Transcatheter mitral valve interventions in high risk and inoperable patients

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COI disclosure

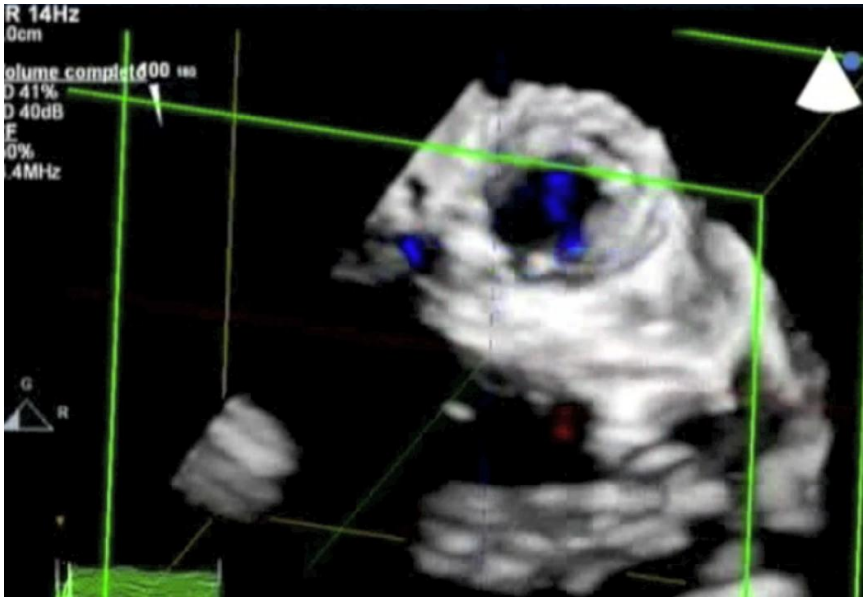
- Francesco Maisano is consultant for ValtechCardio, Abbott Vascular, Medtronic, St Jude Medical, Bioventrix,
- Francesco Maisano receives royalties from Edwards for the Ethilogix rings
- Francesco Maisano is cofounder of 4Tech, RtoL and AFfix

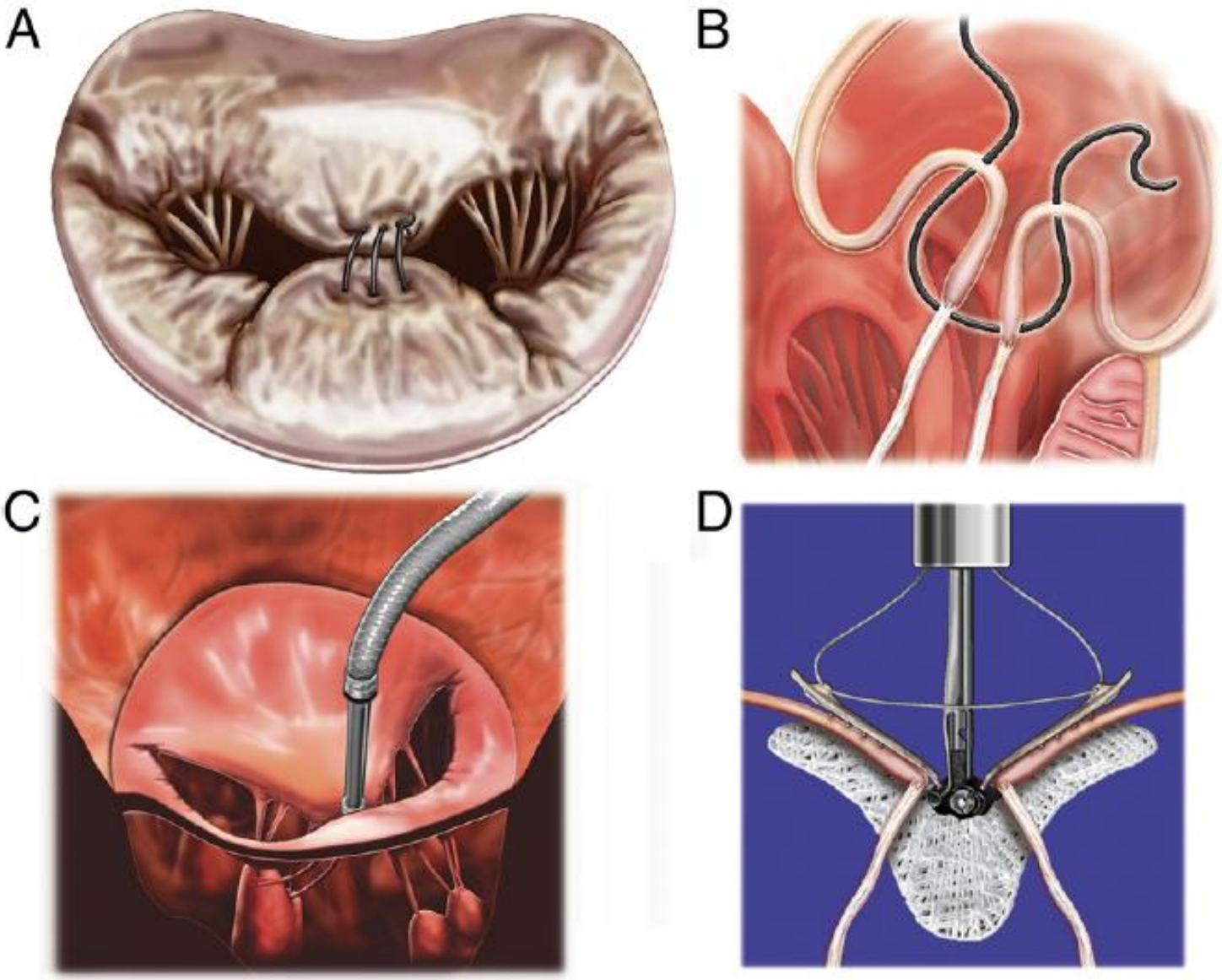
Current management of MR

- Indications, timing and therapeutic options vary according upon MR mechanism, etiology and patient characteristics
- Surgery remains the gold standard and it is the first choice for low-risk patients
- A variety of alternative transcatheter interventions are emerging to treat high-risk or inoperable patients

MV transcatheter treatments in clinical practice

- Leaflet repair
  - Mitraclip
    - FMR and DMR
  - Neochord
    - DMR
- Annulus repair
  - Carillon
    - FMR pts
- MV replacement
  - Sapien XT
    - Valve in valve
    - Valve in ring
- Perivalvular leak closure

