Heart Vessels (2017) 32:843–849
DOI 10.1007/s00380-016-0934-7

ORIGINAL ARTICLE

Results of mitral valve repair with an adjustable annuloplasty ring 2 years after implantation

Simon H. Sündermann[1,2] · Markus Czesla[3] · Jörg Kempfert[1] · Thomas Walther[4] · Patrick Nataf[5] · Ehud Raanani[6] · Stephan Jacobs[1,2] · Ottavio Alfieri[7] · Francesco Maisano[8] · Volkmar Falk[1,2,9]

Received: 4 August 2016 / Accepted: 9 December 2016 / Published online: 23 December 2016

Abstract We aimed to investigate the safety and medium-term durability of an adjustable mitral annuloplasty ring in patients undergoing surgery for mitral valve regurgitation. Forty-five patients requiring mitral valve repair were enrolled into this prospective, multicentre study between May 2012 and May 2013 in six hospitals in Europe and Israel. Study endpoints evaluated the performance and safety of the device assessed using inter-individual comparisons. Implantation was performed through a sternotomy in ten patients and mini-thoracotomy in 35 patients. The ring was adjusted after declamping and weaning from cardio-pulmonary bypass under echocardiographic guidance if the coaptation surface was not optimal, or in cases of residual mitral regurgitation. Follow-up was performed up to 2 years post-procedure. Mean age was 61 ± 12 years. Ring adjustment was performed in 71% of patients to optimise the results of mitral valve repair. Following the procedure, 11/45 patients (24%) who had had mild residual mitral regurgitation had no mitral regurgitation following ring adjustment. Two patients with severe mitral regurgitation post-procedure had mild regurgitation following ring adjustment. Coaptation length increased significantly after adjustment. One patient died before hospital discharge due to complications unrelated to the adjustable ring. One patient had to undergo re-operation at 39 days post-procedure due to endocarditis. At 2 years of follow-up, 78% of patients had no residual mitral regurgitation and 22% had mild residual mitral regurgitation. Adjustable mitral annuloplasty ring implantation was safe in all patients. Mitral valve repair with the adjustable ring was durable in all patients who reached 2 years follow-up.
Clinical Trial Registration NCT01617720.

Keywords Mitral regurgitation · Mitral valve annuloplasty

Electronic supplementary material The online version of this article (doi:10.1007/s00380-016-0934-7) contains supplementary material, which is available to authorized users.

✉ Simon H. Sündermann
suendermann@dhzb.de

[1] Department of Cardiothoracic and Vascular Surgery, Deutsches Herzzentrum Berlin, Augustenburger Platz 1, 13353 Berlin, Germany

[2] DZHK (German Centre for Cardiovascular Research), Partner Site Berlin, Berlin, Germany

[3] Klinikum Passau, Department of Cardiac Surgery. Innstrasse 76, 94032 Passau, Germany

[4] Department of Cardiac Surgery, Kerckhoff-Klinik, Benekestr. 2-8, 61231 Bad Nauheim, Germany

[5] Department of Cardiac Surgery, Assistance Publique-Hôpitaux de Paris, Bichat Hospital, Paris, France

[6] Department of Cardiac Surgery, Sheba Medical Center, Tel-Hashomer, Israel

[7] Department of Cardiovascular Surgery, San Raffaele Hospital, Milan, Italy

[8] University Hospital of Zurich, Heart Center, Zurich, Switzerland

[9] Charité, Universitätsmedizin Berlin, Berlin, Germany

Introduction

The aim of mitral valve repair is to eliminate mitral regurgitation (MR) and increase the area of coaptation between the anterior and posterior leaflet. Mitral annuloplasty is an essential component of durable mitral valve repair, as it provides efficient annular remodelling and reduces the annular dimension to increase coaptation length. This, in turn, reduces leaflet stress and provides the basis for a

durable repair [1, 2]. Correct sizing of the annuloplasty ring is crucial and this is usually done using a sizing template that is applied under direct vision while the heart is arrested and in diastolic phase. Over- or under-sizing of the annuloplasty ring can lead to residual regurgitation or mitral valve stenosis, respectively. Furthermore, systolic anterior motion of the anterior leaflet can sometimes result and cause left ventricular outflow tract (LVOT) obstruction due to excessive under-sizing.

