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Novel epicardial off-pump device for mitral regurgitation: acute evaluation☆,☆☆

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Abstract

Objective: This study evaluates the ability of a novel epicardial annuloplasty device Mitral Touch (MAQUET Cardiovascular LLC, San Jose, CA, USA) to reduce functional mitral regurgitation (MR) in a rapid ventricular pacing-induced dilated cardiomyopathy model in dogs. **Methods:** A median sternotomy was performed in 13 dogs after MR induction by rapid ventricular pacing (230 beats/min for an average of 35.6 ± 12.8 days). Two-dimensional epicardial echocardiographic and haemodynamic measurements were performed to evaluate the baseline MR grade, the septal–lateral (S–L) dimension of the mitral annulus, mitral valve (MV) geometry and left ventricular function. The Mitral Touch was implanted by sliding the anterior arm onto the floor of the transverse sinus and positioning the posterior arm just apical to the atrioventricular groove on the left ventricular posterolateral wall. The 24-mm-long device was implanted in eight dogs, the 27-mm-long device in four and the 30-mm standard length device in one. MR grade, S–L dimension and haemodynamics data acquisition were immediately rechecked after device implantation. **Results:** All implantations, which took only approximately 30 s to deploy, were performed on beating hearts without cardiopulmonary bypass. In one early case, after extended manipulation with undersized devices, an atrial laceration was created and bleeding occurred. Design changes were made to eliminate this complication. The MR grade was significantly ($p = 0.003$) reduced from 3.1 ± 1.1 at baseline to 1.4 ± 0.8 after device implantation. The S–L dimension at end of systole was also significantly ($p = 0.001$) reduced from 2.7 ± 0.4 cm at baseline to 2.3 ± 0.3 cm after device implantation (% reduction: 15.1 ± 10.6%). The mitral valve coaptation length was significantly ($p = 0.0001$) increased from 0.36 ± 0.11 cm to 0.50 ± 0.08 cm, and the mitral valve tethering area was significantly ($p = 0.0003$) decreased from 1.36 ± 0.38 cm^2 to 0.81 ± 0.29 cm^2 after Mitral Touch implantation. **Conclusions:** This new epicardial device was effective in significantly reducing MR and S–L dimensions acutely on the beating heart without requiring the use of cardiopulmonary bypass. Further studies are necessary to confirm the long-term maintenance of MR and S–L reductions.

Keywords: Mitral valve repair; Minimally invasive surgery; Off-pump surgery

1. Introduction

Chronic ischaemic mitral regurgitation (MR), also called 'functional' MR or 'secondary' MR, is an independent predictor of higher mortality and higher risk of developing heart failure in the post-myocardial infarction population [1,2]. Although there is consensus that patients with moderately severe to severe functional MR should undergo surgical repair at the time of revascularisation and that trace to mild MR can probably be left alone, the optimal management of moderate MR continues to be a subject of continuing debate and controversy [3,4]. The most common surgical approach to repair functional MR is a downsizing mitral annuloplasty, usually combined with coronary artery bypass grafting (CABG). Mitral annuloplasty for advanced heart failure patients is limited because of concerns regarding considerable surgical morbidity and mortality [5], because the operation requires access to and manipulation of the valve annulus via a left atriotomy, and stitching in the ring is a time-consuming process. Furthermore, the procedure currently requires the patient to be placed on cardiopulmonary bypass (CPB) to facilitate the treatment. Recently, several devices for treating functional MR have been developed that can be placed percutaneously or minimally invasively without CPB. Some of them are in clinical trials for

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diagnostic evaluation [6], and permanent implants are ongoing [7]. Numerous issues need to be addressed, however, before they become a standard therapy for functional MR.

We are developing an epicardiac mitral annuloplasty device, which can reduce the septal—lateral (S—L) dimension, resulting in the improvement of MR without employing CPB. Earlier, we demonstrated the feasibility of this treatment in normal dogs [8]. In that study, the device was effective in reducing S—L dimension and 1+ MR without CPB. The purpose of the present study was to evaluate this novel device in dogs with experimentally induced functional MR. This study was undertaken to assess feasibility and monitor acute echocardiographic and haemodynamic changes.

