MitraClip in the ICCU: Which Patient will Benefit?

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Conflict of Interest

- No relevant disclosures

Complex Question

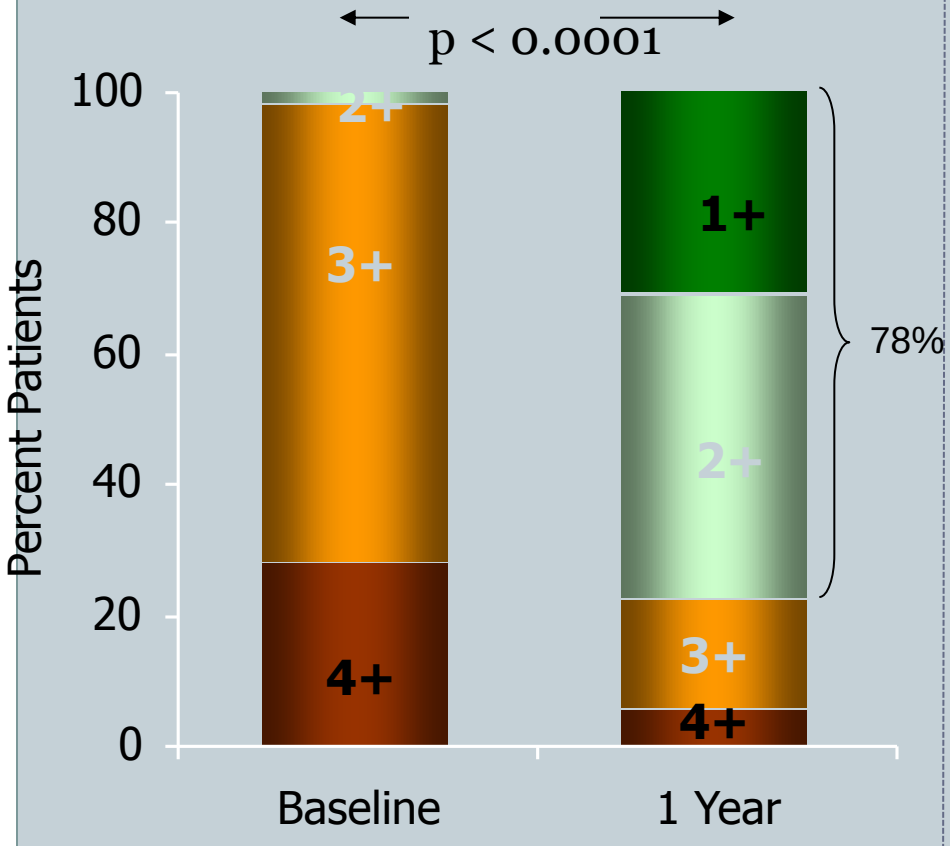
- Which patients will achieve the most benefit from the procedure?
- Which patients will benefit at all from the procedure?
  - Who won't benefit from MitraClip?
- For which patients is MitraClip the best procedure?

What is MitraClip?

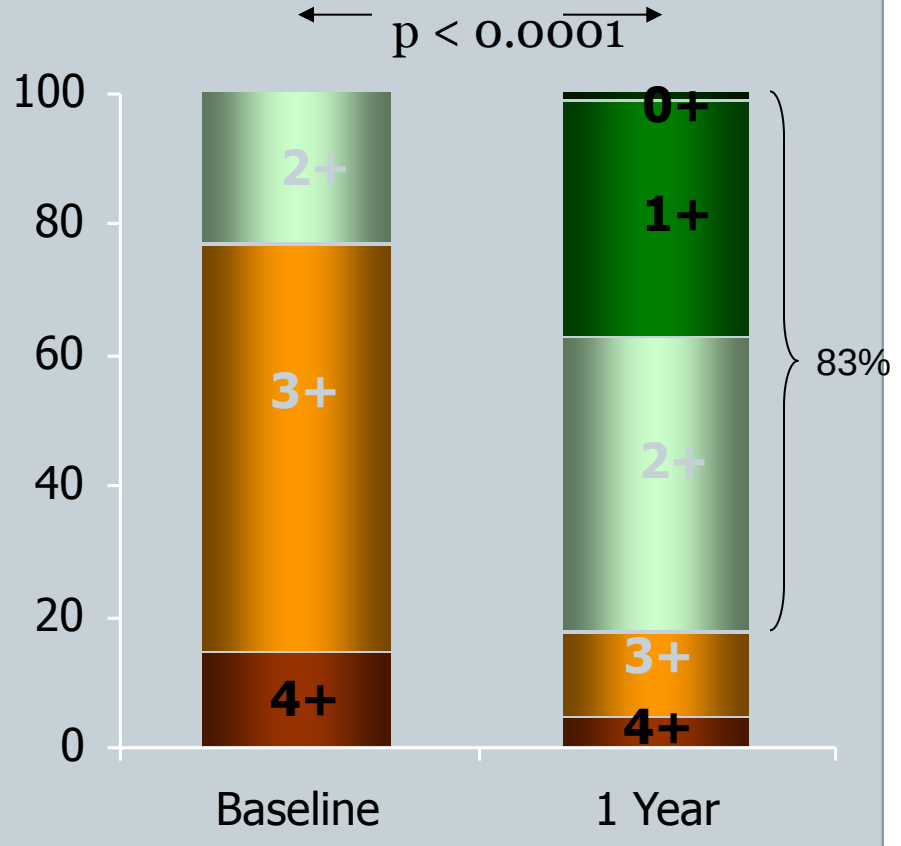
Core Lab MR Grade at 1 Year (matched)

EVEREST II and Continued Access High Surgical Risk Patients

EVEREST II
High Surgical Risk Patients
(n=54 matched cases)



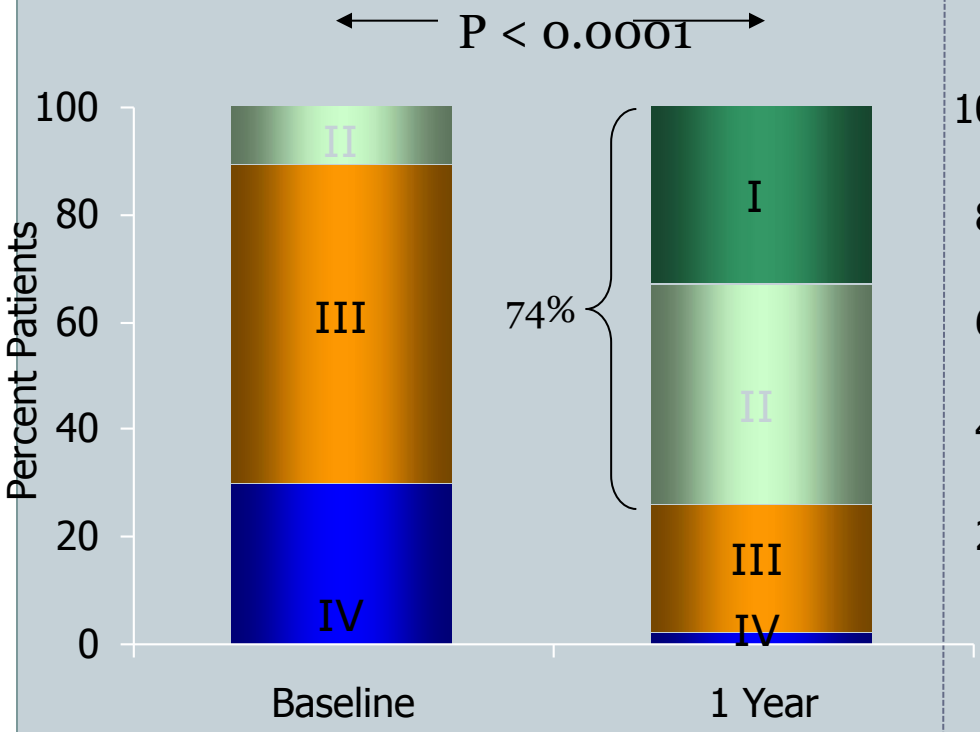
Continued Access
High Surgical Risk Patients
(n=69 matched cases)



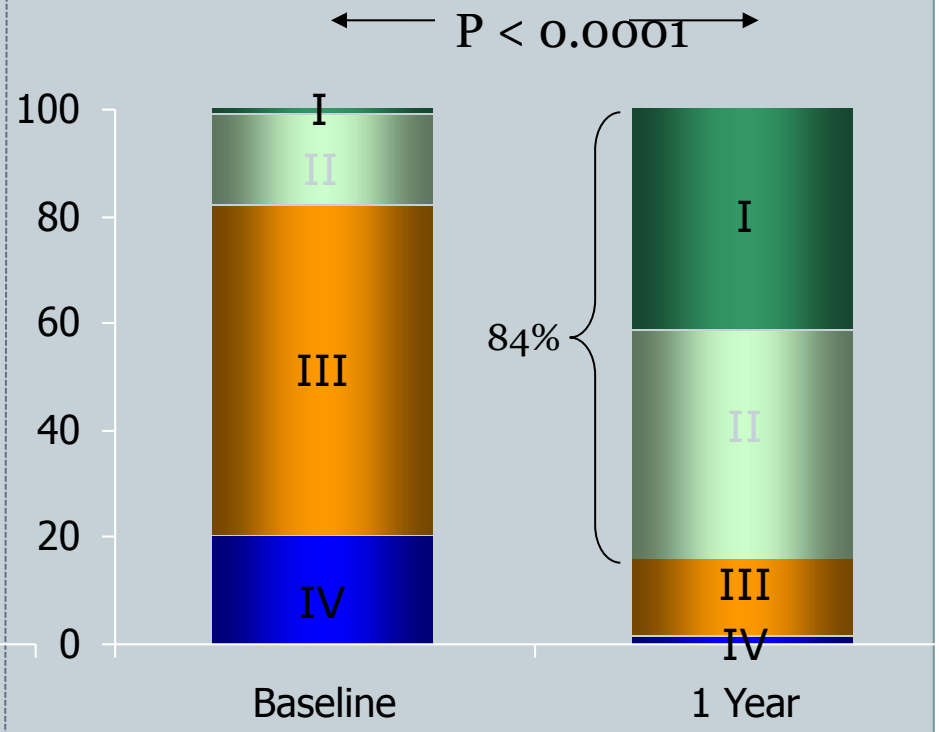
NYHA Functional Class at 1 Year

EVEREST II and Continued Access High Surgical Risk Patients

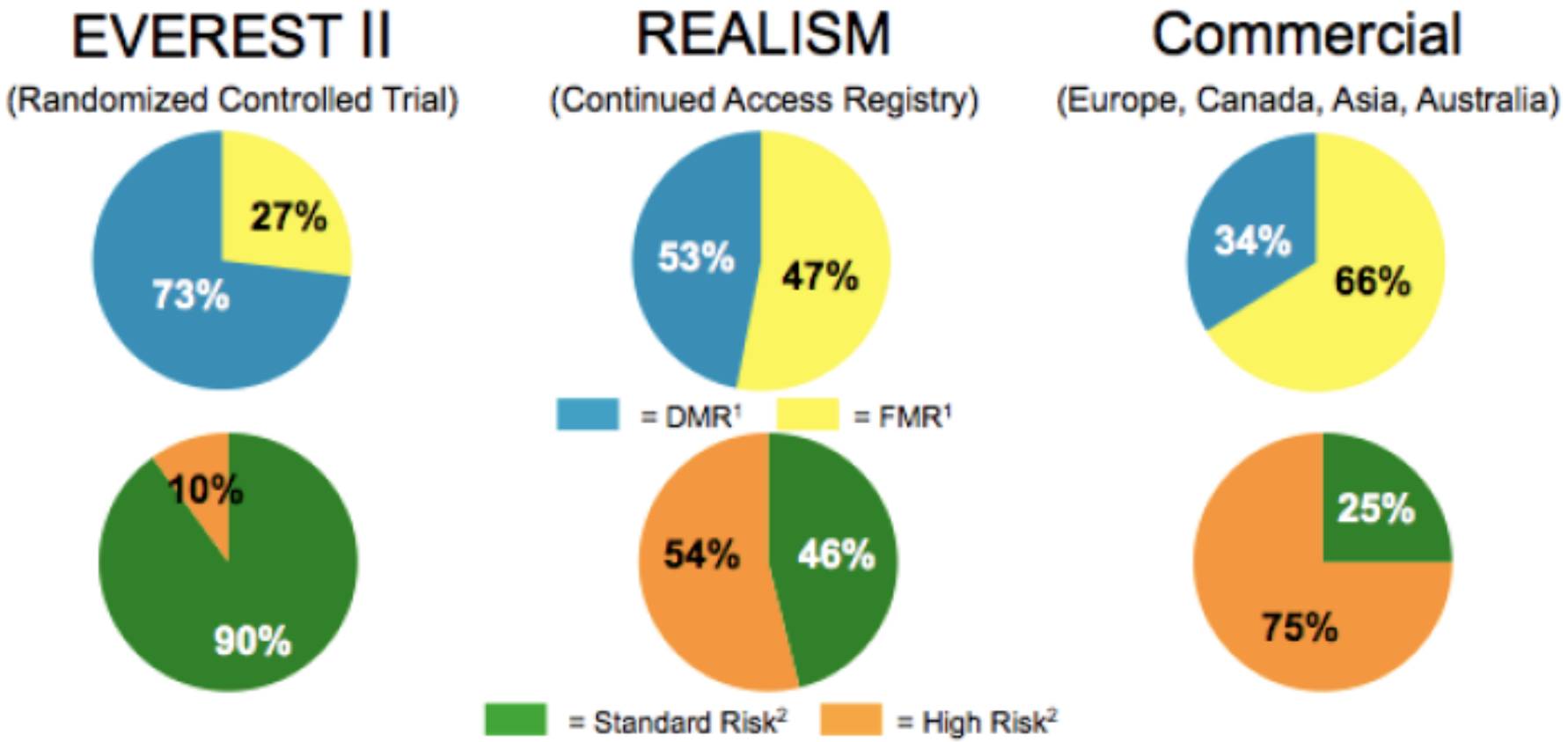
EVEREST II
High Surgical Risk Patients
(n=54 matched cases)



