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# Robotic mitral valve repair: a European single-centre experience†

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## Abstract

**OBJECTIVES:** We report the outcomes of robotic valve repair for degenerative mitral regurgitation (MR) in our Institution.

**METHODS:** Between February 2012 and July 2016, 134 patients underwent robotic mitral valve (MV) repair with the da Vinci Si system. All the operations were performed through a mini-thoracotomy in the fourth right intercostal space, cardiopulmonary bypass and mild hypothermia. The clinical and echocardiographic follow-up was 100% complete.

**RESULTS:** There was no hospital death. The mean cross-clamp and cardiopulmonary bypass time were 112±23 and 159±33 min, respectively. Pre-discharge echocardiograms showed none-to-mild residual MR in all patients. Median follow-up was 24.1 months. We observed 1 early and 4 late reoperations on the MV for an overall freedom from reoperation of 98.2% and 94.1% at 12 and 36 months, respectively. Furthermore, echocardiographic follow-up revealed freedom from recurrence of MR greater than Grade 1+ of 92.5% and 80.7% at 12 and 36 months, respectively. Nevertheless freedom from recurrence of MR greater than Grade 2+ was 97.2% at 12 and 36 months.

**CONCLUSIONS:** Robotic MV repair is a feasible and safe option for the treatment of degenerative MR in selected patients with excellent perioperative outcomes. Early and midterm results are remarkable and are associated with low risk of late recurrence of MR and reoperation. Long-term follow-up is needed to confirm the durability of valve repair.

**Keywords:** Robotic mitral repair • Mitral valve repair • Minimally invasive mitral repair

## INTRODUCTION

Minimally invasive mitral valve (MV) repair techniques emerged in the last 25 years as alternative approaches to conventional sternotomy, and several authors have shown that minimally invasive MV repair is safe and durable [1–9]. In the field of minimally invasive approach, robotic technology represents the latest development. Data reported from Mihaljevic *et al.* [10] showed that robotic approach for degenerative posterior leaflet prolapse is the least invasive technique and represents an excellent alternative to the conventional sternotomy or right mini-thoracotomy with similar outcomes. Various authors [11–14] have already reported the technical advantages of robotic technology (3D visualization with high-resolution, ×10 magnification of the operating field, fine dexterity of robotic forceps allowing access to the entire subvalvular apparatus). Despite very good results reported in the literature [10–15], only few centres in Europe launched a robotic programme due to the concern about its technical complexity, longer operative time and costs [16, 17]. To our knowledge, results of large series of robotic MV repair from European centres have never been reported. Aim of this study was to analyse our experience with the robotic MV repair for degenerative mitral regurgitation (MR), with special focus on early and the midterm valve-related morbidity and mortality.

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## MATERIALS AND METHODS

### Patient characteristics

Data for this study were extracted from our institutional database of MV repair. We selected all patients who underwent robotic MV repair for degenerative MR. In the early experience, we considered for robotic repair only patients in whom a simple procedure was anticipated. However, after a short learning period, we no longer exclude any patients on the basis of the complexity of valve lesions, therefore in our current practice, we consider for robotic MV repair all patients with degenerative MV

regurgitation. Contraindications to robotic MV repair included the presence of acute infective endocarditis; previous cardiac or thoracic surgery; severe mitral calcifications; severe femoral or iliac vascular disease precluding a safe peripheral cannulation; or the need for other concomitant procedures on the coronary arteries, aorta or aortic valve. Preoperative evaluation included patient's clinical history, a comprehensive physical examination, chest X-ray and 12-lead electrocardiogram. All patients also received an electrocardiogram-gated volumetric computed tomography of the chest, abdomen and pelvis before surgery for the assessment of thoracic and abdominal aorta to rule out significant atherosclerotic disease that may result in significant perioperative vascular complications. All patients >35 years of age or with multiple risk factors for coronary disease underwent a coronary angiogram. Moreover, all patients with either persistent or paroxysmal atrial fibrillation were considered for CryoMaze procedure and left atrial appendage exclusion. A dedicated research nurse updated clinical and echocardiographic follow-up. The ethics review board of the hospital approved the study.

