



1

Surgery for Failed Transcatheter Treatments

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Cardiac Surgeon and Chair of Cardiothoracic Surgery
Minneapolis Heart Institute®

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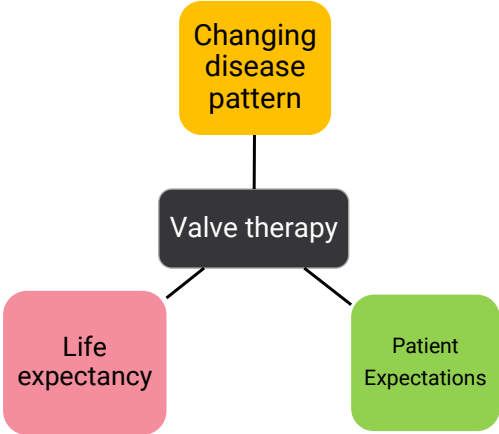
Disclosures

- Consultant / Honorarium / Grants/Advisory board
 - Edwards Lifesciences
 - Medtronic Inc
 - Boston Scientific
 - Abbott
 - Anteris
 - Meril



3

Heart Valve therapy continues to evolve



4

Ideal Heart Valve – Ten Commandments

1. Should not block blood flow
2. Closes promptly and completely
3. Nonthrombogenic
4. Resists infection
5. Chemically inert
6. Does not kill cells
7. Easy to permanently implant
8. Allows healing to occur
9. Pleasing to the patient (noise free)
10. **Last for a life time**

Does not exist

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From Mechanical valves to Tissue Valves



Starr-Edwards Model 1260 introduced 1968. Teflon and polypropylene sewing ring, cast Stellite 21 cage. Still in use.

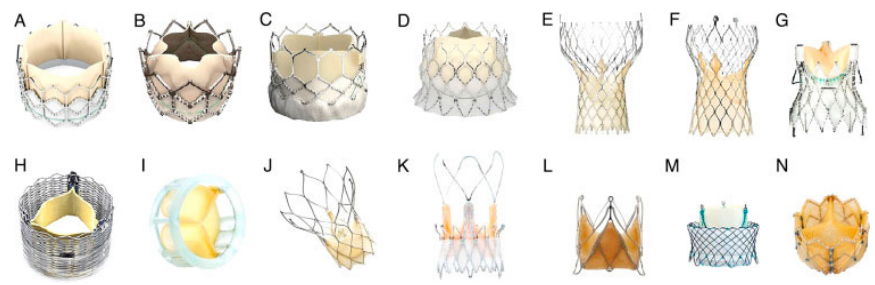


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Tissue valves to Transcatheter Valves



Attractive options for patients
Less Invasive
Shorter Hospital stay



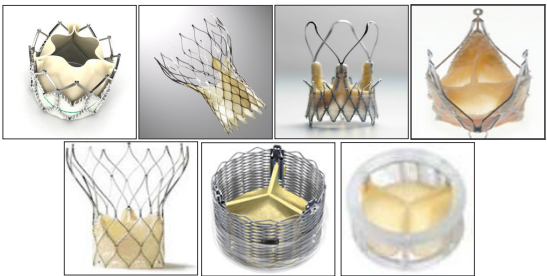
7

TAVR journey

Alain Cribier: First Transcatheter Aortic Valve Implantation (TAVI) April 16, 2002



April 16, 2002 8 days post implantation



CE Marked Devices in 2014



8

Advances

Valve Design **Delivery System** **Imaging**

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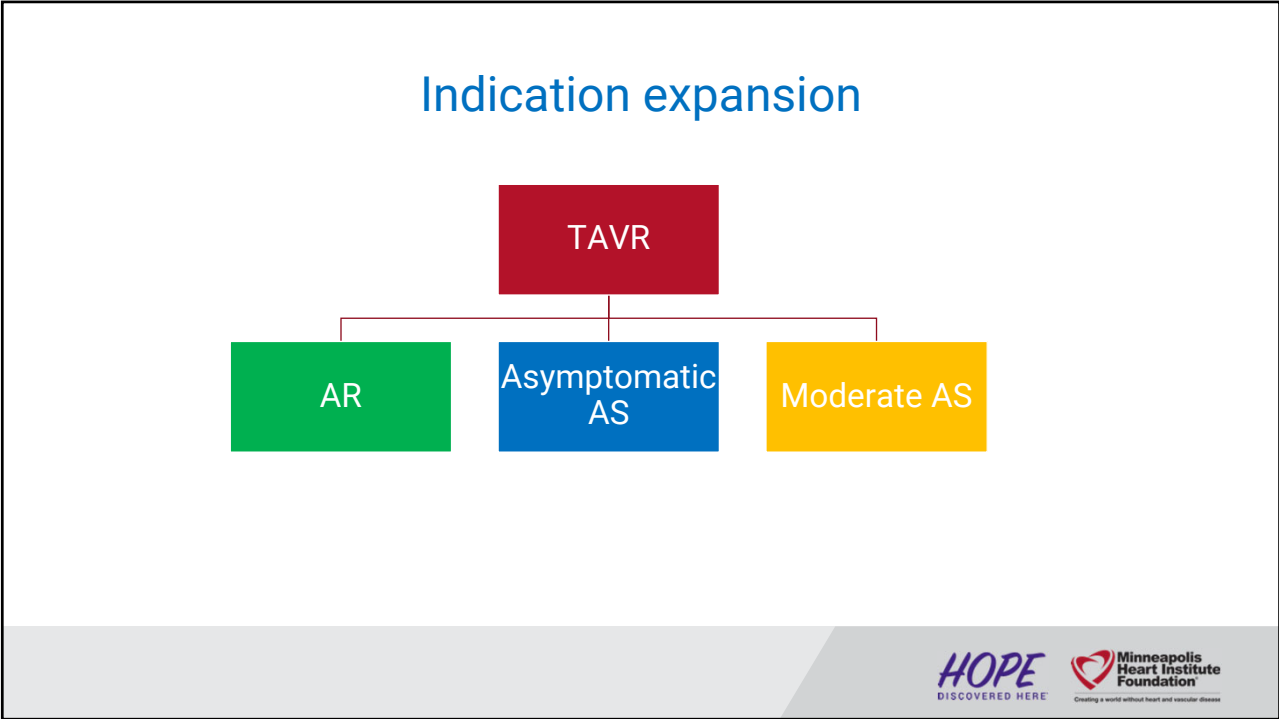
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TAVR Approved for All risk cases

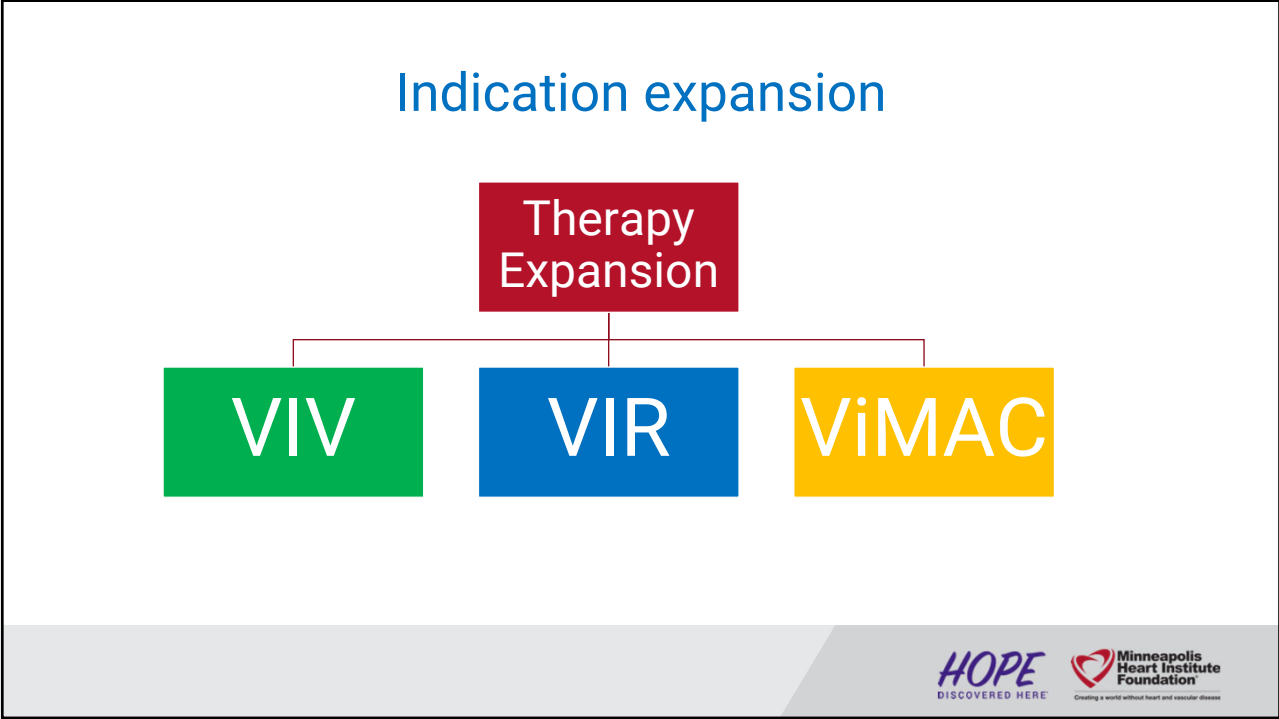
2019 ACC

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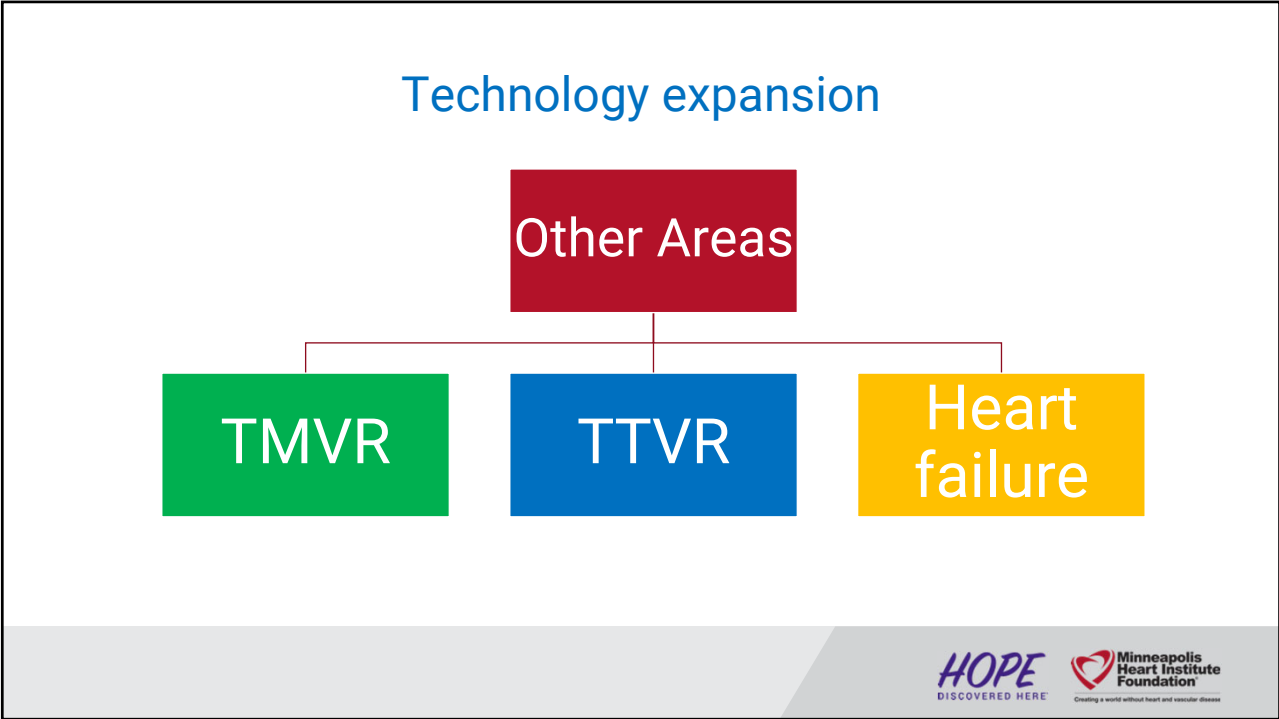
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Role of Surgery in the treatment of valve disease?



