



How to treat the Failed Bioprosthetic SAVR/TAVR Valves

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SCHOOL OF MEDICINE

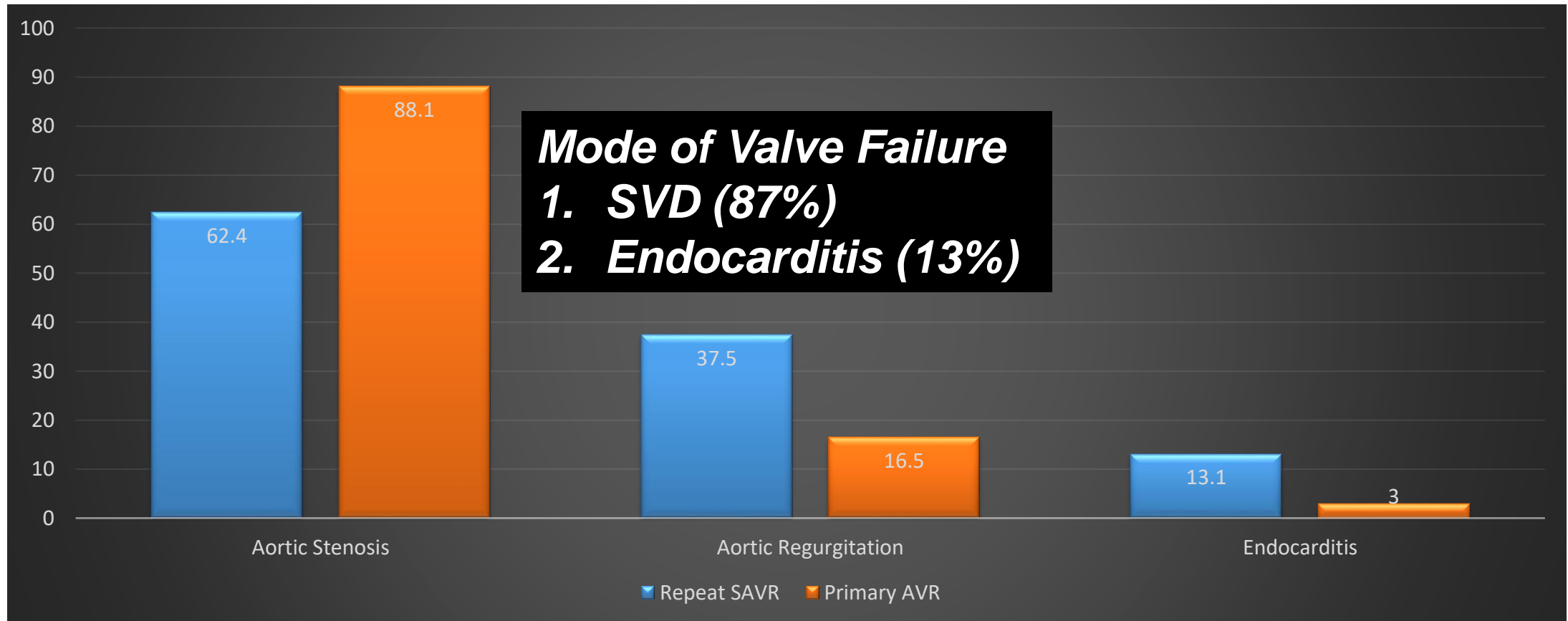
NATIONAL LEADERS IN MEDICINE

Disclosure

- Advisory Board, Consultant- Edwards Lifesciences, Abbott
- Consultant, Speaker- Medtronic

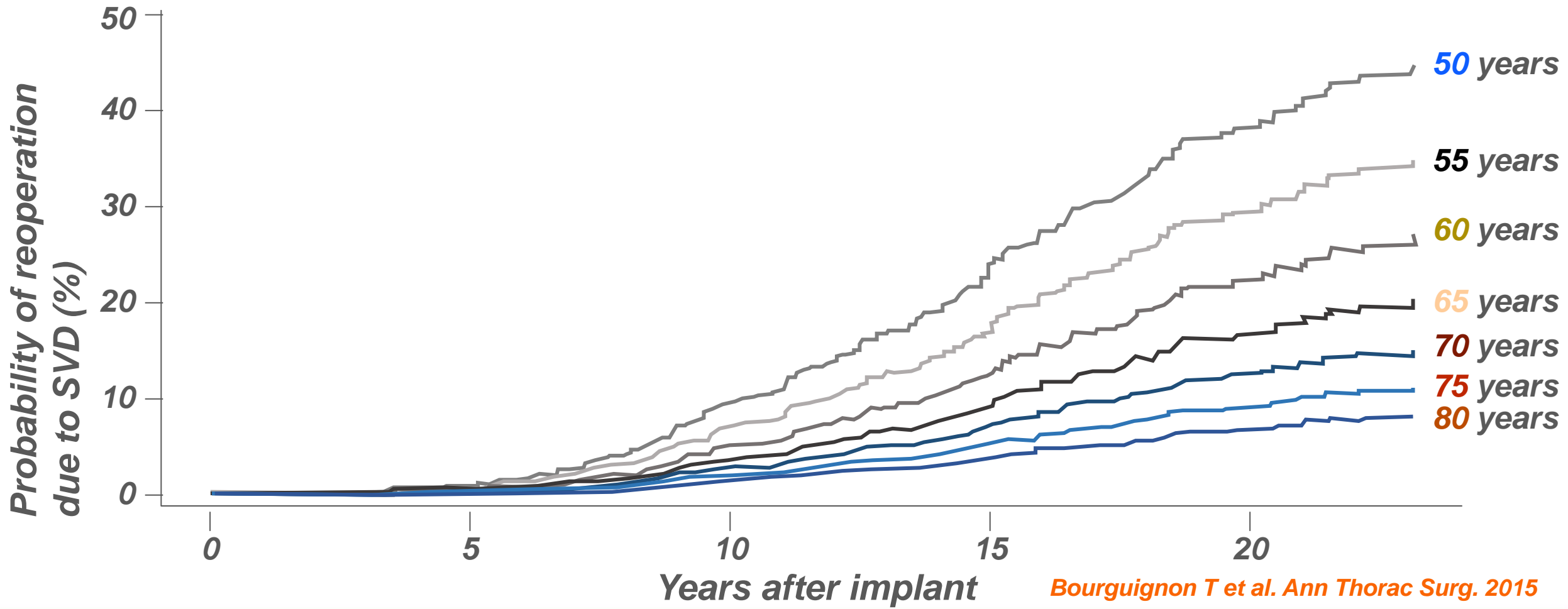
How do the Surgical Valves Fail

2011-2013 STS ACSD That underwent Repeat SAVR

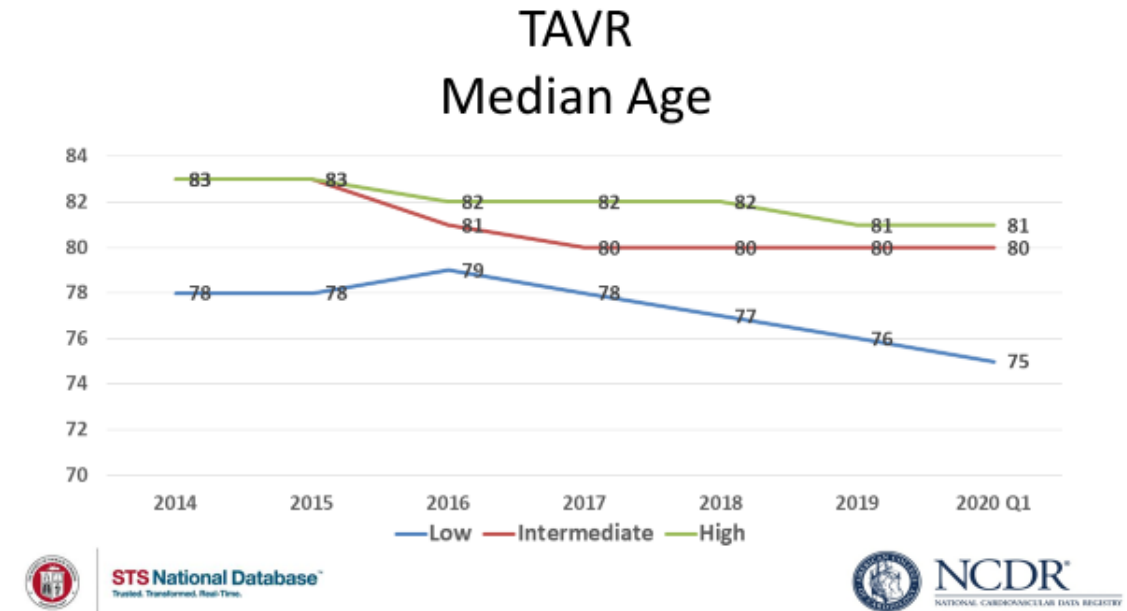
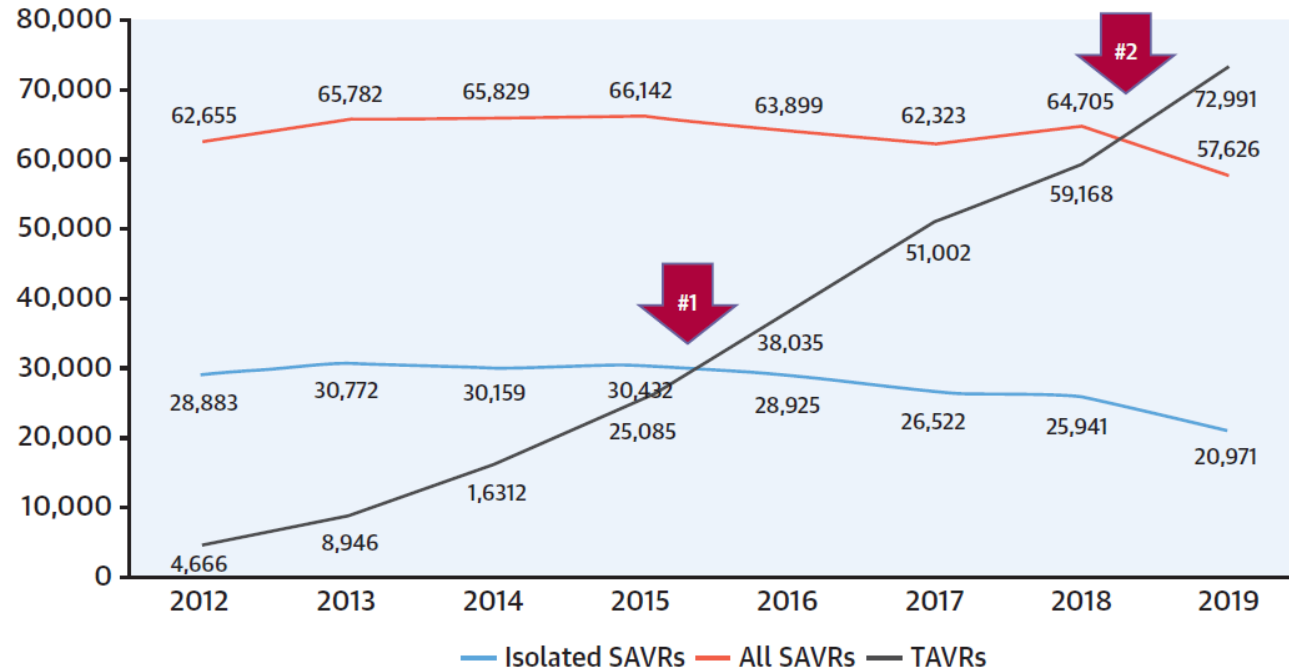


Kaneko et al. Ann Thor Surg 2015

All Bioprosthetic Valves Fail!



