

TAVR failure due to Structural Valve Degeneration

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Disclosure Statement of Financial Interest Vinayak Bapat

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship

- Consulting/honoraria
- Consulting/honoraria
- Consulting/honoraria

Company

- Edwards LifeSciences
- Medtronic Inc
- Boston Scientific Inc

This presentation is not about SAVR vs TAVR

But

Understanding challenges we will face with TAVR degeneration

Implications with TAVI in low risk/Young patients

Age/risk boundary = avoiding second intervention

Hemodynamics = durability

PV leak

Coronary
disease

Other Valvular
issues

Anticoagulation?

Implications with TAVI in low risk/Young patients

Age/risk boundary = avoiding second intervention

Idea of 'Age cut off' used for Tissue Valve

Avoid
Anticoagulation

Avoid
Reoperation

Definition of Young???

- Average age for Low risk trials is around 73 years.
- Are these young patients or old?

My View: Definition should be based on
Life Expectancy and Valve Durability

Patient lives longer than the valve = Young
Valve works longer than the Patient = Old

Young or old according to Guidelines for SAVR

2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines

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

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Favor Mechanical Prosthesis

Favor Bioprosthesis

Age <50 y

Age >70 y

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.

European 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

A bioprosthesis should be considered in patients >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

indicated because of high bleeding risk (previous major bleed, comorbidities, unwillingness, compliance problems, lifestyle, occupation).	I	C
A bioprosthesis is recommended for reoperation for mechanical valve thrombosis despite good long-term anticoagulant control.	I	C
A bioprosthesis should be considered in patients for whom there is a low likelihood and/or a low operative risk of future redo valve surgery.	IIa	C
A bioprosthesis should be considered in young women contemplating pregnancy.	IIa	C
A bioprosthesis should be considered in patients >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	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.

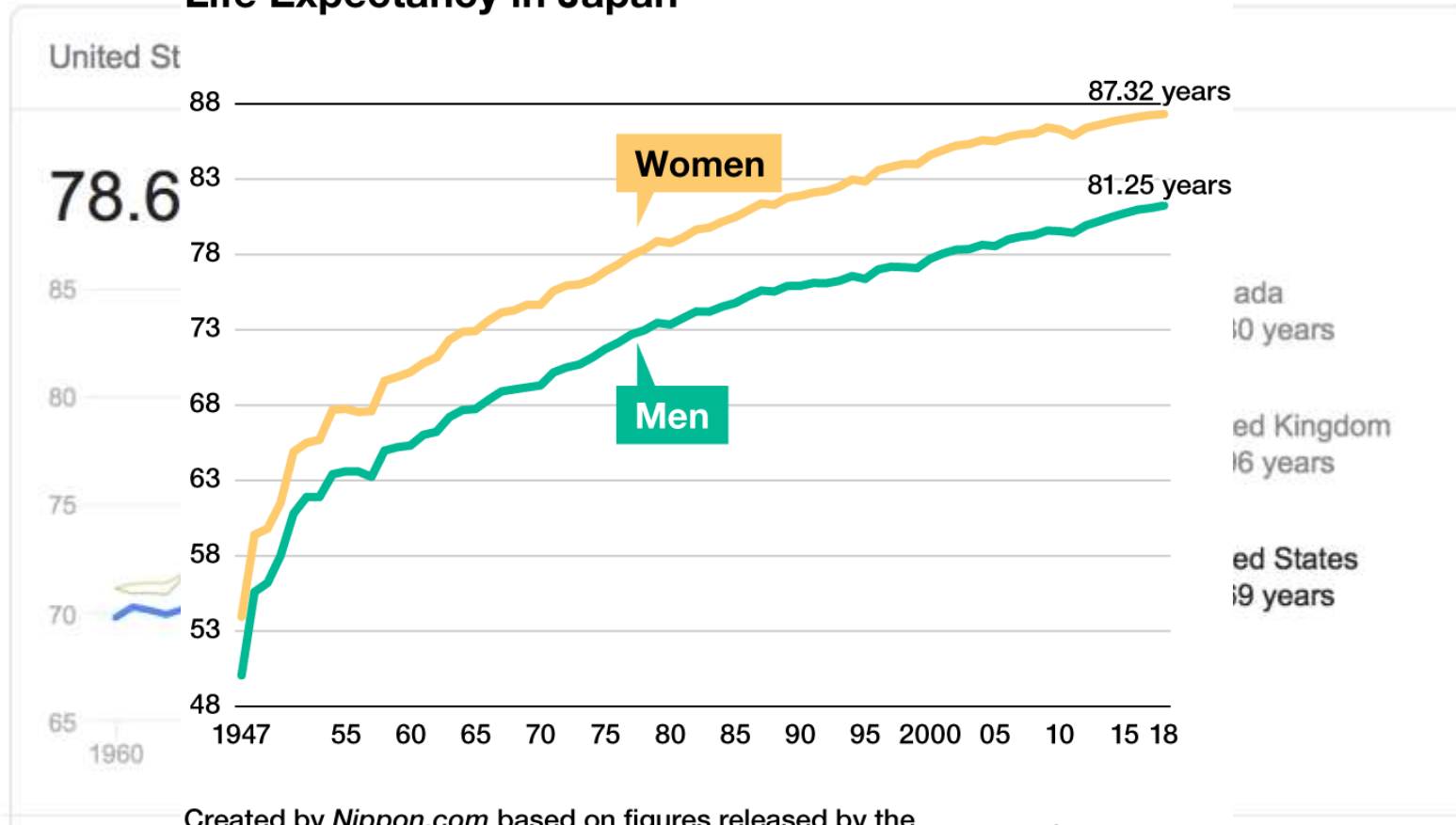
**Based on Durability of Surgical tissue valves = 15 years
 Data from same manufacturers who manufacture TAVI devices**

