

Indexed Effective Orifice Area

Evaluation of Bovine Pericardium Bioprostheses



PATIENT-PROSTHESIS MISMATCH (PPM):

"Mismatch can be considered to be present when the effective prosthetic valve area, after insertion into the patient, is less than that of a normal human valve".¹

HOW CAN I IDENTIFY AND DEFINE THE PPM?

A smaller effective orifice area (EOA) than expected in relation to the patient's body surface area (BSA) will result in higher transvalvar gradients. Therefore, the parameter used to characterize PPM is the indexed EOA (EOAi) - that is, the EOA of the prosthesis divided by the patient's BSA.²

$$EOAi = \frac{EOA}{BSA}$$

PPM is present when the EOA of the inserted prosthetic valve is too small relative to BSA.³⁻⁸

HOW CAN I AVOID THE PPM?

AORTIC VALVE

PPM can be prospectively avoided by selecting an aortic prosthesis with:

- An EOAI > 0.85 cm²/m² (indicated in **green**) on the Table 1.
- Values between 0.65 and 0.85 cm²/m² (indicated in **orange**) represents borderline PPM.
- An EOAI ≤ 0.65 cm²/m² (shown in **red**) indicates PPM and should be avoided.⁷⁻¹⁰

Table 1. In vitro indexed effective orifice area (EOAi) values of aortic bovine pericardium bioprostheses.

Valve size (mm)	17	19	21	23	25	27	29	
EOA (cm ²)	1.09	1.45	2.01	2.34	2.88	3.25	3.26	
BSA (m ²)	1.0	1.09	1.45	2.01	2.34	2.88	3.25	3.26
	1.1	0.99	1.32	1.83	2.13	2.62	2.95	2.96
	1.2	0.91	1.21	1.68	1.95	2.40	2.71	2.72
	1.3	0.84	1.12	1.55	1.80	2.22	2.50	2.51
	1.4	0.78	1.04	1.44	1.67	2.06	2.32	2.33
	1.5	0.73	0.97	1.34	1.56	1.92	2.17	2.17
	1.6	0.68	0.91	1.26	1.46	1.80	2.03	2.04
	1.7	0.64	0.85	1.18	1.38	1.69	1.91	1.92
	1.8	0.61	0.81	1.12	1.30	1.60	1.81	1.81
	1.9	0.57	0.76	1.06	1.23	1.52	1.71	1.72
	2.0	0.55	0.73	1.01	1.17	1.44	1.63	1.63
	2.1	0.52	0.69	0.96	1.11	1.37	1.55	1.55
	2.2	0.50	0.66	0.91	1.06	1.31	1.48	1.48
	2.3	0.47	0.63	0.87	1.02	1.25	1.41	1.42
	2.4	0.45	0.60	0.84	0.98	1.20	1.35	1.36
	2.5	0.44	0.58	0.80	0.94	1.15	1.30	1.30

EOA = effective orifice area; BSA = body surface area.

Methodology: ISO 5840-2 (F.4: Pulsatile-flow testing).

EOAI > 0.85 cm²/m² (No PPM)

0.65 cm²/m² < EOAI ≤ 0.85 cm²/m² (Borderline PPM)

EOAI ≤ 0.65 cm²/m² (PPM)

MITRAL VALVE

PPM can be prospectively avoided by selecting a mitral prosthesis with:

- An EOAI > 1.2 cm²/m² (indicated in **green**) on the Table 2.
- An EOAI ≤ 1.2 cm²/m² indicates PPM (shown in **red**) and should be avoided.^{4,11}

Valve size (mm)	25	27	29	31	33	35	
EOA (cm ²)	2.79	2.93	3.56	3.84	4.13	4.48	
BSA (m ²)	1.0	2.79	2.93	3.56	3.84	4.13	4.48
	1.1	2.54	2.66	3.24	3.49	3.75	4.07
	1.2	2.33	2.44	2.97	3.20	3.44	3.73
	1.3	2.15	2.25	2.74	2.95	3.18	3.45
	1.4	1.99	2.09	2.54	2.74	2.95	3.20
	1.5	1.86	1.95	2.37	2.56	2.75	2.99
	1.6	1.74	1.83	2.23	2.40	2.58	2.80
	1.7	1.64	1.72	2.09	2.26	2.43	2.64
	1.8	1.55	1.63	1.98	2.13	2.29	2.49
	1.9	1.47	1.54	1.87	2.02	2.17	2.36
	2.0	1.40	1.47	1.78	1.92	2.07	2.24
	2.1	1.33	1.40	1.70	1.83	1.97	2.13
	2.2	1.27	1.33	1.62	1.75	1.88	2.04
2.3	1.21	1.27	1.55	1.67	1.80	1.95	
2.4	1.16	1.22	1.48	1.60	1.72	1.87	
2.5	1.12	1.17	1.42	1.54	1.65	1.79	

Table 2. In vitro indexed effective orifice area (EOAi) values of mitral bovine pericardium bioprostheses.

EOA = effective orifice area; BSA = body surface area.

Methodology: ISO 5840-2 (F.4: Pulsatile-flow testing)

EOAI > 1.2 cm²/m² (No PPM)

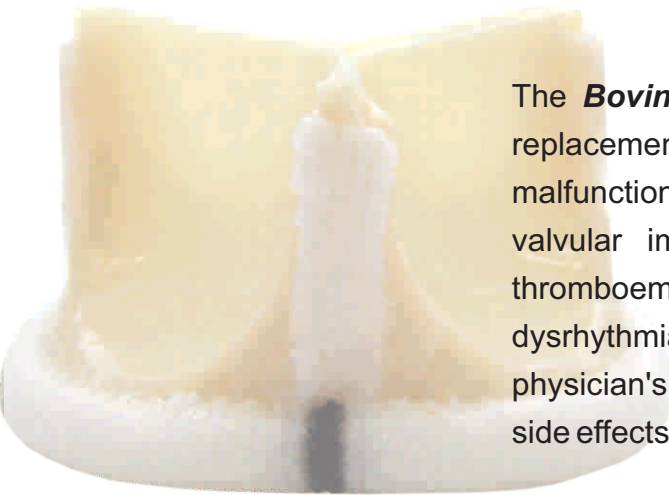
EOAI ≤ 1.2 cm²/m² (PPM)

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A photograph of a bovine pericardium bioprosthesis, showing a white, cylindrical valve structure with a central opening, mounted on a white base. The valve is shown against a blurred background of a yellowish, textured material, likely the bovine pericardium.

The ***Bovine Pericardium Bioprostheses*** are indicated for use as replacement valves in patients with a diseased, damaged, or malfunctioning native or prosthetic valve. Possible side effects for all valvular implants include, but are not limited to: regurgitation, thromboembolic phenomena, resistance to flow, infection, hemolysis, dysrhythmias, and prosthetic dehiscence or failure. Please see the physician's manual for a full description of indications, contraindications, side effects, precautions, warnings and instructions for use.