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Clinical and Hemodynamic Performance of the Sorin Mitroflow Pericardial Bioprosthesis

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1. Introduction

The Mitroflow aortic pericardial bioprosthesis has been available worldwide since 1982, except in the United States, Japan, and China. The original prosthesis was designated model 11, and the model 12, introduced in 1991, was approved in the United States in November 2007. The current model Mitroflow LX is available on the worldwide market, except for Japan and China.

The objective of this review is to document the clinical and hemodynamic performance of the Mitroflow pericardial bioprosthesis and to document the modifications of the Mitroflow LX model and the recently introduced calcium mitigation treatment of pericardial tissue.

2. Device specifications

The Mitroflow pericardial bioprosthesis has had three design changes since its introduction in 1982 (Figure 1A-J).

There are the general specifications of all three models of the prosthesis. The prosthesis is formulated with a single unit acetal homopolymer stent that provides flexibility and strength at implantation without the risk of residual distortion. The stent is low-profile to afford clearance of the coronary ostia, and to avoid interfering with the sinotubular junction in narrow aortic roots. The stent is also creep resistant. The stent is covered with surgical-grade polyester cloth and incorporates a tungsten impregnated radiopaque, medical-grade silicone sewing ring that is tiny and soft so it can be easily attached to the patient's tissue annulus. The silicone sewing ring also provides a secure hemostatic seal. The pericardium is mounted externally to maximize the flow area with wide, synchronous opening of the leaflets. The pericardium is used as a single component without critical stent-post sutures. The pericardial thickness is related to the size of the prosthesis. The pericardial tissue is selected for uniformity, and this tissue is sewn onto the external surface of the covered stent.

