

UPDATE: landscape of transcatheter structural interventions



Francesco Maisano, MD FESC

University Heart Center Zürich

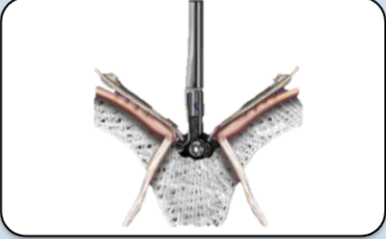


UniversityHospital
Zurich

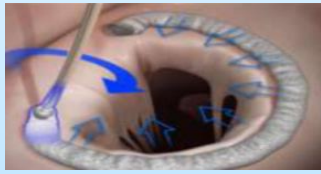
COI

- Consultant for Abbott vascular, ValtechCardio, Medtronic, Edwards Lifesciences, St Jude, Xeltis
- Grants from Abbott, St Jude Medical, Bioventrix, Direct Flow
- Cofounder of 4Tech, Affix, TSP
- Royalties from Edwards Lifesciences

The expanding portfolio of transcatheter mitral repair and replacement

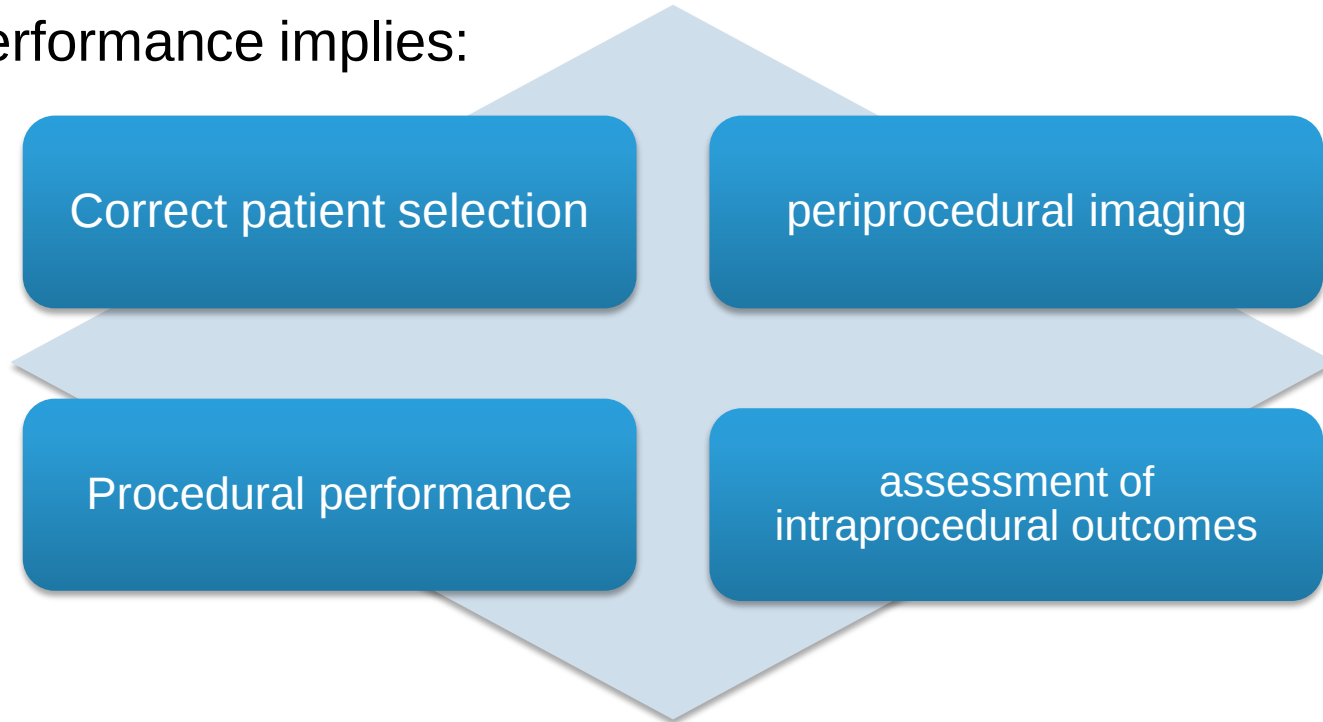
		
MitraClip Neochord Harpoon Chordart	Cardioband Mitralign Carillon Millipede	Tendyne Neovasc CardiaQ Twelve

CE marked therapies

Company	Abbott	NeoChord	CardiacDim	ValTech	Mitralign
Name	MitraClip	DS1000	Carillon	CardioBand TA and TF	Bident and Tricuspid
					
Description	Alfieri technique	NeoChordal implant from the TA approach	Coronary sinus cinching	Surgical ring implanted percutaneously	Plication device
Strengths	Minimal invasiveness	Strong surgical background	simplicity	- Strong surgical background - Atrial delivery	simplicity
Weaknesses	Lack of annuloplasty	TA approach	Limited efficacy	- Complexity - imaging	Efficacy limited in mitral position
Status	>35000	200-300 pts	350-400 pts	>100 - CE mark	>80-100 - CE pending
CEO / Loc.	Miles White / Redwood City, CA	David Chung / Eden Prairie, MN	Rick Stewart / Kirkland, WA	Amir Gross / Or Yehuda, Israel	Rick Geoffrion / Salem, NH

MitraClip is not a palliative therapy... when performed properly,

Proper performance implies:



The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

APRIL 14, 2011

VOL. 364 NO. 15

Percutaneous Repair or Surgery for Mitral Regurgitation

Ted Feldman, M.D., Elyse Foster, M.D., Donald G. Glower, M.D., Saibal Kar, M.D., Michael J. Rinaldi, M.D., Peter S. Fail, M.D., Richard W. Smalling, M.D., Ph.D., Robert Siegel, M.D., Geoffrey A. Rose, M.D., Eric Engerson, M.D., Catalin Lughin, M.D., Alfredo Trento, M.D., Eric R. Skipper, M.D., Tommy Fudge, M.D., George V. Letsou, M.D., Joseph M. Massaro, Ph.D., and Laura Mauri, M.D., for the EVEREST II Investigators*

BACKGROUND

Mitral-valve repair can be accomplished with an investigational procedure that involves the percutaneous implantation of a clip that grasps and approximates the edges of the mitral leaflets at the origin of the regurgitant jet.

METHODS

We randomly assigned 279 patients with moderately severe or severe (grade 3+ or 4+) mitral regurgitation in a 2:1 ratio to undergo either percutaneous repair or conventional surgery for repair or replacement of the mitral valve. The primary composite end point for efficacy was freedom from death, from surgery for mitral-valve dysfunction, and from grade 3+ or 4+ mitral regurgitation at 12 months. The primary safety end point was a composite of major adverse events within 30 days.

RESULTS

At 12 months, the rates of the primary end point for efficacy were 55% in the percutaneous-repair group and 73% in the surgery group ($P=0.007$). The respective rates of the components of the primary end point were as follows: death, 6% in each group; surgery for mitral-valve dysfunction, 20% versus 2%; and grade 3+ or 4+ mitral regurgitation, 21% versus 20%. Major adverse events occurred in 15% of patients in the percutaneous-repair group and 48% of patients in the surgery group at 30 days ($P<0.001$). At 12 months, both groups had improved left ventricular size, New York Heart Association functional class, and quality-of-life measures, as compared with baseline.

CONCLUSIONS

Although percutaneous repair was less effective at reducing mitral regurgitation than conventional surgery, the procedure was associated with superior safety and similar improvements in clinical outcomes. (Funded by Abbott Vascular; EVEREST II ClinicalTrials.gov number, NCT00209274.)

Feldman T et al., J Am Coll Cardiol 2009;54:686–94

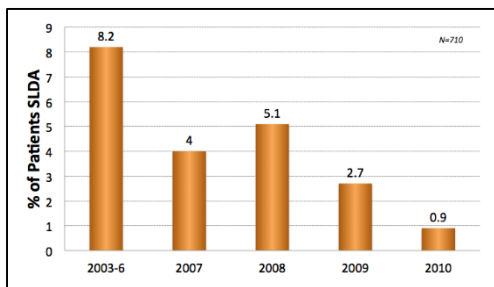
CONCLUSIONS

Although percutaneous repair was less effective at reducing mitral regurgitation than conventional surgery, the procedure was associated with superior safety and similar improvements in clinical outcomes.

