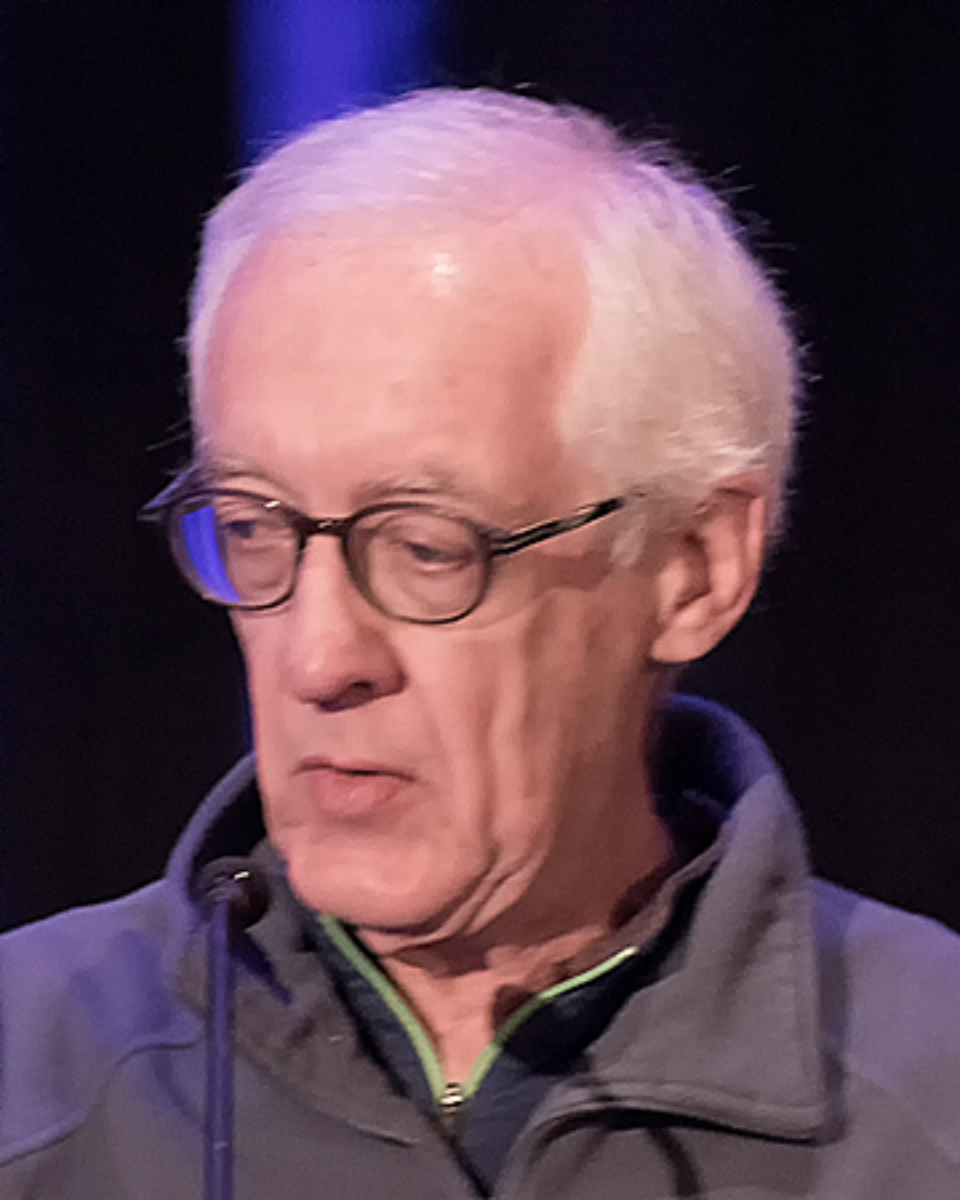


Transcatheter Mitral Innovations, Part II

Michael Mack, M.D.

Baylor Scott & White Health

Conflict of Interest Disclosure

- Co-PI of the COAPT Trial of MitraClip sponsored by Abbott Vascular
- Uncompensated

Transcatheter Mitral Valve: Device Landscape 2015

Edge-to-edge

• MitraCli
•

Coronary sinus annuloplasty

ons Carillon*

Other approaches

• MitraSpacer*

• St. Jude leafle on*

ring

Direct a

vent

• Mi

• Gl

• Valt oband*

• Quantum Cor (RF)

• Micardia enCor

*In patients

>30 Devices !