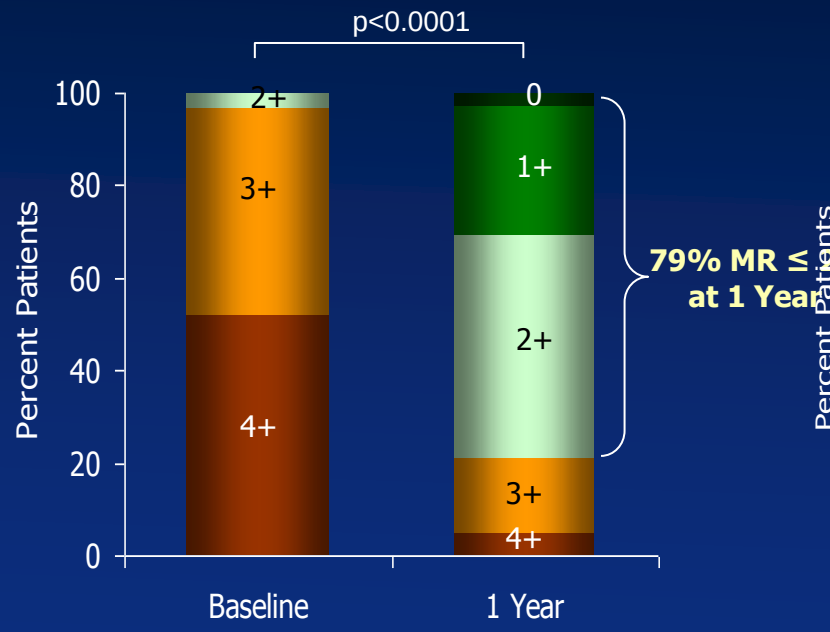




Maisano et al, J Am Coll Cardiol 2011;58: 2174–82

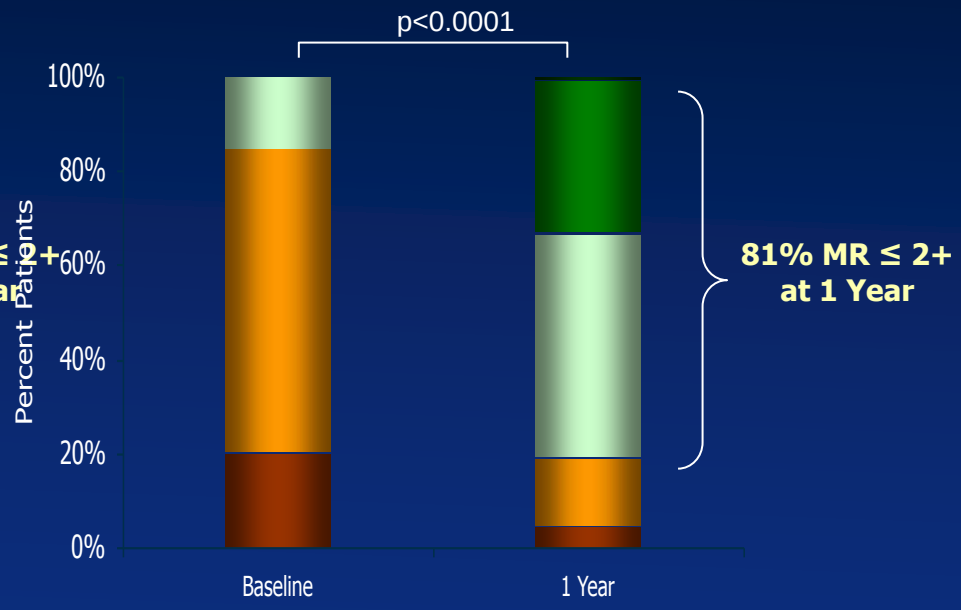
1-Year Mitral Regurgitation Grade

ACCESS-EU
N = 327 Matched Cases



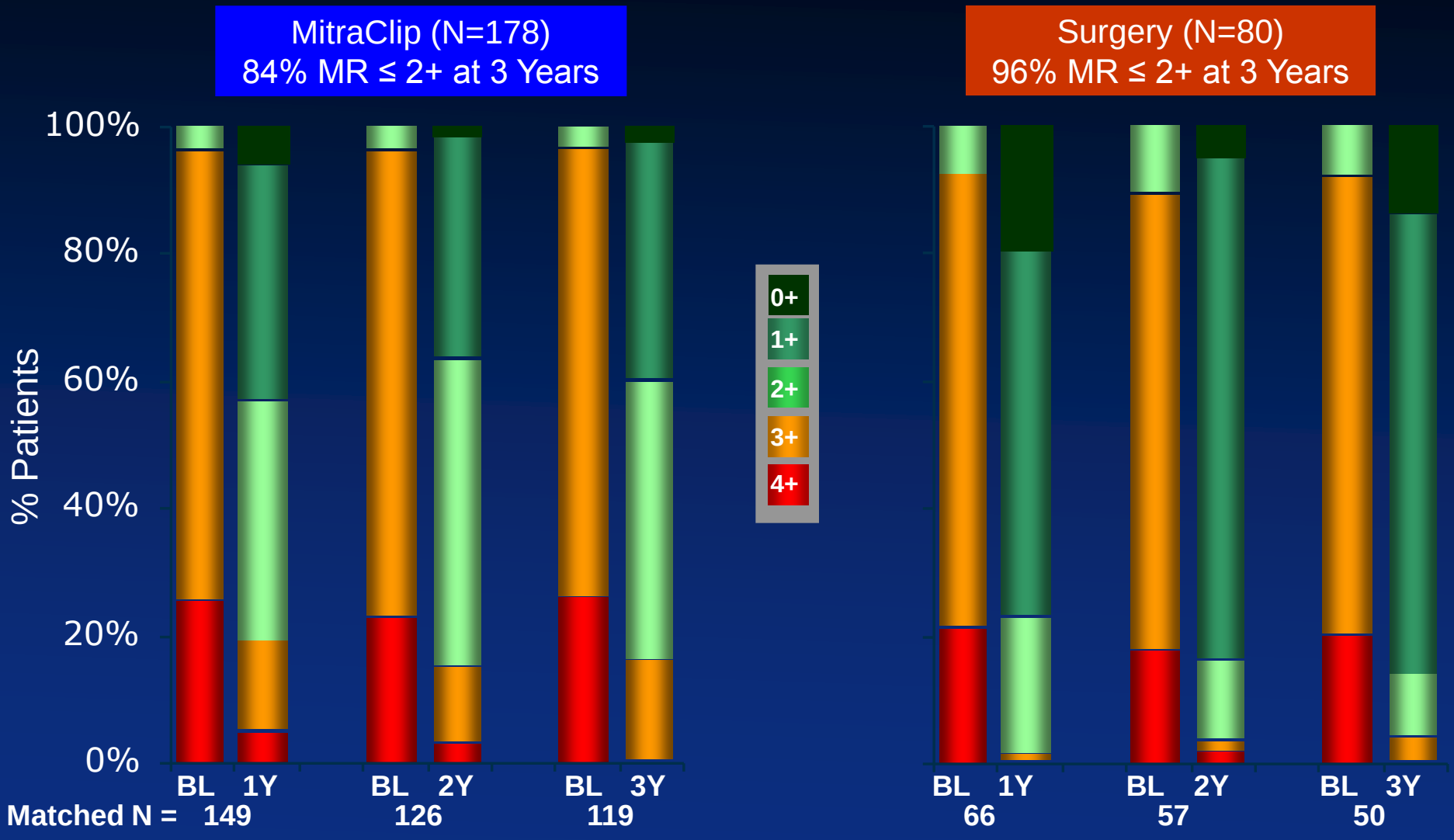
* *As assessed by the sites*

EVEREST II High Risk Cohort
N = 137 Matched Cases



Maisano et al, JACC 2013
Feldman et al, NEJM 2011

Mitral Regurgitation Severity

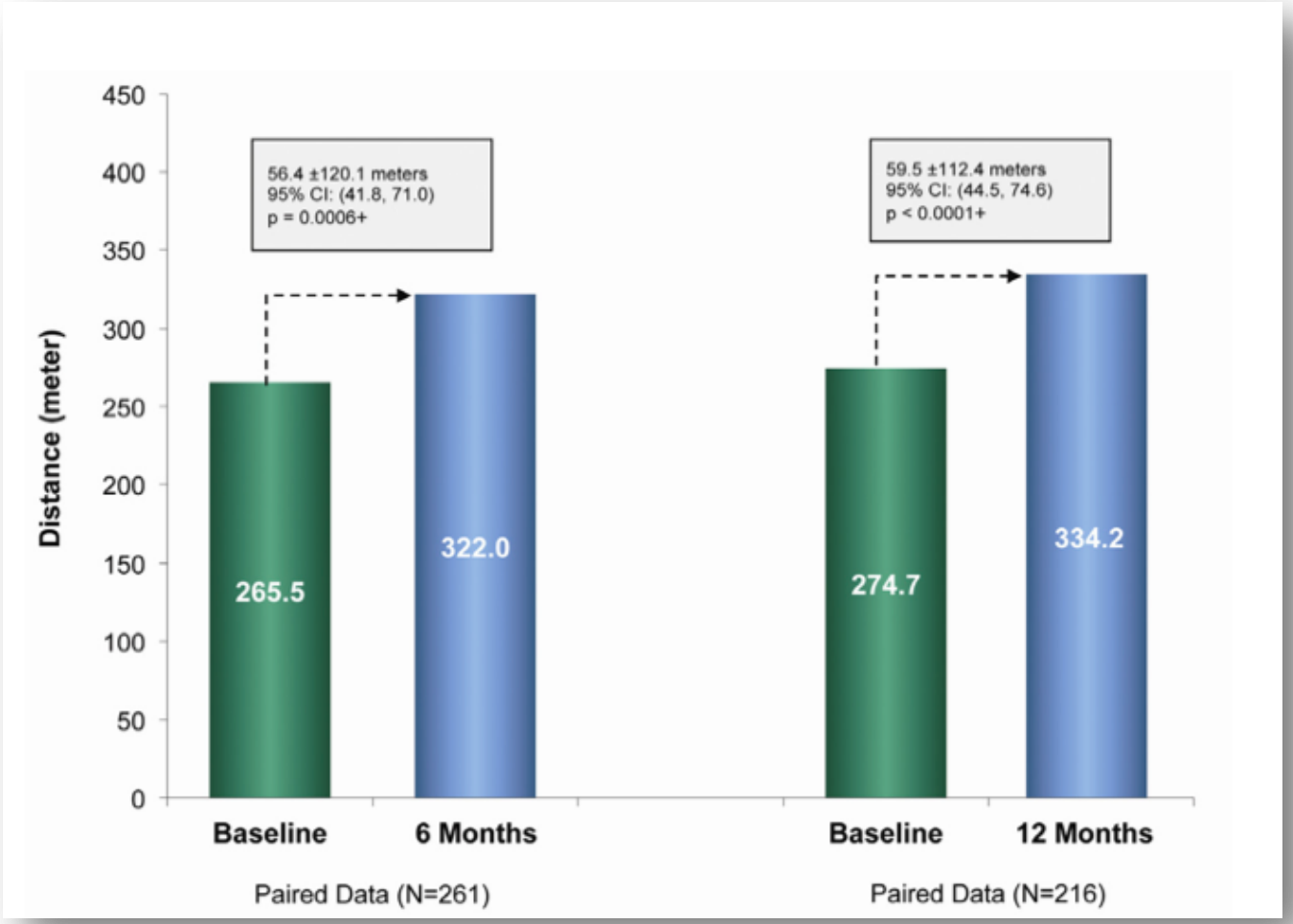


p < 0.05 for all changes from Baseline within groups

EVEREST II RCT data

MitraClip therapy in HF patients improves functional capacity and quality of life