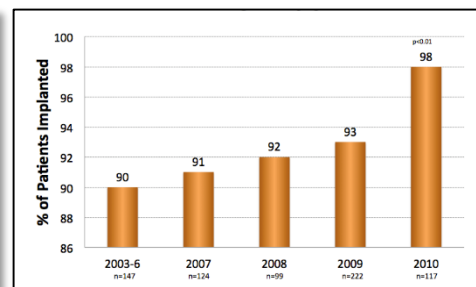
No 3D echo
No previous experience
Learning curve

Flail width
< 15mm

Single Leaflet Attachment

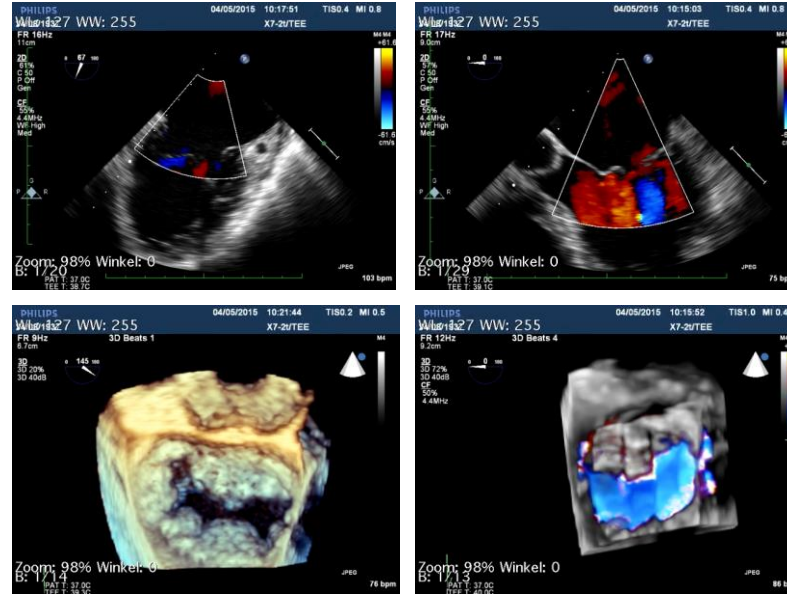


MitraClip Implant Rate



UniversityHospital
Zurich

75 year old man, severe idiopathic FMR , EF 35%
deep indentation between P1 and P2

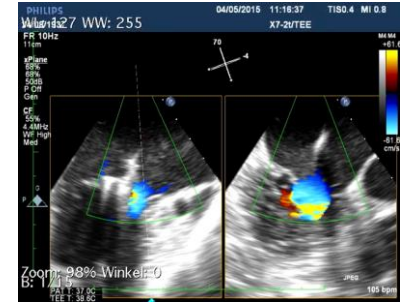
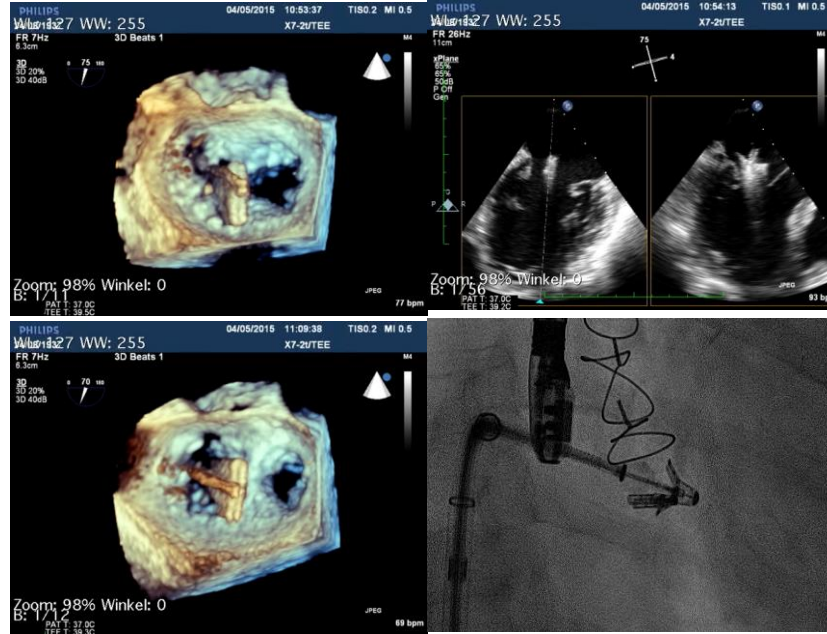


Two converging clips technique

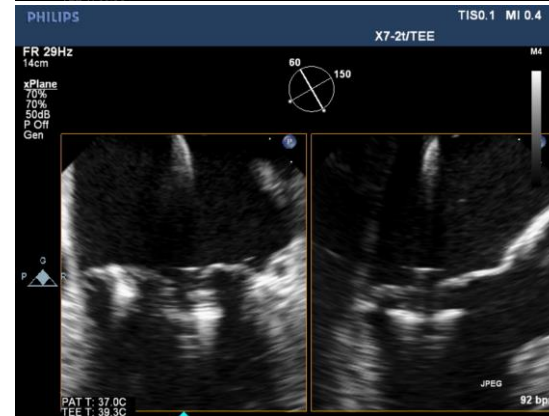
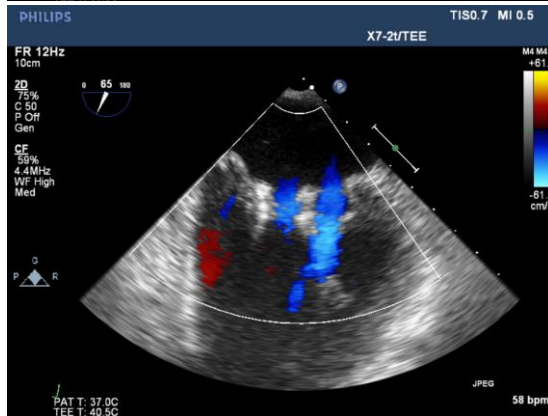
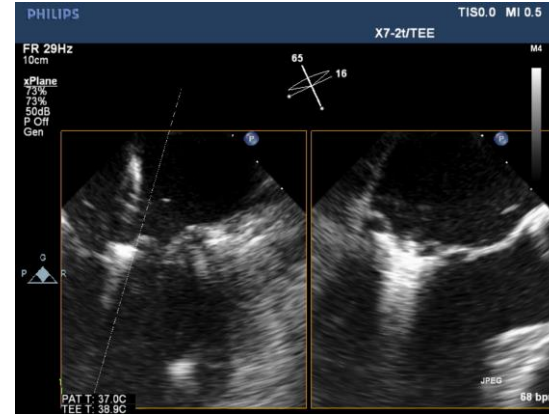
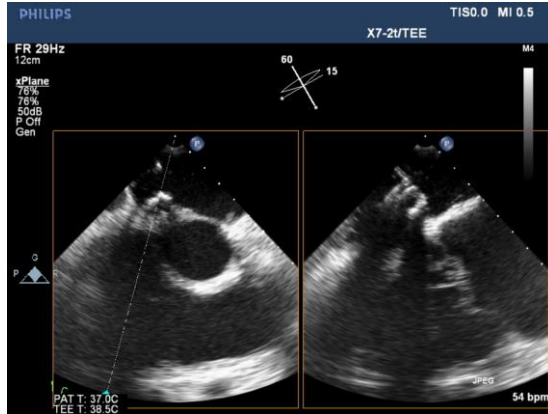
First