Continued Access
High Surgical Risk Patients
(n=89 matched cases)



MitraClip indication for FMR is increasing



- 178 patients
- Implant rate – 89%

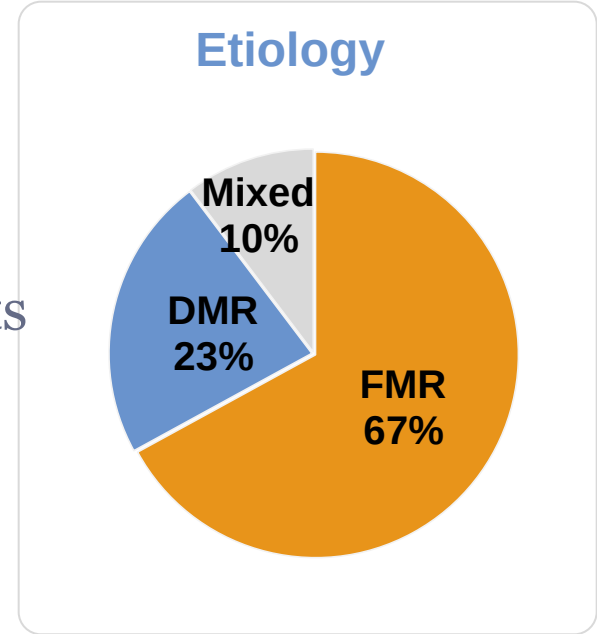
- 571 patients
- Implant rate – 94%

4932 patients
- Implant rate – 95%

Maisano PCR 2012

Commercial MitraClip Implant Experience

- Treating Centers: 225
- Patients[1]: 7,894
- Implant Rate[1]: 96%
- Acute MR reduction[1,2]: 98% of implants
- Etiology
  - Functional MR 67%
  - Degenerative MR 23%
  - Mixed 10%



1. First-time procedures only.
2. Successful implants only.

Data as of 5/31/2013. Source: Abbott Vascular.

The Problem

- Severe LV dysfunction with associated mitral incompetence is responsible for recurrent and prolonged hospital admissions
- The implementation of isolated surgical reduction of MR with no improvement of LV function is a challenging scenario

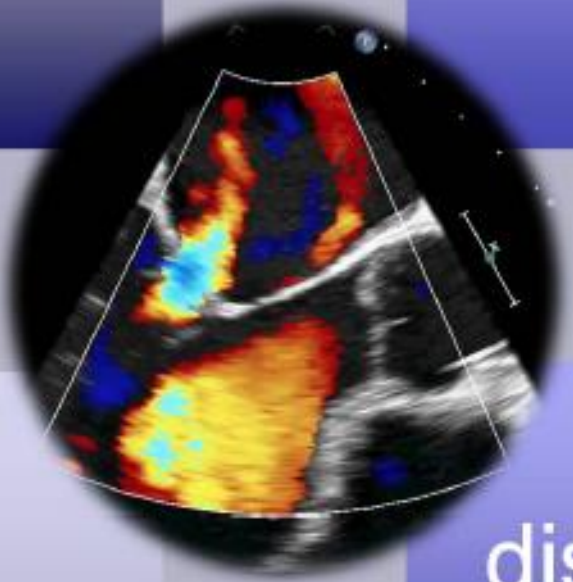
Functional MR

- LV Dysfunction
- Often very high surgical risk
- Surgery leads to clinical benefit
- High recurrence rate following successful MV repair
- Questionable survival benefit
- Interest in a safer and less invasive option

Heart Failure due to MR is Multifaceted

neurohumoral

LV remodeling



ischemia

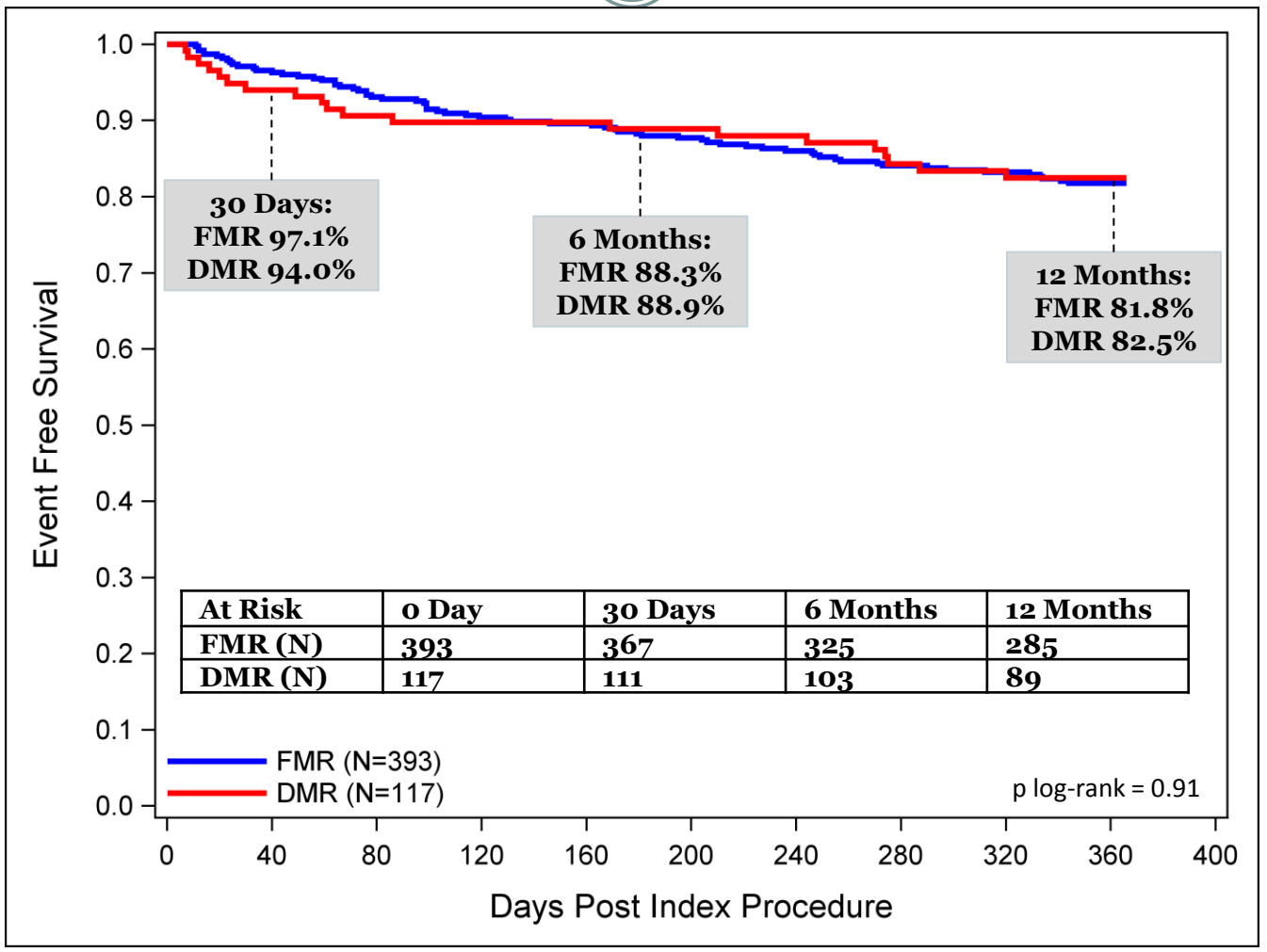
dissynchrony

ACCESS-EU

- The ACCESS-EUROPE (ACCESS-EU) Study is a two-phase prospective, observational, multicenter, post-approval study of the MitraClip® System for the treatment of significant MR
  - ACCESS-EU Phase I enrollment started on October 2, 2008 and closed on April 13, 2011. The last follow-up occurred on June 15, 2012
  - ACCESS-EU Phase II was initiated on September 15, 2011

