Percutaneous Valve in Native With and Without Mitral Valve Calcification: When To Go Hybrid

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Disclosures

None

Percutaneous Valve With Mitral Valve Calcification

- Severe mitral annular calcification can dramatically affect surgical risk
  - Risk of AV groove disruption
  - Increased operative time (pump/clamp time)
  - Debridement can increase stroke risk
  - Small surgical valve size placed
  - Increased paravalvular leak risk
- Elderly patients with comorbid conditions

Background

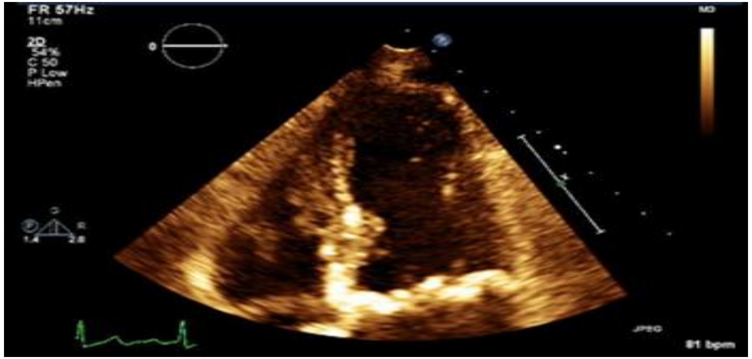
- Mitral annular calcification (MAC) has been reported in nearly 10% of patients in large historical autopsy studies
- CT or echocardiographic determination of MAC has been seen in 8-15% of patients without cardiovascular disease
- The incidence of MAC may be as high as 42% in elderly patients with known cardiovascular disease
- It is estimated that MAC may be found in 24% of patients referred for mitral valve surgery

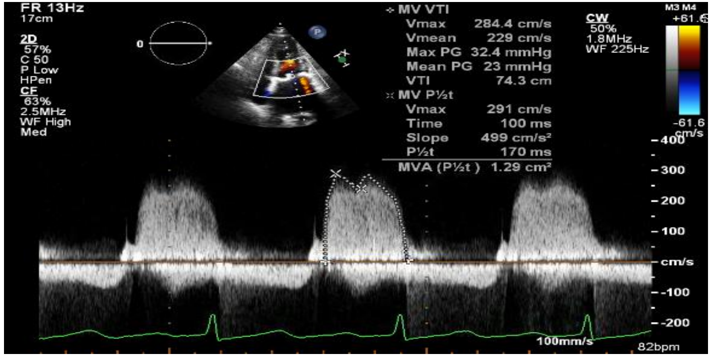
Epiphany: TAVR in MAC

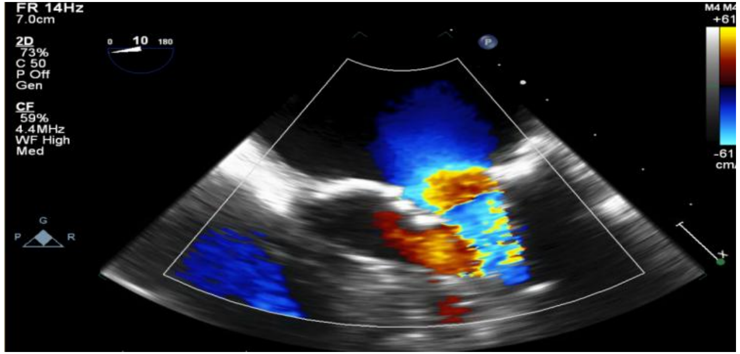
- TAVR seats into calcified annulus
- Balloon mounted TAVR devices have a relatively low profile
- Case reports of TAVR in v-in-v MVR with good results and safety profiles[1,2]
- TAVR in MAC transseptal and transapical with reasonable success in highly selected patients
- Scattered surgical discussion of successful implants.

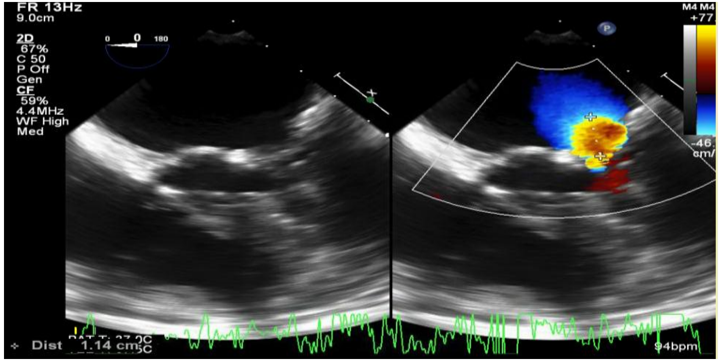
1.Guerro, et al. *J Am Coll Cardiol Intv*. 2016;9(13):1361-1371
2.Himbert, et al. *J Am Coll Cardiol*. 2014;64(23):2557-2558

Imaging: Echo









- Mitral annular calcification
- Mitral stenosis
- Mitral regurgitation
- EF: 60%

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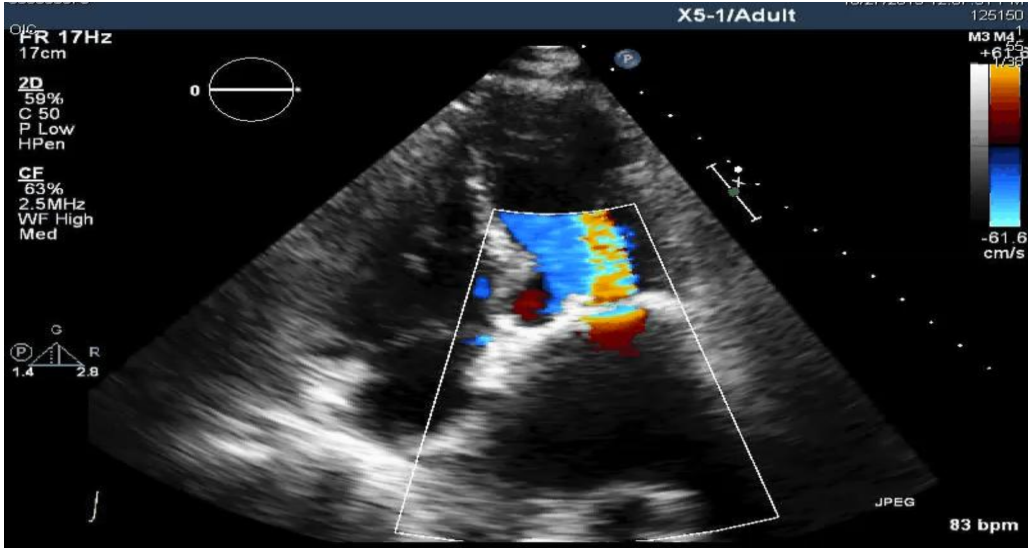
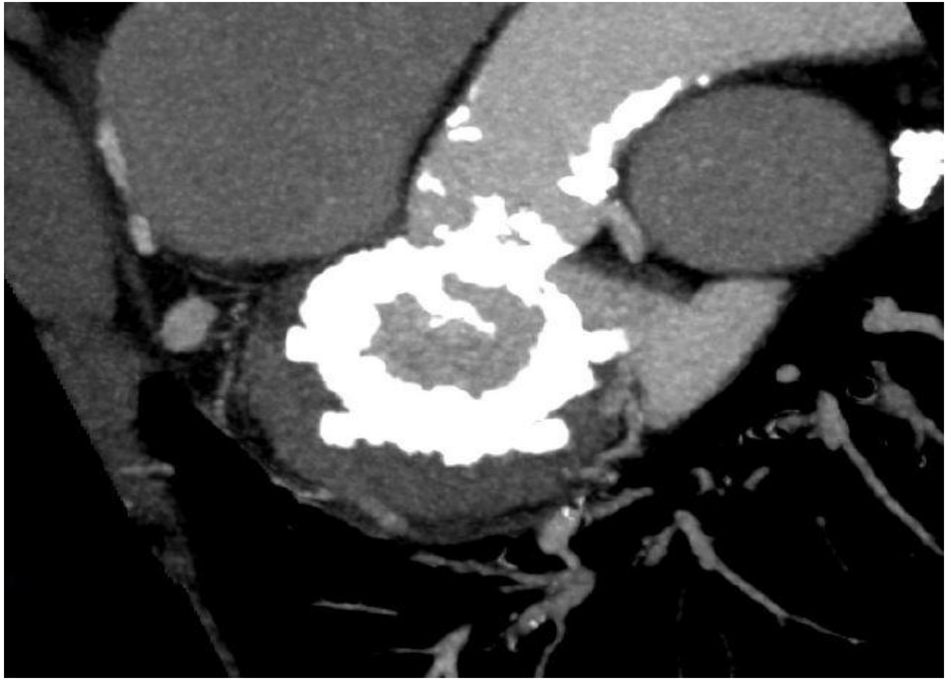
Imaging: TEE

