

# Bioprosthetic Valve Fracture for Optimizing Results of Valve-in-Valve TAVR

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# Disclosures

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## Grant Support/Drugs

- Daiichi-Sankyo
- Astra-Zeneca
- Merck

## Grant Support/Devices

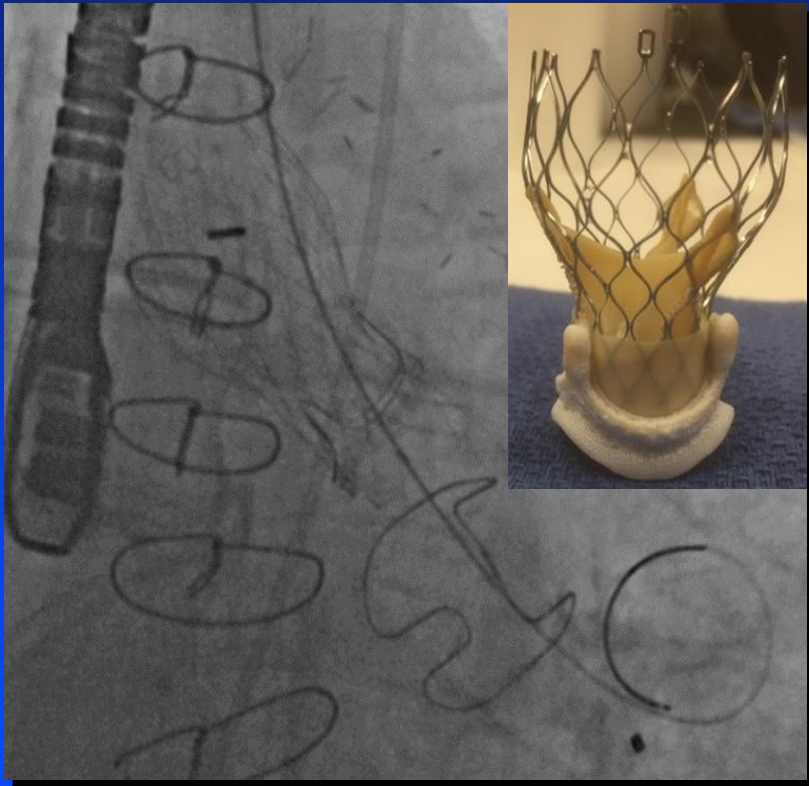
- Edwards Lifesciences
- Medtronic
- Biomet
- Abbott Vascular
- Boston Scientific
- CSI

## Consulting/Advisory Boards

- Medtronic
- Edwards Lifesciences
- Astra-Zeneca
- Cardinal Health

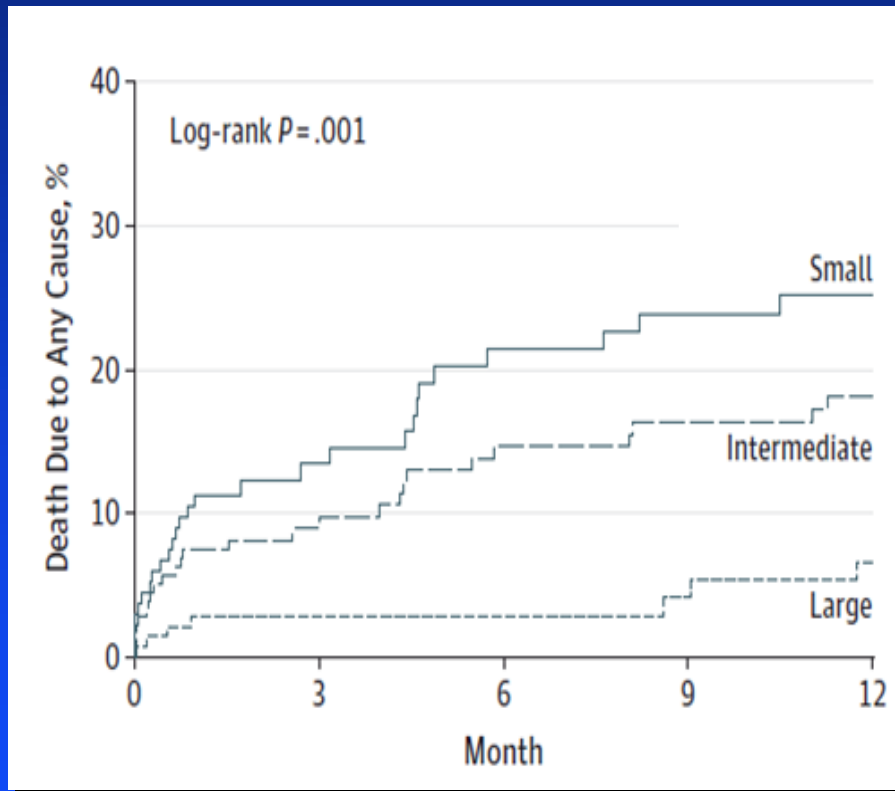
# Valve-in-Valve TAVR

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- 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 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*  $\leq 21$  ( $n=133$ )
  - *Medium* 22-24 ( $n=176$ )
  - *Large*  $\geq 25$  ( $n=139$ )
- Small surgical valve independently associated with 1-year mortality (HR 2.04,  $p=0.02$ )

