



# A ESCOLHA DA BIOPRÓTESE É BASEADA EM MARKETING OU EM DESEMPENHO COMPROVADO?

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## **Declaração de Potencial Conflito de Interesse**

**Nome do Palestrante:**

**Renato A. K. Kalil**

**Título da Apresentação:**

*A ESCOLHA DA BIOPRÓTESE É BASEADA EM MARKETING OU EM DESEMPENHO COMPROVADO?*

**Não possuo nenhum conflito de interesse relacionado a esta apresentação**

# Substitutos Valvares Atuais

- Autólogos: Autoenxerto Pulmonar



- Homólogos: Homoenxertos aórticos, pulmonares



- Heterólogos: Biopróteses de aorta porcina e de pericárdio bovino, equino ou porcino



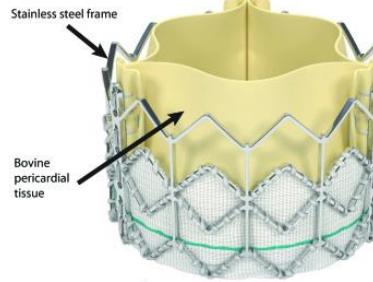
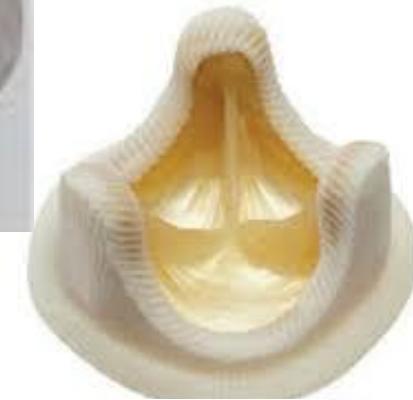
- Mecânicos: Próteses mecânicas de carbono pirolítico



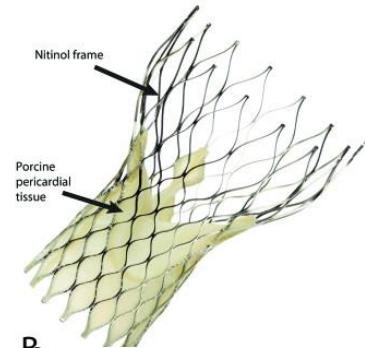
# Processamento das Biopróteses

- Fresh-frozen
- Freeze-dried
- Formaldeido
- *Glutaraldeído*
- Glicerol
- No-React
- L-Hydro
- Liofilização
- Integrity technology
- Pré-incubação em etanol
- Triglycidyl amine
- .....
- Fascia lata
- Dura-máter
- Pericárdio
- Valva aórtica
- Veia jugular bovina

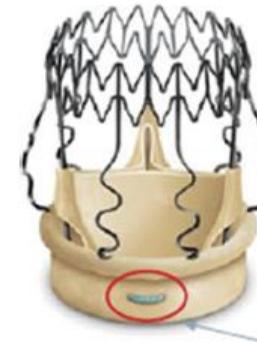
**Biopróteses Consolidadas:**  
**Valva aórtica porcina**  
**Pericárdio bovino**  
**Preservação em glutaraldeído**



A



B



# *Quais são as questões principais na escolha da bioprótese cirúrgica?*

- ***DESEMPENHO HEMODINÂMICO:***

*Gradiente pressórico e alívio da sobrecarga de pressão, orifício efetivo*

- ***DURABILIDADE:***

*Sobrevida a longo prazo sem re-operações, degeneração, calcificação*

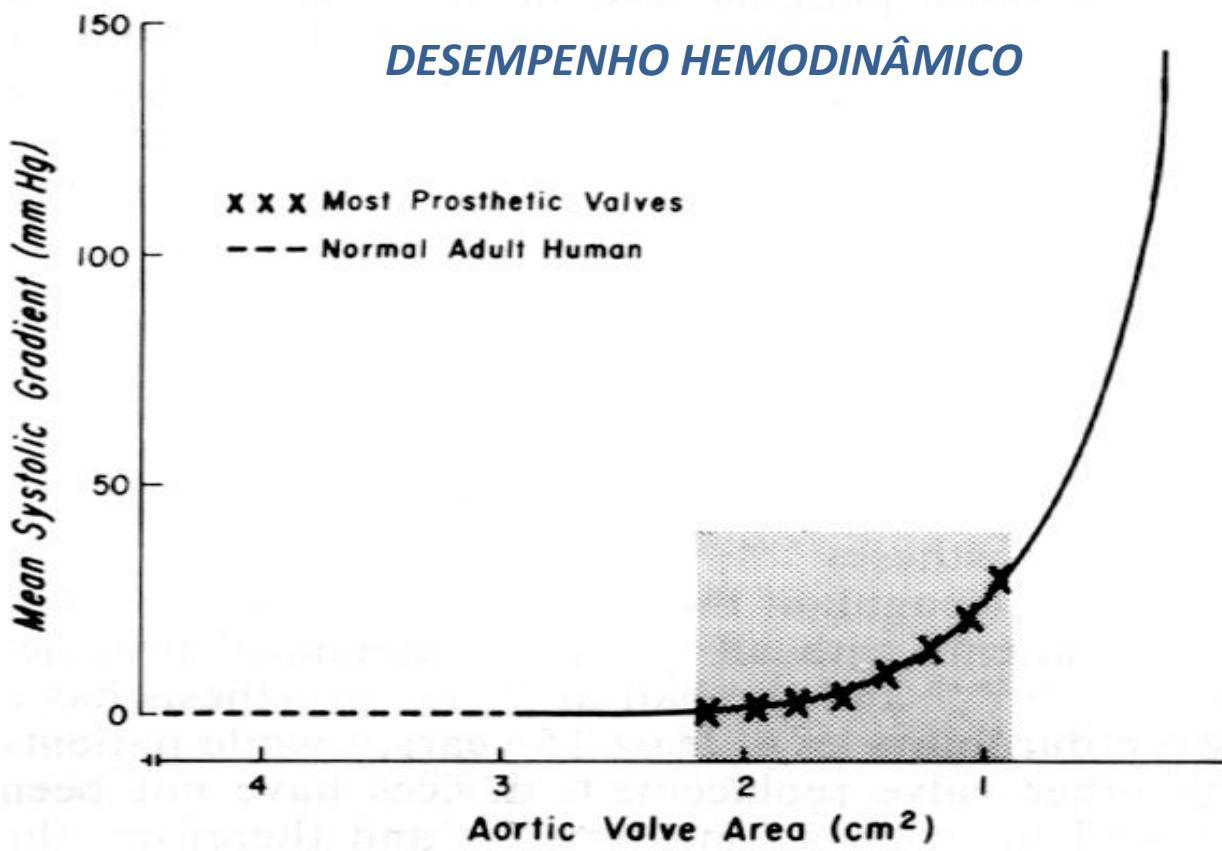
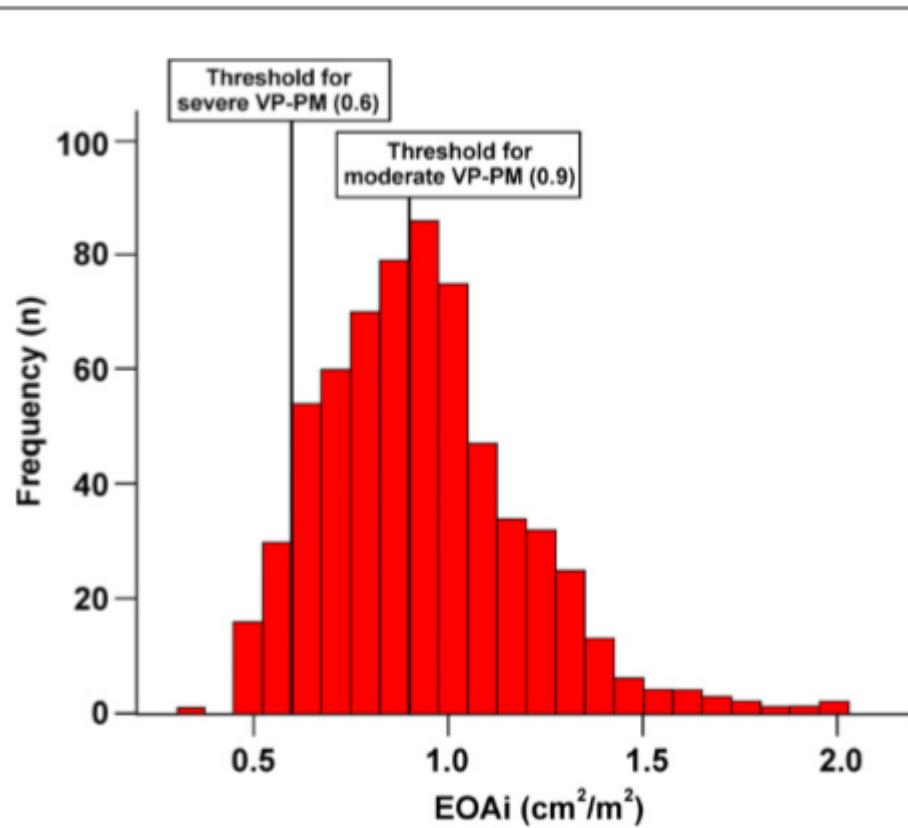


FIGURE 2. Diagrammatic representation of the relationship of mean systolic gradient to the aortic valve area, assuming the cardiac output and velocity of flow are constant. The curve is based upon knowledge of the hydraulics of a stenotic valve<sup>55</sup> and of experimental data.<sup>43</sup> The approximate zone of prosthetic valve area to gradient is based on published data.<sup>2, 4, 8-15, 36, 40, 41</sup>

# *DESEMPENHO HEMODINÂMICO: Gradiente pressórico e alívio da sobrecarga de pressão, orifício efetivo*

*Table 1. Aortic Valve Prostheses and Effective Orifice Areas*

Valve Type	n	Effective Orifice Area ( $\text{cm}^2$ ) for Nominal Valve Size						References
		19 mm	21 mm	23 mm	25 mm	27 mm	29 mm	
<b>Mechanical prostheses</b>								
St. Jude Medical standard	428	1.01	1.33	1.60	1.93	2.35	2.81	[28]
St. Jude Medical Regent	72	1.84	2.47	2.91	3.34	4.28	4.80	[13]
Bjork-Shiley Monostrut/Sorin tilting disk	88	0.90	1.08	1.31	1.96	2.51	4.10	[29, 30]
Carbomedics Standard	15	1.25	1.42	1.69	2.04	2.55	2.63	[4, 9, 17]
Omnicarbon	45	...	1.25	1.49	1.94	2.11	2.27	[28]
MCRI On-X	7	1.50	1.70	2.00	2.40	3.20	3.20	[9, 13, 17]
<b>Bioprostheses</b>								
Carpentier-Edwards Perimount	64	1.08	1.25	1.51	1.62	1.85	...	[4]
Carpentier-Edwards Perimount Magna	27	1.30	1.70	2.10	2.30	...	...	[17]
Medtronic Mosaic	234	1.11	1.28	1.51	1.69	2.04	...	[4]
St. Jude Medical Biocor/Epic	80	...	1.30	1.60	1.80	2.00	3.30	[15, 17]



**Figure 8 EOAI of 1 Prosthesis Type**

Histogram distribution of EOAI at 6 months after aortic valve replacement in 113 patients of the same type and size (Edwards Perimount size 23). The mean value of  $1.82 \text{ cm}^2/\text{m}^2$  may be the only parameter inserted into a reference table. Most patients would have moderate VP-PM, many would have mild VP-PM, and few would have severe VP-PM. Abbreviations as in Figure 7.

Adapted and modified, with permission, from Bleiziffer et al. (45).

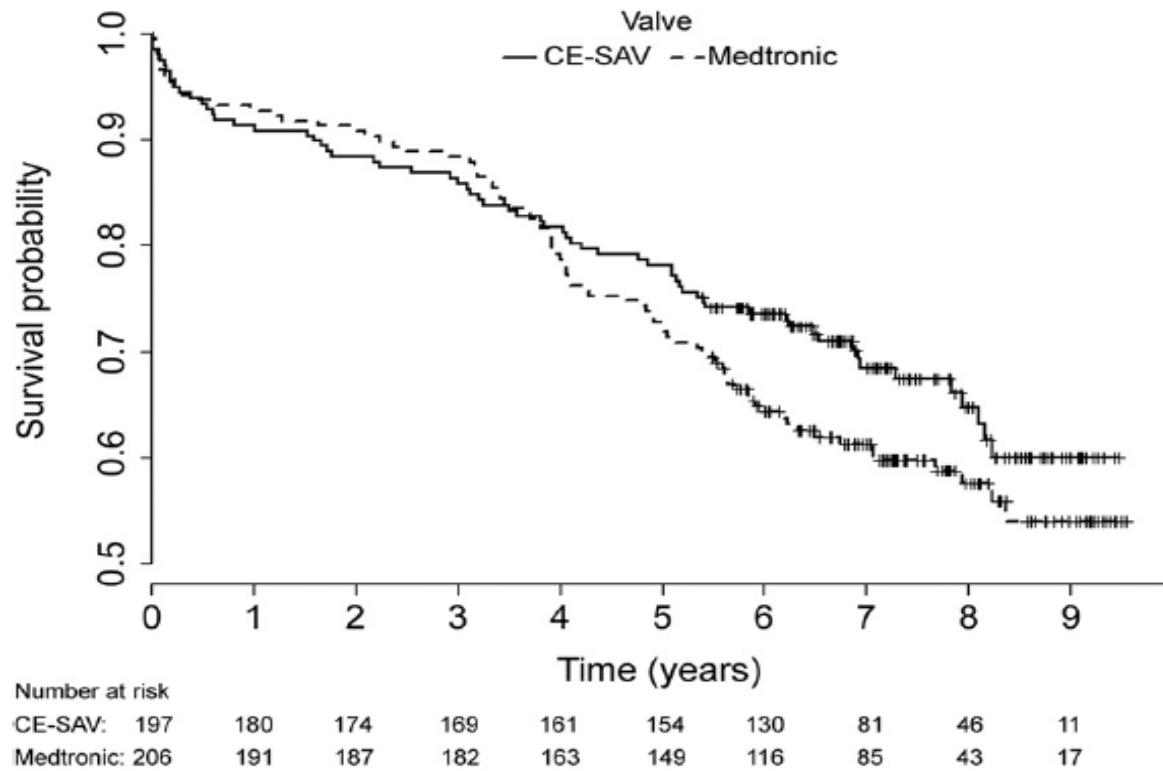


Fig 1. There is no statistically significant difference in the Kaplan-Meier plots of survival between the 2 cohorts of patients (log-rank test  $p = 0.147$ ). (CE-SAV = Carpentier-Edwards supraannular aortic valve.)