8 Invented by Surgeons !!

• Valtech

• ValveXchange

• Lutter Valve

• Medtronic

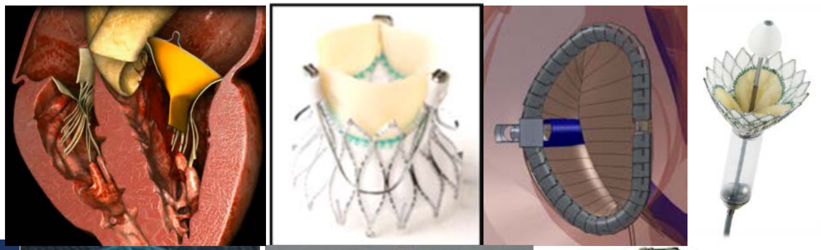
• Tendyne*

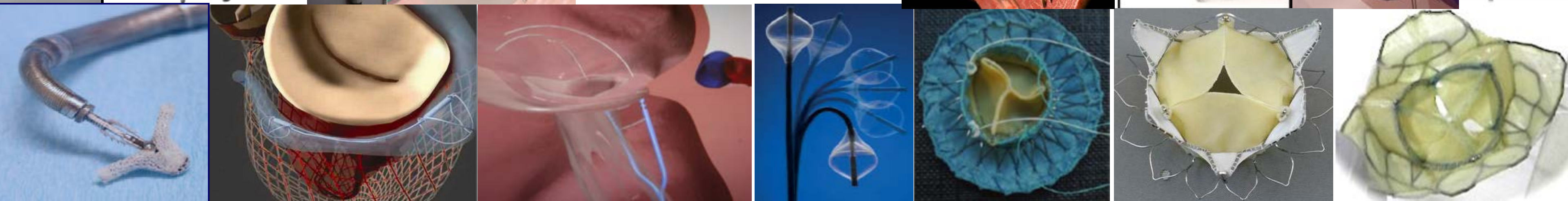
• MitrAssist

• MValve

al

pede





TMV Repair

Edge to Edge

MitraClip

Artificial Chords

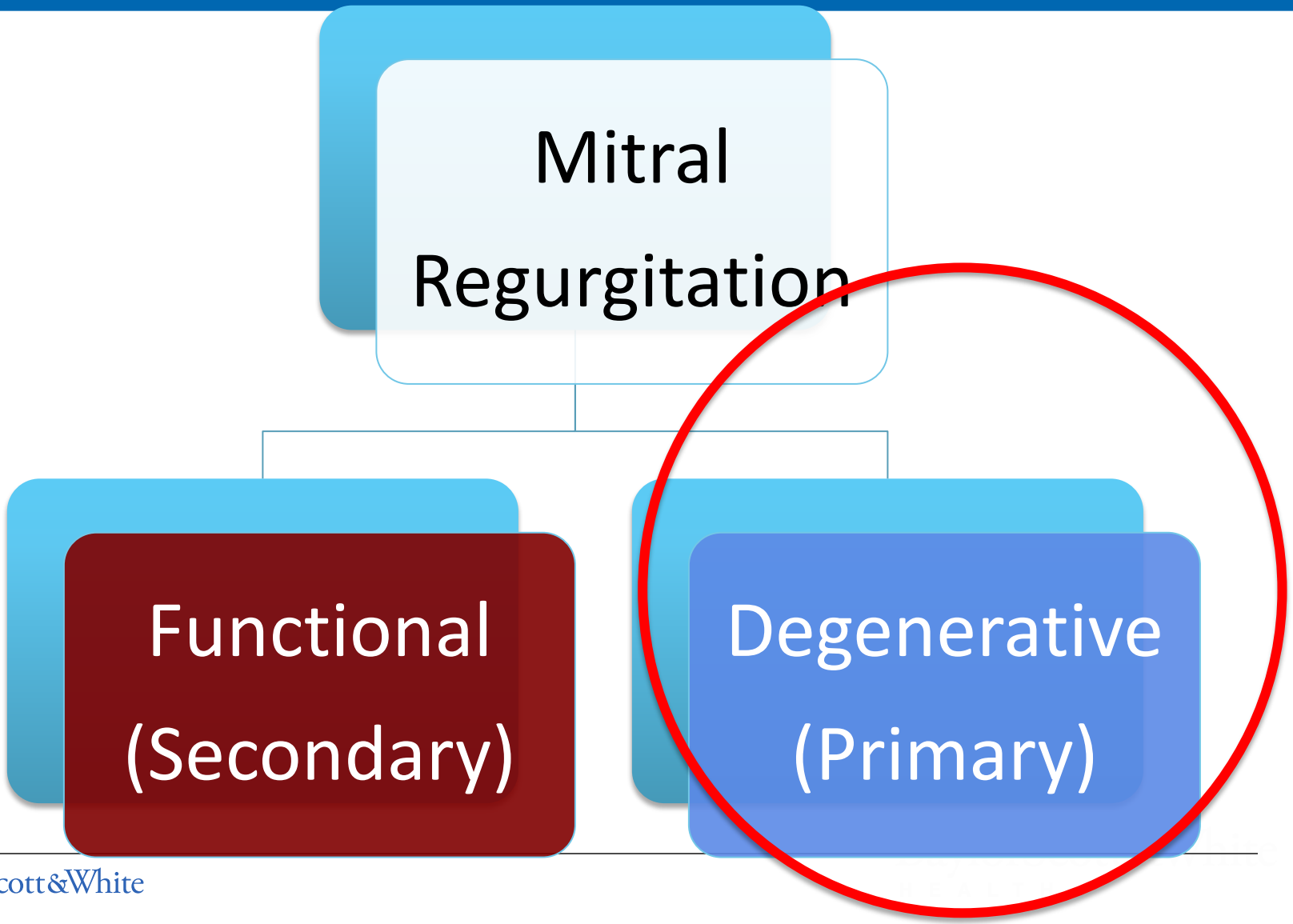
Neochord

Annuloplasty

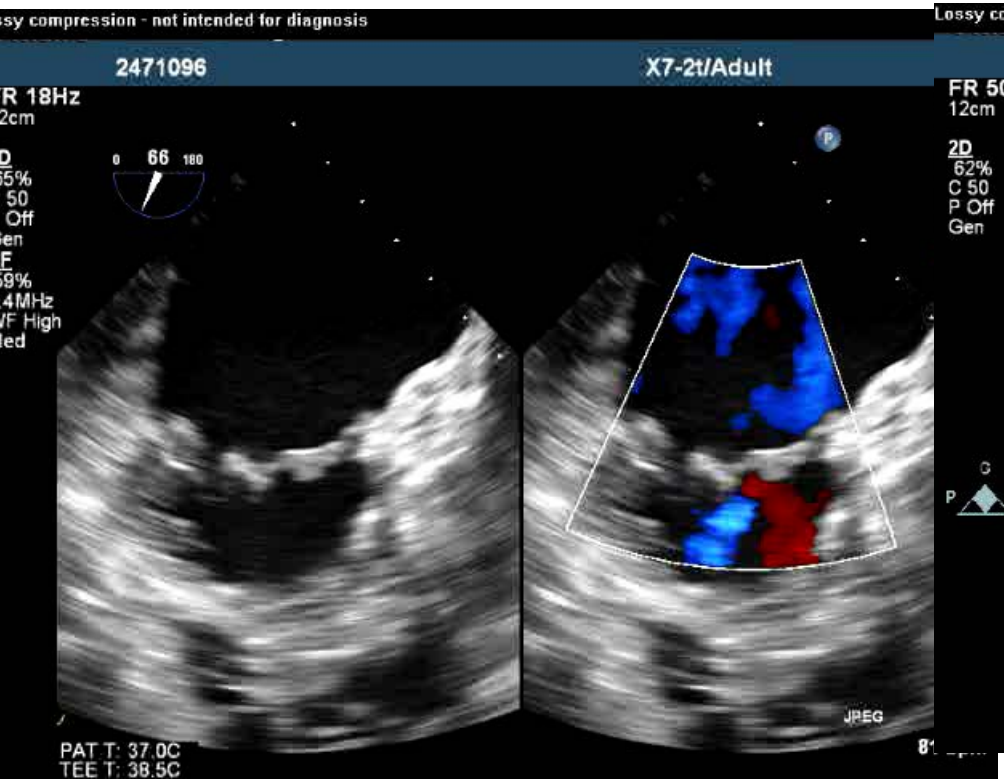
Cardioband

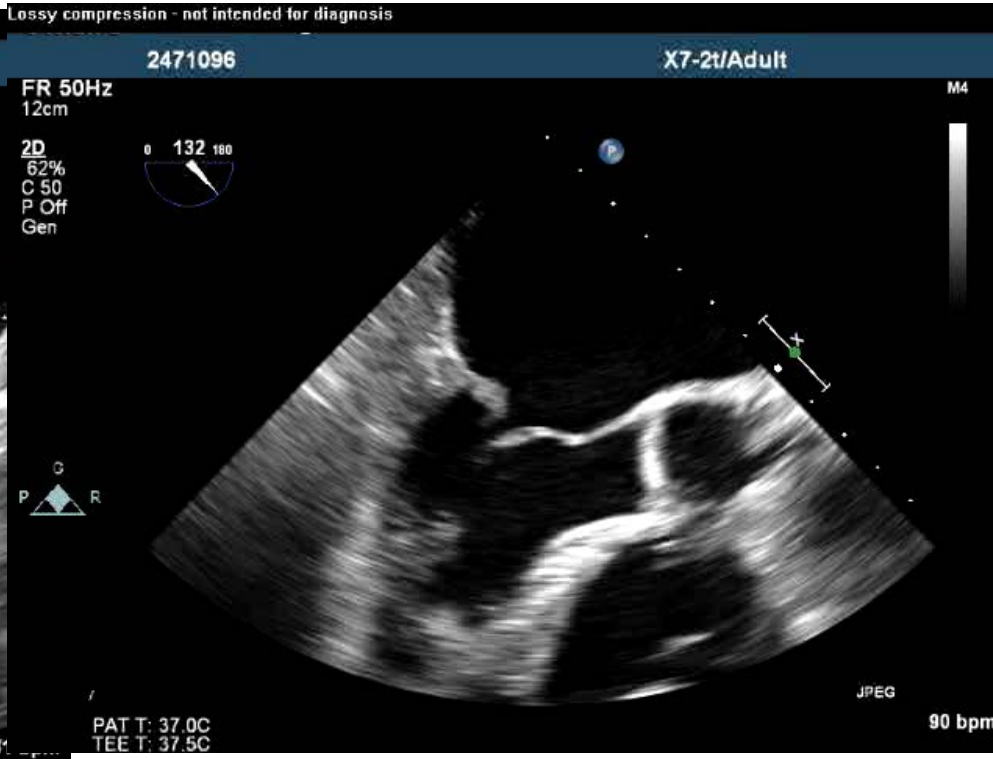
MitraClip

Mitral Regurgitation



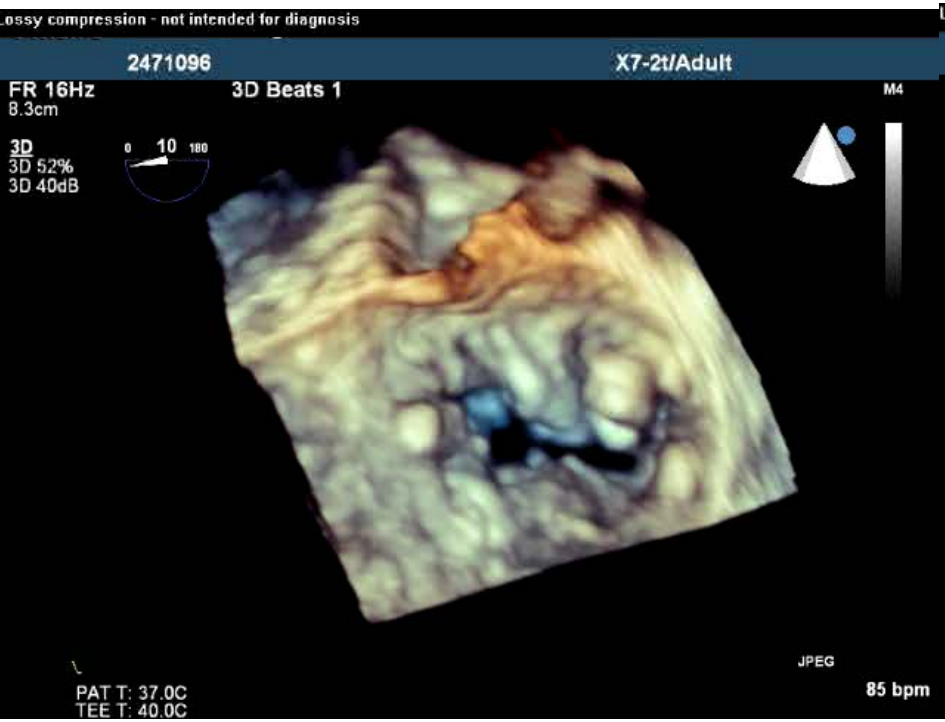
Primary MR

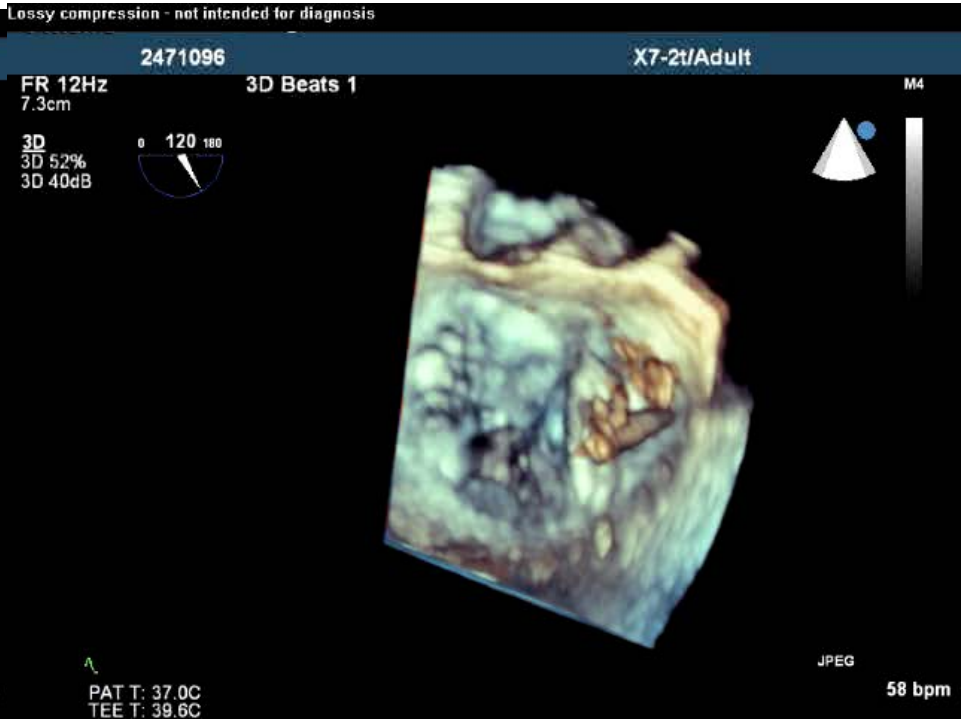




Courtesy Gorav Ailawadi

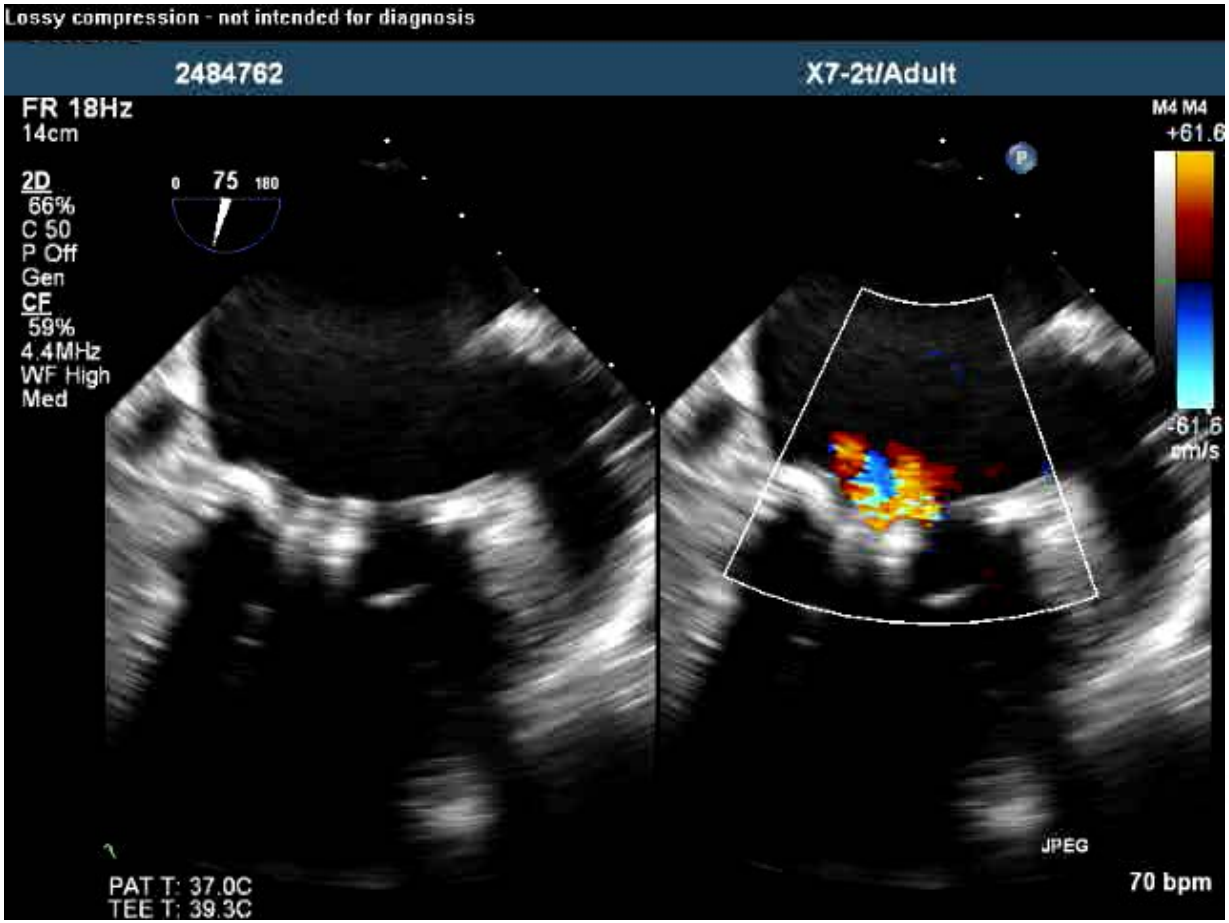
MitraClip® Placement





Courtesy Gorav Ailawadi

MitraClip® Procedure



2 Mitraclips

Courtesy Gorav Ailawadi

MitraClip Clip Delivery System

Approved October 24, 2013

Indication for Use:

The MitraClip Clip Delivery System is indicated for the percutaneous reduction of significant **symptomatic** mitral regurgitation (MR ≥ 3+) due to primary abnormality of the mitral apparatus [**degenerative MR**] in patients who have been determined to be at **prohibitive risk for mitral valve surgery by a heart team**, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the **expected benefit** from reduction of the mitral regurgitation.

Who Is High Risk ?

- STS Risk Score >8-10
- Porcelain aorta
- Hostile chest: Cobalt/mantle radiation, previous sternectomy
- Severe COPD (Prohibitive PFTs: FEV1< 0.8L)
- Pulmonary Hypertension
- Liver disease / cirrhosis
- RIMA or LIMA across midline:
- Frailty / Debility / Immobility
- Severe Mitral Annular Calcification

Recommendations for Chronic Primary MR

Recommendations	COR	LOE
MV surgery is recommended for symptomatic patients with chronic severe primary MR (stage D) and LVEF >30%	I	B
MV surgery is recommended for asymptomatic patients with chronic severe primary MR and LV dysfunction (LVEF 30%–60% and/or LVESD ≥40 mm, stage C2)	I	B
MV repair is recommended in preference to MVR when surgical treatment is indicated for patients with chronic severe primary MR limited to the posterior leaflet	I	B
MV repair is recommended in preference to MVR when surgical treatment is indicated for patients with chronic severe primary MR involving the anterior leaflet or both leaflets when a successful and durable repair can be accomplished	I	B
Transcatheter MV repair may be considered for severely symptomatic patients (NYHA class III/IV) with chronic severe primary MR (stage D) who have a reasonable life expectancy but a prohibitive surgical risk because of severe comorbidities	IIb	B
repair without residual MR is >95% with an expected mortality rate of <1% when performed at a Heart Valve Center of Excellence		
MV repair is reasonable for asymptomatic patients with chronic severe nonrheumatic primary MR (stage C1) and preserved LV function in whom there is a high likelihood of a successful and durable repair with 1) new onset of AF or 2) resting pulmonary hypertension (PA systolic arterial pressure >50 mm Hg)	IIa	B
Concomitant MV repair is reasonable in patients with chronic moderate primary MR (stage B) undergoing cardiac surgery for other indications	IIa	C
MV surgery may be considered in symptomatic patients with chronic severe primary MR and LVEF ≤30% (stage D)	IIb	C
MV repair may be considered in patients with rheumatic mitral valve disease when surgical treatment is indicated if a durable and successful repair is likely or if the reliability of long-term anticoagulation management is questionable	IIb	B
Transcatheter MV repair may be considered for severely symptomatic patients (NYHA class III/IV) with chronic severe primary MR (stage D) who have a reasonable life expectancy but a prohibitive surgical risk because of severe comorbidities	IIb	B
MVR should not be performed for treatment of isolated severe primary MR limited to less than one half of the posterior leaflet unless MV repair has been attempted and was unsuccessful	III: Harm	B

