Prosthetic Selection

(Mechanical, Bioprosthese, homograft)

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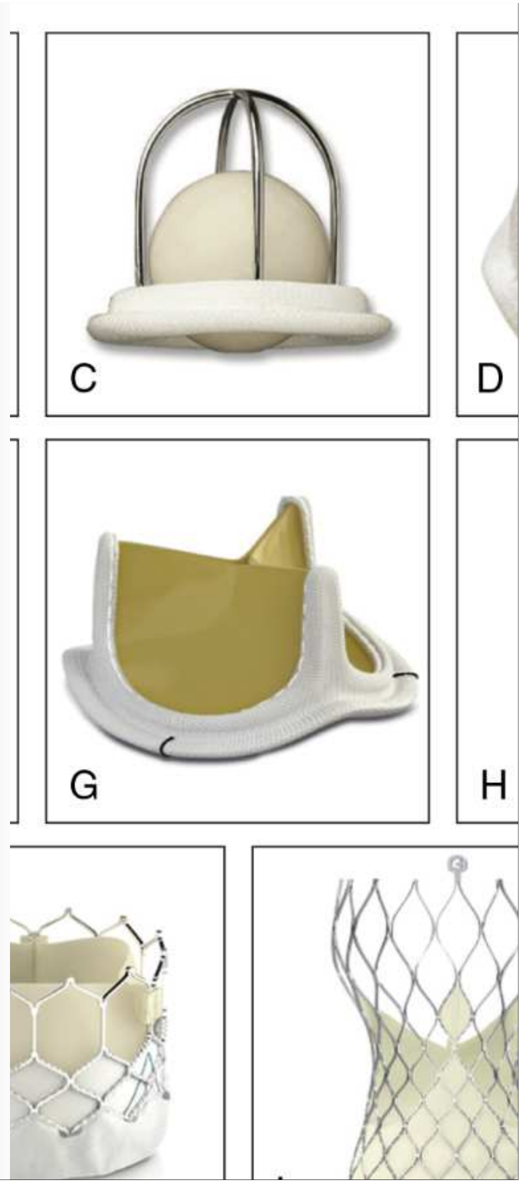
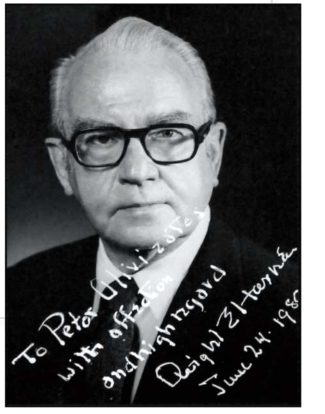


Contents

- Evolution of prosthetic valves
- Type of prosthetic valves
- Current guidelines
- Prosthesis patient mismatch

Ten Commandments (1950's)



Dwight E. Harken

- ***Prostheses must …***

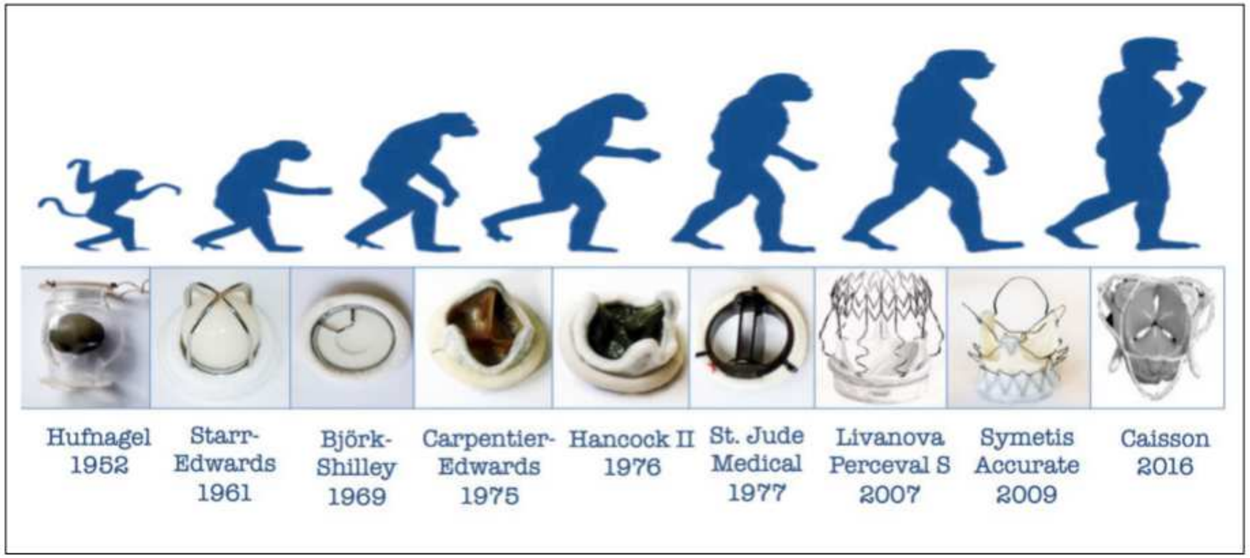
(1) not propagate emboli
(2) be chemically inert and not damage blood elements
(3) offer no resistance to physiological flows
(4) close promptly (less than 0.05 second)
(5) remain closed during the appropriate phase of the cardiac cycle
(6) have lasting physical and geometric features
(7) be inserted in a physiological site (generally the normal anatomical site)
(8) be capable of permanent fixation
(9) no annoy the patient
(10) be technically practical to insert

Ann Thorac Surg 1989;48:S18-9

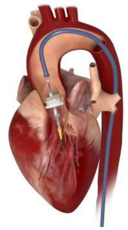
The Ideal Valve has...

- Sufficient structural durability
- Absence of thrombogenicity
- Resistance to infections
- Lack of antigenicity
- No resistance to physiological flows
- Growth potential

Evolutionary Steps in Heart Valve Technology



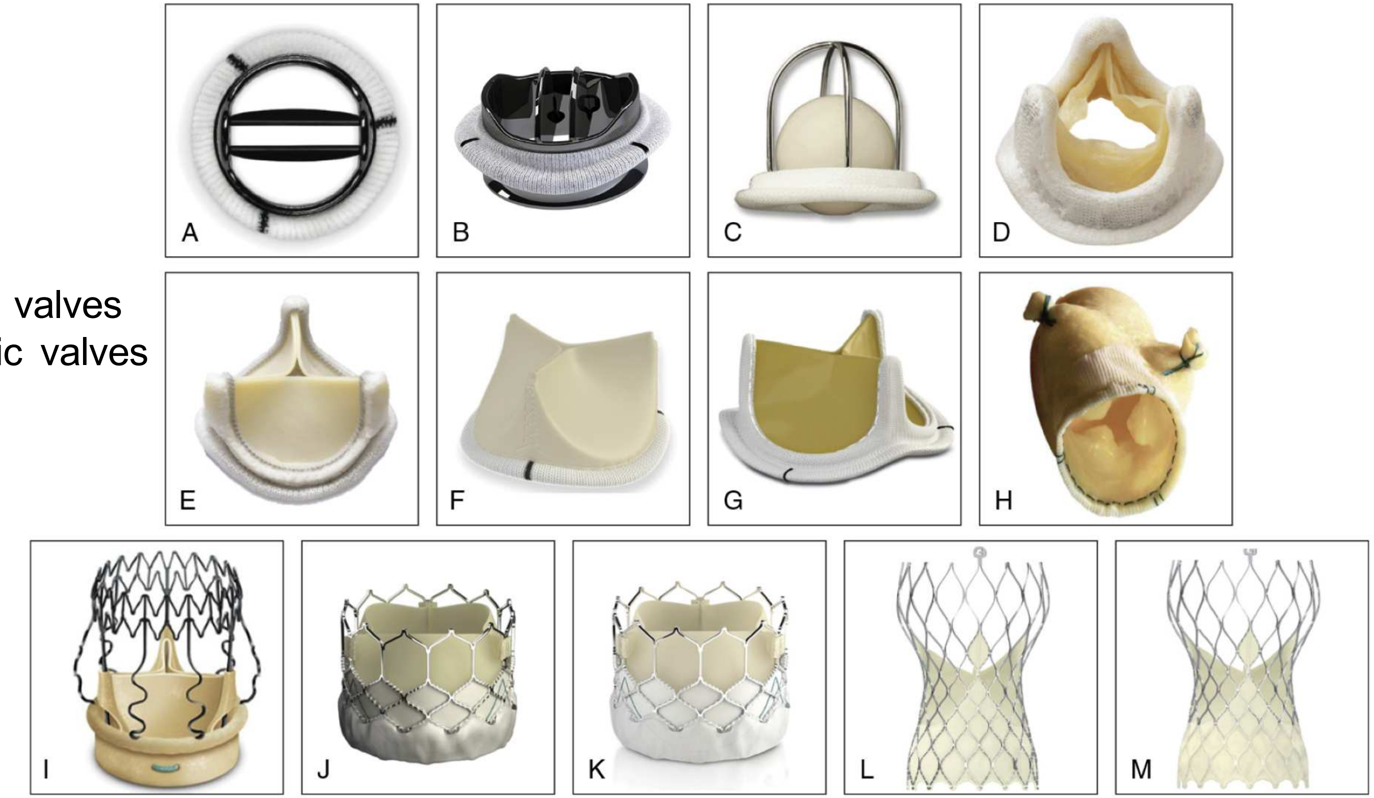
CPB (1953)