Surgery is always second best. If you can do something else, it's better. Surgery is limited. It is operating on someone who has no place else to go.

— John W. Kirklin —

AZ QUOTES

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Role of Surgeon and Surgery: Wider and critical

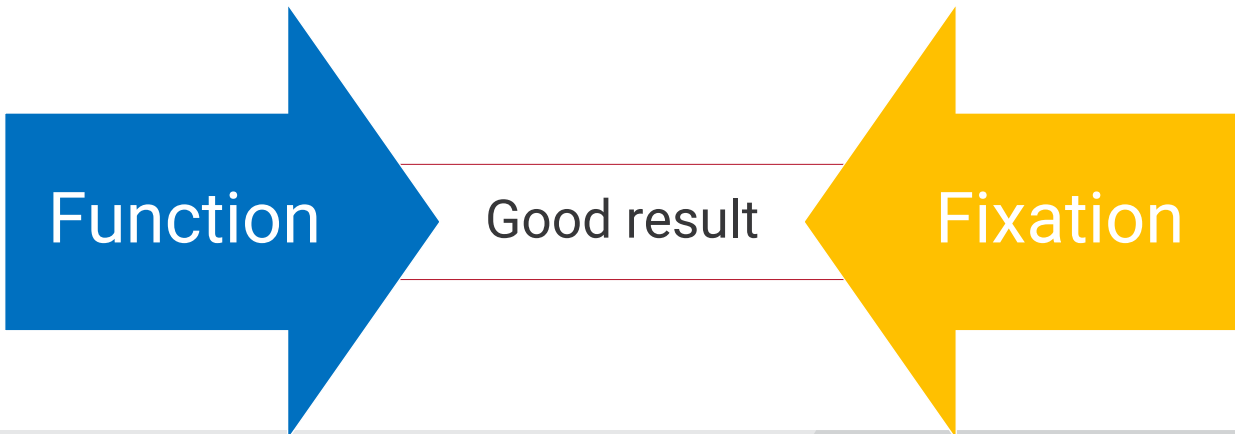


Surgery will continue to play an important role in management of valve patients



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When is Surgery needed?



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Early TAVR failure

- Uncommon
- Better Devices and delivery systems
- Imaging allows us to select appropriate patients
- Gray Zone: Anatomy and Risk profile

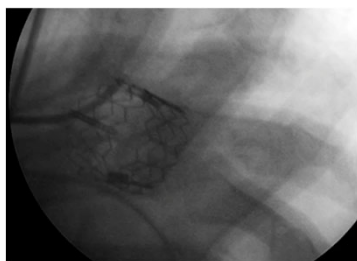


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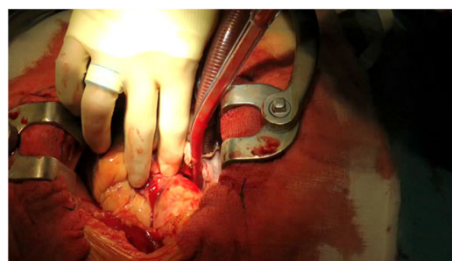
Coronary Obstruction



Acute Embolization



Annular Injury



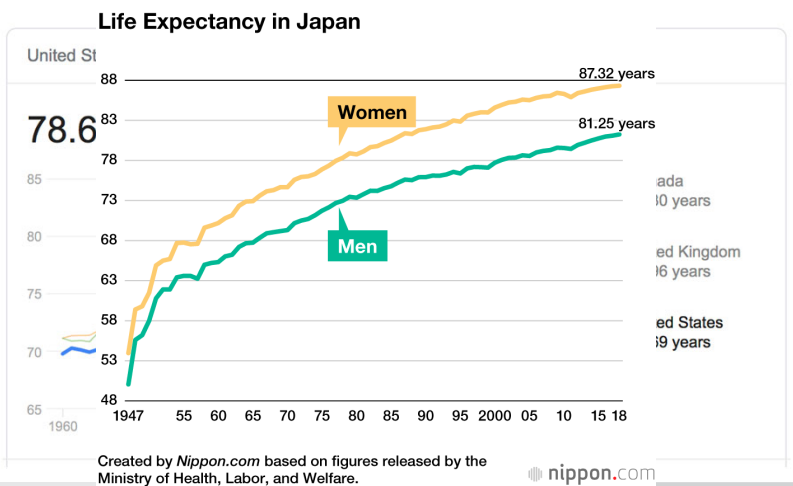
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Lower risk patients and increasing life expectancy

More patients will present with TAV failure



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Mick Jagger Dances 6 Weeks After TAVR on Instagram

By Adam Pick on May 22, 2019

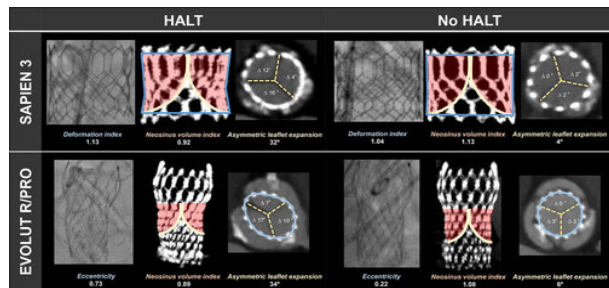
Ya gotta love this...

Just 6 weeks after transcatheter aortic valve replacement surgery, Mick Jagger posts this video at Instagram. As you will see in the video, Jagger is strutting all the great dance moves he has entertained us with for the past 57 years as the lead singer of The Rolling Stones.



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TAVR deformation & Degeneration



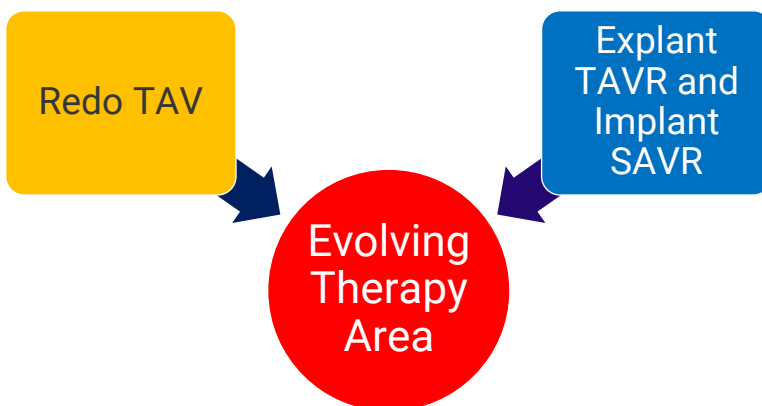
- Degree of oversize**
- Calcification
- Risk of Under-expansion
- Interaction with surrounding anatomy

Miho Fukui. Circulation. Deformation of Transcatheter Aortic Valve Prostheses: Implications for Hypoattenuating Leaflet Thickening and Clinical Outcomes, Volume: 146, Issue: 6, Pages: 480-493, DOI: (10.1161/CIRCULATIONAHA.121.058339) Fukui M, Sorajja P, et al



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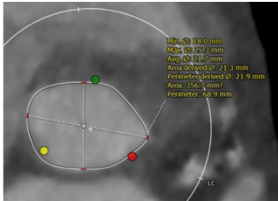
TAVR Failure: Treatment options



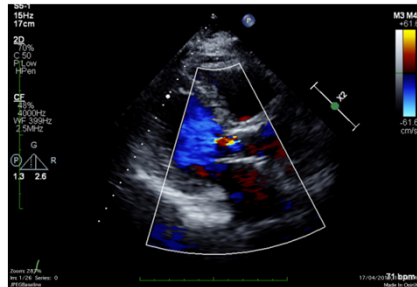
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Case Example

Patient Information	
Age	75
Gender	F
STS Score	4.3



February 2017
TAVR SAPIEN 3 23
Uneventful



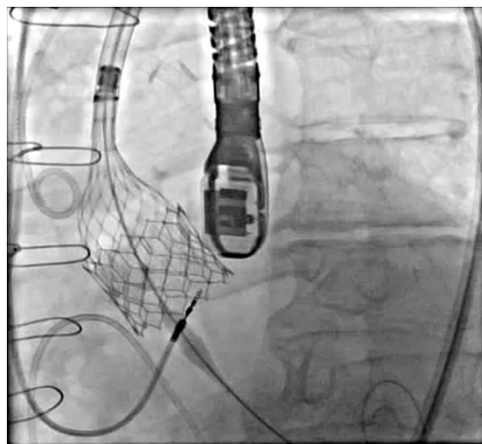
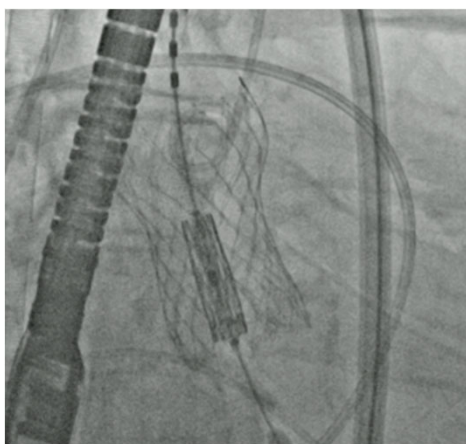
February 2022
Increased Gradients,
Symptomatic Patient

Surgery or Another TAV?



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Appears simple! But is it?

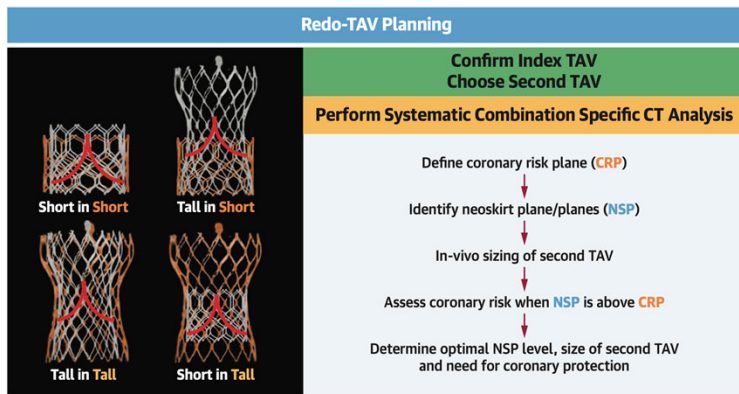


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A Guide to Transcatheter Aortic Valve Design and Systematic Planning for a Redo-TAV (TAV-in-TAV) Procedure



CENTRAL ILLUSTRATION Step-by-Step Redo Transcatheter Aortic Valve Planning



Bapat VN, et al. JACC Cardiovasc Interv. 2024;17(14):1631-1651.