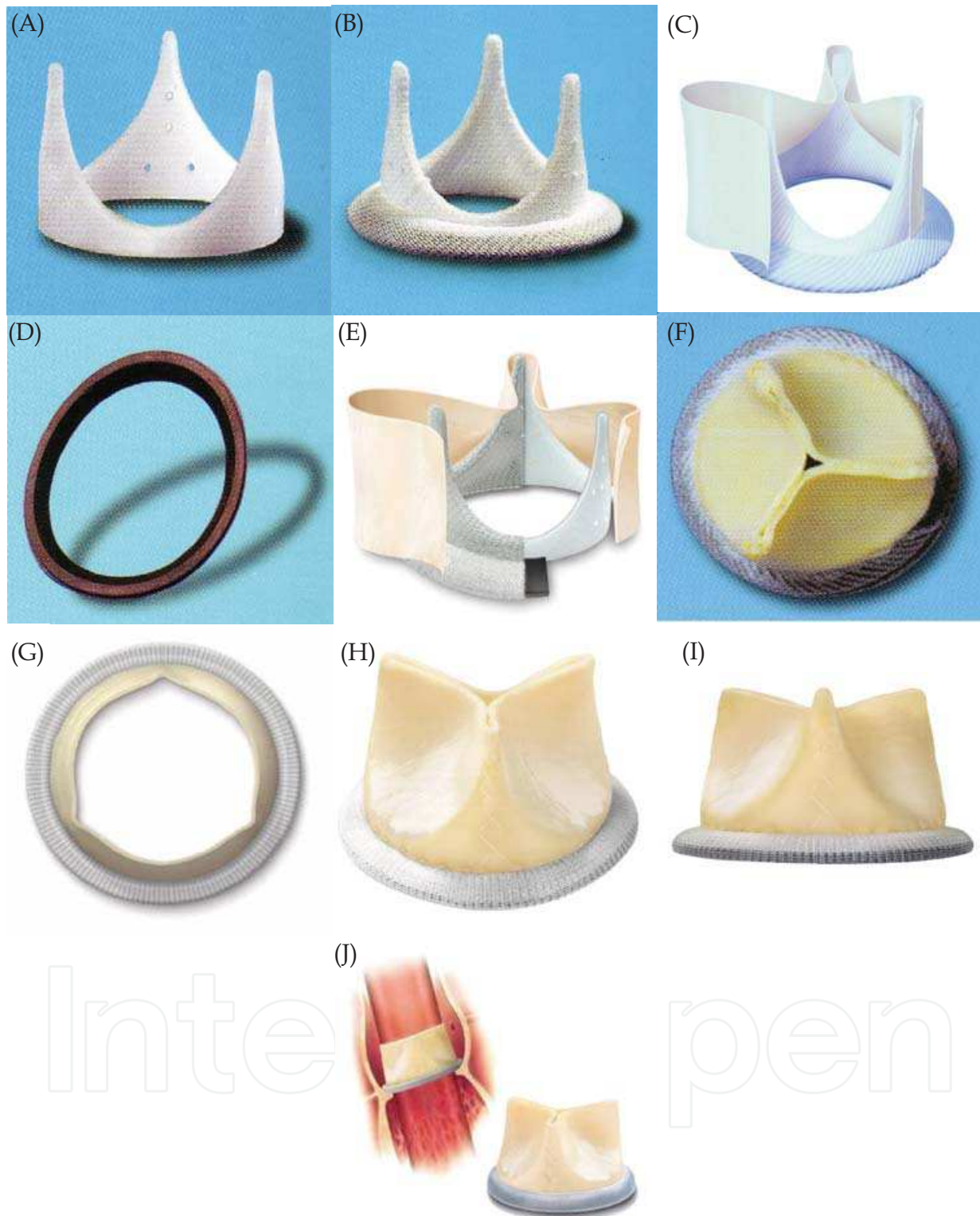


Fig. 1. (A) Acetyl homopolymer stent. (B) Stent covered polyester cloth. (C) Pericardium mounted externally. (D) Silicone sewing ring. (E) Cutaway of Prosthesis. (F) Aortic aspect of prosthesis. (G) Aortic aspect leaflets open. (H) Complete prosthesis - titled profile. (I) Complete prosthesis - lateral profile. (J) Supra-annular implantation of the prosthesis. Model 12 - B,C,F and Model LX - G,H,I

The pericardial tissue undergoes leaflet formation in the model 11 and 12 prostheses, and then fixation in 0.5% glutaraldehyde. The difference between model 11 and model 12 was that the polyester cloth was reversed so that the ribbed side was external rather than internal where there was a risk of abrasion.

The distinctive features of the initial models of the Mitroflow prostheses are inclusive in the current LX model. The design features of the various models are important when evaluating the current LX model. Model LX is a variation of model 12 with manufacturing modifications. The differences between the two models are related to manufacturing processes and minor design variations, but the material components remain the same as in model 12. The changes are these: because model LX uses automatic machine sewing instead of manual sewing for the fabric tube seam in the covered stent, there is a change in the fabric orientation of the covered stent. The number of sewing cuff base seams has been reduced to one seam. Model LX has changed tissue fixation with 0.2% glutaraldehyde of the bovine pericardium from postfixation (after stent application) to prefixation (before stent application) to facilitate tissue application on the stent. This change is from a manual leaflet formation method to an automated leaflet formation method. These manufacturing process improvements for model LX were implemented to increase manufacturing efficiencies, not to affect the design or performance of the prosthesis.

The next major change of the Mitroflow pericardial bioprosthesis is the addition of calcium mitigation therapy. Mitroflow models 11 and 12 did not have calcium mitigation therapy incorporated in the manufacturing process. The manufacturing processes are to control or reduce degeneration of biological tissue, induced by calcification, tissue stress, or both. The major contributing factors in the degeneration of biological tissue (porcine or pericardium) are considered to be residual aldehydes and the presence of phospholipids. The major manufacturers of bioprostheses have used chemical formulations to control one or both of these etiologies since the early 1980s.

The Sorin Group (Milan, Italy and Vancouver, Canada), manufacturer of the Mitroflow pericardial bioprosthesis, has recently completed an evaluation of incorporating calcium mitigation in the manufacturing process of the prosthesis and received market approval in Europe in July 2011 and subsequently in Canada. The Sorin Group has used methodology to control residual aldehydes in their other bioprostheses. This methodology is a detoxification process post-glutaraldehyde with homocysteic acid to neutralize unbound residual aldehydes. The methodology for the Mitroflow bioprosthesis is a chemical solution effective in reducing the phospholipid content of bovine pericardium (Figure 2).

The process has been named phospholipid reduction therapy (PRT), a patented chemical process that uses long-chain alcohol aqueous solutions to remove phospholipids from tissue materials. The process exposes the bovine pericardium to a buffered ethanolic solution containing long-chain aliphatic alcohol for specific times and temperatures. The PRT treatment is a sterile-filtered solution of 5% 1,2-Octanediol in ethanol and HEPES solutions. An evaluation of 5% 1,2-Octanediol in the rat subcutaneous model has revealed a very significant reduction of tissue calcium and phosphorus (Figure 2) (Pettenazzo et al., 2008). Incorporating PRT with homocysteic acid aldehyde control therapy is under consideration to control both known etiologies of tissue mineralization.