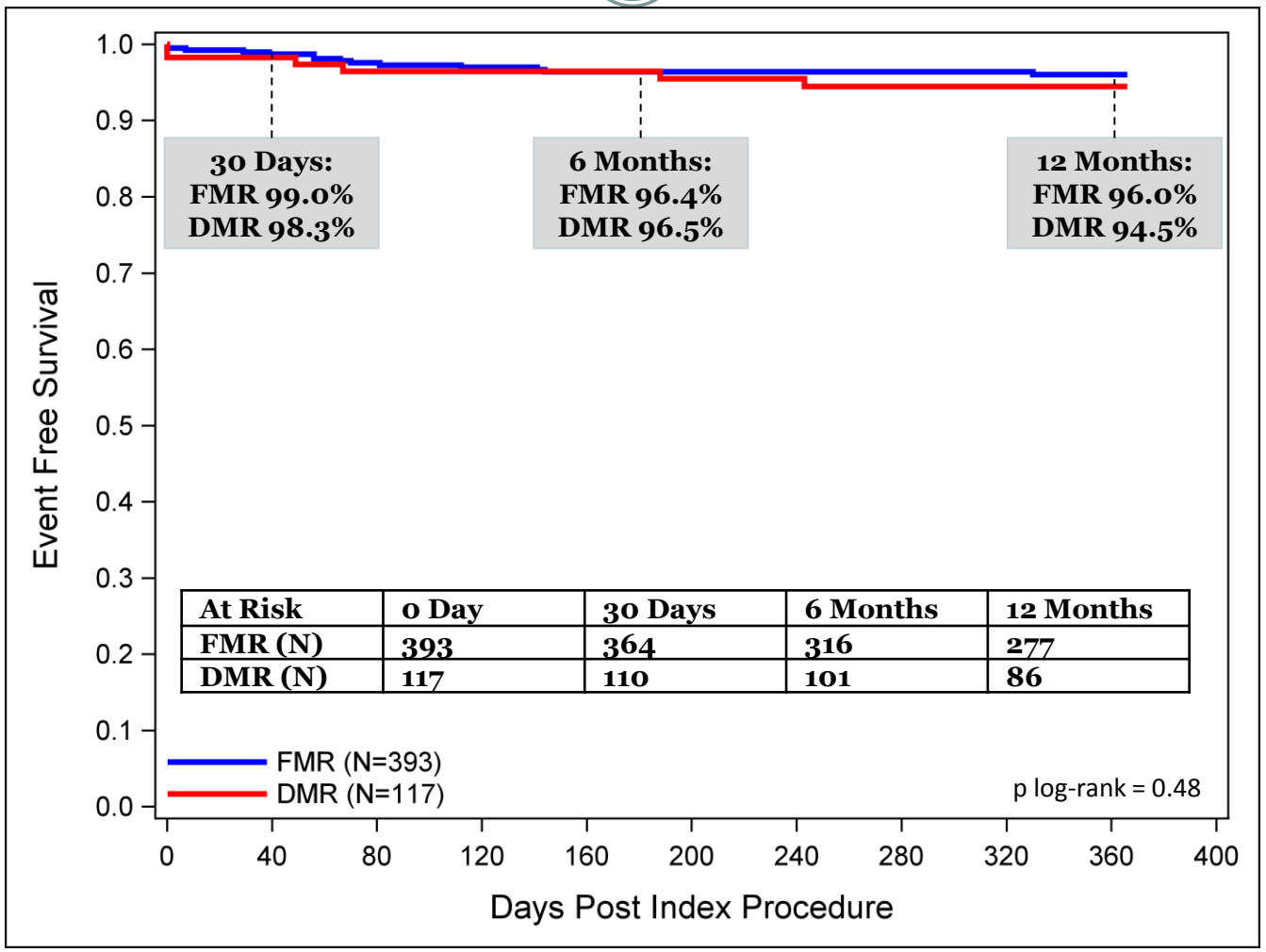
Butter et al EuroPCR 2013

Kaplan-Meier Freedom from Death



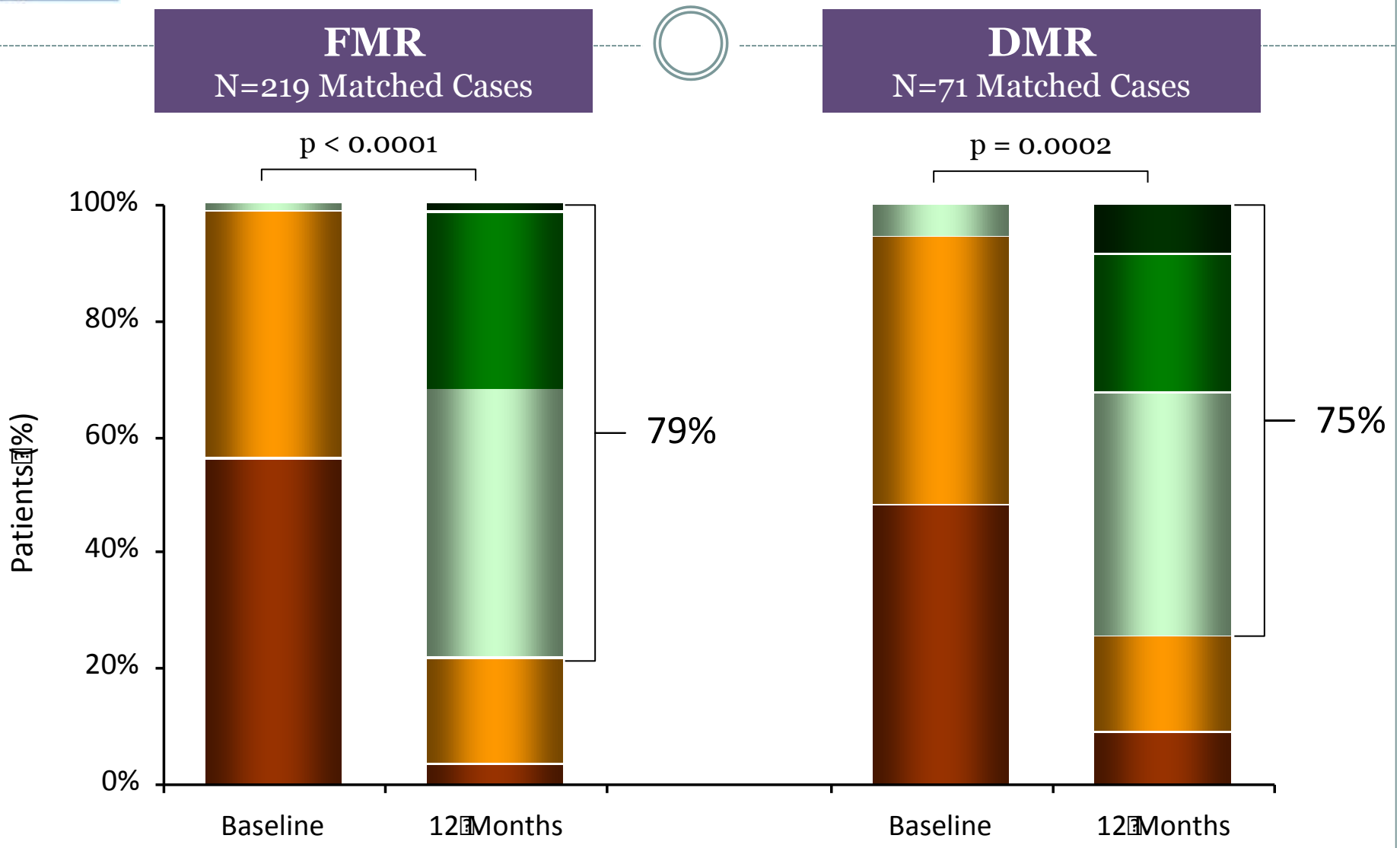
At Risk	0 Day	30 Days	6 Months	12 Months
FMR (N)	393	367	325	285
DMR (N)	117	111	103	89

Kaplan-Meier Freedom from Surgery

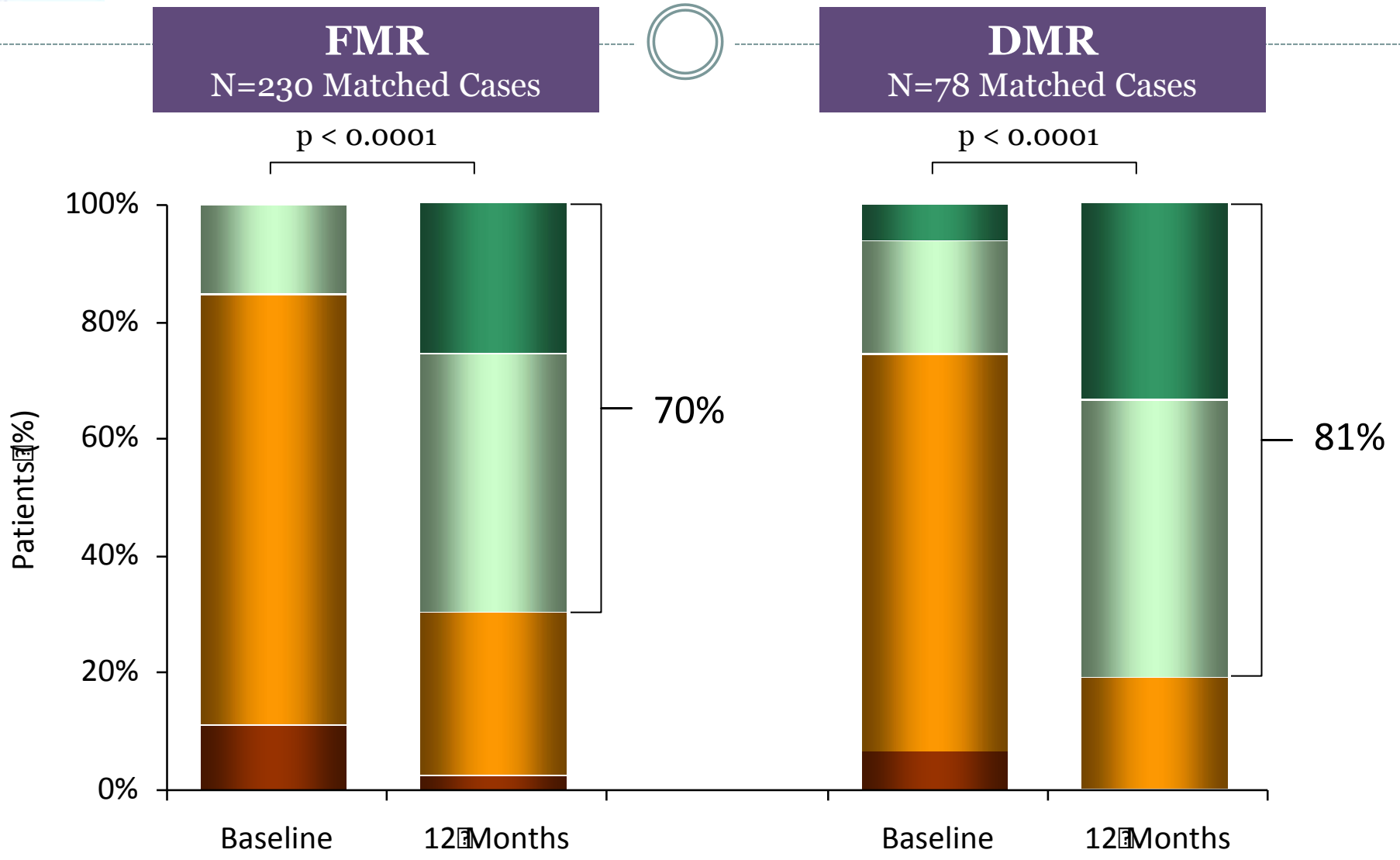


At Risk	0 Day	30 Days	6 Months	12 Months
FMR (N)	393	364	316	277
DMR (N)	117	110	101	86

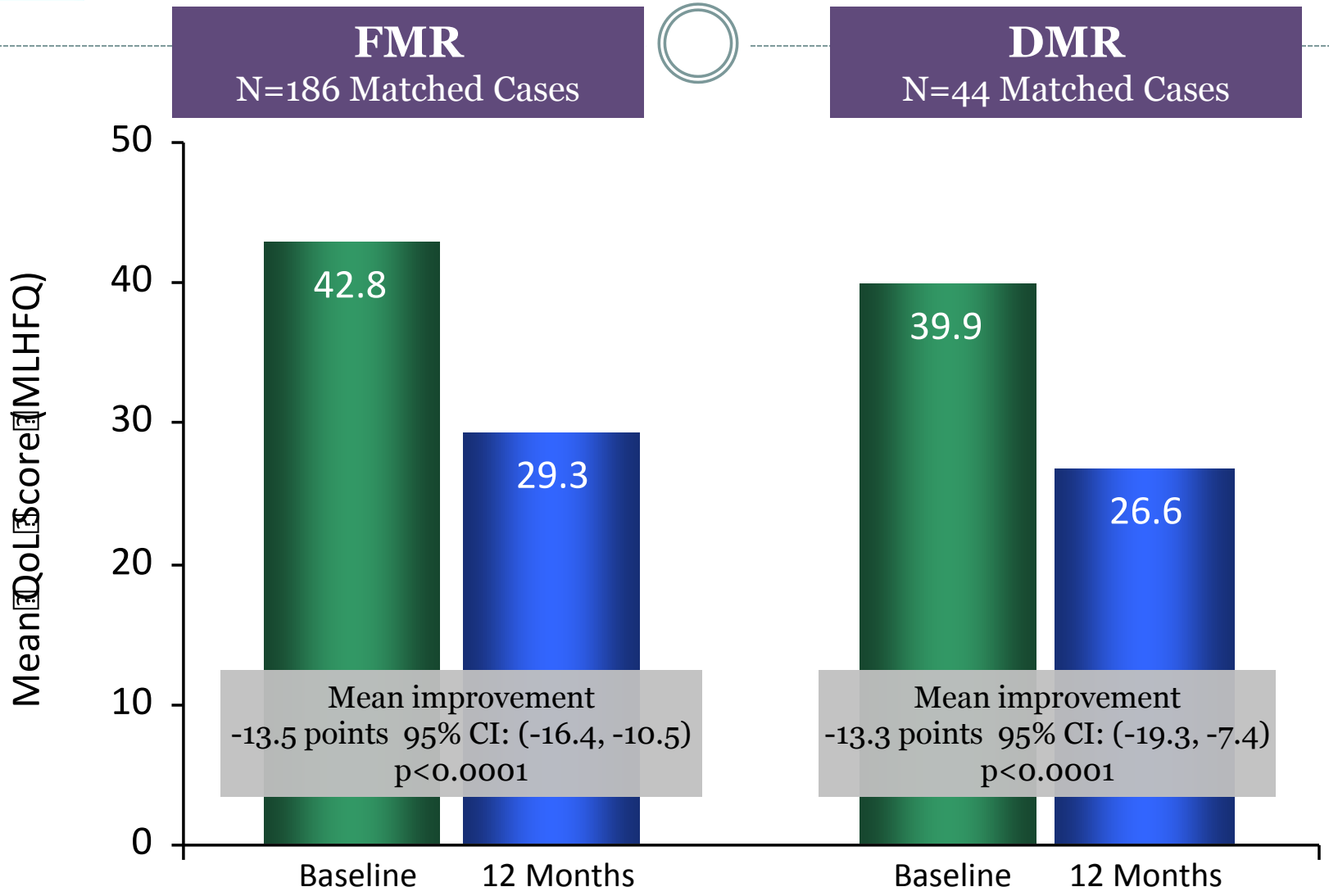
Mitral Regurgitation Grade



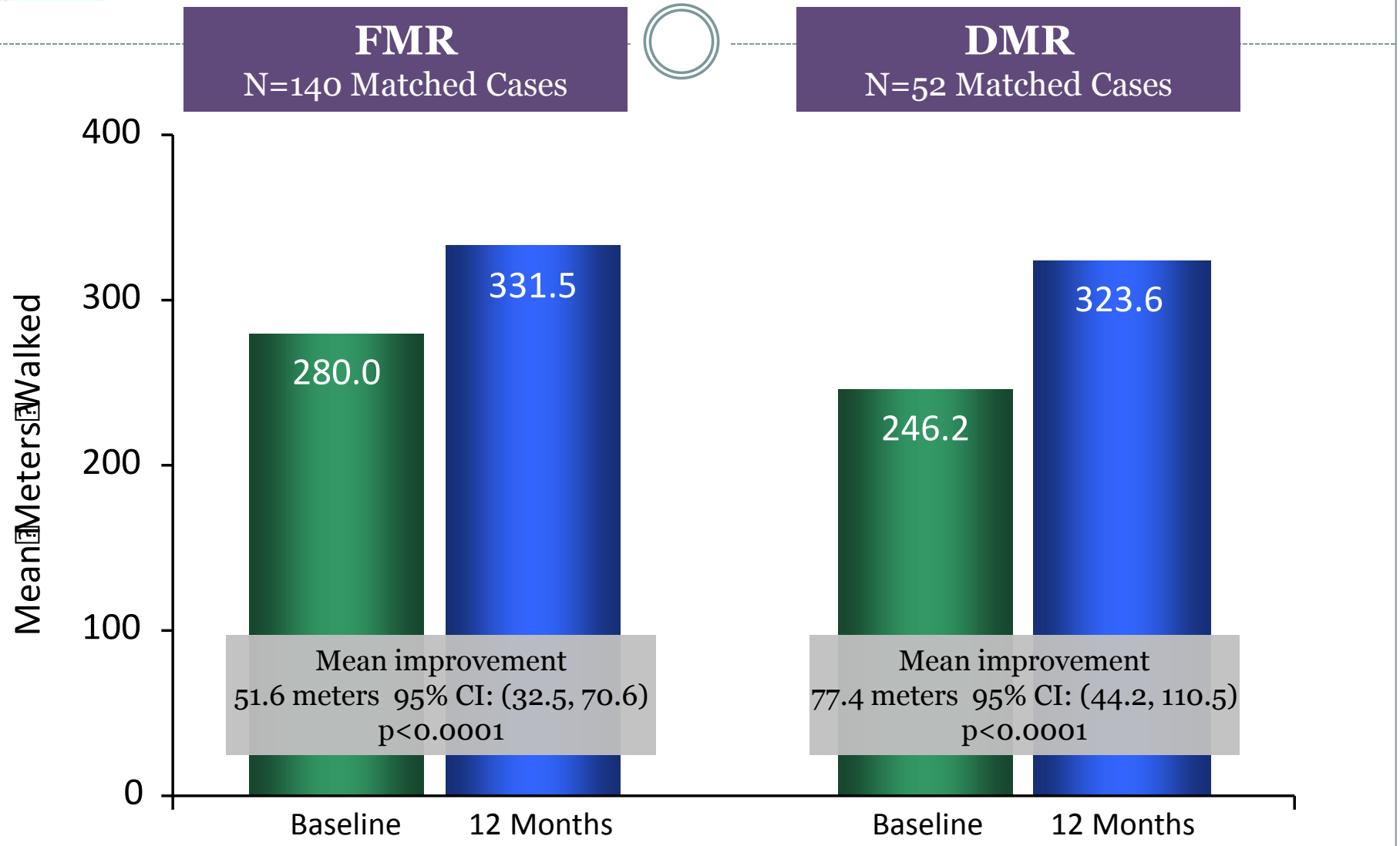
NYHA Functional Class



Quality of Life Score (MLHFQ)



