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Multicentered European Study on Safety and Effectiveness of the On-X Prosthetic Heart Valve: Intermediate Follow-Up

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Background. This study was performed to determine the safety and effectiveness of the On-X valve, a novel mechanical valve substitute.

Methods. Eleven centers participated in a European, multicentered, longitudinal, nonrandomized study of the On-X valve performance. Isolated aortic or mitral valve replacement with an On-X valve was studied in 301 patients. Aortic valve replacement was performed in 184 patients (average follow-up, 5.0 years), whereas mitral valve replacement was performed in 117 patients (average follow-up, 4.4 years).

Results. In patients with aortic valve replacement, mean transvalvular pressure gradients ranged from 8.3 to 4.7 mm Hg and effective orifice areas from 1.5 to 2.7 cm², for 19-mm through 25-mm valves, respectively. After mitral valve replacement, mean gradient was 4.2 mm Hg and effective orifice area by pressure half-time was 2.6 cm² regardless of valve size. Hemolysis was low, with

postoperative serum lactate dehydrogenase at 225 ± 41 IU (mean ± standard deviation) or 253 ± 65 IU, after aortic valve replacement or mitral valve replacement, respectively (upper normal value, 250 IU). At 1 year or greater postoperatively, 91.6% of patients after aortic valve replacement and 84.6% after mitral valve replacement were in New York Heart Association functional class I or II. Adverse event rates in percent per patient-year after aortic valve replacement or mitral valve replacement were thromboembolism, 0.88 or 1.76; thrombosis, 0.11 or 0.20; bleeding, 0.77 or 1.96, respectively. Late mortality was 1.97% or 2.55%, respectively.

Conclusions. At the intermediate follow-up, the On-X valve exhibited improved hemodynamics, low hemolysis with in-range lactate dehydrogenase, and low adverse event rates, particularly in the aortic position.

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The introduction of pure pyrolytic carbon in prosthetic heart valve manufacturing in the mid-1990s allowed the construction of a new valve model, the On-X valve. Pure pyrolytic carbon is stronger than the carbon traditionally used for construction of prosthetic heart valves and does not require silicon carbide additives to gain sufficient strength and wear resistance [1–3]. As such, it was used to construct the On-X valve featuring 90 degrees of leaflet opening, a flared inlet, and a streamlined blood flow. These valve characteristics led to improved fluid dynamics of the valve on the bench, and promised improved hemodynamics and less blood damage than previous valve models [4]. In this paper, we present the interim follow-up results of a clinical study of cardiac valve replacement using the On-X valve.

Patients and Methods

A prospective, nonrandomized, multicentered clinical trial was conducted at 11 centers in Europe to determine the safety and effectiveness of the On-X valve (Medical Carbon Research Institute, Austin, TX; Table 1). The study was approved by the ethics committee of each participating center. All patients included in the study had severe aortic or mitral valve disease requiring valve replacement on the basis of clinical, echocardiographic, and cardiac catheterization data. All patients signed an informed consent before they were included in the study. The first On-X valve implant occurred September 12, 1996. Patients were enrolled through December 1999. All data were current to May 31, 2004, with follow-ups occurring within a 6-month closeout period. The total patient population in this study was 301; of this total, 184 patients underwent aortic valve replacement (AVR) and the remaining 117 patients had mitral valve replacement (MVR). Follow-up was conducted in the physician's office or outpatient clinic, and included a total of 1,423.9 patient-years (913.5 with AVR and 510.4 with MVR) with a

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Table 1. On-X Valve Implants by Center and Position in the European Trial

Center	AVR	MVR	Total
University of Vienna, Austria	12	25	37
University of Barcelona, Spain	12	5	17
University Clinic Regensburg, Germany	8	12	20
University Clinic Giessen, Germany	30	20	50
Hannover Medical College, Germany	19	0	19
City Hospital, Krefeld, Germany	22	13	35
Heart Center, Leipzig, Germany	20	0	20
Ruhr University, Bochum, Germany	20	19	39
University Clinic Mainz, Germany	24	11	35
University Clinic Kiel, Germany	4	0	4
Onassis Cardiac Surgery Center, Athens, Greece	13	12	25
Total	184	117	301

AVR = aortic valve replacement; MVR = mitral valve replacement.

maximum of 6.9 years and a mean of 4.7 years. Follow-up was complete in 98% AVR and 96% MVR patients.

