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MV and TV Intervention: Current Status and Future Perspectives

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Disclosures

Physician name	Company	Relationship
Horst Sievert	4tech Cardio, Abbott, Ablative Solutions, Ancora Heart, Bavaria Medizin Technologie GmbH, Bioventrix, Boston Scientific, Carag, Cardiac Dimensions, Celonova, Cibiem, CGuard, Comed B.V., Contego, CVRx, Edwards, Endologix, Hemoteq, InspireMD, Lifetech, Maquet Getinge Group, Medtronic, Mitralign, Nuomao Medtech, Occlutech, pfm Medical, Recor, Renal Guard, Rox Medical, Terumo, Vascular Dynamics, Vivasure Medical, Venus, Veryan	Consulting fees, Travel expenses, Study honoraria

"Aaaaahhh – Mitral!"

"The next TAVI!"

But the mitral is different from the aortic!

- The problem is usually insufficiency, not stenosis
- Multiple etiologies
- Primary goal is repair, not replacement
- Access more difficult
- Imaging more difficult
- Adjacent structures: Coronary arteries, epicardium, chordae
- Usually there is no rigid calcified annulus to anchor a prosthesis
- Mitral annulus is saddle-shaped, larger and contracting during systole
- The maximum pressure is the systolic LV pressure – much higher than the diastolic aortic pressure
- Paravalvular leak probably less well tolerated
- There is a subvalvular apparatus
- Blockage of the LVOT outflow track is a concern
- Higher risk of clot formation































Over the last decade more than 30 percutaneous mitral valve repair techniques have been developed

- Annuloplasty approaches
 - Coronary sinus annuloplasty
 - Edwards Monarc stopped
 - Cardiac Dimensions Carillon CE mark
 - Viacor Shape Changing Rods (PTMA) stopped
 - NIH-Cerclage in patients
 - St. Jude Medical stopped
 - Ample PS3 → MVRx in patients
 - Direct annuloplasty
 - Mitralign Suture-based Plication CE mark
 - Ancona Heart Accucinch in patients
 - Cordis Direct Plication Annuloplasty stopped
 - ReCor Medical stopped
 - QuantumCor RF Annulus Remodeling stopped?
 - Valtech Cardioband in patients
 - MiCardia variable size ring (hybrid) in patients
 - Mitral Solutions (hybrid) in patients
 - Millipede IRIS in patients
 - Valcare Amend in patients
 - Cardiac Implants
- LV Remodeling
 - Myocor iCoapsys stopped
 - Mardil – BACE device in patients
- Percutaneous Chordal Implants
 - Babic Chords in patients
 - NeoChord CE mark
 - Harpoon in patients
 - Valtech Vchordal (brid) in patients
- Edge to edge repair
 - Mobius (Edwards) stopped
 - Mitra Flex – TransCardiac Therapeutics
 - Evalve - MitraClip CE mark
 - Edwards PASCAL Repair System in patients
 - HeartStich
- Other mitral valve repair techniques
 - Mitra Spacer - CardioSolutions in patients
 - Mistral – Mitralix in patients
 - Middle Peak in patients
 - Mitralix in patients
 - St Jude leaflet plication in patients






... which could be an indicator that none of them really works well

Transcatheter Mitral Valve Repair

Many Players with Different Approaches

Approach	Commercial	Clinical Implants	In Development	IP / Abandoned
Edge to Edge				
Direct Annuloplasty	 	 	    	 
Indirect Annuloplasty		 The ARTO™ System		
Chordal Repair		 	 	
Enhanced Coaptation		 	 	
Ventricular Modification		 		 

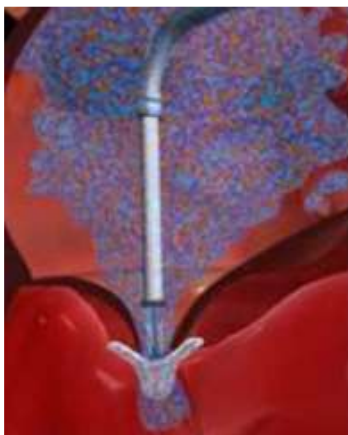
Transcatheter Mitral Valve Repair Therapies with CE Mark

	MitraClip	NeoChord DS 1000	Carillon	CardioBand	Mitralign
Device					
Principle	Alfieri edge to edge	Chordal implant	Coronary sinus cinching	Percutaneous annuloplasty	Leaflet plication
Approach	Transseptal	Transapical	Coronary Sinus	Transseptal (24 Fr delivery system)	Retrograde aortic
Number of Implants	>50,000	>300	>500	~100	~100
Year Received CE Mark	2008	2012	2009	2015	2016

Devices with CE mark

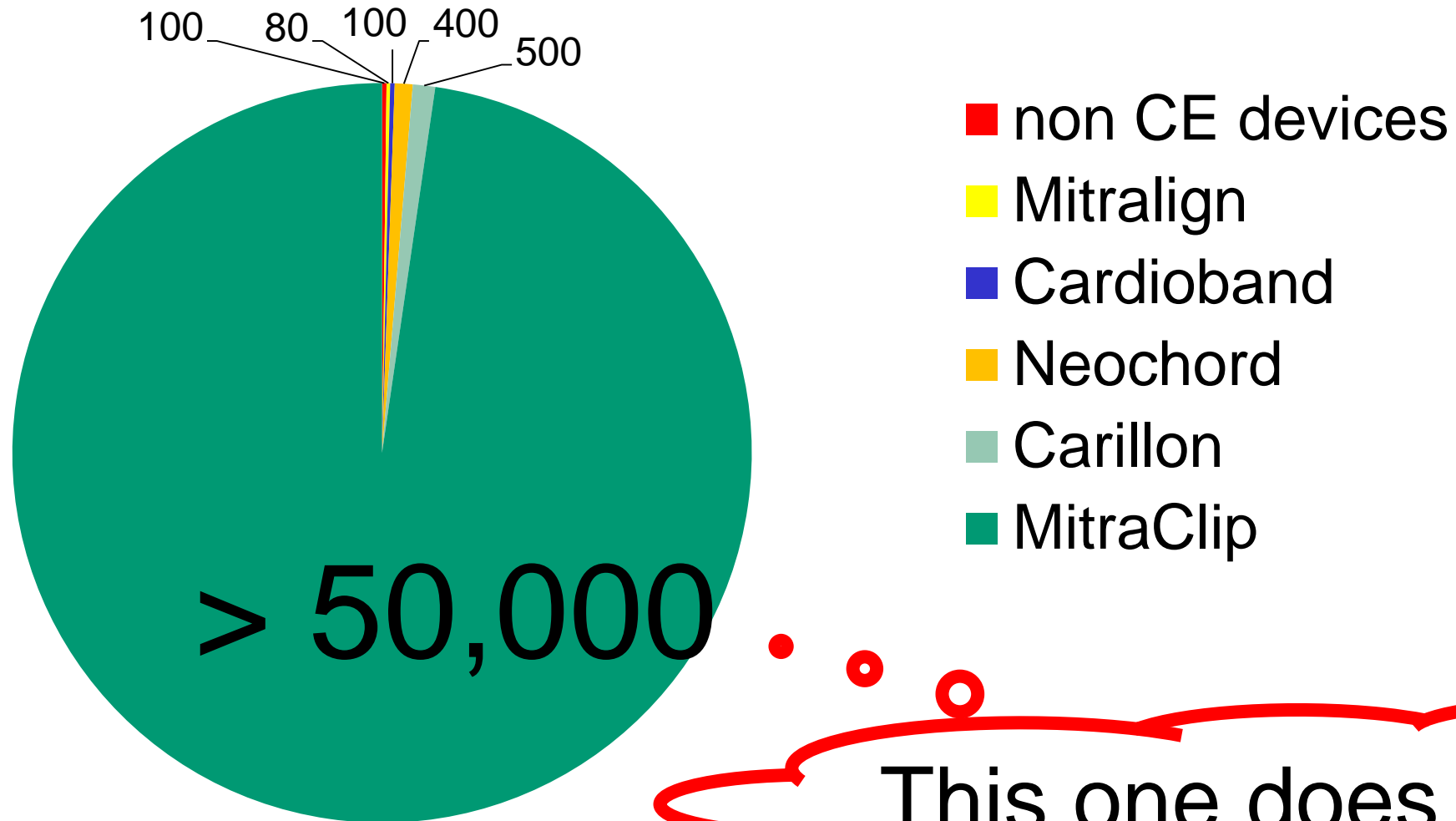
- MitraClip
- Mitralign
- Carillon
- Valtech
- Neochord