2. Materials and methods

2.1. Description of the device

The Mitral Touch is an epicardial annuloplasty device [8]. It consists of a titanium wire backbone, silicone bulking and a polyester fabric cover. The Mitral Touch is implanted by sliding its anterior arm into the transverse sinus and positioning its posterior arm just apical to the atrioventricular (A-V) groove on the posterior left lateral ventricle wall (Fig. 1). The Mitral Touch is secured in place with two or more titanium helical tacks driven through the Mitral Touch flap and into the ventricle wall. The devices come in 21-, 24-, 27- and 30-mm S—L dimensions with a choice of standard or long arm lengths.

2.2. *In vivo* study

The study was approved by the Cleveland Clinic's Institutional Animal Care and Use Committee, and all animals received humane care in compliance with the *Guide for the Care and Use of Laboratory Animals* prepared by the Institute of Laboratory Animal Resources, National Research Council, and published by the National Academy Press, revised 1996.

Functional MR with heart failure was induced in 13 mongrel dogs (mean weight 23.0 ± 2.3 kg) by rapid ventricular pacing at 230 bpm for 4—5 weeks [9]. All the dogs had ascites and increased girth and showed an average of grade 3.1 MR and enlarged end-diastolic left ventricular (LV) volume in echo studies. On the day of study, the pacemaker was turned off to allow resumption of regular sinus rhythm, and anaesthesia was induced with intravenous ketamine (5 mg kg^{-1}) and propofol (2—6 mg kg^{-1}). The animals were ventilated through an endotracheal tube by a respirator (Narkomed 2B', North American Drager, PA, USA), and anaesthesia was maintained with inhalant isoflurane (0.5—2.5%). A catheter with two Millar pressure sensors (model SPC-562, Millar Instruments, Inc., Houston, TX, USA) was placed to record aortic and LV pressures (AoP and LVP, respectively). Pulmonary artery pressure (PAP) and central venous pressure (CVP) were monitored with a thermostat tip balloon catheter. The chest was accessed through a median sternotomy. A 14-mm Transonic flow probe (model 14A165, Transonic Systems Inc, Ithaca, NY, USA) was placed on the ascending aorta to measure cardiac output (CO). A Millar catheter (Millar Instruments, Inc.) was inserted into the left atrium to monitor left atrial pressure (LAP). Baseline haemodynamic and echocardiographic data were collected as the baseline data. Coronary angiography was performed twice at right anterior oblique (RAO) 30° and left anterior oblique (LAO) 60° views with manual injections of contrast material.

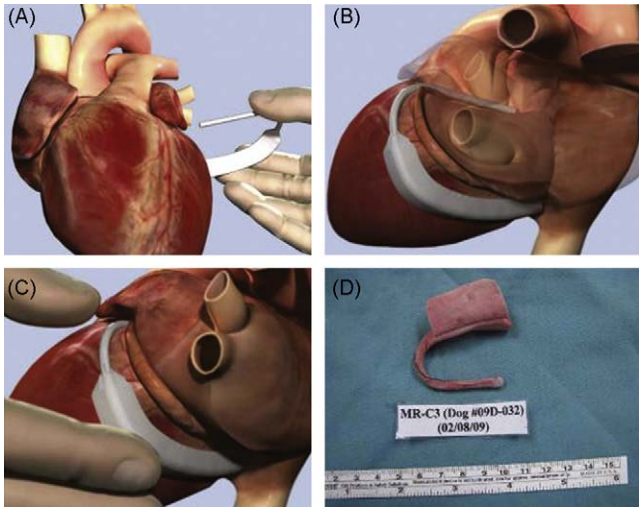

Fig. 1. Illustration of placement of the Mitral Touch. (A) The tip of the anterior arm of the Mitral Touch is toward the transverse sinus, and the posterior arm is just apical to the atrioventricular groove. (B) The Mitral Touch slides onto the heart. (C) The Mitral Touch as properly positioned on the heart. (D) Picture of the Mitral Touch. The tip of the anterior arm is covered by silicone.