Growth of TAVR into Younger Patients

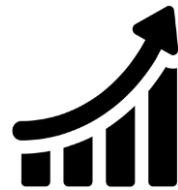


Carroll et al. JACC 2020

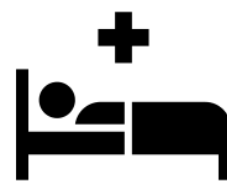
Outcomes of repeat SAVR

- Repeat SAVR is not an easy operation...

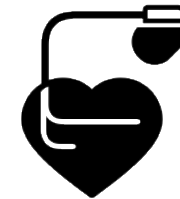
STS database from 2011 – 2013
Outcomes of Repeat SAVR
(Overall n = 3,380;
Previous bioprosthetic valve n = 2,213)



Mean STS PROM
5.4%



Operative Mortality
4.7%

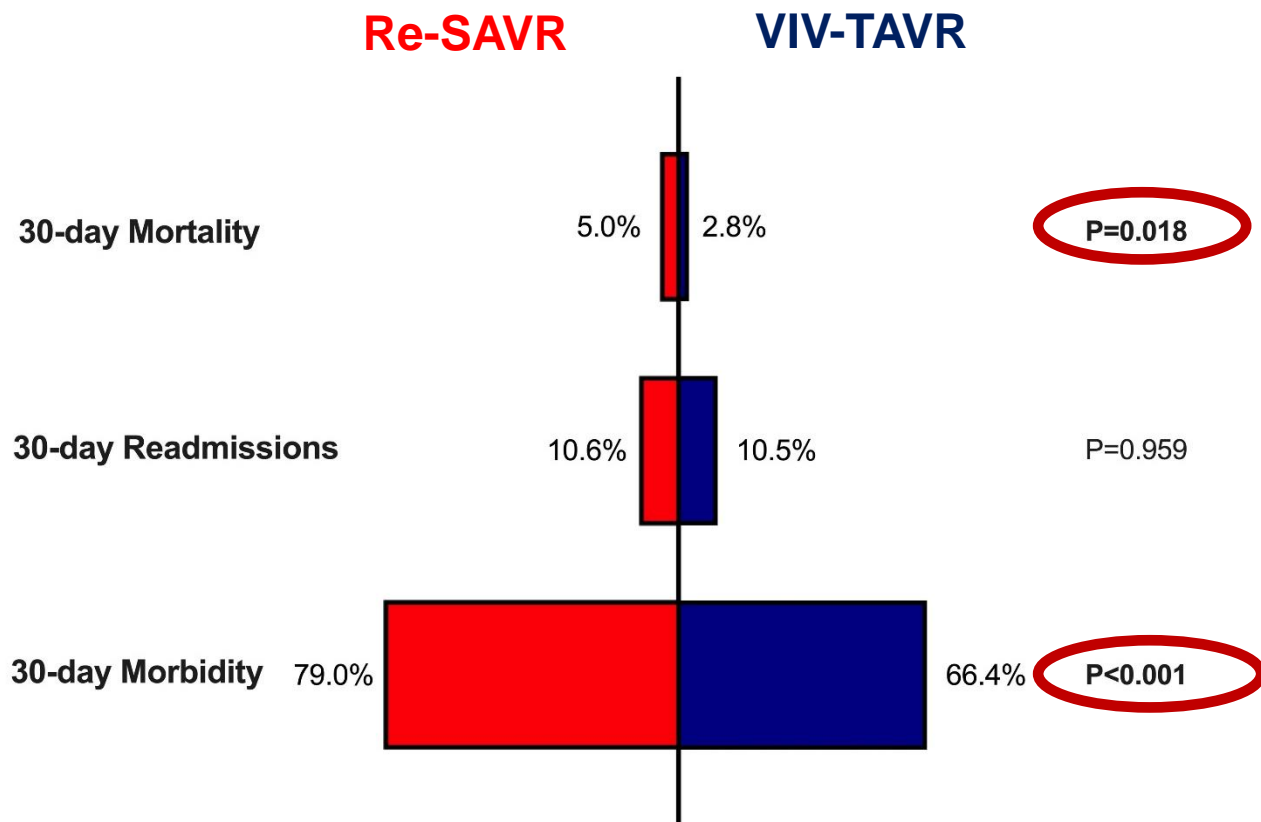


PPMI
11.5%

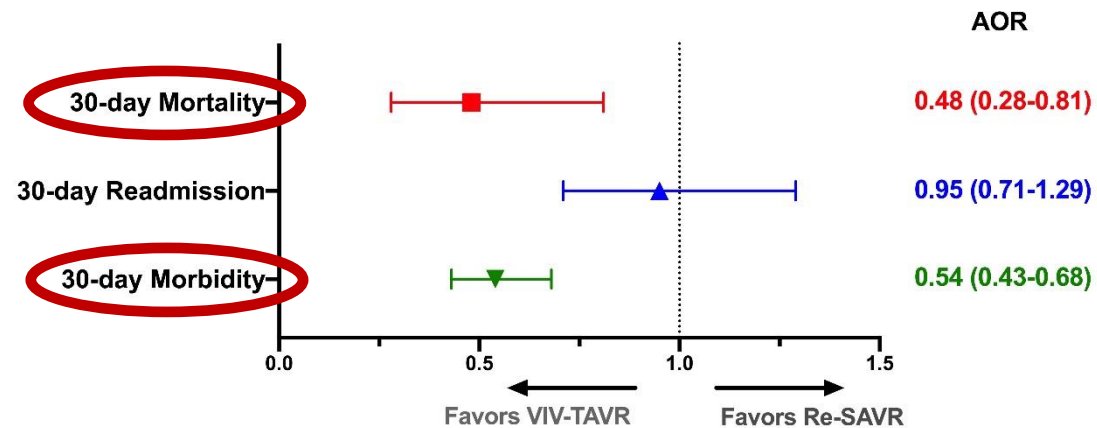
Kaneko et al. Ann Thor Surg 2015

Re-SAVR vs VIV-TAVR

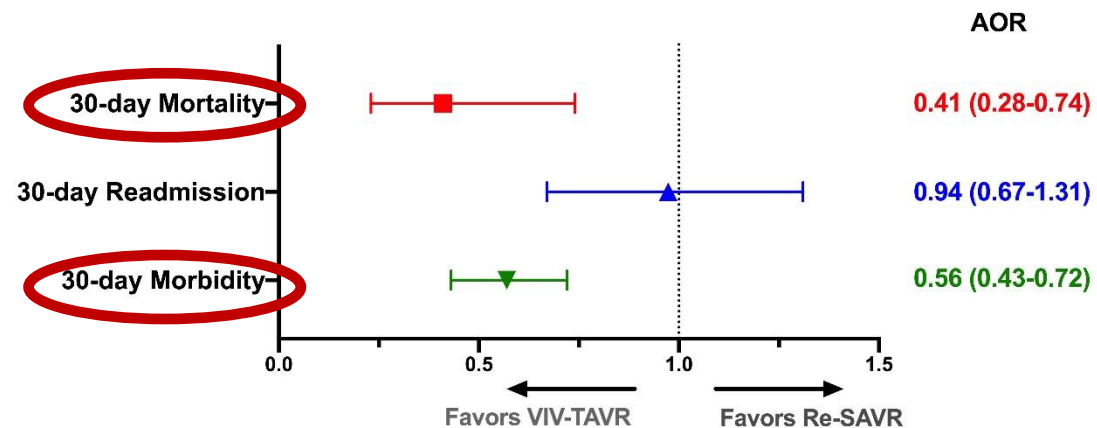
Unadjusted Analysis



Multivariable Regression



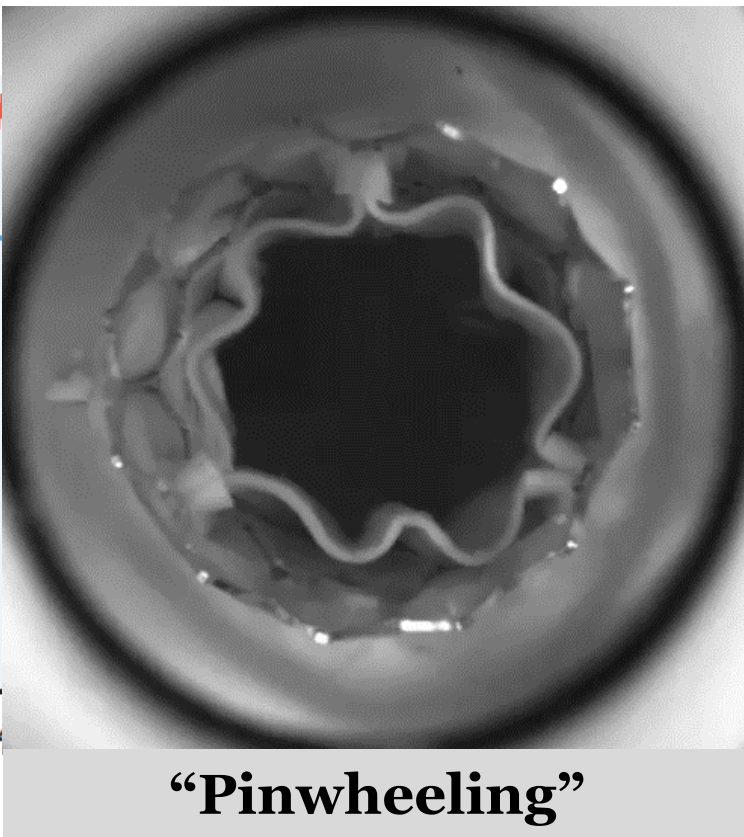
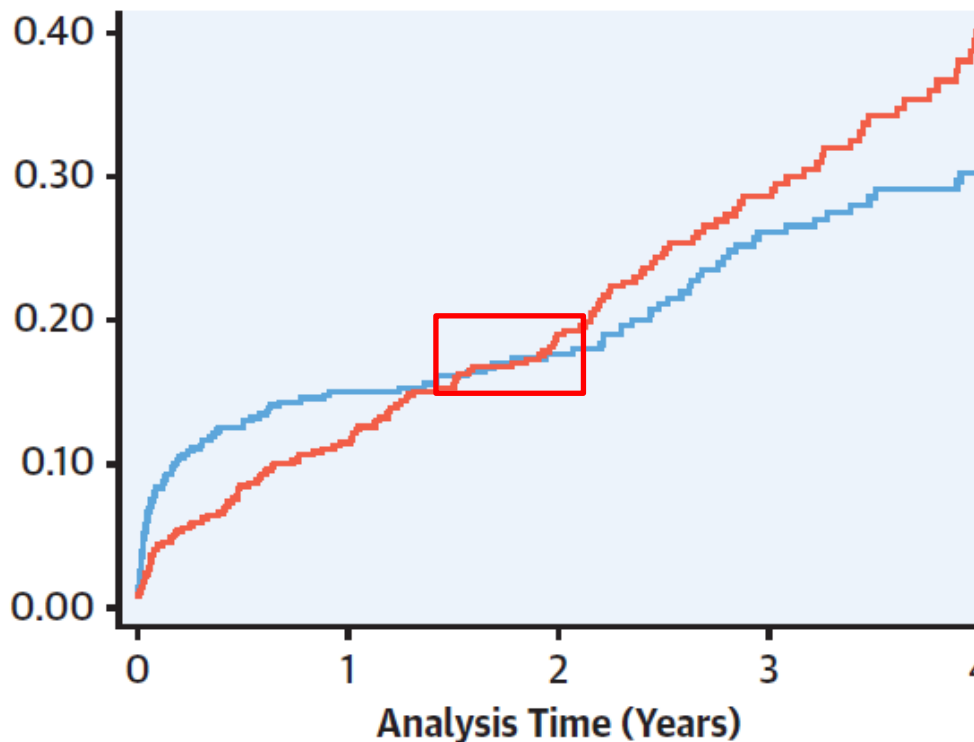
Propensity-score Matching



