Three Years' Experience with the On-X Conform-X Bileaflet Prosthesis for 'Atrialized' Mitral Valve Replacement: A Preliminary Report

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Background and aim of the study: **Positioning of a mechanical prosthesis outside the native annulus facilitates mitral valve replacement, especially when the annulus is small and calcified, and preservation of the posterior leaflet (PML) is desired. Herein is described the authors' initial experience with a new mechanical bileaflet prosthesis comprising a sheltered leaflet housing and a novel, modified asymmetrical sewing ring for an 'atrialized' implantation technique.**

Methods: **Forty-seven patients (24 males, 23 females; mean age 65.8 ± 10.9 years) were operated on for isolated mitral regurgitation or combined stenosis and insufficiency. Ten of the patients underwent valve replacement due to active endocarditis. Preoperative cardiac insufficiency was reflected by a mean NYHA class of 2.6 ± 0.7. The On-X Conform-X bileaflet mitral valve prosthesis (25/33 mm) was implanted in either an epiannular (43 patients) or intra-annular (four patients) fashion, and the PML and its chordae tendineae were preservable in 33 patients (70.2%). All patients were monitored intraoperatively by transesophageal echocardiography (TEE) and postoperatively by transthoracic echocardiography (TTE).**

Results: **TEE and TTE exhibited excellent function with low mean transvalvular gradients early after surgery (4.9 ± 2.7 mmHg) and after three months (4.8 ± 1.4 mmHg). Paravalvular leakage was not detected. Initial postoperative left ventricular (LV) function was almost identical to preoperative findings (ejection fraction: preop. 55.1 ± 13.7%, early postop. 53.7 ± 13.6%) and improved slightly after three months (60.1 ± 6.4%). Clinically significant hemolysis was not apparent (LDH at postoperative day 7: 5.3 ± 0.8 µmol/l·s). Two patients died from multiorgan failure (4.2%) and four are currently in a reduced condition requiring long-term hospitalization (morbidity 8.5%). After three months all other patients were in an excellent clinical state (mean NYHA class 1.5 ± 0.6) and being followed up as outpatients.**

Conclusion: **Current designs of mechanical bileaflet valves require redundant space in the LV cavity for undisturbed leaflet movement. A small annulus, marked fibrosis and calcification of the valvular apparatus can lead to an impedance of prosthetic leaflet motion. Consequently, the native leaflets are often removed. The cylindrical housing of the On-X valve shelters almost the entire motion of the leaflets, allowing an undisturbed function and improved transvalvular flow pattern. The newly developed asymmetrical sewing ring facilitates anchoring of the ring in an 'atrialized' fashion, while the flexibility of the cuff adapts to all native ring diameters larger than 25 mm.**

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After more than 25 years of continuous development, currently available bileaflet mechanical pyrolitic valves are well-engineered, sturdy and reliable. Over 1.5 million implantations worldwide, which exhibit very few valve-related complications, indicate the efficacy of mechanical valve replacement with these devices. In the mitral position, implantation modalities have been adjusted towards the preservation of one or both leaflets in order to maintain the geometry of the left ventricle, thereby providing better long-term function (1). However, degenerative disease often exhibits severe calcifications of the annulus, which may force the surgeon to remove the leaflets and the chordae tendineae to gain space for a correct and undisturbed implantation (2). An 'atrialized' implantation of the mechanical valve has therefore been advocated to preserve the supporting apparatus of the valve while avoiding impedance of the motion of the prosthesis'

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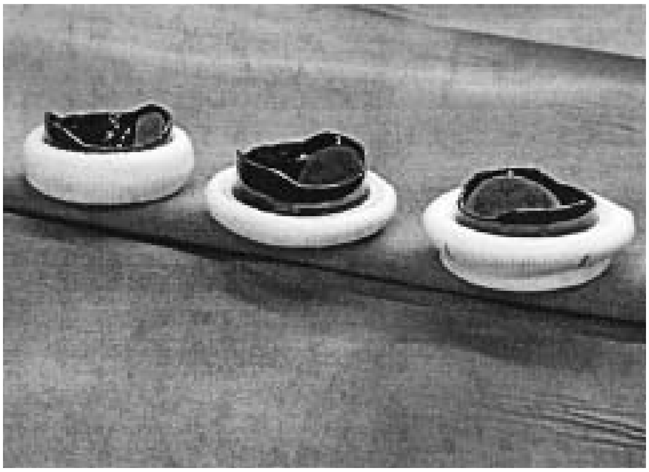

Figure 1: Development of the sewing ring of the On-X mitral valve. Left: Original design, with a sewing ring adopted from the aortic valve. Center: Intermediate design, showing a 'hand-made' asymmetrical sewing ring. Right: Current design manufactured with an asymmetrical, large sewing ring.

