Can We Unlock the Potential of TMVR with Ancillary Techniques?

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Section Head, Structural Heart Therapies
Director, Center for Innovation in Invasive Cardiology (CIIC)

Beth Israel Lahey Health

Beth Israel Deaconess Medical Center

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Disclosures

Beth Israel Deaconess Medical Center

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Honoraria / Consulting / Ad Boards:

- Abbott
- Edwards
- Medtronic
- Jena Valve
- Gore
- Alta

Equity / Stock Options:

- Excision Medical
- ConKay Medical
- Septune
- Arcos Medical
- Sparrow Medical
- Nimble Surgical

What keeps patients from mitral replacement?

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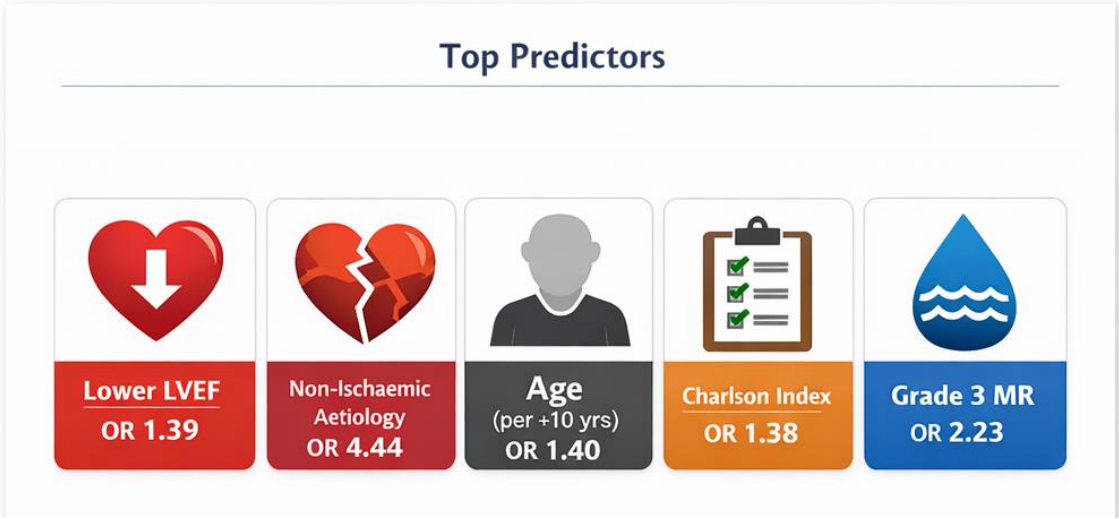
SURGERY

193 MR Patient Referrals
49% Declined for Surgery

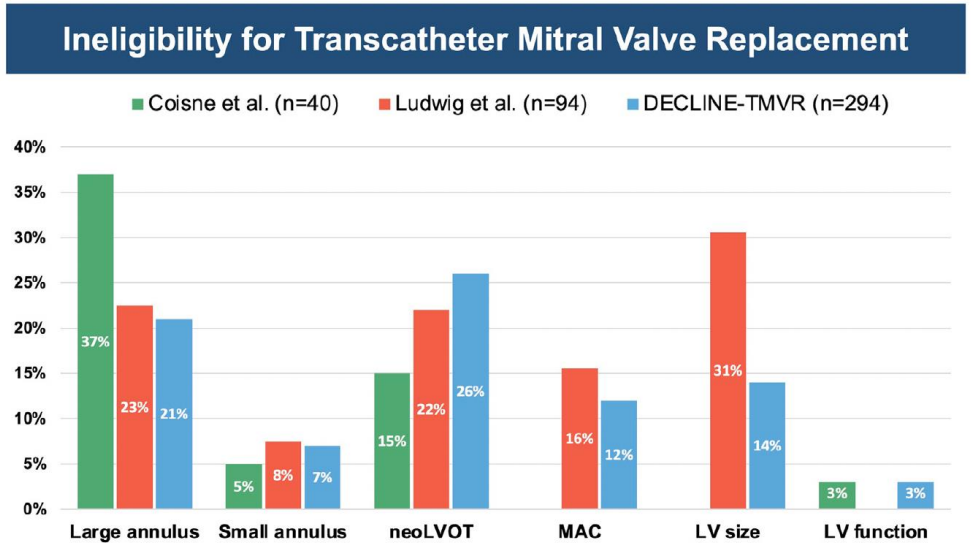


Predominantly Clinical Factors

Adapted from Mirabel M, et al. Eur Heart J. 2007:1358-65

TRANSCATHETER

294 patients Screened for TMVR
70% Deemed Ineligible



Predominantly Anatomic Factors

Scotti et al. Canadian Journal of Cardiology. 2023: 590-592

Anatomic Rationale for Exclusion from TMVR

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Too Small

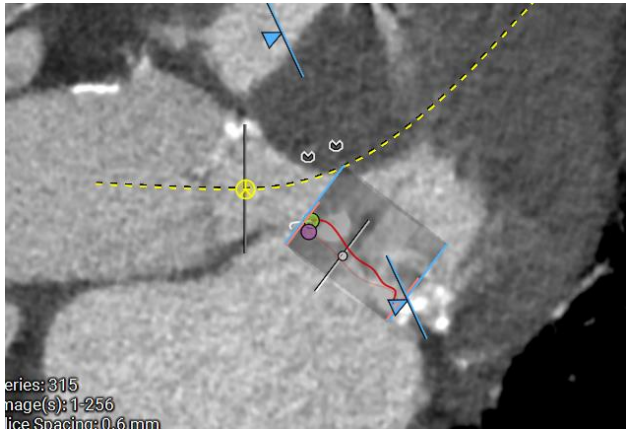
Poor Anchoring

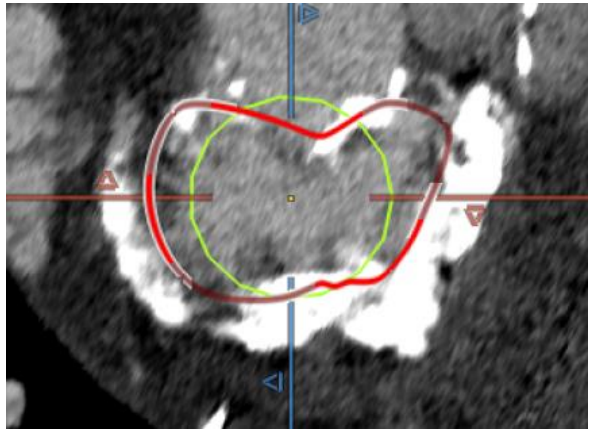
Stuff in the Way

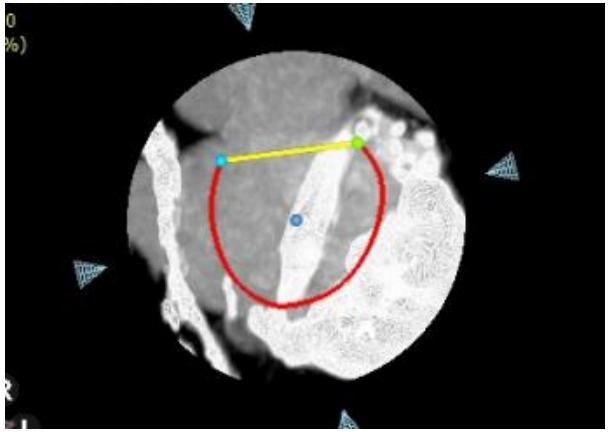
(Below the annulus)

(at the Annulus)

(In the Annulus)







Anatomic Rationale for Exclusion from TMVR

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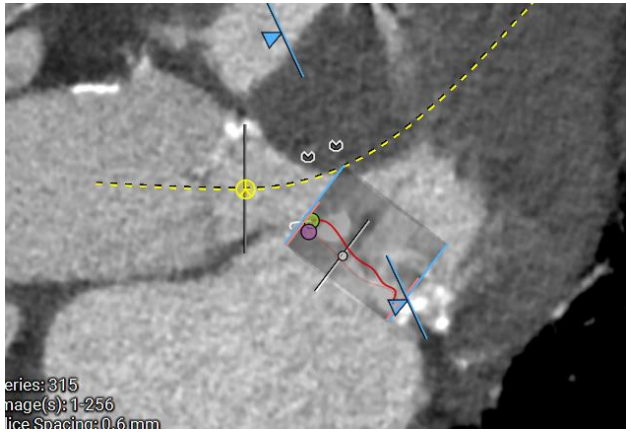

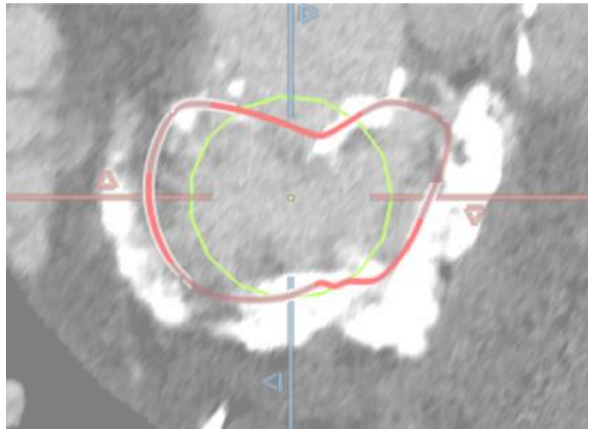

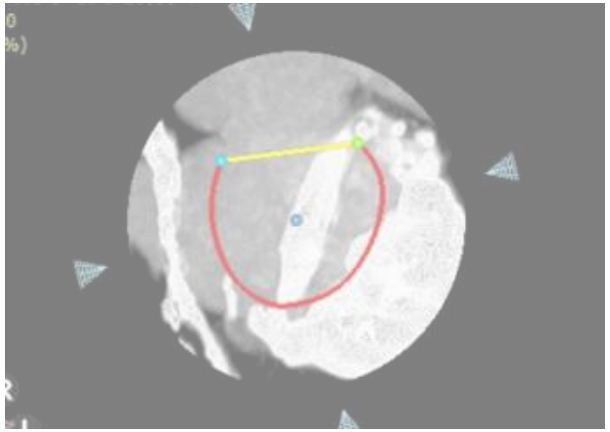

How does a TMVR Obstruct Outflow?

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Mechanism of LVOT Obstruction post TMVR

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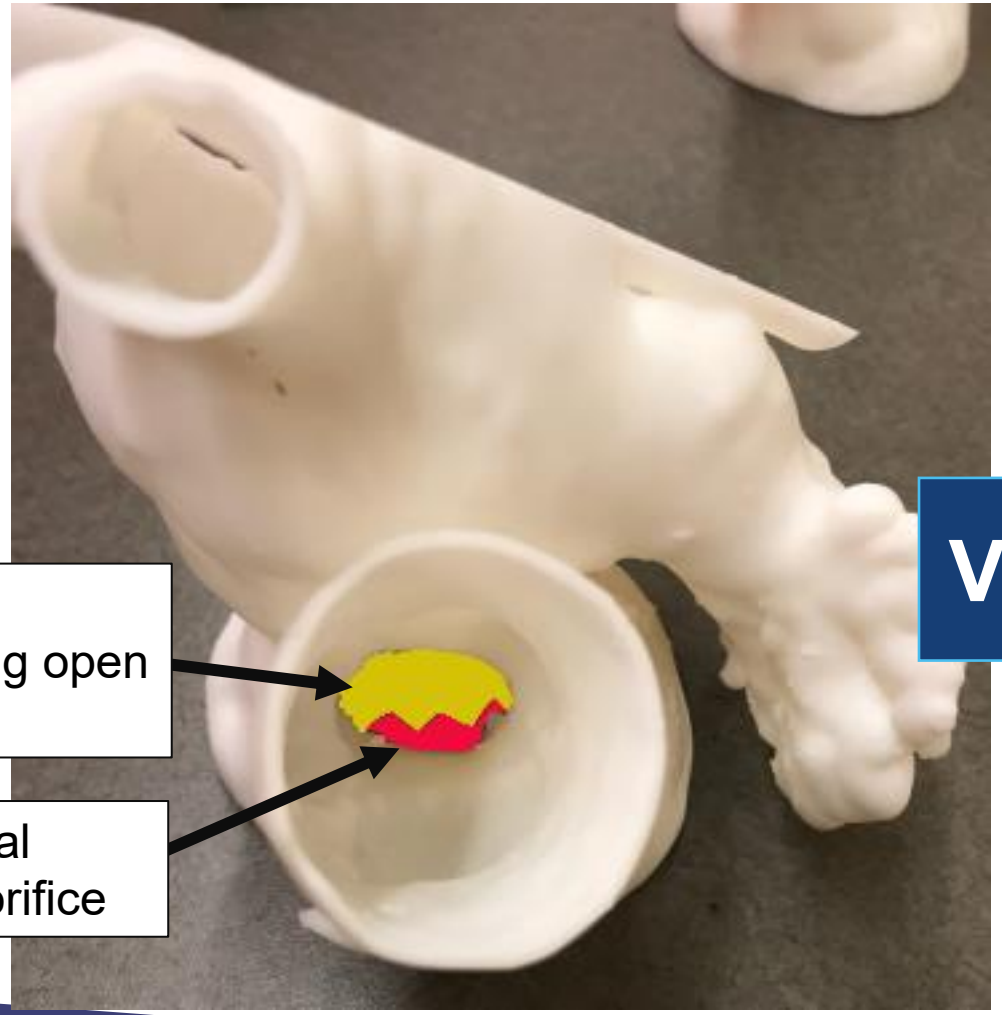

Leaflet covering open cells

Residual LVOT orifice

Vs.

LAMPOON

Laceration of the Anterior Mitral leaflet to Prevent Outflow ObtructioN (LAMPOON)

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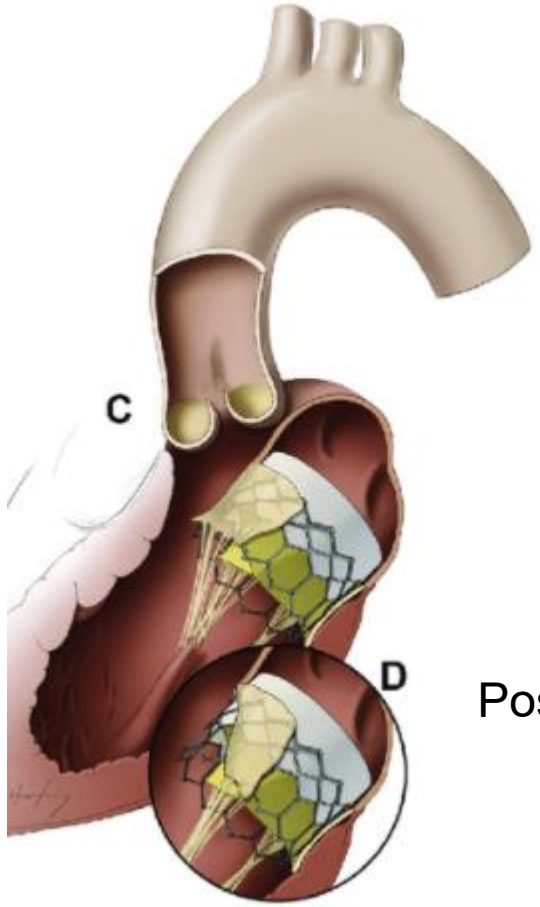
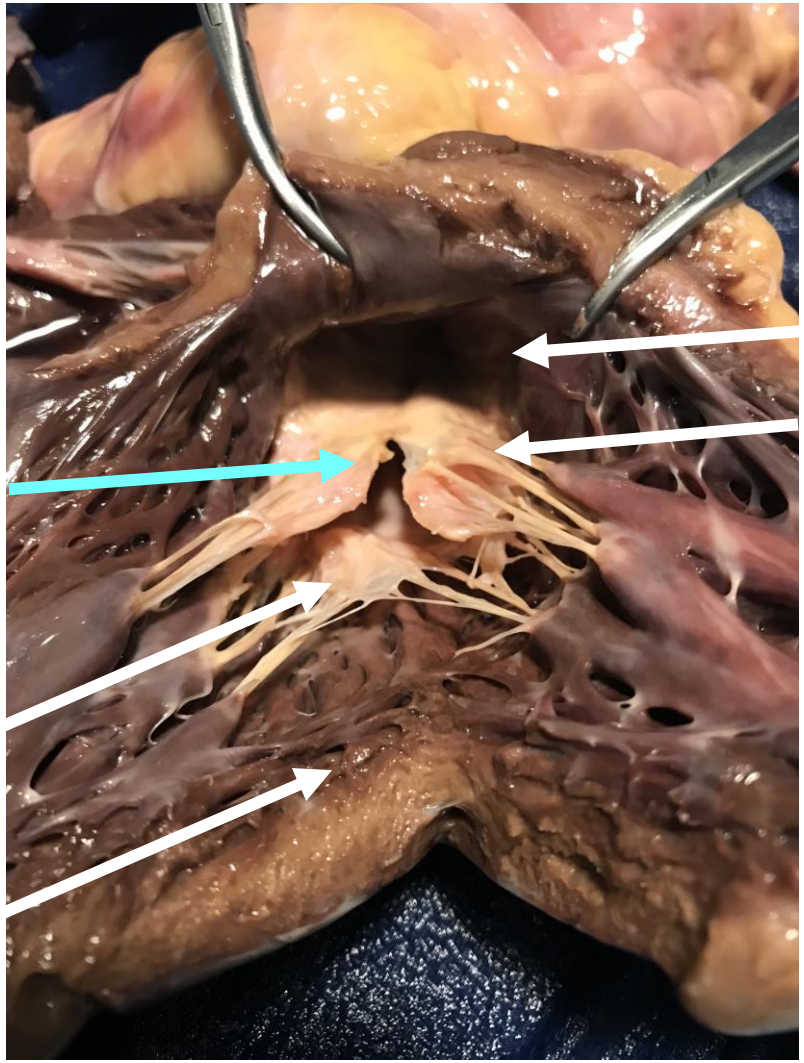


LAMPOON Slice

Posterior mitral leaflet

Ventricle



LVOT

Anterior mitral leaflet

TEE of laceration

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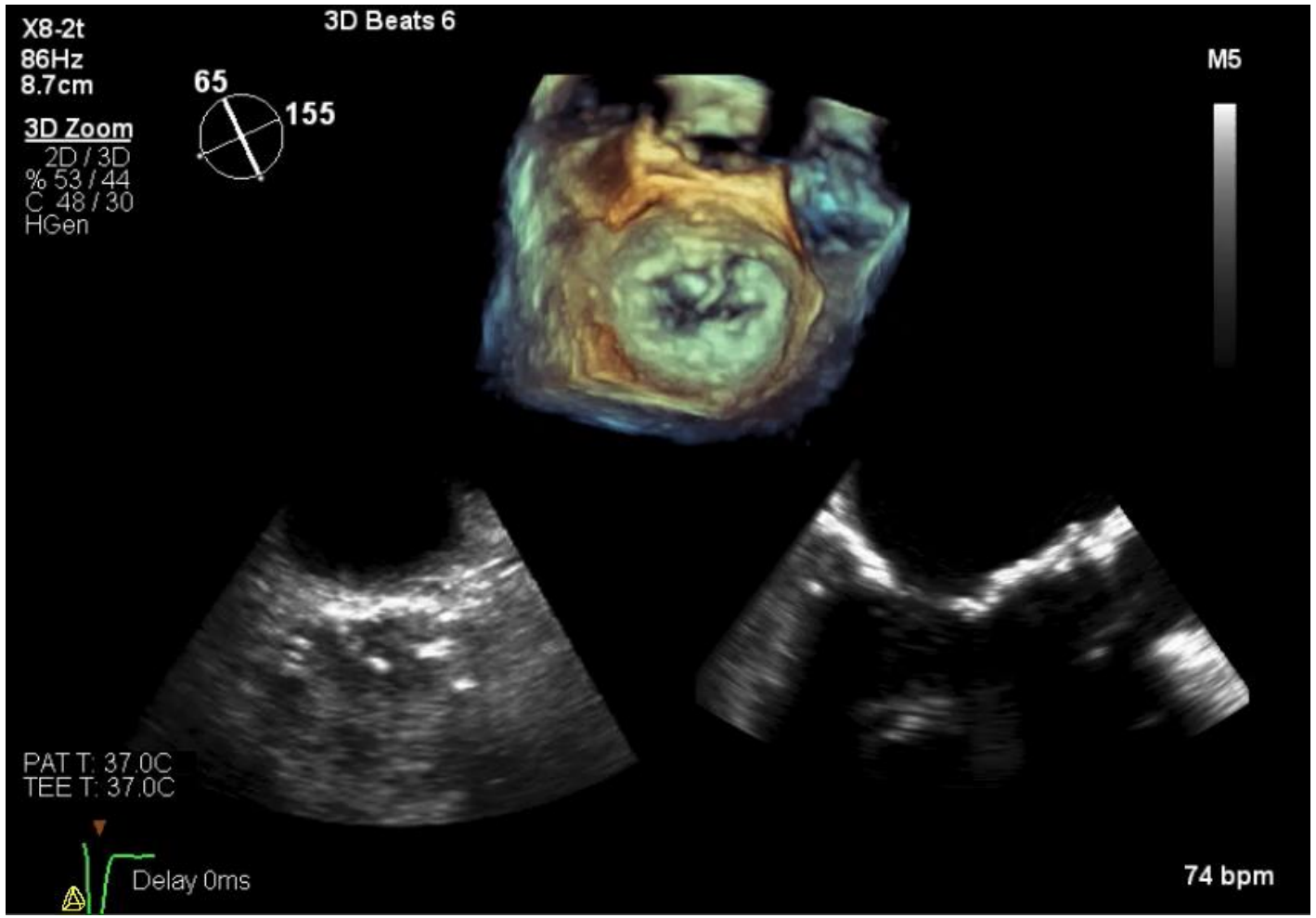

