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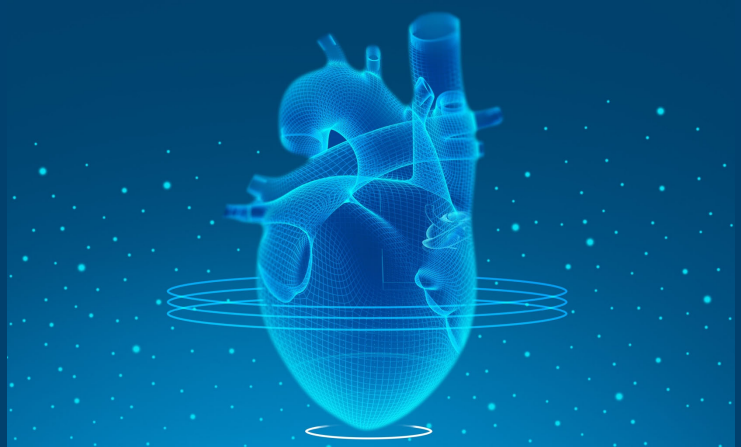
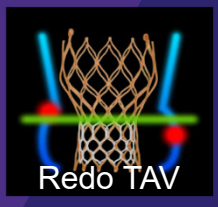
GRAND ROUNDS



1

Redo-TAV therapy: Rationale, Feasibility, and Optimization

Miho Fukui, MD, PhD



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What is Redo-TAV, transcatheter aortic valve, (TAV-in-TAV) therapy?

- All TAVR devices are bioprosthetic valves
- All bioprosthetic valves degenerate
- When degenerated, re-intervention is required
- Redo-TAVR: Implant new device in old device

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Rationale:

Why is this topic important to discuss?

Minneapolis Heart Institute | Allina Health Abbott Northwestern Hospital

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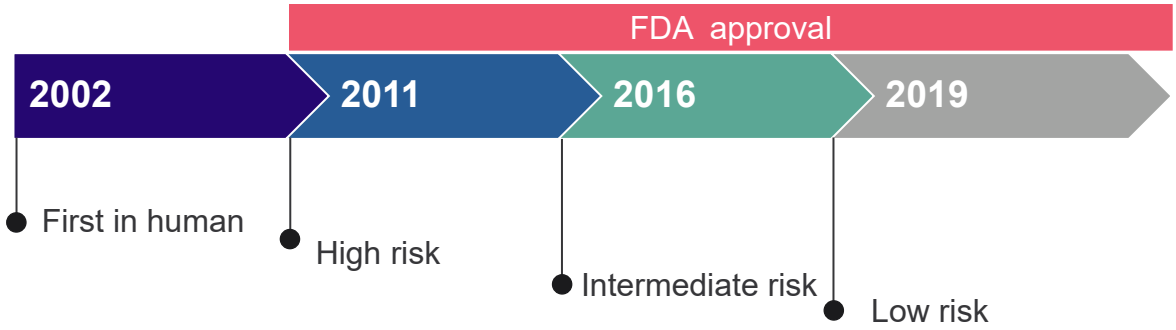
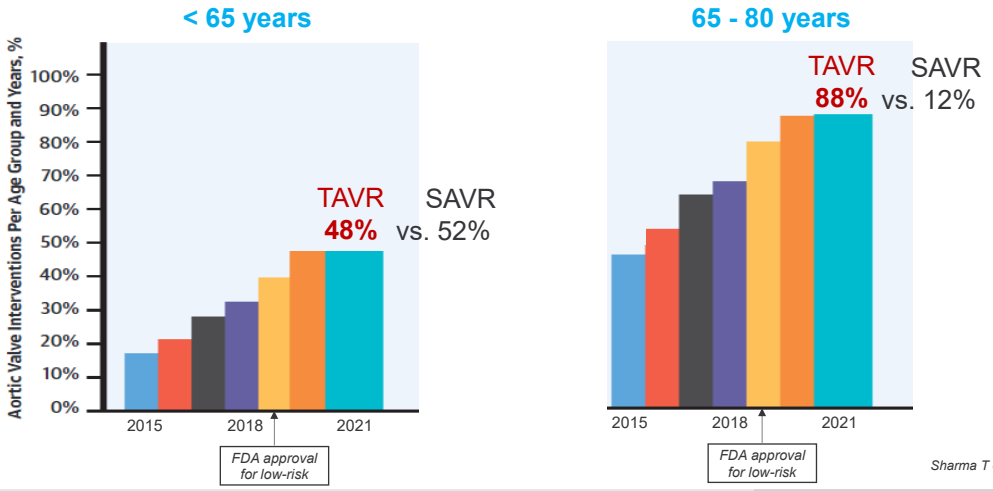
Journey of TAVR



5

TAVR is expanding to patients with longer life expectancy

The Vizient Clinical Data Base 2015-2021 (N = 279,066)

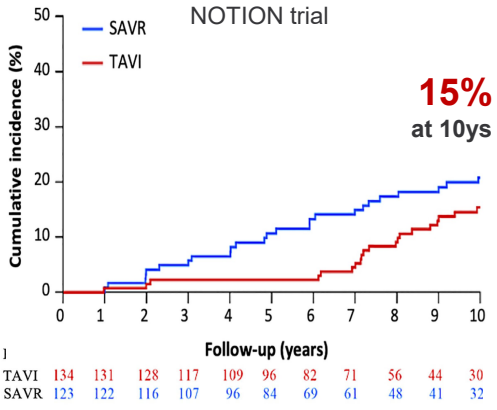


Sharma T et al, JACC 2022;80:2054

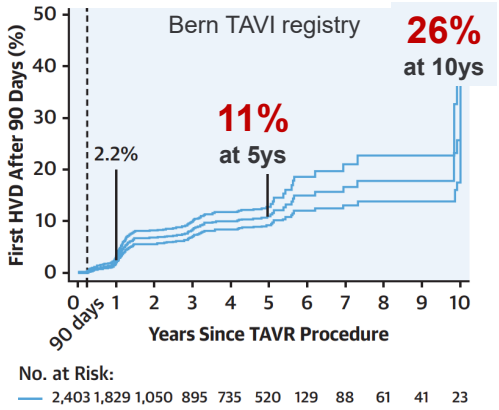
6

Bioprosthetic valve degenerates 5-10 years after implantation

Cumulative incidence of ≥ moderate structure valve deterioration



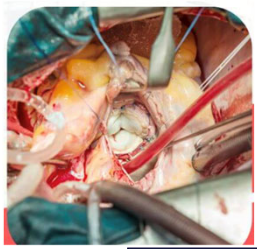
Thyregod et al, EHJ 2024;45:1116



Alaour B et al, JACC CV Interv 2025;18:72

7

Surgery or Re-Transcatheter therapy after TAV failure



TAV failure

TAV explant + SAVR

or

Redo-TAV (TAV-in-TAV)

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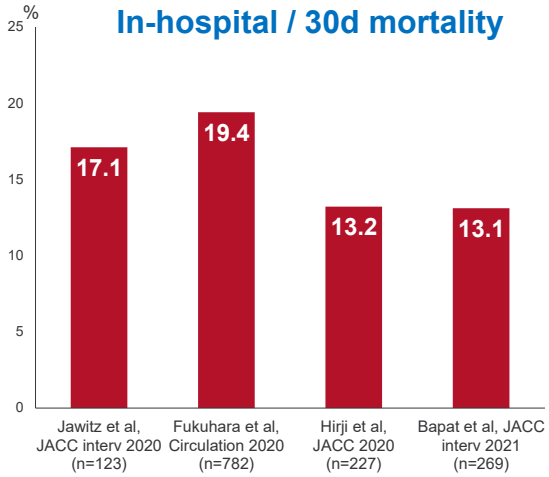
TAV explant + SAVR had higher mortality due to…



- Higher mortality reflects:
  - Early experience from 2015-2020
  - Urgent indications
  - Endocarditis
  - Higher STS/Euroscore at explant
  -
- No difference between:
  - BEV & SEV
  - AVR & Root replacement

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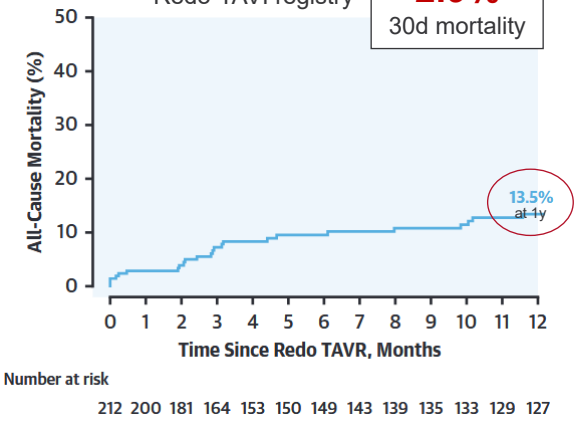
Lower mortality with Redo-TAV when Redo-TAV is feasible

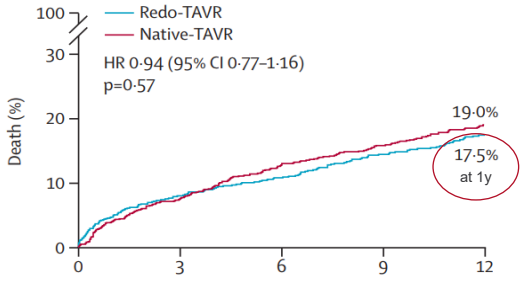
Redo-TAVI registry **2.9%** 30d mortality



Number at risk
212 200 181 164 153 150 149 143 139 135 133 129 127

Landes et al, JACC 2022;15:1543

STS/ACC TVT Registry **4.7%** 30d mortality



Number at risk

Redo-TAVR	1320	782	726	674	537
Native-TAVR	1320	895	820	770	631
(Propensity-matched pairs)					

Makkar et al, Lancet 2023;402:1529

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Redo-TAV has lower 30d but similar 1y mortality to TAV explant

Report From Centers for Medicare and Medicaid Services 2012-2017
N=133,250

	TAV explant + SAVR		Redo-TAV
Matched analysis			
30-day Mortality	**12%**	vs.	**6%**
30-day MACE	**66%**	vs.	**40%**
1-year Mortality	**21%**	vs.	**21%**

Percy et al, JACC Interv 2021;14:1717

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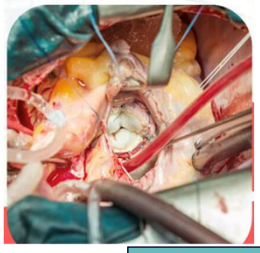
Which would you choose?



