

# Up to Nine-Years' Experience with the Allcarbon Prosthetic Heart Valve

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**Background and aim of the study:** The Allcarbon tilting disc valve has been used for valve replacement at the present authors' institution since 1993. Herein is reported their experience with Allcarbon valve implantation.

**Methods:** Between March 1993 and December 1998, Allcarbon valves were implanted in 599 patients (341 males, 258 females; mean age 36.2 years; range: 7-64 years). Among patients, 238 underwent mitral valve replacement (MVR), 217 aortic valve replacement (AVR), and 144 double valve replacement (DVR). The etiology of valve disease was rheumatic in 91% of cases. Follow up was 95.7% complete; cumulative follow up was 3,185 patient-years.

**Results:** Operative mortality was 2.2% (13/599). Actuarial survival at eight years was  $96.6 \pm 1.2\%$  after MVR,  $96.1 \pm 1.3\%$  after AVR, and  $97.9 \pm 1.2\%$  after DVR. Freedom from valve thrombosis at eight years

was  $97.0 \pm 1.3\%$  after MVR, 100% after AVR, and  $90.0 \pm 9.5\%$  after DVR. Freedom from major bleeding at eight years was  $90.0 \pm 2.7\%$  after MVR,  $93.5 \pm 2.6\%$  after AVR, and  $79.7 \pm 7.6\%$  after DVR. There was one embolic episode after MVR. No structural valve failure was observed. Freedom from reoperation on implanted valves at eight years was  $96.1 \pm 1.4\%$  after MVR,  $97.9 \pm 1.0\%$  after AVR, and  $97.9 \pm 1.5\%$  after DVR. On completion of follow up, 91.3% of survivors were in NYHA class I, 8.5% in class II, and 0.2% in class III.

**Conclusion:** Among a population of mostly young patients with rheumatic valve disease, the Allcarbon valve showed satisfactory clinical performance when implanted in the mitral and aortic positions.

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Different types of mechanical prostheses are currently used for cardiac valve replacement. At the present authors' institution, the Allcarbon tilting disc valve (Sorin Biomedica) has been used for valve replacement since 1993. This valve is the ultimate evolution beginning from the Monocast, the first Sorin tilting disc valve implanted in 1977, through the Carbocast, which was introduced in 1986. The Allcarbon valve comprises a single-piece cage coated with Carbofilm, droplet-shaped struts with optimal hydrodynamic contour, a pyrolytic carbon disc with a  $60^\circ$  opening angle, and a Carbofilm-coated sewing ring. The study aim was to report the authors' nine-year experience with Allcarbon valve implantation.

## Clinical materials and methods

### Patients

Between March 1993 and December 1998 at the Heart Institute, Ho Chi Minh City, a total of 743 Allcarbon valves was implanted in 599 patients (341 males, 258 females; mean age 36.2 years; range: 7 to 64 years). Among the patients, 238 underwent isolated mitral valve replacement (MVR), 217 had isolated aortic valve replacement (AVR), and 144 patients had double valve replacement (DVR).

The indication for MVR was significant lesion of the mitral valve not suitable for repair, for example heavy valve calcification, immobile leaflets, or severe subvalvar disease. The indication for isolated AVR was severe aortic stenosis with or without associated aortic regurgitation, and severe aortic regurgitation with or without associated aortic stenosis. In patients with mitral-aortic valve disease for whom MVR was indicated, concomitant AVR was performed if the aortic regurgitation or aortic stenosis was moderate to severe.

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Table I: Patient characteristics.

Parameter	MVR (n = 238)	AVR (n = 217)	DVR (n = 144)
Male gender (%)	109 (45.8)	147 (67.7)	85 (59.0)
Age (years)*	39.5 ± 8.9 (12-64)	31.6 ± 10.4 (7-56)	37.4 ± 9.7 (9-63)
Preoperative NYHA class			
I	1 (0.4)	0	1 (0.7)
II	195 (81.9)	189 (87.1)	110 (76.4)
III	39 (16.4)	26 (12.0)	32 (22.2)
IV	3 (1.3)	2 (0.9)	1 (0.7)
Preoperative rhythm			
Sinus rhythm	69 (29.0)	164 (75.6)	58 (40.3)
Atrial fibrillation	169 (71.0)	53 (24.4)	86 (59.7)
Cardiothoracic ratio*	0.62 ± 0.08 (0.45-0.9)	0.61 ± 0.07 (0.45-0.88)	0.64 ± 0.07 (0.5-0.85)
Ejection fraction (%)*	63.0 ± 5.9 (50-80)	60.9 ± 8.3 (32-82)	63.5 ± 6.9 (44-81)

\*Values are mean ± SD (range).

