



Robotic mitral valve repair—the Bruxelles experience

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Background: Although the use of the surgical robot facilitates less invasive mitral valve surgery, both real and perceived limitations have slowed the application of this technology. Aim of the present investigation was to report the early and long-term results of robotic mitral valve repair in a single institution over a 10-year period.

Methods: Between March 2012 and May 2022, a total of 278 consecutive patients underwent robotically assisted mitral valve repair at the Cliniques Universitaires Saint-Luc (Brussels, Belgium). Indications have evolved over time allowing the treatment of complex mitral valve lesions. Clinical and echocardiographic follow-up were 97.8% and 86.1% complete, respectively.

Results: Mean age of the study population was 57.8±11.9 years and 221/278 (79.5%) patients were male. Despite being asymptomatic or mildly symptomatic [New York Heart Association (NYHA) class I–II], most of the patients presented with severe mitral regurgitation (MR). Degenerative mitral valve disease was the most common cause of MR. All patients underwent successful mitral valve repair using different techniques, and 25/278 (9.0%) had one or more concomitant procedures associated. The mean cardio-pulmonary bypass and aortic cross clamp times were 153±37 and 106±25 minutes, respectively. There was no operative or in-hospital mortality. Overall survival rate was 97.8%±3.2%, 95.8%±3.2% and 93.7%±3.0% at 3, 7 and 10 years. One early (0.4%) reoperation with re-repair was recorded for ring disruption, while late mitral valve re-repair was necessary in 4/279 (1.4%) patients for recurrent severe MR in three of them and mitral endocarditis in one. The overall freedom from mitral valve reoperation was 98.1%±1.0% at 3, 7 and 10 years. Overall freedom from MR (grade 2+ or more) was 91.7%±3.2%, 77.8%±4.8% and 67.1%±9.2% at 3, 7 and 10 years, respectively.

Conclusions: Robotic mitral valve repair is safe and is associated with excellent clinical and echocardiographic results. The use of robotic technologies allows, after an appropriate learning curve, to reproduce all conventional techniques to treat MR, regardless of the complexity of the valve lesion.

Keywords: Robotic mitral repair; robotic mitral surgery; mitral regurgitation robotic repair; robot-assisted mitral repair



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Introduction

Surgical mitral valve (MV) repair has been proven to be the standard of care for patients with degenerative MV regurgitation, showing several advantages compared to MV replacement (1-5). Minimally invasive MV repair

techniques emerged in the last 25 years as an alternative to conventional surgery, and latest reports from large series of patients have shown results similar or even superior to the traditional approach (6,7). Robotic MV repair is the latest evolution of the minimal invasive techniques and is thought

Table 1 Preoperative patients characteristics

Characteristics	Overall (n=278), n (%) or mean \pm SD
Demography	
Male	221 (79.5)
Age (years), mean \pm SD	57.8 \pm 11.9
BMI (kg/m ²), mean \pm SD	25 \pm 3
Clinical data	
NYHA class I-II	264 (95.0)
NYHA class III	14 (5.0)
AF	29 (10.4)
Hypertension	76 (27.3)
Diabetes mellitus	6 (2.2)
Coronary disease	18 (6.5)
Extracardiac arteriopathy	8 (2.9)
History of cerebrovascular disease	6 (2.2)
Smoking history	56 (20.1)
COPD	6 (2.2)
Echographic data	
LV ejection fraction (%)	64.0 \pm 7.5
PAH	36 (12.9)
RV (mL)	78 \pm 30
MR etiology	
Degenerative	274 (98.6)
Barlow	78 (28.1)
Functional	3 (1.1)
Congenital	1 (0.4)
Posterior prolapse	235 (84.5)
Bileaflets prolapse	23 (8.3)
Anterior prolapse	17 (6.1)

BMI, body mass index; NYHA, New York Heart Association; AF, atrial fibrillation; COPD, chronic obstructive pulmonary disease; LV, left ventricle; PAH, pulmonary arterial hypertension; RV, regurgitant volume; SD, standard deviation.

to provide several advantages (8), excellent ergonomics, and surgical precision (9). After a long experience with video-assisted approach, we moved to robotic MV repair in 2012, with the objective to reproduce the conventional

mitral repair techniques used in open surgery. In this paper we report the early- to long-term outcomes of our robotically assisted MV repair in terms of clinical and echocardiographic results.