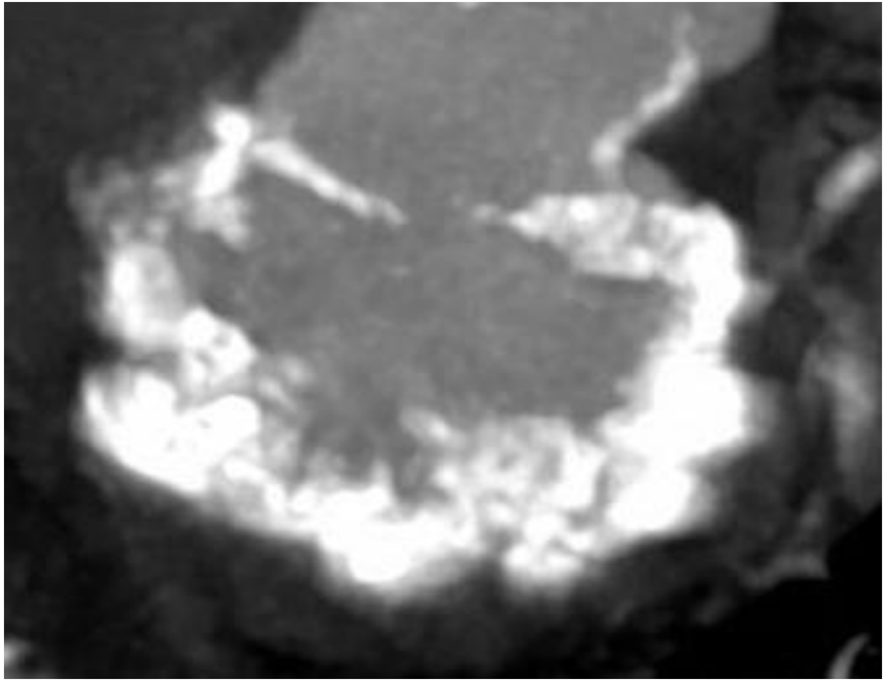


Imaging: Gated CTA Heart for screening

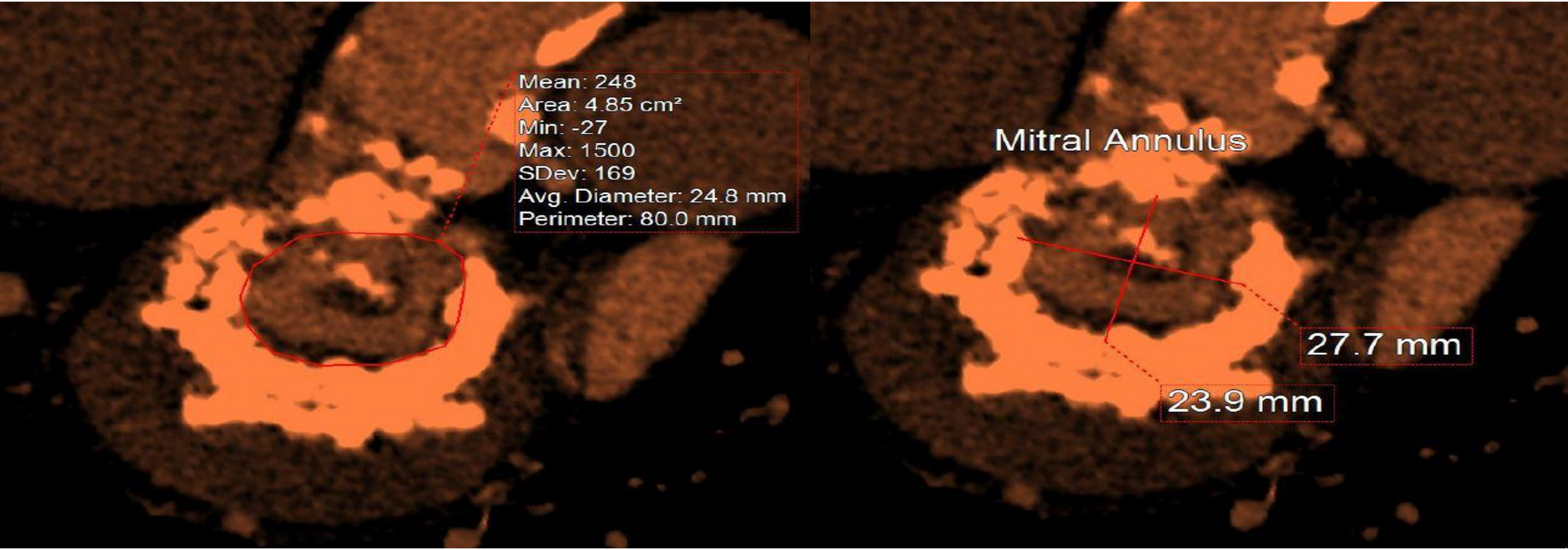
- Burden and distribution of MAC
- Mitral annulus sizing
- Mitral valve planimetry
- Septal thickness
- Septal-Mitral annulus plane distance
- THV mannequin embedding (Annulus & LV)

Imaging: Gated CTA Heart for screening





Imaging: Gated CTA Heart for screening



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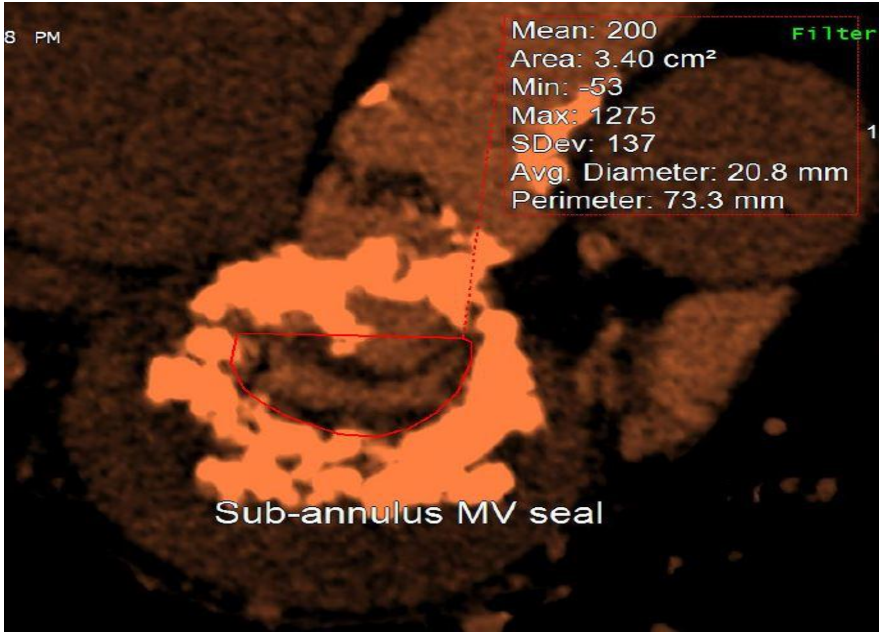

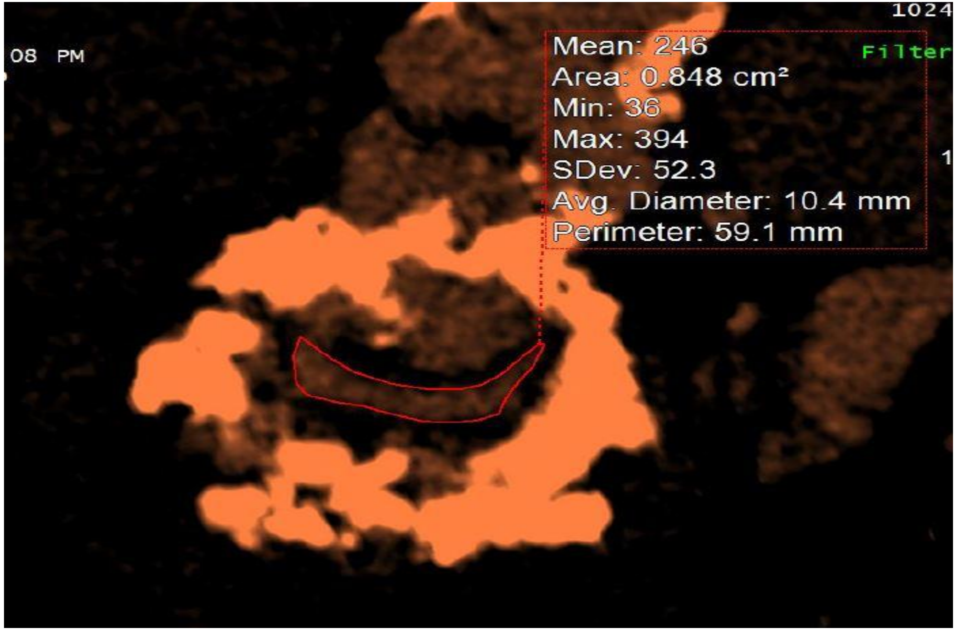

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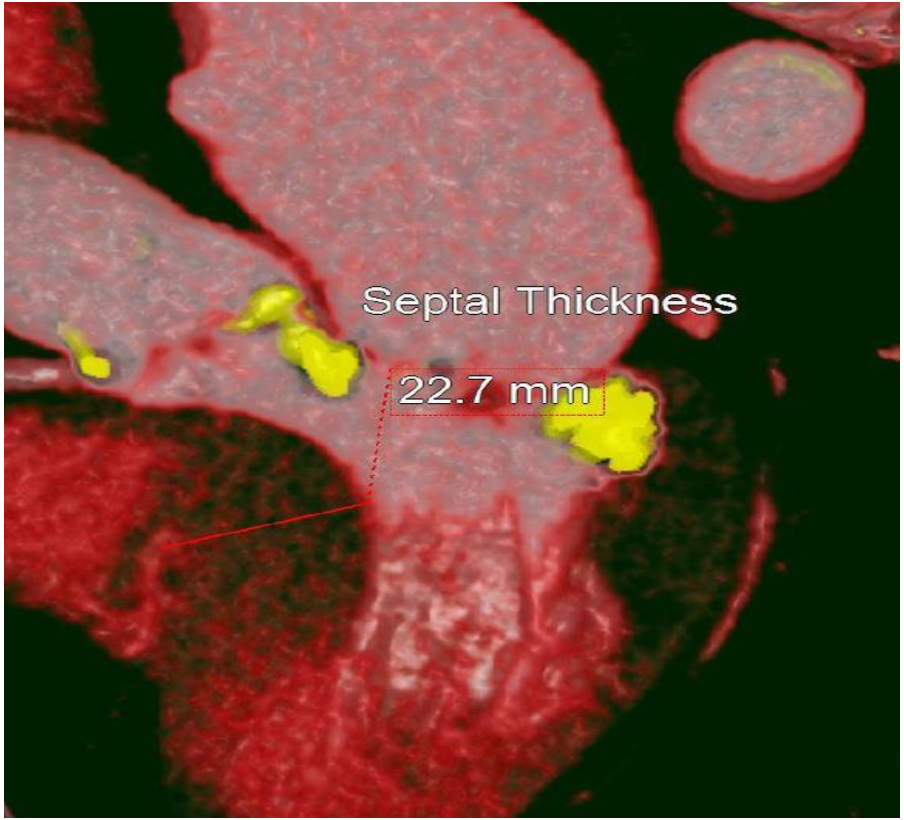

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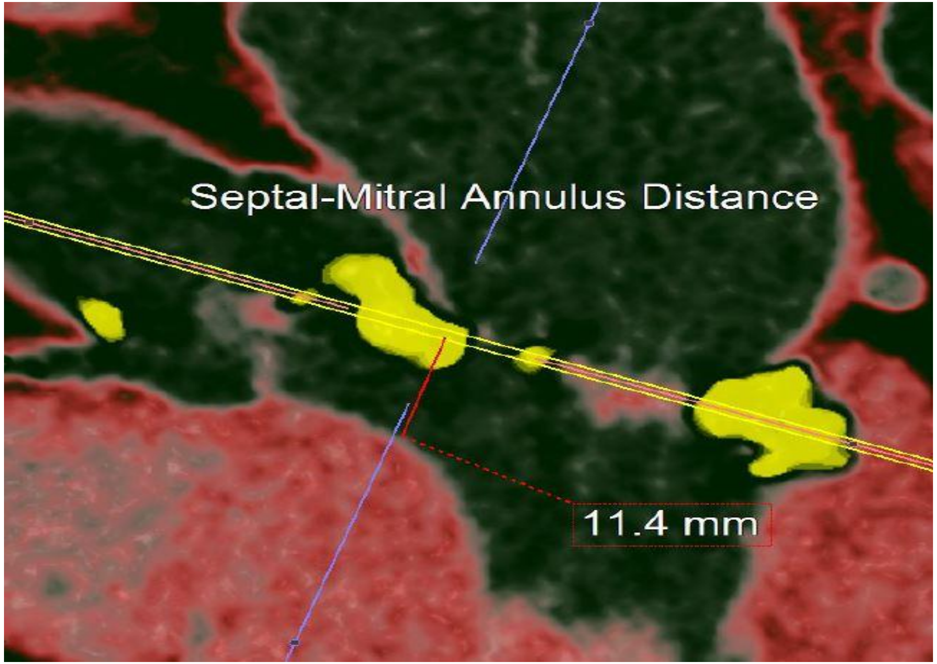

