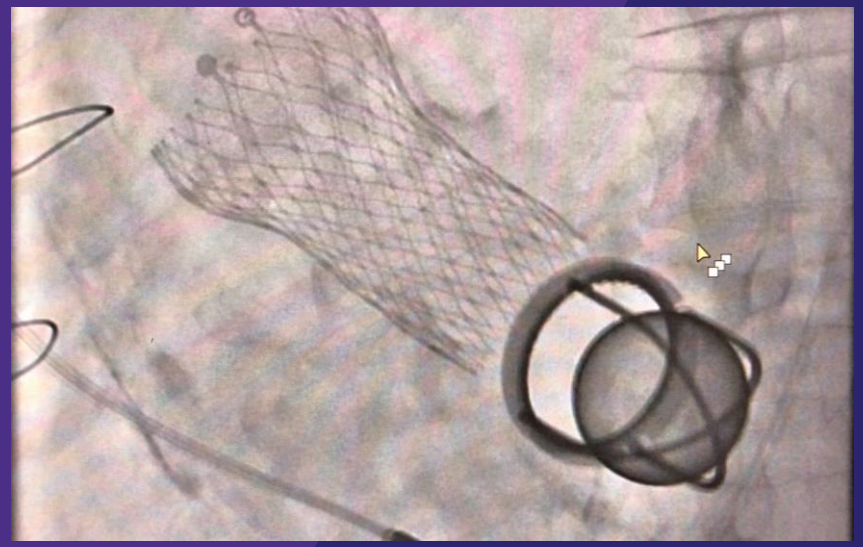
SAVR is the best, now and for lifetime management…



Vinayak Bapat, FRCS.CTh

Cardiac Surgeon and Chair of Cardiothoracic Surgery
Minneapolis Heart Institute®

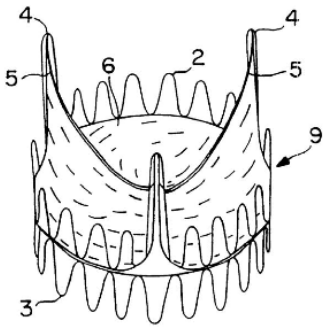
HOPE DISCOVERED HERE

Minneapolis Heart Institute Foundation
Creating a world without heart and vascular disease

Disclosures

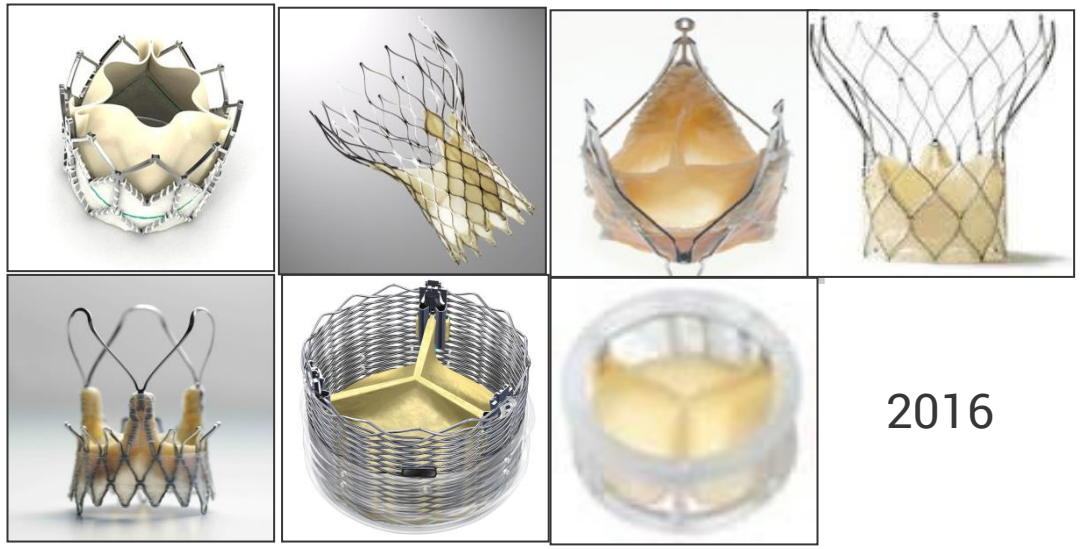
- Consultant / Honorarium / Grants
  - Edwards Lifesciences
  - Medtronic Inc
  - Boston Scientific
  - Abbott
  - 4C
  - Anteris

On top of this……Rapid ascent of TAVR



1980's

2002



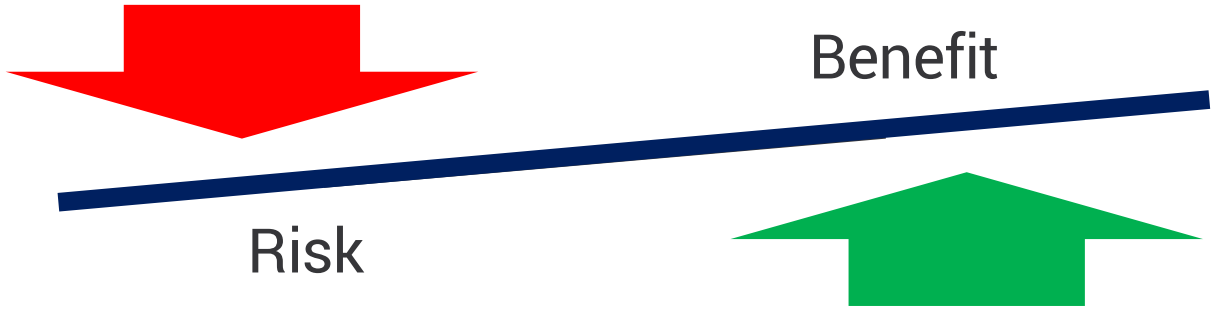
2016

To a refined predictable procedure

- Embolic protection devices
- PV leak solution
- CT analysis software
- Recapturable valves
- Small Profile delivery systems
- Early discharge
- Valve in Valve
- Valve in MAC
- Development of other Transcatheter technologies

TAVI approved for all risk profiles - 2019

Inoperable, high-risk, Intermediate and Low risk patients



Is the TAVR new Gold Standard for AS for all patients?