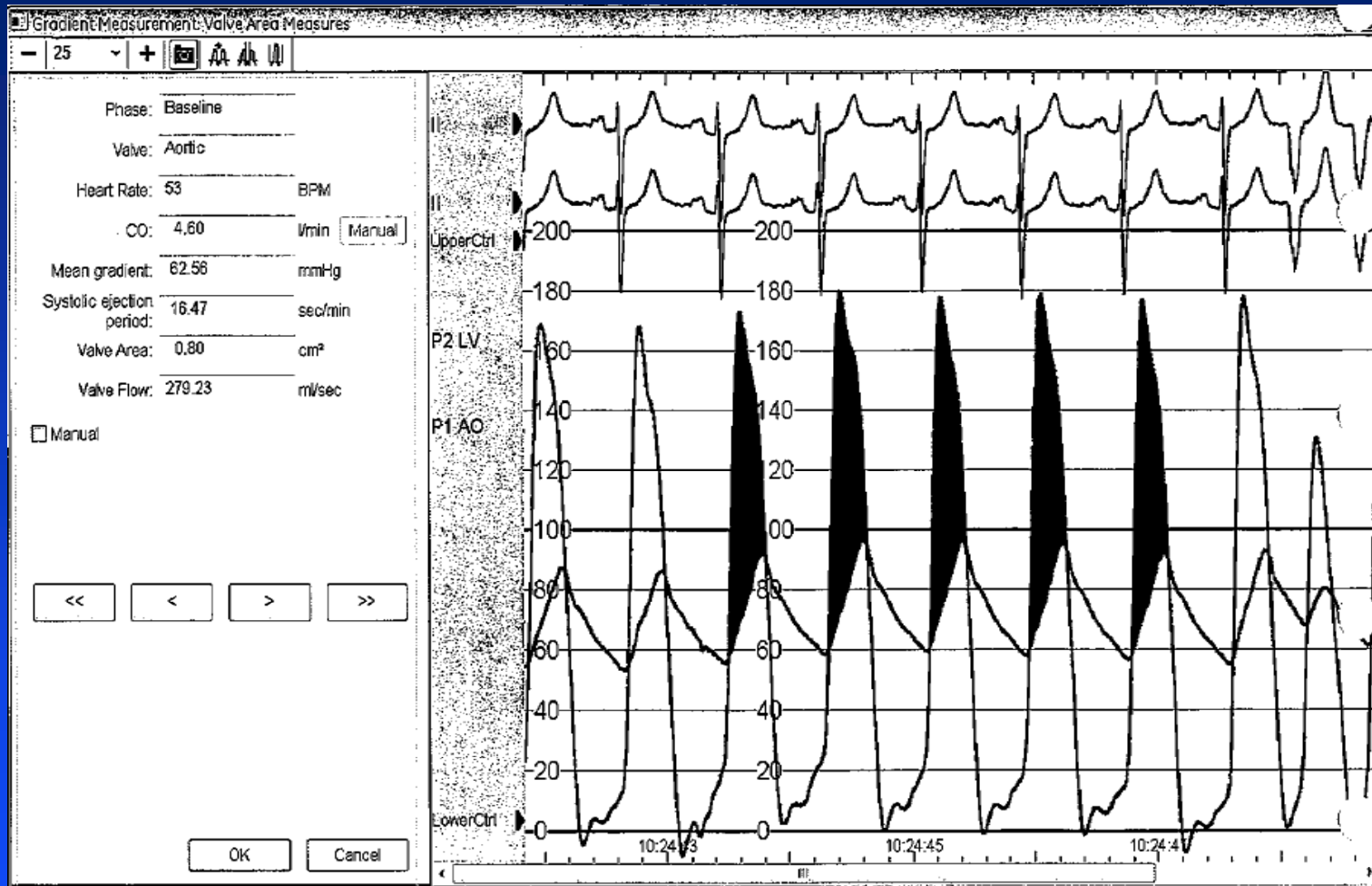
# Patient P.M.

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- 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 size, LVEF 65%, aortic valve gradient 60 mmHg (peak 79 mmHg) with trivial AI
- Referred for redo AVR vs. TAVR → felt to be high risk due to patent grafts and proximity of RV to sternum → ViV TAVR

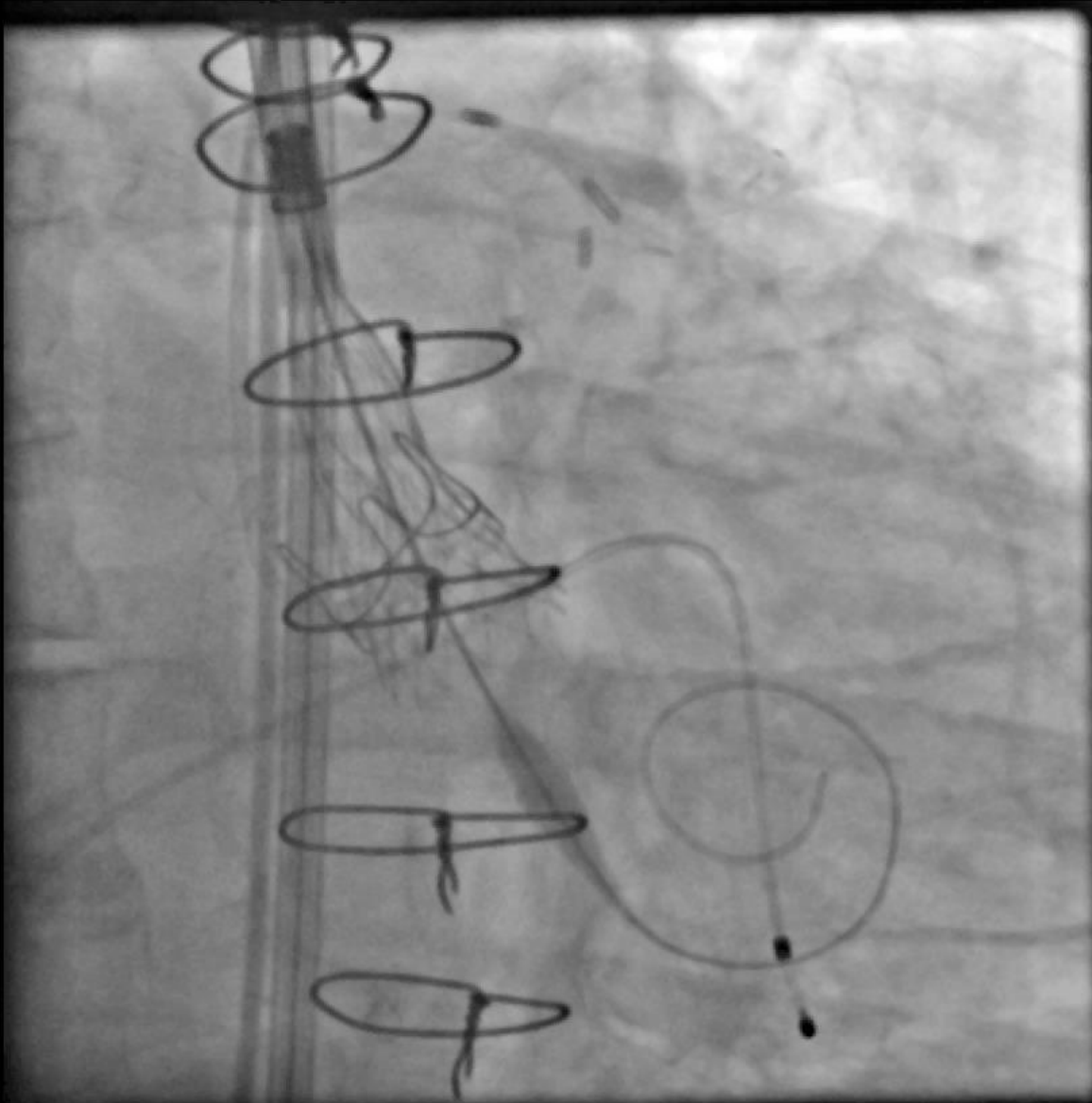
#19 Magna Valve: True Internal Diameter 17 mmHg  
Planned for 23 mm CoreValve EVOLUT

