

Carpentier-Edwards Standard and Supraannular Porcine Bioprostheses: Comparison of Technology

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Background. Performance with regard to structural valve deterioration (SVD) with the Carpentier-Edwards standard (CE-S) and supraannular (CE-SAV) (Baxter Healthcare Corp, Irvine, CA) porcine bioprostheses was evaluated to determine whether progress in reduction of structural failure has been achieved with technological changes.

Methods. The CE-S was implanted during 567 aortic valve replacement (AVR) and 486 mitral valve replacement (MVR) procedures, and the CE-SAV was implanted during 1,670 AVR and 1,096 MVR procedures. The failure mode of early stent dehiscence with the CE-SAV prosthesis, thought to be controlled by manufacturing changes in 1986 and 1987, supported comparison of the CE-SAV with censored cases of stent dehiscence. Stent dehiscence accounted for only 1.2% (1 of 81) and 14.1% (29 of 205) of AVR and MVR CE-SAV failures, respectively.

Results. The only difference for AVR for freedom from SVD occurred in the 21- to 40-year age group at 15 years and was 68% for the CE-SAV and 31% for the CE-S ($p < 0.05$). In the 61- to 70-year age group, freedom from SVD at 15 years was 76% for the CE-S and 84% for the

CE-SAV; for the 71-year or higher age group, freedom from SVD was 89% and 95%, respectively ($p = \text{NS}$). For MVR freedom from SVD was different only in the 71-year or higher age group and was 90% for the CE-S and 59% for the CE-SAV ($p < 0.05$). Freedom from SVD was reduced but was similar ($p = \text{NS}$) for the other age groups. For AVR the actual freedom from SVD at 15 years for the CE-S and CE-SAV was, respectively, 79% and 72% for the 51- to 60-year age group, 86% and 91% for the 61- to 70-year age group, and 98% and 98% for the 71-year or higher age group. For MVR, these rates were, respectively, 69% and 75% for the 61- to 70-year age group and 96% and 89% for the 71-year and higher age group.

Conclusions. The technologic advancements made in the second-generation CE-SAV bioprosthesis to reduce the incidence of structural failure have not uniformly been successful. The actual freedom from SVD provides evidence for implantation of porcine bioprostheses for AVR in age groups 61 to 70 years and 71 years or higher and for MVR in the age group 71 years or higher.

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Porcine bioprostheses have been utilized for cardiac valve replacement operations for 25 years. During the latter half of this 25 years there has been an extensive diminution of the use of porcine bioprostheses, greater for mitral than for aortic valve replacement, because of the progression of structural valve deterioration (SVD) occurring between 8 and 15 years after implantation [1-9]. Structural valve deterioration has now been extensively documented as the major complication of porcine bioprostheses necessitating reoperation [1-16]. Structural valve deterioration has also been well documented to occur less commonly in older age groups [16-18].

The second-generation porcine bioprostheses, namely the Carpentier-Edwards supraannular (CE-SAV), Hancock II (Medtronic Inc, Irvine, CA), and Medtronic Intact

bioprostheses, have been designed to reduce the failure modes responsible for SVD. It is important to extend the comparison of the first- and second-generation prostheses to determine whether there has been an improvement in the clinical performance of the second-generation bioprostheses with regard to a reduction of the incidence of SVD. Both the Carpentier-Edwards standard (CE-S) and CE-SAV porcine bioprostheses have the same structural support, with an Elgiloy (Baxter Healthcare Corp, Irvine, CA) wire stent to reduce stress on the porcine tissue by providing flexibility. The porcine tissue is treated with the surfactant polysorbate 80, an antimineralization agent. The prostheses differ in the tissue glutaraldehyde fixation pressures. The porcine tissue of the CE-S is fixed with glutaraldehyde at 60 mm Hg and the CE-SAV at 2 mm Hg. The CE-S is an intraannular prosthesis, and the CE-SAV has a supraannular configuration to maximize the effective orifice of the prosthesis.

The CE-S porcine bioprosthesis was introduced in 1975

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and the CE-SAV in 1982. After the introduction of the standard Hancock and CE-S first-generation bioprostheses it became evident over time that there were three drawbacks, namely, calcification in children, fatigue lesions, and transvalvular gradients. Carpentier and colleagues [19] introduced the CE-SAV in 1982 with several considered improvements, namely a supraannular configuration to reduce transvalvular gradients, optimized flexibility to reduce tissue stress, improved tissue preservation with reduction of glutaraldehyde fixation pressure to 2 mm Hg, and reduction of strut height of the mitral model so as to minimize protrusion within the ventricular cavity.