6-Minute Walk Distance



Considerations for Patient Selection

Patient screening

- Suitable patient
- Suitable mitral valve anatomy
- Suitable monitoring possibilities

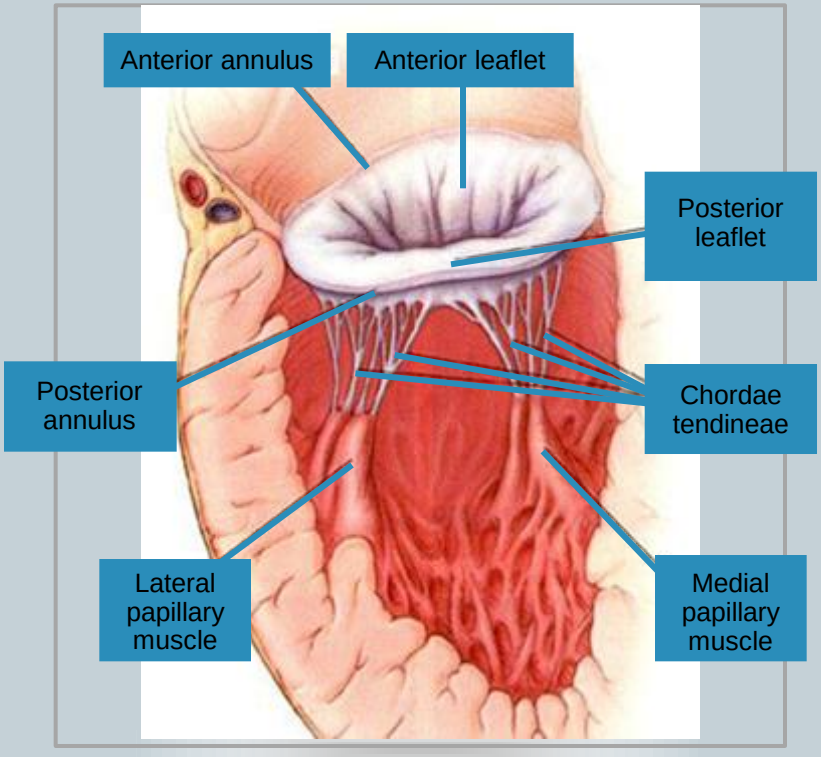
MitraClip
Patient Selection Considerations

Recommended criteria

- Moderate to severe MR (Grade 3 or more out of 4 grades)
- Pathology in A2-P2 area
- Coaptation length >2mm (depending on leaflet mobility)
- Coaptation depth <11mm
- Flail gap < 10mm
- Flail width < 15mm
- Mitral valve orifice area >4cm² (depending on leaflet mobility)
- Mobile leaflet length > 1cm

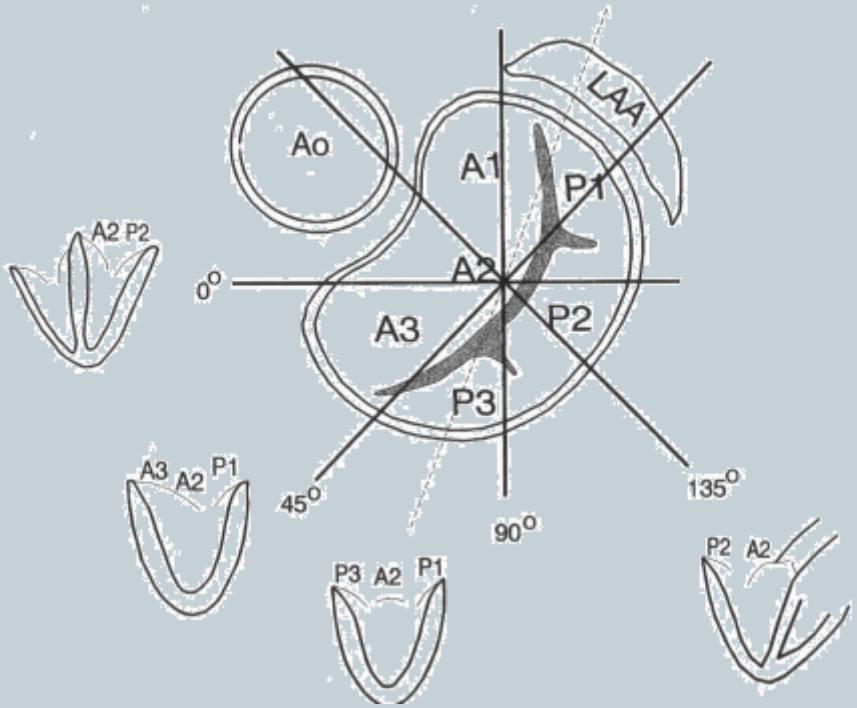
1. The current patient considerations are based on EVEREST II and commercial European experience to date. The MitraClip Patient Selection Conideration document has been endorsed by the Crossroads faculty.

Mitral Valve Anatomy



The mitral valve apparatus includes the annulus, the leaflets, the chordae tendineae, and papillary muscles.

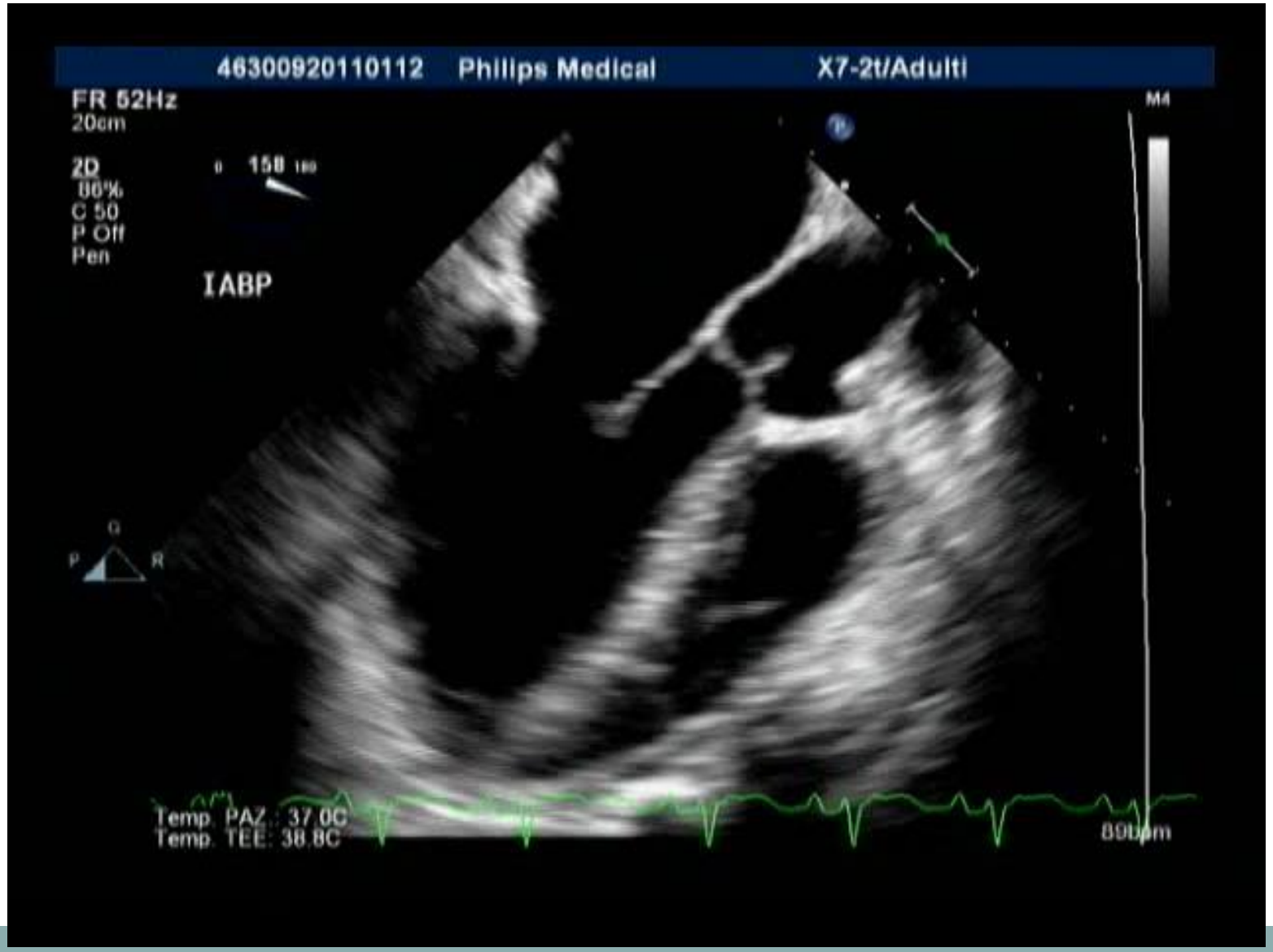
modified from Carpentier, A. et al. *Carpentier's Reconstructive Valve Surgery*. Saunders Elsevier; 2010.



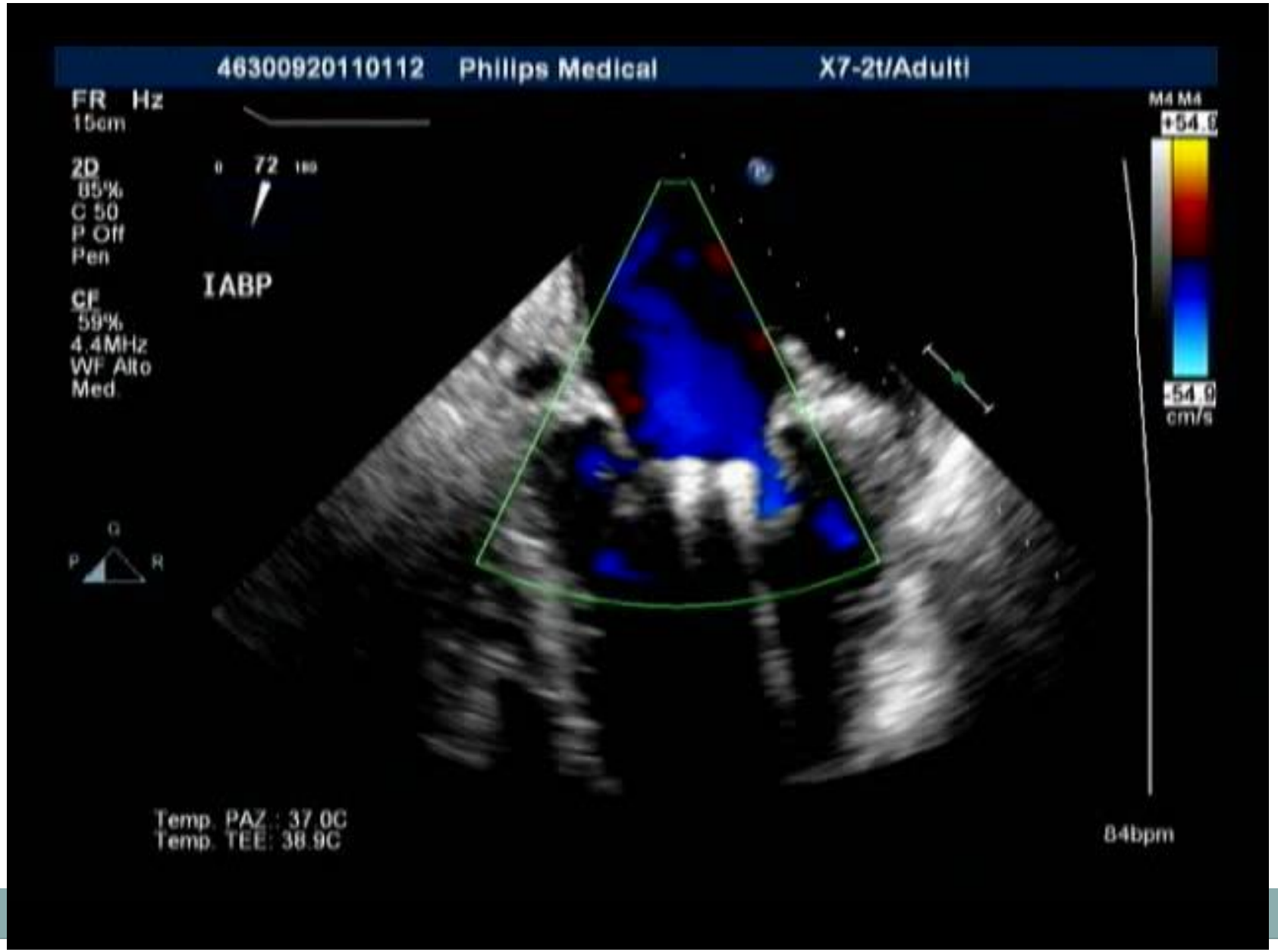
The leaflets are normally asymmetric—the anterior leaflet has a larger surface area, but occupies a smaller amount of annular circumference.