LAMPOON FDA-Sponsored IDE Trial

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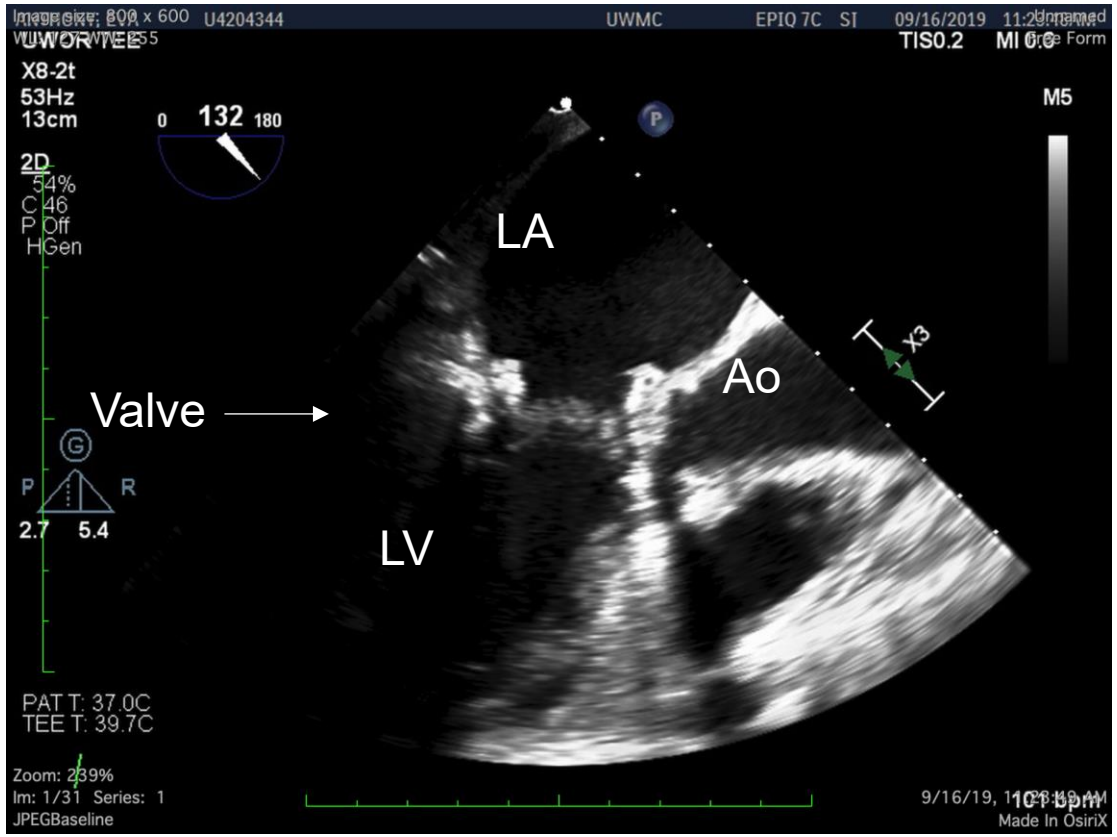
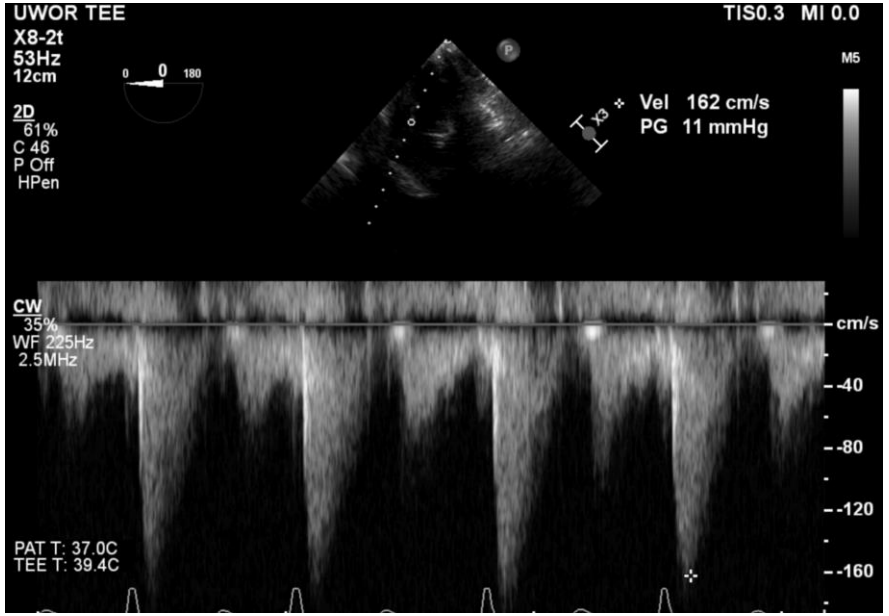


LAMPOON 30 patient IDE:
TMVR in ring or MAC with a Sapien 3
Technical success 100%
0% LVOT Obstruction
93% 30-day survival
No neurologic events

Khan. JACC. 2019



LVOT Velocity 1.6 m/s

The LAMPOON Issue: Not Valve Agnostic

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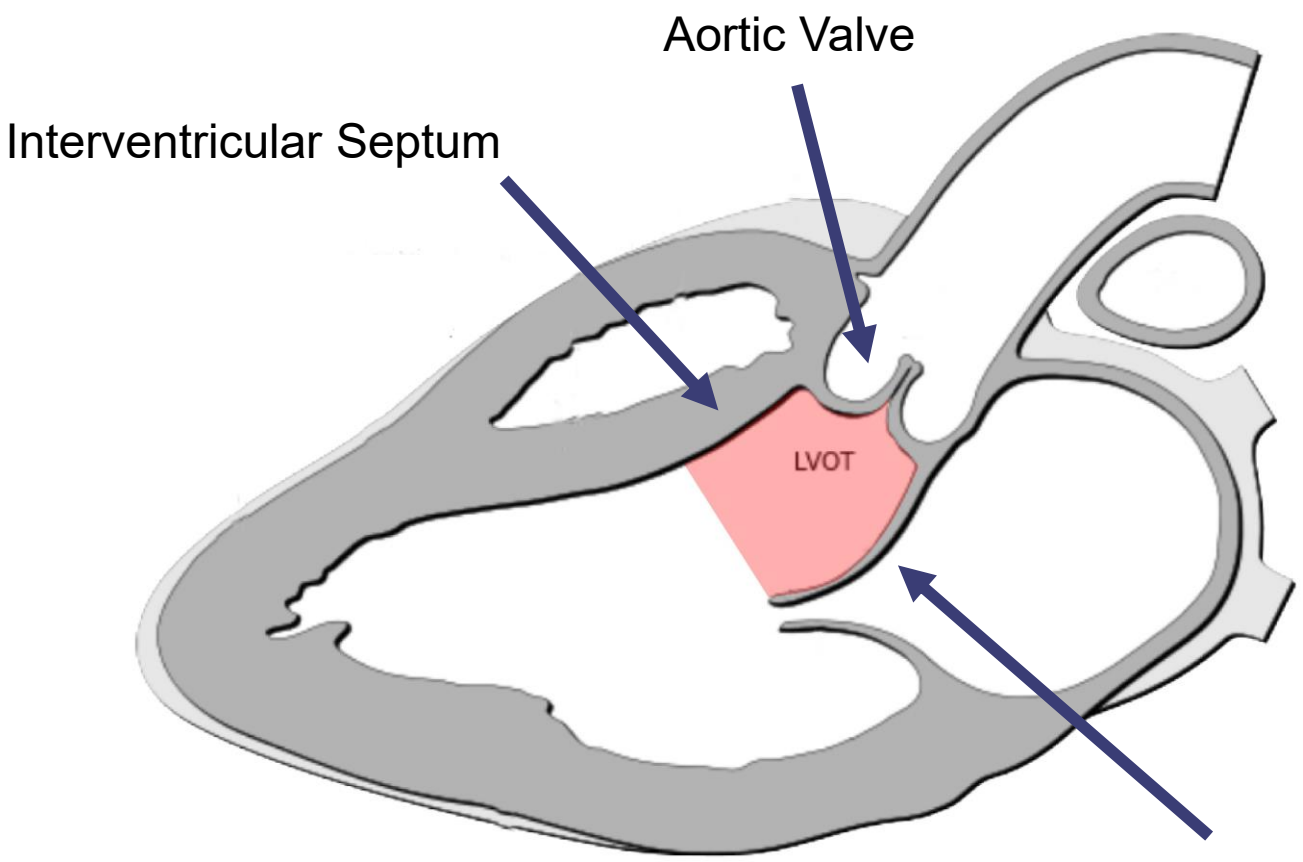
When valve is covered, removing the mitral leaflet is not helpful



SESAME *SEptal Scoring Along the Midline Endocardium*

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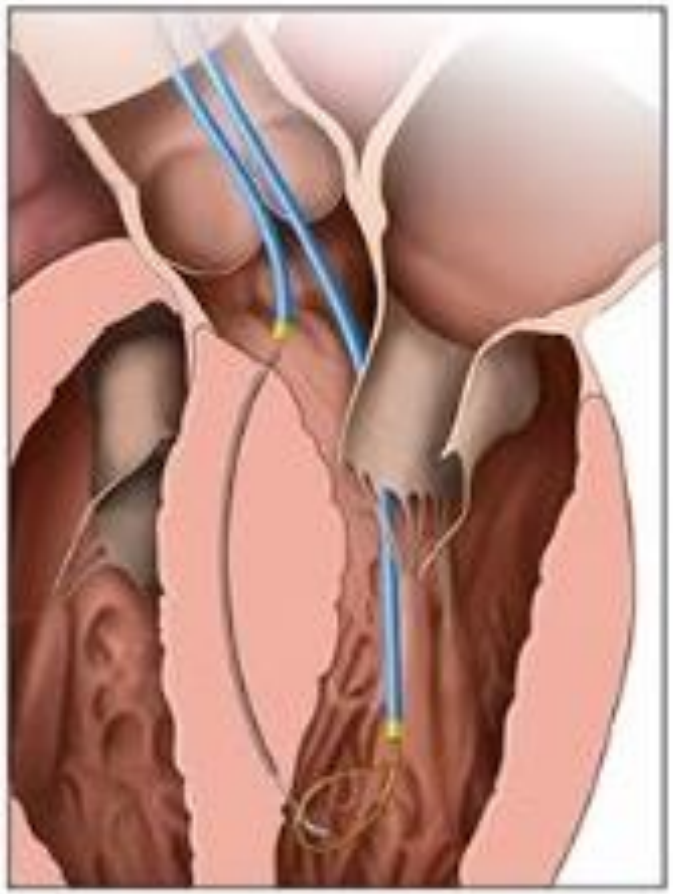

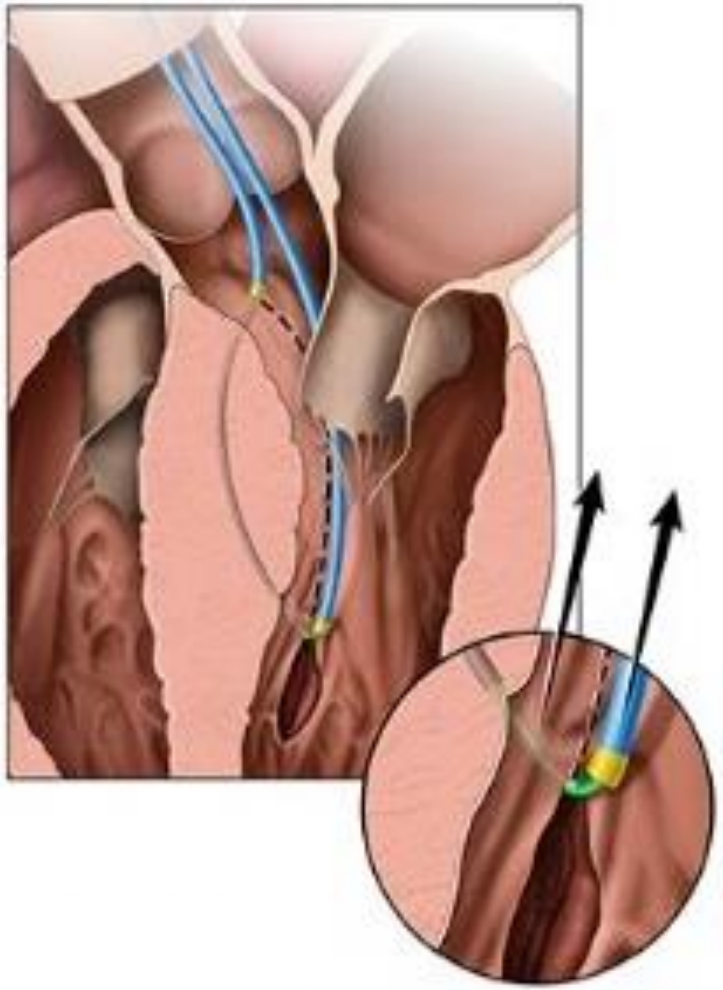

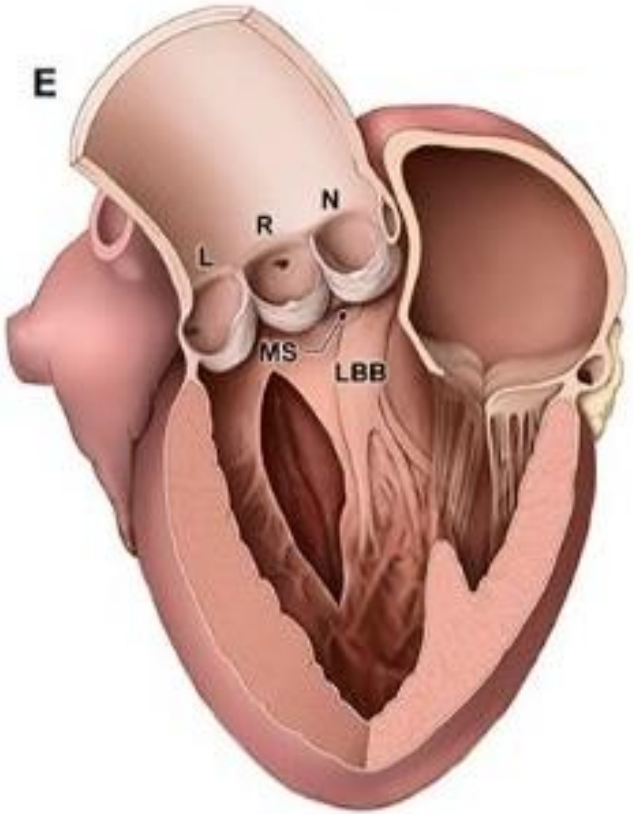

Khan et al. 2022 Circ Cardiov Interv

Myocardial Laceration

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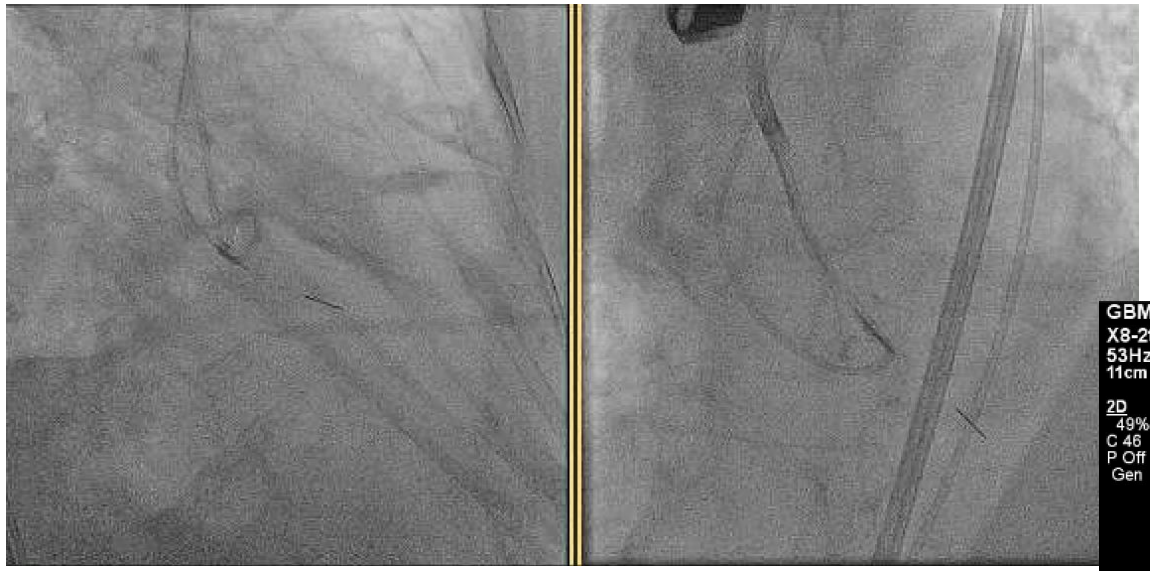
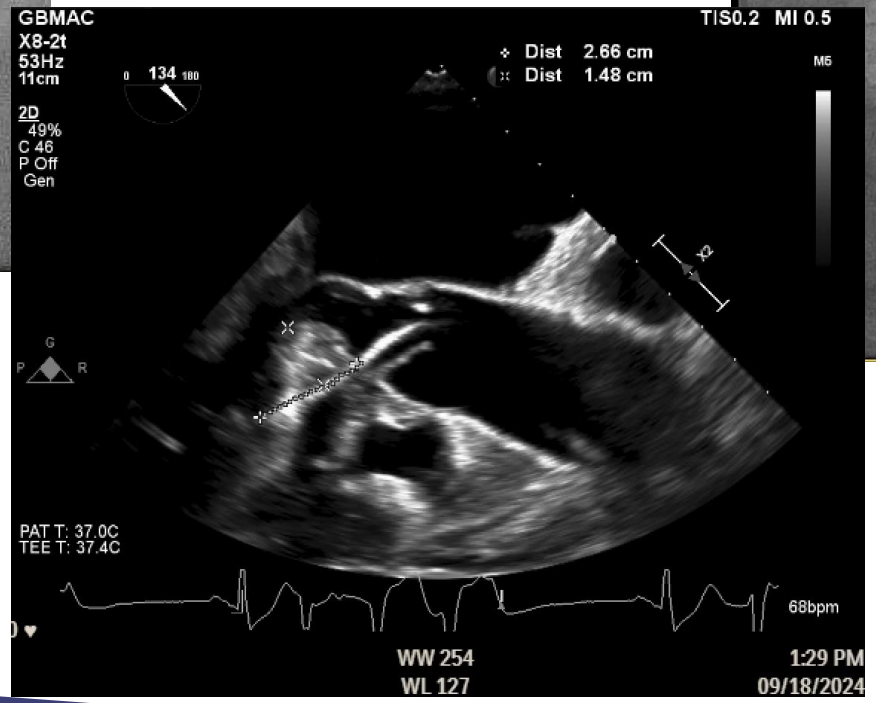


Traversing muscle in biplane fluoro

Confirm position / depth



Lacerate with electrosurgery

TTE imaging of SESAME Laceration

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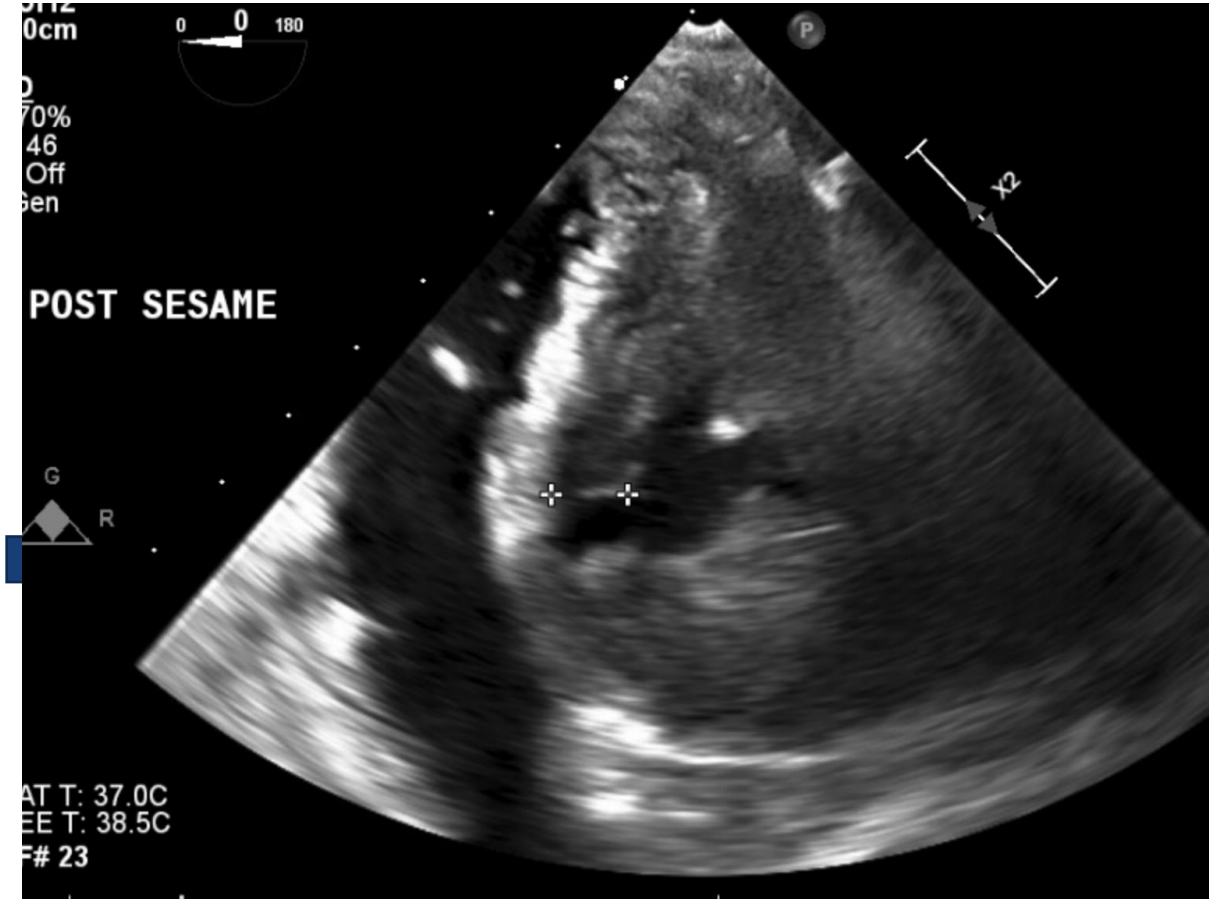