CRP = coronary risk plane; CT = computed tomography; NSP = neoskirt plane; TAV = transcatheter aortic valve.

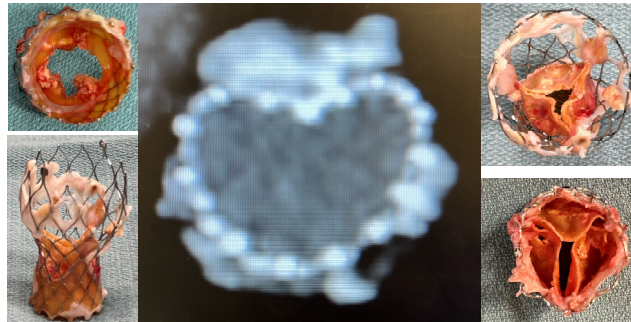
Bapat VN et al
JACC Int 2024: Vol 17:



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When we consider surgery?

- Infective endocarditis
- Additional issues: other valves, coronaries, PV leak
- **When Redo-TAV is not feasible**
- **When Redo-TAV is not a good strategy for lifetime management**
- Early structural failure of TAV devices and PPM



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Fukuhara et al
Adult

Surgical explantation of transcatheter aortic bioprostheses: Results and clinical implications 2019

Shinichi Fukuhara, MD, Alexander A. Brescia, MD, MSc, Suzuna Shiomi, BS, Carlo M. Rosati, MD, Bo Yang, MD, Karen M. Kim, MD, MSc, and G. Michael Deeb, MD

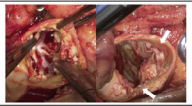
ABSTRACT

Objective: Despite the rapid adoption of transcatheter aortic valve replacement (TAVR) and worldwide interest in its implantation, TAVR valve explantation has not been well described.

Methods: We retrospectively reviewed 1442 consecutive patients who underwent a TAVR procedure between 2011 and 2019, in which TAVR explantation was performed in 15 patients (1.0%). In addition, 2 patients from outside institutions also underwent TAVR explantation at our institution. We reviewed the clinical details of these 17 patients.

Results: The frequency of TAVR explant increased over time from 0 to 1 during the period from 2011 to 2015 to 6 in 2019. The mean age was 73.0 ± 9.3 years. The majority of patients (88.2%) were in New York Heart Association functional class IV heart failure. The Society of Thoracic Surgeons Predicted Risk of Mortality score was significantly higher at the time of explantation than at the time of the original TAVR (3.5% vs 9.9%; $P < .001$). The indication for explantation included structural valve degeneration (23.5%), severe paravalvular leak (41.2%), TAVR procedure-related complications (23.5%), endocarditis (5.9%), and bridge-to-definitive surgery (5.9%). Neointimalization of the TAVR valve into the aortic wall requiring intense aortic endarterectomy was noted in all 5 of the TAVR valves older than 1 year, in which 2 (40%) required unplanned aortic root repair. There were 2 (11.8%) in-hospital mortalities.

Conclusions: Surgical TAVR valve explant is increasing and may become common in the near future. The clinical effects of explanting chronically implanted valves with the potential need for aortic repair is not negligible. These data should be used to more appropriately select TAVR candidates as TAVR practices expand into younger and lower risk patients. (*J Thorac Cardiovasc Surg* 2020; ■■■■■)



A 53-year-old balloon expandable device and post-device explant of disintegrated aorta.

CENTRAL MESSAGE
With an increasing frequency of surgical transcatheter valve explantation, judicious clinical judgment is crucial in appropriately selecting transcatheter valve therapy as an initial valve strategy.

PERSPECTIVE
The evolution of TAVR over the past decade has been unprecedented resulting in an increase of surgical TAVR explantation scenarios. The clinical impact of explanting older valves with the potential need for unplanned aortic repair is not negligible. Providers should be judicious in selecting TAVR candidates as it continues to expand into lower risk and younger candidates.

See Commentary on page XXX.

1442 TAVR (2011-2019)

Explant: 15 Mean age: 73 (SD 9.3 yrs)

Higher STS PROM at explant: 9.9



Indications:

- PVL 41.2%,
- TAVR complications 23.5%,
- SVD 23.5%**,
- Endocarditis 5.9%

Root replacement: 2 patients

11.8% in-hospital mortality

Fukuhara S et al. *J Thorac Cardiovasc Surg* 2020;
DOI: <https://doi.org/10.1016/j.jtcvs.2019.11.139>


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Hirji SA, Kaneko T et al. *JACC* 2020 :76:1848-59

Incidence, Characteristics, Predictors, and Outcomes of Surgical Explantation After Transcatheter Aortic Valve Replacement – A Population-Based, Nationally Representative Analysis


All US Patients Undergoing Index TAVR Procedure
(CMS Data 2012-2017)

N=132,515



2020

Surgical Explantation
0.2% (N=227)



Median Time:
212 days (IQR 69-398)

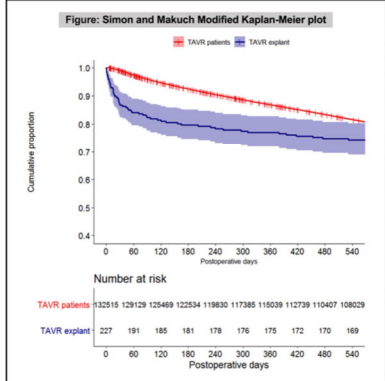
↓

≤30 Days: **8.8%**
≤6 Months: **46.3%**
≤1 year: **70.9%**



→

30-Day Mortality: **13.2%**
1-Year Mortality: **22.9%**

Figure: Simon and Makuch Modified Kaplan-Meier plot

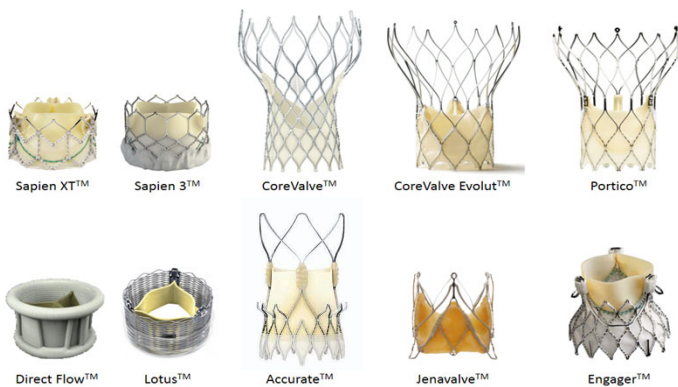


Hazard Ratio for Surgical Explantation
4.03 [95%CI:1.81 – 8.98]

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Consideration 1: TAVI valves vary in Construct and interaction with native anatomy

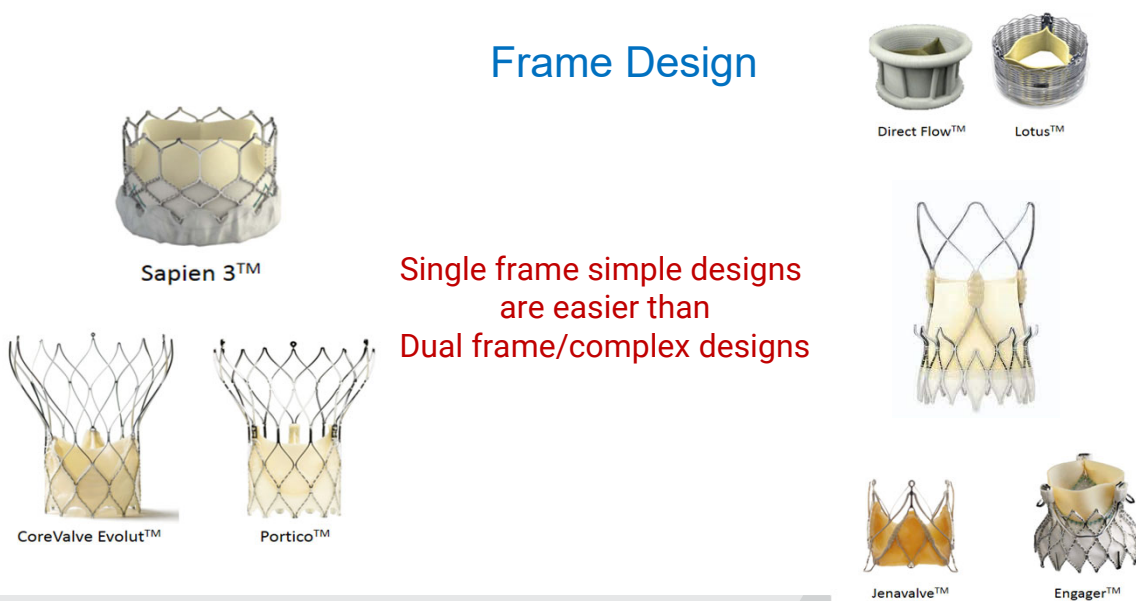


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Frame Design



Single frame simple designs
are easier than
Dual frame/complex designs

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Frame Design

Short vs Tall frames

The image displays six different transcatheter aortic valve prostheses (TAVI) with various frame designs. On the left, there are two columns of three valves each: Sapien XT™ and Sapien 3™ (top row), Direct Flow™ and Lotus™ (middle row), and Jenavalve™ and Engager™ (bottom row). On the right, there are two valves in the top row: CoreValve Evolut™ and Portico™, and a single valve centered in the bottom row. The valves are shown in various orientations, highlighting their unique frame structures and leaflet designs.

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Consideration 2: Anticipating challenges

Pre-operative CT analysis

- Strategy for myocardial protection
- Relationship with surrounding structures
- Possible procedure required
 - AVR
 - AVR with Root enlargement
 - Root replacement
 - Mitral involvement

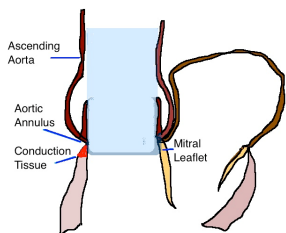
The image is a cross-sectional CT scan of the chest, focusing on the aortic root. A red vertical line and a yellow horizontal line are overlaid on the scan to indicate the level of the valve annulus. The scan shows the aortic root, the surrounding myocardium, and the relationship with other structures like the coronary arteries and the mitral valve.