Cardiovasc Med 2017;20:285-292

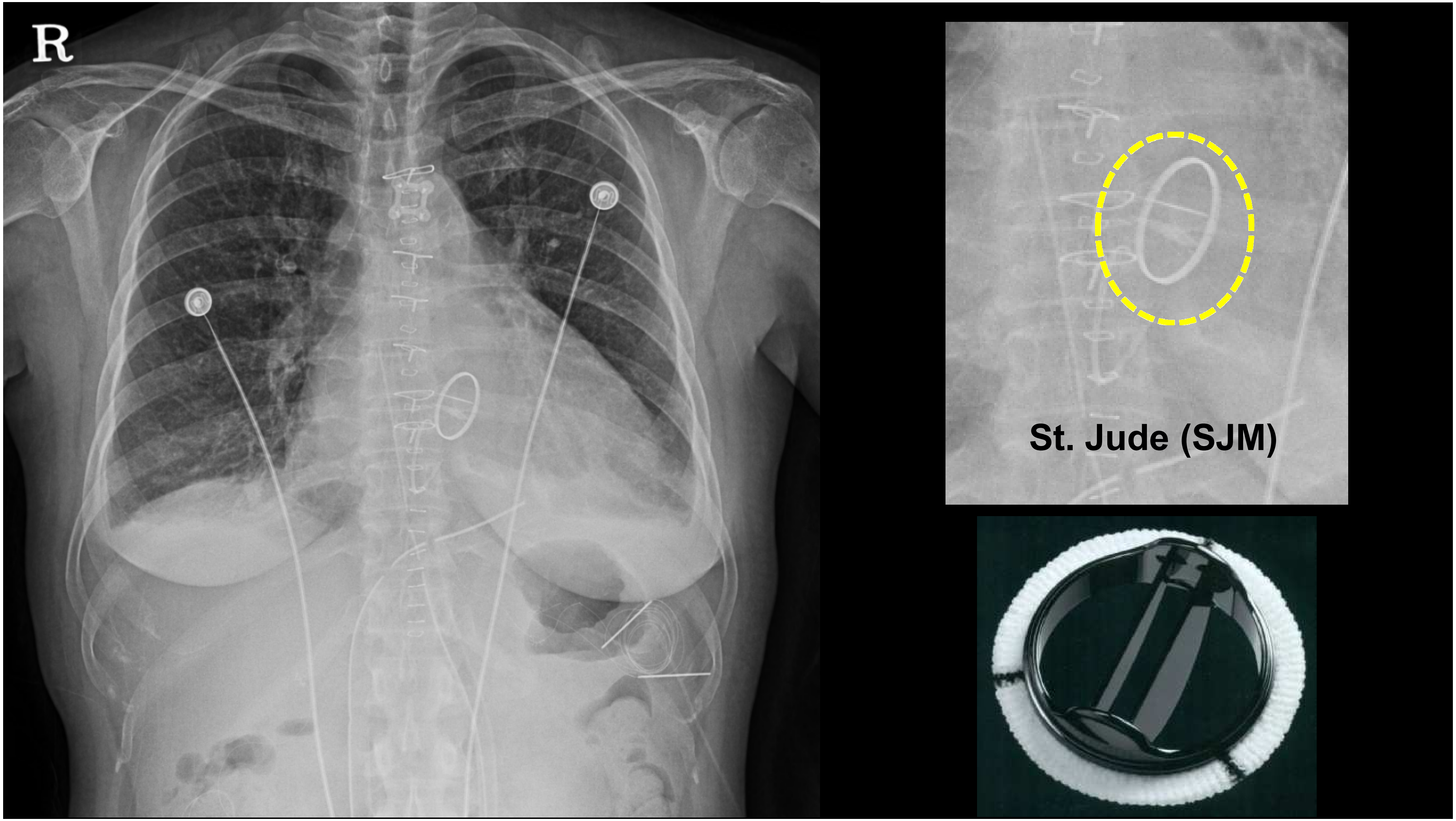
Types of Prosthetic Valves

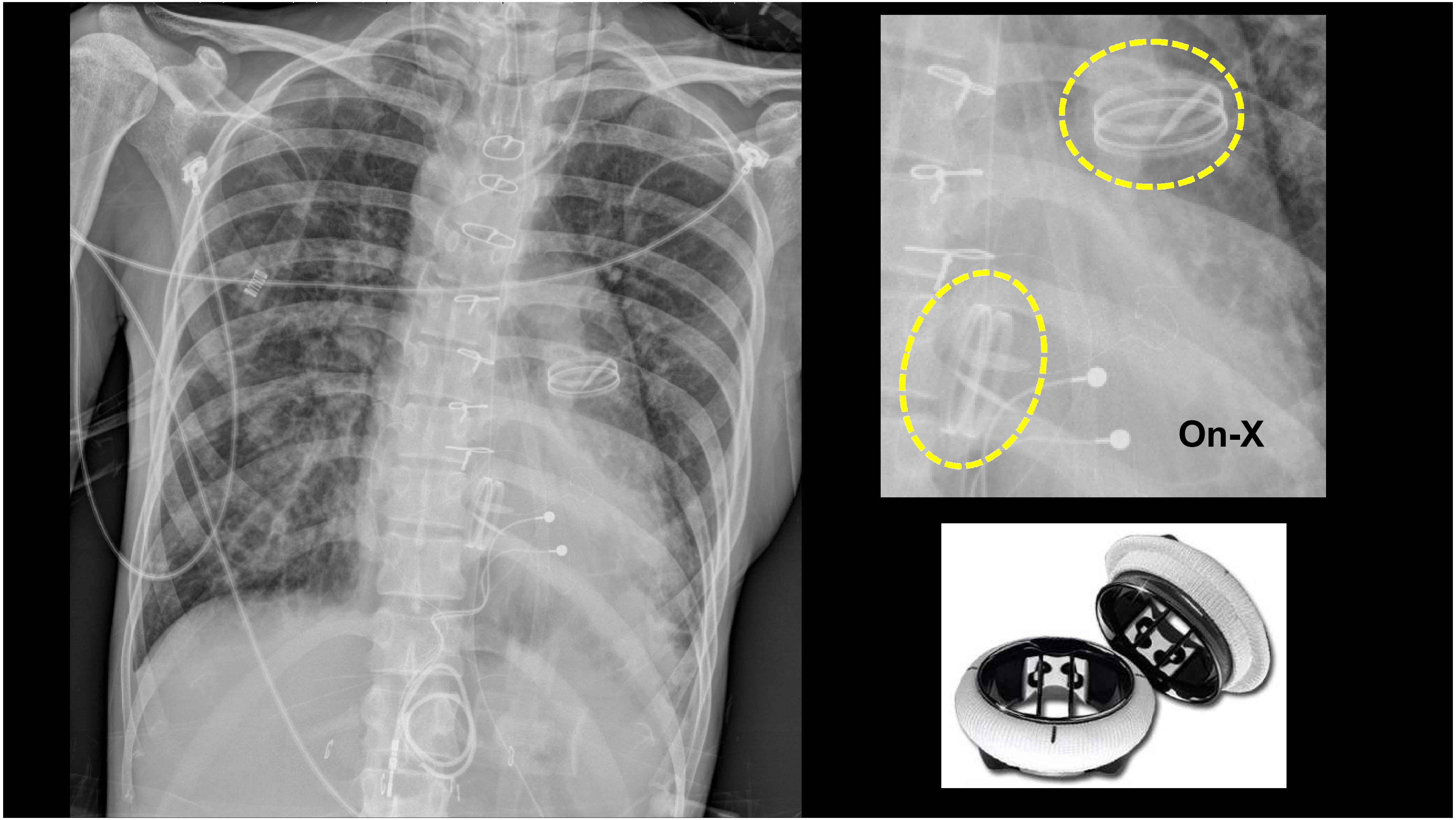
- Mechanical valves
- Tissue valves
  - Xenografts
    - Stented bioprosthetic valves
    - Stentless bioprosthetic valves
    - Sutureless valves
    - Transcatheter valves
  - Homografts
  - Autografts



Mechanical bileaflet valves

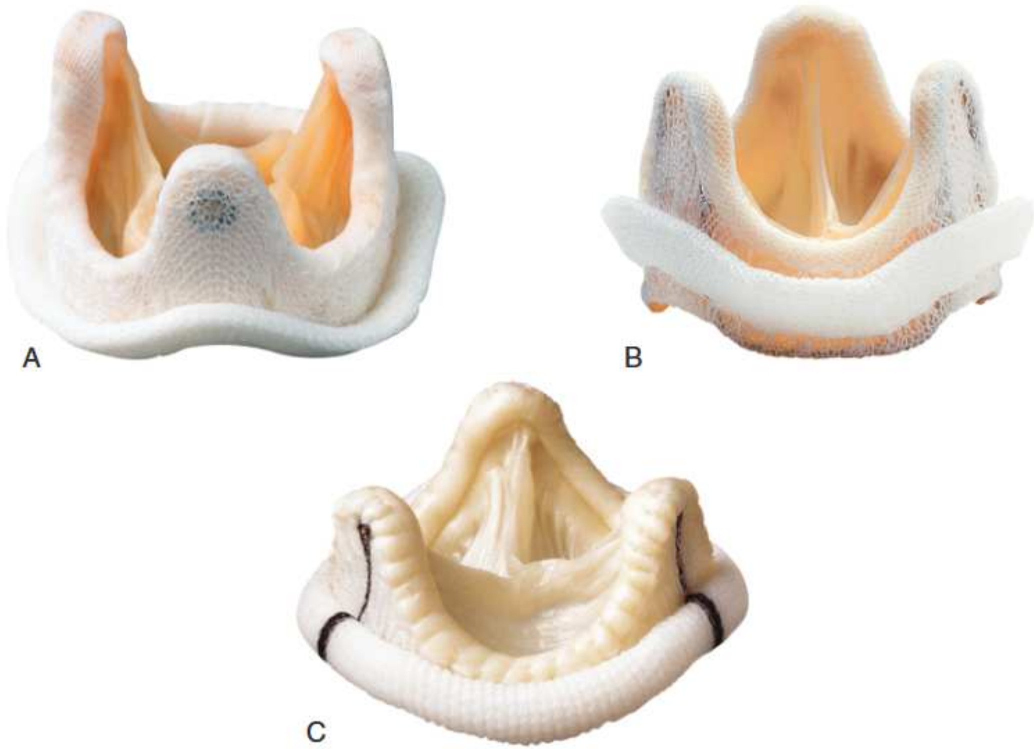
A. Open pivot (Medtronic)
B. Regent (St. Jude Medical)
C. Top Hat (Sorin Group)
D. On-X (On-X Life Technologies)


R
St. Jude (SJM)


