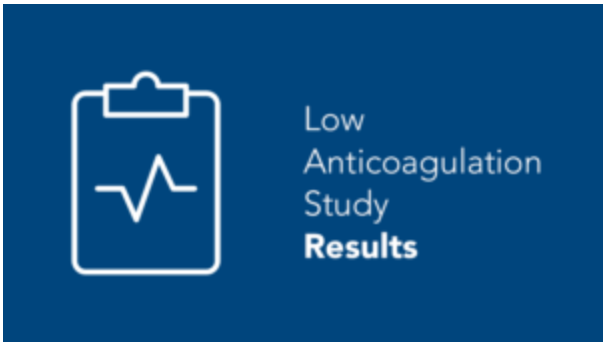
Onx Low Anticoagulation Study Results



2001 US FDA approves On-X Aortic Valve

2002 US FDA approves On-X Mitral Valve

2006 US FDA approves IDE lowered anticoagulation clinical for the On-X heart valve. Prospective Randomized On-X Valve Anticoagulation Clinical Trial (PROACT) is initiated.

2009 Enrollment complete in the high-risk aortic patient group of the Prospective Randomized On-X Valve Anticoagulation Clinical Trial (PROACT).

2011 US FDA approves On-X Ascending Aortic Prosthesis

2013 US FDA approves Chord-X™ ePTFE suture for mitral valve repair and replacement

2013 US FDA approves On-X aortic heart valve with anatomic sewing cuff

2013 Enrollment complete in the low-risk aortic patient group and the mitral patient group of the Prospective Randomized On-X Valve Anticoagulation Clinical Trial (PROACT)

2015 US FDA approves On-X aortic heart valves with INR 1.5–2.0 after 3 months standard anticoagulation, based on results from the high risk AVR group of the Prospective Randomized On-X Valve Anticoagulation Clinical Trial (PROACT)

FDA Clinical Results

Hemolysis

Postoperative serum lactate dehydrogenase (SLDH) levels are in the normal range, indicating minimal hemolysis[8].

	Upper normal = 250		
Valve	**3-6 Months**	**1 Year**	**2 Years**
Aortic	222	225	229
Mitral	262	253	261
Double	238	246	243

Morbid Event Rates

FDA clinical trials for the On-X valve produced the lowest morbid event rates of all carbon valves. The following tables compare On-X clinical data with those of other valves.

On-X Morbid Event Rates Comparison – Aortic Position (% per pt-year)

Event	On-X[1]	SJM[2]	CMI[3]	ATS[4]	MH[2]
Thromboembolism	1.03	1.71	1.11	2.08	1.50
Thrombosis	0	0.19	0.03	0.00	0.20
Hemorrhage	0.59	2.00	1.82	1.96	0.80
Totals	1.62	3.90	2.96	4.04	2.50

On-X Morbid Event Rates Comparison – Mitral Position (% per pt-year)

Event	On-X[1]	SJM[2]	CMI[3]	ATS[4]	MH[2]
Thromboembolism	1.00	1.86	2.05	4.00	2.00
Thrombosis	0	0.14	0.47	0.53	0.40
Hemorrhage	0.50	1.34	1.92	0.53	1.90
Totals	1.50	3.34	4.44	5.07	4.30

Comparison On-X Morbid Event Rates – On-X Aortic vs. Tissue Aortic (% per pt-year)

Event	On-X[1] N=184 (2.8) 514**	SJM[2] N=577 (2.0) 1325**	CMI[3] N=868 (1.4) 1241**	ATS[4] N=267 (9.1) 2335**
Structural Dysfunction	0.0	0.0	0.0	2.0
Valve-Related Death	0.2	0.5	1.3	1.6
Thromboembolism	1.0	1.5	2.1	1.6
Totals	1.8	2.3	4.0	5.6

* Combined subcoronary, full root and root inclusion.
** Number of patients (average follow-up years) total patient years.

References

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2. Weighted averages calculated from references listed in the On-X Experience, Volume 2, Issue 1, Sept. 2000. (PDF)
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5. Summary of Safety and Effectiveness, St. Jude Medical Toronto SPV® Valve, Food and Drug Administration PMA P970030, November 26, 1997.
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8. Birnbaum D., Laczkovics A, Heidt M, Oelert H, Laufer G, Greve H, Pomar JL, Mohr F, Haverich A, Regensburger D., Examination of hemolytic potential with the On-X® prosthetic heart valve. J Heart Valve Dis. 2000; 9(1):142-5.