

# Using a Regent Aortic Valve in a Small Annulus Mitral Position Is a Viable Option

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**Background.** Outcome of mitral valve replacement in extreme scenarios of small mitral annulus with the use of the Regent mechanical aortic valve is not well documented.

**Methods.** Records were examined in 31 consecutive patients who underwent mitral valve replacement with the use of the aortic Regent valve because of a small mitral annulus.

**Results.** Mean age was  $60 \pm 14$  years. Mitral stenosis or mitral annulus calcification was present in 30 of 31 patients (97%). Concurrent procedures were performed in 17 of 31 patients (55%). Median valve size was 23 mm. Mean mitral

gradient coming out of the operating room was  $4.2 \pm 1.5$  mm Hg and at follow-up echocardiogram performed at a median of 32 months after the procedure was  $5.8 \pm 2.4$  mm Hg.

**Conclusions.** A Regent aortic mechanical valve can be a viable option with a larger orifice area than the regular mechanical mitral valve in a problematic situation of a small mitral valve annulus. Moreover, the pressure gradients over the valve are acceptable intraoperatively and over time.

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Mitral valve replacement in patients with a small mitral annulus (<25 mm diameter) can be technically difficult and is associated with increased risk of poor outcomes [1, 2]. Available options in patients with a small annulus are limited and involve substantial risk of mitral annular disruption, ventricular dysfunction, or perivalvular leak [1, 3–8].

The St. Jude Regent prosthesis (St. Jude Medical, St. Paul, MN) has been in clinical use since 2000 for aortic valve replacement [9]. Advantages of the St. Jude Regent over standard mechanical prostheses include a reduced sewing cuff size and a reduced frame diameter to allow a greater orifice area for a given annular size relative to other devices (Fig 1) [10]. Although many reports exist of the Regent device in the aortic position [11], little information exists about the use or outcomes of St. Jude Regent prostheses in the mitral position.

## Patients and Methods

After institutional review board approval, a retrospective review was performed of all patients undergoing a mitral valve replacement with the use of the mechanical Regent aortic valve between 2006 and 2014 with follow-up echocardiography available.

Sternotomy patients had standard median sternotomy performed with the mitral valve accessed through a trans-septal approach and bicaval cannulation with

anterograde and retrograde cardioplegic arrest. The remaining patients underwent a 6-cm right anterolateral thoracotomy in the fourth intercostal space. Cardiopulmonary bypass with vacuum assist was initiated from the femoral vein and either the right axillary artery or the ascending aorta. Either cardioplegic arrest with anterograde and retrograde cardioplegia or ventricular fibrillation was used.

Intraoperatively, the anterior leaflet was resected in all patients without the preservation of anterior chords. The posterior leaflet and posterior chords were preserved in all patients with minimal posterior annular debulking as needed to seat the prosthesis without tissue protruding into the orifice. Once the mitral valve was found to be too small for a 25-mm mechanical prosthesis after reasonable debridement, a 21- or 23-mm Regent prosthesis was chosen, based on the ability to insert a 21- or 23-mm St. Jude sizer into the mitral annulus. Supra-annular pledgeted sutures were then placed circumferentially. In areas of annular calcification, the needles were driven through or around the calcified material. The Regent aortic valve was removed from its handle and reversed to be implanted in the mitral position. After tying all sutures, the annulus was inspected for any potential perivalvular leaks. If present, any area of potential leakage was secured with additional supra-annular pledgeted sutures.

Data analysis was performed with StatsDirect (Cheshire, UK). All categorical data were expressed as proportions and continuous variables were expressed as mean  $\pm$  SD or median with data range. Survival was calculated with the Kaplan-Meier method as estimate  $\pm$

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Fig 1. Photographs compare the 23-mm Regent prosthesis with the standard 25-mm St. Jude mechanical prosthesis.

SE. Statistical significance was defined as a *p* value less than 0.05.

### Results

The 31 patients were predominantly women and of small size (Table 1). The predominant valve disease causes were rheumatic (55%), mediastinal radiation (16%), and calcific

Table 1. Patient Demographic Characteristics

Characteristic	Value
Age, years	60 ± 14
Female sex	25 (81)
Mitral stenosis	30 (97)
Mitral regurgitation	12 (39)
Mitral annular calcification	13 (42)
Redo	14 (45)
Mediastinal radiation	6 (19)
NYHA CHF class 3 or 4	11 (35)
Ejection fraction <50%	3 (10)
Lung disease	11 (35)
Renal disease (Cr ≥2.0)	1 (3)
Coronary disease	7 (23)

Values are n (%) or mean ± SD.

CHF = congestive heart failure; Cr = creatinine; NYHA = New York Heart Association.