## Surgical technique

Conventional general anaesthesia with dual lumen endotracheal intubation was used in all cases. All patients had an intraoperative transoesophageal echocardiogram before incision to confirm the severity of MR, identify the mechanism of regurgitation, confirm the feasibility of robotic approach and assess the result of repair at the end of the procedure. All cases were performed on cardiopulmonary bypass and mild hypothermia (32°C). Cardiopulmonary bypass was instituted by cannulation of right femoral artery and vein. All operations were performed with the da Vinci Si system (Intuitive Surgical, Inc., Sunny Vale, CA, USA) through a right minithoracotomy (4 cm) in the fourth intercostal space (ICS) used as working port, camera and aortic vent access. All cases were performed using an atraumatic rib retractor (Alexis wound-protection system; Applied Medical, Rancho Santa Margarita, CA, USA). The left arm of the robot was inserted through the third ICS in the anterior axillary line. The right arm was inserted through the fifth ICS in the mid-axillary line. The dynamic left atrial retractor was placed in the mid-clavicular line in the fourth ICS. A long cannula for cardioplegia and vent (DLP 14-gauge 7F; Medtronic Inc., Minneapolis, MN, USA) was inserted into the ascending aorta. During the procedure, the right hemithorax was inflated with carbon dioxide through the port of the left robotic arm. Nearly all cases were performed with the use of a transthoracic Chitwood aortic clamp (Scanlan International, Minneapolis, MN, USA) positioned through the second ICS at the mid-axillary line. Only few cases were performed with an intra-aortic occlusion device (Intraclude, Edwards Lifesciences, Irvine, CA, USA). Myocardial protection was achieved with the use of intermittent antegrade crystalloid cardioplegia administered every 30 min. If a concomitant CryoMaze procedure and left atrium appendage exclusion were planned, they were performed before the MV repair. The Cryocath (Medtronic CryoCath LP, Montreal, Quebec, Canada) was inserted through the mini-thoracotomy to perform a pulmonary vein isolation box lesion and a connecting lesion to the mitral annulus. Standard MV repair techniques were used in all cases. Robotic instruments were used for all leaflet resection/reconstruction procedures and for neo-chordal implantation. In our early experience, annuloplasty was performed with the use of a posterior band (ATS band, Medtronic Inc.), but after 14 consecutive cases, we started to use a complete ring as we usually do in conventional open MV repair. Annuloplasty band or ring was secured to the mitral annulus using interrupted U stitches of coated, braided polyester sutures and tying the knots extracorporeally with either a knot-pusher or the Cor-Knot device (LSI solution, Victor, New York, NY, USA). Only in few cases during the initial period the posterior band was secured with 2 polytetrafluoroethylene (Gore–Tex suture, W. L. Goreand Associates, Inc., Flagstaff, AZ, USA) running sutures.

## Follow-up

A research nurse conducted the clinical follow-up through outpatient visit or telephone interview. MV function was assessed on transthoracic echocardiogram (TTE) obtained in all patients prior to hospital discharge and at 1 month, 6 months and than yearly or when clinically indicated. The degree of regurgitation, evaluated by colour flow Doppler mapping, was defined as none, mild (Grade 1+), moderate (Grade 2+), moderate to severe (Grade 3+) and severe (Grade 4+). Morbidity and mortality were reported according to the 2008 Society of Thoracic Surgeons/American Association for Thoracic Surgery/European Association for Cardio-Thoracic Surgery guidelines [18]. Early reoperations were defined as all reoperations on the MV occurring during the first 30 days after surgery, while all other reoperations were classified as late procedures. The clinical and echocardiographic follow-up was 100% complete. Except for 8 patients who had only discharge and 1-month TTE, all patients received at least a TTE at 6 months after the operation.

## Statistical analyses

Continuous data are presented as mean ± standard deviation. Categorical variables were reported as proportions. Student's *t*-test was used to detect significant differences between groups for continuous variables and $\chi^2$ or Fisher's exact test (when one or more of the cells had an expected count of 5 or less) for the analysis of proportions. Failure time analysis on reoperation and recurrence of MR was performed with the Kaplan–Meier method. Patients were censored at last available follow-up entry. In the survival analysis of recurrence of MR, patients were censored at last available follow-up echo. Statistical analyses and graphs were realized using the STATA 11.2 software (StataCorp, College Station, TX, USA).