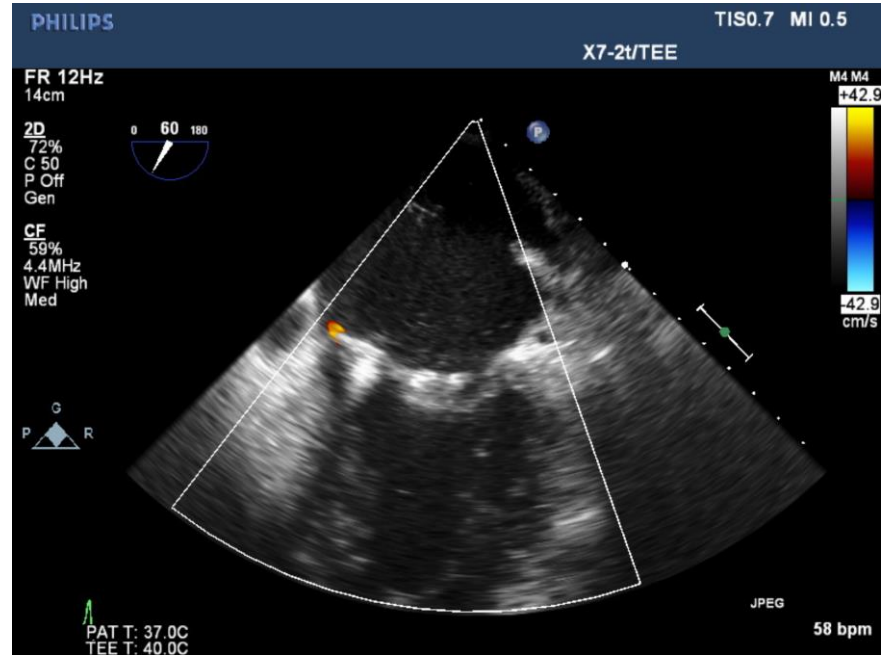
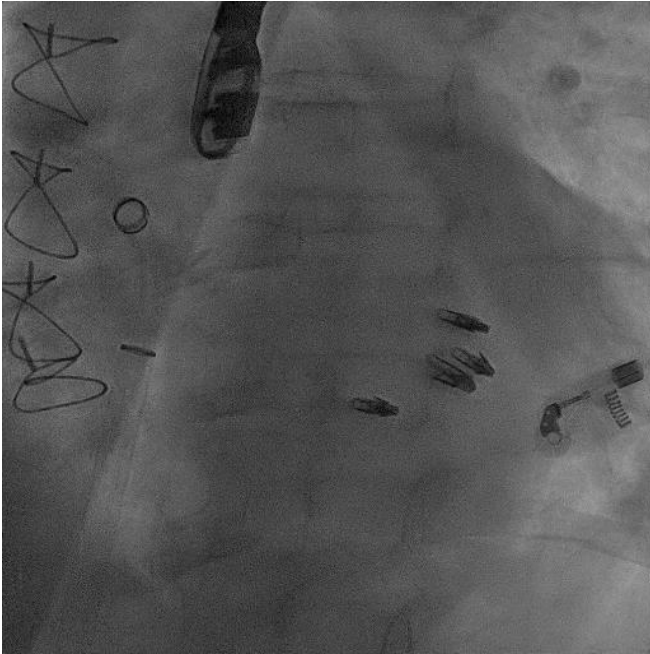
Second



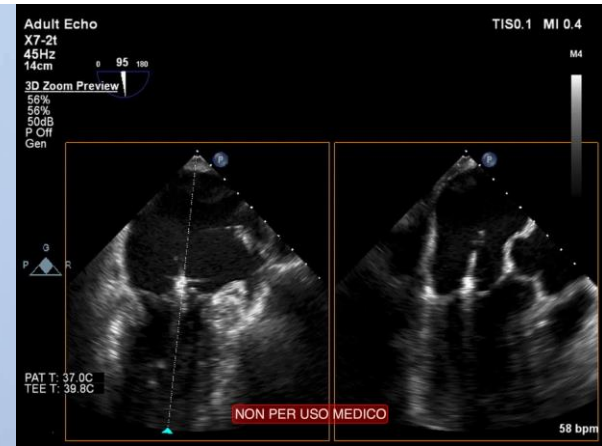
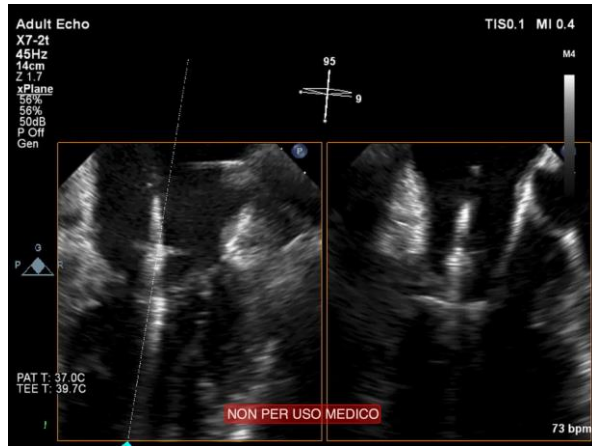
Atypical Echo projections, multiple clip implant



Final result, after 4 Clips



New system: MitraClip NT active grippers improve leaflet grasping in DMR



Modern MitraClip therapy

- With experience, anatomical indications are becoming wider
- Palliative approach should be acceptable only in inoperable patients
- In treating high risk but operable patients the quality bar needs to be raised

Neochordae therapies

Neochord

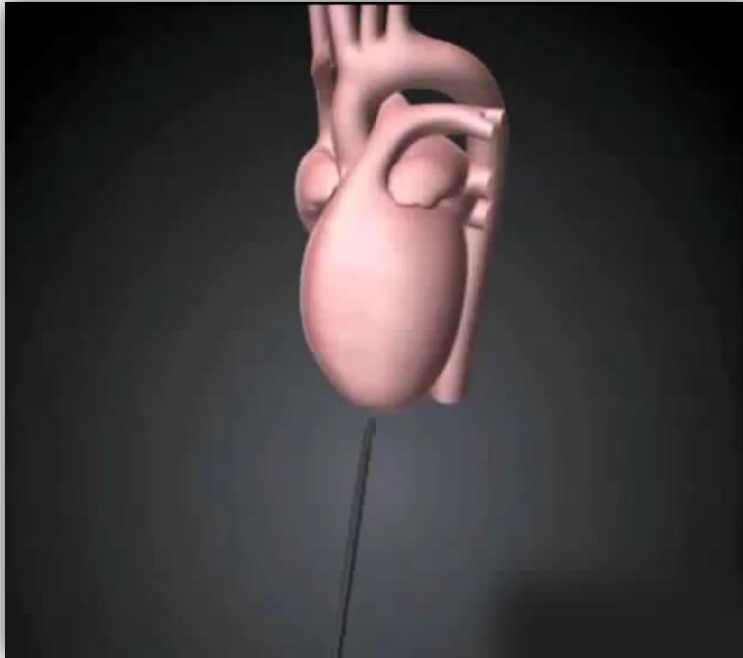
Harpoon

Chordart



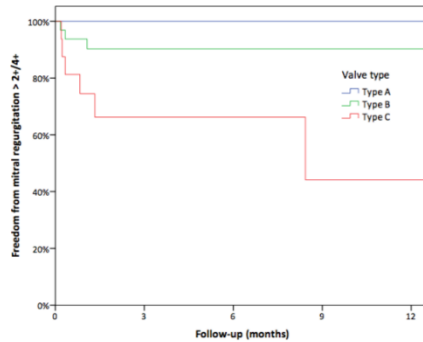
Neochord

Slowly increasing the experience, durability improved



Neochord

Freedom from MR >2+/4+ according to MV anatomical type



Department of Cardiac, Thoracic and Vascular Sciences, University of Padua – Italy



TOP-MINI Global Experience



TACT TRIAL 30 Pts

TACT Registry Sites	# Pts	Non-Registry Sites	# Pts
VILNIUS, LITHUANIA	48	BOLOGNA, ITALY	12
BORDEAUX, FRANCE	12	MILAN MONZINO, ITALY	9
PADOVA, ITALY	63	DUISBURG, GERMANY	8
HAMBURG UKE, GERMANY	6	ANTALYA, TURKEY	7
MILAN SAN RAFFAELE, ITALY	3	GOETTINGEN, GERMANY	8
HAMBURG St G., GERMANY	3	ANKARA, TURKEY	5
DRESDEN, GERMANY	1	COLOGNE, GERMANY	3
BASEL, SWITZERLAND	1	AMSTERDAM, NETH.	2
		TRIER, GERMANY	4
		TORINO, ITALY	3
		PALERMO, ITALY	2
		VIENNA, AUSTRIA	1
		LEIPZIG, GERMANY	1
		LYON, FRANCE	1
		TURKU, FINLAND	4
		BRESCIA, ITALY	1
		BRUSSELS, BELGIUM	1
		TOTAL	70