TAV failure

TAV explant + SAVR

or

Redo-TAV (TAV-in-TAV)

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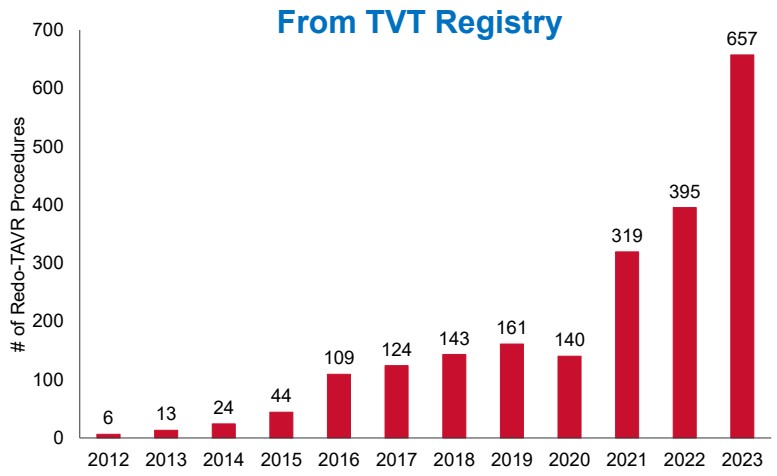
Number of Redo-TAV case has increased



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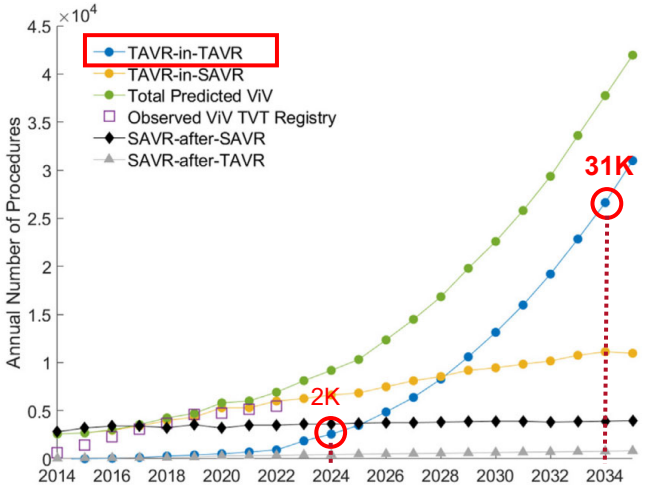
Need for Redo-TAV will be increasing



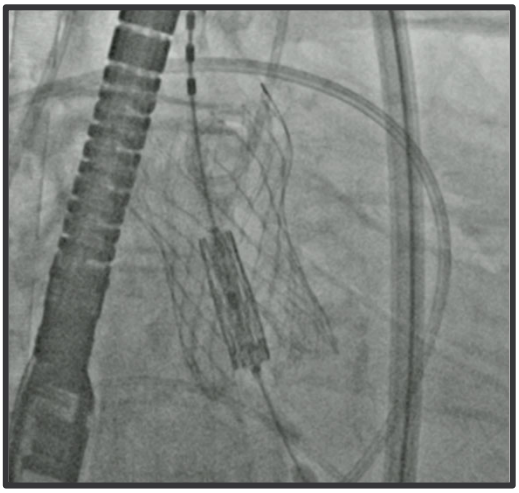
Genereux et al, Structural Heart 2024

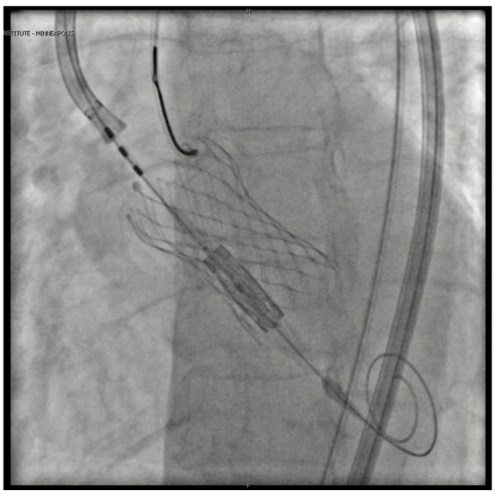
14

BIG WAVE of Redo-TAV is coming

15

Appeared simple! But is it?





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Similar with TAV-in-SAV?

TAV-in-SAV

- **Valve dimensions maintained**
- **Valves are implanted at annulus**
- **Valves have similar heights**

Sizing
Implant position
Coronary Risk

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TAV in TAV is Not as simple as TAV in SAV

TAV in SAV

- Valve dimensions maintained
- Valves are implanted at annulus
- Valves have similar heights

Sizing
Implant position
Coronary Risk

TAV in TAV

- **In-vivo shape and size varies**
- **Depth of implant varies**
- **Valves have different structures**

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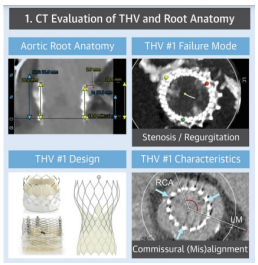
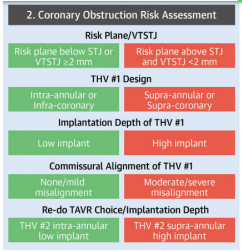
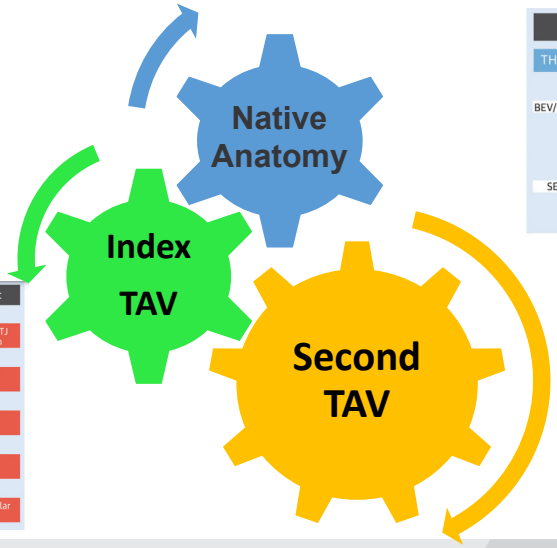
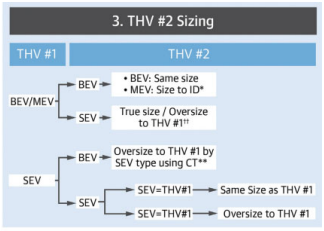
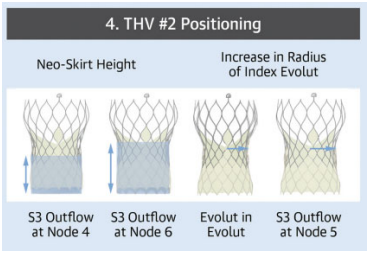
Need to consider native anatomy, index TAV and second TAV











Tarantini et al, JACC interv 2022

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Feasibility:

Can we perform Redo-TAV therapy for our patients safely?

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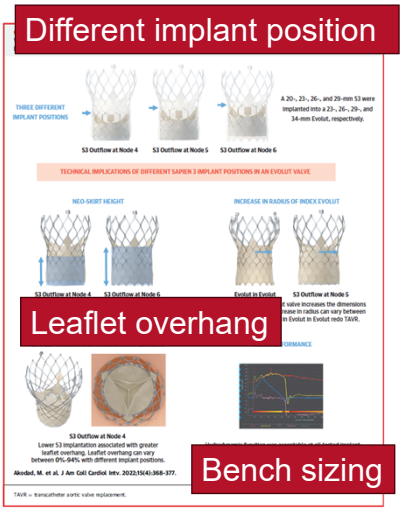
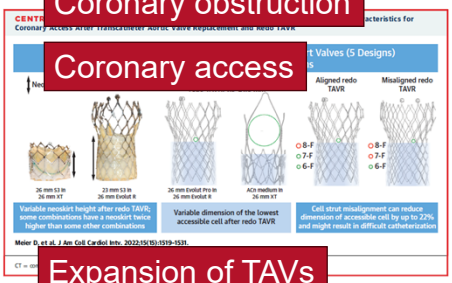
Many considerations to take into account…

Different implant position

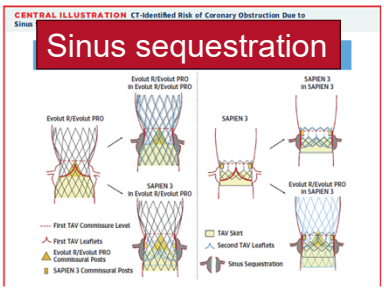


Coronary obstruction

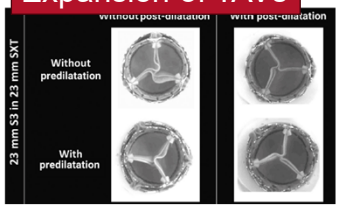
Coronary access



Sinus sequestration



Expansion of TAVs



Leaflet overhang

Bench sizing

Pinwheeling

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I know the problems,

rather than discuss them,

Let's find out solutions!!!

