Bioprosthetic Valve Fracture for Optimization of ViV TAVR: When, Why, and How?

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Disclosures

Grant Support/Drugs

- Daiichi-Sankyo
- MyoKardia/BMS

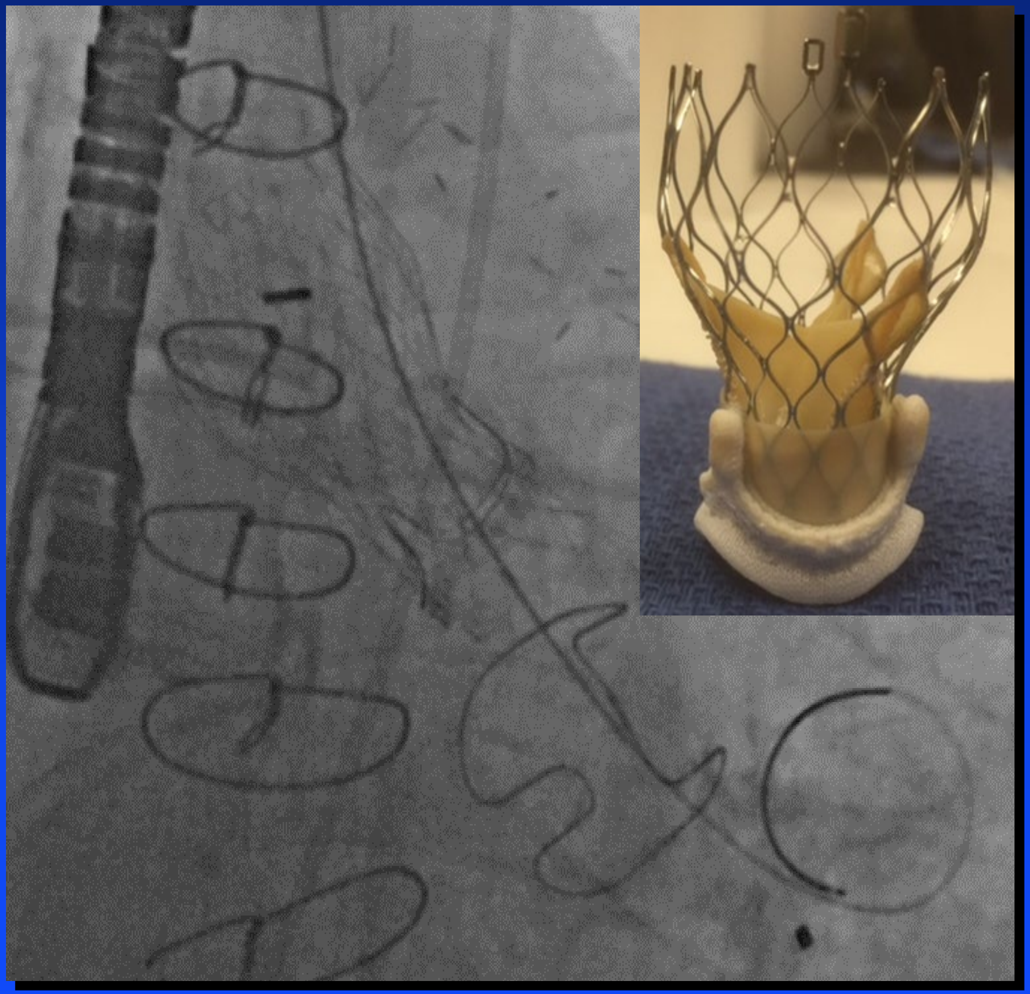
Grant Support/Devices

- Edwards Lifesciences
- Medtronic
- Corvia
- I-Rhythm
- Abbott Vascular
- Boston Scientific
- Phillips
- Brain-Q