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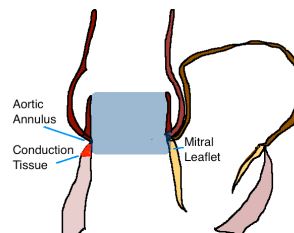
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Surrounding Structures: Planning and preventing injury



1. Plan Clamping and Aortotomy**
2. Dissect from aorta carefully
3. Use ice slush to soften the stent frame
4. Easier to separate THV from native aortic leaflets



1. Annular damage?
2. LVOT flare**
3. Mitral leaflet proximity
4. Conduction tissue proximity
5. Injury to aorta while explanting

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Explantation of Evolut R after 5 years

Evolut Explant 5
years

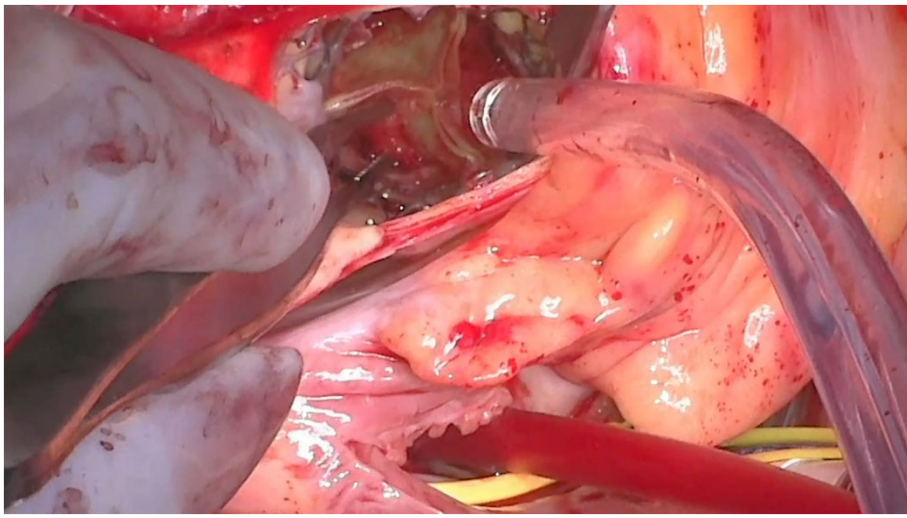
Vinayak Bapat

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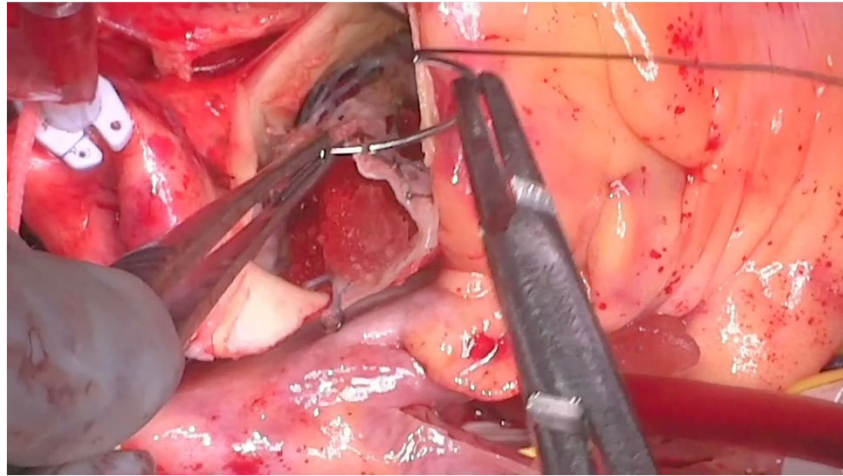
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Use Ice slush to Soften the stent frame



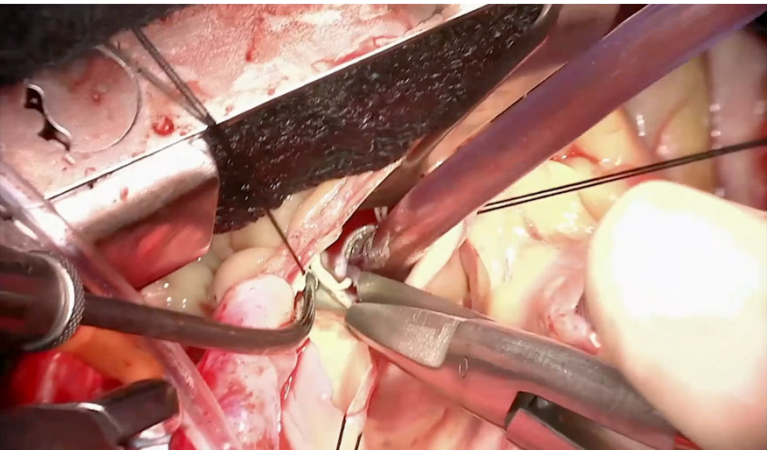
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Use Sutures to snare the outflow in a tubing



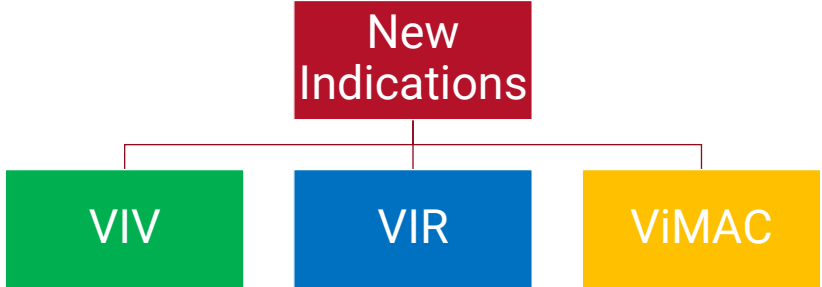
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Crocodile Roll




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Indication Expansion

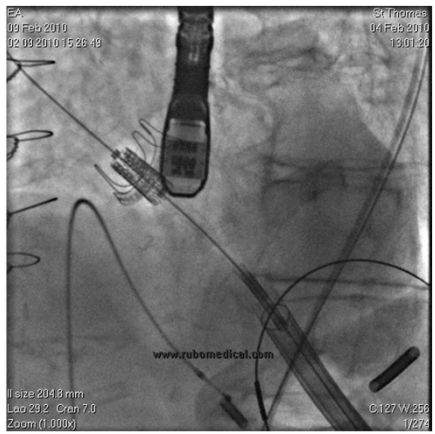




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Aortic VIV



Circular shape
Perfect anchoring
Good visualization under Xray

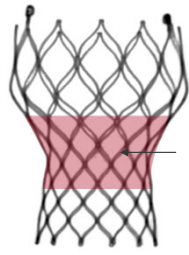


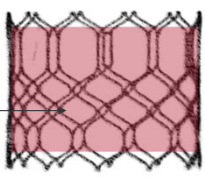
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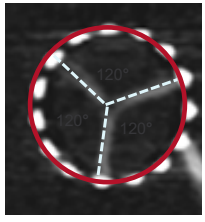
THV deformation after VIV

In vitro
(Ideal)

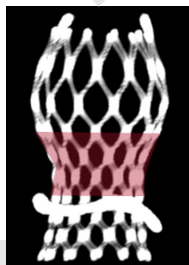



Functional portion



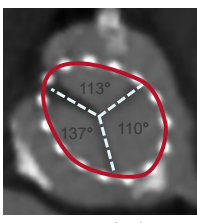


In Vivo
~Real world~







Under-expansion



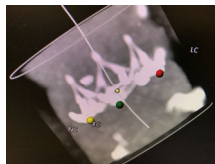
Eccentricity

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Case example

- 64 Year =old Patient
- COPD, Obese
- SAVR: Trifecta 19 (2017)
- Shortness of breath returns in 14 months
- Initially blamed at worsening COPD
- Valve Gradients increasing slowly
- No HALT



08:22
Trifecta - Size: 19

Metric Imperial Reset

Height: 152 cm
Weight: 96 kg

Calculate

Consider Severe PPM based on Reference EOA

BMI:	41.55	kg/m ²
BSA:	2.01	m ²
iEOA:	0.70	cm ² /m ²

Additional Assessment

Home Optimal Valve Sele... Check Valve Funct... Additional Resour...

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Plan?

- High risk for redo- surgery?
- VIV with suboptimal result?
- Trifecta 19
Non fracturable
True ID = 17
ER = 23

08:30
Stented Trifecta

Abbott Pericardial leaflets
Leaflets sutured outside the stent

Fluoroscopic Markers
Stent Frame

19 21 23 25 27
29

08:30
Size: 19

Stent ID 17 Height 15 True ID 17

Non-Fracturable
True Balloon Size: N/A

THV CURRENT THV ARCHIVED

08:30
THV Selector: Current

Acurate NEO USE WITH CAUTION
Allegra USE WITH CAUTION
Evolut 23
Portico USE WITH CAUTION
S3 20

Use With Caution

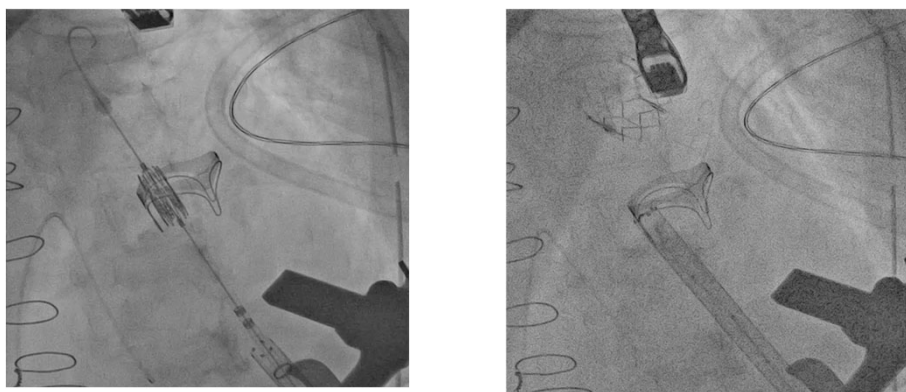
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- Decided to perform VIV
- 6 months – NYHA class 3-4
- Airlifted to our Hospital
- Underwent, explant and Root enlargement with Inspiris 23



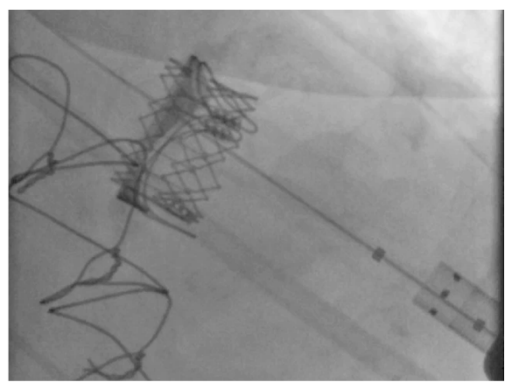
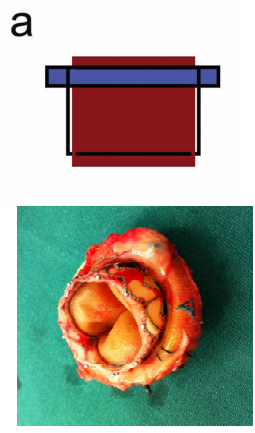
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Mitral VIV: different challenges



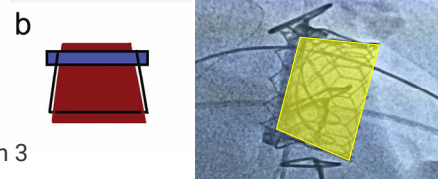
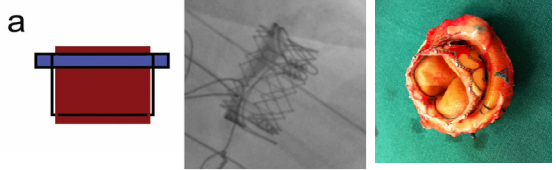
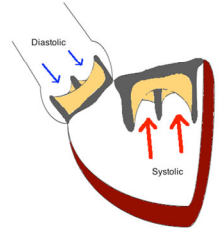
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Very unique indeed!