MitraClip



Catheter Mitral Valve Repair

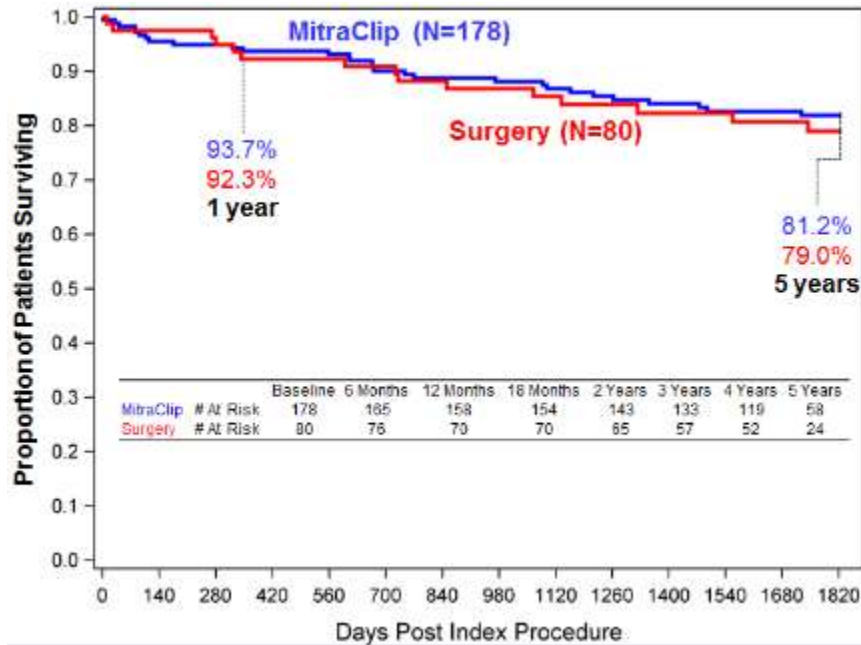
2003 - 2017



EVEREST II

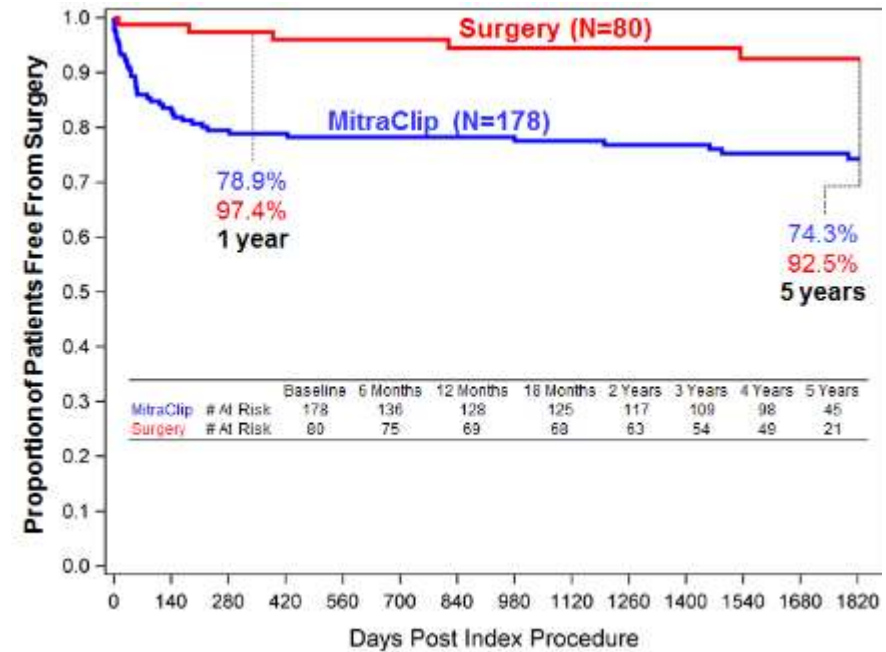
MitraClip 5-Year Results

Death



- Regarding survival, MitraClip is as good as surgery

(Re-) Surgery



- Functional result is not as good as surgery
- Need for surgery after MitraClip comes from early failure – not late failure

MitraClip for functional mitral regurgitation (FMR)

- COAPT Trial - completed enrolment
- RESHAPE HF2 Trial
- MATTERHORN
- MITRA-FR (ISS) - completed enrolment

The new MitraClip NT/XT

- Nitinol grippers with 120° opening
- Enhanced steerability of the delivery system
- M knob rotation more sensitive
- Facilitated delivery system removal
- Larger version



Devices with CE mark

- MitraClip
- **Mitralign**
- Carillon
- Valtech
- Neochord

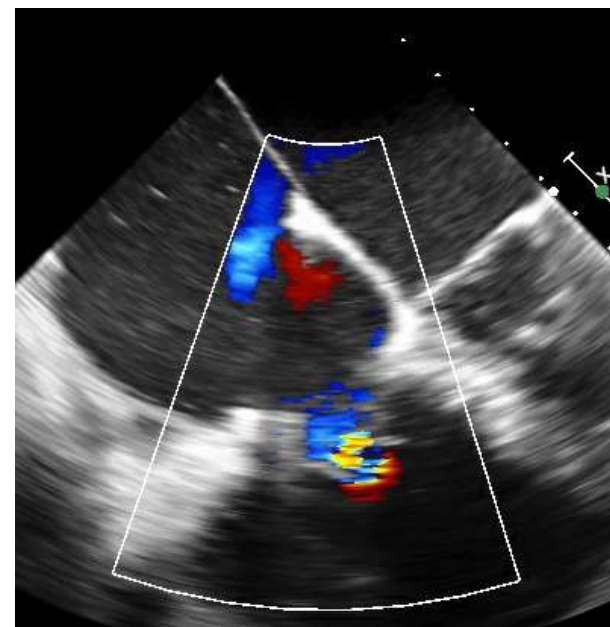
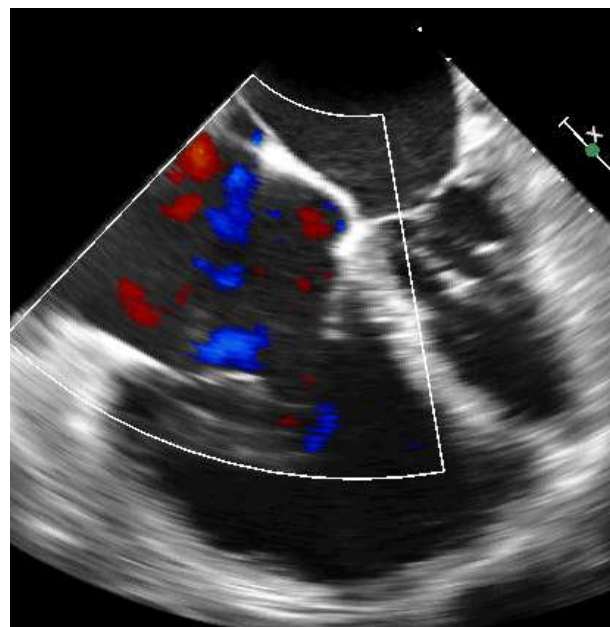
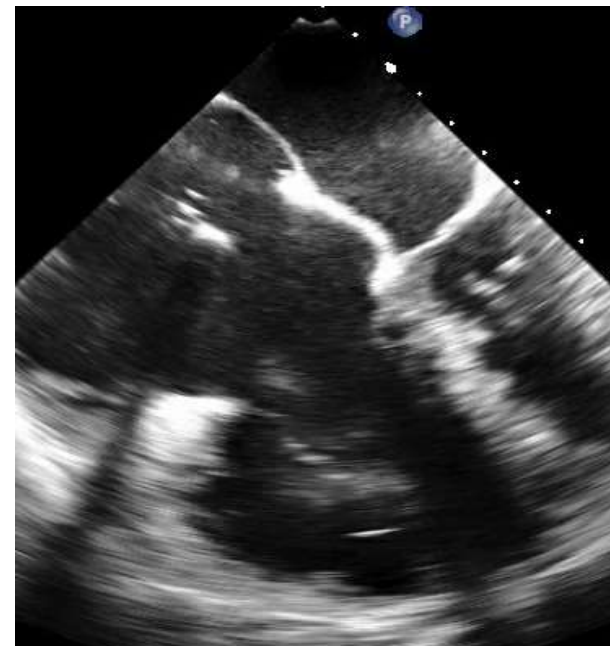
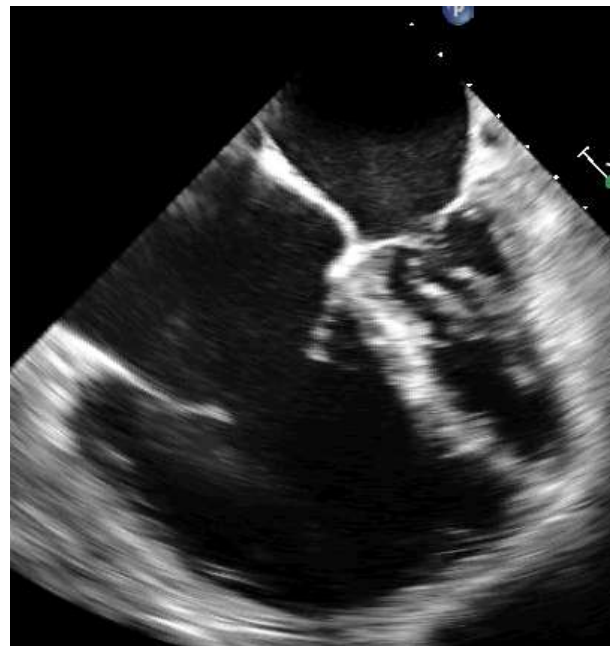
Mitralign