CT Imaging of SESAME Laceration Results

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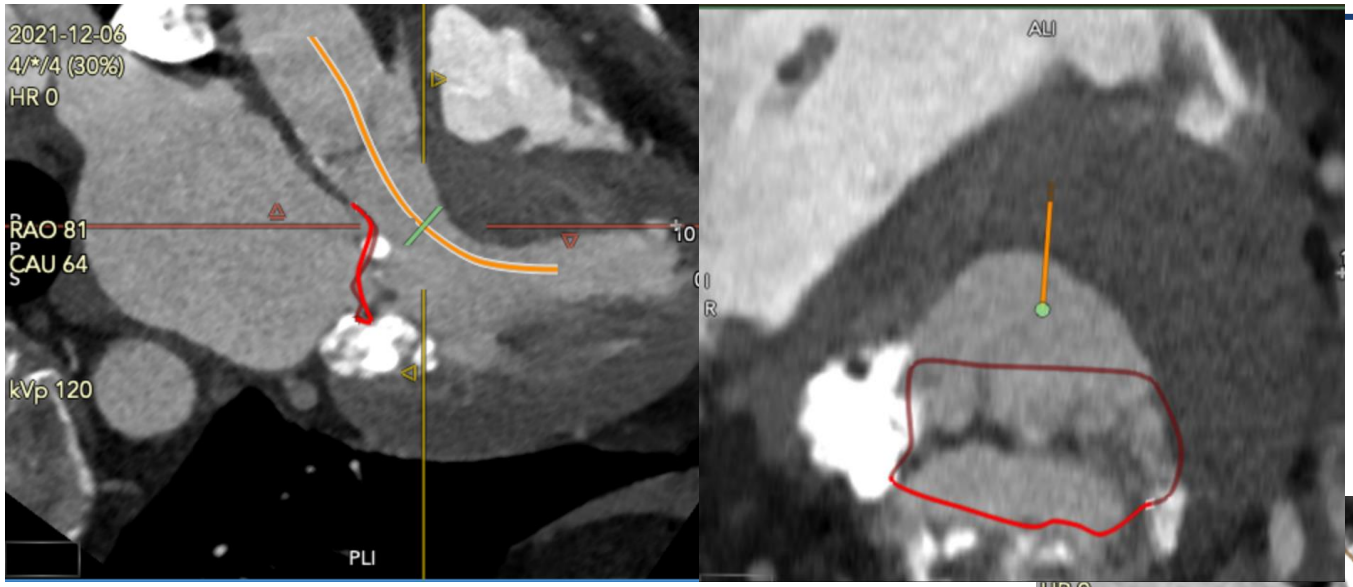
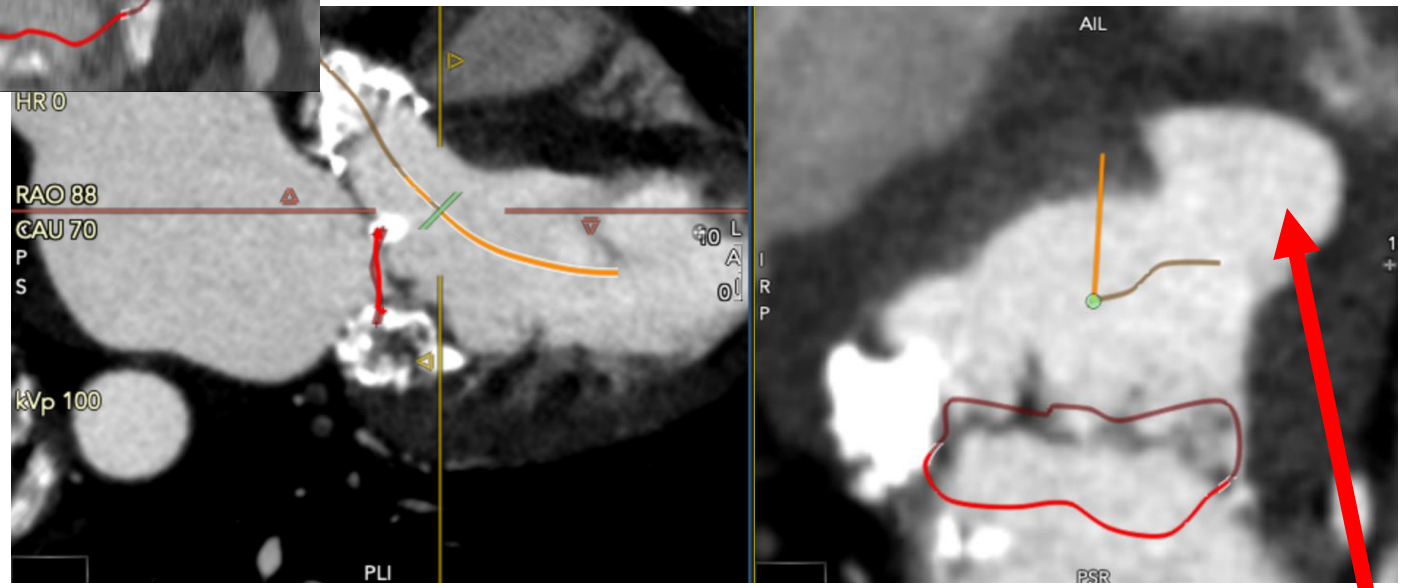


Pre-SESAME (and pre-TAVR)

4 weeks Post-SESAME



248 mm^2

Two Human Case Series of SESAME

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VOL. 83, NO. 14, 2024

ORIGINAL RESEARCH

Transcatheter Myotomy to Reduce Left Ventricular Outflow Obstruction

Adam B. Greenbaum, MD,[a,*] Hiroki A. Ueyama, MD,[b,*] Patrick T. Gleason, MD,[a] Jaffar M. Khan, PhD, BM, BCh,[b,c] Christopher G. Bruce, MB, ChB,[a,b] Rim N. Halaby, MD,[b] Toby Rogers, PhD, BM, BCh,[b,d] George S. Hanzel, MD,[a] Joe X. Xie, MD,[a] Isida Byku, MD,[a] Robert A. Guyton, MD,[a] Kendra J. Grubb, MD,[a] John C. Lisko, MD,[a] Nikoloz Shekiladze, MD,[a] Errol K. Inci, MD,[a] Elizabeth A. Grier, MD,[a] Gaetano Paone, MD,[a] James M. McCabe, MD,[a] Robert J. Lederman, MD,[b,†] Vasilis C. Babaliaros, MD[a,†]

EuroIntervention
2025;21:e1-e10
published online e-edition xxx 2025
DOI: 10.4244/EIJ-D-25-00131

ORIGINAL RESEARCH

SESAME technique: septal scoring along the midline endocardium

James M. McCabe[1*], MD; Shauna Newton[1], MD; Barbara A. Danek[1], MD; David Elison[1], MD; Christine J. Chung[1], MD; Richard Sheu[2], MD; Srdjan Jelacic[2], MD; Gregory J. Condos[3], MD; Ester Canovas[2], MD; Adam B. Greenbaum[4], MD; Vasilis C. Babaliaros[4], MD; Robert J. Lederman[5], MD; G. Burkhard Mackensen[2], MD, PhD

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This paper also includes supplementary data published online at: https://eurointervention.pcronline.com/doi/10.4244/EIJ-D-25-00131

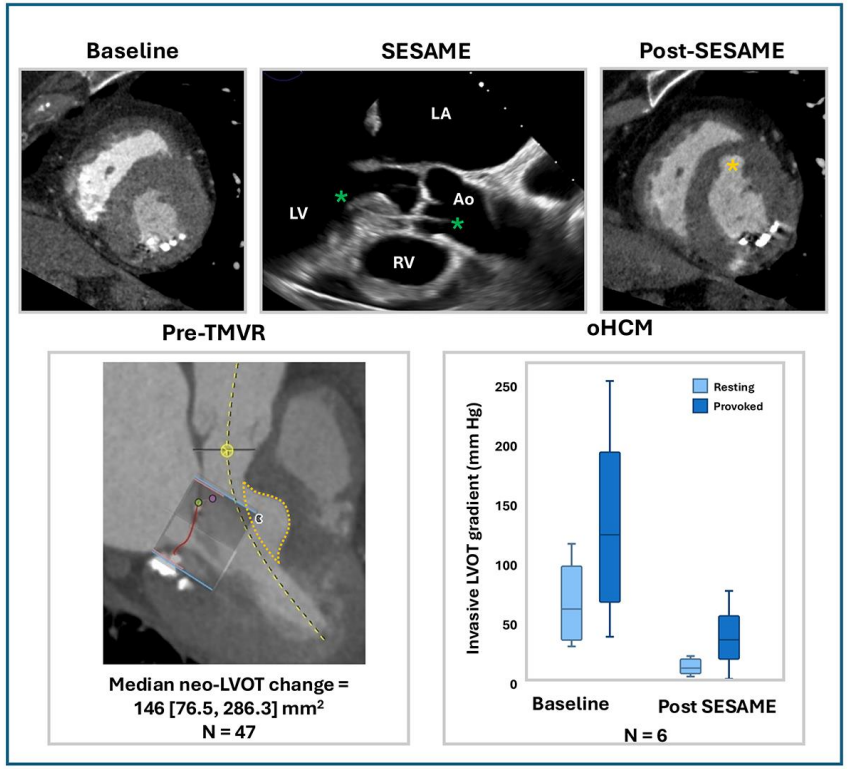
Median
NeoLVOT gained **146** mm²

TABLE 6 Evolution of Outflow Tracts 43 Days (34-56 Days) After SESAME

	Baseline (n = 51)	Day 30 (n = 51)	Difference[a]	95% CI[a]	P Value[a]	Latest (n = 51)	Difference[a]	95% CI[a]	P Value[a]
LVOT, mm²									
All	288 ± 74	381 ± 126	−93	−135 to −52	<0.001	383 ± 136	−95	−139 to −52	<0.001
HCM	266 ± 69	344 ± 62	−78	−148 to −7.9	0.032	338 ± 71	−72	−146 to 3.2	0.059
Gradient	278 ± 84	403 ± 178	−125	−212 to −37	0.007	416 ± 189	−138	−230 to −45	0.005
No gradient	305 ± 66	373 ± 67	−68	−109 to −26	0.002	368 ± 80	−64	−108 to −19	0.006
Neo-LVOT, mm²									
All	65 ± 64	206 ± 176	−141	−206 to −75	<0.001	214 ± 172	−149	−210 to −89	<0.001
Gradient	39 ± 43	218 ± 229	−179	−298 to −59	0.006	225 ± 231	−186	−307 to −66	0.005
No gradient	86 ± 71	193 ± 99	−106	−167 to −46	0.001	204 ± 104	−118	−176 to −61	<0.001
Skirt-neo-LVOT, mm²									
All	169 ± 24	241 ± 102	−72	−127 to −16	0.015	237 ± 101	−68	−123 to −13	0.018
Gradient	166 ± 27	246 ± 139	−80	−196 to 37	0.2	246 ± 139	−80	−196 to 37	0.2
No gradient	173 ± 21	236 ± 56	−63	−111 to −15	0.016	229 ± 50	−56	−99 to −13	0.015

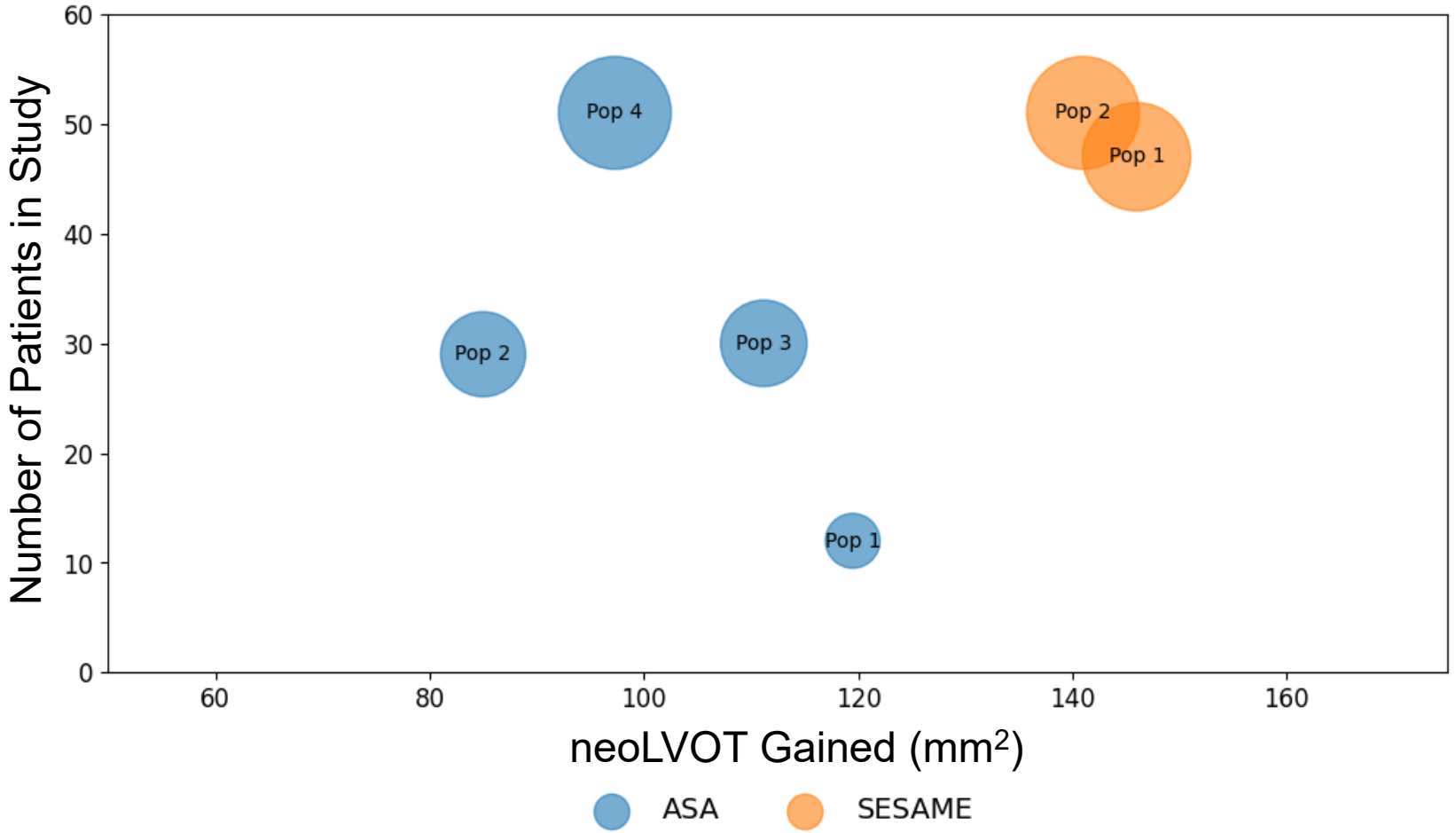
Values are mean ± SD unless otherwise indicated. [a]Welch 2-sample *t*-test.
Abbreviations as in Table 1.

Median NeoLVOT gained: **141** mm²



BIDMC Structural Heart

Alcohol vs SESAME for NeoLVOT prior to TMVR



ASA
1. Wong et. CCI. 2023. 1341-47
2. Belfekih et al. CCI. 2025. 1241-50
3. Wang et al. JACC CI. 2019. 1268-79
4. Gonzalez et al. CCI. 2024. 1023-34

SESAME
1. McCabe et al. EuroIntervention. 2025.
2. Greenbaum et al. JACC. 2024

*No direct head-to-head trials

Anatomic Rationale for Exclusion from TMVR

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Too Small

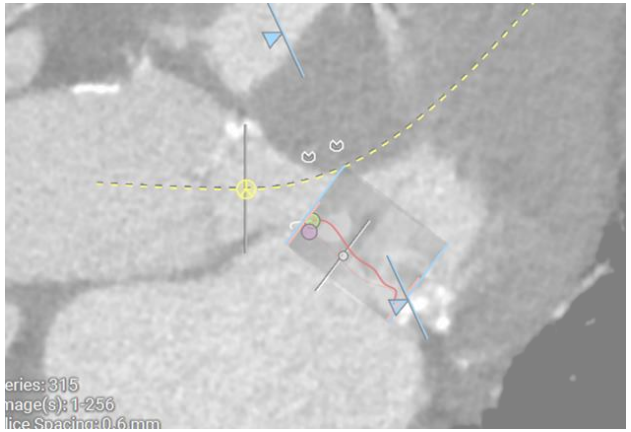
Poor Anchoring

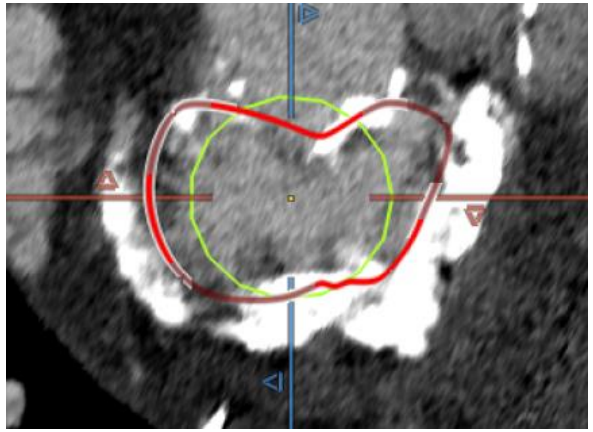
Stuff in the Way

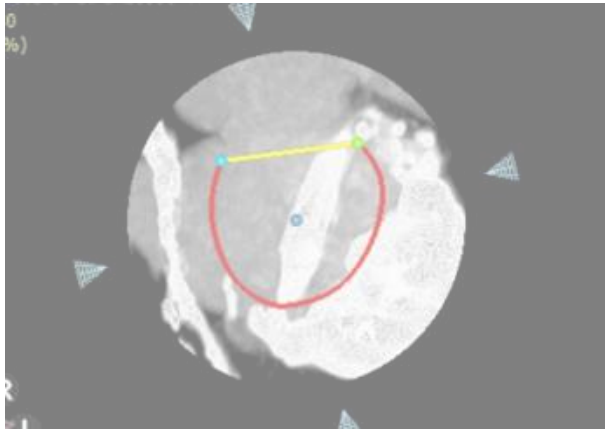
(Below the annulus)

(at the Annulus)

(In the Annulus)







Atrial Displacement of the TMVR is a 'Big' Concern

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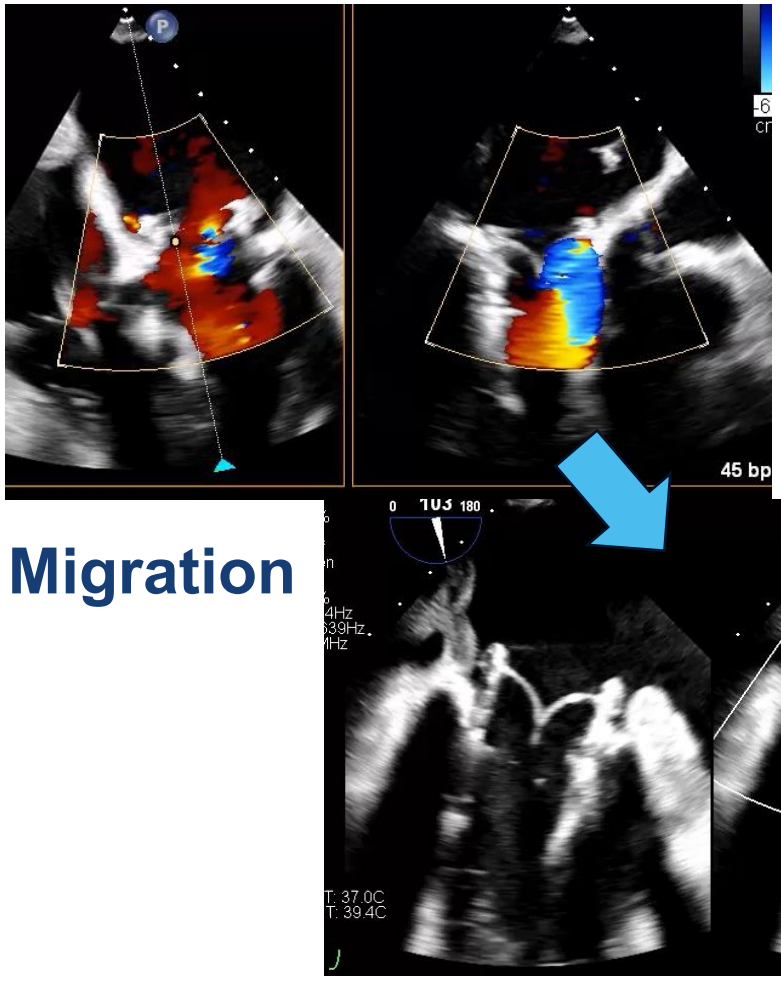
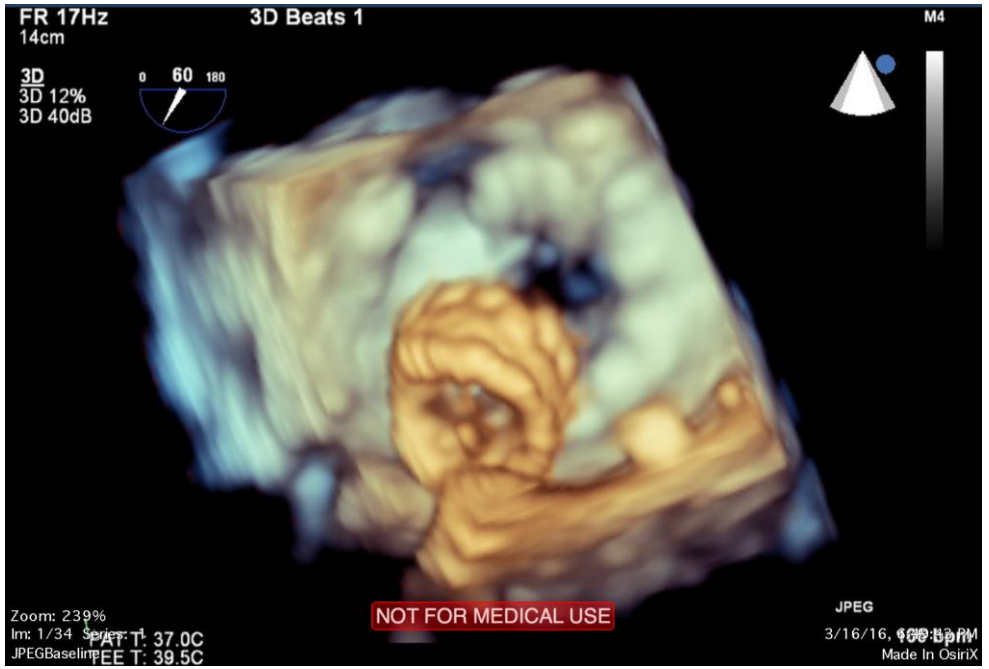