The Sorin Group (2011) has documented in their product literature the specifications and *in vitro* effective orifice areas (EOA) by valve size. The reported internal diameter/EOA for size 19 was 15.4 mm/1.7 cm²; size 21, 17.3 mm/2.1 cm²; size 23, 19.0 mm/2.8 cm²; and size 25, 21.0 mm/3.2 cm².

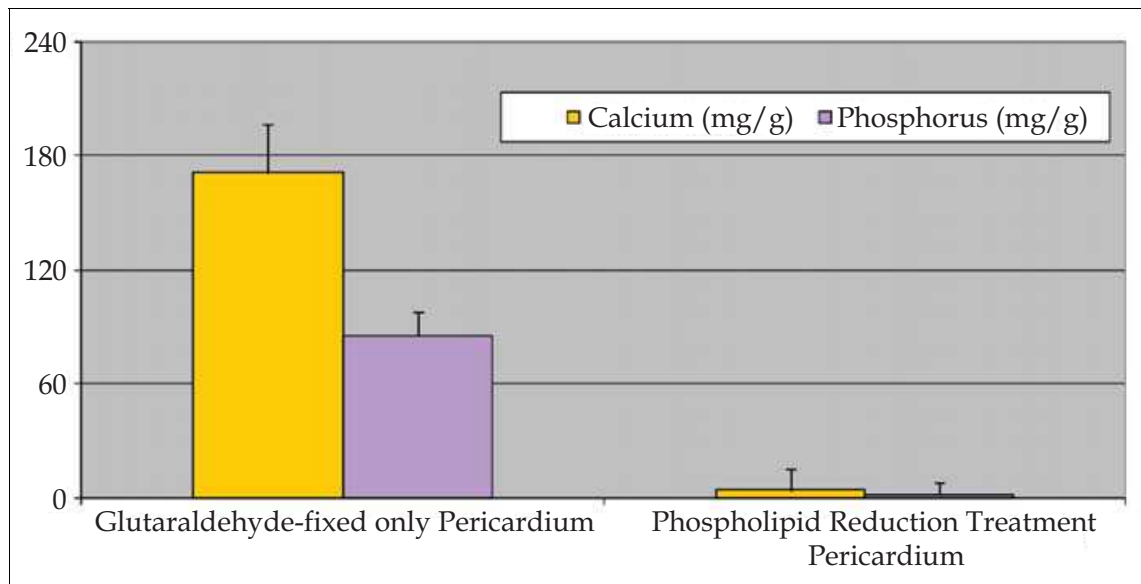


Fig. 2. Results of Phospholipid Reduction Therapy (PRT) in subcutaneous rat model Pettenazzo et al Eur J Cardiothorac Surg 2008

3. Implantation technique

The Mitroflow bioprosthesis can be implanted using either supra-annular or infra-annular techniques. The supra-annular technique is preferable to get the largest valve implanted and to optimize hemodynamic performance (Figure 1J). The supra-annular positioning facilitates a one-to-one annular match and optimal blood flow. The native annulus should be adequately debrided for placement of supra-annular suturing. Since the sewing cuff of the prosthesis is flat and non-scalloped, it may be optimal on some occasions, especially with bicuspid anatomy, to place non-pledgeted everting mattress sutures at the commissures and standard non-everting mattress sutures in the remainder of the annulus for supra-annular implantation.

4. Clinical performance

The clinical performance of the Mitroflow aortic bioprosthesis is comparable to that of other marketed porcine and pericardial bioprostheses (Jamieson, 2011).

The clinical performance of the Mitroflow pericardial bioprosthesis has been reported by several investigative groups (Table 1) (Benhameid et al., 2008; Minami et al., 2005; Yankah et al., 2008; Yankah et al., 2010; Jamieson et al., 2009; Alvarez et al., 2009; ISTHMUS investigators, 2011; Conte et al., 2010; Jamieson et al., 2009). Actuarial freedom from structural valve deterioration provides an assessment of durability while actual cumulative incidence analysis documents structural valve deterioration in patient groups, such as elderly patients, who are subject to competing risks of death. Actuarial freedom from structural valve deterioration (SVD) overestimates the incidence of SVD, while actual analysis provides the actual risk of failure in specific population groups.