Consulting/Advisory Boards

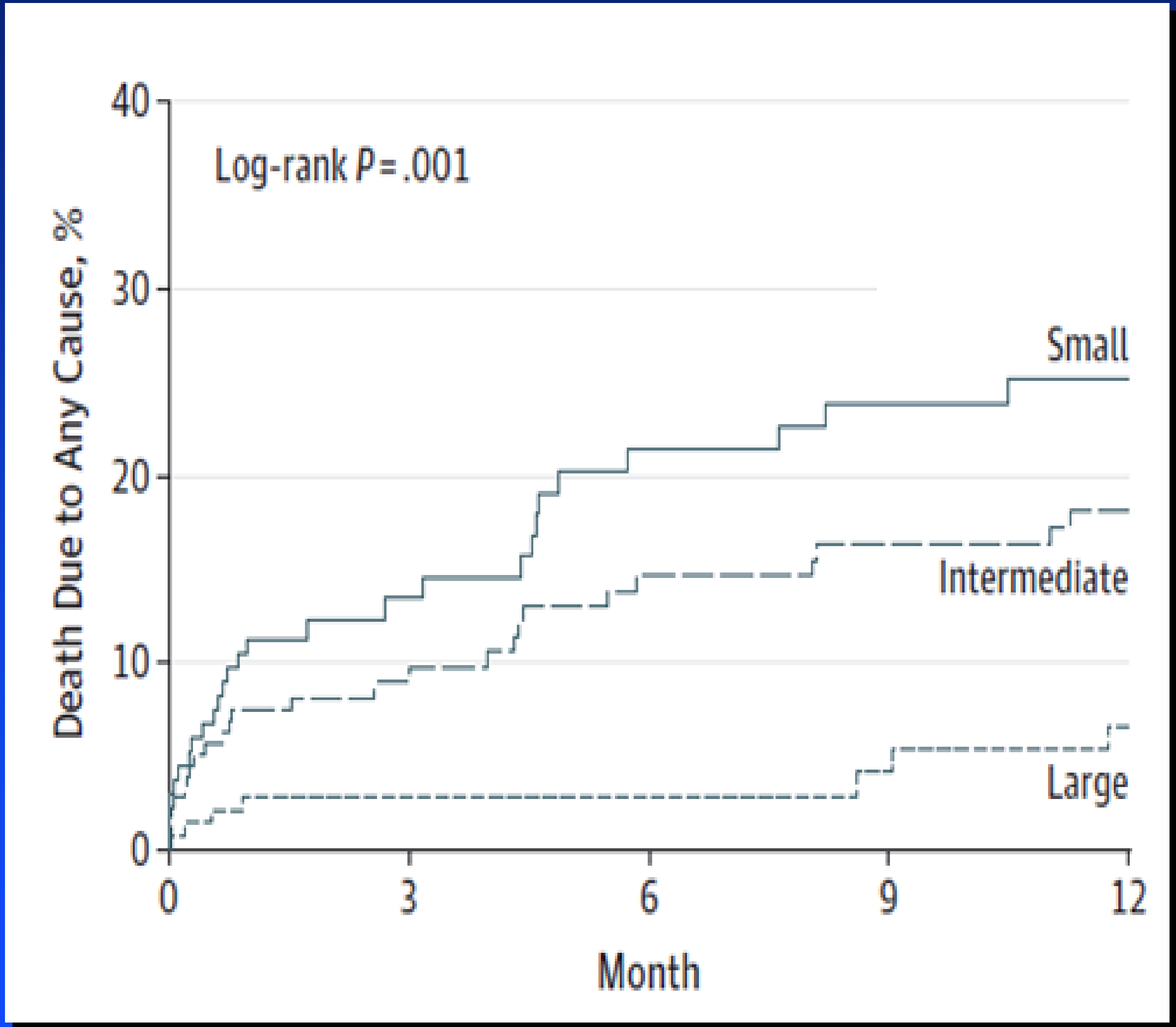
- Medtronic
- Boston Scientific
- Corvia
- Edwards Lifesciences
- Abbott Vascular
- Impulse Dynamics

Valve-in-Valve TAVR



- VIV TAVR is an effective alternative to redo surgery in high or intermediate risk patients with failing tissue valves.
- However, VIV TAVR can be problematic with small surgical bioprostheses because of further reduction in the effective orifice leading to patent-prosthesis mismatch and high residual gradients.