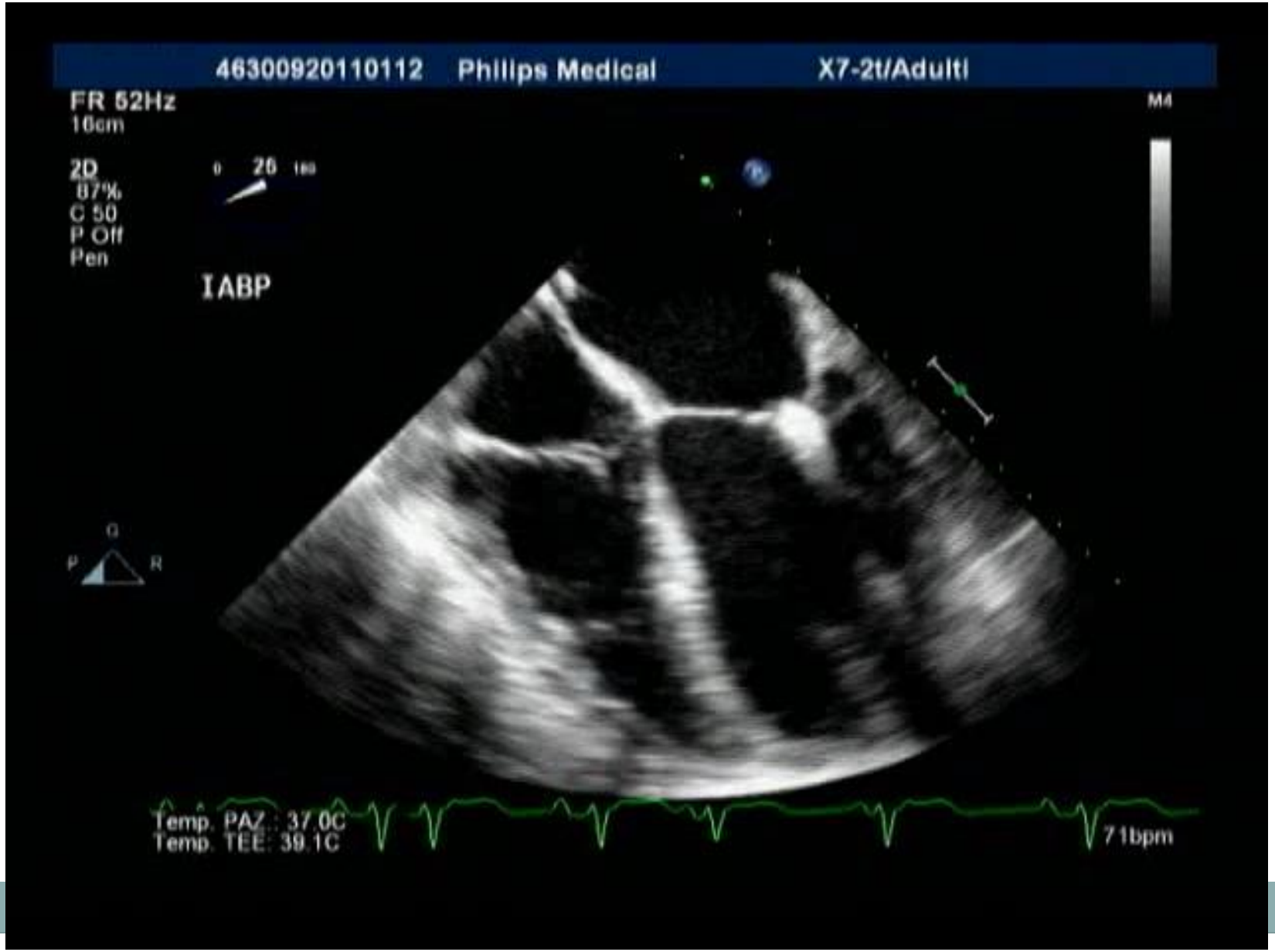
(Foster GP et al. Accurate localization of mitral regurgitant defects using multiplane transesophageal echocardiography. Ann Thorac Surg 1998)

Procedure


46300920110112 Philips Medical X7-2t/Adulti
FR 52Hz
20cm
2D
86%
C 50
P Off
Pen
158
IABP
M4
Temp. PAZ: 37.0C
Temp. TEE: 38.8C


46300920110112 Philips Medical X7-2t/Adulti
FR 52Hz
15cm
2D
85%
C 50
P Off
Pen
167
IABP
M4
Temp. PAZ: 37.0C
Temp. TEE: 39.1C
92bpm

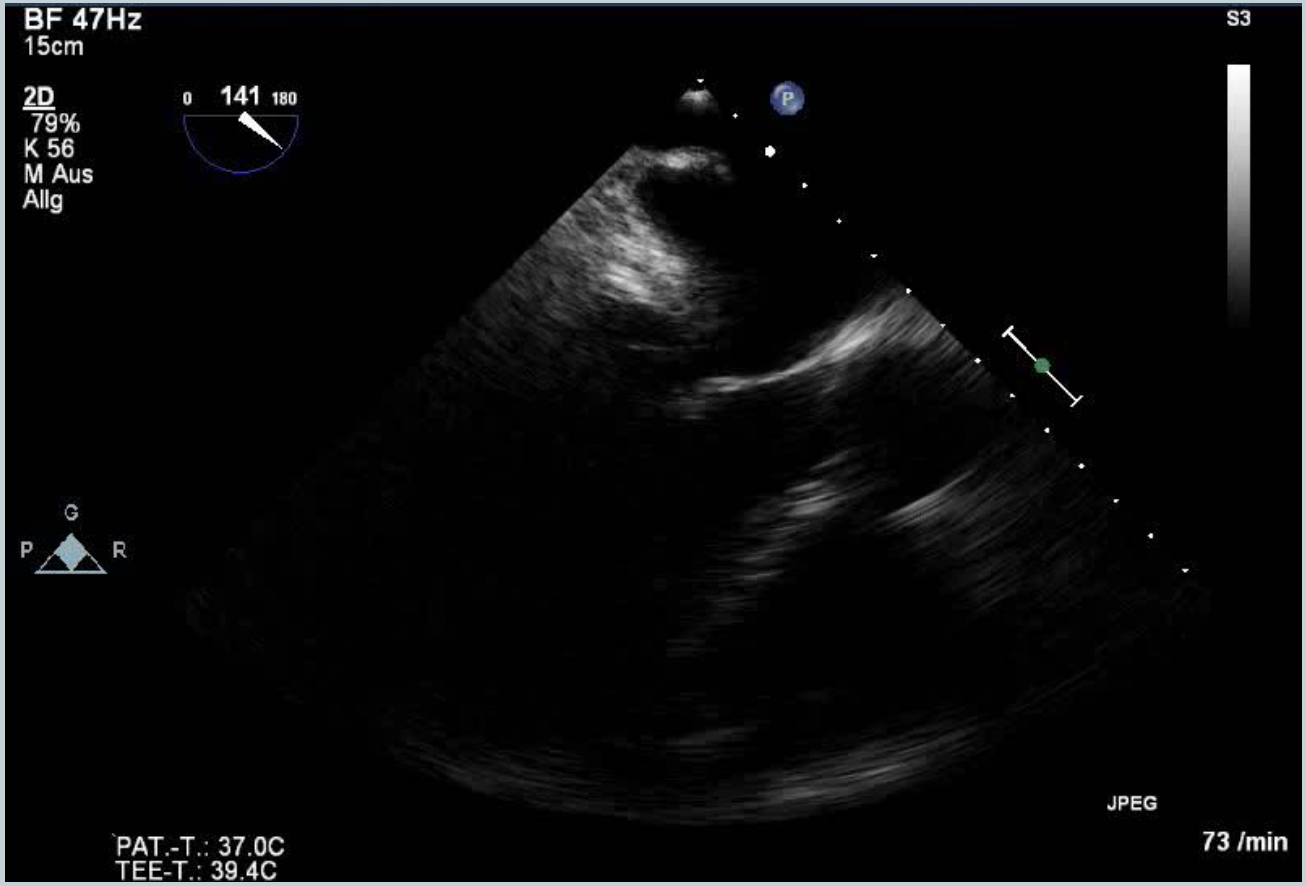

46300920110112 Philips Medical X7-2t/Adulti
FR Hz
15cm
2D
85%
C 50
P Off
Pen
CF
59%
4.4MHz
WF Alto
Med
72
IABP
M4 M4
cm/s
Temp. PAZ : 37.0C
Temp. TEE: 38.9C
84bpm


46300920110112 Philips Medical X7-2t/Adulti
FR 52Hz
16cm
2D
87%
C 50
P Off
Pen
IABP
M4
Temp. PA2 : 37.0C
Temp. TEE: 39.1C
71bpm

Most Important Echo View: TEE LAX!

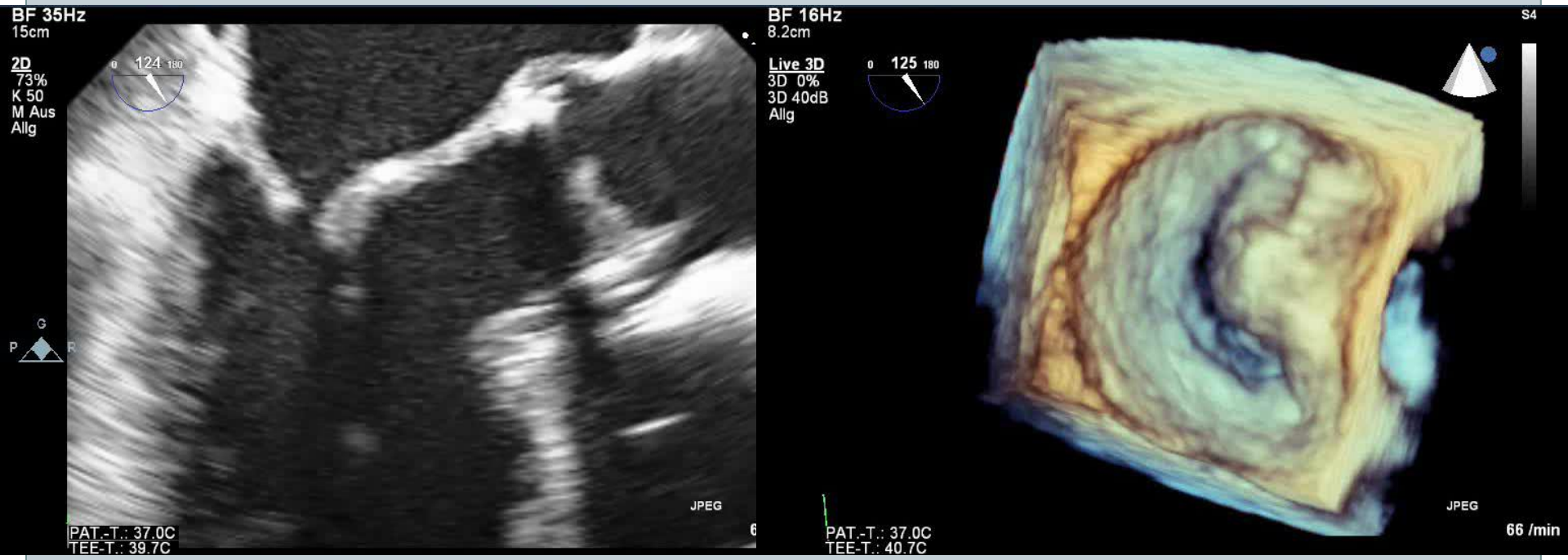
- A good quality TEE LAX view is a strong indicator for good procedure guidance!
- Both AML and – more important – PML can be seen.
- Leaflet grasping and insertion can perfectly be observed in this case.

Rejected for MitraClip



No suitable TEE quality, PML cannot be seen

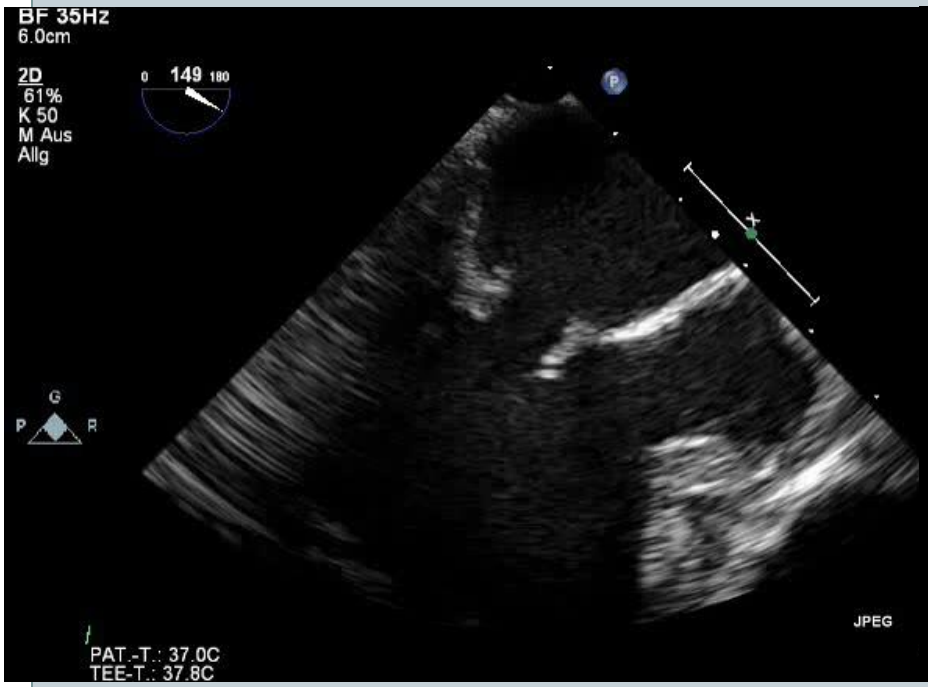
Rejected for MitraClip

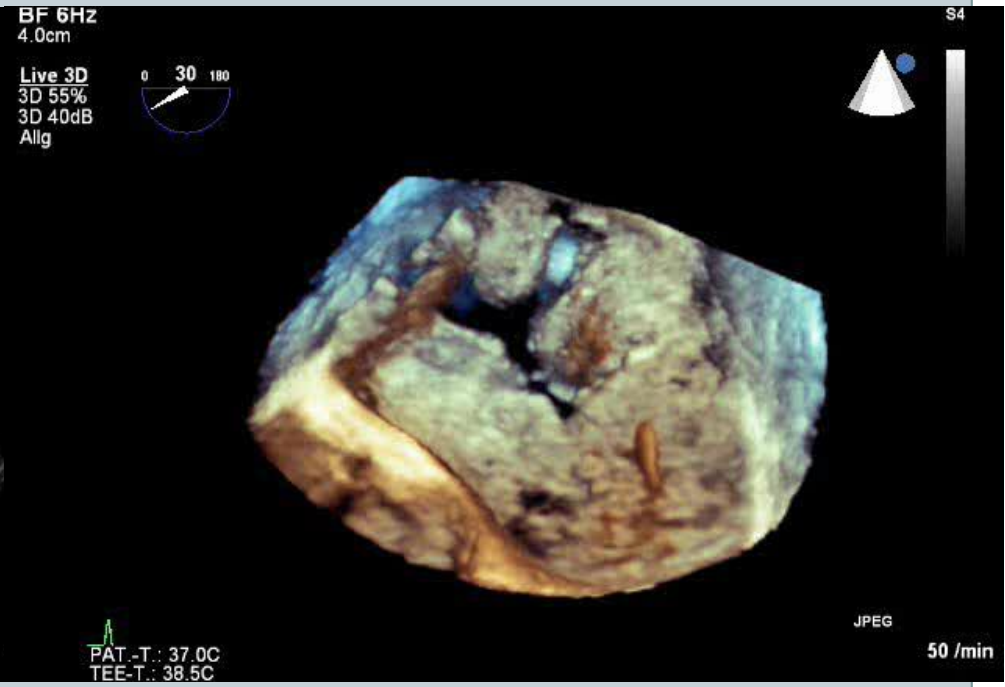


Mitral valve stenosis (valve area < 4 cm^2)

