




Comparison of flexible and rigid annuloplasty rings in isolated mitral regurgitation

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ABSTRACT

Objectives: The aim of this study was to examine the early and midterm results of various annuloplasty rings in terms of residual mitral regurgitation (MR) in patients undergoing mitral valve repair.

Patients and methods: In the retrospective study, 298 patients (157 males, 141 females; mean age: 58.8±14.3 years; range, 16 to 82 years) underwent repair between September 2009 and April 2012. Two hundred eleven were assigned to the flexible ring group (Group 1), whereas 87 were included in the rigid ring group (Group 2). Mitral pathologies were divided into three subgroups: ischemic, degenerative, and rheumatic.

Results: The causes of mitral pathology were ischemic in 36.2%, degenerative in 54.4%, and rheumatic in 9.4%. Concomitant surgical procedures were present in 87%. The follow-up period ranged from 2 days to 33 months, with a mean of 15.8±7.5 months. The 30-day mortality rate was 9.2% and 10.4% in Groups 1 and 2, respectively. There was a high rate of successful repair in the rigid group with 88.5% and acceptable rate of repair in the flexible group with 72%. Mitral regurgitation was significantly reduced after intervention regardless of the ring type ($p<0.01$). Significant improvement in NYHA class was observed in both groups. Recurrent regurgitation was detected in 27.9% of patients in Group 1 and 11.5% in Group 2. Recurrence occurred within three to nine months following the surgery. Reoperation rates for residual MR were 3.3% ($n=7$) vs. 1.1% ($n=1$) in Groups 1 and 2, respectively ($p=0.293$).

Conclusion: Saddle-shaped rings provide a mechanical benefit through a low and uniform force distribution and improve repair durability compared to flat rings. As a result, the rigid ring had a significant advantage, particularly in degenerative and rheumatic subgroups, but there was a loss of superiority in late ischemic MR due to left ventricle remodeling.

Keywords: Mitral valve, mitral valve annuloplasty, mitral valve insufficiency.

Annuloplasty is an essential component in mitral valve (MV) repair, which is currently the gold standard treatment for symptomatic severe mitral regurgitation (MR).^[1] The choice of ring for MV repair is left to the surgeon's preferences, and there are no specific guidelines for regulation. In time, MV repair has become the preferred operative technique with the increased experience of surgeons. The success of repair may vary by ring type, annuloplasty technique, and left ventricle (LV) remodeling.^[2,3] The use of flexible rings is justified for degenerative MV disease, whereas saddle shaped-rigid ring is elected in patients with ischemic or myxomatous MR.^[4,5] Hence, we compared the early and midterm results of MV repair with flexible and rigid rings in three subgroups.

PATIENTS AND METHODS

In the retrospective study, 298 patients (157 males, 141 females; mean age: 58.8±14.3 years; range, 16 to 82 years) underwent MV repair due to

isolated MR at the Koşuyolu High Specialization Education and Research Hospital between September 2009 and April 2012. The causes of mitral pathology were ischemic in 36.2%, degenerative in 54.4%, and rheumatic in 9.4%. Follow-up data regarding echocardiographic parameters and complications were determined at the patient's last visit or by telephone interview. The mean additive European System for Cardiac Operative Risk Evaluation (EuroSCORE) was calculated in both groups. Demographic data, comorbidities, degree of MR, and LV function were similar, except for New York Heart Association

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(NYHA)>2 ($p=0.031$), EuroSCORE ($p=0.001$), and hypertension ($p=0.026$, Table 1). Overall, 76.5% of patients defined NYHA class III/IV symptoms. Primary endpoints involved recurrent MV regurgitation, NYHA, and LV positive remodeling.