On-X

Stented porcine valves

A. Mosaic, Hancock II (Medtronic)
B. CE Standard (Edwards Lifesciences)
C. Epic (St. Jude Medical)

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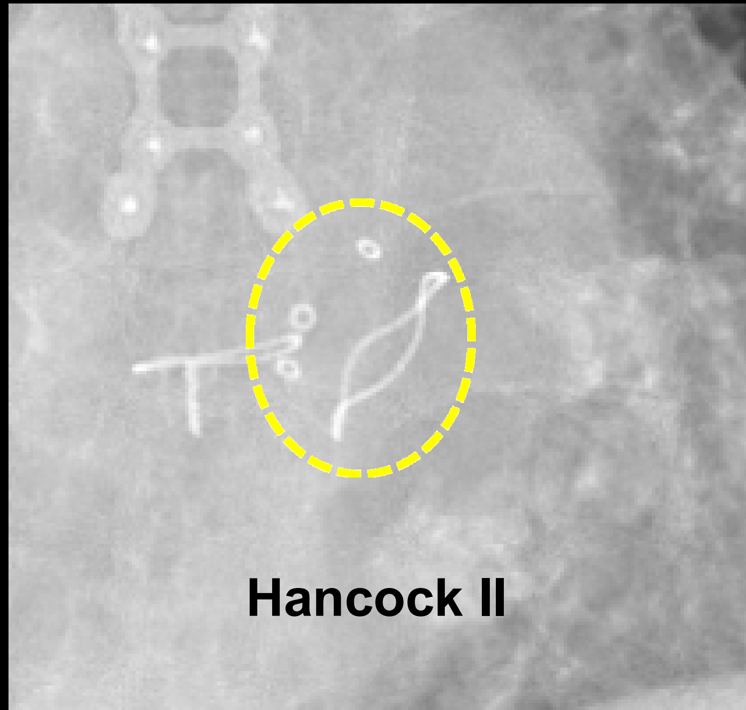
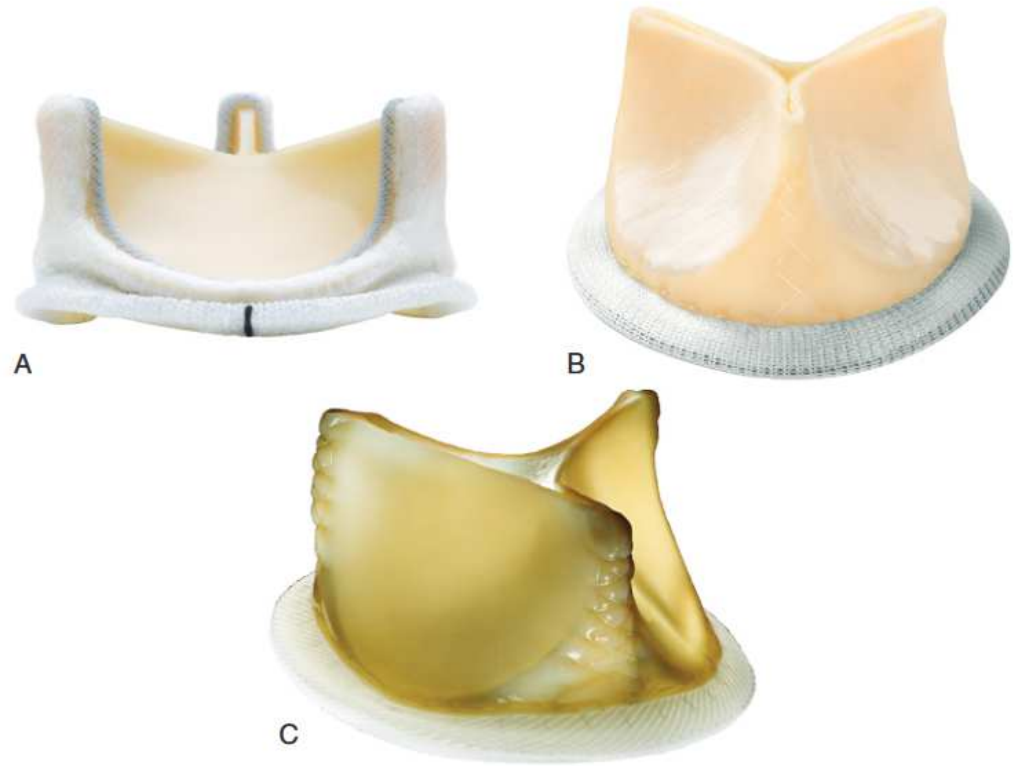
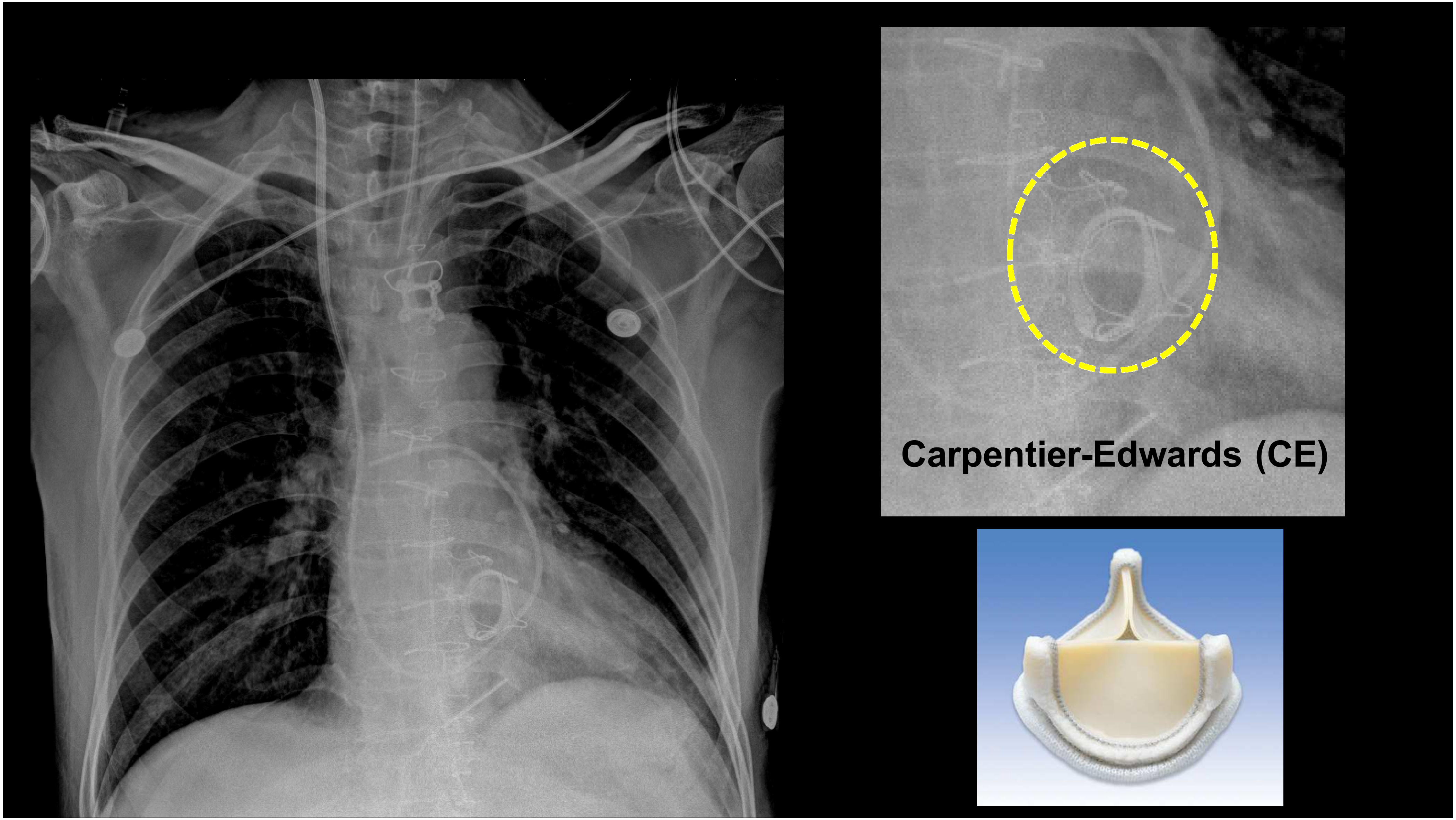

Hancock II


Stented bovine pericardial valves

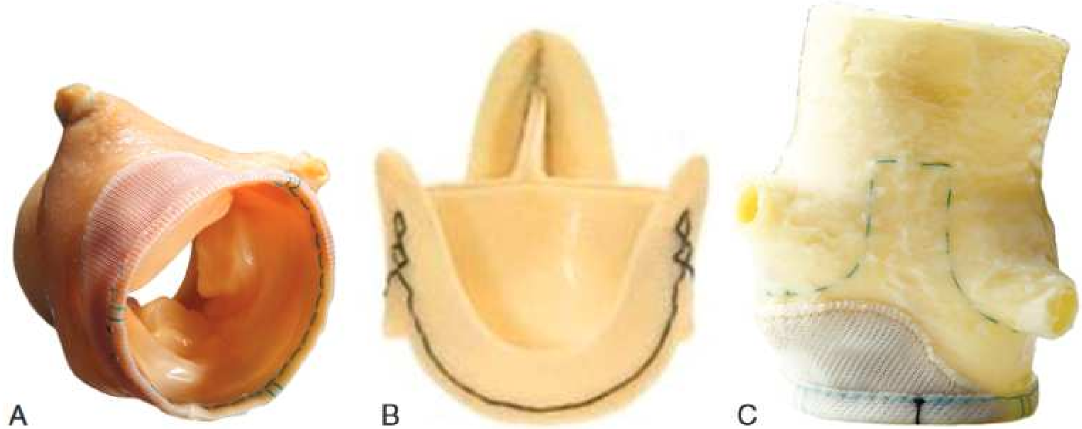
A. CE PERIMOUNT (Edwards Lifesciences)
B. Mitroflow (Sorin Group)
C. Trifecta (St. Jude Medical)




Carpentier-Edwards (CE)