# Baseline Hemodynamics



Mean gradient = 63 mmHg      AVA 0.8 cm<sup>2</sup>

Lessy Compression - not intended for diagnosis



Valve  
Implant  
(23 mm  
CoreValve  
EVOLUT)

# Post-TAVR and Post-Dilation



Mean gradient = 44 mmHg      AVA 1.0 cm<sup>2</sup>



# In-Lab Conversation (Paraphrased)

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- *IC*: This isn't good. We still have almost as high a gradient as when we started
- *CTS*: I know how to treat this. We can break the surgical valve.
- *IC*: What??? Are you crazy?
- *CTS*: I heard about it at a meeting recently. A surgeon from LA said he had done it a few times
- *IC*: Really? I still think you're crazy. Just like when you told us that transcatheter TAVR was a good idea.

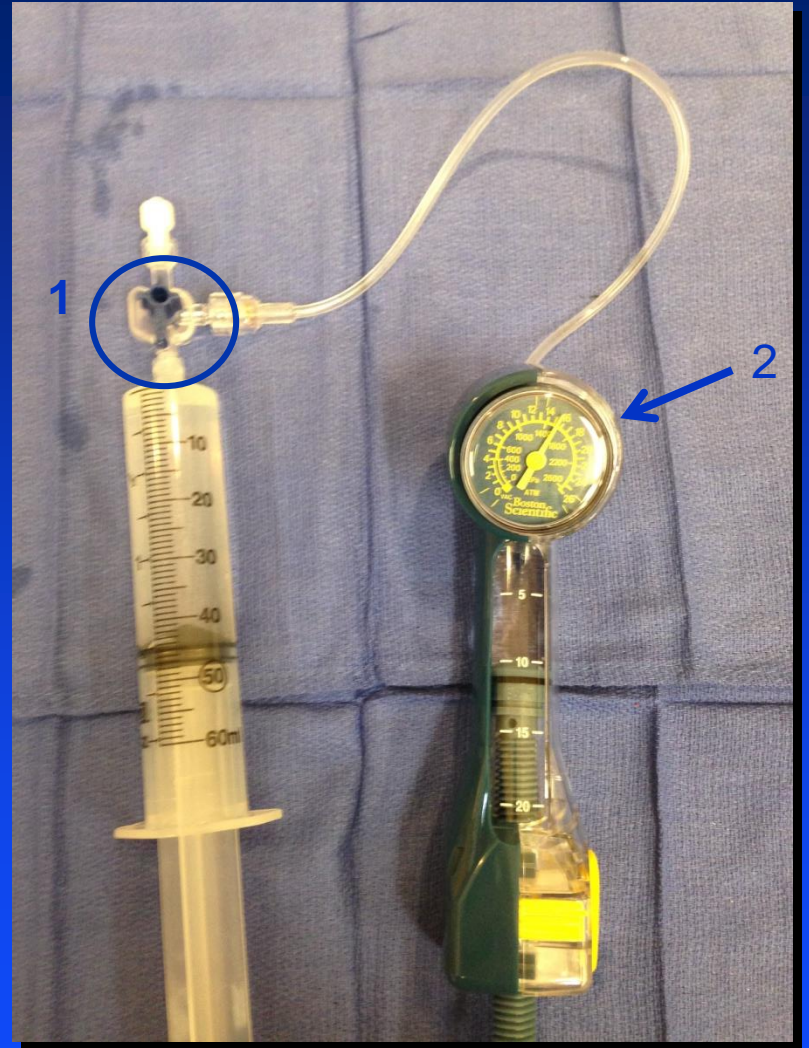
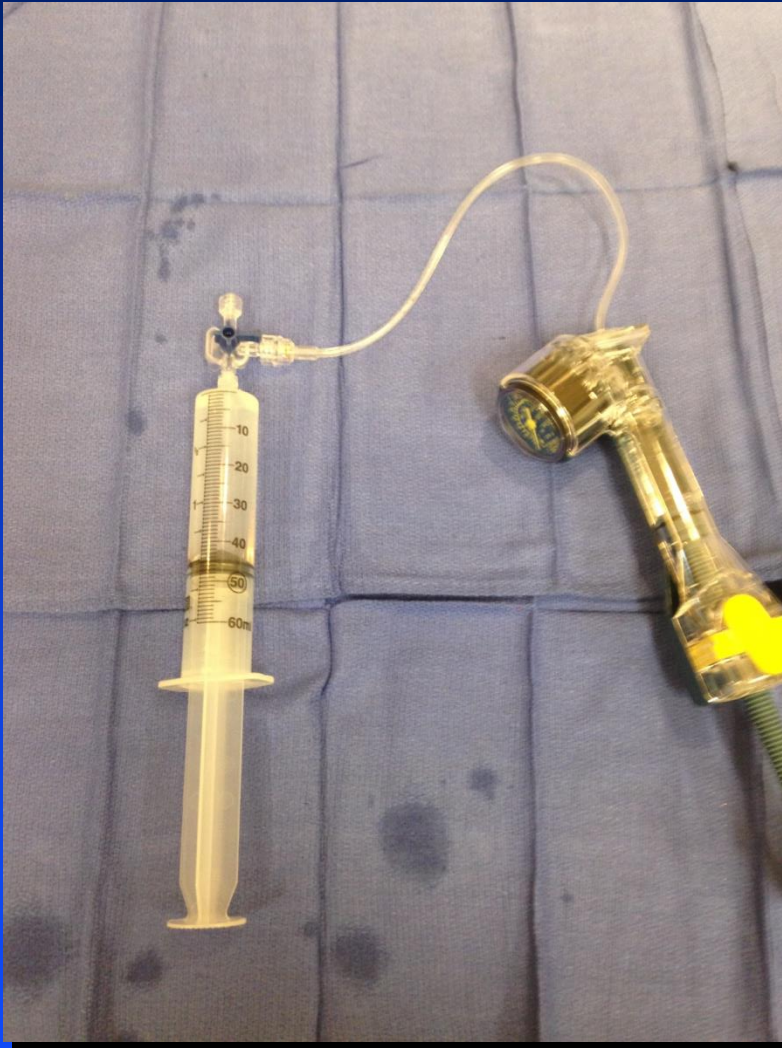
# Here's what you'll need...