Total Clinical Experience: 237 cases

Type A: Isolated P2 prolapse/flail

Courtesy of R. Colli, Padova

Type B: Multisegment prolapse/flail (P1-P2,P2-P3 or P1-P2-P3)

Type C: Anterior Prolapse/flail, Paracommissural, Annular and Leaflet Calcifications

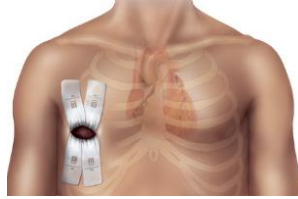


UniversityHospital
Zurich

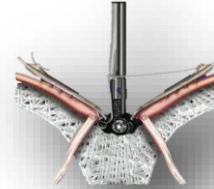
anatomy

simple

complex



Invasivity vs performance where is the sweet spot?



low risk

intermediate

high risk

clinical presentation



University Hospital
Zurich

DIRECT AND INDIRECT ANNULOPLASTY WITH CLINICAL EXPERIENCE



CARILLON

• ABOUT 500 PTS

CARDIOBAND

• ABOUT 100 PTS

MITRALIGN

• ABOUT 80 PTS

ARTO

• ABOUT 20 PTS

VALCARE

• FIM TA

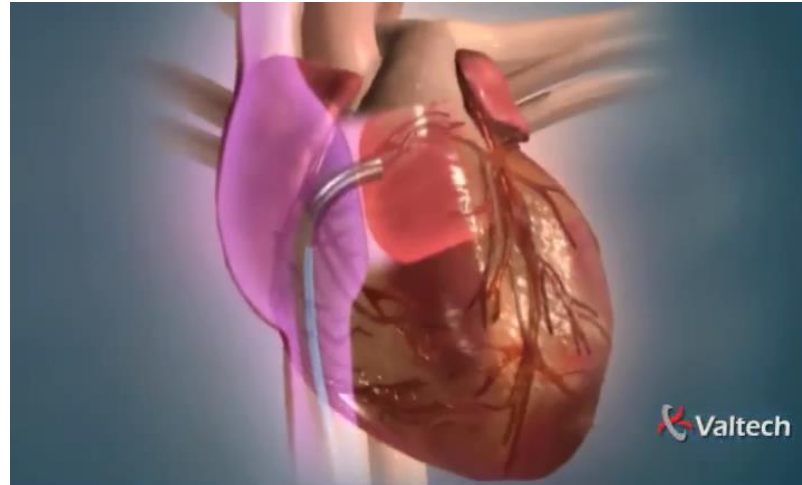
MILLIPEDE

• FIM SURGICAL

Direct Annuloplasty by Cardioband

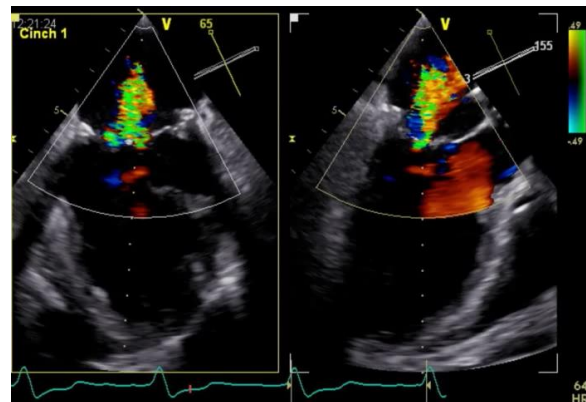
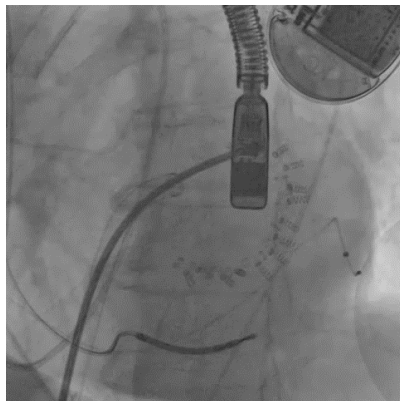
**Trans-femoral venous access
(transeptal) – best for safety**

- **Supraannular fixation** like in surgery
- **Significant Reduction of Annular dimensions** – device enables reduction of up to size 28 surgical ring
- Preserves the native anatomy – **keeps future options open**

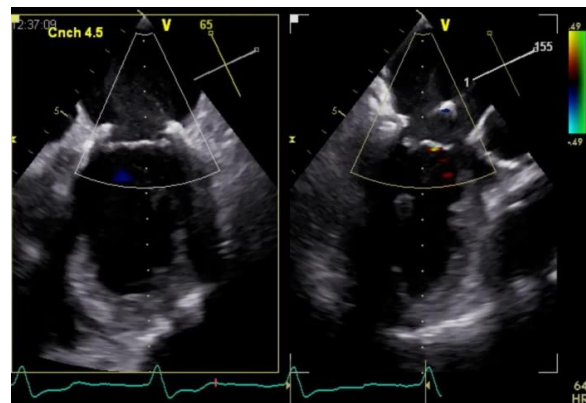
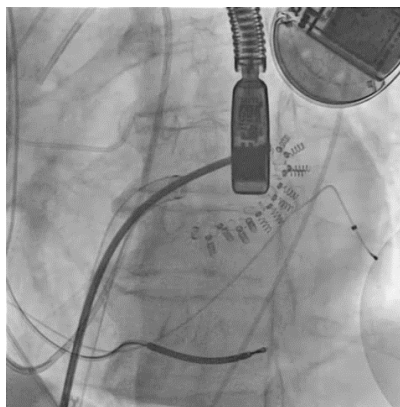


dynamic adjustment of annular reduction

Baseline



Final size Post Adjustment

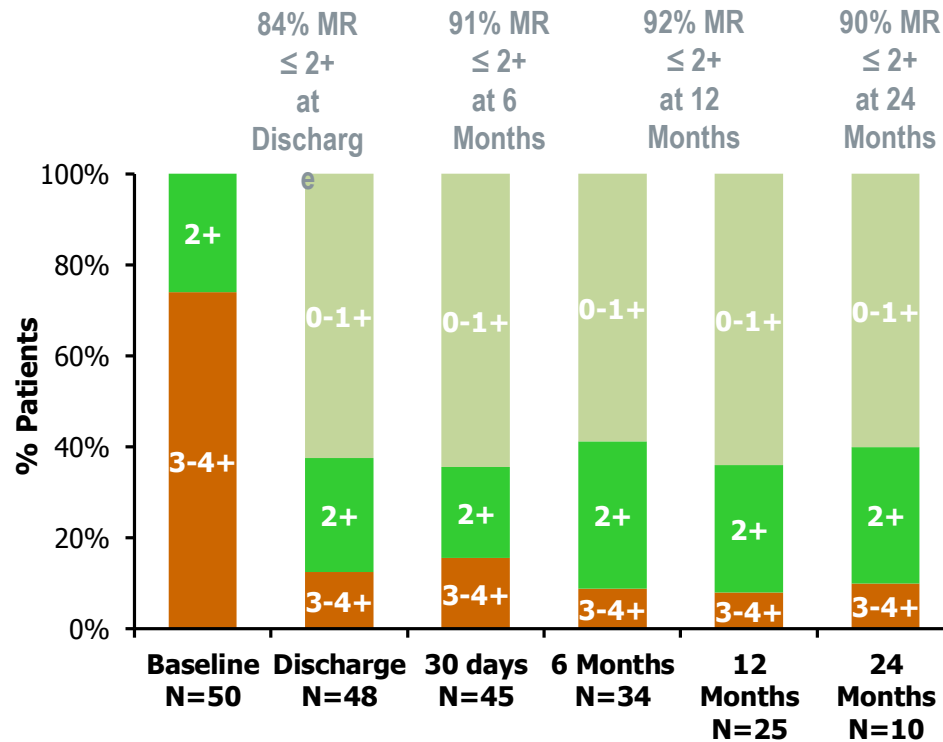


30 Day Events*	Patients Experiencing Event, # (%)
Death	2 (4%)
Hemorrhagic Stroke**	1 (2%)
Need for elective Mitral Operation**	1 (2%)
Ischemic attack	1 (2%)
Major Bleeding Complications	1 (2%)
Renal Failure	2 (4%)
Myocardial Infarction	0 (0%)
Respiratory Failure	0 (0%)
Cardiac Tamponade	1 (2%)

