
BSA (m <sup>2</sup> )	62	1.9 ± 0.2
Cardiac output (l/min)	62	5.7 ± 1.4
Cardiac index (l/min/m <sup>2</sup> )	62	2.9 ± 0.7
Peak velocity (m/s)	44	1.2 ± 0.3
Peak gradient (mmHg)	48	5.9 ± 3.0
Mean gradient (mmHg)	47	2.8 ± 1.7
MVA (cm <sup>2</sup> )	42	3.4 ± 1.7
MVA index (cm <sup>2</sup> /m <sup>2</sup> )	42	1.8 ± 0.9
Stroke volume (ml)	58	78.3 ± 19.8
LVEF (%)	61	64.7 ± 15.2
Fractional shortening (%)	61	30.9 ± 10.5
LV end-diastolic diameter (mm)	61	50.3 ± 6.9
LV end-systolic diameter (mm)	61	35.0 ± 8.3
Interventricular septum thickness (mm)	61	11.1 ± 1.7
Posterior wall thickness (mm)	61	11.0 ± 1.6
LV end-diastolic volume (ml)	58	102.9 ± 38.3
LV end-systolic volume (ml)	57	56.9 ± 28.8

\*Values are mean ± SD.

BSA: Body surface area; LVEF: Left ventricular ejection fraction; MVA: Mitral valve area.

Table VI: Postoperative left ventricular (LV) function measured at 3-6 months.

Parameter	No. of patients
Mitral valve area	
≥1.5 cm <sup>2</sup>	40 (95.2)
<1.5 cm <sup>2</sup>	2 (4.8)
LVEF	
≥40%	56 (91.8)
<40%	5 (8.2)
LV diastolic diameter	
Normal (≤56 mm)	48 (78.7)
Enlarged (>56 mm)	13 (21.3)
LV systolic diameter	
Normal (≤40 mm)	49 (80.3)
Enlarged (>40 mm)	12 (19.7)
LV contractility	
Normal FS (≥27%)	44 (72.1)
Altered FS (<27%)	17 (27.9)

Values in parentheses are percentages.  
FS: Fractional shortening.

#### Patient status and valve function

Postoperatively, 98.4% of patients were in NYHA classes I/II. All patients in preoperative NYHA classes III/IV showed functional improvement to classes I/II after valve repair (one class II patient moved to class III). Postoperative echocardiography assessment was performed at a mean of 4.7 months after mitral valve repair (range: 3.1 to 6.9 months). Echocardiographic

assessments after valve repair showed a significant decrease ( $p < 0.01$ ) in the severity of MR. During the postoperative period, 56 patients (90.3%) had grade 0/1 (none or trivial) MR, five (8.1%) had mild (grade 1 to 2) MR, and one patient (1.6%) had moderate (grade 3) MR that required reoperation six months after valve repair. None of the remaining patients had clinically significant MR.

The results of the Doppler echocardiographic studies, which included flow velocities, pressure gradients, mitral valve area and left ventricular dimensions, are presented in Table V. The average peak and mean pressure gradients were  $5.9 \pm 3.0$  and  $2.8 \pm 1.7$  mmHg, respectively, and the mean mitral valve area was  $3.4 \pm 1.7$  cm<sup>2</sup>. The calculated mitral valve area was within normal limits (mitral valve area  $\geq 1.5$  cm<sup>2</sup>) in 95.2% of the patients; mild residual mitral valve stenosis was indicated in only two patients (Table VI). Ventricular contractility, assessed by the shortening fraction, was normal in 72% of patients, and LV diameters were normal in 79-80% (Table VI). At the postoperative study mitral repair patients exhibited a significant decrease in LV end-diastolic diameter (LVEDD) and LVEDD index (Fig. 2). There was no change in LV end-systolic diameter, interventricular septum thickness, or posterior wall thickness from baseline to postoperative assessment.

Table VII: Summary of studies of mitral valve repair using either flexible or rigid rings in patients who underwent ring annuloplasty.

Condition/ Outcome	Study*														
	Present study	5	27	29	21	22	28	23	30	31	7	32	29	24	33
Baseline characteristics															
Annuloplasty ring <sup>+</sup>	A	CE	CE	CE	CP	Co	Co	Sg	CE	CE	CE	CE	Sc	D	CE
Predominant disease <sup>‡</sup>	Deg	Deg	Deg	Deg	Deg	Deg	Deg	Deg	Mix	Mix	Mix	Mix	Mix	Rh	Rh
No. of patients	69	133	117	155	137	150	197	75	148	275	206	94	30	327	308
% with prosthesis	100	100	85	100	100	100	100	100	84	97	96	87	100	100	99
Mean age (years)	55	65	60	65	49	58	58	60	51	37	48	49	65	45	18
NYHA class III/IV (%)	17	58	76	76	44	23	23	59	79	59	97	95	67	65	96
Results															
Mean follow up (years)	1.0	2.7	1.1	3.3	0.9	0.7	3.4	1.2	2.2	4.9	13.2	5.7	1.5	8.6	5.0
Operative mortality (%)	1.5	3.0	4.3	3.2	2.0	0	0	3.0	5.4	4.0	5.3	3.0	0	3.4	2.6
Late mortality (%/yr)	0.0	4.1	6.0	5.8	0	3.0	2.0	1.2	3.1	0.6	1.4	3.3	8.8	1.5	3.0
Reoperation (%/yr)	1.5	0.9	2.6	0.8	3.4	4.7	1.5	0	2.5	1.6	1.0	2.7	6.7	1.1	5.0