NO

Myth 1: All TAVRs will function same !

- Trials on which the approval was given

PATIENTS IN THE TRIALS

- Symptomatic Aortic Stenosis
- Tricuspid Valve
- >65 years old
- No/minimal LVOT Calcium
- Transfemoral access
- Aortic Valve Anatomy Suitable for TAVR
- Majority Male
- None or Mild CAD
- Relatively Normal LV Function

NOT ENROLLED IN TRIALS

- Other valvular disease
- Aortic Regurgitation
- Bicuspid Valves
- Unsuitable Valve Anatomy
  - LVOT Calcium
  - Low coronary arteries
- Significant Peripheral Vascular Disease
- Many patients <65 years
- Complex CAD
- Severe LV Dysfunction

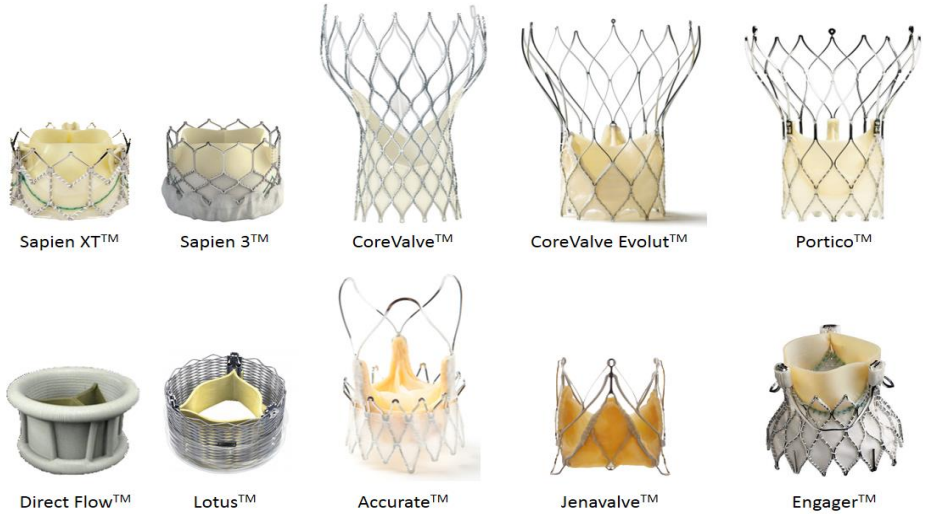
But TAVR designs are evolving constantly

TAVR discontinued

- Lotus
- Directflow
- Engager
- Sapien XT
- CoreValve

SAVR discontinued

- Trifecta
- Mitraflo?



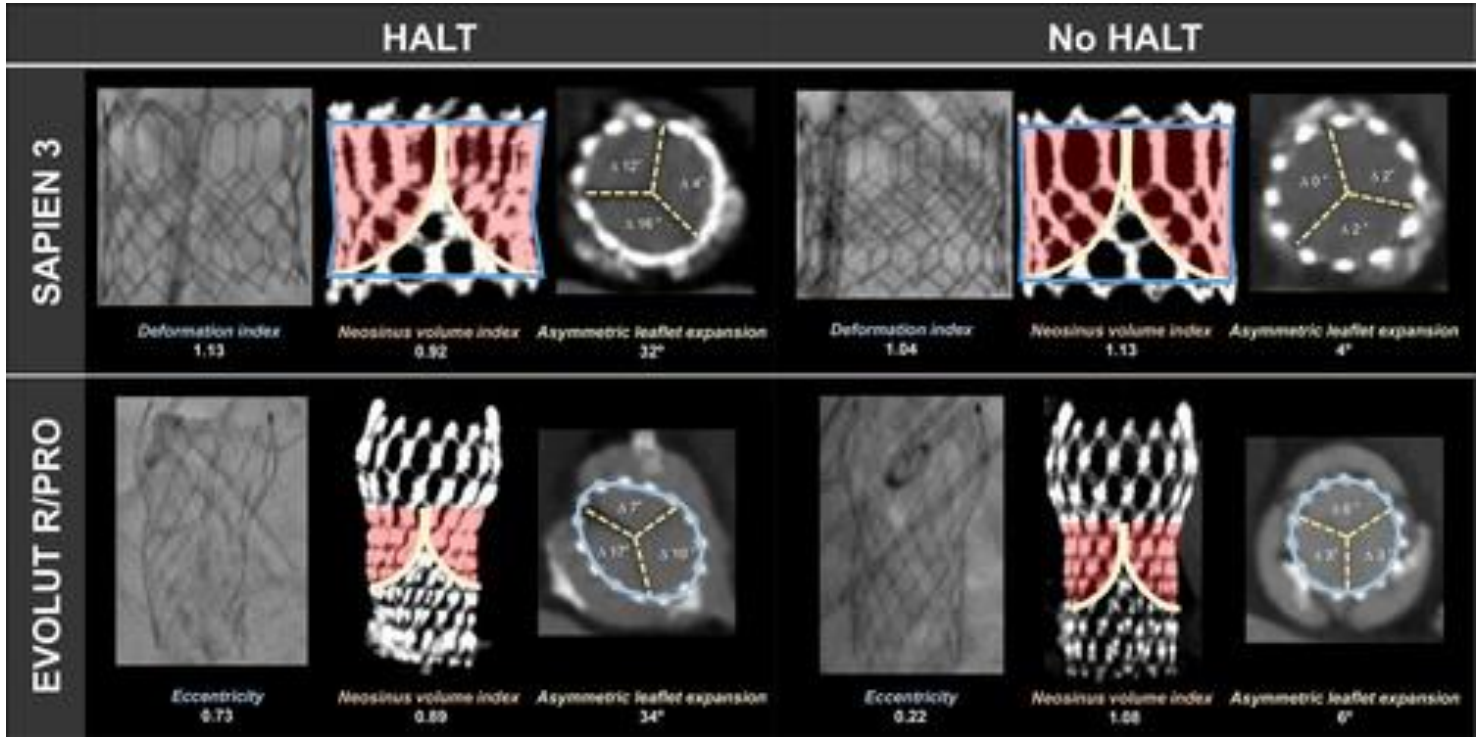
And now we have X4, FX, Navitor 😀

If TAVR is so good, then WHY CHANGE???