(16%). Most patients (97%) had underlying preoperative mitral stenosis (Figs 2 and 3), but 39% also had at least moderate mitral regurgitation preoperatively. Of the 14 patients with prior operation, 9 of 31 patients (29%) had had prior mitral repairs with small rings. One patient

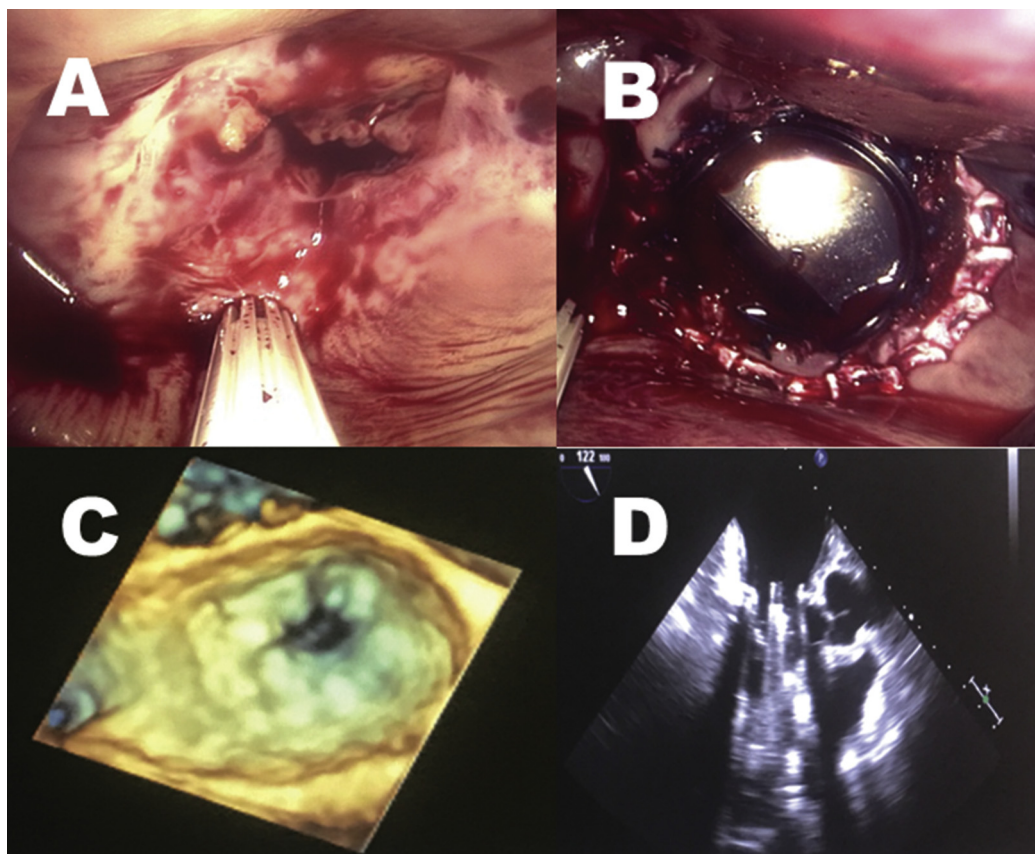


Fig 2. Intraoperative photographs and echocardiograms showing (A and C) a small and severely calcified rheumatic valve preoperatively and (B and D) a 23-mm Regent mechanical prosthesis in place postoperatively.