Advancing life expectancy with the increased prevalence of aortic valve degenerative disease brings the need for an aortic bioprosthesis with excellent hemodynamic performance and comparable durability. The University of British Columbia and collaborating centers have

published extensively on the Mitroflow pericardial bioprosthesis model 11 (Benhameid et al., 2008) and model 12 (Yankah, 2010; ISTHMUS Investigators, 2011, Lorusso, 2011 – Personal Communication – ISTHMUS Investigators).

Author	Prosthesis	Mean Age	Age Group	Freedom from SVD (%)		Time Interval (Years)
				Actuarial	Actual	
Jamieson et al. (2009)	Mitroflow		≥60	85.2 ± 3.9*	93.3 ± 1.8*	12
			≥65	85.0 ± 4.0*	94.2 ± 1.8*	12
			61-70	95.7 ± 4.3*	97.4 ± 2.6*	10
			>70	83.2 ± 4.6*	94.0 ± 1.9*	12
Yankah et al. (2008)	Mitroflow	73.2 ± 0.22	≥65	71.8 ± 6.0*	92.6 ± 4.6*	20
			≥70	84.8 ± 0.7*	96.6 ± 0.8*	20
ISTHMUS (2010)	Mitroflow	75.3 ± 6.8	<60	54.4 ± 3.4	60.9 ± 4.3	18
			61-70	62.0 ± 2.6	68.3 ± 3.3	18
			>70	78.2 ± 2.6	89.3 ± 2.5	18
			<60	75.4 ± 2.9**	87.4 ± 2.3**	18
			61-70	87.0 ± 1.6**	92.9 ± 0.4**	18
			>70	94.6 ± 0.6**	97.1 ± 0.5**	18

* Reoperation,

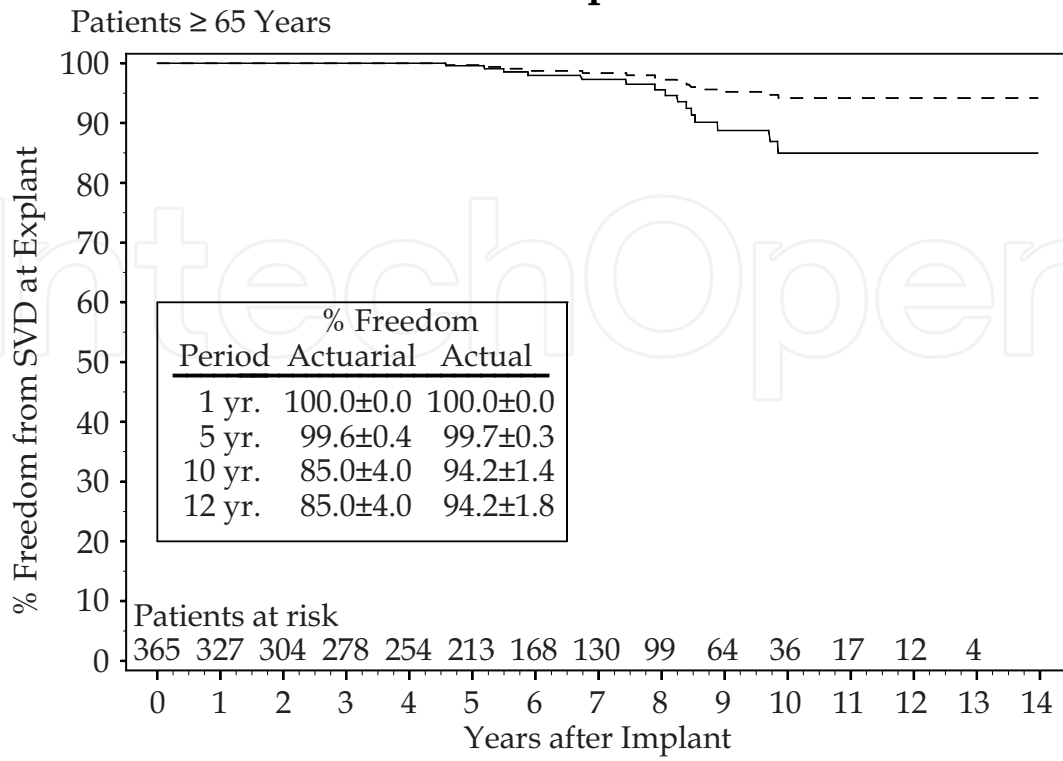
** Reoperation, Autopsy & Echocardiography (non-prospective) Lorusso – Personal Communication 2011.