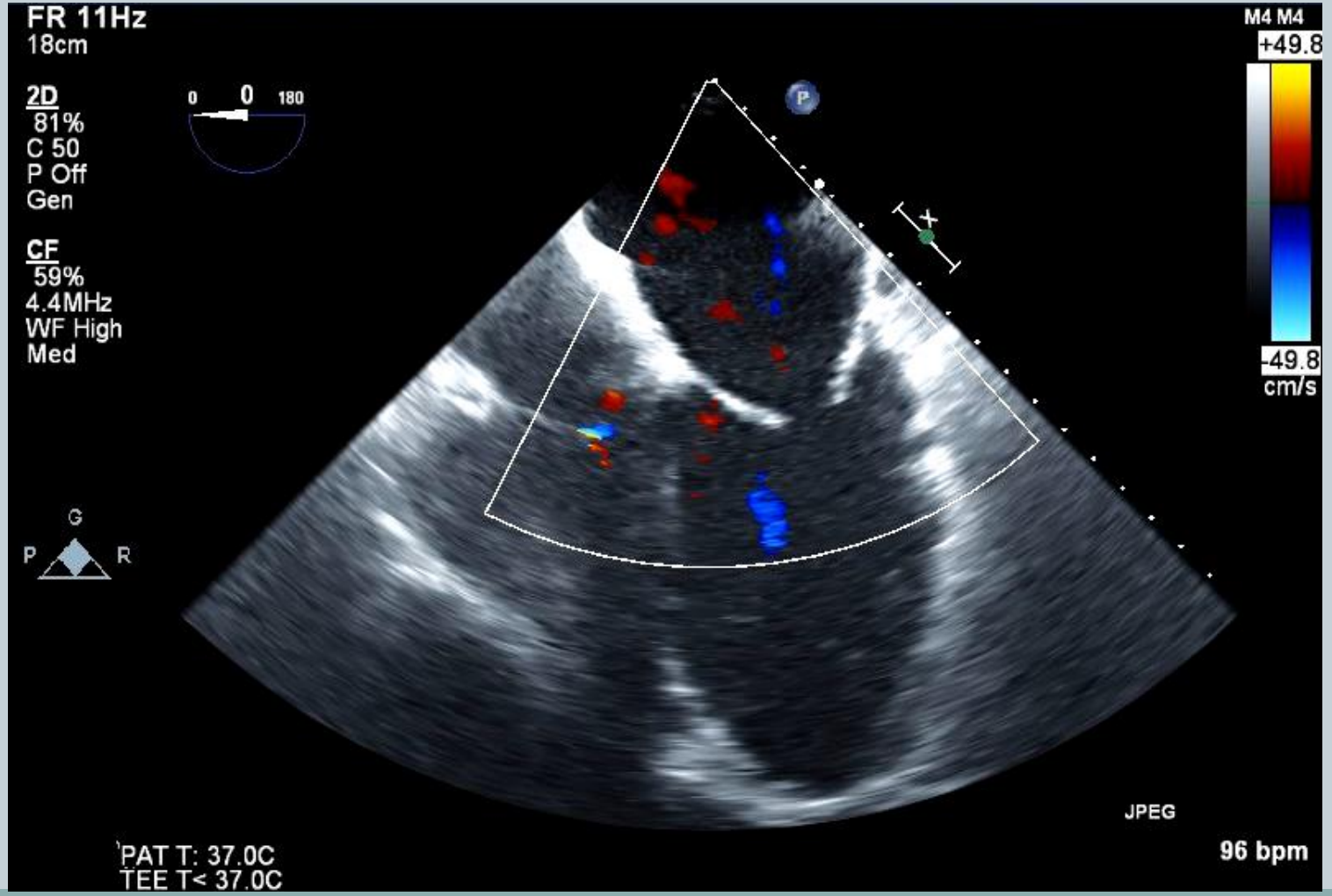
Rejected for MitraClip

Barlow‘s disease, cleft

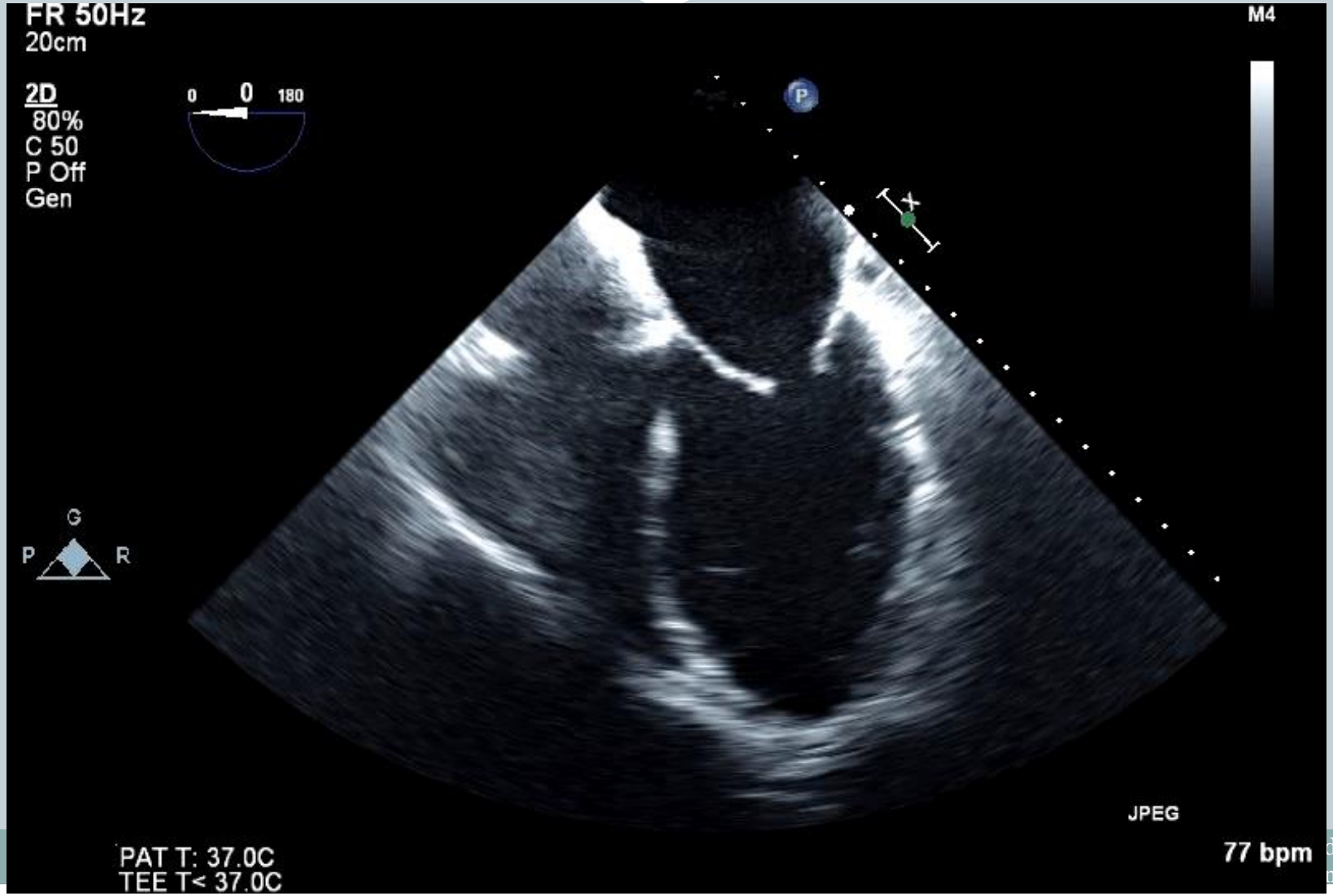




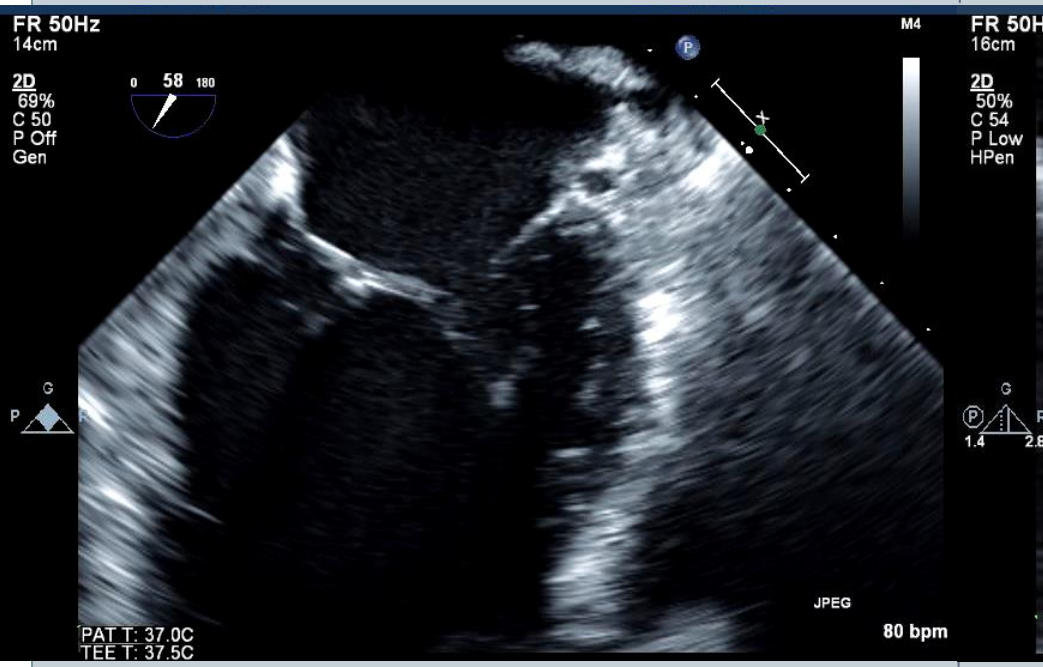
Malcoaptation

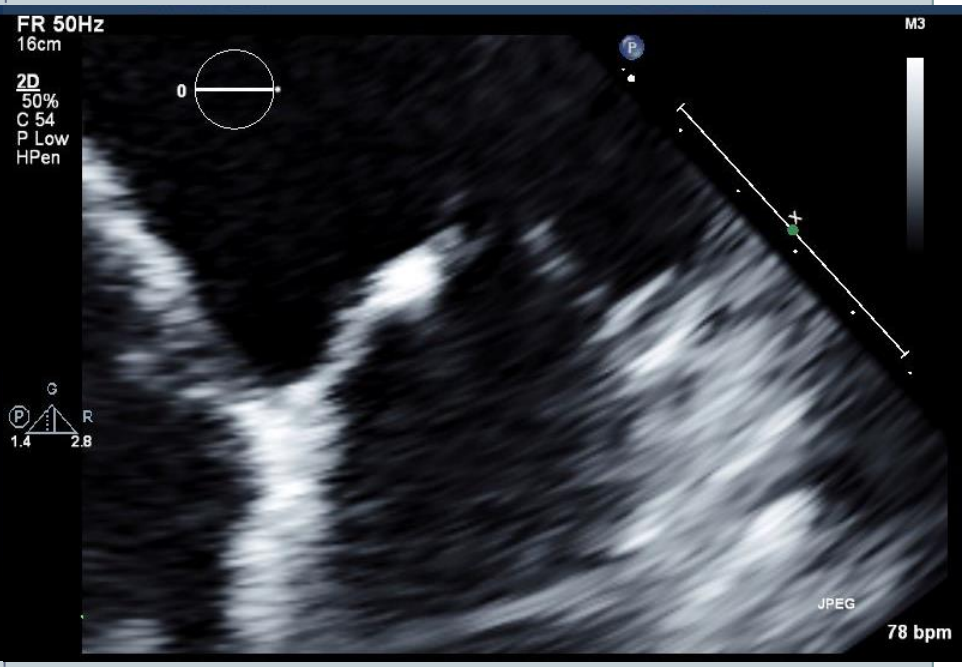


Malcoaptation

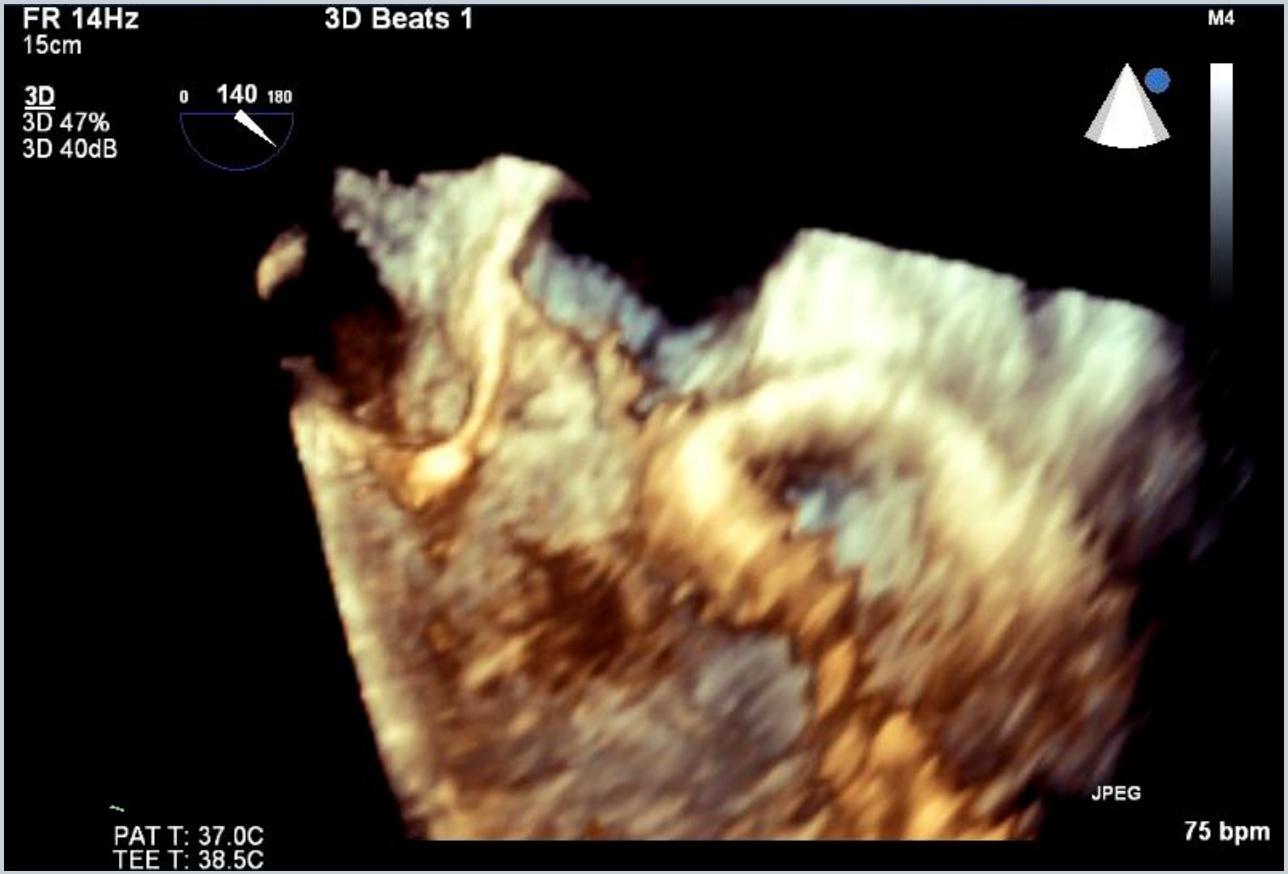


Calcified Leaflet Tip





Calcified Leaflet Tip



Screening Process

TEE is mandatory for patient screening

- Significant MR?
- No severe calcification in mitral leaflet / annulus?
- No severe leaflet restriction?
- No too severe flail leaflet?
- No cleft between A2/P2?
- No prior surgery of mitral valve?
- No intracardiac mass or thrombus?
- No presence of mitral stenosis?
- All echo views for procedure guidance are obtainable and in good quality ?