Impact of Surgical Valve Size on 1-Year Mortality



VIVID Registry

- 459 pts with failed surgical bioprostheses treated with ViV TAVR (59% balloon expandable, 41% self-expanding)
- Patients stratified based on size of original surgical valve
  - *Small ≤ 21 (n=133)*
  - *Medium 22-24 (n=176)*
  - *Large ≥ 25 (n=139)*
- Small surgical valve independently associated with 1-year mortality (HR 2.04, p=0.02) → possibly due to patient-prosthesis mismatch

Dvir D, et al. JAMA 2014;312:162-170

Bioprosthetic Valve Fracture

- Basic technique and hemodynamic benefits
- Advanced technical considerations
  - *Management of valves that can’t be fractured*
  - *Balloon and valve sizing*
  - *Timing of BVF*
- When not to fracture

Patient P.M.

- 71 y.o. man with bioprosthetic valve degeneration
- Underwent AVR/CABG x 3 in 2007 (19 mm Magna)
- Did well until late 2015 when he began to notice increasing DOE and fatigue
- Echo: normal LV and RV, severe bioprosthetic AS, Mean gradient=60 mmHg
- High risk for repeat SAVR due to patent grafts and proximity of RV to sternum→ ViV TAVR

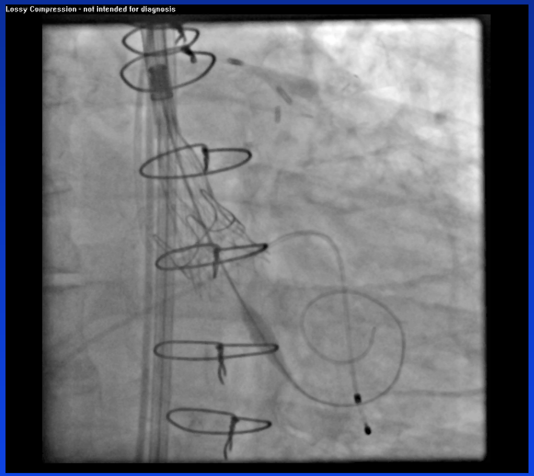
19 mm Magna
True ID = 17 mm

VIV App recommends
23 mm EVOLUT

Planned for 26 mm EVOLUT with BVF given small surgical valve size

Hemodynamics before and after ViV TAVR

Baseline



After 26 mm EVOLUT

Mean gradient = 63 mmHg
AVA 0.8 cm2

Mean gradient = 44 mmHg
AVA 1.0 cm2

BVF with 20 mm True Balloon (18 atm)