Surgical technique

Patients who had concomitant mitral stenosis and patients without ring annuloplasty were excluded. Depending on the type of ring used in annuloplasty, we divided patients into 2 groups: flexible ring (St. Jude Medical® Flexible Tailor™ Annuloplasty Ring, Inc. St. Paul, MN, USA), group 1; rigid ring (St. Jude Medical® Rigid Saddle Ring with EZ Suture™ Cuff, Inc. St. Paul, MN, USA), group 2. Depending on the valve pathology, each group was divided into three subgroups: ischemic, degenerative, and rheumatic. The flexible ring ($n=211$, 70.8%) was mainly selected for patients with a degenerative

base, and the rigid ring was chosen in ischemic or functional MR for down-sizing. However, ring choice was determined by the availability or the surgeon's discretion during that period. Concomitant procedures were tricuspid valve reconstruction, coronary artery bypass grafting, aortic valve replacement, ascending aortic interposition, and atrial septal defect closure, as can be seen in Table 2.

Echocardiographic data

The endpoints of interest include early and late mortality, alterations in NYHA, LV ejection fraction (EF), left atrial (LA) size, LV diameters, freedom from reoperation, and residual MR. Mitral regurgitation was reported as none, mild, moderate, or severe, based on the American Society of Echocardiography guidelines.^[6] All MR grades were site-determined. Indications for surgery were defined as Class I symptomatic (severe MR with symptoms), Class I asymptomatic (severe

Table 1							
Preoperative data							
	Flexible (Group 1) (n=211)			Rigid (Group 2) (n=87)			<i>p</i>
	n	%	Mean±SD	n	%	Mean±SD	
Age (year)			59.0±14.6			58.3±13.7	0.716
Female	95	45		46	52.9		0.217
Coronary artery disease	103	48.3		38	43.7		0.402
Renal failure	25	11.8		11	12.6		0.848
Obstructive lung disease	52	24.6		25	28.7		0.464
Diabetes mellitus	47	22.3		16	18.4		0.456
Hypertension	82	38.9		22	25.3		0.026*
Atrial fibrillation	56	26.5		29	33.3		0.401
MR etiology							
Ischemic	74	35.1		34	39.1		
Degenerative	121	57.3		41	47.1		
Rheumatic	16	7.6		12	13.8		
Logistic EuroSCORE I			3.7±1.2			4.9±2.0	0.001*
NYHA Class III-IV	172	81.5		56	64.3		0.031*
Echocardiographic data							>0.05
LA (mm)			45.0±7.9			46.3±8.3	
LVEDD (mm)			57.2±7.4			58.5±7.4	
LVESD (mm)			41.9±8.7			42.9±8.9	
LVEF, %			47.8±14.0			48.2±13.7	
MR moderate	24	11.4		7	8		
MR severe	187	88.6		80	92		

SD: Standard deviation; MR: Mitral regurgitation; EuroSCORE: European system for cardiac operative risk evaluation; NYHA: New York Heart Association; LA: Left atrium; LVEDD: Left ventricular end diastolic diameter; LVESD: Left ventricular end systolic diameter; LVEF: Left ventricular ejection fraction.

Table 2
Surgical data

	Flexible (Group 1) (n=211)					Rigid (Group 2) (n=87)				
	n	%	Mean±SD	Median	Min-Max	n	%	Mean±SD	Median	Min-Max
Mitral valve repair										
P2 plication	140	66.4				10	11.5			
Triangular resection	0	0				3	3.4			
Quadrangular resection	3	1.4				3	3.4			
Alfieri stitch	5	2.4				1	1.1			
Chordal transfer	4	1.9				0	0			
Neochordae implantation	20	9.5				5	5.7			
Concomitant procedures										
Tricuspid reconstruction	64	30.3				31	35.6			
CABG	83	39.3				32	36.8			
Aortic reconstruction/AVR	15	5.7				6	6.8			
ASD closure	7	3.3				1	1.1			
Bentall	2	0.9				1	1.1			
Ascending aortic replacement	5	2.4				1	1.1			
X-clamp time (min)			72.5±30.1		18-182			79.2±27.7		31-171
CPB time (min)			115.5±47.9		44-471			120.4±40.1		52-240
Length of ICU (d)			5.45±6.94	4	1-58			4.9±6.1	8	1-32
Length of hospital stay (d)			8.98±4.17	3	3-32			7.4±2.7	6	5-20

SD: Standard deviation; CABG: Coronary artery bypass graft; AVR: Aortic valve replacement; ASD: Atrial septal defect; CPB: Cardiopulmonary bypass; ICU: Intensive care unit.

