

Cite this article as: Andreas M, Doll N, Livesey S, Castella M, Kocher A, Casselman F *et al.* Safety and feasibility of a novel adjustable mitral annuloplasty ring: a multicentre European experience. *Eur J Cardiothorac Surg* 2016;49:249–54.

# Safety and feasibility of a novel adjustable mitral annuloplasty ring: a multicentre European experience<sup>†</sup>

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Received 14 September 2014; received in revised form 12 December 2014; accepted 19 December 2014

## Abstract

**OBJECTIVES:** Recurrent mitral regurgitation is a significant problem after mitral valve repair in patients with functional valve disease. We report the safety and feasibility of a novel adjustable mitral annuloplasty device that permits downsizing of the anterior–posterior diameter late after initial surgery.

**METHODS:** In this multicentre, non-randomized, observational register, patients with moderate or severe mitral regurgitation undergoing surgical mitral valve repair with the MiCardia EnCor<sub>SQ</sub><sup>™</sup> Mitral Valve Repair system were evaluated. Patient characteristics, operative specifications and results as well as postoperative follow-up were collected for all five centres.

**RESULTS:** Ninety-four patients with a median age of 71 (64–75) years (EuroSCORE II  $6.7 \pm 6.3$ ; 66% male, 48% ischaemic MR, 37% dilated cardiomyopathy and 15% degenerative disease) were included. Operative mortality was 1% and the 1-year survival was 93%. Ring adjustment was attempted in 12 patients at a mean interval of  $9 \pm 6$  months after surgery. In three of these attempts, a technical failure occurred. In 1 patient, mitral regurgitation was reduced two grades, in 2 patients mitral regurgitation was reduced one grade and in 6 patients, mitral regurgitation did not change significantly. The mean grade of mitral regurgitation changed from  $2.9 \pm 0.9$  to  $2.1 \pm 0.7$  ( $P = 0.02$ ). Five patients were reoperated after  $11 \pm 9$  months (Ring dehiscence: 2; failed adjustment: 3).

**CONCLUSION:** We conclude that this device may provide an additional treatment option in patients with functional mitral regurgitation, who are at risk for reoperation due to recurrent mitral regurgitation. Clinical results in this complex disease were ambiguous and patient selection seems to be a crucial step for this device. Further trials are required to estimate the clinical value of this therapeutic concept.

**Keywords:** Functional mitral regurgitation • Ischaemic mitral regurgitation • Annuloplasty • Mitral valve reconstruction

## INTRODUCTION

Mitral regurgitation is the second-most common heart valve disease requiring surgical therapy [1]. Mitral valve replacement was the initial surgical approach, but was gradually substituted by mitral valve repair in suitable patients due to improved outcome

[2]. Further, the preservation of the subvalvular apparatus was recognized as a crucial step to avoid left ventricular failure and to reduce mortality also in patients undergoing mitral valve replacement [3]. The initial set of repair strategies developed by Carpentier was recently updated by introducing the artificial chordae technique. It enables the protection of the native valve tissue rather than resection and reconstruction [4, 5]. Stabilization of the mitral annulus was early identified as a pivotal part of the Carpentier's triad of mitral valve repair. Therefore, various types of rings were

<sup>†</sup>Presented at the 28th Annual Meeting of the European Association for Cardio-Thoracic Surgery, Milan, Italy, 11–15 October 2014.

developed to provide optimal support in different disease entities such as ischaemic mitral regurgitation or Barlow's disease [6, 7]. Indications for surgical valve repair were even broadened recently in degenerative mitral valve disease to include also asymptomatic patients with severe mitral regurgitation under distinct conditions [1].

