Why should we consider ACURATE Neo2

: Based on Clinical Evidence



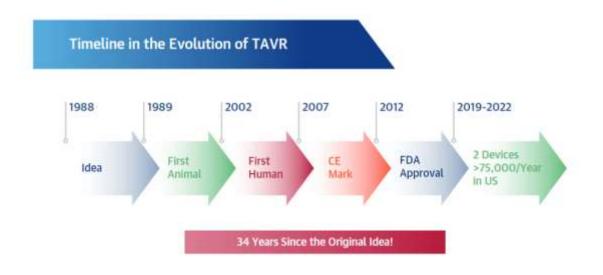
Jeehoon Kang
Cardiovascular Center,

Seoul National University Hospital, Korea

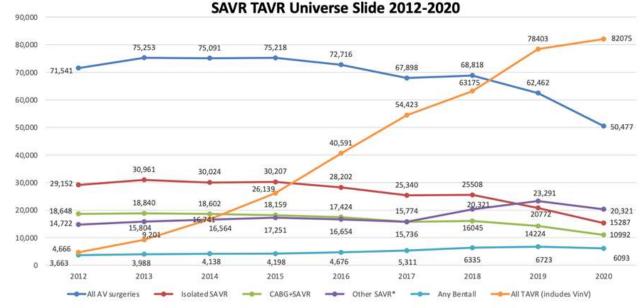
Current trend of TAVI



- During a >30 years evolution, rapid(?) increase of TAVI
- To lower risk/younger age patients.









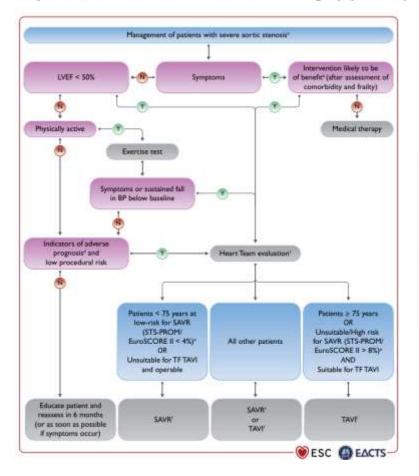


Recent Guidelines of TAVI



2021 ESC/EACTS Guidelines for the management of valvular heart disease

Developed by 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)



Treatment modality is determined by...

Heart Team evaluation
Age (75 years old) and high risk (STS,
EuroSCORE) and suitability of TAVI

Previous guidelines

Current guidelines

			inche choice.	
Revised	SAVR is recommended in patients at low surgical risk (STS or EuroSCORE II <4% or logistic EuroSCORE I <10%, and no other risk factors not included in these scores, such as frailty, porcelain aorta, sequelae of chest radiation).	ŀ	SAVR is recommended in younger patients who are low risk for surgery (<75 years and STS-PROM/ EuroSCORE II <4%) or in patients who are operable and unsuitable for transfemoral TAVI.	1
Revised	TAVI is recommended in patients who are not suitable for SAVR as assessed by the Heart Team.	1	TAVI is recommended in older patients (≥75 years), or in those who are high-risk (STS-PROM/ EuroSCORE II >8%) or unsuitable for surgery.	1
12 0 0			27/12 25/74 1/74	

TAVI in patients not suitable for SAVR

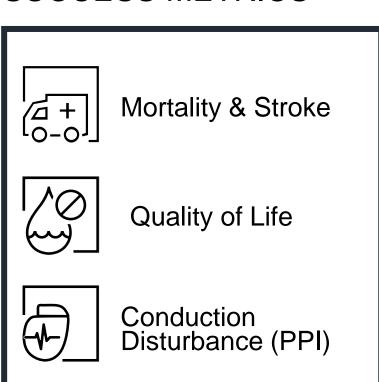


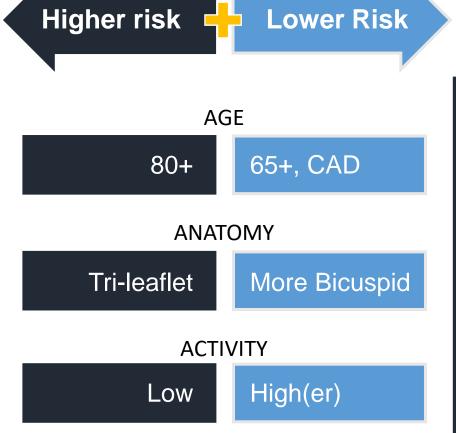
SAVR in patients not suitable for TAVI

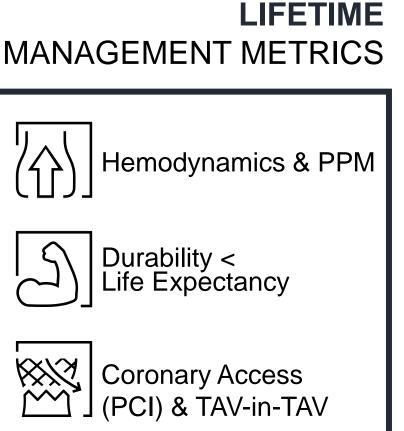
Shift in the metrics of 'what matters?'



PROCEDURAL SUCCESS METRICS

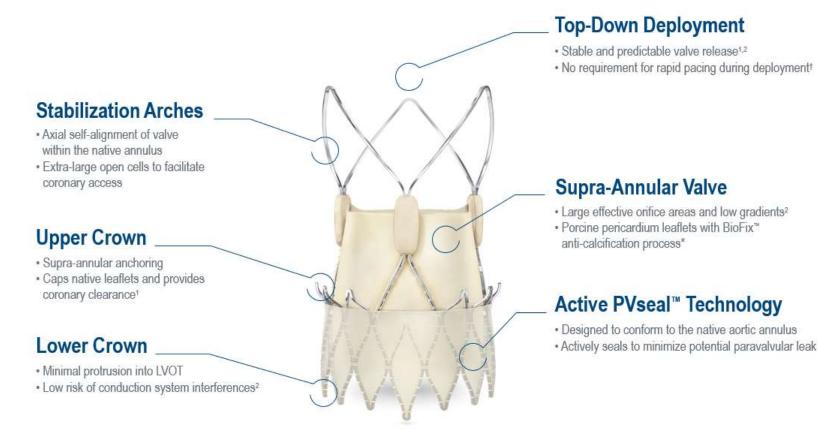






The ACURATE neo2 valve





In regards of device specific characteristics

- **✓** Hemodynamics
- ✓ PVL and conduction disorders
- ✓ Coronary access and Commissure alignment