Hirji, Kaneko et al. EHJ 2020

Re-SAVR vs VIV-TAVR

A



Number at risk

— SAVR =	717	459	404	348	307	265	223	191	165
— TAVR =	717	527	466	410	349	282	220	174	135

Deharo et al. JACC 2020

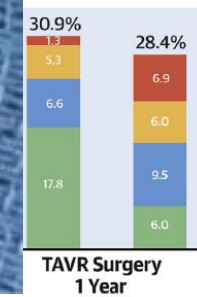
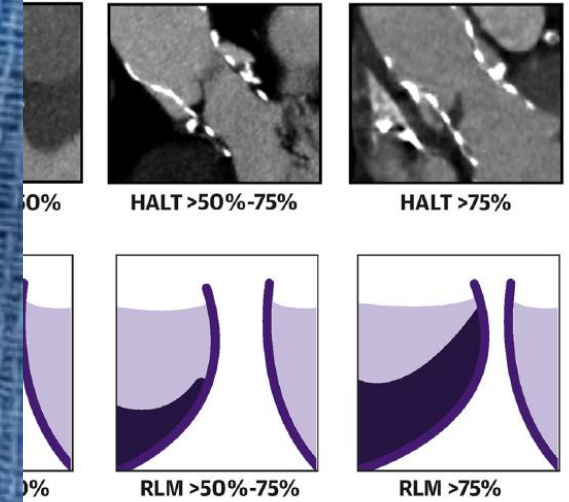
Leaflet Thrombosis

Both P3 & P4 result in high HALT rates



The Big Question: How to Minimize Leaflet Thrombosis?

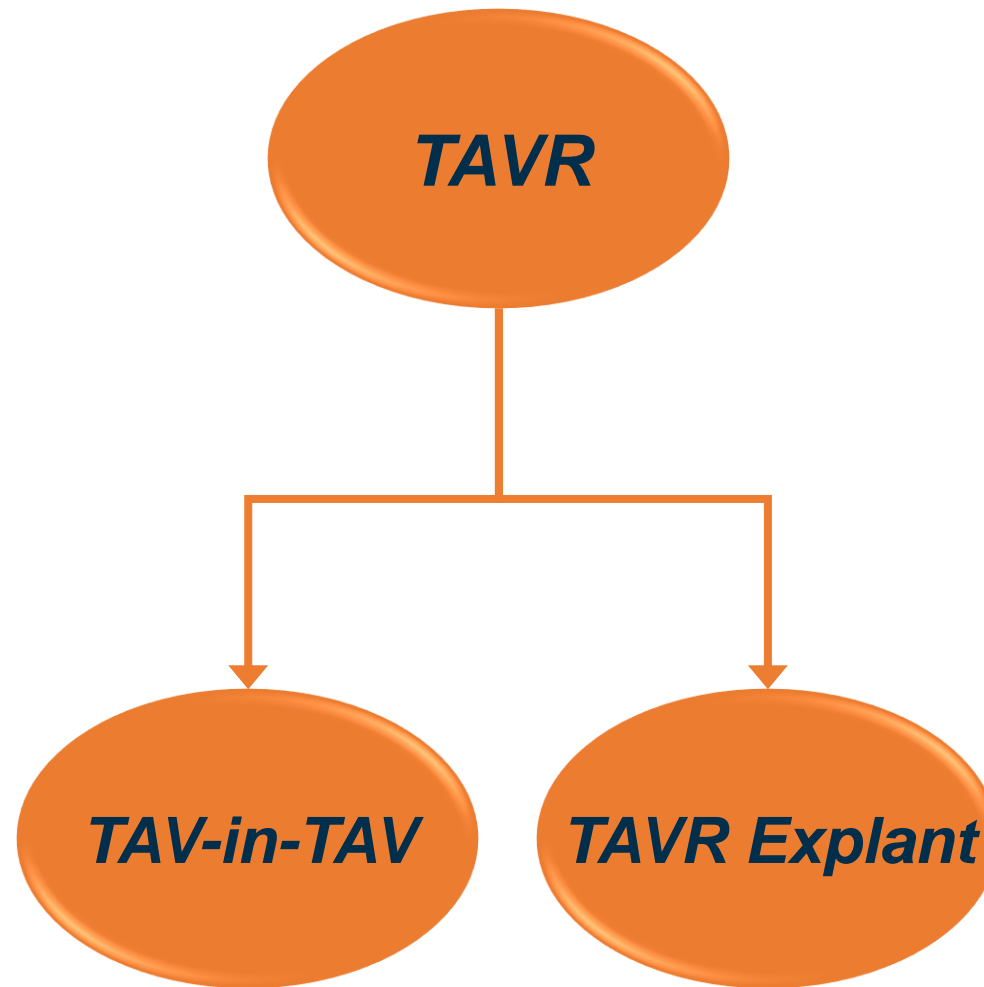
Makkar et al. JACC



Legend: ≤25% HALT, >25%-50%, >50%-75%, >75%

Blanke, P. et al. J Am Coll Cardiol. 2020;75(19):2430-42.

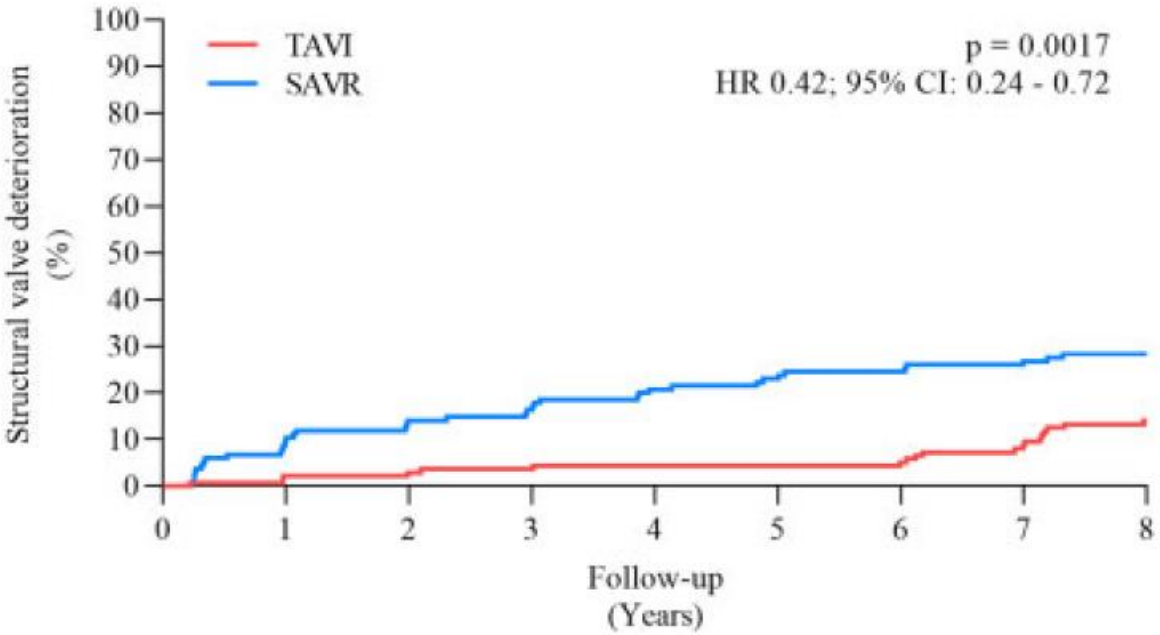
Failed TAVR (Structural Valve Deterioration)



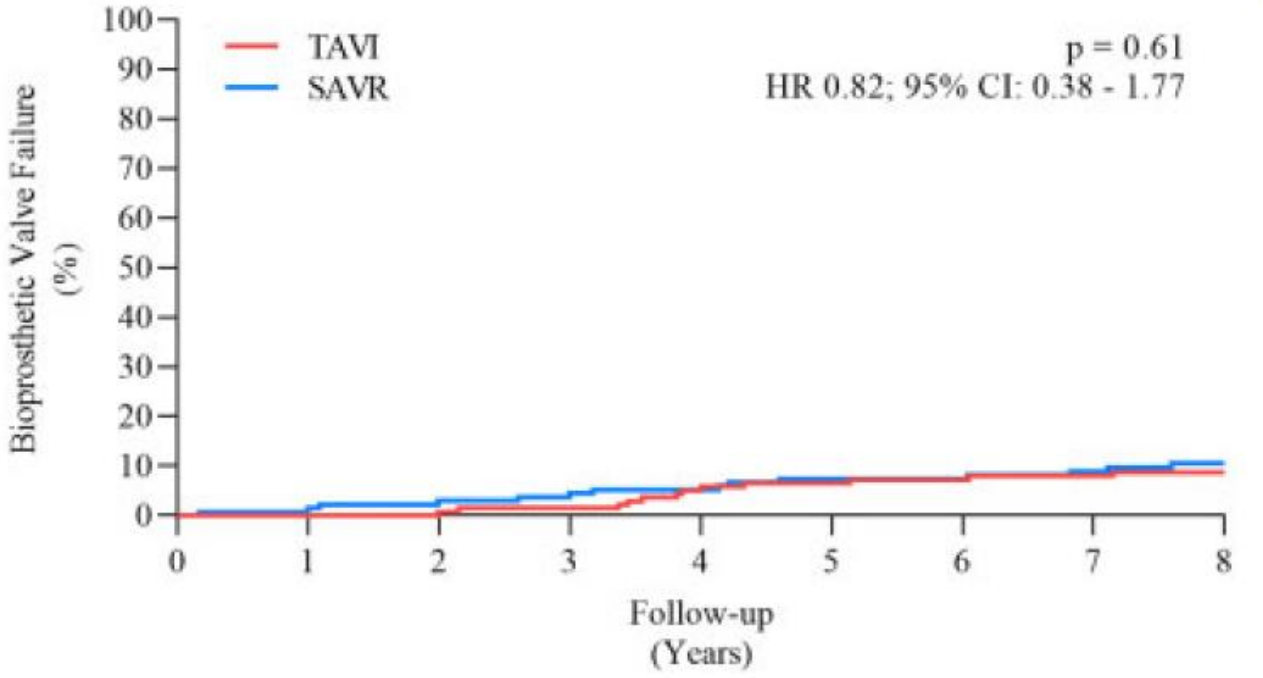
NOTION 8-year outcome

- SVD**
- 1) $MG \geq 20, \uparrow 10$
 - 2) Mod PPM
 - 3) BV Thrombosis
 - 4) Endocarditis