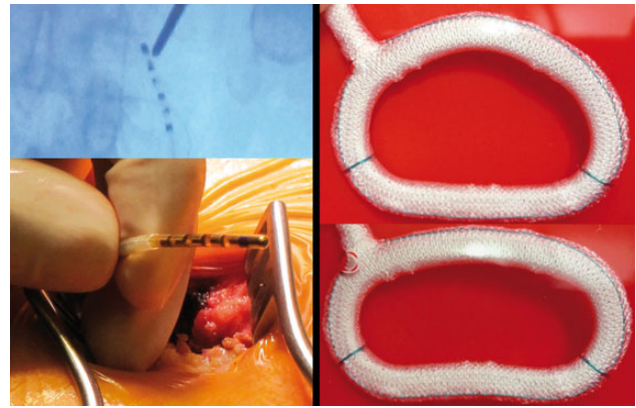
The gratifying history of mitral valve repair in degenerative disease could not be repeated in patients suffering from functional mitral regurgitation so far. This complex disease involving the left ventricle presents with a comparable high number of recurrent mitral regurgitation up to 30% after mitral valve repair [2, 8–10]. A report of successful surgical treatment in this high-risk patient population was published by Bolling [11]. The ring should be undersized in this disease entity to improve leaflet coaptation [12]. Furthermore, a disease-specific rigid ring was developed [13]. However, due to conflicting results in this complex disease, current guidelines recommend a rather conservative approach for surgical valve repair in these patients [3].

The problem of recurrent mitral regurgitation after mitral valve repair in patients with ischaemic mitral valve disease was addressed by a small number of research groups providing adjustable devices. The primary development provided devices only adjustable during the primary procedure after the cessation of cardiopulmonary bypass and the first echo assessment of the repaired valve [14, 15]. This promising treatment concept was developed further to enable the ring adjustment through a wire using a small percutaneous approach. This new deformable nickel–titanium (Nitinol)-based annuloplasty ring described herein is heated up for 45 s, which induces a change of geometry to a preformed shape (reduced anterior–posterior diameter). This new medical device was first implanted in the market-approval DYANA II study (publication under review). The adjustment procedure was previously described in detail [16, 17]. The investigators of this trial were invited to participate in an international register to monitor the long-term experience with this device, and define the indications in order to improve the benefits of an adjustable mitral ring. In addition, usability, safety and adverse events were assessed. We report herein the experience with the adjustable MiCardia EnCor<sub>SQ</sub><sup>TM</sup> Mitral Valve Repair system from all patients implanted in one to the five centres participating in the international register.

## MATERIALS AND METHODS

Data were collected in an open, single-arm, multicentre, observational register. Patients with mitral regurgitation in whom the MiCardia EnCor<sub>SQ</sub><sup>TM</sup> Mitral Valve Repair system (Dynamic Annuloplasty Ring System; MiCardia Corp., Irvine, CA, USA) was implanted at any participating centre were invited. An informed consent was obtained from each patient to acknowledge that his or her medical records will be collected in the register. Patients unable to understand study-related procedures were excluded from participation in the register. All variables of interest were assessed according to the centres' standard of clinical care. No additional examinations were mandated. Data were entered in an international web-based register. Relevant register entries were cross-checked by a central coordinator. Furthermore, all data entries were controlled for plausibility by the authors, and verified by the participating centre prior to publication.

The implantation of this D-shaped mitral ring followed the standard technique for mitral annuloplasty. A smaller ring size was implanted in patients with ischaemic mitral regurgitation to



**Figure 1:** Adjustment procedures. (A) (Left side): The subcutaneous lead is located by X-ray and accessed through a small incision; (B) (right side): The ring adjusts to its preformed shape with a reduced anterior–posterior diameter during the activation.

‘downsize’ the mitral annulus. A permanent lead was attached to the ring in the P2/P3 region. It was routed through the atrial wall to a subcutaneous pocket. If an adjustment was required, the lead was accessed by a small incision, and connected to the generator (Fig. 1A). The ring adjusted its form during activation procedure to a preformed shape with a reduced anterior–posterior diameter (Fig. 1B).

The ring was implanted between April 2011 and July 2014. Follow-up examinations were recorded at hospital discharge, 30 days, 6 months and 12 months. Further examinations were performed whenever applicable at 24 and 36 months. The follow-up intervals after ring adjustment were based on the adjustment procedure, and followed the same schema as described above. Primary end-points were survival, valve-related adverse events and adjustment procedures. Secondary end-points were the progression of mitral regurgitation and postoperative NYHA status. Transthoracic echocardiographic evaluations were conducted at the follow-up time-points. Transoesophageal echocardiographic evaluations were conducted during the surgical procedure and during the ring adjustment. NYHA functional classification was determined during the general medical examination at every follow-up evaluation. Adverse events were recorded at the time they presented and/or at each scheduled follow-up examination. The closing period for the databank analysis was August–September 2014.