YES!

Good chance for technical / procedural success!

Patient Success

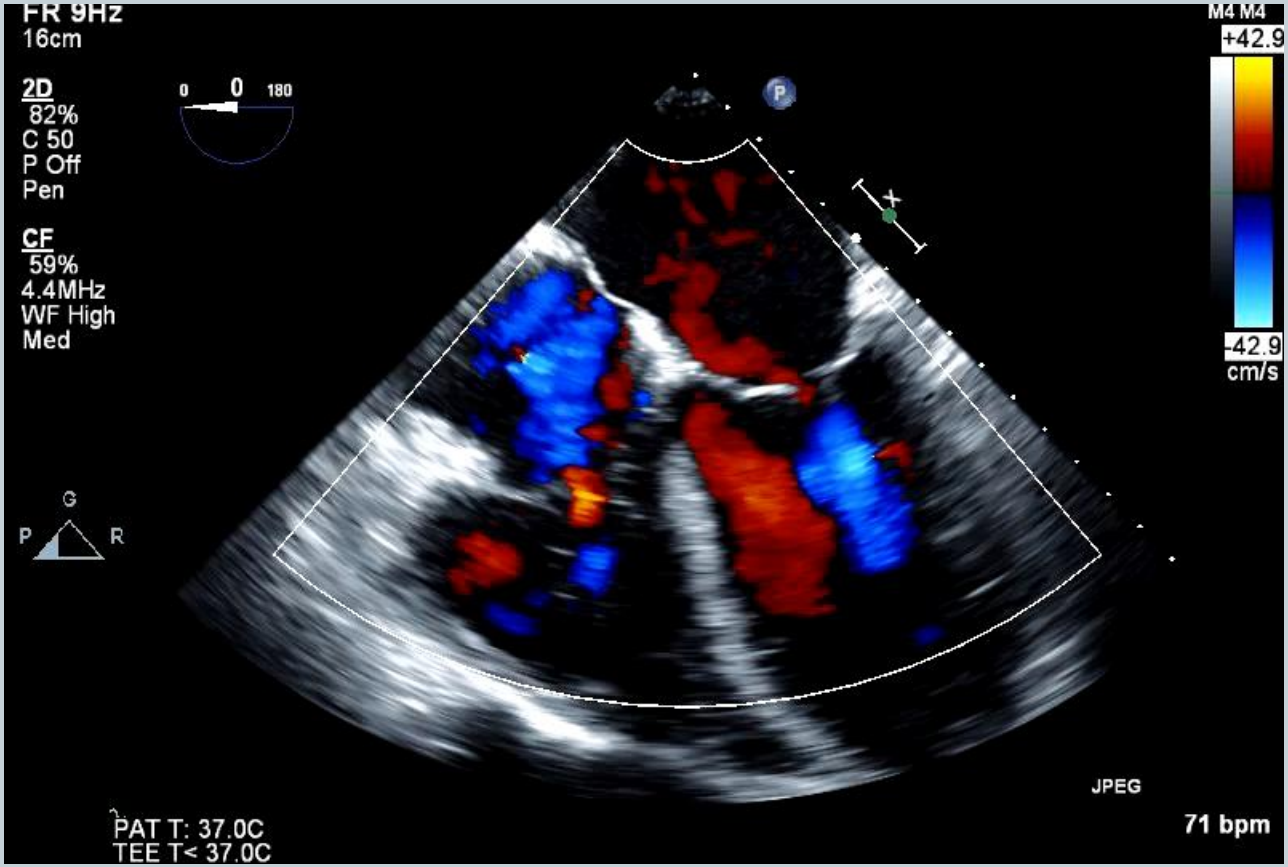
- Technical and procedural success
- Echocardiographic benefit
  - Reduced MR
  - LV remodelling
- Clinical benefit
  - Reduced hospitalizations
  - Improved Functional Class
  - Impact of and on comorbidities

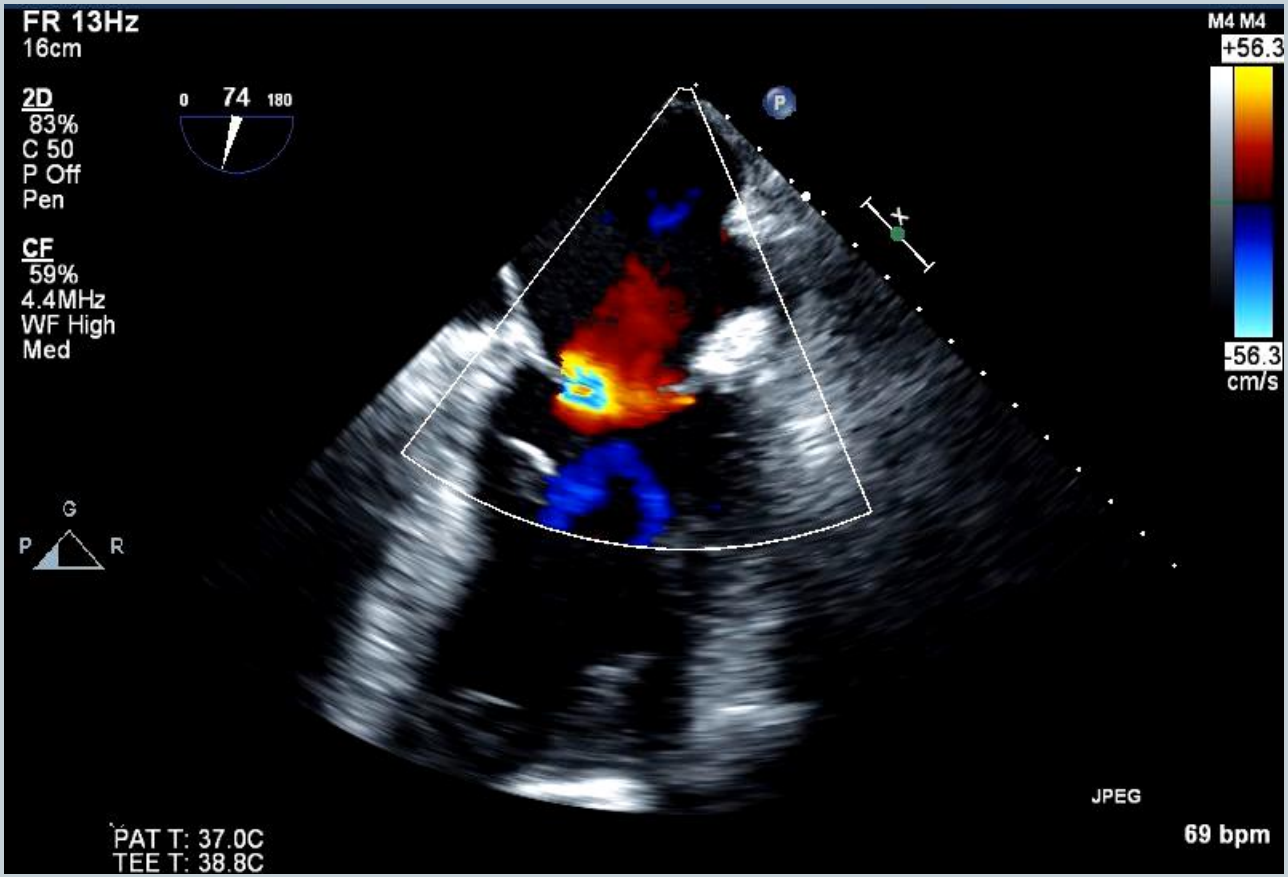
The Patient that Succeeds

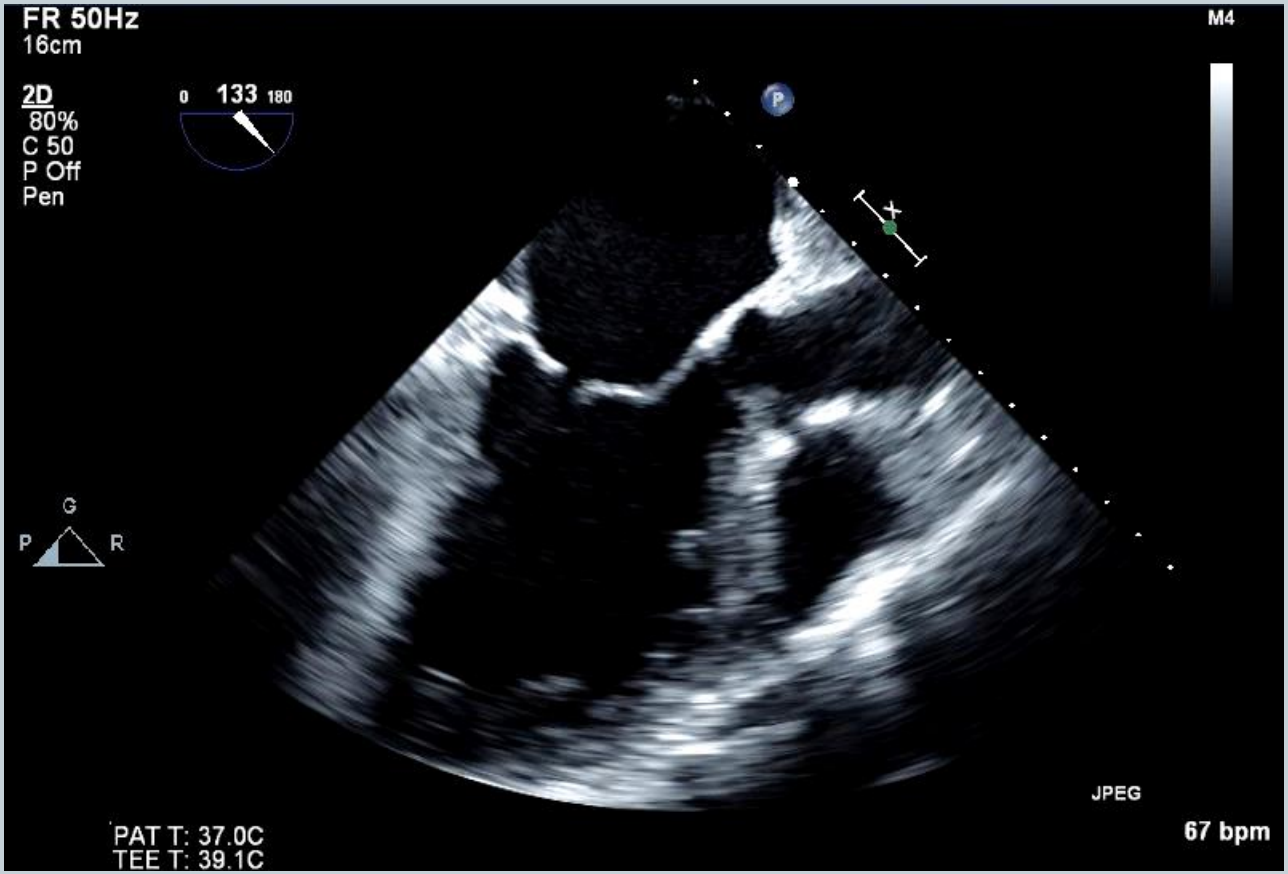
- 59 year old man
- Diabetes, HTN, hypercholesterolemia
- 1998 AMI cath (TVD) -> CABG
- FC II
- Last two years: MR2+ -> 3+
- Moderately impaired LV Function
- VF -> ICD
- Clinical deterioration
  - FCIII -> FCIV
- Anasarca with bilateral pleural effusions
- Referred for MitraClip consideration