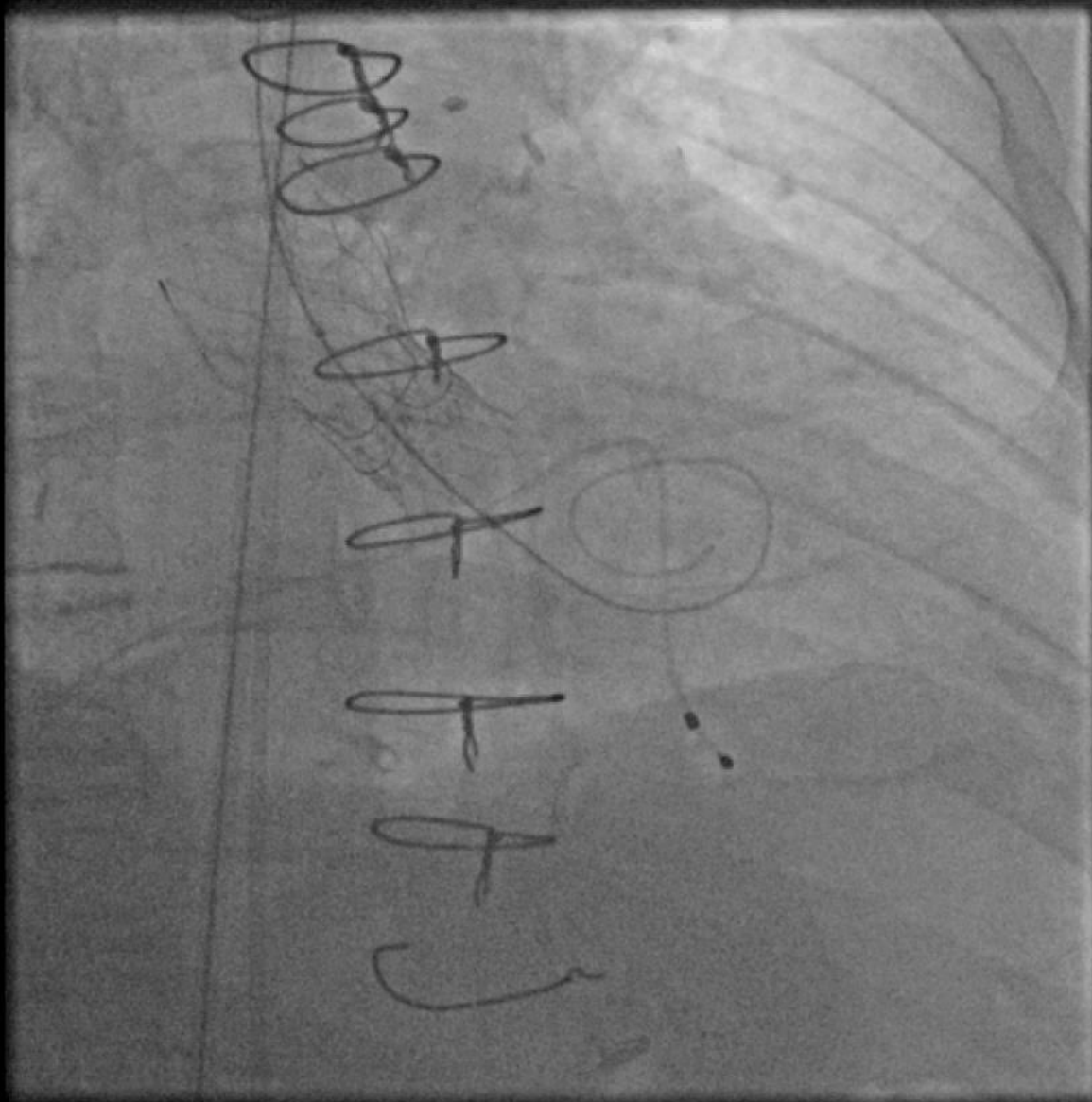
- 1 True Dilatation or ATLAS-GOLD Balloon
- 1 60 cc luer lock syringe filled with dilute contrast
- 1 PTCA inflator
- 1 high-pressure stopcock

\* *Disclaimer: This is 100% off-label use and requires exceeding balloon RBP considerably*

And here's the set-up...