* VARC Guidelines (European Heart Journal, 2012, 33:2403-2414)

** Part of the Death case

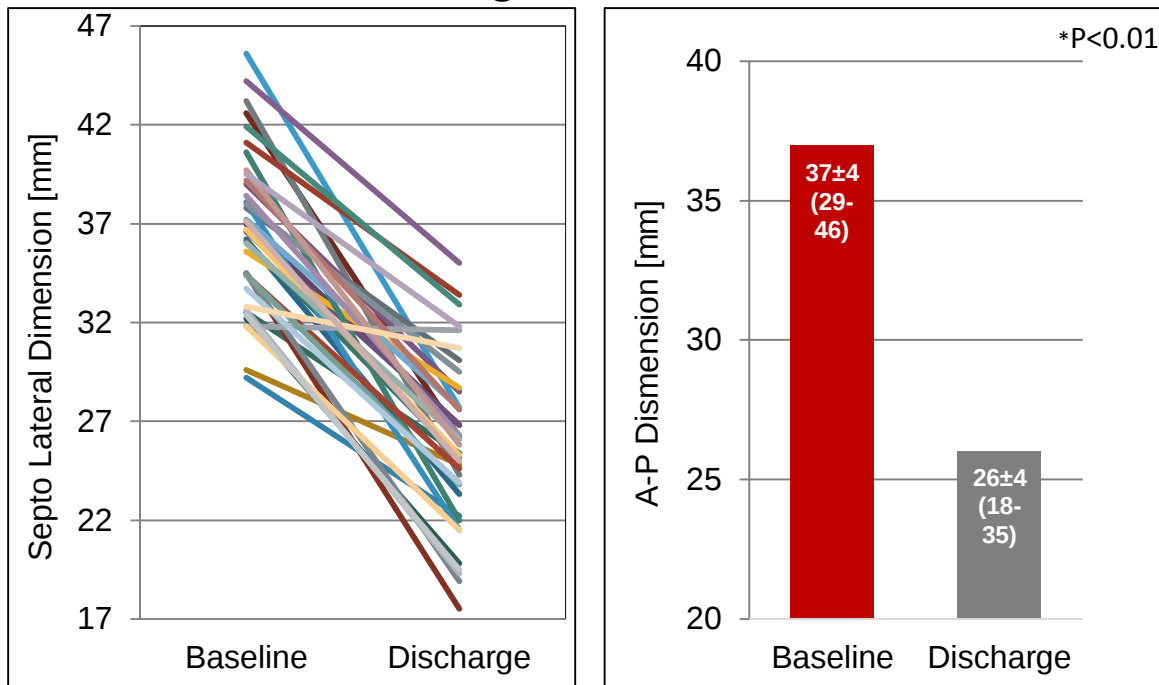
One additional death case per ITT - compassionate



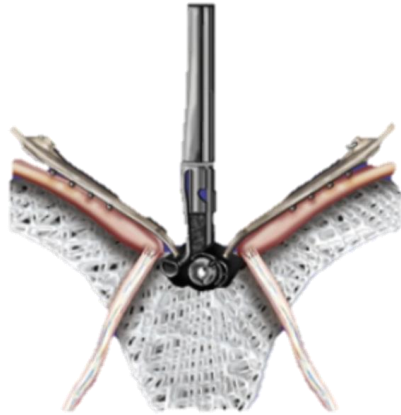
*Dr. Paul Grayburn –
Baylor University

Annular Reconstruction by Significant Reduction in Septo

30% average reduction in A-P

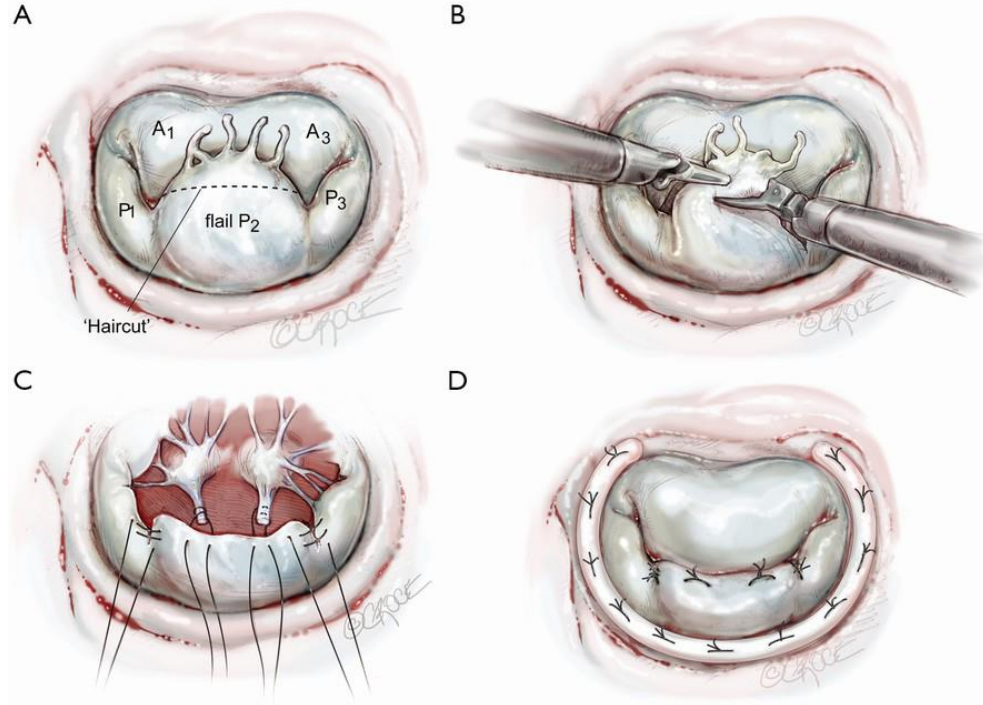


Combination of MitraClip and Annuloplasty



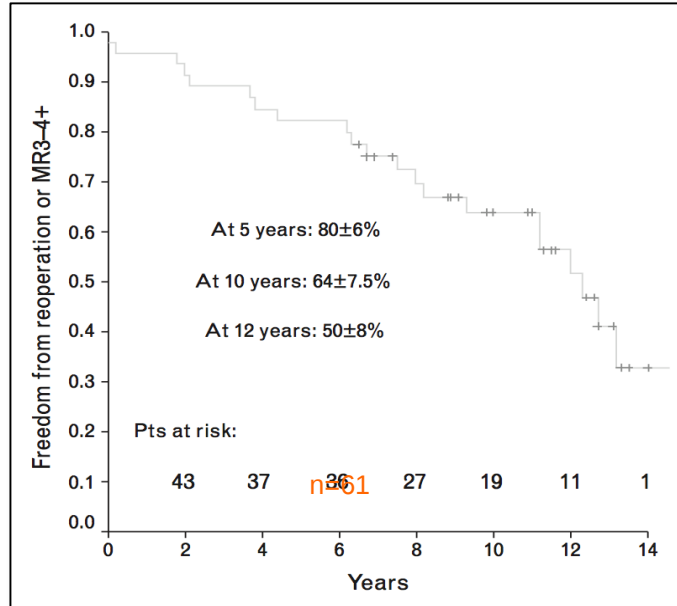
- Improve long term durability
- Improve MR reduction in FMR and DMR

Combination of leaflet repair and annuloplasty, a surgical standard



DMR

Edge-to-edge surgical mitral valve repair in the era of MitraClip: what if the annuloplasty ring is missed?



Freedom from reoperation & recurrence of MR 3-4+ with initial residual MR 0-1+ at discharge.