## Randomized Trial of Carpentier-Edwards Supraannular Prosthesis Versus Mosaic Aortic Prosthesis: 6 Year Results

Table 5. Gradients at 5 Years

Valve Size	No. of Patients With CE-SAV	Average Gradient CE-SAV (mm Hg)	No. of Patients With Mosaic Valve	Average Gradient Mosaic (mm Hg)	t Test p Value
19	7	$35.3 \pm 11.6$	7	$53.9 \pm 23.3$	0.082
21	21	$33.1 \pm 18.3$	20	$37.70 \pm 17.2$	0.417
23	23	$27.4 \pm 11.9$	17	$38.03 \pm 21.2$	0.052
25	5	$35.9 \pm 11.4$	9	$31.94 \pm 10.3$	0.512
27	8	$23.5 \pm 6.4$	9	$24.9 \pm 23.2$	0.867
29	5	$25.382 \pm 10.5$	1	24.00	NA

CE-SAV = Carpentier-Edwards supraannular aortic valve; NA = not available.

# *DESEMPENHO HEMODINÂMICO: Gradiente pressórico e alívio da sobrecarga de pressão, orifício efetivo*

*Table 4. Adjusted All-Cause Mortality After Aortic Valve Replacement According to Effective Orifice Area Index*

Prosthesis-patient mismatch*	Total All-Cause Mortality				<i>p</i> Value
	Hazard Ratio	95% CI Lower	95% CI Upper		
Absent, EOAI > 0.85 cm <sup>2</sup> /m <sup>2</sup> (Reference)	1.00	...	...		...
Moderate, EOAI 0.65–0.85 cm <sup>2</sup> /m <sup>2</sup>	1.00	0.80	1.24		0.97
Severe, EOAI < 0.65 cm <sup>2</sup> /m <sup>2</sup>	1.14	0.82	1.58		0.44
Change in model coefficients with PPM-2 log likelihood = 5179.1				$\chi^2$ (2) = 0.72, <i>p</i> = 0.70	

\* Prosthesis-patient mismatch was entered at second step of hazard model and the mortality risk is adjusted for all other covariates.

CI = confidence interval; EOAI = effective orifice area index; PPM = patient prosthesis mismatch.

*In conclusion, PPM alone was not an independent predictor of short-term morbidity or late mortality in patients undergoing AVR.*

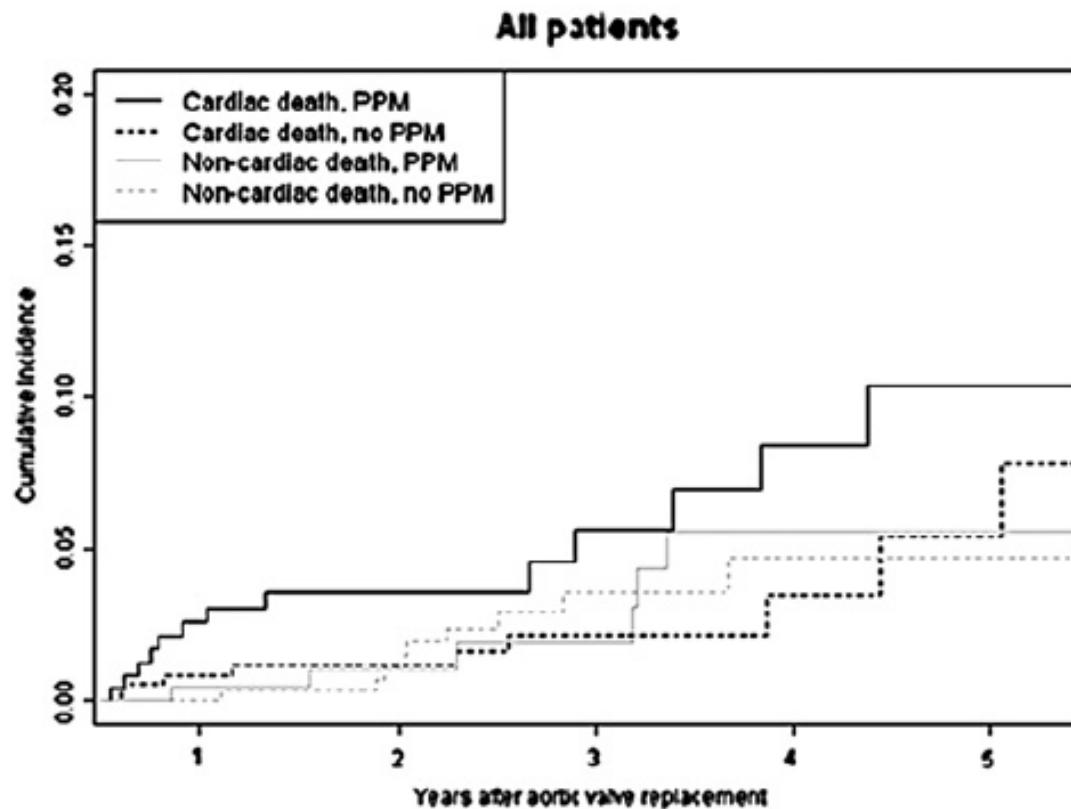
*However, PPM was associated with decreased long-term survival in older patients, those undergoing concomitant CABG, or those with LV dysfunction or NYHA class III or IV symptoms.*

**Effective orifice area values taken from the manufacturers' technical specifications obtained from in vitro tests conducted by the manufacturers**

Prosthesis	Size					
	19	21	23	25	27	29
Carpentier (cm <sup>2</sup> )	1.3	1.5	1.8	2.0	2.1	2.2
St Jude Biocor (cm <sup>2</sup> )	NA	1.2	1.4	1.7	2.1	NA
St Jude Standard (cm <sup>2</sup> )	1.16	1.51	2.03	2.59	3.08	NA
Braile (cm <sup>2</sup> )	1.3	1.6	1.9	2.4	2.6	3.1

NA = non-available

## *Impact of the indexed effective orifice area on mid-term cardiac-related mortality after aortic valve replacement*



Conclusions:

There was a significantly improved survival for larger EOAs following AVR.  
Strategies to avoid PPM should become paramount during AVR.

# Patient-Prosthesis Mismatch in Patients With Aortic Stenosis Undergoing Isolated Aortic Valve Replacement Does Not Affect Survival

Período 1997 a 2007 n = 801

Próteses mecânicas e biológicas

PPM grave = 48 (6%), moderado = 462 (57%), ausente = 291 (36,4%)

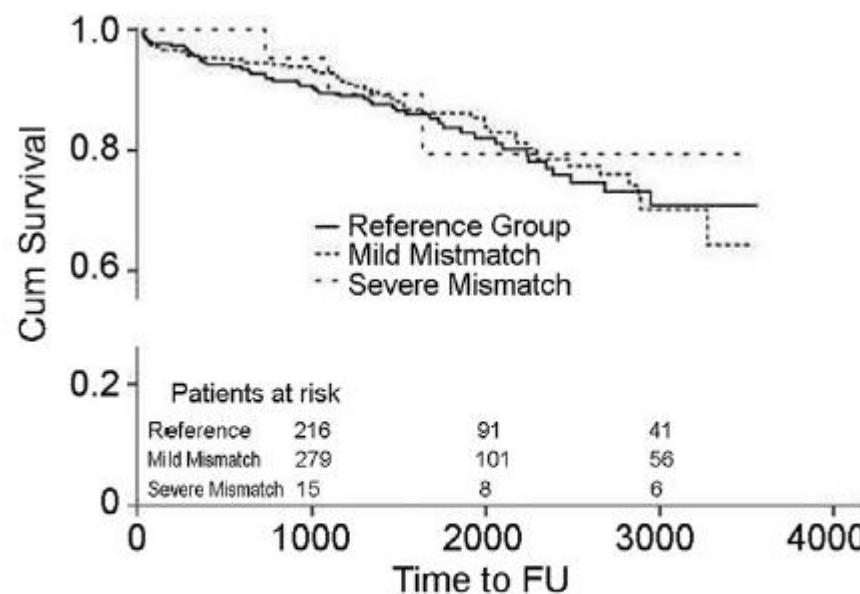


Fig 1. Cumulative (Cum) survival during follow-up (FU) by reference group (solid line), those with mild patient-prosthesis mismatch (dotted line), and those with severe patient-prosthesis mismatch (dashed line).

# The impact of prosthesis–patient mismatch on long-term survival after aortic valve replacement: a systematic review and meta-analysis of 34 observational studies comprising 27 186 patients with 133 141 patient-years

Limiar = 0,85cm<sup>2</sup>/m<sup>2</sup>

PPM em 44,2% do total de 27 artigos

Limiares = 0,65 e 0,85cm<sup>2</sup>/m<sup>2</sup> em 7 artigos

grave= 9,8%

mod.=34,2%

## Conclusions

Although the adverse effect of PPM on long-term survival has been denied in some studies, this meta-analysis of 34 studies with 27 186 patients demonstrates a significant increase in all-cause and cardiac-related mortality over long-term follow-up after AVR. Current efforts to prevent PPM should therefore receive more emphasis and widespread acceptance to improve long-term survival.

# **CONCLUSÃO 1**

## **DESEMPENHO HEMODINÂMICO:**

*Desempenho hemodinâmico é semelhante em biopróteses 23mm ou maiores  
Em <21mm, pericárdio tem vantagem*

*Efeito de “mismatch” na sobrevida é discutível  
Entretanto, deve ser evitado, principalmente em idosos, FE baixa e NYHA >III*

*Se “mismatch” presente: acompanhar evolução, HVE, sintomas*

*Individualizar condutas, avaliando riscos/benefícios*

**A ESCOLHA: Em tamanhos < 21mm, preferir pericárdio ou fazer ampliação, exceto em casos de menor superfície corporal**

# *Quais são as questões principais na escolha da bioprótese cirúrgica?*

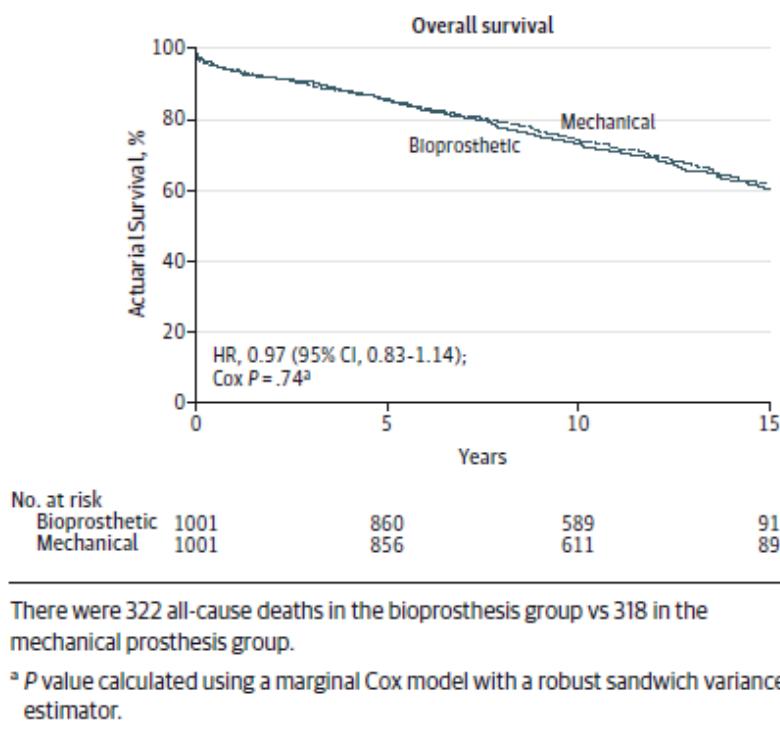
- ***DESEMPENHO HEMODINÂMICO:***

*Gradiente pressórico e alívio da sobrecarga de pressão, orifício efetivo*

- ***DURABILIDADE:***

*Sobrevida a longo prazo sem re-operações, degeneração, calcificação*

**Figure 1. Overall Survival Among Propensity-Matched Patients Aged 50 to 69 Years After Bioprosthetic vs Mechanical Aortic Valve Replacement**



## Survival and Long-term Outcomes Following Bioprosthetic vs Mechanical Aortic Valve Replacement in Patients Aged 50 to 69 Years

**DESIGN, SETTING, AND PARTICIPANTS** Retrospective cohort analysis of 4253 patients aged 50 to 69 years who underwent primary isolated aortic valve replacement using bioprosthetic vs mechanical valves in New York State from 1997 through 2004, identified using the Statewide Planning and Research Cooperative System. Median follow-up time was 10.8 years (range, 0 to 16.9 years); the last follow-up date for mortality was November 30, 2013. Propensity matching yielded 1001 patient pairs.