The purpose of the present report was to determine whether the technologic changes introduced in 1982 with the CE-SAV have provided improved durability over the first-generation CE-S. The experience with the Carpentier-Edwards prosthesis has been gained since 1975 at the affiliated teaching hospitals of the University of British Columbia—St Paul's Hospital—Heart Center, Vancouver General Hospital and Royal Columbian Hospital. The 10-year experience with the two prostheses was previously documented, and the present report provides the 15-year comparison with regard to freedom from SVD.

Patients and Methods

The CE-S porcine bioprosthesis was implanted between 1976 and 1988 during 567 aortic valve replacement (AVR) and 486 mitral valve replacement (MVR) procedures. The CE-SAV porcine bioprosthesis was implanted in 1,670 AVR and 1,096 MVR procedures from 1981 to 1997. The mean and median age of the overall recipients of the CE-S and CE-SAV is shown in Table 1. The patient population included those with isolated replacements and valve replacements with concomitant procedures, primarily coronary artery bypass grafting.

The patient population was classified into five age groups: 21 to 40 years, 41 to 50 years, 51 to 60 years, 61 to 70 years and 71 years or older. A comparison of the mean and median ages for the different age groups for both prostheses according to AVR and MVR is shown in Table 1.

Structural valve deterioration of both the CE-S and CE-SAV porcine bioprostheses was evidenced in the majority of cases by a combination of calcification and tears and in the minority of cases by either primary calcification or isolated tears. The failure mode of stent dehiscence was previously reported with the CE-SAV prosthesis [11, 12]. In the CE-SAV population there were 81 cases of SVD with AVR and 205 cases with MVR. Stent dehiscence was identified in 1 AVR and 29 MVR cases. The one aortic prosthesis with stent dehiscence was explanted at 172.1 months. Of the 29 MVR cases the mean time to explantation was 102.9 months (range, 44.7 to 162.7 months).

The results in the CE-SAV population were analyzed in two ways: First, the stent dehiscence cases were included with the total cases of SVD, and second, the stent dehiscence cases were censored from the assessment of the influence of SVD on clinical performance [12]. Since 1986

Table 1. Comparison of Mean and Median Age Between CE-S and CE-SAV for Mitral and Aortic Valve Replacement by Age Groups

Age Group (y)	MVR										AVR									
	CE-S					CE-SAV					CE-S					CE-SAV				
	Mean	SD	Median	Max	Min	Mean	SD	Median	Max	Min	No. of Pts	<i>p</i> Value ^a	Mean	SD	Median	Max	Min	No. of Pts	<i>p</i> Value ^a	
21-40	33.3	5	34	40	21	33.1	5	34	40	21	0.7700	56	32.1	5.7	33	40	21	58	0.1817	
41-50	46.6	2.8	47	50	41	46.0	3	46	50	41	0.1881	55	46.4	2.7	47	50	41	77	0.8542	
51-60	55.9	2.8	56	60	51	56.2	2.7	57	60	51	0.3612	152	56.0	2.8	56	60	51	235	0.0326	
61-70	65.1	2.7	65	70	61	66.0	3	66	70	61	0.0022	197	65.6	2.9	66	70	61	538	0.0002	
≥71	74.0	2.8	73.5	82	71	75.2	3.3	74	86	71	0.0114	107	74.6	3.2	74	85	71	762	0.0003	
Overall	57.3	11.8	59	82	21	63.7	12	66	86	21	0.0000	567	59.6	12.7	62	85	21	1670	0.0000	

^a Wilcoxon rank-sum test.

AVR = aortic valve replacement;

MVR = mitral valve replacement;

CE-S = Carpentier-Edwards standard bioprosthesis;

Pts = patients; SD = standard deviation.

CE-SAV = Carpentier-Edwards supraannular bioprosthesis;

Max = maximum; Min = minimum;

Max = maximum; Min = minimum;

Min = minimum;

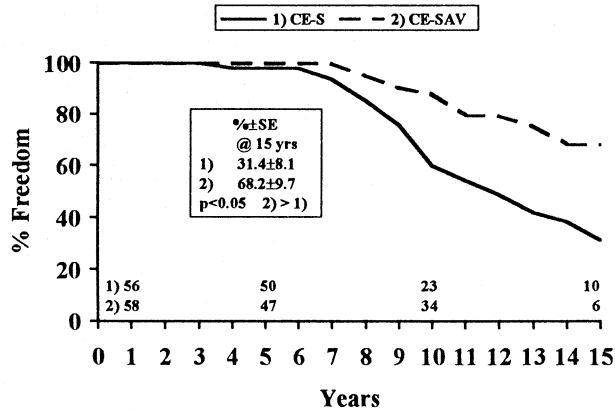


Fig 1. Freedom from structural valve deterioration after aortic valve replacement: 21- to 40-year age group. (CE-S = Carpentier-Edwards standard bioprosthesis; CE-SAV = Carpentier-Edwards supraannular bioprosthesis; SE = standard error.)