\*Study number refers to reference list.

+A: AnnuloFlex ring; CE: Carpentier-Edwards ring; CP: CE Physio ring; Co: Cosgrove-Edwards band; Sg: St. Jude Medical-Seguín ring; Sc: Sculptor ring; D: Duran ring.

‡Deg: Degenerative disease; Mix: Mostly degenerative or rheumatic, but neither >70%; Rh: Rheumatic.

## Discussion

Mitral valve repair is considered to be the 'gold standard' in surgery of degenerative mitral valve insufficiency, and has excellent long-term results (19). Even an attempted valve repair that fails and is converted to replacement at the same operation does not increase morbidity or mortality (20). In addition to leaflet repair techniques, the annuloplasty ring is an integral part of the operation. In the present study, the effectiveness of the AnnuloFlex ring was demonstrated by the low incidence of recurrent mitral insufficiency (grade 3/4) of 1.5%, and the high percentage of patients in NYHA classes I and II (98.4%). A similar reduction in MR after successful mitral repair has been reported with other annuloplasty rings (21-23).

After mitral valve repair, the majority of the patients retained a normal valve area, shortening fraction and LV diameters, demonstrating that implantation of the AnnuloFlex ring does not impair LV function. Bernal et al. (24) reported that 14.7% of patients implanted with the Duran flexible ring had below normal mitral valve area, and that 91% of the patients had normal LV systolic diameters. Okada et al. (10) observed that mitral repair with a flexible ring results in larger mitral valve areas than repair with a rigid ring.

A significant decrease in LVEDD was observed, while all other LV dimensions were unchanged. The primary cardiac diseases in the AnnuloFlex patients were left atrial enlargement (87%) and LV dilatation (57%). Therefore, the decrease in LVEDD may reflect successful correction of MR after mitral valve repair using an AnnuloFlex ring.

In terms of mortality and reoperation, the clinical outcomes of the AnnuloFlex ring were similar to, or better than, those reported using other annuloplasty rings (Table VII). Part of the reason for these results may be attributed to the better health of the AnnuloFlex patients at operation (83% were in NYHA classes I/II), which reflects the practice of medicine at the authors' institutions. Although it is difficult to compare results obtained from different patient populations, this type of comparison shows that results with the AnnuloFlex ring were similar to those achieved with other annuloplasty rings.

Recurrent MR is typically due to the progression of valvular disease, and is the most prevalent cause of late reoperation after mitral valve repair (7,21,22). The one-year freedom from reoperation for recurrent MR was 98.4% in the present series, and the corresponding incidence of reoperation 1.5% per year, compared to rates of 0-6.7% per year observed in other studies (Table VII). The low incidence of recurrent MR and resultant late reoperation in the present study reflected the stability of the repair procedures using the

AnnuloFlex ring. The use of a partial ring (in 91% of the cases) did not influence early repair durability.

In the present study there were no cases of LV outflow tract obstruction due to systolic anterior motion. Systolic anterior motion of the mitral valve and LVOT obstruction have been reported after mitral valve repair with both rigid and flexible rings (13,21,25,26). Although there is no conclusive evidence that the type of annuloplasty ring impacts LV function, the data do suggest that a flexible ring results in better preservation of mitral annular function (25,27). Whilst dehiscence of the annuloplasty ring is sometimes reported as a cause of reoperation after mitral repair (24,26), ring dehiscence was not observed in the present study. Dehiscence is primarily associated with fragility of the annulus, the degree of cardiac dilatation, and the degree of annulus narrowing, rather than the type of annuloplasty ring.

This experience with the AnnuloFlex ring demonstrated a low incidence of thromboembolism (minor events with no residual effects) for a one-year freedom from embolism of 95%. The actuarial freedom from embolism observed was similar to that found with other annuloplasty rings (5,22,24). Carpentier et al. (21) suggested that the low incidence of thromboembolism in their series was due to the low transvalvular gradients and large valve orifice areas (mean 3.55 cm<sup>2</sup>) achieved with the flexible Physio ring. Similar mitral valve areas (mean 3.4 cm<sup>2</sup>) were obtained in the present study.