- Pledgets are delivered percutaneously through the posterior annulus
- The annulus is plicated



Mitralign for Tricuspid



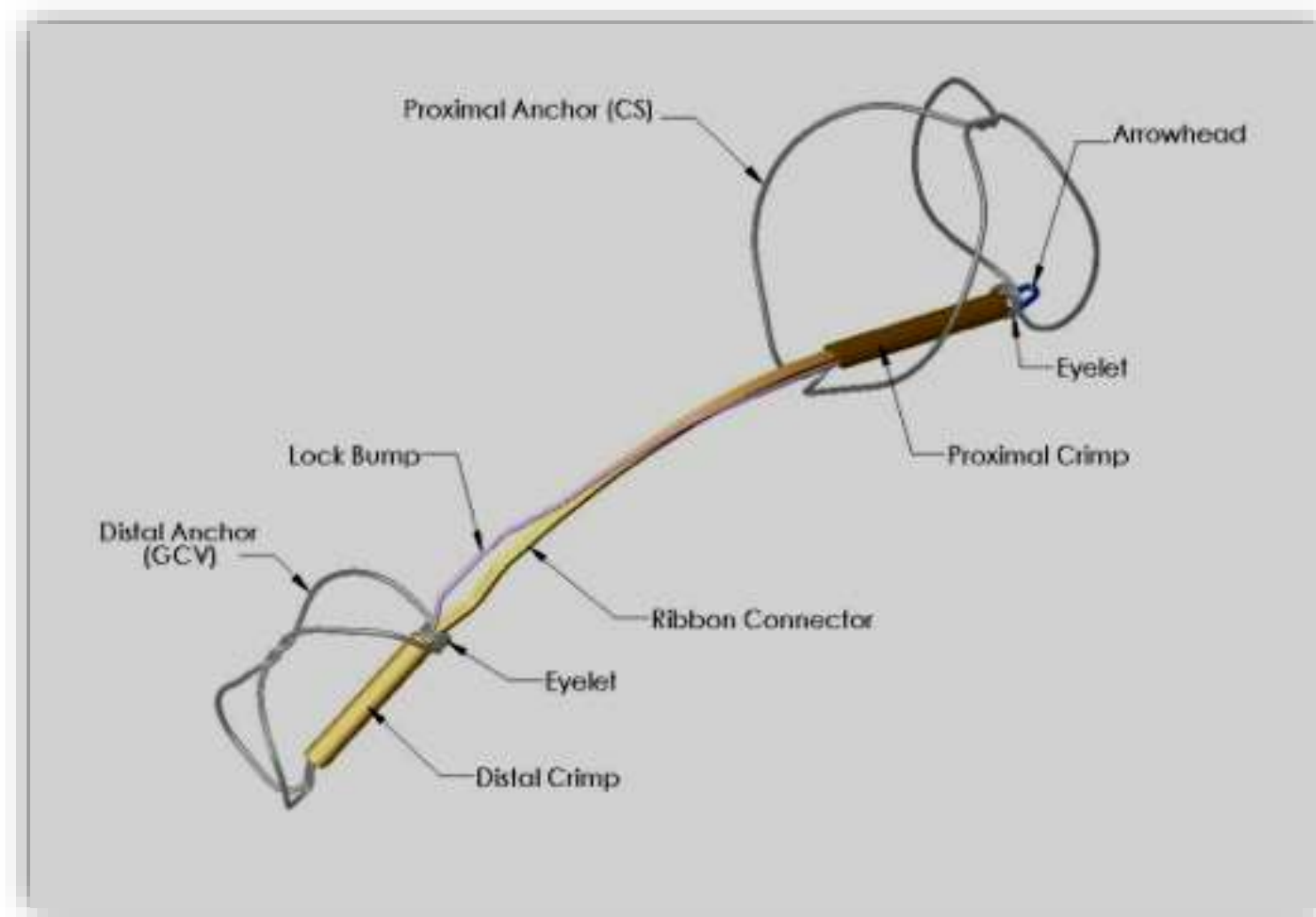
Baseline

Post

Devices with CE mark

- MitraClip
- Mitralign
- **Carillon**
- Valtech
- Neochord

Carillon

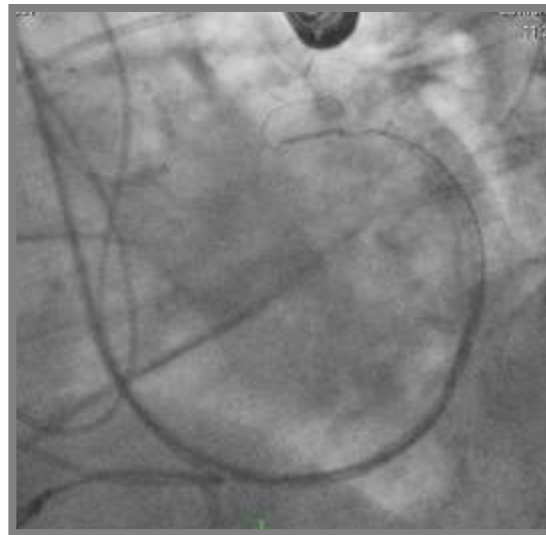


Coronary Sinus Annuloplasty approach

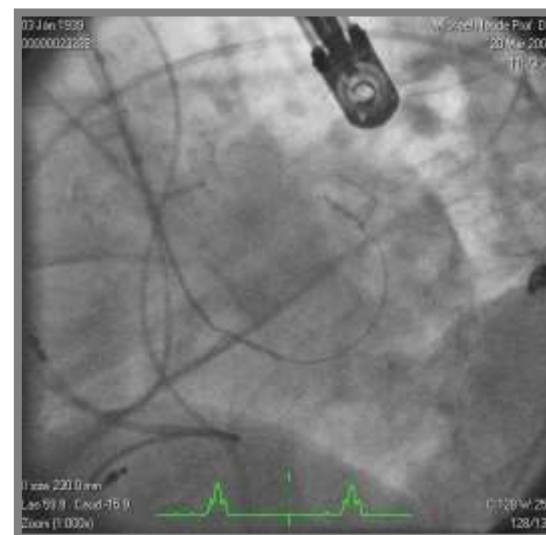
Carillon