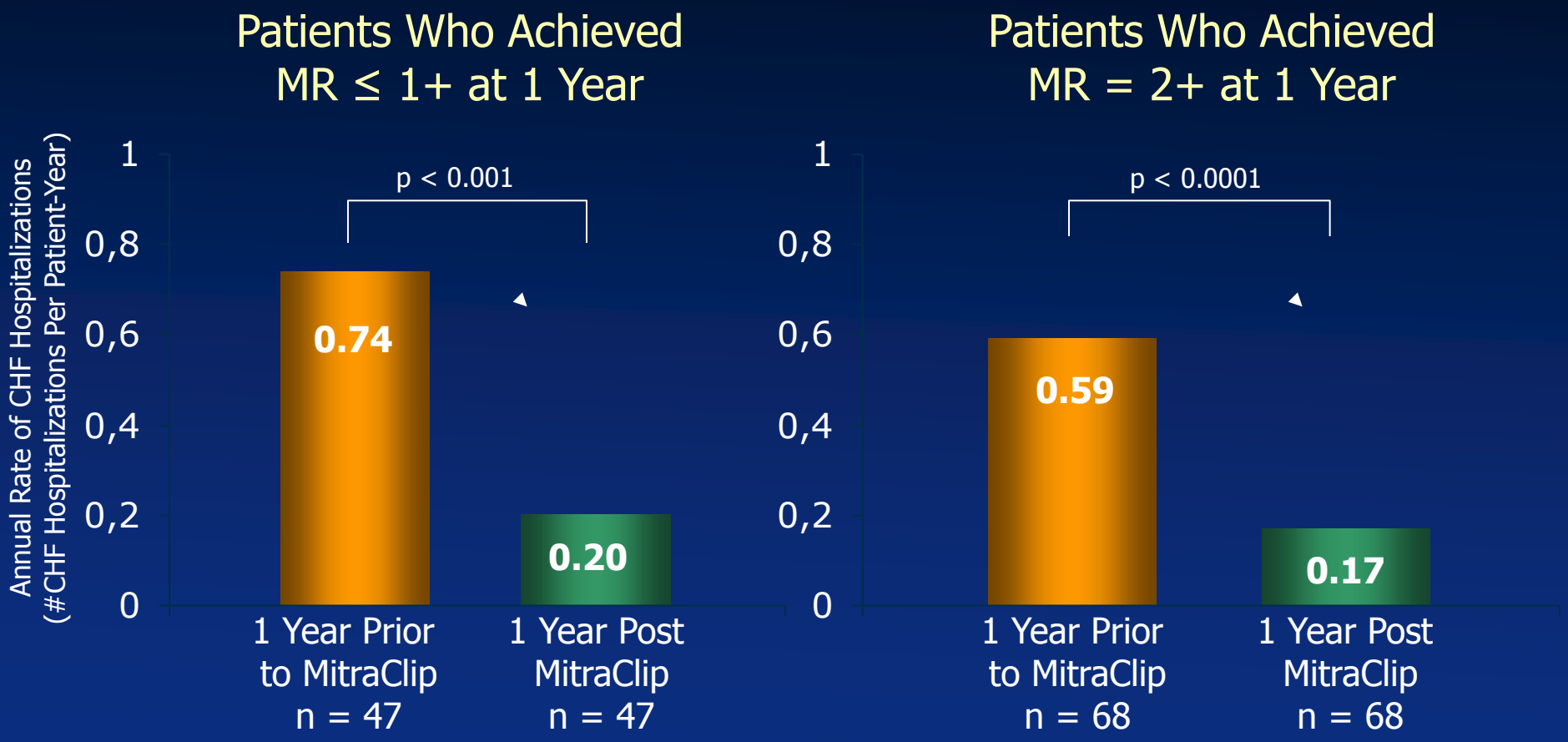
6mwd increases following MC therapy



Maisano et al, JACC 2013

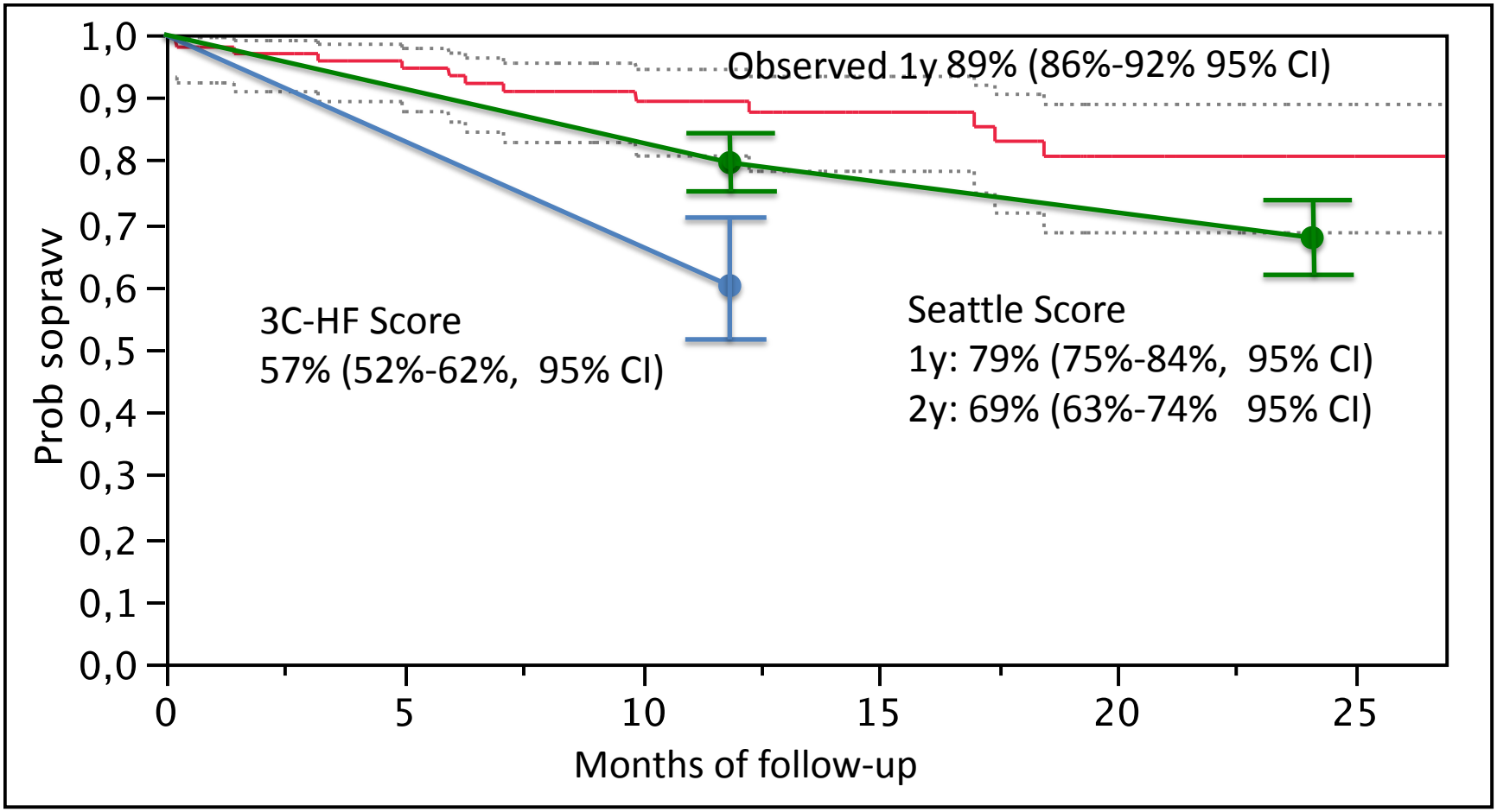
Hospitalizations for CHF

EVEREST II High Surgical Risk Cohort Evaluated by Residual MR



FMR treatment is associated to survival benefit?

KM observed vs predicted survival in HF patients submitted to MitraClip therapy

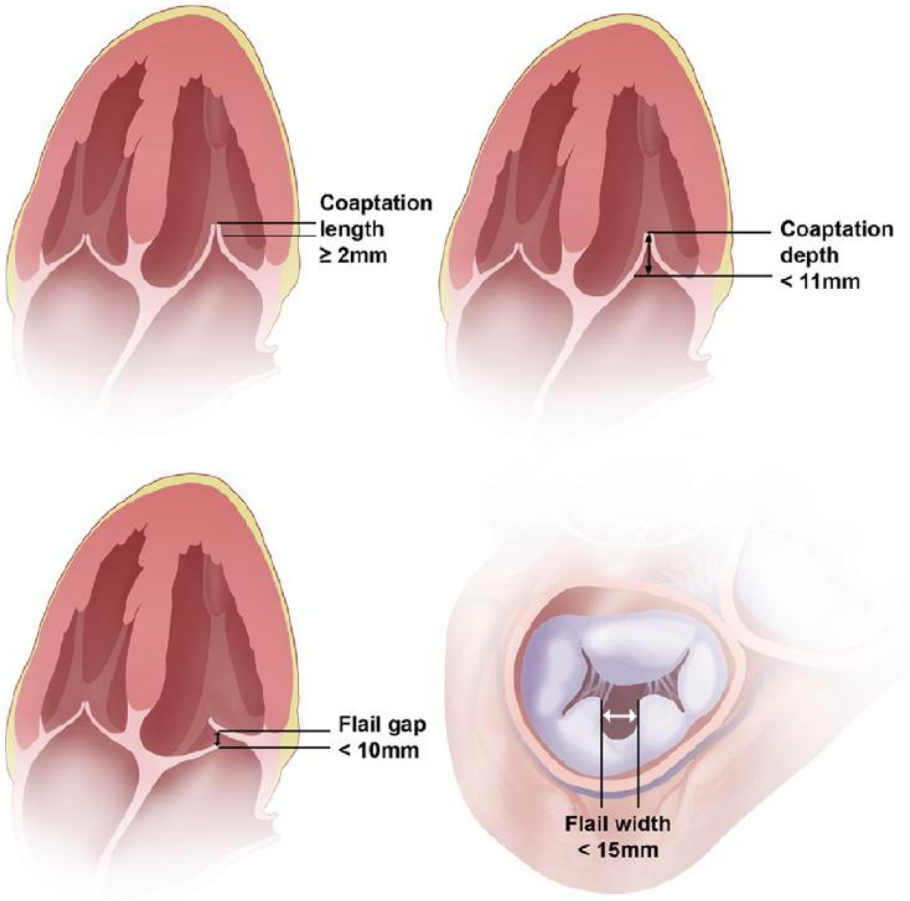


San Raffaele Hospital unpublished data

MitraClip anatomical patient selection considerations

Recommended criteria[1]

- Pathology in A2-P2 area
- Coaptation length > 2 mm (depending on leaflet mobility)
- Coaptation depth < 11 mm
- Flail gap < 10 mm
- Flail width < 15 mm
- Mitral valve orifice area > 4cm^2 (depending on leaflet mobility)
- Mobile leaflet length > 1 cm



1. The current patient considerations are based on EVEREST II and commercial European experience to date. The MitraClip Patient Selection Coniderations document has been endorsed by Expert Opinion (Crossroads institute).

Mitraclip for FMR

- Surgical treatment of FMR is associated with
  - High hospital mortality
  - High recurrence rate
  - Long hospital stay
  - Unproven survival benefit
- Mitraclip for FMR
  - Procedure more simple than for DMR
  - Improvement of symptoms at low risk
  - HRR suggests survival benefit
  - Failure does not modify the surgical option

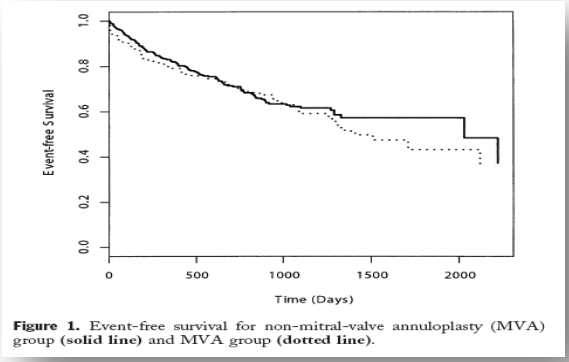
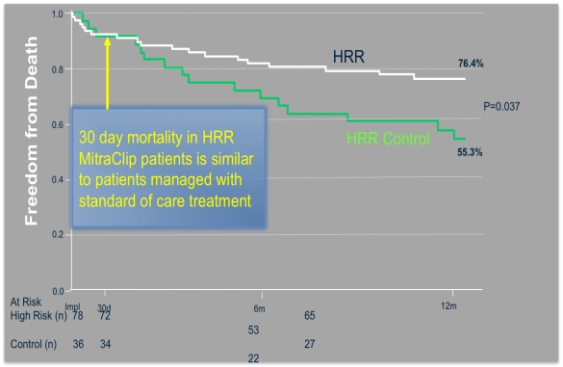


Figure 1. Event-free survival for non-mitral-valve annuloplasty (MVA) group **(solid line)** and MVA group **(dotted line)**.



Indication for MitraClip in FMR

Table 13 **Indications for mitral valve surgery in chronic secondary mitral regurgitation**

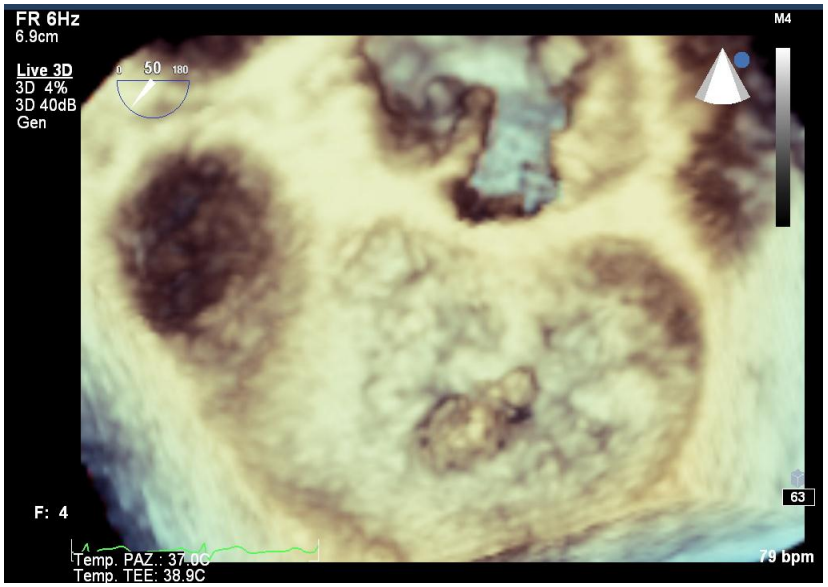
	Class [a]	Level [b]
Surgery is indicated in patients with severe MR[c] undergoing CABG, and LVEF >30%.	I	C
Surgery should be considered in patients with moderate MR undergoing CABG.[d]	IIa	C
Surgery should be considered in symptomatic patients with severe MR, LVEF <30%, option for revascularization, and evidence of viability.	IIa	C
Surgery may be considered in patients with severe MR, LVEF >30%, who remain symptomatic despite optimal medical management (including CRT if indicated) and have low comorbidity, when revascularization is not indicated.	IIb	C

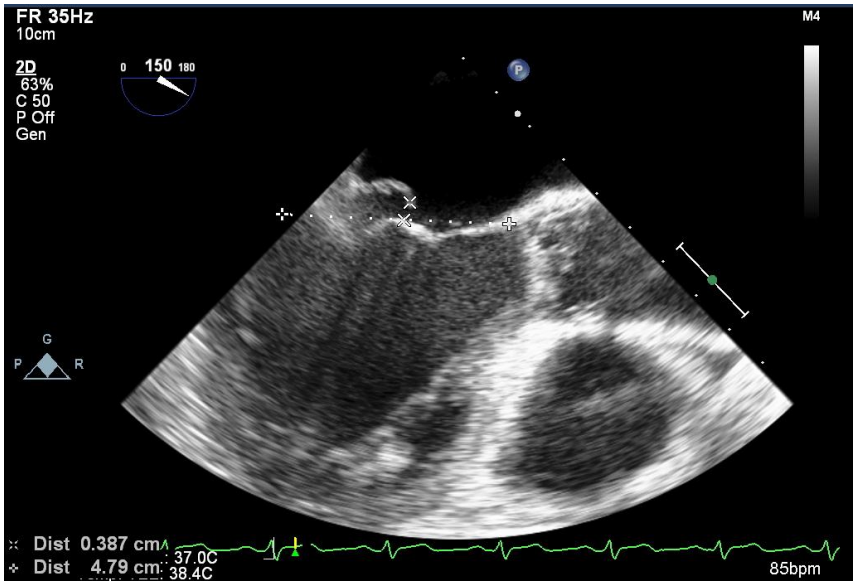
Surgery and MitraClip share the same reccomendation class and level of evidence