Standard statistical techniques were used. Normal descriptive statistics gave means, standard deviations, medians, and ranges as appropriate. Early rates were straight percentages against numbers of implants or patients. Late-event rates were calculated using the actuarial life table methods (Kaplan–Meier) and were presented as percent survival or freedom from the event. Late rates were also linearized to follow-up time as a percent per patient-year of follow-up. All events were recorded and classified according to the American Association for Thoracic Surgery/Society of Thoracic Surgeons guidelines [5]. Statistical analysis was completed according to a prescribed validated plan designed to meet US regulatory requirements by independent statisticians (Applied Logic Associates, Houston, TX).

For echocardiography, standard imaging views were used; values were the average of at least three heartbeats

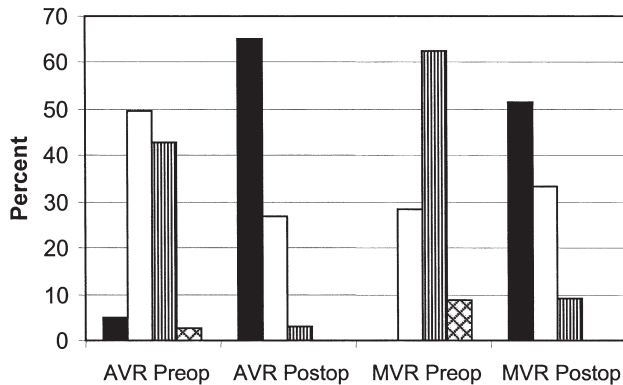


Fig 1. New York Heart Association classification at preoperative and 1-year postoperative intervals. Classes I (black bars), II (white bars), III (striped bars), and IV (cross-hatched bars) are shown. (AVR = aortic valve replacement; MVR = mitral valve replacement; Postop = postoperatively; Preop = preoperatively.)

Table 2. Implant Size Distributions for Aortic and Mitral Valves

AVR	19 mm	21 mm	23 mm	25 mm	27/29 mm	Total
N	17	35	70	38	24	184
%	9.2	19.0	38.0	20.6	13.0	100

MVR	25 mm	27/29 mm	31/33 mm	Total
N	17	70	30	117
%	14.5	59.8	25.6	100

AVR = aortic valve replacement; MVR = mitral valve replacement.

for patients in sinus rhythm and at least five heartbeats for patients in atrial fibrillation. Calculations of the effective orifice area (EOA) of all prostheses were performed using the continuity equation on the basis of the velocity time integral ratio. Pressure gradients in the aortic position were calculated using the two-term Bernoulli equation, whereas in the mitral position, the one-term short form was used. All echocardiographic data were reviewed and confirmed by a core echocardiographer (John Chambers, MD) at St. Thomas's Hospital, London, United Kingdom.

Mean age of the patients at operation was 60.2 ± 8.4 years for the AVR group and 60.0 ± 10.2 years for the MVR group. Sex distribution was 121 male (65.8%) for AVR and 54 male (46.2%) for MVR. Preoperative New York Heart Association classification distributions were as shown in Figure 1, with the majority of patients in class II or III. Preoperative cardiac rhythm among the AVR patients was sinus in 161 patients (87.5%) and atrial fibrillation in 14 (7.6%), whereas in MVR patients, sinus rhythm was present in 52 (44.4%) and atrial fibrillation in 63 (53.9%). Predominant cause of valve disease in AVR patients was calcific in 92 (50.0%), degenerative in 51 (27.7%), and rheumatic in 24 (13.0%), whereas in MVR patients, it was calcific in 15 (12.8%), degenerative in 32

Table 3. Early (≤ 30 days) Adverse Event Rates (% , N)

Event	AVR	MVR
Thromboembolism	0.5, 1	0.8, 1
Thrombosis	0.0	0.0
Bleeding event	0.5, 1	0.0
Major bleed	0.5, 1	0.0
Paravalvular leak	2.2, 4	1.7, 2
Major paravalvular leak	0.5, 1	0.8, 1
Prosthetic endocarditis	0.0	0.0
Hemolysis	0.0	0.0
Structural dysfunction	0.0	0.0
Nonstructural dysfunction	0.0	0.0
Valve-related reoperations	1.1, 2	0.8, 1
Explants	0.5, 1	0.8, 1
Sudden death	0.0	0.0
Valve-related mortality including sudden death	0.5, 1	0.0
Overall mortality	2.2, 4	6.0, 7

AVR = aortic valve replacement; MVR = mitral valve replacement.