Hemodynamics



✓ **Supra-annular self-expandable valves** are associated with favorable hemodynamics compared with balloon-expandable valves

5-Year Outcomes After TAVR With Balloon-Expandable Versus Self-Expanding Valves

Results From the CHOICE Randomized Clinical Trial

	Balloon-Expandable Valve $(n = 121)$	Self-Expanding Valve (n = 120)	p Value
Death	7.5 4.5 M.		
From any cause	63 (53.4)	54 (47.6)	0.38
From cardiovascular causes	37 (31.6)	25 (21.5)	0.12
Stroke	21 (17.5)	19 (16.5)	0.73
Repeat hospitalization for heart failure	30 (28.9)	26 (22.5)	0.75
Myocardial infarction	2 (1.6)	7 (6.1)	0.08
Bleeding			
Life threatening	21 (17.3)	18 (16.2)	0.77
Major	28 (26.3)	20 (22.0)	0.26
Minor	17 (14.3)	12 (10.4)	0.37
Vascular complications			
Major	14 (11.6)	14 (12.1)	0.89
Minor	5 (4.2)	3 (2.6)	0.51
New pacemaker*	28 (25.4)	40 (40.4)	0.01

	Balloon-Expandable Valve (n = 36)	Self-Expanding Valve (n = 41)	p Value
Effective orifice area, cm ² Number of patients	1.6 ± 0.5 39	1.9 ± 0.5 45	0.02
Mean gradient, mm Hg Number of patients	12.2 ± 8.7 47	6.9 ± 2.7 52	0.001
Transvalvular aortic regurgitation None/trace Mild Moderate Severe Number of patients	46 (97.9) 1 (2.1) 0 (0.0) 0 (0.0) 47	49 (94.2) 3 (5.8) 0 (0.0) 0 (0.0) 52	0.62
Paravalvular aortic regurgitation None/trace Mild Moderate Severe Number of patients	28 (59.6) 19 (40.4) 0 (0.0) 0 (0.0) 47	28 (53.8) 24 (46.2) 0 (0.0) 0 (0.0) 52	0.69
Total aortic regurgitation None/trace Mild Moderate Severe	27 (57.4) 20 (42.6) 0 (0.0) 0 (0.0)	25 (48.1) 27 (51.9) 0 (0.0) 0 (0.0)	0.42
Left ventricular ejection fraction, %	54.4 ± 10.2	$\textbf{57.2} \pm \textbf{8.4}$	0.15
Left ventricular end-systolic dimension, mm	34.4 ± 12.0	29.1 ± 6.7	0.02
Left ventricular end-diastolic dimension, mm	$\textbf{45.5} \pm \textbf{7.7}$	$\textbf{41.7} \pm \textbf{6.8}$	0.02
Systolic pulmonary artery pressure, mm Hg	30.9 ± 12.0	29.0 ± 12.7	0.49
Moderate/severe mitral regurgitation	15/47 (31.9)	9/48 (18.7)	0.13
Moderate/severe tricuspid regurgitation	10/45 (22.2)	13/47 (27.6)	0.54

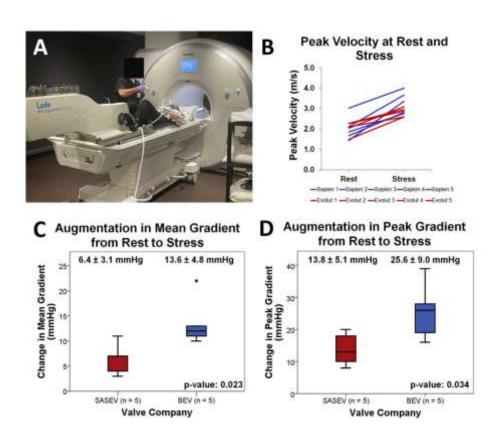
	Balloon-Expandable Valve (n = 121)	Self-Expanding Valve (n = 120)	p Value
Bioprosthetic valve dysfunction Components	28 (22.5)	26 (20.9)	0.91
SVD	6 (6.6)	0 (0.0)	0.018
Moderate SVD	4 (5.6)	0 (0.0)	0.047
Severe SVD	2 (0.9)	0 (0.0)	0.20
NSVD	17 (17.8)	23 (26.7)	0.20
Moderate/severe PPM	14 (15.9)	13 (16.0)	1.0
Moderate/severe PVL	3 (2.5)	10 (8.5)	0.08
Valve thrombosis	6 (7.3)	1 (0.8)	0.06
Endocarditis	2 (1.0)	4 (3.4)	0.39

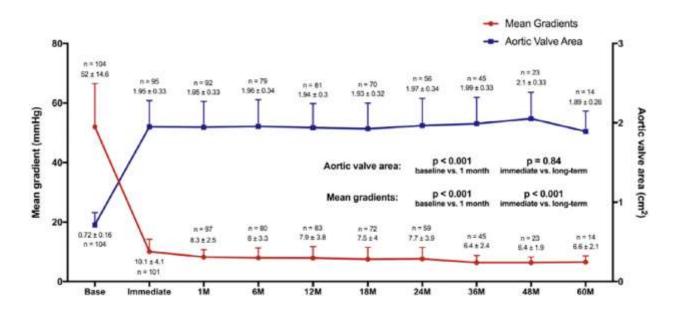
 Forward flow hemodynamics were significantly better with the SE valve.
 Structural valve deterioration was uncommon but occurred more frequently with the BE valve

Hemodynamics



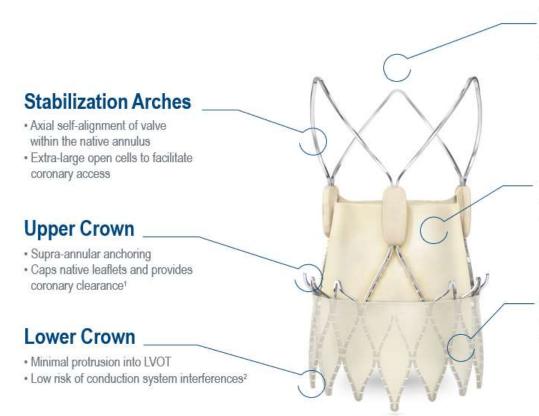
✓ Supra-annular self-expandable valves are associated with favorable hemodynamics compared with balloon-expandable valves, even during stress.