### Based on NY Registry

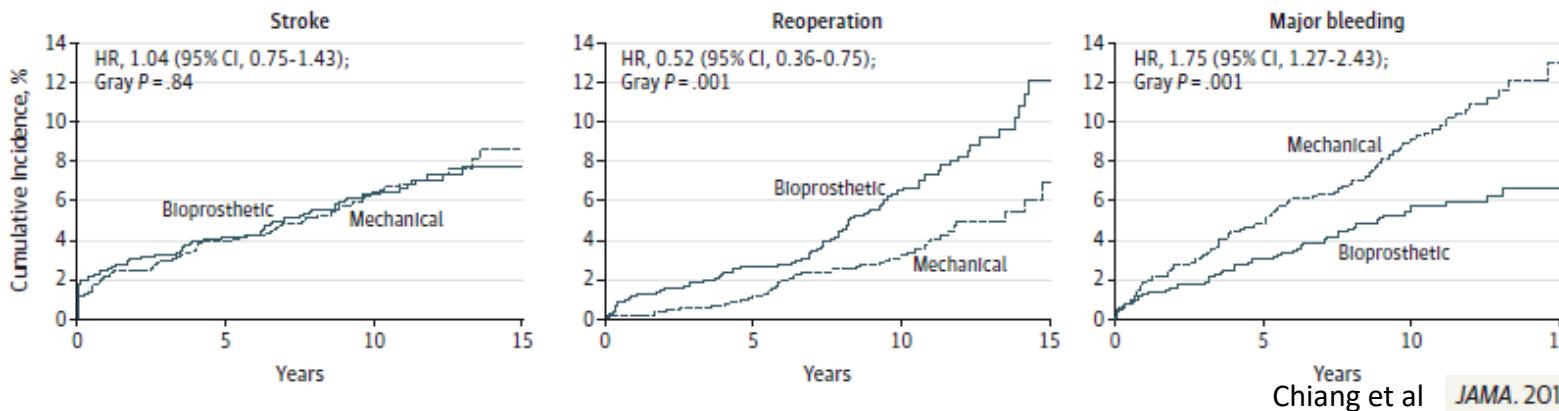
#### Mortality after complications:

**18.7% after stroke**

**9.0% after reoperation**

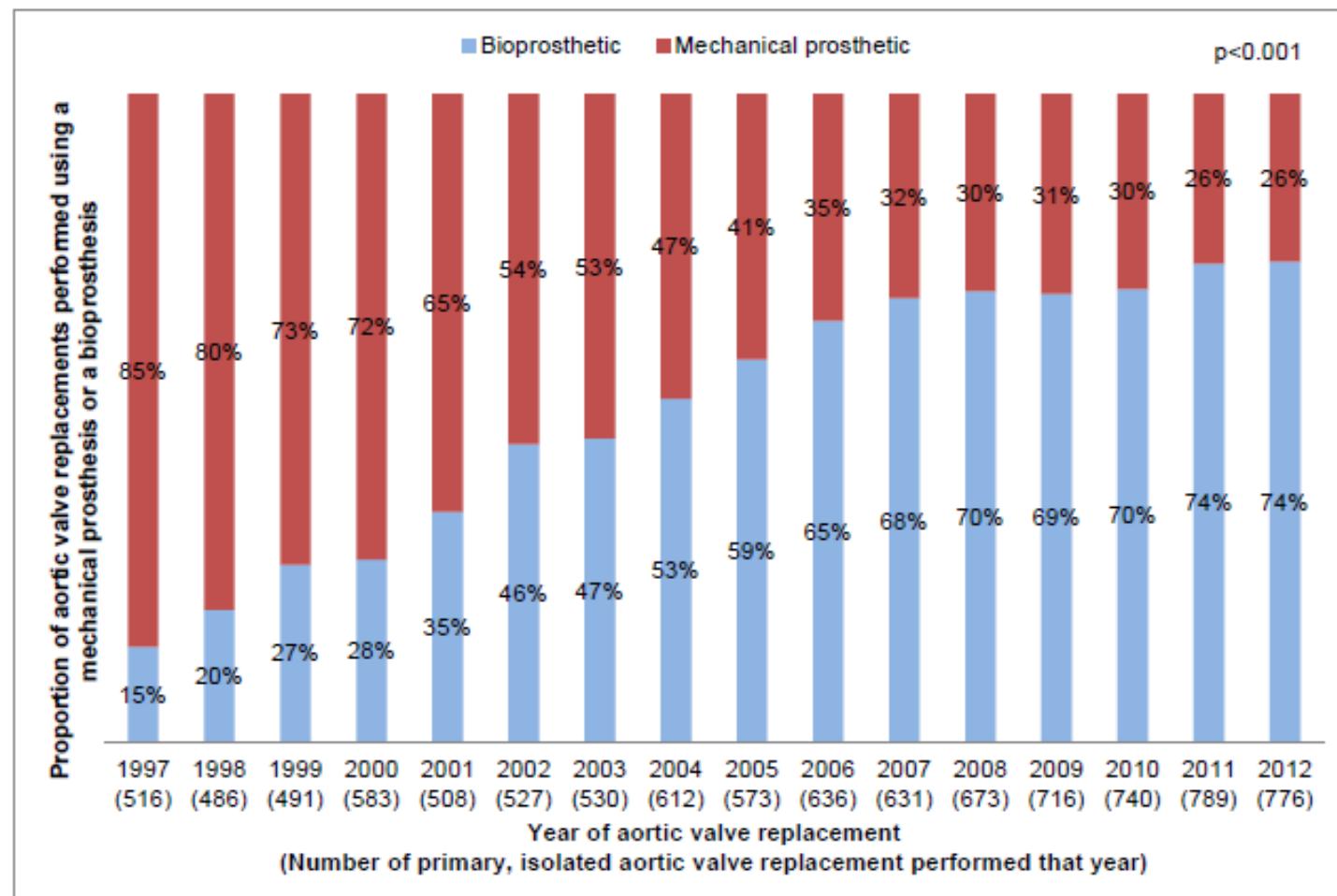
**13.2% after major bleeding**

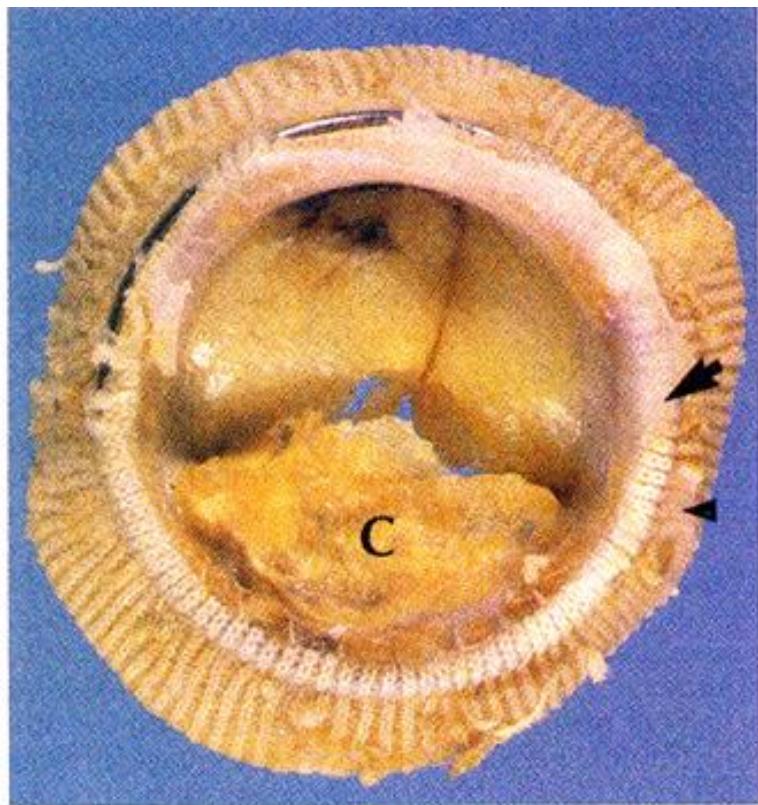
**Figure 2. Cumulative Incidence of Major Morbidity (Stroke, Reoperation, Major Bleeding) Among Propensity-Matched Patients Aged 50 to 69 Years After Bioprosthetic vs Mechanical Aortic Valve Replacement**



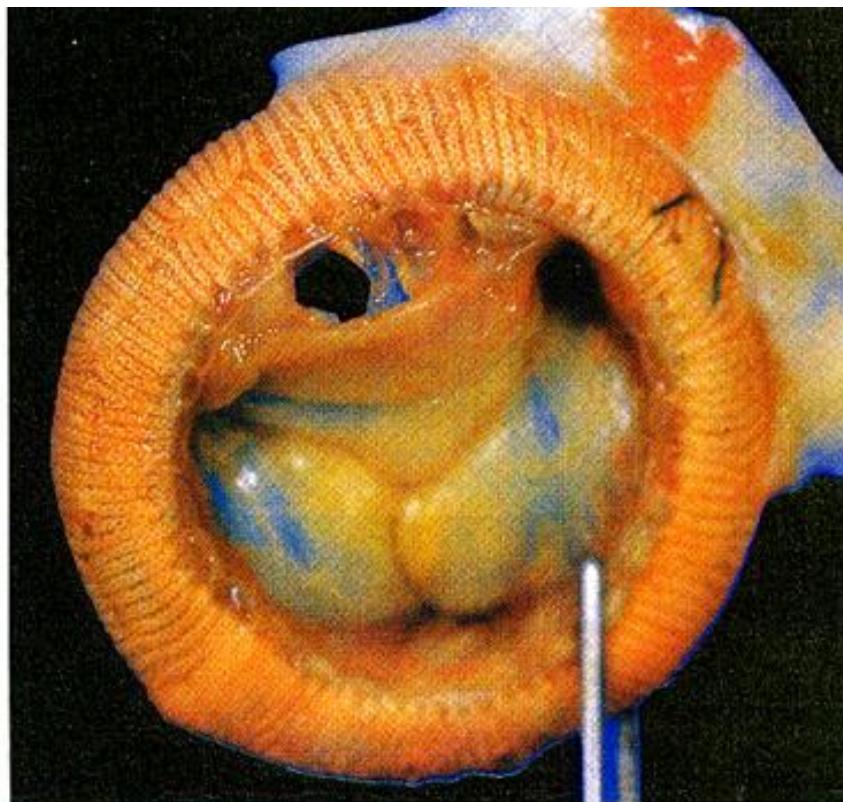
## Survival and Long-term Outcomes Following Bioprosthetic vs Mechanical Aortic Valve Replacement in Patients Aged 50 to 69 Years

**eFigure 2.** Trend in Mechanical versus Bioprosthetic Valve Usage for Aortic Valve Replacement in Patients Aged 50 to 69 in New York State<sup>a</sup>





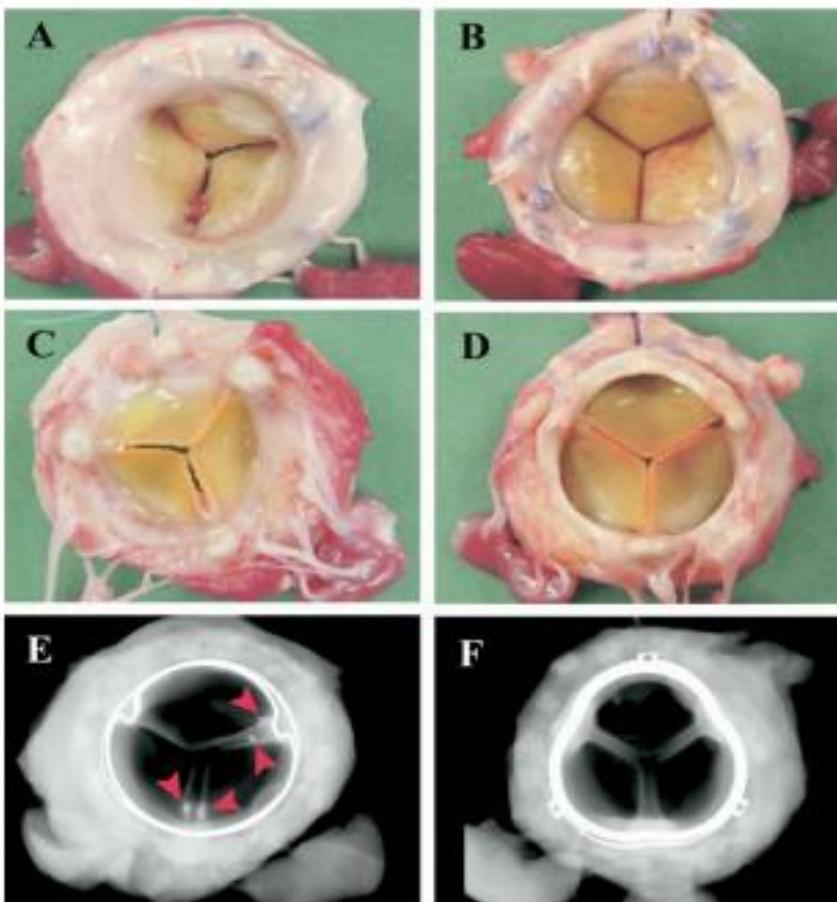
A



B

**FIGURE 57-50** Structural deterioration of bioprosthetic valves. **A**, Valve failure related to mineralization and collagen degeneration. **B**, Cuspal tears and perforations. These processes may occur independently, or they may be synergistic. (**A**, From Virmani R, Burke AP, Farb A: Pathology of valvular heart disease. In Rahimtcola SH [ed]: Valvular Heart Disease. In Braunwald E [series ed]: Atlas of Heart Diseases. Vol 11. Philadelphia, Current Medicine, 1997, p 1.26; **B**, From Manabe H, Yutani C [eds]: Atlas of Valvular Heart Disease. Singapore, Churchill Livingstone, 1998, p 158.)

## Trilogy Pericardial Valve: Hemodynamic Performance and Calcification in Adolescent Sheep



*Fig 2. Typical examples of valves explanted after five months in mitral position: gross examination of the explants and their Faxitron (Wheeling, IL) X-ray pictures. Left panels (A, C, E): explanted Perimount valve (Edwards Lifesciences) (atrial side, ventricular side, and X-ray). Right panels (B, D, F) show an explanted Trilogy valve (Arbor Surgical Technologies Inc) (atrial side, ventricular side, and X-ray). Note the clear commissural calcifications in two commissures of the Perimount (arrowheads).*

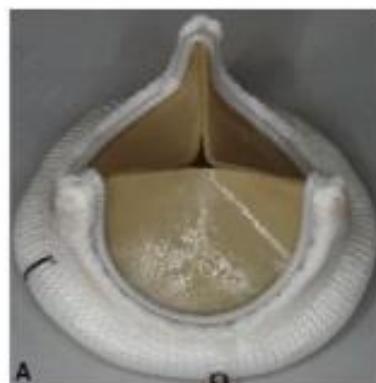
Flameng W et al.  
Ann Thorac Surg 2008;85:587–92



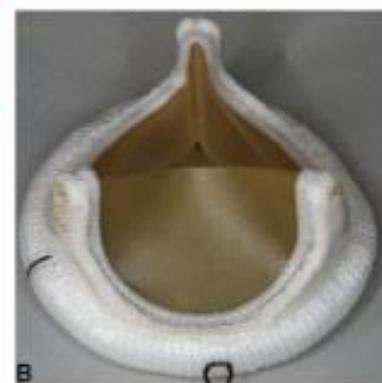
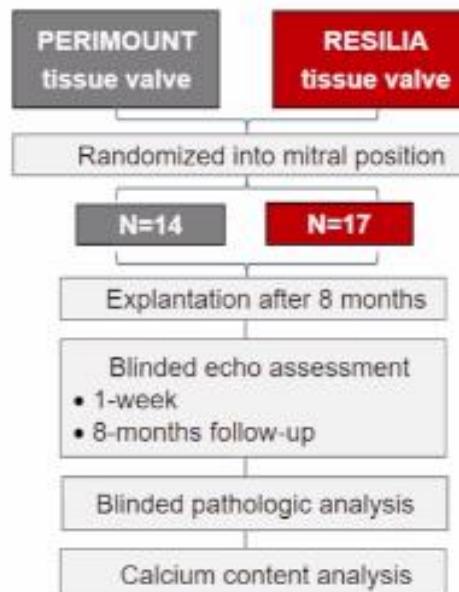
Edwards

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Masters

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## RESILIA tissue



Engineering Technology/Basic Science

Flameng et al

Randomized assessment of an advanced tissue preservation technology in the juvenile sheep model

Willem Flameng, MD, PhD, Hadewich Hermans, MD, Erik Verbeken, MD, PhD, and Bart Meuris, MD, PhD

04:10

Flameng W, et al. J Thorac Cardiovasc Surg. 2015; Jan;149(1):340-5.