An adjustable mitral annuloplasty ring (Cardinal adjustable annuloplasty system, Valtech Cardio, Or Yehuda, Israel) has recently become available that allows size adjustment under echocardiographic monitoring while the heart is beating to achieve optimal results, i.e. by maximising the mitral valve orifice area while preserving sufficient coaptation depth. The results of the feasibility study with this device running from 2010 to 2011 have been reported [3].

Here, we present the results of the subsequent multicentre, post-marketing surveillance study. Safety and medium-term durability of the adjustable mitral annuloplasty up to 2 years were investigated.

Materials and methods

A total of 45 patients were enrolled into this prospective, multicentre study between May 2012 and May 2013 in six hospitals in Europe and Israel (Germany: 2, Switzerland: 1, Italy: 1, France: 1, Israel: 1). Approval for the study was granted by local Ethics Committees and all patients provided written informed consent. All enrolled patients had indication for surgical mitral valve repair due to primary or secondary mitral valve insufficiency according to current guidelines [4]. Patients with endocarditis, severely calcified valve structure, lack of leaflet tissue due to congenital malformations or severe organic lesions with retracted chords were excluded. A further exclusion criterion was, known sensitivity, to nickel or chromium.

Inter-individual comparison was made pre- and post-procedure. The primary endpoint was performance of the device, defined as the effectiveness of the annuloplasty ring in reducing MR and the technical ability to adjust the device size to optimise results. The secondary endpoint was safety of the device according to Guidelines for Reporting Morbidity and Mortality after Cardiac Interventions [5]. Follow-up was performed 30 days, 6 months, 1 and 2 years post-procedure.

The Cardinal adjustable annuloplasty system received the CE mark in 2011. The key difference between the Cardinal annuloplasty system and conventional annuloplasty rings is its ability to allow adjustment of the ring size under echocardiographic guidance after declamping and weaning of the patient from CPB. The ring is available in 3 sizes that cover the full range of annuloplasty sizes (small: 24–32 mm, medium: 28–36 mm, large: 32–40 mm). Its diameter can be enlarged or reduced depending upon individual intra-operative findings to optimise the repair.

Fig. 1 Adjustable mitral annuloplasty ring

The implant is a semi-rigid D-shaped ring with a metal core enclosed in a polyester fabric covering, which is attached to an adjustment mechanism comprised of a spool with an inner wire (Fig. 1). The adjustment mechanism, integrated within the mid-portion of the anterior segment ring, enables size adjustment before and after weaning from cardio-pulmonary bypass (CPB). The contraction wire runs the length of the ring and through the adjustment mechanism. The spool is rotated, while winding a portion of the contraction wires over the spool to adjust the ring size. The spool may also be rotated in the opposite direction to loosen the ring if it is over-contracted. Once the required implant size is reached, the operator disengages the handle from the spool. This triggers a stopping element to rise, which locks the spool in place and disables rotation of the spool in either direction [3].

The adjustable annuloplasty ring system is implanted during CPB, under cardioplegic arrest and direct view, with a conventional suturing technique. Following leaflet repair, standard ring sizers are used to size the ring. The corresponding adjustable annuloplasty ring is selected and mounted on the holder. A video animation showing the function and the implantation of the ring can be found in the online supplement (video 1). In patients with degenerative MR, a slightly under-sized annuloplasty ring should be chosen to retain the option of ring expansion after implantation. In the case of functional MR, under-sizing is not required since the correct size can be achieved by ring contraction