Table 4. Late (>30 days) Adverse Event Rates (%/patient-years, N)

Event	AVR	MVR
Thromboembolism	0.88, 8	1.76, 9
Thrombosis	0.11, 1	0.39, 2
Bleeding event	0.77, 7	1.96, 10
Major bleed	0.33, 3	1.57, 8
Paravalvular leak	0.55, 5	0.98, 5
Major paravalvular leak	0.22, 2	0.39, 2
Prosthetic endocarditis	0.33, 3	0.78, 4
Hemolysis	0.00	0.20, 1
Structural dysfunction	0.00	0.00
Nonstructural dysfunction	0.00	0.00, 0
Valve-related reoperations	0.66, 6	1.18, 6
Explants	0.22, 2	0.78, 4
Sudden death	0.88, 8	0.78, 4
Valve-related mortality including sudden death	1.09, 10	0.98, 5
Overall mortality	1.97, 18	2.55, 13

AVR = aortic valve replacement; MVR = mitral valve replacement.

(27.4%), and rheumatic in 45 (38.5%). In AVR patients, valve lesion was stenotic in 86 patients (46.7%), regurgitant in 39 (21.2%), and mixed in 59 (32.1%), whereas in MVR patients, valve lesion was stenotic in 20 (17.1%), regurgitant in 60 (51.3%), and mixed in 37 (31.6%). Previous cardiac surgery had occurred in 4 patients in the AVR group (2.2%) and in 20 in the MVR group (17.1%). Patients were maintained on permanent warfarin anticoagulation therapy per the protocol requirements based on the 1993 recommendations of Gohlke-Barwolf and collaborators [6]; this occurred for 176 AVR patients (95.6%) with international normalized ratio target 2.5 to 3.5 and in 113 MVR patients (96.2%) with international normalized ratio target 3.0 to 4.5. Although anticoagulation recommendations were changed downward during this trial, the anticoagulation targets initially set in the study were not adjusted [7].

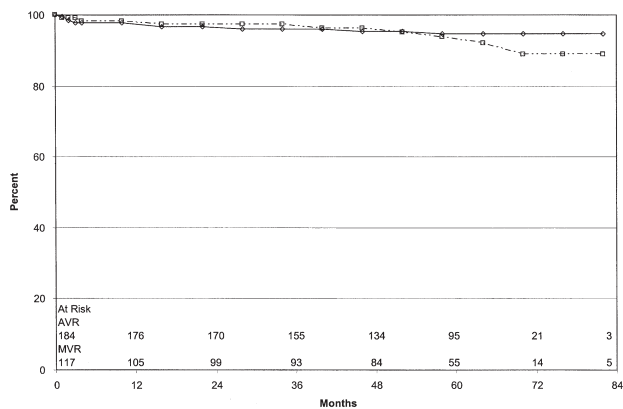


Fig 2. Freedom from thromboembolism in patients undergoing aortic valve replacement (AVR, diamonds and solid line) and mitral valve replacement (MVR, squares and dashed line).

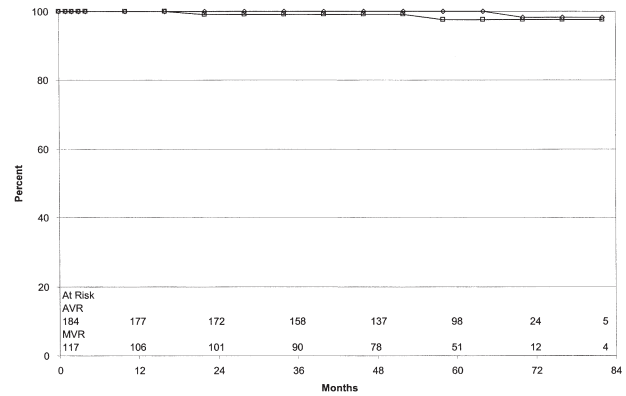


Fig 3. Freedom from thrombosis in patients undergoing aortic valve replacement (AVR, diamonds and solid line) and mitral valve replacement (MVR, squares and solid line).

Valve sizing was done in a standard fashion using the specific sizers provided with the valve. The largest freely passing sizer through the native valve orifice determined the size of the valve to be implanted. Very tight or snug sizer fitting was not accepted. Implant size distribution was as shown in Table 2. As expected, this is a normal distribution with the largest size group being 23 mm in AVR and 27 or 29 mm in MVR. According to valve design, the largest housing size is 25 mm; all larger valve sizes are made by increasing the sewing ring size.

Concomitant procedures were performed in 43 AVR patients (23.4%) and in 48 MVR patients (41.0%); coronary artery bypass grafting was the most frequent concomitantly performed procedure (11.4% in AVR and 17.1% in MVR). Although various suture techniques were successfully used, the dominant method chosen for AVR was interrupted, noneverting mattress sutures, and for MVR, it was interrupted, everting mattress sutures. No preferred valve orientation was seen in AVR, although in MVR, an antianatomic placement was preferred. Operative morbidity was low, with bleeding being the most common event (2.2% in AVR and 6.8% in MVR cases).