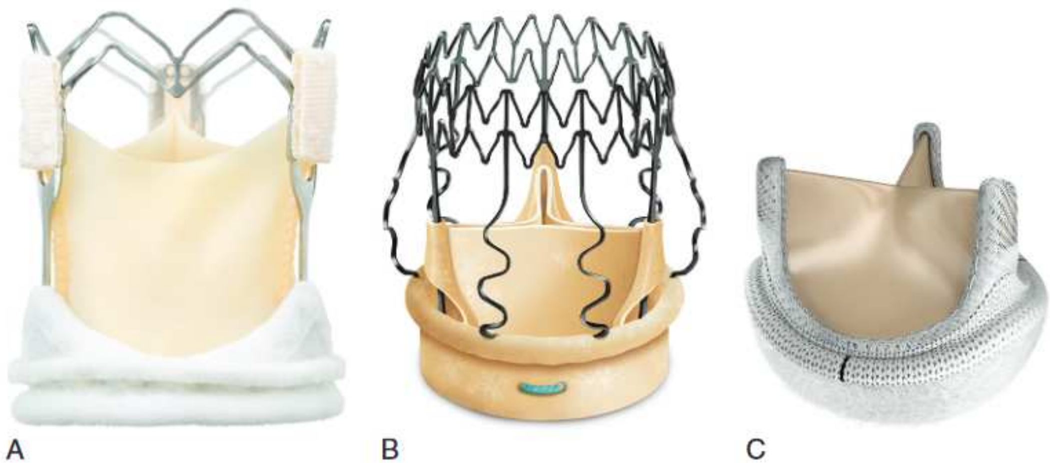
Stentless valves

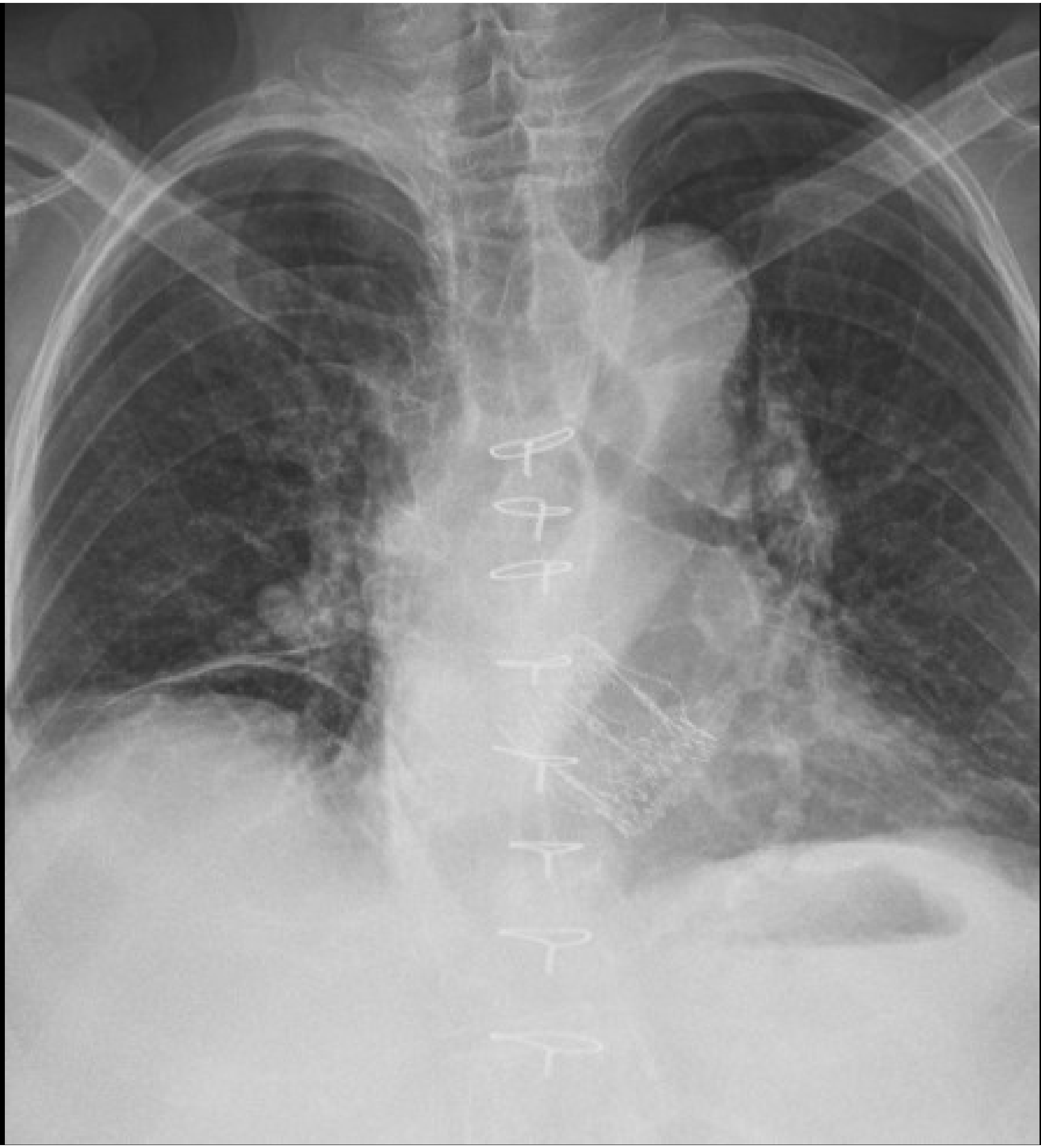
A. Freestyle aortic root bioprostheses (Medtronic)
B. Freedom solo valve (Sorin Group)
C. Prima Plus valve (Edwards Lifesciences)