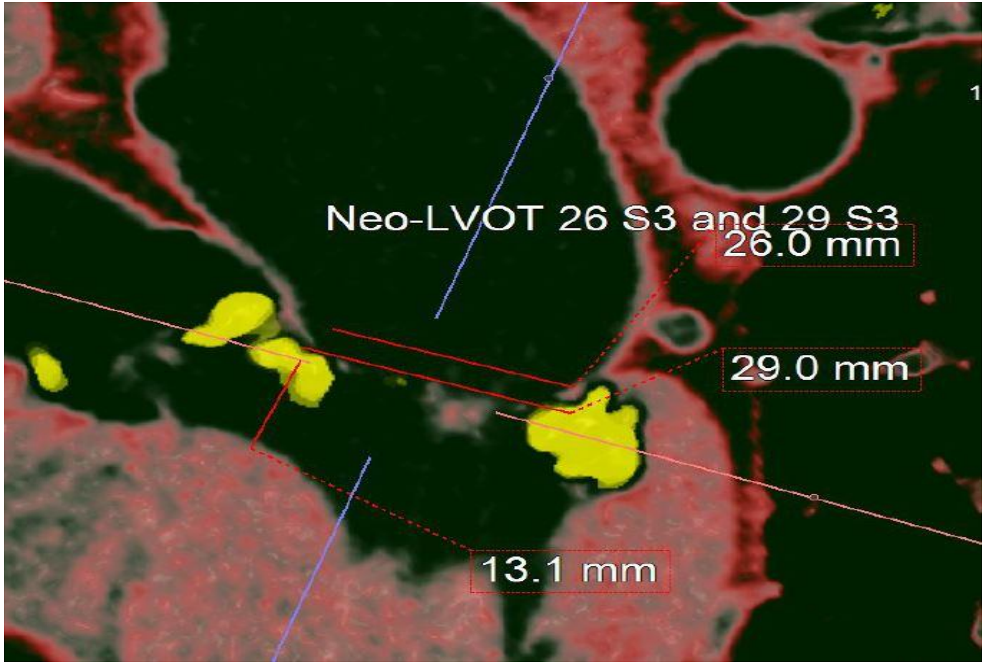

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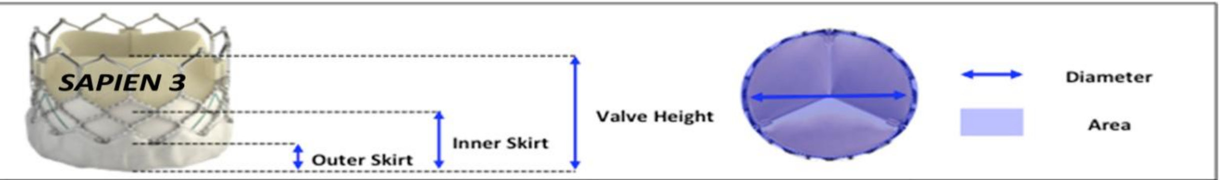
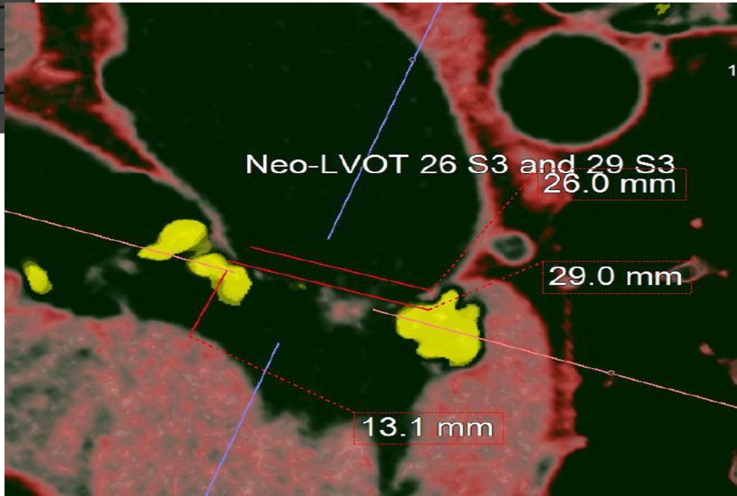


SAPIEN 3	23	26	29
Effective Orifice Area [cm²]	2.11	2.30	2.59
Valve Height [mm] *Crimped / Expanded*	24.5 / 18	27 / 20	31 / 22.5
Foreshortening [mm]	6.5	7	8.5
Inner Skirt Height [mm]	9.3	10.2	11.6
Outer Skirt Height [mm]	6.6	7.0	8.1



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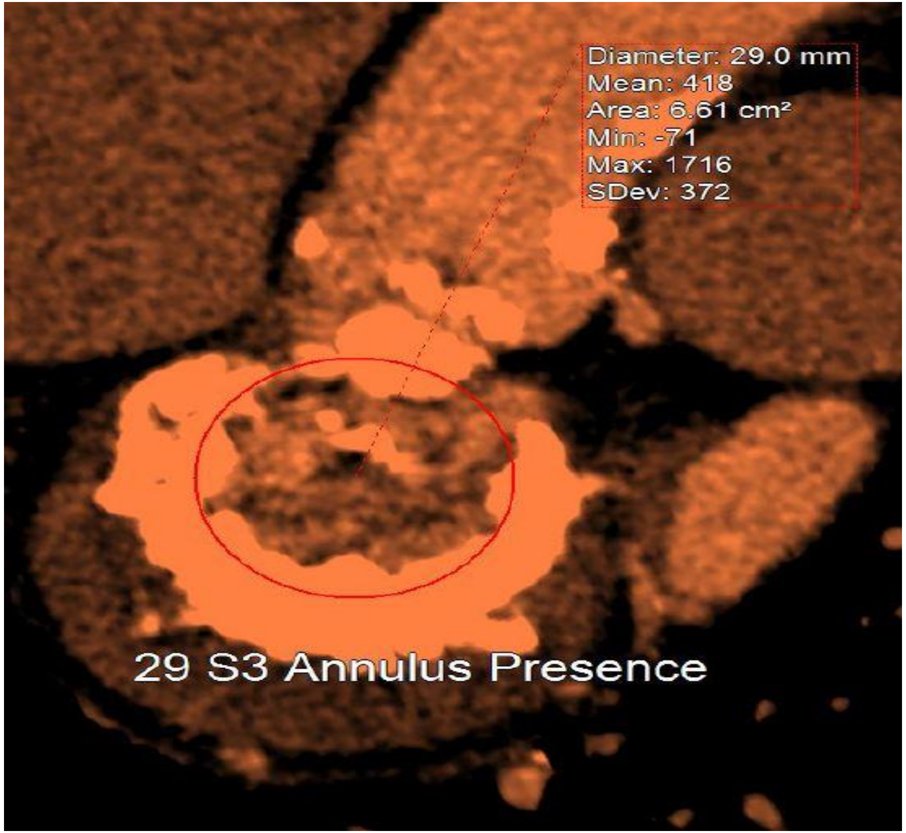


Transcatheter Mitral Valve Replacement in Native Mitral Valve Disease with Severe Mitral Annular Calcification

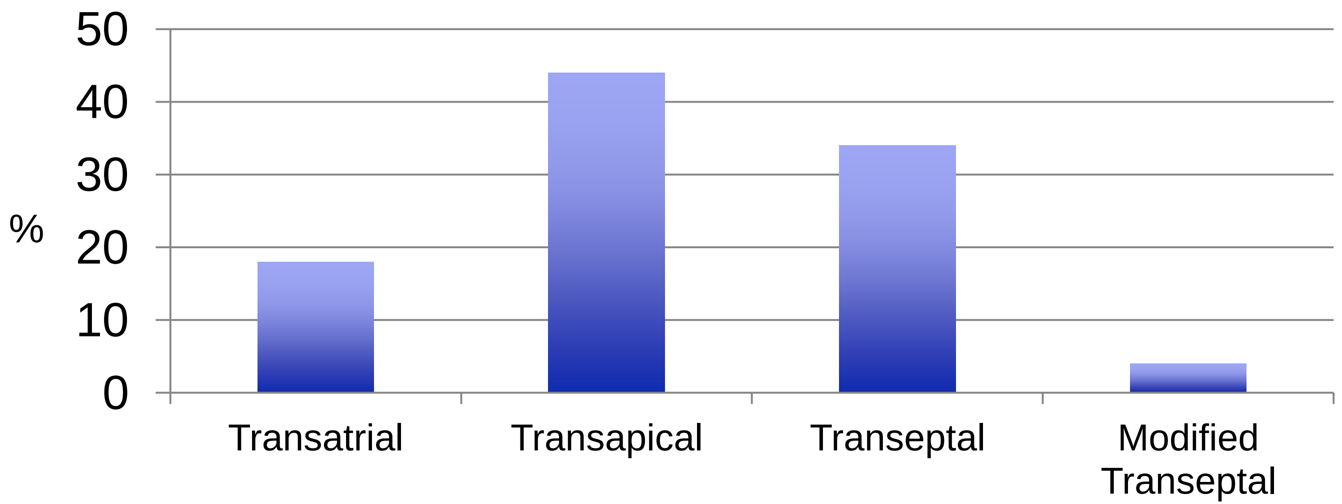
Results from the First Global Registry

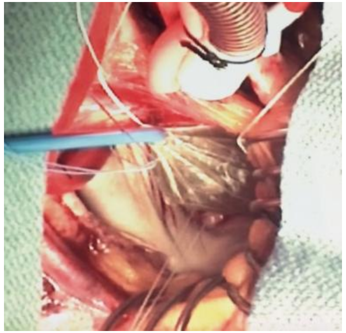
Mayra Guerrero, MD, FACC, FSCAI
Director of Cardiac Structural Interventions
NorthShore University HealthSystem

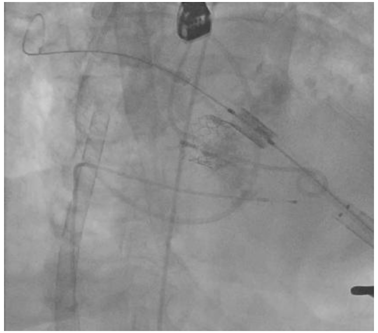
TVT 2016
Chicago, IL
June 17, 2016

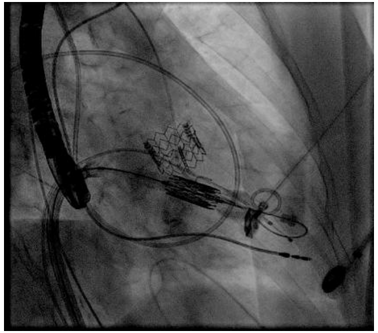
NorthShore University HealthSystem
Evanston Hospital

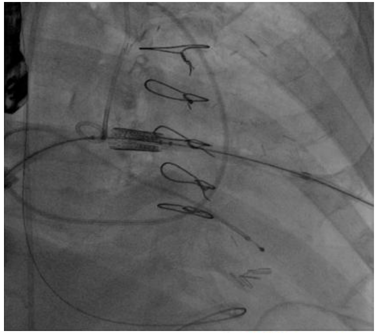
Delivery Approach











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Procedural Outcomes

	n (%)
Technical success by MVARC criteria	78/104 (75%)
Need for second valve (migration=6, MR=7)	13/104 (12.5%)
LVOT obstruction with hemodynamic compromise	11/104 (10.5%)
Valve embolization	4/104 (3.8%)
Conversion to open surgery (embolization=2, LV perforation=1, LVOTO=1)	4/104 (3.8%)
LV perforation (surgery=1, conservative=1)	2/104 (1.9%)
Pulmonary Vein Perforation	1 (0.9%)