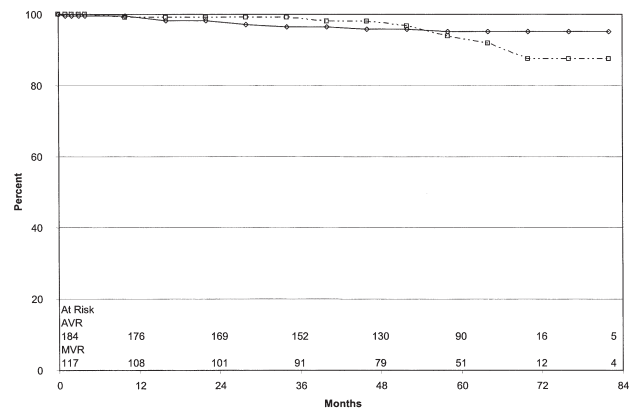


Fig 4. Freedom from bleeding events in patients undergoing aortic valve replacement (AVR, diamonds and solid line) and mitral valve replacement (MVR, squares and dashed line).

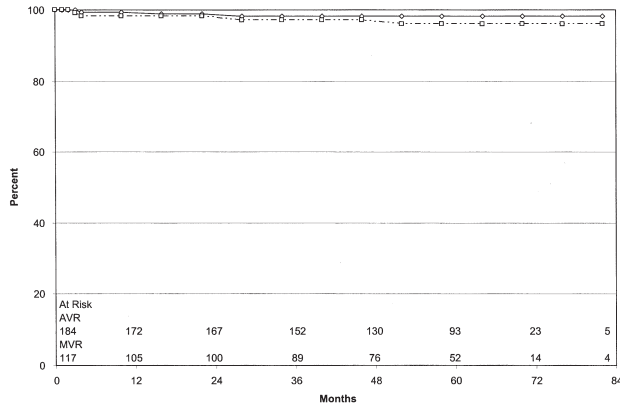


Fig 5. Freedom from prosthetic valve endocarditis in patients undergoing aortic valve replacement (AVR, diamonds and solid line) and mitral valve replacement (MVR, squares and dashed line).

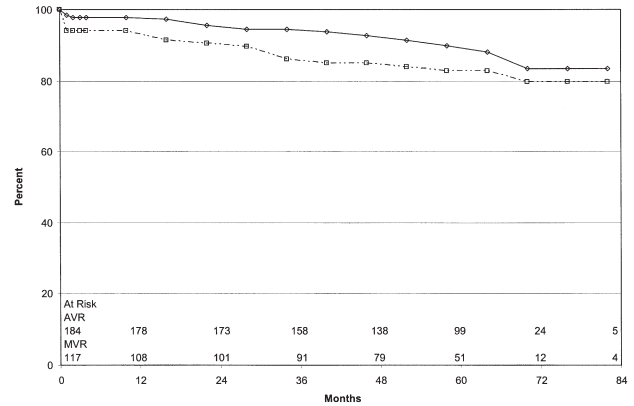


Fig 7. Survival in patients undergoing aortic valve replacement (AVR, diamonds and solid line) and mitral valve replacement (MVR, squares and dashed line).

Results

Early (30-day) and late postoperative events are presented in Tables 3 and 4, respectively.

Aortic Valve Replacement

After AVR, early mortality was 4 patients (2.2%); 1 died of thromboembolism (TE), 2 of cardiac arrest, and 1 of multiorgan failure. From clinical or autopsy evidence, only the TE death was valve-related. Overall late mortality was 18 patients (2.0%/patient-year), whereas valve-related late mortality was 10 patients (1.1%/patient-year).

During late follow-up, TE occurred eight times in 8 patients; only two of those events were major (0.2%/patient-year), one that resulted in death, and another (0.1%/patient-year) that caused a reversible ischemic neurologic deficit lasting 10 days. Of the remaining 6 patients with late TE, five (0.6%/patient-year) were transient ischemic events (lasting less than 24 hours) and one was a peripheral TE. Anticoagulation was insufficient in 3 patients with late TE, acceptable in 1, and unknown in 4 at the time of the event. Freedom from TE at 5 years was $94.7\% \pm 1.7\%$ (Fig 2).

Valve thrombosis in AVR cases occurred in only 1 patient with poor anticoagulant compliance and chronic atrial fibrillation at 5.5 years postoperatively. The valve was cleaned of thrombus at reoperation and was left in place. The patient recovered fully. Because the event occurred after the 5th year, freedom from thrombosis at 5 years was 100% (Fig 3).