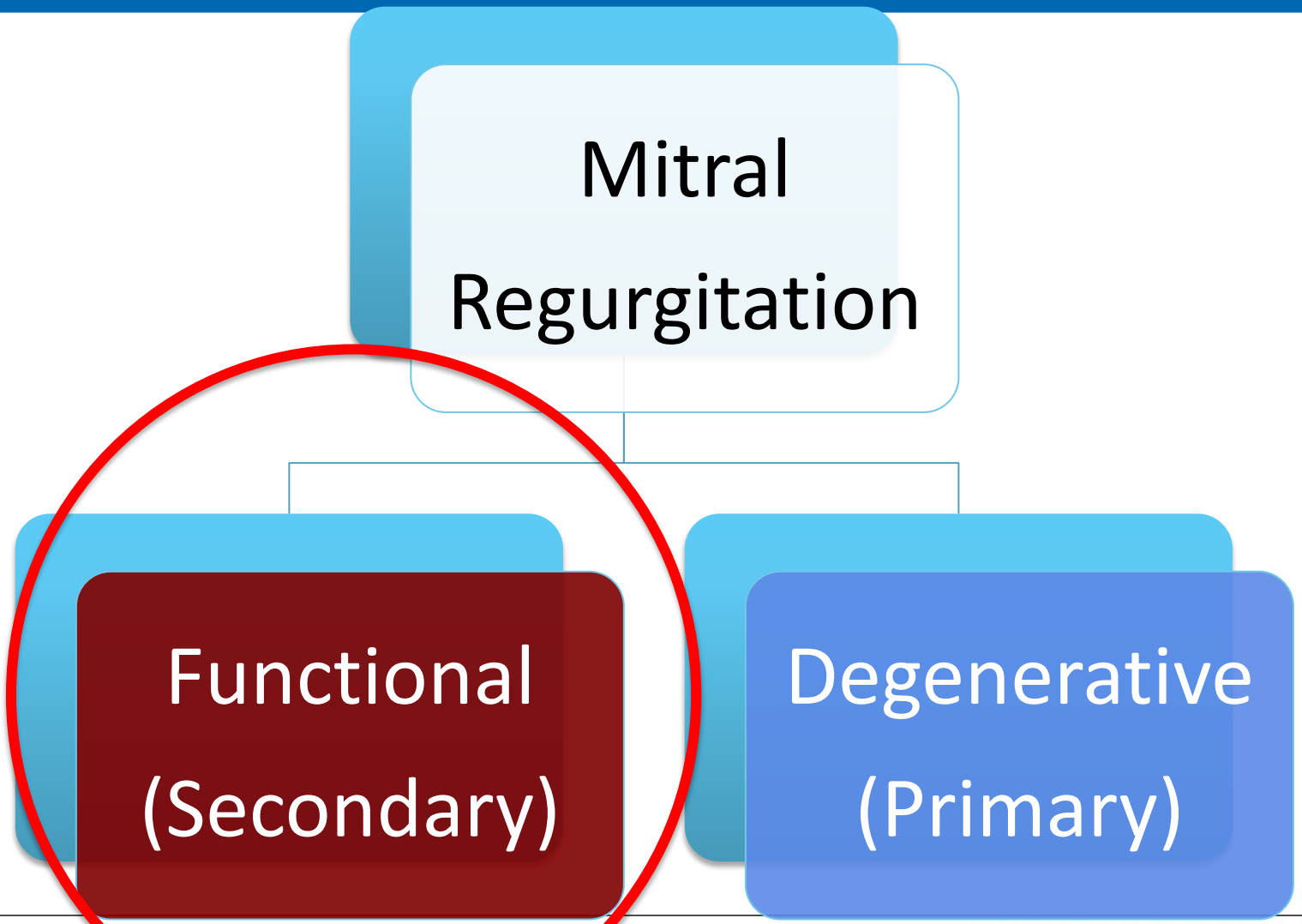
Transcatheter MV repair may be considered for severely symptomatic patients (NYHA class III/IV) with chronic severe primary MR (stage D) who have a reasonable life expectancy but a prohibitive surgical risk because of severe comorbidities | IIb | B

Nishimura, RA et al. 2014 AHA/ACC Valvular Heart Disease Guideline

ACC LBCT –March, 2015

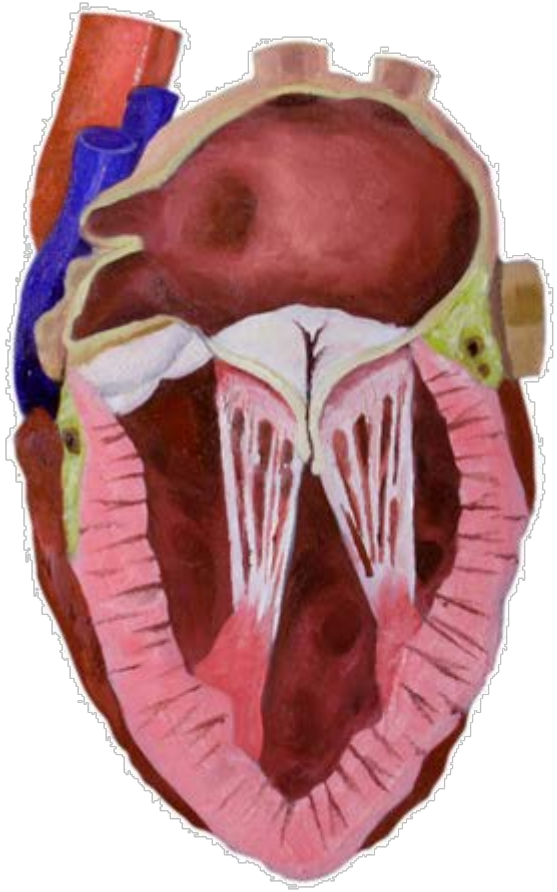
Outcomes of the Initial Experience with Commercial Transcatheter Mitral Valve Repair in the United States

Paul Sorajja, MD, Saibal Kar, MD, D. Scott Lim, MD, Vinod Thourani, MD, Michael Mack, MD, David R. Holmes, Jr., MD, Wesley A. Pederson, MD, Gorav Ailawadi, MD

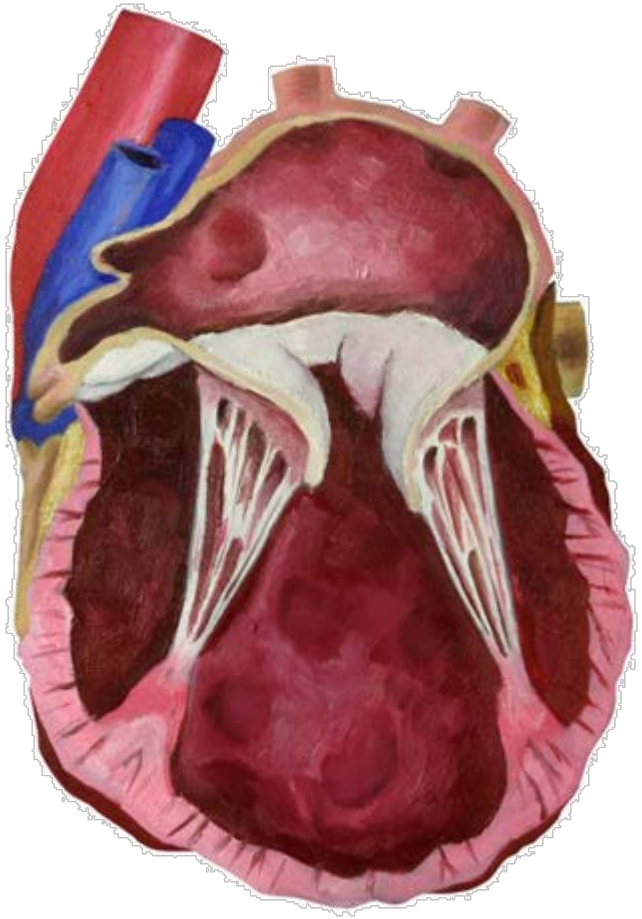

Mitral Regurgitation
Functional (Secondary)
Degenerative (Primary)

Secondary MR

Disease of the Left Ventricle NOT the Mitral Valve

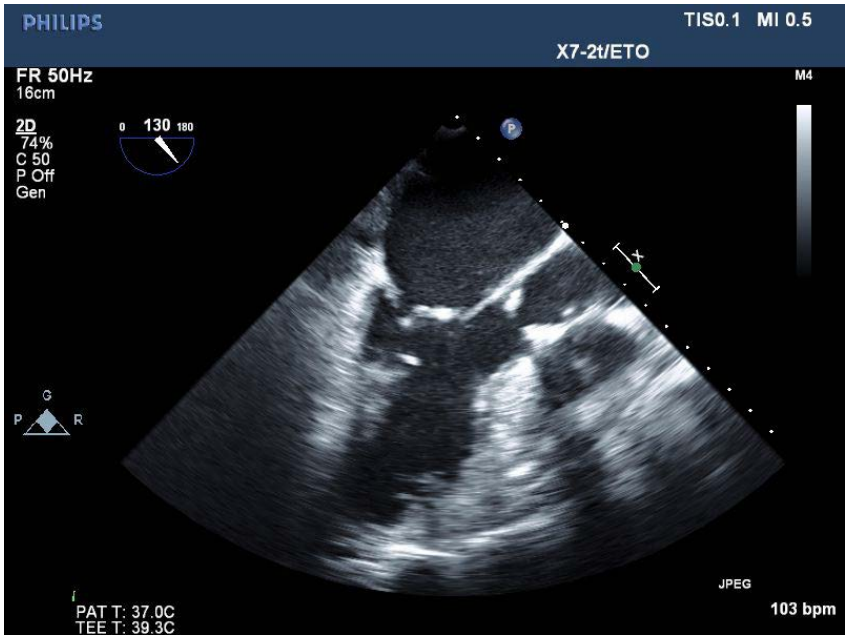


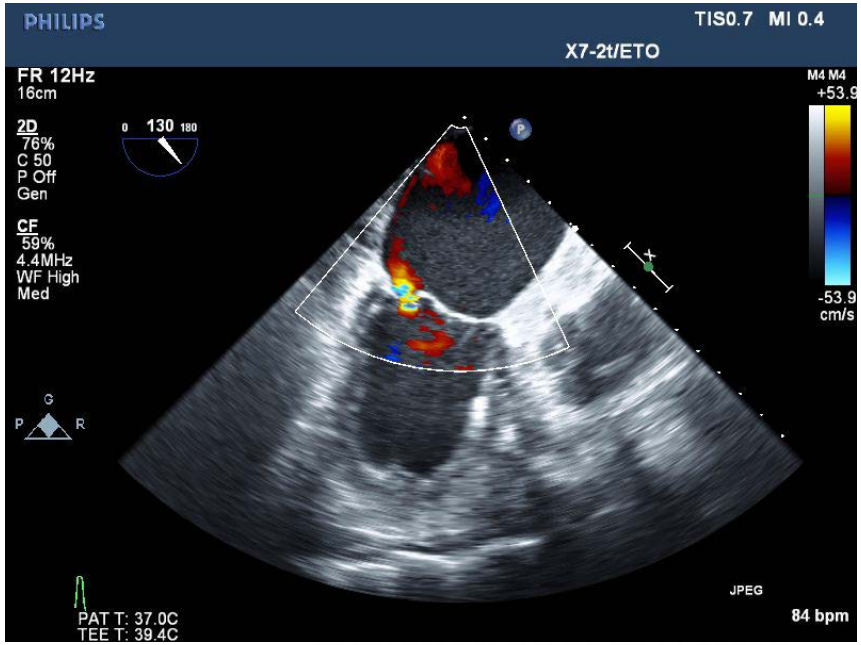
Normal LV



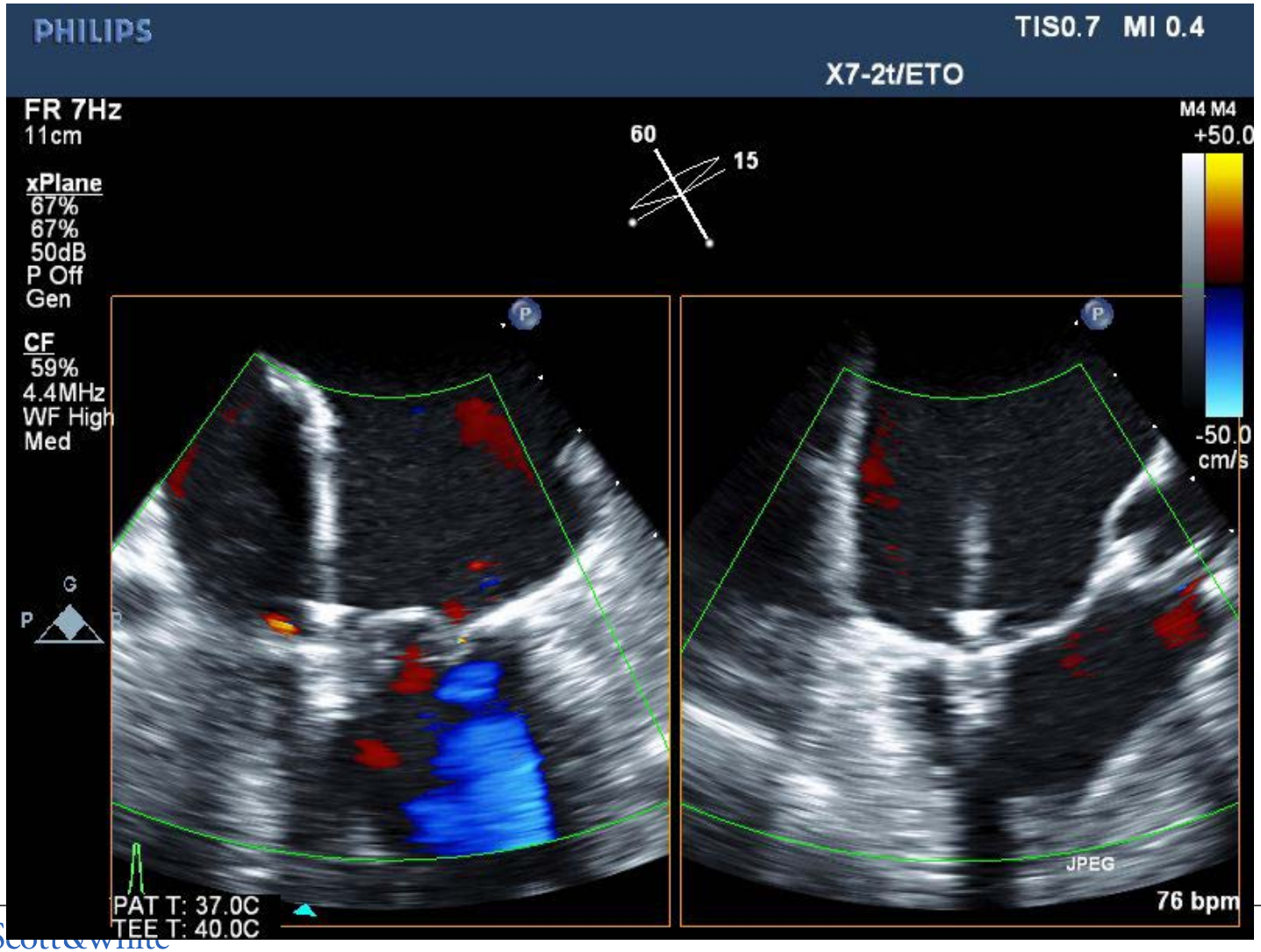
Dilated LV tethering one or both leaflets