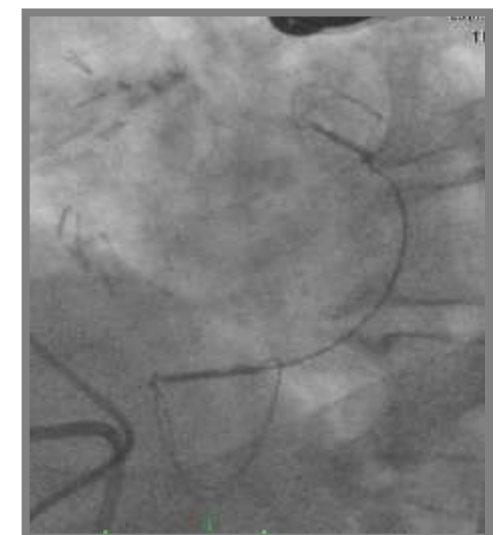
Venogram



Distal Anchor Deployed



Tension to Plicate Tissue

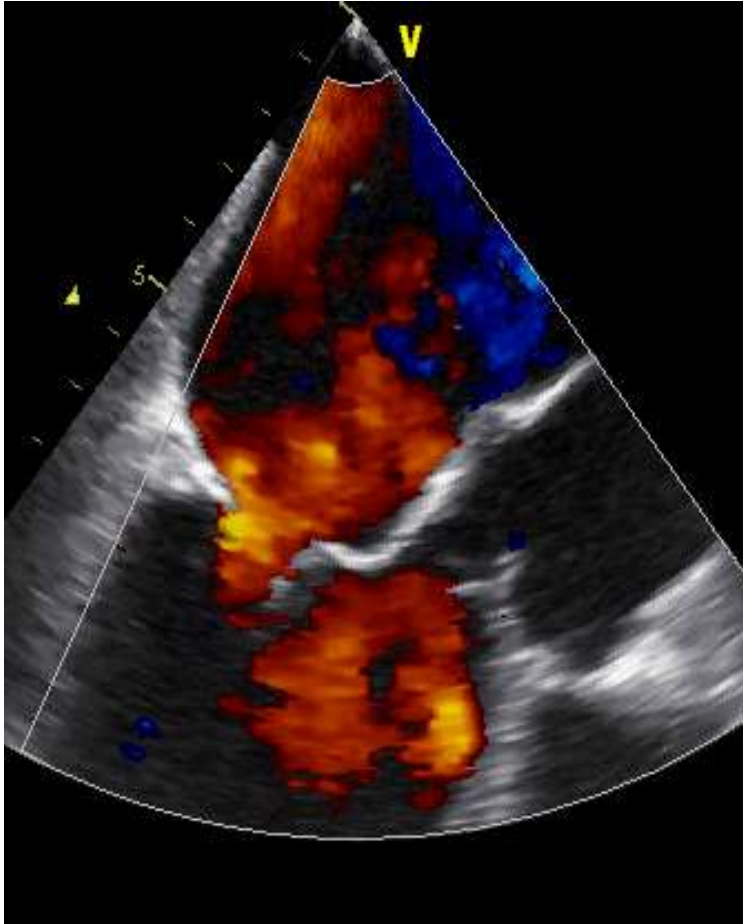


Device Released

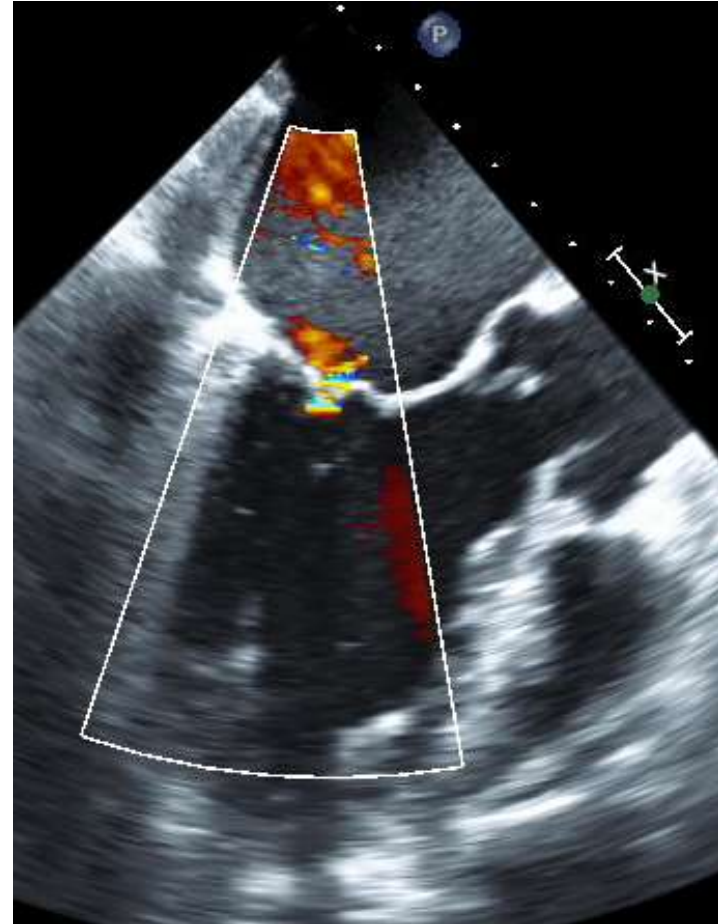
- Adjustable
- Recapturable
- Peri-procedural assessment
 - Mitral insufficiency
 - Circumflex artery

Carillon

before



after 1 month

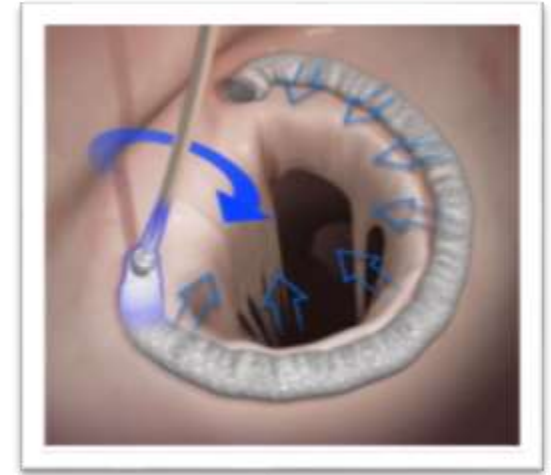
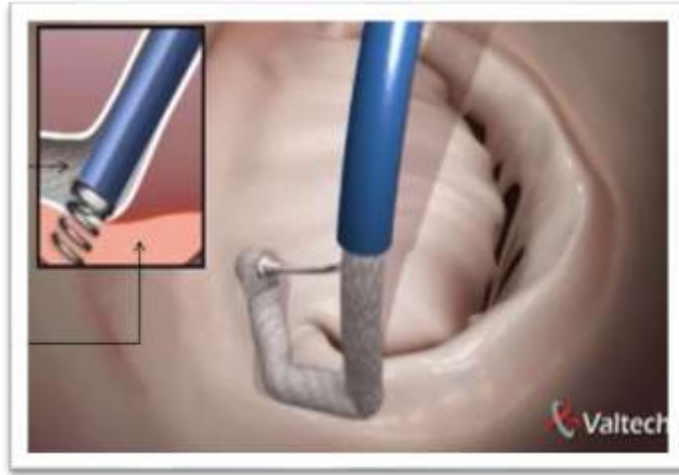