MR and LVEF of 30 to 60% or a LV end-systolic diameter [LVESD] \geq 40 mm), Class IIa asymptomatic without triggers (severe MR and LVEF $>$ 60%, LVESD $<$ 40 mm, and either atrial fibrillation or pulmonary artery systolic pressure $>$ 50 mmHg).^[1] According to the postoperative echocardiographic evaluation, those with MR \geq 2 were classified as recurrent MR. Comparative echocardiograms for each group were performed one month after discharge and at least six months following surgery.

Statistical analysis

Data were analyzed using SPSS version 15.0 (SPSS Inc., Chicago, IL, USA). Categorical variables are presented as absolute values and frequencies (%), and continuous variables are presented as the mean and standard deviation. Comparisons between the groups were carried out using the paired sample t-test or the Wilcoxon test for continuous variables, and Fisher exact test, the chi-square test, or the McNemar test were utilized for categorical variables. Univariate and multivariate Cox proportional hazard functions were used to determine predictors for recurrent MR. Freedom from recurrence and reoperation analysis

are presented as Kaplan-Meier curves. A two-tailed *p*-value of $<$ 0.05 was considered statistically significant.

RESULTS

Eleven (5.2%) of the cases in Group 1 and three (3.4%) in Group 2 had a prior cardiac operation. Obstructive lung disease (25.8%) and hypertension (34.9%) were the most frequent comorbid conditions. Overall, follow-up period ranged from 2 days to 33 months, with a mean of 15.8±7.5 months. Surgical data can be viewed in Table 2. The mean ring size was 29.4±1.5 mm (median: 29 mm) in Group 1 and 31.0±1.8 mm (median; 32 mm) in Group 2. The mean (range) aortic cross-clamp and cardiopulmonary bypass (CPB) times were 72.5±30 (range, 18-182) min and 115.5±47.9 (range, 44-471) min for Group 1 and 79.1±27.6 (range, 31-171) min and 120.4±40.1 (range, 52-240) min for Group 2, respectively. There were no preoperative differences between groups in terms of echocardiographic parameters ($p>$ 0.05). Intraoperative transesophageal echocardiogram (TEE) showed adequacy of

	Flexible (Group 1) (n=211)		Rigid (Group 2) (n=87)		<i>p</i>
	n	%	n	%	
Inotropic support	112	53.1	44	50.6	0.694
Renal failure	30	14.2	13	14.9	0.872
Arrhythmia	33	15.6	22	25.3	0.186
Respiratory failure	40	19.0	8	9.2	0.037*
Infection	16	7.6	7	8.0	0.892
Neurological	8	3.8	1	1.1	0.226
Surgical revision	14	6.6	4	4.6	0.503
Reoperation	7	3.3	1	1.1	0.293

surgical repair (MR<moderate) in all patients. The assessment of repaired MV by post-CPB TEE comprised measure of trans-mitral gradient, leaflet coaptation surface, and LV function. Posterior leaflet segment 2 plication of posterior leaflet and neochordae implantation were more common, and concomitant approaches were comparable in both groups. Cross-clamp and CPB times were shorter in Group 2. There was a higher rate of successful repair in Group 2 with 88.5% compared to the acceptable repair rate of Group 1 with 72%.

Postoperative complications were as follows: renal failure in 14.4%, arrhythmia in 18.5%, respiratory failure in 16.1%, infection in 7.7%, and neurological incident in 3%. There was no significant difference between groups in terms of complications, except for respiratory failure, which was higher in Group 1 ($p=0.037$, Table 3). Atrial fibrillation and ventricular extrasystole were observed and treated medically. One patient in Group 2 needed permanent pace maker following radiofrequency ablation. Surgical revision was needed in 14 patients in Group 1 and four patients in Group 2 due to bleeding, cardiac tamponade, and pleural decortication.