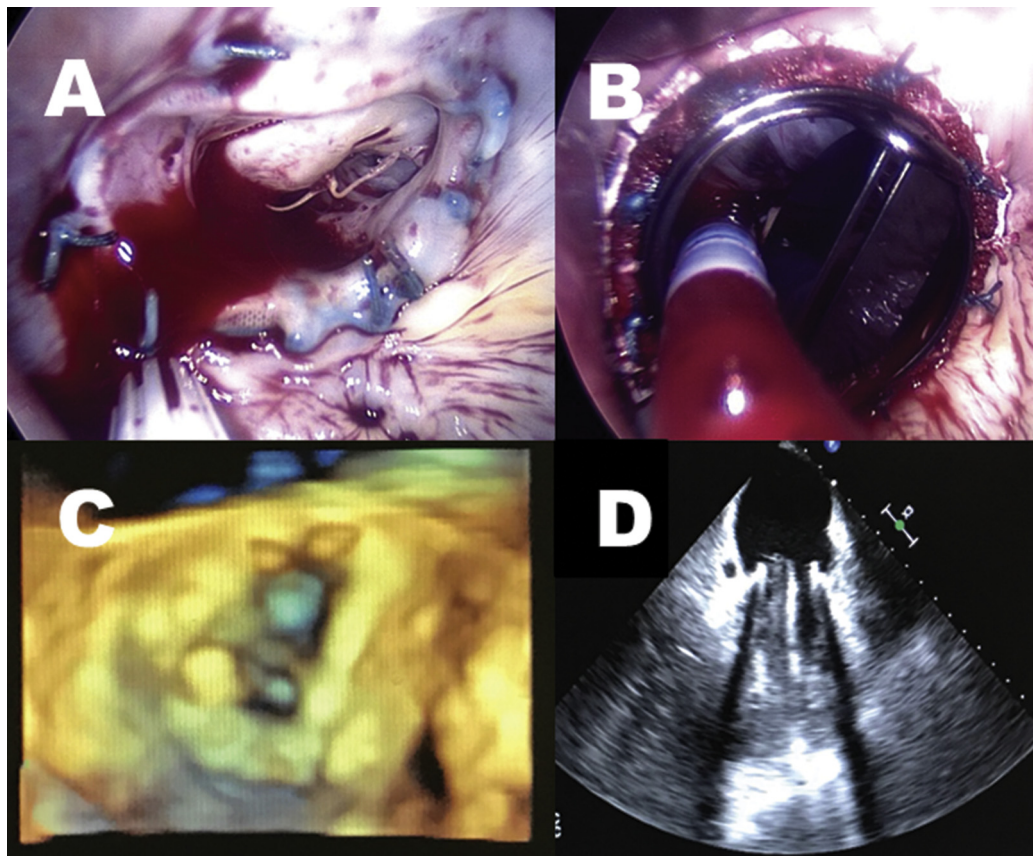


Fig 3. Intraoperative photographs and echocardiograms showing (A and C) a small and scarred native valve preoperatively and (B and D) a 23-mm Regent mechanical prosthesis in place postoperatively.

had a prior mitral replacement with a 21-mm mechanical valve as a child.

Other concurrent procedures were performed in 17 of 31 patients (55%), including tricuspid repair ( $n = 10$ ), coronary bypass ( $n = 4$ ), and aortic valve replacement ( $n = 8$ ). The most common Regent valve size was 23 mm in 24 patients (77%), with the remainder being 21-mm ( $N = 7$ ) prostheses. The mean intraoperative bypass mitral valve gradient across the Regent prosthesis was  $4.2 \pm 1.5$  mm Hg (versus preoperative mitral gradient of  $13 \pm 4$  mm Hg). Two perioperative deaths occurred, both because of respiratory failure and sepsis in patients with prior mediastinal radiation therapy for lymphoma. The complication rate was otherwise relatively low in this high-risk group of patients (Table 2).

At median echocardiogram follow-up of 32 months, the mean mitral gradient was  $5.8 \pm 2.4$  mm Hg, which was slightly but significantly statistically increased ( $p = 0.001$ ) from the immediate after pump mitral gradient ( $4.2 \pm 1.4$  mm Hg) (Fig 4). No significant difference was found in the gradient between the 21-mm and 23-mm valves immediately after pump or at follow-up ( $p = 0.8$ ). By follow-up echocardiogram, the right ventricular systolic pressure had fallen from  $49 \pm 17$  mm Hg to  $37 \pm 13$  mm Hg ( $p = 0.003$ ).

Five-year patient survival was  $82\% \pm 7\%$ . Causes of death were respiratory failure in 3 patients with

mediastinal radiation, sudden death in 1 patient, and failure to thrive in an 83-year-old patient. At a median patient follow-up of 66 months (range: 2 to 108 months), no patient required reoperation. One patient had a late mild perivalvular leak, but none had mitral dehiscence or clinically significant mitral stenosis. Median clinical heart failure symptoms at follow-up were New York Heart Association (NYHA) class I, significantly improved from preoperative symptoms of class II ( $p = 0.001$ ). At late follow-up, living patients were NYHA class I in 19 of 26 patients (73%), class II in 5 of 26 patients (19%, with 4 of 5 having clinically significant lung disease), and class III in 1 patient with severe tricuspid regurgitation.