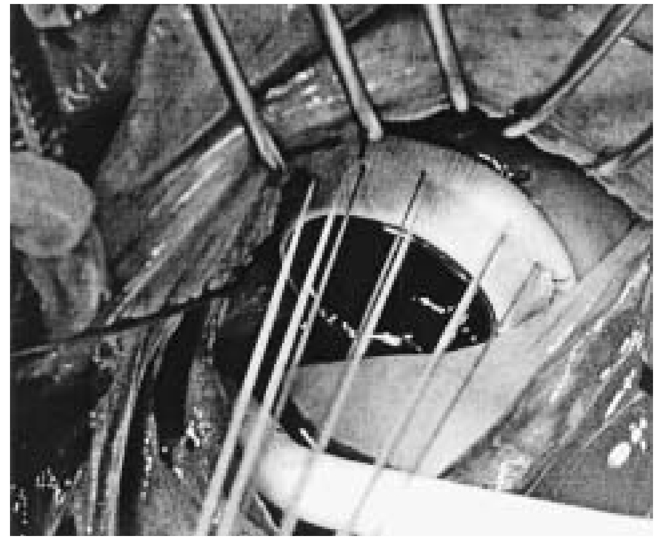

Figure 2: The 'atrialized' implantation technique of the On-X Conform-X mitral valve. Routine suture placement in an epiannular fashion with interrupted Teflon pledget reinforced mattress sutures (2/0 braided synthetic material).

leaflets (1,2). This can be accomplished with a valve design comprising a sewing ring, which alleviates an atrialized fixation. For this purpose, the On-X bileaflet prosthesis, which comprises a cylindrical housing, has been modified with a flexible, asymmetrical sewing ring and implanted in a first clinical series.

Clinical material and methods

Patients

Between January 2002 and December 2004, 47 patients were operated on for mitral valve disease with or without concomitant conditions at the authors' institutions. Thirty-one patients exhibited a preoperative NYHA class III or more, while 16 were operated on under recompensated conditions of NYHA class II (mean NYHA class 2.6 ± 0.7). Twenty-three patients underwent isolated mitral valve replacement (MVR), while the remaining 24 underwent MVR in combination with various procedures (Table I). Ten patients were operated upon due to active endocarditis. Echocardiography was performed preoperatively in all patients.

Development of the valve design

The On-X valve is based on the current bileaflet valve technology implemented in a cylindrical housing. In the initial phase, the sewing ring design of the aortic valve was used also for the first mitral valve design. This particular sewing ring, however, appeared to be rather non-adaptive to variances of the native mitral valve annulus. In order to facilitate an 'atrialized' implantation, a sewing ring modification was performed. This preliminary design comprised a first step towards an asymmetrical positioning as well as a more flexible cuff. In the final manufacturing process the sewing ring was further enlarged, internally reinforced and positioned entirely asymmetrical to optimize handling, circumference adaptation and atrialization (Fig. 1)

Operative procedure

All patients were operated upon via a median sternotomy by means of standard cardiopulmonary bypass with bicaval venous cannulation, moderate hypothermia, and retrograde cold blood cardioplegia. Access to the mitral valve was established via the interatrial groove. The anterior leaflet was entirely removed in all patients. In 13 patients the posterior leaflet was also removed due to active endocarditis (10 cases) or fibrous shrinking, whilst it was preserved in 33 patients. In five of the patients with a preserved PML a partial leaflet decalcification was performed. Implantation of the On-X Conform-X 25/33 mm valve (Medical Carbon Research Institute, LLC, Austin, Texas, USA) was performed in the majority of patients (n = 43) in an epiannular fashion with interrupted Teflon pledget reinforced mattress sutures (2/0 braided synthetic material) (Fig. 2), while an intra-annular implantation with otherwise identical material was performed in four patients. The valves were immersed in neomycin directly prior to implantation.

Table I: Demographic and operative data.