Table 1 Baseline characteristics

Age (years)	61 ± 12
Age range (years)	35–84
Male, *n* (%)	27 (60)
Female, *n* (%)	18 (40)
BMI (kg/m^2), mean ± SD	25 ± 4
NYHA*, *n* (%)	
I	8 (19)
II	22 (51)
III	11 (25)
IV	2 (5)
Systemic hypertension, *n* (%)	22 (49)
Diabetes mellitus, *n* (%)	3 (6)
Dyslipidaemia, *n* (%)	10 (22)
Coronary artery disease, *n* (%)	6 (13)
Chronic lung disease, *n* (%)	3 (7)
Prior cerebrovascular accident, n (%)	3 (7)
Prior myocardial infarction, *n* (%)	4 (9)
Prior arrhythmias, *n* (%)	15 (33)
Valvular disease other than mitral regurgitation	
Moderate tricuspid stenosis	1 (2)
Moderate tricuspid regurgitation	2 (4)
Severe tricuspid regurgitation	2 (4)

* NYHA Class was not assessed in 2 subjects

BMI body mass index, *NYHA* New York Heart Association

after implantation. Following completion of the implant, ring size can be adjusted according to standard water testing of the mitral valve. The left atrium is then closed in the usual fashion, with the exception that the adjustment handle traverses the atriotomy suture line so that the final ring size adjustment can be performed after weaning from CPB.

Haemodynamic status should be stable at the time of adjustment, with near-physiological arterial pressure and optimal loading conditions. Adjustment is guided by transesophageal echocardiography (TEE), focusing on residual MR, degree of leaflet coaptation and the presence of transmitral gradients. If residual MR is present, size reduction can be attempted. In absence of residual MR, the ring size can still be adjusted to obtain a larger surface of coaptation. The length of coaptation is assessed in left ventricular outflow tract (LVOT) view, scanning the coaptation line in different segments. The length of coaptation should ideally be 8 mm or more throughout the coaptation line. In the case of systolic anterior motion (SAM), the ring may be enlarged until normal leaflet coaptation is obtained. In the case of functional mitral stenosis, the ring may be re-expanded. Following final ring size adjustment, the adjustment handle is removed. A final TEE evaluation of MV function is performed. The operation is then completed in standard fashion.

Echocardiography was used pre-, intra- and post-operatively to assess mitral valve geometry and function. Transoesophageal echocardiography was the preferred modality for baseline assessment and for peri-operative assessment. Coaptation length was calculated as average of multiple measurements. Post-operative examinations were performed by transthoracic echocardiography. All echocardiographic data was assessed by an independent, external laboratory (Corelab, Baylor, TX, USA).

All serious adverse events (SAEs) were recorded and adjudicated by an independent Clinical Event Committee (CEC). Adverse events (AEs) were reported according to the Valve Academic Research Consortium (VARC) guidelines [5].

Statistical analysis has been performed using the IBM SPSS Statistics, Version 22.0, IBM Corp., Armonk, NY, USA. Continuous variables are presented as mean ± standard deviation (SD). The level of significance was set at $p = 0.05$.

Results

Forty-five patients with a mean age of 61 ± 12 years were enrolled in the study. Baseline characteristics are given in Table 1. Left ventricular ejection fraction (LVEF) was not significantly impaired in most patients [63 ± 11% ($N = 39$)]; LVEF was not assessed in six patients. Average left ventricular end diastolic volume was 161 ± 36 mL and left ventricular end systolic volume was 64 ± 26 mL ($N = 30$); however, in 15 patients the images were judged as not measurable by Corelab. Eight patients (18%) had moderate MR (i.e. grade 2 + MR), and 37 patients (82%) had severe MR (i.e. grade 3–4 + MR). Most patients (84%) presented with a type II pathology due to prolapsing leaflets according to Carpentier's classification [6], 7% had normal leaflet motion (type I pathology) and 9% had restricted leaflet motion (type III pathology). Patients with moderate MR had concomitant indication for surgery (coronary vessel disease, atrial fibrillation, persistent foramen ovale).