Table 1. Freedom from Structural Valve Deterioration (SVD)

Benhameid et al. (2008) reported a satisfactory freedom from SVD after 15 years with model 11 for patients ≥70 years old. The majority of other publications provide information on the freedom from SVD in patient populations with model 11 (predominately) and 12 prostheses (Minami et al., 2006; Yankah et al., 2008). These reports provide support for use of the prosthesis in elderly patient populations. Yankah et al. (2008), documented in patients with predominately model 11 prostheses for 20 years, that freedom from SVD was 71.8 ± 6.0% for those ≥65 years old and 84.8 ± 0.7% for those ≥70 years old. Yankah et al. (2010) has since reported on 104 patients <60 years old (age range: 22-60 years) with a linearized rate of 1.9%/patient-year of SVD managed by reoperation with an actual risk of 12% at 10 years. Klieverik et al. (2007) concluded that the Mitroflow valve demonstrated an important complementary role to allograft and pulmonary autografts if implanted in appropriately selected patients.

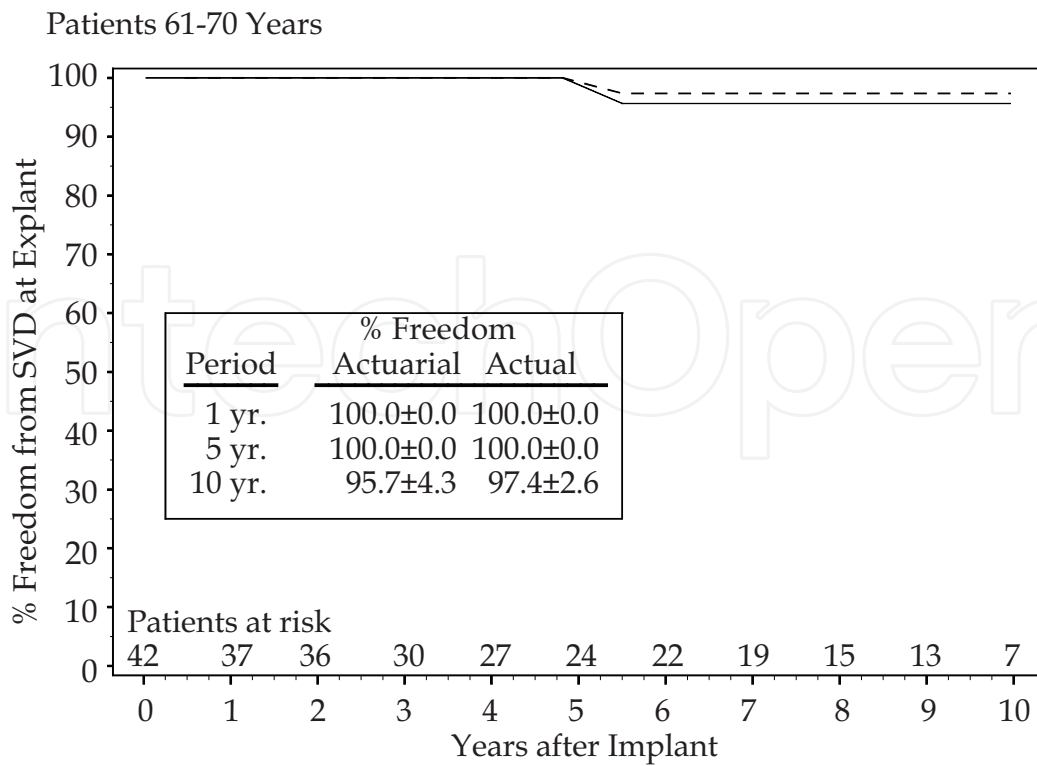
The predominant publication on Mitroflow model 12 is Jamieson et al. (2009) (Figure 3A-D). This report provides preliminary support for using the prosthesis in patients 61-70 years old, as well as in patients >70 years old. The 12-year freedom from SVD (actual/actuarial) at explant was 94.4%/85.2% for those ≥60 years old, 94.2%/85.0% for those ≥65 years old, and 94.0%/83.2% for those >70 years old. For patients 61-70 years old, at 10 years, the freedom from SVD at explant was 97.4%/95.7%.