Parameter	Value
Age (years)*	65.8 ± 10.9
Gender	
Male	24 (51)
Female	23 (49)
NYHA class	
I	1 (2.1)
II	15 (32.0)
III	29 (61.7)
IV	2 (4.2)
LV function	
EF >50%	31 (66.0)
EF <30%	9 (19.1)
ECG	
Sinus rhythm	30 (63.8)
Atrial fibrillation	15 (32.0)
Other	2 (4.2)
Mitral valve lesion	
Stenosis	25 (53.0)
Regurgitation	12 (25.5)
Mixed	10 (21.2)
Comorbidity	
MI (<90 days before)	9 (19.1)
Diabetes mellitus	21 (44.6)
Renal failure (creatinine >200 µmol/l)	8 (17.0)
Chronic dialysis	2 (4.2)
Stroke history	7 (14.9)
EuroSCORE*	6 ± 3
MVR combined with CABG	12 (25.5)
AVR	7 (14.9)
ASD closure	1 (2.1)
ATT	2 (4.2)
DeVega plasty	2 (4.2)
CPB time (min)*	
MVR only	89.7 ± 25.4
Combined procedures	151.9 ± 59.1
Cross-clamp time (min)*	
MVR only	69.5 ± 15.8
Combined procedures	96.4 ± 23.6

*Values are mean ± SD.
Values in parentheses are percentages.
ASD: Atrial septal defect; ATT: Ablative thermotherapy; AVR: Aortic valve replacement; CABG: Coronary artery bypass grafting; CPB: Cardiopulmonary bypass; EF: Ejection fraction; MI: Myocardial infarction; MVR: Mitral valve replacement.

Assessment

Intraoperatively, transesophageal echocardiography (TEE) was performed to assess adequate implantation, analysis of leaflet motion, paravalvular leakage, left ventricular outflow tract (LVOT) obstruction, and peak transvalvular gradients (HP Sonos 5500; Agilent Technologies Inc., Andover, MA, USA) (Fig. 3). Intraoperatively, early postoperatively, and at three months postoperatively, LV function, valve function, paravalvular leakage and transvalvular gradients were assessed by means of transthoracic echocardiography (TTE) (HP Sonos 5500). The extent of hemolysis (serum levels of lactate dehydrogenase and conjugated bilirubin) was assessed initially and after seven days. The early and intermediate outcome and quality of life (cardiac insufficiency/NYHA class I-IV) were assessed after three months.

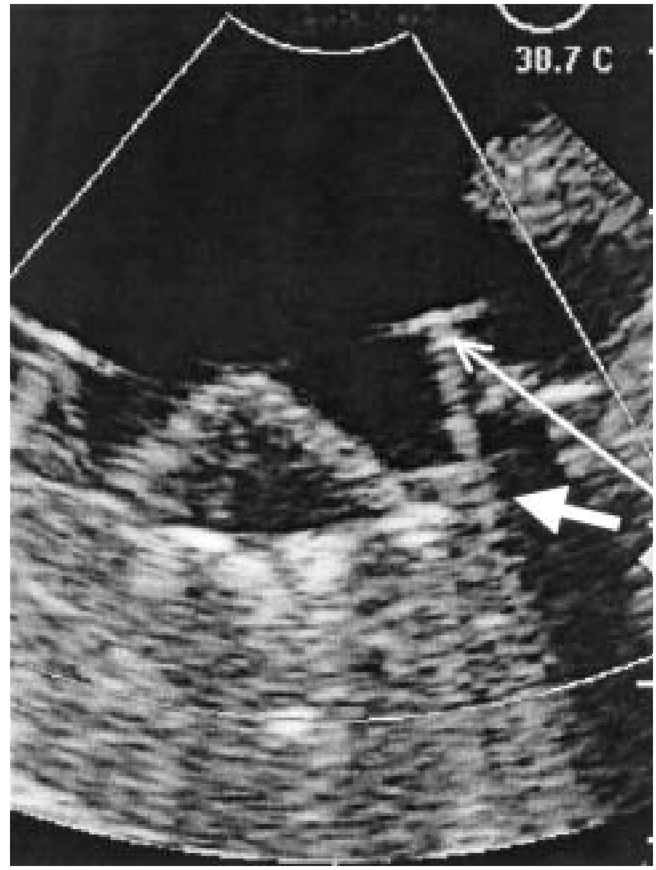

Figure 3: Intraoperative TEE showing the implanted valve with closed leaflets. Note the 'atrialized' positioning of the housing (distance between the top of the prosthesis: long thin arrow and the native annulus: short thick arrow).

Statistical analysis

All values were reported as mean ± SD. The statistical analysis comprised Student's *t*-test for parametric data and the Mann-Whitney test for non-parametric data.

Results

Intraoperative course

In all patients, correct positioning of the valve, undisturbed movement of both leaflets, absence of LVOT obstruction and absence of paravalvular leakage

Table II: Early postoperative and three-month follow up data.