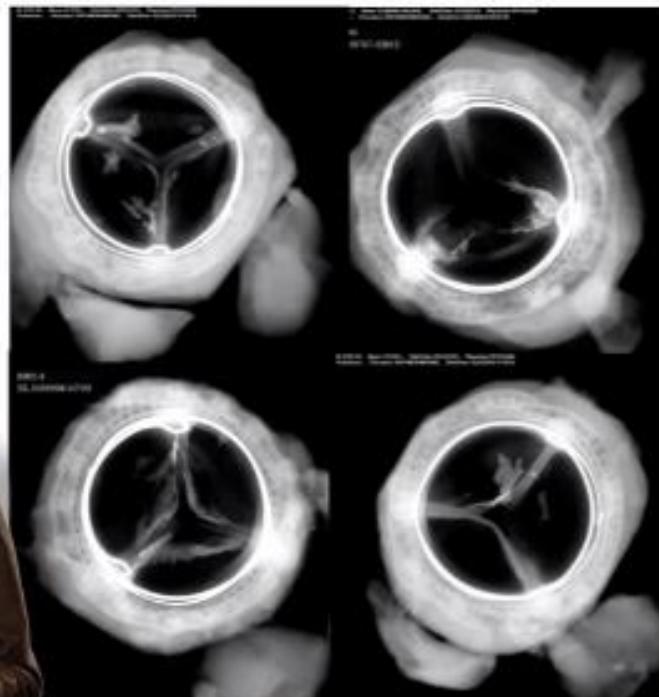


Edwards

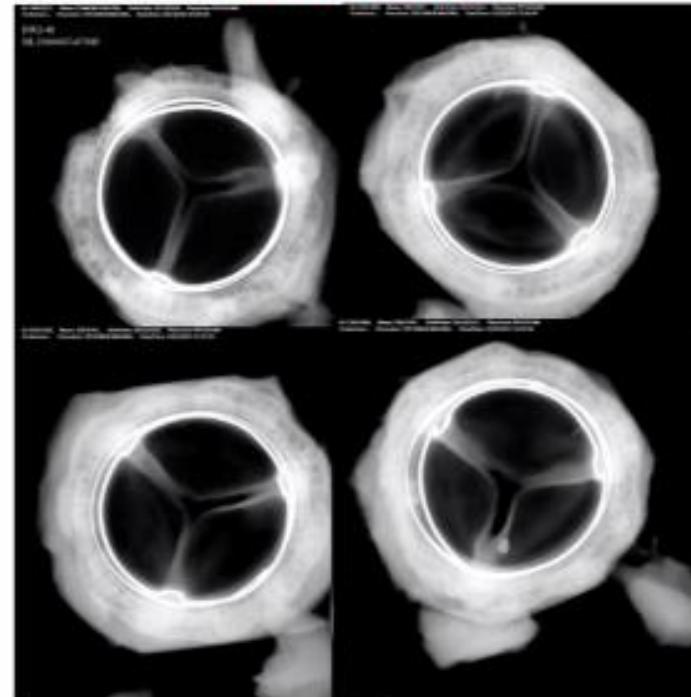


## RESILIA tissue

PERIMOUNT tissue valves



RESILIA tissue valve



Echocardiographic analysis showed overt commissural and leaflet calcifications in the PERIMOUNT valve control group

Flameng W, et al. J Thorac Cardiovasc Surg. 2015 Jan;149(1):340-5.

# The COMMENCE trial: 2-year outcomes with an aortic bioprosthesis with RESILIA tissue.

2013 - 2016, n = 689

age =  $67.0 \pm 11.6$  years

At 2 years, New York Heart Association class improved in 65.7%,  
Effective orifice area was  $1.6 \pm 0.5$  cm<sup>2</sup>;  
Mean gradient was  $10.1 \pm 4.3$  mmHg;

One-year actuarial freedom from all-cause mortality for isolated AVR and for all patients was 98.2% and 97.6%, respectively.

**Two-year** actuarial freedom from mortality in these groups was 95.3% and 94.3%, respectively.

## CONCLUSIONS:

These data demonstrate excellent early safety and effectiveness of aortic valve replacement with a novel bioprosthetic tissue (RESILIA™)



Válvula SJM E

Primeira válvula  
comprovado pro-  
mais de 15 anos.  
exclusiva tecnol-  
proteger contra

## Análise Competitiva

Produtos	Linx AC Technology <sup>1,2,3,4</sup> Epic/Epic Supra	Edwards XenoLogix <sup>5</sup> PERIMOUNT™/Magna™	Edwards ThermaFix™ PERIMOUNT™/Magna™	Medtronic AOA <sup>7</sup> Mosaic™/Ultra™	Medtronic T6 <sup>6</sup> Hancock II™
① Redução de aldeídos livres	✓		✓	✓	
② Extração de Lipídios	✓	✓	✓		✓
③ Minimiza a absorção de colesterol	✓				
④ Estabiliza o colágeno dos folhetos	✓				

*Não há dados clínicos disponíveis que avaliem o impacto a longo prazo do tratamento de tecidos com anticalcificação em seres humanos.*

- Baseado em um projeto de estabilidade hemodinâmica comprovada de até 17 anos de pós-implantação.<sup>8</sup>

Projetado para durar

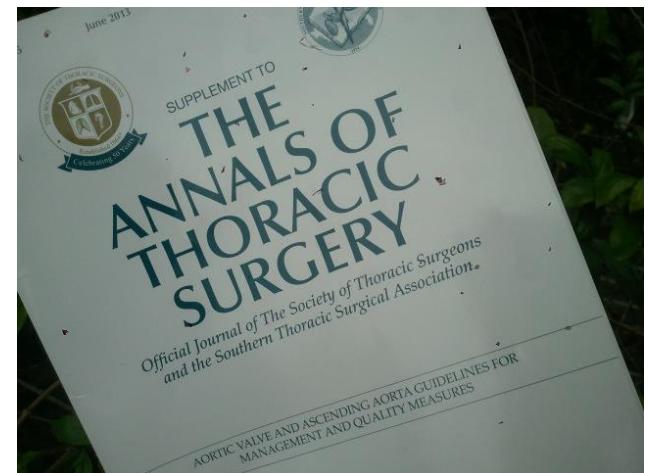
- Feito com o comprovado desempenho de bioprótese aórtica PERIMOUNT, com mais de 27 anos de experiência clínica<sup>9,10</sup>
  - O Carpentier-Edwards ThermaFix process é a única tecnologia de anti-calcificação projetada para confrontar os locais de maior ligação de cálcio.



\*Nenhum dado clínico está disponível para avaliar o impacto de longo prazo nos pacientes sob tratamento de tecidos Edwards.

## Referências

# Existem biopróteses com durabilidade superior?



sites. To mitigate valve calcification most companies have developed proprietary tissue treatments aimed at removing residual glutaraldehyde or phospholipid moieties to reduce calcium binding and hopefully enhance durability. Among these are treatment with alcohol and various antisurfactants but none has proved superior to others.

Aortic Valve and Ascending Aorta Guidelines  
for Management and Quality Measures

Ann Thorac Surg 2013;95:S1–S66

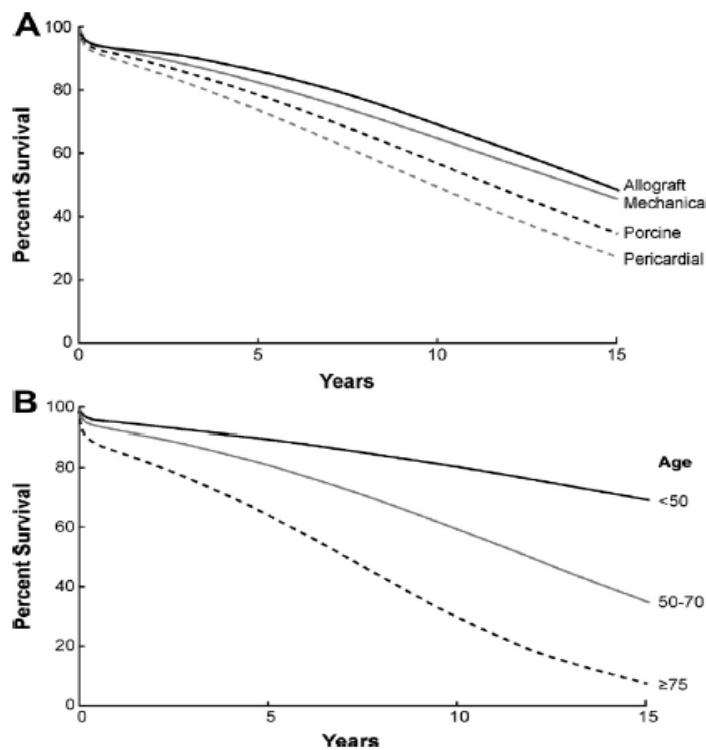


Fig 2. (A) Relationship of late survival to years after aortic valve insertion in 13,258 patients, divided by aortic valve prosthesis. (B) Survival by age.

operation; (3) effective orifice area (EOA) including gradients and energy loss; and (4) long-term durability, with no difference in survival compared with other devices, but better than the untreated population.

Clearly, there are few, if any medical procedures that are as effective in relieving symptoms, improving quality of life, and also increasing long-term survival as much as AVR for aortic stenosis (AS) or aortic regurgitation (AR), but for perhaps the exception of heart transplantation, but the latter adds the problem of managing new medications and increased monitoring. Recent data from 3,600 Medicare patients show that there is a reduced hospital readmission rate and increased survival among high-risk Medicare patients (aged  $\geq 65$  years) treated with AVR for severe AS,

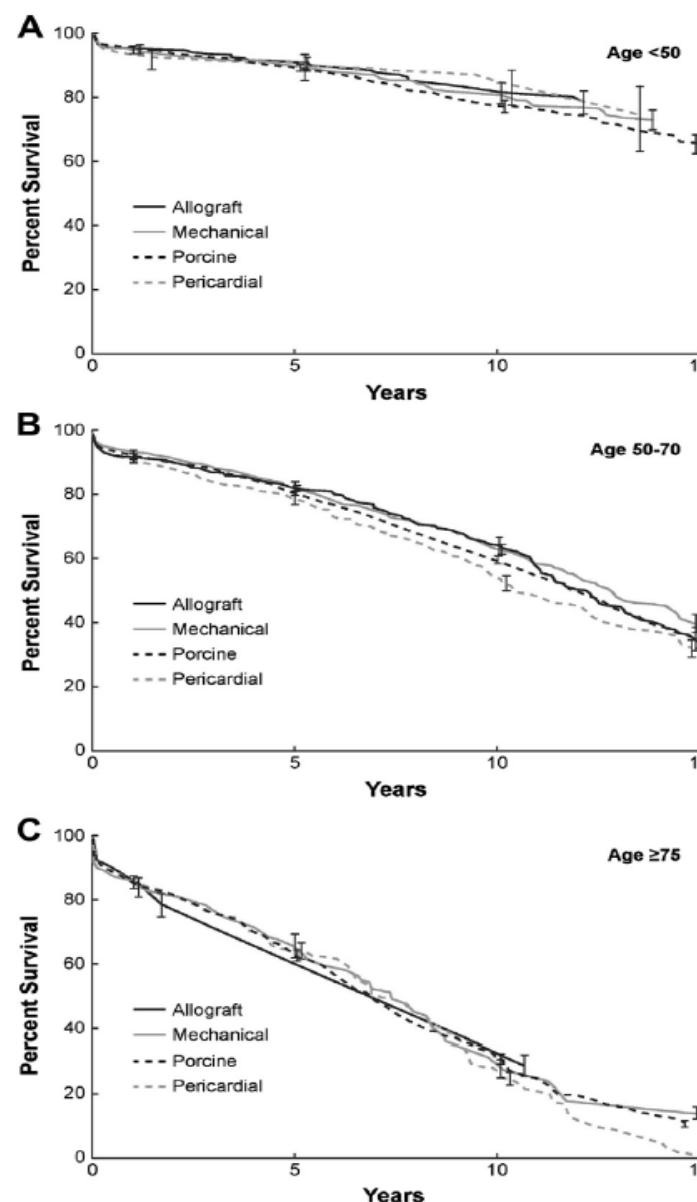


Fig 3. Survival by age groups: (A) younger patients; (B) middle-aged patients; (C) elderly patients. Note that differences disappear.