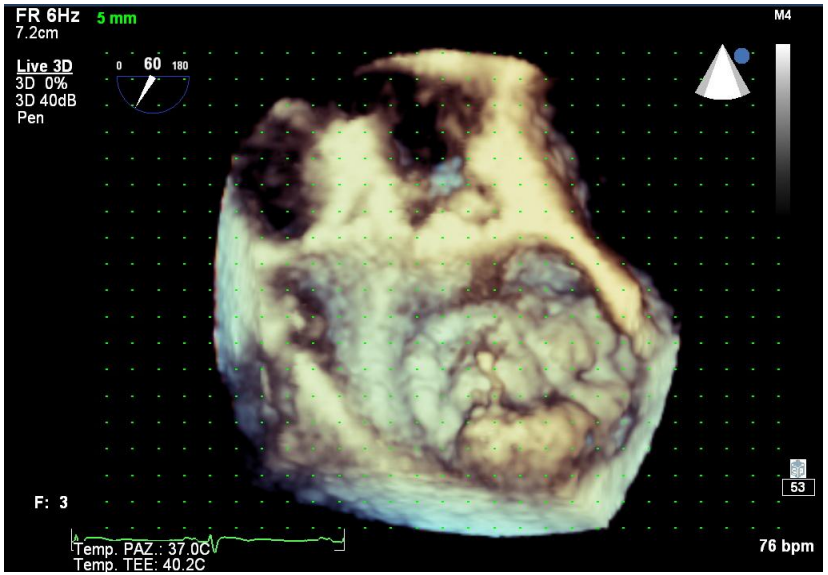
The percutaneous mitral clip procedure may be considered in patients with symptomatic severe secondary MR despite optimal medical therapy (including CRT if indicated), who fulfil the echo criteria of eligibility, are judged inoperable or at high surgical risk by a team of cardiologists and cardiac surgeons, and who have a life expectancy greater than 1 year (recommendation class IIb, level of evidence C).

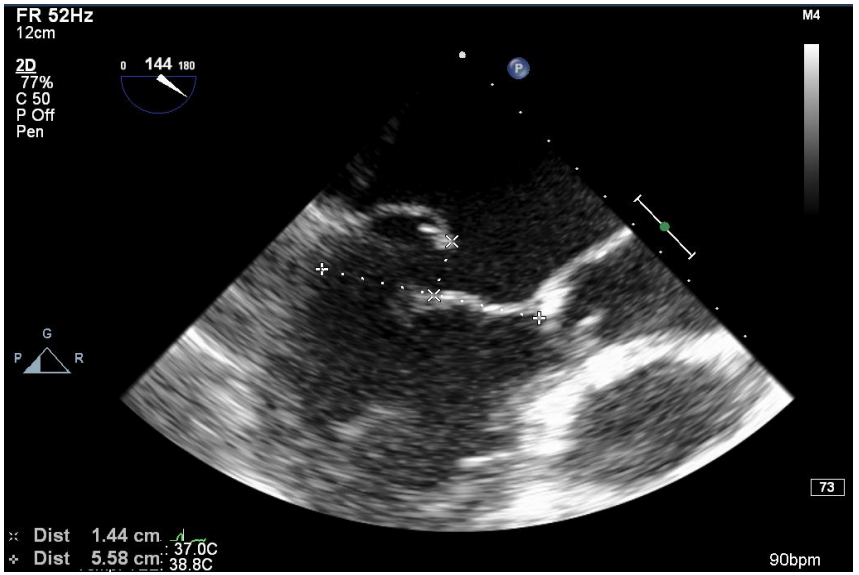
Mitraclip for DMR

- In experienced centers, DMR is treated with surgical repair at low risk, long term durability of repair is achieved in the majority of patients
  - 50% of Euro Heart Survey patients were not referred to surgery (Mirabel EHJ 2007)
  - Age and comorbidity increase the risk of surgery (STS database, 2010)
  - Surgery is not associated with improved QoL in most elderly patients (Maisano et al EJCTS 2009)


FR 6Hz
6.9cm
Live 3D
3D 4%
3D 40dB
Gen
M4
F: 4
Temp. PAZ.: 37.0C
Temp. TEE: 38.9C
79 bpm

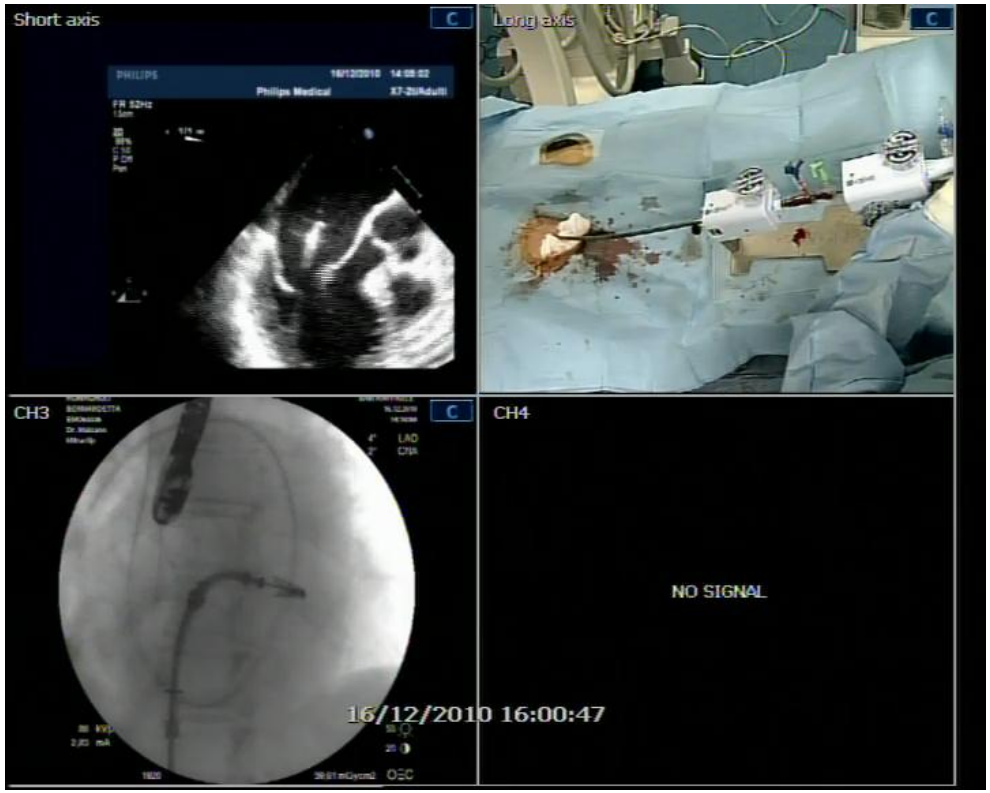

FR 35Hz
10cm
2D
63%
C 50
P Off
Gen
M4
Dist 0.387 cm
Dist 4.79 cm
37.0C
38.4C
85bpm


FR 6Hz
5 mm
7.2cm
Live 3D
3D 0%
3D 40dB
Pen
M4
F: 3
Temp. PAZ.: 37.0C
Temp. TEE: 40.2C
76 bpm


FR 52Hz
12cm
2D
77%
C 50
P Off
Pen
M4
Dist 1.44 cm
Dist 5.58 cm
37.0C
38.8C
90bpm

MitraClip for DMR

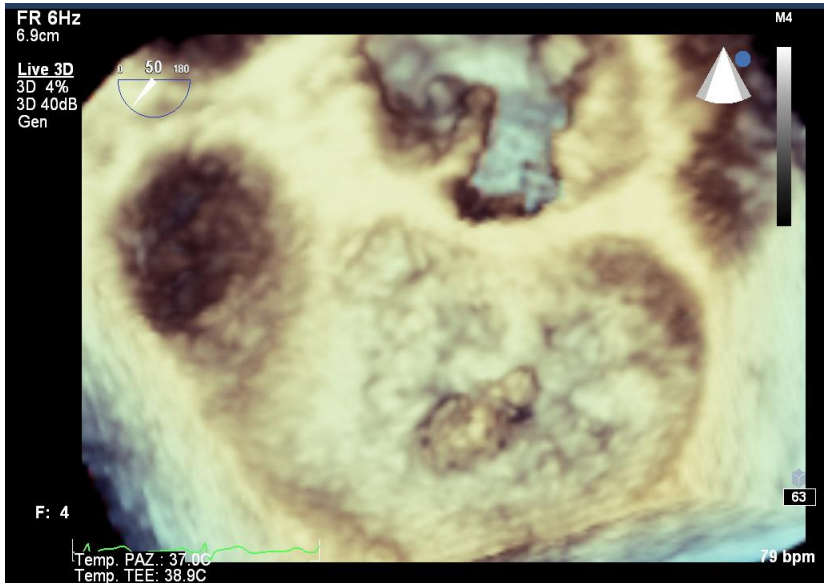
- 75 yo, female
- Obese
- Oxygen dependent