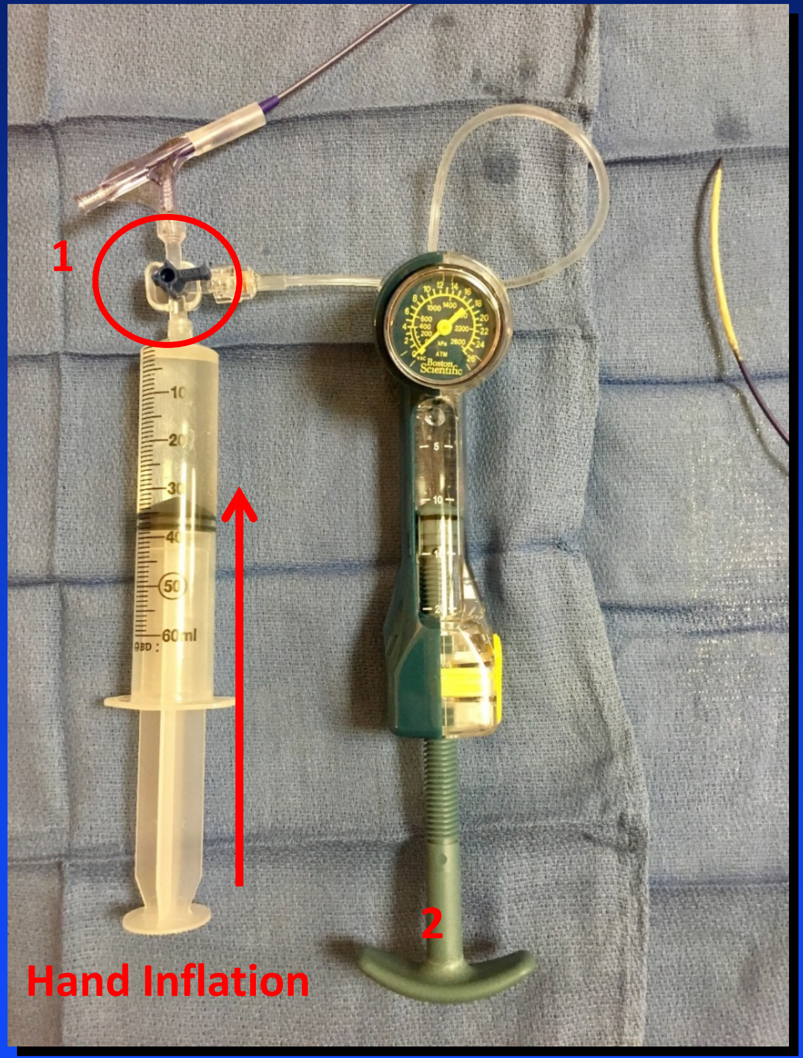
Mean gradient = 18 mmHg
AVA 1.9 cm2

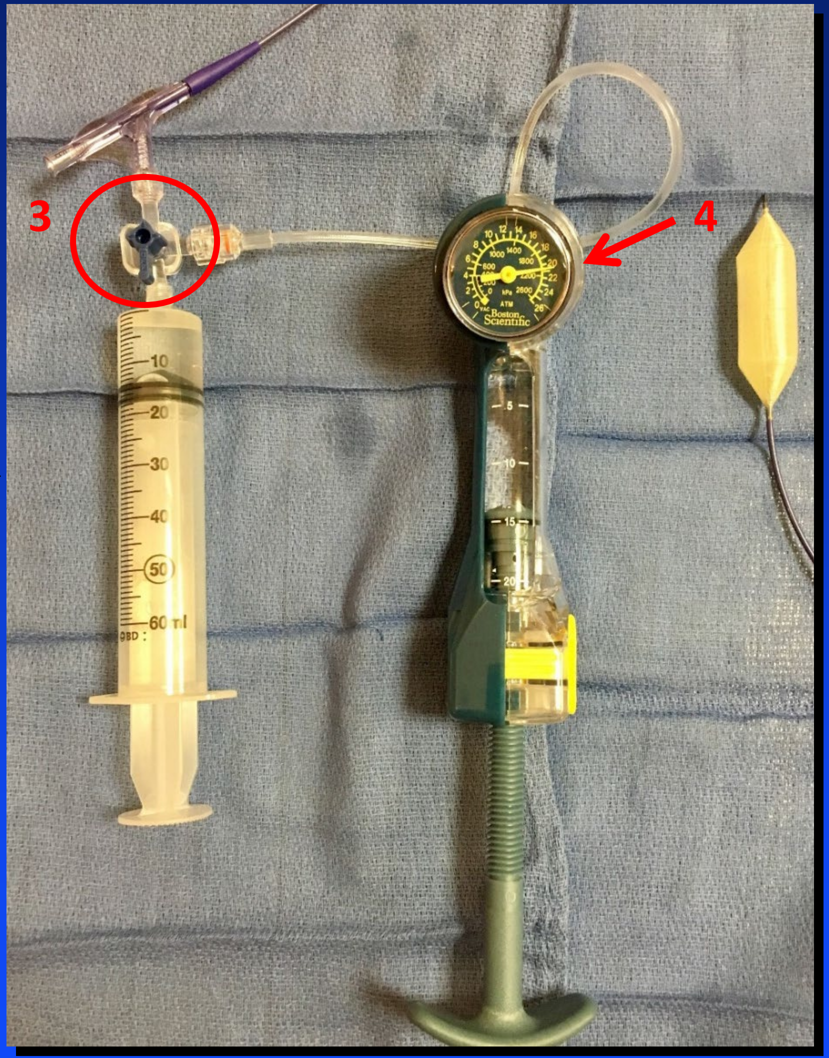
Here's what you'll need…

- 1 True Dilatation, ATLAS, or ATLAS-GOLD Balloon (Bard)→ Kevlar wrapped
- 1 60 cc luer lock syringe filled with dilute contrast
- 1 PTCA indeflator
- 1 high-pressure stopcock

