Clinical Update Number Forty-Two

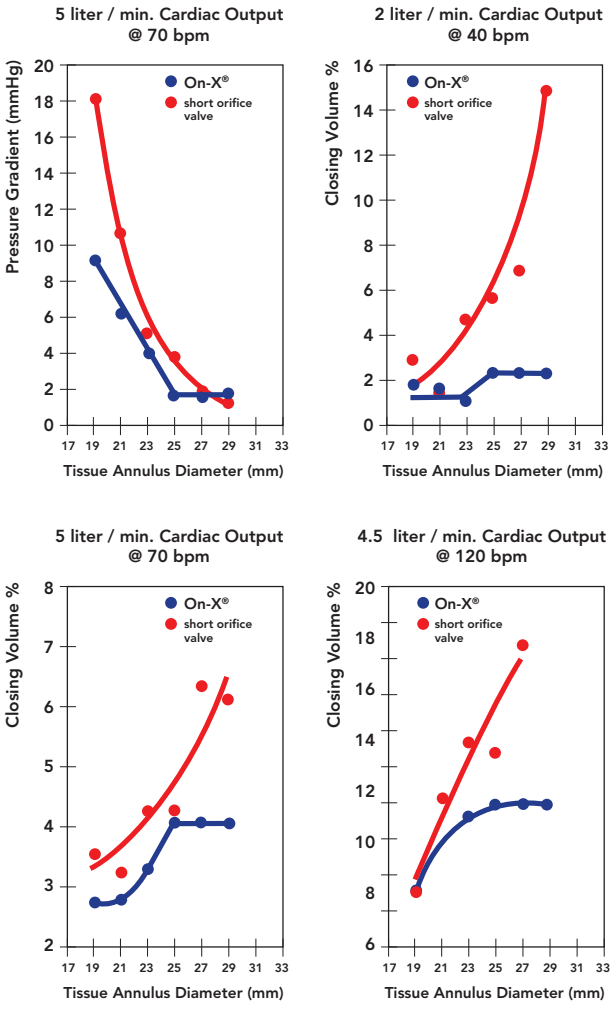
Optimal flow in a mitral valve

Less mismatch with the On-X mitral valve proves that optimal flow is achieved at a smaller nominal size.[1]

The On-X valves were designed to be less turbulent

Low complication rates, less blood destruction and low gradients provide compelling evidence that an inlet flare, near natural valve length and 90° leaflet opening angle provide less turbulence even in larger sized On-X mitral valves. Determining optimal size without gaining increased closing (or trapped) volume was taken into consideration in developing the On-X valves. As you can see in Figure 1, regurgitant closing volume increases greatly for large sizes of a short orifice valve at all heart rates—an undesirable effect.

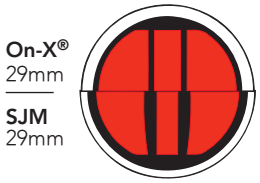
Figure 1. Optimum Geometric Orifice Area (GOA)[2]



Larger geometric orifice areas (GOA's) with leaflets in place for the On-X valve

Sizing designations for mechanical valve orifices have not been standardized and have been confusing for the cardiovascular surgical community. A comparison of valve geometric orifice areas listed in the data provided to the United States Food and Drug Administration (US FDA) shows that only one valve manufacturer makes a larger mitral valve orifice than the On-X valve mitral and aortic orifice 25 (Figure 2).[3-7]

Figure 2. Comparison of Geometric Orifice Areas with Leaflets in Place[3-7]



TAD (mm)	On-X	SJM	CMI	ATS
23	3.13	2.09	1.82	1.60
25	3.73	2.54	2.28	1.94
27	3.73	3.12	2.82	2.30
29	3.73	3.64	3.33	2.70
31	3.73	4.25	3.33	3.08
33	3.73	4.25	3.33	3.08

SJM = St. Jude valve; CMI = CarboMedics valve;
ATS = ATS valve; TAD = tissue annulus diameter

Greater effective orifice area (EOA) and less mismatch

A Canadian study shows less mismatch for the On-X mitral valve overall compared with other valves (Table 1).[1] Figures 3-5 show that even though other valve brands increase the GOA for each size, the gradient and EOA values for all large sized valves are essentially the same.[8-11] Therefore, increasing GOA beyond optimal flow does not make sense when increased turbulence, blood destruction and noise are a concern. Replacement of mitral regurgitation or stenosis with a prosthetic that has a large trapped volume and a limited EOA is essentially implanting regurgitant disease.

Table 1. Mitral Valve Comparison[1]

Valve Brand	Number of patients	EOA	IEOA
On-X	85	2.4	1.3
SJM	209	2.2	1.28
CMI	121	2.3	1.26

SJM = St. Jude valve; CMI = CarboMedics valve;
IEOA= indexed effective orifice area