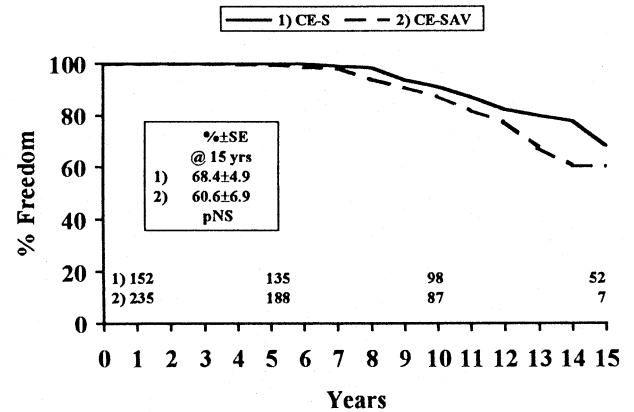


Fig 3. Freedom from structural valve deterioration after aortic valve replacement: 51- to 60-year age group. Abbreviations as in Figures 1 and 2.

the change in the manufacturing process from extensive trimming of the aortic wall near the commissures to “reduced trimming” has controlled the failure mode of stent dehiscence: 96.6% (28 of 29) of the stent dehiscence cases involved extensively trimmed prostheses and were implanted between 1982 and 1986. For this reason the CE-SAV population was analyzed with and without stent dehiscence to determine the performance of the CE-SAV prosthesis representative of post-1986 implantation. This methodologic assumption enabled the CE-SAV prosthesis to be evaluated with and without stent dehiscence and to be compared with the performance of the CE-S prosthesis.

The “Guidelines for Reporting Morbidity and Mortality After Cardiac Valvular Operations” was utilized for defining SVD and served as the basis of our methodology [20]. The diagnosis of SVD was made at reoperation and at autopsy and by echocardiography.

Structural valve deterioration is compared between the

two bioprostheses by assessment of actuarial and actual freedom from SVD [20, 21]. The CE-SAV was evaluated with and without stent dehiscence and compared with the performance of the CE-S.

The Kaplan-Meier method was used to estimate the actuarial freedom from SVD, and the log rank test was used to compare the survival curves between the two bioprosthesis types for each specific age group. For the analysis of actual freedom from SVD, an analog of the Kaplan-Meier method was used to estimate the actual risk probabilities [21-23]. The Wilcoxon rank-sum test was performed to compare the age distribution between the two bioprostheses by specific age groups. All reported *p* values are two-tailed.

Results

The freedom from SVD for AVR for the five age groups is shown in Figures 1 to 5. The comparison is only between

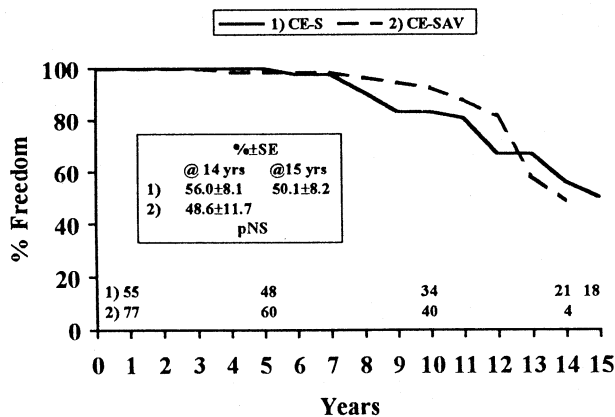


Fig 2. Freedom from structural valve deterioration after aortic valve replacement: 41- to 50-year age group. (NS = not significant; other abbreviations as in Fig 1.)