Thirty-day mortality rate was 10.4% in Group 1, whereas it was 9.2% in Group 2. Causes of death were cardiac in 28 patients, multiorgan failure in 16, and cerebrovascular accident in two. Deceased patients had higher EuroSCORE values ($p=0.001$). Follow-up was available in 294 (98.6%) patients; furthermore, late echocardiogram was applied in 76.4% and 92.5% for group 1 and 2, respectively. The mean time of

follow-up/echocardiographic control was 11.1 ± 7.0 months (median: 12; range, 2 days to 25 months) in Group 1 and 9.8 ± 6.0 months (median: 9; range, 3 days to 22 months) in Group 2. The late mortality rate was 6.6% ($n=14$) in Group 1 and 3.4% ($n=3$) in Group 2.

The decrease in LA and LVEDD was more significant in ischemic ($p=0.03$, $p=0.029$) and

Univariate analysis	<i>p</i>	
Echocardiographic		
LVEDD		0.001
LVESD		0.001
LVEF		0.144
Mitral regurgitation		
Moderate		0.060
Severe		
Ring type		
Flexible		0.002
Rigid		
Ring no		0.209
Concomitant procedures		0.118
Multivariate analysis	Odds ratio	<i>p</i>
Preoperative MR	3.698	0.038
Preoperative LVEDD	1.036	0.001
MR: Mitral regurgitation; LVEDD: Left ventricular end diastolic diameter; LVESD: Left ventricular end systolic diameter; LVEF: Ejection fraction.		

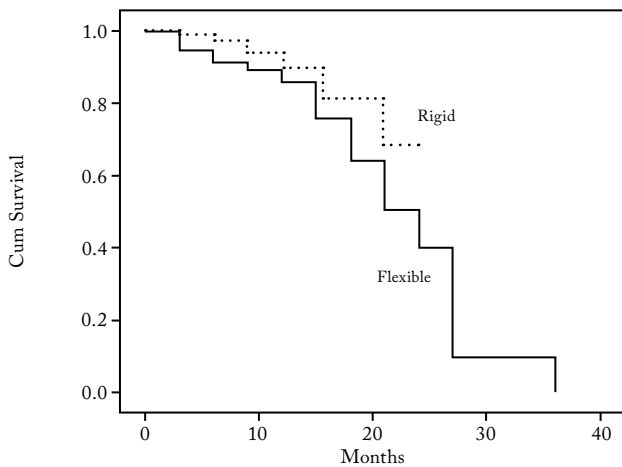


Figure 1. Recurrence free survival.

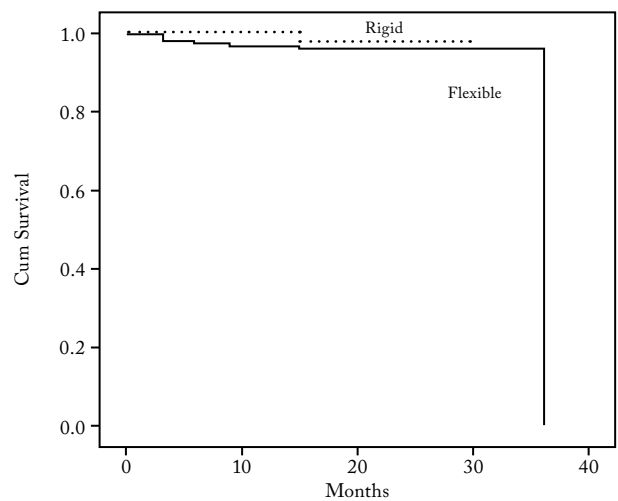


Figure 2. Reoperation free survival.

degenerative ($p=0.05$, $p=0.014$) subgroups of rigid rings. Nevertheless, systolic function did not improve and did not differ between ring types ($p>0.05$). There is no statistical difference in the reduction of LA ($p=0.184$), LVEDD ($p=0.488$), and EF ($p=0.777$) between rings in the rheumatic subgroup.