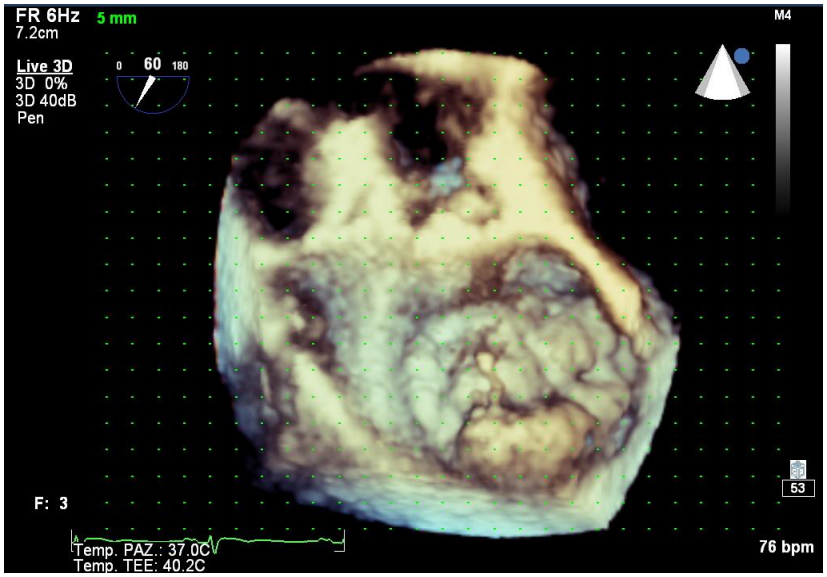
MitraClip for DMR

MR 4+ to trivial
Discharged home on day 2 post procedure

DMR options



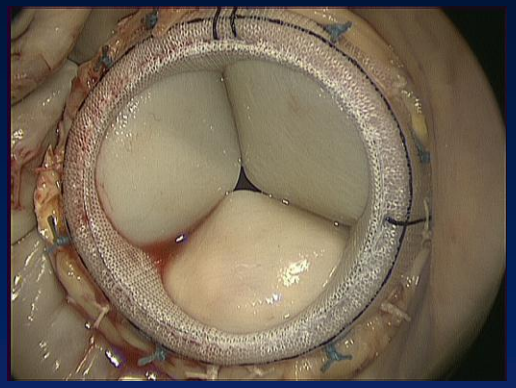
MitraClip



Neochord

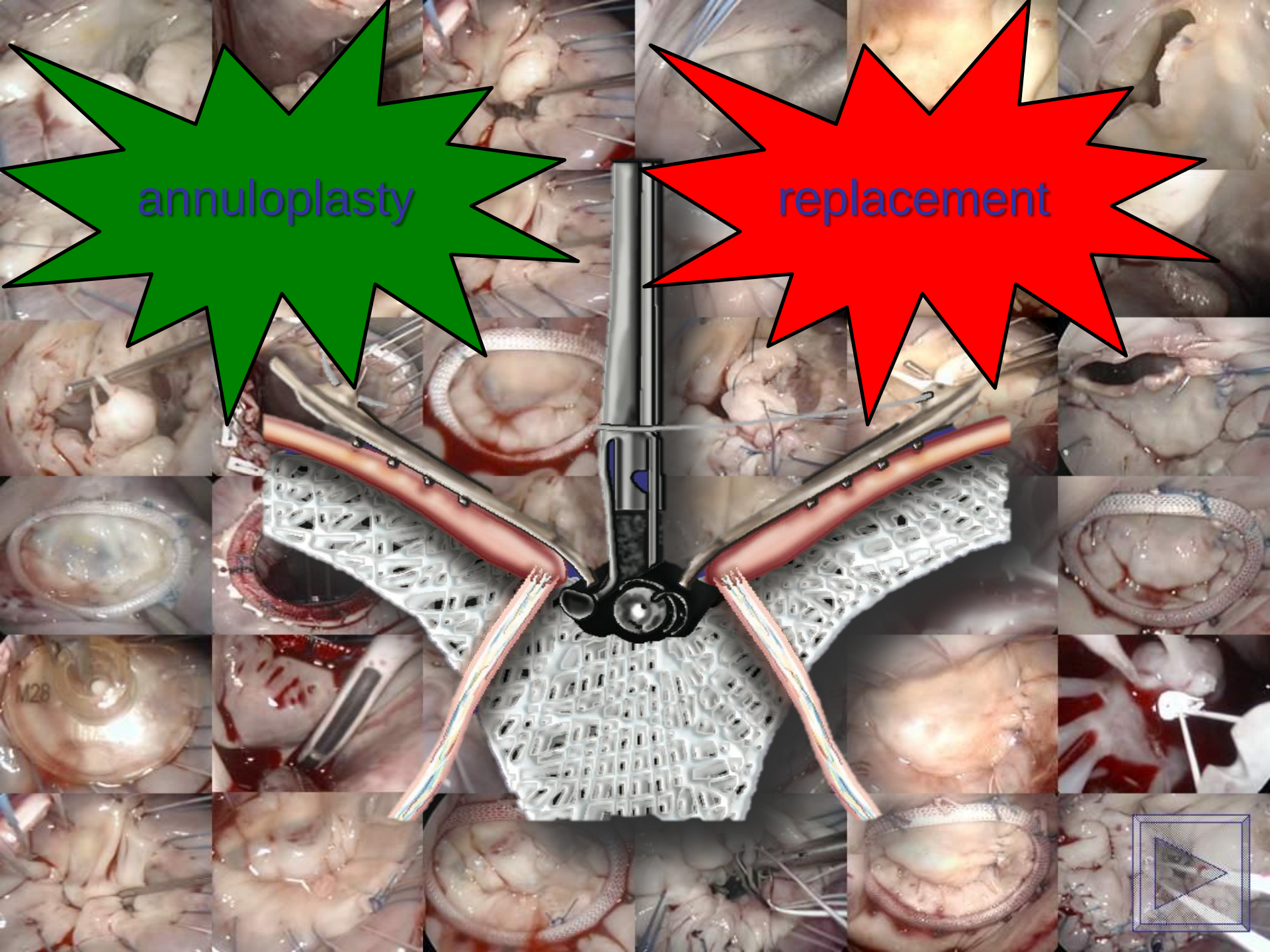
Surgery for mitral regurgitation

Repair or replacement

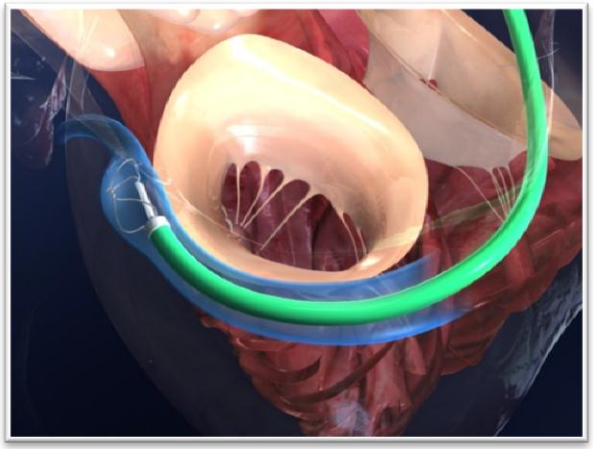


+

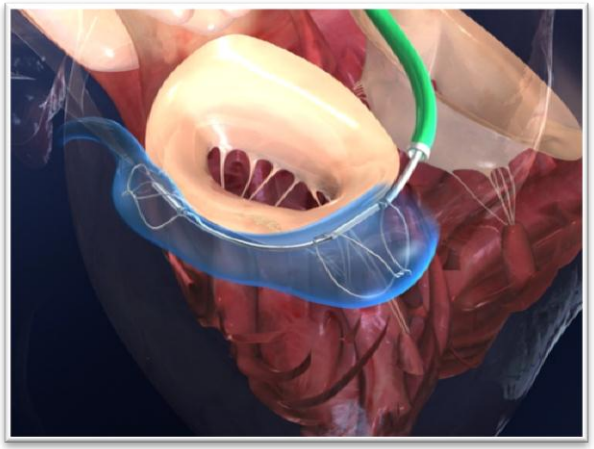
Atrial fibrillation ablation, left appendage closure, tricuspid valve treatment, (left ventricle)


annuloplasty
replacement

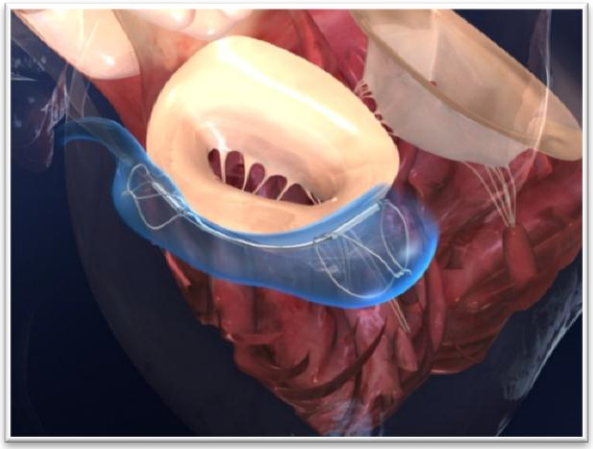
CARILLON® Implant Procedure



Patients undergo the CARILLON® procedure with fluoroscopic guidance in the cath lab



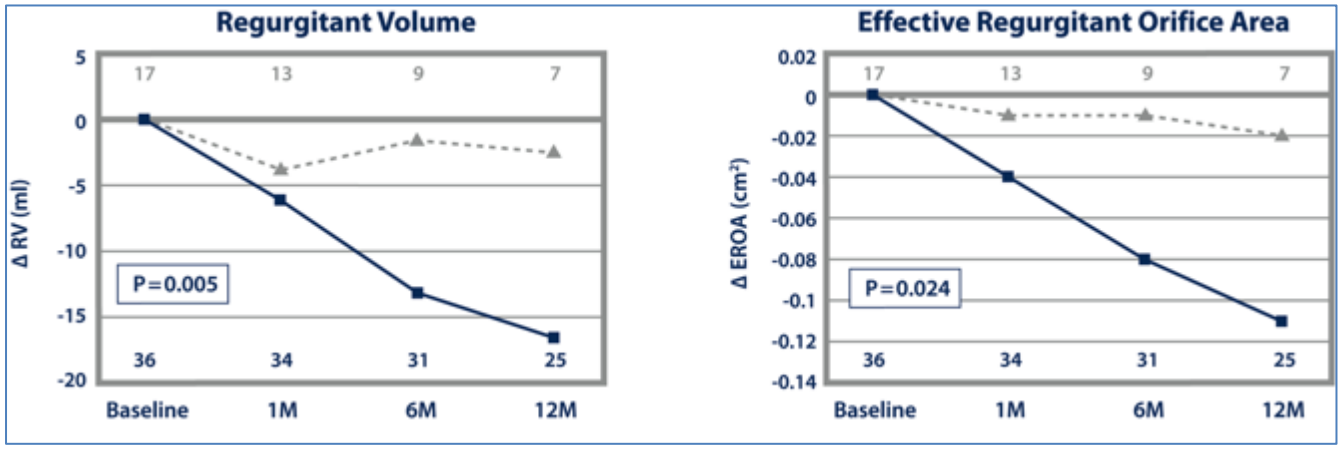
Peri-procedural assessment of MR reduction by echo imaging (TTE or TEE)



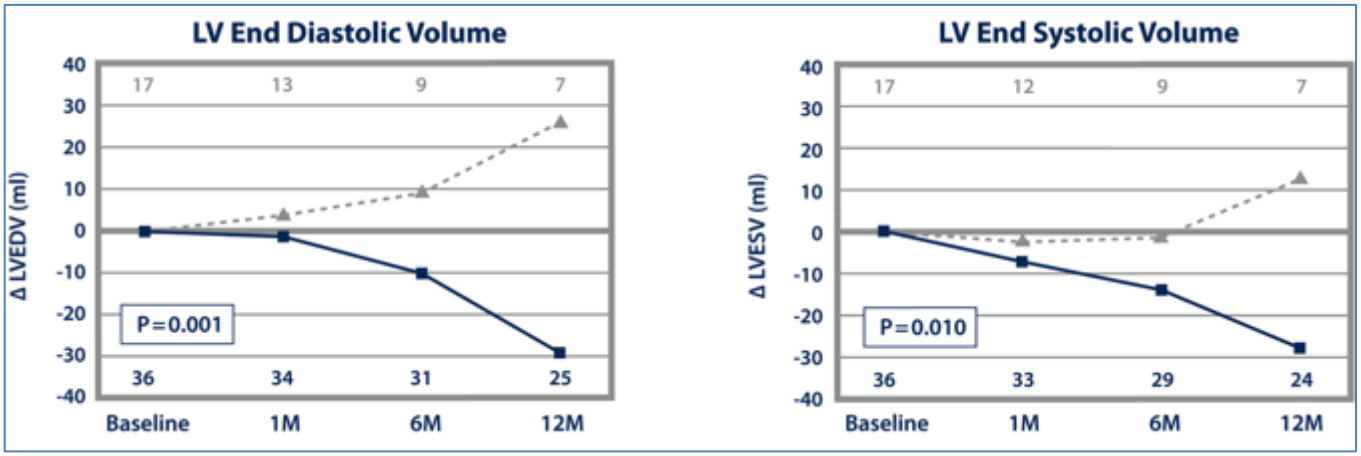
Patients with MR reduction and no safety concerns receive permanent implants

TITAN Trial

Reduction in Mitral Regurgitation



Reverse Remodeling

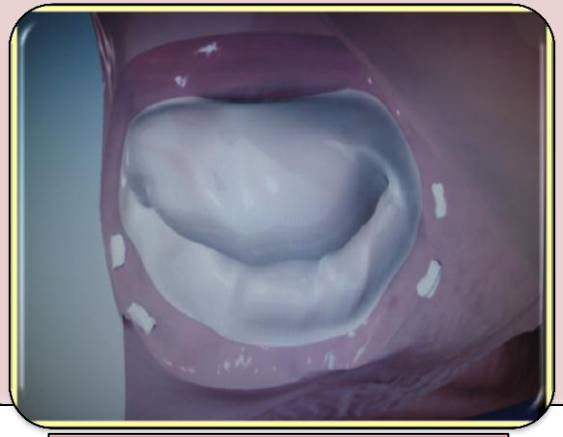


Between groups comparison of paired absolute differences from baseline

Hoppe UC, Siminiak T, Haude M, et.al., European Heart J 2010:31;160-1.