- BVF**
- 1) Valve related Death
 - 2) Hemodynamic severe SVD
 - 3) AV Reintervention



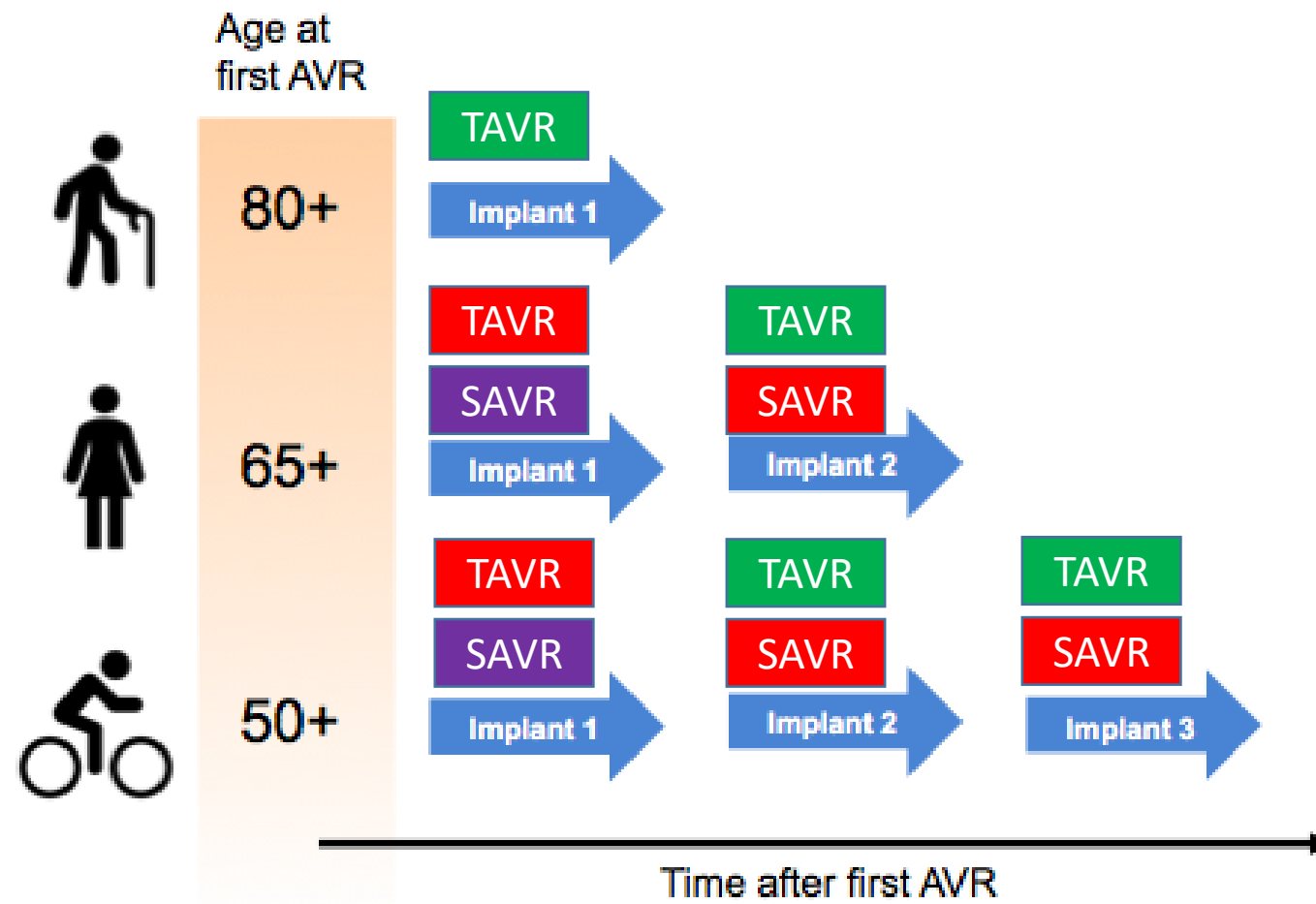
TAVI	145	130	126	115	107	94	80	68	50
SAVR	135	113	105	97	84	75	62	54	40



TAVI	145	133	128	118	109	96	82	73	60
SAVR	135	125	121	113	103	94	82	73	55

Jørgensen et al. EHJ 2021

Why is TAVI Explant so important?



Outcomes of Surgical Explantation of TAVR— A Population-Based, Nationally-Representative Analysis

Tsuyoshi Kaneko, Sameer A. Hirji, Edward D. Percy, Siobhan McGurk,
Alexandra Malarczyk, Morgan T. Harloff, Farhang Yazdchi, Ashraf A. Sabe,
Vinayak N. Bapat, Gilbert H. L. Tang, Deepak L. Bhatt, Vinod H. Thourani,
Martin B. Leon, Patrick O’Gara, Pinak B. Shah

Baseline Characteristics

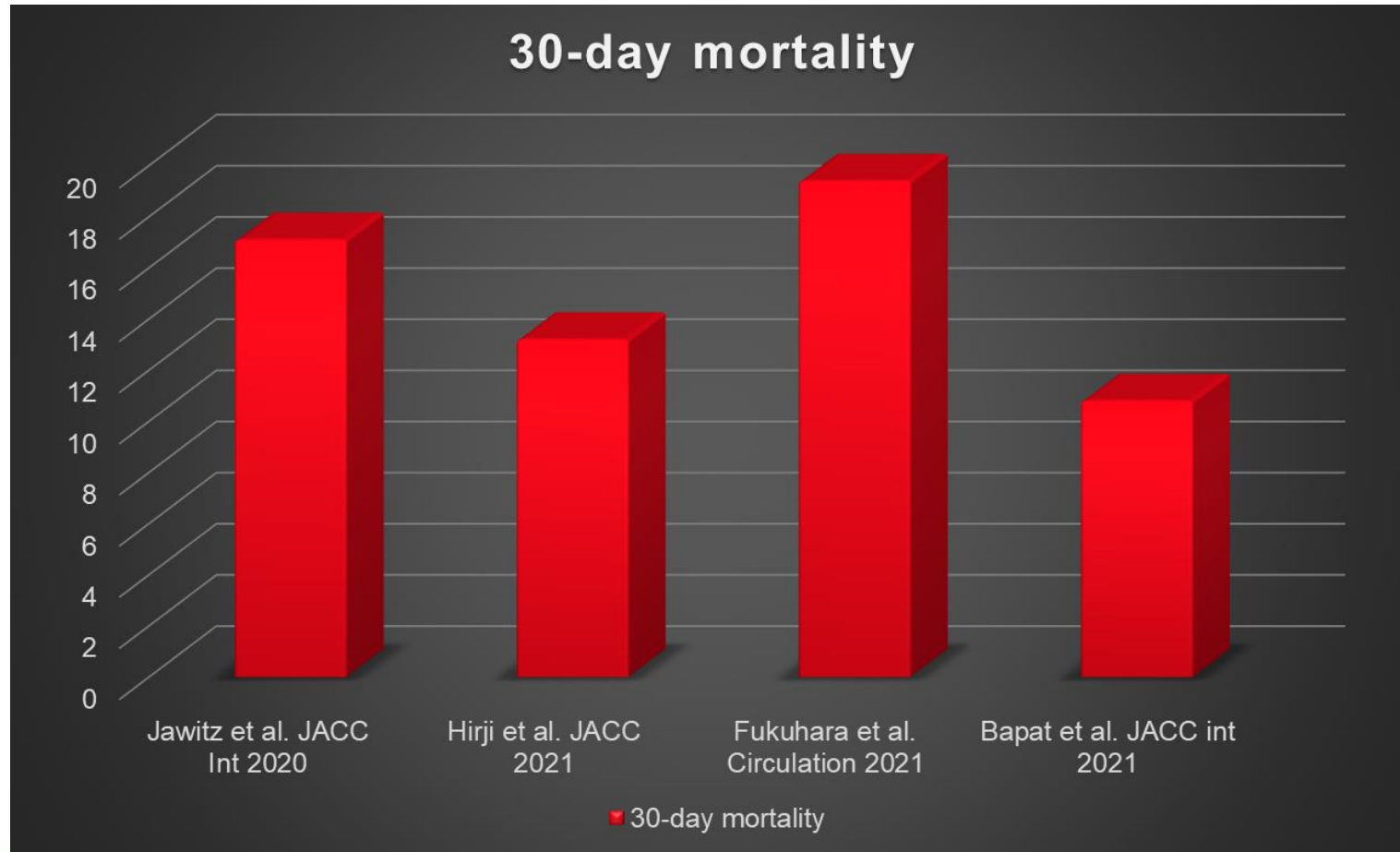
	<i>TAVR Requiring Surgical Explantation (N=227)</i>	<i>TAVR Not Requiring Explantation (N=132,288)</i>	<i>P-Value</i>		<i>TAVR Requiring Surgical Explantation (N=227)</i>	<i>TAVR Not Requiring Explantation (N=132,288)</i>	<i>P-Value</i>
Age, (mean, SD)	73.7 (8.9)	81.7 (8.1)	0.001	Atrial Fibrillation, (%)	52 (22.9)	35,627 (26.9)	0.137
≥85 yo, (%)	18 (7.9)	55,693 (42.1)	0.001	Ischemic Heart Disease, (%)	159 (70.0)	99,740 (75.4)	0.062
Women, (%)	80 (35.2)	62,181 (47.0)	0.001	Heart Failure, (%)	127 (55.9)	87,059 (65.8)	0.002
Dyslipidemia, (%)	156 (68.7)	91,153 (68.9)	0.947	Previous PCI, (%)	27 (11.9)	11,092 (8.4)	0.066
Hypertension, (%)	186 (81.9)	110,211 (83.3)	0.598	Previous CABG Surgery, (%)	55 (24.2)	27,650 (20.9)	0.220
Diabetes, (%)	118 (52.0)	58,806 (44.5)	0.023	Charlson Score, (Median, IQR)			0.001
PVD, (%)	29 (12.8)	17,897 (13.5)	0.837	Lower-Risk profile (<8)	34 (15.0)	3,149 (2.4)	
Stroke or TIA, (%)	14 (6.2)	10,998 (8.3)	0.332	Medium-Risk profile (8-12)	159 (70.0)	102,548 (77.5)	
Anemia, (%)	114 (50.2)	67,780 (51.2)	0.791	Higher-Risk profile (>12)	34 (15.0)	26,591 (20.1)	
COPD, (%)	69 (30.4)	34,323 (25.9)	0.128				
CKD, (%)	100 (44.1)	63,901 (48.3)	0.137				