2.3. Mitral Touch implantation

The Mitral Touch was then implanted by sliding the anterior arm onto the floor of the transverse sinus and positioning the posterior arm just apical to the atrioventricular groove on the LV posterolateral wall (Fig. 1). The 24-mm-long device was implanted in eight dogs, the 27-mm-long device in four dogs and the 30-mm standard length device in one dog. We palpated the transverse sinus and evaluated the location of the anterior arm tip. We evaluated the degree of MR and the S—L dimension by epicardiac echocardiography. The device was secured by placing two to three helical tacks through the Mitral Touch flap into the posterior wall of the left ventricle. After Mitral Touch implantation, haemodynamic and echocardiographic data were immediately collected. Coronary angiography was performed in the same manner as before implantation.

2.4. Echocardiographic analysis

Echocardiographic data were collected using a Vivid 7 echocardiography machine (GE Medical, Milwaukee, WI, USA). LV end-diastolic and end-systolic volumes (LVEDV and LVESV), ejection fraction (EF), the S—L and commissure—commissure (C—C) dimensions of the mitral annulus and the degree of MR were collected. MR grade was graded from 0 to 4+ according to the extent and width of the regurgitation jet, and MR/LA was defined as the ratio of MR jet area to LA area. MR volume and effective regurgitant orifice area (EROA) were

measured using the proximal isovelocity surface area (PISA) method [10]. The S–L dimension of the mitral annulus was measured using a three-chamber apical view, and the LV diameters at mid-papillary muscle level were measured using the short-axis view. LV volumes and EF were determined by the modified Simpson's rule with images obtained from apical four- and two-chamber views. The peak mitral valve (MV) pressure gradient, the MV coaptation length, which was the distance of the leaflet coaptation, and the MV tethering area, which was defined as the area enclosed by the annular plane and two leaflets, were measured in apical four- and two-chamber views [11]. For each study, data from three beats of normal sinus rhythm were collected and averaged for the final reading.

2.5. Necropsy

The animal was sacrificed by rapid intravenous injection of potassium chloride (80 mEq) after full heparinisation (500 IU kg^{-1}, IV). The heart was harvested with precautions to avoid damaging relevant cardiac tissue and disrupting the implanted device. The heart was examined for abnormal findings, and the locations of the anterior and posterior arms were checked. We measured the distances from the tip of the posterior arm to the posterior descending coronary artery (PDA), from the anterior and posterior arms to the mitral annulus and from the posterior arm to the papillary muscle.

2.6. Data analysis

All haemodynamic data were recorded digitally at a sample rate of 200 Hz using the 'PowerLab' data acquisition system in ADICHT files (the Chart data acquisition file from ADInstruments (Colorado Springs, CO, USA)) and saved as Excel files by the Chart program. The following data analyses were performed during each condition using a Visual Basic program on Excel software.

Data are expressed as mean ± standard deviation. For all the data except for the MR degree, a paired *t* test was used to analyse data obtained before and after device implantation. We performed Wilcoxon's signed rank test to compare the MR degree, as it was a non-parametric value using SPSS statistical software (SPSS v. 16.0, SPSS Inc., Chicago, IL, USA). A *p* value of less than 0.05 was considered statistically significant.

3. Results

Device implantation was uneventful taking only approximately 30 s to deploy under beating heart conditions in all dogs, except one. In that case, after much manipulation with undersized devices, massive bleeding occurred when we positioned the device (24-mm long) because the suture edge at the tip of the device pierced the LA wall. After this incident, the tip of the anterior arm was covered by silicone to reduce friction to the tissue during implantation, which totally eliminated the bleeding complication in the rest of the experiments.

Table 1 summarises the echocardiographic findings. By two-dimensional (2D) echocardiography, MR was reduced in all animals. On average, MR decreased significantly from 3.1 ± 1.1 at baseline to 1.4 ± 0.8 following implantation (Fig. 2). MR jet area and MR/LA area ratio also significantly improved after Mitral Touch implantation. There were significant decreases in EROA and MR volume between baseline and following implantation. End-diastolic and end-systolic S–L dimensions also decreased significantly following implantation. Despite significant C–C dimension decreases at end-diastole, there were no significant changes at end-systole. The MV coaptation length was significantly increased, and the MV tethering area was significantly decreased after Mitral Touch implantation. Peak MV pressure gradient was unchanged and revealed no mitral stenosis. There were no significant changes in LVEDV or LVESV or between LV diastolic and systolic diameter at mid level between baseline and after implantation.