Devices with CE mark

- MitraClip
- Mitralign
- Carillon
- **Valtech**
- Neochord

Valtech-Cardioband

Direct Annuloplasty With A Surgical-like Ring Implanted Percutaneously

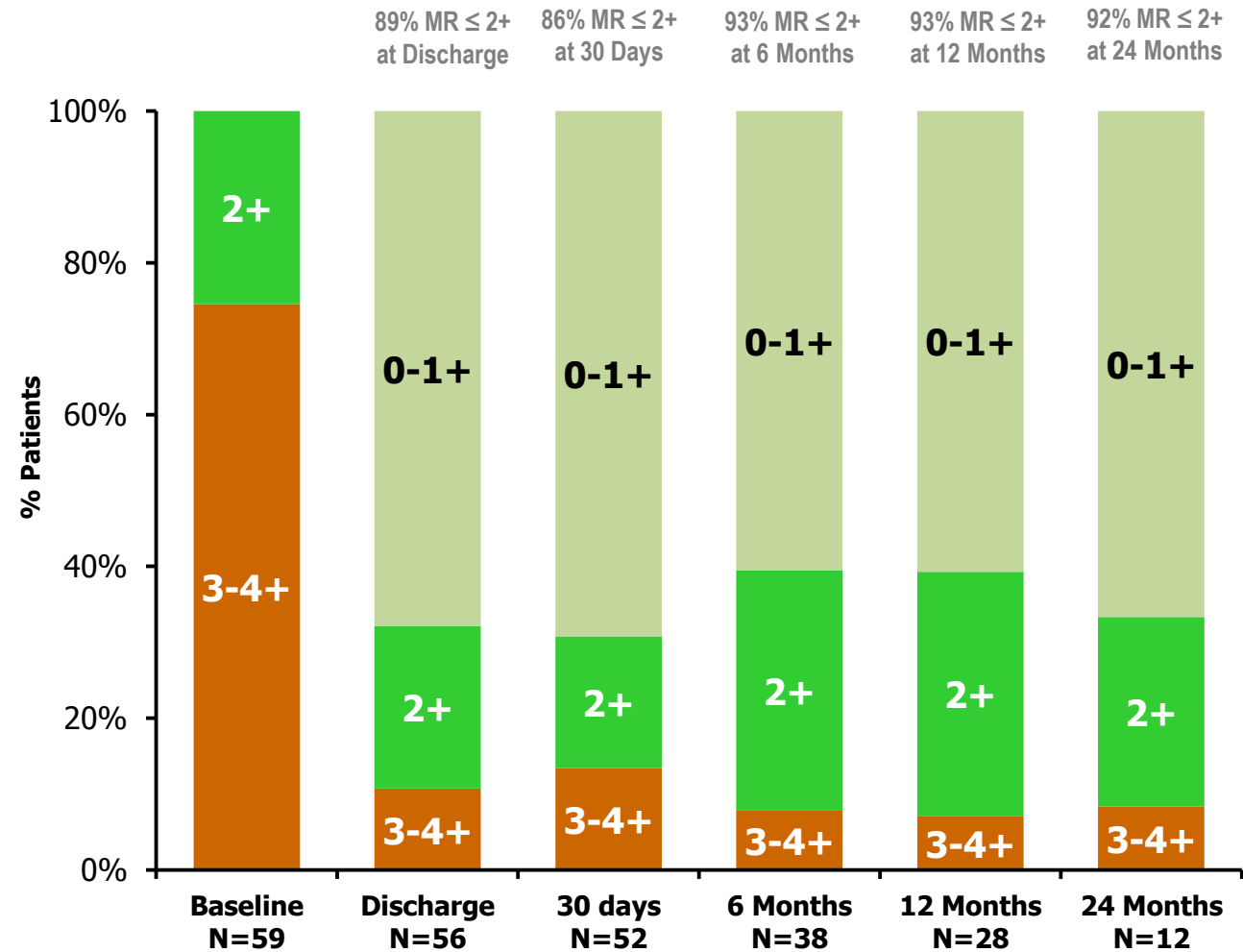
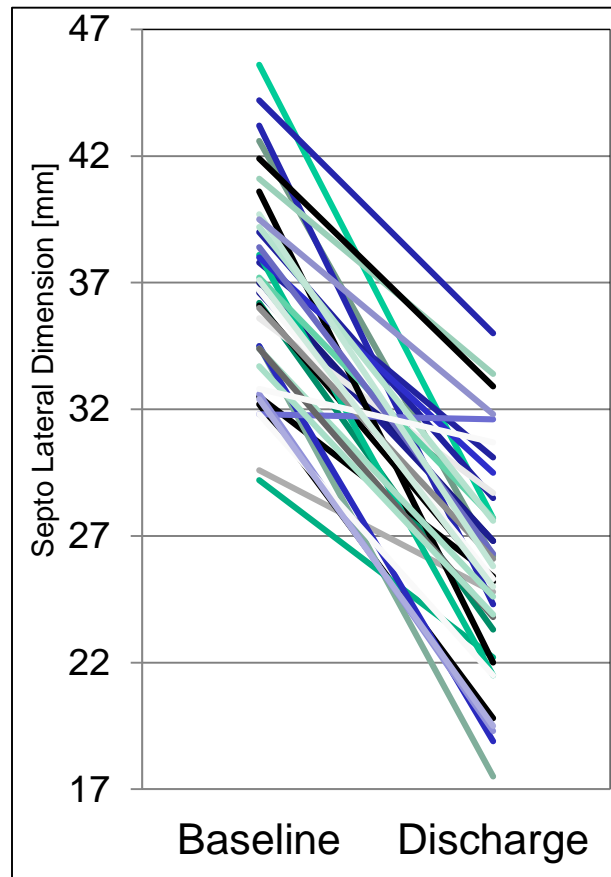


- Supraannular fixation by anchors
- Implanted via a transeptal approach
- Echo/fluoroscopic guidance



Result: Acute Animal

Annular Reconstruction by 30% Reduction in Septo Lateral (A-P) Dimension, 90% patients with MR≤2+ At 12 Months By Core Lab



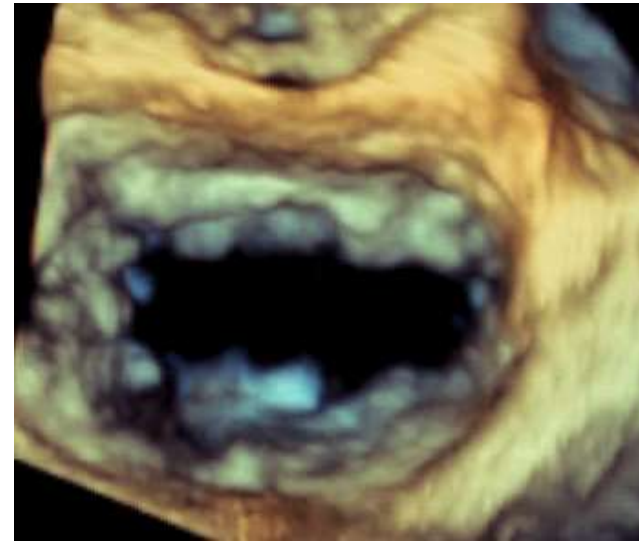
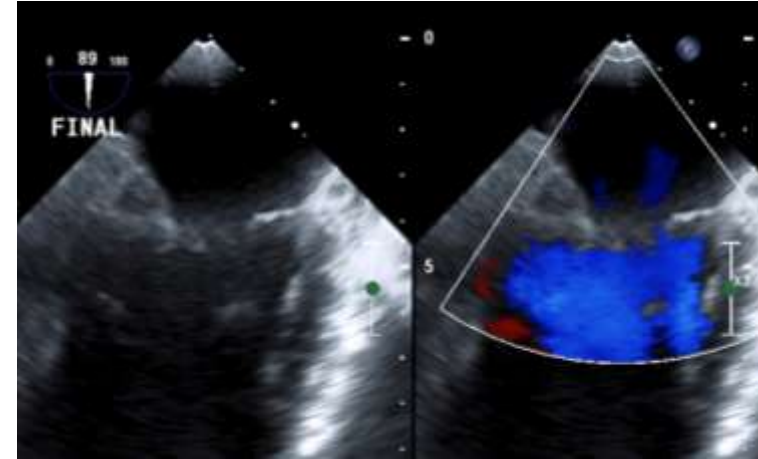
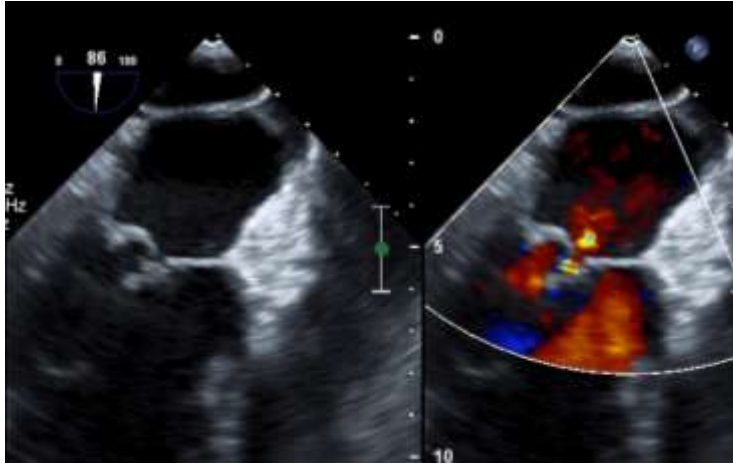
Devices with CE mark