Echocardiography

- Severe MR
- Moderate LV dysfunction
  - Not severe
- TIG 46mmHg
- Eccentric Jet
- Central Jet Orifice


FR 9Hz
16cm
2D
82%
C 50
P Off
Pen
CF
59%
4.4MHz
WF High
Med
0
0
180
G
P
R
M4 M4
+42.9
-42.9
cm/s
JPEG
71 bpm
PAT T: 37.0C
TEE T< 37.0C


FR 13Hz
16cm
2D
83%
C 50
P Off
Pen
CF
59%
4.4MHz
WF High
Med
0
74
180
M4 M4
+56.3
-56.3
cm/s
G
P
R
JPEG
69 bpm
PAT T: 37.0C
TEE T: 38.8C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16cm
2D
80%
C 50
P Off
Pen
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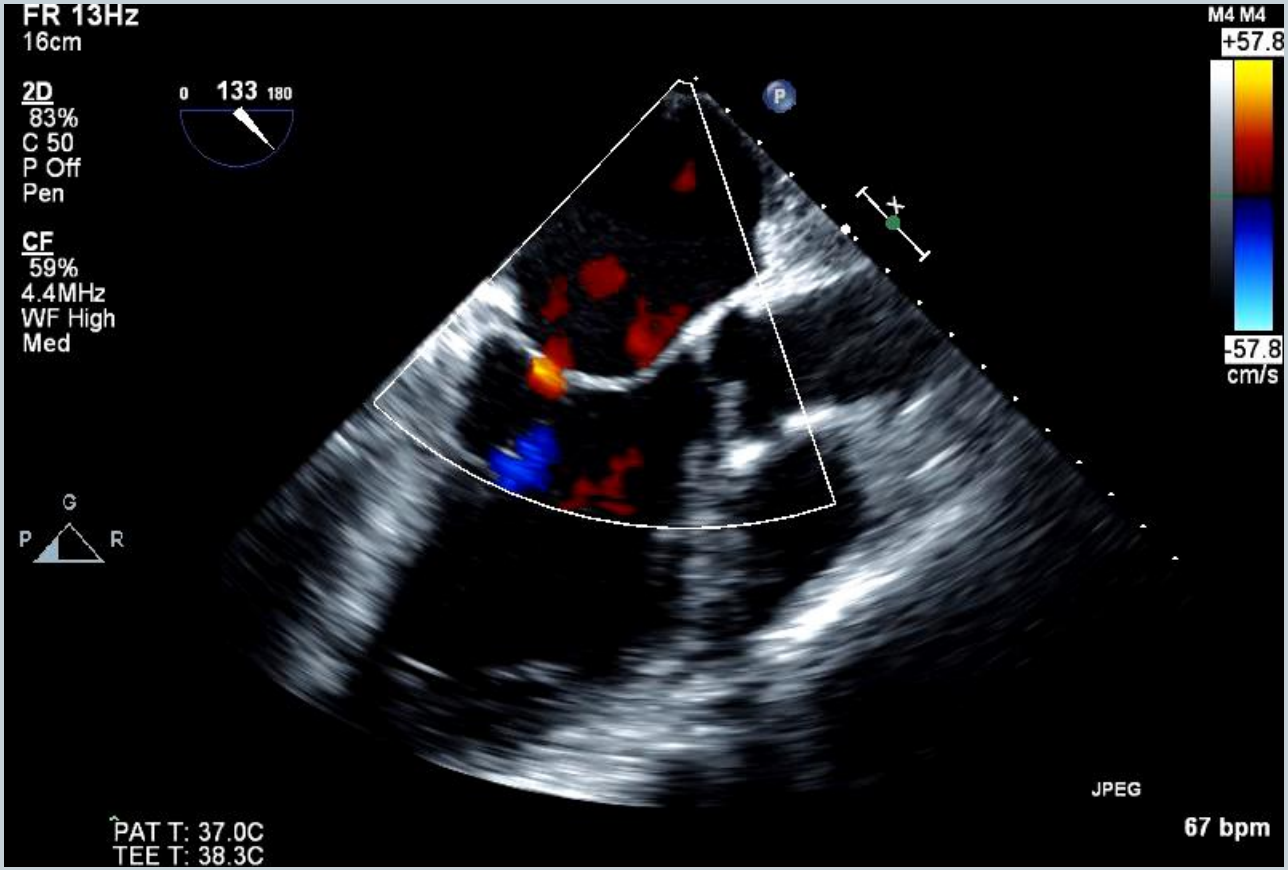
133
180
M4
G
P
R
JPEG
67 bpm
PAT T: 37.0C
TEE T: 39.1C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16cm
2D
83%
C 50
P Off
Pen
CF
59%
4.4MHz
WF High
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133
180
M4 M4
+57.8
-57.8
cm/s
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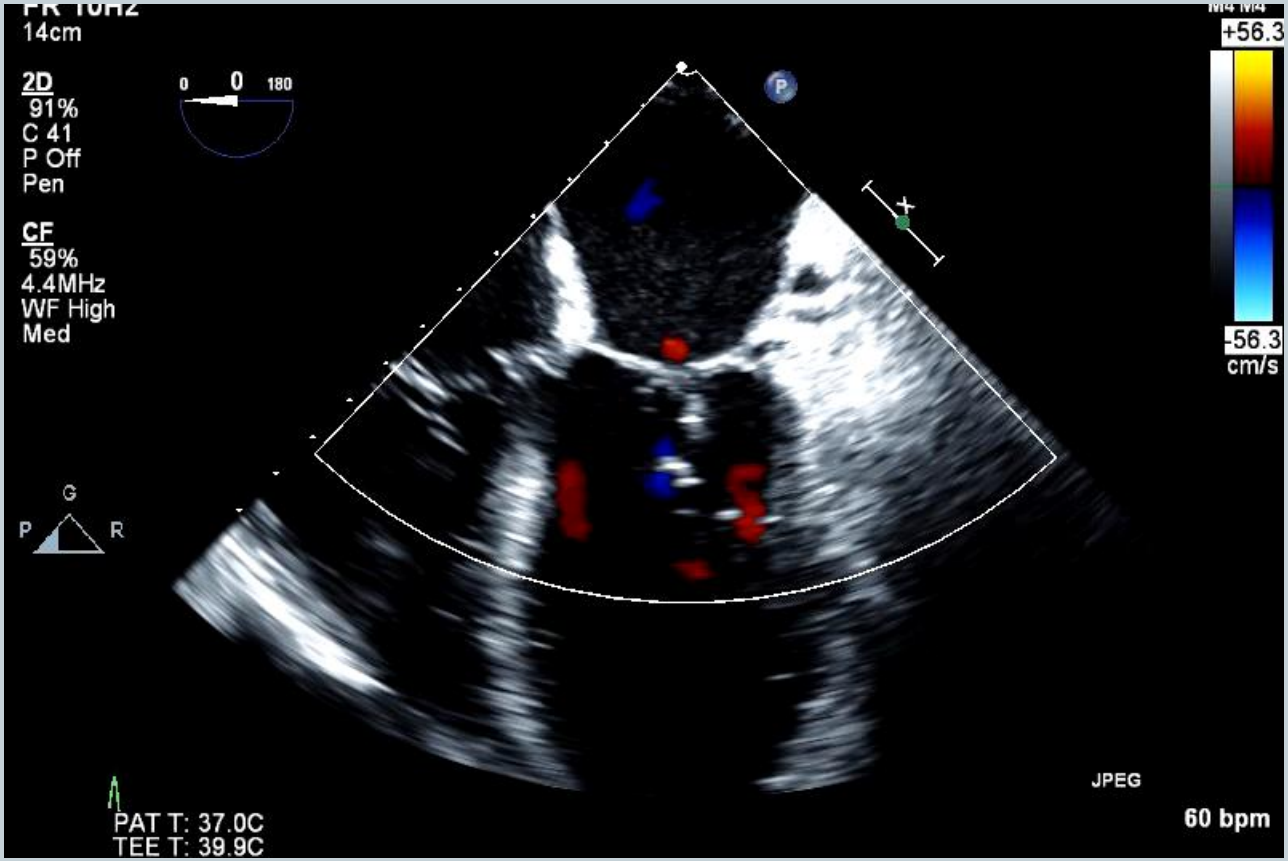
R
JPEG
67 bpm
PAT T: 37.0C
TEE T: 38.3C

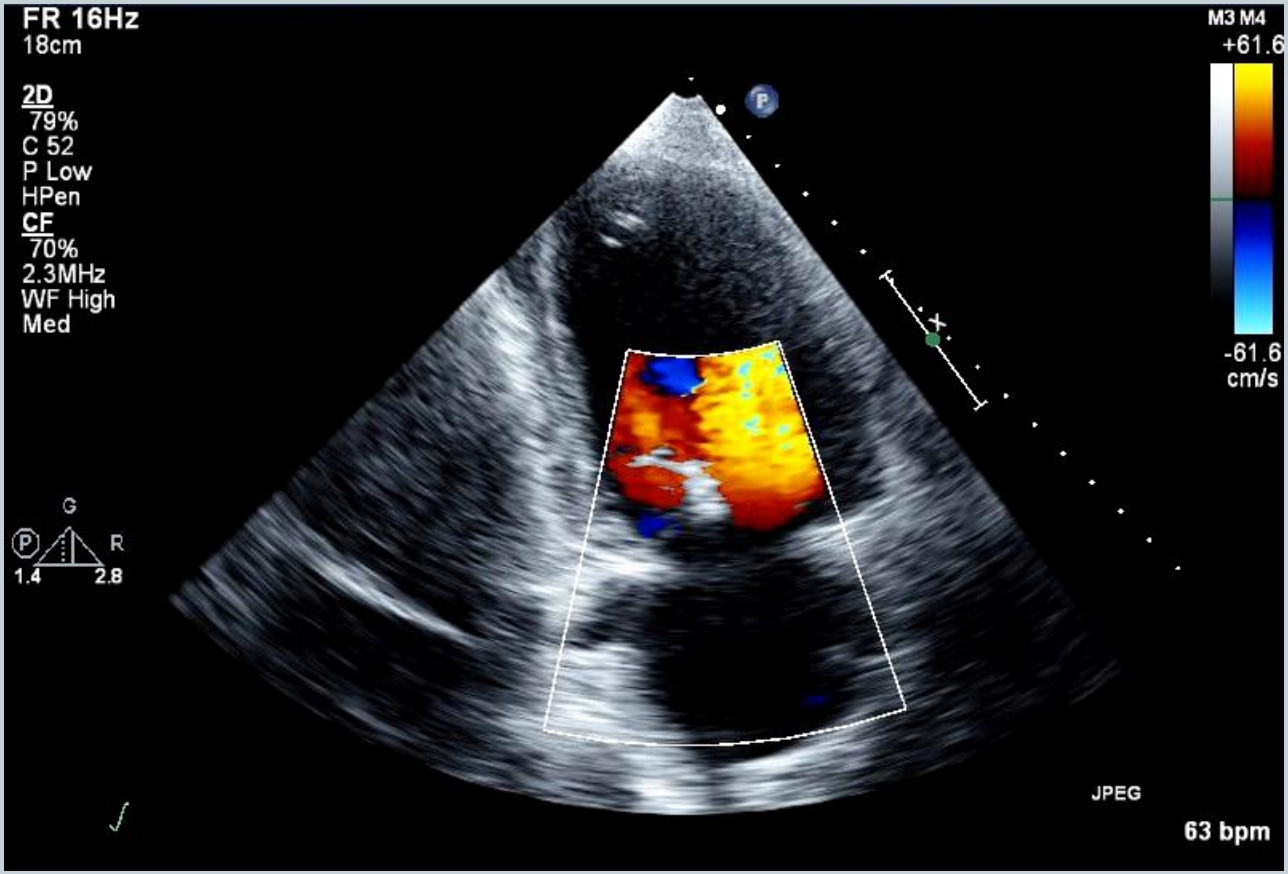
Procedure Completion



6 Month Follow-up
January 2013

- Mild MR
- FC II
- Working full time
- Essentially unrestricted in daily function
- Thrilled!!

6 Months post



The Place of MitraClip

- MitraClip & medical therapy
- MitraClip & CRT
- MitraClip & PCI
- MitraClip & TAVI
- MitraClip & annuloplasty
- MitraClip & other novel technologies