# Pericárdica e Porcina, 3 modelos

1870 SAID ET AL  
PERICARDIAL VS PORCINE FOR AVR IN THE ELDERLY

Ann Thorac Surg  
2012;93:1868–75

n=2979  
>65anos  
período  
1993-2007,  
Mayo,  
Mass Gen e  
Brigham

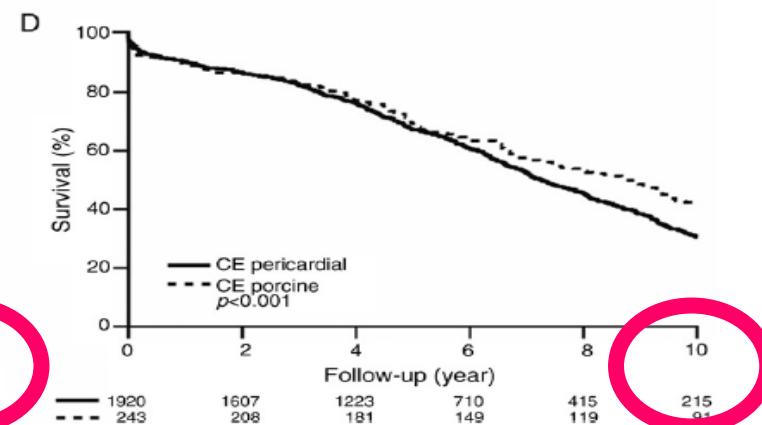
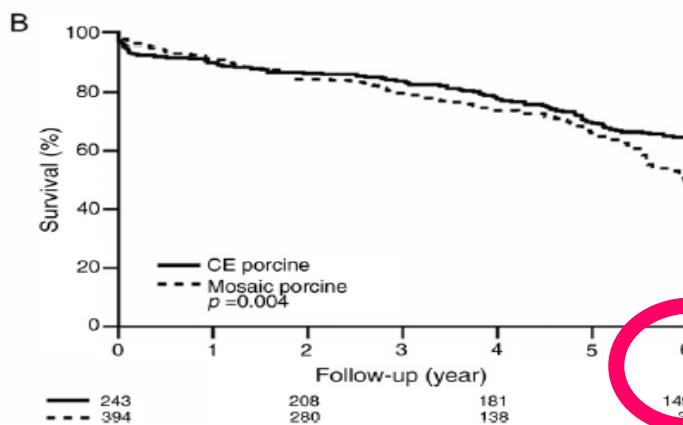
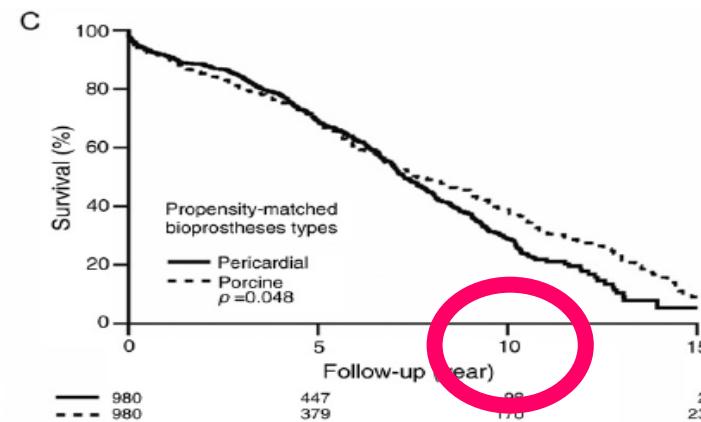
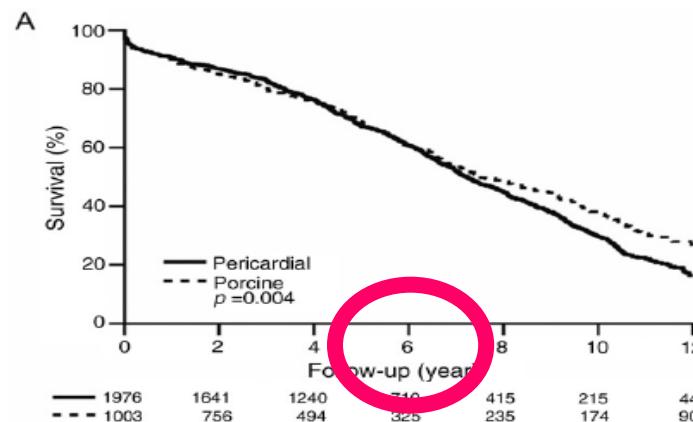


Fig 1. Kaplan-Meier graphs show survival of elderly patients after aortic valve replacement. (A) There was no survival advantage for patients with pericardial (solid line) over porcine (dashed line) bioprostheses ( $p = 0.05$ ). (B), Survival is shown between the two most commonly used porcine brands, the Medtronic Mosaic (dashed line) and the Carpentier-Edwards Perimount (CE, solid line). (C) Survival is compared between propensity-matched pericardial (solid line) and porcine (dashed line) bioprostheses types. (D) There was no survival advantage for the Carpentier-Edwards (CE) Perimount (solid line) over the porcine type (dashed line); in fact, the porcine brand appeared to have a survival advantage ( $p < 0.001$ ).

# Do Pericardial Bioprostheses Improve Outcome of Elderly Patients Undergoing Aortic Valve Replacement?

Sameh M. Said, MD,\* Elena Ashikhmina, MD, PhD, Kevin L. Greason, MD, Rakesh M. Suri, MD, PhD, Soon J. Park, MD, Richard C. Daly, MD, Harold M. Burkhart, MD, Joseph A. Dearani, MD, Thoralf M. Sundt III, MD, and Hartzell V. Schaff, MD

Division of Cardiovascular Surgery, Mayo Clinic, Rochester, Minnesota; Division of Cardiac Surgery, Massachusetts General Hospital, Boston, Massachusetts; and Division of Anesthesia, Brigham and Women's Hospital, Boston, Massachusetts

**Background.** Pericardial bioprostheses have favorable echocardiographic hemodynamics in the aortic position compared with porcine valves; however, there are few data comparing clinical outcomes. Our objective was to assess the late results of the two valve types.

**Methods.** We reviewed 2,979 patients aged 65 years or older undergoing aortic valve replacement with pericardial ( $n = 1,976$ ) or porcine ( $n = 1,003$ ) prostheses between January 1993 and December 2007. The most common pericardial prostheses were Carpentier-Edwards Perimount and Mitroflow, and the most common porcine valves were Medtronic Mosaic, Carpentier-Edwards, Hancock modified orifice, and St. Jude Biocor. Follow-up extended to a maximum of 16 years (mean,  $5.2 \pm 3.5$  years).

**Results.** Survival at 5, 10 and 12 years was, respectively, 68%, 33%, and 21% overall, was 68%, 30%, and 16% for

patients with pericardial bioprosthesis, and was 69%, 38% and 27% for the porcine group. In a multivariate model, long-term survival was reduced in patients with diabetes, renal failure, prior myocardial infarction, congestive heart failure, and older age, but late survival was not higher in the pericardial valve group. Overall freedom from reoperation was 96%, 92%, and 90% at 5, 10, and 12 years, and freedom from explant was 98%, 96%, and 94% during the same period. The reason for explant was structural valve deterioration in 50 patients (2%).

**Conclusions.** Despite the better hemodynamic performance documented in prior investigations, pericardial valves do not confer any survival advantage over porcine valves in patients aged 65 years or older undergoing aortic valve replacement.

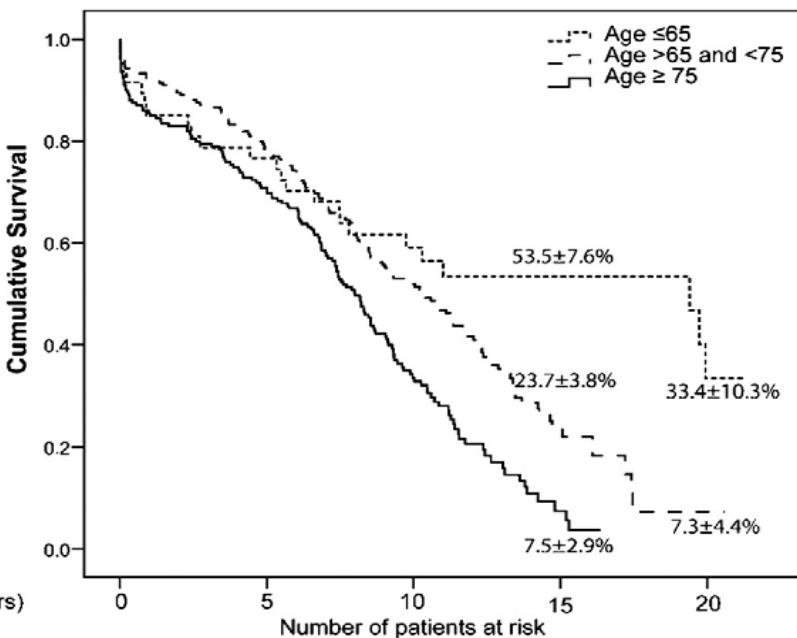
(Ann Thorac Surg 2012;93:1868–75)

© 2012 by The Society of Thoracic Surgeons

# Sobrevida Biopróteses Ao

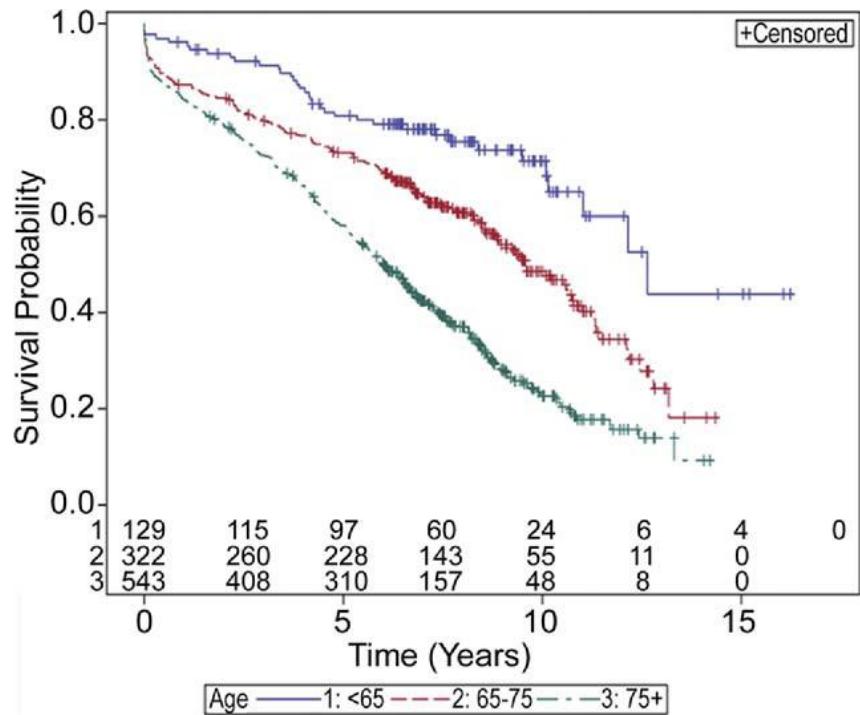
## Biocor StJude porcina

Eichinger WB e cols  
German Heart Center Munich  
Ann Thorac Surg 2008;86:1204 –11



## Carpentier-Edwards Pericardial Bioprostheses

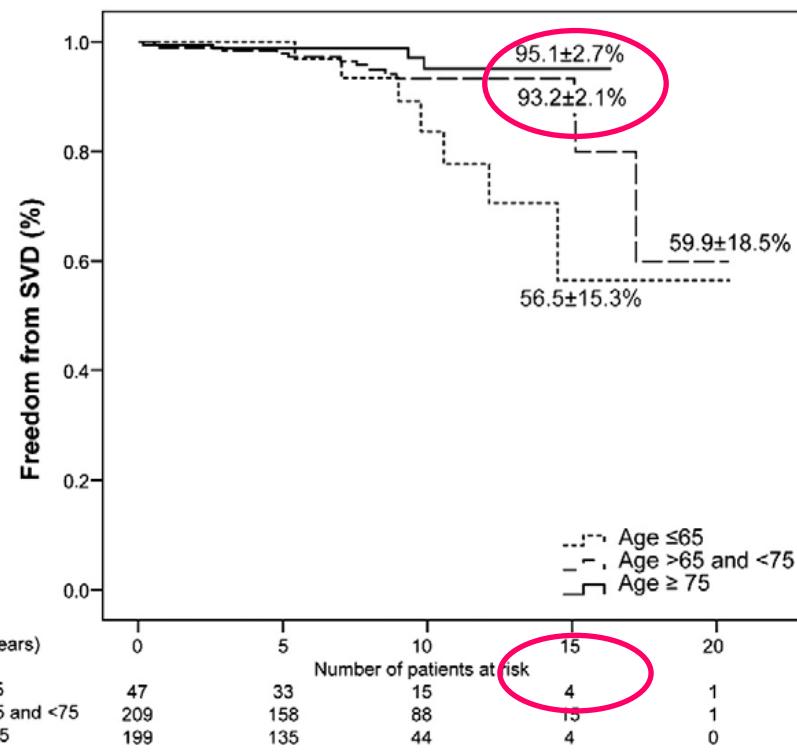
McClure RS e cols, Brigham and Women's Hospital ,Harvard Medical School  
Ann Thorac Surg 2010;89:1410-1416



# Sobrevida livre de degeneração estrutural da bioprótese Ao

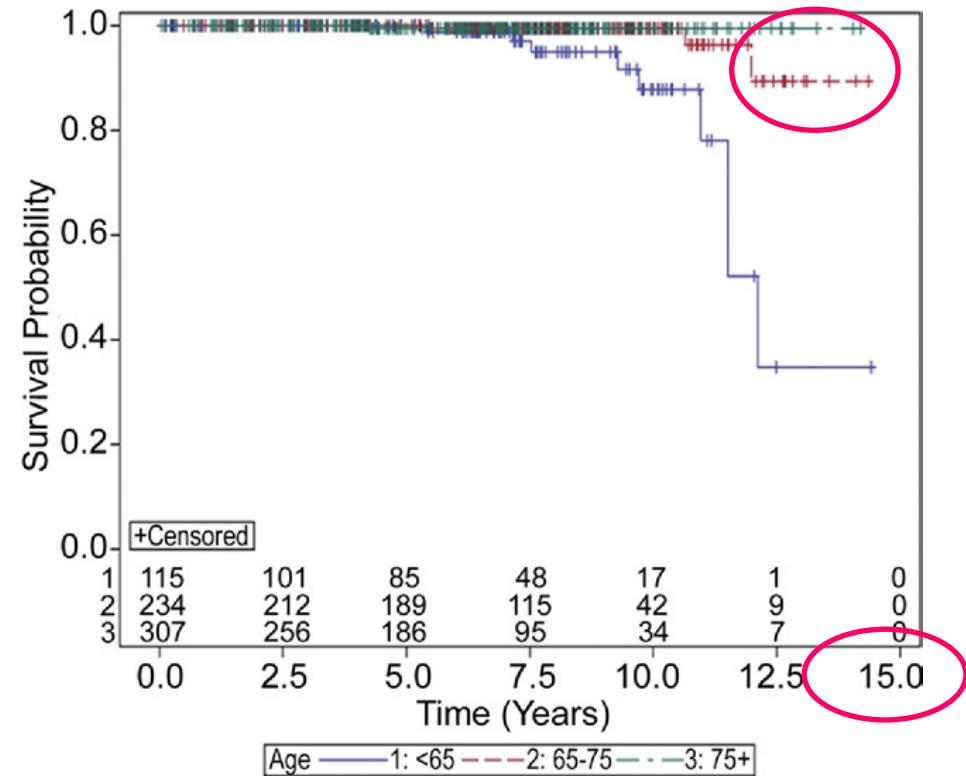
## Biocor StJude porcina

Eichinger WB e cols  
German Heart Center Munich  
Ann Thorac Surg 2008;86:1204–11