Migration



Embolization

Prosthesis Choice Increasing

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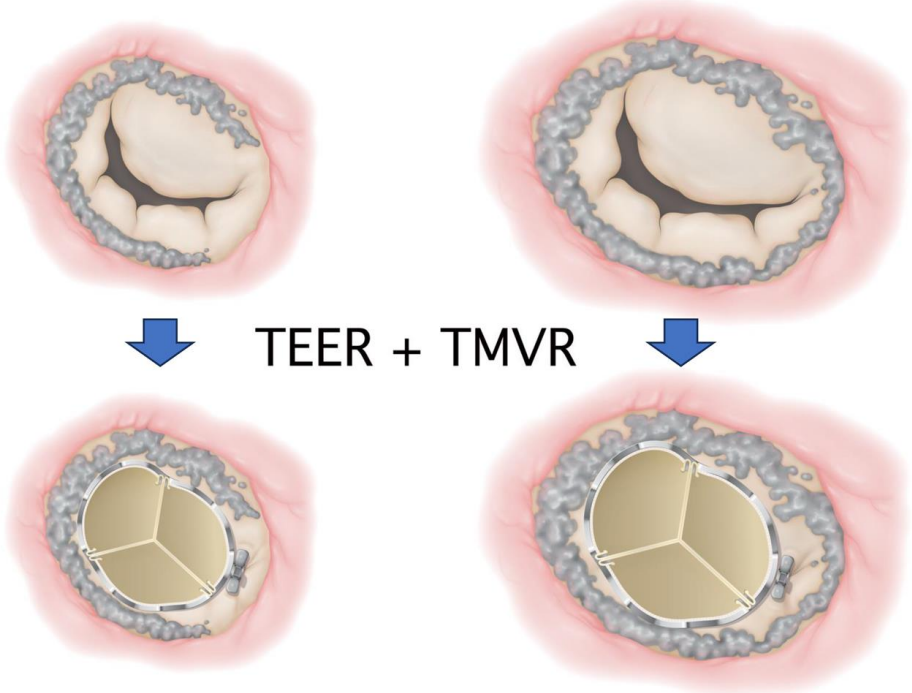
Sapien 3	Commercial M3	Alta Valve (ATLAS Trial)	Intrepid (APOLLO Trial)
			
Annular dimensions	Annular dimensions	Annular dimensions	Annular dimensions
NeoLVOT	NeoLVOT	Atrial size	NeoLVOT
Skirt NeoLVOT	LV dimensions 1 cm below annulus	% Atrial Contraction	
Calcification distribution	Calcification distribution	Atrial tilt angle	
AML Length	**Do Not Allow for Anterior Mitral Leaflet Modification to Improve LVOT**		

Annular Reduction by Cinching with TEER In the Commissure (ARCTIC) TMVR

Non-Circumferential MAC

Large Annulus



	N = 13 Patients
Median Annular Area	930 mm2
Median Commisural Length	39.1 mm
Mean # of Clips / Patient	1.5
LAMPOON Performed	5
MVARC Success	11
Paravalvular Leak ≤ 1+	12
Valve Embolization	1
PVL Closure Device Use	2

Condos GJ, et al. *Circ Cardiovasc Interv*. 2024;17:e01422

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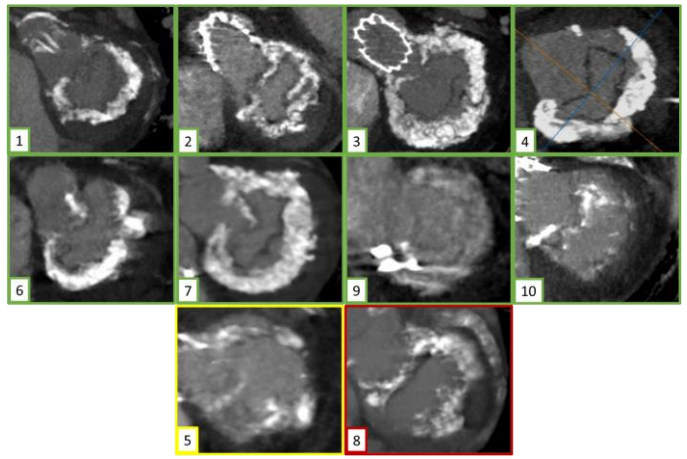


Circulation: Cardiovascular Interventions
Volume 17, Issue 11, November 2024; Page e014224
https://doi.org/10.1161/CIRCINTERVENTIONS.124.014224

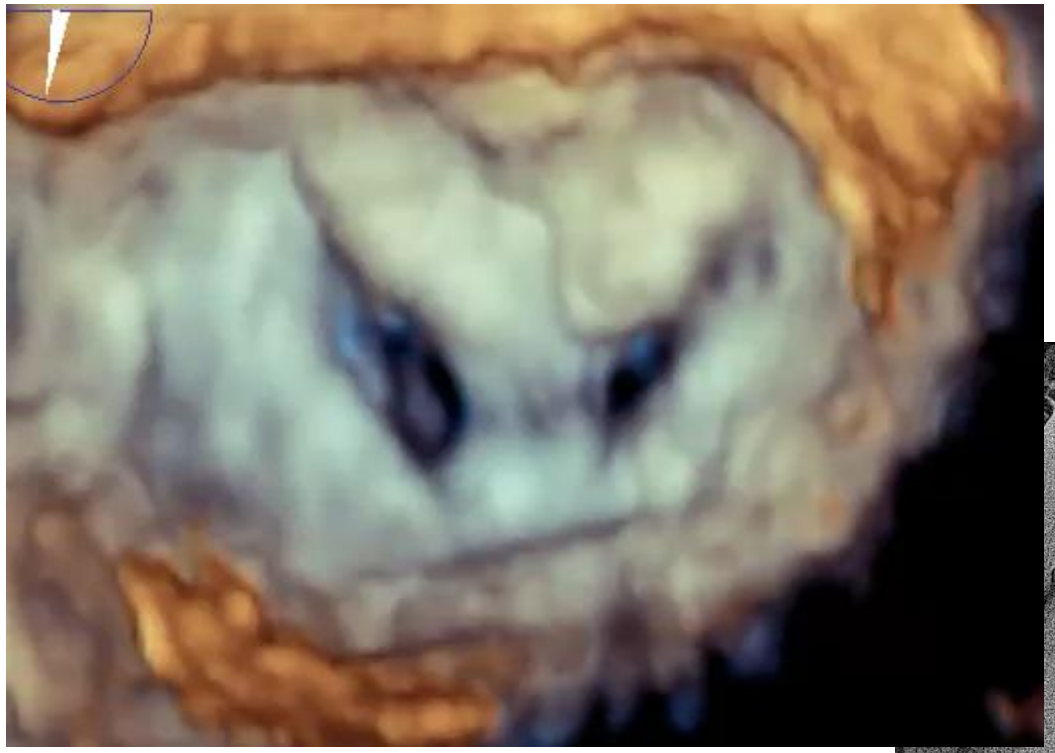
American Heart Association.

STRUCTURAL HEART DISEASE

Transcatheter Mitral Valve Replacement Using Annular Reduction by Cinching With TEER in the Commissure (ARCTIC)

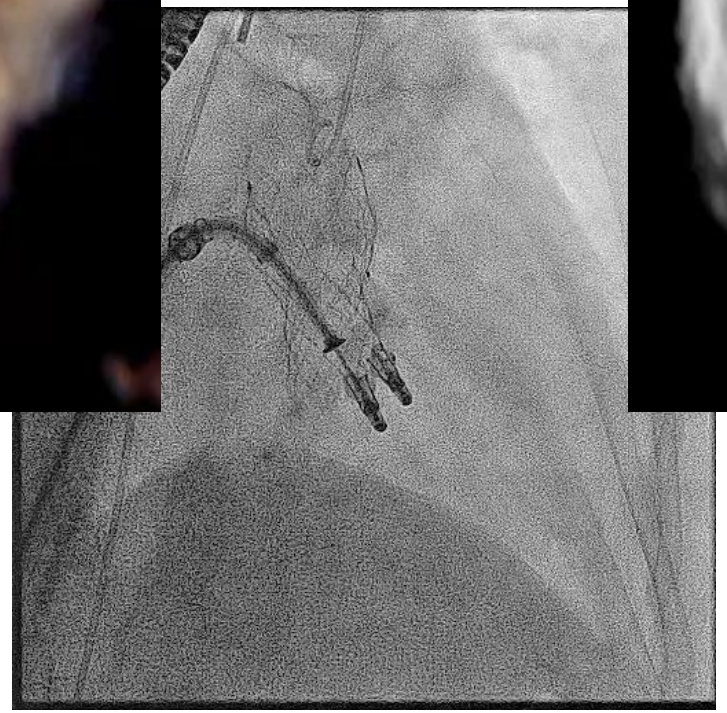
Gregory J. Condos, MD, David Elison, MD, Logan L. Vincent, MD, Rafael Harari, MD, Cristina Sanina, MD, Srdjan Jelacic, MD, Richard Sheu, MD, Christine J. Chung, MD, Gabriel S. Aldea, MD, G. Burkhard Mackensen, MD, PhD, and James M. McCabe, MD

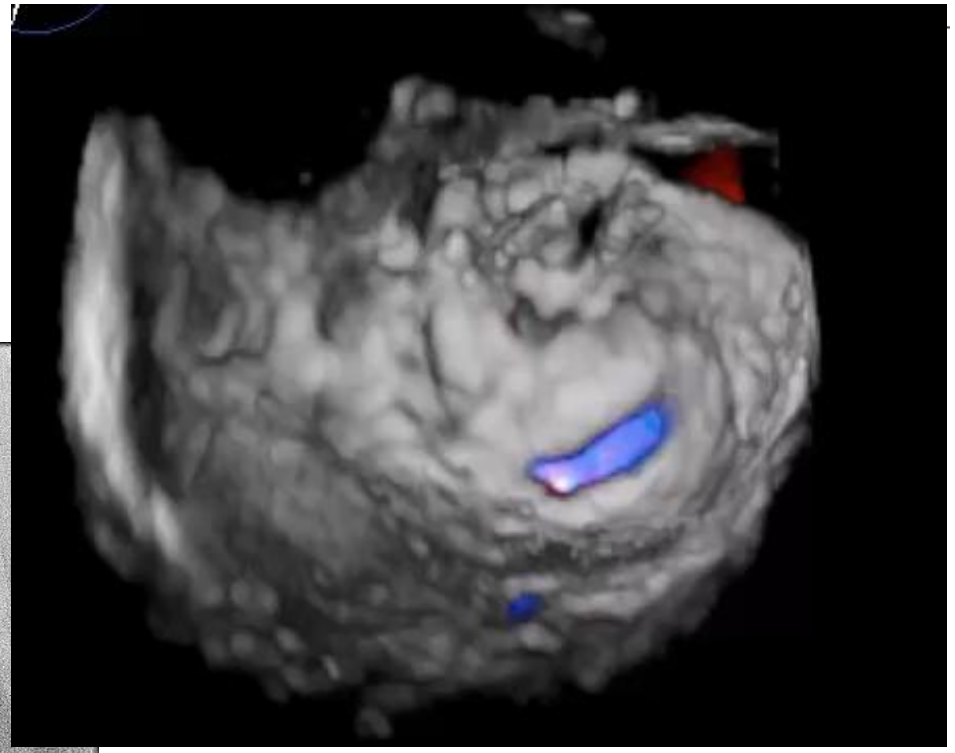
Example 1



Baseline gradient 11 mmHg

By CTA: 39 x 29 mm valve





Gradient now 26 mmHg

LAMPOON Still Possible

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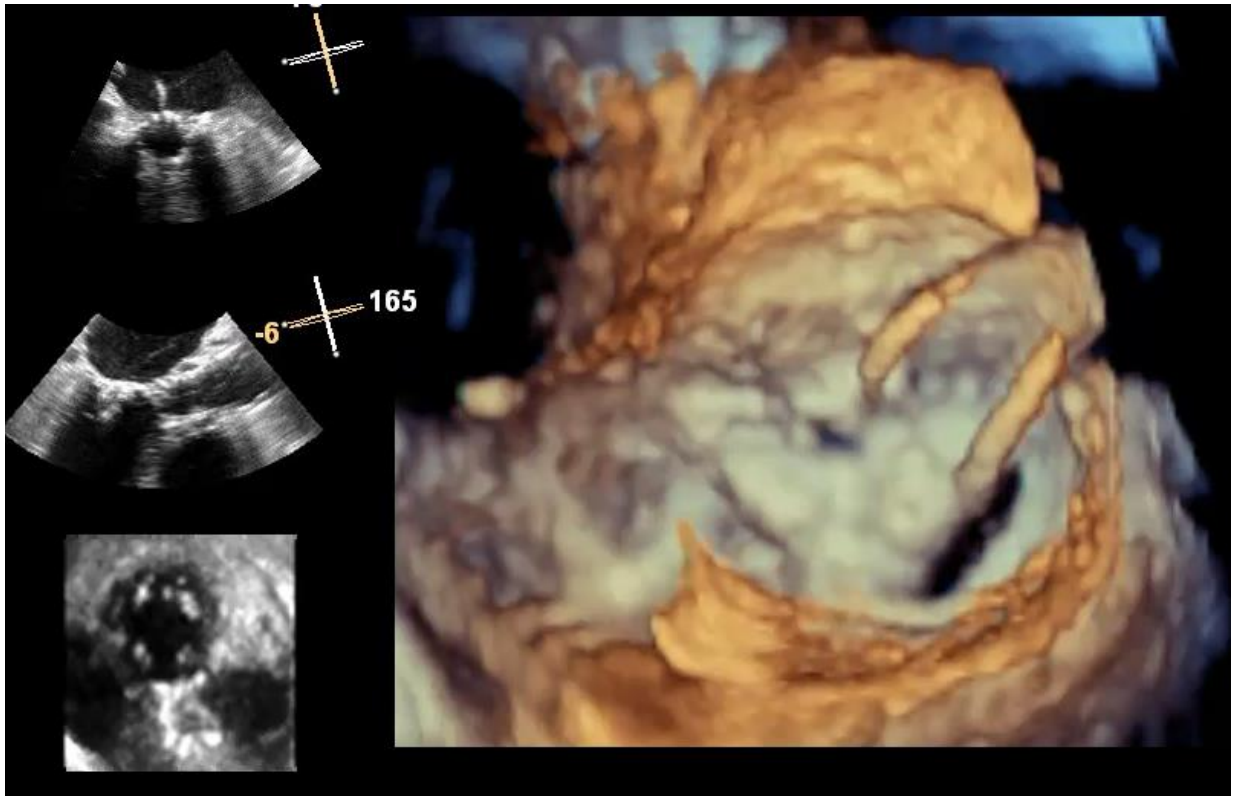

Final Result

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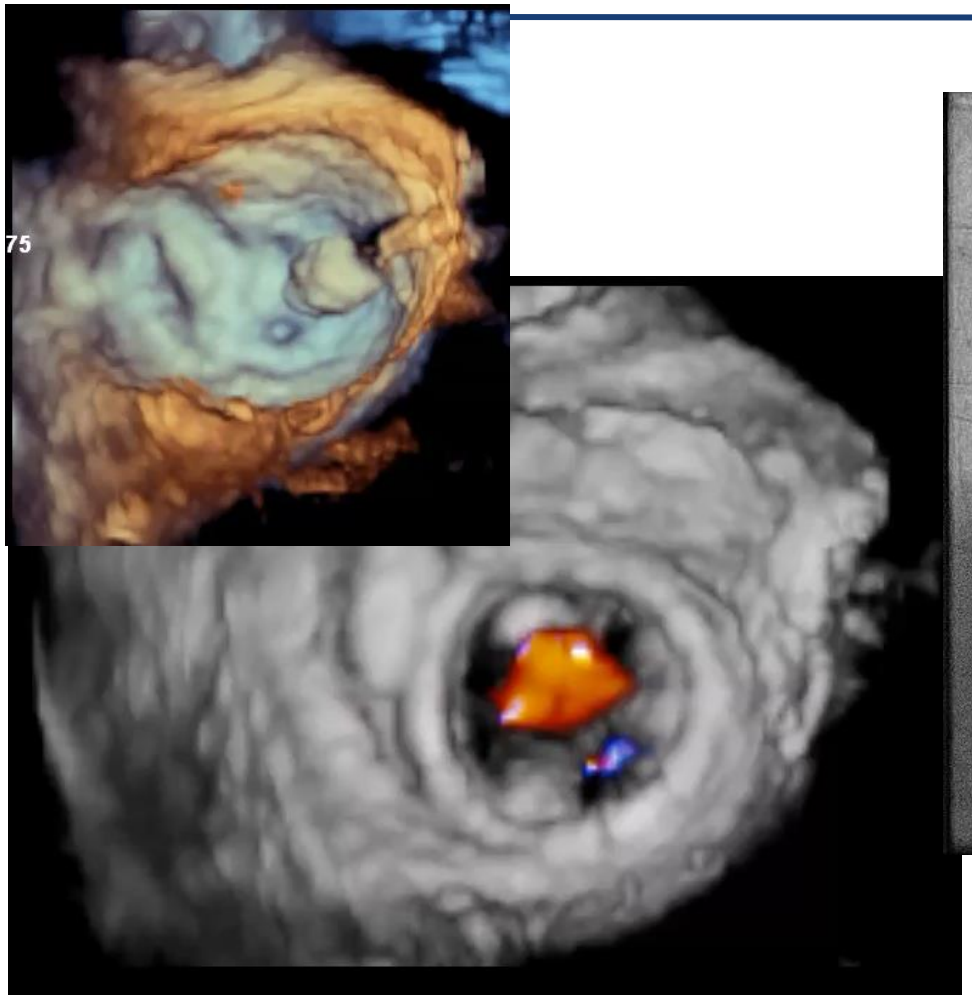
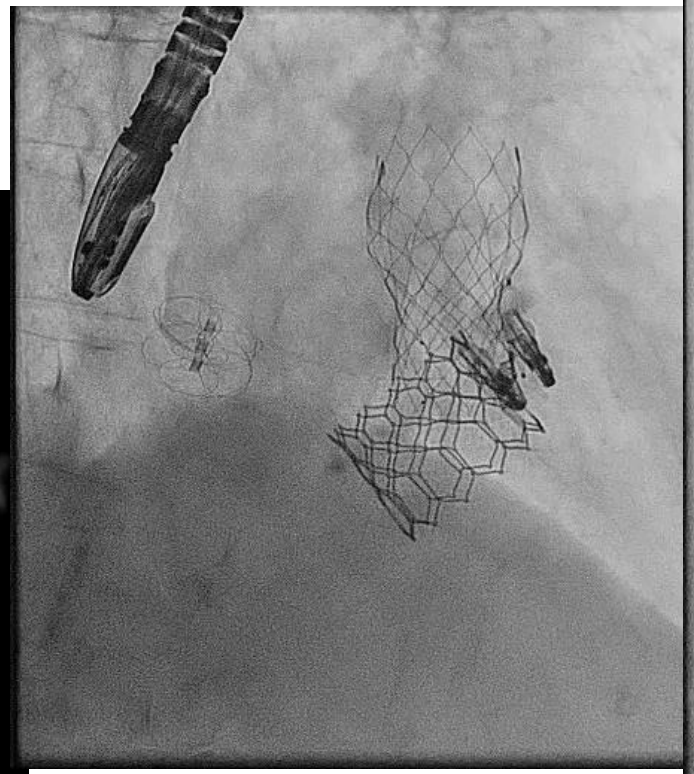
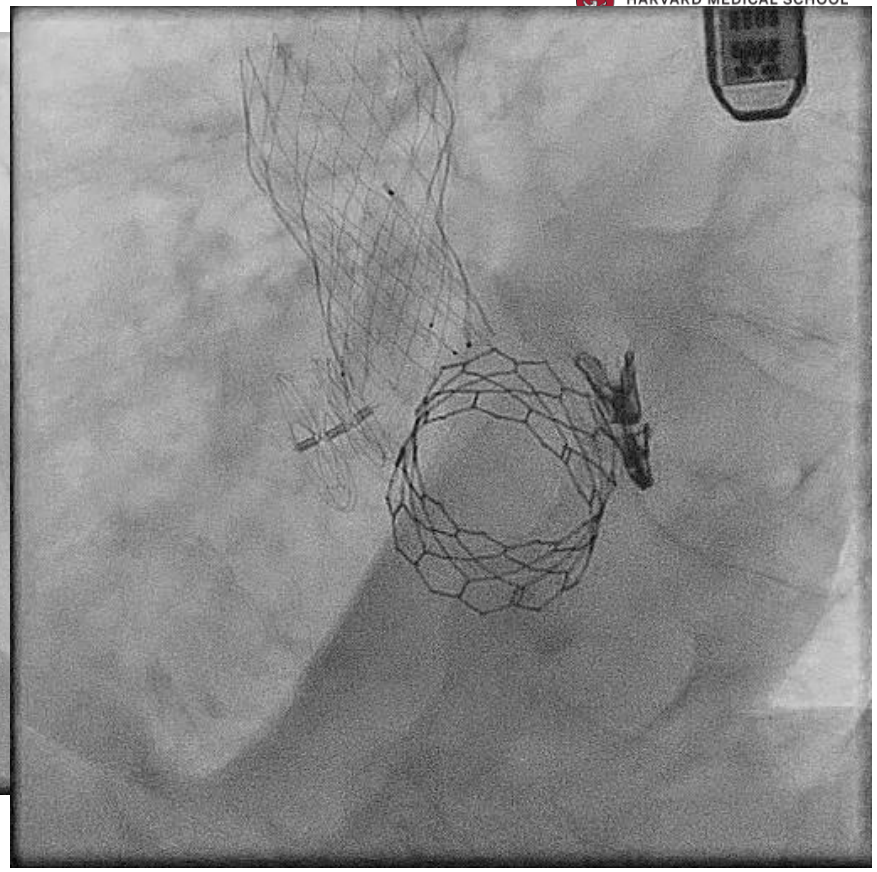
HARVARD MEDICAL SCHOOL