** <u>Disclaimer</u>: This is 100% off-label use and may require exceeding balloon RBP considerably*

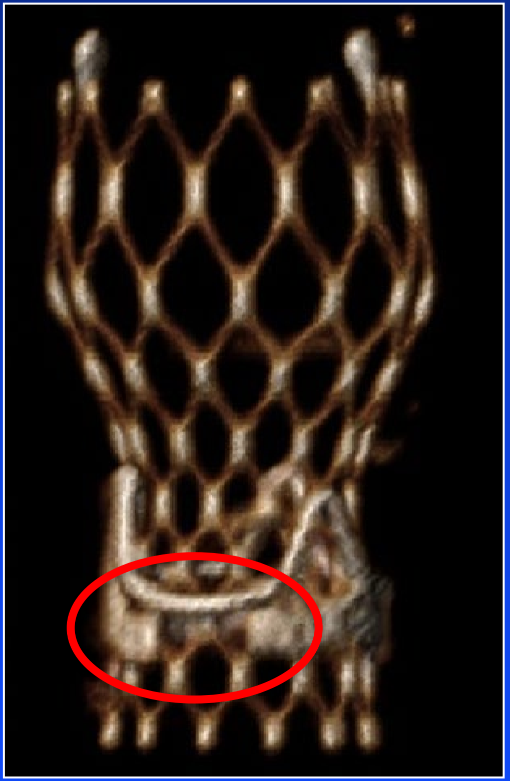
And here's the set-up…





How Surgical Valves Fracture

23 mm EVOLUT in 21 mm Magna Valve

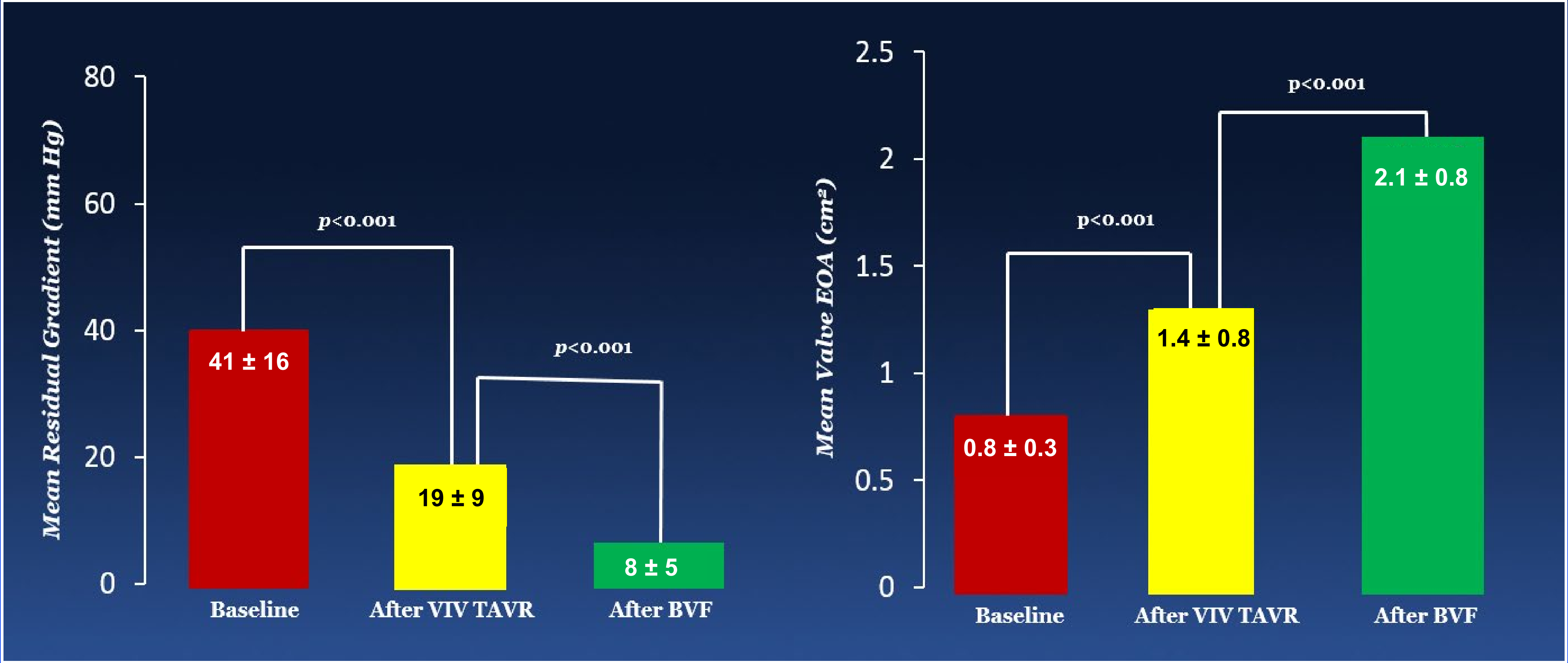


Single Fracture Point

Sewing Ring Otherwise Intact

Hemodynamic Effects of BVF

66 Patients undergoing VIV TAVR followed by BVF



Allen KA, et al. JTCVS 2019

Not All Valves Can Be Fractured

Valves that can be fractured
Biocor Epic
Magna/Magna Ease
Mitroflow
Mosaic
Perimount (newer generation, perforated ribbon)
Inspiris

Chhatrwialla AK, et al. Circ Cardiovasc Interv. 2018

Not All Valves Can Be Fractured

