

Selection of Valve Prostheses

가톨릭대학 성빈센트병원
조민섭

Types of Prosthetic Valve

- Bioprosthetic
 - Porcine valve
 - Bovine pericardial valve
- Mechanical valve
 - Ball in Cage
 - Disc valves
 - Single tilting valves
 - Bileaflet valves

Types of Substitues Depending on Source

- Autograft
 - Ross operation
- Homograft
 - Cadaveric human aortic and Pul. Valves
- Heterograft
 - Bioprosthetic ; Porcine, Bovine peircardial

History

- 1952 Hunfnagel ball valve
 - place in descending thoracic aorta
- 1956 Murray
 - Aortic homograft in descending thoracic aorta



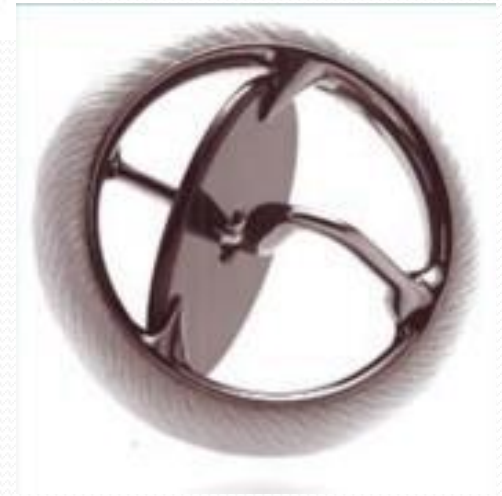
History

- 1961 Star-Edward Caged ball valve



History

- 1966 Wada, Tilting disc valve
- 1967 Lillehei-Kaster
- 1969 Bjork Shiley
- 1977 Medtronic-Hall tilting disc valve



History

- 1977 St. Jude Medical Valve , bileaflet
 - Most commonly implanted mechanical valves
 - Low bulk and flat profile
 - Superior hemodynamics
 - have a greater effective opening area
 - lower transvalvular pressure gradient at any outer diameter and cardiac output



Flow Pattern of Mechanical prostheses

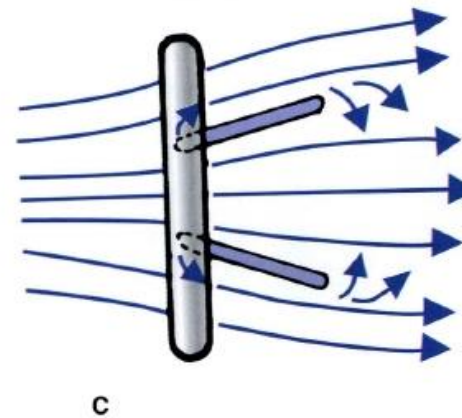
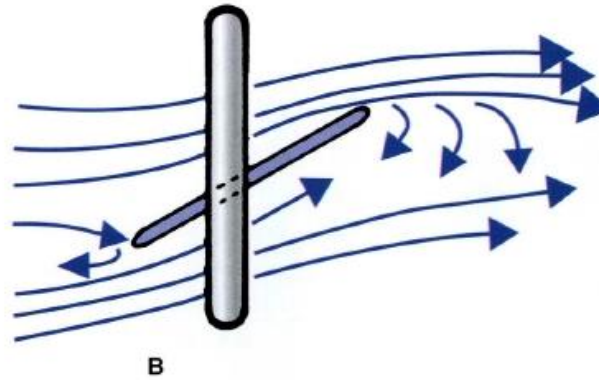
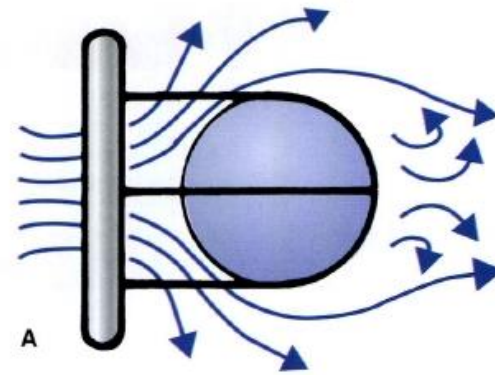
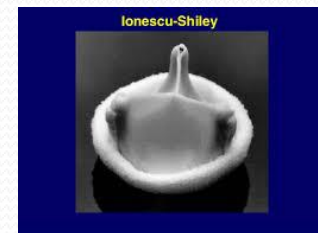


FIGURE 42-4 Flow characteristics of different mechanical valve designs. (A) Ball-and-cage. (B) Tilting-disk. (C) Bileaflet.