The ACURATE neo2 valve





Top-Down Deployment

- Stable and predictable valve release^{1,2}
- No requirement for rapid pacing during deployment[†]

Supra-Annular Valve

- · Large effective orifice areas and low gradients2
- Porcine pericardium leaflets with BioFix™ anti-calcification process*

Active PVseal™ Technology

- · Designed to conform to the native aortic annulus
- · Actively seals to minimize potential paravalvular leak

In regards of device specific characteristics

- √ Hemodynamics
- ✓ PVL and conduction disorders
- ✓ Coronary access and Commissure alignment



🗸 Paravalvular leak (PVL)

✓ PVL is common after TAVI and has been linked with worse survival. The prevalence of PVL after TAVI varies from 7% to 40%.

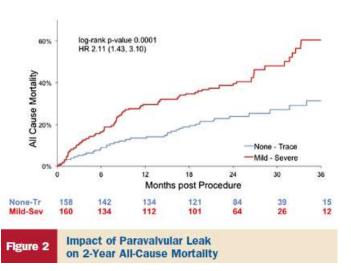
All node All node

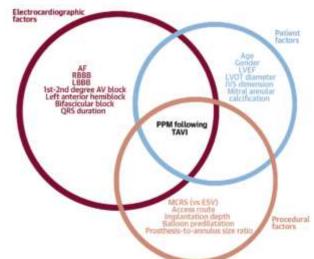
✓ Pacemaker (PM) implantation

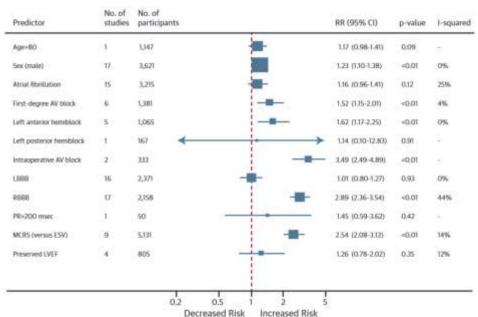
✓ AV conduction disturbances requiring PPM implantation are common (upto 40%) and clinically important adverse events.

✓ Related to the close proximity of the AV conduction system to the aortic valvular

complex.









The ACURATE neo Transcatheter Heart Valve

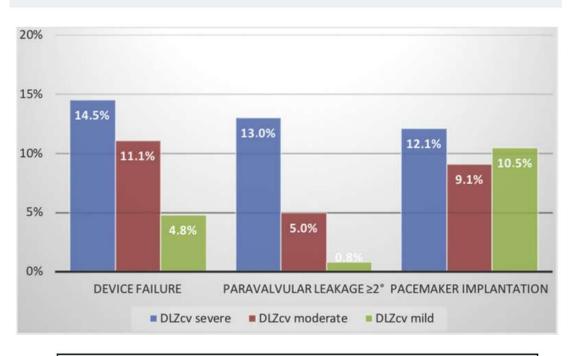
A Comprehensive Analysis of Predictors of Procedural Outcome

Won-Keun Kim, MD, ^{a,b,c,a} Helge Möllmann, MD, PhD, ^{d,a} Christoph Liebetrau, MD, PhD, ^{a,c} Matthias Renker, MD, ^a
Andreas Rolf, MD, PhD, ^{a,c} Philippe Simon, ^a Arnaud Van Linden, MD, ^a Mani Arsalan, MD, ^a Mirko Doss, MD, PhD, ^b
Christian W. Hamm, MD, PhD, ^{a,c} Thomas Walther, MD, PhD^c

✓ Study population: A total of 500 patients with severe AS undergoing TF-TAVR using the ACURATE neo prosthesis (2012.5-2017.9)

TABLE 2 Procedural Outcomes and Complicat	tions (n = 500)
Device success (VARC-2)	448 (89.6)
All-cause 30-day mortality	16/483 (3.3)
Post-procedural ejection fraction, %	65.0 (60.0-65.0)
Post-procedural P _{mean} , mm Hg	8.0 (6.0-11.0)
Post-procedural AVA, cm ²	1.6 (1.4-1.9)
Second-degree or greater PVL (post-procedure)	32/499 (6.2)
Second-degree or greater PVL (at discharge)	24/499 (4.8)
Pacemaker implantation	51 (10.2)
Second valve	9 (1.8)
Conversion to sternotomy	9 (1.8)
Device embolization	6 (1.2)
Aortic root injury	0
Aortic dissecti <mark>o</mark> n	1 (0.2)
Ventricular septum defect	1 (0.2)
Ventricular perforation	6 (1.2)
Coronary obstruction	0
Major bleeding	38 (7.6)
Major vascular complication	46 (9.2)
Major stroke	1 (2.0)
AKI stage 2 or 3	15 (3.0)





Multivariate Analysis	Odds Ratio	95% CI	p Value
CV _{Ann} , per mm ³	1.007	1.003-1.010	<0.001
Cover index for perimeter-derived annular diameter in diastole, per %	0.867	0.773-0.971	0.014
Plaque protrusion at annular level	2.756	1.138-6.670	0.025
Stent holder movement aortic	5.593	1.299-24.076	0.02



Effectiveness and Safety of the ACURATE Neo Prosthesis in 1,000 Patients With Aortic Stenosis



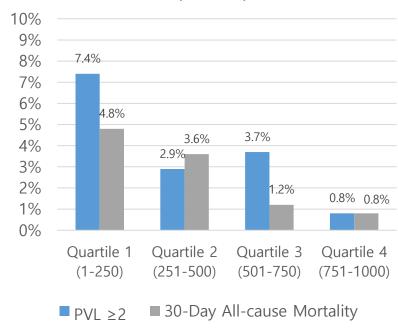
Won-Keun Kim, MD^{a,b,*}, Helge Möllmann, MD, PhD^c, Christoph Liebetrau, MD, PhD^a, Matthias Renker, MD^a, Thomas Walther, MD, PhD^d, and Christian W. Hamm, MD, PhD^{a,b}