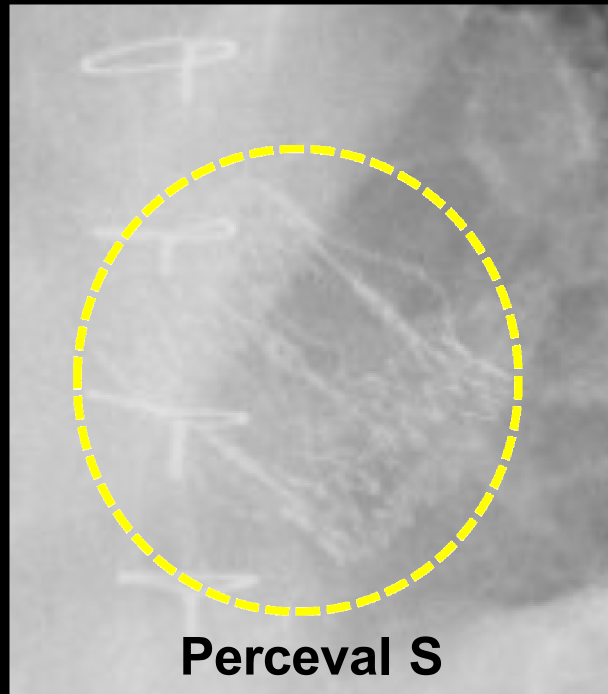


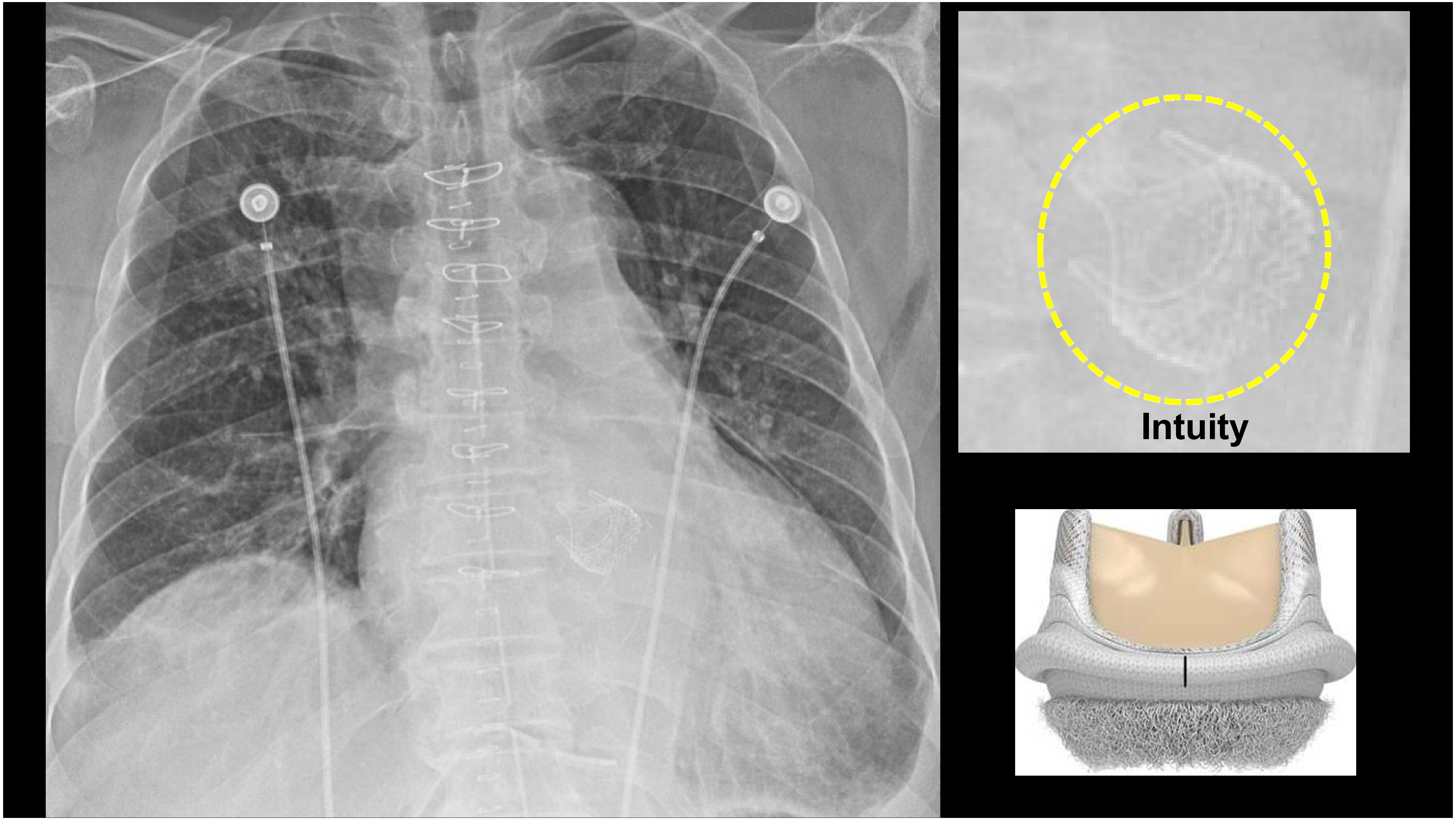
Sutureless valves

A. 3f Enable (Medtronic)
B. Perceval S (Sorin Group)
C. Intuity (Edwards Lifesciences)

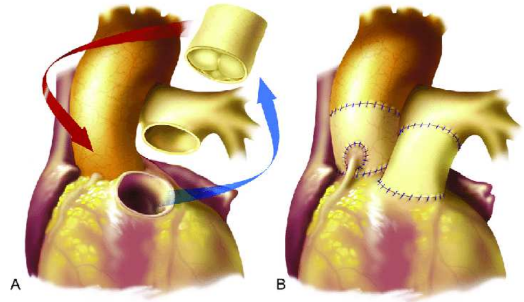





Perceval S


Intuity

Types of Substitutes



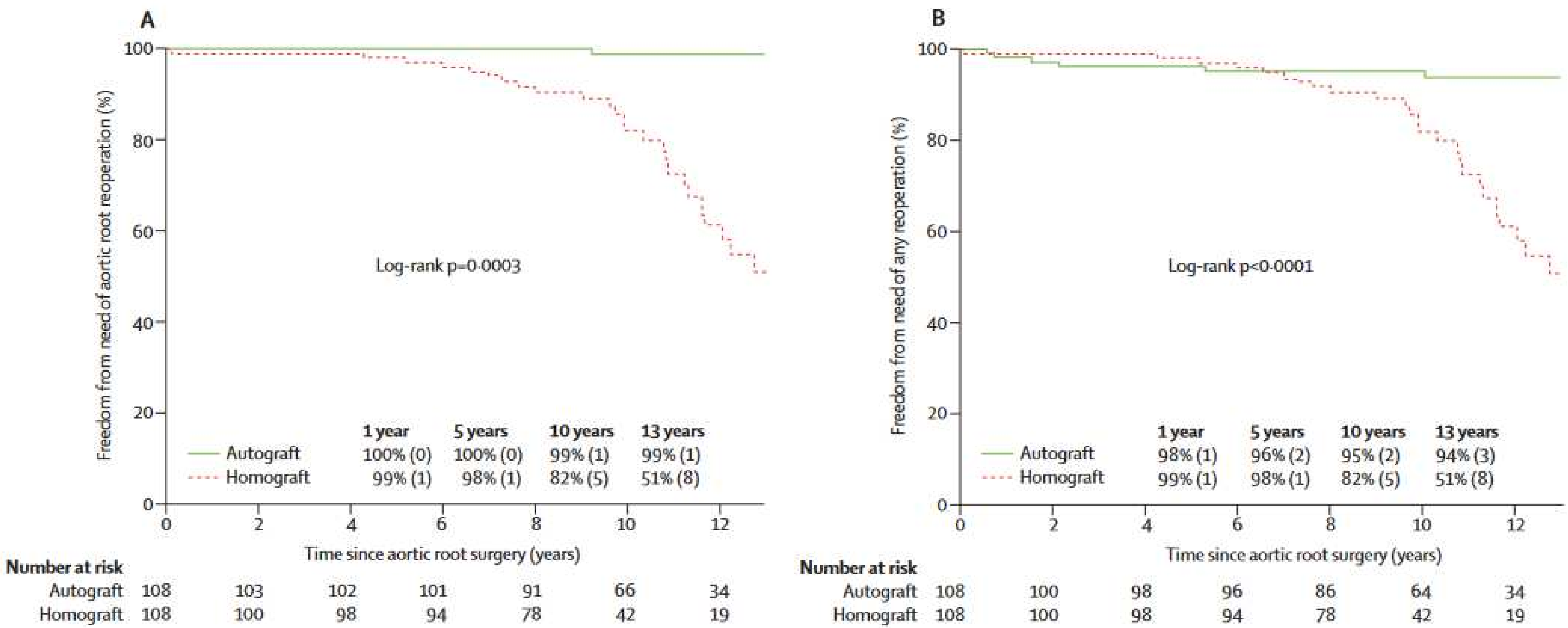
- Autograft
  - Ross operation
- Homograft (Allograft)
  - Cadaveric human aortic and pulmonary valves
- Heterograft (Xenograft)
  - Bioprosthetic ; porcine, bovine pericardial

Homograft

- Harvested from human cadavers within 24 hours of death
- Treated with antibiotics and cryopreserved at -196°C
- Mostly implanted in form of a total root replacement with reimplantation of the coronary arteries
- Used in aortic valve and root endocarditis in the active phase d/t resistant of infection
- No required immune suppression and routine anticoagulation
- Long-term durability : not superior to current-generation pericardial valves
- Technically challenging for reoperation d/t excessive root and leaflet calcification

Long-term outcomes after autograft versus homograft aortic root replacement in adults with aortic valve disease: a randomised controlled trial

Ismail El-Hamamsy, Zeynep Eryigit, Louis-Mathieu Stevens, Zubair Sarang, Robert George, Lucy Clark, Giovanni Melina, Johanna J M Takkenberg, Magdi H Yacoub

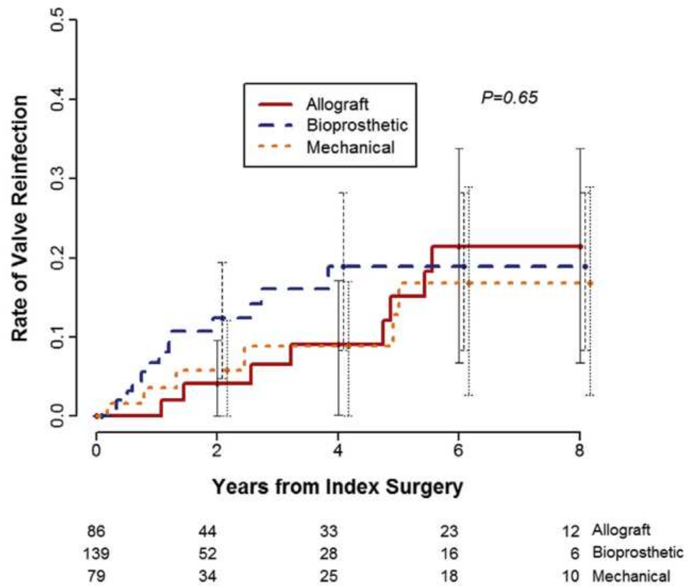


Lancet 2010;376:524-531

ACQUIRED: AORTIC VALVE

Are homografts superior to conventional prosthetic valves in the setting of infective endocarditis involving the aortic valve?

Joon Bum Kim, MD, PhD,[a,b] Julius I. Ejiofor, MD,[c] Maroun Yammine, MD,[c] Janice M. Camuso, RN,[a] Conor W. Walsh, BA,[d] Masahiko Ando, MD, PhD,[a] Serguei I. Melnitchouk, MD,[a] James D. Rawn, MD,[c] Marzia Leacche, MD,[c] Thomas E. MacGillivray, MD,[a] Lawrence H. Cohn, MD,[c] John G. Byrne, MD,[c] and Thoralf M. Sundt, MD[a]



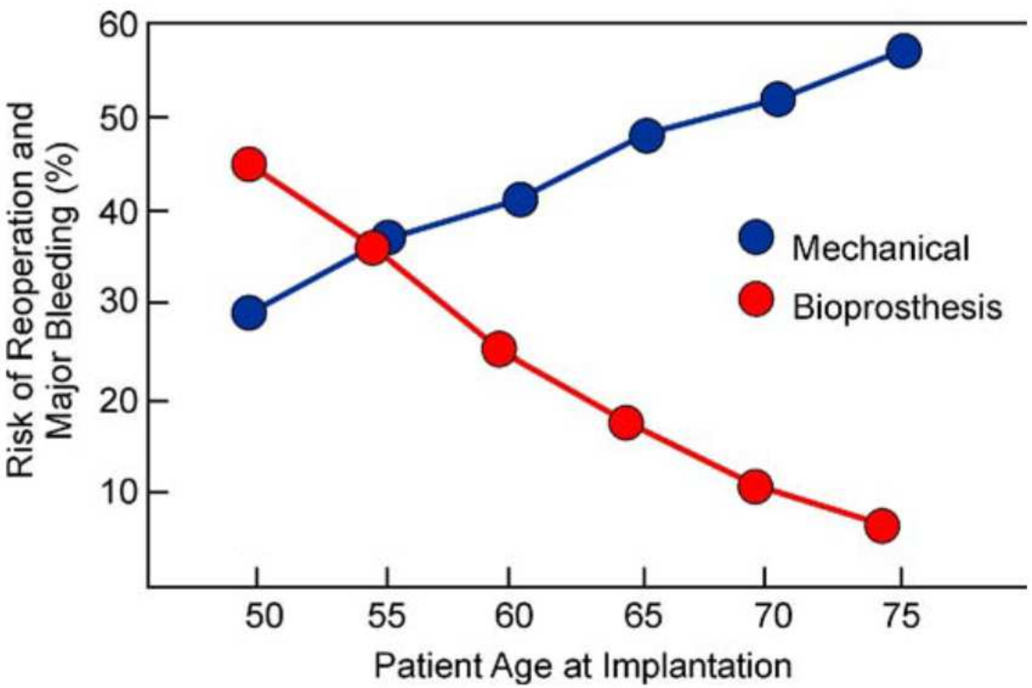
- Technically complex
- Durability
- Scarcity

J Thorac Cardiovasc Surg 2016;151:1239-48

Choice of Valve Prosthesis

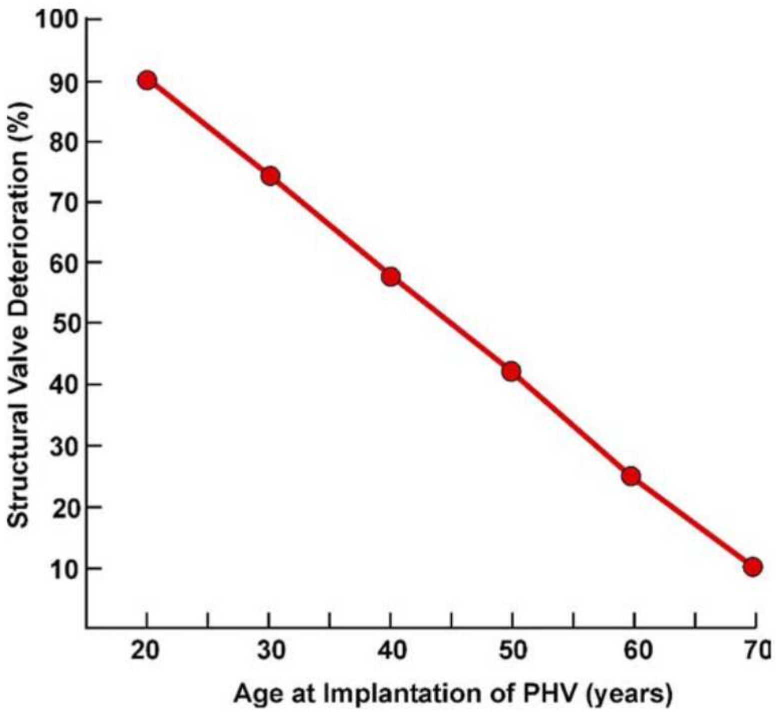
- Mechanical *vs* bioprosthetic valve
  - Age
  - Life expectancy
  - Preference
  - Indications or contraindications to anticoagulation
  - Comorbidities
- Choosing a valve providing optimal hemodynamics