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Key considerations for Redo-TAV feasibility

1) **2nd TAV compatibility**
2) **Implant Position**
3) **2nd TAV sizing**
4) **Coronary Risk**

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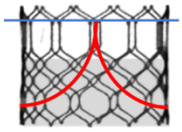
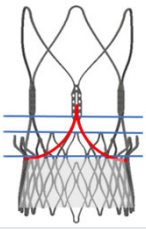
Landmarks on TAV devices

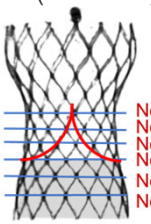
Sapien 3 (Edwards Lifescience)



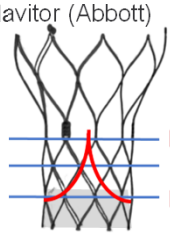
ACURATE neo2 (Boston Scientific)



Evolut (Medtronic)



Navitor (Abbott)



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1) TAV compatibility: Four combinations

Index TAV: Short | **Index TAV: Tall**

*Index TAV = first implanted TAV
Second TAV = new TAV inside index TAV

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1) TAV compatibility: Four combinations

Short in Short | **Tall in Short** | **Tall in Tall** | **Short in Tall**

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2) Implant position: Neoskirt and Neoskirt Plane (NSP)

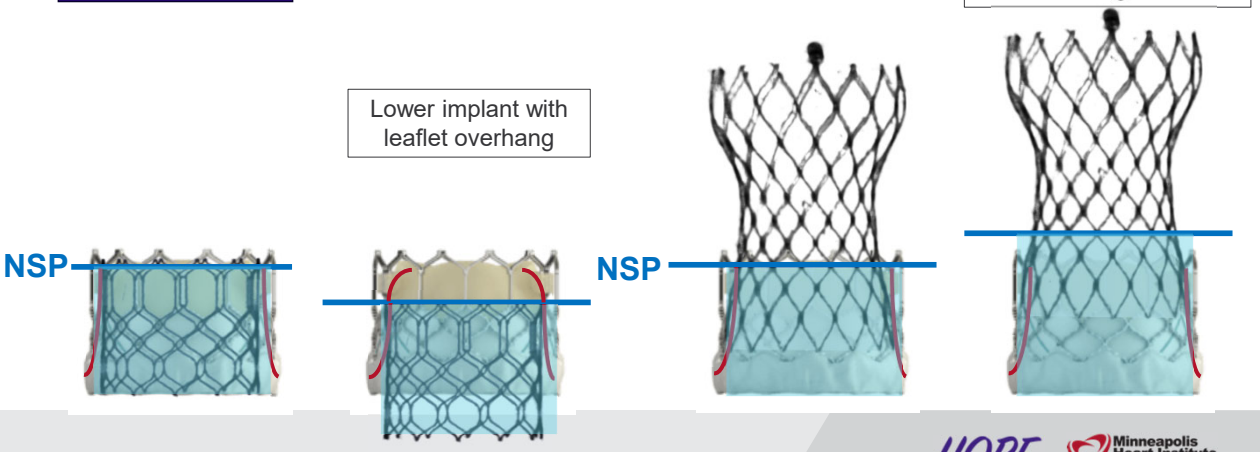
Combination of : Index TAV **Pinned** leaflets + Inner Skirt of Second TAV

Short in Short

Lower implant with leaflet overhang

Tall in Short

Higher implant than node 3 results in higher NSP



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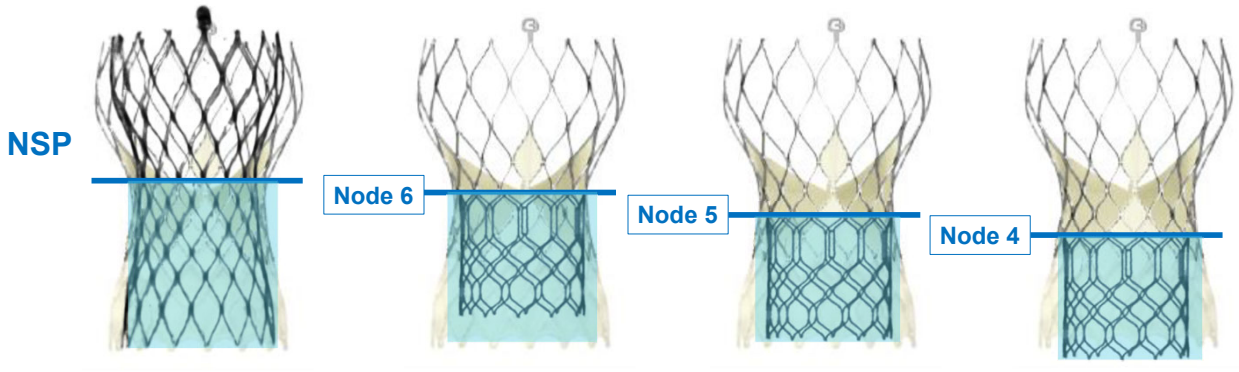
2) Implant position: Neoskirt and Neoskirt Plane (NSP)

Tall in Tall

Short in Tall

NSP level can be adjusted



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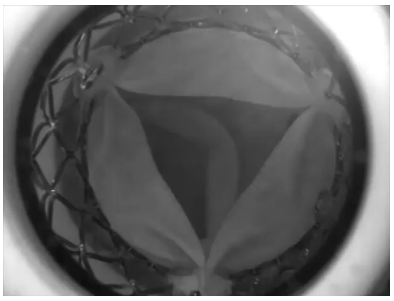
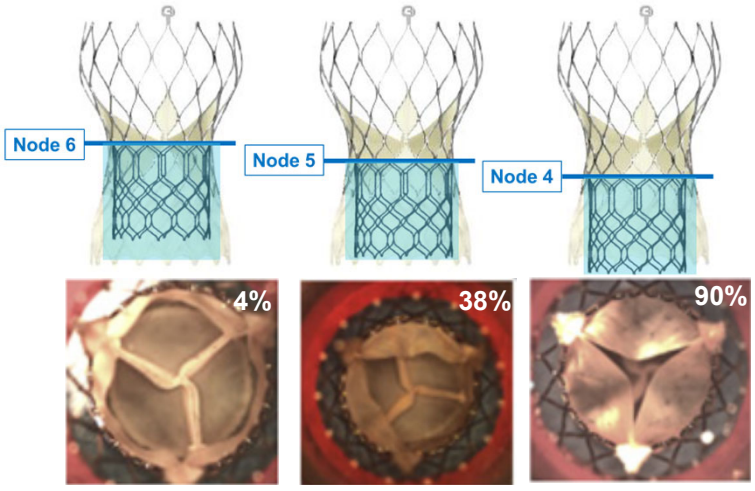
Leaflet Overhang & Neoskirt Plane (NSP)





Sathananthan..*J et al, Eurointervention 2021;21;17:856*
Akodad. M et al, JACC interv 2022;15:368

Acceptable hemodynamics (mean gradient & regurgitant fraction)

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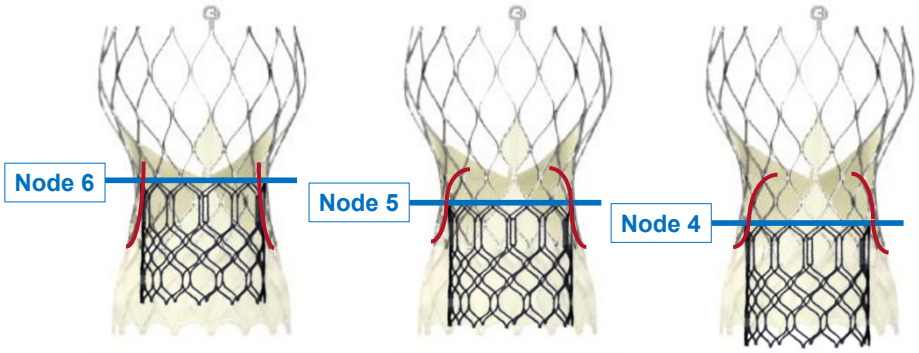
How to choose implant position?