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High Closing pressures



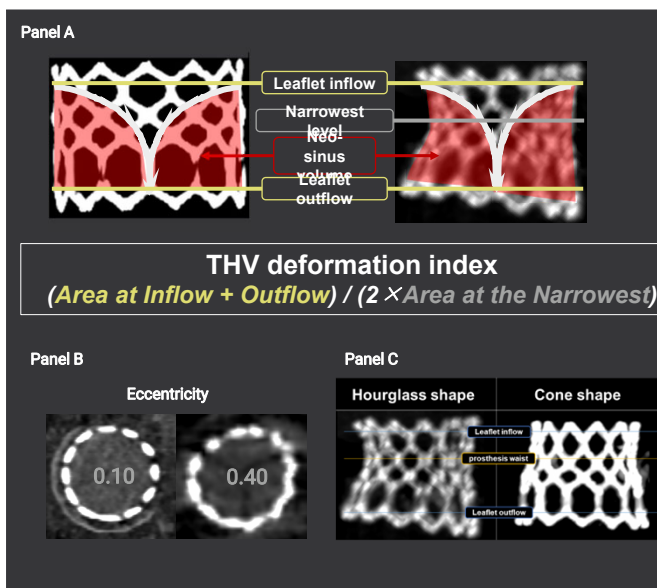
Reduced incidence with Sapien 3

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MVIV and deformation

1. Degree of oversizing and deformation
2. Risk of HALT
3. Need for anticoagulation
4. Good Follow up

Valve modification
Intermediate valve sizes!

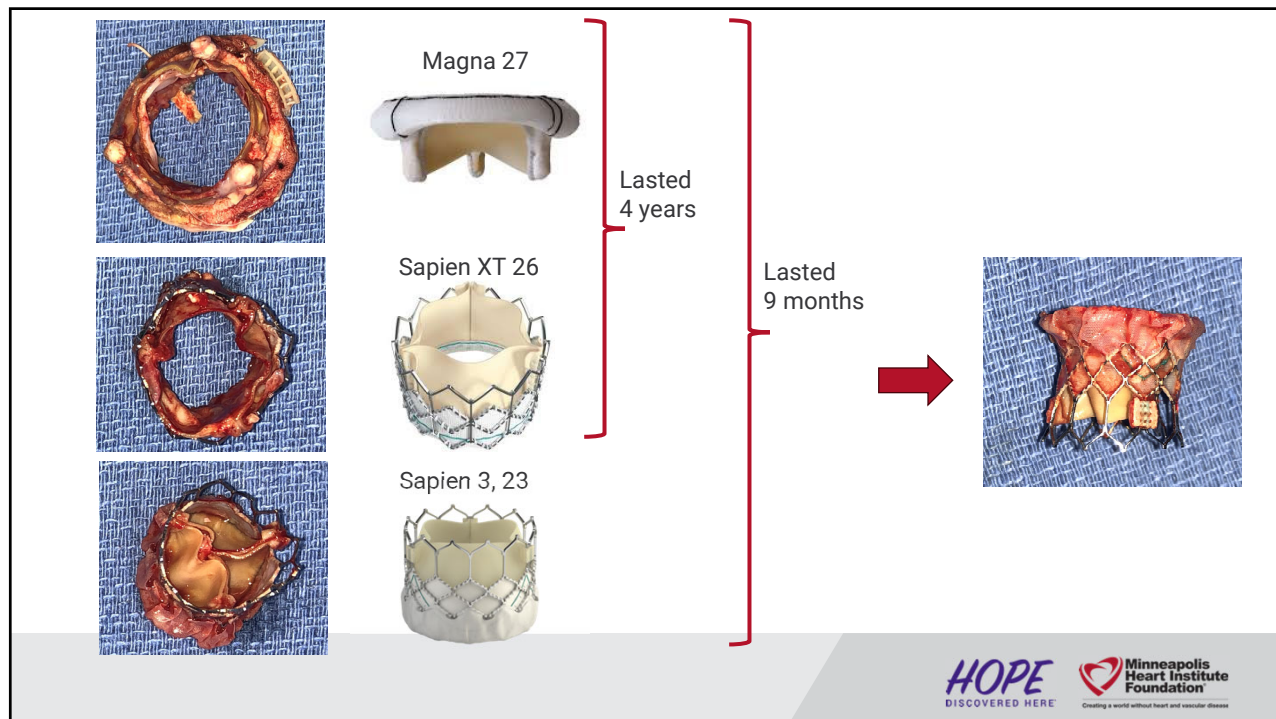


Fukui, Bapat et al, Eurointervention

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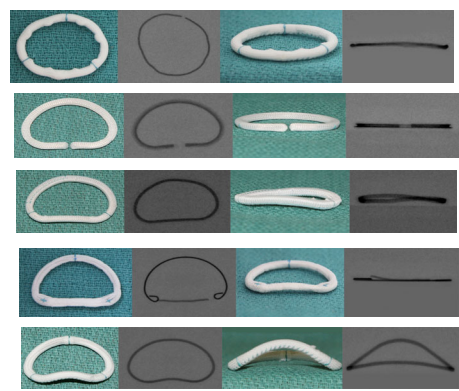
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Mitral Valve in Ring: more complicated

- Shape - Complete/Incomplete/Bands
- Rigidity - Rigid/Semirigid/Flexible
- Radio opacity- good/Intermediate/ none
- Edwards – 5 rings
- Medtronic – 6 rings
- St Jude – 4 rings
- Sorin – 6 rings
- Sizes – 24 to 40



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Circular shape
 Minimal deformation

Avoid embolisation





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Semirigid Ring	Rigid Ring	Complete Band	Incomplete Band
Sorin Memo 3D	St. Jude Rigid Saddle Ring	Duran Ancore band	Cosgrove Band
Anchor. ✓ Circularity ✓	Anchor. ✓ Circularity ✗	Anchor. ?? Circularity ✓	Anchor ✗ Circularity ✗

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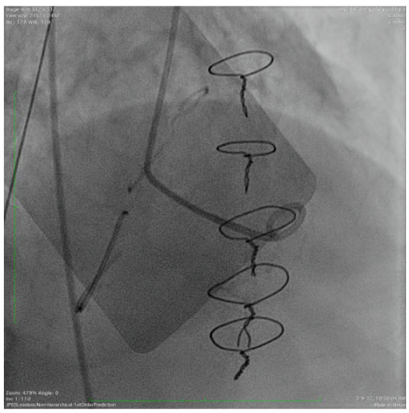
Suitable	Intermediate	Unsuitable
<ol style="list-style-type: none"> 1. Memo 3D 2. Memo 4D 3. Physio 1 4. Physio 2 5. CG Future Ring 6. Simulus Semirigid Ring * 7. Simuform Semirigid Ring* 8. Seguine <p>* Simulus is now rebranded as Simuform Semirigid ring</p>	<ol style="list-style-type: none"> 1. Sovering 2. Annuloflex 3. Duran Ancore Ring 4. Simulus Flexible ring 5. SimuPlus Flexible Ring 6. Tailor Ring 	<ol style="list-style-type: none"> 1. Annuloflo 2. IMR 3. Geoform 4. Myxo 5. Classic CE ring 6. Profile 3D 7. Rigid Saddle 8. Incomplete Bands <ol style="list-style-type: none"> a. Cosgrove band b. Physioflex Ring c. Duran Ancore Band d. CG future Band e. Simulus Band f. SimuPlus Band g. Tailor Band

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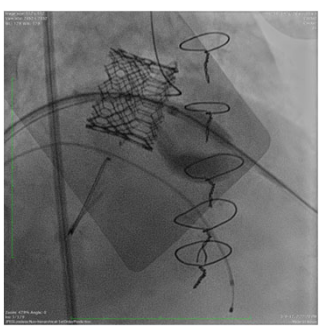
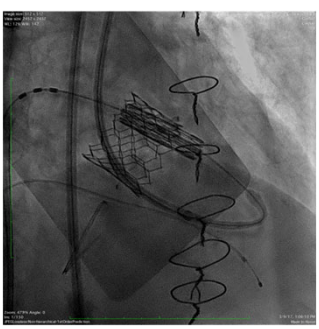
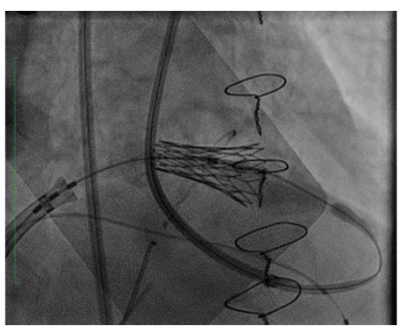
Case example: Unsuitable Ring = Suboptimal result

- 76-Year old, female patient
- NYHA class 3
- Past history:
 - MR and TR
 - Open heart surgery (8 years ago)
 - Mitral repair (Incomplete band)
 - Tricuspid repair (Rigid ring)

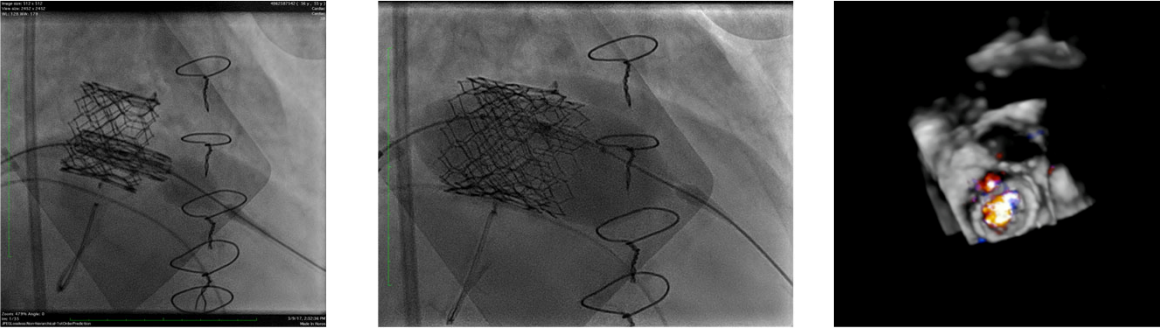


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Mitral VIR



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Underwent Surgery Next day with successful explant and good outcome

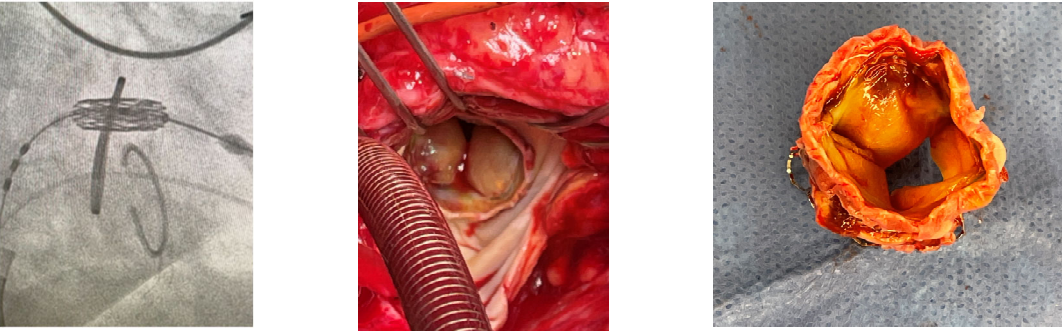
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Fixation is not the only important thing!