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Evanston Hospital

30 Day/Procedural Mortality

26/104 (25%)

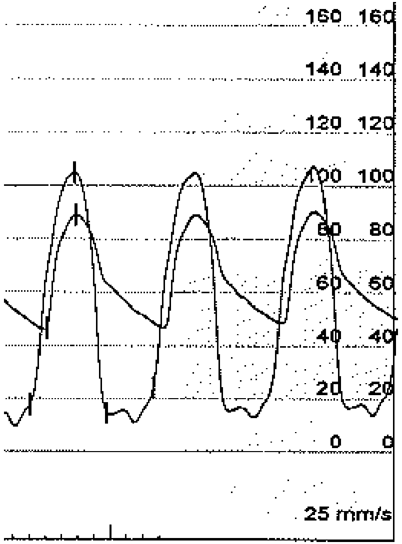
	n (%)
Cardiovascular	11/104 (10.6 %)
LVOT Obstruction	3 (2.9%)
LV Perforation	2 (1.9%)
Complete AV block	1%
MI due to air emboli / Pulmonary vein perforation	1%
Stroke	2 (1.9%)
PEA arrest	1 %
MR	1 %
Non-Cardiac	15/104 (14.4 %)
Multi-organ failure	9 (8.6%)
Pneumonia	3 (2.9%)
Thoracentesis related bleeding complication	1%
Infection	2 (1.9%)

Concerns for TAVR in MAC

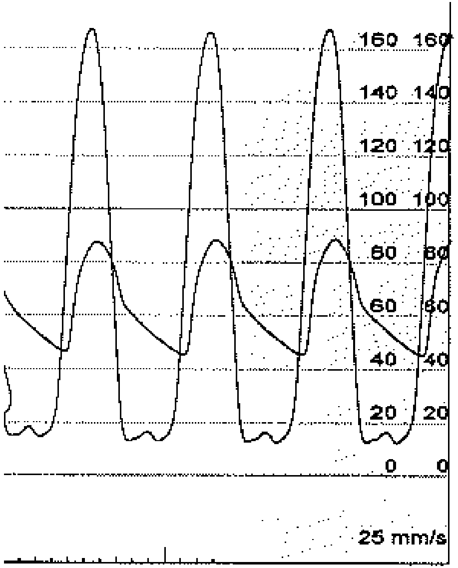
- Device embolization
- LVOT obstruction
  - From device
  - From leaflet
  - From ventricular septal thickness
- Difficulty in determining positioning for deployment
  - 17.2% needing a second valve deployed*****
- PVL
- High mortality rate reported
  - All cause 30 day mortality ~30%*****

*****Guerrero, et al. *J Am Coll Cardiol Intv*. 2016;9(13):1361-1371

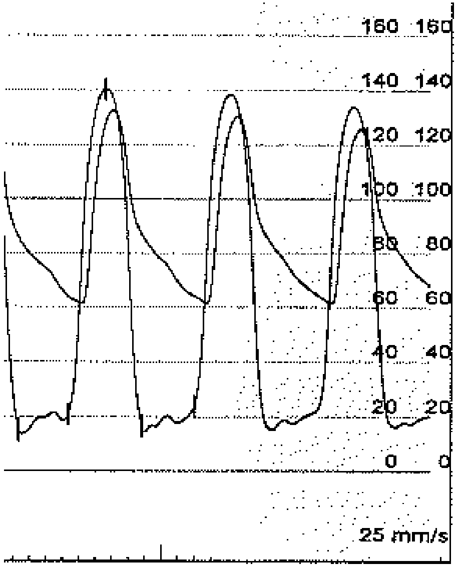
Septal ablation to treat LVOT Obstruction after TMVR



Baseline



After TMVR



Alcohol Septal Ablation

Courtesy of Dr. William O’Neill

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MITRAL:
Mitral Implantation of TRAnscatheter vaLves

- Investigator initiated, prospective multi-center clinic trial
- rgical patients with symptomatic severe MAC
- Sev

92 pts presented

-high risk
-both

Highly selected group of patients

Geurrero, M. TVT 2017

MAC Primary Safety Endpoints

	N(%)
Technical success at exit from Cath Lab	22 (73.3%)
LVOTO (1 TS, 1 TA, 1 Tatrial)	3 (10%)
Need for 2nd valve	1 (3.3%)
>2+ MR	2 (6.6%)
LV perforation (transatrial)	1 (3.3%)
VSD (transatrial)	1 (3.3%)

Primary Safety Endpoints

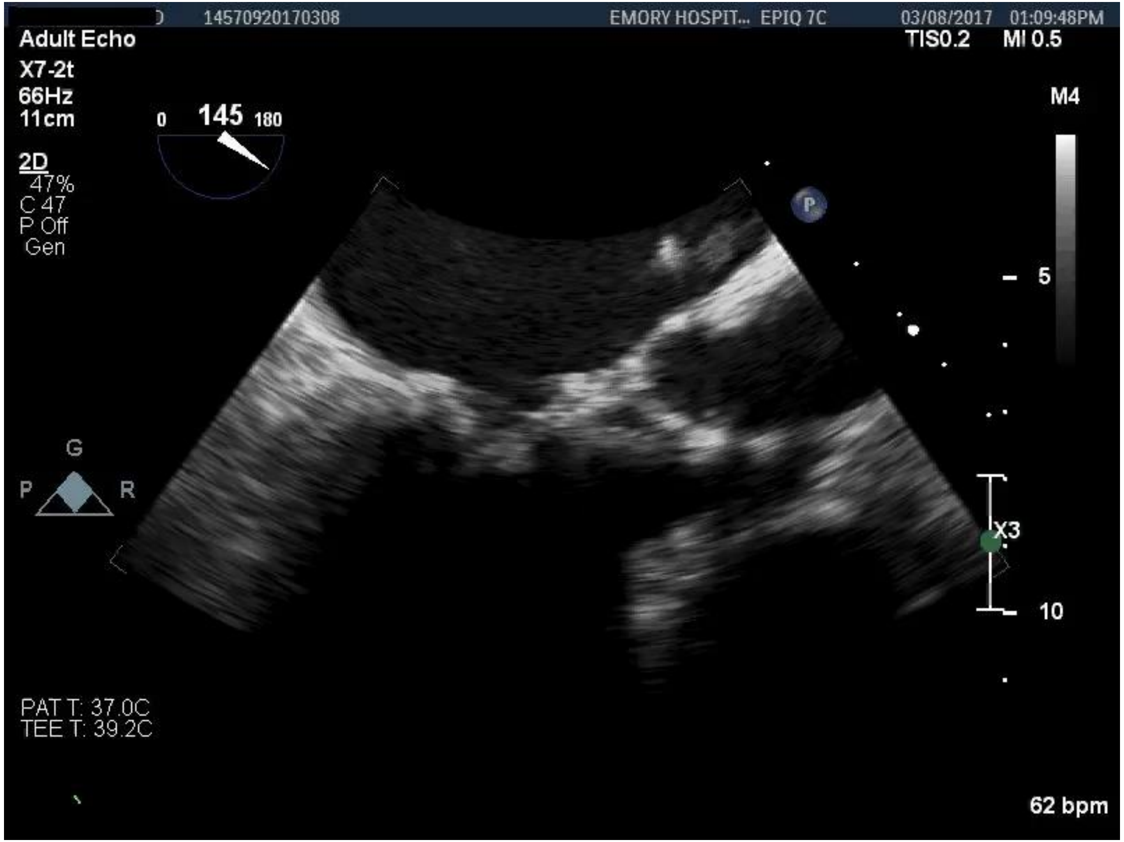
	N (%)
Procedural Success at 30 days	15/29 (51.7)
Death	5(17.2)
Hemolysis	3 (10.3)
Bleed (GIB, hemothorax)	2 (6.9)
HF requiring an ASD closure	1 (3.4)
Acute kidney injury	1 (3.4)
LV perforation during transatrial TMVR)	1 (3.4)
3+MR	1 (3.4)