### Comment

This series consisted entirely of adult patients. The Regent mechanical valve could also have value in small pediatric patients who are expected to grow. Long-term data were not available for use of the Regent valve in the pediatric population. In adults, the small mitral annulus can result from extensive mitral annular to leaflet calcification, small patient size, or prior mitral repair with a small annular ring. Surgical options in patients with a small mitral annulus are limited and technically challenging. These can include extensive annular debridement and reconstruction [1, 3, 4], placement of

Table 2. Operative Characteristics and Outcomes

Characteristic and Outcome	Value
Sternotomy	10 (32)
Pump time, minutes	200 ± 52
Clamp time, minutes	120 ± 50
Length of stay, median, days	9
Range	5–123
Operative death	2 (6)
Stroke	1 (3)
Reoperation for bleeding	0 (0)
Prolonged ventilation (>12 hours)	4 (13)

Values are n (%) or mean ± SD unless otherwise indicated.

prosthesis in a supra-annular intra-atrial position [5], or placement of a transcatheter aortic prosthesis in the mitral position [6]. All of these techniques are associated with increased risk of ventriculoatrial disruption, ventricular dysfunction due to chordal resection, perivalvular leakage, bleeding, or obstruction of the left ventricular outflow tract [7, 8]. To our knowledge, this is the largest series of mitral valve replacement with the use of the aortic Regent device for a small mitral valve annulus (<25 mm). In this series, the immediate and short-term outcomes were excellent with relatively few complications in this high-risk group of patients.

The Regent prosthesis facilitated excellent clinical and hemodynamic outcomes with little posterior annular debridement with larger geometric orifice area in comparison with other mechanical mitral valves (Table 3). The design of the prosthesis, with small cuff and reduced frame, generates an excellent effective orifice area from a small prosthesis. In addition, the leaflets need little room for intraventricular clearance, which is ideal in a small left ventricular cavity commonly associated with a small mitral annulus. Although the Regent device is only approved by the Food and Drug Administration for the aortic position, it is available in sizes 17 through 29 mm. The 19-mm device has an effective orifice area of 1.5 cm<sup>2</sup>, whereas the

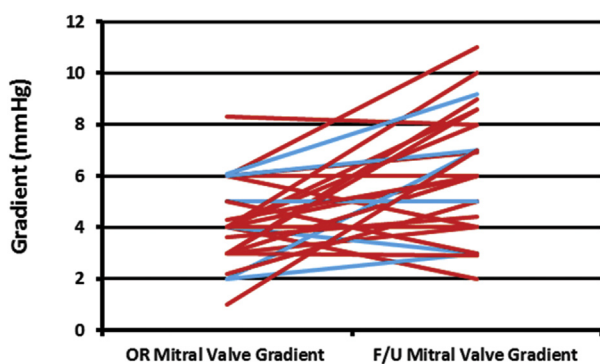


Fig 4. Mean transmitral gradients across the Regent prosthesis immediately postoperatively versus last follow-up ( $p = 0.001$ ). Valves sized 21 mm are shown in blue. Valves sized 23 mm or larger are shown in red. (F/U = follow-up; OR = operative.)

Table 3. Comparison of Valve Geometric Orifice Area

Valve Size	Regent SJ Valve Geometric Orifice Area, cm <sup>2</sup>	Standard SJ Valve Geometric Orifice Area, cm <sup>2</sup>
19	2.39	1.63
21	2.90	2.06
23	3.45	2.55
25	4.02	3.09

Data were derived from St. Jude Medical Product Catalog.

SJ = St. Jude.

21- through 25-mm sizes all have effective orifice areas of 2.0 cm<sup>2</sup> or greater, typical of a standard 25-mm or larger mitral prostheses [9] (Fig 1). The Regent device has been in clinical use in the aortic position since 2000 without any reported intrinsic mechanical failures. Pannus ingrowth in the mitral position for standard St. Jude mechanical prostheses has been rare. One might therefore expect that those patients with good initial outcome from a Regent mitral device should be at relatively low risk of late valve dysfunction, new perivalvular leak, or pannus ingrowth, as seen in Figure 3. As a cautionary note, the operating surgeon must remove the Regent valve from the holder and reverse the valve orientation to ensure proper function in the mitral position.

This study is limited in being a small series of highly selected patients in whom using a Regent prosthesis was deemed a more suitable option than alternatives such as extensive annular debridement and reconstruction. Although short- to intermediate-term follow-up was available, we do not have long-term follow-up in these patients (many of whom have other life-limiting illnesses), and we do not have the results of exercise testing in these patients. However, the short- to intermediate-term improvement in clinical symptoms suggests that this option allowed these patients safe symptomatic improvement in short- to intermediate-term follow-up. Although the follow-up resting mitral valve gradients in these patients were variable, these gradients were generally not much different from 5 ± 5 mm Hg gradients seen in standard mitral prostheses [12], with many other clinical variables such as heart rate and cardiac output affecting the resting mitral gradient.

These results suggest that placement of an aortic Regent prosthesis in the small mitral annulus could be an additional option for replacement of small mitral valves. In this limited series, this approach has allowed excellent short- and intermediate-term outcomes while avoiding the technical difficulties and risks associated with other alternative approaches. Further experience should show if there are any relative contraindications to this approach or any long-term failures.

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