History-Tissue

- 1962 Ross and Boyes, 1st Allograft from cadaver
- 1964 Duran and Gunning, Porcine aortic valve (1st Heterograft)
- 1967 Ross, 1st Pulmonary autograft
- 1970 Hancock porcine graft
- 1976 Carpentier & Edwards Porcine valve
- 1976 Ionescu & Shiley Pericardial valve



1969-1970 : Introduction of the Bjork-Shiley and Lillehei-Kaster tilting-disc valves

1970 : Introduction of the Hancock porcine xenograft

1976 : Introduction of the Ionescu-Shiley pericardial xenograft

1976 : Introduction of the Carpentier-Edwards porcine xenograft

1977 : Introduction of the Medtronic Hall tilting-disc valve

1977 : First bileaflet St. Jude Medical valve implanted

1992 : First clinical trials of stentless mitral valve

1993 : FDA approval of the CarboMedics bileaflet valve

1997 : First FDA-approved stentless bioprosthetic aortic valve, the Toronto SPV valve

1952 : First clinical use of a cardiac valvular prosthesis

1950

1960

1970

1980

1990

2000

...

1962 : Introduction of the Starr-Edwards ball-and-cage valve

Mid-1960 : Development of low-profile caged-disk valve

1980 : Carpentier – Edwards pericardial valve

2000 : FDA approval of the Medtronic Mosaic valve

2000 : FDA approval of the ATS Open Pivot bileaflet mechanical valve

2001-2002 : FDA approval of the On-X bileaflet aortic and mitral valve

2002 : First successful percutaneous transcatheter valve replacement

Mechanical Valves

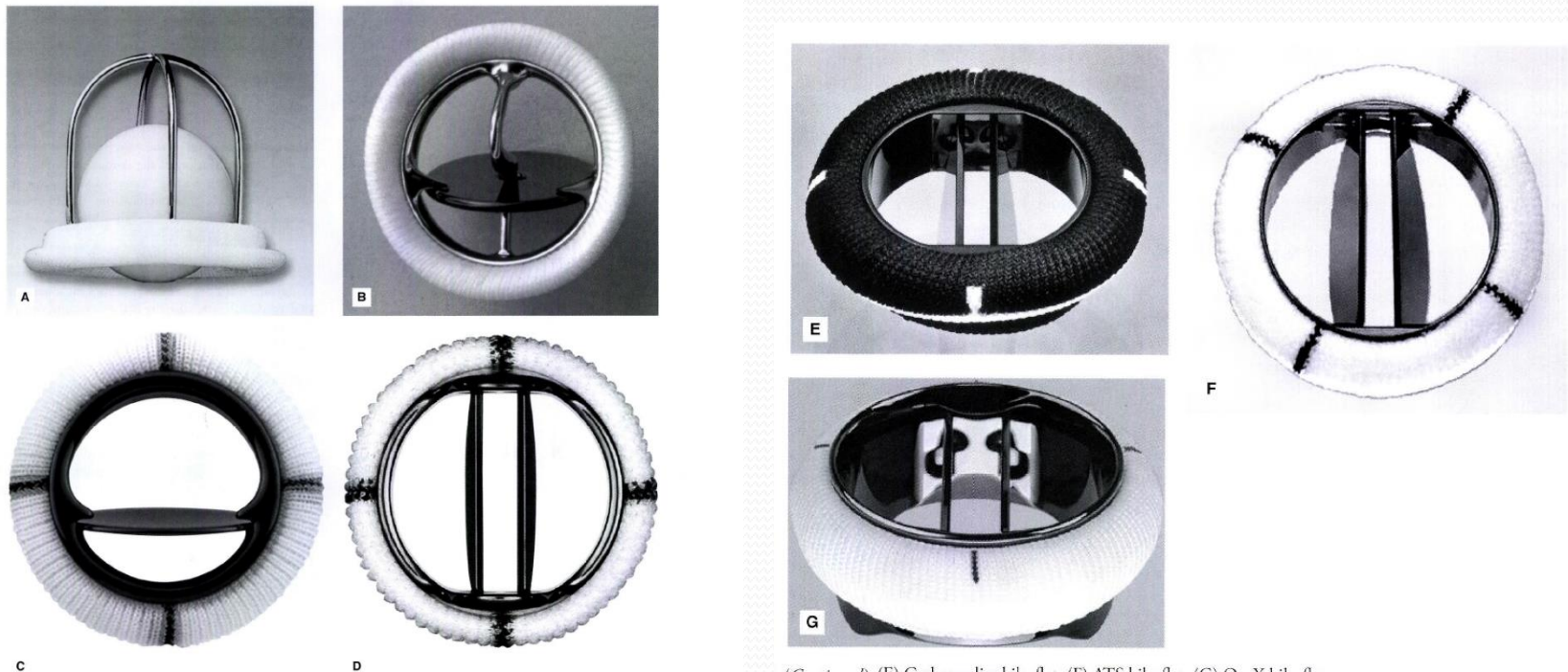


FIGURE 42-1 FDA-approved mechanical mitral valves. (A) Starr-Edwards ball-and-cage. (B) Medtronic Hall tilting-disk. (C) Omnicarbon tilting-disk. (D) St. Jude Medical bileaflet.

(Continued) (E) Carbomedics bileaflet. (F) ATS bileaflet. (G) On-X bileaflet.