Predictors of paravalvular leak				
Variable	Univariate Analysis Odds ratio [95% CI]	P	Multivariable Analysis Odds ratio [95% CI]	р
Prosthesis size	1.08 [0.89; 1.31]	0.444		
AVCS, per AU	1.0006 [1.0004; 1.0009]	< 0.001	1.0003 [1.0001; 1.0006]	< 0.001
Compact peri-annular calcification	9.20 [4.99; 16.93]	< 0.001	6.15 [3.13; 12.08]	< 0.001
Bicuspid aortic valve	1.88 [0.72; 4.93]	0.201		Occosin-
Cover index annulus, per %	0.87 [0.79; 0.95]	0.001	0.89 [0.80; 0.99]	0.026
Annulus/STJ height-ratio	0.07 [0.01; 0.94]	0.045	0.03 [0.02; 0.45]	0.012
Pmean, per mmHg	1.01 [0.99; 1.03]	0.140	Assaultinonevitorias	W 400 WOOD
Implantation depth at NCC, per mm	0.93 [0.83; 1.05]	0.254		
Implantation depth at LCC, per mm	0.85 [0.75; 0.97]	0.012		

ACURATE neo learning curve

Variable	Quartile I (Case 1-250)	Quartile 2 (Case 251–500)	Quartile 3 (Case 501-750)	Quartile 4 (Case 751-1000)	p
Cover index (%)	3.87 [1.86; 6.37]	5.13 [3.04; 7.30]	5.38 [3.39; 7.52]	6.17 [4.20; 7.90]	< 0.001
Aortic valve calcium score (AU)	2395 [1646; 3111]	2049 [1494; 2872]	1955 [1385; 2893]	1989 [1280; 2726]	< 0.001
Compact peri-annular Ca++ formation	64 (25.6%)	41 (16.4%)	42 (16.8%)	29 (11.6%)	0.001
Implantation depth at LCC (mm)	5.0 [3.0; 6.0]	6.0 [5.0; 7.0]	6.0 [4.0; 6.0]	5.0 [4.0; 6.0]	< 0.001
Device success (VARC-2)	171 (85.5%)	177 (88.5%)	181 (90.5%)	186 (93.0%)	0.002
≥moderate PVL at discharge	18/243 (7.4%)	7/241 (2.9%)	9/246 (3.7%)	2/246 (0.8%)	0.001
≥moderate PVL procedural	21/246 (8.5%)	13/249 (5.2%)	11 (4.4%)	3 (1.2%)	0.002
Permanent pacemaker	25 (10.0%)	26 (10.4%)	26 (10.4%)	17 (6.8%)	0.444
TVH embolization	5 (2.0%)	4 (1.6%)	3 (1.2%)	3 (1.2%)	0.496
Need for second THV	3 (1.2%)	7 (2.8%)	4 (1.6%)	3 (1.2%)	0.462
Major vascular complication	32 (12.8%)	26 (10.4%)	14 (5.6%)	16 (6.4%)	0.013
Major stroke	4 (1.6%)	7 (2.8%)	5 (2.0%)	5 (2.0%)	0.820
30-day all-cause mortality	12 (4.8%)	9 (3.6%)	3 (1.2%)	2 (0.8%)	0.012

Center learning curve across quartiles of 1,000 ACURATE *neo™* cases with respect to PVL and 30-day mortality



** Cover Index =

(Prosthesis diameter-Annulus size)

Prosthesis diameter

Kim et al. Am J Cardiol 2020;131:12-16

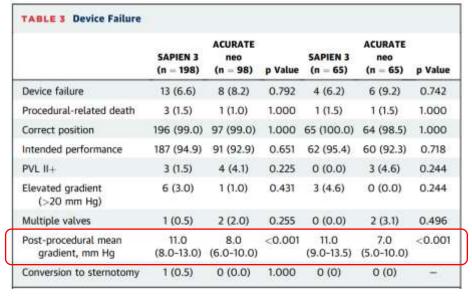


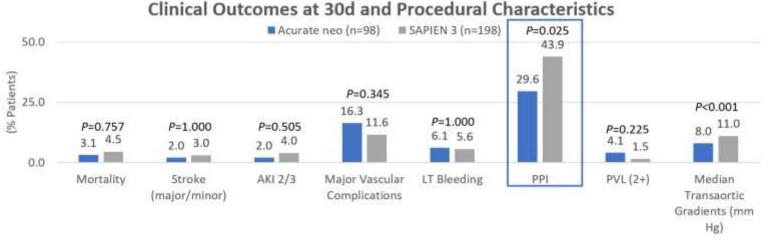
✓ Comparison of PPI between two THVs

Transcatheter Valve SELECTion in Patients With Right Bundle Branch Block and Impact on Pacemaker Implantations Oliver Husser, MD,*.* Costanza Pellegrini, MD,** Won-Keun Kim, MD,* Andreas Holzamer, MD,**

Oliver Husser, MD, ", "Costanza Pellegrini, MD, "Won-Keun Kim, MD, "Andreas Holzamer, MD, "
Thomas Pilgrim, MD, "Stefan Toggweiler, MD, "Urich Schäfer, MD, "Johannes Blumenstein, MD, "
Florian Deuschl, MD, "Tobias Rheude, MD, "Michael Joner, MD, "Michael Hilker, MD, "Christian Hengstenberg, MD,
Helge Möllmann, MD"

- ✓ The SELECT RBBB (Transcatheter heart valve SELECTion in Patients
 with Right Bundle Branch Block multicenter registry) registry
- ✓ Patients with Complete RBBB, enrolled from 7 Centers in Germany and Switzerland (January 2014-July 2017, N=296)