Methods

Study design

Between March 2012 and May 2022, a total of 278 consecutive patients underwent robotically assisted MV repair for degenerative MR in one Institution. The mean age was 57.8 \pm 11.9 years and 221 out of 278 (79.5%) were male. Overall, 264/278 (95.0%) patients were asymptomatic or mildly symptomatic [New York Heart Association (NYHA) class I-II]. Most presented with a grade 4+ MR. The main etiology (274/278 patients, 98.6%) was a degenerative MV disease. Mean LVEF was 64.0% \pm 7.5%. Mean regurgitant volume was 78 \pm 30 mL. Preoperative characteristics are listed in *Table 1*. Inclusion criteria for valve lesions have evolved over time, from single scallop prolapse to anterior/bileaflet/multi-scallops prolapses and/or extensive Barlow's disease. Patients with concomitant procedures were also enrolled. A preoperative thoraco-abdominal angio-computed tomography (CT) was routinely performed in all cases to rule out the presence of anatomical contraindications. All patients signed an informed consent form. The local ethics committee approved this investigation. Candidacy for robotic MV repair, exclusion criteria and operative technique have been previously reported (10).

Follow-up (FU)

Trans-oesophageal echocardiogram (TEE) was performed perioperatively to assess the MV function and repair results. A transthoracic echocardiogram (TTE) was performed before hospital discharge. MV regurgitation was evaluated by Doppler mapping. It was defined as none, mild (grade 1+), moderate (grade 2+), moderate-to-severe (grade 3+) and severe (grade 4+). The 2008 Society of Thoracic Surgeons/American Association for Thoracic Surgery/European Association for Cardio-Thoracic Surgery guidelines were used to report morbidity and mortality (11). Early MV reoperations were defined as those occurring in the first 30 postoperative days while operations beyond the first postoperative month were considered as late reoperations. A routine clinical and echocardiographic FU was obtained

Table 2 Operative details

Variables	Overall (n=278), n (%) or mean \pm SD
MV repair	278 (100.0)
MV replacement	0 (0.0)
Mitral repair procedures	
Ring annuloplasty	273 (98.2)
Complete ring	259 (93.2)
Posterior band	14 (5.0)
Leaflet resection	166 (59.7)
Quadrangular resection	6 (2.2)
Triangular resection	159 (57.2)
Butterfly resection	1 (0.4)
Sliding pasty	4 (1.4)
Annular decalcification	3 (1.1)
Neochords	190 (68.3)
AML	40 (14.4)
PML	171 (61.5)
Neochords+ leaflets resection	89 (32.0)
Chordal transfer	2 (0.7)
Commissuroplasty	22 (7.9)
AL	4 (1.4)
PM	18 (6.5)
Cleft repair	58 (20.9)
Concomitant procedures	
Tricuspid annuloplasty	12 (4.3)
AF ablation surgery	10 (3.6)
LA closure	26 (9.4)
PFO closure	47 (16.9)
ASD closure	3 (1.1)
CPB time (min)	153 \pm 37
ACC time (min)	106 \pm 25
Operative time (min)	269.8 \pm 127.6
Conversion to open	6 (2.2)
Second run of CPB	15 (5.4)

MV, mitral valve; AML, anterior mitral leaflet; PML, posterior mitral leaflet; AL, anterior-lateral; PM, posterior-medial; AF, atrial fibrillation; LA, left appendage, PFO, patent foramen ovale; ASD, atrial septal defect; CPB, cardiopulmonary bypass; ACC, aortic cross clamp; SD, standard deviation.

postoperatively. Further clinical FU and echocardiographic data were obtained yearly from our echocardiographic database, by patients' referring physicians contacts or by patients' phone interviews. The mean clinical FU was 39 months and the mean echocardiographic FU was 35 months. Clinical FU and echographic FU were 97.8% and 86.1% complete respectively.