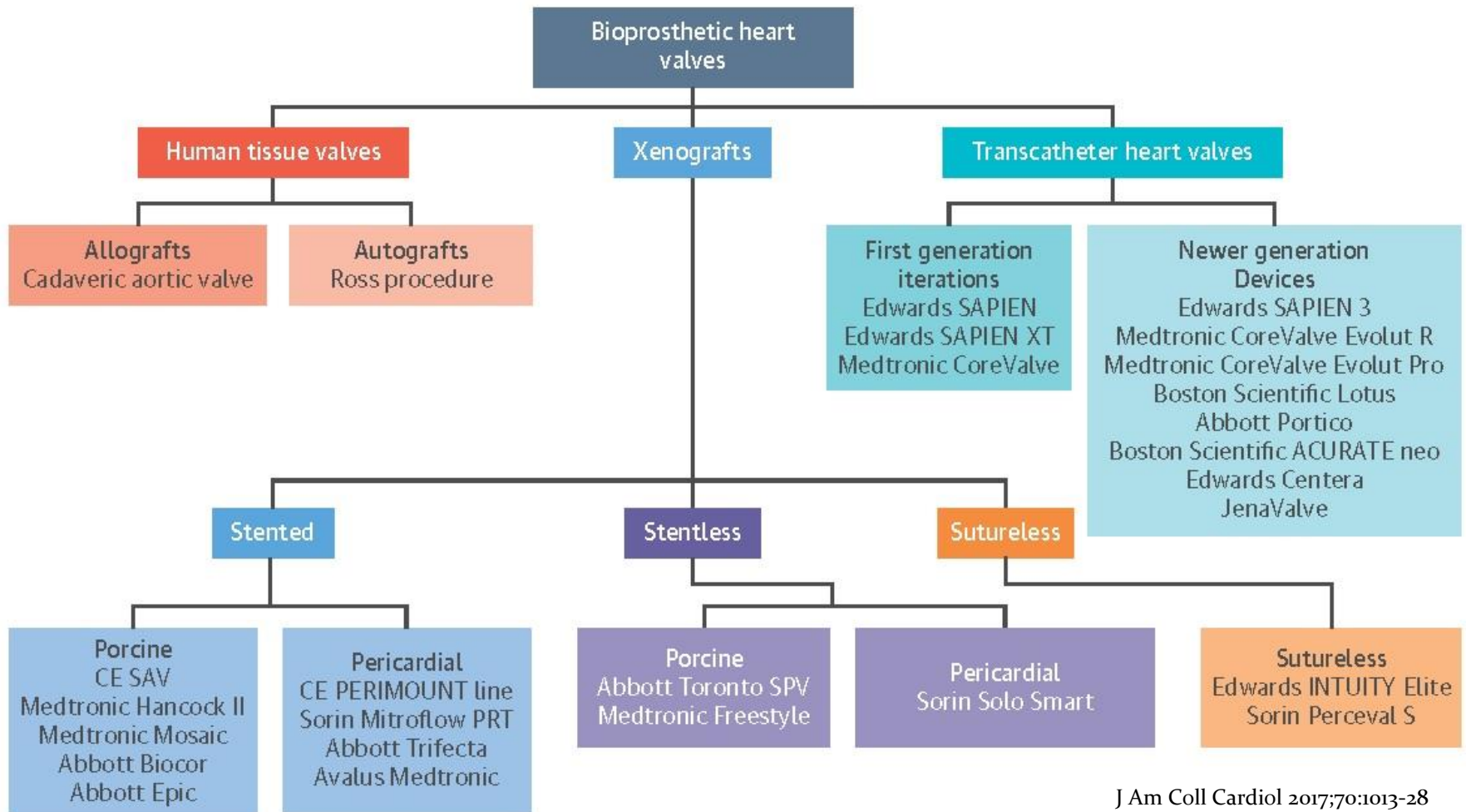
Bileaflet Valves



FIGURE 76-1 ■ Mechanical bileaflet valves. **A**, Open Pivot Mechanical Valve. **B**, The Regent mechanical valve. **C**, The Top Hat mechanical valve. **D**, The On-X Heart Valve. (**A**, Courtesy Medtronic, Inc., Minneapolis, MN. **B**, Courtesy St. Jude Medical, Inc., Minneapolis, MN. **C**, Courtesy Sorin Group, Inc., Milan, Italy. **D**, Courtesy On-X Life Technologies, Inc., Austin, TX.)

Bioprosthetic valves

A



Stented porcine valves



Carpentier-Edwards SAV™



Medtronic Hancock II



Medtronic Mosaic*



Abbott Epic™

Stentless porcine valves



Abbott Toronto SPV™



Medtronic Freestyle*

Sutureless valves



Edwards INTUITY Elite*



Sorin Perceval S*

Stented pericardial valves



Carpentier-Edwards Perimount Magna Ease™



Sorin Mitroflow™



Abbott Trifecta™



Avalus Medtronic™

Stentless pericardial valves



Sorin Solo Smart™

Transcatheter heart valves



Edwards SAPIEN® 3



Medtronic CoreValve® Evolut R®



Medtronic CoreValve® Evolut PRO®



Boston Scientific Lotus™