- MitraClip
- Mitralign
- Carillon
- Valtech
- Neochord

NeoChord DS1000 Artificial Chordae Delivery System



Neochord



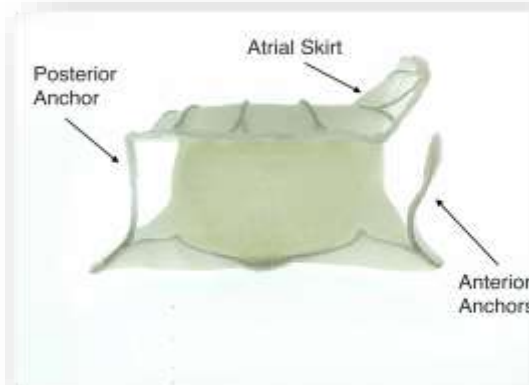
before

after

In clinical trials/compassionate use

- MVRx
- AMEND Valcare
- Millipede
- Mitral Cerclage
- Ancona Heart
- PASCAL
- Mistral
- Mitra Spacer
- Hapoon
- VenTouch - Mardil

Transcatheter Mitral Valve Replacement



Transcatheter mitral valve implantation

Edwards CardiAQ	in patients	ValveXchange
Edwards Fortis	in patients	MitrAssist
Neovasc Tiara	in patients	Braile Quattuor
Abbott Tendyne	in patients	Cephea
Medtronic Intrepid	in patients	Direct Flow
HighLife	in patients	Sinomed Accufit
M-valve	in patients	MitralHeal
Caisson	in patients	HT Consultant Saturn
NCSI NaviGate	in patients	Lutter valve
St. Jude		Transcatheter Technologies Tresillo
Micro Interventional		Verso
Valtech CardioValve		Transmural Systems

Mitral valve interventions

- MitraClip is currently the leading concept in the field of mitral valve repair
- Many others are in an earlier stage
 - we do not know yet which ones will really make it into clinical practice
- Like in surgery, there will not be just one solution
 - We will need different techniques for different morphologies, often in combination
- Mitral valve implantation is developing very fast but there are problems we did not expect initially
 - LVOT obstruction, thrombus formation, ...

The “Forgotten” Tricuspid Valve

Tricuspid regurgitation (TR) is frequent and important

- Prevalence in the general population 0.8%
 - increasing with age
- TR is common in patients with mitral valve disease
- It is an **independent** predictor of mortality

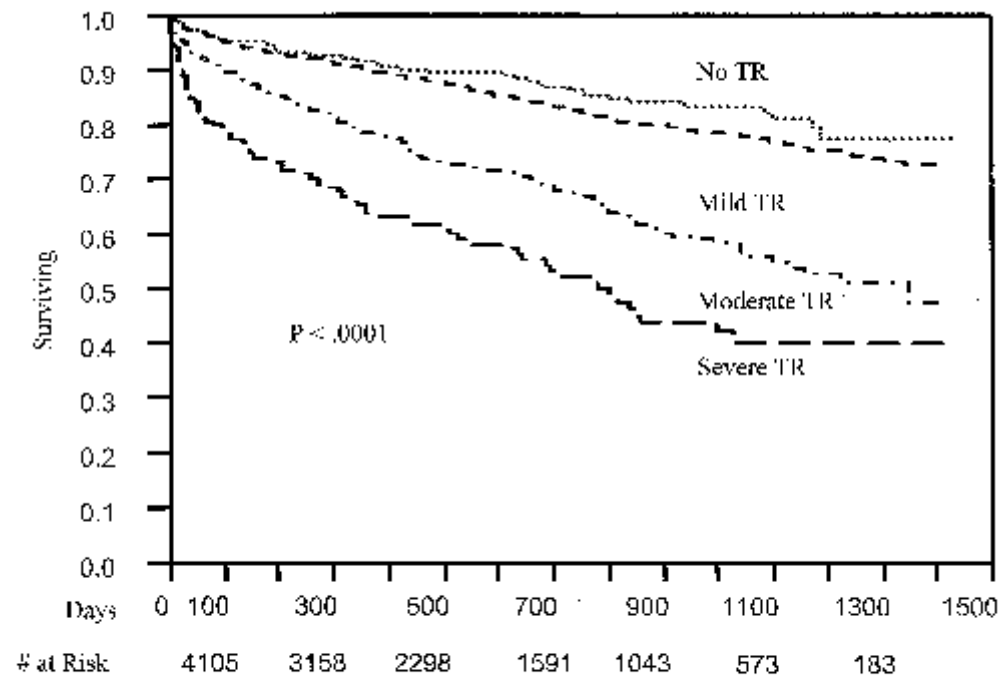


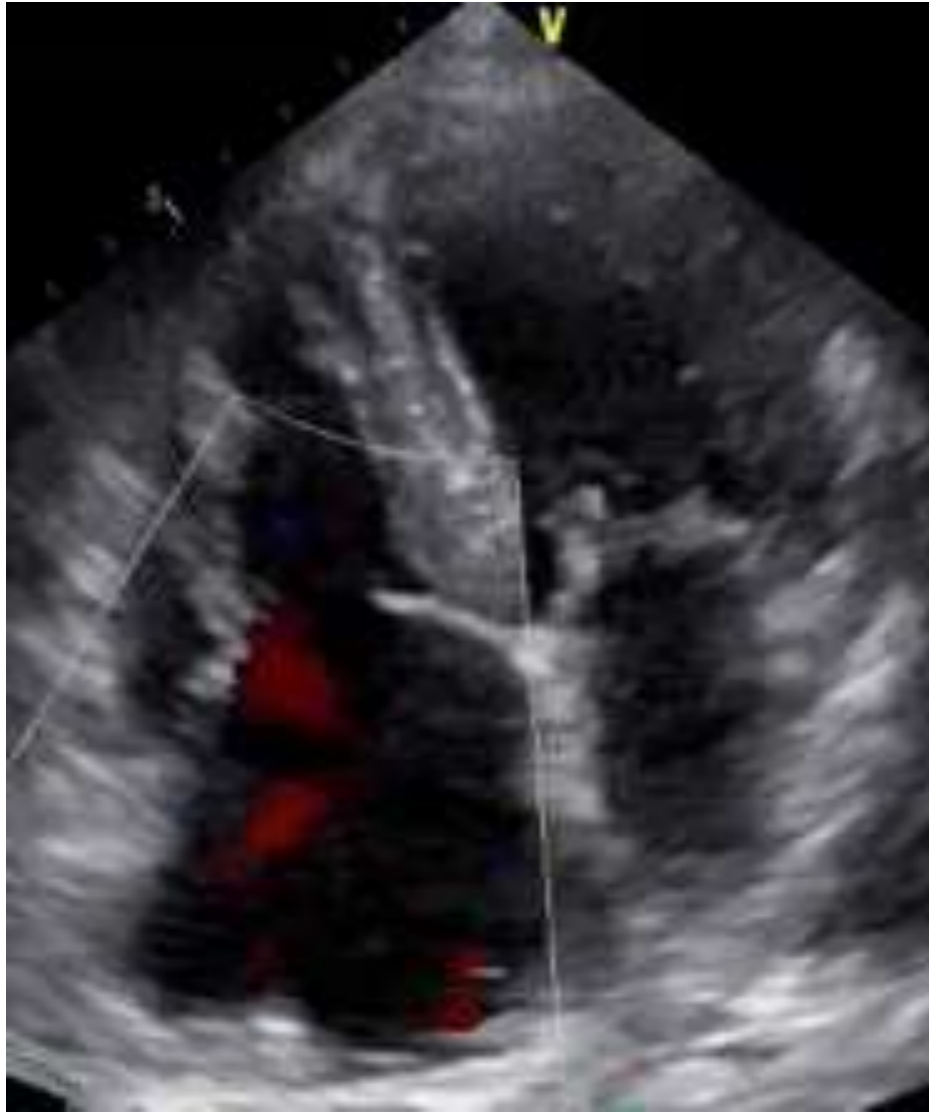
Figure 1. Kaplan-Meier survival curves for all patients with tricuspid regurgitation (TR). Survival is significantly worse in patients with moderate and severe TR.