Myth 2: Circularity does not affect performance

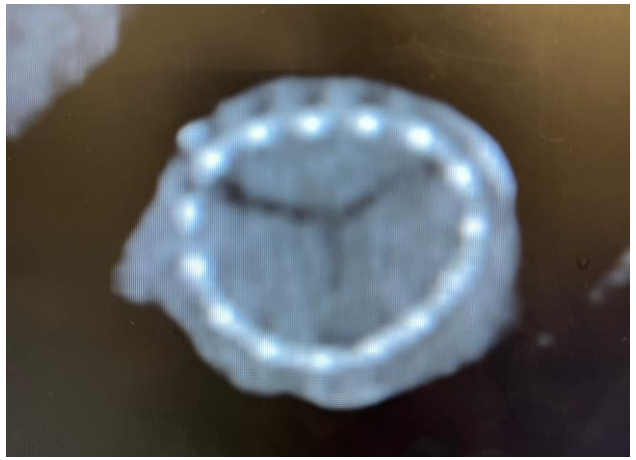
- SAVR
  - Circular stent frame
  - Leaflets are never touched
  - Valve remains circular after implantation
  - Anti-calcification treatment is well documented

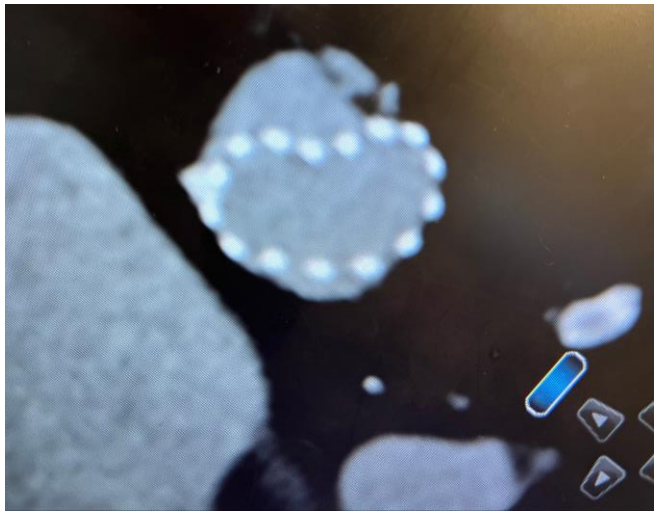
TAVR deformation



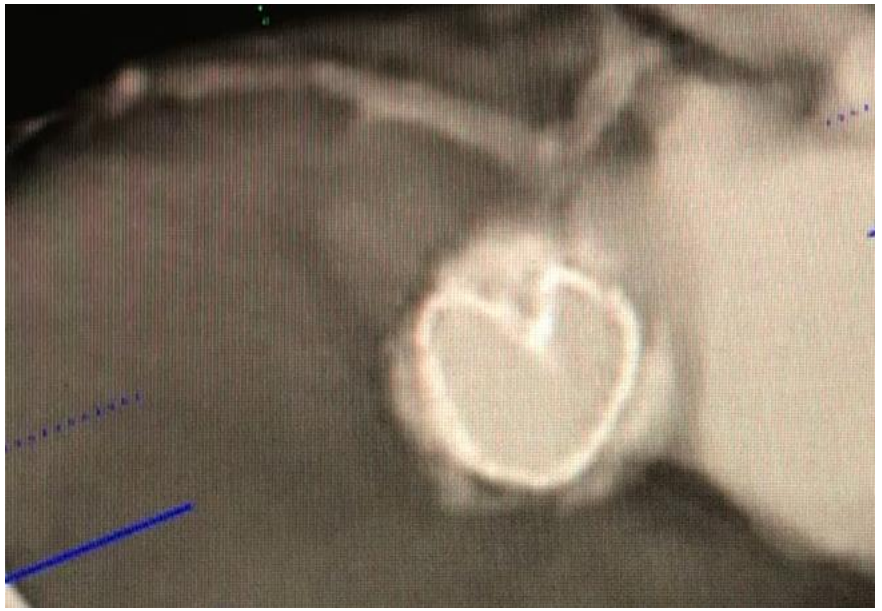
Never fully expanded

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)

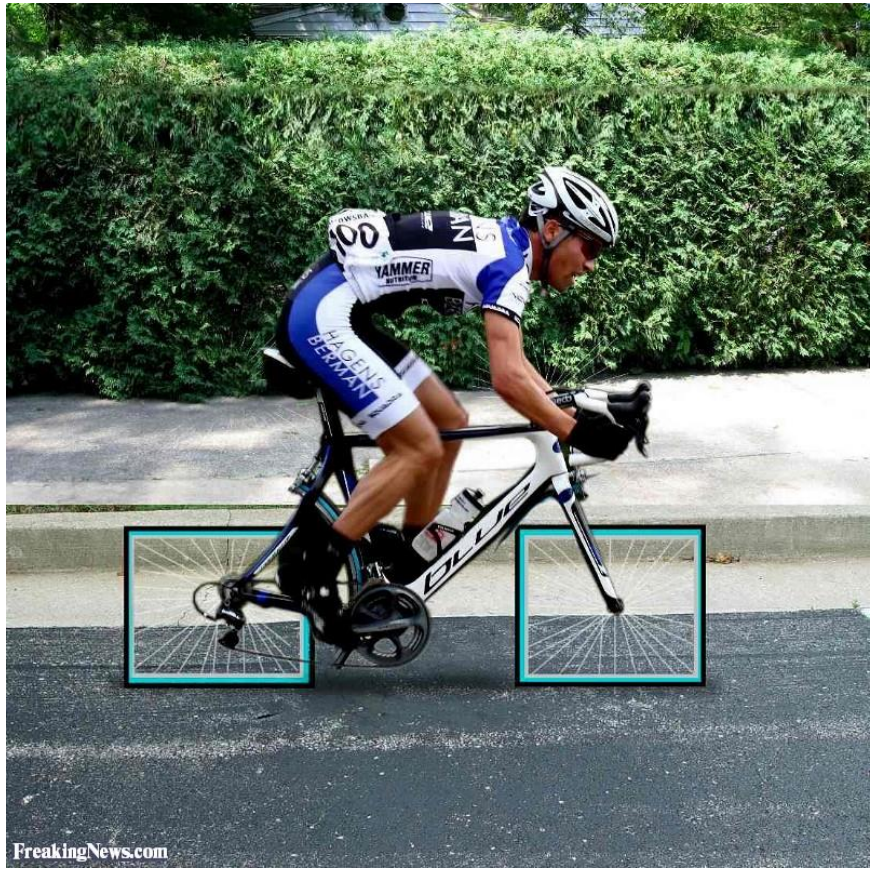




Valentine day special !!