Table 2 summarises the haemodynamic findings. The mean LAP and end-diastolic LVP decreased significantly after implantation. There were no significant changes in mean AoP or systolic LVP. There were no significant changes in CO or stroke volume (SV) after Mitral Touch implantation. Coronary angiography revealed no stenosis or occlusions in the left coronary artery after implantation in all performed cases.

Table 3 summarises the necropsy findings. The anterior arm of the device is located at the floor of the transverse sinus, and the posterior arm at the atrioventricular groove on the LV posterolateral wall (Fig. 3). The tacks did not damage any coronary arteries. We observed a hole, 1.5 cm in length, on the roof of the LA in the dog that had massive bleeding when we positioned the device.

4. Discussion

Implantation of the Mitral Touch acutely reduced S–L dimension and increased MV coaptation length, resulting in significant reduction of functional MR in the rapid ventricular pacing-induced functional MR canine model. MR was consistently reduced in all animals after device implantation. The MV tethering area was significantly decreased. There was no significant change in LV volumes. There were small but statistically significant decreases in the LAP ($p = 0.037$) and end-diastolic LVP ($p = 0.029$) with a small increase in the CO (p = NS), suggesting an improvement in cardiac function after Mitral Touch implantation. No obstruction of the right and left coronary angiography was confirmed, nor was any evidence of ischaemia found in any other portion of the myocardium.

The Mitral Touch, which was designed to restore the S–L dimension, has the advantage of no blood contact due to an epicardiac device and its being placed without CPB and open-heart access. The Mitral Touch implantation took only approximately 30 s to deploy in this series of experiments. The patients with type I MR (annular dilation) are the most eligible for this device implantation. The patients with Type IIIb valve dysfunction, which is characterised by leaflet restriction related to ventricular dilatation and papillary muscle displacement with or without associated annular dilation, may also be eligible.

Functional MR often occurs in patients with ischaemic cardiomyopathy, and what the optimal treatment for

Table 1
Echocardiographic data.

	Baseline	Post implantation	*p* value
MR assessment			
Grade (0 to 4+)	3.1 ± 1.1	1.4 ± 0.8	0.003
MR jet area, two-chamber (mm^2)	7.2 ± 4.3	2.7 ± 2.1	0.008
MR volume (mm^3)	15.4 ± 7.8	4.5 ± 2.6	0.0004
PISA radius	0.6 ± 0.2	0.4 ± 0.1	0.002
Alias velocity	27.2 ± 9.9	18.8 ± 4.9	0.06
EROA (mm^2)	0.16 ± 0.08	0.05 ± 0.03	0.002
MR/LA, two-chamber	0.45 ± 0.18	0.20 ± 0.16	0.004
MV geometry			
MV tethering area (cm^2)	1.36 ± 0.38	0.81 ± 0.29	0.0003
MV coaptation length (cm)	0.36 ± 0.11	0.50 ± 0.08	0.0001
Peak MV gradient (mmHg)	7.0 ± 1.7	6.8 ± 3.1	0.83
Mitral annular dimension at end-systole			
S–L dimension (cm)	2.7 ± 0.4	2.3 ± 0.3	0.001
C–C dimension (cm)	3.3 ± 0.4	3.0 ± 0.4	0.08
Mitral annular dimension at end-diastole			
S–L dimension (cm)	2.3 ± 0.4	2.0 ± 0.2	0.01
C–C dimension (cm)	3.0 ± 0.4	2.6 ± 0.4	0.04
Mid level LV dimension at end-diastole			
S–L dimension (cm)	5.1 ± 0.5	4.9 ± 0.7	0.25
C–C dimension (cm)	5.9 ± 0.4	5.9 ± 0.3	0.89
Mid level LV dimension at end-systole			
S–L dimension (cm)	4.3 ± 0.6	4.6 ± 0.6	0.12
C–C dimension (cm)	5.4 ± 0.5	5.3 ± 0.6	0.73
LV volume			
End-diastolic volume (mm^3)	116 ± 28	109 ± 21	0.37
End-systolic volume (mm^3)	86 ± 22	83 ± 21	0.68
Ejection fraction (%)	26.6 ± 5.4	24.5 ± 6.3	0.42
LVOT flow (m/s)	1.60 ± 0.19	1.64 ± 0.09	0.09