## Carpentier-Edwards Pericardial Bioprosthesis

McClure RS e cols, Brigham and Women's Hospital ,Harvard Medical School  
Ann Thorac Surg 2010;89:1410-1416



# Long-Term Durability of Bioprosthetic Aortic Valves: Implications From 12,569 Implants

Ann Thorac Surg  
2015;99:1239–47

JOHNSTON ET AL  
BIOPROSTHETIC AORTIC VALVE DURABILITY  
1243

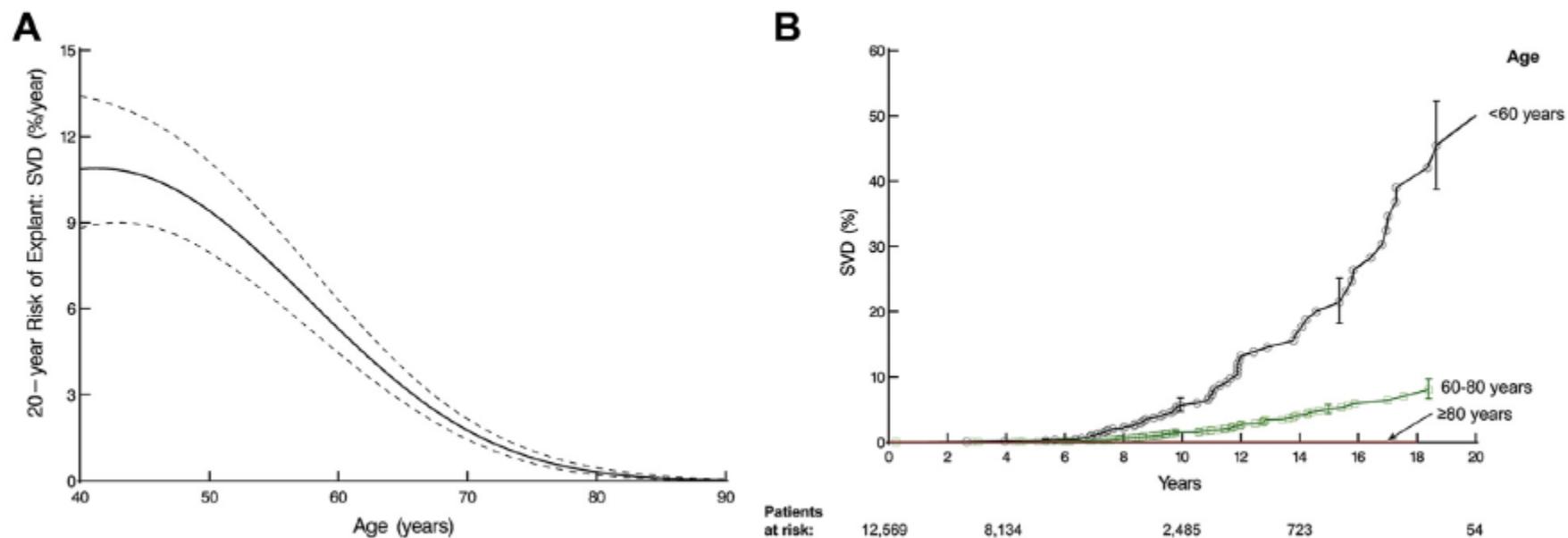


Fig 3. Age and probability of explant owing to structural valve deterioration (SVD). (A) Nomogram of age relationship to SVD from multivariable equation based on preoperative variables alone. (B) Patients are grouped according to age range. Each symbol represents an explant, vertical bars are 68% confidence limits, and numbers along the horizontal axis are patients remaining at risk.

Cleveland Clinic.  
Carpentier Perimount Pericardial

# Late outcome analysis of the Braile Biomédica® pericardial valve in the aortic position

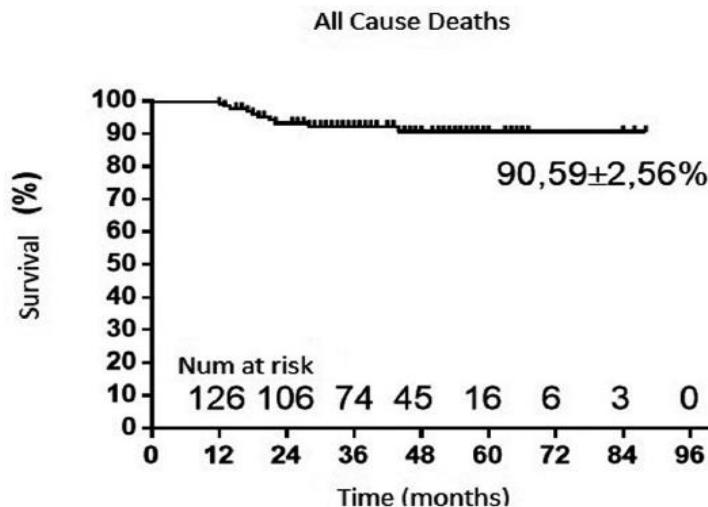


Fig. 1 - Kaplan-Meier survival curve after 88 months of aortic valve prosthetic implantation.

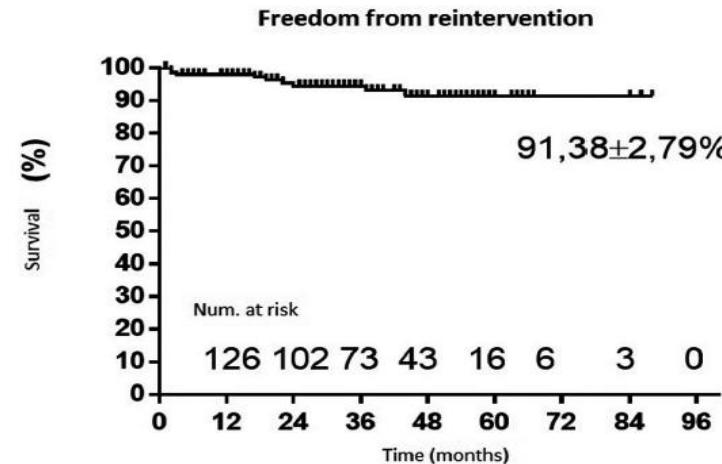


Fig. 2 - Kaplan-Meier freedom from reintervention curve after 88 months of aortic valve prosthetic implantation.

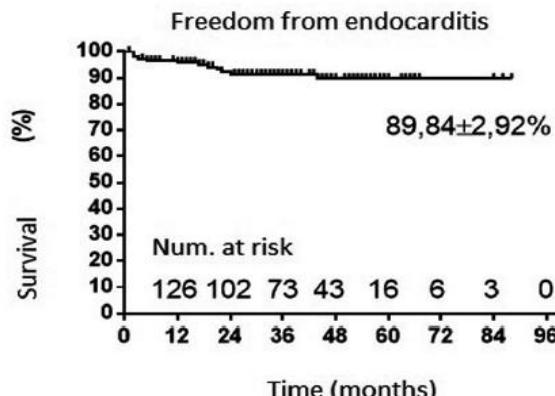
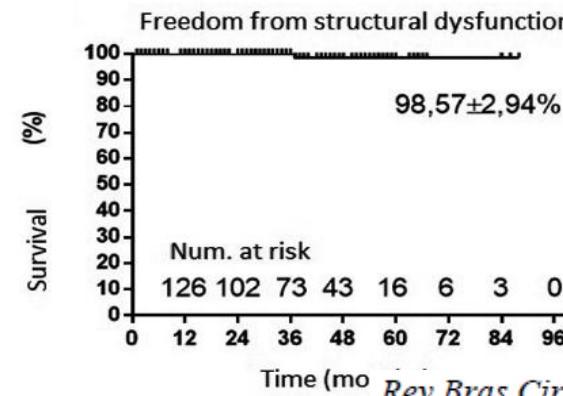


Fig. 3 - Kaplan-Meier curves, freedom from endocarditis and from structural valve dysfunction after 88 months of aortic valve prosthetic implantation.



# Hancock II Bioprostheses for Aortic Valve Replacement: The Gold Standard of Bioprosthetic Valves Durability?

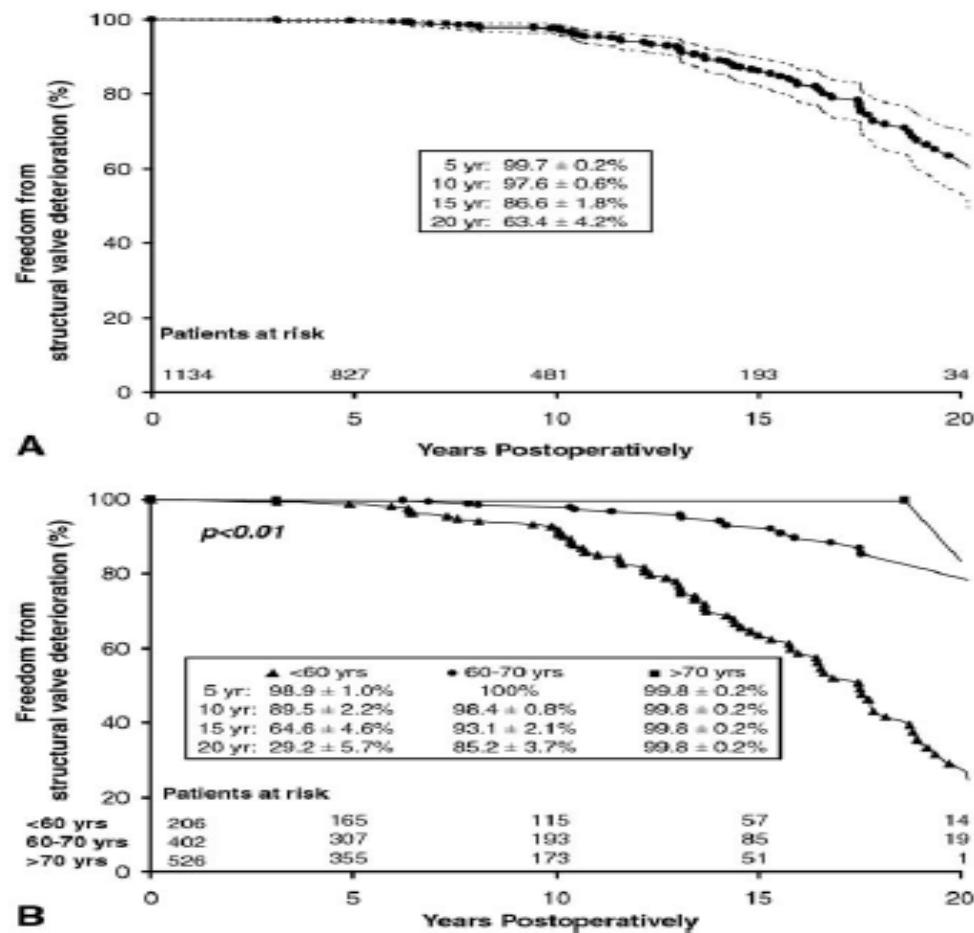
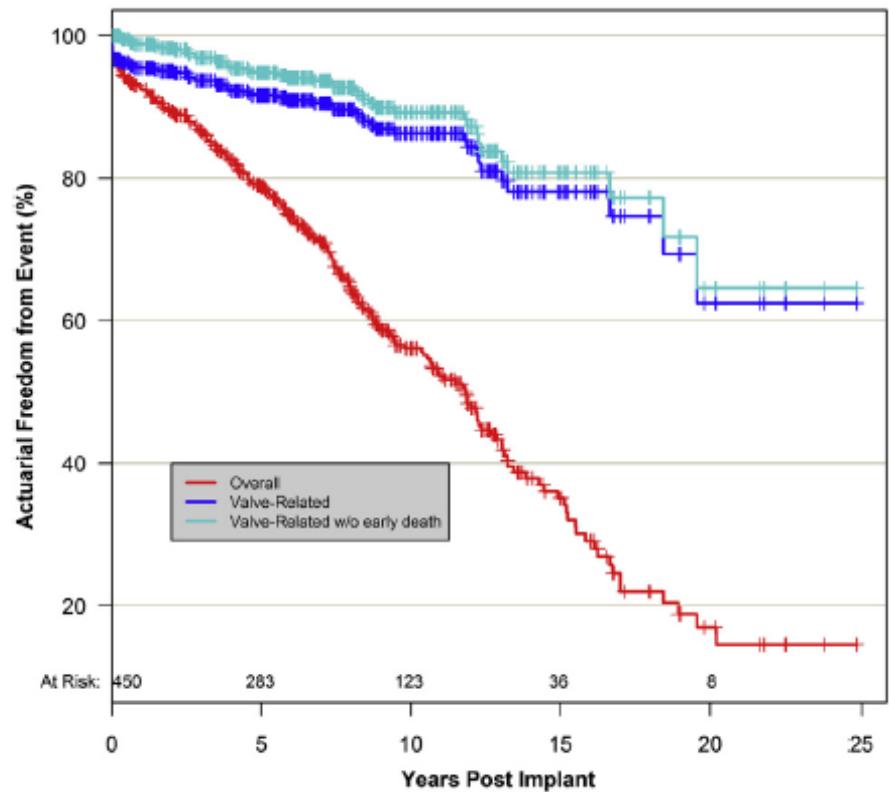