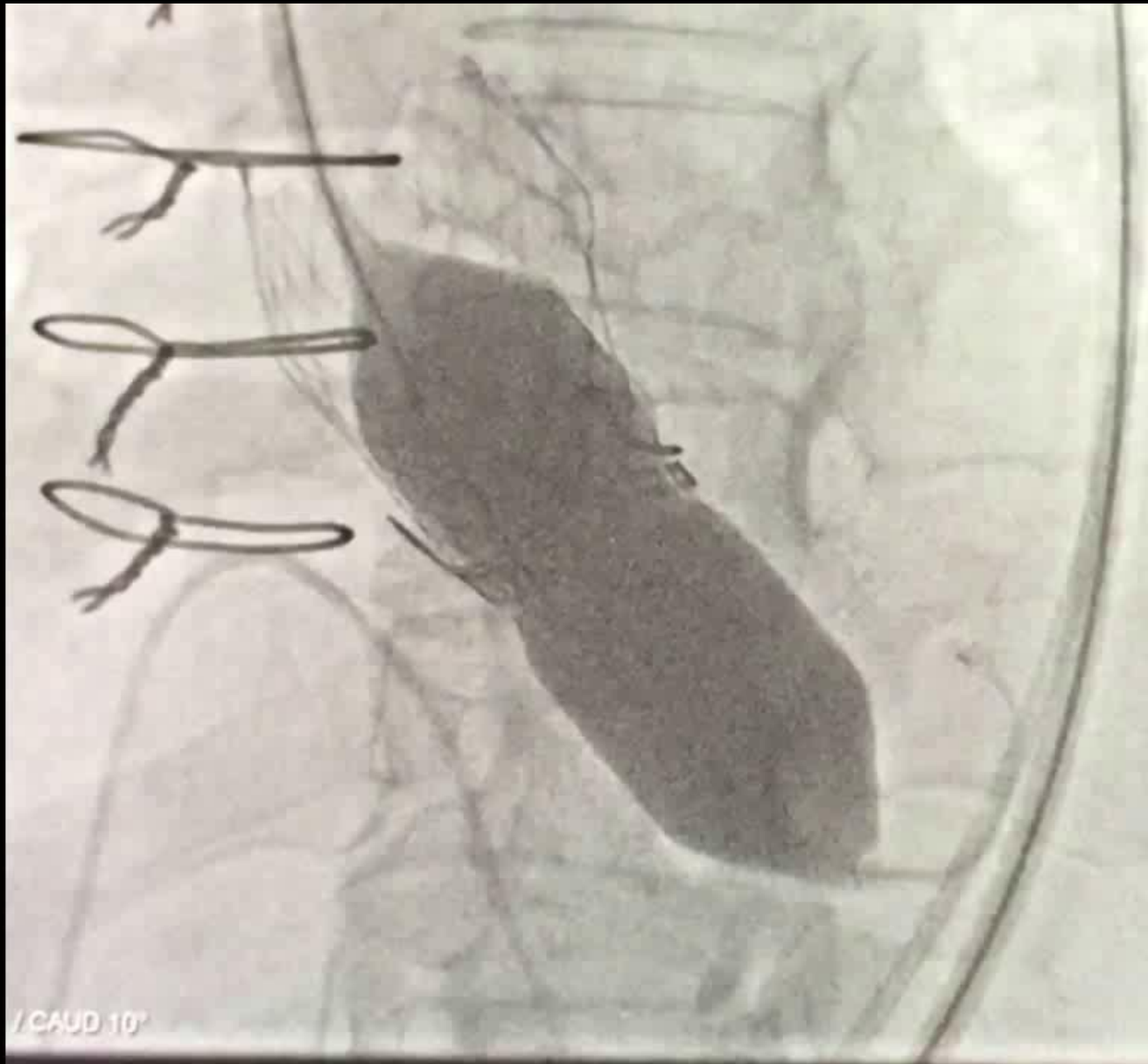
Lossy Compression - not intended for diagnosis



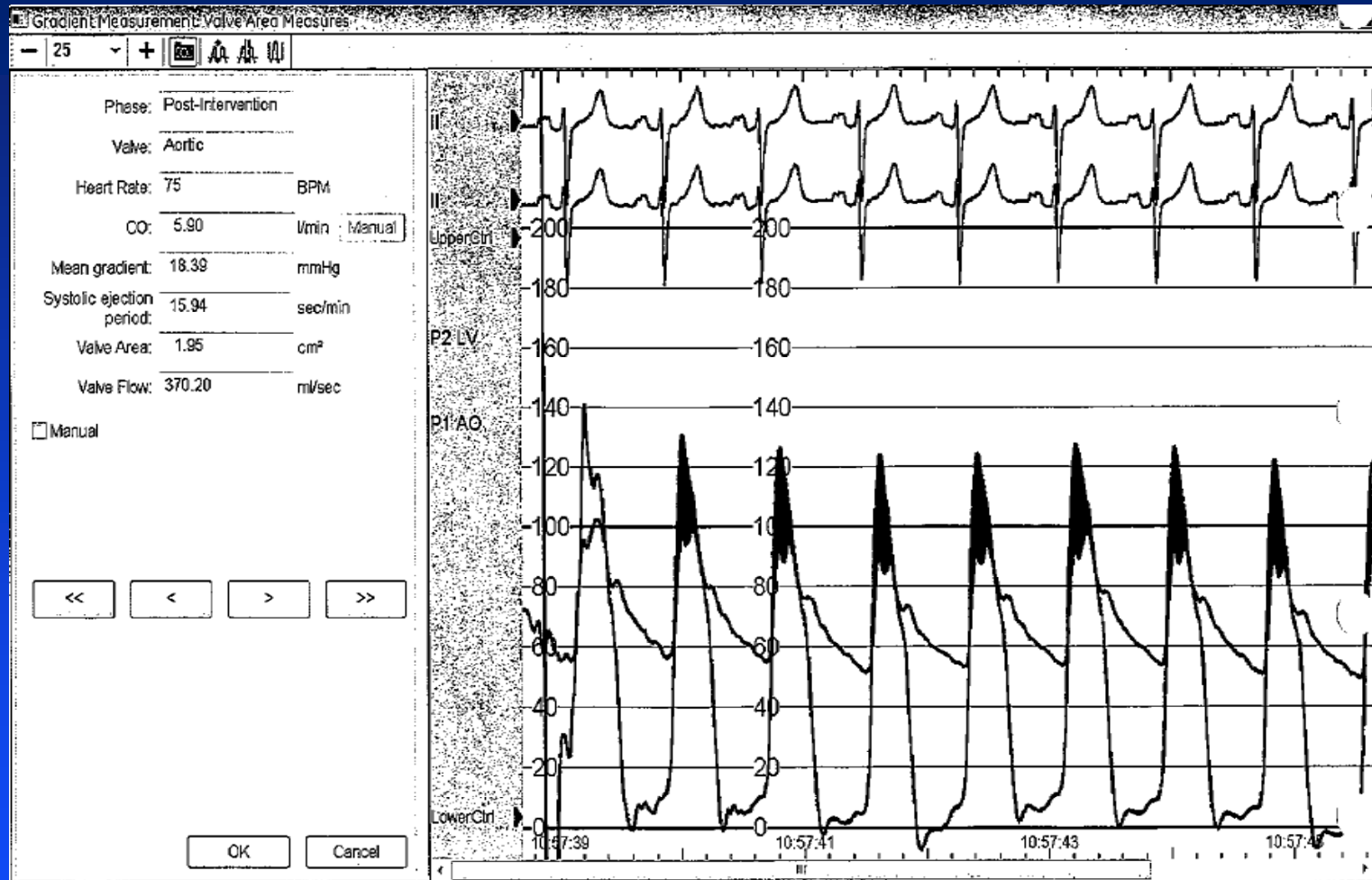
High  
pressure  
post-dilation

20 mm Tru  
Balloon

# BVF: More Photogenic Example



# Post- 20 mm Tru Balloon (16 atm)



Mean gradient = 18 mmHg      AVA 1.9 cm<sup>2</sup>

# And here's how it works...

## Images and Case Reports in Interventional Cardiology

### Fracturing the Ring of Small Mitroflow Bioprostheses by High-Pressure Balloon Predilatation in Transcatheter Aortic Valve-in-Valve Implantation