Valves that can be fractured	Valves that can be "remodeled"
Biocor Epic	C-E Standard
Magna/Magna Ease	C-E SAV
Mitroflow	Perimount (older generation)
Mosaic	Trifecta
Perimount (newer generation, perforated ribbon)	
Inspiris	

Chhatrwialla AK, et al. Circ Cardiovasc Interv. 2018

Not All Valves Can Be Fractured

Valves that can be fractured	Valves that can be "remodeled"	Neither
Biocor Epic	C-E Standard	Avalus
Magna/Magna Ease	C-E SAV	Hancock II
Mitroflow	Perimount (older generation)	
Mosaic	Trifecta	
Perimount (newer generation, perforated ribbon)		
Inspiris		

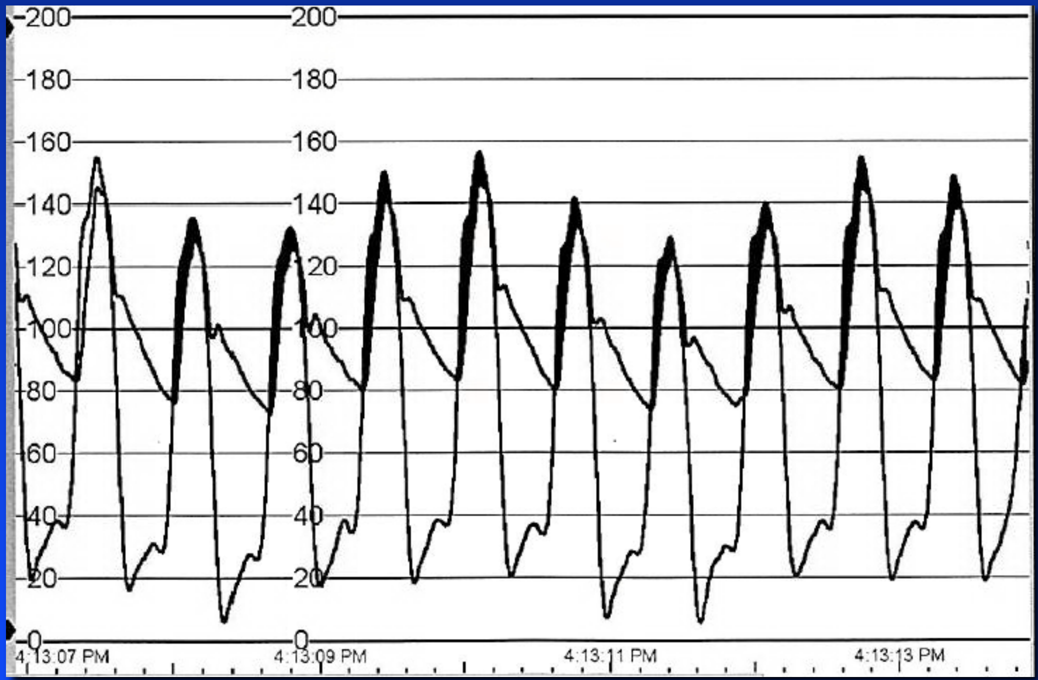
Chhatrwialla AK, et al. Circ Cardiovasc Interv. 2018

Bioprosthetic Valve Remodeling (BVR)