# RESULTS

## Study population

Between February 2012 and July 2016, 322 patients underwent isolated MV repair in our centre, of whom, 134 had robotic MV repair. Five patients were converted to full or partial sternotomy before completion of the robotic MV repair due to poor surgical exposure in 2 cases, aortic bleeding from an aortic tear during aortic vent placement in 1 case, an unsatisfying echocardiographic result after an uneventful robotic repair in 1 case and an unexpected robotic system breakdown in another case. Consequently, 129 patients had a complete robotic MV repair. Patients' demographic characteristics are shown in Table 1. Most of the patients were asymptomatic (50%) or mildly symptomatic

**Table 1:** Preoperative patients characteristics

| | (*n* = 134) |
|---|---|
| Characteristics | |
| Age (years), mean ± SD | 57.5 ± 12 |
| Male sex, *n* (%) | 108 (80.6) |
| BMI (kg/m$^2$), mean ± SD | 24.8 ± 3.4 |
| NYHA class, *n* (%) | |
| I | 67 (50) |
| II | 58 (43.3) |
| III | 9 (6.7) |
| IV | 0 (0) |
| Comorbidities | |
| Hypercholesterolaemia, *n* (%) | 36 (27) |
| Hypertension, *n* (%) | 36 (27) |
| Diabetes, *n* (%) | 3 (2.2) |
| Coronary artery disease, *n* (%) | 6 (4.5) |
| Previous PCI, *n* (%) | 3 (2.2) |
| Serum creatinine mg/dl, mean ± SD | 0.93 ± 0.18 |
| Stroke, *n* (%) | 1 (0.7) |
| Transient ischaemic attack, *n* (%) | 1 (0.7) |
| Peripheral vascular disease, *n* (%) | 3 (2.2) |
| Current smoker, *n* (%) | 10 (7.5) |
| COPD, *n* (%) | 3 (2.2) |
| History of atrial fibrillation, *n* (%) | 16 (12) |
| Pulmonary hypertension, *n* (%) | 17 (12.7) |
| Echocardiographic data | |
| LVEF, mean ± SD | 62.7 ± 6.5 |
| Grade of MR, *n* (%) | |
| Grade 3+ MR | 21 (15.7) |
| Grade 4+ MR | 113 (84.3) |
| Regurgitant volume (ml/beat), mean ± SD | 82.6 ± 36 |
| ERO (mm$^2$), mean ± SD | 56.9 ± 23 |
| Prolapse category, *n* (%) | |
| Posterior | 105 (78.3) |
| Anterior | 11 (8.2) |
| Bileaflet | 15 (11.2) |
| No prolapse | 3 (2.2) |
| Valve pathology, *n* (%) | |
| Fibroelastic deficiency | 110 (82) |
| Barlow disease | 24 (18) |

BMI: body mass index; NYHA: New York Heart Association; PCI: percutaneaous coronary intervention; COPD: chronic obstructive pulmonary disease; LVEF: left ventricular ejection fraction; MR: mitral regurgitation; ERO: effective regurgitant orifice.

**Table 2:** Operative characteristics

| | (*n* = 134) |
|---|---|
| Mitral valve repair type | |
| Annuloplasty, *n* (%) | |
| Posterior band | 14 (10.6) |
| Complete ring | 118 (88) |
| Leafleat resection, *n* (%) | |
| Triangular | 45 (33.6) |
| Quadrangular | 3 (2.2) |
| Neochordae, *n* (%) | |
| Anterior | 30 (22) |
| Posterior | 91 (68) |
| Chordal transfer, *n* (%) | 4 (3) |
| Commissural repair, *n* (%) | 20 (15) |
| Concomitant procedures | |
| CryoMaze procedure, *n* (%) | 3 (2.2) |
| Patent foramen ovale closure, *n* (%) | 30 (22.4) |
| Tumour resection, *n* (%) | 1 (0.7) |
| Perfusion time | |
| Cardiopulmonary bypass time (min), mean ± SD | 159 ± 33 |
| Cross-clamp time (min), mean ± SD | 112 ± 23 |