On-table TEE was performed to all patients in both groups. Mitral regurgitation was strongly reduced after intervention regardless of the ring type ($p<0.01$). A gradient >5 mmHg was not detected following

valve repair. For the purpose of tailored selection of annuloplasty ring, we subdivided each group into ischemic, degenerative, and rheumatic pathology and examined the effect of ring type on valve pathologies. Improvement in MR with rigid ring was significantly better in degenerative ($p=0.001$, MR grade: 1.4 ± 0.9 in group 1 *vs.* 0.7 ± 0.8 in group 2) and rheumatic ($p=0.031$, MR grade: 1.6 ± 1.3 *vs.* 0.6 ± 0.5) subgroups. However, there was no significant difference in terms of postoperative MR grade between rings in ischemic

MR pathologies	Pre- <i>vs.</i> postoperative changes	Flexible	Rigid	<i>p</i>
		Mean±SD	Mean±SD	
Ischemic	Mitral regurgitation (°)	2.1±1.0	2.4±0.8	0.049*
	Left atrium (mm)	0.5±5.8	1.8±3.0	0.030*
	LVEDD (mm)	0.9±4.7	3.0±3.8	0.029*
	Ejection fraction (%)	-1.2±9.5	0.7±10.2	0.230
Degenerative	Mitral regurgitation (°)	2.4±1.0	2.9±1.1	0.001**
	Left atrium (mm)	0.1±6.9	3.5±4.6	0.005**
	LVEDD (mm)	0.9±5.9	4.1±5.3	0.014*
	Ejection fraction (%)	2.3±9.5	-0.5±8.1	0.177
Rheumatic	Mitral regurgitation (°)	1.8±1.4	3.0±1.0	0.023*
	Left atrium (mm)	-0.5±3.9	1.9±3.6	0.184
	LVEDD (mm)	2.1±7.5	3.2±6.5	0.488
	Ejection fraction (%)	1.9±8.7	0.6±14.4	0.777

SD: Standard deviation; LVEDD: left ventricular end diastolic diameter; * $p\leq0.05$; ** $p\leq0.01$.

subgroups ($p=0.507$). Significant improvement in NYHA was observed in both groups; nevertheless, a larger number of patients remained in NYHA class II-III in Group 1 ($n=29$, 13.7%) than in Group 2 ($n=2$, 2.2%).

Recurrent MR was detected in 27.9% of Group 1 and 11.4% of Group 2 at various grades. Recurrence mostly occurred within three to nine months following surgery. One patient was reoperated on the second postoperative day due to partial detachment of the annuloplasty ring. Severe late MR was observed in 22 (10.4%) patients in Group 1, whereas one (1.1%) was detected in Group 2. The reoperation rate for severe MR was 3.3% ($n=7$) and 1.1% ($n=1$) in Groups 1 and 2, respectively ($p=0.293$). The mean reoperation time was 12.9 ± 8.3 months (median: 3 months). Predictors for recurrent MR by multivariate analysis were the degree of MR ($p=0.038$) and LVEDD ($p=0.001$, Table 4). There was no significant difference between ring types regarding recurrence-free survival (19.6 ± 1.1 months in Group 1 *vs.* 19.5 ± 0.7 months in Group 2, $p=0.086$, Figure 1). Reoperation-free survival was 35.0 ± 0.4 months in Group 1 and 27.7 ± 0.3 months in Group 2, and it showed no significant difference between groups ($p=0.422$, Figure 2).

DISCUSSION

The main goals of reconstructive surgery are the restoration of normal leaflet motion with a large surface of coaptation and stabilization of the annulus with remodeling annuloplasty.^[7,8] Although various annuloplasty rings are available on the market, there is still lack of data on absolute assets of ring functions.^[7,9] Flexible rings tend to preserve the contractile performance of LV; Yokote et al.^[10] demonstrated that transverse diameter is more affected and did not restrain the annular mobility. Flexible rings can only be used for degenerative MV diseases. Rigid, downsizing rings have been associated with reduced risk of long-term recurrent MR in patients with ischemic or functional MR.^[11,12] Despite these findings, it remains a matter of surgeon's preference. To tailor the selection of the annuloplasty ring, our patients were divided into subgroups according to the MV pathology and early and midterm changes in echocardiography and clinical status were evaluated. In Groups 1 and 2, rates of successful repair were acceptable (72% *vs.* 88.5%), the rate of immediate reoperation within 30 days was 0.3%, and the 30-day mortality rate was fair