Comparison of Risks



J Thorac Cardiovasc Surg 2009;137:881-6

SVD of Biological Valves at 15-20 years



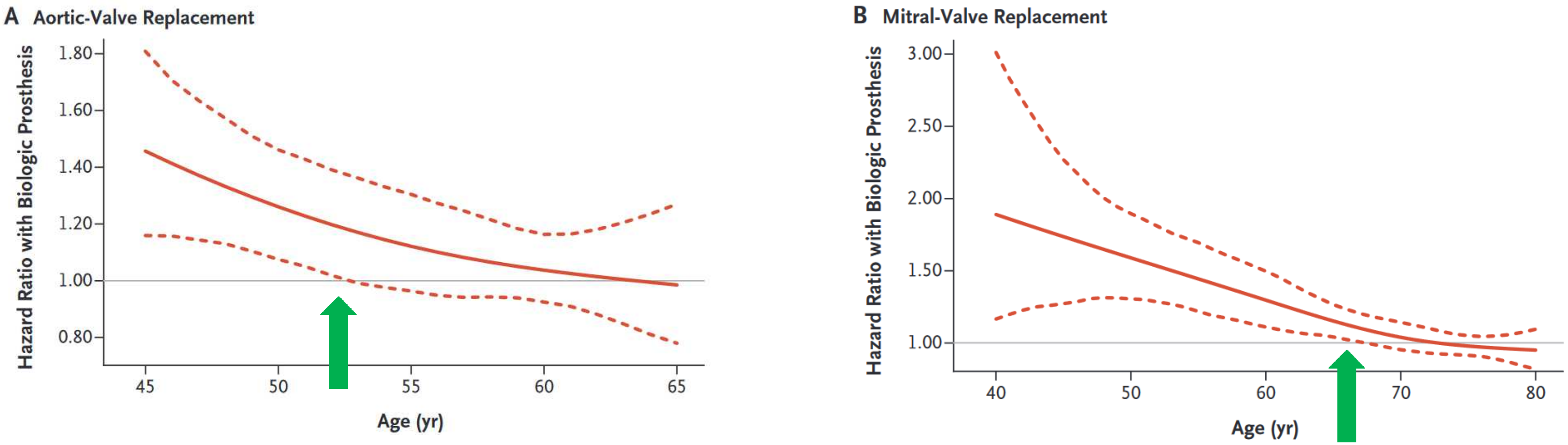
J Am Coll Cardiol 2010;55:2413 –26

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

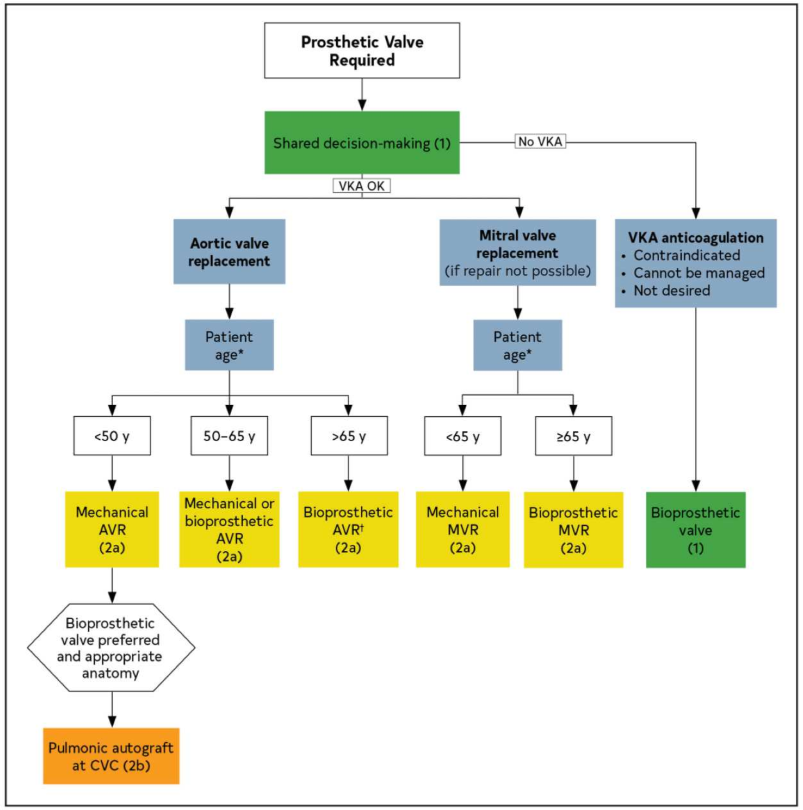
Mechanical or Biologic Prostheses for Aortic-Valve and Mitral-Valve Replacement

Andrew B. Goldstone, M.D., Ph.D., Peter Chiu, M.D., Michael Baiocchi, Ph.D., Bharathi Lingala, Ph.D., William L. Patrick, M.D., Michael P. Fischbein, M.D., Ph.D., and Y. Joseph Woo, M.D.



N Engl J Med 2017;377:1847-57

2020 ACC/AHA Guidelines



Circulation 2021;143:e72-227

2020 ACC/AHA Guidelines

Favor Mechanical Prosthesis	Favor Bioprosthesis
Age <50 y Increased incidence of structural deterioration with bioprosthesis (15-y risk: 30% for age 40 y, 50% for age 20 y) Lower risk of anticoagulation complications	Age >65 y Low incidence of structural deterioration (15-y risk: <10% for age >70 y) Higher risk of anticoagulation complications
Patient preference (avoid risk of reintervention)	Patient preference (avoid risk and inconvenience of anticoagulation)
Low risk of long-term anticoagulation	High risk of long-term anticoagulation
Compliant patient with either home monitoring or close access to INR monitoring	Limited access to medical care or inability to regulate VKA
Other indication for long-term anticoagulation (eg, AF)	Access to surgical centers with low reoperation mortality rate
High-risk reintervention (eg, porcelain aorta, prior radiation therapy)	Access to transcatheter ViV replacement
Small aortic root size for AVR (may preclude ViV procedure in future)	TAVI valves have larger effective orifice areas for smaller valve sizes (avoid patient–prosthesis mismatch)

Circulation 2021;143:e72-227

2021 ESC/EACTS Guidelines

Mechanical prostheses		
A mechanical prosthesis is recommended according to the desire of the informed patient and if there are no contraindications to long-term anticoagulation.[c]	I	C
A mechanical prosthesis is recommended in patients at risk of accelerated SVD.[d]	I	C
A mechanical prosthesis should be considered in patients already on anticoagulation because of a mechanical prosthesis in another valve position.	IIa	C
A mechanical prosthesis should be considered in patients aged <60 years for prostheses in the aortic position and aged <65 years for prostheses in the mitral position.[462, 464, e]	IIa	B
A mechanical prosthesis should be considered in patients with a reasonable life expectancy for whom future redo valve surgery or TAVI (if appropriate) would be at high risk.[f]	IIa	C
A mechanical prosthesis may be considered in patients already on long-term anticoagulation due to the high risk for thromboembolism.[f]	IIb	C

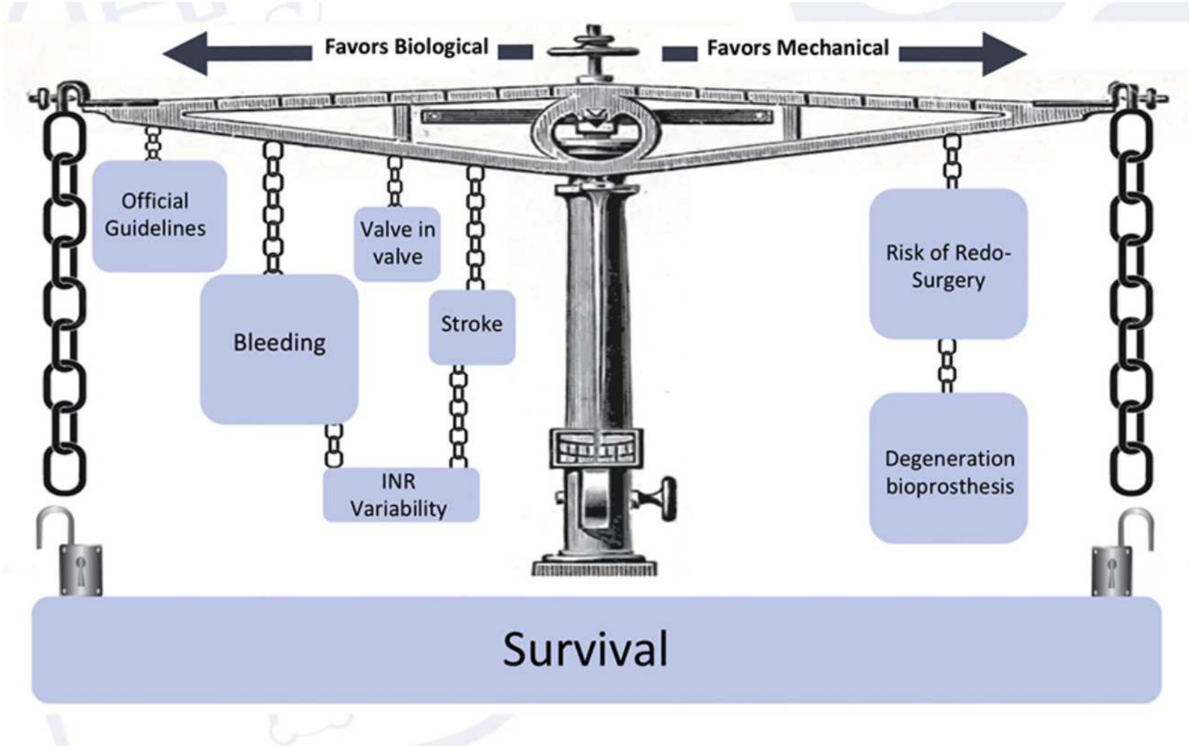
Eur Heart J 2022;43:561-632

2021 ESC/EACTS Guidelines

Biological prostheses		
A bioprosthesis is recommended according to the desire of the informed patient.	I	C
A bioprosthesis is recommended when good-quality anticoagulation is unlikely (adherence problems, not readily available), contraindicated because of high bleeding risk (previous major bleed, comorbidities, unwillingness, adherence problems, lifestyle, occupation) and in those patients whose life expectancy is lower than the presumed durability of the bioprosthesis.[g]	I	C
A bioprosthesis is recommended in case of reoperation for mechanical valve thrombosis despite good long-term anticoagulant control.	I	C
A bioprosthesis should be considered in patients for whom there is a low likelihood and/or a low operative risk of future redo valve surgery.	IIa	C
A bioprosthesis should be considered in young women contemplating pregnancy.	IIa	C
A bioprosthesis should be considered in patients aged >65 years for a prosthesis in the aortic position or aged >70 years in a mitral position.	IIa	C
A bioprosthesis may be considered in patients already on long-term NOACs due to the high risk for thromboembolism.[466–469 f]	IIb	B