Direct annuloplasty

the only approach with a proven surgical background



Mitralign

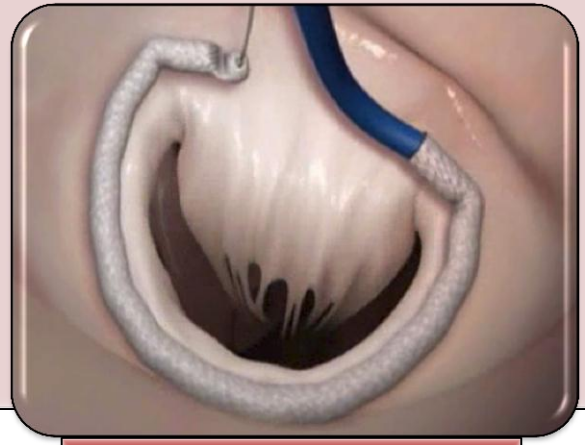
Bident

- Arterial access
- Transannular cinchin

GDS

Accucinch

- Arterial access
- Subannular cinching

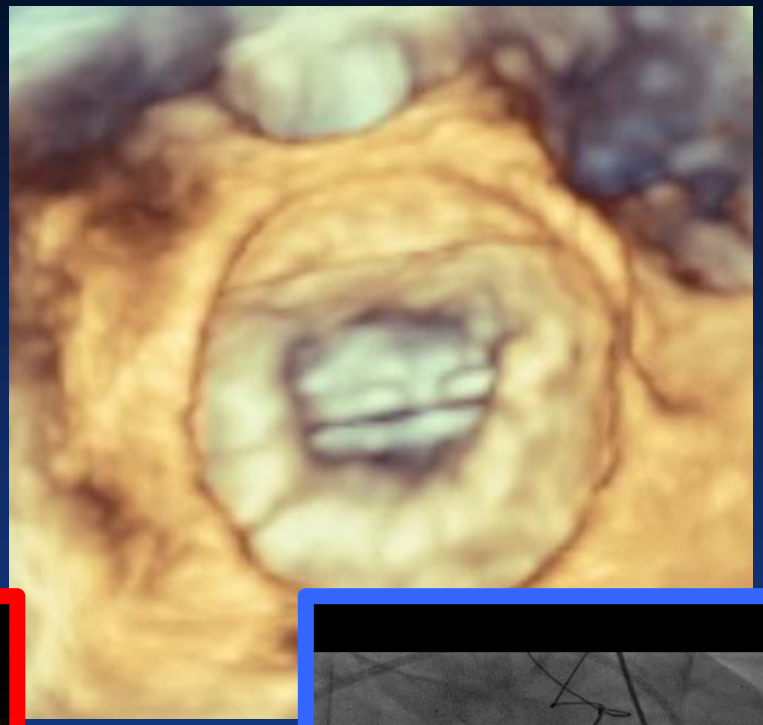


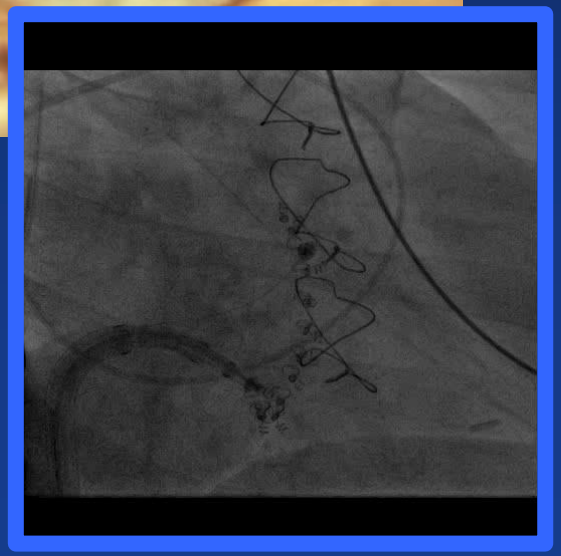
Valtech

Cardioband

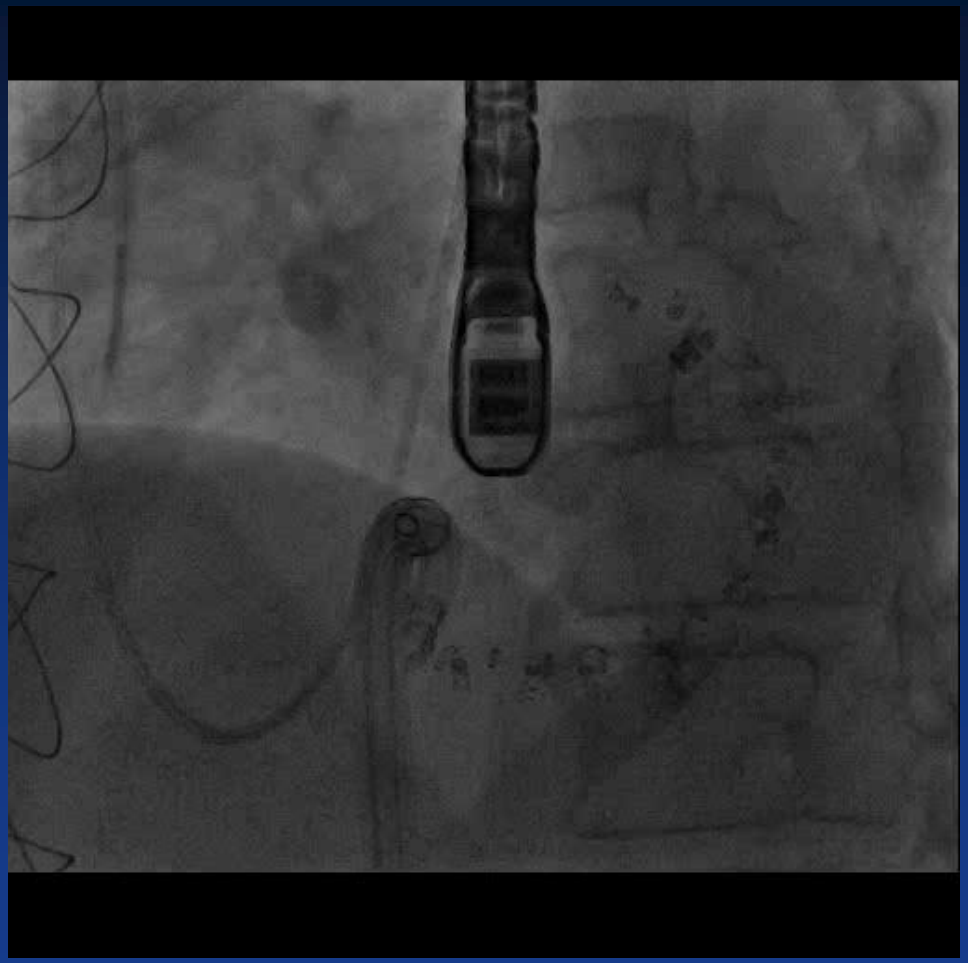
- Venous access
- Annular fixation

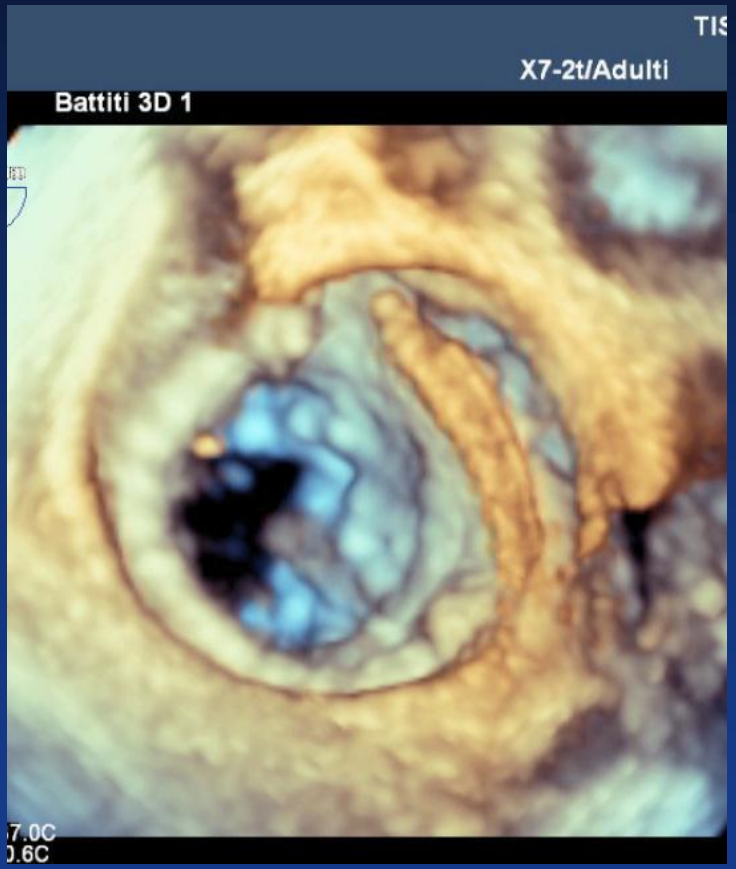
Find the difference….





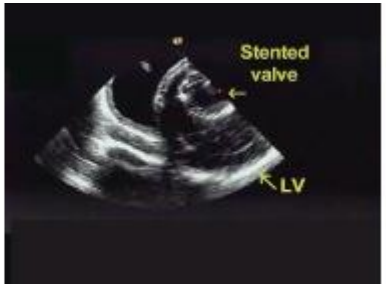
A surgical ring implanted percutaneously (FIM Cardioband implant)

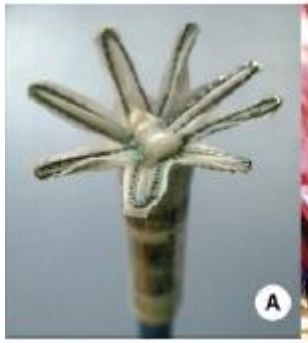


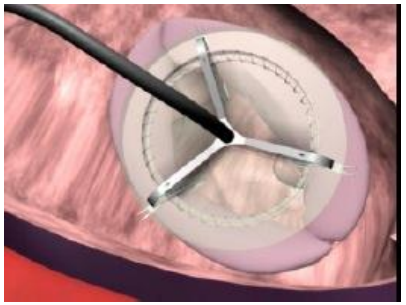


Transcatheter MVR

- Larger device
- Anchoring
- Asymmetric anatomy
- Interaction with the aortic valve and LVOT
- PVL more problematic
- Durability