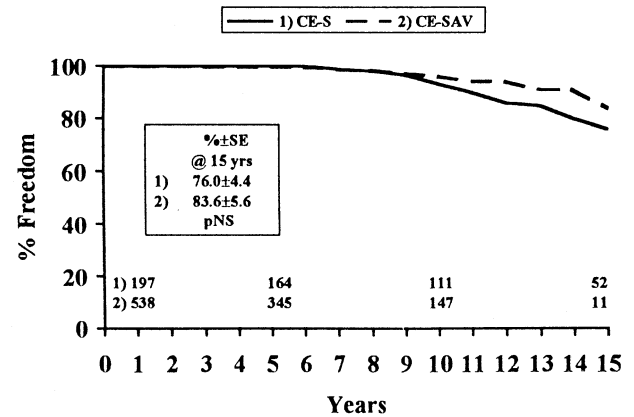


Fig 4. Freedom from structural valve deterioration after aortic valve replacement: 61- to 70-year age group. Abbreviations as in Figures 1 and 2.

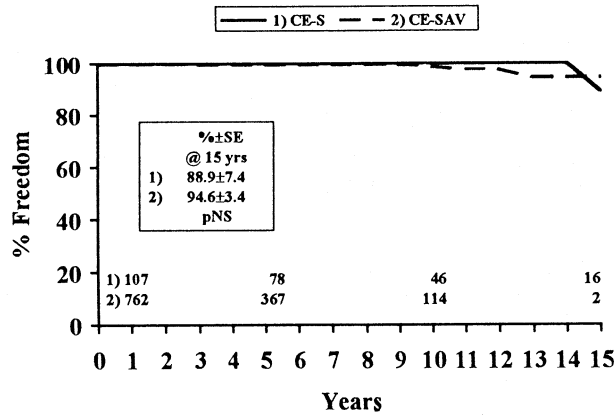


Fig 5. Freedom from structural valve deterioration after aortic valve replacement: 71-year or older age group. Abbreviations as in Figures 1 and 2.

the CE-S and CE-SAV because the only case of stent dehiscence occurred at the 16-year interval in the age group 61 to 70 years. The explanted prosthesis had dehiscence of two struts, with central regurgitation. The leaflets showed only minimal degenerative changes.

The only significant difference between the two prostheses for AVR occurred in the 21- to 40-year age group (Fig 1). Freedom from SVD at 15 years was (\pm SEM) 68.2% \pm 9.7% for the CE-SAV and 31.4% \pm 8.1% for the CE-S ($p < 0.05$). In the 61- to 70-year age group freedom from SVD at 15 years was 76.0% \pm 4.4% for the CE-S and 83.6% \pm 5.6% for the CE-SAV ($p = NS$) (Fig 4). In the 71-year or older age group, freedom from SVD at 15 years was 88.9% \pm 7.4% and 94.6% \pm 3.4%, respectively, for the CE-S and CE-SAV ($p = NS$).

Freedom from SVD at 15 years for MVR for the five age groups is shown in Figures 6 to 10. The comparison evaluates CE-S and CE-SAV both with and without stent dehiscence. The only age group that revealed a significant difference between prostheses was the 71-year or older age group, where the CE-S was superior to the

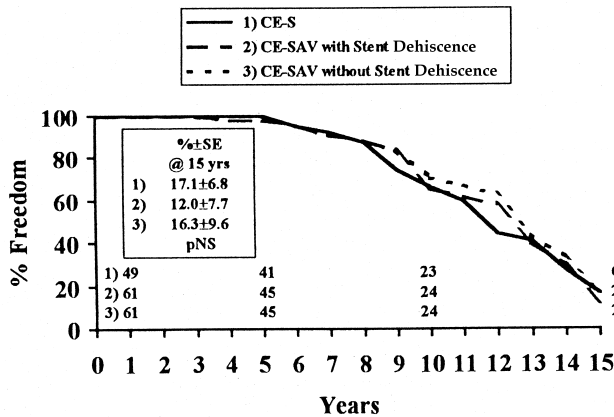


Fig 6. Freedom from structural valve deterioration after mitral valve replacement: 21- to 40-year age group. Abbreviations as in Figures 1 and 2.

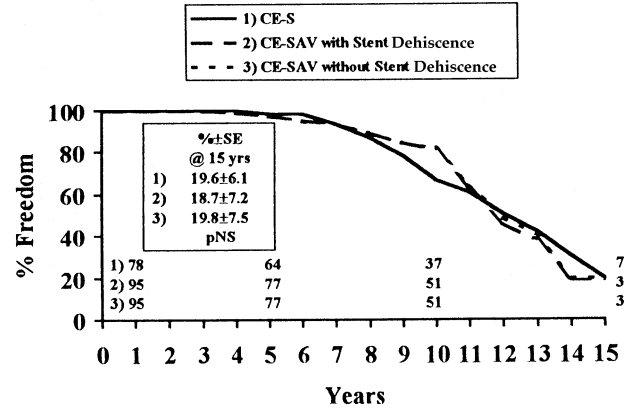


Fig 7. Freedom from structural valve deterioration after mitral valve replacement: 41- to 50-year age group. Abbreviations as in Figures 1 and 2.