Surgery was performed through a right mini-thoracotomy in 35 patients and through a median sternotomy in 10 patients. Additional mitral valve repair procedures were performed in 39 patients (87%). Chordal repair was performed in the majority of procedures [73% ($N = 33$)]. Leaflet resection was performed in 13% ($N = 6$), sliding plasty was performed in 4% ($N = 2$), cleft closure was performed in 4% ($N = 2$) and edge-to-edge repair was performed in 2% ($N = 1$). Some patients had multiple mitral valve repair procedures. Most patients had isolated mitral valve repair without concomitant surgery [67% ($N = 30$)]. In two patients (4%) concomitant coronary artery bypass grafting (CABG) was performed, in 2 patients (4%) a

Table 2 Patients undergoing ring adjustment

$N = 33$ pts who underwent ring adjustment		
MR grade	Post implantation* *N* (%)	End of procedure** *N* (%)
None	19 (59)	30 (94)
Mild	11 (34)	2 (6)
Moderate	0 (0)	0 (0)
Severe	2 (6)	0 (0)

* Post implantation: after CBP weaning

** End of procedure: after Cardinal ring adjustment post-pump

persistent foramen ovale was closed and in 11 patients (24%), additional atrial fibrillation ablation was performed. Atrial fibrillation ablation was combined with additional procedures in 6 patients: In three patients with left atrial appendage closure, in one patient with tricuspid valve repair, in one patient with aortic tumor excision and in one patient with closure of both atrial appendages and tricuspid valve repair.

Implantation of the Cardinal adjustable annuloplasty ring was feasible in all patients. A medium size ring was selected in most cases [51% ($N = 23$)], a large ring in 15 patients (33%) and a small ring in 7 patients (16%). Adjustment was performed in 32 patients (71%) to optimise the result of the mitral valve repair (Table 2). In 11 patients with mild residual MR after implantation, it was possible to reduce the grade of MR to zero by adjustment. In 2 patients with severe MR after implantation, a reduction to mild MR was achieved after adjustment. Both of these patients had significant right ventricle dysfunction. In one patient the procedure did not include any other concomitant procedures (although she had had severe regurgitation of the tricuspid valve, which was repaired 2 weeks before MR with an annuloplasty). The second patient underwent CABG in addition to the annuloplasty. As the aetiology of the MR was functional, no leaflet or sub-valvular repair was performed in either patient. Both patients had a small ring implanted, starting with the maximum diameter according to sizing with the common sizing tool. Initially, severe MR was present which could be reduced to mild in both patients by reducing the ring diameter. In 41 patients (91%) there was no MR at the end of the procedure; in 4 patients (9%) mild MR was present post-operatively.

The coaptation length of the mitral valve leaflets increased significantly after adjustment (7.6 ± 2 vs. 9.5 ± 2.4 mm ($p < 0.001$ [Fig. 2]). Importantly, the minimal coaptation length post- adjustment was 7 vs. 4 mm pre-adjustment. In addition, none of the patients were found to have SAM. In two patients, ring size was enlarged to minimize the risk of SAM. Mean septo-lateral diameter of the mitral annulus was reduced from 3.7 ± 0.5 to 1.9 ± 0.4 cm

