bwqic

Difference between AoV and MV

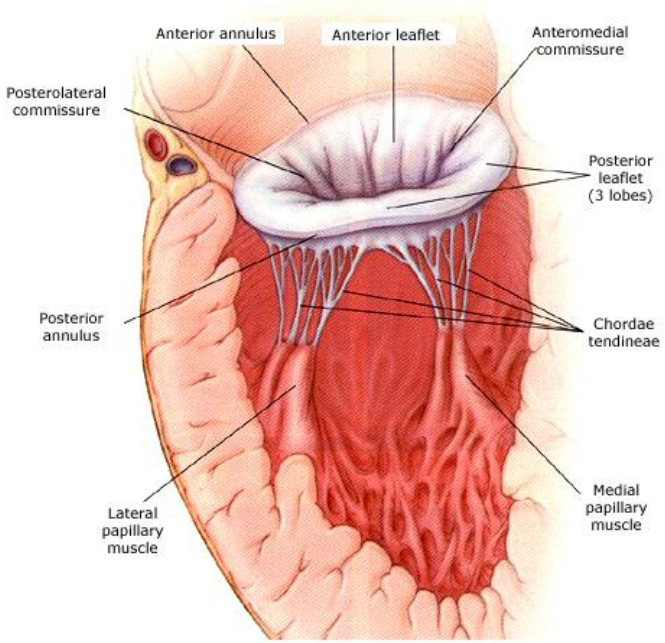
Aortic Valve

Mitral Valve

Transcatheter Mitral Valve Devices Mechanism of Action

Annulus

- **Indirect annuloplasty**
  - Coronary sinus approach
  - Asymmetrical approach
- **Direct annuloplasty**
  - Mechanical cinching
  - Energy mediated cinching
  - Hybrid



Leaflets

- Edge-to-Edge
- Leaflet ablation
- Space occupier

Left Ventricle

- LV (and MA) remodeling

Chordal implants

- Transapical
- Transapical-Transseptal

MV replacement

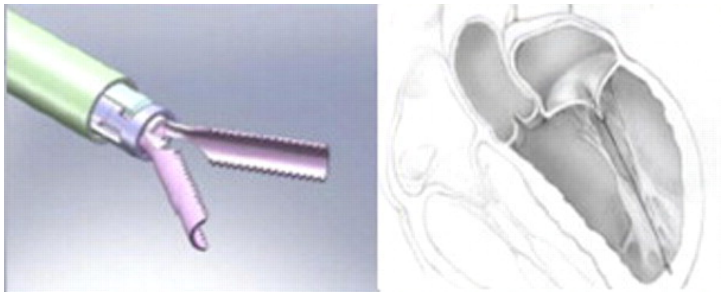
- Right mini-thoracotomy
- Transapical
- Transseptal

Otto *N Engl J Med* 2001:345:740-746

Leaflets

- Edge-to-Edge
- Leaflet ablation
- Space occupier

Edge-to-Edge (leaflet plication)



Device:

Mitraclip / (Mitraflex) / (Mobius)

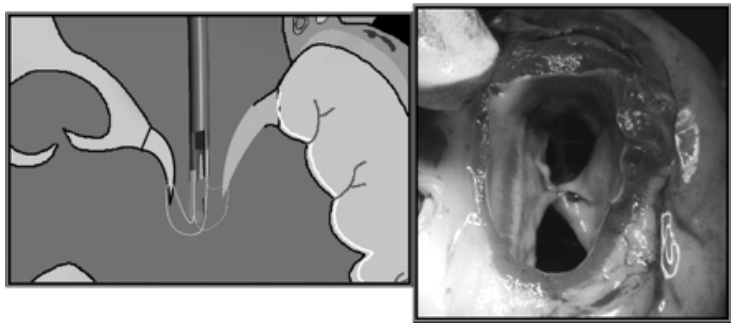
Status:

Randomized trials

Principle:

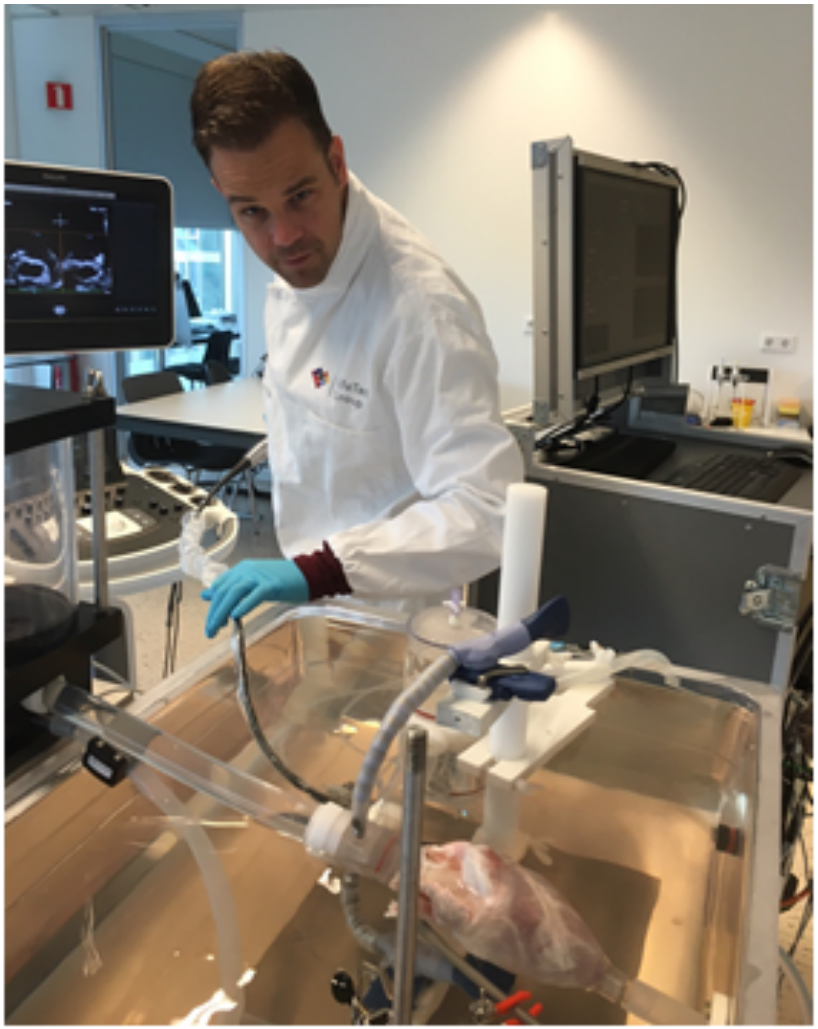
Based on the surgical Alfieri technique which brings the anterior and posterior leaflets together with a suture, creating a "double orifice" MV.

This re-establishes leaflet coaptation, thereby reducing MR.



Limitations:

- Surgical Alfieri typically used with annuloplasty, because suboptimal results without annuloplasty
- Possibility of causing iatrogenic MS