Values in parentheses are percentages.

AVR: Aortic valve replacement; DVR: Double valve replacement; MVR: Mitral valve replacement.

The lesion of the replaced mitral valves was pure or predominant mitral stenosis in 264 patients (69.1%), pure or predominant mitral regurgitation in 51 (13.4%), and mitral stenosis associated with moderate to severe mitral regurgitation in 67 (17.5%). The lesion of the replaced aortic valves was aortic stenosis in 26 (7.2%) patients, aortic regurgitation in 179 (49.6%), and combined aortic stenosis and regurgitation in 156 (43.2%).

The etiology of valve disease was rheumatic in 545 (91%) patients, congenital in 36 (6%), and endocarditis in 16 (2.7%) patients. In addition, one patient had severe hemolysis after mitral valvuloplasty for rheu-

matic mitral regurgitation, and another had structural deterioration of a Carpentier-Edwards aortic bioprosthesis.

Clinical, electrocardiographic, radiologic and echocardiographic (for ejection fraction) variables are summarized in Table I.

#### Surgical procedures

Standard cardiopulmonary bypass was instituted in all cases. Myocardial protection was achieved by moderate systemic hypothermia with intermittent cold crystalloid cardioplegia. The operative data are listed in Table II.

Table II: Valve size and concomitant surgical procedures.

Valve size (mm)	MVR	AVR	DVR (M/A)
19	0	10	0/10
21	0	63	0/57
23	2	66	3/64
25	3	47	7/11
27	59	28	37/2
29	88	0	47/0
31	56	3	35/0
33	30	0	15/0
Concomitant surgical procedure			
Mitral valvuloplasty	0	119	0
Tricuspid valvuloplasty	126	39	55
Closure of VSD	0	19	0
Closure of ASD	1	1	0
Reconstruction of Valsalva sinus	0	7	0
Bentall operation	0	6	0

ASD: Atrial septal defect; M/A: Mitral position/aortic position; VSD: Ventricular septal defect.  
Other abbreviations as Table I.

### Postoperative anticoagulation

All patients received oral acenocoumarol, commencing during the evening of the first postoperative day. Patients unable to take oral medications at this time were given heparin until they could take oral acenocoumarol and their International Normalized Ratio (INR) reached the target range. The target range for INR during the first three months was 2.5-3.5. Beginning from the fourth month, the target range for INR was 2-3 for patients with isolated AVR, and 2.5-3.5 for those with MVR or DVR. Antiplatelet agents were not used.

### Follow up

Follow up data were collected and categorized according to the 1996 guidelines for reporting morbidity and mortality after cardiac valvular operations (1). Patients were invited for clinical examination and echocardiographic study at the authors' institution. For patients living far from Ho Chi Minh City, information was obtained by mailed questionnaire. For those patients who had severe bleeding events, the INR value was recorded on hospital admission; for those with valve thrombosis, the three closest INR values before thrombosis was diagnosed were recorded.

Follow up was 95.7% complete. In total, 402 (67%) patients were followed by direct contact, and 311 (52%) were followed up for more than five years. The cumulative follow up was 3,185 patient-years (pt-yr) for the entire cohort, and 1,239 pt-yr after MVR (median 5.1 years; maximum 8.8 years), 1,204 pt-yr after AVR (median 5.6 years; maximum 9 years), and 742 pt-yr after DVR (median 5 years; maximum 9 years).

### Statistical analysis

Kaplan-Meier survival analysis was used to estimate the survival and freedom from events. The events were also expressed in linearized form (%/pt-yr). All early and late events were included for calculation of the actuarial estimates and the linearized rates.