CardiaQ

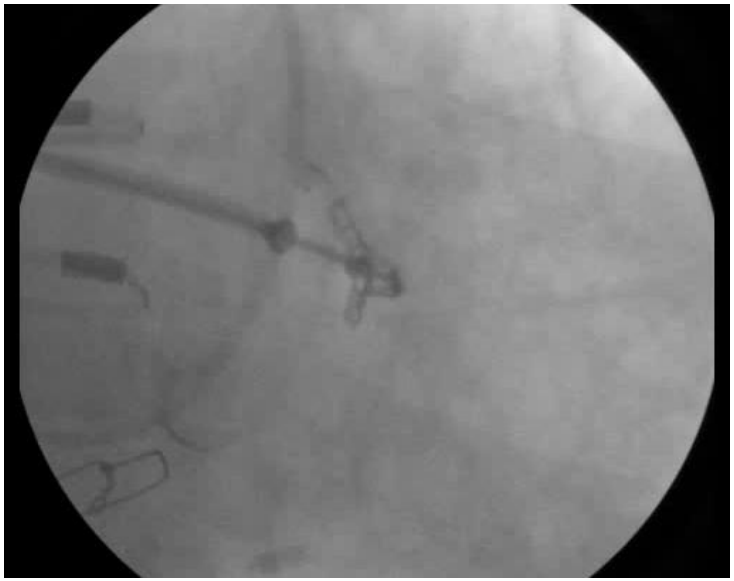

Image size: 512 x 512
View size: 760 x 596
WL: 87 WW: 118
101210-2010 (5 m , 1 d)
Coro ND — Coro ND
1
20
146
87
28
Zoom: 149% Angle: 0
Im: 1/601
Uncompressed
Position: HFS
12/11/10 4:32:39 AM
Made In OsiriX

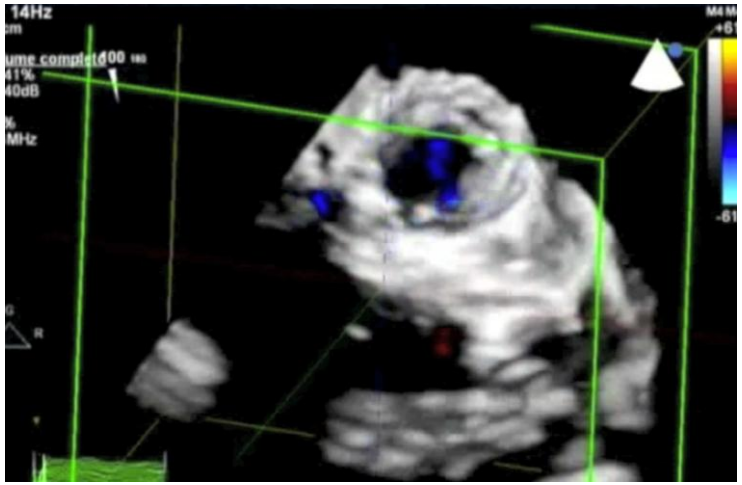
Recurrent MR/MS following mitral valve surgery

- Following mitral valve repair with ring annuloplasty
  - Secondary MR
  - Primary MR
- Following mitral valve replacement
  - Structural valve deterioration
    - Regurgitation
    - Stenosis
  - PV leak (prosthesis dehiscence

Recurrent MR following failed MVA

- Medical therapy
- REDO surgery
- Valve In Ring
- MitraClip





MitraClip vs Valve in ring

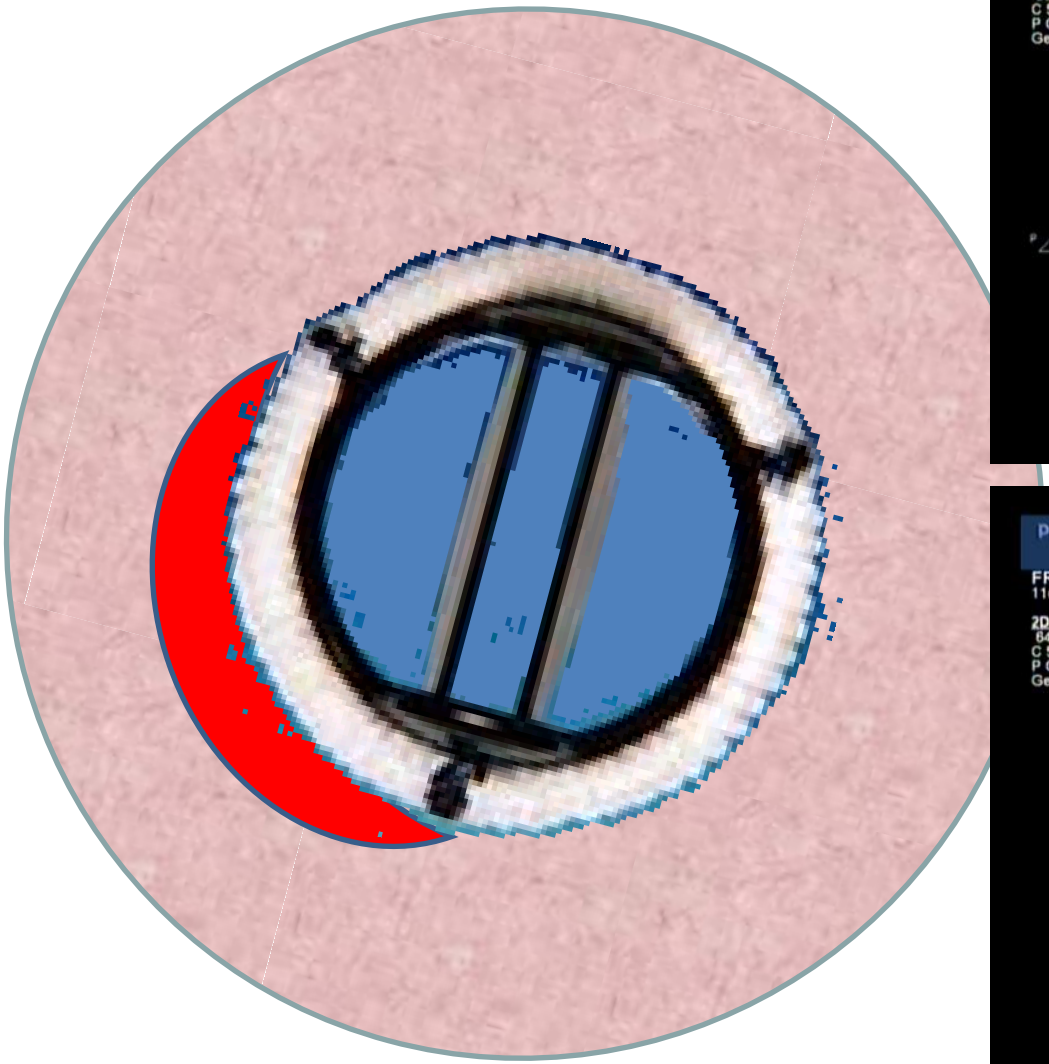
MitraClip

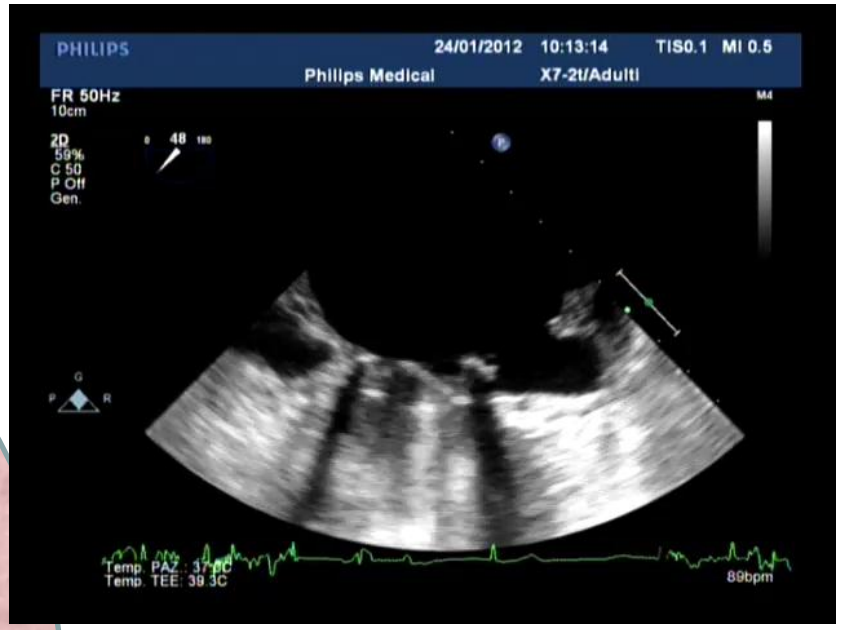
- Large ring (MVA>4cm2)
- Incomplete ring
- Ring dehiscence
- Anatomical eligibility for MC

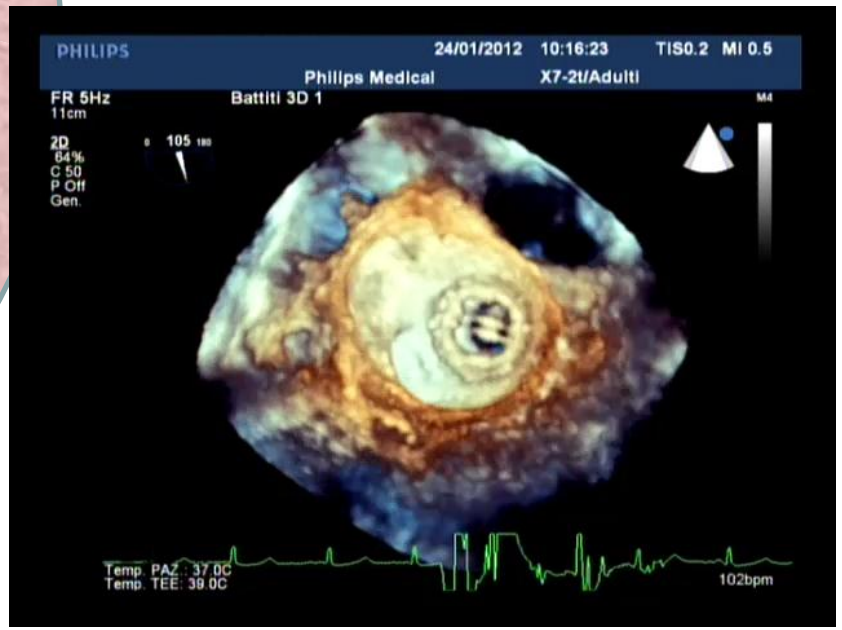
Valve in Ring

- Small ring
- Complete ring
- Flexible ring (??)
- No dehiscence
- Restricted leaflet motion