Bleeding events occurred eight times in 8 patients, one early and seven late postoperatively. None of these events led to death, although the early event and three late events were classified as major events. Anticoagulant status was elevated in 1 patient, in range in 1 patient, and unknown in all others at the time of the event. Freedom from bleeding events at 5 years was $95.1\% \pm 1.7\%$ (Fig 4).

Other late valve-related events included three cases of endocarditis, five paravalvular leaks, and eight sudden or unexplained deaths without autopsy. Each patient with endocarditis underwent reoperation; 2 of them recovered whereas 1 patient died. Of the paravalvular leaks, two were major requiring surgical repair. Actuarial curves for endocarditis and paravalvular leak are given in Figures 5

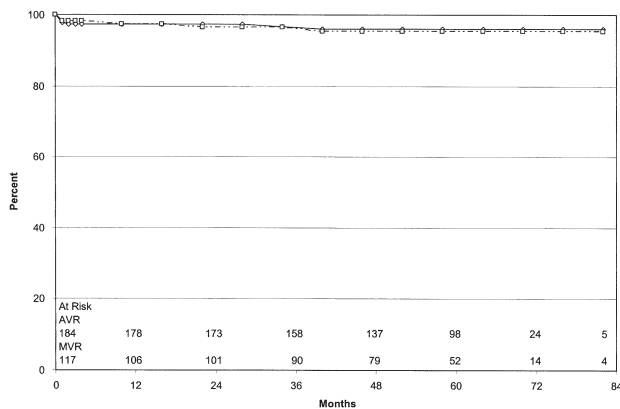


Fig 6. Freedom from paravalvular leak in patients undergoing aortic valve replacement (AVR, diamonds and solid line) and mitral valve replacement (MVR, squares and dashed line).

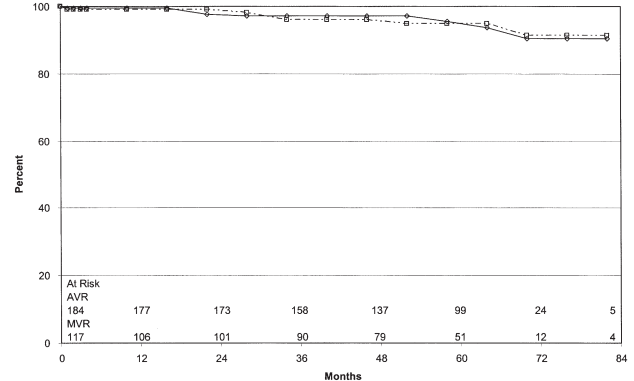


Fig 8. Freedom from valve related mortality including sudden or unexplained death in patients undergoing aortic valve replacement (AVR, diamonds and solid line) and mitral valve replacement (MVR, squares and dashed line).

Table 5. Postoperative Lactate Dehydrogenase at 1 Year^a

Valve Type and Size	Number	Mean	Standard Deviation	Median
AVR all	139	225	41	224
19 mm	12	203	34	189
21 mm	29	212	32	214
23 mm	51	223	38	224
25 mm	27	238	37	236
27/29 mm	21	232	56	225
MVR all	69	253	65	238
25 mm	10	246	49	230
27/29 mm	46	264	71	245
31/33 mm	13	227	52	231

^a Values reported in IU, upper normal, 250.

AVR = aortic valve replacement; MVR = mitral valve replacement.

and 6, respectively. Total aortic valve-related morbidity and mortality was 3.5%/patient-year (32 events).

Mitral Valve Replacement

Early mortality was 7 patients (6.0%), not valve-related. Causes of death were uncontrolled intraoperative bleeding after thrombolysis (n = 1), sepsis (n = 3), respiratory arrest (n = 1), ventricular rupture (n = 1), and cancer (n = 1). There were 13 late deaths overall (2.6%/patient-year); only 5 of them (0.8%/patient-year) were valve-related, including 4 sudden or unexplained deaths and 1 as a result of bleeding. Five-year survival was 82.8% ± 3.6% (Fig 7); freedom from valve-related mortality was 94% ± 2.2% (Fig 8).

There were ten episodes of TE observed in 8 MVR patients; one was early and nine were late events. One patient had three separate late episodes of TE, which resulted in a permanent neurologic deficit. There was one transient event (0.2%/patient-year), three reversible ischemic neurologic deficits (0.6%/patient-year) that lasted 3, 7, and 20 days, and five events with permanent deficits (1.0%/patient-year). Seven of the nine late events (1.4%/patient-year) were considered major. Anticoagulation was insufficient in four late events, acceptable in one, and unknown in four at the time of the event. Freedom from TE at 5 years was 93.5% ± 2.6% (Fig 2).