Idea behind these recommendations

- Reliable hemodynamics
- Valve out lasting the patients in majority cases
- Avoidance of Anticoagulation
- Patient takes risk of only one procedure

Lets Define Young

Life Expectancy in Japan



Created by *Nippon.com* based on figures released by the Ministry of Health, Labor, and Welfare.

nippon.com

If same age definition was applied to TAVR

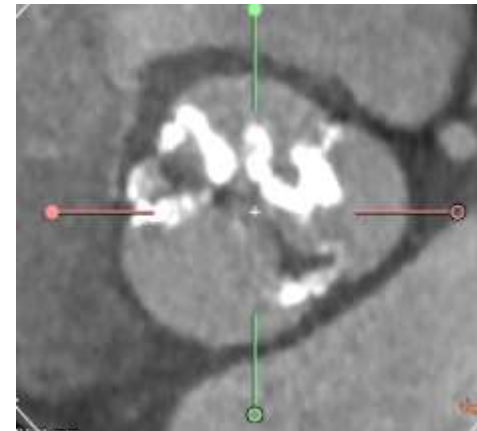
- Based on current predictions TAVR will last for 10 years
- Hence, if we implant it in
 - EU/NA at age < 65, or
 - Japan/Korea < 70

Reintervention for SVD will not be uncommon

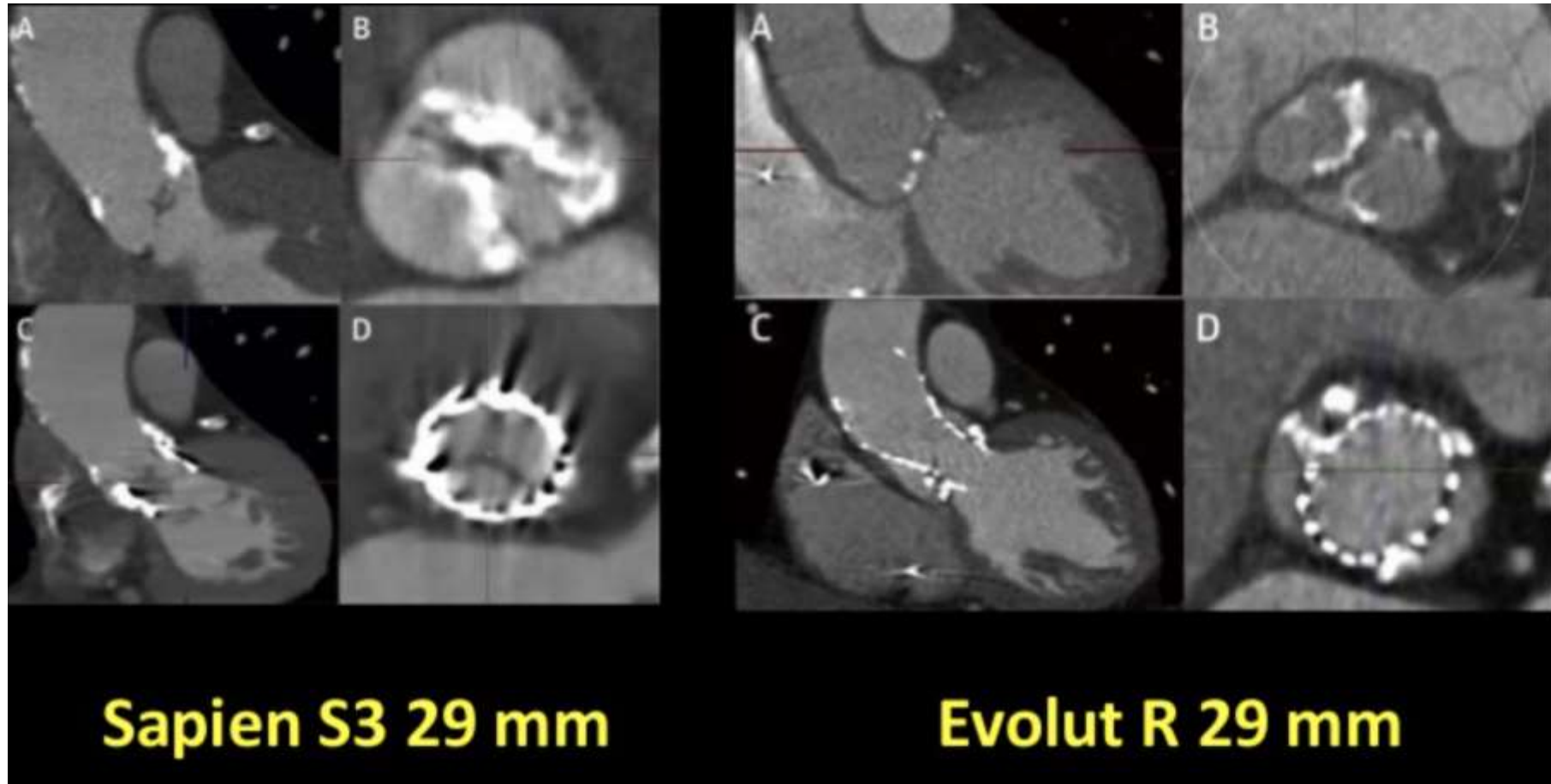
That is the best case scenario.....