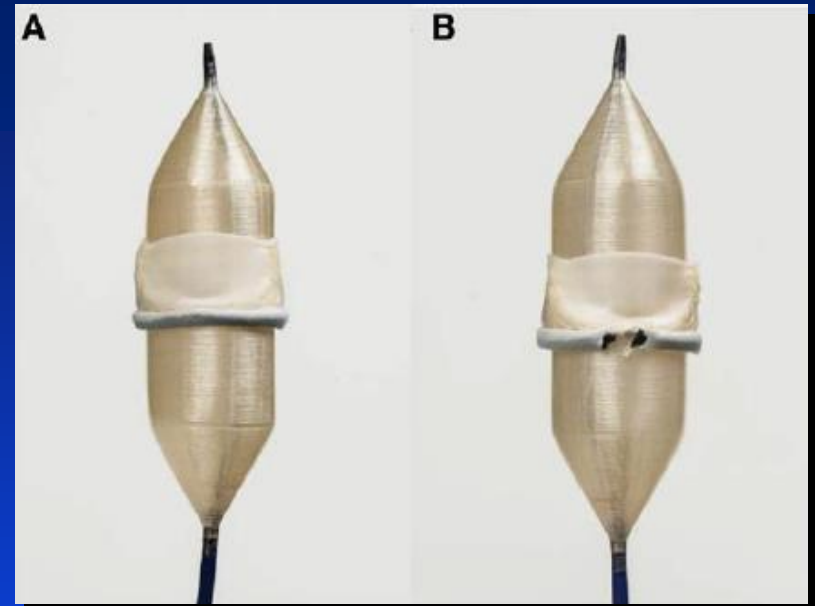
Jens Erik Nielsen-Kudsk, MD, DMSc; Evald Høj Christiansen, MD, PhD;  
Christian Juhl Terkelsen, MD, DMSc; Bjarne Linde Nørgaard, MD, PhD;  
Kaare Troels Jensen, MD, PhD; Lars Romer Krusell, MD; Mariann Tang, MD; Kim Terp, MD;  
Kaj-Erik Klaaborg, MD; Henning Rud Andersen, MD, DMSc

Early deterioration of Mitroflow aortic bioprostheses (Sorin Group Inc), particularly small sizes 19 and 21 mm, has been reported.<sup>1</sup> Treatment of failing bioprostheses by transcatheter valve-in-valve (ViV) therapy has become an alternative to repeat surgery.<sup>2,3</sup> However, ViV treatment is problematic with small surgical bioprostheses because of a further reduction in the effective valve orifice. One way to overcome this challenge may be to fracture the ring of the surgical valve by high-pressure balloon dilatation before implanting a larger size transcatheter valve. The feasibility of this approach was recently reported for an Edwards Perimount bioprosthesis (19 mm) in the pulmonic position.<sup>4</sup> We report the first cases in vitro and in man of high-pressure balloon dilatation to fracture the ring of small dysfunctional Mitroflow aortic bioprostheses followed by transcatheter ViV implantation.

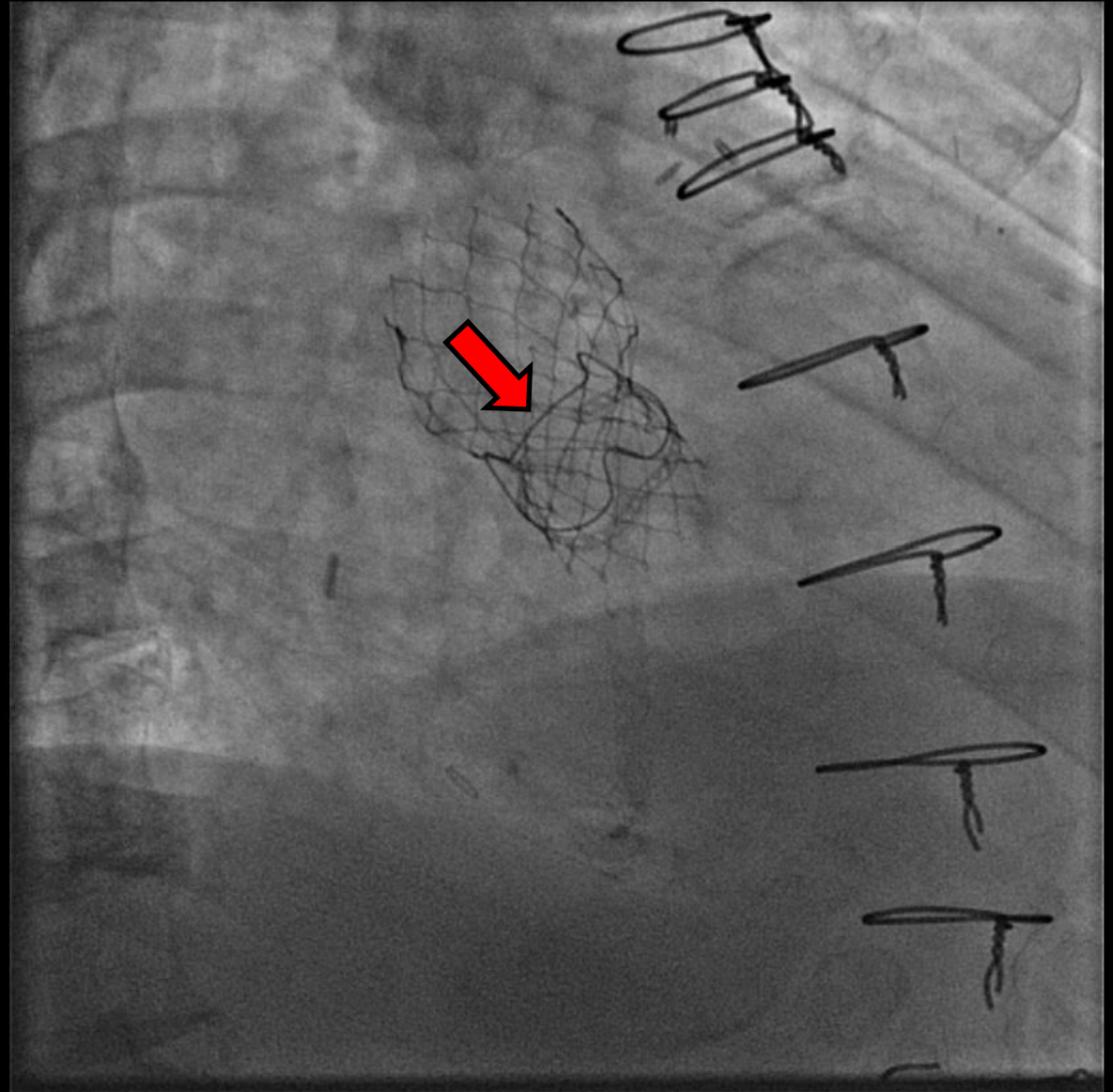
The Mitroflow bioprosthesis is built from a bovine pericardial sheet sutured to the outside of an acetyl stent to form the leaflets. The sewing ring is made from soft radiopaque