Trans-septal Valve in MAC

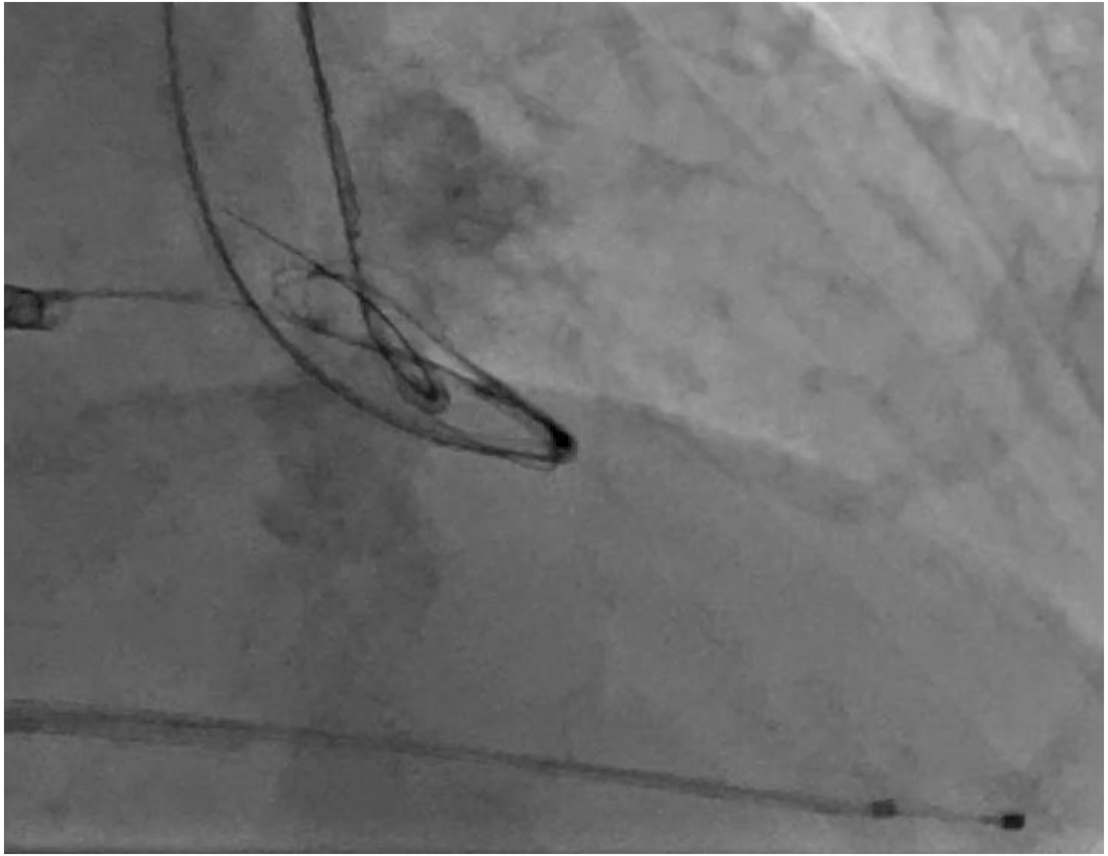
Vinod H. Thourani, MD

AATS Mitral Conclave
April, 2017

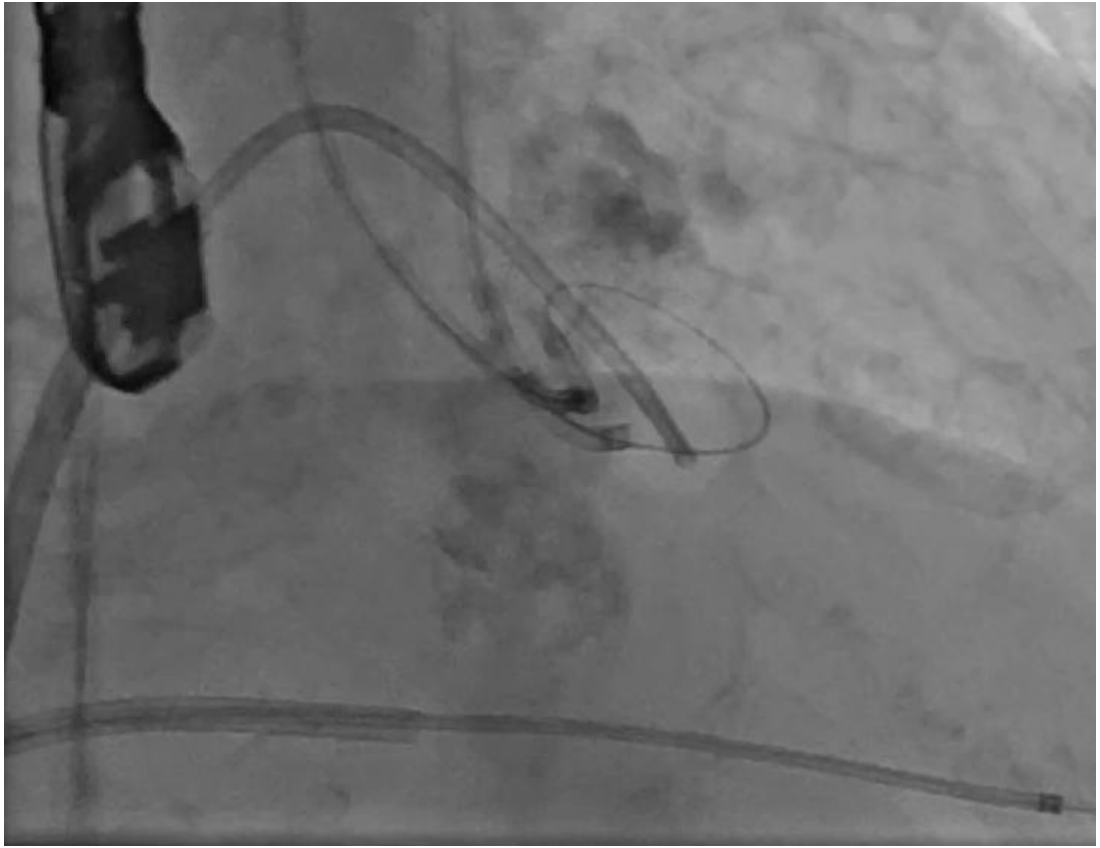
Wire Ready to LAMPOON



Snare Wire from Aorta to LA

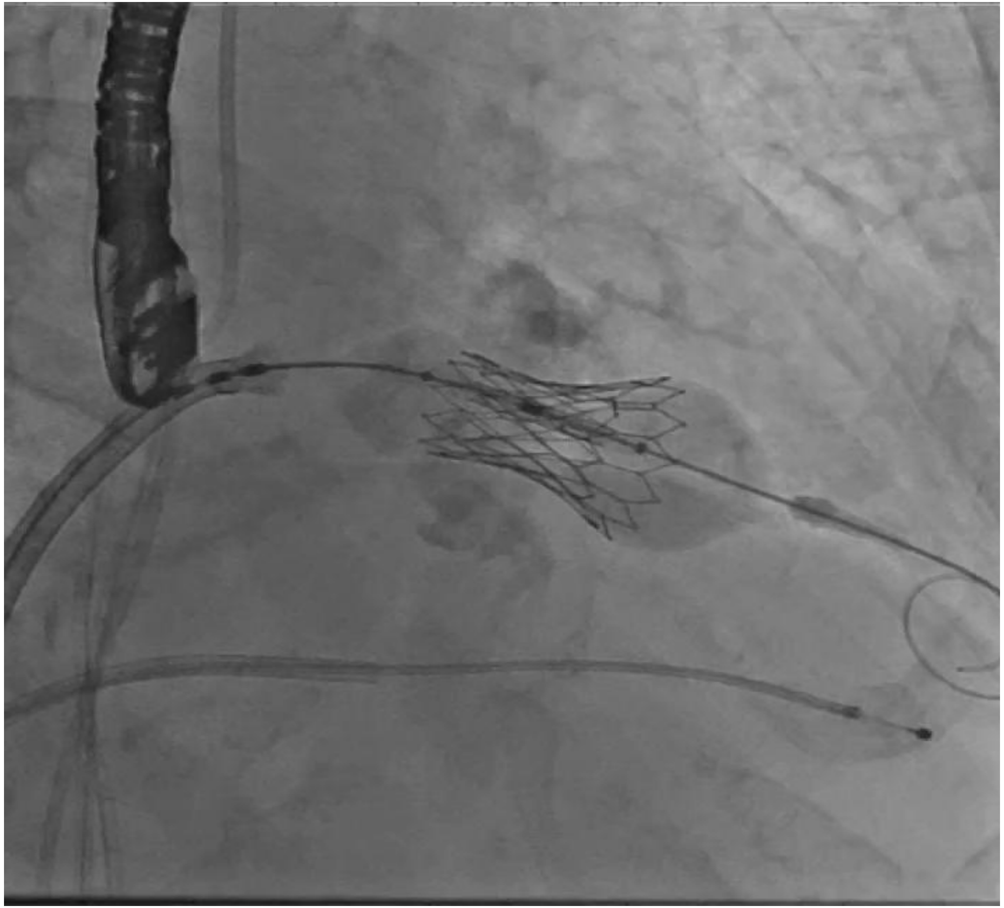


LAMPOON Loop Made

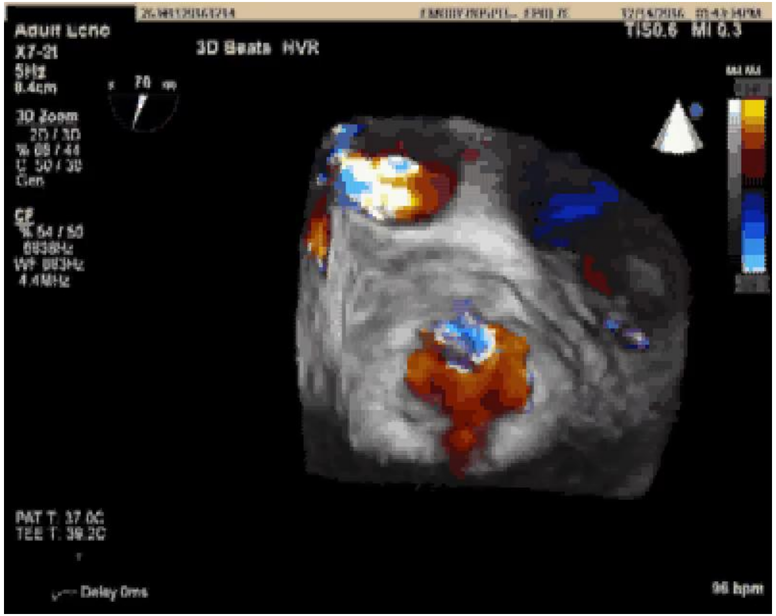


LAMPOON Burn

Valve Deployment



Post Valve 3D TEE



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When To Go Hybrid

Concept for SITRAL

- Surgical Implantation of TRAnscatheter vaLve in native mitral annular calcification
- Potential benefits:
  - Reduce LVOTO risks
  - Reduce risk of embolization
  - Reduce PVL risk
  - Orient the valve into standard surgical configuration (posts at the trigones)
  - Control device depth (re-deploy if necessary)
- Performed in minimally invasive approach to reduce physical recovery

Implantation of Transcatheter Aortic Prosthesis in 3 Patients With Mitral Annular Calcification

Heike Baumgarten, MD, John J. Squiers, BSE, William T. Brinkman, MD, J. Michael DiMaio, MD, Ambarish Gopal, MD, Michael J. Mack, MD, and Robert L. Smith, MD

(Ann Thorac Surg 2016;102:e433–5)

- This is an off label use of a transcatheter valve
- Approach is right mini thoracotomy via 4^{th} IS
- Utilizes CPB
- Can also address septal thickness with septal myectomy and TR with annuloplasty

Typical case (Off Label)

- 84 Year old female
- MS with MAC
- NYHA IV
- Medical History: HTN, PVD S/P R fem-pop, Brain stem tumor removal 1992 (benign) with right facial droop, subclavian steal syndrome
- Normal coronaries
- STS-PROM MVR 8.1%

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Preoperative TTE

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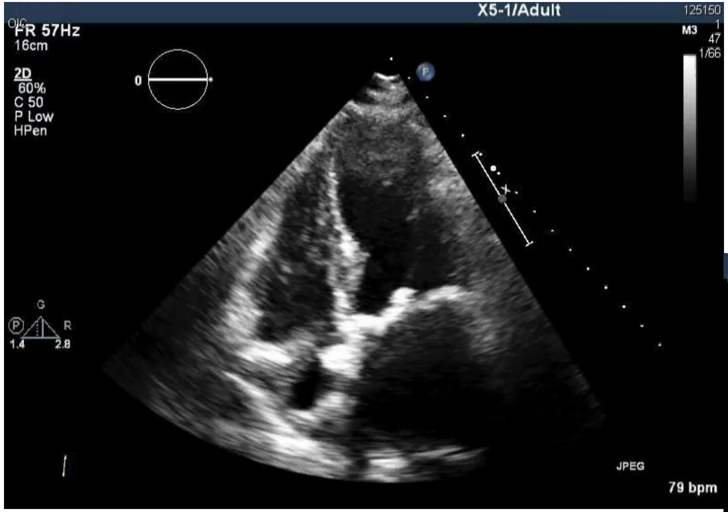
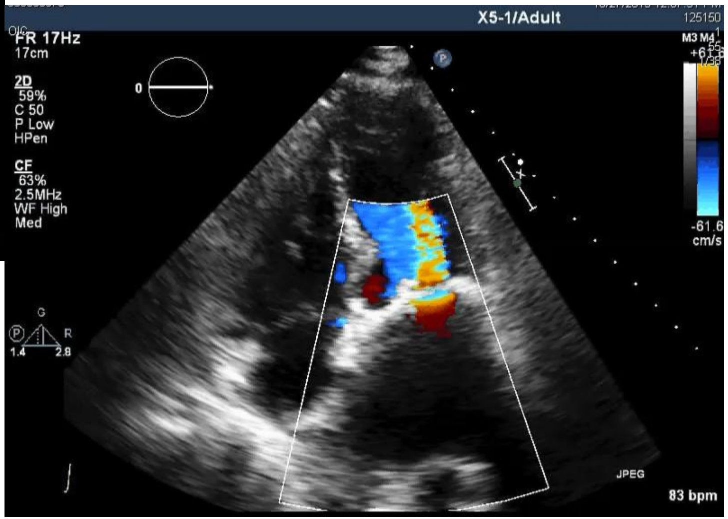
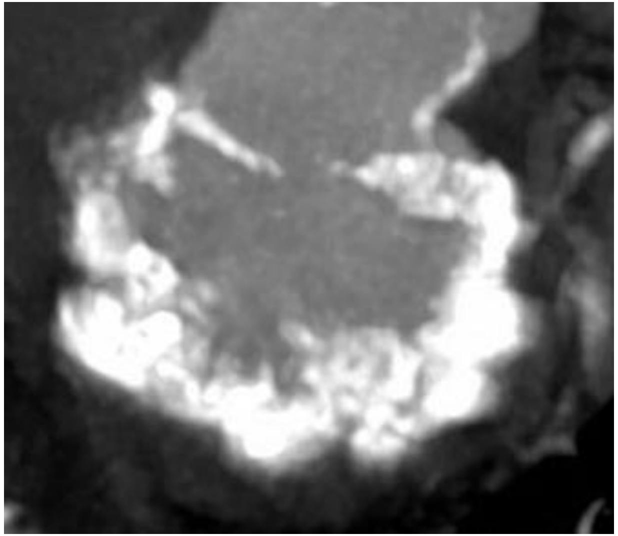