Abbott Portico™



Boston Scientific ACURATE neo™



Edwards Centra®



JenaValve™

TABLE 76-1 Mechanical Valve Choices

Valve Type	Manufacturer	Name	Position	Available Sizes (mm)	
Bileaflet	Medtronic	Open Pivot AP360	Aortic	16-26	
		Open Pivot AP	Aortic	16-26	
		Open Pivot Standard	Mitral	16-26	
	St. Jude Medical	Masters		Aortic	19-31
				Mitral	25-33
		Masters HP		Aortic	19-33
				Mitral	17-27
	Sorin Group	Regent		Aortic	17-27
				Mitral	19-27
		Bicarbon Fitline*		Aortic	19-31
				Mitral	19-33
			Bicarbon Overline*	Aortic	16-24
			Bicarbon Slimline*	Aortic	17-27
			Carbomedics Top Hat	Aortic	19-27
			Carbomedics OptiForm	Mitral	23-33
			Carbomedics Reduced	Aortic	19-29
			Carbomedics Standard	Aortic	19-31
	On-X	Carbomedics Standard Pediatrics		Mitral	21-33
				Aortic	16-18
		Carbomedics Orbis*		Mitral	16, 18, 21
			Aortic	19-31	
Standard Sewing Ring			Mitral	21-33	
			Aortic	19-27/29	
		Mitral	23-31/33		
Conform-X Sewing Ring		Aortic	19-27/29		
		Mitral	25/33		
Anatomic Sewing Ring		Aortic	19-27/29		

*Available only outside the United States.