Two instances of mitral valve prosthesis thrombosis occurred in patients with chronic atrial fibrillation, one of whom had quit taking the anticoagulant, whereas no information was available concerning compliance with anticoagulation for the other patient. The patients were treated with thrombolytic therapy, and their anticoagulation was brought into range; they eventually recovered, although a cerebral bleed occurred as a result of thrombolysis in 1 patient. Freedom from thrombosis at 5 years was 97.6% ± 1.7% (Fig 3).

Bleeding events occurred ten times in 6 patients, only late postoperatively. One patient had four separate but recurring pulmonary bleeds. Eight of ten events were considered major, of which one led to death. Anticoagu-

lation status at the time of the events was unknown in all these cases. Freedom from bleeding events at 5 years was 91.8% ± 3.3% (Fig 4).

Other late valve-related events included five paravalvular leaks, four cases of endocarditis, one possible hemolytic anemia, and four sudden or unexplained deaths without autopsy. Of the paravalvular leaks, two were major (one case was repaired at reoperation, the other required valve replacement). Three endocarditis cases underwent reoperation (two valves explanted and replaced, one valve cleansed); one endocarditis case resolved after a 4-week course of antibiotics. The hemolytic anemia resolved spontaneously after 4 weeks. Actuarial curves for endocarditis and paravalvular leak are given in Figures 5 and 6, respectively. Total mitral valve-related morbidity and mortality was 6.86%/pt/yr (35 events).

New York Heart Association Classification

New York Heart Association functional classification for patients at the 1-year postoperative interval is shown in Figure 1. There was significant improvement from the preoperative status observed in 73.3% of AVR patients and in 80.8% of MVR patients. In patients without adverse events, none showed deterioration in New York Heart Association status postoperatively.

Echocardiography

Echocardiographic measurements of aortic peak and mean transvalvular pressure gradients were 15.9 ± 4.8 mm Hg and 8.3 ± 2.9 mm Hg for 19-mm valves (n = 13), 14.7 ± 6.6 mm Hg and 7.8 ± 3.4 mm Hg for 21-mm valves (n = 22), 12.3 ± 6.2 mm Hg and 6.6 ± 3.2 mm Hg for 23-mm valves (n = 55), and 9.3 ± 5.1 mm Hg and 4.7 ± 2.8 mm Hg for all valves with 25-mm orifice (n = 47), respectively. The EOAs were 1.53 ± 0.26 cm², 2.01 ± 0.48 cm², 2.31 ± 0.79 cm², 2.75 ± 0.75 cm², and 2.0 ± 0.6 cm², respectively. For all mitral valves (orifice diameter 25 mm, n = 89), peak and mean gradients were 11.2 ± 4.8 mm Hg and 4.2 ± 1.8 mm Hg, respectively, and EOAs were 2.0 ± 0.6 cm².

Data for sizes 25 mm and up are given as a group because of identical valve housing and leaflets. Data are given for patients in the 1-year or greater postoperative period.

Hemolysis

Results of 1-year postoperative blood lactate dehydrogenase (LDH) levels by valve position and size are shown in Table 5. Upper normal value for LDH in this study was 250 IU. Normal range LDH was observed in most patients (median 89.6% of upper normal for AVR and 95.2% for MVR).

Complete Blood Counts

Except for the MVR patient with temporary anemia (see above, *Mitral Valve Replacement*), patients had normal values for all the components of a complete blood count, including hemoglobin, red blood cell count, and reticulocyte count.

Comment

The major concern for mechanical valves is the long-term need for warfarin-based anticoagulation as it relates to the thrombogenic potential of these valves and to bleeding from erroneously high anticoagulant dosage. In this study, the patients were maintained on permanent anticoagulation with warfarin at a slightly higher level than now recommended owing to the change of anticoagulation recommendations for bileaflet valves in 1998, while this study was ongoing [7]. We did not lower international normalized ratio targets then to keep the study consistent. Given that constraint, the study still produced a low linearized rate sum of thrombotic and bleeding events of 1.76%/patient-year in AVR and 4.01%/patient-year in MVR patients. In a review of the literature on mechanical valves, Akins [8] reported this composite rate to be 4.28%/patient-year in AVR and 4.16%/patient-year in MVR for St. Jude Medical valves. The On-X valve in the present study outperformed this estimate in AVR.

Operative mortality of 2.2% for AVR and 6.0% for MVR was consistent with contemporary reports from The Society of Thoracic Surgeons database of 4.3% for AVR and 6.4% for MVR [9]. Overall late mortality in this report compares well to a contemporary study [10], whereas valve-related mortality including sudden and unexplained deaths (1.09%/patient-year after AVR, and 0.98%/patient-year after MVR) is similar to a contemporary study reported by the US Food and Drug Administration from a premarket study (1.15%/patient-year after AVR and 1.07%/patient-year after MVR) [11]. For other valve-related events, such as endocarditis and paravalvular leak, this study resulted in event rates similar to published composite rates for other mechanical valves [12–15].