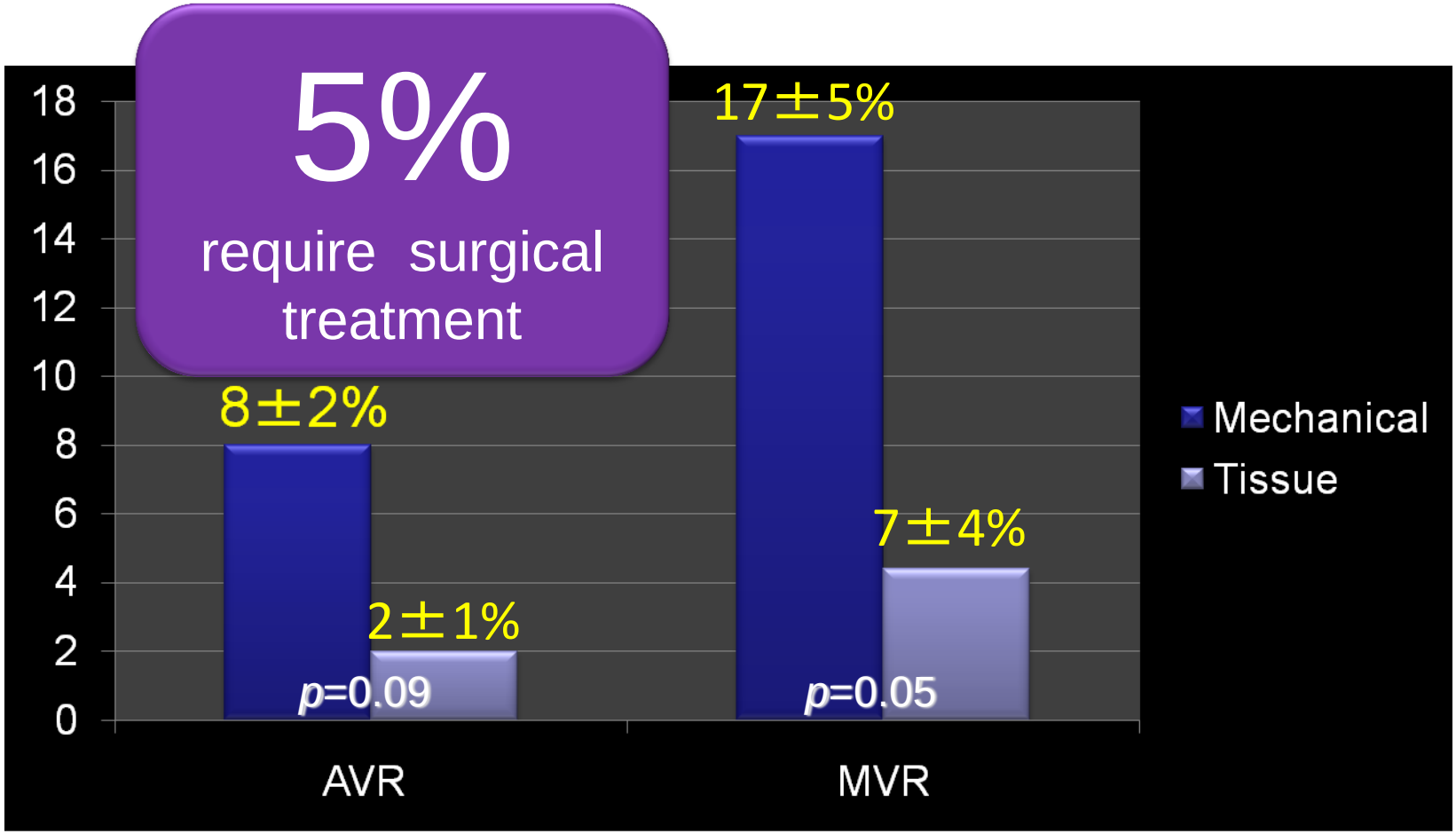
Perivalvular leak







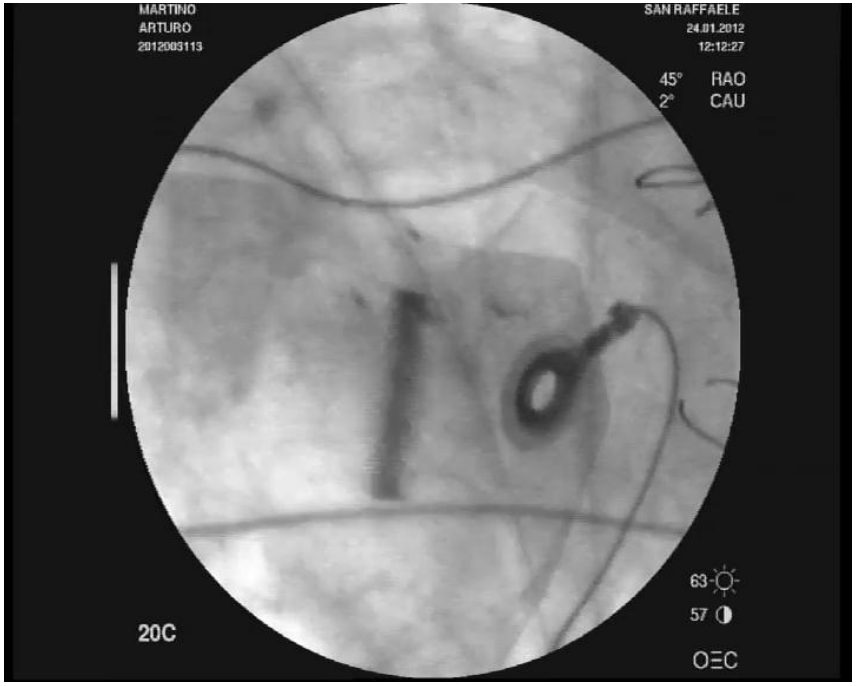
Incidence of PVL at 15 years in (VA trial)



Hammermeister et al, JACC 2000

PVL closure


PHILIPS
24/01/2012 12:04:27 TIS0.1 MI 0.4
Philips Medical X7-2t/Adulti
FR 5Hz
8.0cm
Battiti 3D 1
2D
67%
C 50
P Off
Pen.
30
Temp. PAZ: 37.0C
Temp. TEE: 38.9C
106bpm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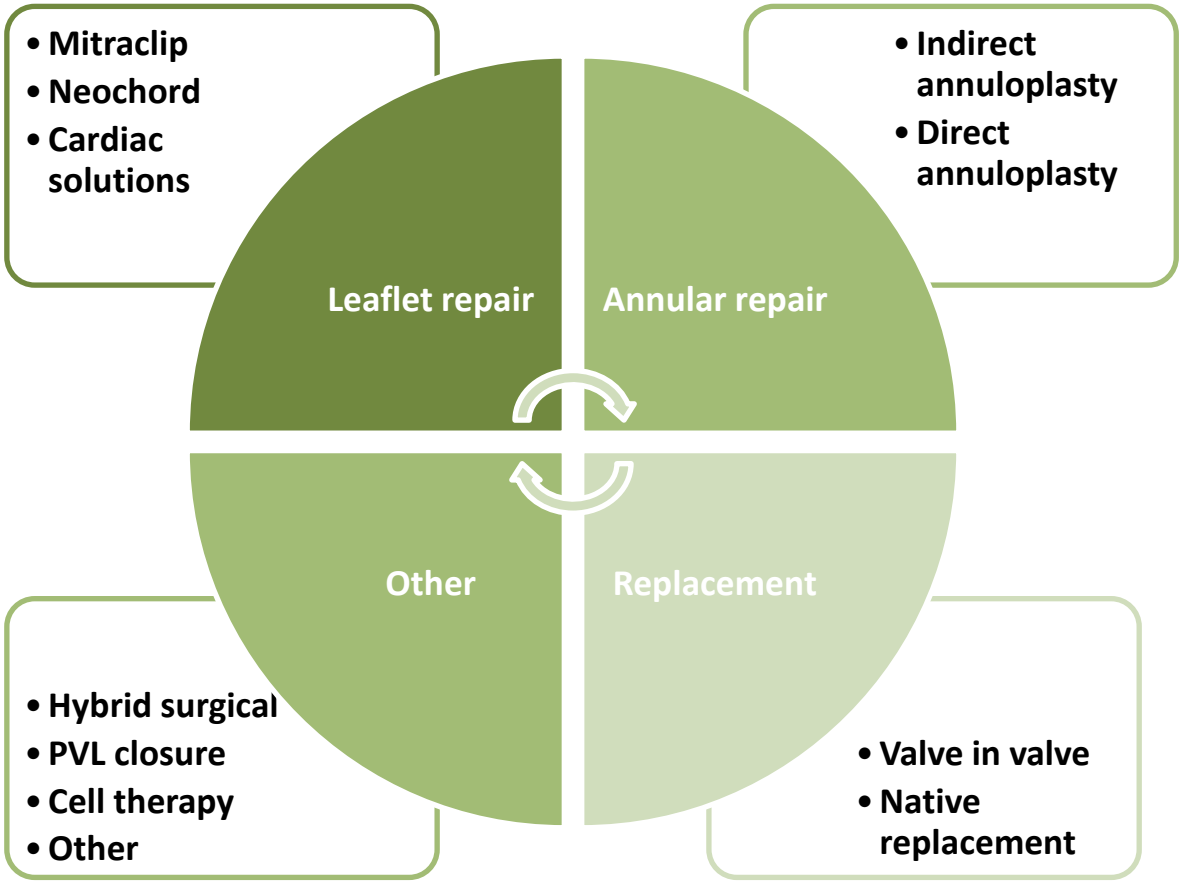
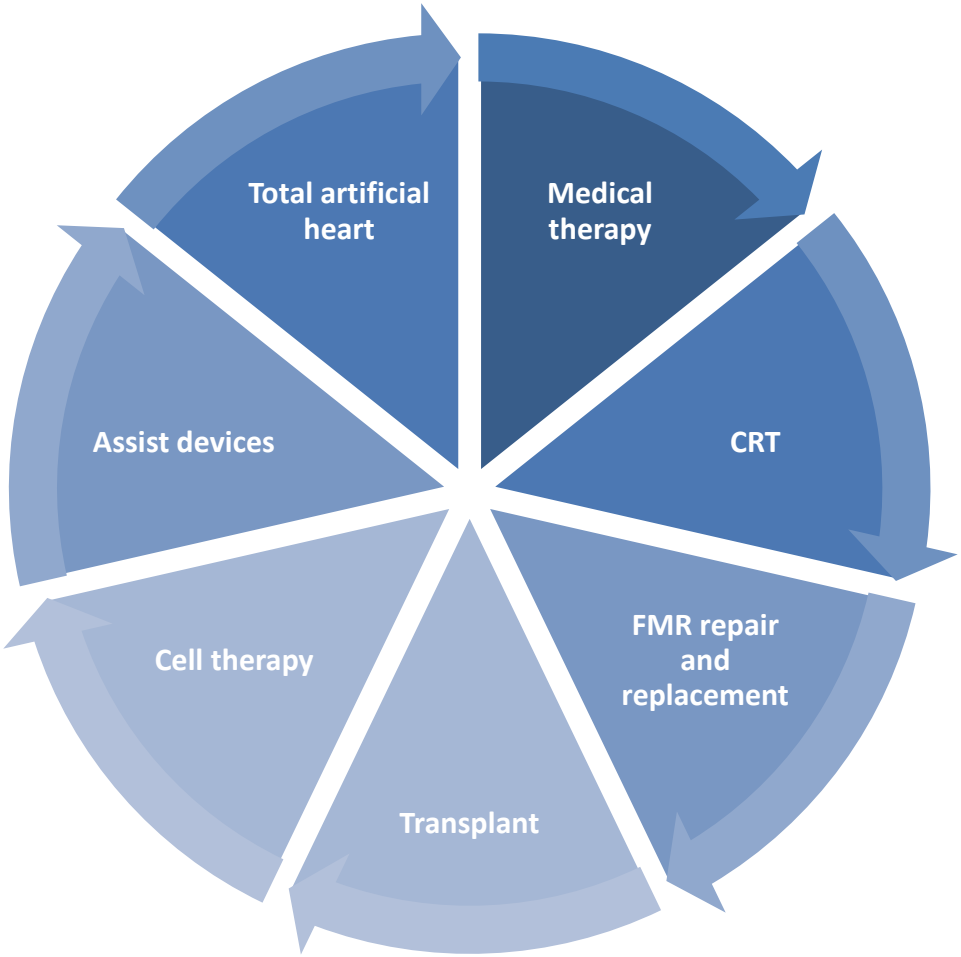
Transcatheter treatment of FMR

a tailored approach



Modern management of HF

multidisciplinary team approach



Percutaneous MR devices

- Presence of MR is one of the most powerful prognostic factors increasing mortality and health care expenses in Heart Failure patients
- Non-surgical treatments of MR are emerging as a viable and effective method to improve survival and contain costs
- MitraClip is the most common therapy today, but more options will become available in the next future including “surgical like” percutaneous annuloplasty and replacement