Procedural and In-Hospital Outcomes

TAVR Requiring Surgical Explantation (N=227)			
PROCEDURAL OUTCOMES		IN-HOSPITAL COMPLICATIONS	
Time-to-surgical-explant, days (Median, IQR)	212 (69-398)	Bleeding Complications, (%)	127 (55.9)
<i>Type of Valve Placed</i>		Transfusion with blood products, (%)	82 (36.1)
Mechanical, (%)	47 (20.7)	Permanent Stroke, (%)	13 (5.7)
Bioprosthetic, (%)	180 (79.3)	Acute Kidney Injury, (%)	66 (29.1)
<i>Concomitant Procedures</i>		Complete Heart Block, (%)	26 (11.5)
Coronary artery bypass grafting, (%)	19 (8.4)	Length of Stay, days (Median, IQR)	11 (8-16)
Other valve procedures, (%)	10 (4.4)	Intensive Care Unit Stays, Days (Median, IQR)	5 (1-10)
<i>Etiology/Indication</i>		30-day Mortality, (%)	30 (13.2)
Endocarditis, (%)	47 (20.7)	90-day Mortality, (%)	40 (17.6)
Bioprosthetic valve failure, (%)	180 (79.3)	1-year Mortality, (%)	52 (22.9)

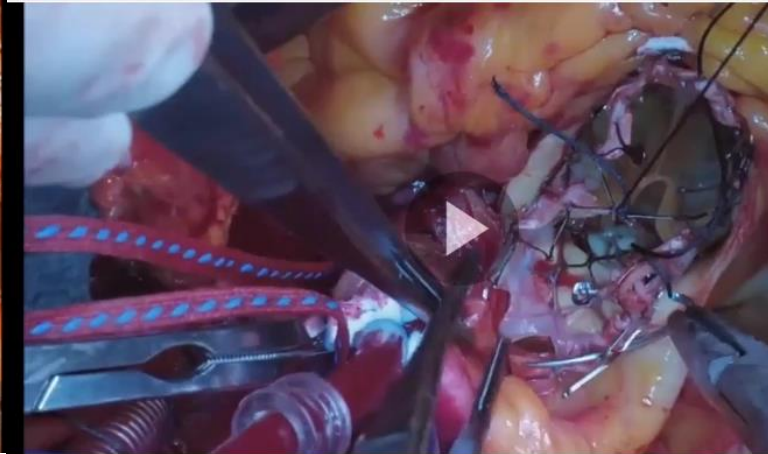
Concerns about TAVR Explant

- TAVR Explant has high mortality

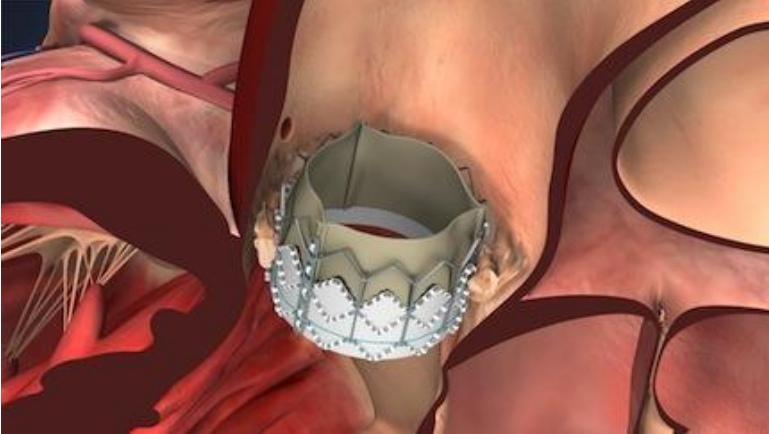


Concerns about TAVR Explant

TAVI Explant is Technically Challenging



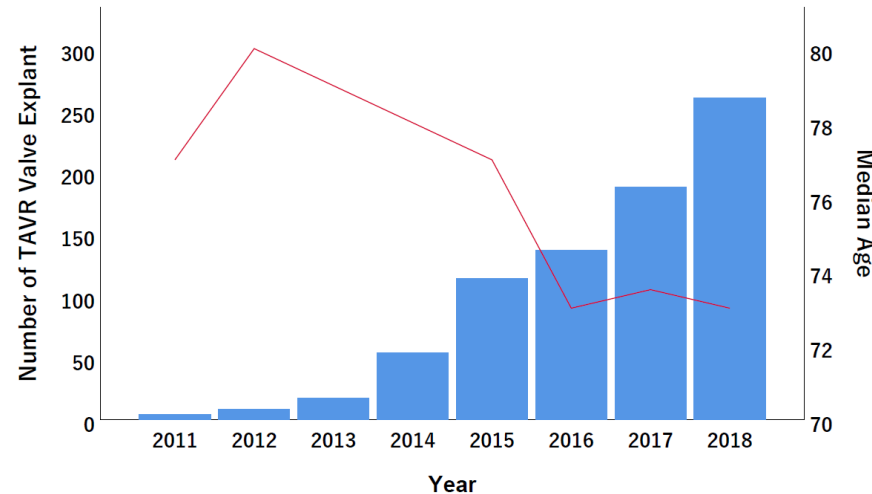
Courtesy of Michael Chu MD



1. Dissection of the Stent Frames from the Aorta
2. Deforming the Frames
3. Getting into the plane between the native valve and TAVR
4. Operating before other valvular disease develop

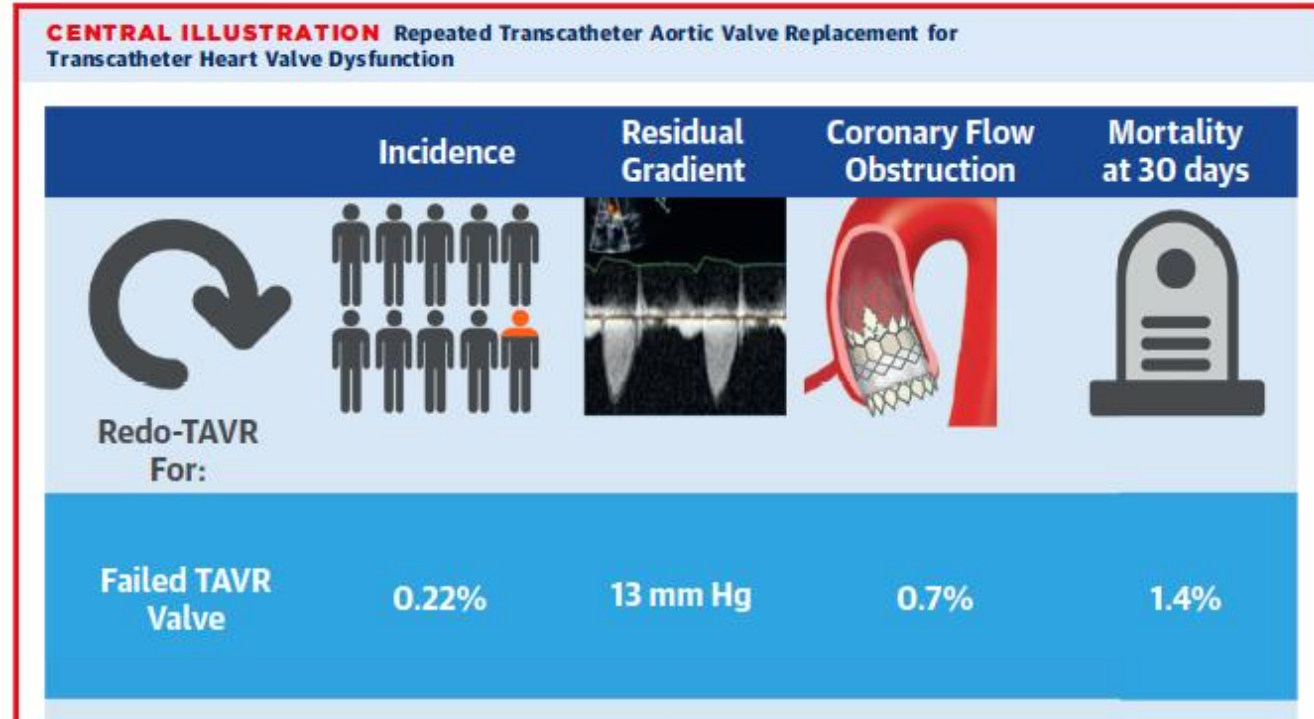
Concerns about TAVR Explant

TAVI Explant is done in only small number of surgeons



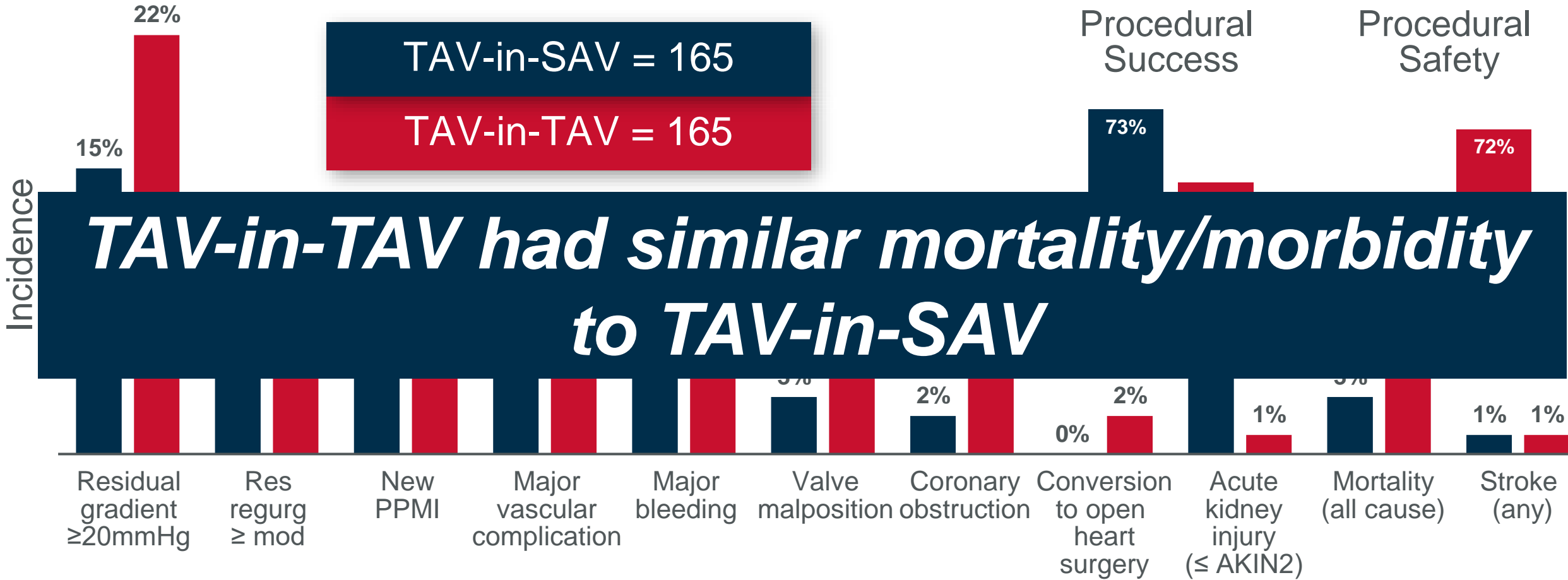
Performed by 483 surgeons (median 1.0 case per surgeon [IQR 1.0–2.0]) from 313 centers (median 1.0 case per center [IQR 1.0–3.0]).