Statistical analysis

IBM SPSS statistics software version 27 was used for statistical analysis. Numeric variables are presented as means \pm standard deviation for normally distributed data or medians (interquartile range) for non-normally distributed data. Categorical variables are presented as frequencies (percentages). Failure time analysis on reoperation and recurrence of MR was performed with the Kaplan-Meier method (95% confidence interval as dotted lines). Patients were censored at last available FU entry. In the survival analysis of recurrence of MR, patients were censored at last available FU echo. For all these tests, a P value of less than 0.05 was the chosen significance level.

Results

Operative and peri-operative outcomes (in-hospital)

Annuloplasty with complete ring was performed in 259/278 (93.2%) patients. Only 14 patients (5.0%) of our initial experience received posterior band (partial annuloplasty). A total of 47/278 (16.9%) had one or more concomitant procedures and 12 (4.3%) of them received a tricuspid annuloplasty ring. Six patients (2.2%) were converted to full sternotomy due to pleural adhesions (0.4%), significant blood backflow precluding an adequate surgical exposure (0.4%), technical equipment failure (0.4%), aortic tear during insertion of the cardioplegia canula (0.4%), intraoperative critical bleeding with hemodynamic instability requiring emergency sternotomy (0.4%) and residual MR with systolic anterior motion (SAM) (0.4%). In 15 (5.4%) patients a second run of cardiopulmonary bypass (CPB) was necessary to correct a residual MR or SAM in 14 patients (5.0%) and in one case for an aortic regurgitation due to a non-coronary cusp restriction caused by an annular stitch (0.4%), detected at the intraoperative post-procedural TEE. The mean CPB and aortic cross clamp (ACC) times were 153 \pm 37 minutes and 106 \pm 25 minutes, respectively. Operative details are listed in *Table 2*. There was no hospital mortality. Five patients (1.8%) needed a definitive

Table 3 Immediate postoperative outcomes and complications	
Clinical data	Overall (n=278), n (%)
New onset of AF	67 (24.1)
Pacemaker	5 (1.8)
STEMI	2 (0.7)
Traumatic ASD	1 (0.4)
Diaphragmatic paralysis	1 (0.4)
Reoperation for bleeding	11 (4.0)
Early MV reoperation	1 (0.4)

AF, atrial fibrillation; STEMI, S-T elevation myocardial infarction; ASD, atrial septal defect; MV, mitral valve.

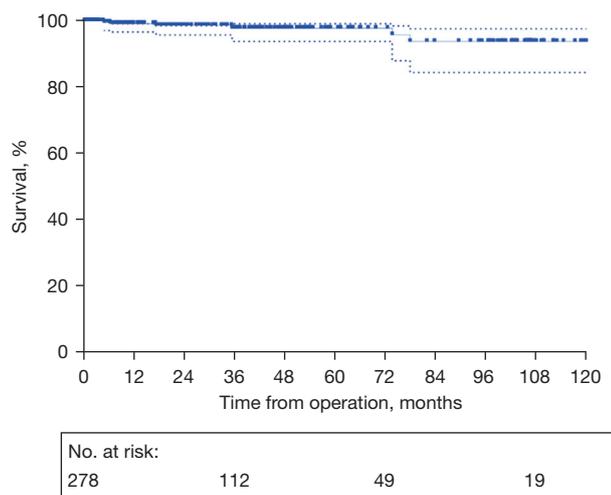


Figure 1 Overall survival.

pacemaker implantation for permanent atrioventricular block. No femoral artery or vein complications at the site of cannulation were observed. Two patients out of 278 (0.7%) suffered from an immediate postoperative acute coronary syndrome requiring urgent diagnostic angiography. One patient had severe right coronary artery vasospasm which was successfully treated with nitrate infusion. The second patient was diagnosed with circumflex artery occlusion requiring an urgent surgical revascularization. One patient (0.4%) needed an early MV reoperation for a recurrent MR due to a ring dehiscence 12 days after the robotic MV repair. This patient was re-operated through a full sternotomy and underwent successful MV re-repair.