On-X heart valves
product group of On-X Life Technologies, Inc.™

Figure 3. Geometric Orifice Area Comparison

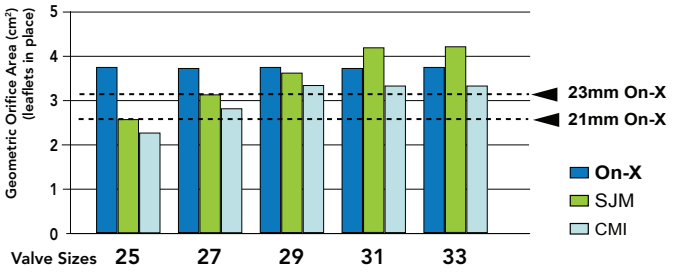


Figure 4. Mitral Effective Orifice Area Comparison

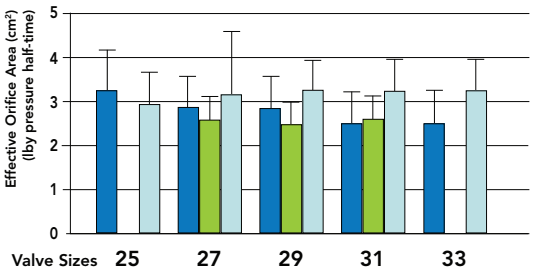
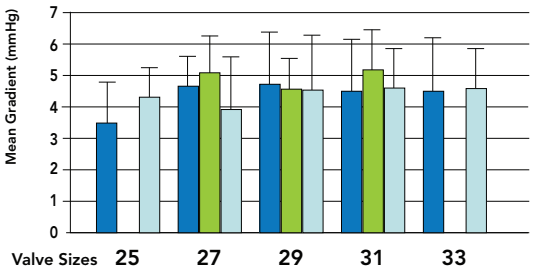


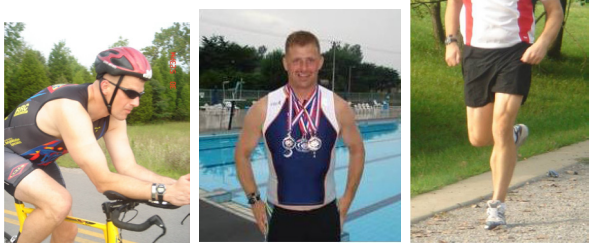
Figure 5. Mitral Mean Gradient Comparison



Iron man competition for an On-X mitral valve

This optimal flow has been proven to be effective even in a 6'5", 230 pound man who completed a triathlon 10 months after his implant surgery and continues to propel him through more rigorous exercises like the half iron man competiton.

Figure 4. Patient with On-X mitral valve



Lowest mitral complication rates for the On-X valve

In recent trials for FDA approval, the On-X valve showed the lowest overall mitral complication and mortality rates (Table 2). These low rates and reduced LDH levels are evidence of lower turbulence for the On-X valve.[3-7,13]

Table 2. Comparison of Mitral Hematological Clinical Event Rates [4,6,7,12]

Clinical Event	On-X (FDA)	On-X 12 year	ATS	CMI
Thromboembolism	1.7	0.9	4.0	2.8
Thrombosis	0	0.1	0.5	0.7
Hemorrhage	1.4	1.0	0.5	2.1
Mortality	2.2	2.0	3.5	4.4
Composite	3.1	2.0	5.0	5.6

ATS = ATS valve, CMI = CarboMedics valve

Less mismatch, lower complication and mortality rates, less closing regurgitation and low blood destruction all prove that the On-X mitral valve is the right one for your mechanical valve patients.

References

1. Lam BK, Chan V, Hendry P, et al. The impact of patient–prosthesis mismatch on late outcomes after mitral valve replacement. J Thorac Cardiovasc Surg 2007;133:1464-73
2. Wu ZJ, Gao BZ, Slonin JH, Hwang NHC. Bileaflet mechanical heart valves at low cardiac output. J ASAIO 1996;42:M747
3. Some values calculated at On-X Life Technologies, Inc. from base data provided by approval submissions.
4. On-X® Prosthetic Heart Valve. Summary of Safety and Effectiveness Data submitted to the United States Food and Drug Administration. PMA P000037. Approval date May 30, 2001 and March 6, 2002
5. SJM Regent® Valve. Clinical Study Summary (package insert)
6. CarboMedics® Prosthetic Heart Valve. Summary of Safety and Effectiveness Data submitted to the United States Food and Drug Administration. PMA P900060. Approval date April 13, 1993
7. ATS Open Pivot® Bileaflet Heart Valve. Summary of Safety and Effectiveness Data submitted to the United States Food and Drug Administration. PMA P990046. Approval date October 13, 20001.
8. Chambers J, Laczkovics A, Greve H, et al. Early postoperative echocardiographic hemodynamic performance of the On-X® prosthetic heart valve - a multi-center study. J Heart Valve Dis 1998;7(5):569-73
9. 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
10. Aoyagi S, Yasunaga H, Sato T, et al. Doppler echocardiographic evaluation of the St. Jude Medical valve. Artif Organs Today 1995;5(1):49-56
11. Messner-Pellec P, Wittenberg O, Leclercrcq F, et al. Doppler echocardiographic evaluation of the Omnicarbon cardiac valve prostheses. J Cardiovasc Surg 1993;34:195-202
12. Chambers JB, Pomar JL, Mestres CA, Palatianos GM. Clinical event rates with the On-X bileaflet mechanical heart valve: A multicenter experience with follow-up to 12 years. J Thorac Cardiovasc Surg 2012. Article in press. Available online February 2012 (6 pages)
13. Birnbaum D, Laczkovics A, Heidt M, et al. Examination of hemolytic potential with the On-X® Prosthetic Heart Valve. J Heart Valve Dis 2000;9:142-45

On-X aortic and mitral valves are FDA approved.

Headquarters and Manufacturing Facilities:

1300 East Anderson Lane, Building B
Austin, Texas 78752 U.S.A.
Telephone: (512) 339-8000
Facsimile: (512) 339-3636
www.onxlti.com
onx@onxlti.com

On-X life technologies, inc.™
designed for life