Descriptive statistics were applied to report demographic data, operative specifications and results as well as follow-up findings. Mean and standard deviation were calculated for continuous data with a Gaussian distribution and median with interquartile range was calculated for non-Gaussian distributed data. A Wilcoxon signed-rank was applied to compare NYHA status prior to and after surgery as well as mitral regurgitation prior to and after adjustment. Survival and the time to the first adjustment or reoperation were calculated applying the Kaplan–Meier method. All adverse events were collected according to the current guidelines for assessment of heart valve procedures [18]. A subgroup analysis was performed for different patient categories depending on the underlying mitral valve disease (degenerative, ischaemic and dilative mitral regurgitation). Survival was compared between groups using the log-rank test. The postoperative event rates including adjustments were compared between groups using the  $\chi^2$  test. A *P*-value of 0.05 or below was regarded as statistical

significant. SPSS 21.0 (IBM, Armonk, New York, USA) was applied for calculations.

## RESULTS

Five centres participated in the register and a total of 94 patients were enrolled. The mean follow-up was  $14 \pm 11$  months, 6% did not want to participate in the follow-up visits, and were therefore lost to follow-up after discharge. The patients' demographic characteristics, risk factors, procedural specifications and concomitant procedures are depicted in Tables 1 and 2. The study population consisted of a high percentage of patients with functional (ischaemic or dilated cardiomyopathy) mitral regurgitation. Accordingly,

our patient population had a high operative risk (EuroSCORE II  $6.7 \pm 6.3$ ) and a significant number of comorbidities (Table 1). Six patients were operated under emergency conditions. The majority of patients required concomitant procedures (78%, Table 2). Whenever appropriate and available, a minimally invasive approach was performed (30%, Table 2). Most patients received a ring annuloplasty only (78%). Neochords were preferred over other leaflet procedures in patients who required a more complex valve repair, as patients with degenerative mitral disease were also included in this register (Table 2).

Operative mortality in the first 30 days was 1% (cardiac arrest due to hyperpotassemia during postoperative acute renal failure). Four more patients died (4%), 2 due to decompensated heart failure, 1 from sepsis after prolonged postoperative hospitalization and 1 after reoperation due to recurrent mitral regurgitation (the ring could not be adjusted due to technical reasons). Survival was 93% after 1 and 3 years, and was similar between disease groups.

Although 9.5% of the register patients required an early revision for bleeding, no patient had a bleeding from the area where the lead exits the left atrium. Two patients had a postoperative stroke (Table 3). One patient receiving phenprocoumon had a gastrointestinal bleeding event. No other potentially valve-related adverse events (except reoperations) occurred. There was no significant difference regarding survival, adverse events or adjustment procedures between patients with ischaemic, dilative or degenerative mitral regurgitation (Table 3). Furthermore, no difference could be detected between patients receiving annuloplasty alone compared with more complex mitral valve procedures. NYHA status improved significantly 6 months after surgery ( $3.0$  vs  $1.5$ ;  $P < 0.001$ ). The progression of recurrent mitral regurgitation prior to adjustment is depicted in Fig. 2 and compared with patients without adjustment.

Adjustment of the ring was attempted in 12 patients at a mean interval of  $9 \pm 6$  months after surgery. The adjustment failed for technical reasons in 3 of these patients due to a defect in the implanted wire connected to the temperature probe in the ring. This defect could later be solved with a new external connection wire, which blinds the adjustment device for the internal error, and did not occur thereafter. In 1 patient with successful adjustment, mitral regurgitation was reduced two grades, in 2 patients MR was reduced one grade, and in 6 patients, mitral regurgitation did not change significantly. The mean grade of mitral regurgitation changed from  $2.9 \pm 0.9$  to  $2.1 \pm 0.7$  ( $P = 0.02$ ). A follow-up of  $>6$  months was available for only 2 patients after adjustment and their grade of mitral regurgitation remained stable.