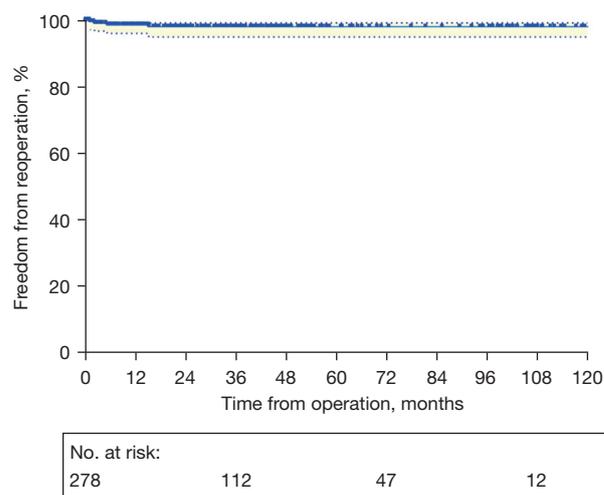


Figure 2 Freedom from MV reoperation. MV, mitral valve.

Median ICU and hospital stay were 2 [interquartile range (IQR) =0] and 7 (IQR =2) days, respectively. All immediate postoperative outcomes and complications are listed in *Table 3*.

Mid- and long-term outcomes

Six patients (2.2%) died during FU. Causes of death were stroke (N=1), cancer (N=1), car accident (N=1) and sudden unexpected unexplained death in three patients (1.1%). Overall survival rate was $97.8\% \pm 3.2\%$, $95.8\% \pm 3.2\%$ and $93.7\% \pm 3.0\%$ at 3, 7 and 10 years, respectively (*Figure 1*). Four patients (1.4%) underwent late MV reoperation (*Table 3*) and the MV was successfully re-repaired in all cases. Causes of mitral reoperations were recurrent severe MR for three of them and mitral endocarditis for one patient. The overall freedom from MV reoperation was $98.1\% \pm 1.0\%$ at 3, 7 and 10 years (*Figure 2*). Overall freedom from MR (grade 2+ or more) was $91.7\% \pm 3.2\%$, $77.8\% \pm 4.8\%$ and $67.1\% \pm 9.2\%$ at 3, 7 and 10 years, respectively (*Figure 3*). *Table 4* shows the last FU details.

Discussion

This study reports our entire experience with robotically assisted MV repair over 10 years and it is the first of its kind to report on long-term outcomes. The robotic approach was started after a long experience with conventional techniques, that was used to perform all types of MV surgery, and after a short period of standard

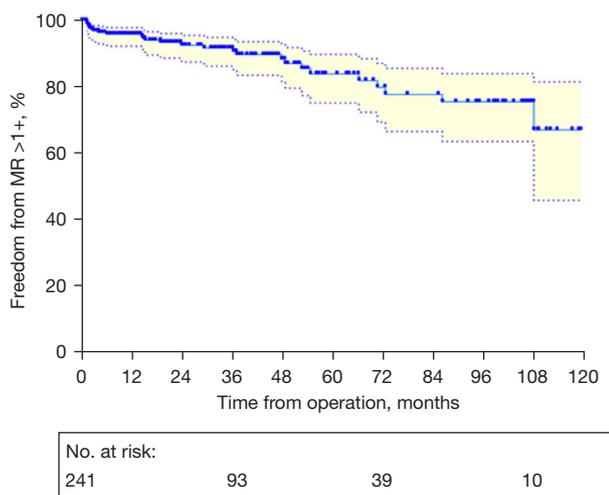


Figure 3 Freedom from recurrent MR grade 1+. MR, mitral regurgitation.