**Table 3:** Postoperative complications

| Complications | (*n* = 134) |
|---|---|
| Myocardial infarction, *n* (%) | 1 (0.7) |
| Stroke (minor), *n* (%) | 1 (0.7) |
| Reversible neurologic injury, *n* (%) | 1 (0.7) |
| Prolonged mechanical ventilation >24 h, *n* (%) | 6 (4.5) |
| Bleeding requiring reoperation, *n* (%) | 3 (2.2) |
| Infection, *n* (%) | 5 (3.7) |
| Renal insufficiency, *n* (%) | 3 (2.2) |
| New on-set atrial fibrillation/atrial flutter, *n* (%) | 26 (19.4) |
| Pacemaker implantation, *n* (%) | 2 (1.4) |
| Pleural effusion requiring drainage, *n* (%) | 3 (2.2) |
| Femoral arterial or vein complication, *n* (%) | 0 |
| Readmission within 30 days, *n* (%) | 6 (4.5) |
| MV reoperation, *n* (%) | 5 (3.7) |
| MV replacement | 0 |
| MV re-repair | 5 (3.7) |

MV: mitral valve.

(43.3%) at admission and the majority were in sinus rhythm. Almost all patients had a normal left ventricular function and mean left ventricular end-systolic dimension was 34.5 ± 4.5 mm on preoperative TTE. Further, the majority of patients (78.3%, *n* = 105) had an isolated posterior leaflet prolapse, 11 (8.2%) patients had an anterior leaflet prolapse alone, whereas 15 (11.2%) had disease of both leaflets. Three (2.2%) patients had no prolapse, and the mechanism of MR was related to annular dilatation. Fibroelastic deficiency pattern was identified in 110 (82.1%) patients, while in 24 (18%) a pattern of Barlow disease was observed (10 formae frustae and 14 extensive Barlow disease).

## Operative data

The techniques used for MV repair are summarized in Table 2. Briefly, the most common techniques were leaflet resection and neo-chordae implantation associated with ring annuloplasty. Only in 2 patients aged 80 and 76 years with small annulus and posterior calcification, the MV repair was performed without annuloplasty. In 10 patients (7.4%), the initial repair was not satisfactory (in 6 cases for residual significant MV regurgitation and in 4 for persistent systolic anterior motion) and a second pump run was necessary to achieve a satisfactory echocardiographic result. None of these patients was converted to full sternotomy.

## Morbidity and mortality

There was no operative mortality. Postoperative complications are listed in Table 3. In cases of chest re-exploration for bleeding, a full sternotomy was never deemed necessary. Three (2.2%) patients had postoperative serum creatinine >2.0 mg/dl, but none of them required dialysis. The mean length of stay in the intensive care unit and the mean hospital stay were 2.0 ± 1.5 and

**Table 4:** Echocardiographic data

| MR severity | Preoperative ($n$ = 134) | Postoperative ($n$ = 134) | Follow-up ($n$ = 134) |
|---|---|---|---|
| None | 0 | 72 (53.7%) | 47 (35%) |
| Mild | 0 | 62 (46.3%) | 73 (55%) |
| Moderate | 0 | 0 | 11 (8.5%) |
| Moderate to severe | 21 (15.7%) | 0 | 3 (2.3%) |
| Severe | 113 (84.3%) | 0 | 0 |

MR: mitral regurgitation.

8.1 ± 4.4 days, respectively. One early reoperation occurred at the eighth postoperative day for recurrent MV regurgitation. This early failure was due to ring and leaflet dehiscence on the posterior mitral annulus. Pre-discharge echocardiograms showed none-to-mild residual MR in all patients (Table 4). Six patients (4.4%) were readmitted within 30 days of the operation. The causes for readmissions were pleural effusion in 2 patients (1.4%), pleural effusion associated with pericarditis in 2 (1.4%) and haemothorax in 2 patients (1.4%), respectively.

## Clinical and echocardiographic follow-up

Median follow-up was 24.1 months (interquartile range: 8.6–35.8 months). During follow-up, 2 patients died due to non-cardiac-related causes (1 for car accident and 1 for pancreatic adenocarcinoma). Overall survival at 12 and 36 months is 99.1% and 97.9%, respectively.