Risk of coronary obstruction or access

Leaflet overhang

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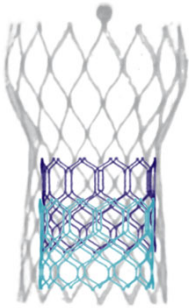
3) 2nd TAV Sizing: In-vivo sizing may be better

Strategies: In-vivo / In-vitro / pre-index native annulus

1. Under- & Uneven expansion is common

2. Size may change by TAV size and position

Evolut 26

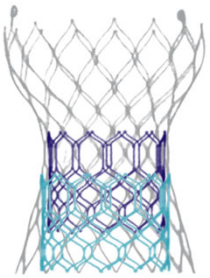


Node 6

Node 4

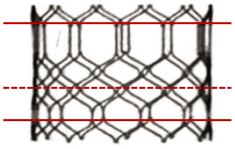
S3 size may not change

Evolut 34



S3 size may change

3) 2nd TAV Sizing: Each TAV has unique sizing strategy

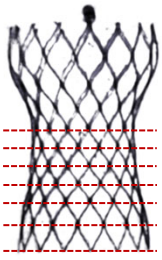


Outflow

Waist (Narrowest)

Inflow

Short & Tall 2nd TAV
Average of areas at the 3 levels

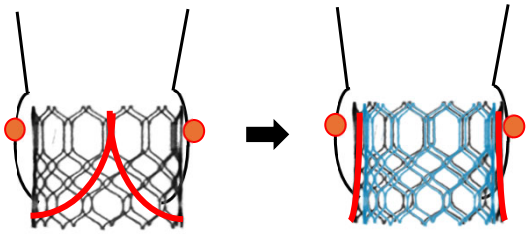


Short: Average of areas at NSP and 3 nodes below

Tall: Same or one size smaller size of Evolut

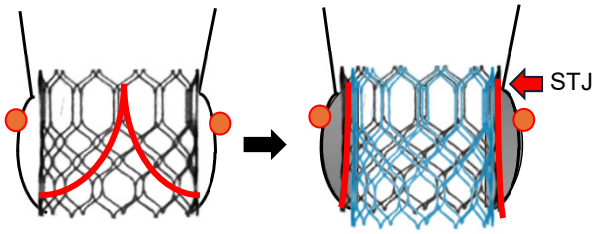
4) Coronary Risk

Direct Coronary Obstruction



Post Redo-TAV

Sinus Sequestration



Post Redo-TAV

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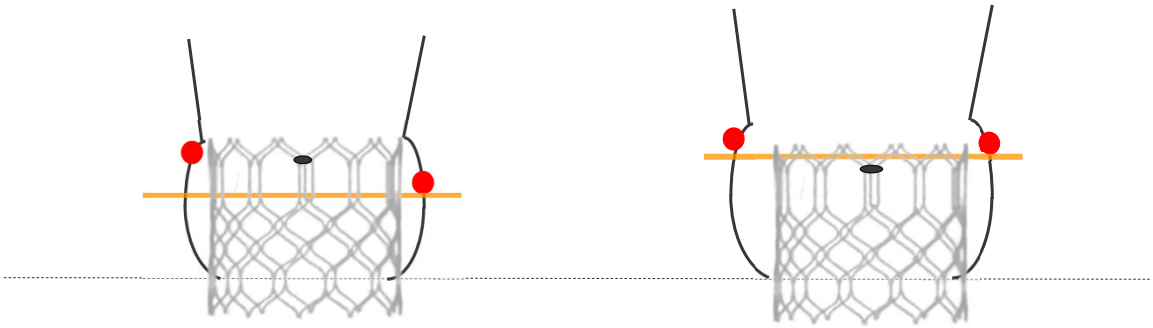
4) Coronary Risk Analysis: Coronary Risk Plane (CRP)

CRP: Plane below the LOWEST coronary ostia



CRP: Below top of commissure tab

CRP: Above top of commissure tab

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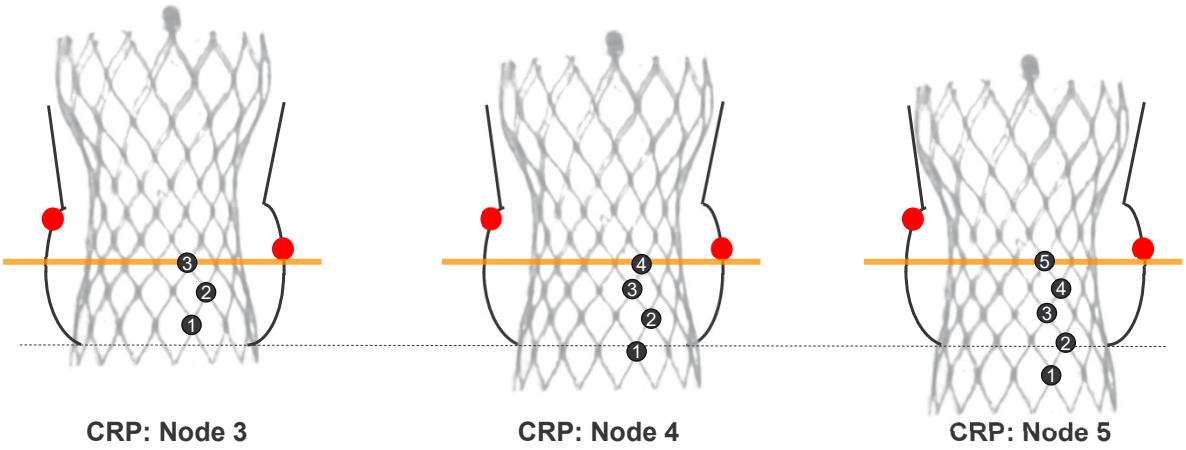
4) Coronary Risk Analysis: Coronary Risk Plane (CRP)

CRP: Plane below the LOWEST coronary ostia



CRP: Node 3 | CRP: Node 4 | CRP: Node 5

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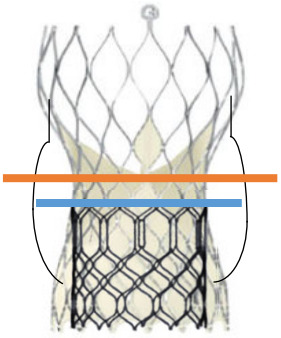
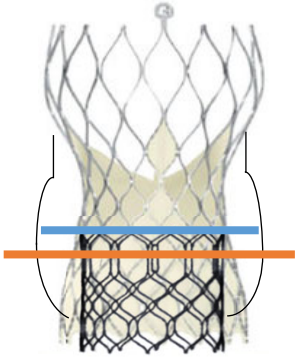
4) Coronary Risk Analysis: When?

CRP
Coronary risk plane
NSP
Neoskirt plane





NSP
CRP

Low risk of coronary
Skip VTA measurement

Need coronary assessment
After second TAV sizing

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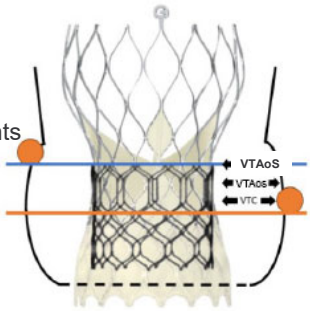
4) Coronary Risk Analysis: How?

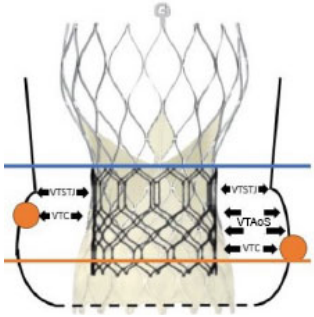
VTA (valve to aorta) = VTC, VTAoS and VTSTJ*

NSP below STJ: VTAoS and VTC

NSP above STJ: VTSTJ, VTAoS and VTC

Multiple Measurements
Take smallest





*VTC = Valve to coronary
VTAoS = Valve to Aortic sinus
VTSTJ = Valve to ST junction

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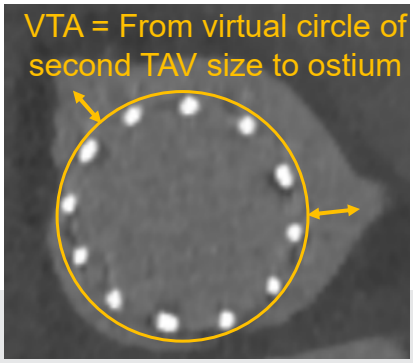
4) Coronary Risk Analysis: How?

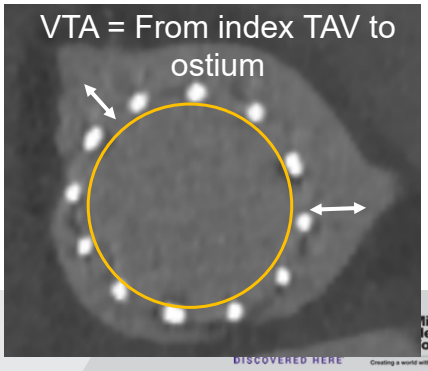
BEV could expand index TAV and increase coronary risk
→ Use virtual circle of second TAV size chosen

When virtual circle of second TAV is

Outside of index TAV



On / Inside of index TAV



38

4) Coronary Risk Analysis: Risk classification

VTA > 4 mm	VTA 2-4 mm	VTA < 2 mm
Minimal Risk of Coronary obstruction & good coronary access	Possible Risk of Coronary obstruction & difficult coronary access	Very high risk of Coronary obstruction & Difficult coronary access

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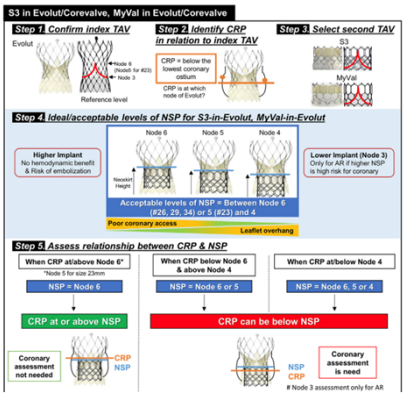
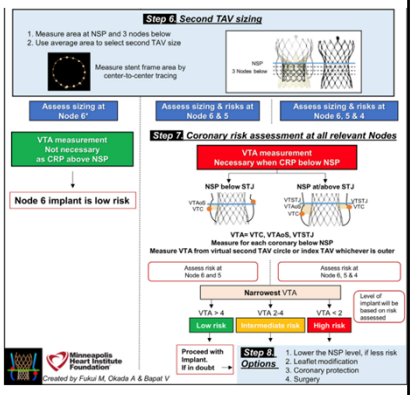
We need systematic algorithm for patient safely

A Guide to Transcatheter Aortic Valve Design and Systematic Planning for a Redo-TAV (TAV-in-TAV) Procedure

Vinayak N. Bapat, MBBS, MCh,[a,b] Miho Fukui, MD, PhD,[a] Syed Zaid, MD,[c] Atsushi Okada, MD, PhD,[a]