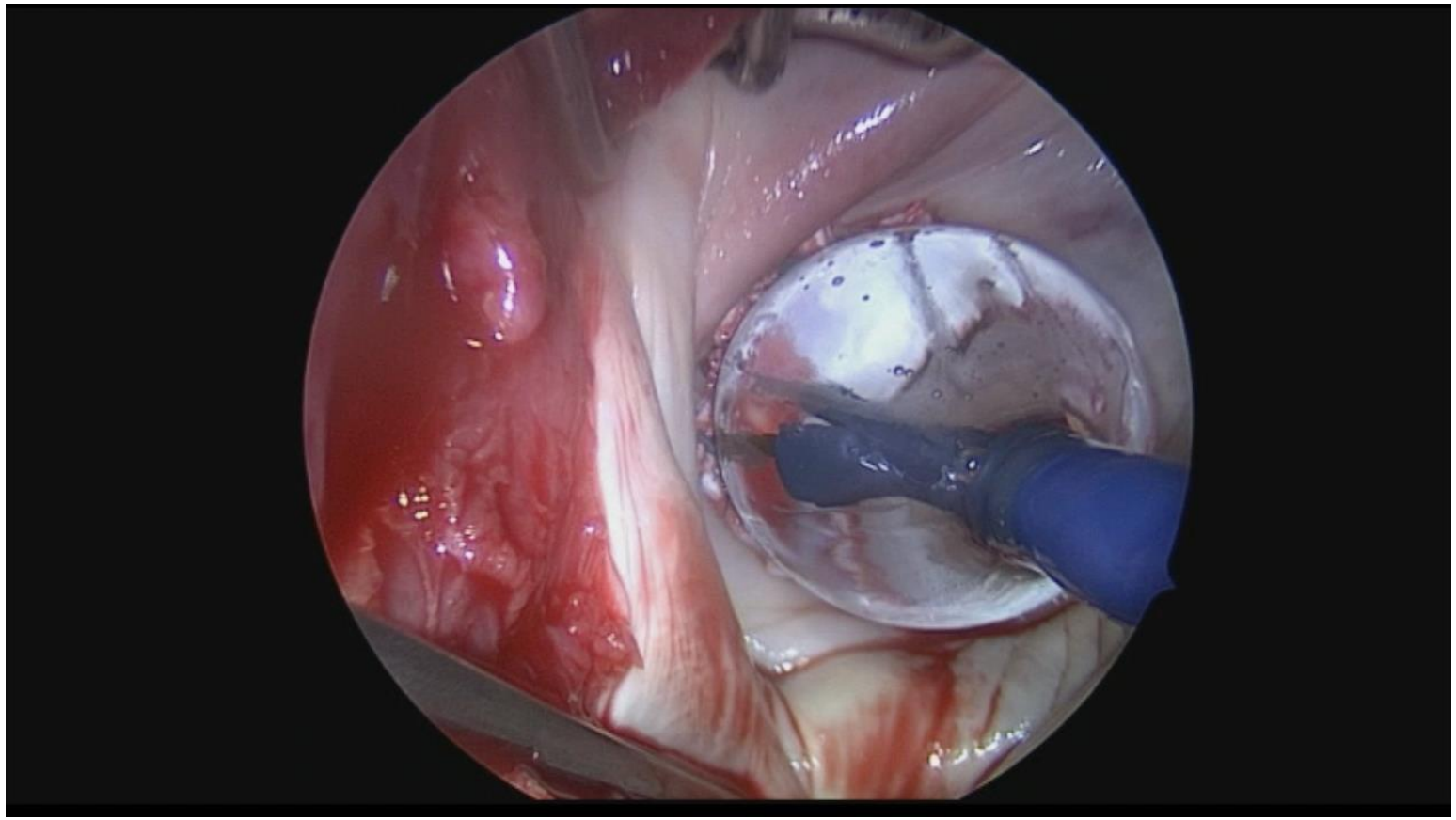


Anyone for square wheels???



Best case scenario – it will still be less than perfect

Myth 3: Balloon doesn’t affect TAVR leaflets !