Exampe 2: Prior Mantle Radiation – MS

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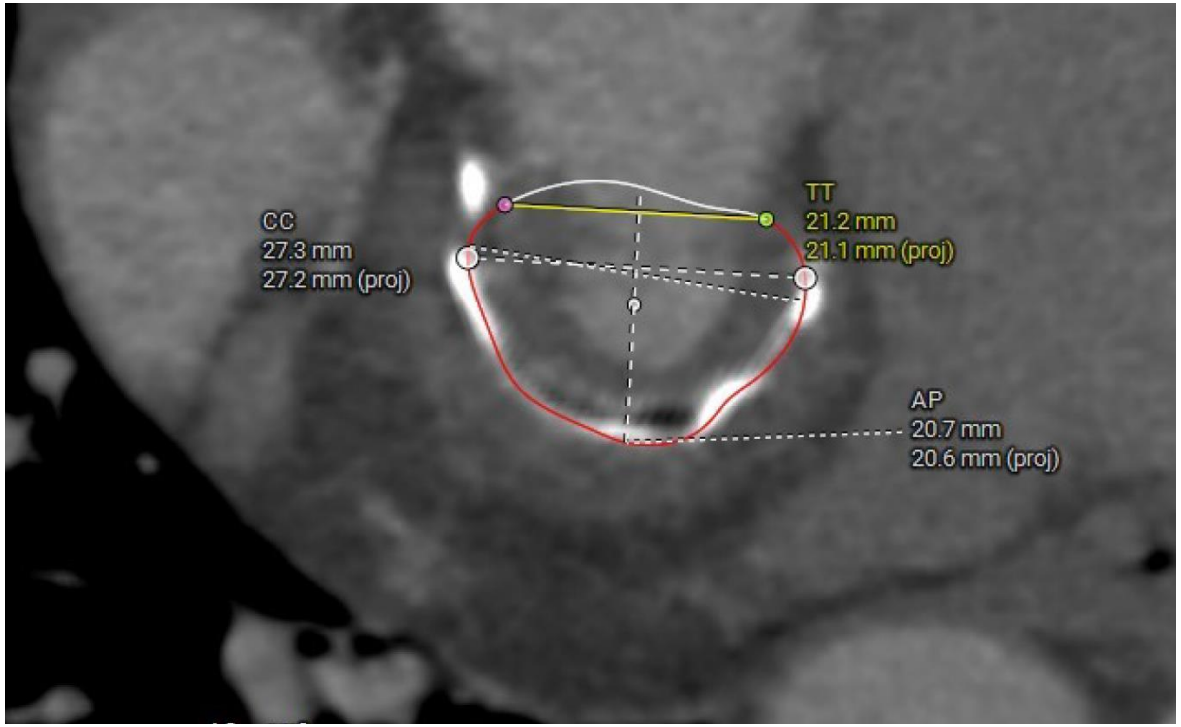
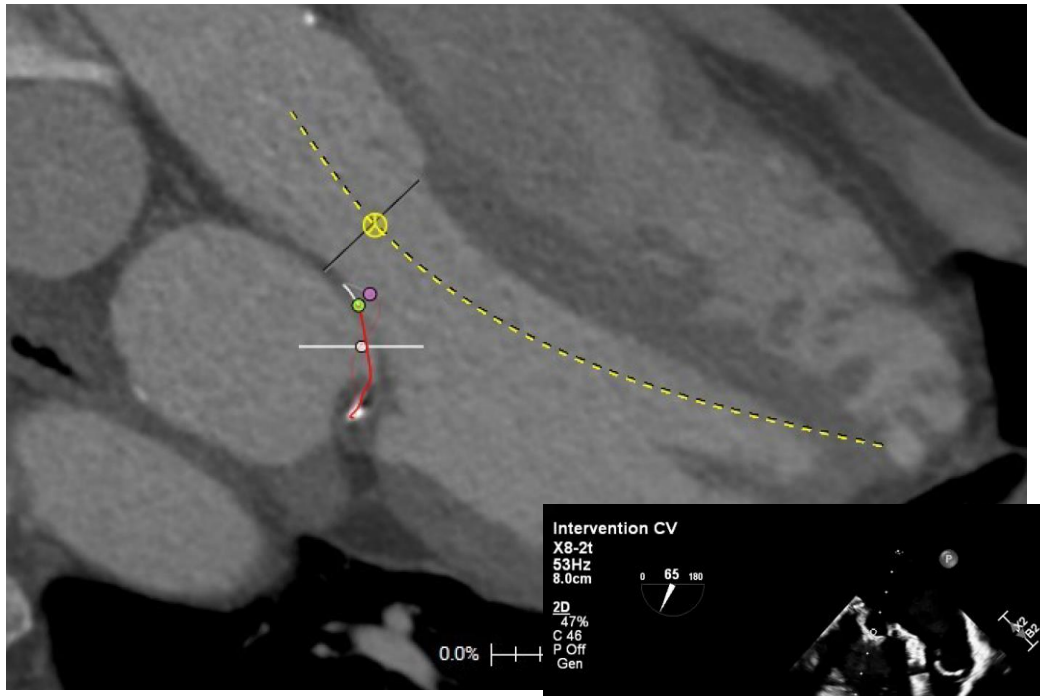
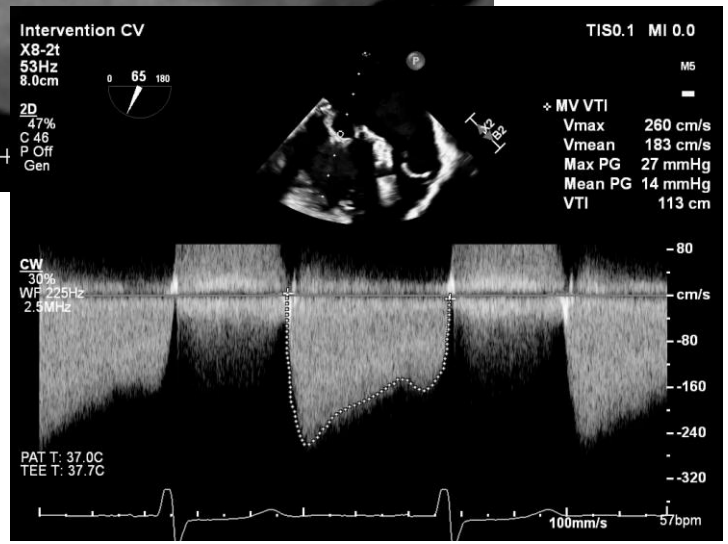
HARVARD MEDICAL SCHOOL TEACHING HOSPITAL







Incomplete Cosgrove band (Felt)

Clips on Either Commissure

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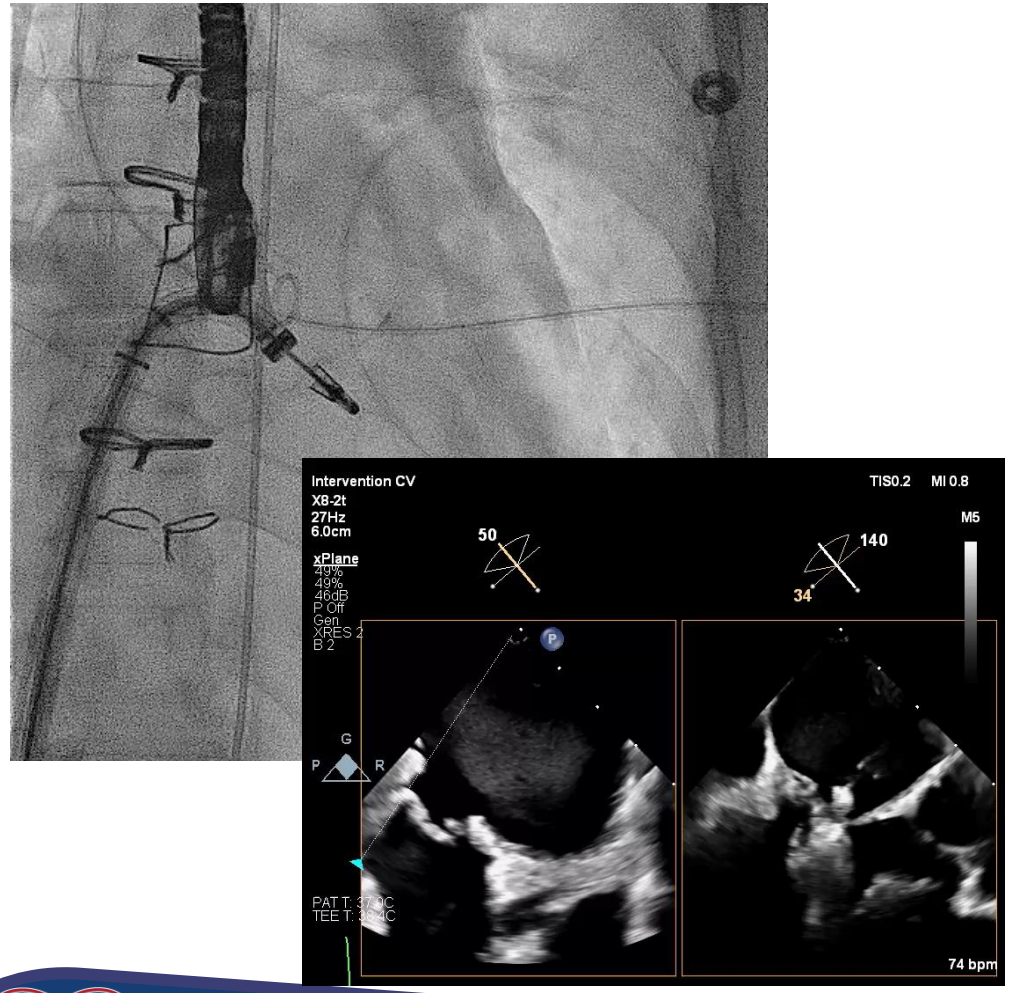

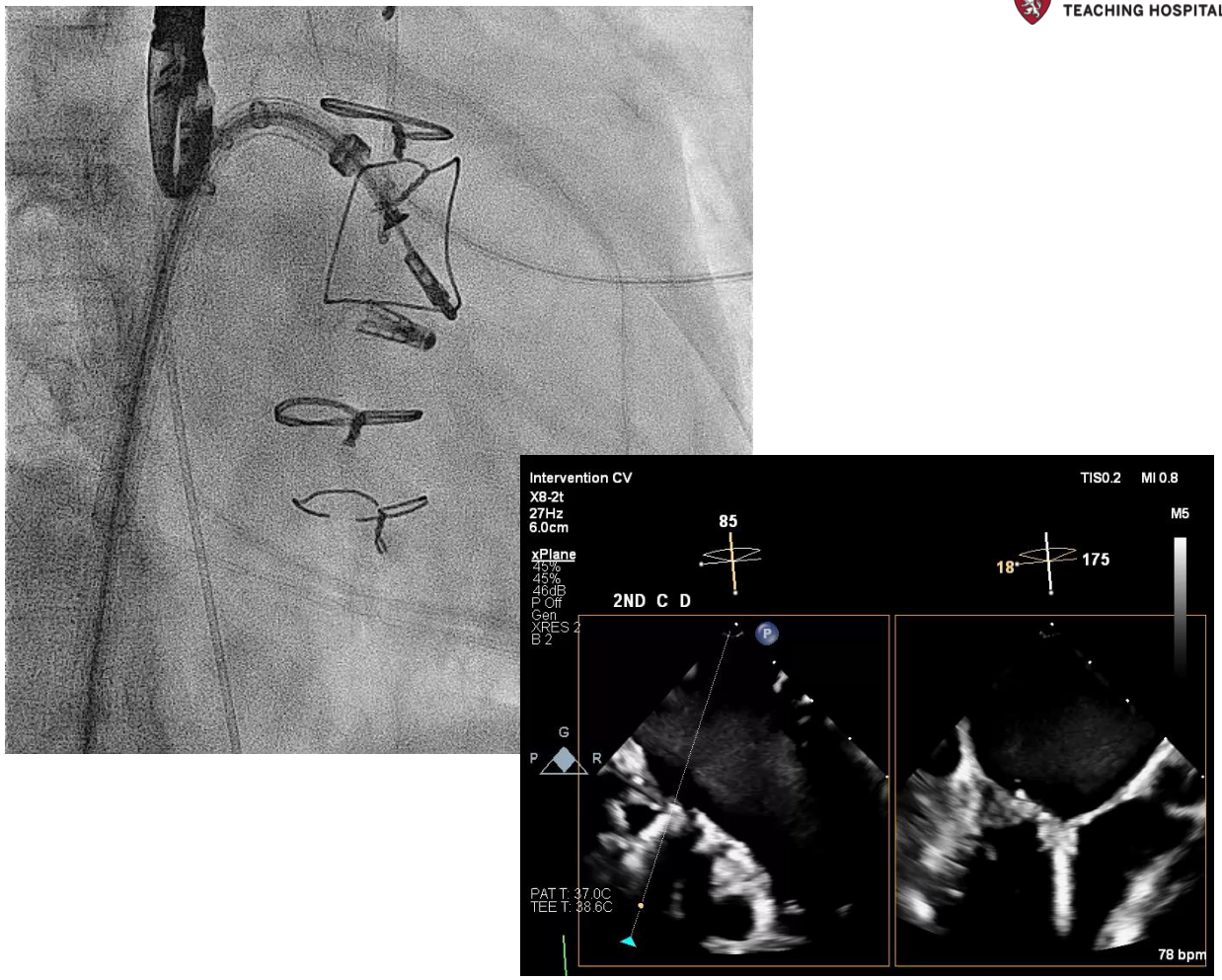

LAMPOON Between Clips

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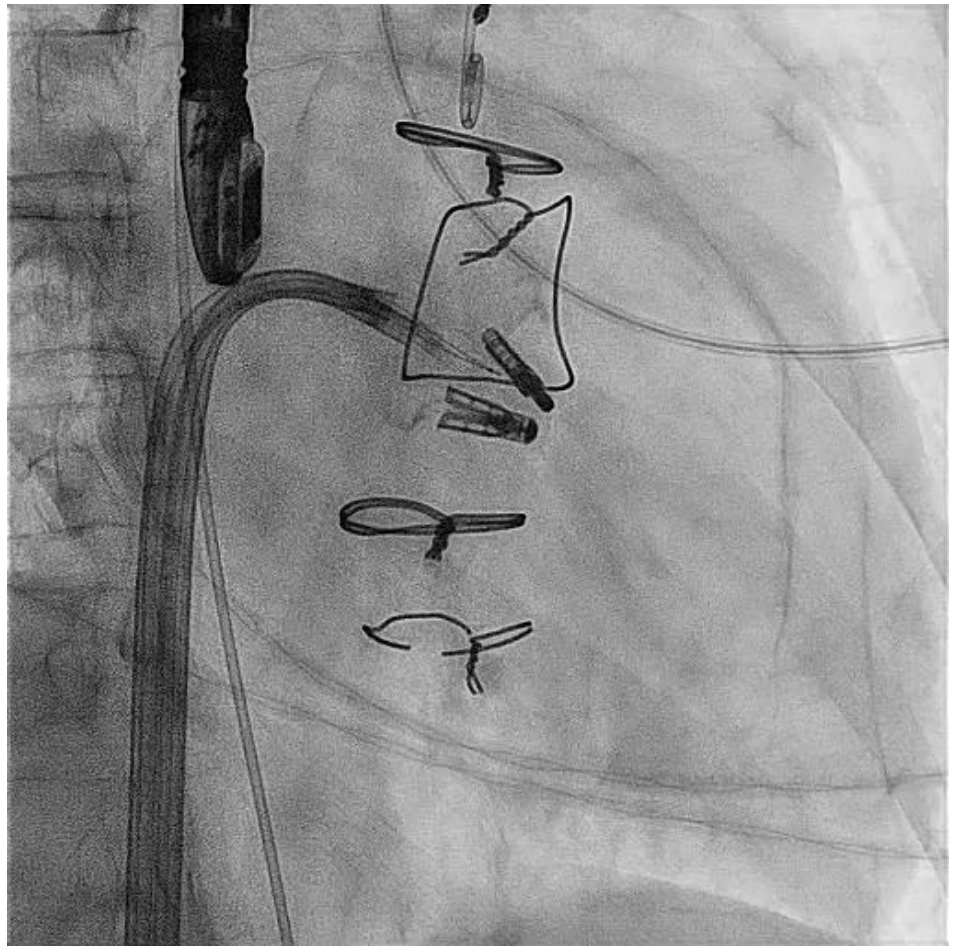

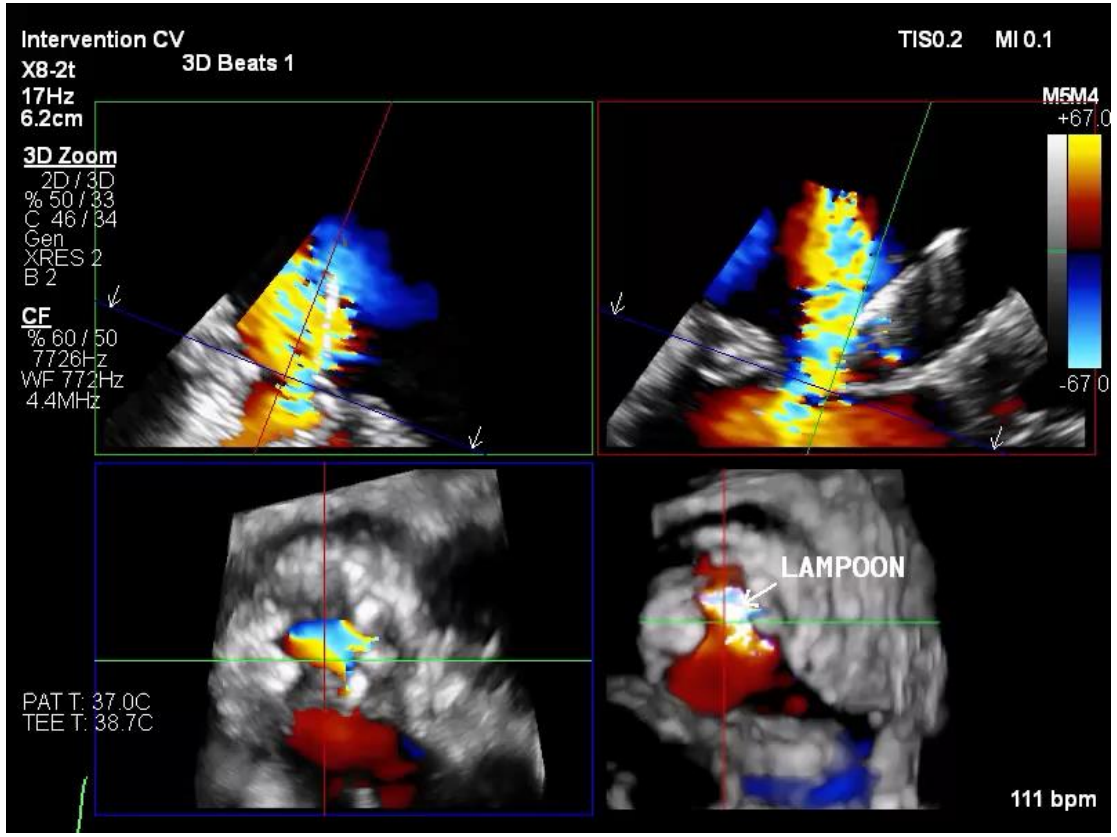

Mitral Valve Anchored by Clips

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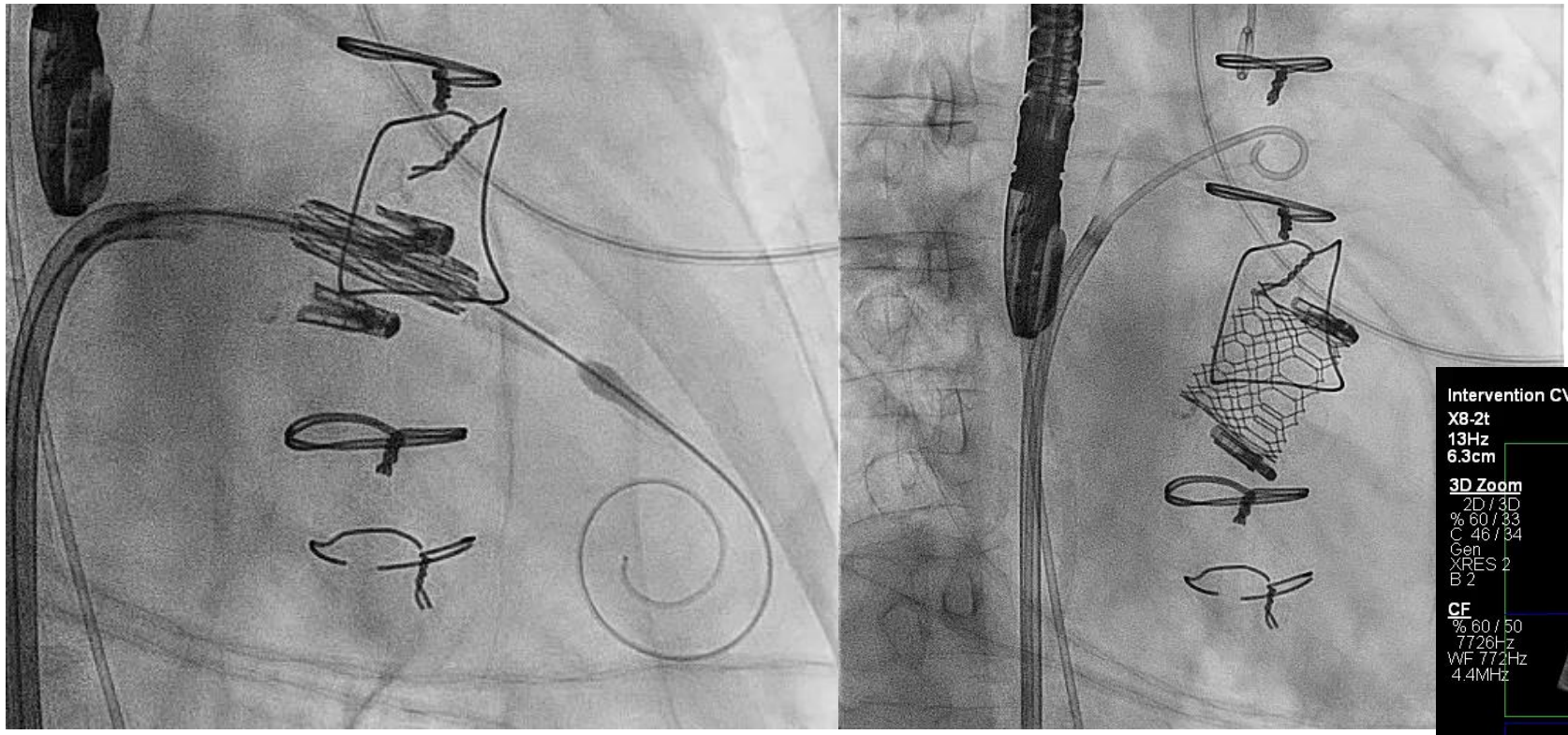