TABLE 76-2 Bioprosthetic Valve Choices

Valve Type	Manufacturer	Name	Position	Available Sizes (mm)	
Stented porcine	Medtronic	Hancock II	Aortic	21-29	
		Hancock II Ultra	Mitral	25-33	
		Mosaic	Aortic	21-29	
	Edwards Lifesciences	Mosaic Ultra	Aortic	19-29	
		Carpentier-Edwards Standard Porcine (2625 and 6625)	Mitral	25-33	
		Carpentier-Edwards S.A.V. Porcine (2650)	Aortic	19-31*	
		Carpentier-Edwards Duraflex Low Pressure Porcine [†] (6625LP)	Mitral [†]	25-33	
		Carpentier-Edwards Duraflex Low Pressure Porcine with Extended Sewing Ring [‡] (6625-ESR-LP)	Mitral	27-35	
		St. Jude Medical	Epic	Aortic	21-29
			Epic	Mitral	25-33
			Epic Supra	Aortic	19-27
	Biocor		Aortic	21-29	
	Stented bovine pericardial	Edwards Lifesciences	Biocor Supra	Mitral	25-33
			Carpentier-Edwards PERIMOUNT (2700 and 2700TFX)	Aortic	19-29
			Carpentier-Edwards PERIMOUNT RSR (2800 and 2800TFX)	Aortic	19-29
Carpentier-Edwards PERIMOUNT Plus (6900P and 6900PTFX)			Mitral	25-33	
Carpentier-Edwards PERIMOUNT Magna (3000 and 3000TFX)			Aortic	19-29	
Sorin Group		Carpentier-Edwards PERIMOUNT Magna Ease (3300TFX, 7300TFX)	Mitral	25-33	
		Mitroflow	Aortic	19-29	
		Soprano Armonia [†]	Aortic	19-33	
		Pericarbon More [†]	Mitral	19-33	
		Trifecta	Aortic	19-29	
Stentless	St. Jude Medical	Freestyle	Aortic	19-29	
		3f	Aortic	19-29	
	Sorin Group	Pericarbon Freedom [†]	Aortic	15-29	
		Freedom Solo [†]	Aortic	19-27	
	Edwards Lifesciences	Prima Plus	Aortic	21-29	
	Sutureless bovine pericardial	Medtronic	3f Enable [†]	Aortic	19-29
Sorin Group		Perceval S [†]	Aortic	S, M, L, XL	
Edwards Lifesciences		Edwards Intuity [†]	Aortic	19-27	
Transcatheter	Edwards Lifesciences	Sapient	Aortic	23, 26	
		Sapient XT	Aortic	23, 26, 29	
	Medtronic	CoreValve	Aortic	23, 26, 29, 31	
	St. Jude Medical	Portico [†]	Aortic	25	

*Sizes 19, 29, and 31 available only outside the United States.

[†]Available only outside the United States.

[‡]Available only in the United States.

RSR, Reduced sewing ring.