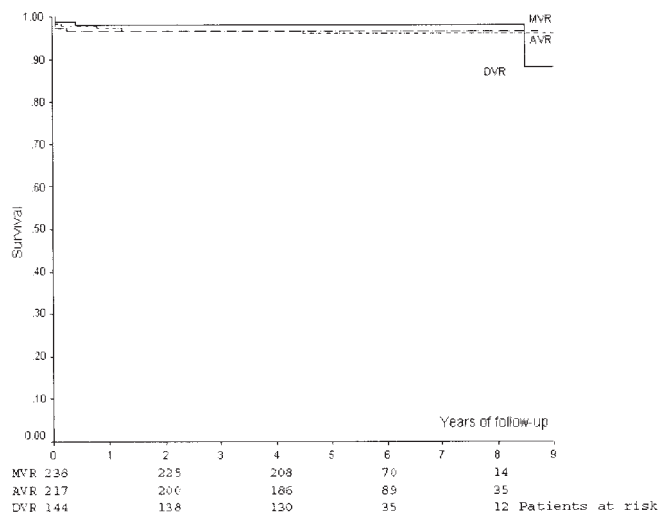


Figure 1: Actuarial survival at eight years. AVR: Aortic valve replacement; DVR: Double valve replacement; MVR: Mitral valve replacement.

## Results

### Mortality

Thirteen patients died within one month of surgery; thus, the 30-day mortality was 2.2%. The 30-day mortality was 2.9% after MVR (seven deaths), 1.8% after AVR (four deaths), and 1.4% after DVR (two deaths). There were seven late deaths. The causes of 30-day and late mortality are listed in Table III.

Actuarial survival at eight years was 93.9% ± 2.9% for all patients, 96.6% ± 1.2% after MVR, 96.1% ± 1.3% after AVR, and 97.9% ± 1.2% after DVR (Fig. 1).

### Valve thrombosis

Seven patients (two males, five females; age range 33 to 53 years) had valve thrombosis in the mitral position; these included six patients in the MVR group and one patient in the DVR group. The valve size was 27 mm in three patients, 29 mm in one patient, 31 mm in

Table III: Causes of death among patients.

Cause of death	MVR	AVR	DVR
30-day deaths			
Congestive heart failure	5	3	2
Severe sepsis	1	1	-
Cerebral bleeding	1	-	-
Late deaths			
Congestive heart failure	-	1	-
Prosthetic valve endocarditis	1	1	-
Cerebral bleeding	-	-	1
Sudden death	-	2	1

Abbreviations as Table I.

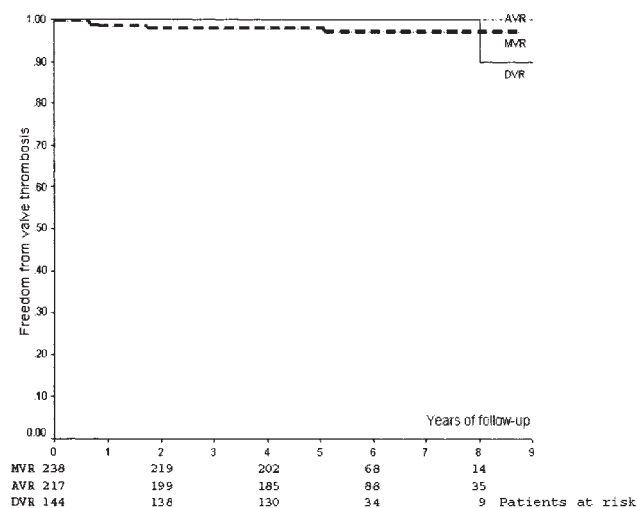


Figure 2: Freedom from valve thrombosis at eight years. Abbreviations as Figure 1.