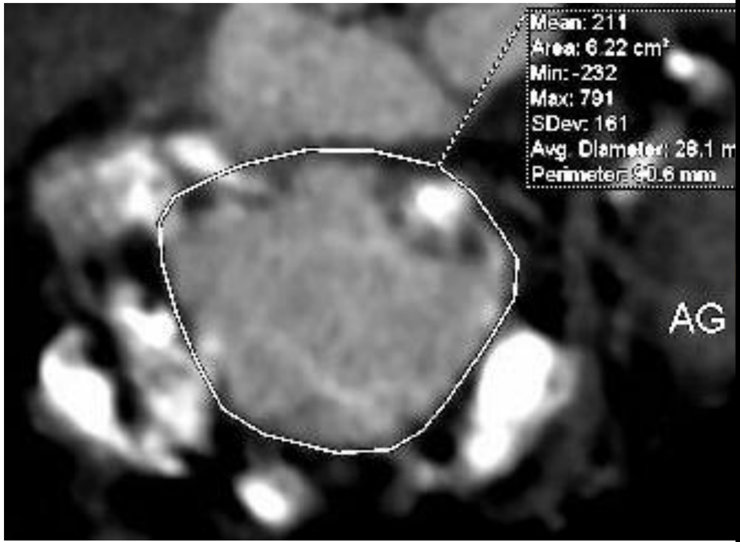
MV gradient: 23 mmHg
MVA: 0.8 cm^2
RVSP: 68 mmHG



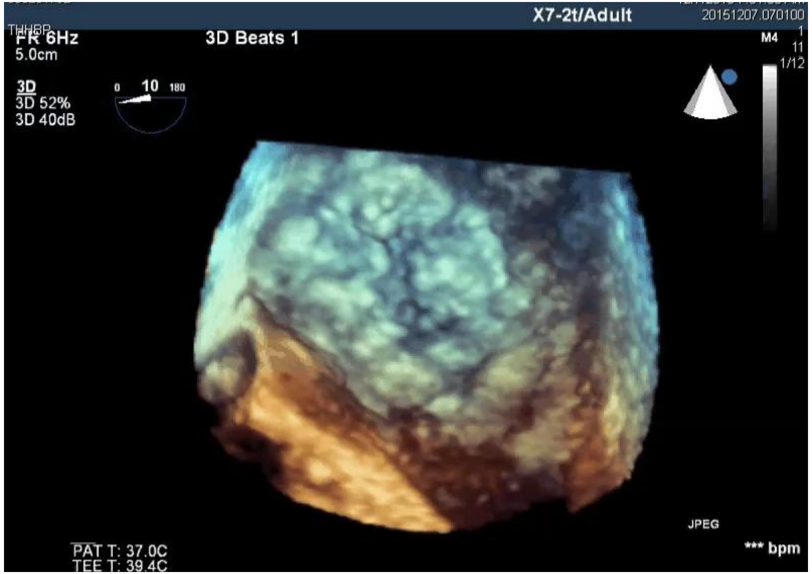
Planning CTA

Severe concentric MAC
Extensive calcification penetrating ventricular wall
Porcelain aorta

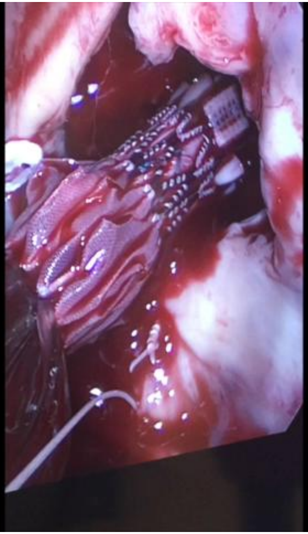




Intraoperative TEE



Intraoperative Course

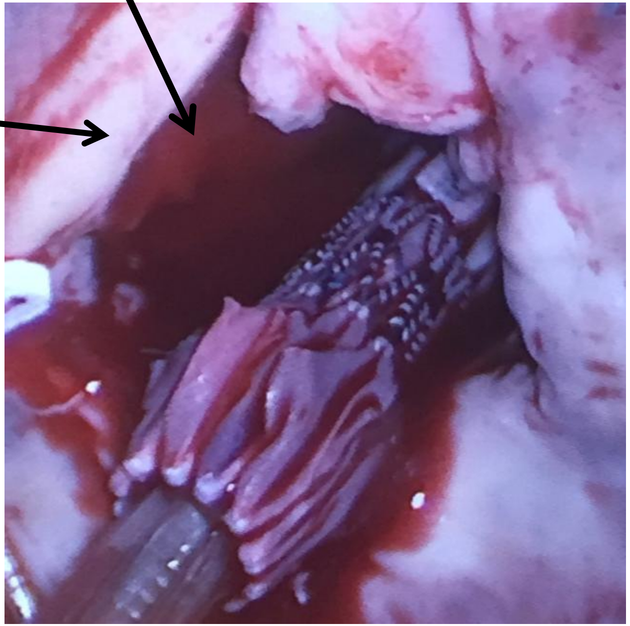


- MI MVR via right mini thoracotomy or robotic approach with femoral bypass and cold fibrillatory arrest
- Resection of A2 and chords, septal myectomy can be performed
- Balloon sizing of the mitral annulus
- Pledgeted sutures are placed in the trigones and at the annulus on P2 from ventricular to atrial position with possible felt buttress
- The valve is positioned with the valve skirt at the level of the annulus
- Thoracoscopic visualization is used to watch full valve deployment
- The sutures are then placed through the cuff of the valve and secured