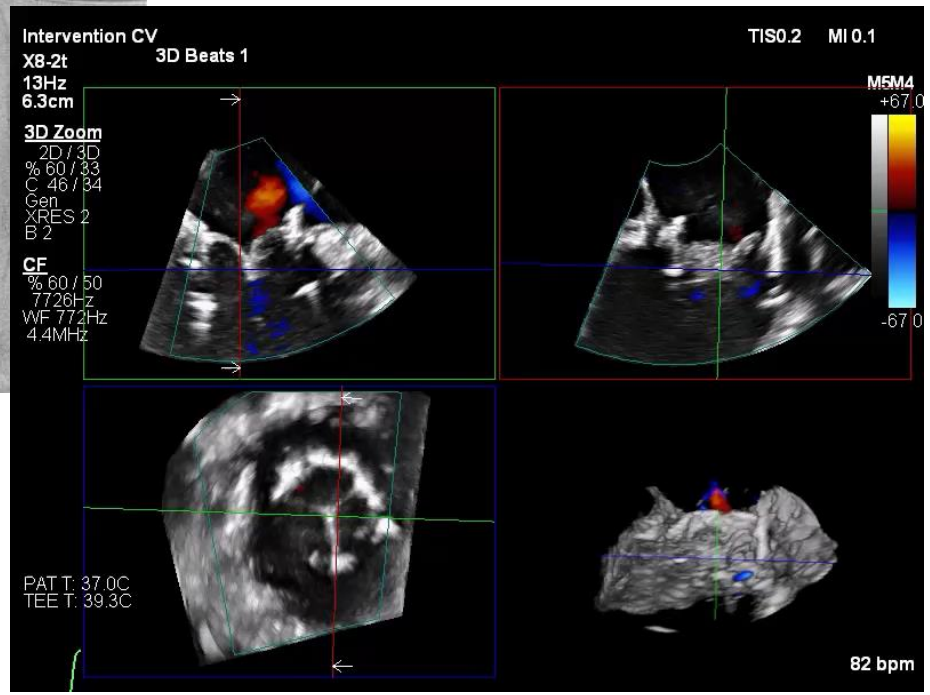

Anatomic Rationale for Exclusion from TMVR

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Too Small

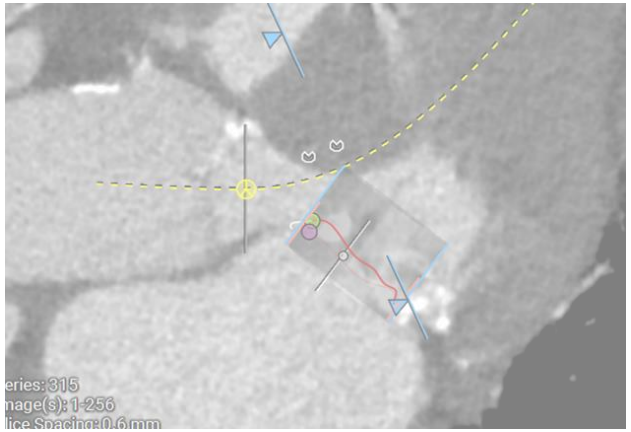
Too Big / Soft

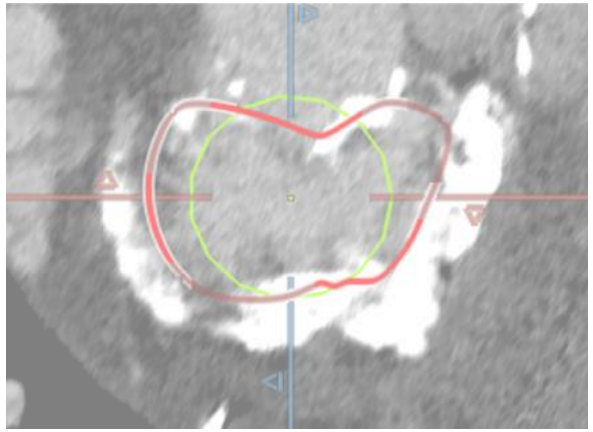
Stuff in the Way

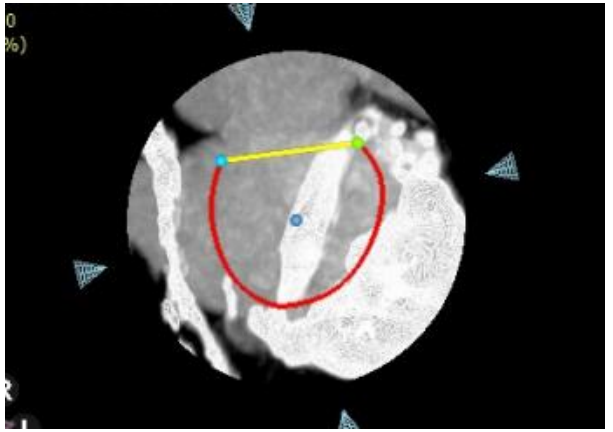
(Below the annulus)

(at the Annulus)

(In the Annulus)







M-TEER: Not Always the Desired Results

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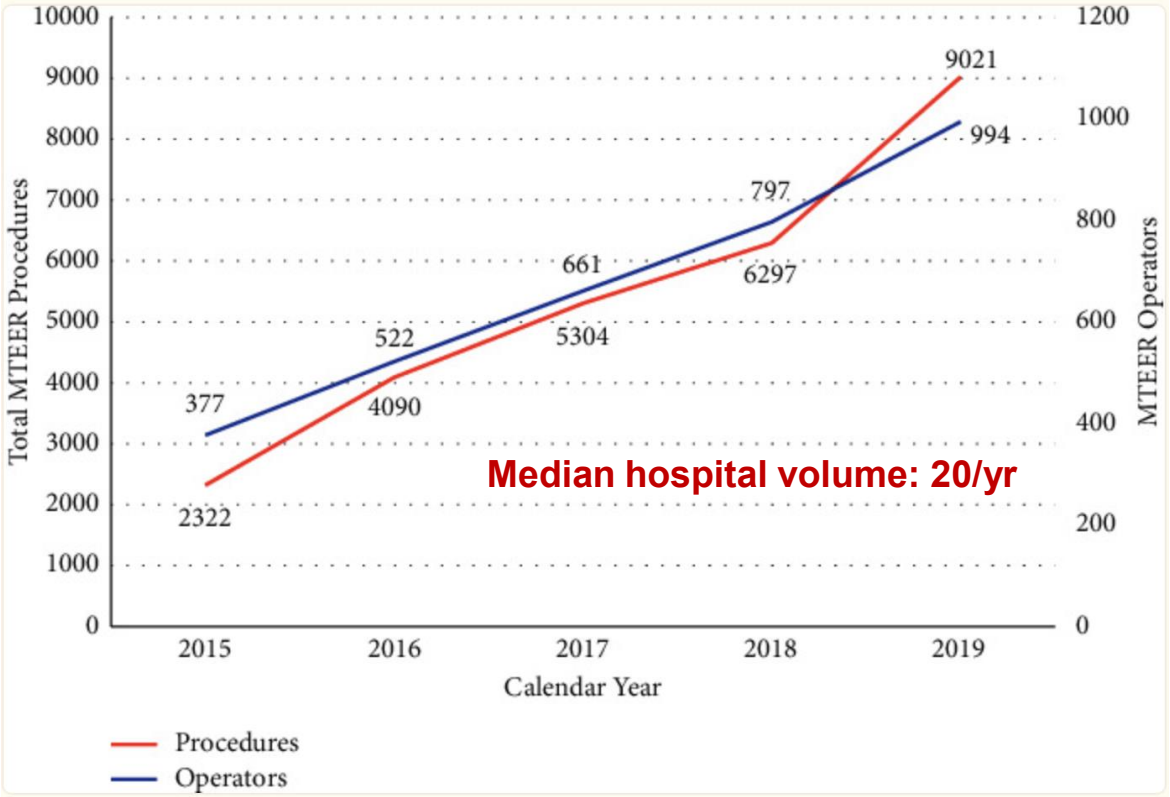
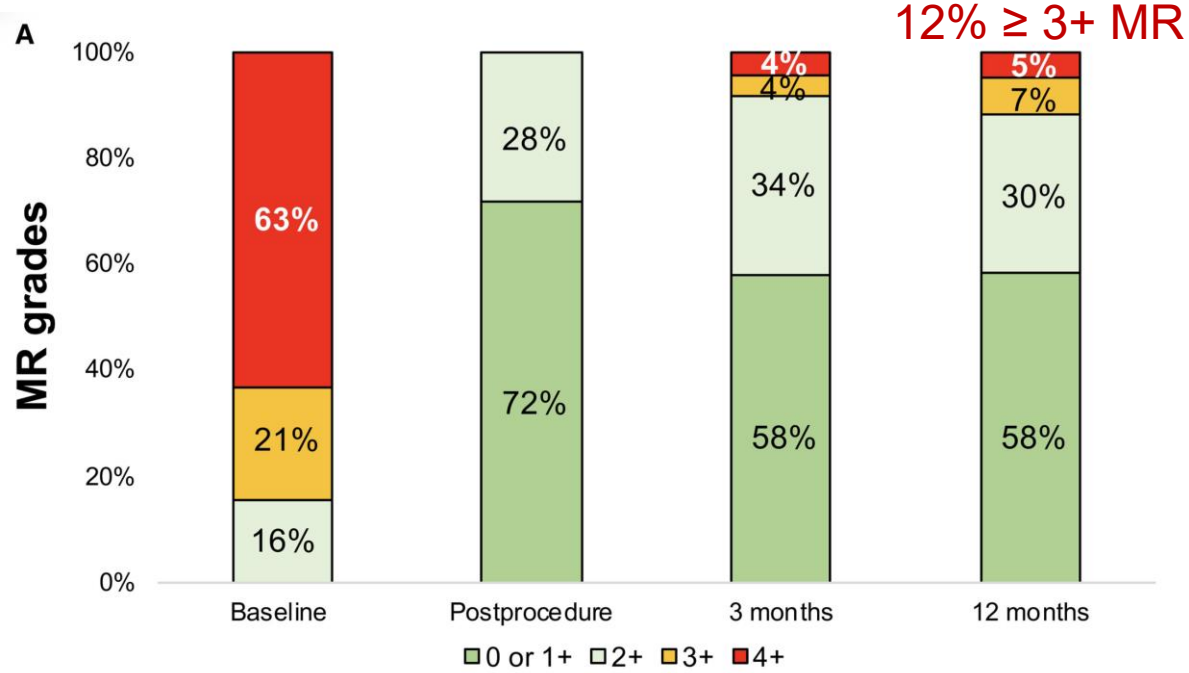
CMS Claims Data



Kumar et al. J Interv Cardiol. 2023

Mitraclip Patients Rhineland Heart Failure Network 2010-18

12% ≥ 3+ MR



Sugiura et al. Circ Cardvasc Int. 2022

Last Case Example: Clip Removal

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HARVARD MEDICAL SCHOOL TEACHING HOSPITAL

84 year old male living in North Carolina

Multiple heart failure admissions / year for many years. Preserved left ventricular ejection fraction.

On midodrine for persistent hypotension.

Complex medical history

Patient's Surgical / Procedural History

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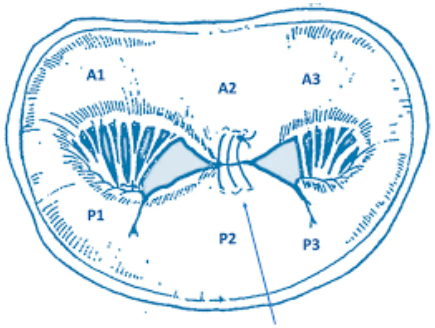
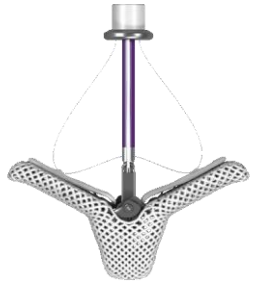
Surgical aortic valve replacement in 2009 for bicuspid aortic stenosis in Boston

Complicated surgery that resulted in a mitral Alfieri Stitch at that time without annuloplasty

Alfieri stitch technique



Persistent mitral valve regurgitation – mitraclip to the mitral valve at a different Boston institution in 2016



His Mitral Valve

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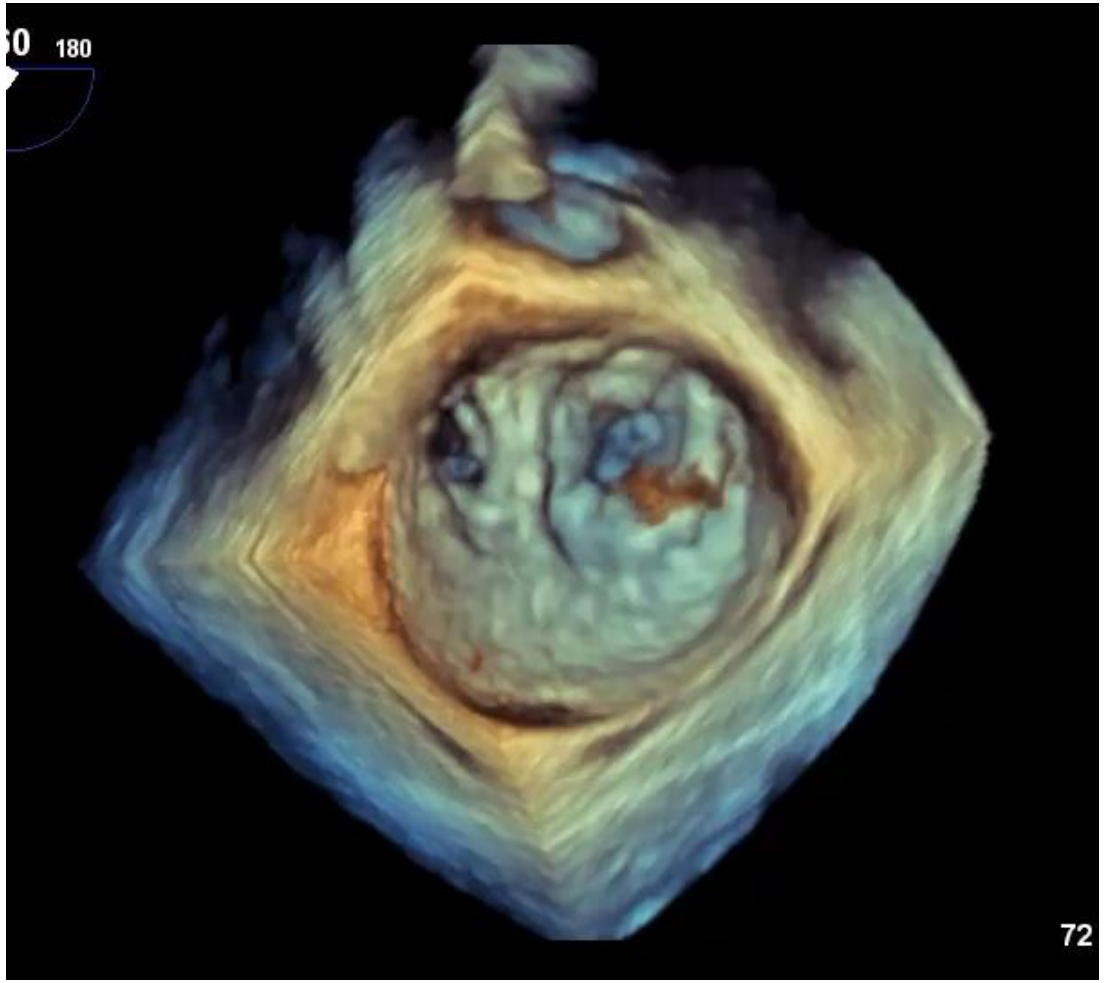

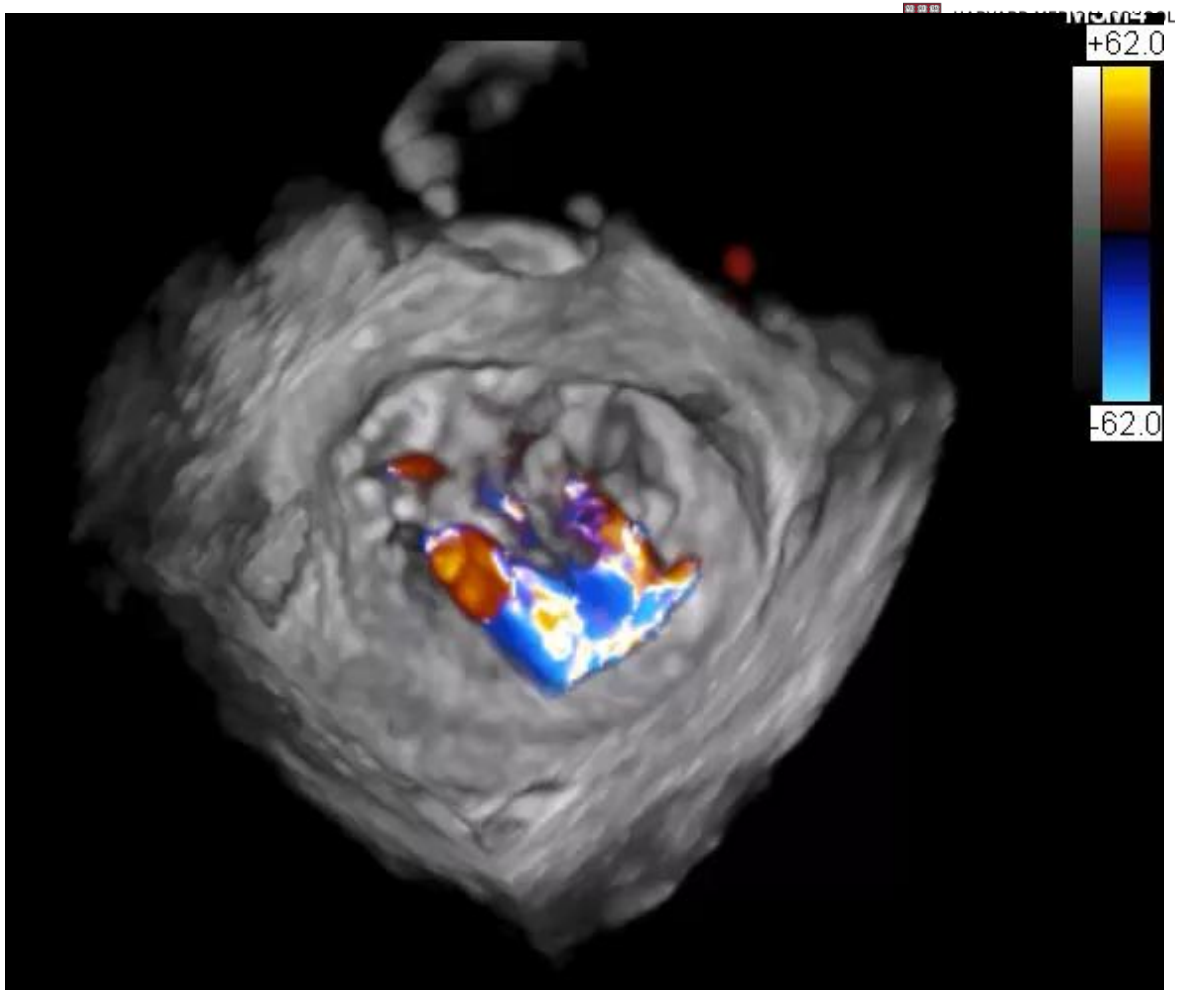

Persistent severe regurgitation and now moderate stenosis

Local CT Scan:

1. Clip & stitch in the way
2. Nothing to anchor TMVR to
3. No space in LVOT

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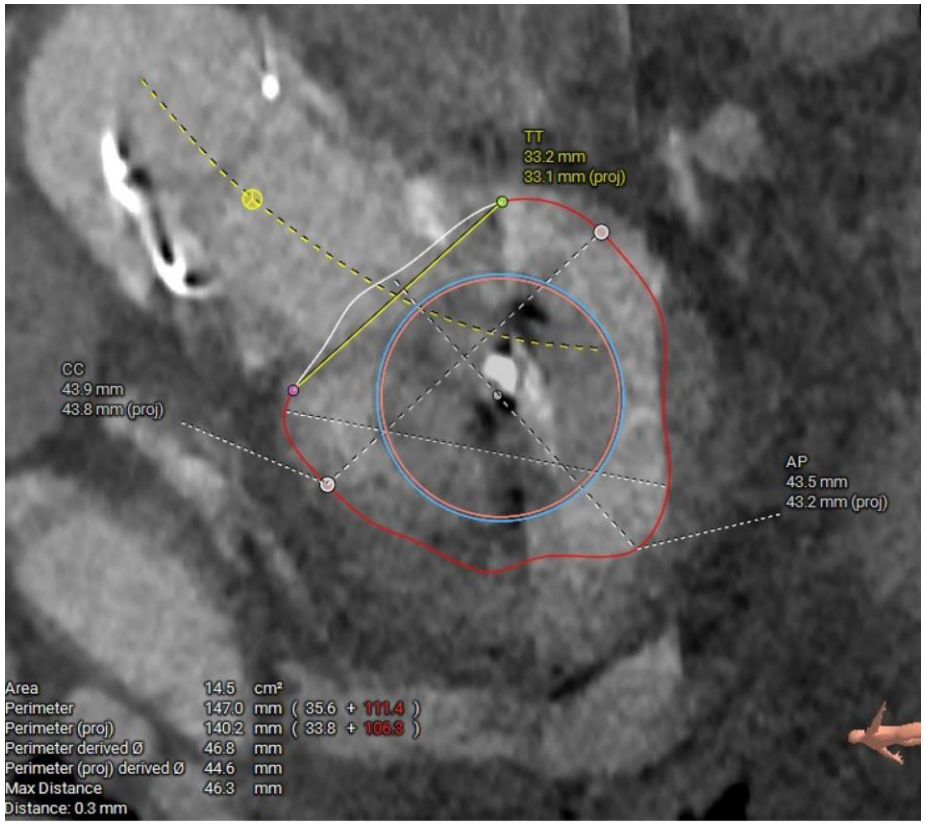
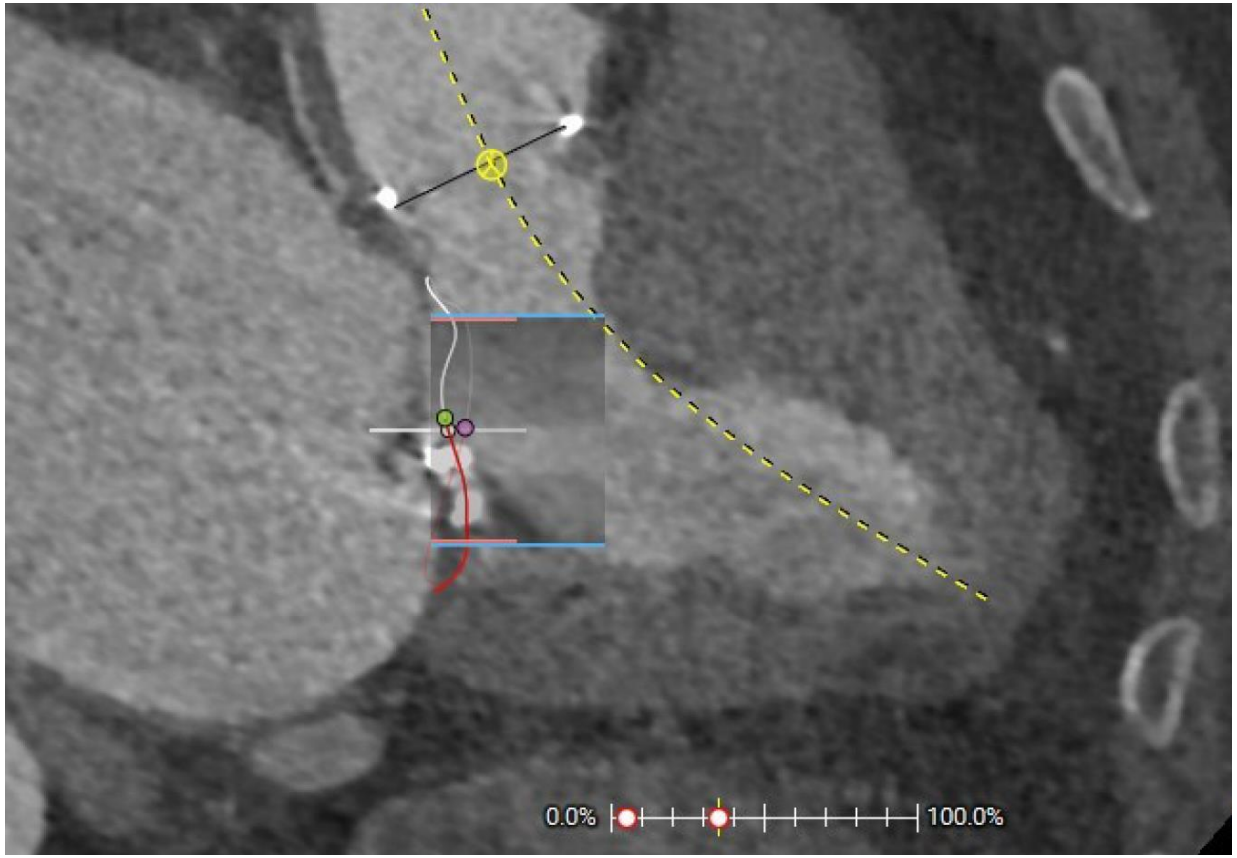


Field cut noted across annulus



Arrived Very Sick

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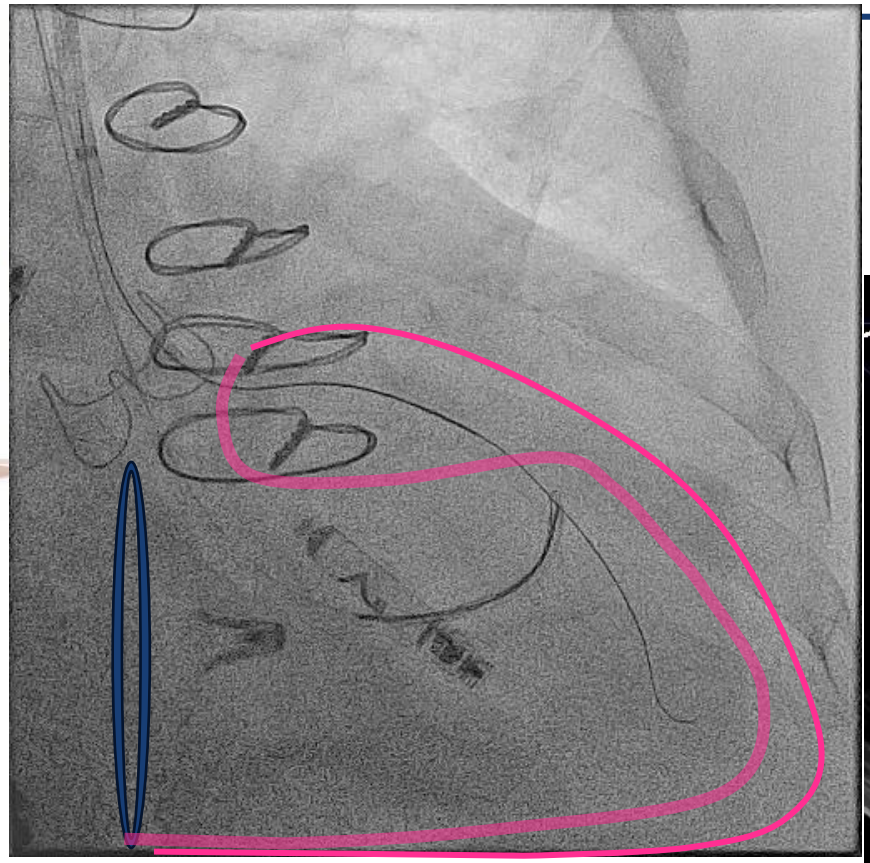
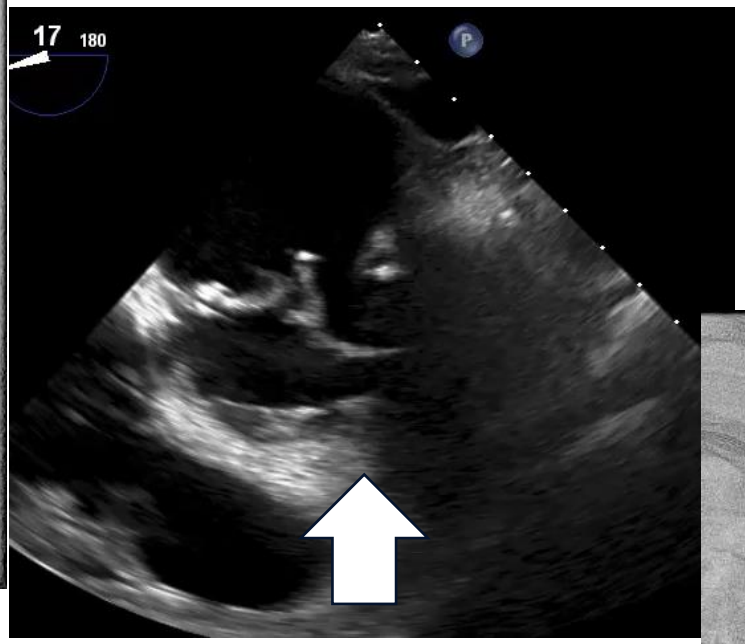


Mitral Valve

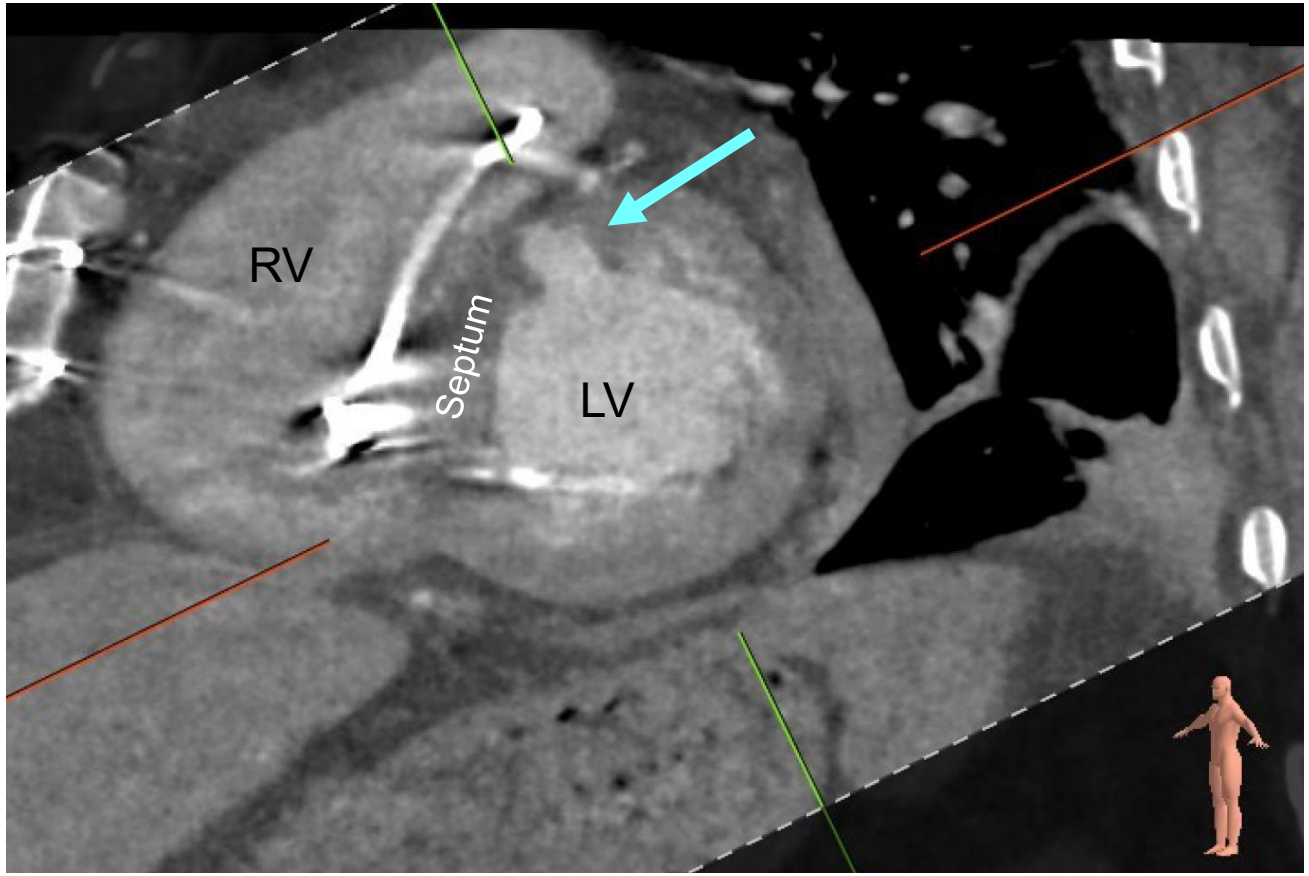
LV Muscle

Arrived in Seattle with NYHA class IV symptoms
RHC: cardiogenic shock [Cardiac Index 1.8]



SESAME performed
Balloon pump placed

CT Scan 2 days later



CT scan submitted to device manufacturer & FDA who granted emergency use to proceed with TMVR using a trial-based, M3 valve

This still requires re-creating a single mitral valve orifice!

Alfieri Lacerated; AML & PML lacerated off Clip

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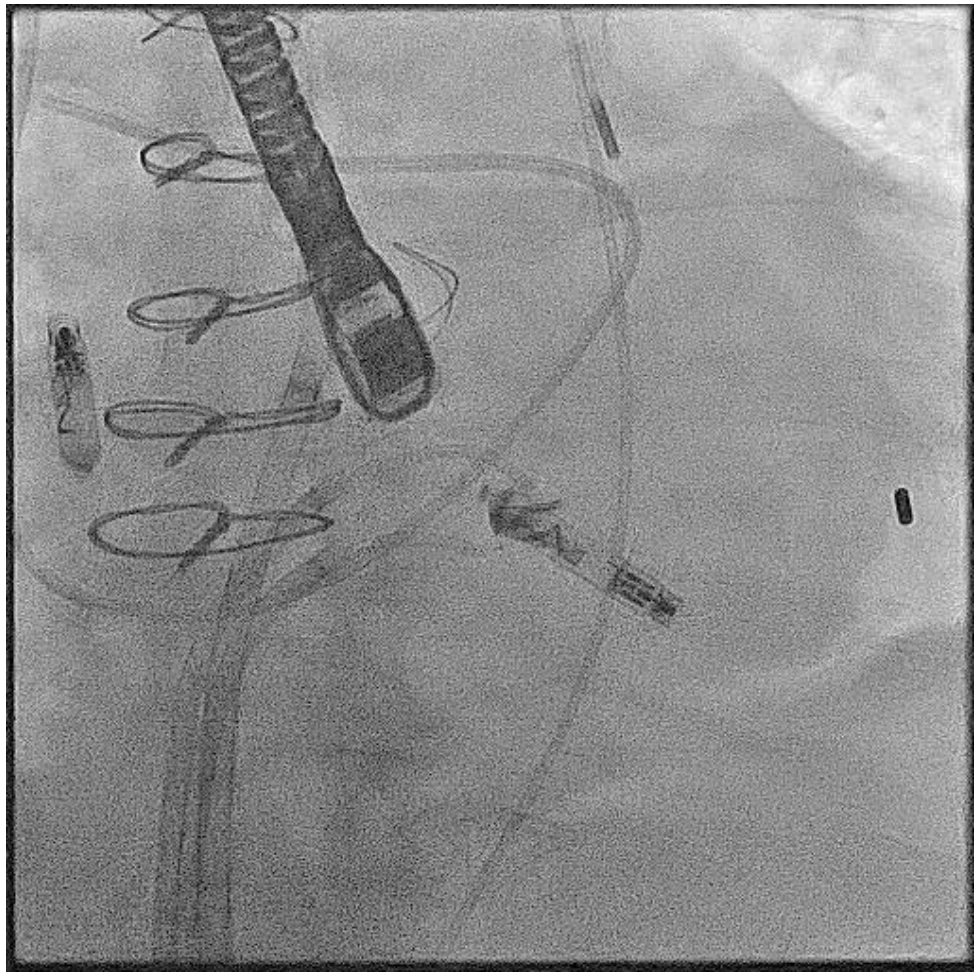

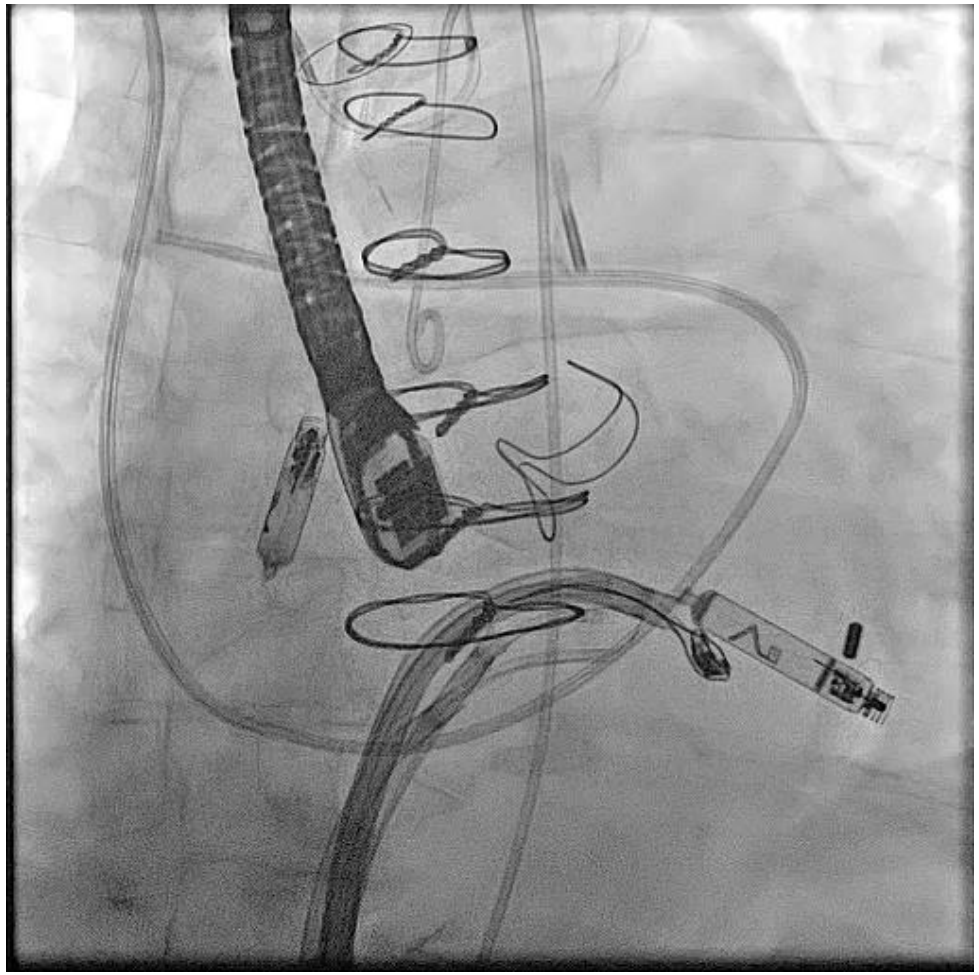

Clip Removed

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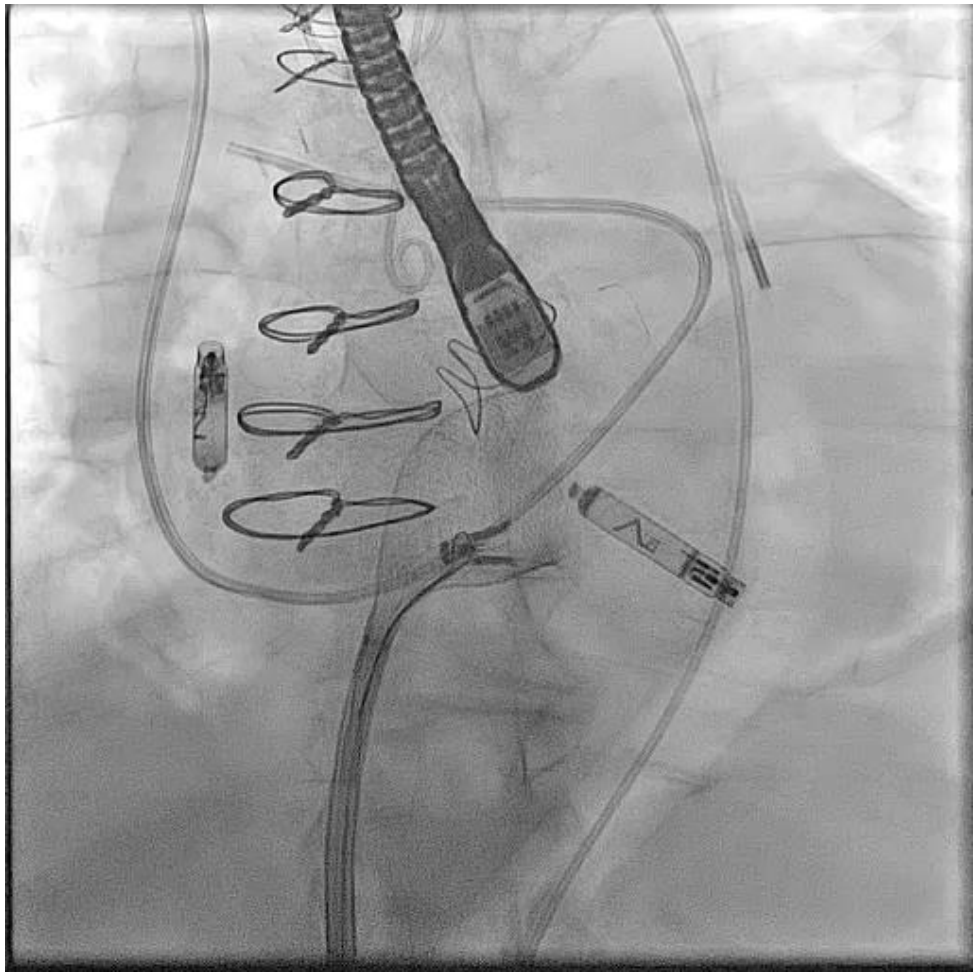
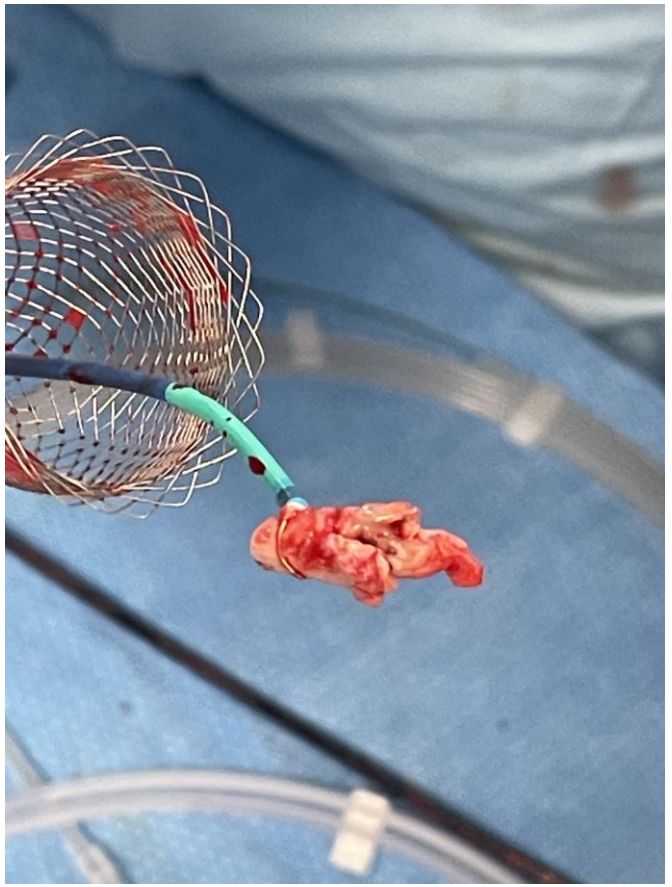
HARVARD MEDICAL SCHOOL TEACHING HOSPITAL