Repeat TAVR

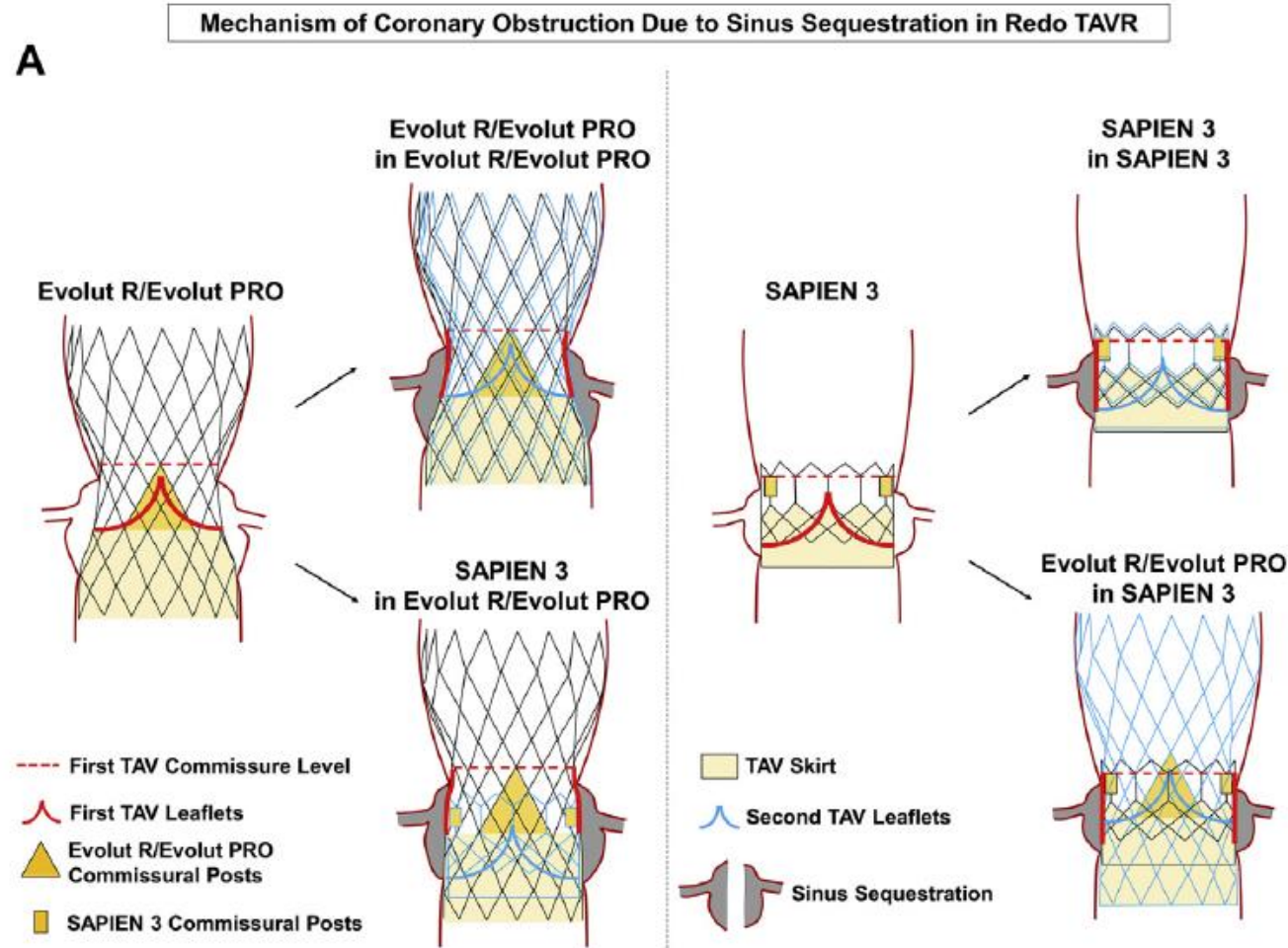


Landes et al. JACC 2020

Higher Procedural Success in TAV-in-TAV



Issue with TAV-in-TAV: Sinus Sequestration



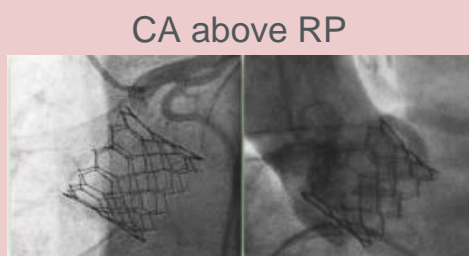
Ochiai et al. JACC int 2020

SAPIEN 3/ULTRA
N = 72

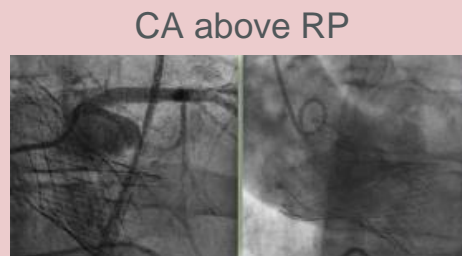
EVOLUT R/PRO
N = 26

ACURATE NEO
N = 39

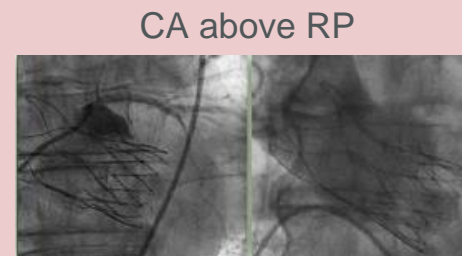
TAV-in-TAV
feasible
(40.9%)



68.1%



19.2%

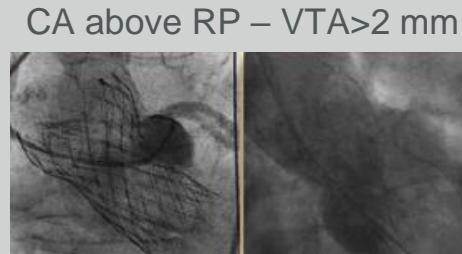


5.1%

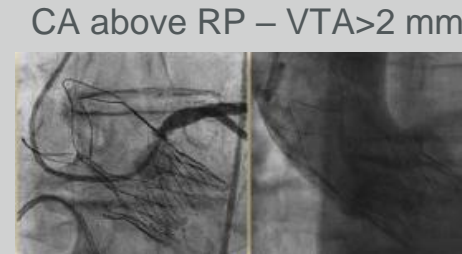
TAV-in-TAV
theoretically
feasible
(27.7%)



8.3%

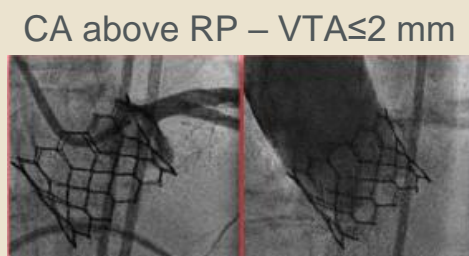


42.3%

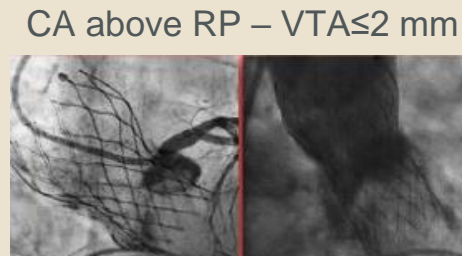


53.8%

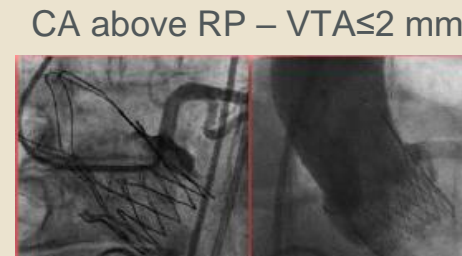
TAV-in-TAV
unfeasible
(31.4%)