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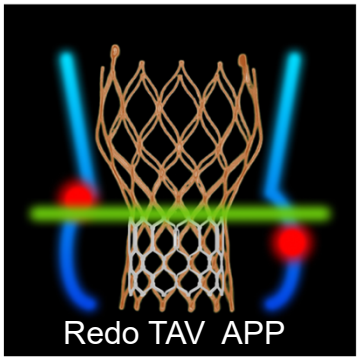
App is practical tool for everyday practice can support your planning and procedure

Download on the App Store

GET IT ON Google Play



REDO TAV

Supported by

Minneapolis Heart Institute Foundation

Joseph F. and Mary M. Fleischhacker Family Foundation

ViV Aortic | ViV Mitral | Valve PPM | Redo TAV

Developed by
Dr. Miho Fukui
Dr. Vinayak (Vinnie) Bapat

Contributions by
Dr. Atsushi Okada

KRUTSCH

mplsheart.org/apps

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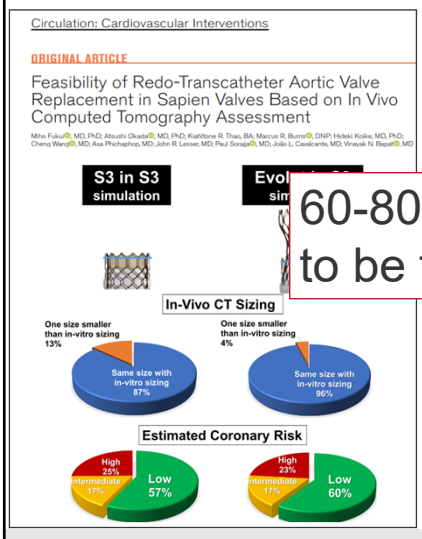
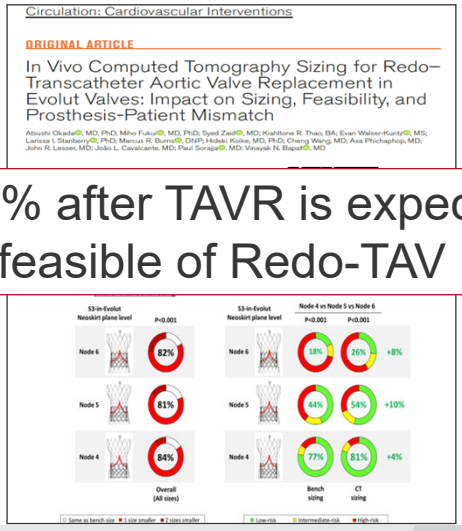
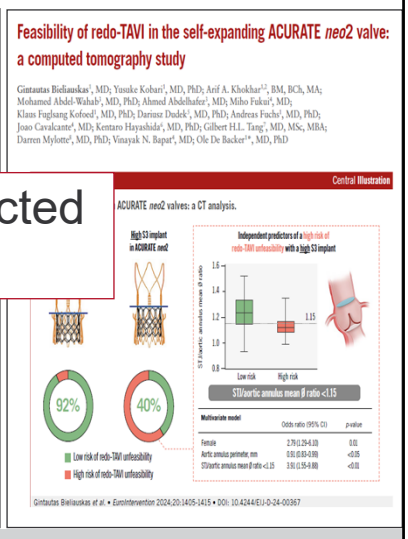
Simulation studies of Redo-TAV feasibility with App algorithm







60-80% after TAVR is expected to be feasible of Redo-TAV

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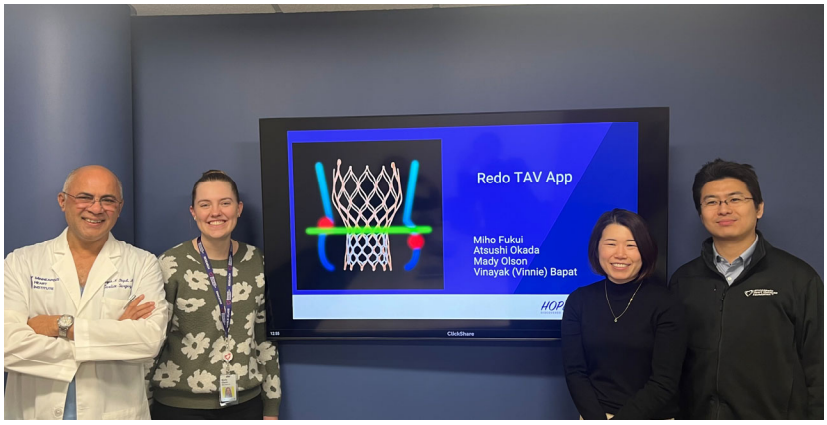
Development of APP is collaboration work



With
-KOLs
-Industry partners
-App developer

Under the support of
Fleischhacker Family

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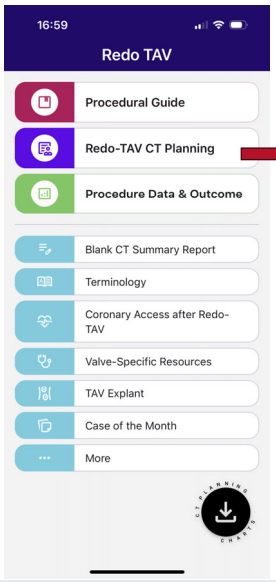
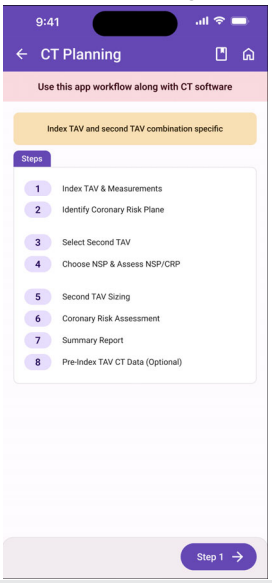
Home Screen



CT Planning



Steps

1 Index TAV & Measurements
2 Identify Coronary Risk Plane
3 Select Second TAV
4 Choose NSP & Assess NSP/CRP
5 Second TAV Sizing
6 Coronary Risk Assessment
7 Summary Report
8 Pre-Index TAV CT Data (Optional)

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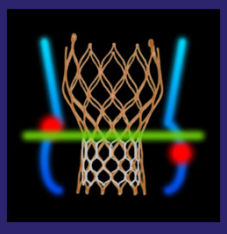
Optimization:

How can we achieve better outcomes?

45

Case: Index Evolut R #29



Redo TAV APP

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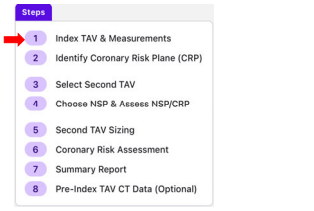
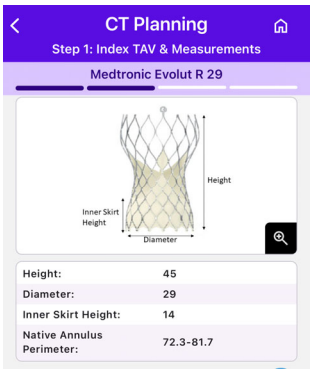
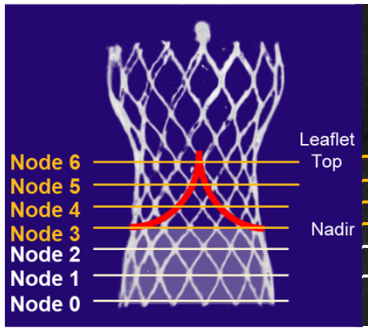
Step 1. Index TAV & Measurements

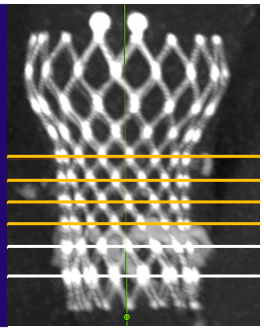


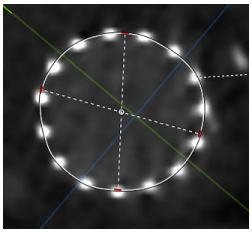


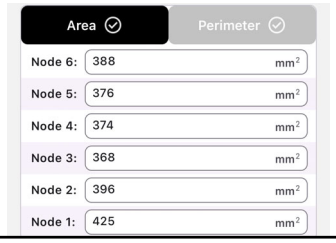
In-vitro shape



CT image of this case







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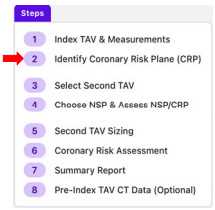
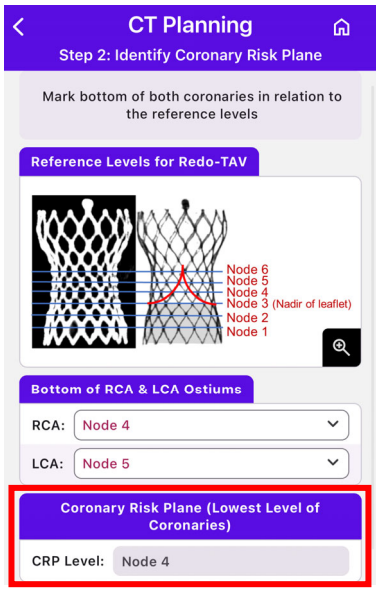
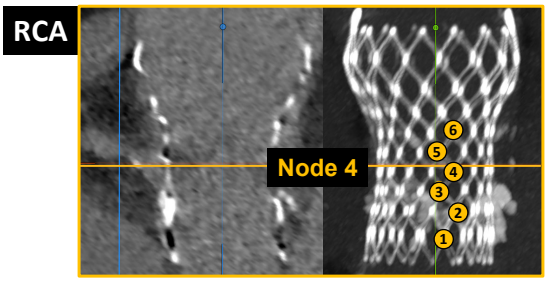
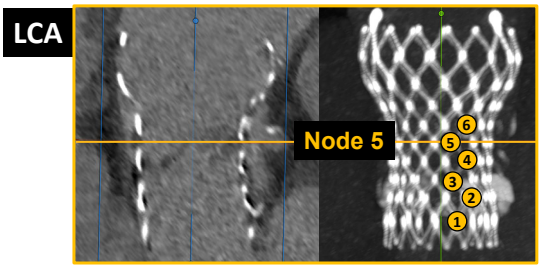
Step 2. Identify Coronary Risk Plane (CRP)