Secondary MR

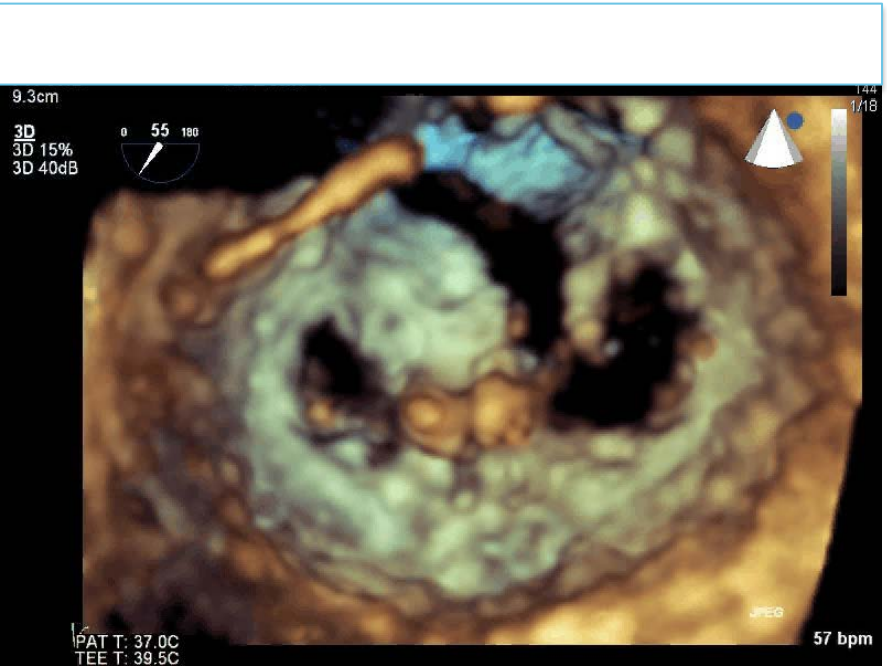


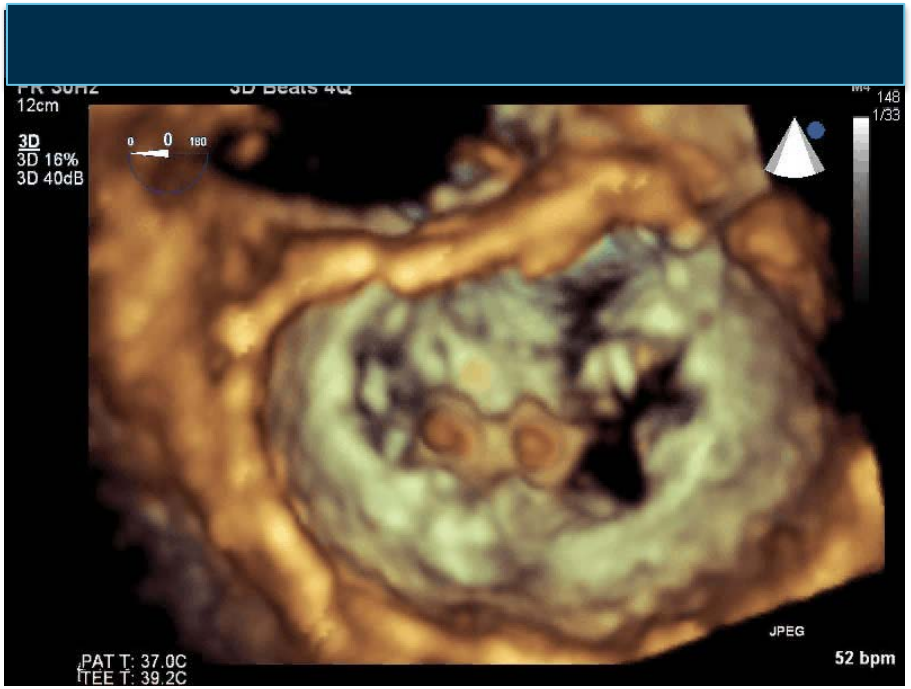


Secondary MR

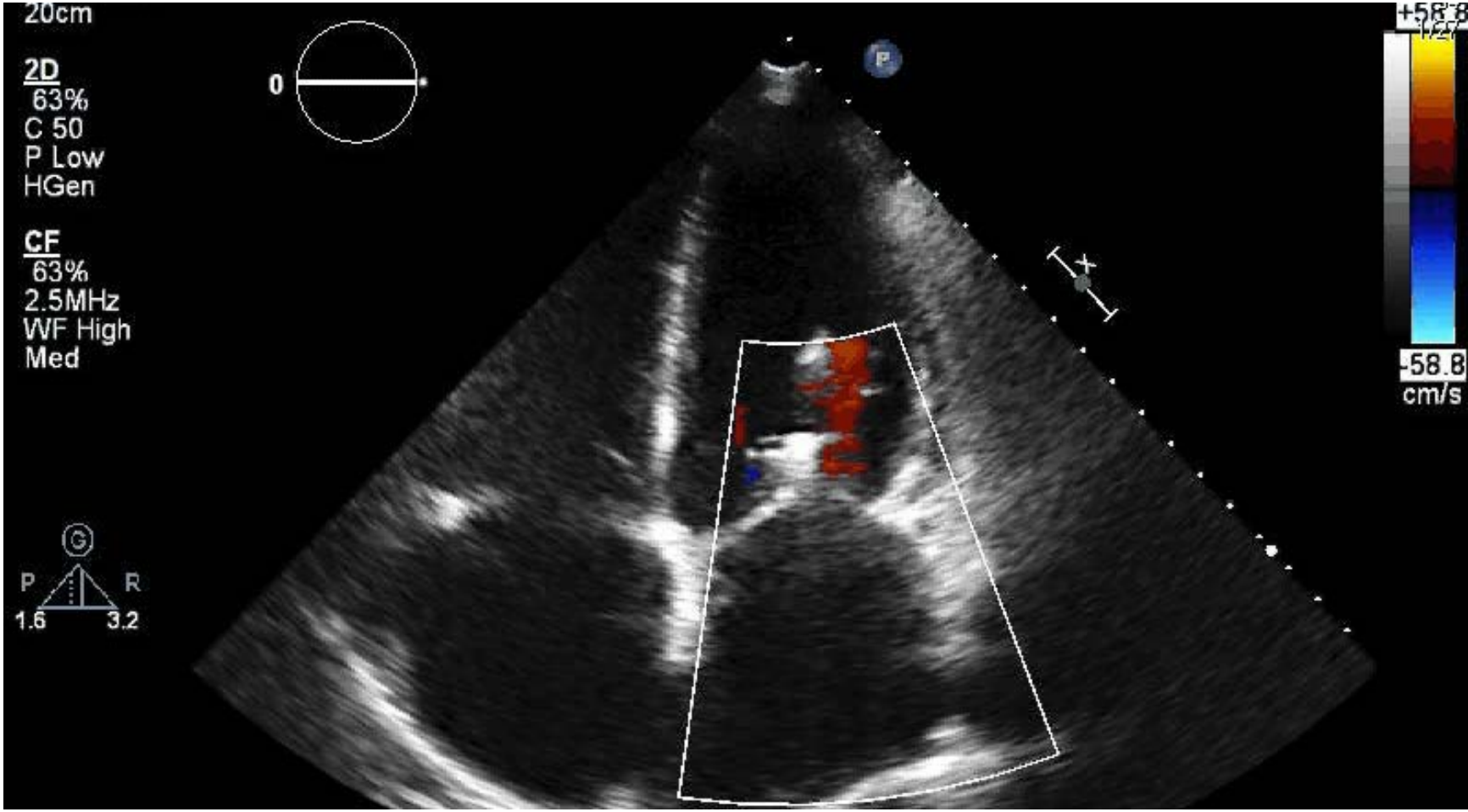


MitraClip for Secondary MR





TTE 30 Days Post Procedure



COAPT: Trial design

~420 patients enrolled at up to 75 US sites

Signi… …b)

Not appropriate fo… …cal heart team)

Enrollment
February 2015
Sites-72
Patients-
182

MitraC… group
N=… …of care
…

Clinical and TTE follow-up:
1, 6, 12, 18, 24, 36, 48, 60 months

PIs: Michael Mack and Gregg W. Stone
Sponsor: Abbott Vascular

Worldwide Experience

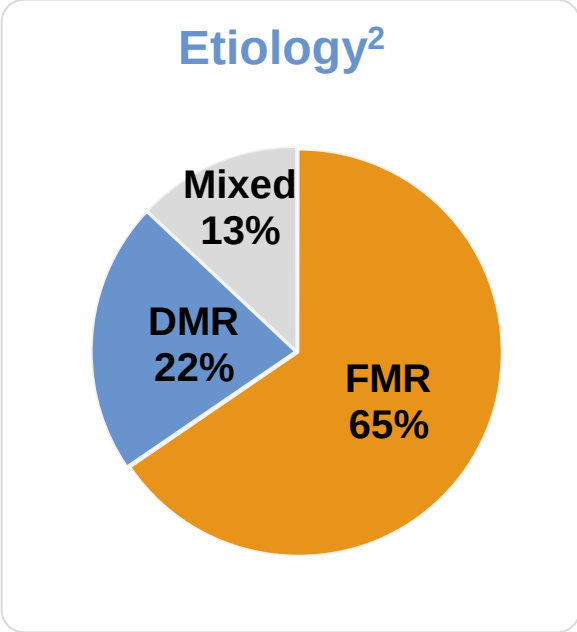
Study	Population	N*
EVEREST I (Feasibility)	Feasibility patients	55
EVEREST II (Pivotal)	Pre-randomized patients	60
EVEREST II (Pivotal)	Non-randomized patients (High Risk Study)	78
EVEREST II (Pivotal)	Randomized patients (2:1 Clip to Surgery)	279 184 Clip 95 Surgery
REALISM (Continued Access)	Non-randomized patients	899
Compassionate/Emergency Use	Non-randomized patients	66
ACCESS Europe Phase I	Non-randomized patients	567
ACCESS Europe Phase II	Non-randomized patients	286
Commercial Use	Commercial patients	17,655
Total		**19,850** **+95 surgery**

*Data as of 01/31/2015. Source: Abbott Vascular

MitraClip | Abbott Vascular

Commercial MitraClip Implant Experience

- Treating Centers: 463
- Patients[1]: 18,508
- Implant Rate[1]: 96%
- Etiology[2]
  - Functional MR 65%
  - Degenerative MR 22%
  - Mixed 13%

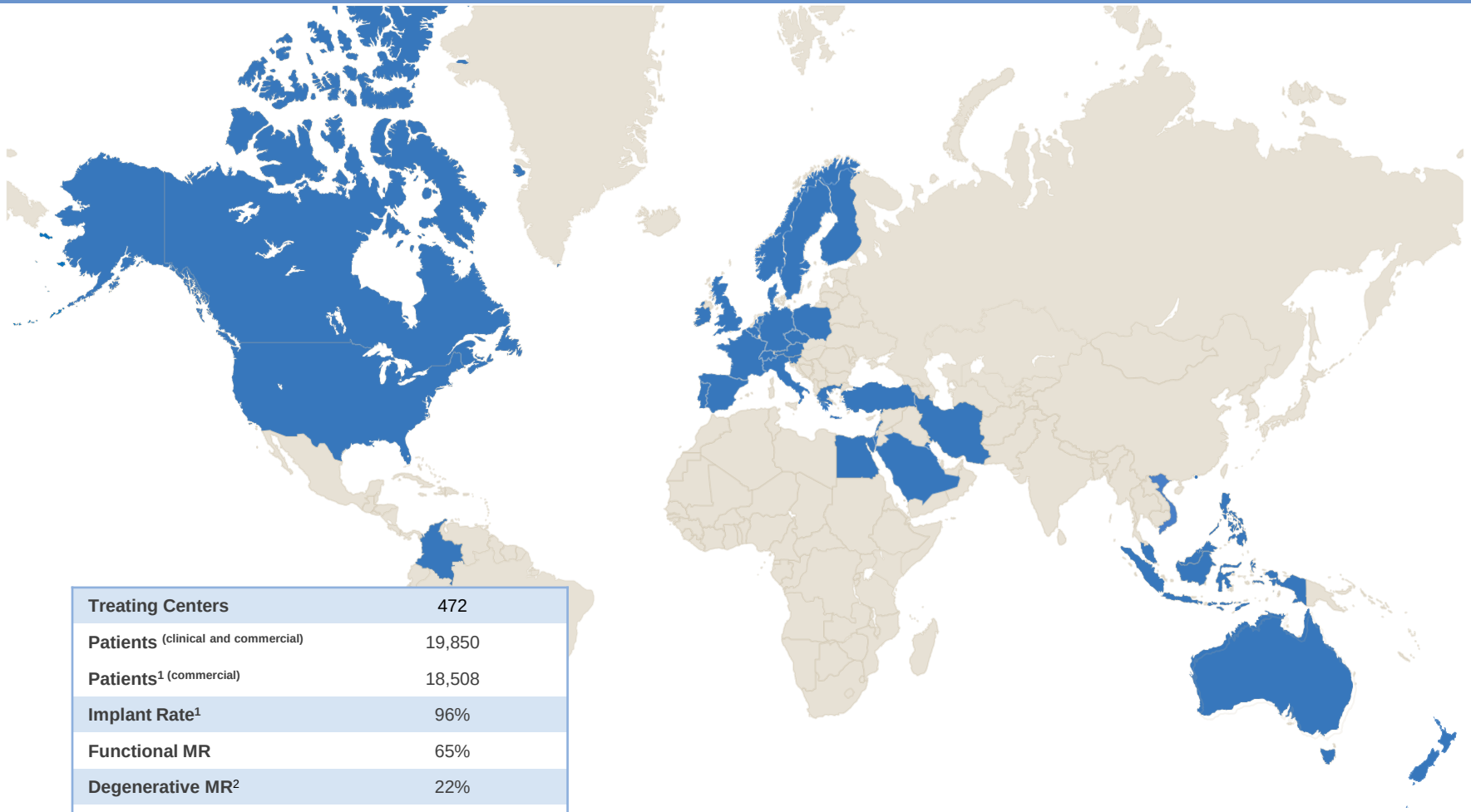


1. First-time procedures only. Includes commercial patients, ACCESS I and ACCESS II patients
2. Etiology not inclusive of U.S. cases as of 04/14/2014

Data as of 01/31/2015. Source: Abbott Vascular.