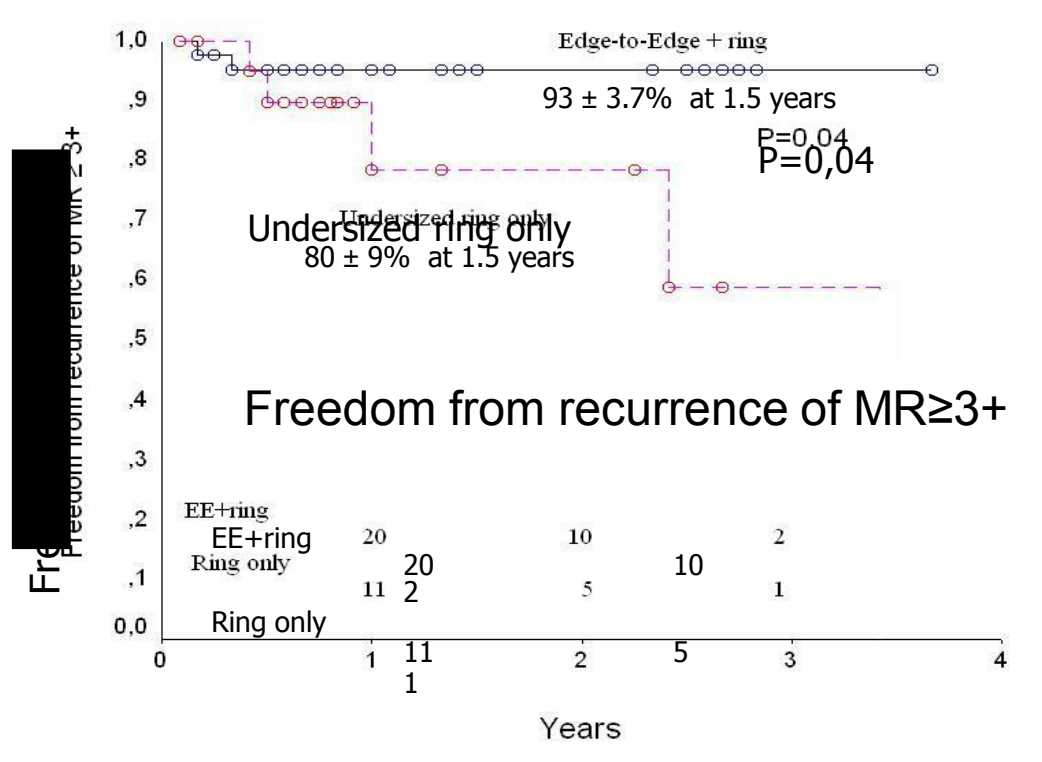
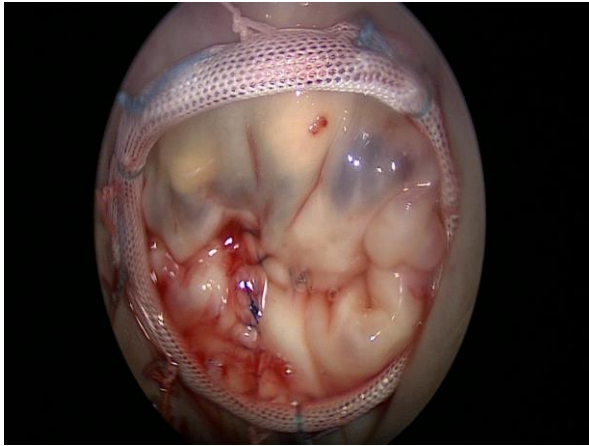
Mechanism of MR:

- bileaflet prolapse in 46%
- anterior leaflet prolapse in 18%
- posterior leaflet in 36%

The omission of annuloplasty was due to important annular calcification in 59%.

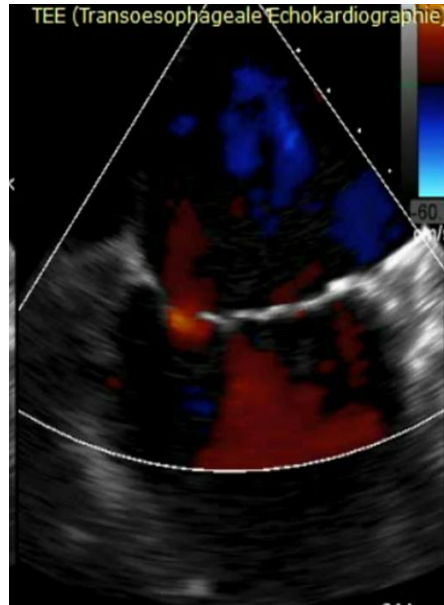
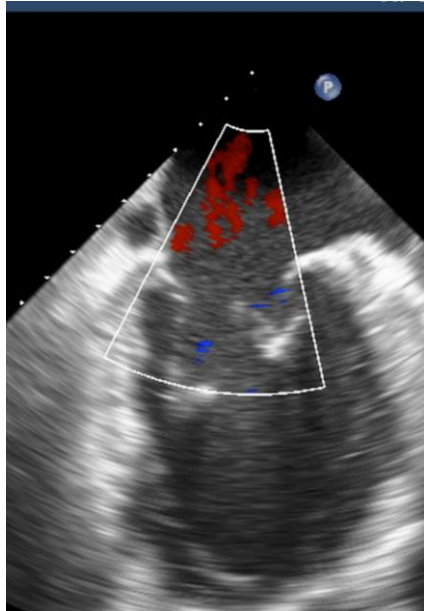
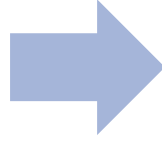
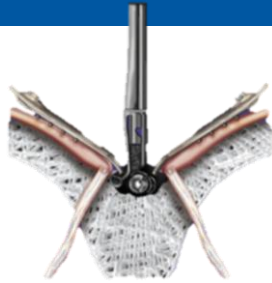
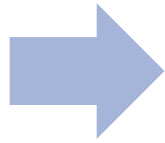
In the remaining patients, annuloplasty was intentionally avoided because of the presence of only mild annular dilatation/deformation.

FMR: synergistic role of the annuloplasty and Alfieri repair



De Bonis et al. Circulation 2005;112[suppl I]:I 402-I408

Baseline



Combination of leaflet repair and annuloplasty is standard practice in surgical repair

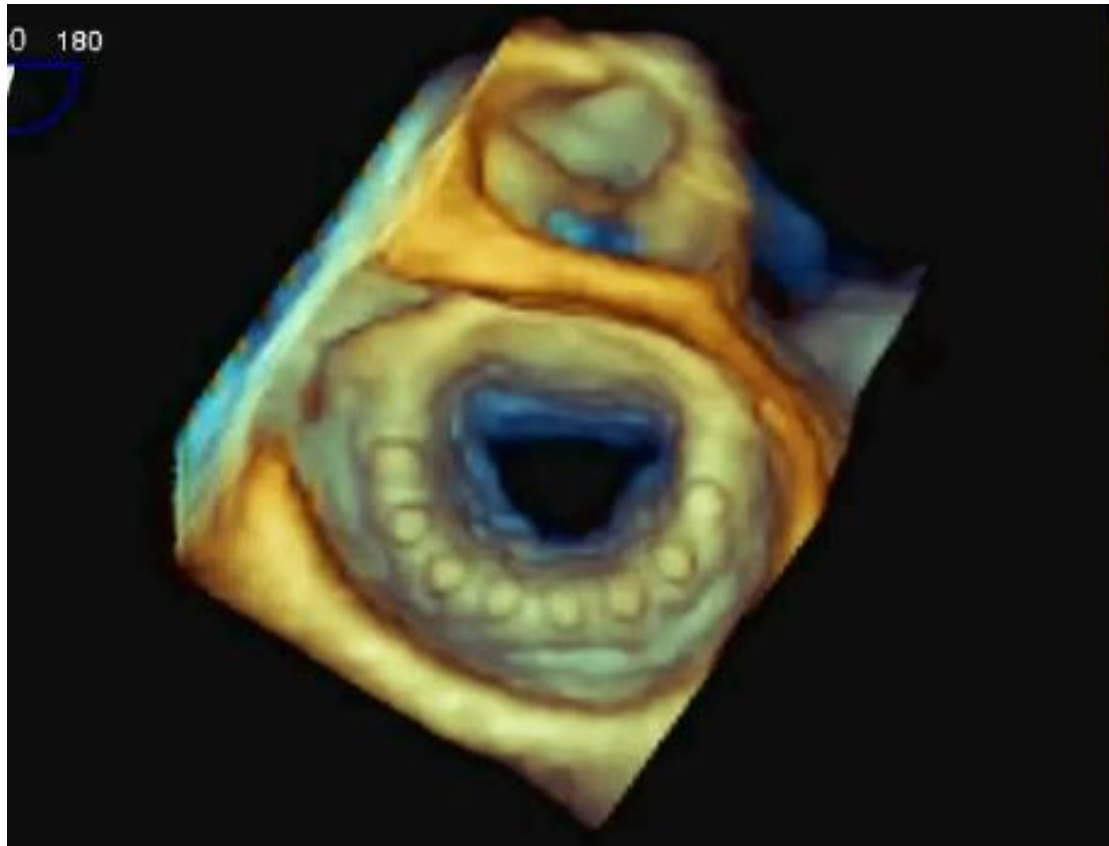
In transcatheter interventions, a staged or combined approach is possible