Intraoperative Photos

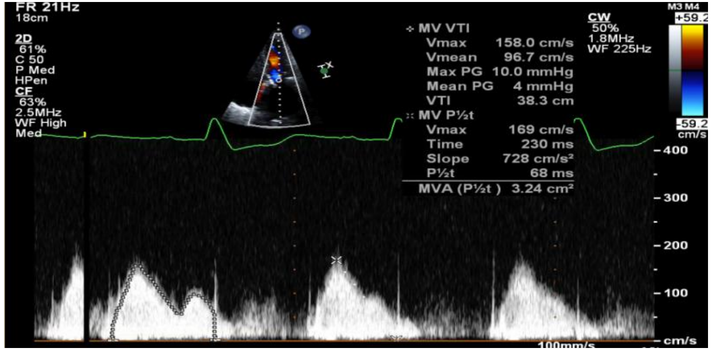
Septal Myomectomy

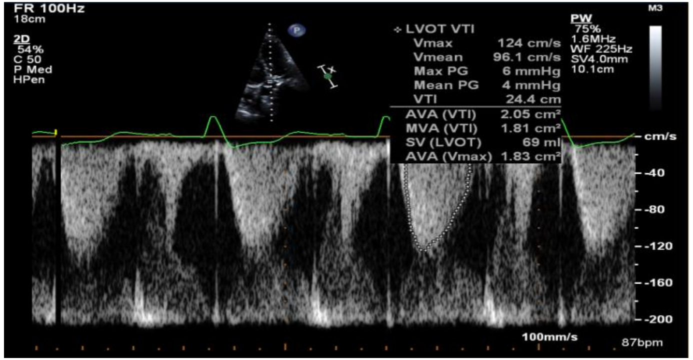
Removed portion of A2

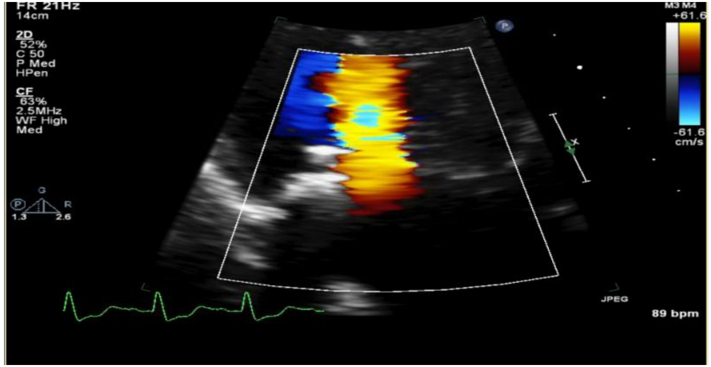


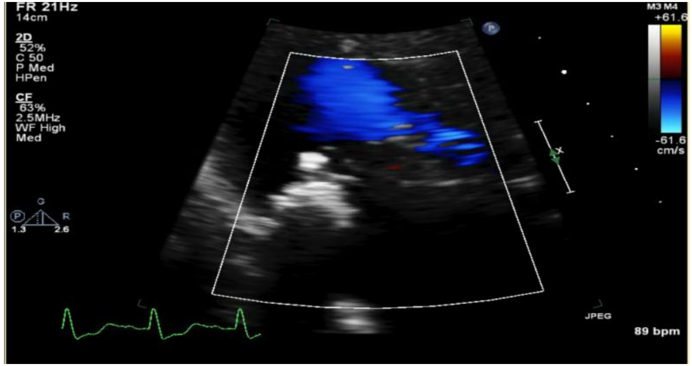
Post Implantation 3D TEE

Postoperative Imaging
POD #1 TTE





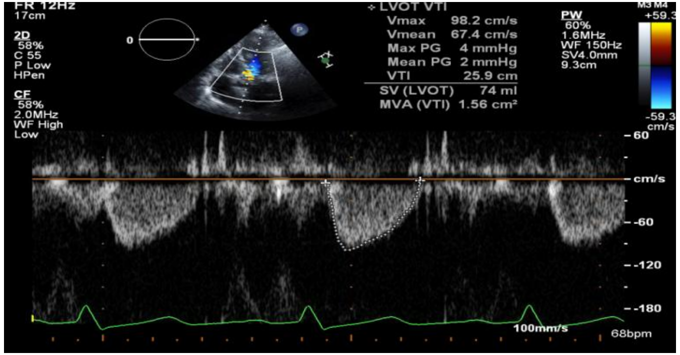


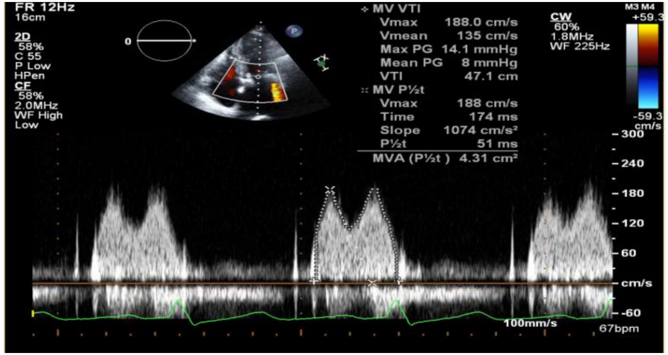


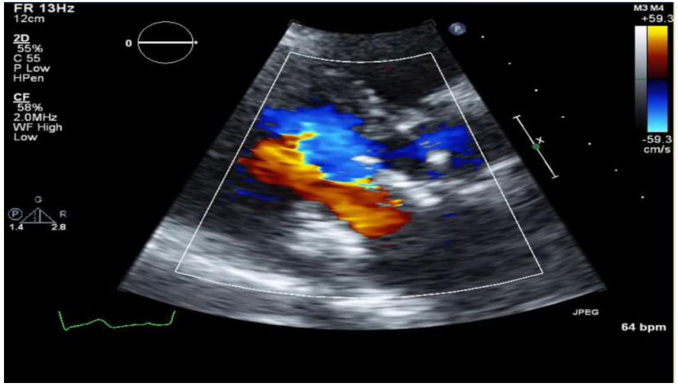
- Mean gradient of 4 mmHg across the mitral valve
- Mean gradient of 4 mmHg across the LVOT
- Laminar flow seen through both

Postoperative TTE

Follow Up Imaging at 7 months-TTE

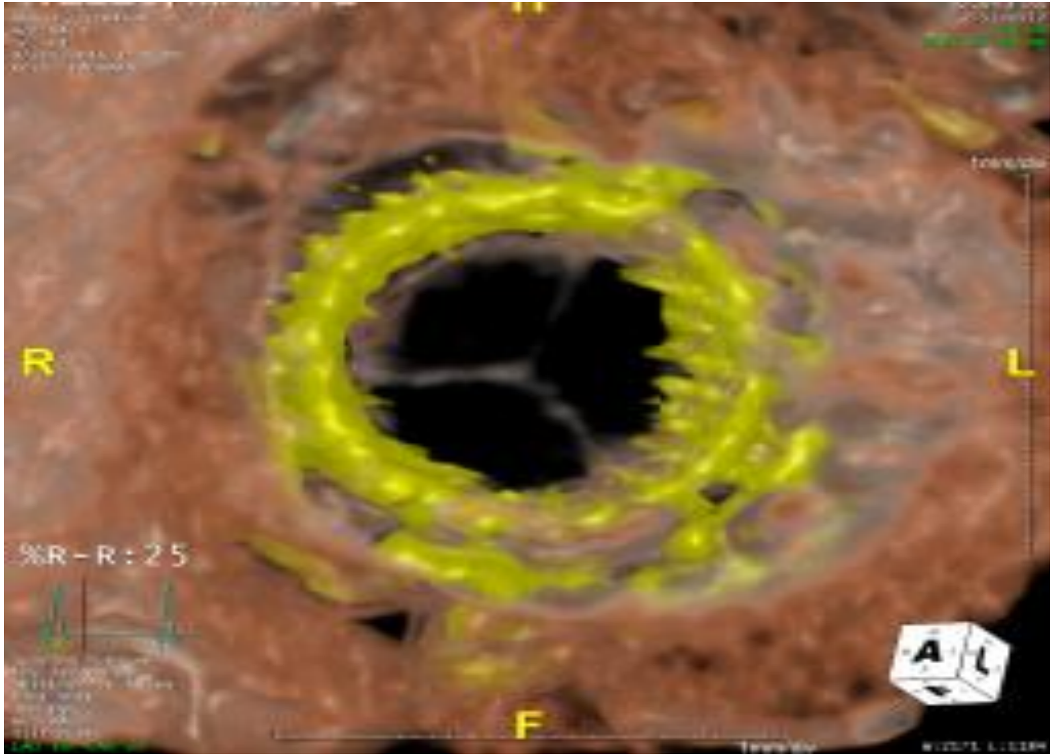






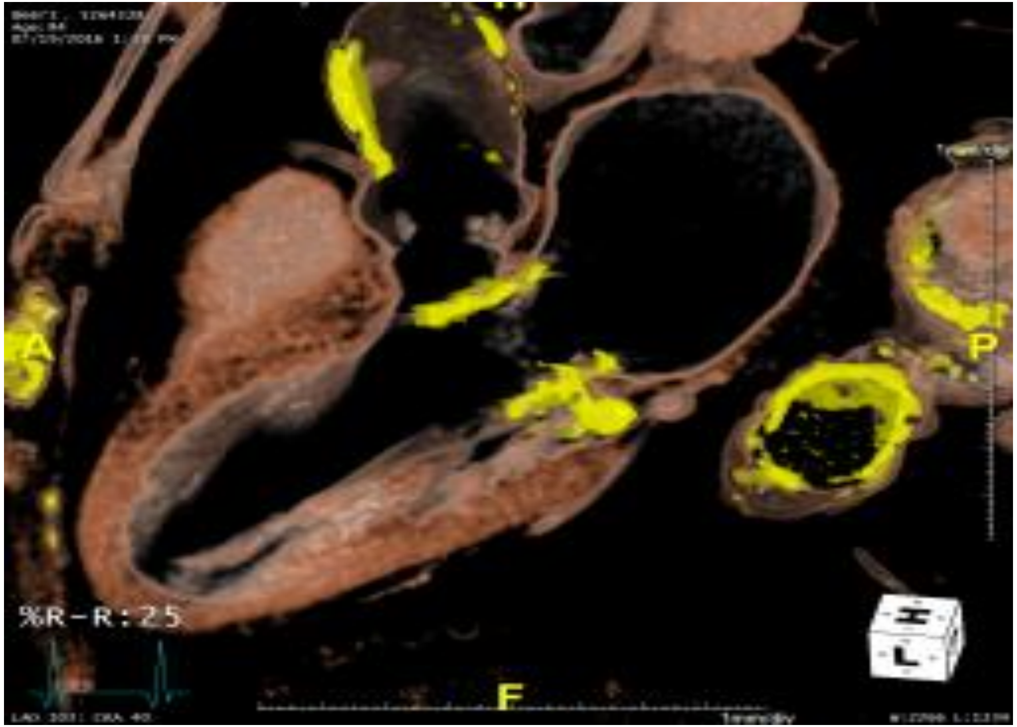
- Mitral valve mean gradient 8mmHg
- LVOT mean gradient 2 mmHg
- Laminar flow through both
- EF: 65%

Follow Up Imaging
Short Axis 4D CTA

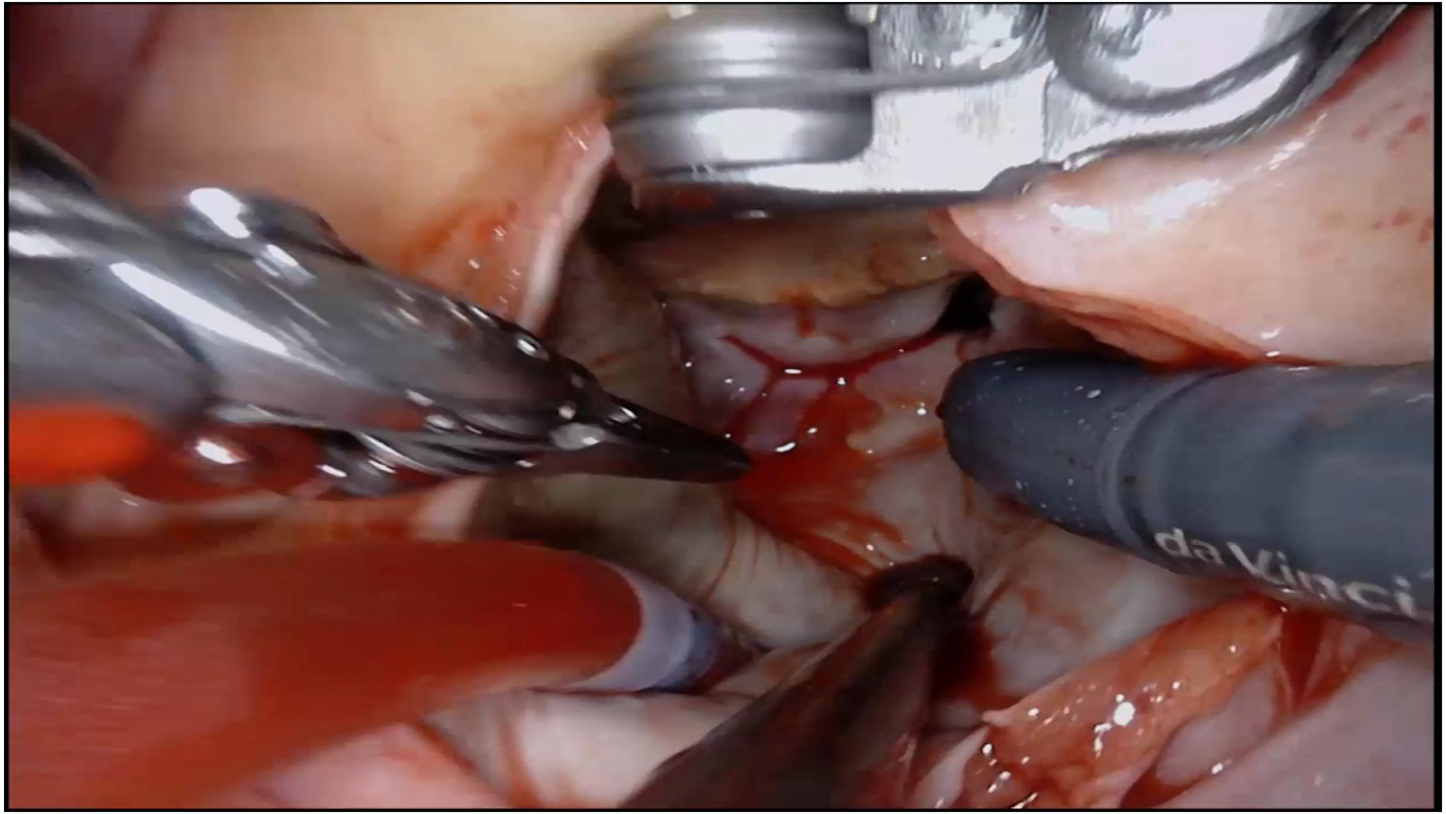


No thrombus is seen on the leaflets and the valve is fully expanded with complete leaflet excursion.