MitraClip | Abbott Vascular

MitraClip Therapy
Current Global Adoption



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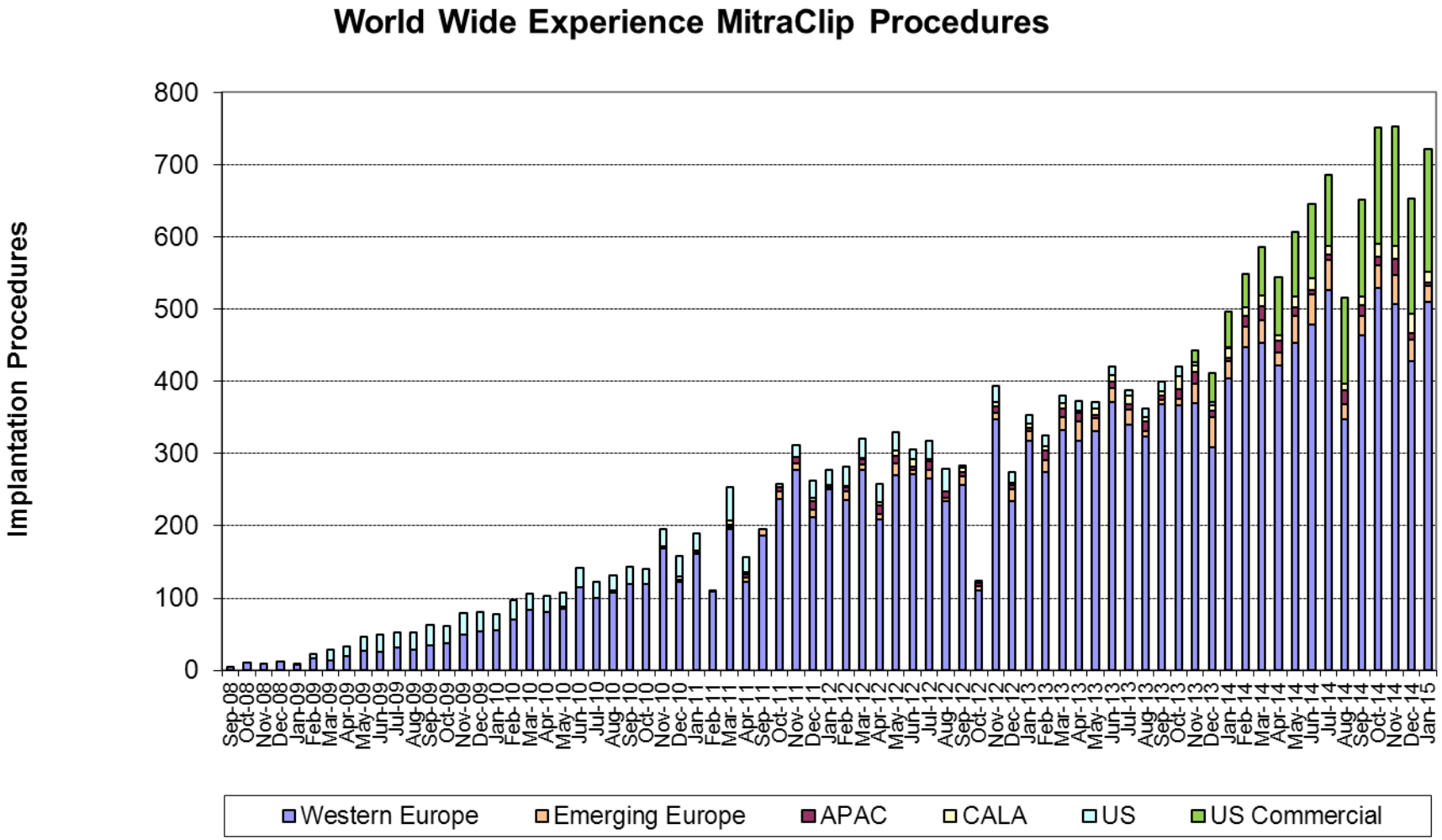
Mixed	13%

1. First-time procedures only. Includes commercial patients, ACCESS I and ACCESS II patients
2. Etiology not inclusive of U.S. cases as of 04/14/2014

MitraClip | Abbott Vascular

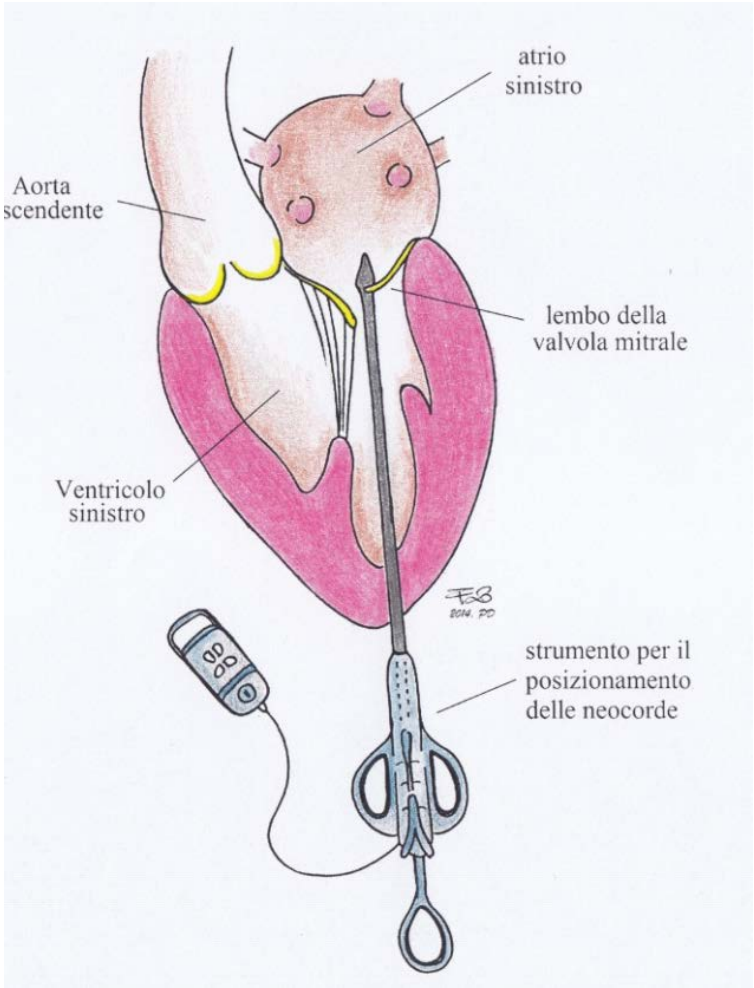
Global MitraClip Procedures

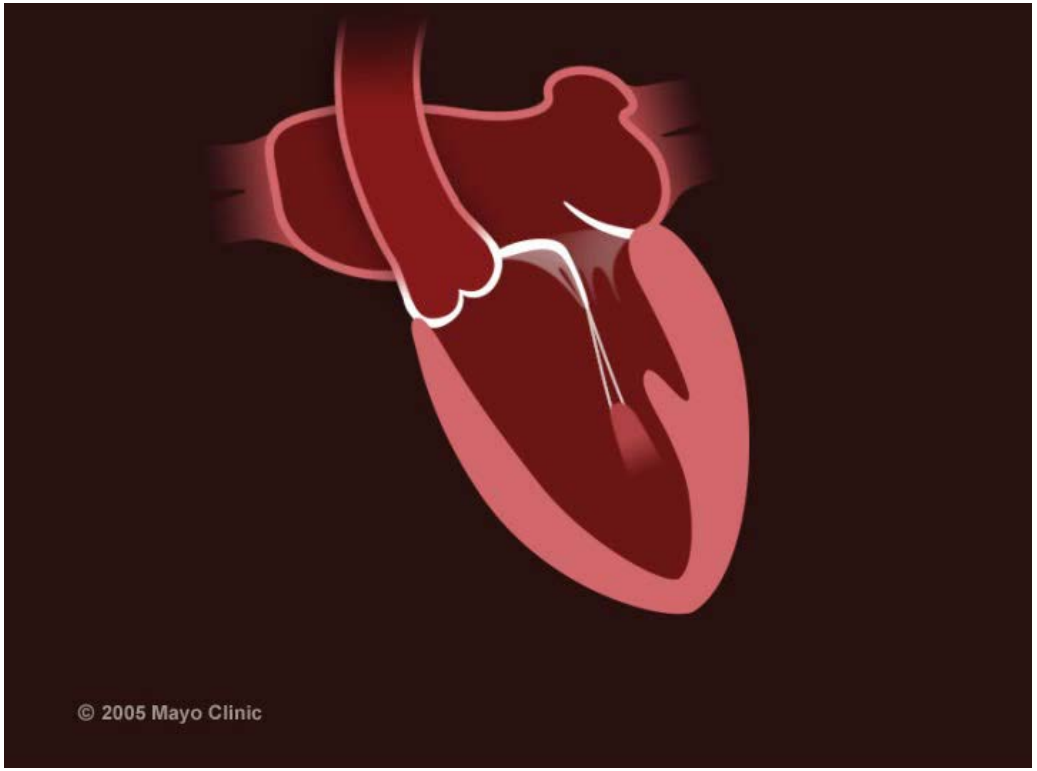


Data on file at Abbott Vascular as of 01/31/2015

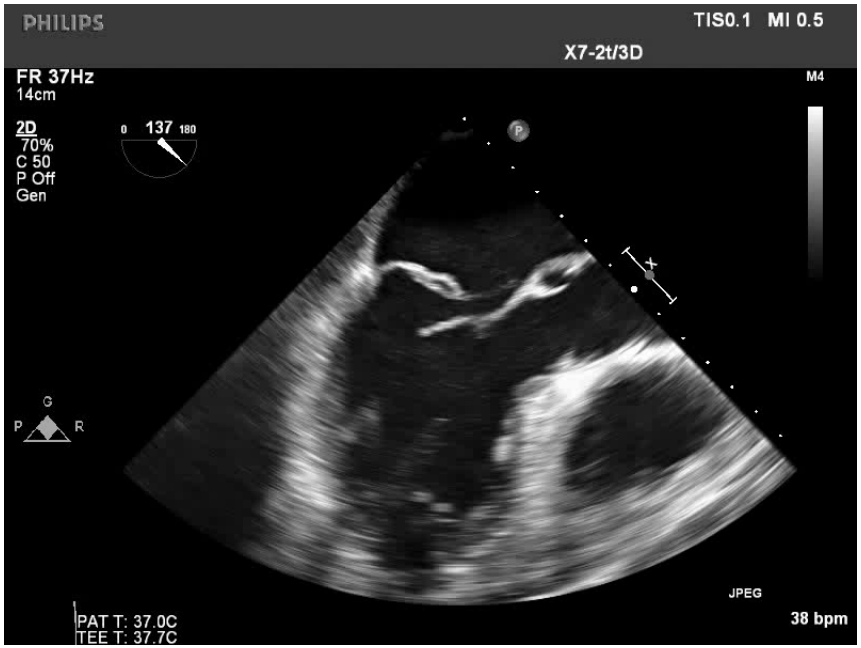
MitraClip | Abbott Vascular

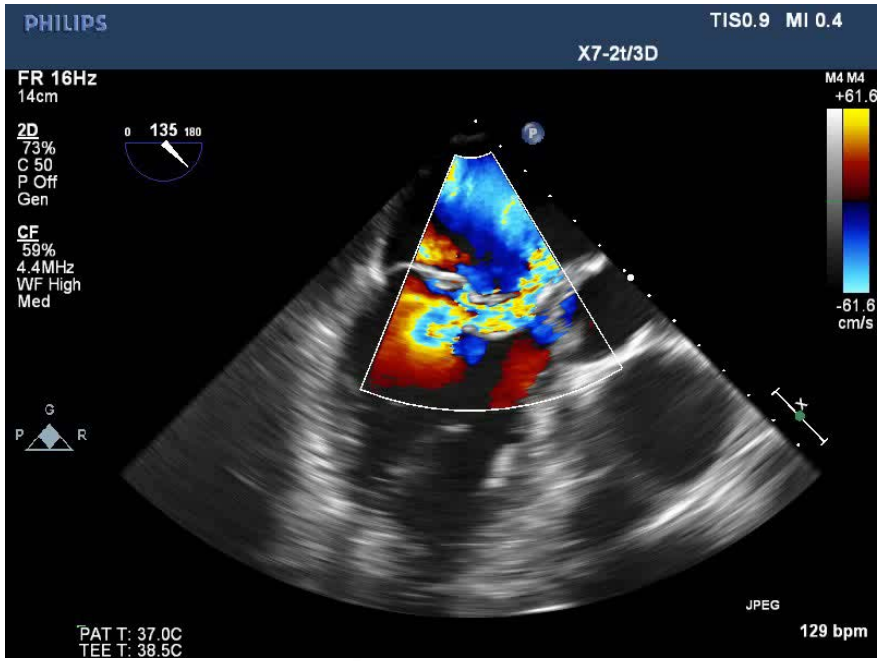
Transapical Off-Pump Neochord implantation