Table 4 Last follow-up	
Clinical data	Overall (n=278), n (%)
AF	17 (6.1)
Flutter	4 (1.4)
Cardiac reoperation	6 (2.2)
Non mitral	1 (0.4)
Mitral	5 (1.8)
Early MV reoperation	1 (0.4)
Late MV reoperation	4 (1.4)
Thromboembolic events	
Stroke	3 (1.1)
Transient ischemic attack	4 (1.4)
Bleeding event	2 (0.7)
Endocarditis	1 (0.4)

AF, atrial fibrillation; MV, mitral valve.

minimally invasive surgery. Despite the good clinical and echocardiographic results achieved with standard techniques (12-15), we switched to robotically assisted mitral surgery because we believe this innovative tool has the advantage of enhanced precision, reproducibility, better exposure and ergonomics. In 2012, after an appropriate training with simulation, dry and wet labs, we introduced the use of the da Vinci robotic system in our Institution.

Following experts' indications during the very first steps of our program, we started with selecting patients with simple mitral pathologies (such as single scallop prolapse) and we used a posterior band as annuloplasty technique. After the initial successful series, we abandoned the posterior band and started to reproduce our own techniques that includes complete annuloplasty ring and a wide range of leaflet repair techniques, associated or not to concomitant procedures. After few years of experience, we were able to address all patients with degenerative mitral regurgitation, and perform simple to complex mitral repairs with a high surgical precision and excellent visualization of the MV, as recently reported by us (16). Robotic technologies allow us to reproduce a large range of MV repair techniques without compromise between invasiveness and quality of repair with a low rate of complication. As a matter of fact, our consolidated MV surgery program allowed for excellent results also in this particular setting with no hospital mortality and a 100% success rate of valve repair. From most series, mortality rate lies between 0.5% and 1% (7,8,17-22). It is also of note that no cannulation issues occurred on the femoral vessels which speaks for gentle cannulation and good patient selection. The rates of major cardiac or neurological events and reoperation were low and similar to those previously reported (13,14,18,21). The rate of post-operative permanent pace-maker was low, even in consideration of an extensive use of complete annuloplasty rings. Freedom from mitral regurgitation grade 2+ or more and from reoperation are in agreement with the reports of other groups (23,24). As usual for a European center, the hospital stay was longer than reported in US centers. This may be due to the different health care systems, but not to clinical issues. We report one early and four late reoperations due to MR recurrence in four patients and one endocarditis. In all cases the MV was successfully re-repaired thanks to our large experience with reoperations, as shown before (25). In conclusion, our data on a large series of patients undergoing MV repair demonstrate that the robotic approach is safe and is an excellent treatment option and should be encouraged and supported in Europe as in the US. Unfortunately, in Europe the diffusion of the robotic technologies didn't meet the same success as in the United States. And this lack of diffusion was not related to unsatisfactory results, but rather to the complexity of development of a robotic program, the steep learning curves, the need to train a dedicated team and higher costs. Furthermore, the recent changes in the European regulatory system concerning the use of medical devices

formally consider robotic intracardiac procedures “off-label”. The “off-label” for intracardiac robotic procedures is because these procedures are classified as class III, meaning highest risk category, and the company producing the device used is currently not pursuing certification. The decision was probably made because of slow adoption of robotic MV surgery in Europe and therefore making these procedures a very small market segment.

For this reason, the initiation of a European registry on outcome data of robotic as well as the recent creation of a European Association for Cardio-Thoracic Surgery (EACTS)-endorsed European Robotic Cardiac Surgery Task Force, are key point to the diffusion of this excellent approach.

Limitations

The most important limitation is related to the retrospective nature of the study. Furthermore, the clinical and echocardiographic follow up were not performed in the same center and by the same cardiologist with different evaluation of the clinical and echocardiographic data.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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