At last follow-up, 115 patients (85.8%) were in NYHA Class I and 19 (14.2%) in NYHA Class II. During follow-up, 4 patients were reoperated on the MV. The reasons for late reoperations were acute infective endocarditis in 1 case (0.7%), recurrent MR associated with posterior leaflet prolapse in 2 cases (1.4%) and to a tear in the leaflet with an elongated neo-chordae in 1 case (0.7%). Freedom from MV reoperation at 12 and 36 months is therefore 98.2% [95% confidence interval (CI): 93.0–99.5] and 94.1% [95% CI: 86.2–97.6], respectively (Fig. 1). In all cases of reoperation, the MV was re-repaired. At last available cardiac echo (Table 4), 89% of the patients had none or trivial MR, 11 (8.2%) patients had 2+ MR and 3 (2.2%) had 3+ MR. Freedom from MR recurrence greater than Grade 1+ was 92.5% [95% CI: 85.6–96.2] and 80.7% [95% CI: 68.3–88.7] at 12 and 36 months, respectively (Fig. 2). Freedom from MR recurrence greater than Grade 2+ was 97.2% [95% CI: 91.7–99.1] at both 12 and 36 months (Fig. 3).

## DISCUSSION

Since Carpentier published the results of the 'French correction' in 1983, MV repair has become the gold standard approach for degenerative MR [21]. Traditionally, most of MV repair have been performed through a median sternotomy. However, in the last 25 years, minimally invasive techniques have been proposed to reduce patient's morbidity related to the complete sternotomy. The aim of these techniques was to limit patient trauma while preserving the quality of the valve repair. Robotic technology

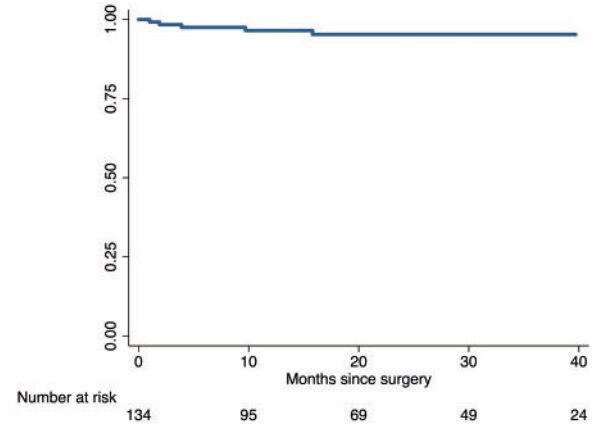


**Figure 1:** Kaplan–Meier actuarial survival curves showing freedom from reoperation on the mitral valve. Patients were censored at last available follow-up.

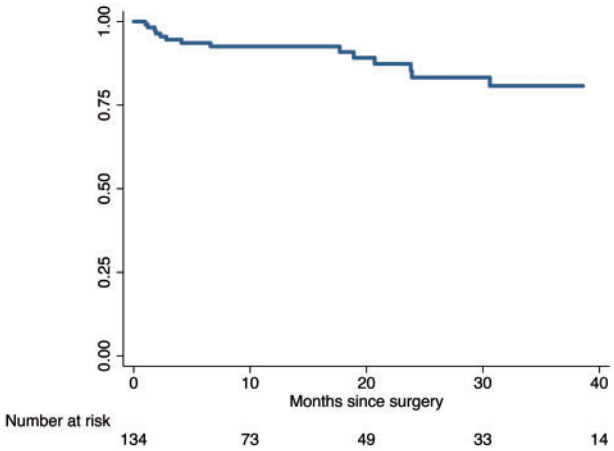


**Figure 2:** Kaplan–Meier actuarial survival curves showing freedom from recurrent mitral regurgitation greater than Grade 1+. Patients were censored at last available echo follow-up.