CE-SAV. Freedom at 15 years was 89.9% \pm 7.6% for the CE-S and 57.3% \pm 14.2% for the CE-SAV with stent dehiscence and 58.7% \pm 14.5% for the CE-SAV without stent dehiscence ($p < 0.05$, CE-S $>$ CE-SAV). In all groups younger than the 71-year or older age group, there was no difference between the prostheses and between inclusion or exclusion of stent dehiscence in the CE-SAV analysis ($p = NS$). Freedom from SVD at 15 years was less than 20% for age groups 21 to 40 and 41 to 50 years, less than 30% for 51 to 60 years (CE-S), and 35% or less for 61 to 70 years. Stent dehiscence accounted for only 14.1% (29 of 205) (Figs 6-9) of the cases of SVD in the total MVR CE-SAV population and did not significantly influence freedom from SVD ($p = NS$).

The comparison of actual versus actuarial freedom from SVD for AVR and MVR is demonstrated in Figures 11 and 12 for both the CE-S and CE-SAV. The numerical values are detailed in Tables 2 and 3.

Comment

Structural valve deterioration remains the major valve-related complication of porcine bioprostheses. The expe-

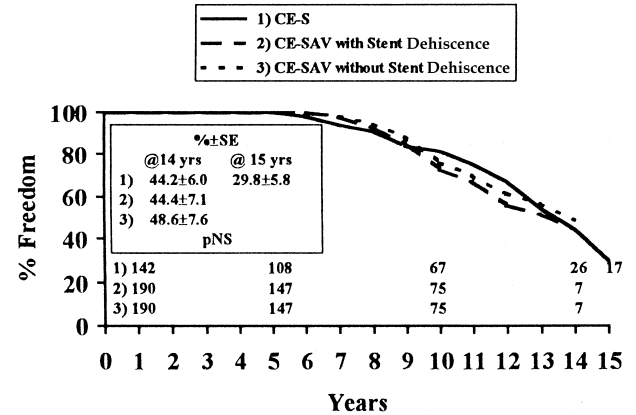


Fig 8. Freedom from structural valve deterioration after mitral valve replacement: 51- to 60-year age group. Abbreviations as in Figures 1 and 2.

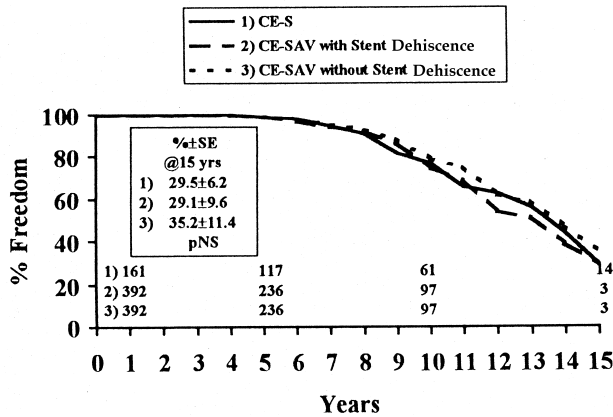


Fig 9. Freedom from structural valve deterioration after mitral valve replacement: 61- to 70-year age group. Abbreviations as in Figures 1 and 2.

rience with the first-generation Hancock standard and the CE-S has received extensive documentation [1-9]. The latest report from the Stanford University experience, primarily with the Hancock standard porcine bioprostheses, revealed an AVR freedom from SVD of 78% at 10 years and 49% at 15 years and an MVR freedom from SVD of 69% and 32% at 10 and 15 years, respectively [5]. The 1995 publication from the University of British Columbia documented a freedom from SVD with the CE-S of 86% at 10 years and 58% at 15 years for AVR and 70% and 21%, respectively, for MVR [4]. It has always been thought that these two population comparisons are representative of the performance of the two prostheses because of similar mean ages. In 1997 Fiane and colleagues [9] reported a 10-year freedom from SVD of 89% for AVR and 76% for MVR with the CE-S. Bernal and coworkers [2] reported a 15-year freedom from SVD with the CE-S of 62% for AVR and 33% for MVR. Fann and colleagues [5] identified younger age, later year of operation, and valve site (MVR > AVR) as significant risk factors of structural valve deterioration. The Hancock