Five patients (5%) required a reoperation after  $11 \pm 9$  months. Two patients had a ring dehiscence after deliberately downsizing the ring during the primary surgery (no adjustment was attempted in these patients). Two patients with recurred mitral regurgitation could not be adjusted due to the technical problem described above, and were therefore reoperated conventionally receiving a mitral valve replacement. The last patient was adjusted, but the mitral regurgitation did not improve significantly and the valve was successfully replaced prior to discharge. All adjustments or reoperations were performed during the first 2 years after surgery (Fig. 3).

**Table 1:** Preoperative patient characteristics

Demographic data		Risk factors	
Age (years)	71 (64–75)	EuroSCORE II	$6.7 \pm 6.3$
Gender (m%/f%)	66/34	Emergent surgery	6 (6%)
Weight (kg)	79 (70–88)	Coronary artery disease	54 (57%)
Height (cm)	$171 \pm 9$	Cardiomyopathy	45 (48%)
BMI (kg/m <sup>2</sup> )	26.6 (24.2–29.0)	Previous MCI	34 (36%)
NYHA III	74%	Hypertension	63 (67%)
NYHA IV	12%	Pulmonary HTN	31 (33%)
Echocardiography		Previous stroke/TIA	6 (6%)
Degenerative MR	15%	Hyperlipidaemia	48 (51%)
Ischaemic MR	48%	Smoking	15 (16%)
Dilatative MR	37%	COPD	16 (17%)
Severe MR	89%	LVEDD (mm)	61 (57–67)
Ejection fraction (%)	$47 \pm 16$	LVESD (mm)	42 (34–55)

BMI: body mass index; HTN: hypertension; LVEDD: left ventricular end-diastolic diameter; LVESD: left ventricular end-systolic diameter; MCI: myocardial infarction; MR: mitral regurgitation; TIA: transient ischaemic attack.

**Table 2:** Procedural specifications

Procedural specifications		Concomitant procedures	73 (78%)
Full sternotomy	66 (70%)	Coronary bypass surgery	38 (40%)
Right thoracotomy	22 (23%)	Number of grafts	$2 \pm 1$
Mini-sternotomy	6 (7%)	Aortic valve replacement	10 (11%)
Ring only	73 (78%)	Tricuspid reconstruction	20 (21%)
Neochords	19 (20%)	CRYOMAZE	26 (28%)
Leaflet plasty	6 (6%)	Closure left atrial appendage	20 (21%)
Ring size	$30 \pm 2$	Aortic procedure	3 (3%)
ECC (min)	$157 \pm 48$	ASD/VSD	3 (3%)
ACT (min)	$102 \pm 29$	Pacemaker/ICD	4 (4%)

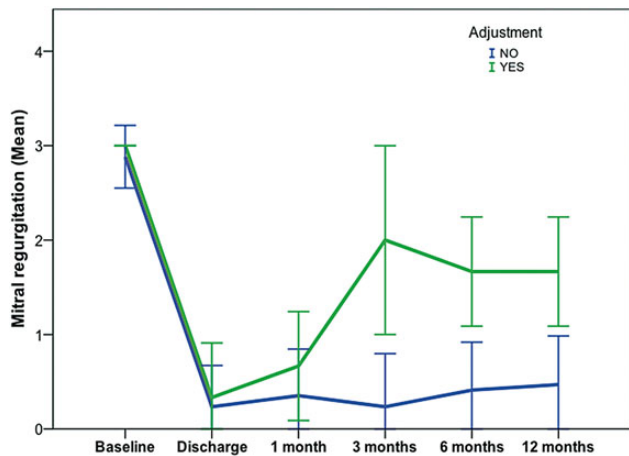
ACT: aortic cross-clamp time; ASD: atrial septal defect; ECC: extracorporeal circulation; ICD: implantable cardioverter/defibrillator; VSD: ventricular septal defect.