Long term function is also critical



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Mitral Annular Calcification

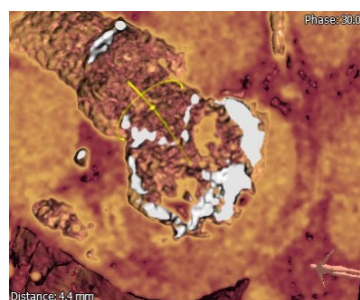
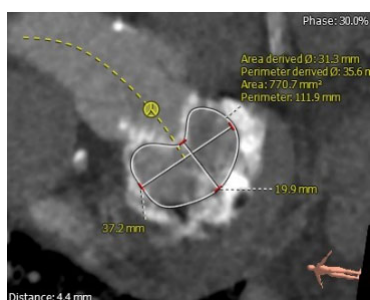


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Case Example: TAV in MAC



High Risk
Morbid Obesity
Oxygen

- Area 770mm², Perimeter 111
- Scattered “popcorn” calcium
- Greater asymmetry
- No support aorto-mitral curtain

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29 S3 with 5 cc extra

29mm S3 #2



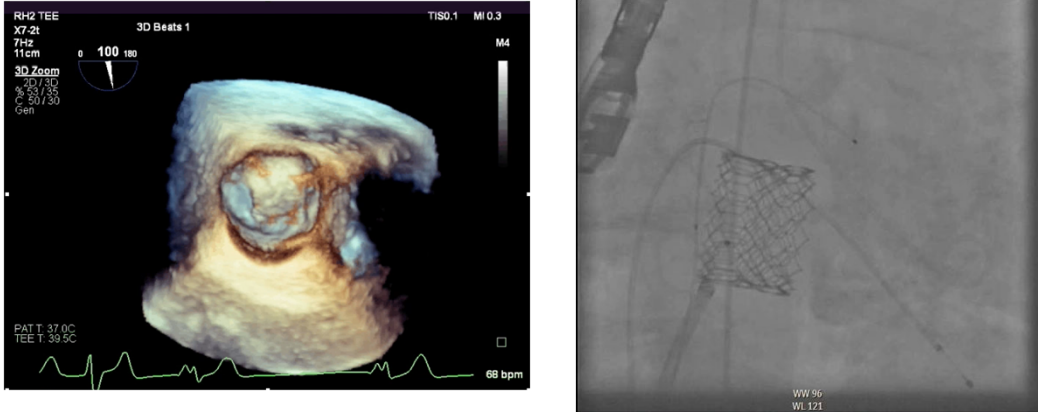
29 mm Edwards Sapien S3

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Result !

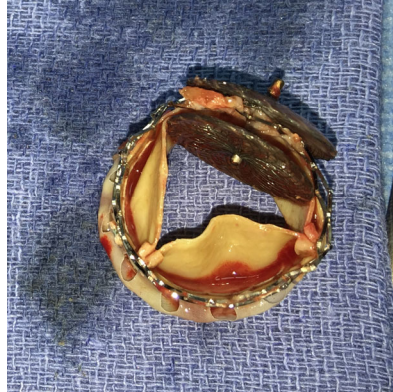
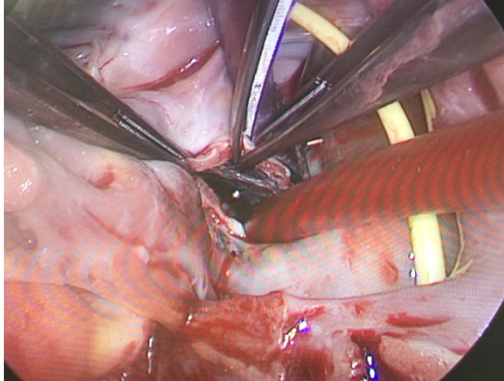


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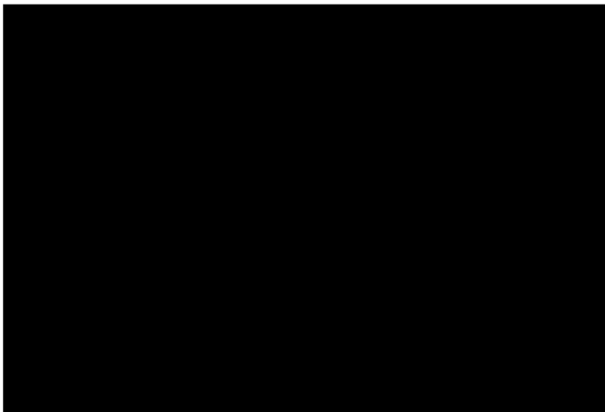
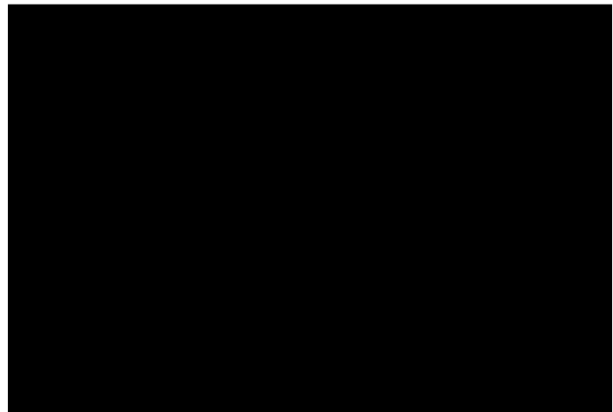
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Removal of the Septal closure and TAVR device

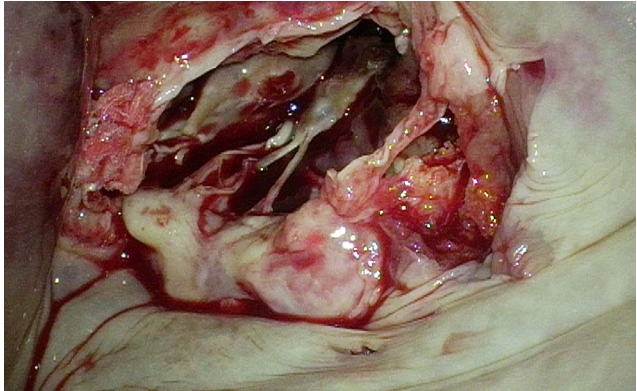


61



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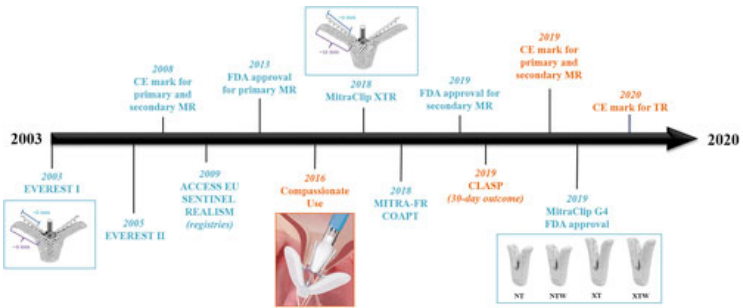
Annular Rupture



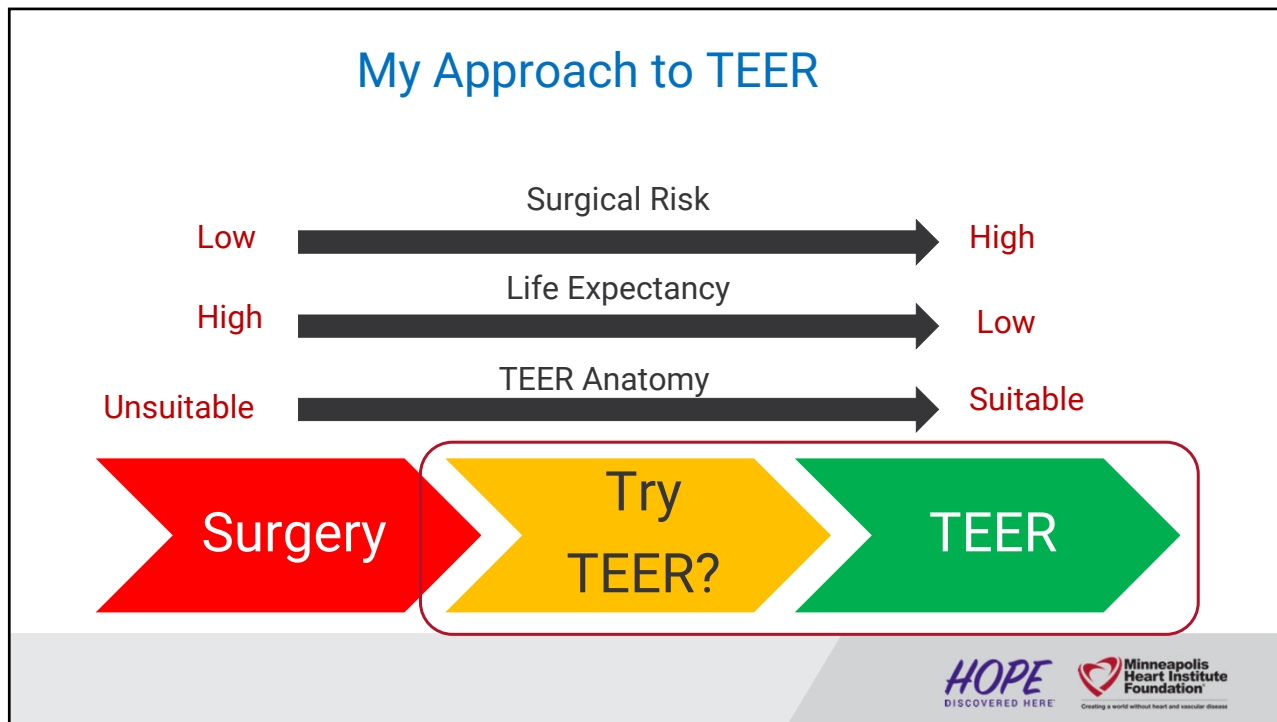
63

Mitraclip

- **Mitraclip:** Dominant device in this filed with excellent safety record
- Multiple iterations now available to facilitate 'ease of implant' and challenging anatomies



64



65

Case Example: Multivalve disease

- 88-year-old
- Severe MR, moderate to severe TR and moderate AS
- Low BMI, active but frail

Plan
Commercial Mitraclip
Enroll in Tricuspid trial
Observe AS

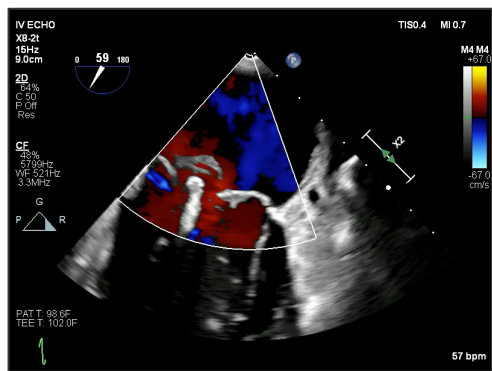
The echocardiogram images show the following technical details:

- Left Image (Mitral Regurgitation):** IV ECHO, XB 2t, 8.5cm, 114 Hz, 2D, 75% C 50, F Off, C on, PAT T: 98 BP, TEE T: 101.7F, 74 bpm.
- Right Image (Tricuspid Regurgitation):** IV ECHO, XB 2t, 8.5cm, 114 Hz, 2D, 75% C 50, F Off, C on, PAT T: 98 BP, TEE T: 101.7F, 67 bpm.