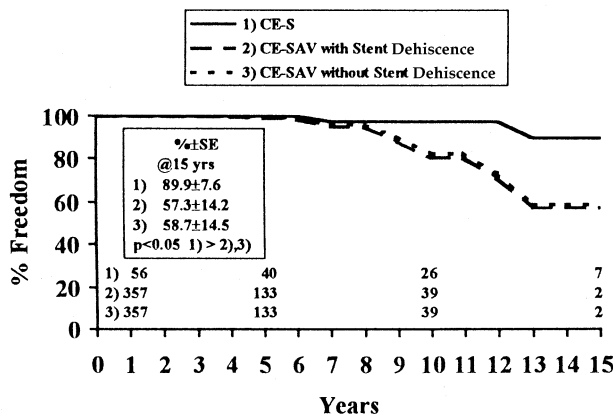


Fig 10. Freedom from structural valve deterioration after mitral valve replacement: 71-year or older age group. Abbreviations as in Figures 1 and 2.

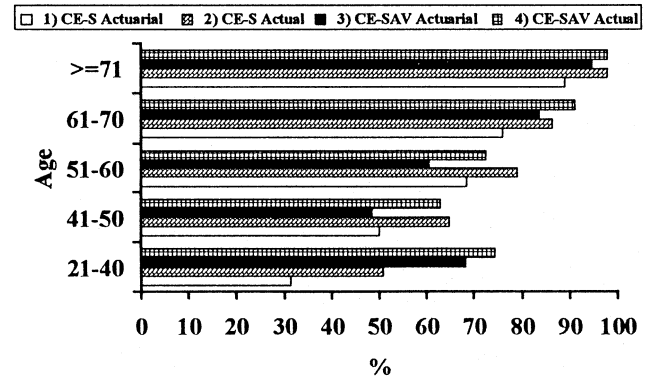


Fig 11. Actual versus actuarial freedom from structural valve deterioration after aortic valve replacement. Abbreviations as in Figures 1 and 2.

modified orifice porcine bioprosthesis for aortic implantation, also a first-generation bioprosthesis but designed as a composite prosthesis, has a 15-year performance similar to an aortic standard prosthesis [6, 8].

The current evaluation failed to demonstrate clinically relevant differences with regard to freedom from SVD for various age groups for AVR and MVR between the CE-S and CE-SAV, except for CE-SAV greater than CE-S for AVR in the age group 21 to 40 years and CE-S greater than CE-SAV for MVR in the age group 71 years or older.

The extended experience at the University of British Columbia revealed not only the documented modes of failure responsible for SVD but also stent dehiscence causing normal-appearing tissue to separate from the region of the stent post and the resultant release of two leaflets with mitral regurgitation as the ultimate consequence [10-12, 15]. The failure mode was initially seen in the fourth and fifth years after implantation. Stent dehiscence, in general, has been an uncommon mode of valve failure, occurring rarely as a late phenomenon of standard porcine bioprostheses.

Stent dehiscence, in the current CE-SAV evaluation

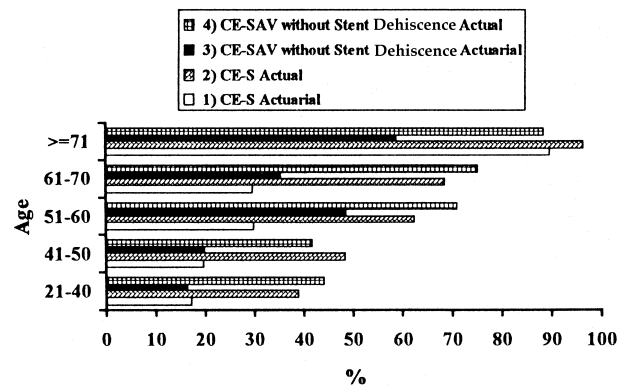


Fig 12. Actual versus actuarial freedom from structural valve deterioration after mitral valve replacement. Abbreviations as in Figures 1 and 2.



Fig 13. Carpentier-Edwards supraannular mitral porcine bioprosthesis with stent dehiscence.

was identified in 29 mitral prostheses and 1 aortic prosthesis (Fig 13). The mean time since implantation to identification at reoperation was 102.9 months (range, 44.7 to 162.7 months) for the mitral prostheses, whereas it occurred late with the single aortic prosthesis at 172.1 months. This aortic prosthesis had dehiscence of the tissue from two stent posts. Nistal and coworkers [24], Allard and associates [26], and Terada and Wanibuchi [26] found that more than one commissural stent post may be involved with dehiscence.