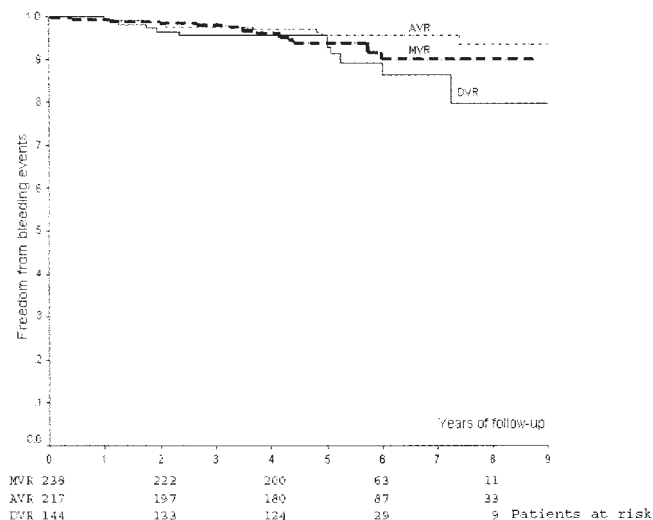


Figure 3: Freedom from bleeding events at eight years. Abbreviations as Figure 1.

two patients, and 33 mm in one patient. All seven patients were in chronic atrial fibrillation. In six cases the closest INR values before the diagnosis of valve thrombosis were repeatedly below the target range (<2.5). Five patients were in NYHA class III and two were in class II at the time of diagnosis of valve thrombosis. One patient was treated successfully with intravenous infusion of streptokinase, and six patients were reoperated on at the authors' institution for prosthesis replacement. There were no deaths on reoperation.

Actuarial freedom from valve thrombosis at eight years was  $97 \pm 1.3\%$  after MVR,  $100\%$  after AVR, and  $90 \pm 9.5\%$  after DVR (Fig. 2). The linearized rate of valve thrombosis was  $0.22\%$  per pt-yr for all patients,  $0.48\%$  per pt-yr for those with MVR,  $0$  for those with AVR, and  $0.13\%$  per pt-yr for those with DVR.

### Bleeding events

A total of 37 patients had bleeding events requiring hospitalization (16 after MVR, nine after AVR, 12 after DVR). The INR on hospital admission was noted in 34 patients who presented to the authors' institution (Table IV). Three patients for whom the INR was

Table IV: International Normalized Ratio (INR) values at hospital admission in patients with severe bleeding events.

INR value	MVR (n = 16)	AVR (n = 9)	DVR (n = 12)
2.5-3.5	1	1	1
3.6-5	2	3	3
>5	11	5	7
Unknown	2	0	1

Abbreviations as Table I.

unknown were admitted to local hospitals.

Actuarial freedom from bleeding events at eight years was  $90 \pm 2.7\%$  after MVR,  $93.5 \pm 2.6\%$  after AVR, and  $79.7 \pm 7.6\%$  after DVR (Fig. 3). The linearized rate of bleeding events was  $1.16\%$  per pt-yr for all patients,  $1.29\%$  per pt-yr after MVR,  $0.75\%$  per pt-yr after AVR, and  $1.62\%$  per pt-yr after DVR.

### Other valve-related complications

No structural valve failure was observed in any patient. Only one embolic episode (which presented as an ischemic stroke) occurred in a patient with MVR; thus, the overall linearized rate of embolism was  $0.03\%$  per pt-yr.

Paravalvular leak in the absence of endocarditis occurred in two patients with MVR, in one patient with AVR, and in three patients with DVR (two in the mitral position and one in the aortic position). Prosthetic valve endocarditis developed in two patients with MVR and in five with AVR.

The number and linearized rates of valve-related complications in each group are summarized in Table V.

Actuarial survival without valve-related complications at eight years was  $84.8 \pm 2.8\%$  after MVR,  $89.8 \pm 2.2\%$  after AVR, and  $83.7 \pm 4.6\%$  after DVR.

### Reoperation

A total of 14 reoperations was performed on inserted Allcarbon valves. Among the MVR group, six patients had prosthesis replacement for valve thrombosis, one patient had prosthesis replacement for paravalvular leak, and one had prosthesis refixation for paravalvular leak. In the AVR group, one patient had prosthesis refixation for paravalvular leak and three patients had

Table V: Valve-related complications.