23.6%



38.5%



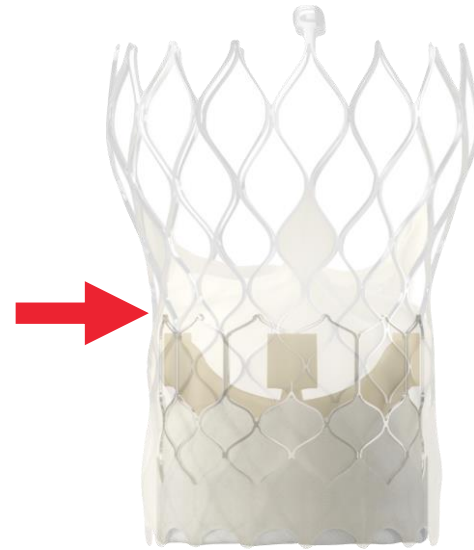
41.1%

Fovino LN, et al. J Am Heart Assoc. 2020

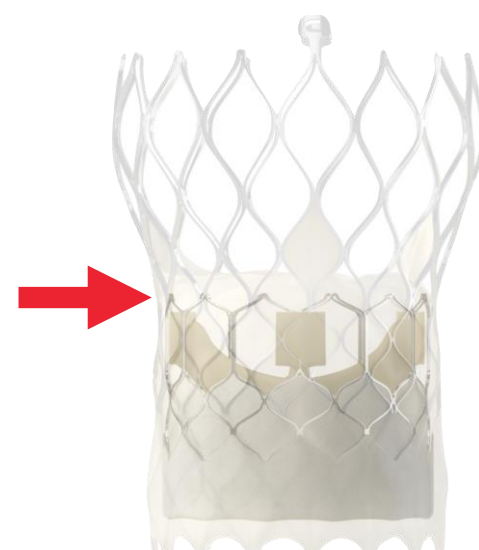
Leaflet overhang



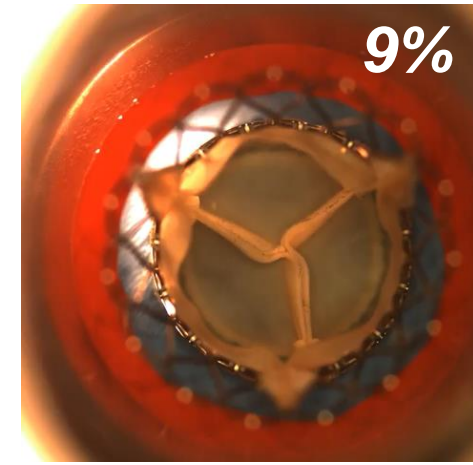
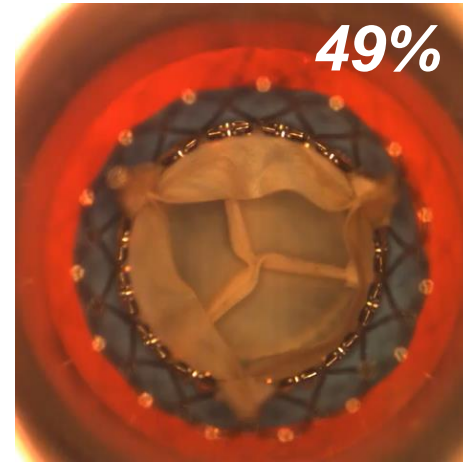
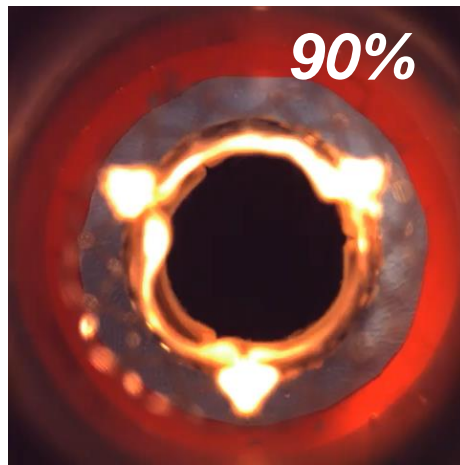
S3 Outflow at Node 4



S3 Outflow at Node 5



S3 Outflow at Node 6

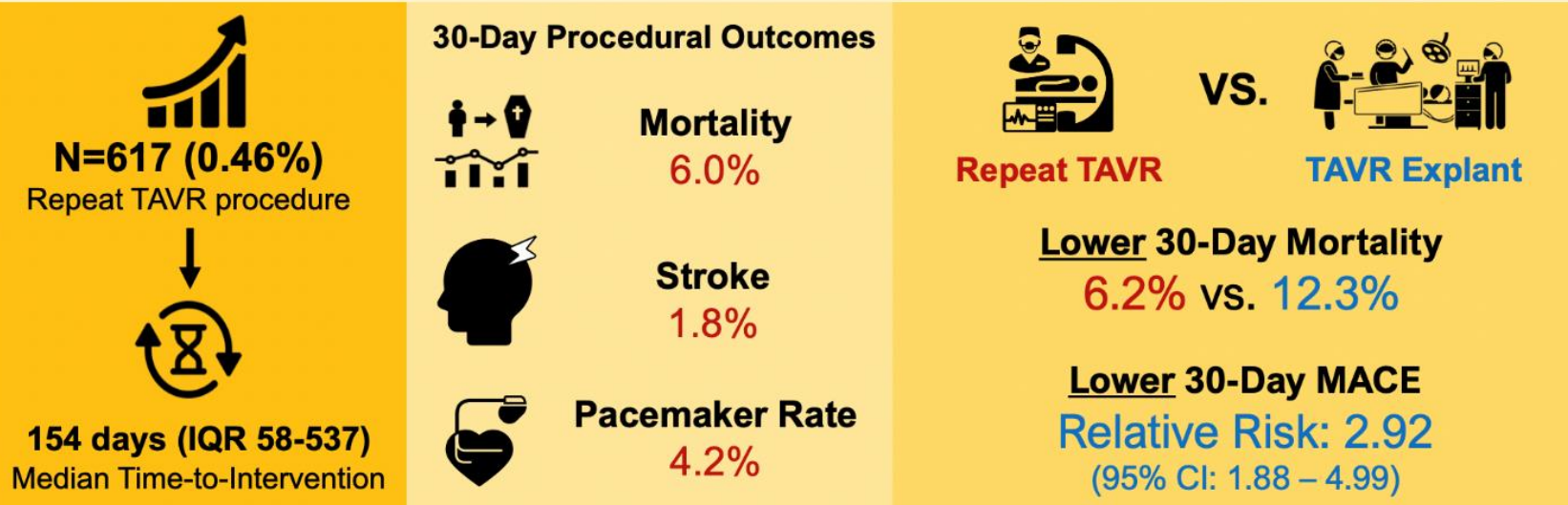


△ Leaflet overhang: 81%

TAV-in-TAV vs TAVR Explant-CMS

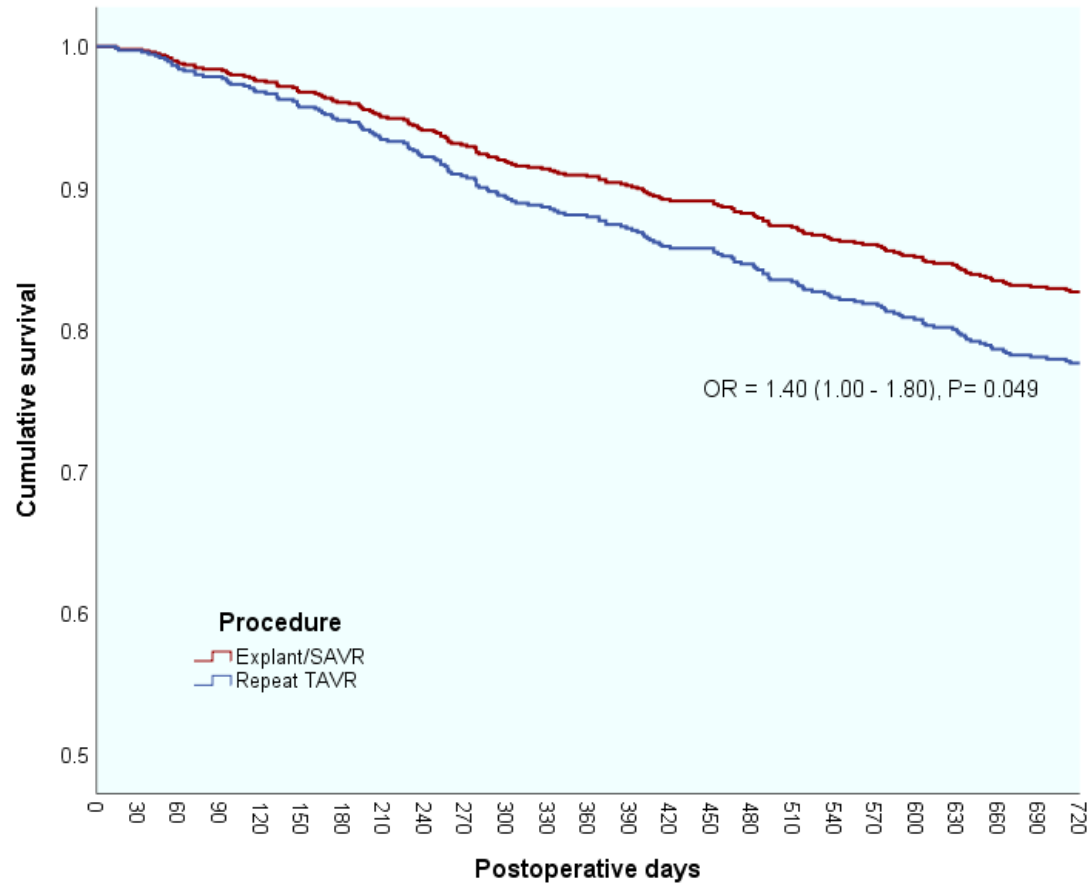
Contemporary Repeat Transcatheter Aortic Valve Replacement Outcomes in the United States

 Fee-For-Service Medicare Beneficiaries  Nationally Representative, Multicenter Analysis  N= 133,250 patients  2012 - 2017

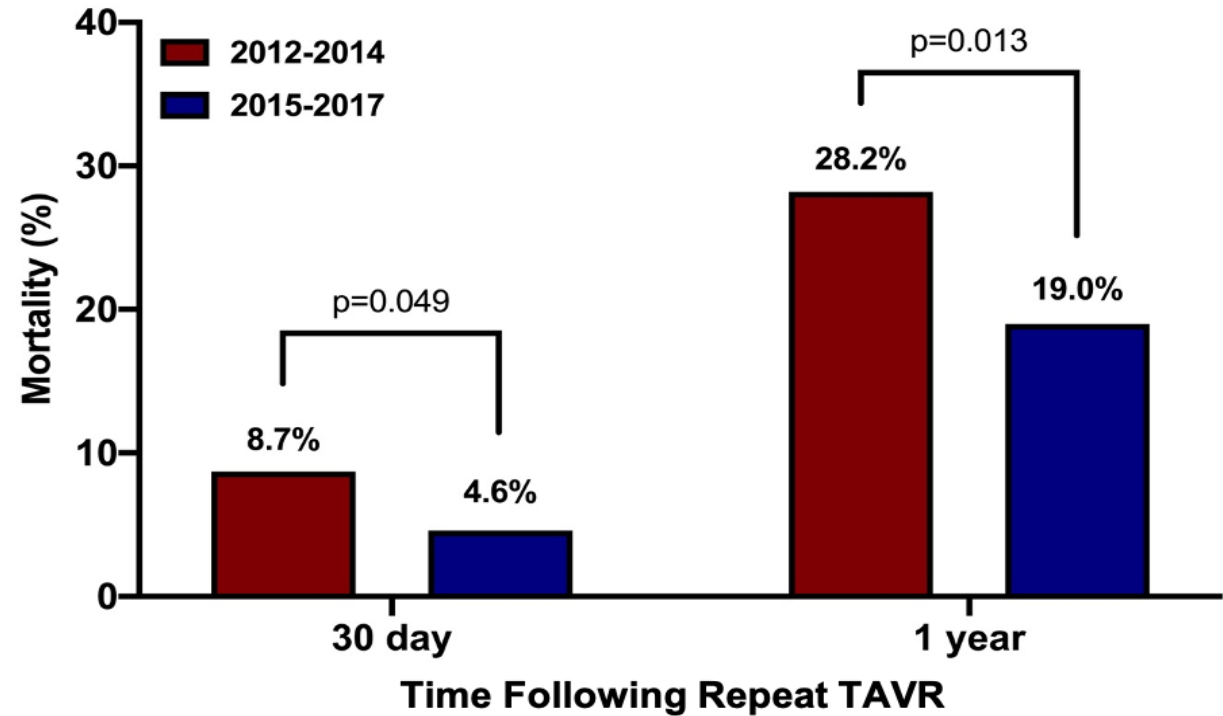


Repeat TAVR can be performed with **acceptable 30-day mortality** and may be considered as a potential option in appropriate patients