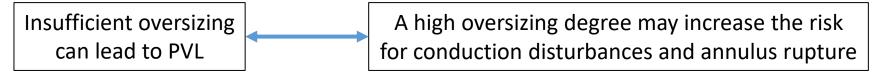




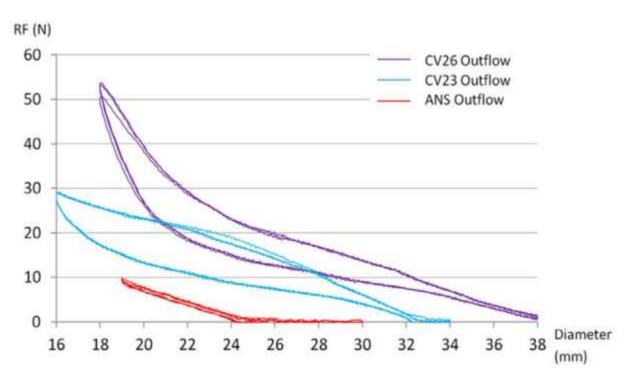
Clinical Cardiovascular

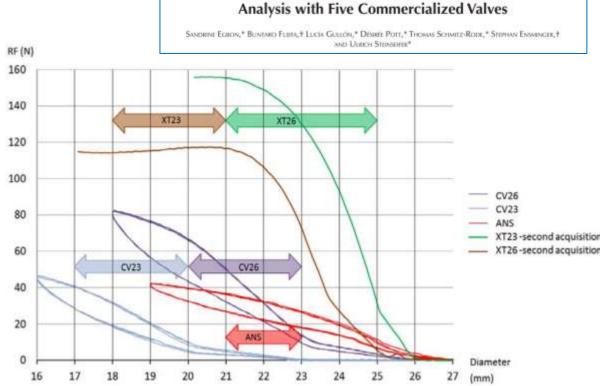
S Egron et al. ASAIO J 2018

One important factor that determines PVL and PPI



→ A device character, the Radial Force should be considered.





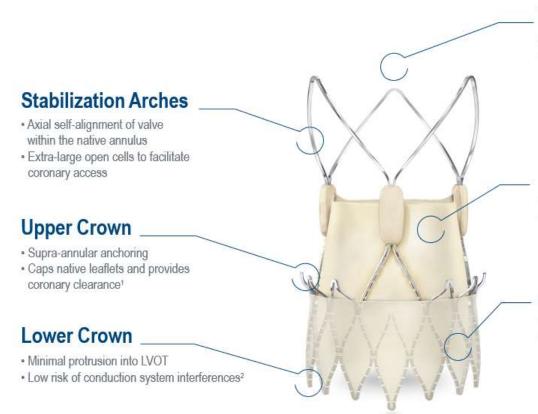
Radial Force: An Underestimated Parameter in Oversizing

Transcatheter Aortic Valve Replacement Prostheses: In Vitro

ASARO Iounul 2018

The ACURATE neo2 valve





Top-Down Deployment

- Stable and predictable valve release^{1,2}
- No requirement for rapid pacing during deployment[†]

Supra-Annular Valve

- · Large effective orifice areas and low gradients2
- Porcine pericardium leaflets with BioFix™ anti-calcification process*

Active PVseal™ Technology

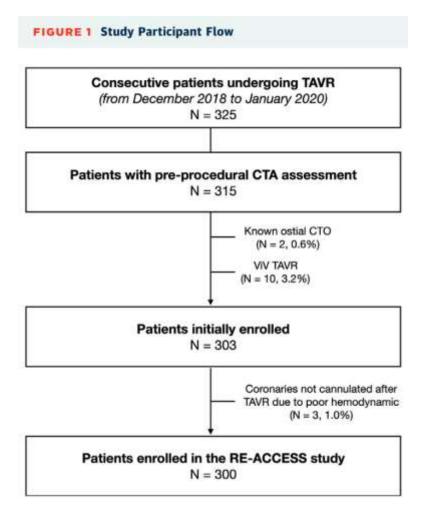
- · Designed to conform to the native aortic annulus
- · Actively seals to minimize potential paravalvular leak

In regards of device specific characteristics

- √ Hemodynamics
- ✓ PVL and conduction disorders
- ✓ Coronary access and Commissure alignment



- ✓ The prevalence of CAD in TAVR patients ranges from 40% to 75%.
- ✓ Post-TAVR CAG, and PCI may increase, particularly among younger patients.



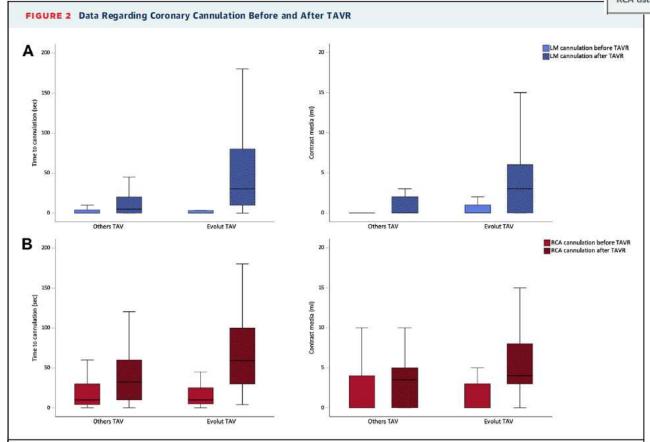
	Overall (N = 300)	Coronary Artery Accessible (n = 277)	Coronary Artery Not Accessible (n = 23)	p Value
Mean TAV implantation depth, mm	-6.2 ± 2.9	-6.2 ± 3.0	−5.0 ± 1.2	< 0.01
TAV/annular oversizing by area, %	22.4 ± 19.8	20.1 ± 18.7	$\textbf{36.9} \pm \textbf{10.9}$	< 0.01
TAV/annular oversizing by perimeter, %	12.3 ± 8.5	11.3 ± 8.1	23.5 ± 4.5	< 0.01
TAV-SoV relation, %*	-12.6 ± 9.8	-13.6 ± 9.3	-0.7 ± 7.7	< 0.01
TAV-SoV relation, %†	-19.6 ± 7.8	-19.9 ± 7.9	-16.8 ± 6.1	0.03
Medtronic Evolut R/PRO 23 mm 26 mm 29 mm 34 mm	123 (41.0) 0 (0.0) 78 (26.0) 36 (12.0) 9 (3.0)	101 (36.5) 0 (0.0) 62 (22.4) 30 (10.8) 9 (3.2)	22 (95.7) 0 (0.0) 16 (69.6) 6 (26.1) 0 (0.0)	<0.01
Edwards SAPIEN 3/ULTRA 20 mm 23 mm 26 mm 29 mm	96 (32.0) 0 (0.0) 24 (8.0) 45 (15.0) 27 (9.0)	95 (34.3) 0 (0.0) 23 (8.3) 45 (16.2) 27 (9.7)	1 (4.3) 0 (0.0) 1 (4.3) 0 (0.0) 0 (0.0)	<0.01
Boston Scientific Acurate neo Size S Size M Size L	72 (24.0) 21 (7.0) 39 (13.0) 12 (4.0)	72 (26.0) 21 (7.6) 39 (14.1) 12 (4.3)	0 (0.0) 0 (0.0) 0 (0.0) 0 (0.0)	<0.01
Abbott Portico 23 mm 25 mm 27 mm	9 (3.0) 0 (0.0) 6 (2.0) 3 (1.0)	9 (3.2) 0 (0.0) 6 (2.2) 3 (1.1)	0 (0.0) 0 (0.0) 0 (0.0) 0 (0.0)	0.38