Parameter	Postoperative day		After 3 months
	1	7	
Mean transvalvular gradient (mmHg)	-	4.9 ± 2.7	4.8 ± 1.4
Ejection fraction (%)	-	53.7 ± 13.6	60.1 ± 6.4
Cardiac output (l/min)*	-	5.3 ± 1.3	5.6 ± 1.7
Hemolysis			
LDH (µmol/l·s)	6.2 ± 1.4	5.3 ± 0.8	-
Bilirubin (conj.) (µmol/l)	11.8 ± 4.9	10.5 ± 2.6	-
NYHA class	-	-	1.5 ± 0.6

Values are mean ± SD.
*Cardiac output was calculated from echocardiography (= flow/time-interval over the aortic valve × aortic valve area × heart rate).
LDH: Lactate dehydrogenase.

was shown by means of TEE. In the seven individuals who underwent additional aortic valve replacement, no impedance of the implantation of the aortic valve by the ring of the mitral valve prosthesis was apparent. The mean cross-clamp time of the combined procedures was significantly longer than in the isolated MVR patients (Table I).

Postoperative course

All patients were successfully weaned from cardiopulmonary bypass after a mean reperfusion time of 48 ± 16 min, and transferred to the intensive care unit (ICU). Two patients died before postoperative day 6 as a result of multiorgan failure (4.3%); a pathological examination showed correct implantation of the valve and did not reveal any signs of incorrect function of the valve leaflets. In three patients (6.4%), temporary postoperative intra-aortic balloon pump support was required. Rethoracotomy for bleeding was required in three patients. In addition, three patients were fitted with a pacemaker postoperatively due to a persistent atrioventricular block. Minor neurological complications (transitional psychosis) were apparent in five patients (10.6%), and a major neurological complication arose in one patient. Four patients underwent a prolonged ICU stay (>7 days), and two of these required a percutaneous tracheostomy. All patients were subsequently transferred to the normal ward and discharged after 12-60 days (mean hospitalization 20.8 ± 10.9 days).

Early postoperative assessment

Directly prior to discharge, TTE showed regular valve function. The ejection fraction was almost identical to preoperative values (56.5 ± 14.1% versus 53.7 ± 13.6%). No paravalvular leakage was found. The mean transvalvular gradient was 4.9 ± 2.7 mmHg (range: 1.5 to 6.5 mmHg). At the first postoperative day, the mean LDH activity was 6.2 ± 1.4 µmol/l·s (normal range: 2 to 4 µmol/l·s), conjugated bilirubin was 11.8 ± 4.9 µmol/l (normal range: 0 to 3.4 µmol/l), while at postoperative day 7 the LDH activity was 5.3 ± 0.8 µmol/l·s and conjugated bilirubin 10.5 ± 2.6 µmol/l.

Intermediate postoperative assessment

Four of the surviving patients required long-term hospitalization due to a poor clinical condition (8.5%). All other patients were discharged in good condition and controlled as outpatients. TTE performed after three months again showed a regular function in all cases. The mean gradient after three months remained constant when compared to the early results (4.8 ± 1.4 mmHg; range: 2.3 to 6.9 mmHg). The ejection fraction was slightly, though not significantly, improved (60.1 ± 6.4%) compared to early postoperative values. All but one of the discharged patients showed a significant clinical improvement of their clinical situation. The preoperative mean NYHA class was significantly improved after three months ($p = 0.03$) (Table II).

Discussion

As early as 1964, Lillehei et al. reported on the preservation of one or both leaflets of the native mitral valve during replacement with a mechanical prosthesis (3). Although the subject was subsequently neglected for over a decade, it was revived by Hetzer et al. in 1979 (4). Interestingly, leaflet and chordae preservation was initially thought to be mainly necessary in order to avoid ventricular rupture (5). However, subsequent clinical studies exhibited an improved left ventricular function in patients, in whom the entire valvular apparatus had been preserved (6-11). Several studies have focused on the impact of the annular-papillary continuity on left ventricular performance, showing that indeed the entire apparatus of valve, chordae tendineae and papillary muscles are integral components of the physical properties of the left ventricle (7,11,12). Recent clinical studies have provided evidence that, preferably, the posterior leaflet should be spared, thereby allowing for an improved long-term outcome (11,13-16), whereas preservation of the anterior leaflet may cause undesired sequelae such as intraprosthetic regurgitation or LVOT obstruction (17-20).