## DISCUSSION

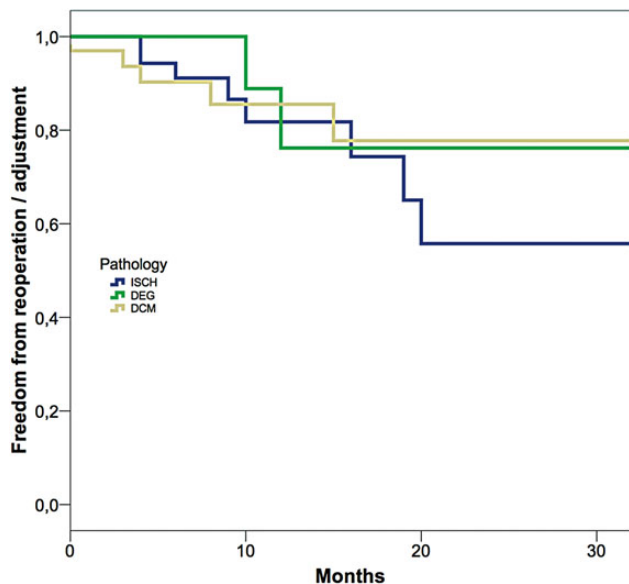
This register-based manuscript reports the post-market-release performance of a novel, adjustable mitral ring. The registered

**Table 3:** Valve-related long-term adverse events

Factor	Total	Ischaemic	Dilative	Degenerative	P-value
Reoperation	5 (6%)	3 (7%)	1 (3%)	1 (10%)	0.66
Embolism					0.29
Stroke	2 (2%)	1 (2%)	0 (0%)	1 (7%)	
Transient ischaemic attack	0 (0%)	-	-	-	
Emboli	0 (0%)	-	-	-	
Bleeding event	1 (1%)	0 (0%)	0 (0%)	1 (7%)	0.29
Endocarditis	0 (0%)	-	-	-	
Adjustment	12 (13%)	6 (13%)	4 (11%)	2 (14%)	0.95



**Figure 2:** Postoperative progression of mitral regurgitation. Patients who later required adjustment (green) had early recurrent mitral regurgitation compared with patients without adjustment.



**Figure 3:** Freedom from reoperation/adjustment. A Kaplan-Meier analysis was performed for the three disease groups; ISCH (blue): ischaemic mitral regurgitation; DEG (green): degenerative mitral regurgitation; DCM (yellow): dilated cardiomyopathy, P = 0.75 between groups.

patients represent a real-world patient population with a varying number of minimally invasive procedures between centres and a high number of comorbidities and concomitant procedures. According to the results of the market-release trial (under review) and several expert meetings, the investigators implanted the ring predominantly in patients with a high likelihood for recurrent mitral regurgitation due to progressive ventricular or annular dilatation. This is reflected by the high percentage of patients with ischaemic or dilative mitral regurgitation in this register (Table 1). These patients have a higher preoperative risk profile, which leads to an increased EuroSCORE II for this report. However, the observed 30-day mortality is well below the predicted mortality. If all in-hospital deaths are counted, the outcome in these high-risk patients is still favourable. Therefore, we can support the results of other trials reporting good early operative results [19]. Leaving reoperation aside, the number of valve-related adverse events was low. The postoperative rate of embolic complications including stroke is comparable with other reports [10]. However, the short intra-atrial course of the lead may be an area of concern. Therefore, a surgical adaptation of the implantation procedure was recently published, suggesting the plication of the endocardium above the intra-atrial course of the lead [20].

A significant number of patients did indeed develop recurrent mitral regurgitation after good initial operative results (Fig. 1). A technical defect in the internal wire to the temperature probe early in the study period limited the number of successful adjustments, and increased the number of reoperations. Ring adjustment was successful in less than half of our patients. The clinical results of the adjustment procedures are ambiguous and the follow-up after adjustment is short. However, no patient experienced an adverse event during or after adjustment and every patient tolerated the adjustment well. In contrast, 1 patient died early after reoperation.

Our data add to the discussion about the optimal treatment for patients with functional mitral regurgitation. Mitral valve repair was superior to mitral valve replacement in ischaemic mitral regurgitation according to a meta-analysis [21]. However, a large Italian study and a recent randomized, controlled trial did not find a significant difference regarding survival between repair and replacement in ischaemic mitral regurgitation [10, 22]. The randomized trial showed a higher perioperative mortality in the replacement group, but the repair group developed recurrent mitral regurgitation and mortality increased during the first year. The other recent study revealed an increased rate of reoperation in the repair group [22]. The adjustable mitral ring reported herein may therefore offer



a third alternative in addition to conventional mitral repair and mitral replacement. The higher perioperative mortality after replacement could eventually be avoided and increasing mortality during follow-up after repair is potentially reduced by ring adjustment. However, patients with severely dilated left ventricles may benefit from initial valve replacement. These questions should be addressed in future clinical trials.