- ✓ In the RE-ACCESS study, a total of 23 TAVR cases (7.7%) with unsuccessful coronary cannulation post-procedure.
- ✓ Predictors of failure for coronary access were...

Selective Coronary Artery Access After Transcatheter Aortic Valve Replacement in the Overall Population **Univariate Analysis** p Value **Multivariate Analysis** p Value TAV-SoV relation 1.2 (1.1-1.3) < 0.01 1.1 (1.0-1.2) < 0.01 Mean TAV implantation depth 1.2 (1.0-1.4) 0.05 1.7 (1.3-2.3) < 0.01 Evolut TAV 38.3 (5.1-288.7) 0.01 29.6 (2.6-335.0) < 0.01 LM ostium height 0.9 (0.7-1.0) 0.16 RCA ostium height 0.9 (0.8-1.1) 0.26

TABLE 4 Logistic Regression Analysis of Computed Tomographic Angiographic and Procedural Characteristics With Lack of Feasibility of





Transcatheter Aortic Valve/ Sinuses of Valsalva Relation Odds Ratio 1.1; 95% CI: 1.0-1.2; p < 0.01



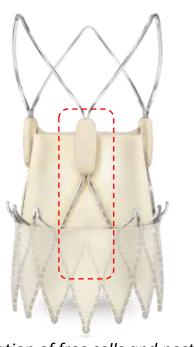
Transcatheter Aortic Valve Implant Depth Odds Ratio 1.7; 95% CI: 1.3-2.3; p < 0.01



Evolut Transcatheter Aortic Valve Odds Ratio 29.6; 95% CI: 2.6-335.0; p < 0.01



- ✓ The high rate of successful coronary access is due to the large opening cells at the stabilization arches and the established method of commissural alignment.
- ✓ Understanding the commissure alignment