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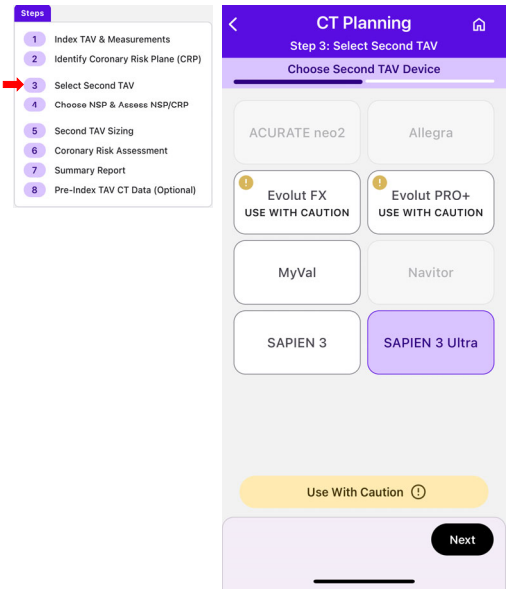
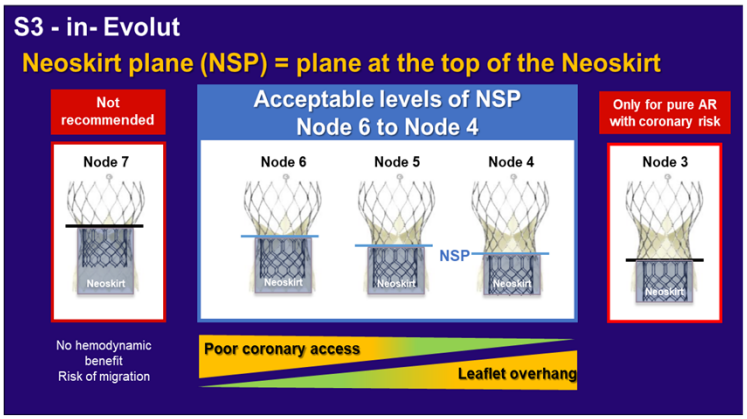
Step 3. Select Second TAV & levels of implant





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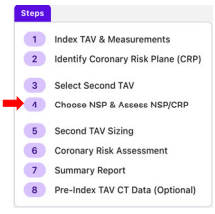
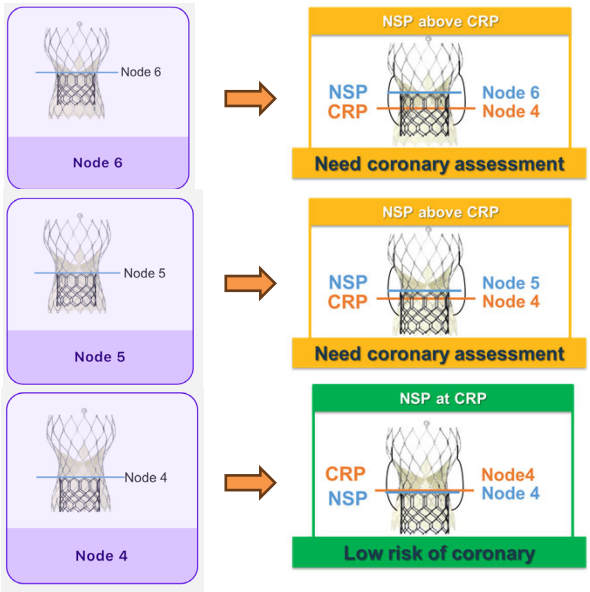
Step 4. Choose NSP & Assess NSP/CRP relation



CRP=Node 4



NSP = Neoskirt Plane
Plane at Top of Neoskirt

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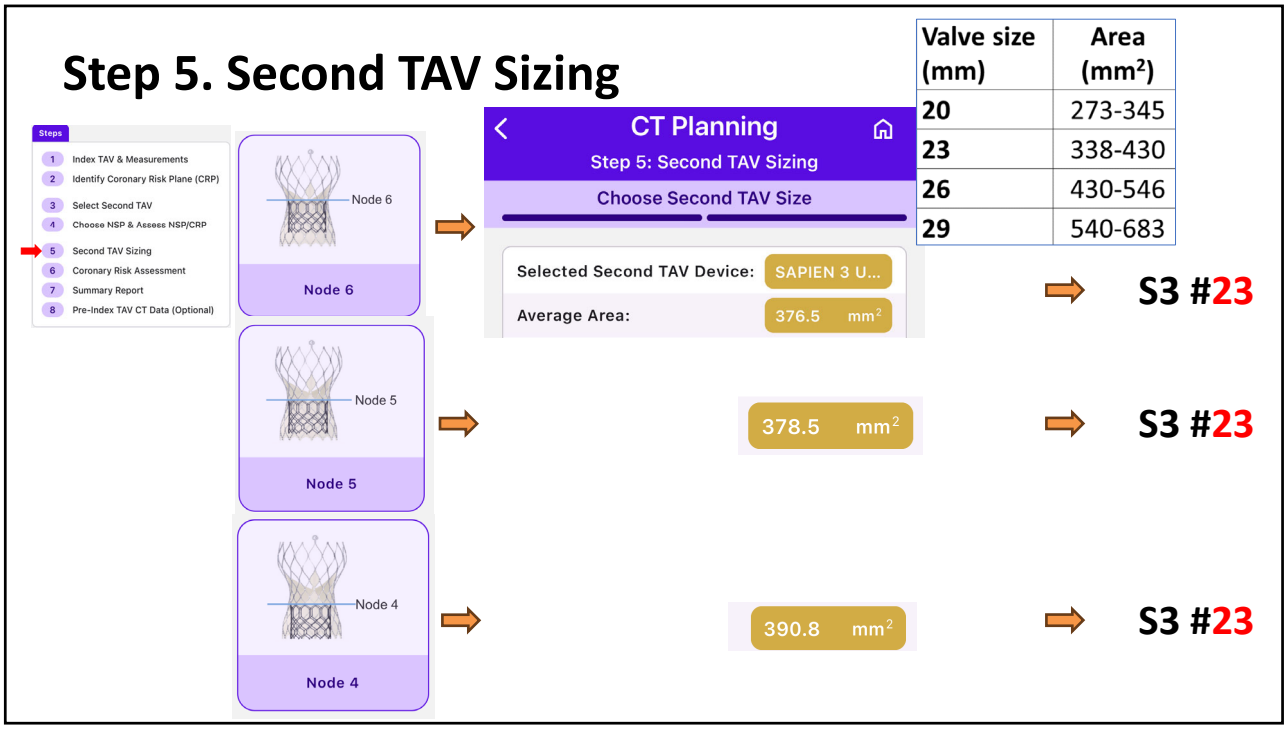
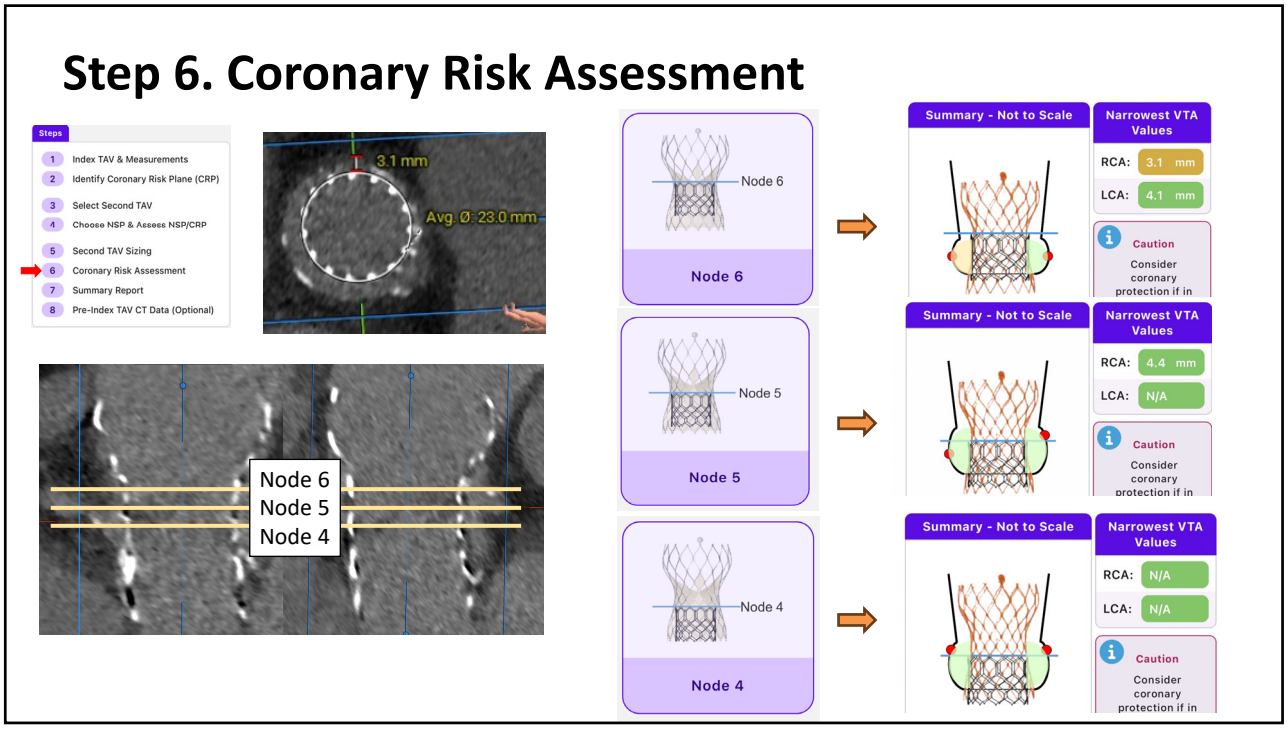