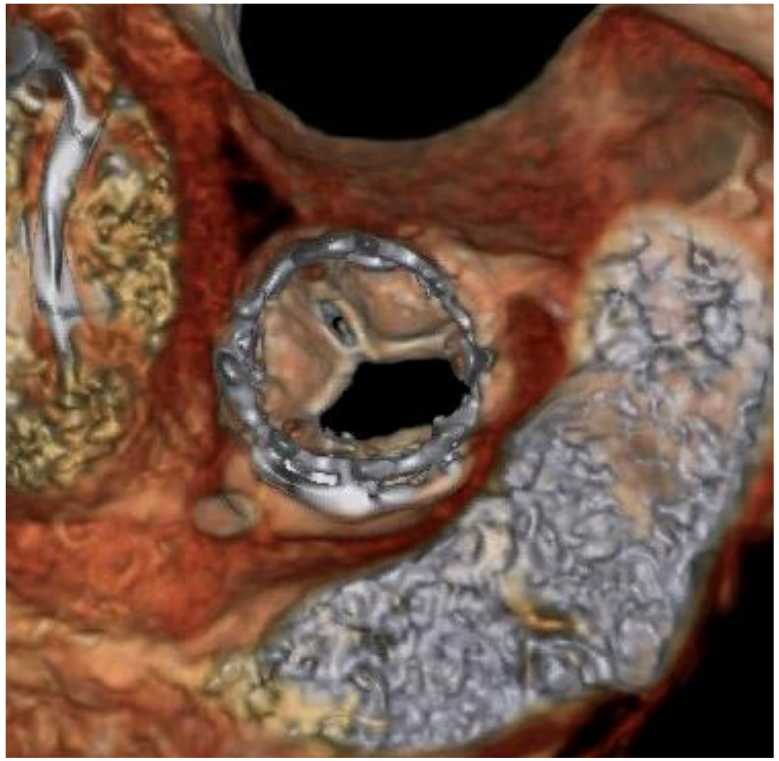


No wonder HALT is seen with more frequency in TAVR

ORIGINAL ARTICLE

Possible Subclinical Leaflet Thrombosis in Bioprosthetic Aortic Valves

R.R. Makkar, G. Fontana, H. Jilaihawi, T. Chakravarty, K.F. Kofoed, O. de Backer, F.M. Asch, C.E. Ruiz, N.T. Olsen, A. Trento, J. Friedman, D. Berman, W. Cheng, M. Kashif, V. Jelnin, C.A. Kliger, H. Guo, A.D. Pichard, N.J. Weissman, S. Kapadia, E. Manasse, D.L. Bhatt, M.B. Leon, and L. Søndergaard



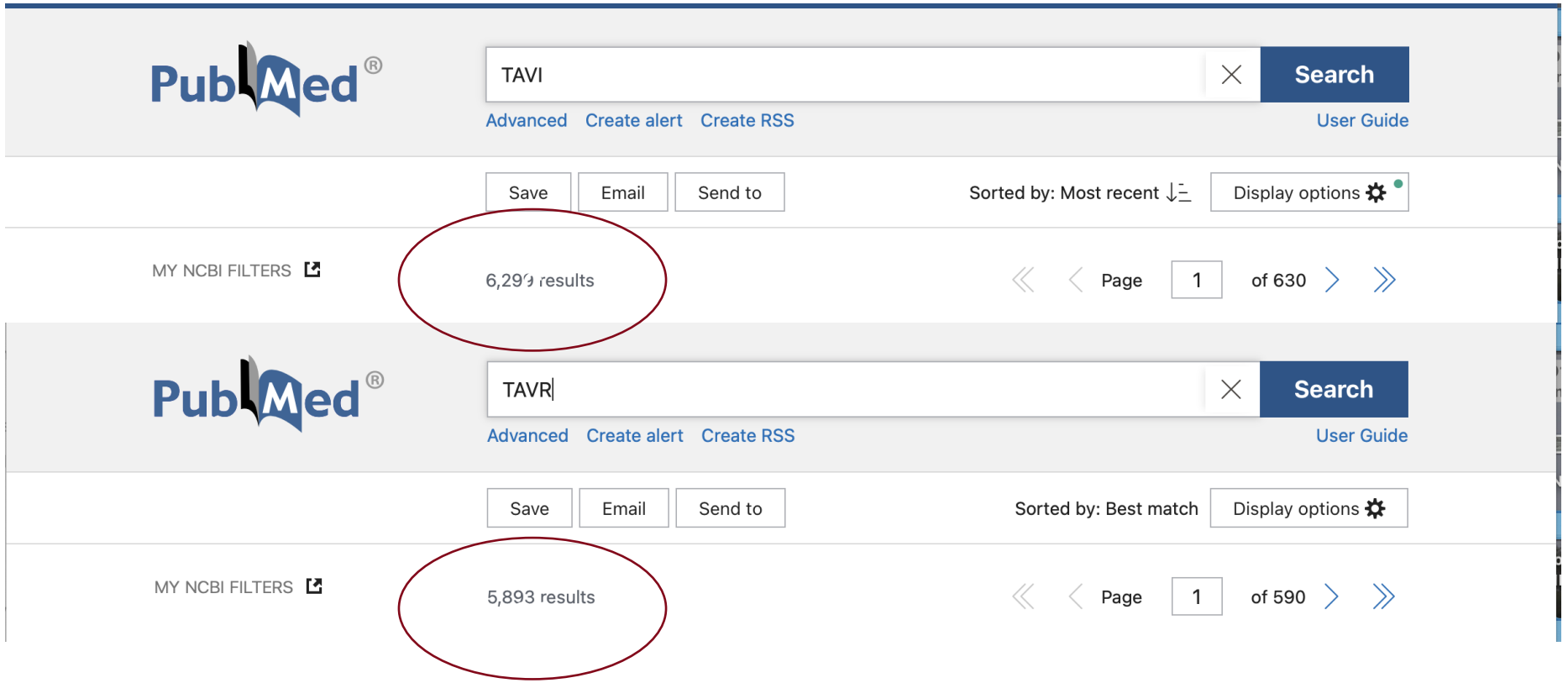
- Incidence 40% in PORTICO IDE study
- Incidence 13% in RESOLVE and SAVORY registries
- Association with neurologic events (3 strokes and 3 TIAs)

Myth 4: PPM only matters in SAVR

- Confusing
- In TAVR at present no one knows how to measure EOA !!!

** EOA was larger for SAVR than TAVR in Partner 3 trial

Myth 5: TAVR durability is amazing !



Highest number of
1. Self reported Multicenter studies
2. White papers
3. Expert opinions

Durability definitions have been modified to suit TAVR

On one hand

JACC Cardiovasc Interv. 2021 Mar 8;14(5):586-588. doi: 10.1016/j.jcin.2020.10.030. Epub 2021 Mar 1.

Long-Term Durability of the Next-Generation Acurate neo 2 Transcatheter Heart Valve: Insights From Bench Testing to 25 Years

Janarthanan Sathananthan, Uri Landes, Lionel Flaction, Arnaud Humair, Stéphane Delaloye, Stefan Toggweiler, Lars Søndergaard, David A Wood, John G Webb

PMID: 33663791 DOI: 10.1016/j.jcin.2020.10.030

Free article

JACC Cardiovasc Interv. 2020 Jan 27;13(2):235-249. doi: 10.1016/j.jcin.2019.07.049. Epub 2019 Sep 28.