- Younger patients = Increase chance of Bicuspid
- Suboptimal anatomy = suboptimal results
- Key exclusions: Bicuspid, Severe Calcified aortic complex, LVOT calcification

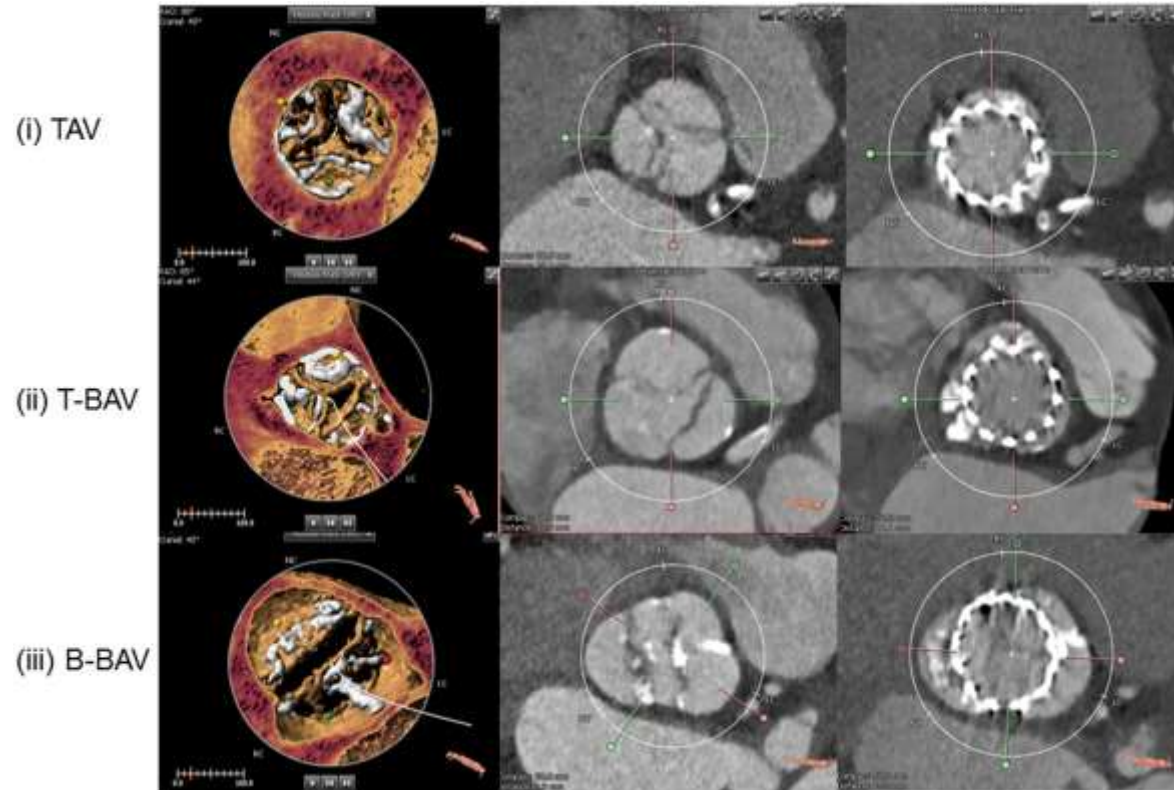
In these patients the Intervention will be sooner?



TAVR shape in Bicuspid



Eccentricity Index of S3 in Bicuspid



Similar to Tricuspid Valves ??

Kawamori et al
Journal of the American College of Cardiology
Volume 68, Issue 18 Supplement, November 2016

Common causes of failure

- SVD
- Leaflet thrombosis
- IE
- PV leak
- leaflet damage – crimping and balloon dilatation

Second Intervention will be common..

TAVR in
TAVR

Promise !

Explant
TAVR and
Implant
SAVR

Reality !

Which
is
better??