8 years in situ

Removing the Clip Removes “Some Leaflet” Too

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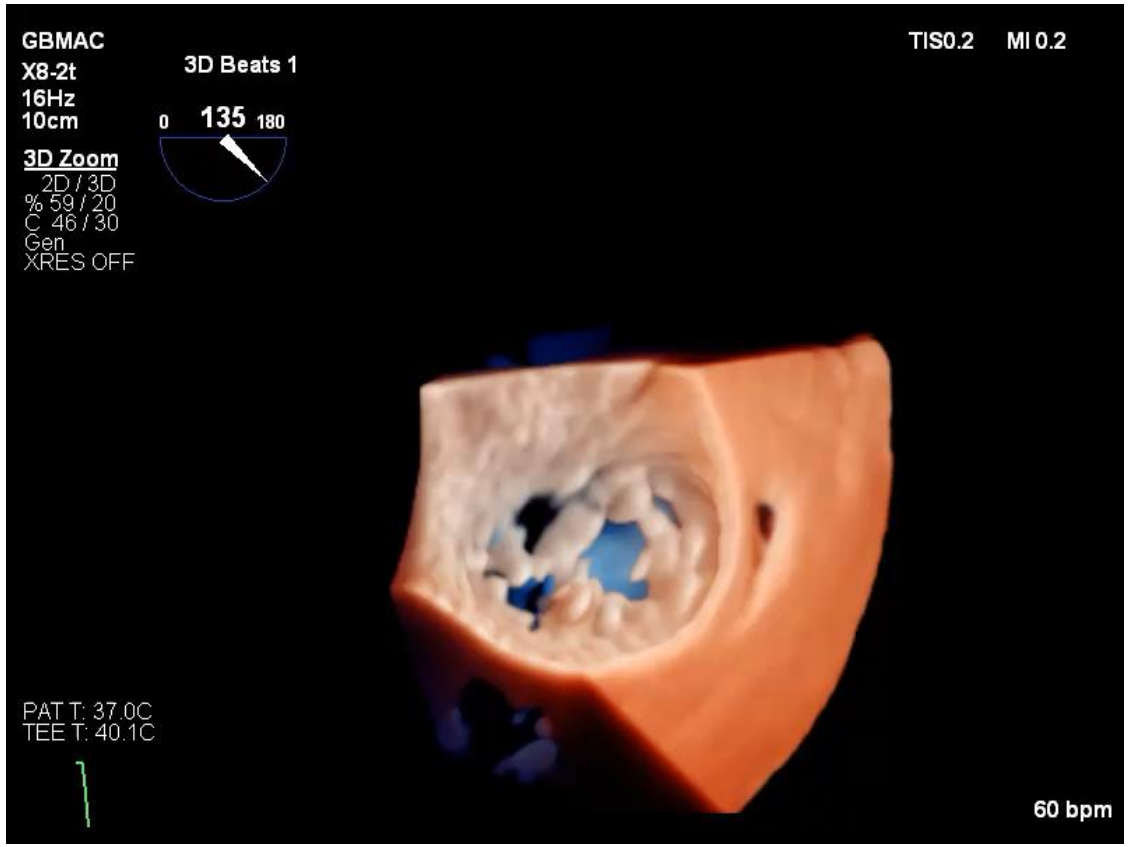
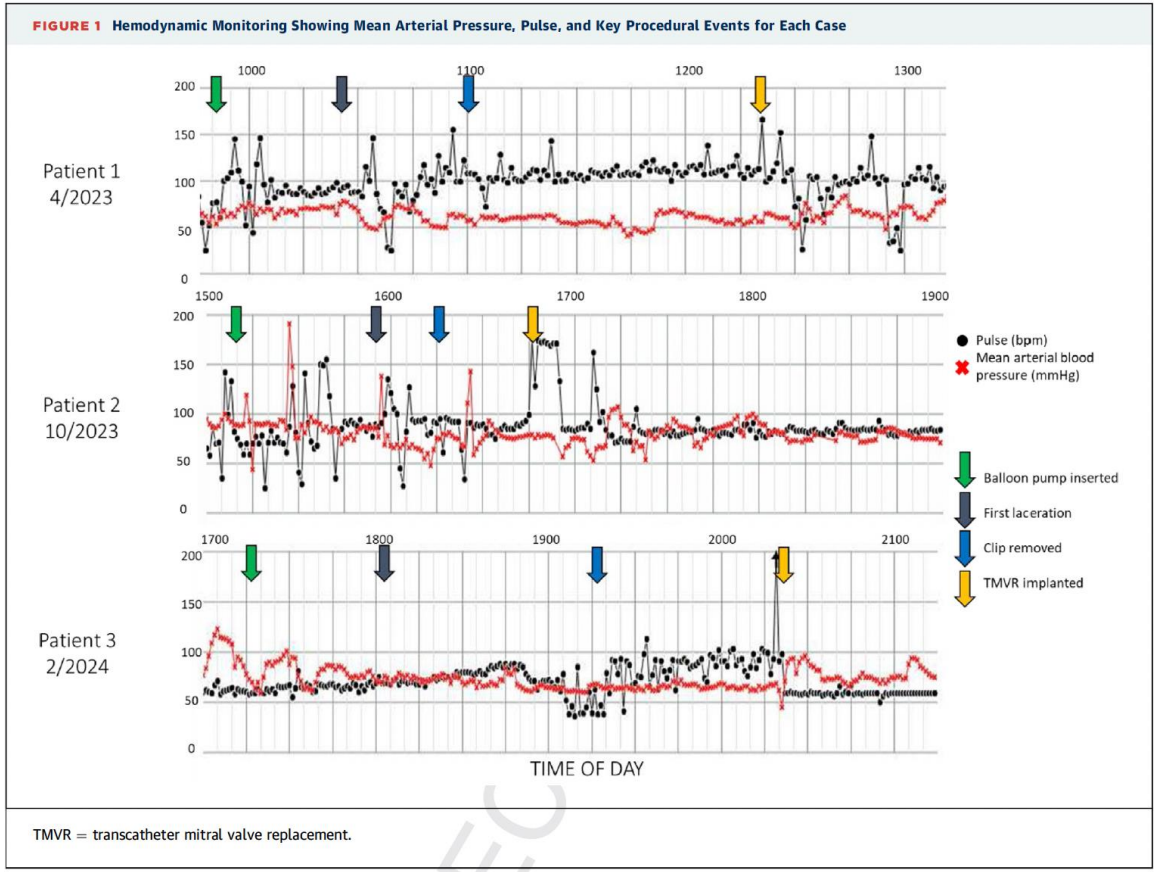


Hemodynamically tolerated with just an IABP



Condos et al. JACC CI. 2024

BIDMC Structural Heart

Mitral Valve Replacement Implanted

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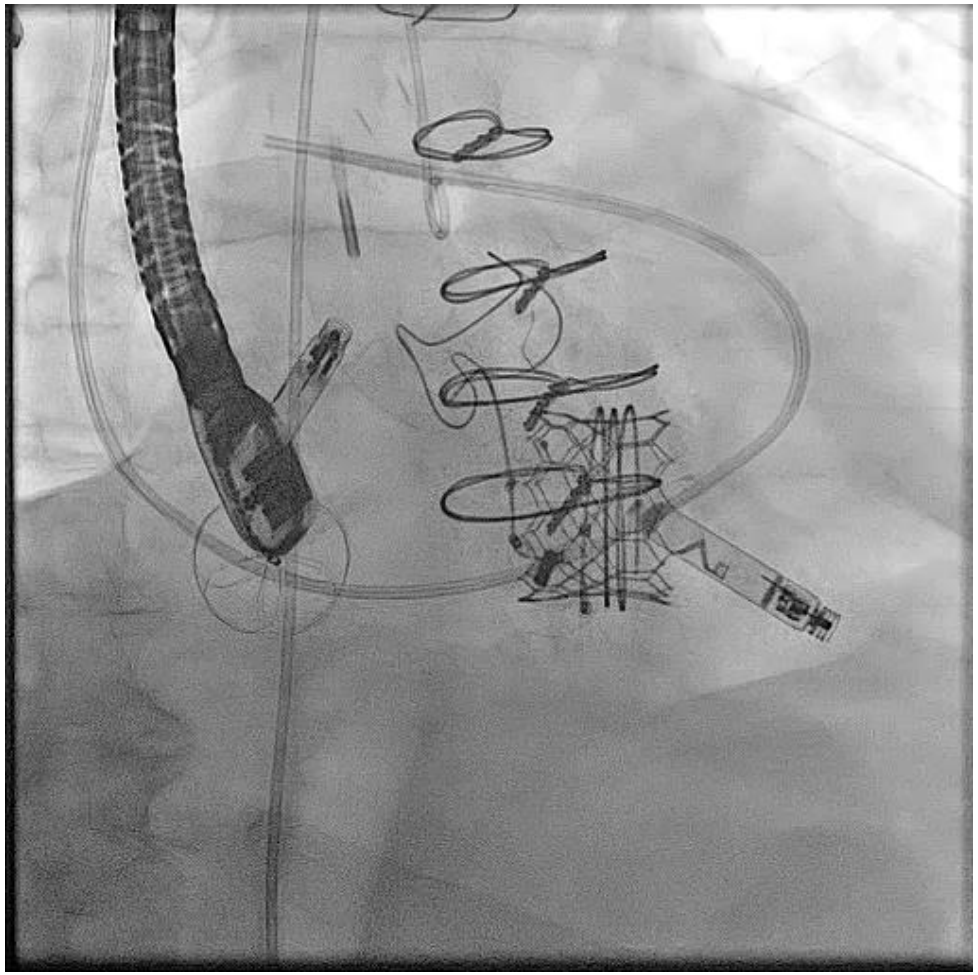

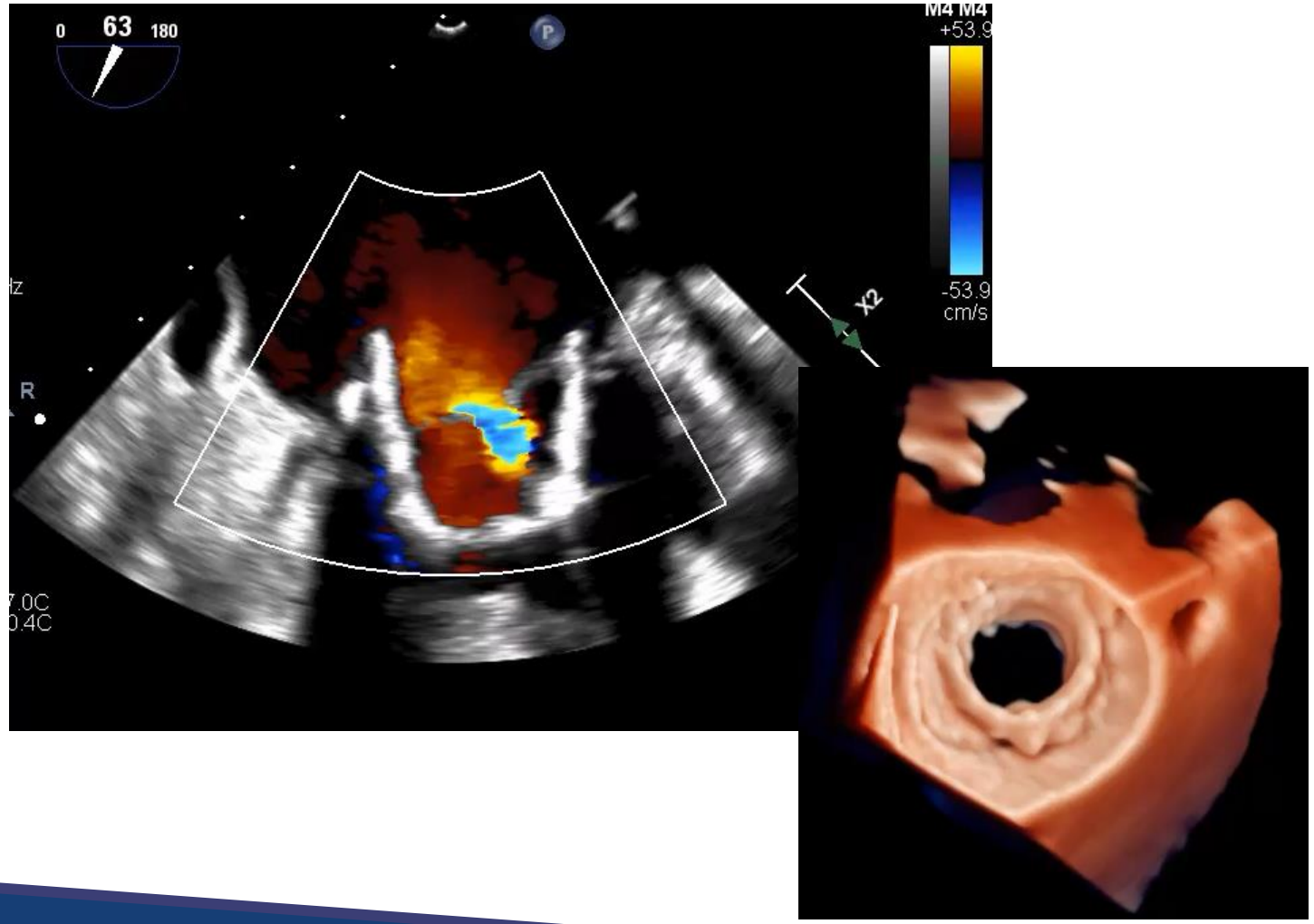

FRONTEER TMVR

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Fully-percutaneous Removal Of Non-functional TEER followed by TMVR

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 17, NO. 4, 2024

PUBLISHED BY ELSEVIER

IMAGES IN INTERVENTION

First-in-Human Percutaneous Excision of a Failed MitraClip Followed by Transcatheter Mitral Valve Replacement

David Elison, MD,[a] Gabriel Aldea, MD,[b] Srjdan Jelacic, MD,[c] Christine J. Chung, MD,[a] G. Burkhard Mackensen, MD,[c] James M. McCabe, MD[a]

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 17, NO. 13, 2024

PUBLISHED BY ELSEVIER

IMAGES IN INTERVENTION

Hemodynamic Tolerance of TEER Device Extraction Followed by TMVR

Gregory J. Condos, MD,[a] David Elison, MD,[a] Srdjan Jelacic, MD,[b] Richard Sheu, MD,[b] Christine J. Chung, MD,[a] Gabriel S. Aldea, MD,[c] G. Burkhard Mackensen, MD, PhD,[b] James M. McCabe, MD[a]

Follow Up

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Many week hospitalization

Ultimately discharged and flew back to his home in NC

Cr normalized

No repeat hospitalizations

Living independently

Celebrated his 85th birthday and re-applied for his driver's license

18 Months Later in NC

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Removed Clips

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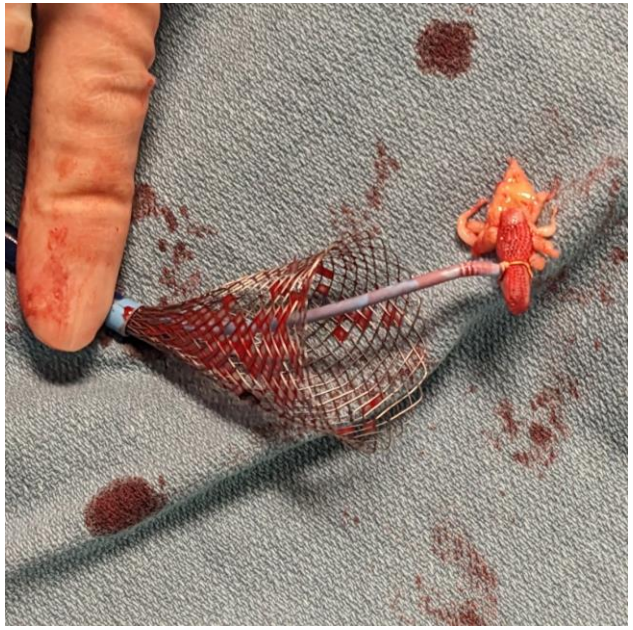
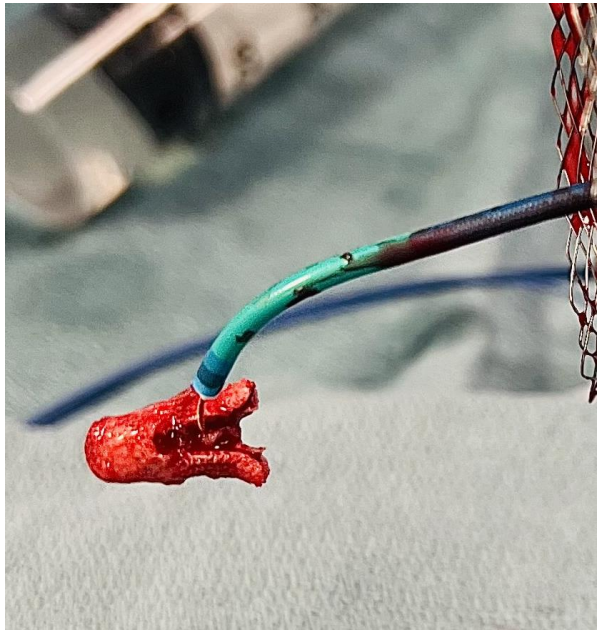


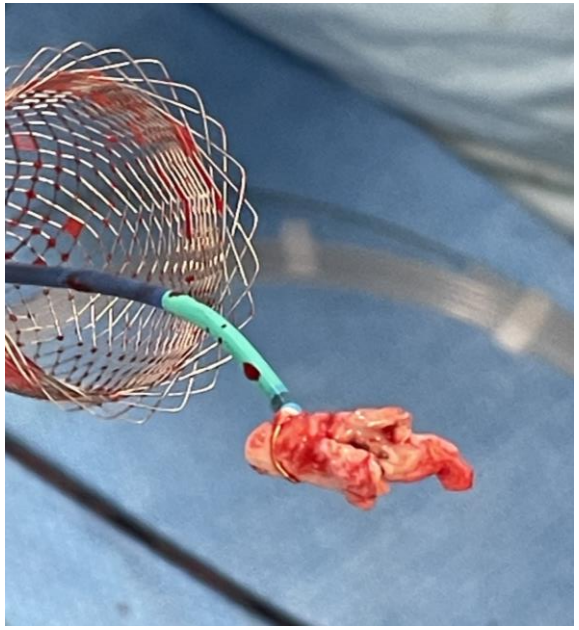
Case 1

In situ: ~ 2 years



Case 2

In situ: ~ 6 months



Case 3

In situ: ~ 9 years

Case 4

In situ: ~ 5 years

Complexity is the volume of attachments even external to the grip arms

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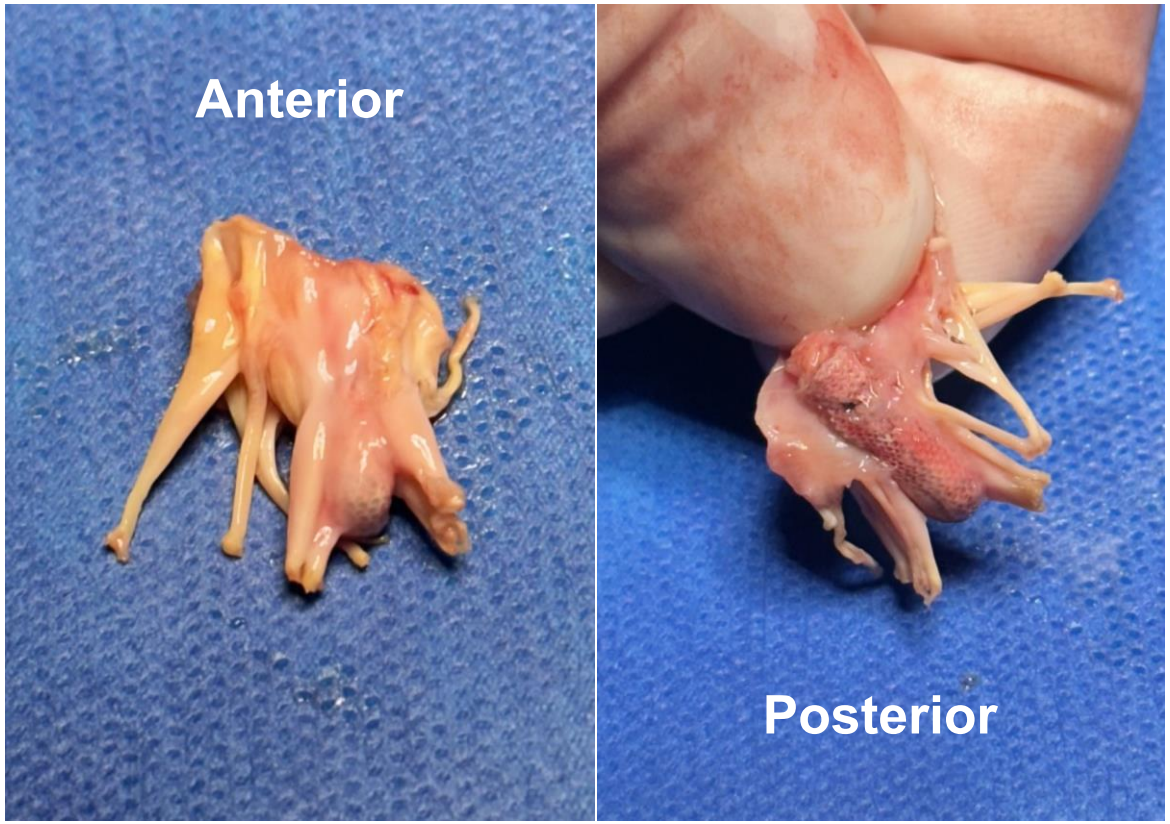

2 year old clip removed by Dave Daniels at Sutter

Conclusions

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HARVARD MEDICAL SCHOOL TEACHING HOSPITAL

Anatomic challenges for TMVR remain substantial

Procedural techniques can enable early-stage technologies

Proof of concept techniques are engendering technology iteration to address unmet needs