SVD at Explant



(A)

SVD at Explant



(B)

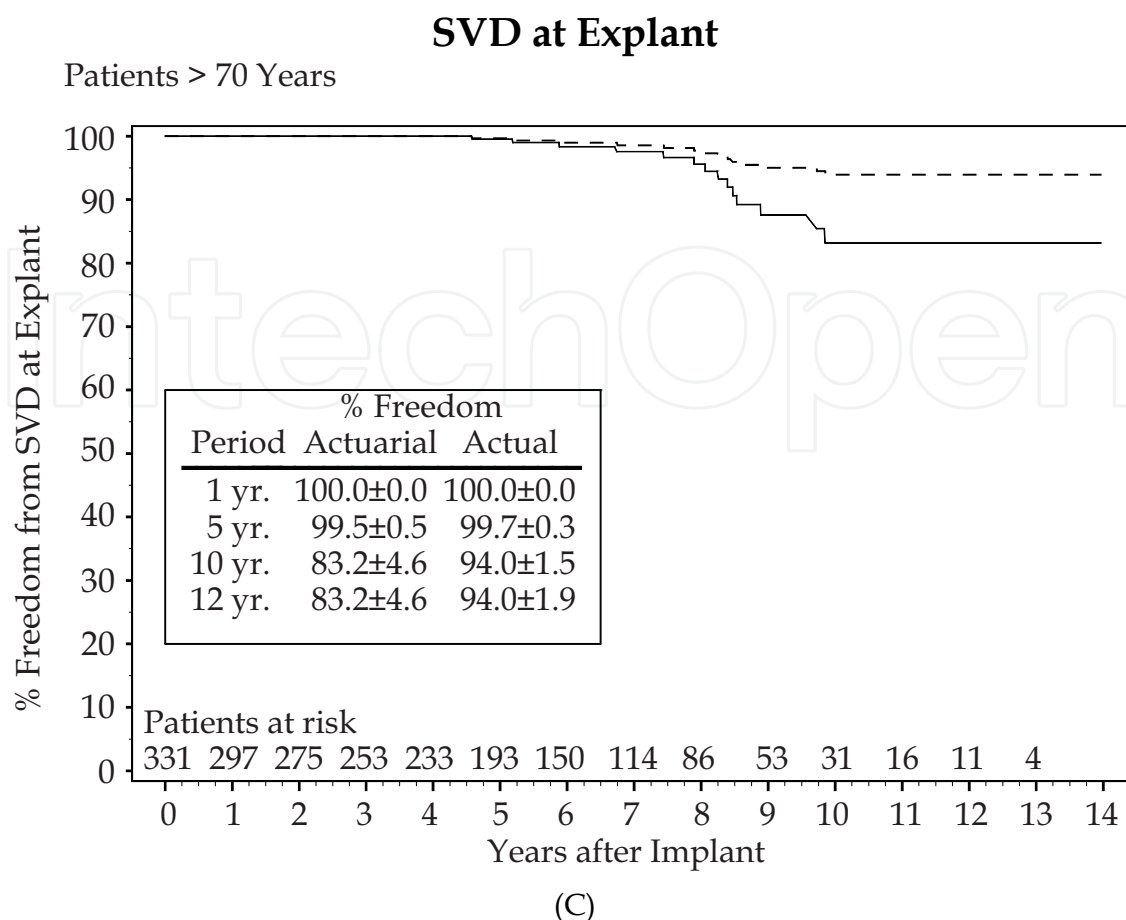


Fig. 3. Freedom from Structural Valve Deterioration (SVD) at Explant (A) ≥ 65 years, (B) 65-70 years, (C) >70 years

There always remains a concern about the true incidence of SVD unless there is a prospective echocardiographic program, because elderly patients may not be evaluated for prosthesis failure or presented for reoperation. The results in the 61-70 years old age group is encouraging, even though small in number, because patients with a failed prosthesis because of SVD in that age group would more likely to be referred for reoperative surgery.

In another recent report on the Mitroflow model 12, Alvarez et al. (2009) reported the freedom from SVD by reoperation, as well as the freedom from bioprosthesis degeneration determined from prospective echocardiographic assessment. These authors report their freedom from SVD at an advanced interval with a minimal number of patients at risk. The freedom from SVD at a more appropriate interval seems to be very similar to that documented in Jamieson et al. (2009). We believe that because Alvarez et al. (2009) did a prospective echocardiographic study, some patients had prophylactic reoperative surgery.