heart valve in vitro in one of the fractured 21 mm Mitroflow bioprostheses.

After in vitro testing and informed consent, we performed this procedure in 2 patients with small Mitroflow bioprostheses (19 and 21 mm) and high risk to redo surgery (Table). High-pressure balloon predilatation by an ATLAS Gold balloon led to fracturing of the stent ring of the Mitroflow valves with subsequent successfully ViV with an SAPIEN XT valve 20 mm (19 mm Mitroflow) and a SAPIEN III 23 mm valve (21 mm Mitroflow; Table). The procedures were performed in general anesthesia guided by fluoroscopy and TEE. Rapid right ventricular pacing (180 bpm) and cardiopulmonary support (CPS 2 l/min; right atrium to left femoral artery) were used during the high-pressure balloon predilatation and at the time of ViV implantation. The Mitroflow valve ring fractured at a pressure of 16 atm (Mitroflow 19 mm) and 11 atm (Mitroflow 21 mm) evident by a sudden drop in inflation pressure and resolution of the waist in the balloon with expansion to its full diameter (Figure 2; Movie 1 and 2 in the Data



Final  
Appearance  
(1 week f/u)





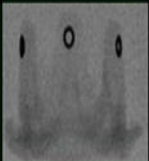


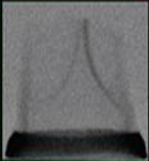








# Valves that can and cannot be fractured

To date, the only valves that cannot be fractured are:

Trifecta (St. Jude)  
Hancock II (MDT)

Manufacturer/ Brand	Valve Size	Bard TRU Balloon Fracture/Pressure	Bard Atlas Gold Balloon Fracture/Pressure	Appearance After Fracture
<b>St. Jude Trifecta</b>				
	19 mm	NO	NO	
	21 mm	NO	NO	
<b>St. Jude Biocor Epic</b>				
	21 mm	YES / 8 ATM	YES / 8 ATM	
<b>Medtronic Mosaic</b>				
	19 mm	YES / 10 ATM	YES / 10 ATM	
	21 mm	YES / 10 ATM	YES / 10 ATM	
<b>Medtronic Hancock II</b>				
	21 mm	NO	NO	
<b>Sorin Mitroflow</b>				
	19 mm	YES / 12 ATM	YES / 12 ATM	
	21 mm	YES / 12 ATM	YES / 12 ATM	
<b>Edwards MagnaEase</b>				
	19 mm	YES / 18 ATM	YES / 18 ATM	
	21 mm	YES / 18 ATM	YES / 18 ATM	
<b>Edwards Magna</b>				
	19 mm	YES / 24 ATM	YES / 24 ATM	
	21 mm	YES / 24 ATM	YES / 24 ATM	

1. Balloons sized 1 mm larger than valve size.  
2. Medtronic Mosaic and Sorin Mitroflow have no metal in ring therefore appearance after fracture unchanged.