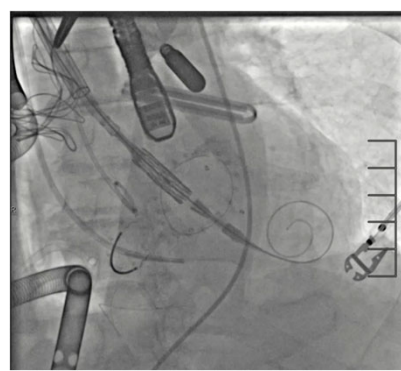
The bottom right corner contains the logos for **HOPE DISCOVERED HERE** and the **Minneapolis Heart Institute Foundation** with the tagline "Creating a world without heart and vascular disease".

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Procedure



Unsatisfactory result
Two clips deployed,
One SLD, Increase in MR

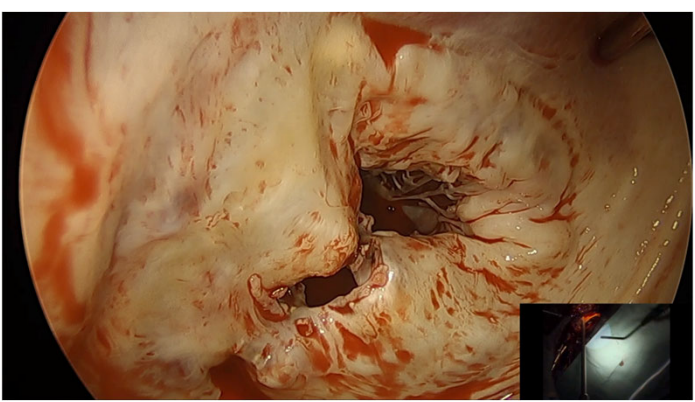
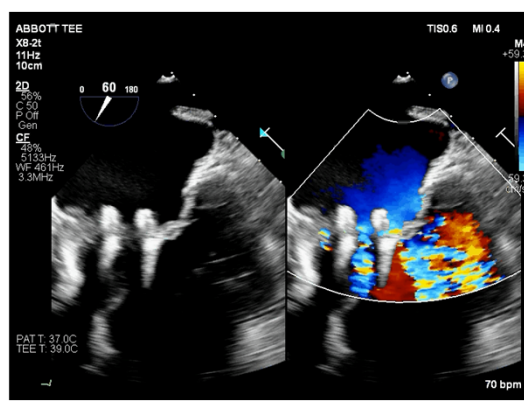


One month later

MVR,
TV repair,
on pump TAVR

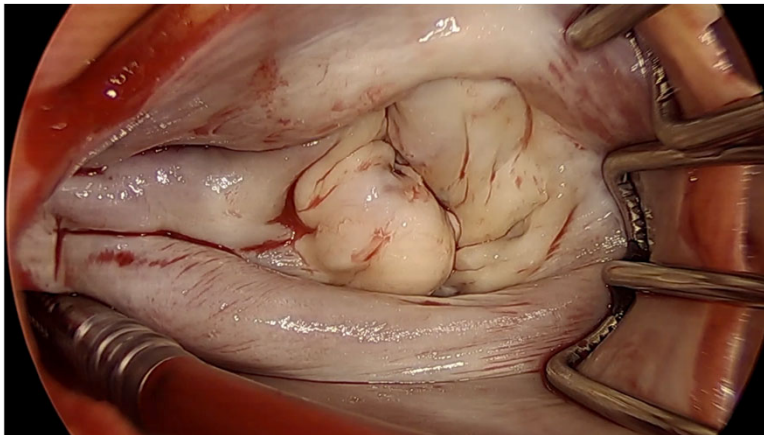
67

Failed Mitraclip



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Complex clefts and Barlow disease



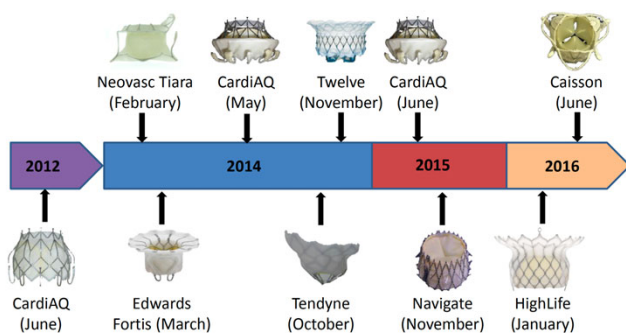
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TMVR

TMVR may provide opportunities to improve MR reduction and clinical outcomes in expanded patient populations

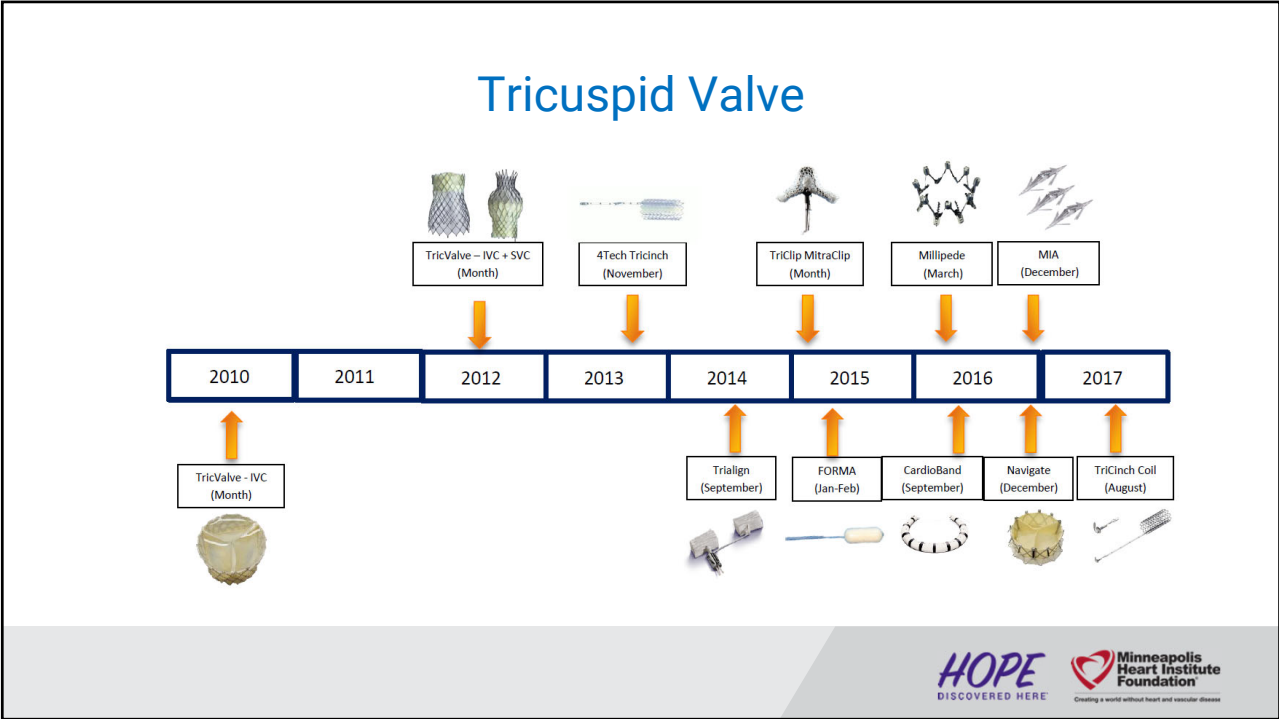


1. Alta Valve
2. Cardiovalve
3. Cephea
4. Innovalve
5. Saturn

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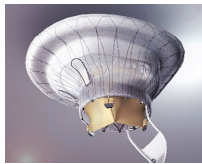


71

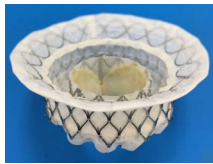
TMVR and TTVR examples



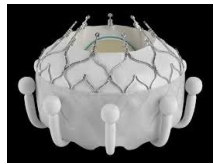
Navigate



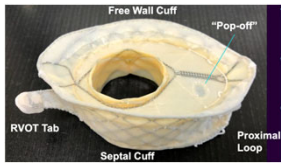
Lux



Intrepid



Evoque

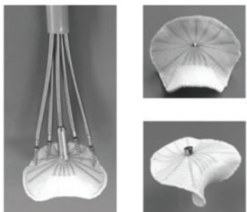

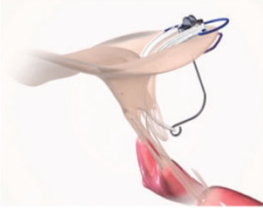



Vdyne

All devices have had complications necessitating Surgery

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Half Valve Concepts for Mitral Regurgitation

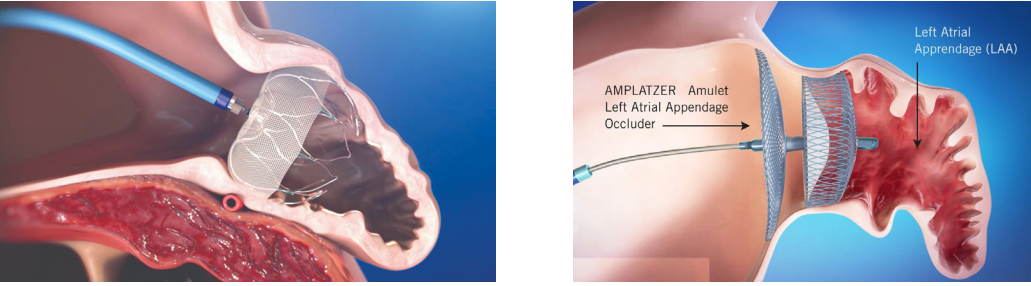
PLAR 	Sutra 
Mitral Butterfly 	Half Moon 

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Left Atrial Appendage Closure Devices