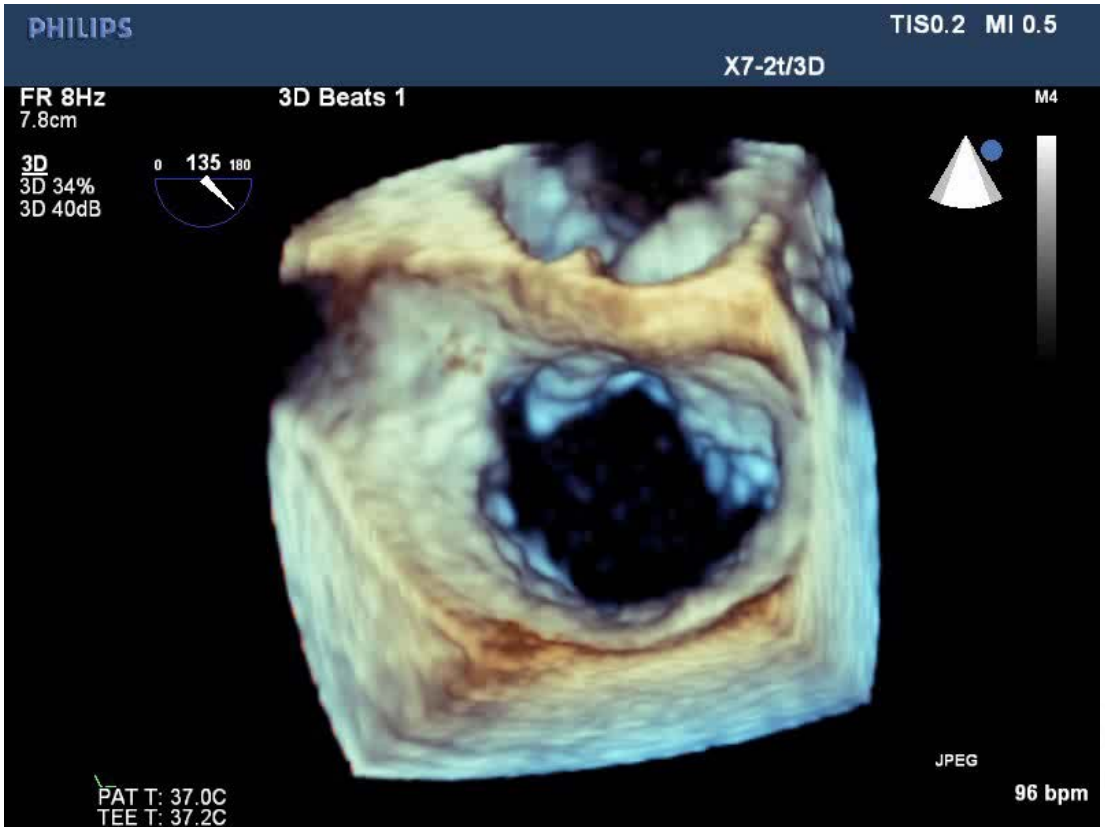


NeoChord Procedure





NeoChord Procedure



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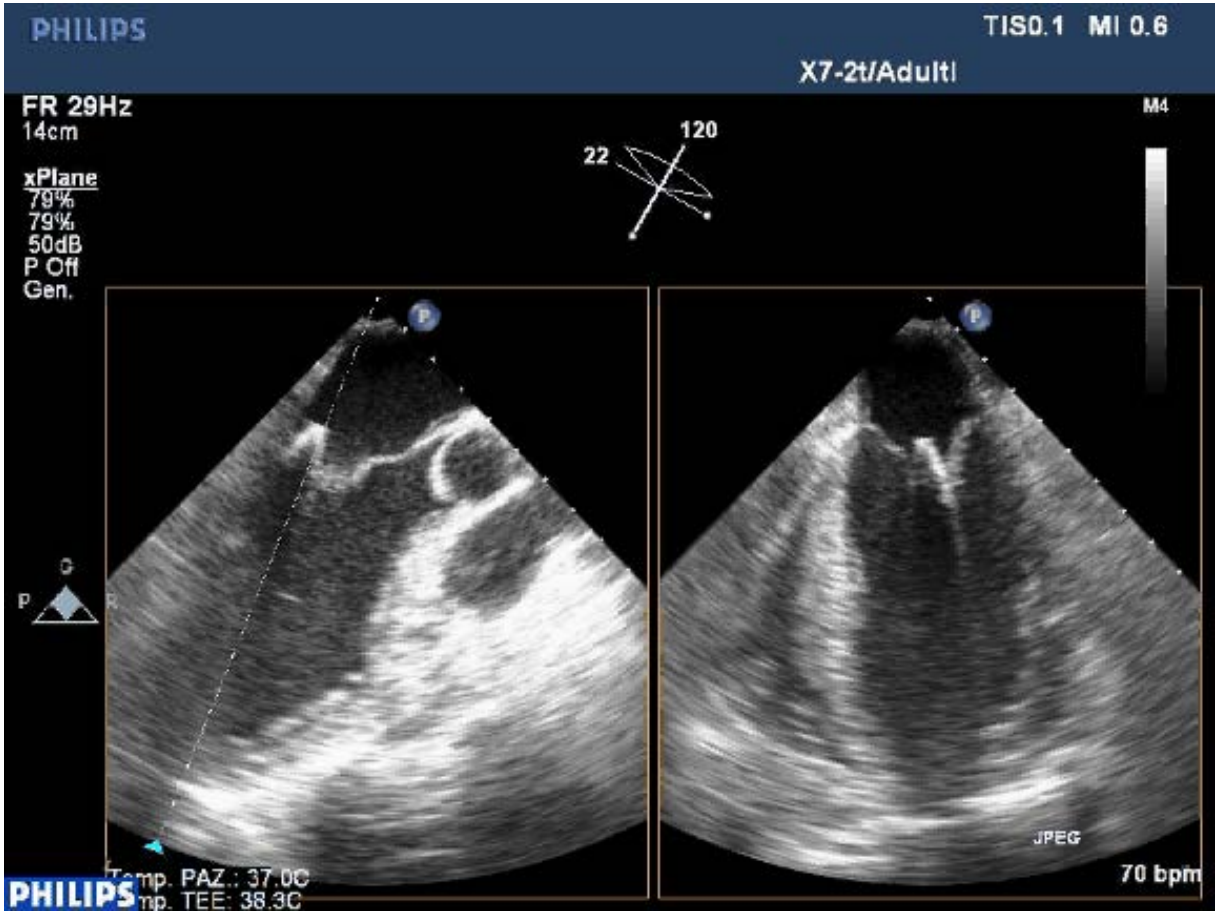

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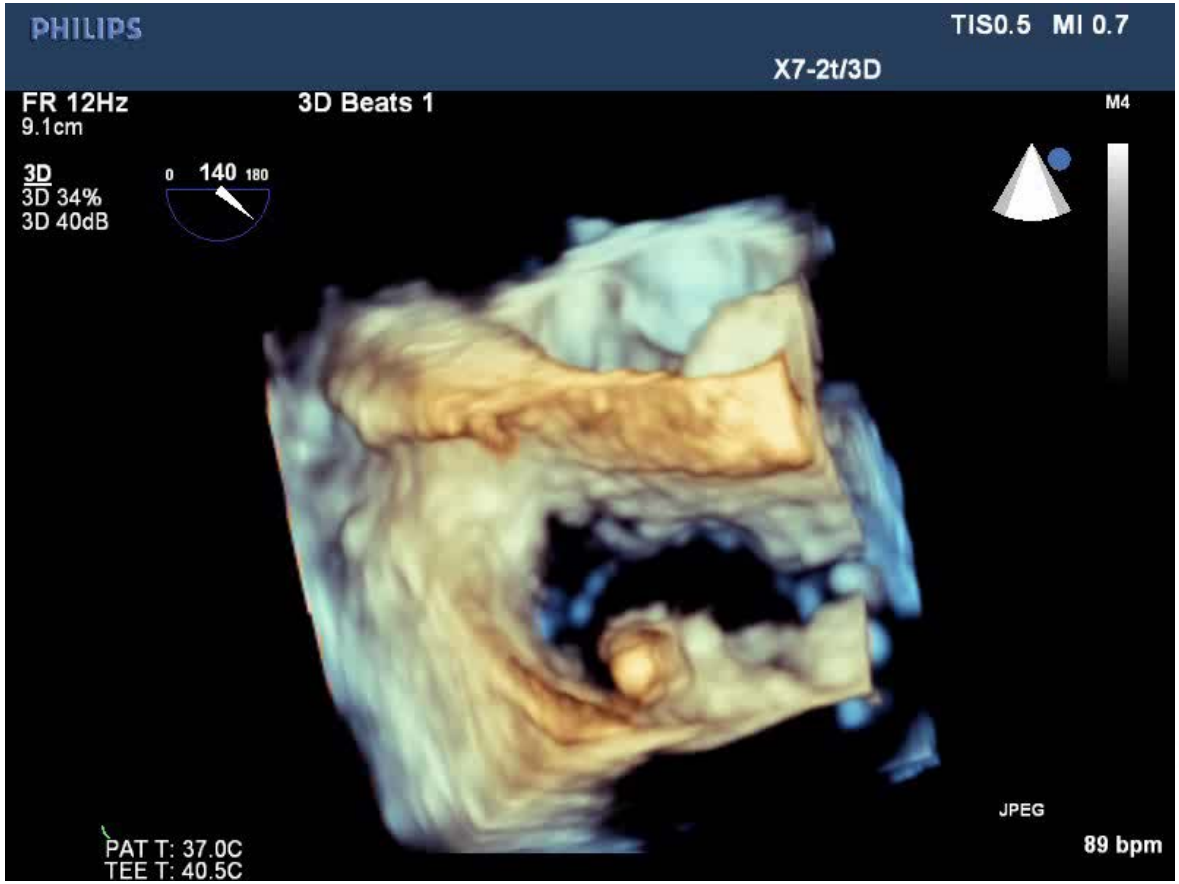