Complication	MVR	AVR	DVR
Structural valve failure	0	0	0
Paravalvular leak	2 (0.16)	1 (0.08)	3 (0.4)
Valve thrombosis	6 (0.48)	0	1 (0.13)
Embolism	1 (0.08)	0	0
Bleeding	16 (1.29)	9 (0.75)	12 (1.62)
Endocarditis	2 (0.16)	5 (0.42)	0

Values in parentheses are % per patient-year.  
Abbreviations as Table I.

prosthesis replacement for prosthetic valve endocarditis. In the DVR group, one patient underwent prosthesis re-fixation for paravalvular leak in the aortic position and one had prosthesis replacement for paravalvular leak with hemolysis in the mitral position.

Otherwise, four AVR patients underwent reoperation for MVR (three had severe hemolysis after mitral valvuloplasty and one patient had progression of rheumatic mitral regurgitation).

One patient died six weeks after reoperation as a result of *Staphylococcus aureus* prosthetic valve endocarditis. Despite prosthesis replacement and prolonged antibiotherapy, the infectious process remained uncontrolled.

Actuarial freedom from reoperation on inserted Allcarbon valves at eight years was  $96.1 \pm 1.4\%$  after MVR,  $97.9 \pm 1\%$  after AVR, and  $97.9 \pm 1.5\%$  after DVR.

#### NYHA functional status

At the time of the last follow up examination, 91.3% of survivors were in NYHA class I, 8.5% in class II, and 0.2% in class III.

## Discussion

Today, most of the mechanical valves implanted are of the bileaflet type, as this design is generally perceived as being more 'modern' and less susceptible to thrombosis and embolism compared to tilting disc designs. Among the tilting disc valves, the Medtronic-Hall valve is the most intensively studied. A review of the published long-term results with five mechanical valves showed the Medtronic-Hall valve to be slightly superior to bileaflet valves, particularly when implanted in the aortic position (2). In the 1998 American College of Cardiology/American Heart Association guidelines for the management of patients with valvular heart disease, the recommended target INR range was 2-3 for bileaflet and Medtronic-Hall valves in the aortic position, and 2.5-3.5 for other disc valves and Starr-Edwards valves in the aortic position (3).

The Allcarbon valve is a tilting disc valve with a dif-

ferent design from that of the Medtronic-Hall valve. In the present series, patients who underwent isolated AVR with the Allcarbon valve were anticoagulated to a target INR range of 2-3, and with this relatively low-level anticoagulation no thrombosis or embolism was encountered. All seven cases of valve thrombosis occurred in the mitral position in patients with risk factors (all seven patients were in chronic atrial fibrillation and six were insufficiently anticoagulated). The overall rate of valve thrombosis in the present series was in the low range compared to results reported for other mechanical valves (2,3).

One remarkable finding of the present study was the very low rate of embolism. In many reported series of valve replacement with other mechanical valves (including bileaflet valves), the rate of embolism exceeded 1% per pt-yr (4-6). Compared to patients in those series, the present group were younger, and this may in part be responsible for the low rate of embolism, as younger patients have a lower risk for embolism of atherosclerotic origin. However, in the present authors' opinion, the features of the Allcarbon valve also contributed to this result. The Allcarbon valve is a recent version of the Sorin tilting disc prosthesis, and prior reports on earlier versions of this valve showed the rate of thromboembolic events to be in the low range (1.2-1.44 and 0.32-1.3%/pt-yr for the mitral and aortic positions, respectively) (7,8). In the Allcarbon valve, the cage, occluder disc and sewing ring are each coated with Carbofilm, this design having a clear and important impact on the improvement of hemocompatibility.

The rate of major bleeding among the present patients was comparable to that reported for other mechanical valves (4,5). As shown in Table IV, in the majority of cases bleeding was related to excessive anticoagulation. The fact that the rate of bleeding in the AVR group was lower than in the two other groups demonstrated the benefit of low-level anticoagulation to a target INR range of 2-3.

With regard to other valve-related complications such as paravalvular leak and prosthetic valve endo-

carditis, the present results were comparable to those observed with other mechanical valves (2,4,5,9).

*In conclusion*, among a population of mostly young patients with rheumatic valve disease, the Allcarbon valve showed satisfactory performance in both the mitral and aortic positions. Mortality and the rates of valve-related complications were low. For those patients who underwent isolated AVR with the Allcarbon valve, anticoagulation with a target INR range of 2-3 was adequate.

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