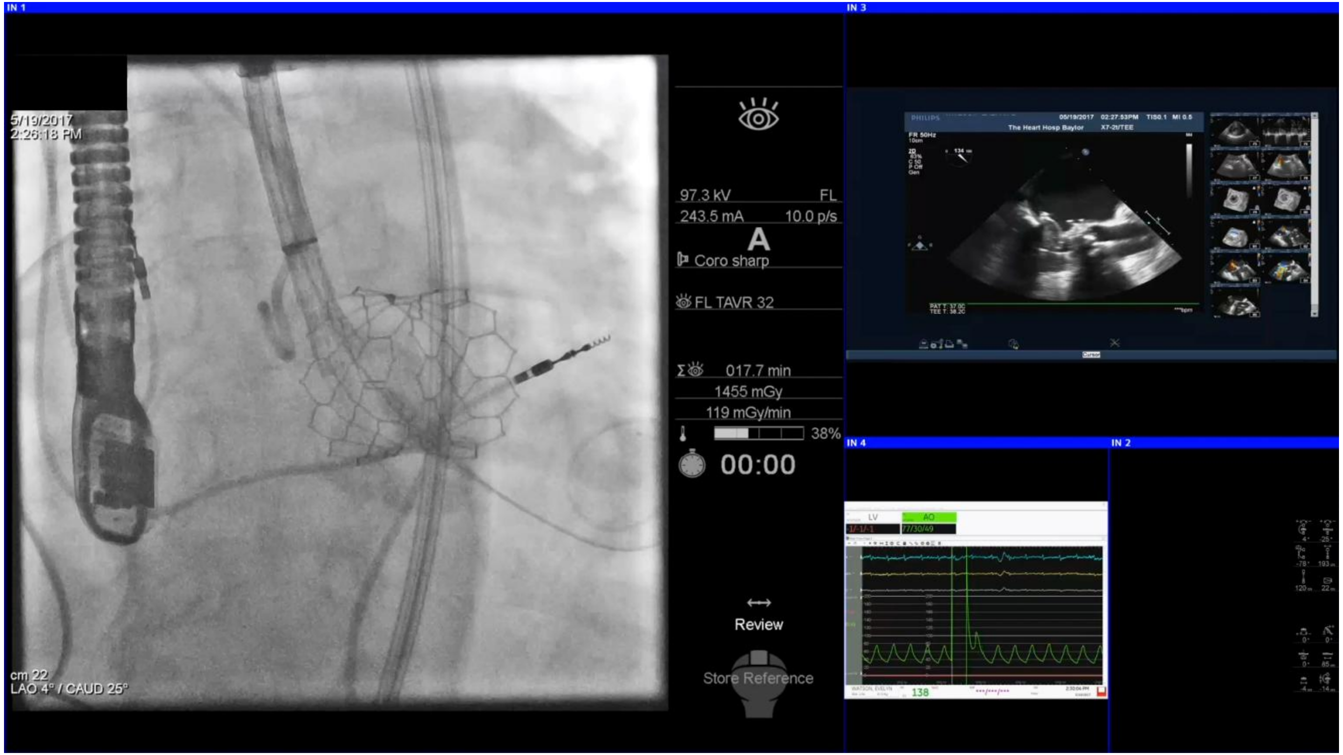
Follow Up Imaging
Long Axis 4D CTA



90 yo Female Severe AS and MS



Even can add a TAVR same day



THHBP Experience-First Ten Cases

STS-PROM	Indication	Concomitant Procedure	Age	Sex	Preop Mean MV Gradient	Preop Mean LVOT Gradient	Valve Type	Valve Size	LOS	Disposition	Postop Mean MV Gradient	Postop Mean LVOT Gradient
17.3	Stenosis	None	87	F	11	2	Sapien XT	26	5	Rehab	10	7
8.1	Mixed	Myomectomy	84	F	23	1	Sapien 3	26	8	Rehab	4	4
9.3	Mixed	Tricuspid Annuloplasty	86	F	9	1	Sapien 3	29	24	LTAC	4	6
14.2	Mixed	Tricuspid Annuloplasty	78	F	13	4.2	Sapien 3	29	11	Home	4	7
6.5	Stenosis	Myomectomy	77	F	12	5	Sapien 3	26	11	Rehab	6	2
4.0	Stenosis	Myomectomy	71	F	8	Unknown	Sapien XT	26	32	Death	8	9
12.6	Mixed	PFO closure	76	F	15	2	Sapien XT	26	8	Home	6	3
6.1	Stenosis	Myomectomy	70	F	17	4	Sapien XT	26	11	Home	6	2
8.9	Mixed	Myomectomy	83	F	7	3	Sapien 3	29	8	Rehab	5	1.5
9.5	Mixed	AVR, TVR, Myomectomy	80	F	5	5	Sapien XT	29	13	Rehab	6	3

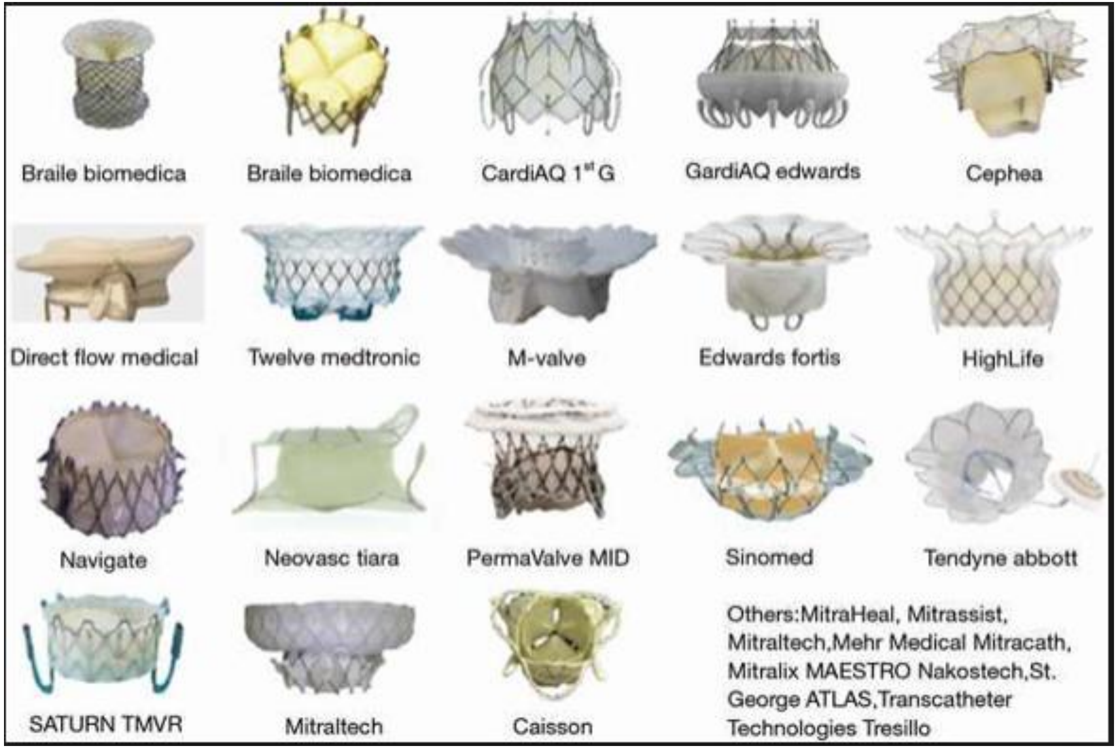
Case Series-THHBP

- 14 off-label procedures have been completed at The Heart Hospital Baylor Plano, additional procedures have been completed as part of the SITRAL study
- Nine cases were performed via right thoracotomy
- Two case were done through sternotomy due to concomitant AVR and TVR
- Three cases were done robotically
- Technical and hemodynamic success was achieved in all patients
    - 2 In-hospital death (salvage patients, 1 died of ascending cholangitis & 1 from multi system organ gailure)
    - 1 Acute kidney injury (stage 2)

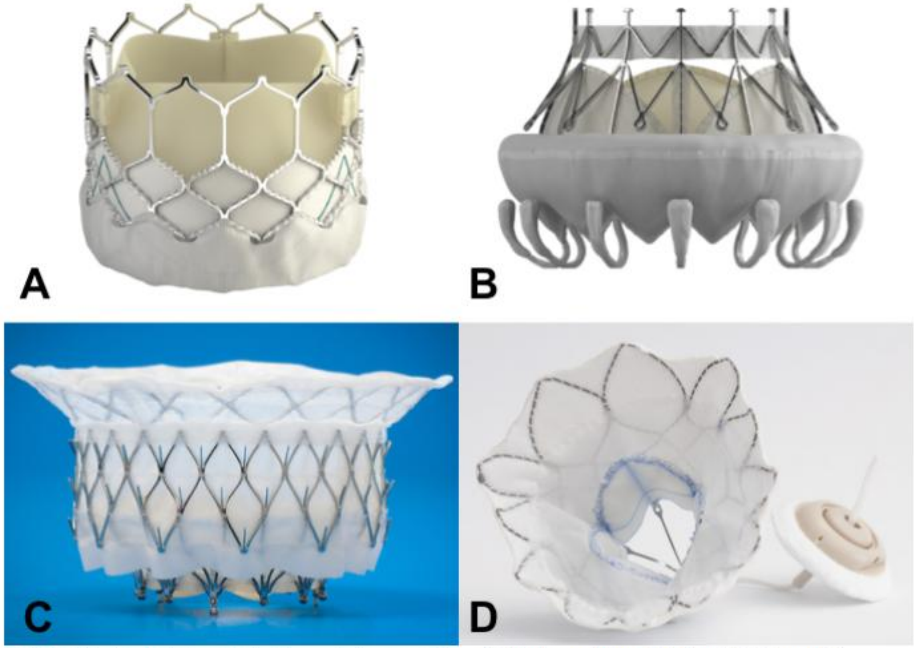
Case Series

- More than 20 procedures have been completed at 3 institutions
  - Technical and hemodynamic success was achieved in all patients
  - 2 Deaths (salvage patients, 1 died of ascending cholangitis & 1 died of multi system organ failure)
  - 2 Postoperative pacemaker
  - 1 Stroke
  - 1 Acute kidney injury (stage 2)

Transcatheter Mitral Valve Options Without MAC



Transcatheter Mitral Valve Options Without MAC



SAPIEN 3™ valve (**A**). *Reprinted with permission from Edwards Lifesciences (Irvine, CA).* CardiAQ-Edwards™ Transcatheter Mitral Valve (**B**). *Reprinted with permission from Edwards Lifesciences (Irvine, CA).* Medtronic Intrepid™ transcatheter heart valve (**C**) *Reprinted with permission from Medtronic (Minneapolis, MN).* Tendyne™ Mitral Valve System (**D**) *Reprinted with Permission from Tendyne Holdings, LLC, a subsidiary of Abbott Vascular (Roseville, MN).*

Summary

- Transcatheter approaches for addressing high risk patients with mitral valve disease are advancing
- Transcatheter approaches for addressing mitral valve disease complicated by MAC are allowing treatment in otherwise often untreatable patients
- The results thus far are relatively safe and effective though there needs to be improvement
- Surgical assistance in delivery does contribute to greater control in device delivery, reducing the post-placement lvoto, and stabilizing the device after placement

Anticipation

- With time, we will identify patients who are suitable candidates for a completely percutaneous, transseptal approach for valve replacement in the native mitral annulus and others who require a more invasive procedure due to structural hindrances that require additional intervention