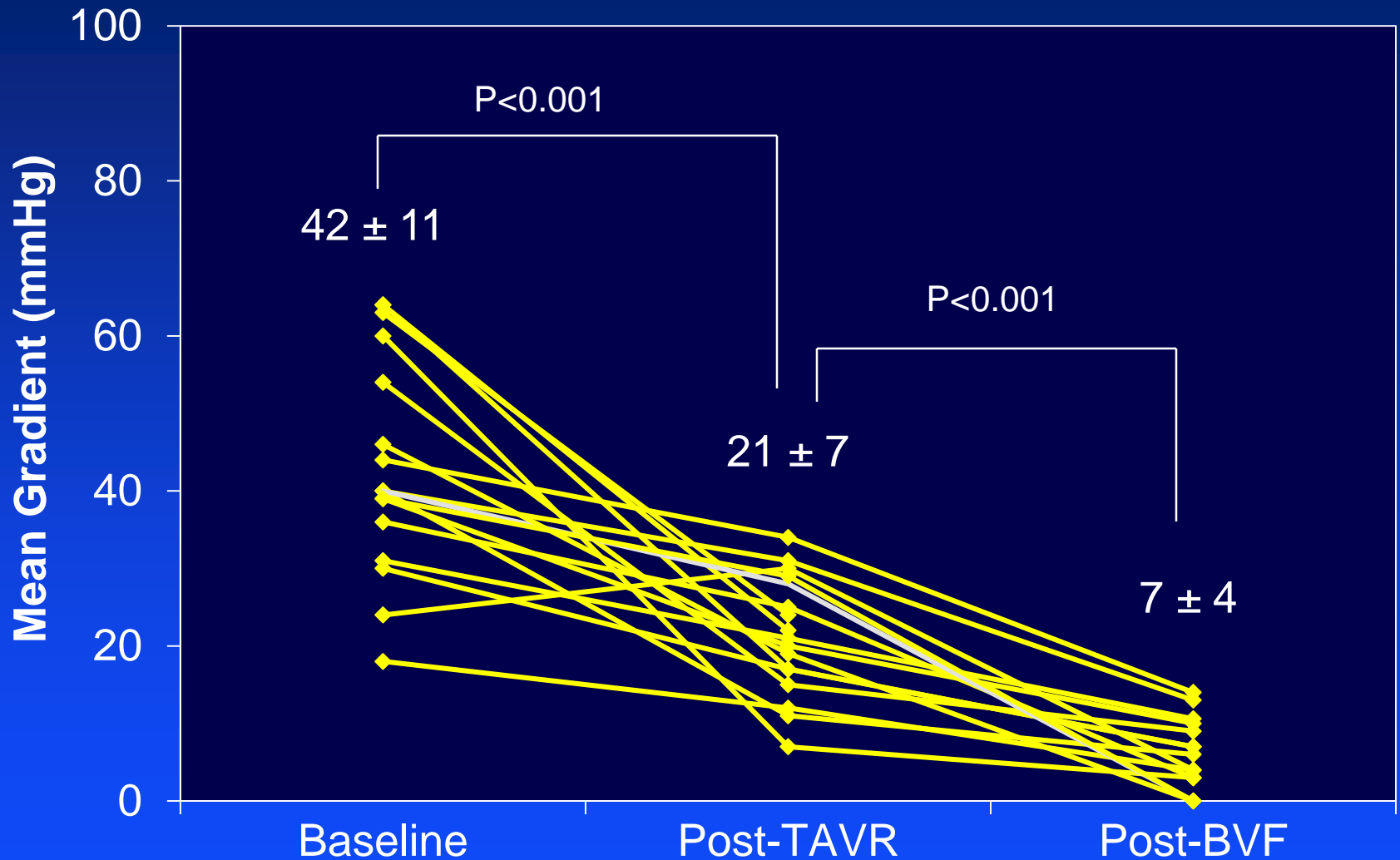
# BVF Clinical Series

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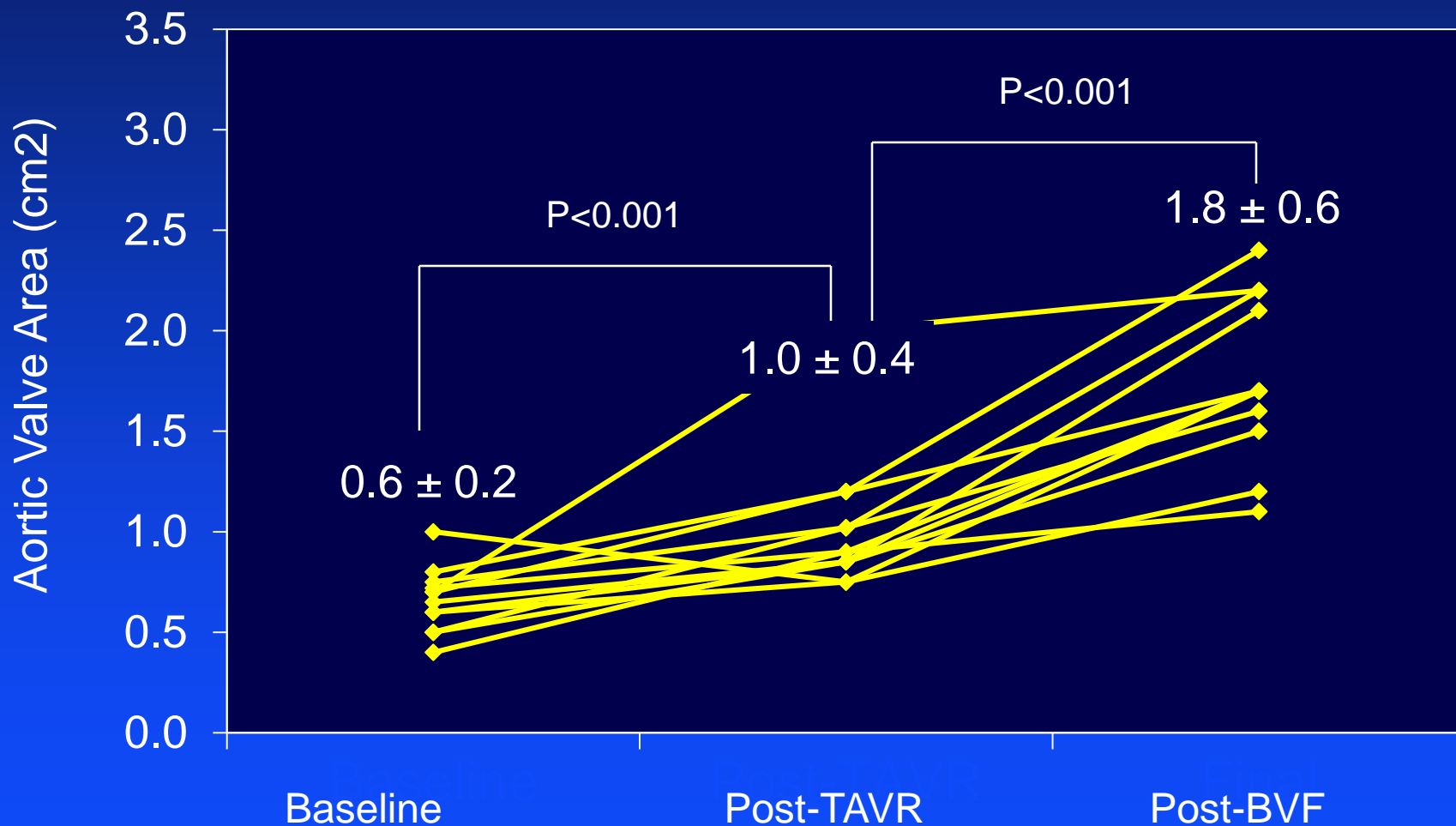
- 20 consecutive patients\* from 7 US centers treated with bioprosthetic valve fracture at the time of ViV TAVR (8 at MAHI)
- Mean age 76 years; mean STS-PROM 8.4%
- Valves treated: Mitroflow, Perimount, Magna/Magna-Ease, Biocor Epic/Epic-Supra, and Mosaic
- Treated with both self-expanding (n=12) and balloon expandable (n=8) TAVR valves
- 15/20 underwent BVF after TAVR valve deployed

\* 30 cases in full series  
as of 6/11/17

# Mean Gradient



# Effective Orifice Area (AVA)



# Intentional Fracture of Bioprosthetic Valves

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- For patients with small bioprosthetic valves who are high risk for re-do AVR, BVF may offer a “solution” to high residual gradients after ViV implantation
- Bench testing demonstrates that most surgical valves can be fractured (except Trifecta and Hancock II)
- Clinical experience to date suggests that BVF is safe
- Unresolved questions
  - *Timing of BVF (pre vs. post-TAVR) → impact on safety and long-term TAVR valve durability*
  - *Should all ViV procedures undergo BVF (even with a low gradient) to allow for better TAVR valve geometry and function*

# Acknowledgements- MAHI TAVR Team

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