In our series 96.6% (28 of 29) of the mitral prostheses with dehiscence were implanted between 1982 and 1986. Since the introduction of the prosthesis in 1982, the tissue had been prepared such that the aortic wall had been extensively trimmed. With the identification of the stent dehiscence most likely related to extensive aortic wall trimming, the manufacturer altered the way in which the tissue was prepared. In 1986 they introduced "reduced trimming" of the aortic wall of large mitral prostheses and in 1987 this practice was extended to all sizes of mitral and aortic prostheses. Nistal and coworkers [24] and Baldelli and colleagues (Baldelli, personal communication, June, 1995) have demonstrated extensive thinning of the aortic wall compared with the native aortic root. Baldelli and colleagues (Baldelli, personal communication, June, 1995) also demonstrated a trend toward reduced trimming of the aortic wall in prostheses formulated after the change in the manufacturing process.

Because we believe that the problem of early stent dehiscence with the CE-SAV has been resolved, freedom from SVD was calculated with and without stent dehiscence to provide an appropriate representation of the CE-SAV performance. In the latter calculation the cases of stent dehiscence were censored. In 1995 we used the same technique of evaluation and noted trends in greater freedom from SVD at 10 years with the CE-SAV prosthesis [11]. The literature has limited documentation on the CE-SAV prosthesis except for that provided by us [10-12, 15].

Evaluation of the MVR CE-SAV over 15 years revealed 205 cases of SVD in a total of 1,027 implants (20%). Of the 205, 29 (14.1%) were due to stent dehiscence. Of the

Table 2. Comparison of Actual Versus Actuarial Freedom From Structural Valve Deterioration for Aortic Valve Replacement at 15 Years

Age Group (y)	Actual (%)		Actuarial (%)	
	CE-S	CE-SAV	CE-S	CE-SAV
21-40	50	74	31	68
41-50	65	63 (14 y)	50	49 (14 y)
51-60	79	72	68	61
61-70	86	91	76	84
≥71	98	98	89	95

Abbreviations as in Table 1.

remainder, 20 were due to primary dystrophic calcification, 46 to tears, 86 to a combination of tears and calcification, and 24 to unknown causes [15]. Freedom from SVD without stent dehiscence can be considered representative of the CE-SAV prostheses. There were no clinically relevant differences between the CE-S and CE-SAV at 15 years with regard to freedom from SVD. For AVR freedom from SVD at 15 years was 76% for CE-S and 84% for CE-SAV ($p = \text{NS}$) in the 61- to 70-year age group and 89% for CE-S and 95% for CE-SAV ($p = \text{NS}$) in the 71-year or older age group. For MVR freedom from SVD at 15 years was 30% for CE-S and 35% for CE-SAV ($p = \text{NS}$) in the 61- to 70-year age group and 90% for CE-S and 59% for CE-SAV in the 71-year or older age group ($p < 0.05$, CE-S > CE-SAV). This statistical benefit may not be real because in the early experience in the 1980s, patients with SVD may not have been identified.

The second-generation Hancock II and Medtronic Intract porcine bioprosthesis have had limited documentation, and the experience has not reached 15 years [13, 14, 27, 28]. David and colleagues [27, 28] have evaluated the performance of the Hancock II prosthesis at 10 and 12 years in a population with a mean age of 65 years. At 10 years the freedom from SVD for the Hancock II was 92% for AVR and 81% for MVR. At 12 years the freedom from SVD for the Hancock II was reported as 95% for AVR and 82% for MVR in an extended population of 1,128 patients. From our experience with the CE-SAV, freedom from SVD at 12 years was 83% for AVR and 51% for MVR,

Table 3. Comparison of Actual Versus Actuarial Freedom From Structural Valve Deterioration for Mitral Valve Replacement at 15 Years

Age Group (y)	Actual (%)			Actuarial (%)		
	CE-S	CE-SAV		CE-S	CE-SAV	
		\bar{c} SD	\bar{s} SD		\bar{c} SD	\bar{s} SD
21-40	38	36	44	17	12	16
41-50	48	39	42	20	19	20
51-60	62	67 (14 y)	71 (14 y)	30	44 (14 y)	49 (14 y)
61-70	69	70	75	30	29	35
≥71	96	87	89	90	57	59

\bar{c} = with; \bar{s} = without; SD = stent dehiscence; other abbreviations as in Table 1.

inclusive of stent dehiscence. Mykén reported that the St Jude Medical-Biocor porcine bioprostheses, in a population with a mean age of 67 years, had a freedom from SVD determined at reoperation of 80% for AVR and 90% for MVR at 13 years.

