

Excerpt from:

Comparative Hydrodynamic Evaluation of Bioprosthetic Heart Valves

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Study Objective: To compare in-vitro hydrodynamic performance of commercially available bioprosthetic heart valves under identical test conditions.

Methods: In-vitro steady forward flow and pulsatile flow tests were performed on aortic and mitral bioprosthetic valves in accordance with ISO/FDA guidelines) at two different institutions to obtain objective hemodynamic performance measures. Measurements were recorded at various flow rates, flow and pressure to obtain mean pressure gradients and effective orifice areas.

Table 1. Summary of valves tested

Valve Type	Distributor	Material
PERIMOUNT	Edwards Lifesciences	Pericardial
SAV	Edwards Lifesciences	Porcine
Mitroflow-12	Sulzer-Carbomedics	Pericardial
Intact	Medtronic	Porcine
Hancock II	Medtronic	Porcine
Mosaic	Medtronic	Porcine
Biocor	St. Jude Medical	Porcine
Biocor (peri)	St. Jude Medical	Pericardial
Prima Plus	Edwards Lifesciences	Porcine
Toronto SPV	St. Jude Medical	Porcine
Freestyle	Medtronic	Porcine

Results

1. Pressure drop for steady forward flow

“The PERIMOUNT valve reported the lowest pressure drop in all sizes. The newer-generation porcine valves, S.A.V., Hancock II and Mosaic valves, displayed similar pressure drops, and ranked behind the pericardial valves.”

2. Pressure drop for pulsatile flow

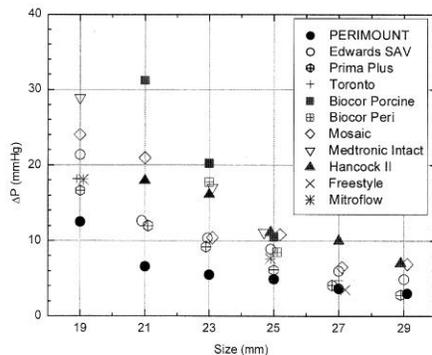


Figure 13: Comparative ΔP for all aortic stented valves at cardiac output 5 l/min.

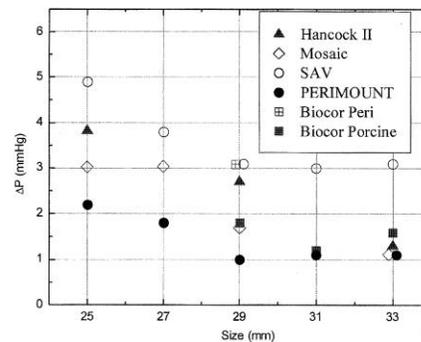


Figure 14: Comparative ΔP for all mitral stented valves at cardiac output 5 l/min.

3. Effective orifice area

Average effective orifice area (cm^2) at 3-7 l/min cardiac outputs
(data represented from Table IV)

Valve Type	Aortic valve size						Mitral valve size				
	19	21	23	25	27	29	25	27	29	31	33
PERIMOUNT	1.22	1.82	1.96	2.12	2.38	2.66	1.76	1.92	2.70	2.76	2.80
SAV	1.06	1.40	1.46	1.52	1.88	2.18	1.20	1.32	1.56	1.58	1.60
Mitroflow-12	1.18	-	-	1.94	-	-	-	-	-	-	-
Intact	0.87	-	-	1.53	-	-	-	-	-	-	-
Hancock II	-	1.20	1.25	1.49	1.52	1.83	1.30	-	1.67	-	2.07
Mosaic	1.02	1.13	1.56	1.50	1.97	2.22	1.58	1.46	2.08	2.60	2.49
Biocor	-	-	1.19	1.57	-	-	-	-	1.96	-	2.04
Biocor (peri)	-	0.90	1.07	1.53	-	-	-	-	1.48	2.53	-
Prima Plus	1.20	1.40	1.55	2.00	2.40	2.93	-: Not tested				
Toronto SPV	1.18	-	-	2.12	2.30	-					
Freestyle	-	-	-	-	2.90	-					

“The EOA for PERIMOUNT valve was the largest among all stented valves, ...”

Conclusions

“The Carpentier-Edwards PERIMOUNT valve showed superior performance at all sizes tested.”

“The testing of valves under identical conditions is a valuable comparative indicator of valve hemodynamic performance.”

See package insert for the Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis for full prescribing information, a copy of which may be obtained by calling the Cardiovascular Surgery Marketing Department at 949-250-2700.

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