Let us not assume that we know
The answer

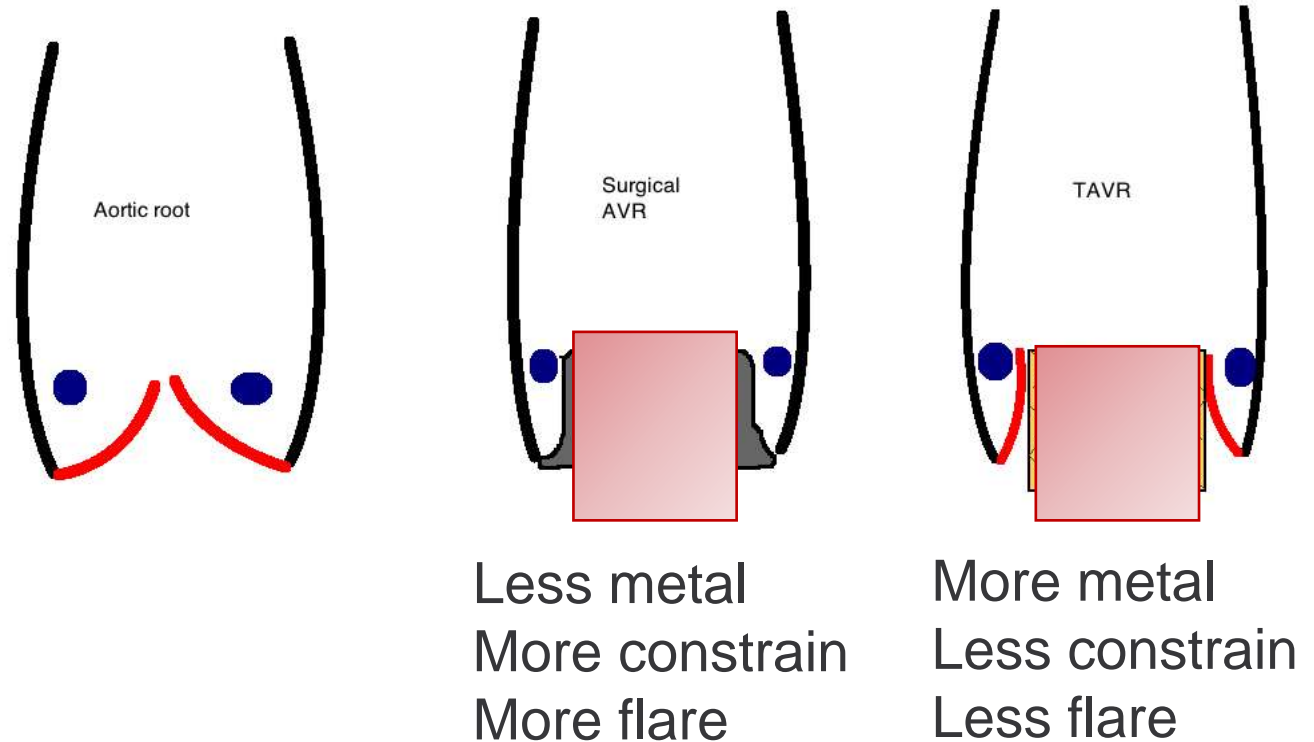
Second Intervention

TAVR in
TAVR

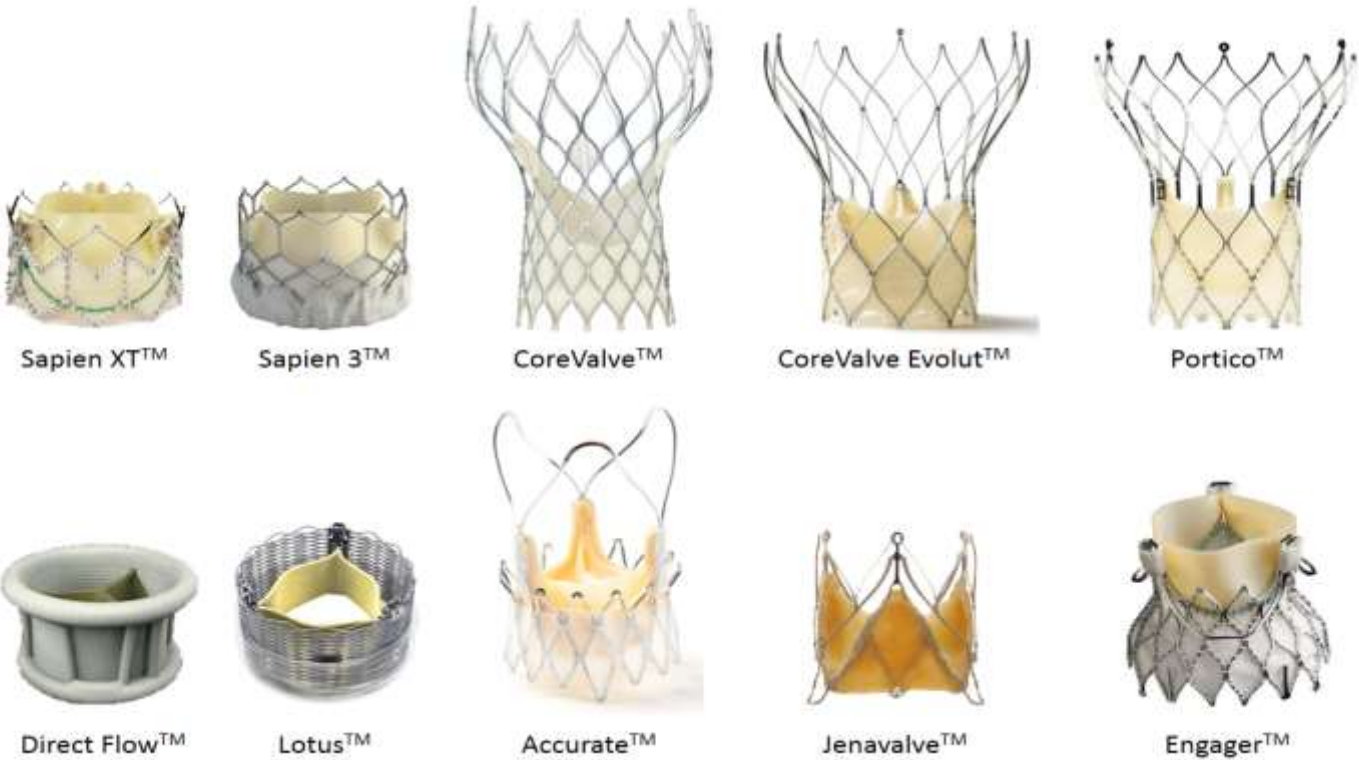
Which
is
better??

THV in THV – good strategy for low risk patients?

- Very few cases till to date
- Most are elderly – inferior hemodynamics are acceptable
- Risk of Valve thrombosis? **
- Need for anticoagulation? **
- Risk of poor hemodynamics? **