The hemodynamic results of the On-X valve compared well with those reported by Wang and associates [16] in a review of the literature on earlier bileaflet valve models. In that review, 19-mm bileaflet aortic valves had mean gradients between 17 and 22 mm Hg and EOAs between 0.9 and 1.0 cm². Our study showed mean gradient of the 19-mm On-X valve was 8.3 mm Hg and EOA was 1.53 cm². This improvement was consistent across all aortic valve sizes. In the mitral position, Wang and associates noted that mean gradients for valve sizes 25 mm and upward did not vary with size, being consistently between 3 and 5 mm Hg. This was also true for EOA being around 2.0 cm² by continuity equation [16]. The On-X valve provides only one size mitral housing, and its mean gradient (4.25 mm Hg) and EOA (2.0 cm²) were consistent with this finding. A recent report on a North American multicentered study of the On-X valve showed improved hemodynamic performance of the valve [17]. Recent bileaflet aortic valve designs have also shown improved hemodynamics [18]. In the report by Emery and colleagues [15] concerning the ATS valve, mean gradient was 22 ± 11 mm Hg and EOA 1.2 ± 0.3 cm², placing the ATS valve results between those of the On-X and the bileaflet valve results reported by Wang and associates [16]. Variability in echocardiographic results was similar in all these reports.

Of particular note in the present study was the evidence of very low blood damage caused by the On-X valve in the aortic or mitral positions, as indicated by the low postoperative LDH levels. Elevation of LDH has been suggested to relate to valve-related adverse events such as TE and bleeding [19]. A typical bileaflet mechanical valve elevates LDH to levels of approximately 120% to 150% of upper normal, whereas tissue valves produce LDH values within upper normal range [20–22]. In this regard, the On-X valve behaved like a tissue valve, suggesting a real improvement in performance that will benefit patients by providing a lower degree of hemolysis.

In conclusion, the mechanical On-X valve exhibited improved hemodynamics, low TE and thrombosis rates, and low degrees of hemolysis, particularly in the aortic position. In this intermediate follow-up study, the On-X valve performed safely and effectively through 5 years of average follow-up and up to 6.5 years of maximum follow-up in isolated AVR or MVR. Longer-term follow-up is needed to describe the valve's performance beyond 10 years, but in the intermediate term, this valve has performed well in every aspect evaluated. The On-X valve at an intermediate follow-up exhibited improved hemodynamics, low TW rates, and low hemolysis.

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References

1. Ely JL, Emken MR, Accuntius JA, et al. Pure pyrolytic carbon: preparation and properties of a new material, On-X carbon for mechanical heart valve prostheses. *Heart Valve Dis* 1998;7:626–32.
2. Ma L, Sines GH. Unalloyed pyrolytic carbon for implanted mechanical heart valves. *J Heart Valve Dis* 1999;8:578–85.
3. Ma L, Sines G. Fatigue behavior of a pyrolytic carbon. *J Biomed Mater Res* 2000;51:61–8.
4. Hwang NH, Reul H, Reinhard P. In vitro evaluation of the long-body On-X bileaflet heart valve. *J Heart Valve Dis* 1998;7:561–8.
5. Edmunds LH Jr, Clark RE, Cohn LH, Grunkemeier GL, Miller DC, Weisel RD. Guidelines for reporting morbidity and mortality after cardiac valvular operations. *Ann Thorac Surg* 1996;62:932–5.
6. Gohlke-Barwolf C, Acar J, Burckhardt D, et al. Guidelines for prevention of thromboembolic events in valvular heart disease. *J Heart Valve Dis* 1993;2:398–410.
7. Bonow RO, Carabello B, de Leon AC, et al. ACC/AHA guidelines for the management of patients with valvular heart disease. Executive summary. A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Management of Patients With Valvular Heart Disease). *J Heart Valve Dis* 1998;7:672–707.
8. Akins CW. Results with mechanical cardiac valvular prostheses. *Ann Thorac Surg* 1995;60:1836–44.
9. Jamieson WR, Edwards FH, Schwartz M, Bero JW, Clark RE, Grover FL. Risk stratification for cardiac valve replacement. National Cardiac Surgery Database. *Ann Thorac Surg* 1999; 67:943–51.
10. Bortolotti U, Milano A, D'Alfonso A, et al. Evaluation of valve-related complications in patients with Sorin Bicarbon prosthesis: a seven-year experience. *J Heart Valve Dis* 2001; 10:795–801.