MR, mitral regurgitation; PISA, proximal isovelocity surface area; S–L dimension, septal–lateral dimension; C–C dimension, commissure–commissure dimension; MV, mitral valve; LV, left ventricle; EROA, effective regurgitant orifice area; MR/LA, ratio of MR jet area to left atrial area; LVOT, left ventricle outflow tract.

functional MR should be is still being debated [12–14]. Although mitral annuloplasty using an annuloplasty ring is the standard surgical technique in many cases, there remain several concerns, including recurrent MR or the need for access via a left atriotomy with CPB. The outcome of the annuloplasty ring placement cannot be adequately assessed until the patient is weaned from bypass. These complications result in added time for the procedure and extended periods under anaesthesia, both of which are typical reasons for increased morbidity/mortality rates in treated patients. The increased morbidity/mortality profile leads directly to

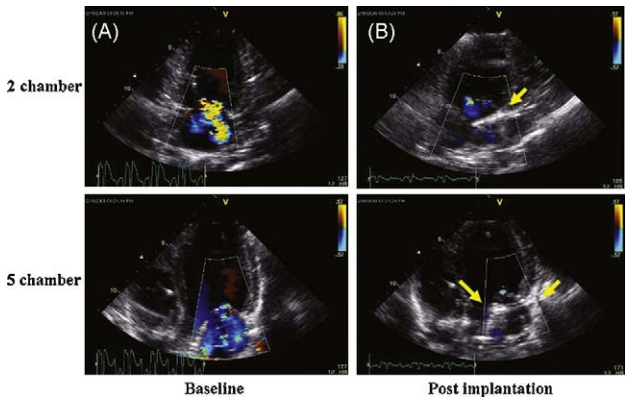

Fig. 2. Mitral regurgitation reduction by 2D echocardiogram in a representative dog. Two- and five-chamber views of the left ventricle at end-systole. Yellow arrows point at the anterior and posterior arms of the Mitral Touch. (A) Baseline; (B) post implantation.

Table 2
Haemodynamic data.

	Baseline	Post implantation	*p* value
HR (bpm)	117 ± 13	110 ± 10	0.10
CO (l/min)	1.6 ± 0.6	1.7 ± 0.6	0.71
SV (ml)	14.0 ± 5.4	15.2 ± 5.5	0.31
LAP_m (mmHg)	25.8 ± 6.4	23.5 ± 4.9	0.037
LVP_{sys} (mmHg)	85 ± 9	85 ± 11	0.42
LVP_{ed} (mmHg)	26.8 ± 6.3	23.2 ± 6.2	0.029
LV d*P*/d*t* max (mmHg/s)	774 ± 144	819 ± 165	0.82
LV d*P*/d*t* min (mmHg/s)	-932 ± 167	-851 ± 216	0.024
AoP_m (mmHg)	66 ± 7	65 ± 11	0.35
SVR (dyne ≅ s≅ m^{-5})	3109 ± 1230	2955 ± 1078	0.32
CVP_m (mmHg)	10.5 ± 3.8	10.0 ± 4.0	0.52
PAP_m (mmHg)	28.5 ± 5.9	25.9 ± 5.6	0.022
PVR (dyne ≅ s ≅ m^{-5})	242 ± 120	219 ± 90	0.84

HR, heart rate; CO, cardiac output; SV, stroke volume; LAP_m, mean left atrial pressure; LVP_{sys}, left ventricular systolic pressure; LVP_{ed}, left ventricular end-diastolic pressure; LV d*P*/dt max, maximum rate of change of left ventricular pressure; LV d*P*/dt min, minimum rate of change of left ventricular pressure; AoP_m, mean aortic pressure; SVR, systemic vascular resistance; CVP_m, mean central venous pressure; PAP_m, mean pulmonary artery pressure; PVR, pulmonary vascular resistance.

Table 3
Necropsy data.