Step 5. Second TAV Sizing
Steps
1 Index TAV & Measurements
2 Identify Coronary Risk Plane (CRP)
3 Select Second TAV
4 Choose NSP & Assess NSP/CRP
5 Second TAV Sizing
6 Coronary Risk Assessment
7 Summary Report
8 Pre-Index TAV CT Data (Optional)
Node 6
Node 6
Node 5
Node 5
Node 4
Node 4
CT Planning
Step 5: Second TAV Sizing
Choose Second TAV Size
Selected Second TAV Device: SAPIEN 3 U...
Average Area: 376.5 mm²
378.5 mm²
390.8 mm²
Valve size (mm) | Area (mm²)
20 | 273-345
23 | 338-430
26 | 430-546
29 | 540-683
S3 #23
S3 #23
S3 #23

51


Step 6. Coronary Risk Assessment
Steps
1 Index TAV & Measurements
2 Identify Coronary Risk Plane (CRP)
3 Select Second TAV
4 Choose NSP & Assess NSP/CRP
5 Second TAV Sizing
6 Coronary Risk Assessment
7 Summary Report
8 Pre-Index TAV CT Data (Optional)
3.1 mm
Avg. Ø: 23.0 mm
Node 6
Node 5
Node 4
Node 6
Node 6
Node 5
Node 5
Node 4
Node 4
Summary - Not to Scale
Narrowest VTA Values
RCA: 3.1 mm
LCA: 4.1 mm
Caution
Consider coronary protection if in
Summary - Not to Scale
Narrowest VTA Values
RCA: 4.4 mm
LCA: N/A
Caution
Consider coronary protection if in
Summary - Not to Scale
Narrowest VTA Values
RCA: N/A
LCA: N/A
Caution
Consider coronary protection if in

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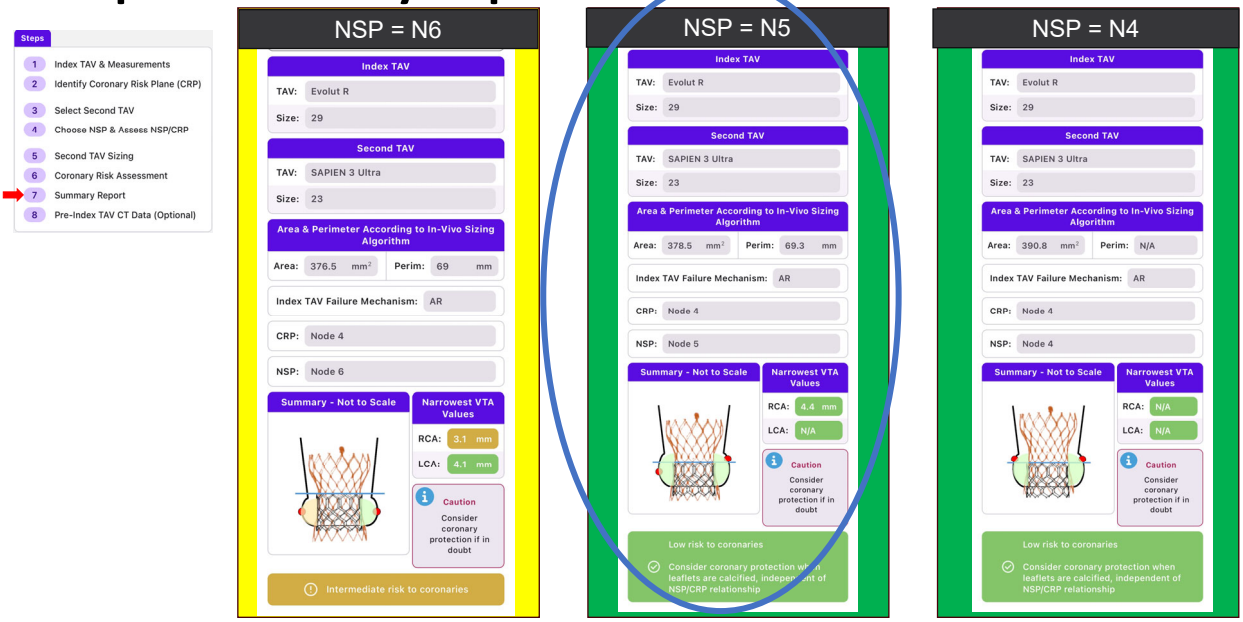
Step 7. Summary Report



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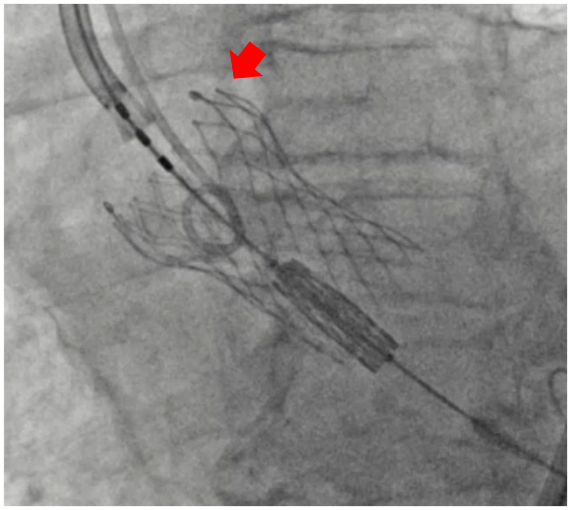
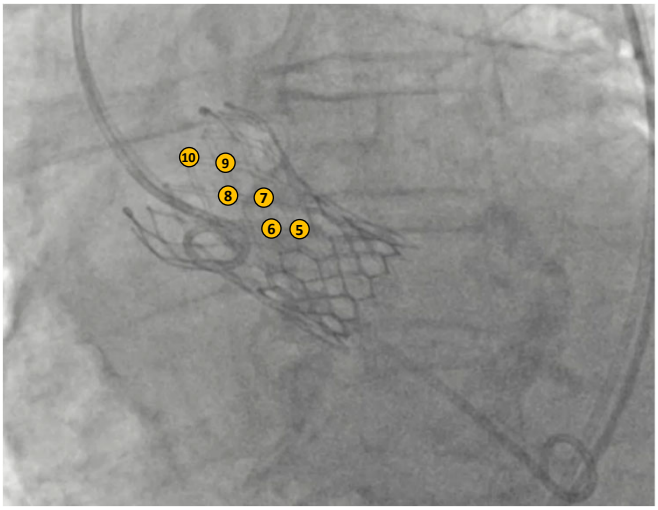
Redo-TAV procedure: Successful implantation





Post-TTE: No transvalvular or paravalvular AR, Mean gradient 8 mmHg

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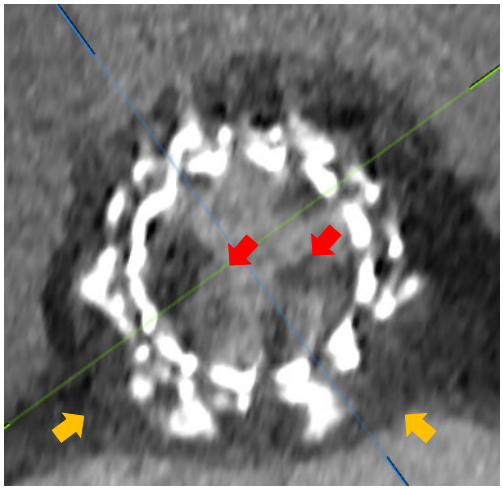
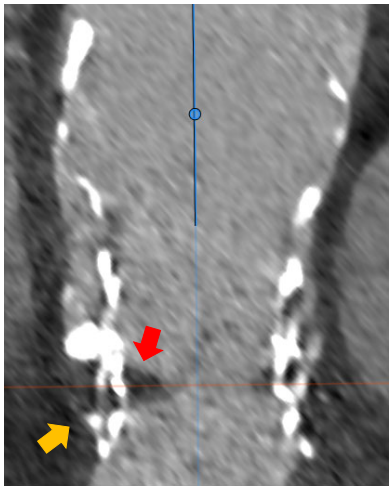
Next day after procedure, patient experienced stroke…

Thrombosis on second TAV leaflets and native-sinus





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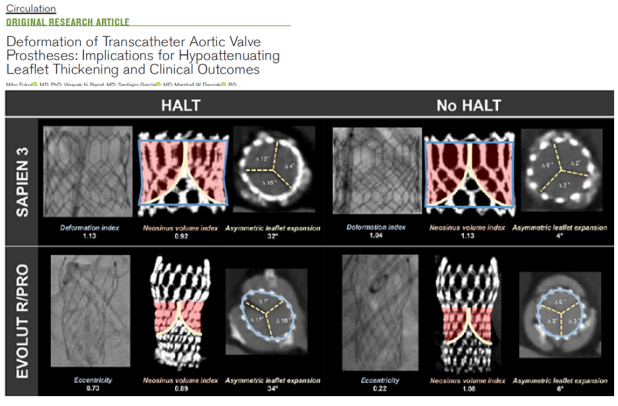
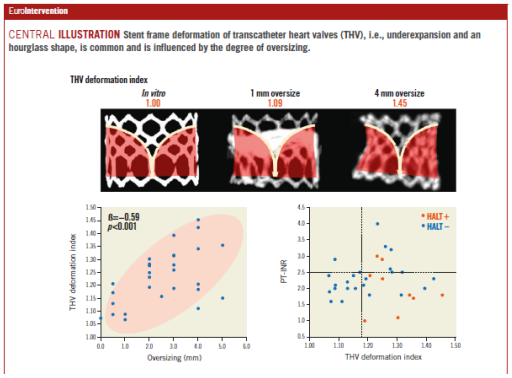
Why did this happen?