11. US Food and Drug Administration. ATS open pivot bileaflet heart valve. Summary of safety and effectiveness data. October 13, 2000, pp 1-15. Available at: <http://www.fda.gov/edrh/pdf/p990046.html>.
12. Vitale N, Cappabianca G, Visicchio G, et al. Midterm evaluation of the Sorin Bicarbon heart valve prosthesis: single-center experience. *Ann Thorac Surg* 2004;77:527-31.
13. Lim KH, Caputo M, Ascione R, et al. Prospective randomized comparison of CarboMedics and St. Jude Medical bileaflet mechanical heart valve prostheses: an interim report. *J Thorac Cardiovasc Surg* 2002;123:21-32.
14. Hannan EL, Racz MJ, Jones RH, et al. Predictors of mortality for patients undergoing cardiac valve replacements in New York State. *Ann Thorac Surg* 2000;70:1212-8.
15. Emery RW, Van Nooten GJ, Tesar PJ. The initial experience with the ATS Medical mechanical cardiac valve prosthesis. *Ann Thorac Surg* 2003;75:444-52.
16. Wang Z, Grainger N, Chambers J. Doppler echocardiography in normally functioning replacement heart valves: a literature review. *J Heart Valve Dis* 1995;4:591-614.
17. McNicholas KW, Ivey TD, Metras J, et al. North American multicenter experience with the On-X prosthetic heart valve. *J Heart Valve Dis* 2006;15:73-9.
18. Bach DS, Goldbach M, Sakwa MP, Petracek M, Errett L, Mohr F. Hemodynamics and early performance of the St. Jude Medical Regent aortic valve prosthesis. *J Heart Valve Dis* 2001;10:436-42.
19. Butchart EG. Prosthetic heart valves. In: Verstraete M, Fuster V, Topol EJ, eds. *Cardiovascular thrombosis: thrombocardiology and thromboneurology*, 2nd ed. Philadelphia, PA: Lippincott-Raven Publishers, 1998:395-414.
20. Skoularigis J, Essop MR, Skudicky D, Middlemost SJ, Sareli P. Frequency and severity of intravascular hemolysis after left-sided cardiac valve replacement with Medtronic Hall and St. Jude Medical prostheses, and influence of prosthetic type, position, size and number. *Am J Cardiol* 1993;71:587-91.
21. Mecozzi G, Milano AD, De Carlo M, et al. Intravascular hemolysis in patients with new-generation prosthetic heart valves: a prospective study. *J Thorac Cardiovasc Surg* 2002;123:550-6.
22. Rodler SM, Moritz A, Schreiner W, End A, Dubsky P, Wolner E. Five-year follow-up after heart valve replacement with the CarboMedics bileaflet prosthesis. *Ann Thorac Surg* 1997;63:1018-25.

Online Discussion Forum

Each month, we select an article from the *The Annals of Thoracic Surgery* for discussion within the Surgeon's Forum of the CTSNet Discussion Forum Section. The articles chosen rotate among the six dilemma topics covered under the Surgeon's Forum, which include: General Thoracic Surgery, Adult Cardiac Surgery, Pediatric Cardiac Surgery, Cardiac Transplantation, Lung Transplantation, and Aortic and Vascular Surgery.

Once the article selected for discussion is published in the online version of *The Annals*, we will post a notice on the CTSNet home page (<http://www.ctsnet.org>) with a FREE LINK to the full-text article. Readers wishing to comment can post their own commentary in the discussion forum for that article, which will be informally moderated by *The Annals* Internet Editor. We encourage all surgeons to participate in this interesting exchange and to avail themselves of the other valuable features of the CTSNet Discussion Forum and Web site.

For January, the article chosen for discussion under the Adult Cardiac Dilemma Section of the Discussion forum is:

Is Extracorporeal Life Support Contraindicated in Elderly Patients?

Shunsuke Saito, MD, Takeshi Nakatani, MD, Junjiro Kobayashi, MD, Osamu Tagusari, MD, Ko Bando, MD, Kazuo Niwaya, MD, Hiroyuki Nakajima, MD, Shunichi Miyazaki, MD, Toshikatsu Yagihara, MD, and Soichiro Kitamura, MD

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Multicentered European Study on Safety and Effectiveness of the On-X Prosthetic Heart Valve: Intermediate Follow-Up

George M. Palatianos, Axel M. Laczkovics, Paul Simon, Jose Luis Pomar, Dietrich E. Birnbaum, Hans H. Greve and Axel Haverich

Ann Thorac Surg 2007;83:40-46

DOI: 10.1016/j.athoracsur.2006.08.010

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