TAV-in-TAV vs TAVR Explant-CMS



Cox Proportional Hazard Model

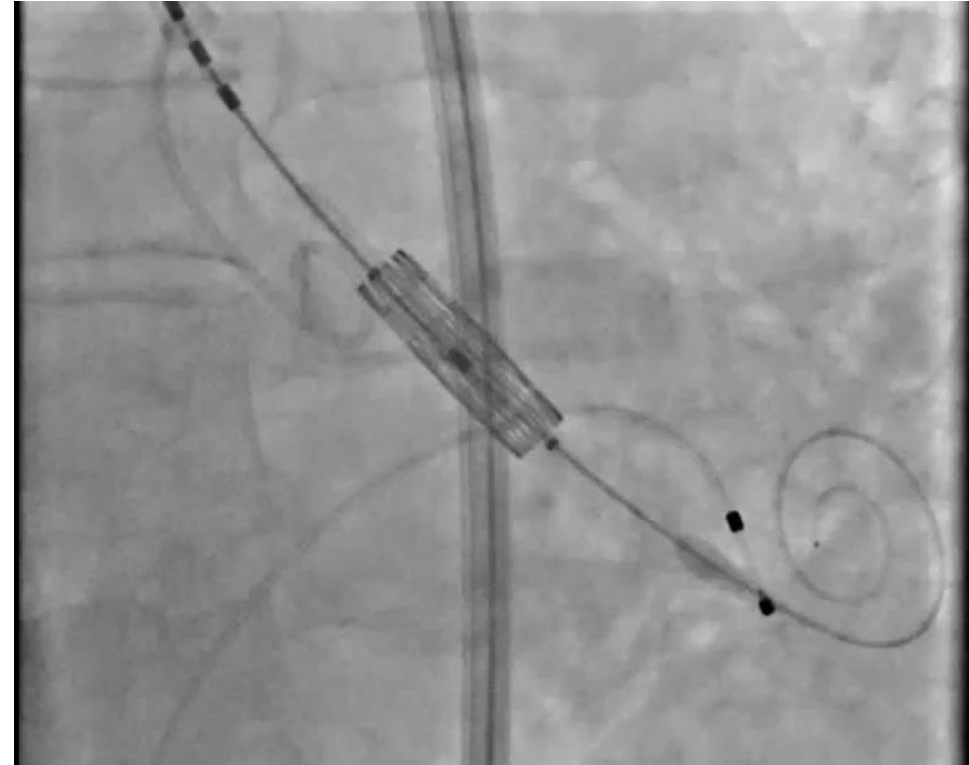


Percy et al. JACC int. 2021.

Do we need to change how we implant index TAVR?

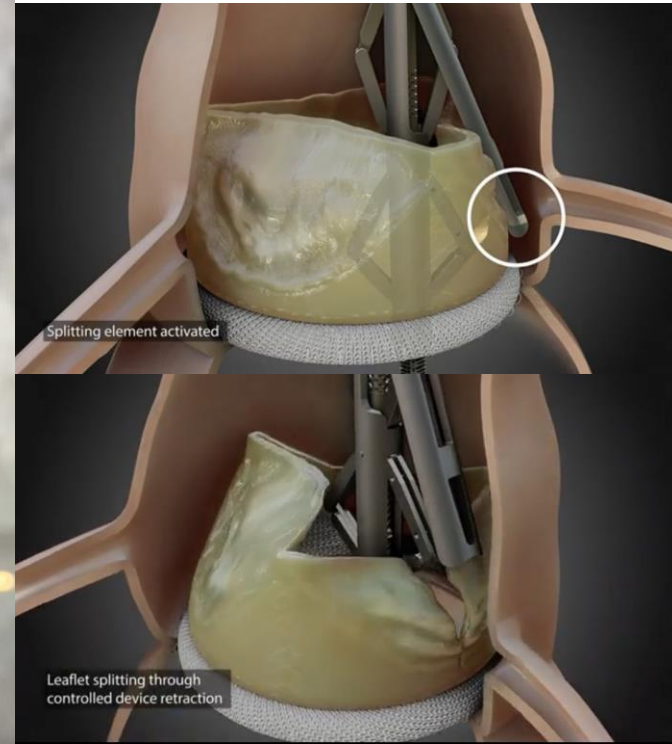
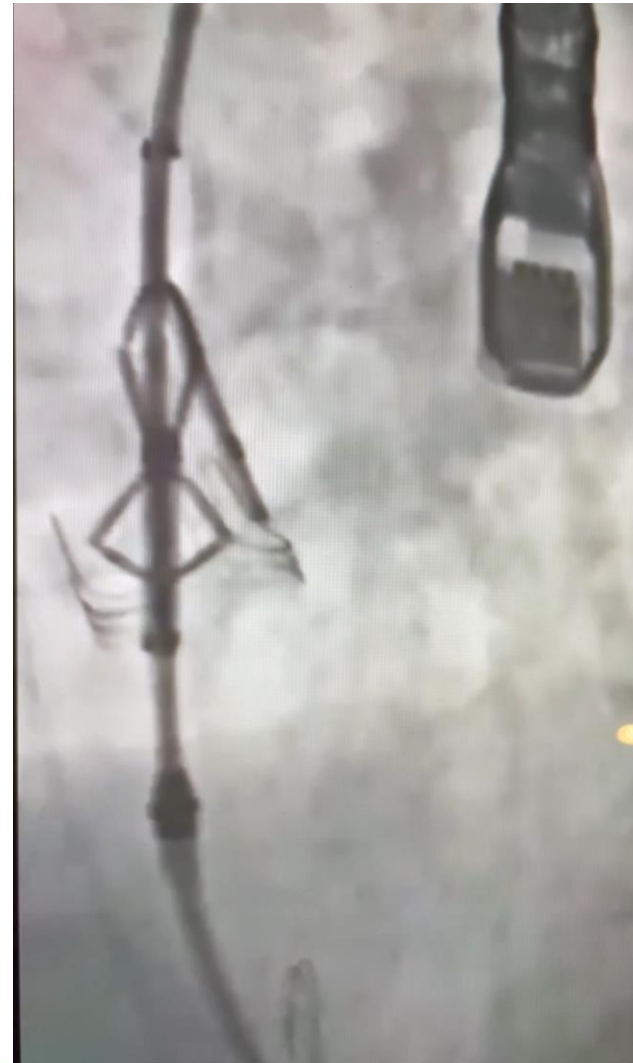
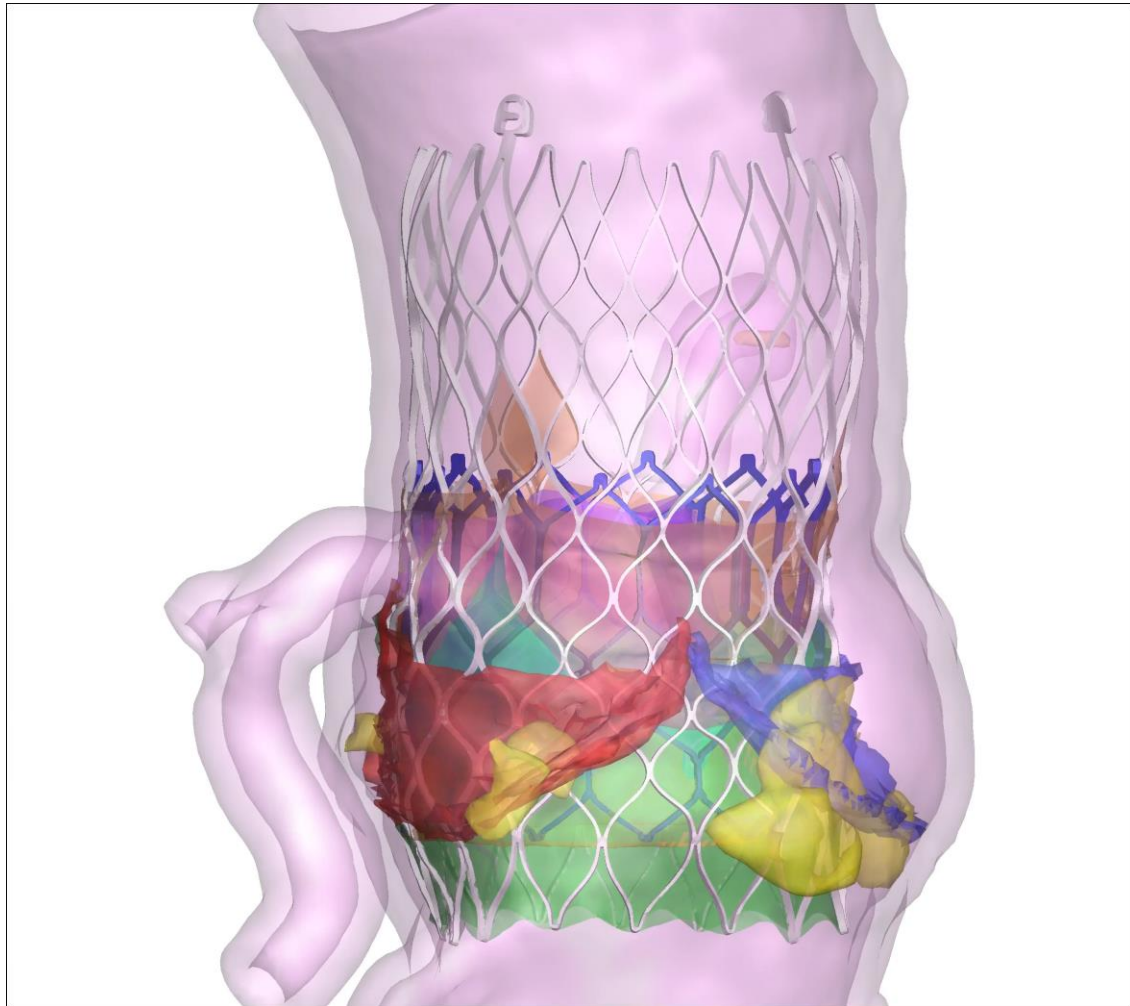


91yo F – High-risk



66yo F – Low-risk

Simulation at Index TAVR & Easier Leaflet modification



Provided by Dasi Simulations