TAVR valves vary in Construct and interaction with native anatomy



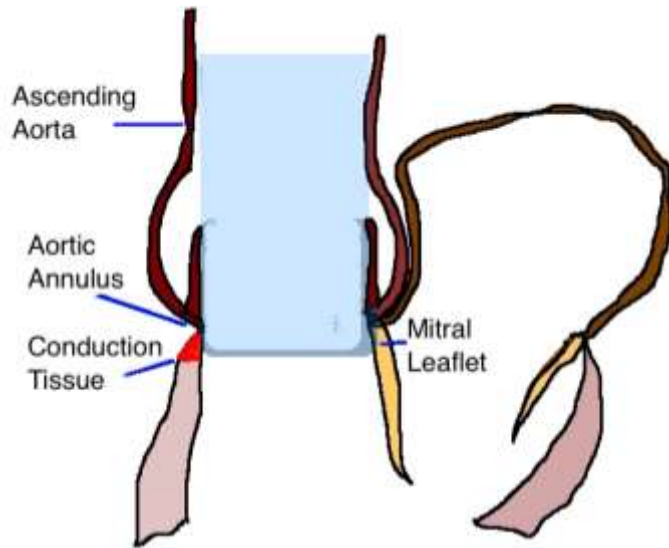
Other option

Explant
TAVR and
Implant
SAVR

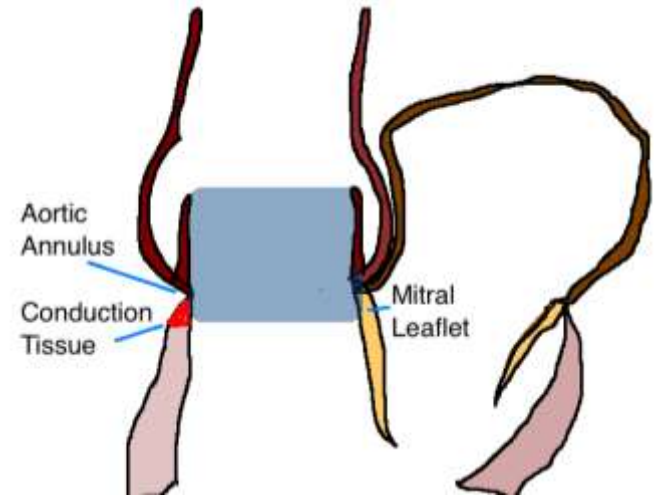
Which
is
better??

Patient will be older

Important Considerations in THV Explant



1. Ascending aorta?
2. Annular damage?
3. Mitral leaflet proximity
4. Conduction tissue proximity
5. Clamping and Aortotomy**



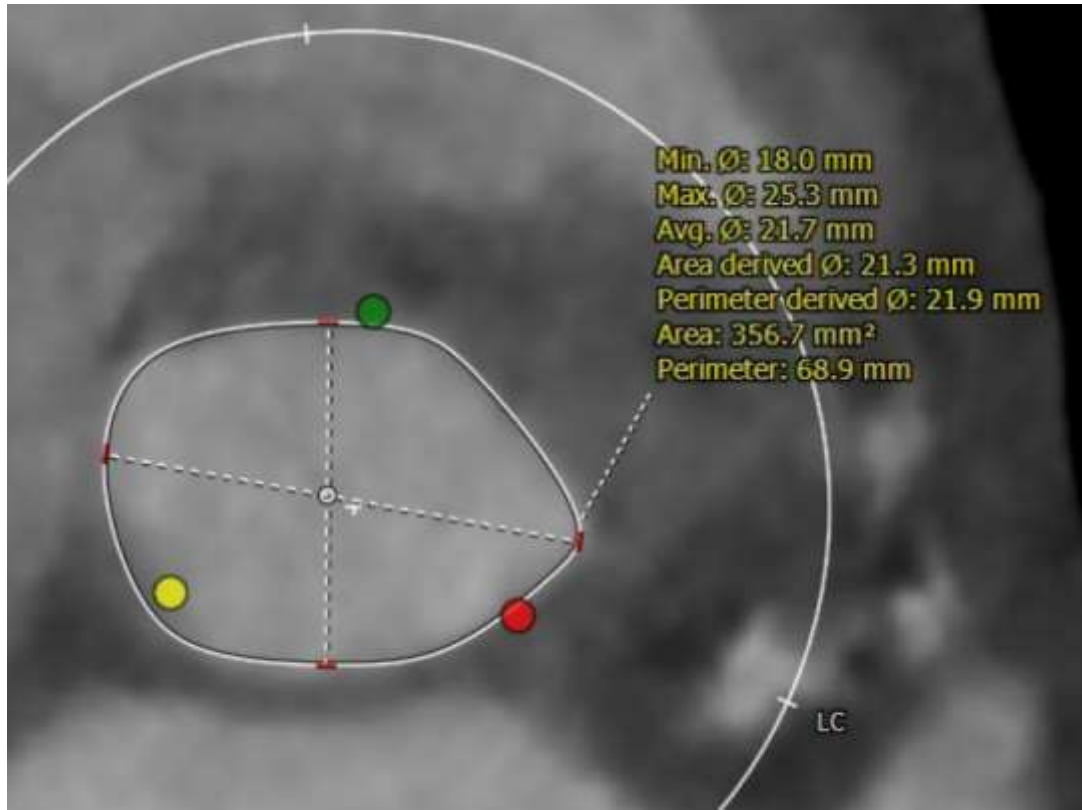
Concern: Will Ascending and Root replacement needed?

Case History

Patient Information	
Age	75
Gender	F
STS Score	4.3
NYHA Class	II
Height	68 in.
Weight	206 lb.
BMI	31.3
Creatinine	2.8
HGB	14.5

- **Relevant History:**
 - HTN; CAD
 - COPD
 - Good Femoral access
 - Discussed in Heart team (another hospital)
 - Planned TAVR