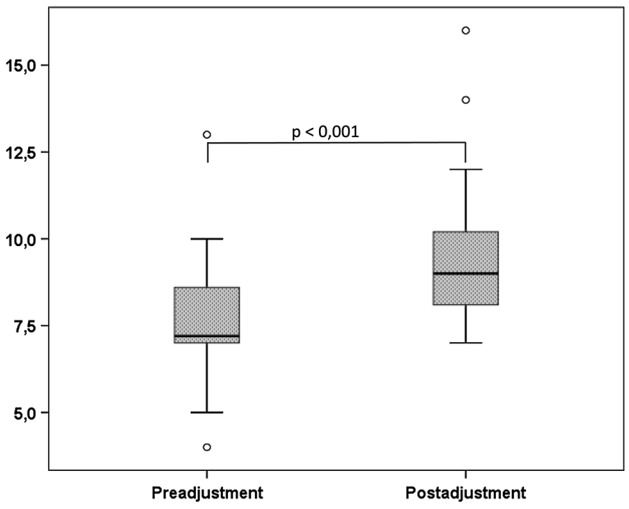

Fig. 2 Change in coaptation length during adjustment manoeuvre

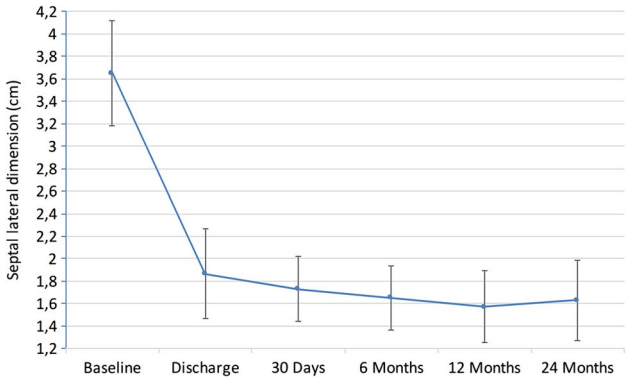

Fig. 3 Diastolic septo-lateral annulus dimension

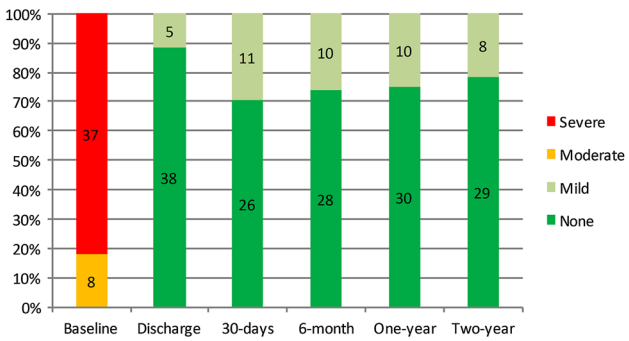

Fig. 4 Grade of mitral regurgitation at baseline at discharge and during follow–up

at discharge (1.7 ± 0.3 cm at 30 days, 1.7 ± 0.3 at 6 month, 1.6 ± 0.3 at 1 year and 1.6 ± 0.4 at 2 years) as shown in Fig. 3. None of the patients required a second session of CPB following the procedure. Mid-term results of the

mitral valve repair were as follows: in 30 patients (75%), no residual MR was found, and mild residual MR was present in 10 patients (25%) after 1 year. For 5 patients, no mitral valve assessment was conducted for the 1 year follow-up: 2 patients had died, 1 patient required mitral valve replacement due to suspected endocarditis, and two patients withdrew consent. After 2 years, 29 patients (78%) had no residual MR and 8 patients (22%) had mild residual MR. One more patient withdrew consent and one patient was lost to follow-up. For one patient, no echo data was available (Fig. 4).

One patient died before hospital discharge. Severe triple-vessel coronary artery disease and severely reduced left ventricular ejection fraction of 30% additionally to severe mitral valve regurgitation were diagnosed. Triple bypass surgery and mitral valve repair was performed. The patient developed low cardiac output post-operatively and required implantation of an extra-corporeal membrane oxygenator (ECMO). The patient died on post-operative day 11 due to multi organ failure. The event was considered unrelated to the study device but related to the procedure, as confirmed by the CEC. A second 81-year- old male patient died 3 months after surgery. In the post-operative course, pneumonia necessitated re-intubation. Two month after the procedure, the patient had cardiac arrest and was resuscitate due to a second pneumonia resulting in hypoxia. Three months after intervention, the patient suddenly died. A fever preceded death and significantly increased inflammatory markers were detected. The event was considered procedure related, as pneumonia is a known complication of surgical interventions, and as non-device related which was confirmed by the CEC. Finally, one patient had to undergo re-operation for mitral valve replacement due to a suspicion of endocarditis 39 days post initial procedure. The 62-year-old female patient underwent tricuspid repair and ablation approximately 2 weeks before the mitral valve intervention. Post-operative mitral valve regurgitation increased and caused dyspnoea. Mitral valve repair was performed using the Cardinal ring. No mitral regurgitation was seen after the operation and the initial postoperative course was uneventful. After one week, the patient developed fever, which was treated with antibiotics but continued. Computed tomography did not find any inflammatory focus. Recurrent mitral valve regurgitation was seen in the echocardiogram. Therefore, re-operation was performed for mitral valve replacement due to the suspicion of endocarditis. Blood cultures and microbiology of the valve tissue were negative. The event was considered as a procedure but not device-related as confirmed by the CEC.