Catheter treatment of tricuspid valve insufficiency

- More technical challenges compared to other valve interventions:
 - Proximity of AV node and RCA
 - Leaflets and chordae are thinner than in mitral
 - Thin RV wall
 - Many patients have pacemaker leads
- Patient selection is difficult
 - difficult assessment of symptoms, variability of clinical status ...
 - when is it too late and when too early?
- Imaging is difficult
- All techniques are in an early stage
 - Less than 1000 patients treated worldwide including 600 Clips

Transcatheter Tricuspid Repair and Replacement

- MitraClip for tricuspid
- FORMA (Spacer)
- Mistral
- Mitralign → Trialign
- 4Tech
- TRAIPTA
- Millipede
- Cardioband TR
- Cardiac Implants
- Caval valve implants
- Cavolve
- Valve in surgical valve
- Tricuspid valve implantation
 - NaviGate
 - Trisol



Before Clip



2 months after Clip

TRILUMINATE - TVRS



MitraClip NT

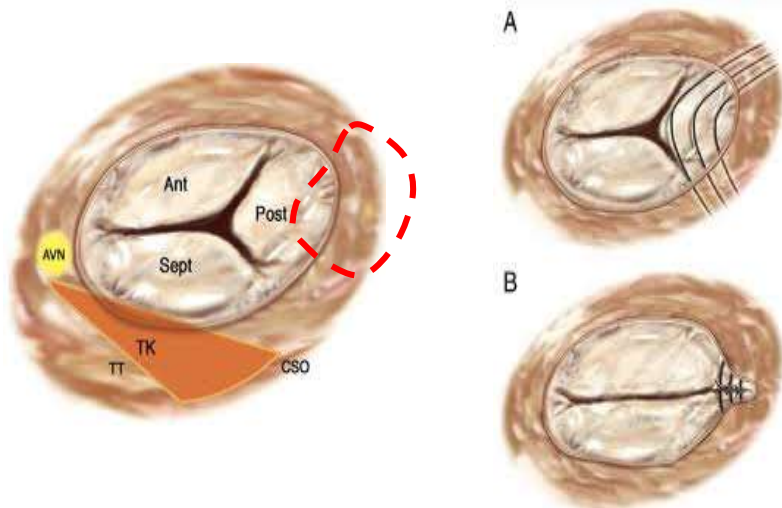


TVRS

Multicenter trial ongoing

Trialign replicates a surgical procedure (Kay Procedure)

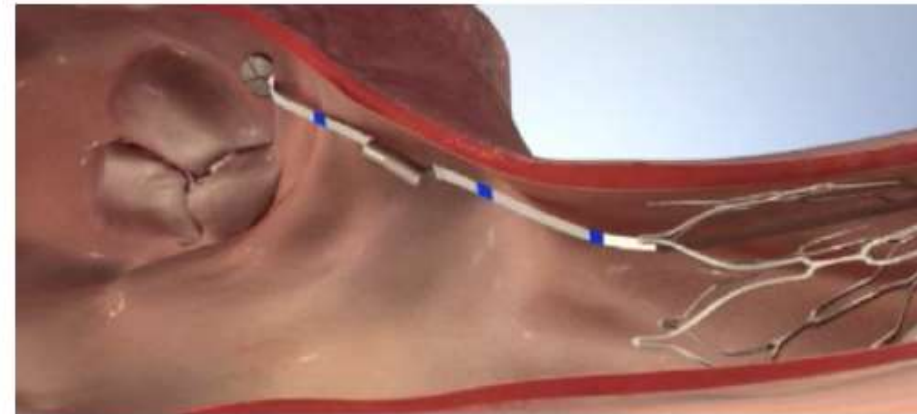
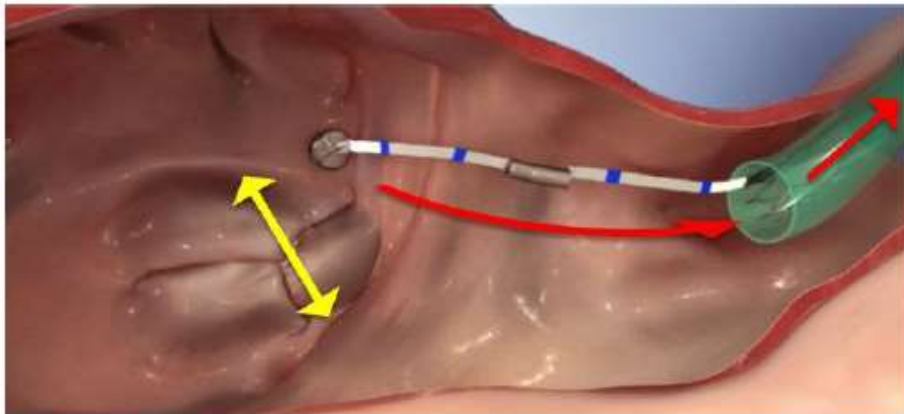
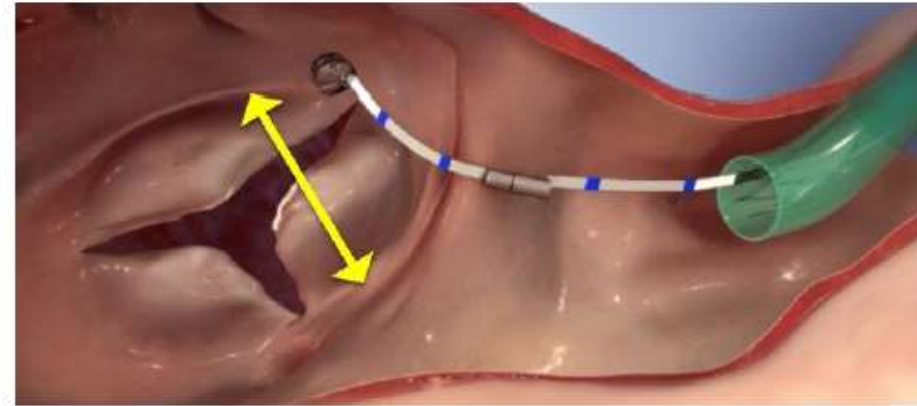
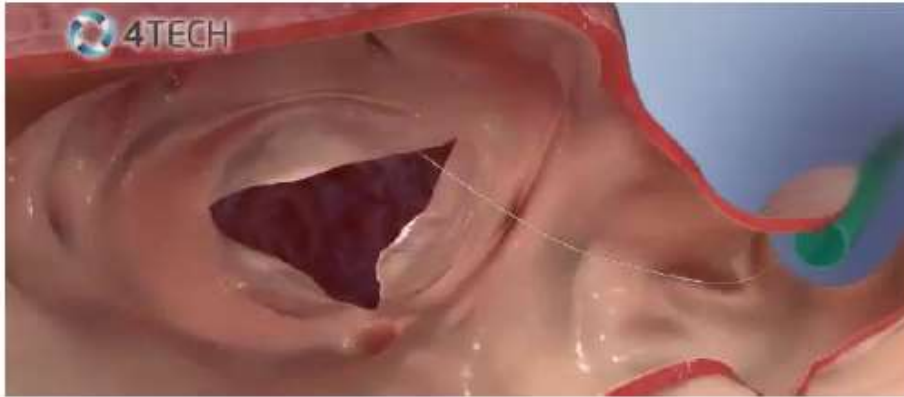
Kay converts an incompetent tricuspid into a competent bicuspid valve



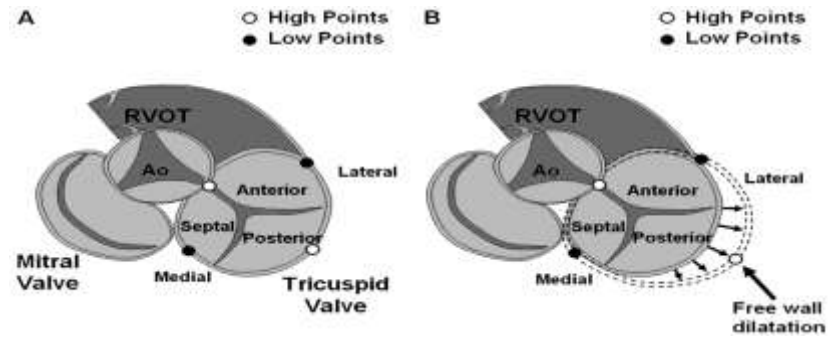
- 1st Pledget is placed at the Antero-Posterior Commissure
- 2nd pledget is placed at the Septo-Posterior Commissure
- Pledgets are cinched together obliterating the posterior leaflet



4Tech TriCinch



Cardioband TR (Valtech)