Prior 21 mm Trifecta (TRUE ID 19mm); VIV TAVR performed with 23 mm Evolut R

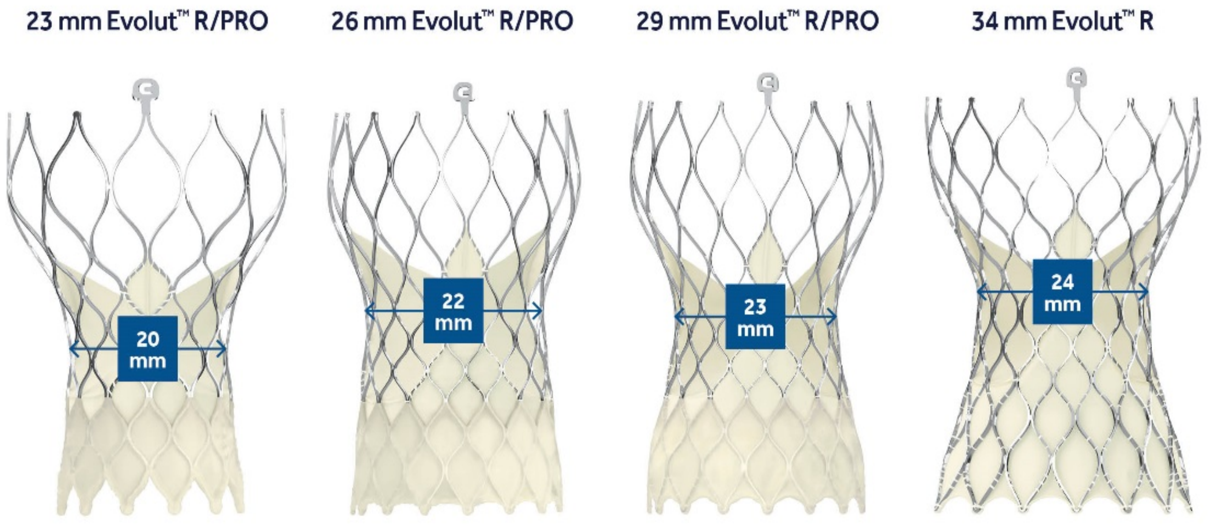
Mean gradient 29 mmHg, AVA 1.0 cm^2 after VIV TAVR→ ***BVR***

22 mm True Balloon (10 atm)



Mean gradient = 13 mmHg
AVA = 1.4 cm^2

Balloon Position (and Sizing) for BVR vs. BVF



Maximum Recommended Balloon Size

<u>BVF</u>

- Constraint at valve ring → keep balloon low (ventricular) to fracture ring
- Can oversize if necessary

<u>BVR</u>

- Constraint at valve frame → balloon higher to expand frame → risk of damage to THV leaflets
- Avoid oversizing

Is it better to perform BVF before or after ViV TAVR?

BVF First

Pros

- No high pressure inflation in the new THV→ ? possible accelerated degeneration

Cons

- Risk for leaflet embolization or acute severe AI with hemodynamic compromise

BVF Second

Pros

- Can assess results before deciding to perform BVF
- High pressure inflation ensures optimal THV expansion

Cons

- High-pressure inflation could lead to acute or subacute injury to the THV

When not to Fracture

- Surgical valves that cannot be fractured/remodeled
  - *Hancock II, Avalus*
- Concern for coronary artery occlusion
  - *Assess virtual THV to coronary distance*
  - *Consider coronary protection or BASILICA if predicted valve-to-coronary distance (after BVF) < 3mm*
- Small STJ or LVOT
  - *Ensure that the anatomy can accommodate the balloon used to perform BVF*
  - *Assess calcium burden*
- Prior root enlargement or replacement
  - *High risk of root rupture*

Summary: BVF for ViV TAVR

- For patients with small bioprosthetic valves who are high risk for re-do AVR, BVF/BVR may offer a "solution" to high residual gradients after ViV implantation
- Most contemporary surgical valves can be fractured (or at least remodeled)
- Clinical experience to date suggests the procedure is generally safe (although not entirely risk-free)
- Unresolved questions
  - *Timing of BVF (pre vs. post-TAVR) → impact on safety and long-term THV durability*
  - *Should all ViV procedures undergo BVF (even with a low gradient) to allow for better TAVR valve geometry and function*