Ideal Prostheses

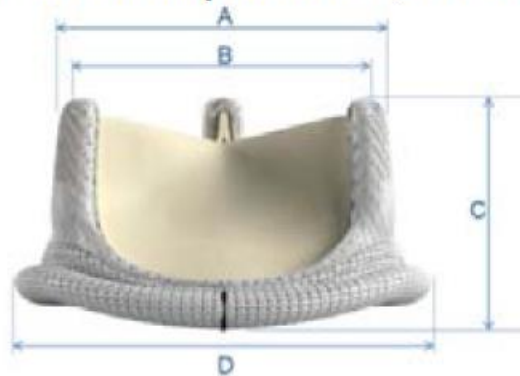
- Good Hemodynamic
- Quiet
- Require no anticoagulation
- Last for life time
- Cheap
- Easy to implant

 **TABLE 29-1: Comparison of Mechanical and Tissue Alternatives for Aortic Valve Replacement**

	Mechanical	Stented bioprosthesis	Stentless bioprosthesis	Allograft	Autograft
Advantages	Long durability Easy implantation Good EOAI	Easy implantation No anticoagulation	Larger EOAI compared with stented valve, Root replacement is available option	Excellent EOAI All biologic material good for use in endocarditis	Excellent EOAI Living valve Long durability possible
Disadvantages	Anticoagulation Emboli/bleeding Noise	Durability limited Poor EOAI in small valve sizes	Durability limited More complex operative technique Harder reoperation	Complex technique Availability limited Durability limited	Complex operation Double valve or Root replacement with potential late failure of either

Diameters of Prostheses

Edwards Pericardial Aortic Bioprosthesis, Model 11000A



Size (mm)	19	21	23	25	27	29
A. Tissue Annulus Diameter (Stent Diameter, mm)	19	21	23	25	27	29
B. Internal Diameter (Stent ID, mm)	18	20	22	24	26	28
C. Profile Height (mm)	13	14	15	16	17	18
D. External Sewing Ring Diameter (mm)	24	26	28	30	32	34

Selection of Prostheses

- 45세 남자
- Severe MS
- No other specific comorbidity

- Homeless
- Heavy smoker
- 수술전일 escape
- 수개월후 숙박업소에 쓰러져 있는 환자를 교회에서 모시고 다시 병원내원

Selection of Prostheses

- 40세 여자
- Severe MS
- 평소 패러 글라이딩 등 extreme sport 즐기는 환자

Factors for selection of Prostheses

- Patient's Age
- Life expectancy
- Preference
- Ix or Cix to Anticoagulation
- Special Patient Groups
- Optimal Hemodynamic performance

Age

- >70 Bioprostheses
- <60 Mechanical

Special Patient Group

- Long term anticoagulation Tx가 필요한 환자
 - A.fib
 - Previous TE events
 - Hypercoagulable state
 - Another mechanical valve in place
 - Intracardiac thrombus
- Ctx to Anticoagulation
 - Women of child-bearing age
 - Bleeding disorder
 - Refuse oral anticoagulation Tx
- ESRD
 - Rapid SVD of Bioprosthesis
 - Bleeding d/t Anticoagulation for Mechanical valve

EOA

- EOA ; Effective orifice area
- $iEOA = EOA/BSA$
- Functional estimate of of the minimal cross sectional area of the transvalvular flow jet
- Dependent on the
 - Geometric area of the prosthesis
 - Shape and size of the LVOT and ascending aorta
 - Blood pressure
 - Cardiac output

Optimal Hemodynamic performance

- $i\text{EOA} > 0.85$; Acceptable
- $0.65 < i\text{EOA} < 0.85$; Moderate PPM
- $i\text{EOA} < 0.65$; Severe PPM

Impact of PPM

- Increase early and late morbidity
- Incomplete left ventricular mass regression
- Reduce recovery of LV function
- Decrease long-term survival

Mean EOA in different valve

Valve type	Size (mm)						Ref
	19	21	23	25	27	29	
Mosaic	1.1	1.2	1.4	1.7	1.8	2	Dumesnil et al
Hancock II	1.2	1.3	1.5	1.6	1.6		Dumesnil et al
Perimount	1.1	1.3	1.5	1.8	2.1	2.2	Dumesnil et al
Magna*	1.3	1.7	2.1	2.3	-	-	Dumesnil et al
Biocor (Epic)*	-	1.3	1.6	1.8	-	-	Dumesnil et al
Mitroflow*	1.1	1.3	1.5	1.8	-	-	Dumesnil et al
Trifecta*	1.1	1.7	1.9	2.7	2.9	2.4	Yadlapati et al
Trifecta*	1.8	2	2.2				Levy et al

*These values are based on a limited number of patients and should thus be interpreted with caution.