Long-Term Durability of Transcatheter Heart Valves: Insights From Bench Testing to 25 Years

Janarthanan Sathananthan [1], Mark Hensey [1], Uri Landes [1], Abdullah Alkhodair [1], Adeeb Saiduddin [2], Stephanie Sellers [3], Anson Cheung [1], Sandra Lauck [1], Philipp Blanke [1], Jonathon Leipsic [1], Jian Ye [1], David A Wood [1], John G Webb [4]

Affiliations + expand

PMID: 31575516 DOI: 10.1016/j.jcin.2019.07.049

Free article

Abstract

Objectives: This study assessed the long-term durability of nominally deployed transcatheter heart valves (THV) to 1 billion cycles (equivalent to 25 years) and non-nominal (overexpansion, underexpansion, and elliptical) THV deployments to 200 million cycles (equivalent to 5 years) with accelerated wear testing.

Background: The long-term durability of THVs is currently unknown. As transcatheter aortic valve replacement expands to lower-risk patients, durability will be of increasing importance.

Methods: SAPIEN 3 THVs, sized 20, 23, 26, and 29 mm were assessed. Nominally deployed

On the other

Multicenter Study > JACC Cardiovasc Interv. 2020 Jan 27;13(2):210-216.
doi: 10.1016/j.jcin.2019.08.042. Epub 2019 Dec 25.

Mid-Term Outcomes of Transcatheter Aortic Valve Replacement in Extremely Large Annuli With Edwards SAPIEN 3 Valve

Aditya Sengupta [1], Syed Zaid [2], Norihiko Kamioka [3], Juan Terre [4], Masaki Miyasaka [5], Sameer A Hirji [6], Mark Hensey [7], Nadim Geloo [8], George Petrossian [9], Newell Robinson [9],

Objectives: The aim of this study was to report the 1-year results of transcatheter aortic valve replacement (TAVR) with the Edwards SAPIEN 3 (S3) valve in extremely large annuli.

Conclusions: S3 TAVR in annular areas >683 mm^2 is feasible, with favorable mid-term outcomes.

Mid-term = 1years!!!

Time scale in TAVI field ???

Myth 6: SAVR is bad for lifetime management but TAVR is good

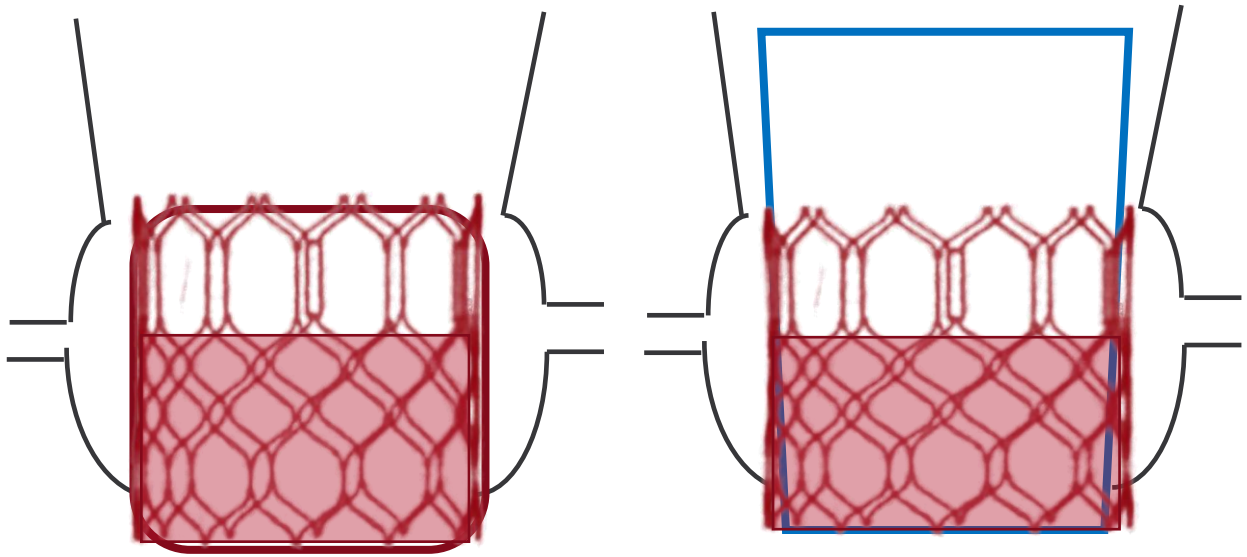
Surgeons criticized for implanting small size SAVR

Root Enlargement
Expandable Valves

With TAVI ?????

Issues with lifetime management

1. Lifetime management does not mean we reduce the life !!!
2. Issues with Coronary access
3. PPM
4. HALT
5. Anticoagulation



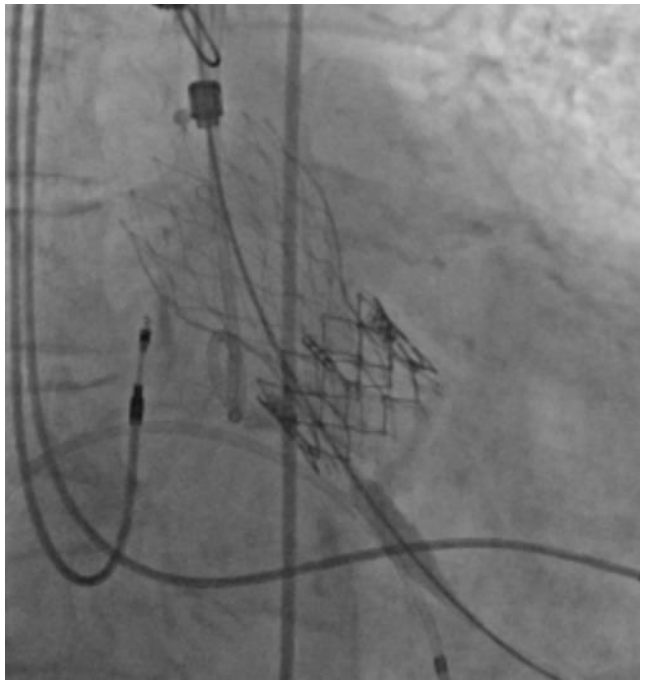
Higher implantations
TAVRs with under expansion
Tall neo-skirts