Both FMR and DMR patients may benefit

The sequence of interventions is an open issue

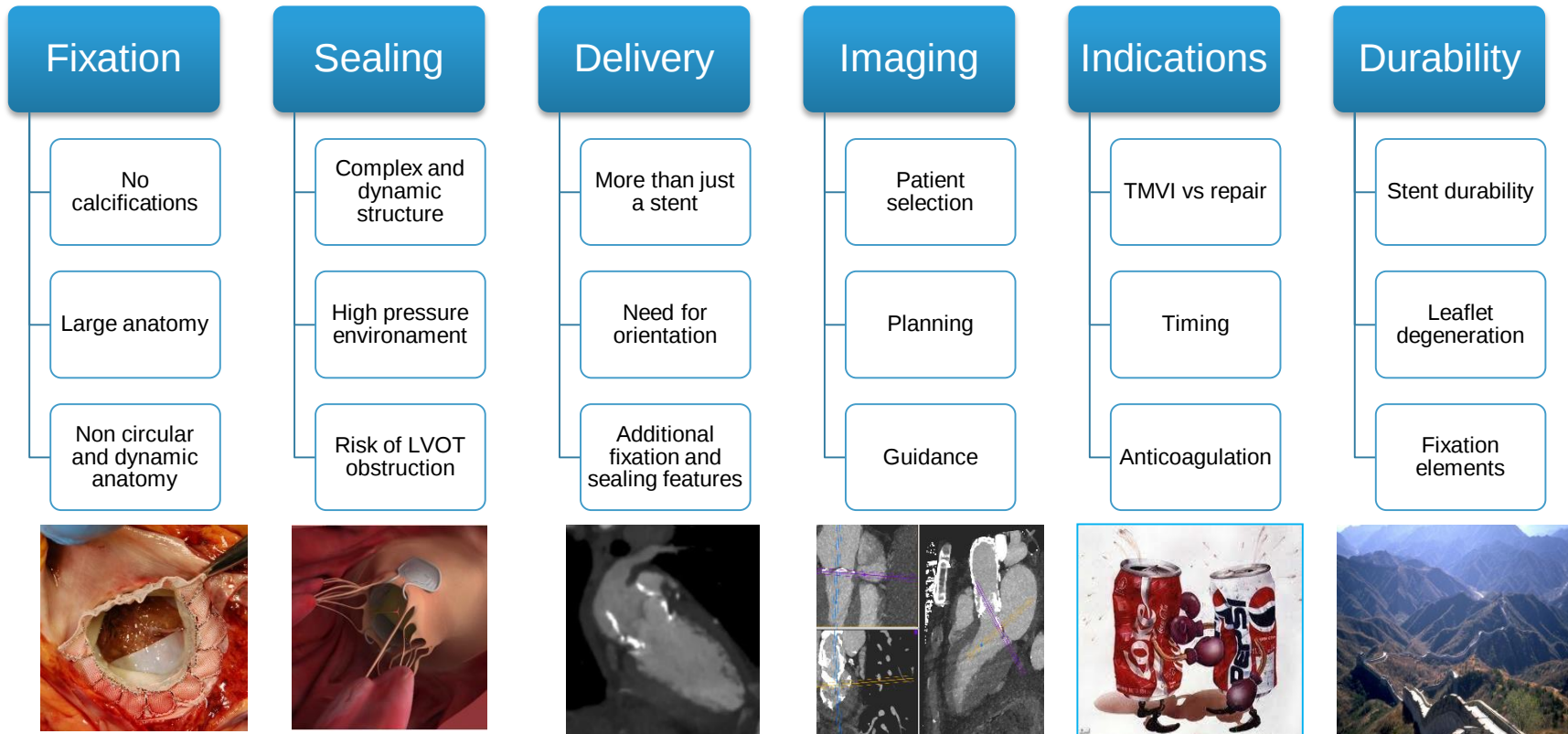


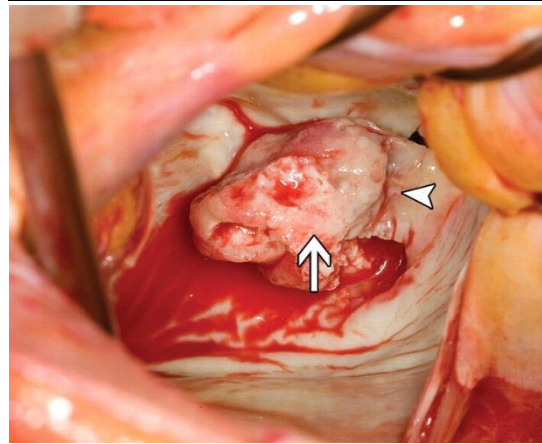
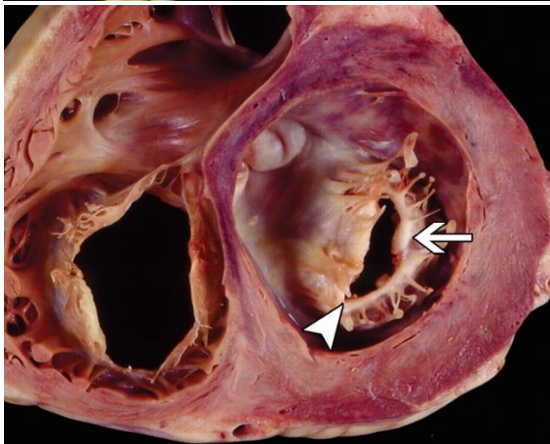
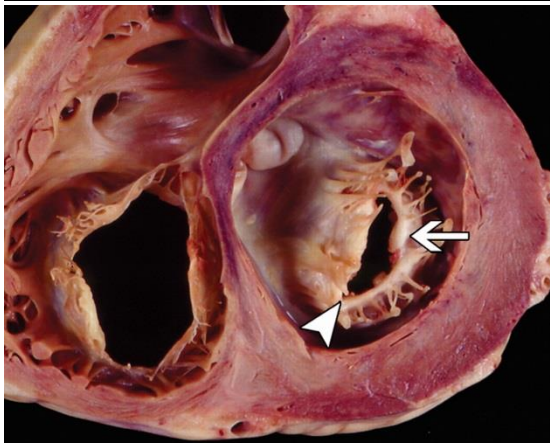
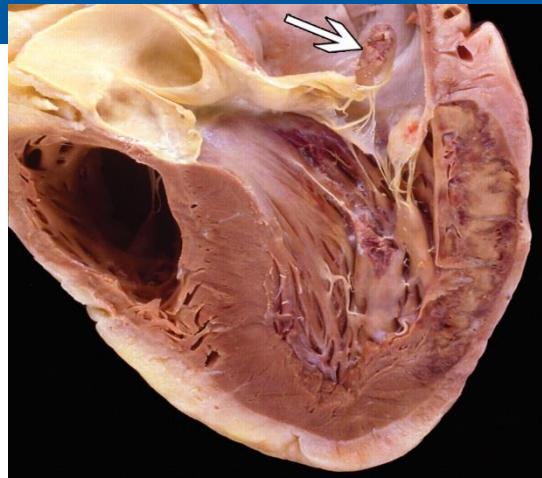
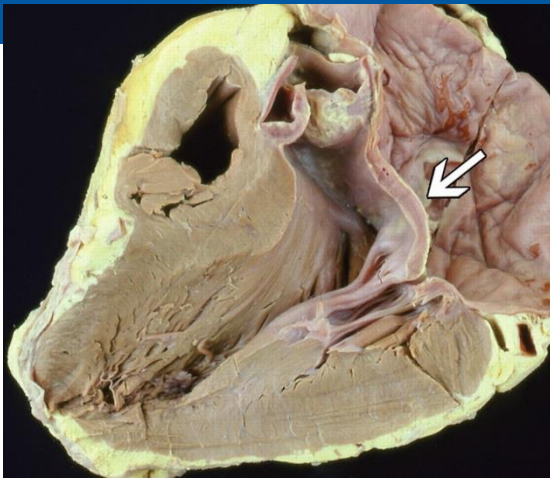
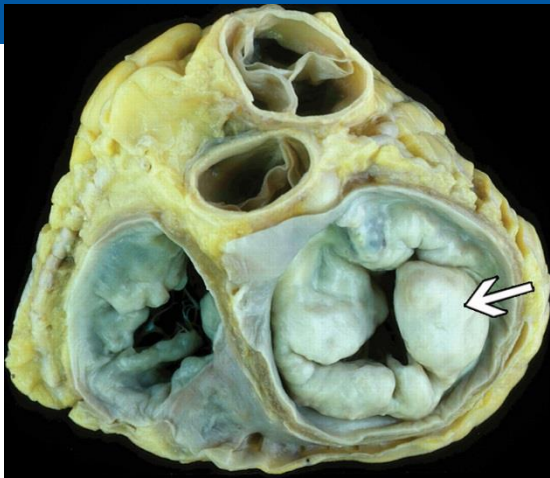
The promises of transcatheter mitral valve implantation