Adapted with permission from Dumesnil JG, Pibarot P. The problem of severe valve prosthesis-patient mismatch in aortic bioprostheses: near extinction? *J Am Soc Echocardiogr.* 2014 Jun;27(6):598-600.

SJM Regent® Valve Effective Orifice Area Index (EOAI) Calculator

Valve Size (mm)	EOAI by Valve Size						
	17	19	21	23	25	27	29
Average EOA* (cm ²)	1.3	1.7	2.0	2.5	2.6	3.5	3.5
BSA (m ²)							
0.6	2.17	2.83	3.33	4.17	4.33	5.83	5.83
0.7	1.86	2.43	2.86	3.57	3.71	5.00	5.00
0.8	1.63	2.13	2.50	3.13	3.25	4.38	4.38
0.9	1.44	1.89	2.22	2.78	2.89	3.89	3.89
1.0	1.30	1.70	2.00	2.50	2.60	3.50	3.50
1.1	1.18	1.55	1.82	2.27	2.36	3.18	3.18
1.2	1.08	1.42	1.67	2.08	2.17	2.92	2.92
1.3	1.00	1.31	1.54	1.92	2.00	2.69	2.69
1.4	0.93	1.21	1.43	1.79	1.86	2.50	2.50
1.5	0.87	1.13	1.33	1.67	1.73	2.33	2.33
1.6	0.81	1.06	1.25	1.56	1.63	2.19	2.19
1.7	0.76	1.00	1.18	1.47	1.53	2.06	2.06
1.8	0.72	0.94	1.11	1.39	1.44	1.94	1.94
1.9	0.68	0.89	1.05	1.32	1.37	1.84	1.84
2.0	0.65	0.85	1.00	1.25	1.30	1.75	1.75
2.1	0.62	0.81	0.95	1.19	1.24	1.67	1.67
2.2	0.59	0.77	0.91	1.14	1.18	1.59	1.59
2.3	0.57	0.74	0.87	1.09	1.13	1.52	1.52
2.4	0.54	0.71	0.83	1.04	1.08	1.46	1.46
2.5	0.52	0.68	0.80	1.00	1.04	1.40	1.40

EOAI = EOA / BSA

 EOAI ≥ .85 cm²/m²**

 .80 cm²/m² ≤ EOAI ≤ .84 cm²/m²**

 EOAI < .80 cm²/m²**

References

*At 12 months post-op. St. Jude Medical, Inc. Pre-Market Approval Application Supplement, SJM Regent heart valve, P810002/S57.

**Pibarot P, Dumesnil, JG. Hemodynamic and clinical impact of prosthesis - patient mismatch in the aortic valve position and its prevention. JACC 2000;36:1131-1141.

FOR INTERNATIONAL USE.

- Labeled size와 actual size는 다르다
- In general, Newer-generation valves have superior performance over older devices

2014 AHA/ACC Guideline

Recommendations	COR	LOE
Choice of valve intervention and prosthetic valve type should be a shared decision process.	I	C
A bioprosthesis is recommended in patients of any age for whom anticoagulant therapy is contraindicated, cannot be managed appropriately, or is not desired.	I	C
A mechanical prosthesis is reasonable for AVR or MVR in patients younger than 60 years who do not have a contraindication to anticoagulation.	IIa	B
A bioprosthesis is reasonable in patients older than 70 years.	IIa	B
Either a bioprosthetic or mechanical valve is reasonable in patients between 60 and 70 years old.	IIa	B
Replacement of the aortic valve by a pulmonary autograft (the Ross procedure), when performed by an experienced surgeon, may be considered in young patients when VKA anticoagulation is contraindicated or undesirable.	IIb	C

2017 AHA/ACC Guideline

Table 3. Factors Used for Shared Decision Making About Type of Valve Prosthesis

Favor Mechanical Prosthesis	Favor Bioprosthesis
Age <50 y	Age >70 y
Increased incidence of structural deterioration with bioprosthesis (15-y risk: 30% for age 40 y, 50% for age 20 y)	Low incidence of structural deterioration (15-y risk: <10% for age >70 y)
Lower risk of anticoagulation complications	Higher risk of anticoagulation complications
Patient preference (avoid risk of reintervention) of valve sounds)	Patient preference (avoid risk and inconvenience of anticoagulation and absence
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)	
Small aortic root size for AVR (may preclude valve-in-valve procedure in future).	