→ Poor Lifetime management options

TAV in TAV registry

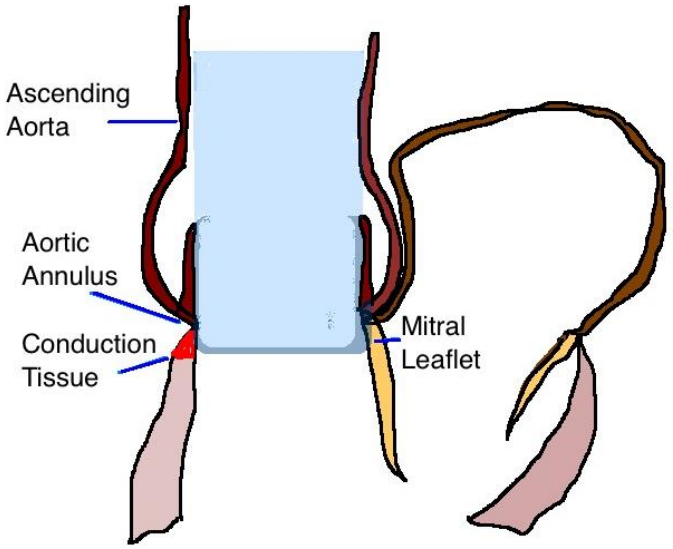
Median duration of reintervention is previously perfect TAVR
Not promising (<3 years)

Residual gradient >20 is common
Residual AR is not uncommon
Pacemaker risk is higher than VIV
Risk of Coronary obstruction is possibility
Need for anticoagulation may be higher

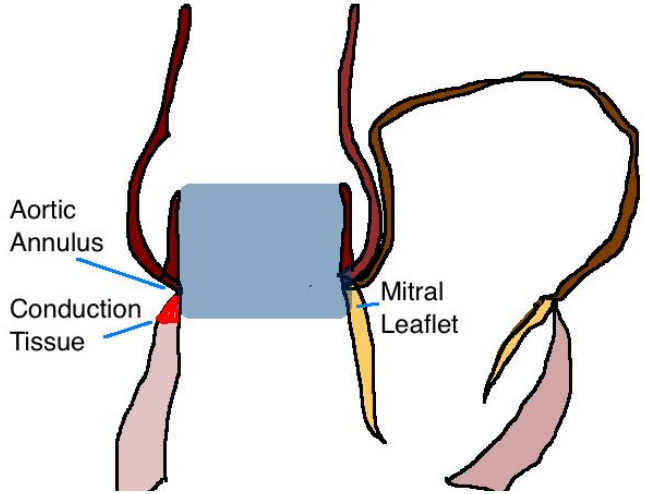


Recent Publications – 30-60% patients will have suboptimal TAV in TAV strategy

TAVR explant



1. Ascending aorta?
2. Annular damage?
3. Mitral leaflet proximity
4. Conduction tissue proximity



Risks are higher than first time AVR and reop AVR

Lifetime management???

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.

heart surgery, Sept. 6, 2004

Dr. Craig R. Smith uses a model of a human heart to explain to reporters the heart bypass surgery he performed on former President Bill Clinton on Sept. 6, 2004

HOPE DISCOVERED HERE

Minneapolis Heart Institute Foundation

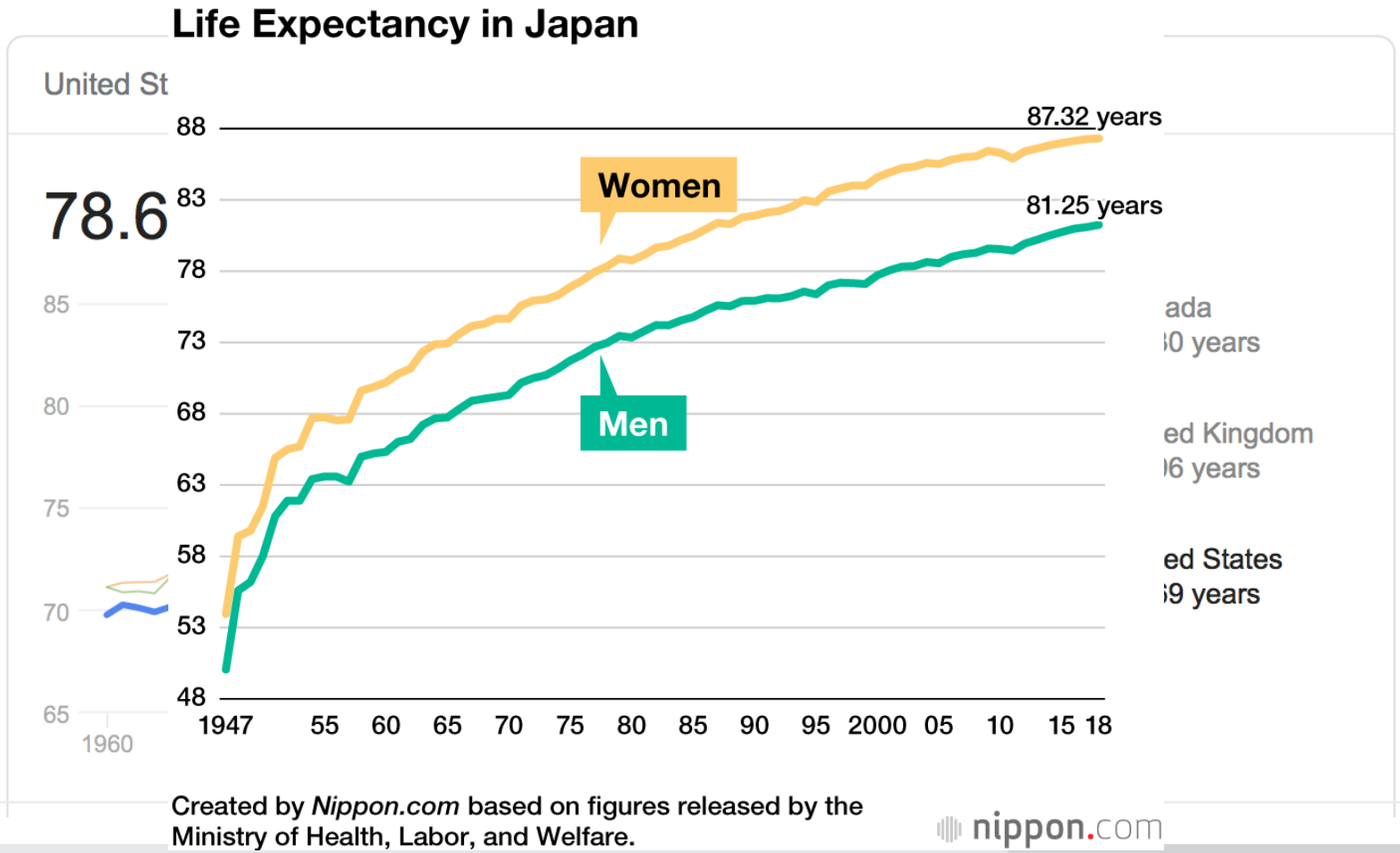
Creating a world without heart and vascular disease