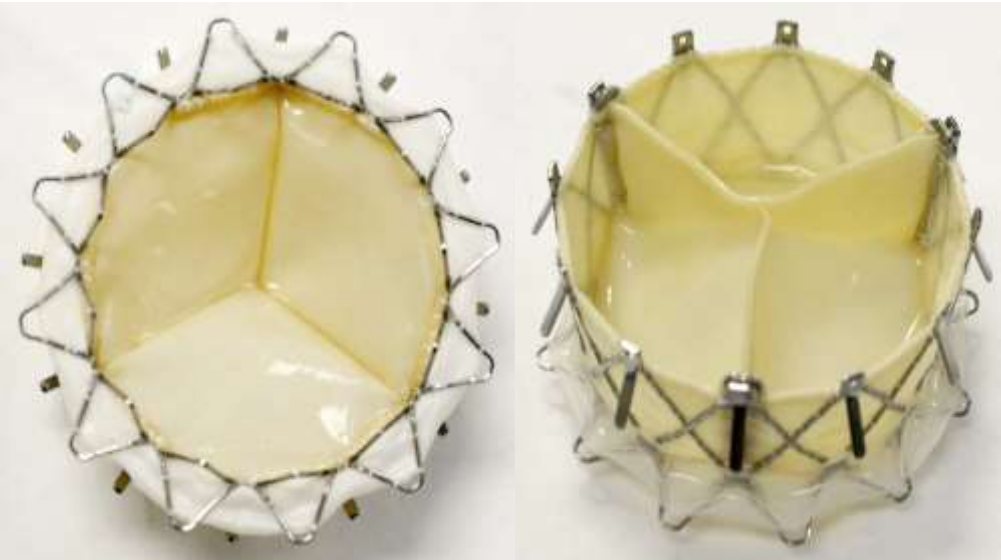
Ton-Nu, T.-T. et al. Circulation 2006;114:143-149

- Annuloplasty technique CE marked for mitral valve
- Same implant and delivery system
- CE mark for TR in 2018



NaviGate

Tricuspid Valve Stent and Delivery Systems

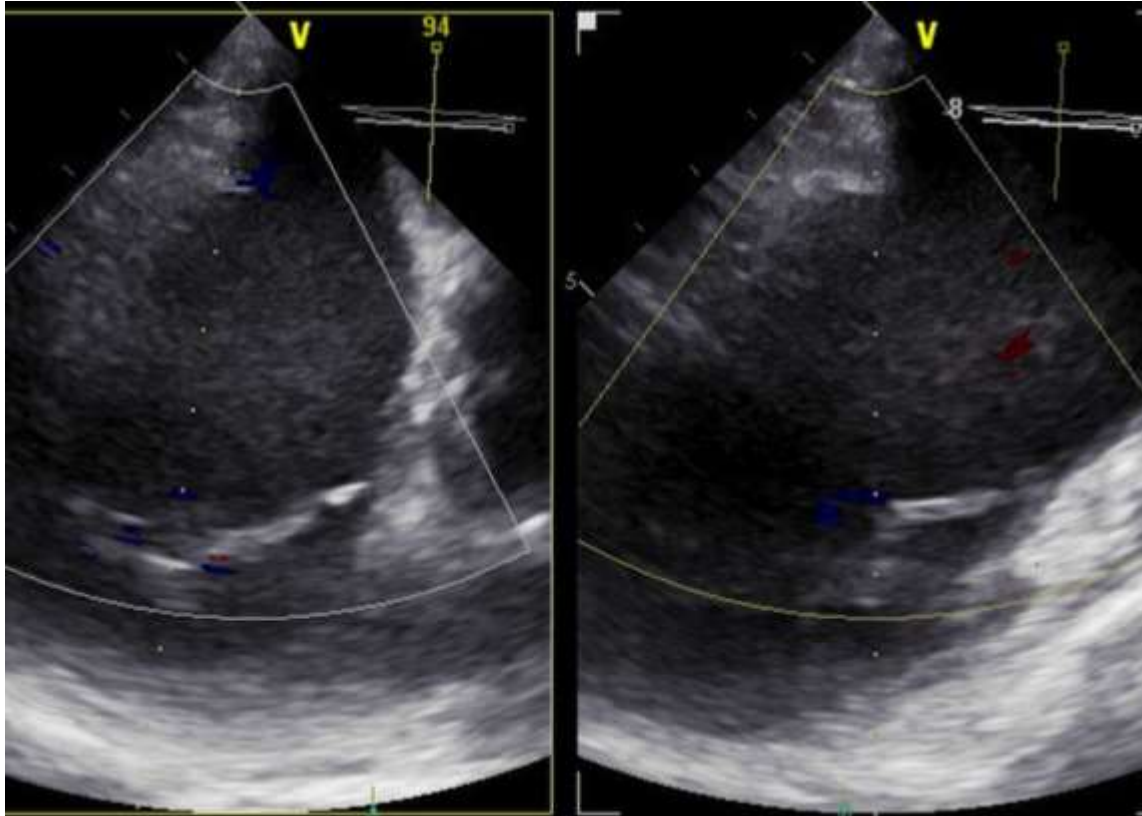


- Nitinol Tapered Stent
- Height 21 mm
- Annular Winglets and leaflet anchors
- Sizes= 36 40, 44, 48, 52 mm.
- Xenogeneic Pericardium

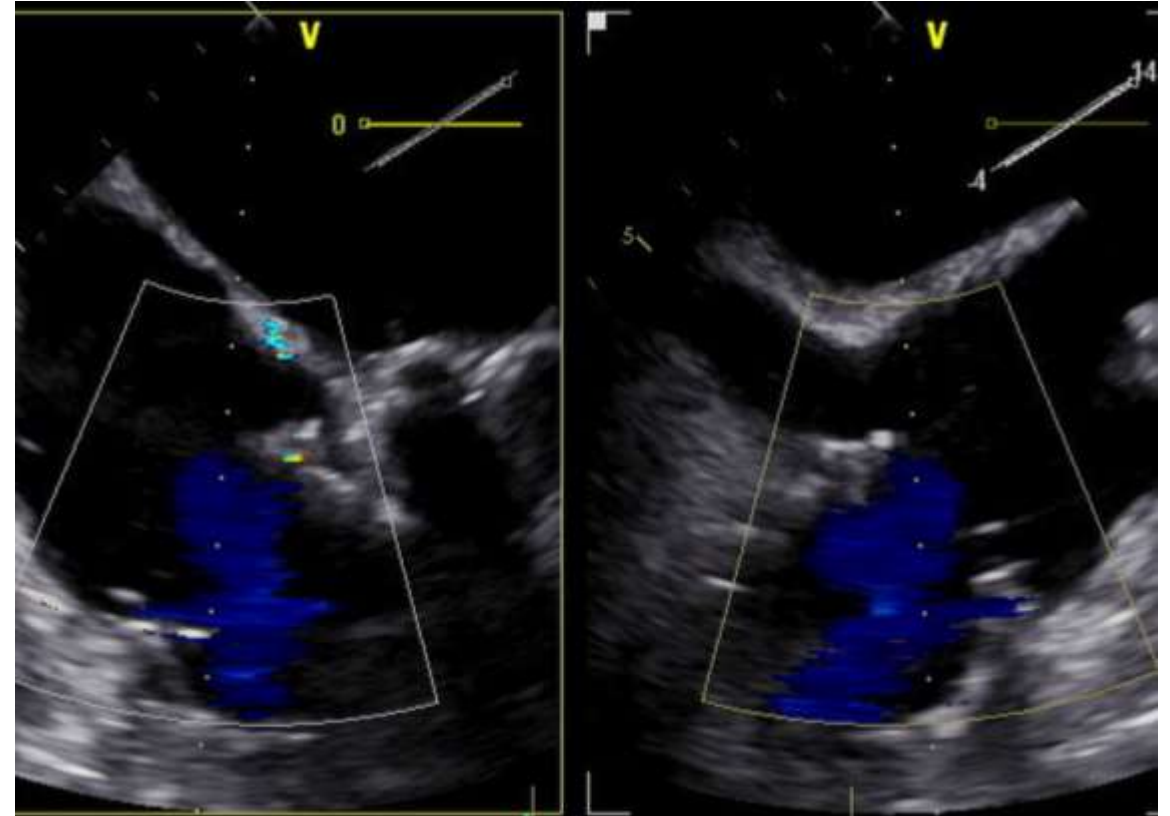
Samir Kapadia



Navigate tricuspid valve implantation 1st patient in Frankfurt



before



after

Tricuspid valve interventions

- Like in the mitral position, we will need different repair techniques for different morphologies, may be in combination
- Imaging is even more complex and even more important than in most other interventions including mitral
- Current results of repair are promising but not optimal yet
- Tricuspid valve implantation has taken off