(9.2% *vs.* 10.4%) according to the period. Compared to a decade ago, it is usual to observe improvement in results with using pre- and perioperative TEE for anatomical details of the valve and the increasing experience of institutions. The majority of patients in our series showed notable improvement of their MR and symptom severity. To assess the effect of ring types on clinical outcomes, Khamooshian et al.^[13] studied degenerative and ischemic MR patients by dividing them into three groups as rigid, flexible, and semi-rigid. They concluded that LVESD reduced with all rings, LVEDD only reduced with rigid and flexible, and LVEF did not alter. Similarly, our results projected that LVEF remained unchanged regardless of ring type. Additionally, the decrease of MR, LA size, and LVEDD was higher in Group 2 than in Group 1 in ischemic (MR, $p=0.049$; LA, $p=0.030$; LVEDD, $p=0.029$) and degenerative (MR, $p=0.001$; LA, $p=0.005$; LVEDD, $p=0.014$) subgroups (Table 5). The decrease in the degenerative subgroup was more significant compared to the ischemic subgroup due to the delay in remodeling in the presence of ischemic preconditioning. Although the decrease in MR was significant with rigid rings in the rheumatic subgroup ($p=0.023$), there was no nominal difference in LA size ($p=0.184$), LVEDD ($p=0.488$), and EF ($p=0.777$) among rings (Table 5). Given the fact that there was slightly more reduction with rigid rings, an overall reduction in the degree of MR was observed with both rings in all MR pathologies. Additionally, we have shown that the incidence observed for recurrent MR in the rigid ring group was significantly lower compared to the flexible ring group (28% *vs.* 11.5%, $p<0.01$). We believe that ring design might be one of the provocative reasons, especially in the presence of ischemic changes. Jensen et al.^[14] concluded that saddle-shaped rings reduce strain on leaflets by uniform annular force distribution compared to flat rings. In our study, perioperative regurgitation up to Grade 2 with a gradient >5 mmHg was considered negligible. Recurrent MR was found to be the most common reason for reoperation.

In univariate analysis in our results, preoperative LVEDD, LVESD, LVEF, MR, ring type, ring number, and concomitant procedures were assessed for predictors of recurrency, and LVEDD ($p=0.001$), LVESD ($p=0.001$), and ring type ($p=0.002$) were found to be statistically significant. Cases having severe preoperative MR showed 3.605-fold higher risk of recurrency (odds ratio: 3.605, 95% confidence

interval: 0.902-10.409). In multivariate analysis, only preoperative MR ($p=0.038$) and LVEDD ($p=0.001$) became significant predictors for recurrent MR. Silberman et al.^[12] searched for similar predictors in the univariate analysis, and preoperative LVESD and ring type were the predictors of late MR. There was no statistically significant difference between ring types on behalf of recurrence-free ($p=0.086$) and reoperation-free ($p=0.422$) survival. The main goal is to overcome the valvular pathology while improving the quality of life with preserved functional capacity. Arnaz et al.^[15] reported a significant improvement in quality of life, and repair was found to be superior to replacement in terms of pain score. In our study, a significant improvement in NYHA was observed in both groups regardless of ring type at a follow-up period of 15.8 ± 7.5 months ($p=0.001$).

There are limitations to this study. Due to its retrospective nature, data for particular fields, such as echocardiography records, may have been missing. Hence, the analyses could have been performed with available values. More detailed information should be added for better insight.

In conclusion, a saddle-shaped ring may expand the mechanical benefits rather than a flat ring by preserving the native mitral annular shape. Our study showed uniform results with both types of rings, improving NYHA class, reducing MR, and decreasing LV dimensions in patients undergoing MV repair. Routine intraoperative TEE should be performed to assess the success of repair for a better late outcome.

Ethics Committee Approval: The study protocol was approved by the Kartal Koşuyolu High Specialization Training and Research Hospital Clinical Research Ethics Committee (date: 27.03.2013, no: 2013/1.10). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patient Consent for Publication: A written informed consent was obtained from each patient.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Concept, design, data collection and analysis, writing and review: Ö.A.; Supervision, materials and analysis: S.S.; Concept and critical review: K.K.

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