*In conclusion*, the present study details the early follow up of patients undergoing mitral valve repair with the AnnuloFlex annuloplasty system. There was no valve-related mortality, and the incidences of recurrent MR and corresponding reoperation were low. Moreover, there were no cases of LVOT obstruction due to systolic anterior motion, and no ring dehiscence or hemolysis. These early results demonstrate that the AnnuloFlex ring is safe and effective when used with other techniques for repair of the mitral valve.

## Acknowledgements

The authors thank Navin Nanda MD, Professor of Medicine and Director, Echocardiography Laboratories, University of Alabama at Birmingham, for his helpful comments on the manuscript.

## References

1. Yun KL, Miller DC. Mitral valve repair versus replacement. *Cardiol Clin* 1991;9:315-327
2. Okita Y, Miki S, Ueda Y, Tahata T, Sakai T, Matsuyama K. Comparative evaluation of left ventricular performance after mitral valve repair or replacement with or without chordal preservation.

- J Heart Valve Dis 1993;2:159-166
3. Cohn LH, Kowalker W, Bhatia S, et al. Comparative morbidity of mitral valve repair versus replacement for mitral regurgitation with and without coronary artery disease. *Ann Thorac Surg* 1988;45:284-290
  4. Craver JM, Cohen C, Weintraub WS. Case-matched comparison of mitral valve replacement and repair. *Ann Thorac Surg* 1990;49:964-969
  5. Akins CW, Hilgenberg AD, Buckley MJ, et al. Mitral valve reconstruction versus replacement for degenerative or ischemic mitral regurgitation. *Ann Thorac Surg* 1994;58:668-676
  6. Carpentier A. Cardiac valve surgery - the "French correction". *J Thorac Cardiovasc Surg* 1983;86:323-337
  7. Deloche A, Jebara VA, Relland JYM, et al. Valve repair with Carpentier techniques: The second decade. *J Thorac Cardiovasc Surg* 1990;99:990-1002
  8. Ghosh PK. Mitral annuloplasty: A ring-side view. *J Heart Valve Dis* 1996;5:286-293
  9. David TE, Komeda M, Pollick C, Burns RJ. Mitral valve annuloplasty: The effect of the type on left ventricular function. *Ann Thorac Surg* 1989;47:524-528
  10. Okada Y, Shomura T, Yamaura Y, Yoshikawa J. Comparison of the Carpentier and Duran prosthetic rings used in mitral reconstruction. *Ann Thorac Surg* 1995;59:658-663
  11. Komoda T, Hetzer R, Uyama C, et al. Mitral annular function assessed by 3D imaging for mitral valve surgery. *J Heart Valve Dis* 1994;3:483-490
  12. Hueb AC, Jatene FB, Moreira LF, et al. Ventricular remodeling and mitral valve modifications in dilated cardiomyopathy: New insights from anatomic study. *J Thorac Cardiovasc Surg* 2002;124:1216-1224
  13. Jebara VA, Mihaileanu S, Acar C, et al. Left ventricular outflow tract obstruction after mitral valve repair - results of the sliding leaflet technique. *Circulation* 1993;88(part 2):30-34
  14. Sahn DJ, DeMaria A, Kisslo J, Weyman A. The Committee on M-mode Standardization of the American Society of Echocardiography. Recommendations regarding quantitation in M-mode echocardiography: Results of a survey of echocardiographic measurements. *Circulation* 1978;58:1072-1083
  15. Helmcke F, Nanda NC, Hsiung MC, et al. Color Doppler assessment of mitral regurgitation with orthogonal planes. *Circulation* 1987;75:175-183
  16. Spain MG, Smith MD, Grayburn PA, et al. Quantitative assessment of mitral regurgitation by Doppler color flow imaging: Angiographic and hemodynamic correlations. *J Am Coll Cardiol* 1989;13:585-590
  17. Edmunds LH, Clark RE, Cohn LH, Grunkemeier GL, Miller DC, Weisel RD. Guidelines for reporting morbidity and mortality after cardiac valvular operations. *J Thorac Cardiovasc Surg* 1996;112:708-711
  18. Lee ET. *Statistical Methods for Survival Data Analysis*. New York, Wiley & Sons, 1992
  19. Braunberger E, Deloche A, Berrebi A, et al. Very long-term results (more than 20 years) of valve repair with Carpentier's techniques in non-rheumatic mitral valve insufficiency. *Circulation* 2001;104(Suppl.1):I8-I11
  20. Northrup WF, DuBois KA, Kshetry VR. Morbidity and mortality of a failed attempt at mitral valve repair converted to replacement at the same operation. *J Heart Valve Dis* 2003;12:700-706
  21. Carpentier AF, Lessana A, Relland JYM, et al. The "Physio-Ring": an advanced concept in mitral valve annuloplasty. *Ann Thorac Surg* 1995;60:1177-1186
  22. Cosgrove DM, Arcidi JM, Rodriguez L, Stewart WJ, Powell K, Thomas JD. Initial experience with the Cosgrove-Edwards annuloplasty system. *Ann Thorac Surg* 1995;60:499-504
  23. Seguin JR, Demaria R, Chaptal PA. Preservation of three-dimensional annular movement with the SJM-Seguin mitral annuloplasty ring. *J Heart Valve Dis* 1996;5:641-646
  24. Bernal JM, Rabasa JM, Vilchez FG, Cagigas JC, Revuelta JM. Mitral valve repair in rheumatic disease - the flexible solution. *Circulation* 1993;88(part 1):1746-1753
  25. Kreindel MS, Schiavone WA, Lever HM, Cosgrove D. Systolic anterior motion of the mitral valve after Carpentier ring valvuloplasty for mitral valve prolapse. *Am J Cardiol* 1986;57:408-412
  26. Alberto-Lopez J, Schnee M, Gaos CM, Wilansky S. Left ventricular outflow tract obstruction and hemolytic anemia after mitral valve repair with a Duran Ring. *Ann Thorac Surg* 1994;58:876-878
  27. Cosgrove DM, Chavez AM, Lytle BW, et al. Results of mitral valve reconstruction. *Circulation* 1986;74(Suppl.1):82-87
  28. Gillinov AM, Cosgrove DM, Shiota T, et al. Cosgrove-Edwards annuloplasty system: Midterm results. *Ann Thorac Surg* 2000;69:717-721
  29. Lee EM, Shapiro LM, Wells FC. Midterm results of mitral valve repair with the Sculptor annuloplasty ring. *Ann Thorac Surg* 1997;63:1340-1345
  30. Galloway AC, Colvin SB, Baumann FG, et al. Long-term results of mitral valve reconstruction with Carpentier techniques in 148 patients with mitral insufficiency. *Circulation* 1988;78(Suppl.1):97-105
  31. Lessana A, Carbone C, Romano M, et al. Mitral valve repair: Results and the decision-making process in reconstruction. *J Thorac Cardiovasc Surg*