Location of free cells and posts





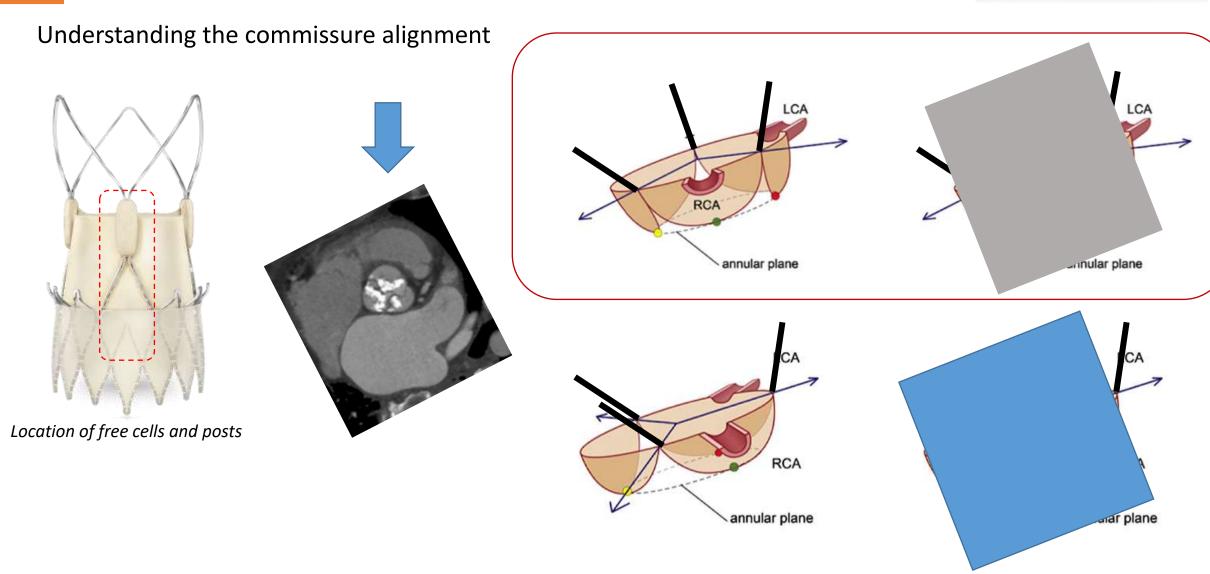


Figure Credits: Bielauskas et al. JACC 2021



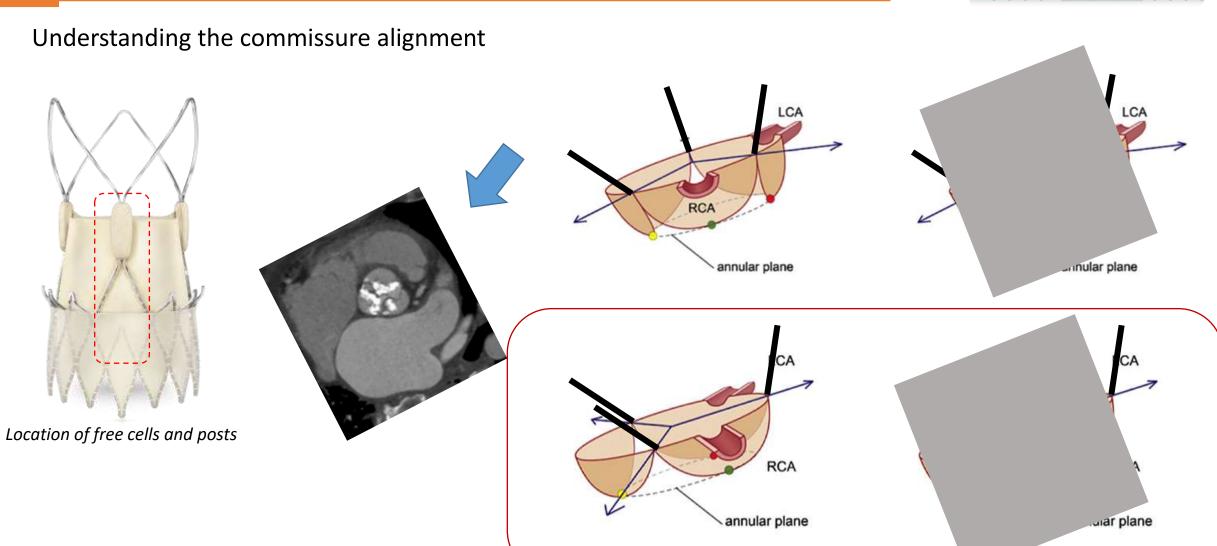
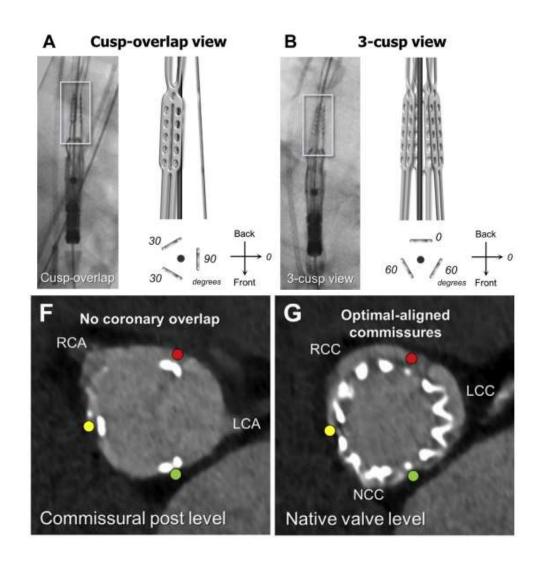
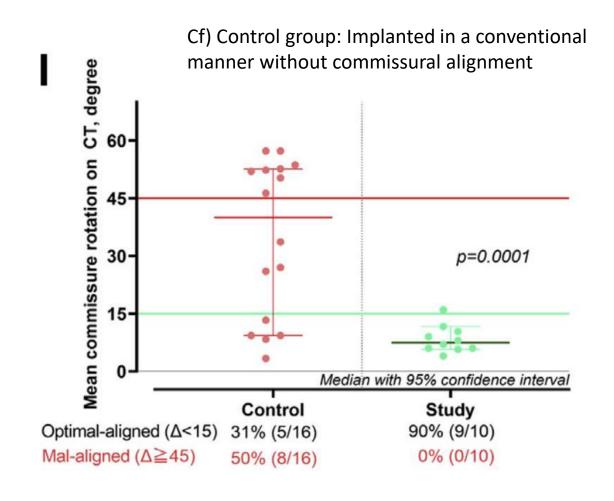


Figure Credits: Bielauskas et al. JACC 2021



Utility of the cusp-overlap technique in achieving commissural alignment with the ACURATE neo valve.



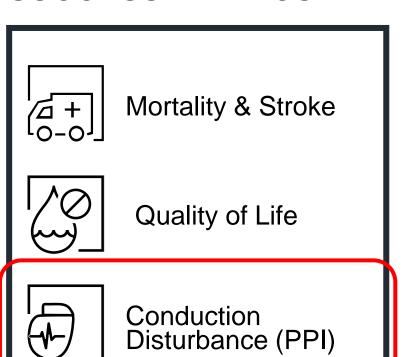


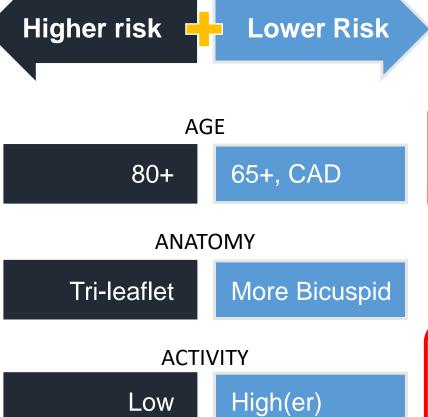
Shift in the metrics of 'what matters?'