The most extensive published report is the multicenter ISTHMUS study (2011) on 1591 patients, of which 91% had model 12 prostheses. The study reported on SVD by actuarial analysis of echocardiographic diagnoses that used the American Association for Thoracic Surgery (AATS), Society of Thoracic Surgeons (STS), and European Association for Cardio-Thoracic Surgeons (EACTS) guidelines. Personal communication from the ISTHMUS

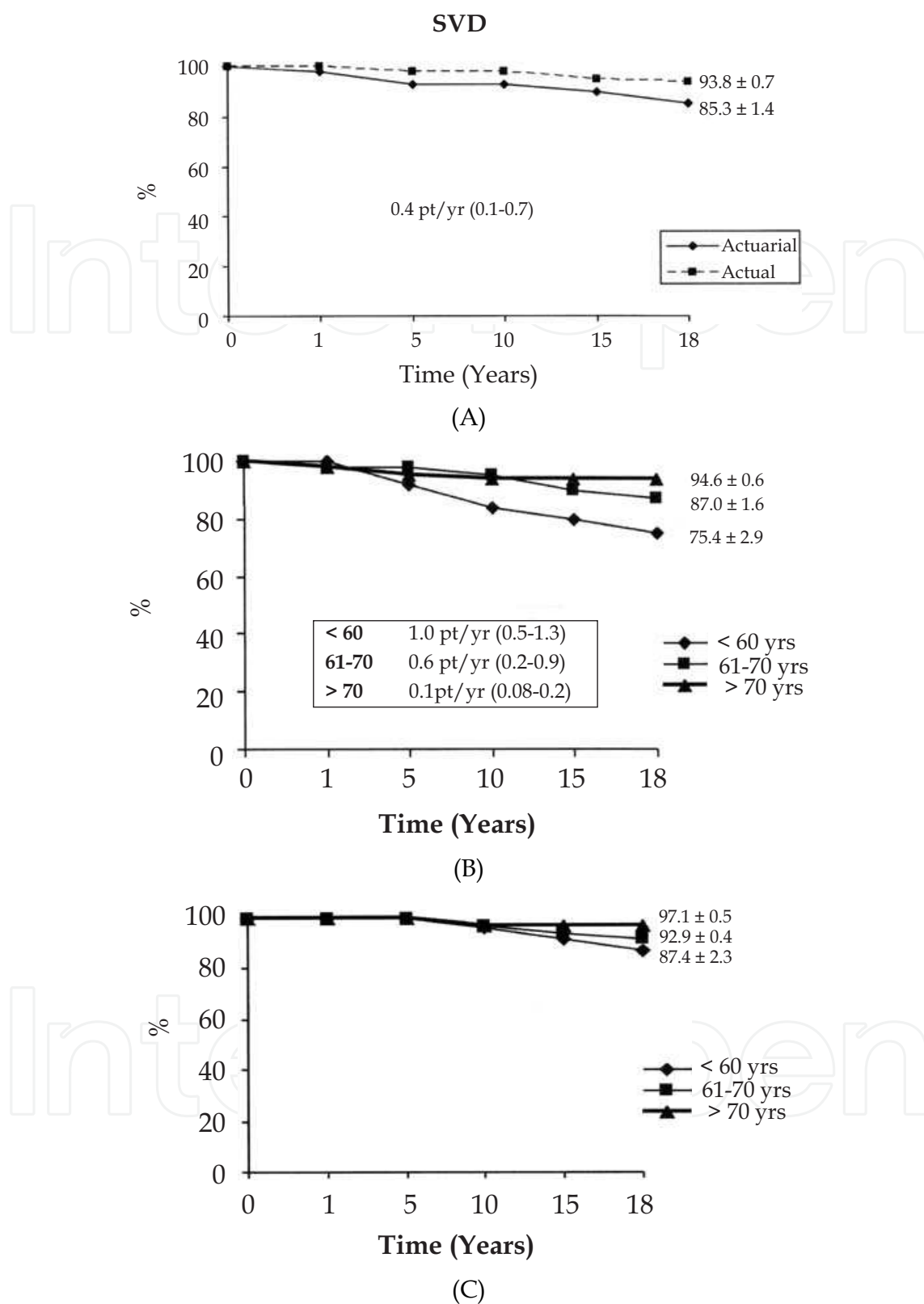


Fig. 4. Freedom from Structural Valve Deterioration (SVD) by clinical relevant symptoms, explantation or autopsy. (A) Overall freedom from SVD Actuarial and Actual. (B) Actuarial freedom from SVD. (C) Actual freedom (cumulative incidence) from SVD. ISTHMUS Investigators - Lorusso (Personal Communication - 2011)

authors (R Lorusso) has provided actual documentation incorporating clinical symptoms, explantation, echocardiographic examination, and autopsy assessment. The 18-year actual/actuarial freedom from SVD incorporating clinical symptoms, explantation, echocardiographic examination and autopsy examination for patients <60 years old was 87.4%/75.4%, for patients 61-70 years old was 92.9%/87.0%, and for patients >70 years old was 97.1%/94.6%.