A total of 38 patients (84%) completed the full 2 years of post-operative follow-up. One patient died before the 30 day follow-up; one patient died, one patient had mitral valve replacement and one patient withdrew consent before 6 month follow up. Another two patients withdrew consent before 1 and 2 year follow-up and one patient was lost to follow-up before the 2 years were completed. Additionally to the two fatal events, the following SAEs were recorded: Blood loss requiring blood transfusion ($N = 3$), wound infection ($N = 1$), arrhythmia ($N = 1$), incisional hernia ($N = 2$, 1 patient had two events), suspected endocarditis resulting in re-operation ($N = 1$) (as noted above), general infection ($N = 2$, one patient had 2 events), re-thoracotomy for pericardial effusion ($N = 1$), breast cancer diagnosed during follow-up ($N = 1$), anxiety ($N = 1$), testicular neoplasm ($N = 1$), cardiac complication requiring intervention ($N = 1$). None of these complications were adjudicated as 'device-related' by the CEC.

Stability or improvement in heart failure, as evaluated by New York Heart Association (NYHA) class, was achieved in all patients but two. The NYHA score worsened from I at baseline to II at 6 month follow-up for one patient and from II at baseline to III at 24 month follow-up for another patient. The first patient suffered from chest-wall hernia between 1 and 6 month follow-up which might explain the worsened NYHA classification. Otherwise, both patients had mild MR throughout the follow-up duration. NYHA class improved for 23 patients (70%) at 6 month follow-up, 19 patients (86%) at 12 month follow-up and 9 patients (69%) at 24 month follow up.

Discussion

Mitral valve annuloplasty is a crucial component of mitral valve repair surgery. The aim is to stabilise the annulus, while preserving an adequately sized mitral orifice, and to create a large area of coaptation of the mitral valve leaflets according to Carpentier´s principles of mitral valve reconstructive surgery [7, 8]. Various commercial annuloplasty rings are available in pre-defined sizes and geometries. The ring type and size are selected according to intra-operative, template based measurements of the annulus size, the anterior leaflet length and by manual measurements of the annulus. However, sizing of the annulus is done under non-physiologic conditions since echocardiography is performed under anaesthesia and intra-operative measurement is conducted while the heart is arrested and in diastolic phase [9]. Rings that are too large can result in persistent or recurrent MR due to insufficient leaflet coaptation, which is correlated with poorer long-term outcome [10]. Excessive under-sizing can result in high-pressure gradients and mitral stenosis. Systolic anterior motion can also occur in patients with excessive leaflet tissue and under-sized rings [11] resulting in LVOT obstruction with the need for immediate re-operation.

To overcome these drawbacks, adjustable mitral annuloplasty systems have been introduced. These include

the MiCardia EnCorSQ™ Mitral Valve Repair system (Dynamic Annuloplasty Ring System; MiCardia Corp, Irvine, CA, USA) which is a deformable nickel-titanium (nitinol)-based annuloplasty ring that can change its geometry to a pre-formed shape (reduced anterior-posterior diameter) when heated up to 45 s. Activation of the device to re-shape its configuration is induced by a permanent lead that is left in a small subcutaneous pocket and is connected to the ring through the atrial wall. It can be activated immediately during the operation up to several months or years after implantation. Adjustment of the ring was attempted during a study in 12 out of 94 patients with recurrent MR after a mean interval of 9 ± 6 months. However, ring adjustment failed in 3 patients for technical reasons and no change in MR could be achieved in 6 patients. A reduction in MR by 2 grades was achieved in 1 patient and a reduction of 1 grade was achieved in 2 [12].