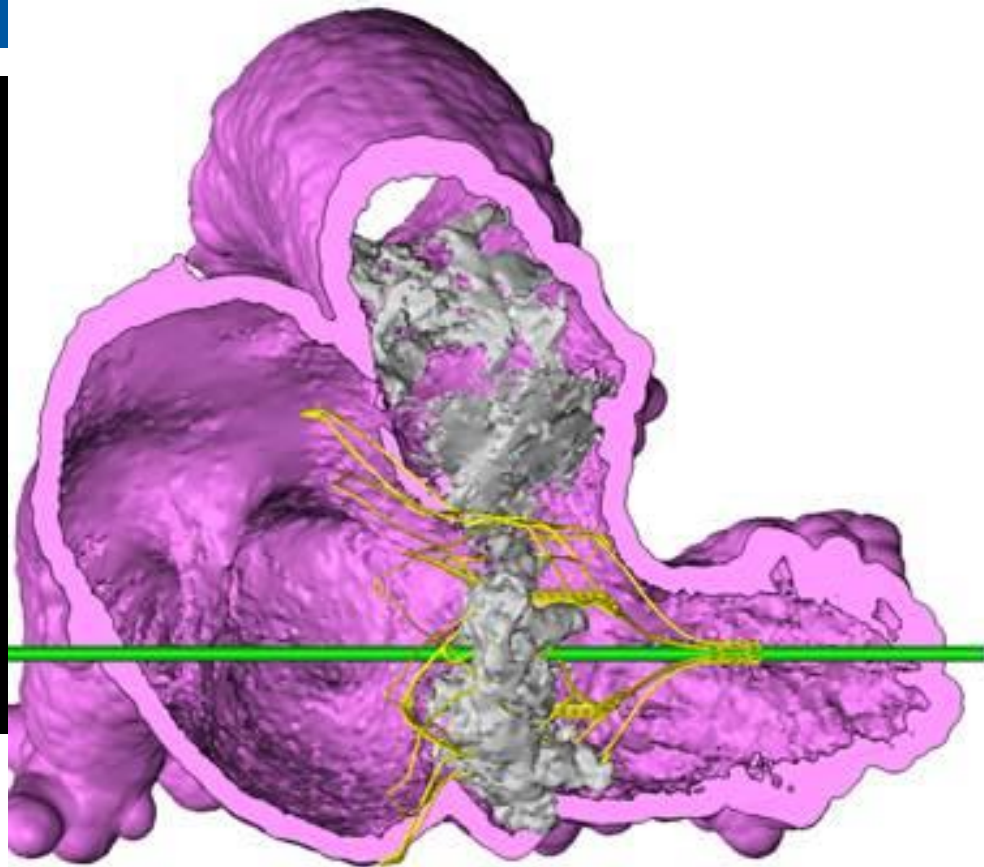
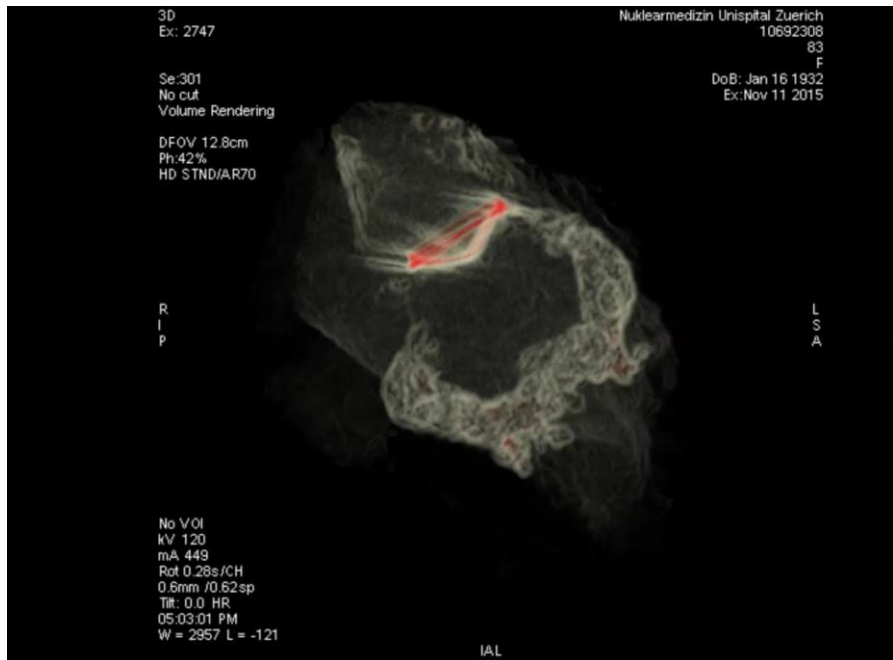


- More similar to TAVI (over the wire, angio-based, stent implant concept..)
- One device for all
- Predictable MR reduction
- Easier to learn and to implement in clinical practice

Clinical and technological challenges



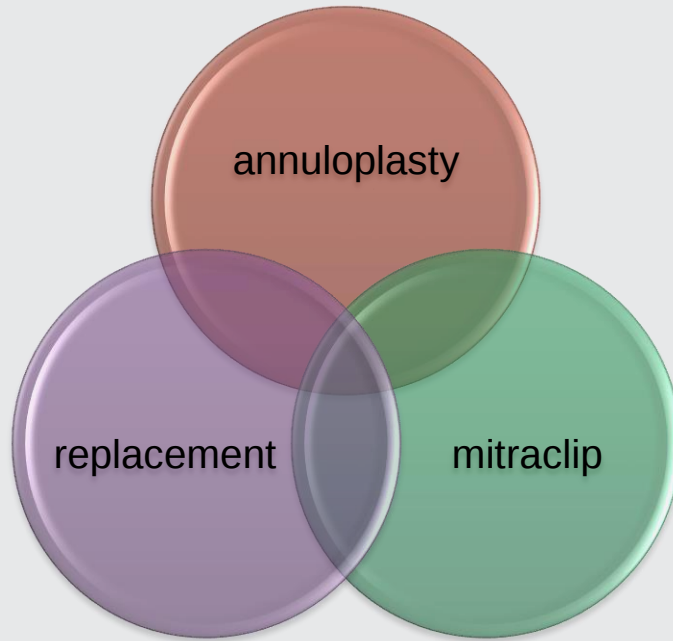




Not always replacement is the best option



The complementary role of transcatheter techniques



Stand-alone Annuloplasty: early treatment FMR

Stand-alone Mitralclip: FMR with asymmetric tethering (IMR)

Stand-alone Mitralclip: DMR

Combined Annuloplasty and MitralClip: DMR and Advanced FMR

MV Replacement: advanced DMR and Advanced FMR