Although several measures have been initiated to overcome the obviously narrow margin of redundant space for an undisturbed motion of the mechanical valve and unlimited blood flow into and out of the left ventricle, the techniques described such as partial resection of the anterior leaflet and lateralized refixation were not generally accepted (8,11,21). In the case of a markedly calcified annulus - which today is often found in degenerative mitral valve lesions - the desired preservation of the posterior leaflet is sometimes problematic because of the narrow inflow and reduced space in the left ventricular cavity. In the routine setting, the entire leaflet apparatus is therefore often removed in order to achieve the required space for implantation (15). Although the design of the mechanical valve may play an important role when overcoming these problems, this has - surprisingly - barely been taken into account in current valve developments.

Whereas much effort has been applied to the artificial structures of the prosthesis itself in terms of wear, pivotal movement, proper washout, and enhanced inner diameter (22,23), little has been undertaken to avoid the disturbance of mechanical leaflet motion in a narrow cavity. That problem, however, can be solved by means of a cylindrical housing serving as a cage in order to avoid any contact with the edges of the leaflets or to diminish material prolapse into the valve's orifice. Decades after the introduction of the Starr-Edwards ball-in-cage valve and its successors (which do have such properties), the 'sheltered housing' concept has only in part been realized so far by the CarboMedics valve design, whereas it is completely absent in the St. Jude Medical (SJM) valve structure (22,23). Another concept comprises placement of the major components of the mechanical prosthesis outside the calcified and rigid native valve ring in order to preserve the scarce remaining space. The atrialized implantation with conventional prostheses has been exemplarily described by Yu et al. in adults (24) and by Adatia and coworkers in infants; in the latter situation this was performed in order to implant the largest possible valve (25). A valve design which alleviates supra-annular implantation has been realized with the CarboMedics 'Top Hat' prosthesis, which has an asymmetrical sewing ring attached to the outflow edge of the valve, allowing for an entirely supra-annular positioning (26). This particular valve, however, is only available for the aortic position.

In the present study, attention was focused on these aspects, and one of the latest developments of pyrolitic bileaflet prostheses has been implanted. The new design (On-X Conform-X valve) comprises a cylindrical housing and an asymmetrical sewing ring in order to combine both advantages. Implanting the valve outside the annulus was accomplished in the large majority of the present patients, utilizing standard epiannular sutures. In contrast to an atrial placement, as described by Yu et al. (24), the pledgets can be placed in the infra-annular region. A flexible positioning can help to avoid highly calcified areas. As a consequence, the sewing ring will then fit onto the annular tissue while parts of the housing of the prosthesis can pass the annulus. Since the outer diameter of the housing is 27 mm it will fit into the majority of orifices, whereas the bulky but pliable sewing ring adapts to a variety of larger annulus diameters.

In patients requiring combined aortic and mitral valve replacement, atrialized implantation may be advantageous since the rim of the prosthesis does not interfere with the rim of the aortic valve prosthesis, thus allowing for implantation of a larger aortic valve. Current bileaflet mitral valves are generally sized from 23 to 33 mm. However, the inner diameter does not exceed 24.2 mm in the CarboMedics valve and 26 mm in the SJM valve, while the thickness of the sewing ring defines the outer size of the larger-sized valves. The excellent flow characteristics of the On-X valve with an inner diameter of 25 mm have already been described by Fraund et al. (27). In order to simplify its use, the new On-X Conform-X prosthesis was therefore produced with only two sizes of inner diameter, but was provided with the described novel sewing ring. This large sewing ring facilitates variability of suture placement so that the 25/33 mm size fits almost all patients, though for very small individuals a 21/25 On-X valve is available.

In the present study it was possible to implant the 25/33 mm valve in all adult patients - even those with a small body surface area. The valves functioned correctly in all patients of this non-selected cohort exhibiting significant comorbidities, and no valve-related problems were seen. Moreover, the mean gradients were within the well-known range as achieved also by other modern bileaflet prostheses (22,23). The valve is constructed from the same pyrolitic carbon material as the CarboMedics and SJM valves, and the pivots operate in a comparable manner to the aforementioned devices. The intermediate functional as well as clinical results were excellent. Although long-term clinical results are not yet at hand, the present authors believe that the long-term performance will be comparable with that of other valves, especially since the mechanical components are identical to those of the previous On-X valve, which exhibited clinical findings consistent with other valves (27).

In conclusion, it was shown that the implemented features of the On-X Conform-X mitral valve facilitate an 'atrialized' implantation, even in non-selected patients. These early results indicate that the valve is a safe and efficient prosthesis, which can be recommended for routine replacement procedures.

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