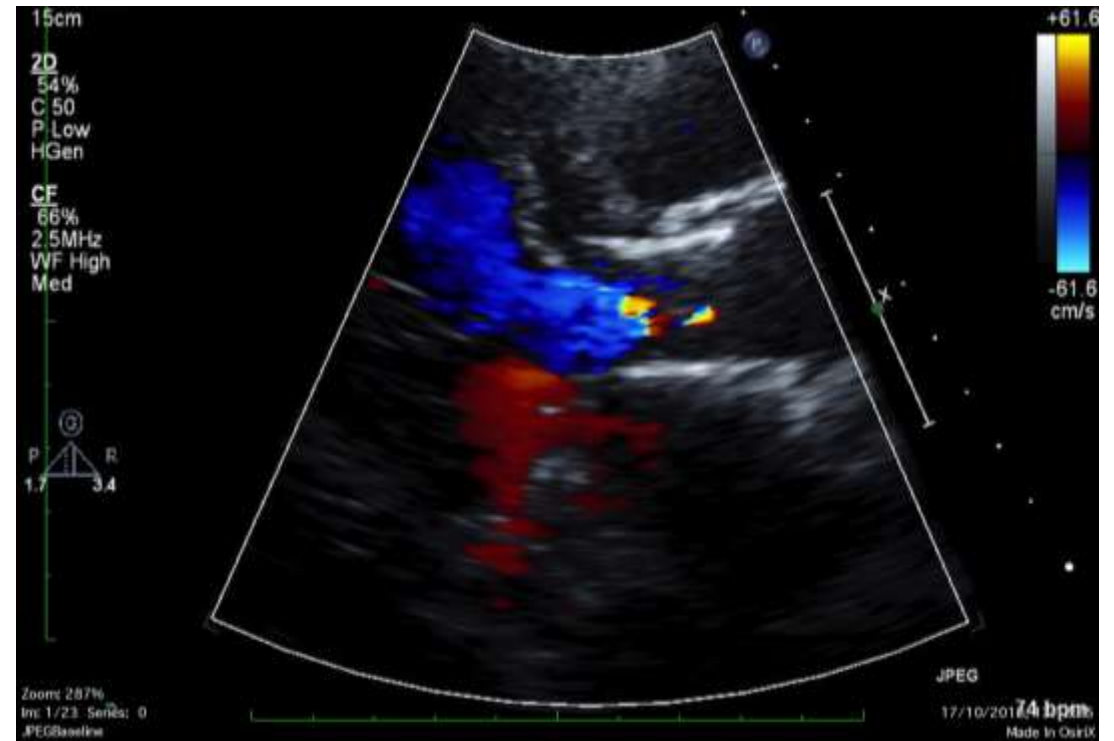
CT Analysis



Aortic Annulus	Measure
Short Annulus Diameter	18
Long Annulus Diameter	25
Annular Area	356
% Oversizing	13%
Planned Valve Size	23

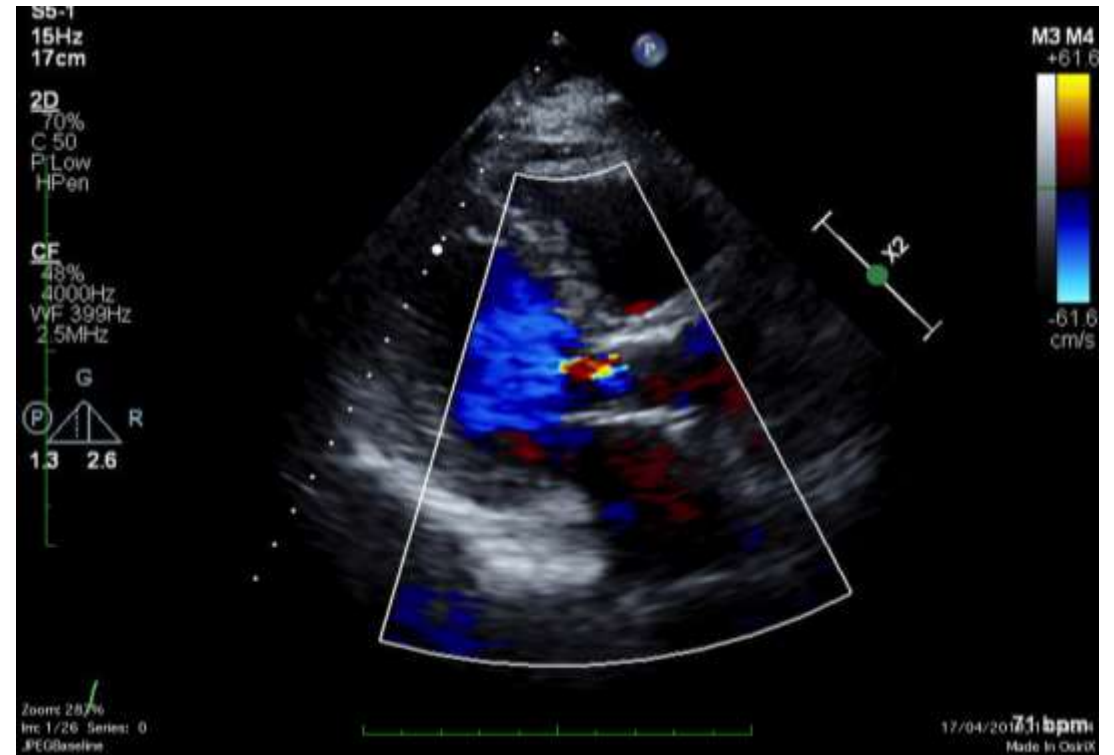
February 2017
TAVR SAPIEN 3 23
Uneventful