The Medtronic Intact porcine bioprosthesis, also a second generation prosthesis, was introduced in 1984 and also has limited evaluation extending toward 10 years. Jamieson and colleagues [13], reporting on a three-center Canadian population with a mean age of 67 years, revealed a freedom from SVD at 10 years of 83% for AVR and of 75% for MVR. This compares to freedom at 10 years of 91% for AVR and 69% for MVR with the CE-SAV prostheses [16]. Freedom from SVD at 10 years for AVR for age group 61 to 70 years was 98.7% for the Medtronic Intact and 94% for the CE-SAV; for age group 71 years or older these rates were 98% for MI and 98% for the CE-SAV. For MVR in the age group 61 to 70 years the freedom from SVD for the Medtronic Intact was 86% at 8 years and 69% at 10 years for the CE-SAV; for the age group 71 years or older the rates were 94% at 8 years for the Medtronic Intact and 82% at 10 years for the CE-SAV. The Hancock II porcine bioprosthesis has not been evaluated by specific age groups, but David and colleagues [29] reported no cases of SVD for AVR or MVR in patients aged 65 years or older at 10 to 12 years. Barratt-Boyes and colleagues [14], reporting on the Medtronic Intact porcine bioprosthesis, revealed a freedom from SVD for AVR of 100% at 8 years and 86% for MVR 60 years or greater.

There have been three cases of stent dehiscence identified at explanation with the Medtronic Intact mitral prosthesis [13]. The mean time to failure for these three cases was 100 months. Barratt-Boyes and Christie (personal communication, February, 1997) were the first to draw attention to the mode of failure with the Medtronic Intact mitral prosthesis. This failure mode is somewhat similar to that identified with the CE-SAV, but the Medtronic Intact is not formulated with reduction of thickness of the aortic wall.

The technologic advancements introduced in 1982 with the second-generation [19] CE-SAV porcine bioprosthesis have not resulted in improvement in durability over the first-generation bioprostheses. The CE-SAV prosthesis has optimized hemodynamic performance with the supraannular design over the original intraannular configuration. It was expected that the reduction of turbulence by the supraannular concept, optimization of stent flexibility, and improved tissue preservation would minimize fatigue lesions and calcification.

The concepts of glutaraldehyde pressure fixation and antimineralization treatment of porcine bioprostheses have received considerable attention. The first-generation porcine bioprostheses were glutaraldehyde fixed at a back pressure of 60 to 80 mm Hg. The CE-SAV has been fixed at 1.5 to 2.0 mm Hg, whereas the Hancock II was fixed at 1.5 mm Hg for a short interval and then fixed at 80 mm Hg. The Medtronic Intact porcine bioprosthesis, in contrast, has zero pressure-fixed aortic valves. Flomenbaum and Schoen [29] have shown that the standard bioprostheses and the Hancock II prosthesis have overall

tissue flattening and compression with near-complete loss of transverse cuspal ridges and collagen crimp. The zero pressure-fixed tissue is virtually identical to relaxed native porcine aortic valve cusps, whereas valves fixed at low pressure (CE-SAV) had intermediate features. The antimineralization treatment is the incorporation of surfactants in the preservation process of all prostheses, except for toluidine blue antimineralization treatment with the Medtronic Intact porcine bioprosthesis.

These properties of preservation have been incorporated in the various prostheses to provide comparable differences in prosthetic performance. There has been no exceptionally demonstrable differences between the first- and second-generation bioprostheses, but all have not reached 15-year documentation or been fully evaluated for the influence of age.

The CE-SAV mitral prosthesis was designed with reduction of strut height to minimize protrusion within the ventricular cavity. The concept of the low-profile bioprosthesis has been given consideration in assessing the mode of failure over the long-term of the low-profile St Jude Medical Bioimplant (Liotta) porcine bioprosthesis. Valve regurgitation has been identified by Ius and colleagues [30] as the usual mode of failure of the Liotta prosthesis in the mitral position. These investigators have determined that commissural tearing of the right coronary cusp was the most common cause of valve regurgitation and occurred even in the presence of minimal calcification. The pathologic findings imply bulging of the right coronary cusp, which increases the risk of increased stress at the commissures, accelerating calcification and tearing. The low-profile design of the CE-SAV mitral prosthesis may also be a contributing factor to structural failure and requires detailed pathologic evaluation.

The second-generation CE-SAV porcine bioprosthesis with technologic changes to reduce fatigue lesions and calcification has not advanced structural integrity to the 15-year interval over the first-generation porcine bioprostheses, especially in the mitral position versus the aortic position.

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