Feasibility study outcomes using the Cardinal adjustable annuloplasty system were previously reported on 30 patients with 12 months' follow-up data [5]. Implantation of the ring was successful in all but 1 patient, who had to undergo mitral valve replacement. At discharge, all patients had MR grade 1 or less. One patient had to undergo re-operation due to ring dehiscence and 1 patient had recurrent MR 2+ after 12 months but did not require re-operation. During the procedures, adjustment was performed in 80% of patients (mainly because of a limited range of available sizes); in 6 patients there was a significant increase in coaptation length and a decrease in MR was achieved. None of these patients has been included in the present study. The single-centre experience of 20 patients included in the post-marketing study has previously been published [13]. Fifteen patients had no MR and 5 patients had trace MR after 24 months. Limitations were the single-centre character of the study with a limited number of patients. Additionally, the follow-up echocardiograms were not validated by a Core Lab.

The main advantage of this adjustable annuloplasty ring is the option to reduce or increase the ring size while the heart is beating, under echocardiographic guidance. The change in size is not only bi-directional (i.e. anterior-posterior) but the inter-commissural distance can also be reduced. However, a limitation of the system is that this adjustment can only be performed intra-operatively so that late adjustment is not possible. In our study, the adjustment mechanism was used in 71% of patients, and in all patients fine-tuning of the ring size was possible to increase the length of coaptation. It should be noted that the study-protocol suggested implantation of a ring with an initial size one above the measured size to prevent initial induction of SAM, with the option of downsizing if the coaptation length was too small or regurgitation remained. The Cardinal annuloplasty ring is mostly affecting the annulus by evenly distributing contraction to the posterior annulus resulting mainly in a reduction of the septo-lateral and less on the anteroposterior diameter. It is a feature of semi-rigid rings to follow native anatomy and allows following its natural tendency towards saddle shape. Since the ring is adjusted to estimated size before implantation, the adjustment post resuscitation is fine-tuning of coaptation length. The current experience does not show any other effects to be considered during adjustment. No intra-operative complications were observed, and therefore, both the performance and safety endpoints were met.

Recurrent MR is known to occur sometimes months or even years after the initial treatment. The causes can be related to rupture or elongation of chordae in the case of degenerative MR or progression of the disease in the case of functional MR. The results in this study at 24 months' follow-up show that a durable mitral valve repair can be achieved with this system. Only mild MR was observed after 24 months and no ring dehiscence occurred in any of the patients. Nevertheless, it might happen in patients who have the ring implanted after the study, that MR recurs. In these cases it would be an improvement if there were a feature enabling late adjustment of the ring, as it is possible with the MiCardia EnCorSQ™ Mitral Valve Repair system.

Mitral valve repair has been proven to be a procedure for which a certain learning curve has to be overcome [14]. Especially for surgeons at the beginning of the learning curve, an adjustable annuloplasty device might be helpful to prevent re-clamping of the aorta in case of missizing of annuloplasty rings.

A limitation of this study is the small sample size of the cohort. Additionally, there was a lost to follow-up rate of 13% for different reasons. It cannot be excluded, that these patients had recurrent MR, although it would probably have come to the investigators' attention. Another issue that should be mentioned as a limitation is that 8 patients had only moderate MR before the intervention.

In conclusion, the Cardinal adjustable mitral annuloplasty ring was suitable for implantation in all enrolled patients with very good intra- and post-operative results. It was possible to increase the coaptation length significantly without any additional risk and without SAM using the adjustment mechanism. Reduction of residual MR was possible and durable mitral valve repair was demonstrated in all patients who reached 24 months follow-up.

Acknowledgement We thank Anne Gale of the Deutsches Herzzentrum Berlin for editorial assistance. This work was supported by Valtech Cardio Ltd.

Compliance with ethical standards

Conflict of interest O.A. is a minor stock holder of Valtech Cardio, F.M. is stock holder and consultant for Valtech cardio, V.F. is a consultant for Valtech Cardio, all other authors declare no conflict of interest.