Echo Early 2018

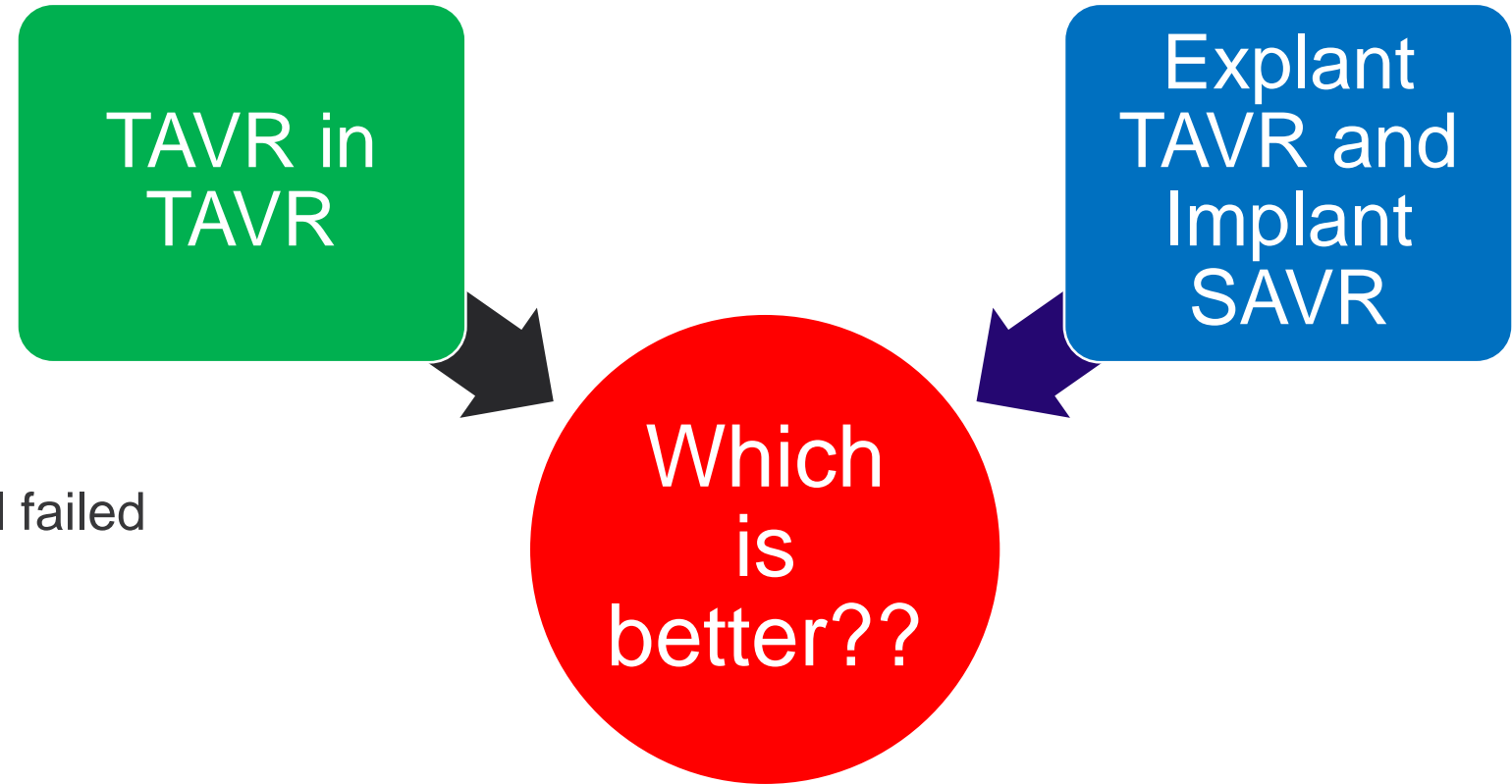


Echo Early 2019

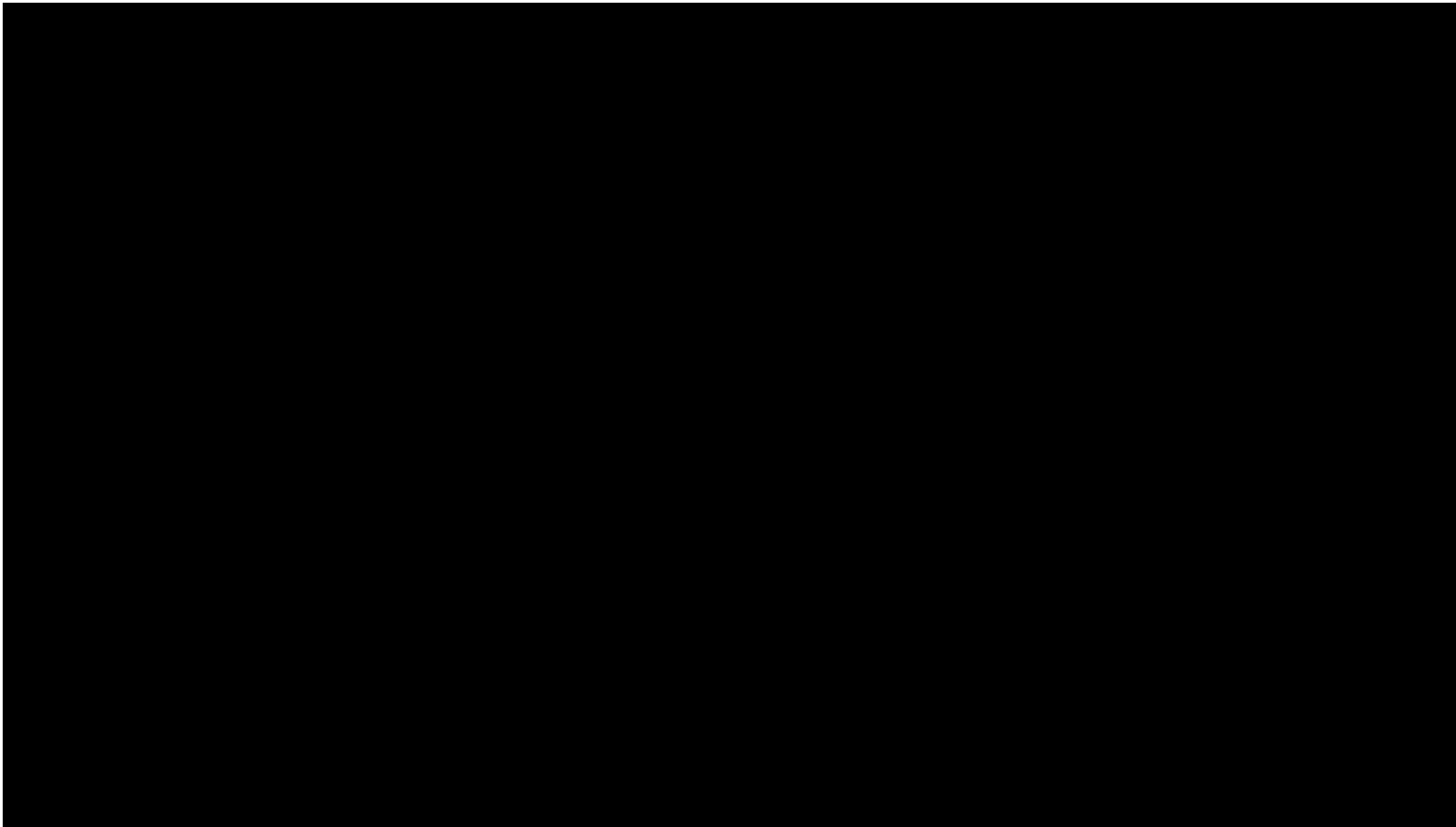
Increased Gradients, Symptomatic Patient