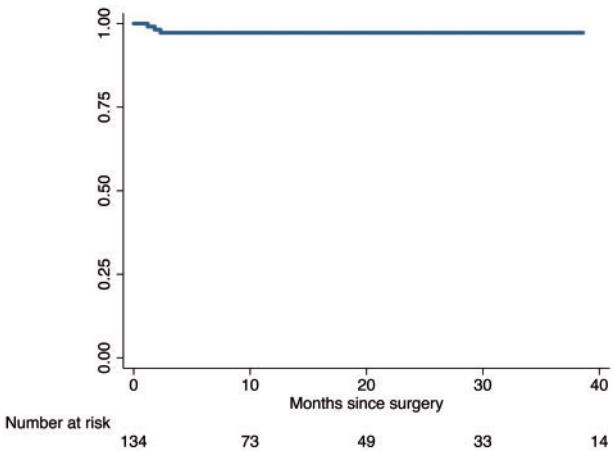


**Figure 3:** Kaplan–Meier actuarial survival curves showing freedom from recurrent mitral regurgitation greater than Grade 2+. Patients were censored at last available echo follow-up.

represents the last evolution in the field of minimally invasive approach and allows performing complex mitral repair through port incisions using optimized, high-definition visualization and fine dexterity with robotic arms [14]. In our opinion, robotic

surgery offers several advantages compared with conventional minimally invasive techniques, namely 3D visualization, ×10 magnification and fine dexterity that allow better visualization of the valvular and subvalvular apparatus and a precise assessment of valve lesions. Further the dual-console system allows a real interaction between the 2 surgeons and enhances the training experience in MV repair.

Despite very good results reported in the literature [10–15], in Europe, only few centres launched a robotic programme due to the concern about its complexity, prolonged operative time and increased costs. In this study, we report the largest single-centre experience of robotic MV repair in Europe. In 2012, we started a robotic programme in our Institution. Initially, we only included patients with simple MV pathology, but with increasing experience, we observed a progressive increase of complex MR cases addressed for robotic repair. Furthermore, we have observed a progressive reduction in the cross-clamp and cardiopulmonary bypass time. Although at the beginning we usually had cross-clamp time of >2 h, currently the mean time is significantly less.

As showed in Table 1, the majority of patients had a Class IIa indication for surgery being asymptomatic, with normal left ventricular ejection fraction and with end-systolic left ventricular diameter >40 mm. These data reflect our policy to address the patients for early surgery in cases of highly reparable MV disease whether by conventional full sternotomy or minimally invasive approach. In our opinion, robotic surgery may further boost the benefits of MV repair [22, 23] in this cohort of young patients providing the most rapid return to normal activity and minimal scar. Among the patients who underwent MV reoperation we recorded 1 early and 4 late failures (3.7%). The early failure was due to ring and leaflet dehiscence from the mitral annulus and occurred few days after the robotic repair. Among the 4 late reoperations, 3 were due to recurrent MR with leaflet prolapse, probably related to a technical error during the initial repair and 1 case to infective endocarditis. Most of the reoperations (3 cases) occurred during the early experience with the robotic technology and probably reflects the influence of the learning curve. Despite this, in all cases, the MV was re-repaired with an excellent postoperative echocardiographic result. Rates of postoperative complications in our series are low, and the majority of them occurred during our initial experience. As shown in Table 3, 2 patients experienced a neurological complication (1 minor stroke and 1 transient ischaemic attack). Both patients had a complete recovery before hospital discharge and none had residual symptoms related to the neurological injury.

Cost-effectiveness analysis of the robotic approach was beyond the scope of this study. Nevertheless, there are already some reports on this issue although the cost-effectiveness of robotic surgery is somewhat limited by heterogeneity of research methods, local cost variations and methods for determining costs associated with surgical outcomes [16–19].

Finally, our current results are comparable to those reported in literature [11, 13] and highlight the quality of the work of our dedicated heart team.

In conclusion, after 4 years of the launch of the robotic programme, we showed similar results to those reported from other authors and we showed that robotic repair for degenerative MV disease represents an excellent approach and the quality of the repair is comparable to conventional approach in our experience. Very good results can be achieved with low risk of complications or MR recurrence. Longer follow-up is needed to confirm the durability of robotic MV repairs.

## Limitations

This study was a single-centre clinical study and was subject to the limitations inherent to a non-randomized observational series. Follow-up echocardiograms were not interpreted by a single echo physician because a large proportion of patients had their examination in other Institutions. Last, longer term follow-up is needed to confirm whether our robotic MV repairs provide equivalent results than the conventional approach.

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