Eur Heart J 2022;43:561-632

Mechanical *vs* bioprosthetic valve

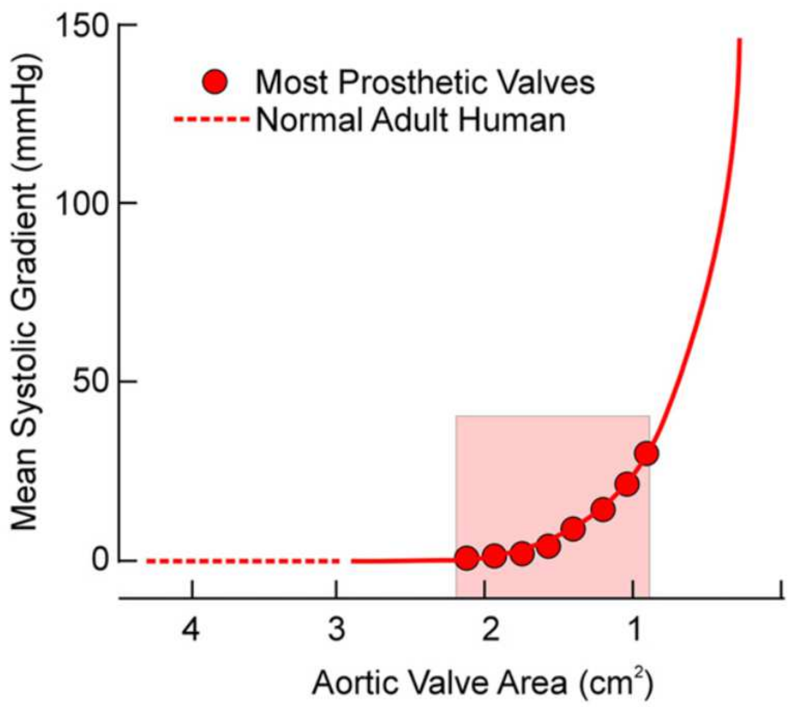


J Thorac Cardiovasc Surg 2019;158:706-14

Choice of Valve Prosthesis

- Mechanical *vs* bioprosthetic valve
  - Age
  - Life expectancy
  - Preference
  - Indications or contraindications to anticoagulation
  - Comorbidities
- Choosing a valve providing optimal hemodynamics

Relationship of Mean Systolic Gradient to AVA



J Am Coll Cardiol 2012;60:1123-35

Effective Orifice Area (EOA)

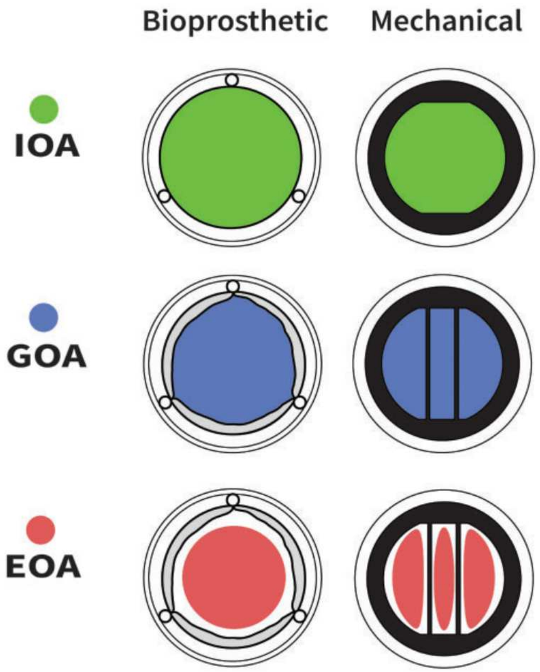


Figure 6: IOA, GOA and EOA in bioprosthetic and mechanical valves. EOA: effective orifice area; GOA: geometric orifice area; IOA: internal orifice area.

$$\text{Indexed EOA}\ (\text{cm}^2/\text{m}^2) = \frac{\text{EOA}\ (\text{cm}^2)}{\text{BSA of the patient}\ (\text{m}^2)}.$$

$$\text{Expected indexed EOA}\ (\text{cm}^2/\text{m}^2) = \frac{\text{Reference EOA}\ (\text{cm}^2)}{\text{BSA of the patient}\ (\text{m}^2)}.$$

Eur J Cardiothorarc Surg 2019;55:1025-36

Prosthesis-Patient Mismatch (PPM)

- Normally functioning prosthetic valve does not allow an adequate cardiac output without an excessive gradient across the valve

- The prosthetic valve is too small for the patient's body size

	Severe PPM	Moderate PPM
BMI < 30kg/m^2	iEOA ≤ 0.65 cm^2/m^2	0.65 < iEOA ≤ 0.85
BMI ≥ 30kg/m^2	iEOA ≤ 0.55 cm^2/m^2	0.55 < iEOA ≤ 0.70

Severe PPM

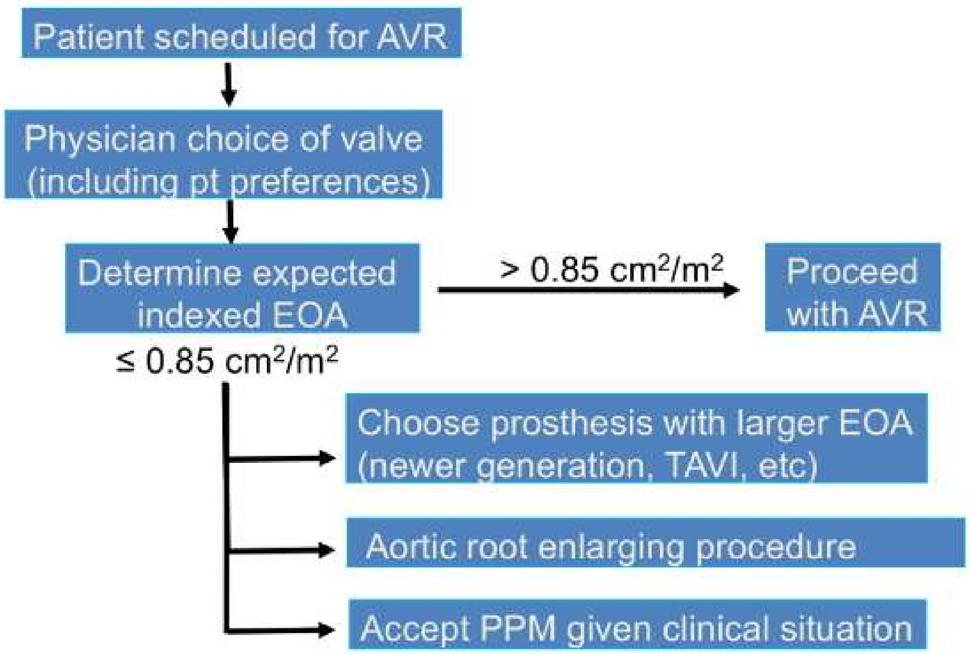
- Less regression of LV mass
- Persistence of reduced coronary flow reserve
- Higher incidence of heart failure
- Early and late mortality

Risk Assessment for PPM

	EOAi by Prosthesis size (mm)					
Prosthesis size (mm)	**19**	**21**	**23**	**25**	**27**	**29**
Average EOA (cm^2)	1.1	1.3	1.5	1.8	2.3	2.7
BSA (m^2)						
0.6	1.83	2.17	2.50	3.00	3.83	4.50
0.7	1.57	1.86	2.14	2.57	3.29	3.86
0.8	1.38	1.63	1.88	2.25	2.88	3.38
0.9	1.22	1.44	1.67	2.00	2.56	3.00
1	1.10	1.30	1.50	1.80	2.30	2.70
1.1	1.00	1.18	1.36	1.64	2.09	2.45
1.2	0.92	1.08	1.25	1.50	1.92	2.25
1.3	0.85	1.00	1.15	1.38	1.77	2.08
1.4	0.79	0.93	1.07	1.29	1.64	1.93
1.5	0.73	0.87	1.00	1.20	1.53	1.80
1.6	0.49	0.88	0.88	0.88	0.88	1.69
1.7	0.65	0.76	0.88	1.06	1.35	1.59
1.8	0.61	0.72	0.83	1.00	1.28	1.50
1.9	0.58	0.68	0.79	0.95	1.21	1.42
2	0.55	0.65	0.75	0.90	1.15	1.35
2.1	0.52	0.62	0.71	0.86	1.10	1.29
2.2	0.50	0.59	0.68	0.82	1.05	1.23
2.3	0.48	0.57	0.65	0.78	1.00	1.17
2.4	0.46	0.54	0.63	0.75	0.96	1.13
2.5	0.44	0.52	0.60	0.72	0.92	1.08

J Am Coll Cardiol 2012;60:1123-35

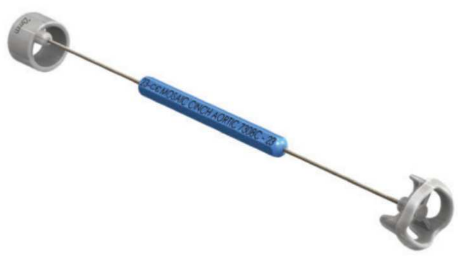
Prosthesis-Patient Mismatch (PPM)



Heart 2019;105:s28-s33

Issues around Sizing and Labelling

- Non-uniform or incomplete reporting of valve materials and physical dimensions
- Non-uniform marking of valve support structures (e.g. sewing rings)
- Unclear definition of labeled valve size and inconsistencies between sizer dimensions and labeled valve size
- Lack of robust information to reliably predict valve hemodynamic performance
- Lack of uniform tools to predict and prevent PPM
- Lack of good-quality, robust clinical data on valve thrombogenicity



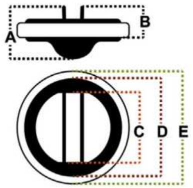
EACTS-STS-AATS Valve Labelling Task Force

- Cardiac surgeons
- Cardiologists
- Engineers
- Regulatory professionals
- Representatives of major valve manufacturing companies

Standardized Approach

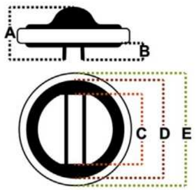
A Mechanical valves, aortic position

Labelled valve size	Physical dimensions				
	Overall profile height	Outflow profile height	Minimum internal diameter	External housing diameter	External sewing ring diameter
	(A)	(B)	(C)	(D)	(E)



B Mechanical valves, mitral position

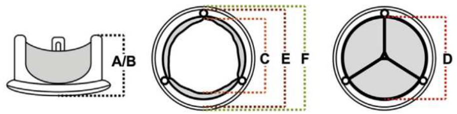
Labelled valve size	Physical dimensions				
	Overall profile height	Outflow profile height	Minimum internal diameter	External housing diameter	External sewing ring diameter
	(A)	(B)	(C)	(D)	(E)