TAVR

- Is good for patients with short life expectancy
- Is good only if good durability data is available for that Model

Not a good Choice if life expectancy is longer

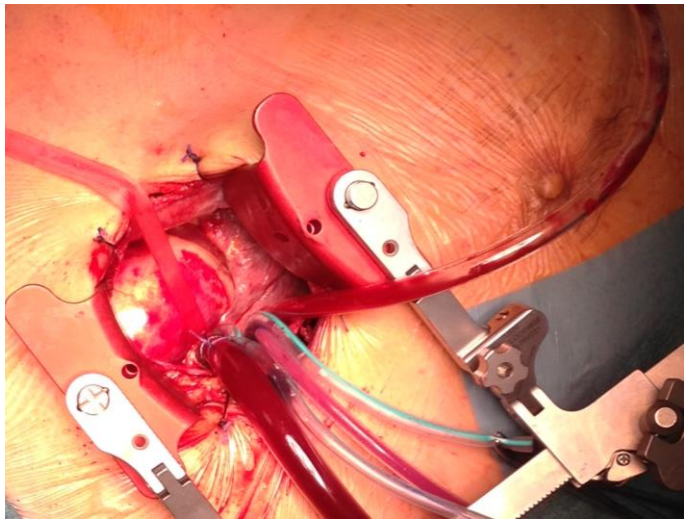
Life expectancy and regional differences



Guidelines for USA/Canada/Europe may not be applicable to other regions

SAVR

- Approach: mini AVR
- Valve choice: Inspiris with V-fit and Reselia tissue*
- Pacemaker: low risk



- Expected recovery: 4 days
- Anticoagulation: none
- Back to work: 3 to 4 weeks

Valve with proven longevity

SHV design (Perimount - INSPIRIS)

1. Platform with > 4 decades of experience
2. Minimal design change
3. Design change focused on durability*
4. Frame optimized for larger EOA for a given size**

TAVR design (SAPIEN - SAPIEN 3)

1. Multiple design changes in short span
2. Design changes focused on ‘small crimp profile’
3. Rigid stent frame = more leaflet strain
4. Circularity, EOA suboptimal for long term performance?

- Resilia tissue: ↑ Durability, uncrimped leaflet
- ** EOA is larger for SAVR than TAVR in Partner 3 trial

What about Second intervention

SAVR

May not be needed

VIV: mid term data promising

Need for anticoagulation: minimal

SAVR reop – good data

TAVR

Need – 100%

TVIV: early data not promising

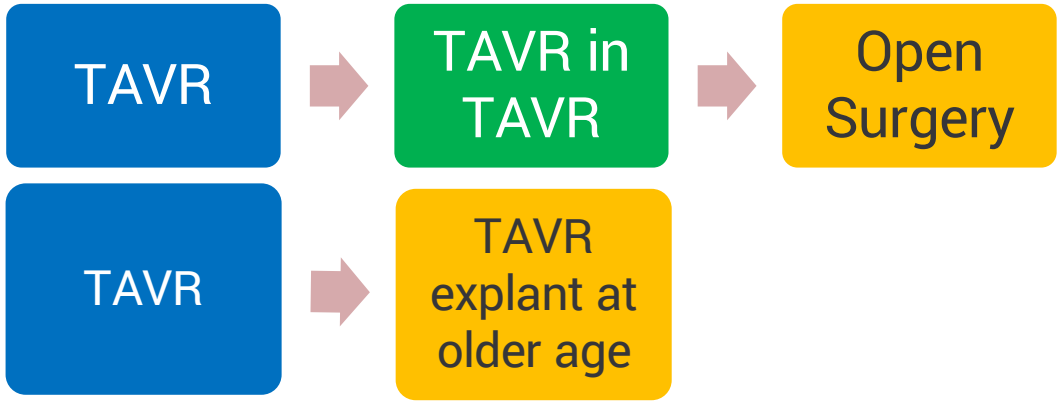
Need for anticoagulation: higher**

TAVR explant – lot of unknowns

* INSPIRIS is design optimized for TAVR

TAVR in these patients – suboptimal for lifetime management

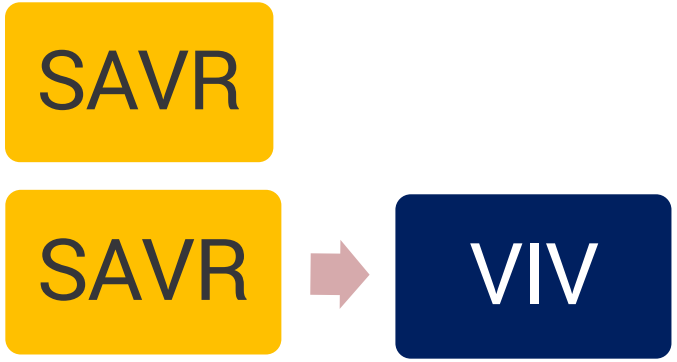
- High chance of 3 interventions
- Each intervention adding additional unknown issues
- Higher cumulative risk of stroke, mortality, need for anticoagulation



Is this worth it for 2-3 weeks of less recovery time??

SAVR is best choice for life time management

- Hemodynamically superior
- Less chance of pacemaker
- Only one procedure may be needed if at all
- If needed VIV with elimination of ‘Russian doll’ effect
- Cumulative risks of various procedures is lower, including need for anticoagulation



But if you think logically

TAVR is Good Compromise

SAVR vs TAVR

SAVR

TAVR