Distance	Average (mm)
Tip of posterior arm to PDA	16.8 ± 13.0
Anterior arm to mitral annulus	5.5 ± 1.9
Posterior arm to mitral annulus	1.9 ± 3.1
Posterior arm to tip of papillary muscle	22.3 ± 4.2

PDA, posterior descending coronary artery.

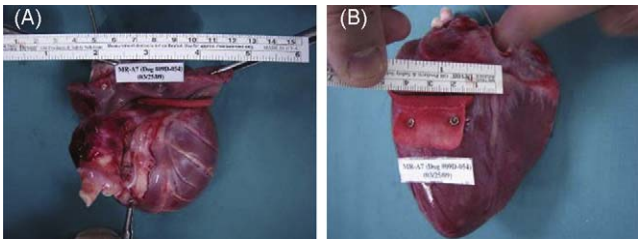

Fig. 3. (A) The anterior arm of the Mitral Touch was located at the floor of the transverse sinus, and the tip of the anterior arm was closed to the right atrium. (B) The location of the posterior pad was just in the right place. The tip of posterior arm was approximately 1.0 cm from the posterior descending coronary artery.

non-treatment of MR in the patient with early-stage heart failure. Therefore, minimally invasive interventions have been developed using several new devices [6,7,9]. Some of them are in clinical trials for diagnostic evaluation [6], and permanent implants are ongoing [7]. There are, however, potential disadvantages to the use of the above annuloplasty devices, such as coronary sinus erosion dissection or perforation, and thrombosis due to the device. Lutter and colleagues [15] demonstrated that implantation of a tricuspid bovine pericardial valved stent in the mitral position was feasible in pigs through a transcatheter approach. Their repositioning rate was high, and they used a normal pig without MR.

One dog was lost by the complication of bleeding during Mitral Touch implantation. The Mitral Touch is implanted by sliding its anterior arm into the transverse sinus and is placed on the roof of the left atrium, which is a thin-walled area. After this case, the tip of the anterior arm was covered by silicone to reduce friction between the device and the tissue during implantation and guided by the finger of operator when it was sliding into the transverse sinus. This design change and technical improvement totally eliminated the bleeding complication during Mitral Touch implantation in the remaining animals.

There are several limitations to this study. In this model of functional MR, valve dysfunction is produced through rapid ventricular pacing rather than ischaemia. Whereas it is true that the underlying aetiology is markedly different, the resulting pathophysiology is similar. Functional MR results from alterations in ventricular and annular geometry that decrease leaflet coaptation. The long-term durability of the fixation stability of the device is unknown, because of the acute assessment of the device efficacy. Moreover, the epicardiac devise migration may obstruct the coronary artery. Chronic studies are needed to evaluate the safety and efficacy of this method in the long term.

5. Conclusion

The new epicardial device Mitral Touch was effective in significantly reducing MR and the S—L dimension acutely on the beating heart without requiring the use of CPB. Further ongoing studies are necessary to confirm the long-term maintenance of MR and S—L reductions.

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Appendix A. Conference discussion

Dr A.S. Kumar (*New Delhi, India*): There are one or two things that we need to consider. The dogs on which you operated all had normal heart

size, they did not have enlarged hearts as we will find in mitral regurgitation.

Dr Fukamachi: This is actually an enlarged heart model by rapid ventricular pacing. The end-diastolic volume is 120 ml. This is pretty much enlarged ventricle for the 25 kg dogs.

Dr Kumar: So if these rings are rigid rings.

Dr Fukamachi: Yes, because it's a titanium based device.

Dr Kumar: Then they will be in touch with the great vessels as well as the left main coronary artery in the transverse sinus. And your results are all very acute results.

Dr Fukamachi: Yes, they were all acute results.

Dr Kumar: So I am most worried what will happen to this rigid part, the anterior part, that's going to be rubbing against these arteries and the left main coronary artery in the long run.

Dr R. Dion (*Genk, Belgium*): How exactly do you size the device that you use?

Dr Fukamachi: That is based on the epicardial or transoesophageal echo. So, based on the measurement, we would use a device that creates 15% reduction in S–L dimension.

Dr Dion: And what do you measure exactly on the TEE to choose the size of the ring?

Dr Fukamachi: The septal–lateral dimension of the mitral annulus.