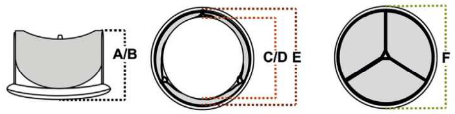
A Bioprosthetic valves, aortic position

Labelled valve size	Physical dimensions					
	Overall profile height	Outflow profile height	Minimum internal diameter	Internal stent diameter	External stent diameter	External sewing ring diameter
	(A)	(B)	(C)	(D)	(E)	(F)

Internally mounted leaflets

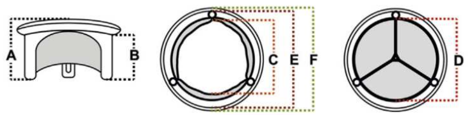


Externally mounted leaflets



B Bioprosthetic valves, mitral position

Labelled valve size	Physical dimensions					
	Overall profile height	Outflow profile height	Minimum internal diameter	Internal stent diameter	External stent diameter	External sewing ring diameter
	(A)	(B)	(C)	(D)	(E)	(F)



Ann Thorac Surg 2021;111:314-26

Standardized Approach

AORTIC Valve chart for "VALVE" by "MANUFACTURER"

This chart is developed according to the standardized criteria of the EACTS-STS-AATS Valve Labelling Task Force

Probability of severe* Prosthesis-Patient Mismatch "MANUFACTURER" - "VALVE MODEL"													
Labelled valve size		19		21		23		25		27		29	
Patient BMI [kg/m²]		<30	≥30	<30	≥30	<30	≥30	<30	≥30	<30	≥30	<30	≥30
Patient BSA [m²]	1.2	9%	3%	7%	4%	4%	3%	2%	1%	1%	1%	0%	0%
	1.3	16%	7%	12%	7%	7%	4%	3%	2%	2%	1%	0%	0%
	1.4	25%	12%	18%	10%	11%	7%	6%	3%	3%	2%	0%	0%
	1.5	34%	18%	24%	15%	15%	10%	8%	5%	5%	3%	0%	0%
	1.6	43%	25%	29%	19%	19%	13%	12%	8%	7%	5%	0%	0%
	1.7	51%	31%	35%	24%	23%	16%	15%	10%	10%	7%	0%	0%
	1.8	58%	38%	40%	28%	28%	20%	19%	13%	13%	9%	0%	0%
	1.9	64%	44%	45%	33%	32%	23%	23%	16%	15%	11%	0%	0%
	2.0	69%	50%	50%	37%	35%	27%	27%	19%	18%	14%	1%	0%
	2.1	74%	55%	54%	41%	39%	30%	30%	22%	21%	16%	1%	0%
	2.2	77%	60%	58%	45%	42%	33%	34%	25%	24%	18%	2%	1%
	2.3	80%	64%	61%	48%	45%	36%	37%	28%	27%	21%	3%	1%
	2.4	83%	68%	64%	51%	48%	39%	40%	31%	30%	23%	4%	2%
	2.5	85%	71%	67%	54%	51%	41%	43%	34%	32%	25%	6%	3%
Study details	EOA, mean±SD [cm²]	1.1 ± 0.2		1.3 ± 0.3		1.6 ± 0.4		1.8 ± 0.4		2.2 ± 0.5		2.8 ± 0.3	
	Patients per valve size (n)	25		52		79		65		43		32	
	Prospective	yes		yes		yes		yes		yes		yes	
	Centers per valve size (n)	3		3		3		3		3		3	
	Pooled data	no		no		no		no		no		no	
	Regulatory	no		no		no		no		no		no	
	Echo core lab	yes		yes		yes		yes		yes		yes	
	Period of data collection	2012 - 2014		2012 - 2014		2012 - 2014		2012 - 2014		2012 - 2014		2012 - 2014	
	Timing of postop echo	3 months		3 months		3 months		3 months		3 months		3 months	

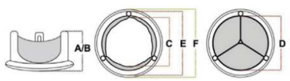
*severe PPM is defined as iEOA: ≤0.65 cm²/m², in patients with BMI <30 kg/m²; and as iEOA: ≤0.55 cm²/m² in patients with BMI ≥30

COLOR CODING: yellow indicates that the percentage probability of severe PPM is greater than or equal to 50%, meaning that the mean indexed EOA is below the severe PPM cutoff level.

DISCLAIMER: This chart is a support tool to estimate the probability of PPM in patients undergoing surgical aortic valve replacement with a particular valve, but the actual risk further depends on specific patient characteristics and operative technique.

Possible implant positions

Labelled valve size	Physical dimensions: Overall profile height [mm] (A)	Outflow profile height [mm] (B)	Minimum internal diameter [mm] (C)	Internal stent diameter [mm] (D)	External stent diameter [mm] (E)	External sewing ring diameter [mm] (F)
19	13	13	17.1	18	19.2	24
21	14	14	19.2	20	21.2	26
23	15	15	21.2	22	23.2	28
25	16	16	23.2	24	25.3	30
27	17	17	25.2	26	27.3	32
29	18	18	27.2	28	29.3	34



Labelled valve size and sizer diameters, defining tissue annulus ranges where specific sizes fit						
Labelled valve size	19	21	23	25	27	29
Diameter, valve related tubular sizer [mm]	18.3	20.2	22.4	24.5	26.1	28.2

DISCLAIMER: Besides tissue annulus diameter, other factors (e.g. patient's anatomy, extent of annular debridement, annular positioning, sewing cuff properties, prosthesis height, surgeon's sizing and suturing technique and sizing before or after placing the annular sutures) can influence the final fit of the prosthesis and should be considered during clinical sizing.

version number v1, issue date 01-01-2020

Figure 10. Standardized Valve Chart: aortic valves. Standardized Valve Charts provide essential information on surgical heart valve (SHV) characteristics in a uniform manner and allow for comparability between different SHV models without demanding radical changes in current SHV designs or labelling. Furthermore, Valve Charts highlight the necessity of considering multiple factors when selecting an SHV for implantation. (BMI, body mass index; BSA, body surface area; EOA, effective orifice area; iEOA, indexed effective orifice area; PPM, prosthesis–patient mismatch.)

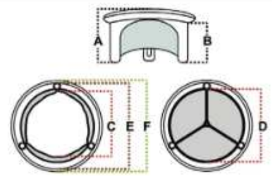
MITRAL Valve chart for "VALVE" by "MANUFACTURER"

This chart is developed according to the standardized criteria of the EACTS-STS-AATS Valve Labelling Task Force

In vivo hemodynamic performance "MANUFACTURER" - "VALVE MODEL"					
Labelled valve size		27	29	31	33
EOA, mean±SD [cm²]		2.2 ± 0.2	2.7 ± 0.3	2.8 ± 0.4	3.1 ± 0.5
Study details	Patients per valve size (n)	21	25	42	44
	Prospective	no	no	no	no
	Centers per valve size (n)	NA	NA	NA	NA
	Pooled data	yes	yes	yes	yes
	Regulatory	no	no	no	no
	Echo core lab	no	no	no	no
	Period of data collection	1997-2008	1997-2008	1997-2008	1997-2008
	Timing of postop echo	3-6 months	3-6 months	3-6 months	3-6 months

Possible implant positions

Labelled valve size	Physical dimensions: Overall profile height [mm] (A)	Outflow profile height [mm] (B)	Minimum internal diameter [mm] (C)	Internal stent diameter [mm] (D)	External stent diameter [mm] (E)	External sewing ring diameter [mm] (F)
27	18	12	23.5	25	27	37
29	19	14	25.5	27	29	39
31	20	15	27.5	29	31	41
33	20	15	29.5	31	33	43



Labelled valve size and sizer diameters defining tissue annulus ranges where specific sizes fit				
Labelled valve size	27	29	31	33
Diameter, valve related tubular sizer [mm]	26.2	28.4	30.5	32.1

DISCLAIMER: Besides tissue annulus diameter, other factors (e.g. patient's anatomy, extent of annular debridement, annular positioning, sewing cuff properties, prosthesis height, surgeon's sizing and suturing technique and sizing before or after placing the annular sutures) can influence the final fit of the prosthesis and should be considered during clinical sizing.

version number v1, issue date 01-01-2020

Ann Thorac Surg 2021;111:314-26

Thank you for your attention

The Ideal Valve has…

- Sufficient structural durability
- Absence of thrombogenicity
- Resistance to infections
- Lack of antigenicity
- No resistance to physiological flows
- Growth potential

2020 ACC/AHA Guidelines

Favor Mechanical Prosthesis	Favor Bioprosthesis
Age <50 y Increased incidence of structural deterioration with bioprosthesis (15-y risk: 30% for age 40 y, 50% for age 20 y) Lower risk of anticoagulation complications	Age >65 y Low incidence of structural deterioration (15-y risk: <10% for age >70 y) Higher risk of anticoagulation complications
Patient preference (avoid risk of reintervention)	Patient preference (avoid risk and inconvenience of anticoagulation)
Low risk of long-term anticoagulation	High risk of long-term anticoagulation
Compliant patient with either home monitoring or close access to INR monitoring	Limited access to medical care or inability to regulate VKA
Other indication for long-term anticoagulation (eg, AF)	Access to surgical centers with low reoperation mortality rate
High-risk reintervention (eg, porcelain aorta, prior radiation therapy)	Access to transcatheter ViV replacement
Small aortic root size for AVR (may preclude ViV procedure in future)	TAVI valves have larger effective orifice areas for smaller valve sizes (avoid patient–prosthesis mismatch)

Circulation 2021;143:e72-227

Effective Orifice Area (EOA)

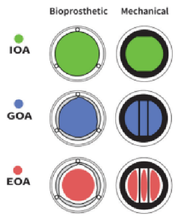


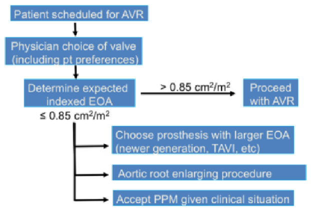
Figure 6: IOA, GOA and EOA in bioprosthetic and mechanical valves. EOA: effective orifice area; GOA: geometric orifice area; IOA: internal orifice area.

$$\text{Indexed EOA } (\mathrm{cm^2/m^2}) = \frac{\text{EOA } (\mathrm{cm^2})}{\text{BSA of the patient } (\mathrm{m^2})}$$

$$\text{Expected indexed EOA } (\mathrm{cm^2/m^2}) = \frac{\text{Reference EOA } (\mathrm{cm^2})}{\text{BSA of the patient } (\mathrm{m^2})}$$

Eur J Cardiothorarc Surg 2019;55:1025-36

Prosthesis-Patient Mismatch (PPM)



Heart 2019;105:s28-s33