AMPLAZER Amulet Left Atrial Appendage Occluder

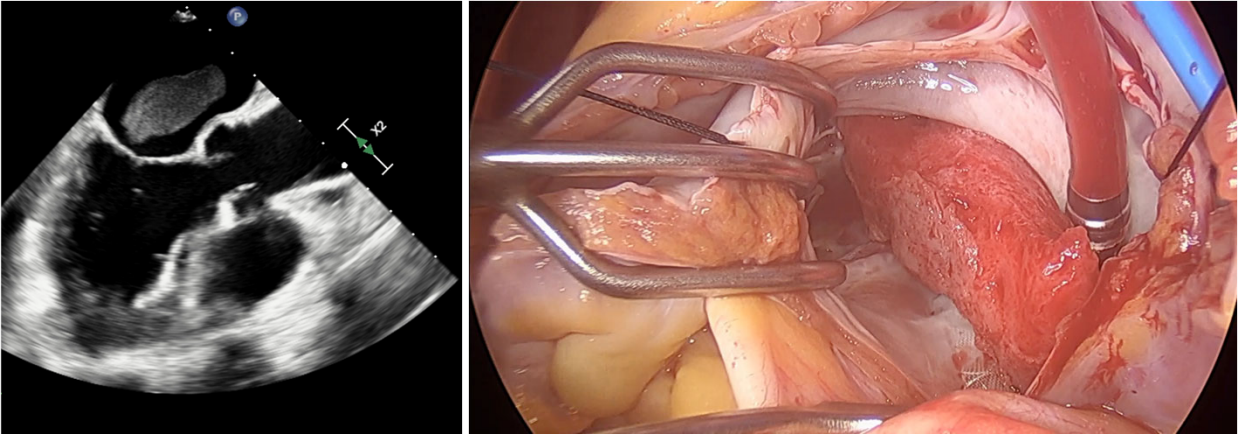
Left Atrial Appendage (LAA)

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Surgery




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Technology has limitations New Technology may not work as expected Hence, Proper selection and back up plan is critical



1. International TAVR-Explant Registry
2. International Cutting-Edge registry
3. Educational videos for explant

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Multiple Options to Treat Patients

Surgical options
Valve replacement
Valve repair

TAVR: 9 products
Both for AS and AR

Commercial
Mid Term results*

Commercial
Mid Term results*
Under Trial

TEER
TMVR
Chords

Harmony
Sapien, Venous P

Commercial
Mid Term results*
Under Trial

TEER
TTVR
Novel Concepts

Commercial
Early and Mid Term results*

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Choice can lead to confusion

Choice can introduce bias

Choice also allows 'Individualized approach'

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Challenge for next 2 decades

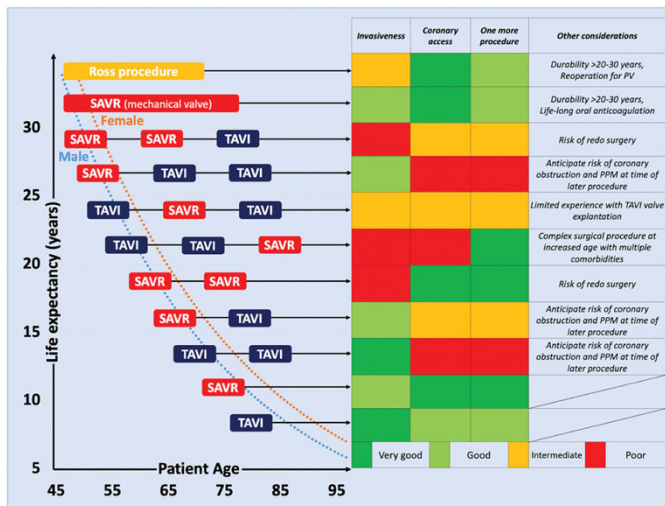
- Can we do it ➔ Should we do it?
- Robust follow up, especially in cases with suboptimal results
- Rediscussing cases in Heart Team meeting for next option

- Educating Surgeons – Transcatheter technology
- Educating Cardiologist – Surgical options

- Patient Education – Building confidence through robust results*



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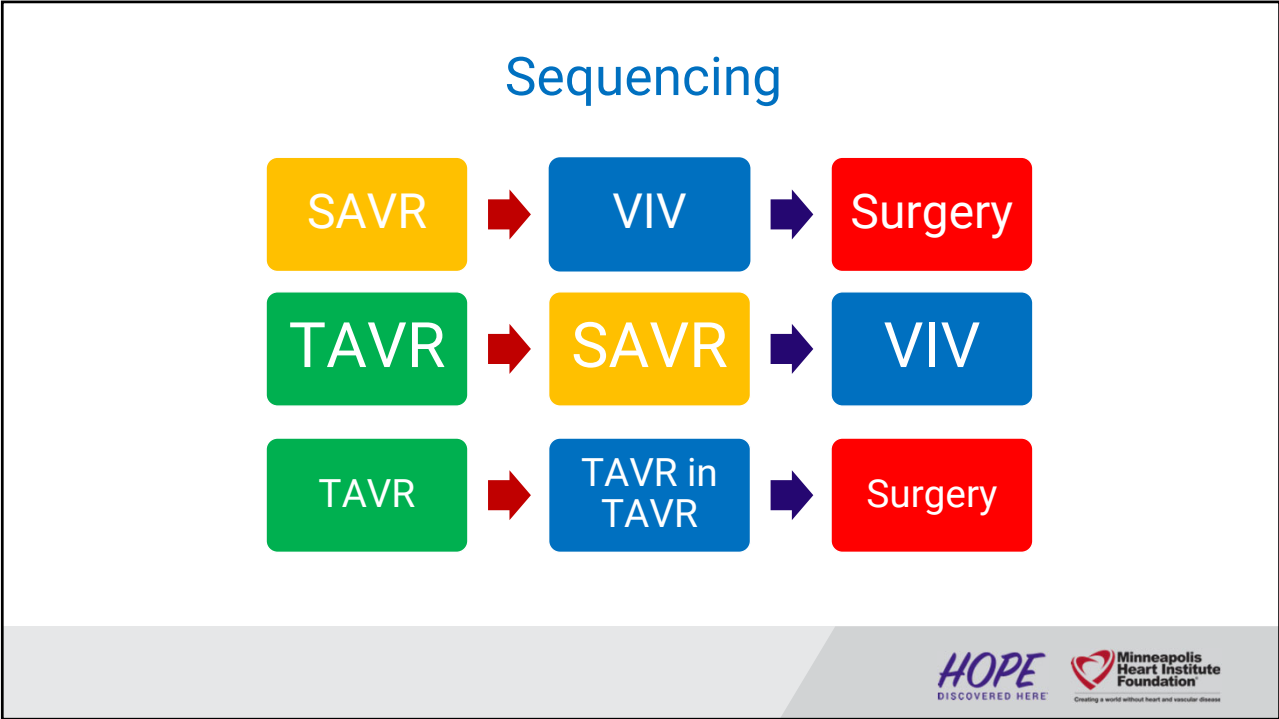
This is the BEST Guess

European Heart Journal (2022) 00, 1–26
<https://doi.org/10.1093/eurheartj/ehac105>

Stephan Windecker ^{1*}, Taishi Okuno ¹, Axel Unbehaun ^{2,3}, Michael Mack ⁴,
Samir Kapadia ⁵, and Volkmar Falk ^{2,3,6,7}



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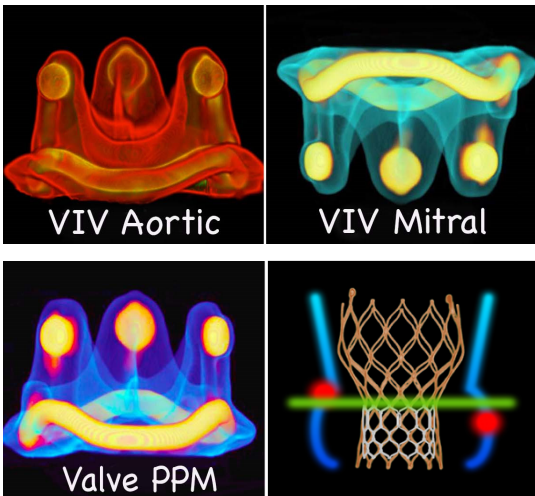


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What efforts are being made?

82



VIV Aortic **VIV Mitral**

Valve PPM


Joseph F. and Mary M. TAV
Fleischhacker Family Foundation

MHIF App Portfolio

Downloaded in >150 countries
Used >250,000 in 2023

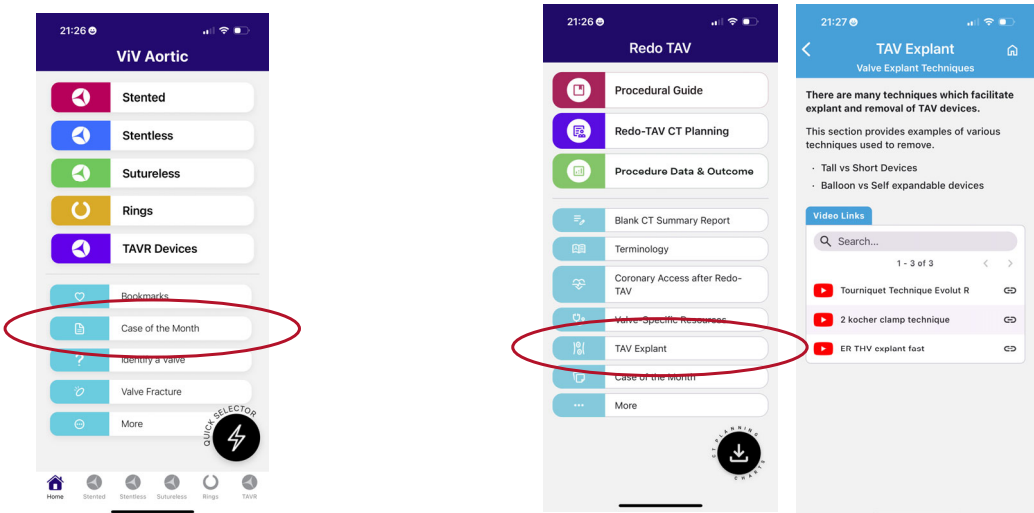
Free
Unbiased
Easy to follow

Case Selection
Case planning
Procedure



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App based learning and dissemination of Good Practice



Viv Aortic

- Stented
- Stentless
- Sutureless
- Rings
- TAVR Devices
- Bookmarks
- Case of the Month**
- Identify a valve
- Valve Fracture
- More

Redo TAV

- Procedural Guide
- Redo-TAV CT Planning
- Procedure Data & Outcome
- Blank CT Summary Report
- Terminology
- Coronary Access after Redo-TAV
- Valve Specific Resources**
- TAV Explant**
- Case of the month
- More

TAV Explant


Valve Explant Techniques

There are many techniques which facilitate explant and removal of TAV devices. This section provides examples of various techniques used to remove.

- Tall vs Short Devices
- Balloon vs Self expandable devices



Video Links

- Tourniquet Technique Evolut R
- 2 kocher clamp technique
- ER THV explant fost



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Working with Industry for better Products

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Research Team







1. National and International Presentations
2. Numerous Key publications
3. Research Projects

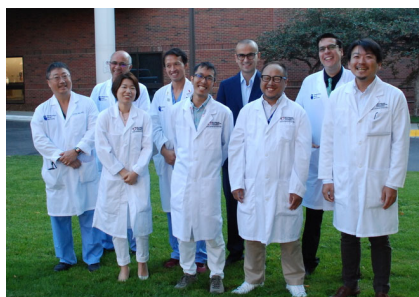



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Elevating Clinical Care



Colleagues in Cardiac Surgery
Abbott Northwestern and United Hospitals



Cardiology Partners and Research Team at MHIF



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Valve Center

- Combine Patient consultation
- Valve team discussion of each case
- Healthy debate
- Mutual Respect
- Confidence in introducing novel technology



Patients have all possible options under one umbrella



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Thank YOU