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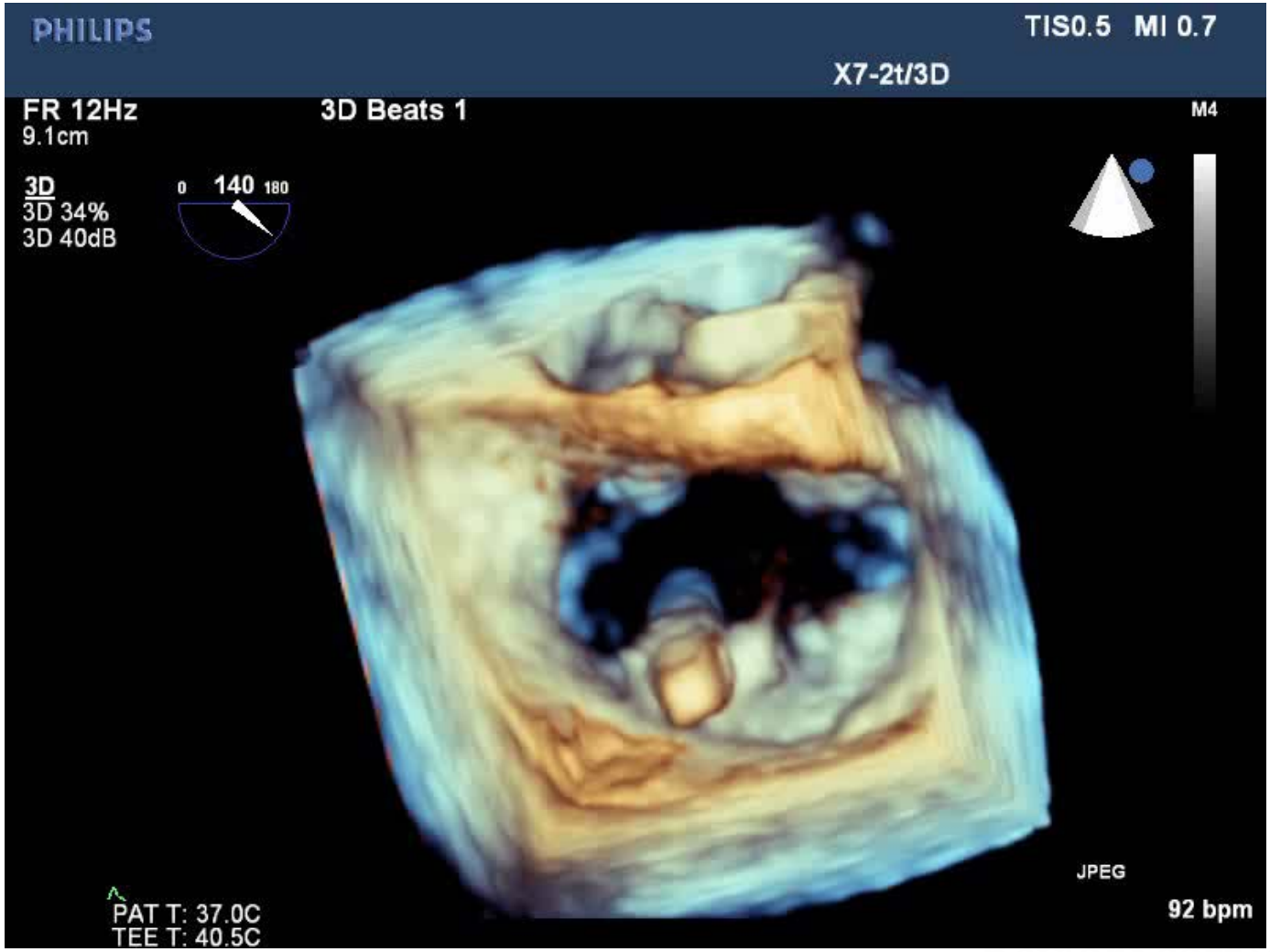
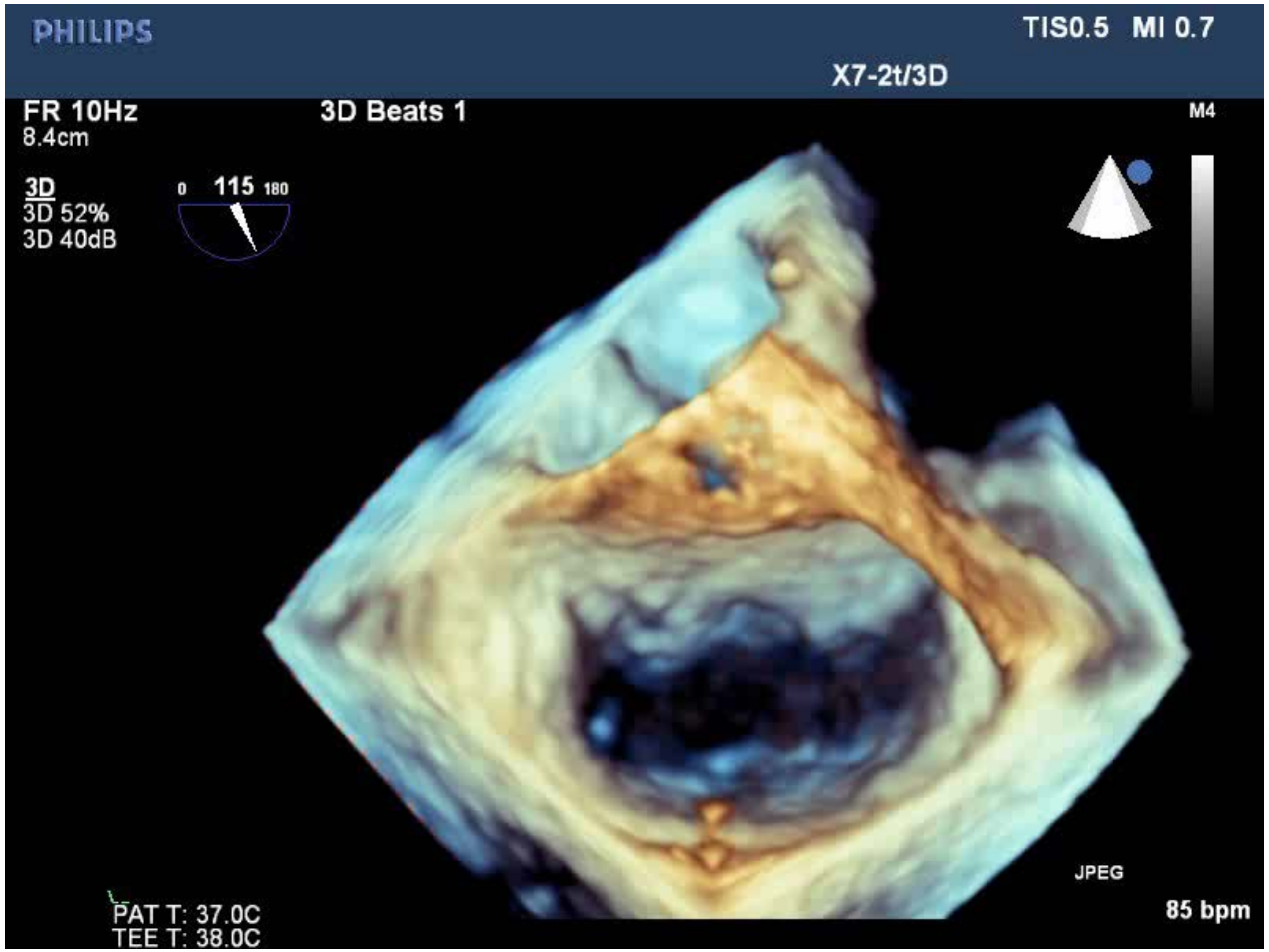
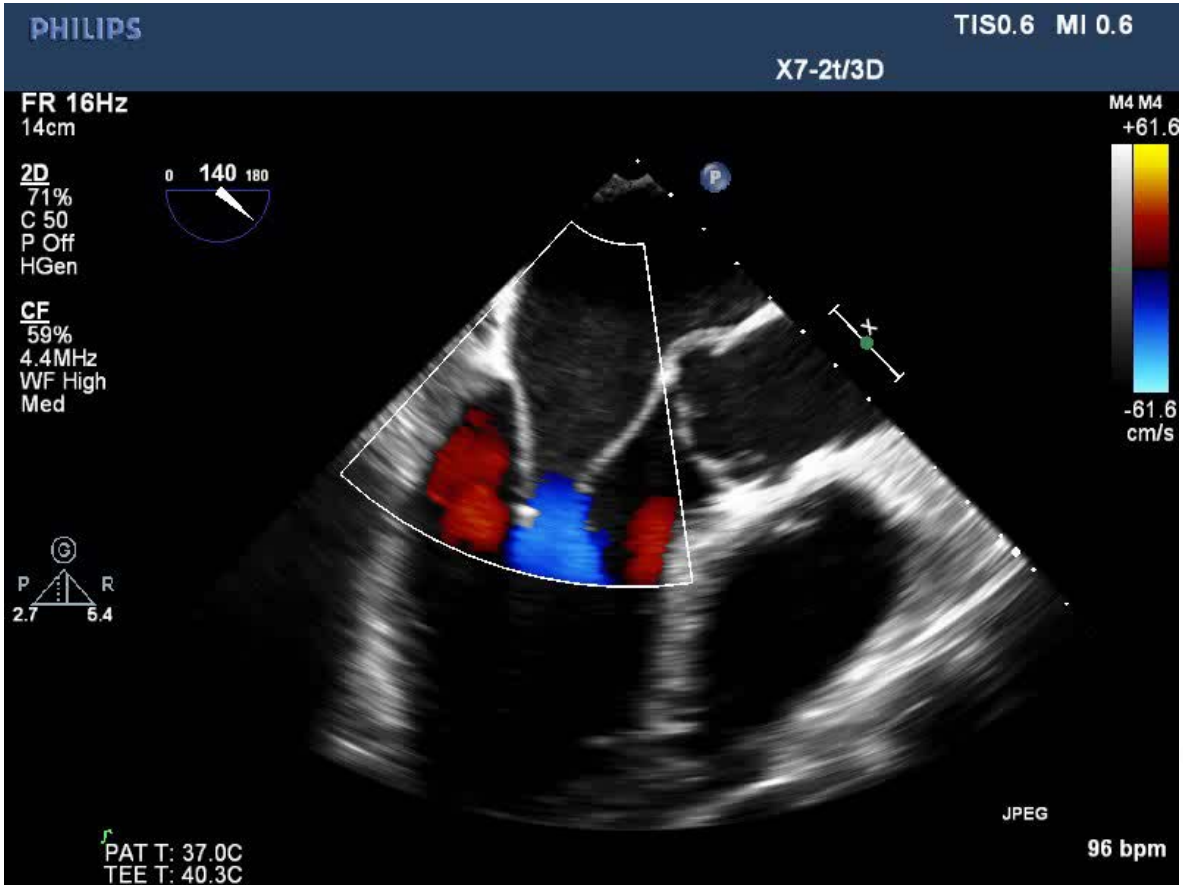


NeoChord Procedure



NeoChord Procedure



NeoChord Experience

First in Man	2009
TACT Trial	2009-2012
30 patients	
CE Mark	Dec 2012
TACT Surveillance Registry	2013
133 patients	

TACT Trial

Journal of the American College of Cardiology
© 2014 by the American College of Cardiology Foundation
Published by Elsevier Inc.

Vol. 63, No. 9, 2014
ISSN 0735-1097/$36.00
http://dx.doi.org/10.1016/j.jacc.2013.07.090

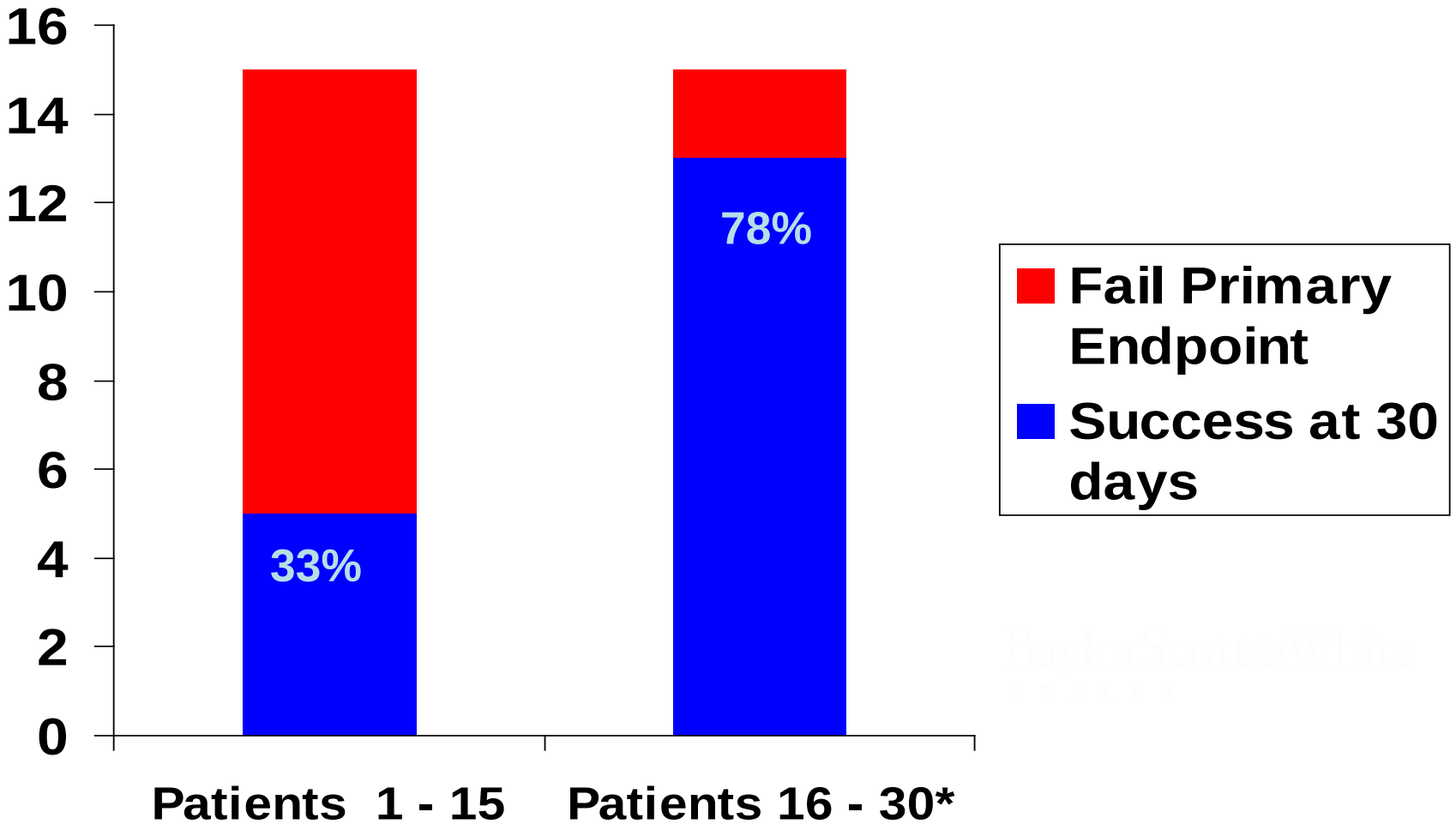
Off-Pump Transapical Implantation of Artificial Neo-Chordae to Correct Mitral Regurgitation

The TACT Trial (Transapical Artificial Chordae Tendinae) Proof of Concept

Joerg Seeburger, MD, PhD,* Mauro Rinaldi, MD, PhD,† Sten Lyager Nielsen, MD,‡ Stefano Salizzoni, MD,† Ruediger Lange, MD, PhD,§ Markus Schoenburg, MD,‖ Ottavio Alfieri, MD, PhD,¶ Michael Andrew Borger, MD, PhD,* Friedrich Wilhelm Mohr, MD, PhD,* Audrius Aidietis, MD, PhD#

Leipzig, Munich, and Bad Nauheim, Germany; Turin and Milan, Italy; Aarhus, Denmark; and Vilnius, Lithuania

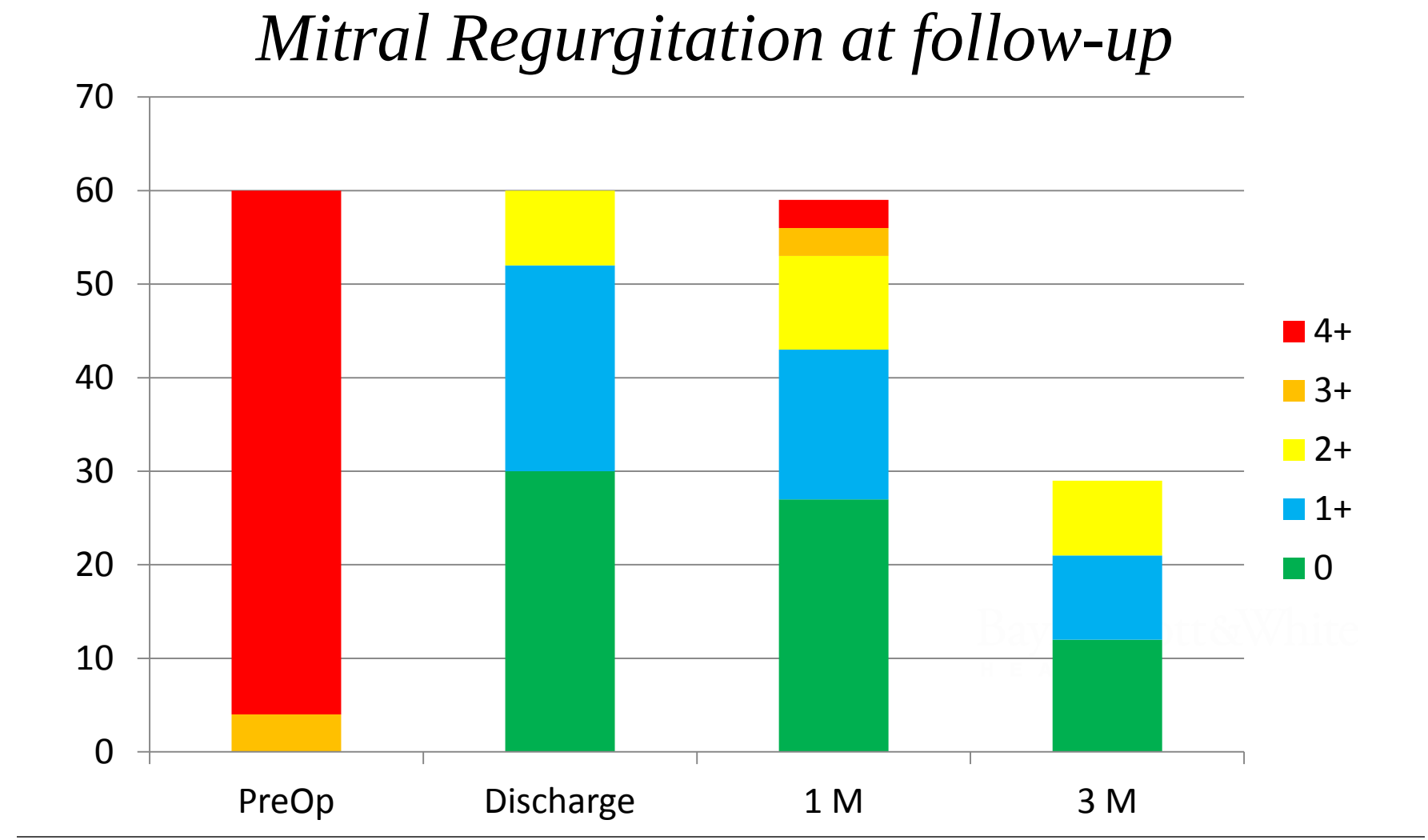
TACT trial
30-days results



Neochord International Independent Registry

Treated patients, N = 60	Median (IQR) n (%)
Successful neochordae implantation (n)	60 (100%)
Neochord implanted (n)	4 (3-4)
- 3	21 (35%)
- 4	26 (43%)
- 5	10 (17%)
- 6	2 (3%)
- 7	1 (2%)
Operative time (minutes)	130 (110-150)