Fukui M, Soraja P, et al. Circulation 2022



Fukui M, Bapat V et al. Eurointervention 2023

TAV deformation could cause HALT/Thrombus

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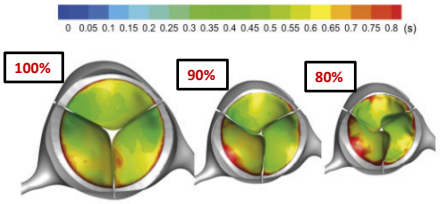
This is also supported by bench testing

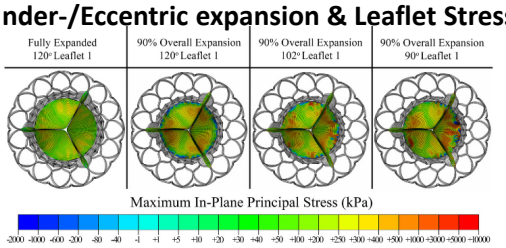
Underexpansion & Flow Stagnation

Blood residence time (i.e. stasis) on transcatheter aortic valve leaflets after 100%, 90%, and 80% stent expansion.



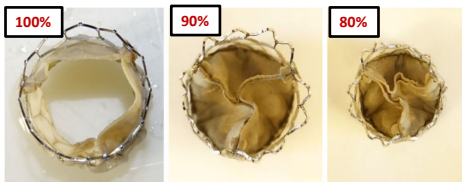
Khodaee F. et al. Interact Cardiovasc Thorac Surg 2020

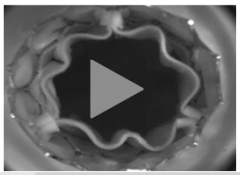
Under-/Eccentric expansion & Leaflet Stress



Qiu D. et al. Int J Numer Method Biomed Eng 2022

Underexpansion & Pinwheeling





Sathananthan J. et al.
JACC intv 2019;12:65

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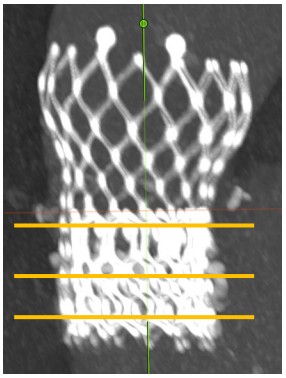
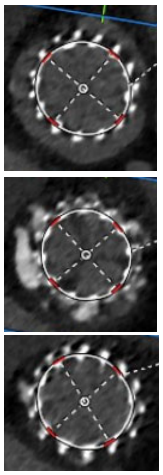
How could the procedure have been optimized?





% S3 expansion

Outflow
86%

Waist
80%

Inflow
87%

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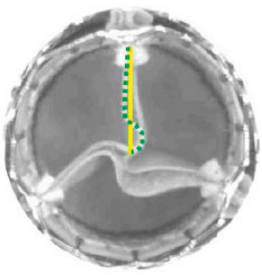
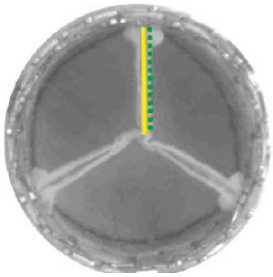
Pre/Post dilatation could be option





Without Pre/Post dilatation

With Pre/Post dilatation

Meier D, et al. *Eurointervention*. 2023;19:757

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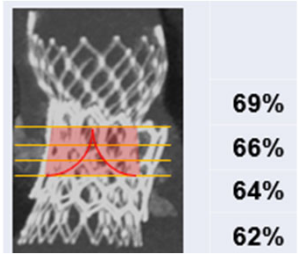
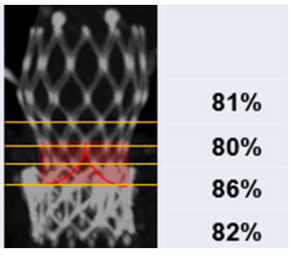
In-vivo sizing & pre/post dilatation are crucial for optimal second TAV expansion & function

Index TAV	SAPIEN #23
Second TAV	S3 #23
Sizing	In-Vitro
Index TAV Expansion	Pre → Post
Pre-Dilatation	-
Inflation volume during Redo-TAV	-1 cc
Post-Dilatation	+ (delivery system, -1cc)
Second TAV Expansion (Area, mm²)	79% (324)
Outflow	51% (210)
Waist	
Inflow	82% (337)





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4 prospective studies of Redo-TAV are ongoing

ReTAVI study
- Europe, Canada, Israel
- Redo-TAV with Sapien family
- Target n=150

REVALVE study
- Europe
- Any combinations of index and second TAVs
- Target n=300-500

REFINE study
- Across all continents
- Focus on Pre/Post CT
- Target n=225

RESTORE study
- U.S.
- Redo-TAV with Evolut or Sapien family
- Target n=250

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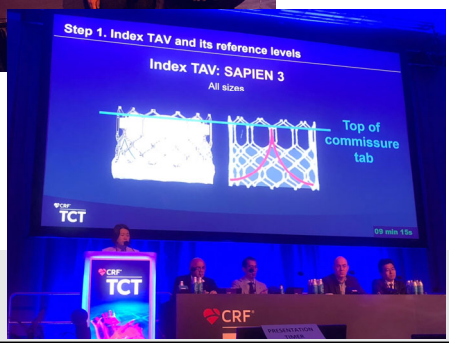
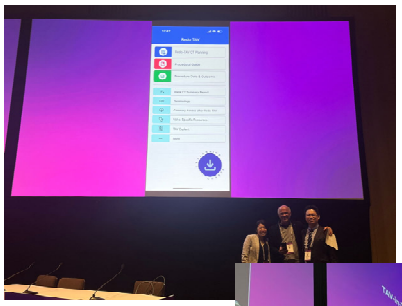
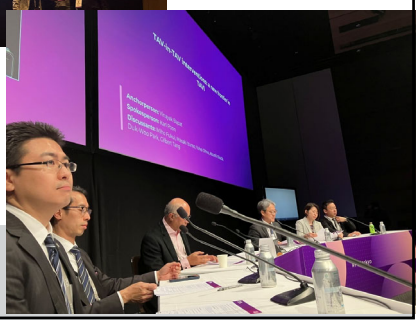
Dedicated session across countries







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First Workshop for Redo-TAV CT planning in Brazil

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Second Workshop at NY valves 2024

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Virtual Redo-TAV Workshop is coming!

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Minneapolis Heart Institute Foundation

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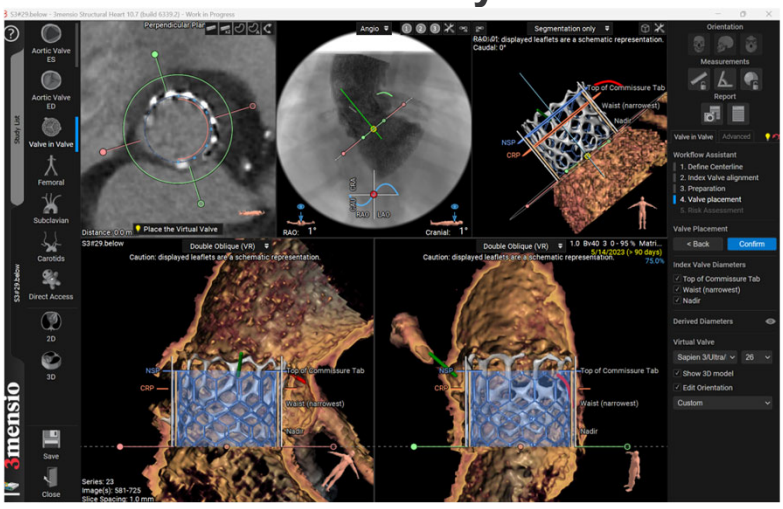
Dedicated CT software module by 3Mensio is coming soon



HOPE DISCOVERED HERE
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Key takeaways

- The number of Redo-TAV is increasing
- Feasibility should be assessed step-by-step on pre-CT with four key considerations:
  - 2nd TAV compatibility
  - Optimal implant position
  - 2nd TAV sizing
  - Coronary Risk
- Strategize the optimization of the procedure

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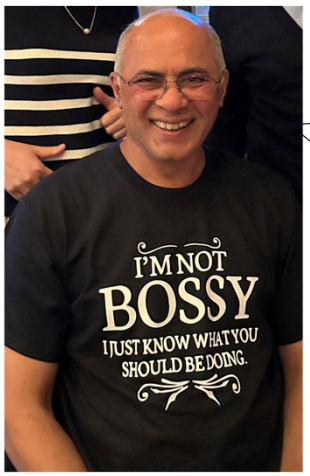
My personal takeaways



Rather than discuss the problems

Let's find out solutions!!!

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