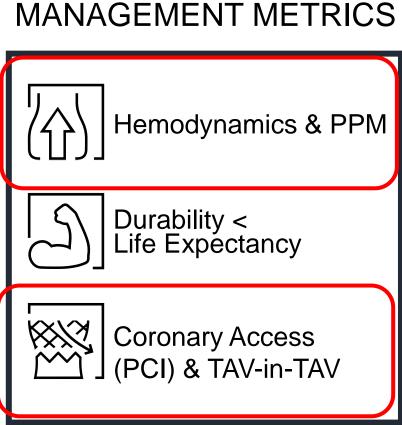


LIFETIME

PROCEDURAL SUCCESS METRICS





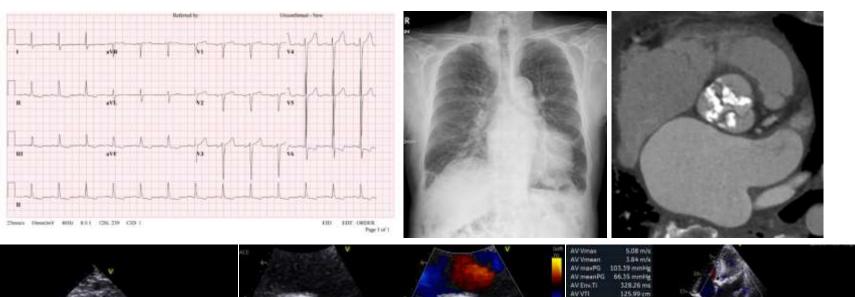


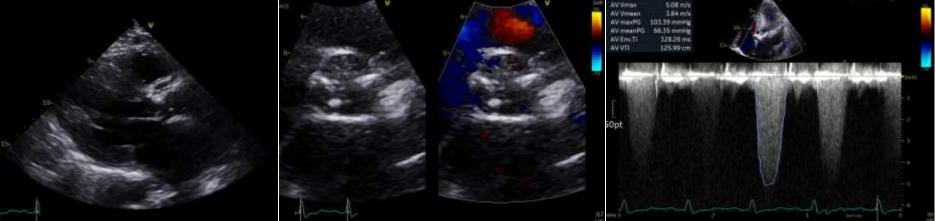
Case



81/M

- ✓ Dyspnea Fc II in 2019: moderate to severe AS → Yearly echo f/u.
- ✓ Aggravated dyspnea (NYHA II~III) → TAVI work up in 2023.4.



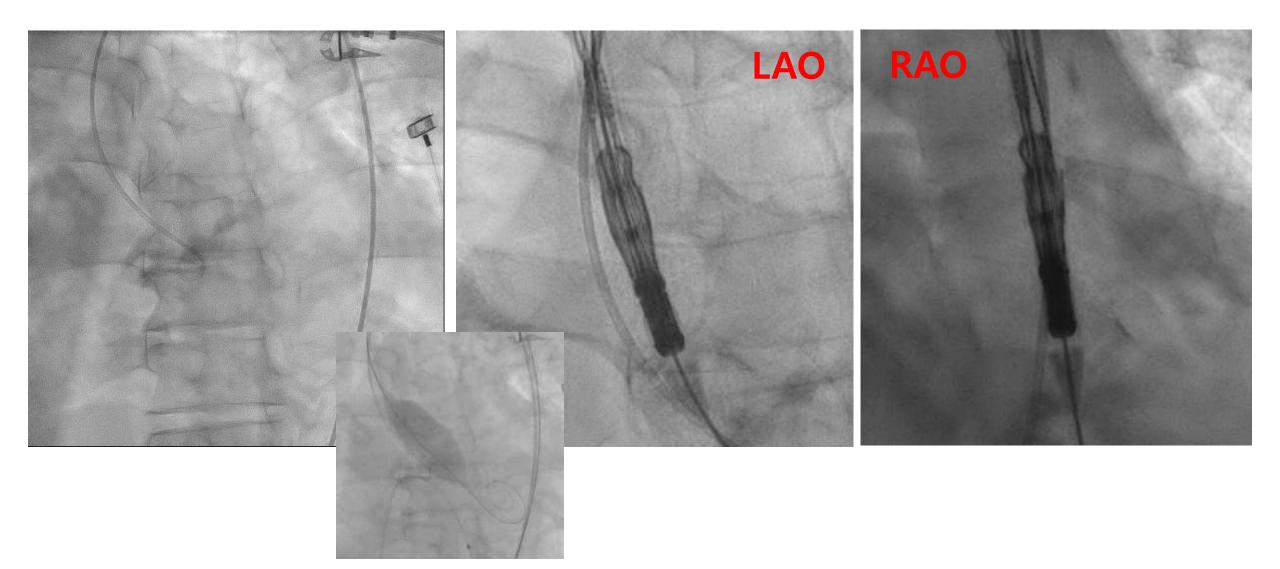








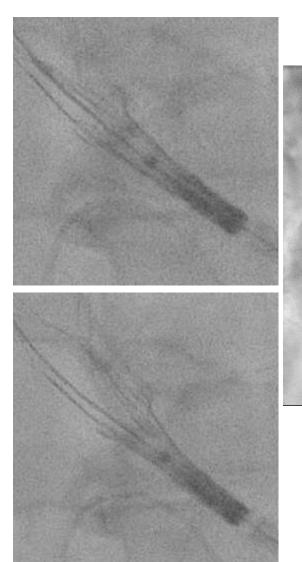
TAVI planned with ACURATE neo2 27mm, 15.1% oversizing index

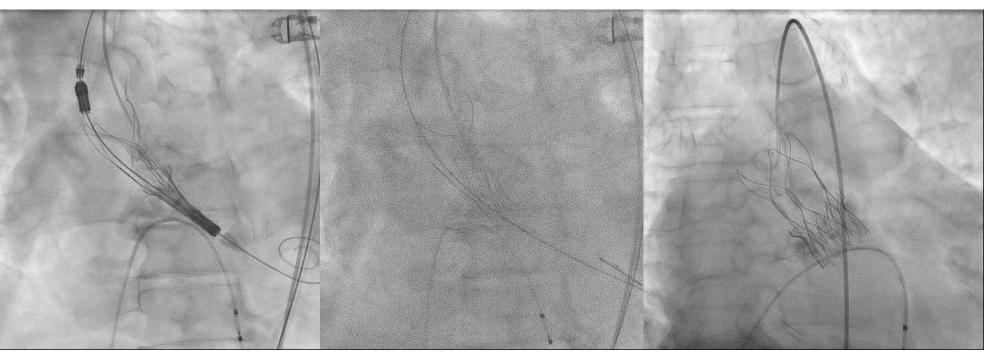






TAVI planned with ACURATE neo2 27mm, 15.1% oversizing index





- Successful valve deployment and post-dilatation of the ACURATE Neo2 27mm
- No PVL, No conduction disorder

Conclusion

- ✓ The indications for TAVI is expanding, with new devices as treatment options.
- ✓ Unlike current generation coronary stents, each devices have distinct characteristics that lead to unique strong points.
- ✓ Meanwhile, the paradigm of treating Severe AS patients with TAVI have shifted from a 'procedural success metrics' to 'lifetime management metrics'.
 - ✓ Superior hemodynamics
 - ✓ Maintaining normal conduction
 - ✓ Easier coronary access etc.
- ✓ Understanding the characteristics of the ACURATE Neo2 will provide more options in the Cath Lab.