Another crucial question in patients with this device is the timing of adjustment. The presence of ischaemic mitral regurgitation represents a significant risk factor, even in patients with mild and moderate mitral regurgitation [23, 24]. Some authors recommend mitral valve repair by annuloplasty in patients with mild or moderate ischaemic mitral regurgitation undergoing myocardial revascularization [25]. According to literature reports and our low-risk experience with the adjustment procedure, it seems reasonable to us to adjust the ring in patients with moderate recurrent mitral regurgitation. This may inhibit further disease progression and optimize the benefit of this new system. To avoid worsening of mitral valve disease after adjustment, mitral valve stenosis should be excluded prior to ring adjustment.

## Limitations

This register-based trial did not have the same stringent follow-up and documentation process compared with company-driven market-release trials. However, we have applied several measures to ensure data quality. Our patient population cannot reflect one distinct disease entity. Although the majority of patients had functional mitral regurgitation, the absence of rigorous inclusion criteria leads to a patient mix including also patients with degenerative mitral regurgitation.

## CONCLUSION

We conclude that this device may provide an additional treatment option in patients with functional mitral regurgitation, who are at risk for reoperation due to recurrent mitral regurgitation. Clinical results in this complex disease were ambiguous and patient selection seems to be a crucial step for this device. Further trials are required to estimate the clinical value of this therapeutic concept.

## ACKNOWLEDGEMENTS

We want to thank Jose Luis Pomar, who gave his scientific advice at several occasions during this project.

## Funding

Some of the patients reported herein were part of the market-release trial for the device, which was funded by MiCardia (MiCardia Corp., Irvine, CA, USA). Reimbursement of administrative costs for the centres was paid for some patients. No direct funding for this report was paid. Funding to pay the Open Access publication charges for this article was provided by a research grant for the market release trial (Micardia Corp., CA, USA).


**Conflict of interest:** none declared.

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## APPENDIX. CONFERENCE DISCUSSION

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**Dr R. Cordoba** (Cordoba, Argentina): My first question is regarding the selection of patients in this study. Did you use any criteria to select patients? If so, please tell us what those criteria were and if they were uniform in all five surgical groups.

The second question is directly related to the device that you used in the research study. Do you positively know if the energy distribution throughout the nitinol ring is effectively uniform during the modification process of such ring?

**Dr Andreas:** First, I will comment on patients' selection. As it was a register trial, every patient who received a ring was added to the register. However, at

the beginning of the implantation procedure there were no strict rules, but after having meetings and developing this product further, we decided to go more to ischemic and functional disease. In summary, there were no strict rules as it is not a randomised trial and it is not a prospective trial. But, we tried to focus on patients with functional and/or ischemic mitral regurgitation; therefore, the proportion of patients with degenerative disease was low.

The second question: The heating wires are wrapped around the length of the nitinol. Therefore, an equal energy distribution is achieved. The nitinol is heated up to 45 degrees, and during the temperature change the nitinol changes the shape.

**Dr C. Hargrove** (Philadelphia, PA, USA): I have got a question. The sizing is confusing to me. So all the rings are 36, is that correct?

**Dr Andreas:** No, they are available 28mm to 36 mm.

**Dr Hargrove:** With different manufacturers 36 mm is not necessarily 36 mm. Even with some manufacturers of the same company, one size 36 is different from another size 36. So how did you determine the size, or what did you base that on?

**Dr Andreas:** The ring comes with a sizer, obviously, and there are different sizes available from I think even 28mm to 36 mm. You size it equal to a normal ring. If you have an ischemic mitral regurgitation, you should downsize the ring as described before.

I'm not sure if 36 in this ring is the same like 36 in other rings. I didn't check this. I used the 36 ring for the video, because the shape-change is the biggest. The change of AP diameter depends on the implanted ring size; a smaller ring, a smaller change.

**Dr R. Lorusso** (Brescia, Italy): I have a question about the technical failure. Could you comment on that?

**Dr Andreas:** There is a temperature wire inside the ring measuring the temperature during the activation, and this is not necessary. In these three cases the temperature wire broke, but you can adjust the ring without measuring the temperature, because after 45 seconds it stops anyway.