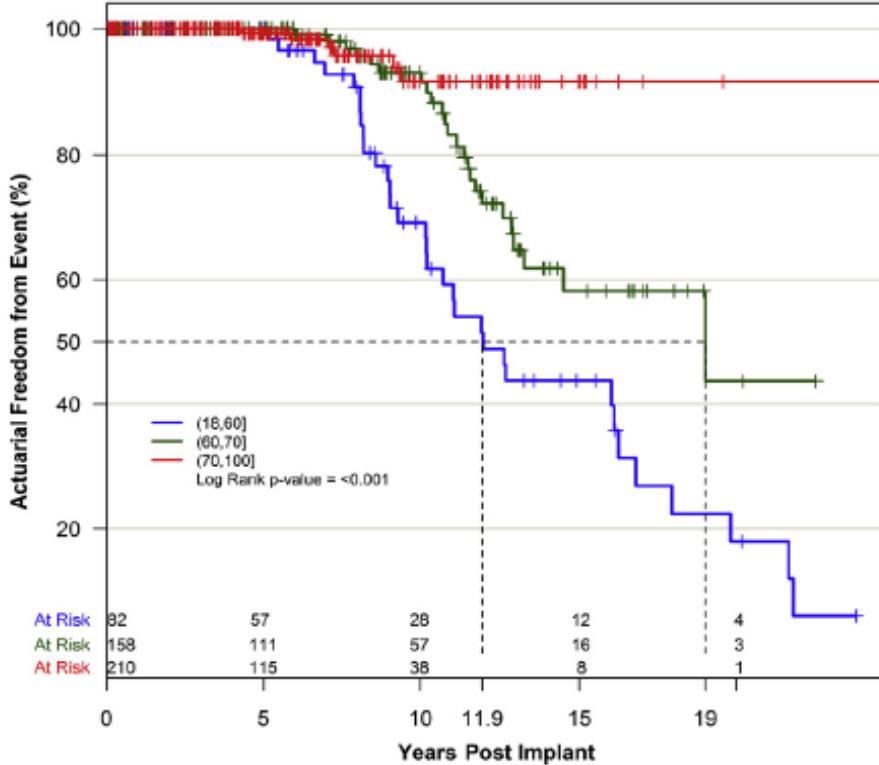
Fig 2. Freedom from structural valve deterioration is shown for (A) all patients (dotted lines on either side of solid line represent upper and lower 95% confidence intervals) and (B) according to age group.

### Actuarial (Kaplan-Meier) Survival

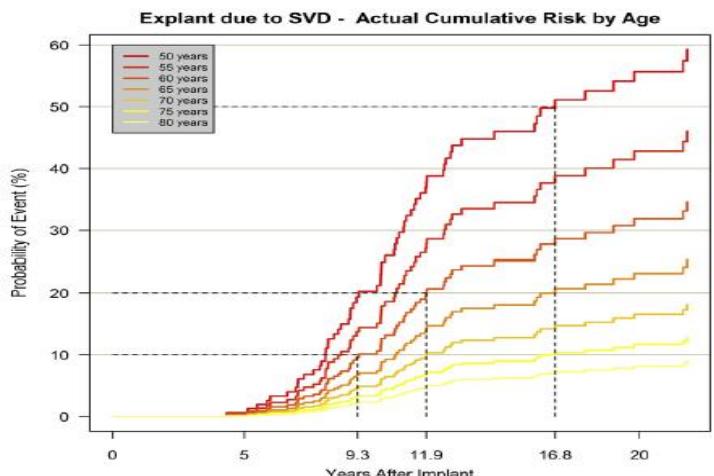


**FIGURE 1.** Kaplan-Meier estimates of overall and valve-related mortality.

### Actuarial Freedom from Explant due to SVD by Age Group



**FIGURE 2.** Kaplan-Meier estimates of explantation because of structural valve deterioration (SVD) stratified by age group.



**FIGURE 3.** Competing risk estimates of explantation because of structural valve deterioration (SVD) stratified by age group.

Bourguignon et al

Acquired Cardiovascular Disease

Very late outcomes for mitral valve replacement with the  
Carpentier-Edwards pericardial bioprosthesis: 25-year follow-up  
of 450 implantations

J Thorac Cardiovasc Surg 2014

# Estratégias de Marketing

## Reposicionamento de Mercado



### 2. Oil of Olay®: Repositioning Rejuvenates a Tired Brand.

Oil of Olay has historically been a small, down-market brand with an aging consumer base.

**Proctor & Gamble:**

**Repositioning the brand for younger demographics as a prestige-like brand**

P&G chose the repositioning strategy. **Pricing would be integral to attracting consumers.**

If a luxury brand is priced too low, people will not believe the luxury position.

If a mass brand is priced too high, it will not sell in sufficient quantity.

P&G's research showed:

- At \$12.99. Few department store buyers expressed interest at this price.
- At \$15.99 purchase intent from both mass-market and department store buyers dropped dramatically.
- Surprisingly, at \$18.99, purchase intent not only went back up, but went way up!

How did P&G's mass-luxury repositioning work?

It succeeded beyond P&G's expectations, exceeding the company's goal of \$1 billion in sales by a factor of 2.5.

What's more, the Oil of Olay experiment led to the successful introduction of other "boutique" product lines such as Regenerist, Definity and ProX. Olay for Olay!

*Harvard Business Review*

("Bringing Science to the Art of Strategy," September 2012)



## Best Selling



Olay  
Regenerist Micro-sculpting Eye Swirl,  
Eye Treatment 0.5 Fluid Ounce

57

\$14.42

## Top Rated



Olay  
Regenerist Advanced Anti-Aging Micro-  
Sculpting Cream 1.70 oz

78

from \$38.59



Olay Olay  
Regenerist...  
R\$ 145,55  
Biovea BR



Creme Hidratante  
Facial - Olay...  
R\$ 149,00  
Mercado Livre



Olay Regenerist  
Serum  
R\$ 111,91  
Biuky.br



Olay Regenerist -  
Creme Anti-...  
R\$ 427,26  
Mercado Livre



Olay Serum  
Regenerist 3...  
R\$ 152,84  
Biuky.br



FREESTUFFFINDER.COM

**Table 2: Leading brands in the US facial skincare market by value, 2008**

Company	Brand	Percentage share by value, 2008
Procter & Gamble Company, The	Olay	16.7%
Procter & Gamble Company, The	Pond's	8.4%
Procter & Gamble Company, The	L'Oreal Paris	5.5%
Johnson & Johnson	Aveeno	5.3%
Johnson & Johnson	Garnier	5.1%
Johnson & Johnson	Neutrogena	4.6%
Johnson & Johnson	Nivea	4.5%
Johnson & Johnson	Noxzema	4.0%
L'Oreal S.A.	Dove	3.8%
L'Oreal S.A.	Clinique	3.6%

Source: Datamonitor's Market Data Analytics

DATAMONITOR

Seguro | https://mail.google.com/mail/u/0/?tab=wm&zx=l7a6ce2l55w2#inbox/164d64c07d046ebb

Apps Bookmarks Personalizar Links Entrada (6) www.bb.com.br Portal Internet Banris Itaú Link Outros favoritos

Gmail ▾

ESCREVER

Entrada (18)  
Com estrela  
Importante  
Enviados  
Rascunhos (78)  
Lixeira

Categorias

AATS  
Academia Slu-Rio...  
CardioPed (1)  
CEPEC  
Comunicação ...  
Conselho Diretor ...  
CTEPH  
Edwards Foundation  
ENSAIOS CLÍNIC...  
EQUIPE CIRÚRGI...  
ESC  
Estância (8)  
EURO ENDO REG...  
HMV (3)  
Karam  
LAOOS III (4)  
M GRUPO  
MITRAL  
Notes  
Pediátrica  
- Busca (6)

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mercado livre Compra Garantida

Sabemos que isso te interessa...  
Compre agora!

R\$ 427<sup>26</sup>

Frete grátis

Olay Regenerist - Creme Anti-Envelhecimento C/ 2 Packs

Ver detalhe

Ativar o Windows  
Acesse Configurações para ativar o Windows.

Exibir todos

10.1016-j.athoracs....ppt 10.1016-j.athoracs....ppt 10.1016-j.athoracs....ppt Repair x Replace is....pdf Michler 2 year out....pdf

Digite aqui para pesquisar

POR PTB2 15:08 31/07/2018

# Posicionamento de Mercado – Biopróteses – RS/Brasil

**xxxxxxxxx Porcina/Bovina R\$ 937,93**

**xxxxxxxx nova pericárdio R\$ 15.000,00**

**xxxxxx anticalcif R\$ 10.000,00**

**MMMM porcina – R\$ 10.000,00**

**BBBBB R\$ 2.141,00**

**LLLLL R\$ 937,93**

DESCRICAQ	VALORES UNIMED	VALORES OUTROS CONVÊNIOS
CCEEE P VALVULA BIOLOGICA MITRAL	12.000,00 Tipo/Cód. 62/1703301 1	16.800,00
CCEEE PERICARDIAL AORTICA	12.000,00 Tipo/Cód. 62/1703301 0	16.800,00
CCEEE ME AORTICA/MITRAL	Sem Tipo/Cód	22.000,00

(\* Valores R\$ 2016)

## Aortic Valve and Ascending Aorta Guidelines for Management and Quality Measures

Writing Committee Members: Lars G. Svensson, MD, PhD (Chair), David H. Adams, MD (Vice-Chair), Robert O. Bonow, MD (Vice-Chair), Nicholas T. Kouchoukos, MD (Vice-Chair), D. Craig Miller, MD (Vice-Chair), Patrick T. O’Gara, MD (Vice-Chair), David M. Shahian, MD (Vice-Chair), Hartzell V. Schaff, MD (Vice-Chair), Cary W. Akins, MD, Joseph E. Bavaria, MD, Eugene H. Blackstone, MD, Tirone E. David, MD, Nimesh D. Desai, MD, PhD, Todd M. Dewey, MD, Richard S. D’Agostino, MD, Thomas G. Gleason, MD, Katherine B. Harrington, MD, Susheel Kodali, MD, Samir Kapadia, MD, Martin B. Leon, MD, Brian Lima, MD, Bruce W. Lytle, MD, Michael J. Mack, MD, Michael Reardon, MD, T. Brett Reece, MD, G. Russell Reiss, MD, Eric E. Roselli, MD, Craig R. Smith, MD, Vinod H. Thourani, MD, E. Murat Tuzcu, MD, John Webb, MD, and Mathew R. Williams, MD

enhance durability. Among these are treatment with alcohol and various antisurfactants but none has proved superior to others.



European Journal of Cardio-Thoracic Surgery 52 (2017) 616–664  
doi:10.1093/ejcts/ezx324 Advance Access publication 26 August 2017



## 2017 ESC/EACTS Guidelines for the management of valvular heart disease

The Task Force for the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Authors/Task Force Members: Volkmar Falk<sup>1</sup> (EACTS Chairperson) (Germany), Helmut Baumgartner<sup>\*</sup> (ESC

**Não citam diferenças de desempenho entre modelos de biopróteses**

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Volume 63, Issue 22, June 2014 >  
Practice Guideline | June 2014

**2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines** FREE

Rick A. Nishimura, MD, MACC, FAHA; Catherine M. Otto, MD, FACC, FAHA; Robert O. Bonow, MD, MACC, FAHA; Blase A. Carabello, MD, FACC; John P. Erwin, III, MD, FACC, FAHA; Robert A. Guyton, MD, FACC; Patrick T. O'Gara, MD, FACC, FAHA; Carlos E. Ruiz, MD, PhD, FACC; Nikolaos J. Skubas, MD, FASE; Paul Sorajja, MD, FACC, FAHA; Thoralf M. Sundt, III, MD; James D. Thomas, MD, FASE, FACC, FAHA

## **CONCLUSÃO 2**

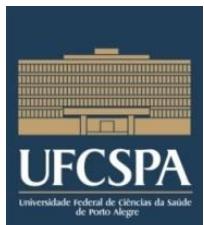
### **DURABILIDADE:**

*Sobrevida a longo prazo sem re-operações,  
degeneração, calcificação*

Apesar de alguns fabricantes apresentarem métodos próprios de fixação na intenção de reduzir calcificações e na esperança de aumentar durabilidade, nenhum método demonstrou resultados clínicos superiores aos demais.

As estratégias de mercado praticadas não encontram suporte nos resultados publicados.

Todas as biopróteses disponíveis apresentam durabilidade semelhante.



# Long-Term Survival After Bovine Pericardial Versus Porcine Stented Bioprosthetic Aortic Valve Replacement: Does Valve Choice Matter?

