

From *Journal of Thoracic and Cardiovascular Surgery* 2004; 127(1):149-59.

“Late incidence and predictors of persistent or recurrent heart failure in patients with aortic prosthetic valves”

Ruel M, Rubens FD, Masters RG, et al. A retrospective study, 1563 patients, 6768 years of patient follow-up, mean follow-up of 4.3 years.

- Patient-prosthesis mismatch (PPM)* results in a 60% increased risk of congestive heart failure after aortic valve replacement (AVR), HR=1.61, p=.044.¹
- Redo AVR results in a 67% increased risk of congestive heart failure, HR=1.67, p=.007.¹
- High postoperative pressure gradients increase the risk of congestive heart failure.

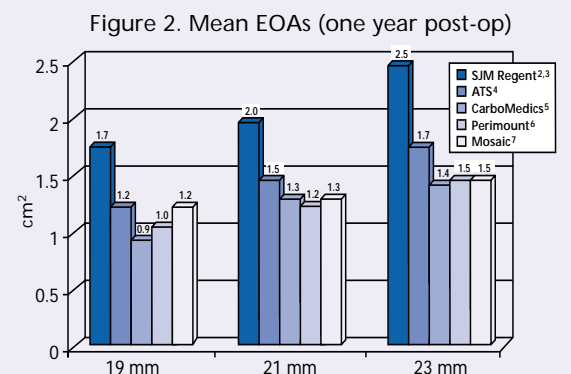
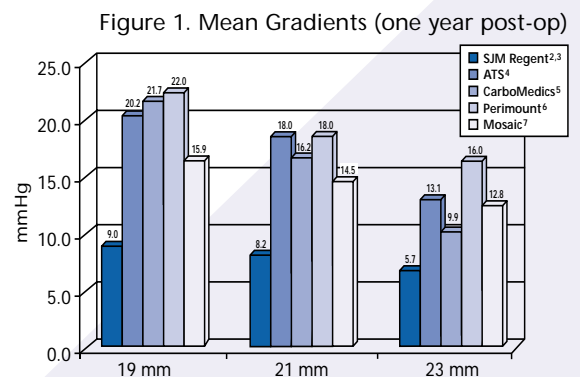
The study found that for every millimeter increase in mean pressure gradient there is a 6% increased risk of congestive heart failure after AVR, HR=1.06, p<.001!

Figure 1 compares mean pressure gradients for commonly implanted prosthetic valves.

- Small Effective Orifice Areas (EOAs) increase the risk of congestive heart failure.

The study found that for every 0.5 cm² decrease in EOA there is a 56% increased risk of congestive heart failure after AVR, HR=1.56,** p=.042.¹

Figure 2 compares EOAs for commonly implanted prosthetic valves.



The SJM Regent[®] valve delivers the largest EOAs of any prosthetic heart valve suggesting that PPM should be uncommon with this valve.^{2,8}

The prevention of PPM is possible at the time of surgery using published in-vivo Effective Orifice Areas for mechanical and tissue prostheses. For PPM reference tools including an EOA-I Pocket Guide and Operating Room Calculator, contact your St. Jude Medical representative or Customer Service at **1-800-544-1664**.

*Defined as $\leq .80$ cm²/m²

**Note: HR=.41 for 1 cm² increases in EOA, therefore, HR for 0.5 cm² decrease EOA $(\frac{1}{.41})^{1/2} = 1.56$

(HR) = Hazard Ratio

References:

- 1 Ruel M, Rubens FD, Masters RG, et al. Late incidence and predictors of persistent or recurrent heart failure in patients with aortic prosthetic valves. *J Thorac Cardiovasc Surg*. 2004 Jan;127(1):149-59.
- 2 Bach et al. Hemodynamics and early clinical performance of the St. Jude Medical Regent mechanical aortic valve. *Ann Thorac Surg* 2002;74:2003-9. N=361, Implant years: 1998-2001.
- 3 St. Jude Medical, Inc., Pre-Market Approval Application Supplement. SJM Regent heart valve, Washington D.C.; U.S. Food and Drug Administration. 2002. P810002/S57. N=160, Implant years: 1998-2001.
- 4 ATS Medical Inc., Pre-Market Approval Application-Summary of Safety and Effectiveness. Washington D.C.; U.S. Food and Drug Administration. 2000. P990046. N=685, Implant years: 1994-1999.
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- 6 Baxter Healthcare Corporation, Pre-Market Approval Application-Summary of Safety and Effectiveness. Washington D.C.; U.S. Food and Drug Administration. 1991. P860057. N=719, Implant years: 1981-1985.
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- 8 Blais C, Dumesnil JG, Baillet R, et al. Impact of valve prosthesis-patient mismatch on short-term mortality after aortic valve replacement. *Circulation*. 2003 Aug 26; 108(8): 983-8.

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