References

1. Witschey WR, Zhang D, Contijoch F, McGarvey JR, Lee M, Takebayashi S, Aoki C, Han Y, Han J, Barker AJ, Pilla JJ, Gorman RC, Gorman JH 3rd (2015) The influence of mitral annuloplasty on left ventricular flow dynamics. Ann Thorac Surg 100:114–1121
2. Maisano F, Caldarola A, Blasio A, De Bonis M, La Canna G, Alfieri O (2003) Midterm results of edge-to-edge mitral valve repair without annuloplasty. J Thorac Cardiovasc Surg 126:1987–1997
3. Maisano F, Falk V, Borger MA, Vanermen H, Alfieri O, Seeburger J, Jacobs S, Mack M, Mohr FW (2013) Improving mitral valve coaptation with adjustable rings: outcomes from a European multicentre feasibility study with a new-generation adjustable annuloplasty ring system. Eur J Cardiothorac Surg 44:913–918
4. Vahanian A, Alfieri O, Andreotti F, Antunes MJ, Barón-Esquivias G, Baumgartner H, Borger MA, Carrel TP, De Bonis M, Evangelista A, Falk V, Lung B, Lancellotti P, Pierard L, Price S, Schäfers HJ, Schuler G, Stepinska J, Swedberg K, Takkenberg J, Von Oppell UO, Windecker S, Zamorano JL, Zembala M (2012) ESC Committee for Practice Guidelines (CPG); Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC); European Association for Cardio-Thoracic Surgery (EACTS); Guidelines on the management of valvular heart disease (version 2012): the Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). Eur J Cardiothorac Surg 42:S1–S44
5. Akins CW, Miller DC, Turina MI, Kouchoukos NT, Blackstone EH, Grunkemeier GL, Takkenberg JJ, David TE, Butchart EG, Adams DH, Shahian DM, Hagl S, Mayer JE, Lytle BW (2008) Councils of the American Association for Thoracic Surgery; Society of Thoracic Surgeons; European Association for Cardio-Thoracic Surgery; Ad Hoc Liaison Committee for Standardizing Definitions of Prosthetic Heart Valve Morbidity. Guidelines for reporting mortality and morbidity after cardiac valve interventions. J Thorac Cardiovasc Surg 135:732–738
6. Carpentier A (1983) Cardiac Valve Surgery – The French Correction. J Thorac Cardiovasc Surg 86:323–337
7. Carpentier A, Deloche A, Dauptain J, Soyer R, Blondeau P, Piwnica A, Dubost C, McGoon DC (1971) A new reconstructive operation for correction of mitral and tricuspid insufficiency. J Thorac Cardiovasc Surg 61:1–13
8. Carpentier A, Adams DH, Filsoufi F (2010) Carpentier's reconstructive valve surgery. Saunders Elsevier, Maryland Heights, pp 1–386
9. Ender J, Eibel S, Mukherjee C, Mathioudakis D, Borger MA, Jacobs S, Mohr FW, Falk V (2011) Prediction of the annuloplasty ring size in patients undergoing mitral valve repair using real-time three-dimensional transoesophageal echocardiography. Eur J Echocardiogr 12:445–453
10. Rizza A, Sulcaj L, Glauber M, Trianni G, Palmieri C, Mariani M, Maffei S, Berti S (2007) Predictive value of less than moderate residual mitral regurgitation as assessed by transesophageal echocardiography for the short-term outcomes of patients with mitral regurgitation treated with mitral valve repair. Cardiovasc Ultrasound 5:25
11. Varghese R, Itagaki S, Anyanwu AC, Trigo P, Fischer G, Adams DH (2014) Predicting systolic anterior motion after mitral valve reconstruction: using intraoperative transoesophageal echocardiography to identify those at greatest risk. Eur J Cardiothorac Surg 45:132–137
12. Andreas M, Doll N, Livesey S, Castella M, Kocher A, Casselman F, Voth V, Bannister C, Encalada Palacios JF, Pereda D, Laufer G, Czesla M (2016) Safety and feasibility of a novel adjustable mitral annuloplasty ring: a multicentre European experience. Eur J Cardiothorac Surg 49:249–254
13. Czesla M, Götte J, Voth V, Doll N (2015) Single-center experience with adjustable annuloplasty ring in degenerative mitral regurgitation. Innovations (Phila) 10:248–251
14. Holzhey DM, Seeburger J, Misfeld M, Borger MA, Mohr FW (2013) Learning minimally invasive mitral valve surgery: a cumulative sum sequential probability analysis of 3895 operations from a single high-volume center. Circulation 128:483–491