- 1990;99:622-630
32. Xu M, McHaffie DJ, Hilless AD. Mitral valve repair: A clinical and echocardiographic study. *Br Heart J* 1994;71:51-56
33. Skoularigis J, Sinovich V, Joubert G, Sareli P. Evaluation of the long-term results of mitral valve repair in 254 young patients with rheumatic mitral regurgitation. *Circulation* 1994;90(part II):167-174

---

*Appendix I: Echocardiography calculations.*

---

(i) Cardiac output

Cardiac output (l/min) was calculated as the product of heart rate and stroke volume:

$$CO = HR \times SV,$$

where HR = heart rate (bpm); and

SV = stroke volume (ml) calculated as:

$$SV = TVI_{LVOT} \times CSA,$$

where  $TVI_{LVOT}$  = systolic velocity time integral of the LVOT; and

CSA = LVOT cross-sectional area.

(ii) Peak pressure gradient

Peak velocity, obtained from continuous-wave Doppler, was converted to peak pressure gradient using the simplified Bernoulli equation;

$$\Delta P_{\text{peak}} = 4(V^2),$$

where  $\Delta P_{\text{peak}}$  = peak systolic pressure gradient in mmHg; and

V = transmitral peak velocity (in m/s) measured with continuous-wave Doppler.

(iii) Mitral valve area

Mitral valve area was calculated by reconfiguration of the continuity equation:

$$MVA = (CSA_{AO} \times TVI_{AO}) / TVI_{MI},$$

where  $CSA_{AO}$  = aortic cross-sectional area measured using 2-D imaging;

$TVI_{AO}$  = velocity time integral of forward blood flow (in cm), derived from the

aortic transvalvular continuous-wave Doppler; and  $TVI_{MI}$  = velocity time integral of forward blood flow (in cm), derived from the

mitral transvalvular continuous-wave Doppler.

(iv) Left ventricular function

Two measures of left ventricular function, fractional shortening (FS) and LV ejection fraction (LVEF), were calculated as follows:

$$FS (\%) = 100 \times (LVEDD - LVESD) / LVEDD, \text{ and}$$

$$LVEF (\%) = 100 \times (LVEDD^3 - LVESD^3) / LVEDD^3,$$

where LVEDD = left ventricular end-diastolic diameter (in mm); and

LVESD = left ventricular end-systolic diameter (in mm).

Cardiac output, mitral valve area and LV dimensions were indexed by body surface area:

$$BSA (m^2) = (71.84 \times \text{height}^{0.725} \times \text{weight}^{0.425}) / 10^4,$$

where height = height in cm; and weight = body weight in kg.