4. Hemodynamic performance

The hemodynamic performance of the Mitroflow aortic bioprosthesis is considered excellent and very important in optimizing management for the small aortic annulus (Table 2).

Author	Size				
	19 mm	21 mm	23 mm	25 mm	27 mm
Yankah et al. (2008)	1.4	1.5	1.85		
Jamieson et al. (2009)	1.4	1.4	1.8	1.8	
Conte et al. (2010)	1.05	1.22	1.37	1.60	1.82

Table 2. Hemodynamic Orifice Areas (cm²) for Mitroflow Aortic Bioprostheses

These three studies show excellent hemodynamic performance of the prosthesis. Jamieson et al. (2009) reported that the *in vivo* effective orifice areas by valve size provide the opportunity of avoiding obstructive characteristics for all valve sizes, including optimizing the management of the small aortic annulus. The EOA for the 19-mm and 21-mm prostheses is 1.4 cm², and for the 23-mm and 25-mm prostheses is 1.8 cm². These EOAs in the population reported prevented prosthesis-patient mismatch in all valve sizes with indexed EOAs ranging from 0.8 to 1.0 cm²/m².

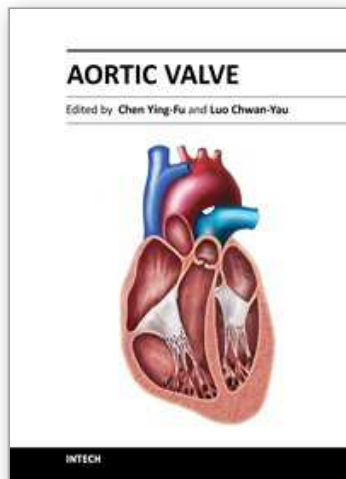
In their study on the hemodynamic performance of 1513 isolated aortic valve replacements, primarily model 11, Yankah et al. (2008) reported that the EOA for size 19-mm prosthesis was 1.4 cm²; the 21-mm, 1.5 cm²; and the 23-mm, 1.85 cm².

The Conte et al. (2010) study of the Mitroflow model 12 prosthesis reported very satisfactory hemodynamic performance. The effective orifice areas for the 19-mm prosthesis was 1.05 cm²; the 21-mm, 1.22 cm²; the 23-mm, 1.37 cm²; the 25-mm, 1.60 cm²; and the 27-mm, 1.82 cm². The mean gradient for the 19-mm prosthesis was 13.4mm Hg.; the 21-mm, 11.5mm Hg.; the 23-mm, 10.6mm Hg.; the 25-mm, 8.6mm Hg.; and 27-mm, 7.3mm Hg.

The Mitroflow LX external mounted pericardial bioprosthesis will continue to provide optimization of hemodynamics regardless of valve size, especially in the small aortic annulus. The addition of anticalcification therapy to the manufacturing process will provide the opportunity to retard or prevent structural valve deterioration of the bioprosthesis and may improve its long-term durability; this prosthesis has clinically been shown to be comparable in durability to other bovine pericardial aortic bioprostheses (Jamieson et al., 2009; Alvarez et al., 2009; ISTHMUS Investigators, 2011).

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Much has evolved in the field of aortic valve disease because of the increase in knowledge in the last decade, especially in the area of its management. This book "Aortic Valve" is comprised of 18 chapters covering basic science, general consideration of aortic valve disease, infective endocarditis, aortic sclerosis and aortic stenosis, bioprosthetic valve, transcatheter aortic valve implantation and a special section on congenital anomalies of the aortic valve. We hope this book will be particularly useful to cardiologists and cardiovascular surgeons and trainees. We also believe that this book will be a valuable resource for radiologists, pathologists, cardiovascular anesthesiologists, and other healthcare professionals who have a special interest in treating patients with aortic valve disease. We are certain that information in this book will help to provide virtually most new areas of aortic valve disease that will be employed in the current era.

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