**Table 1**

Stented Bioprosthetic Aortic Valves Included in Study

Valves	Total (No.)	Isolated AVR (No.)	AVR+CABG (No.)
Bovine pericardial	1,411		
Carpentier-Edwards Perimount <sup>a</sup>	1,273	734	539
Sorin Mitroflow <sup>b</sup>	26	16	10
St. Jude Trifecta <sup>c</sup>	112	51	61
Porcine	599		
St. Jude Biocor <sup>c</sup>	128	46	82
Carpentier-Edwards Porcine <sup>a</sup>	210	111	99
Medtronic Hancock <sup>d</sup>	105	44	61
Medtronic Mosaic <sup>d</sup>	156	140	16

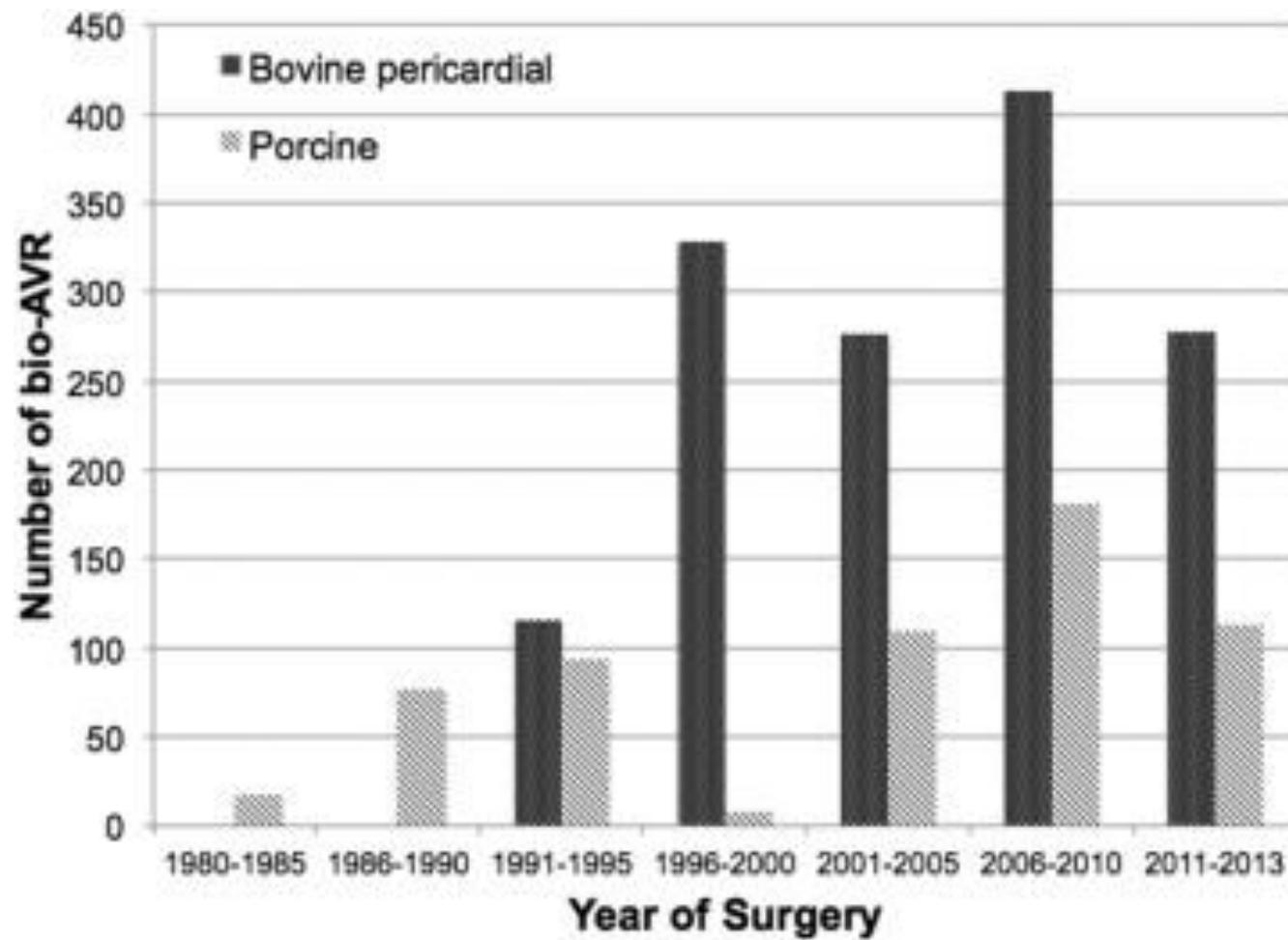


Fig 2

Kaplan-Meier curves for patients with bovine pericardial (solid line) and porcine (dashed line) valves show

(A) survival and

(B) need for aortic valve reoperation.

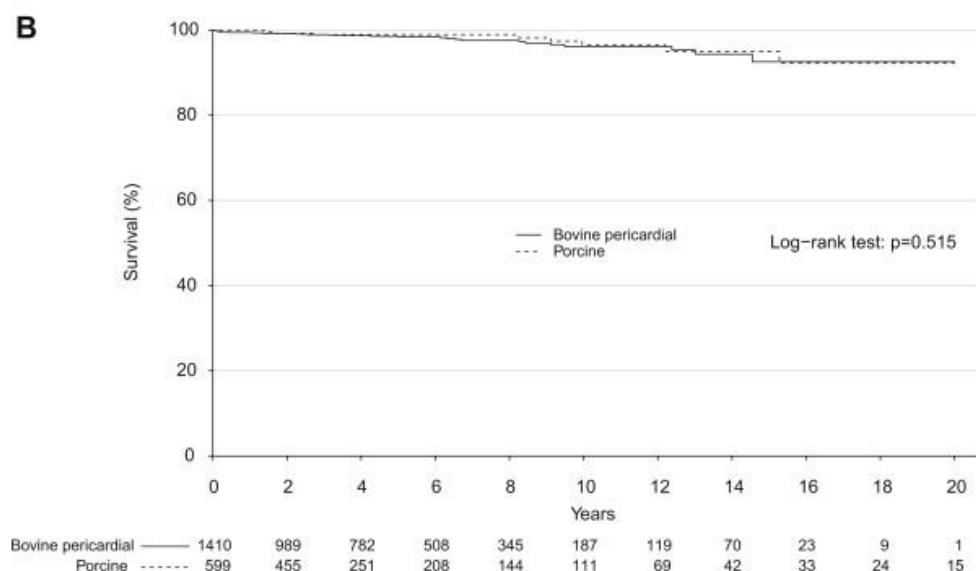
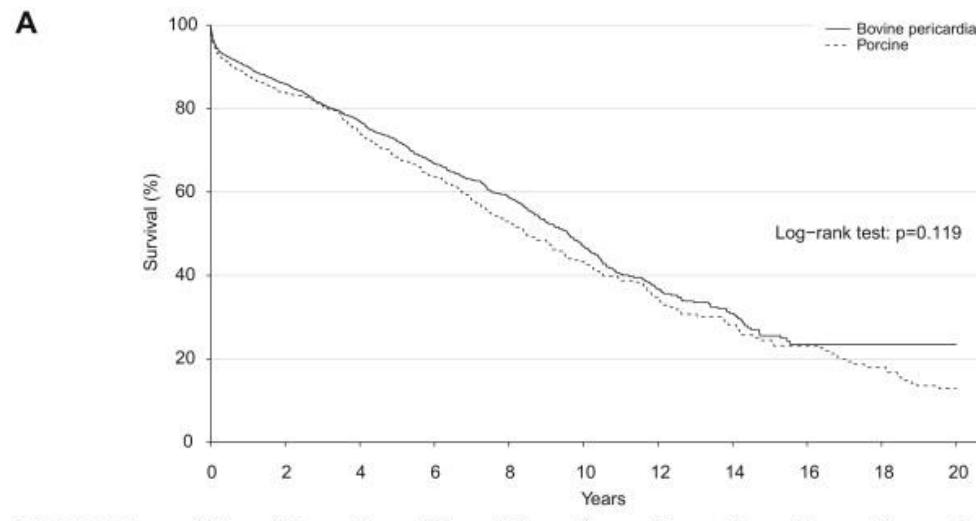
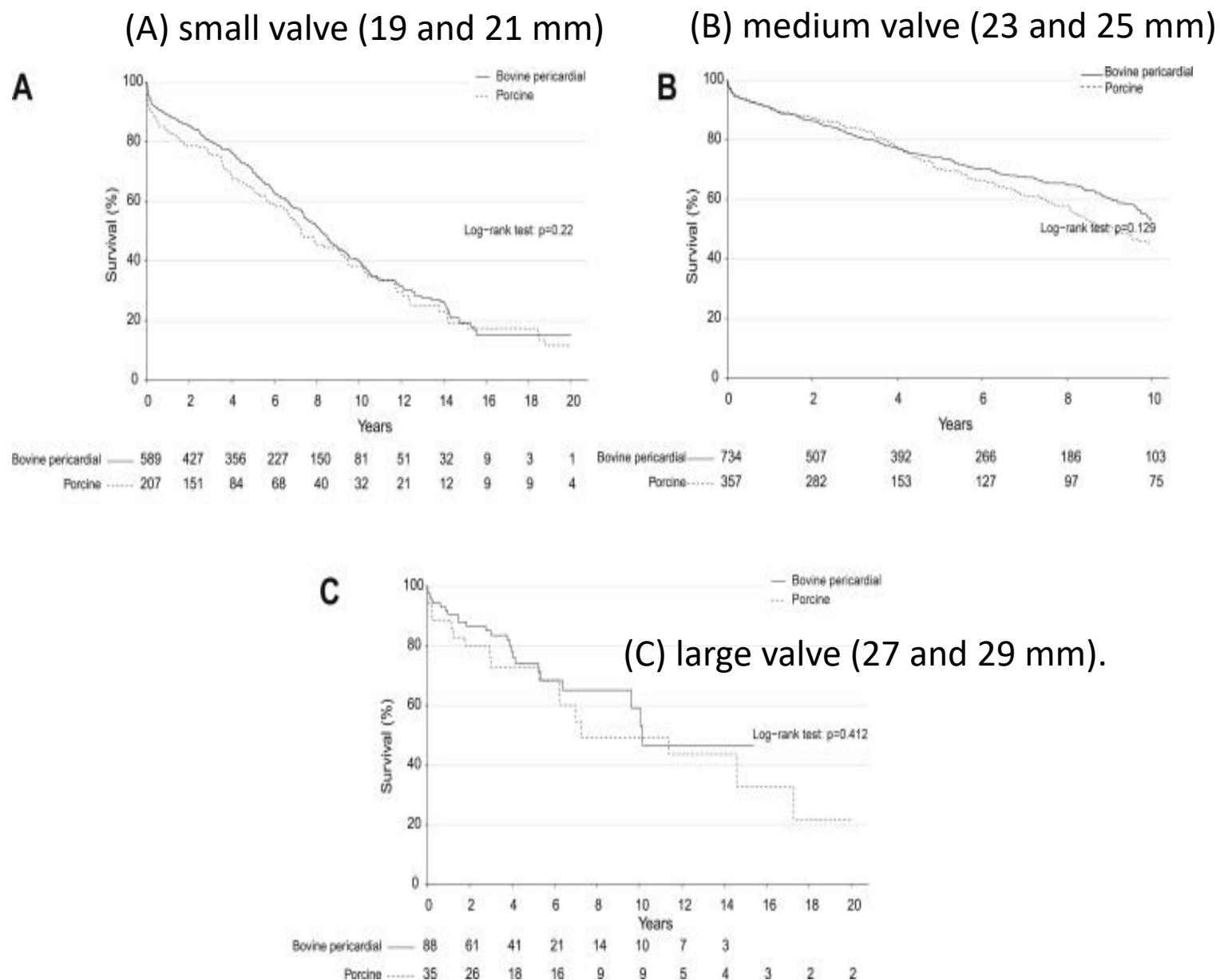
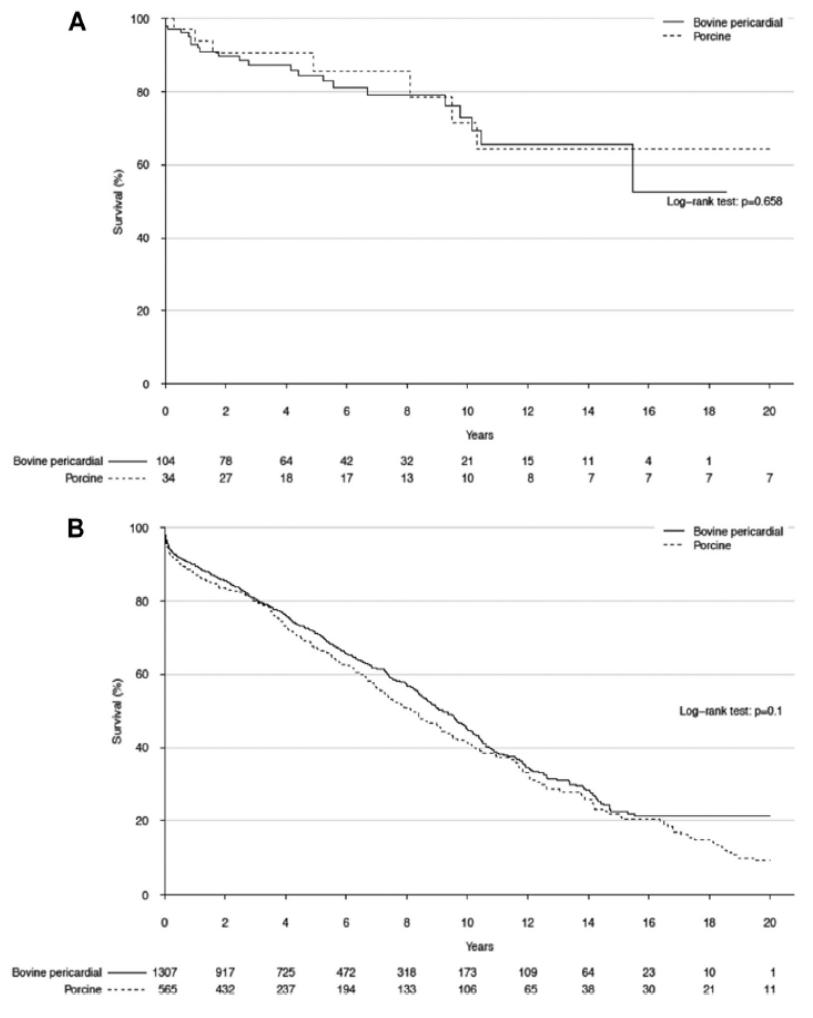


Fig 3  
Overall survival analysis in patients with bovine pericardial (solid line) and porcine (dashed line) valves by subgroups with a...



# Long-Term Survival After Bovine Pericardial Versus Porcine Stented Bioprosthetic Aortic Valve Replacement: Does Valve Choice Matter?

Fig 4. Overall survival analysis in patients with bovine pericardial (solid line) and porcine (dashed line) valves according patient age (A) 18 to 55 years and (B) age older than 55 years at aortic valve replacement.



**Fungível** = 1. Passível de ser substituído por outra coisa de mesma espécie, qualidade, quantidade e valor.  
2. Substituível, não possuindo uma exclusividade que o impeça de ser reposto por coisa da mesma espécie.

In conclusion, for patients undergoing AVR with a stented bioprosthetic valve, with or without CABG, the choice of a porcine vs bovine pericardial bioprosthesis does not appear to affect long-term survival or the need for reoperation, regardless of valve size or patient age. As such, stented bioprosthetic valves would appear to be fungible, and therefore, valve choice should be driven by local market factors similar to other commodities.

Ganapathi et al  
Duke Univ, NC

Ann Thorac Surg  
2015;100:550–9



*A ESCOLHA DA BIOPRÓTESE É BASEADA EM MARKETING OU EM DESEMPENHO COMPROVADO?*

## Conclusões

Escolha de biopróteses devem ser feitas em base de durabilidade aferida em avaliações superiores a 20 anos.

Não existem métodos comprovados de maior durabilidade

Desempenho hemodinâmico difere entre próteses <23mm e deve ser considerado na individualização da escolha

[kalil.renato@gmail.com](mailto:kalil.renato@gmail.com)