- SVD ?
- Leaflet thrombosis?
- Options: Anticoagulation trial failed







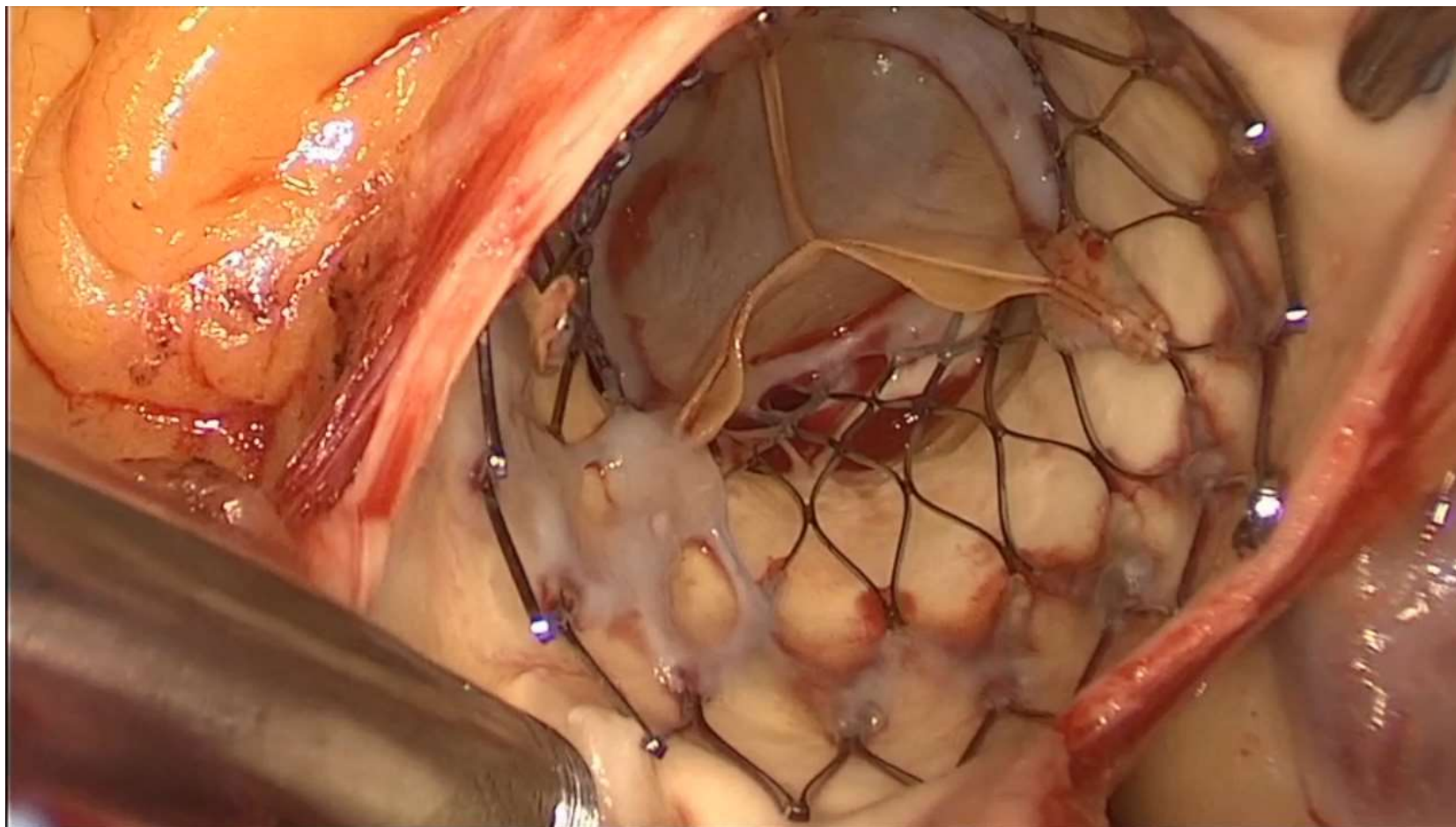
Post dilatation with or without high pressure balloon



Allina Health
ABBOTT
NORTHWESTERN
HOSPITAL

HOPE
DISCOVERED HERE™





Mod-Severe PV leak
Inability to close with devices

Final thoughts

1. Understanding Durability is the key piece for life time management
2. TAVR is a Tissue valve = degeneration
3. TAVR in TAVR and THV extraction experience is limited