Neochord International Independent Registry



Early Outcomes (N=30)

Procedure

- Implants successfully deployed on annulus (30/30)
- Intra-procedure MR reduction ≥1 degree (28/30)
- Average reduction of septolateral diameter 20%

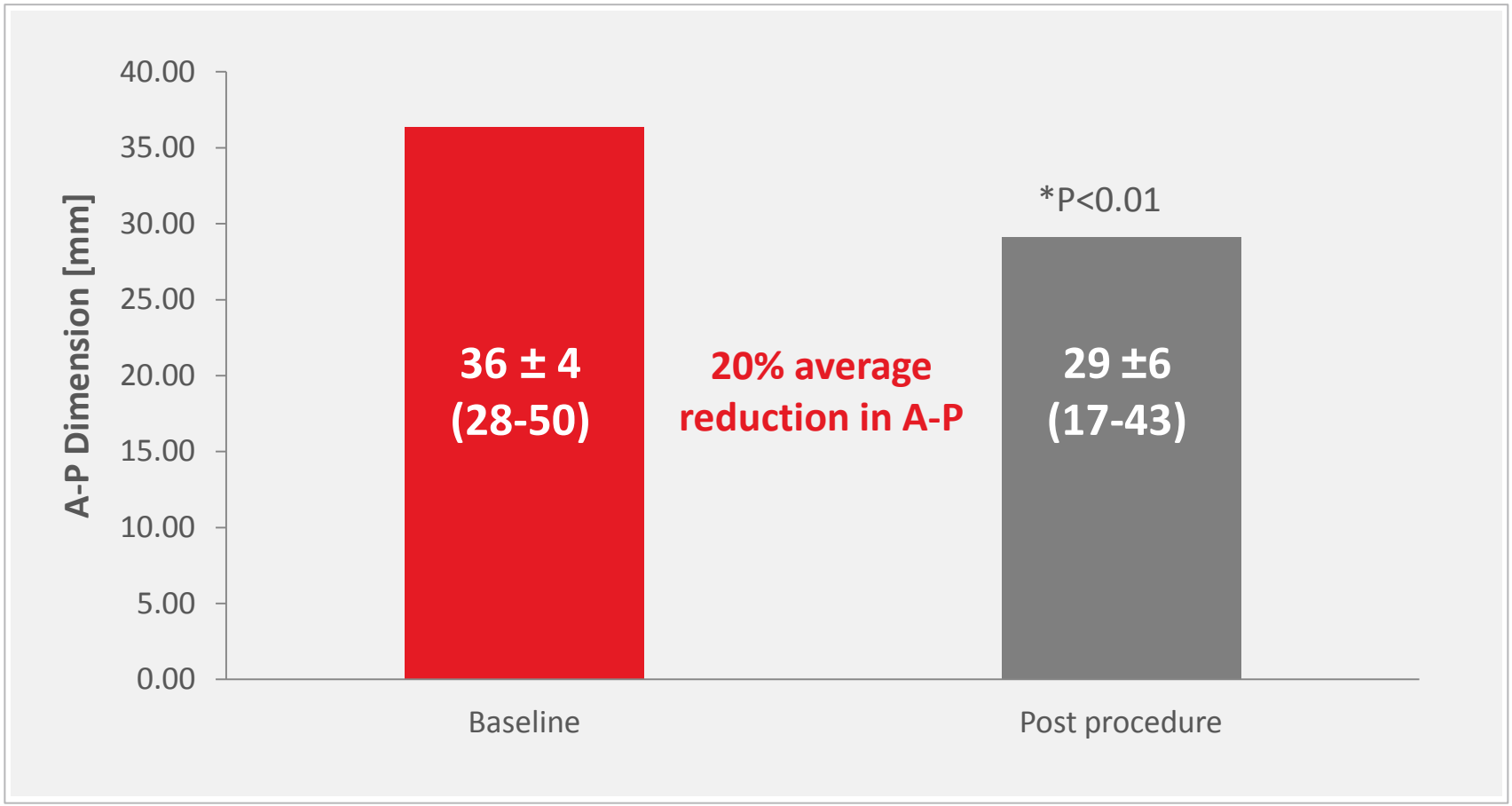
Safety

- Procedural mortality 0/30
- 30 days Mortality (according to VARC) 1/30
- **No Device Related Major Adverse Events as adjudicated by independent committee**

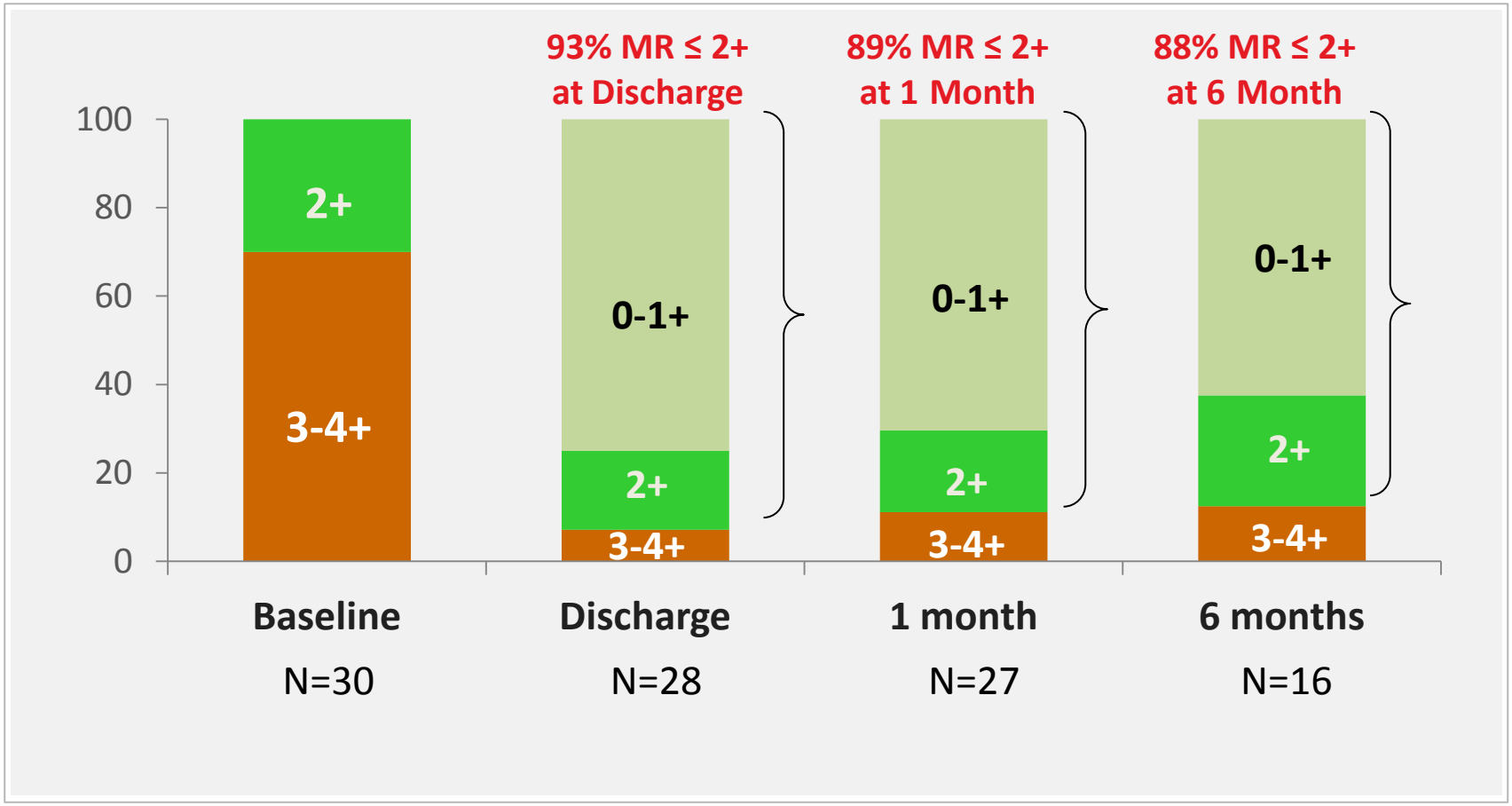
Effectiveness

- MR ≤ 2+ in 1 month follow up (N=27) 89%
- MR ≤ 2+ in 6 month follow up (N=16) 88%
- Accumulative implantation time >270 months

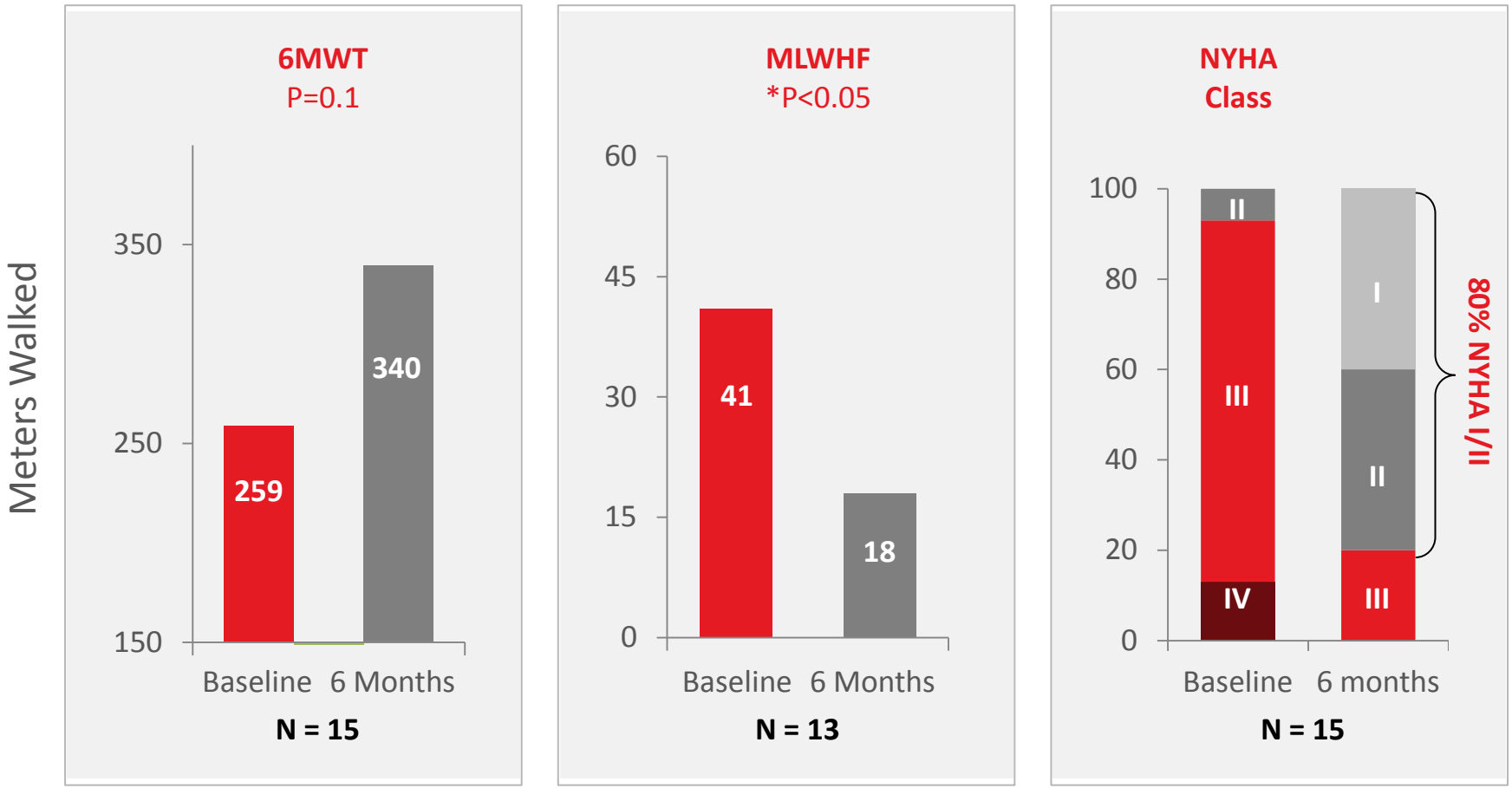
Reduction in Septo Lateral Dimension (N=30)



MR Grade at Endpoints



Functional Improvement at 6 Months



Summary

- Transcatheter mitral valve repair is progressing
- MitraClip experience is ~20,00 patients
- COAPT trial will inform the whole field
- TMVR (Replacement) is imminent