AF indicates atrial fibrillation; AVR, aortic valve replacement; INR, International Normalized Ratio; and VKA, vitamin K antagonist.

2017 ESC/EACTS Guidelines

Choice of the aortic/mitral prosthesis in favour of a mechanical prosthesis; the decision is based on the integration of several of the following factors

Recommendations	Class ^a	Level ^b
A mechanical prosthesis is recommended according to the <u>desire of the informed patient</u> and if there are no contraindications to <u>long-term anticoagulation</u> . ^c	I	C
A mechanical prosthesis is recommended in patients at <u>risk of accelerated structural valve deterioration</u> . ^d	I	C
A mechanical prosthesis should be considered in patients <u>already on anticoagulation because of a mechanical prosthesis in another valve position</u> .	IIa	C
A mechanical prosthesis should be considered in patients <u><60 years of age for prostheses in the aortic position and <65 years of age for prostheses in the mitral position</u> . ^e	IIa	C
A mechanical prosthesis should be considered in patients with a <u>reasonable life expectancy^f for whom future redo valve surgery would be at high risk</u> .	IIa	C
A mechanical prosthesis may be considered in patients <u>already on long-term anticoagulation due to the high risk for thromboembolism</u> . ^g	IIb	C

LV = left ventricular.

^aClass of recommendation.

^bLevel of evidence.

^cIncreased bleeding risk because of comorbidities, compliance concerns or geographic, lifestyle or occupational conditions.

^dYoung age (<40 years), hyperparathyroidism.

^eIn patients 60–65 years of age who should receive an aortic prosthesis and those between 65 and 70 years of age in the case of mitral prosthesis, both valves are acceptable and the choice requires careful analysis of factors other than age.

^fLife expectancy should be estimated at > 10 years according to age, sex, comorbidities and country-specific life expectancy.

^gRisk factors for thromboembolism are atrial fibrillation, previous thromboembolism, hypercoagulable state and severe LV systolic dysfunction.

2017 ESC/EACTS Guidelines

Choice of the aortic/mitral prosthesis in favour of a bioprosthesis; the decision is based on the integration of several of the following factors

Recommendations	Class ^a	Level ^b
A bioprosthesis is recommended according to the <u>desire of the informed patient</u> .	I	C
A bioprosthesis is recommended when <u>good-quality anticoagulation is unlikely</u> (compliance problems, not readily available) <u>or contraindicated because of high bleeding risk</u> (previous major bleed, comorbidities, unwillingness, compliance problems, lifestyle, occupation).	I	C
A bioprosthesis is recommended for reoperation for <u>mechanical valve thrombosis despite good long-term anticoagulant control</u> .	I	C
A bioprosthesis should be considered in patients for whom there is a low likelihood and/or <u>a low operative risk of future redo valve surgery</u> .	IIa	C
A bioprosthesis should be considered in young women <u>contemplating pregnancy</u> .	IIa	C
A bioprosthesis should be considered in patients <u>>65 years of age for a prosthesis in the aortic position or > 70 years of age in a mitral position or those with a life expectancy^c lower than the presumed durability of the bioprosthesis.^d</u>	IIa	C

^aClass of recommendation.

^bLevel of evidence.

^cLife expectancy should be estimated according to age, sex, comorbidities and country-specific life expectancy.

^dIn patients 60–65 years of age who should receive an aortic prosthesis and those between 65 and 70 years of age in the case of mitral prosthesis, both valves are acceptable and the choice requires careful analysis of factors other than age.



감사합니다