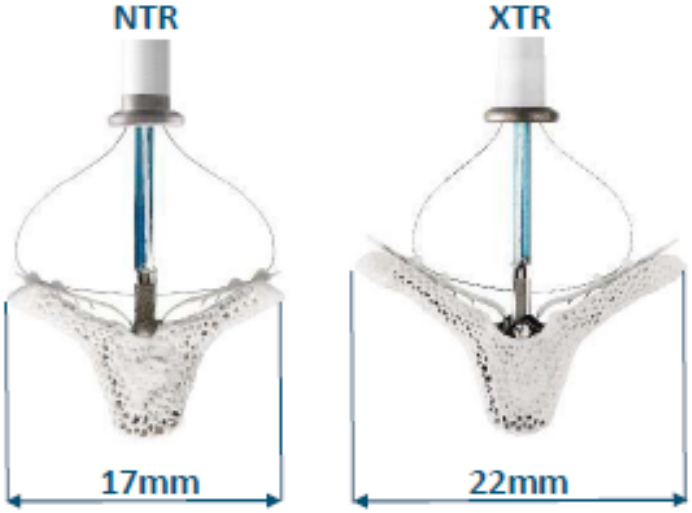


LifeTec Group
Eindhoven

Next generation

MitraClip XTR

CLIP ENHANCEMENT



MitraClip XTR arm and gripper length extended by 3 mm

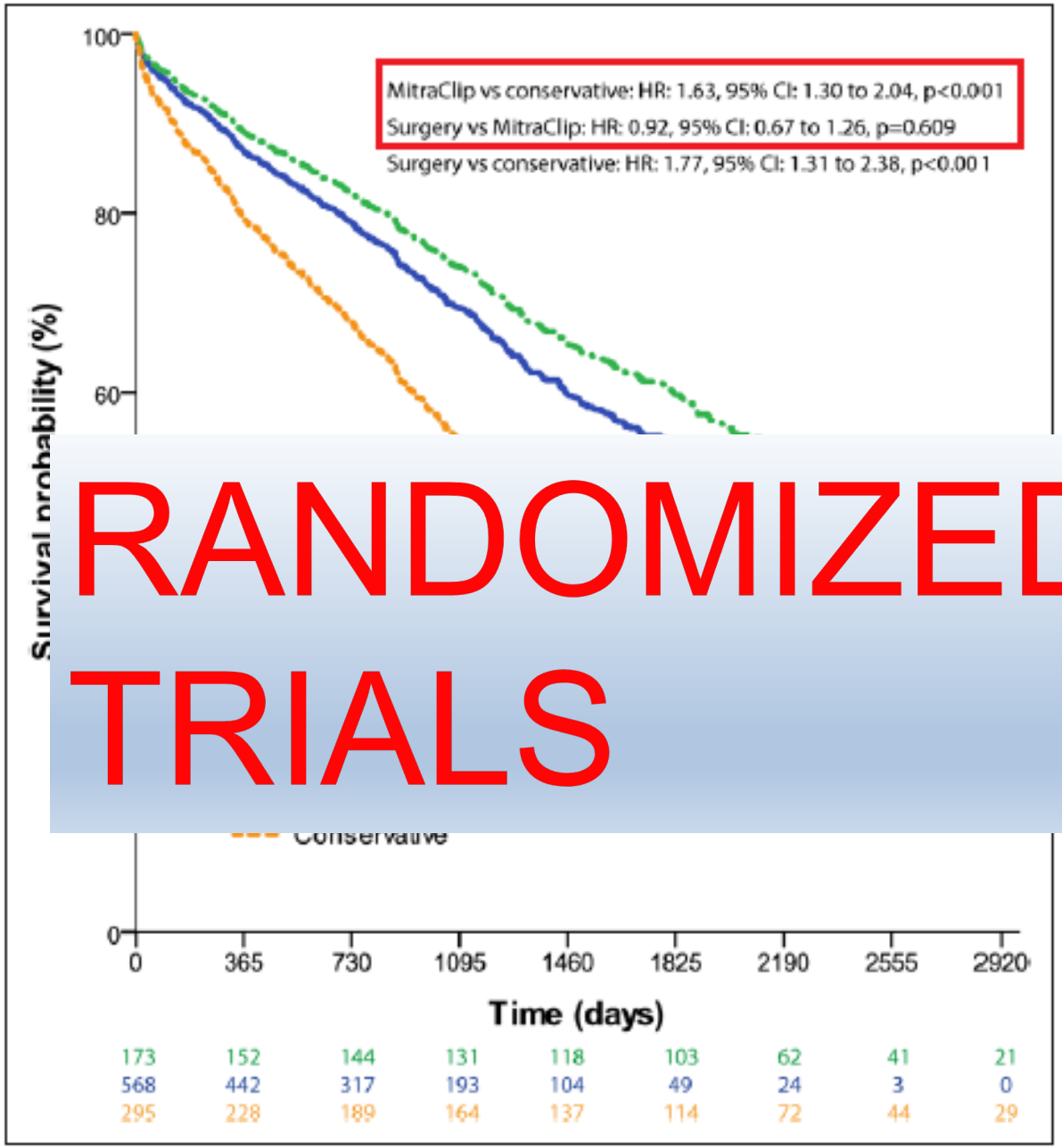
Survival After MitraClip Treatment Compared to Surgical and Conservative Treatment for High-Surgical-Risk Patients With Mitral Regurgitation

Friso Kortlandt, MD; Juliette Velu, MSc; Remco Schurer, MD; Tom Hendriks, MSc; Ben Van den Branden, MD, PhD; Berto Bouma, MD, PhD; Ted Feldman, MD; Johannes Kelder, MD, PhD; Annelies Bakker, MD; Marco Post, MD, PhD; Pim Van der Harst, MD, PhD; Frank Eefting, MD; Martin Swaans, MD, PhD; Benno Rensing, MD, PhD; Jan Baan Jr, MD, PhD; Jan Van der Heyden, MD, PhD

Circulation: cardiovasc Intervention 2018 Jun

Table. Baseline Characteristics

				P Value			



RANDOMIZED TRIALS

and matching

Severe	98 (20.2)	26 (19.7)	38 (20.8)			

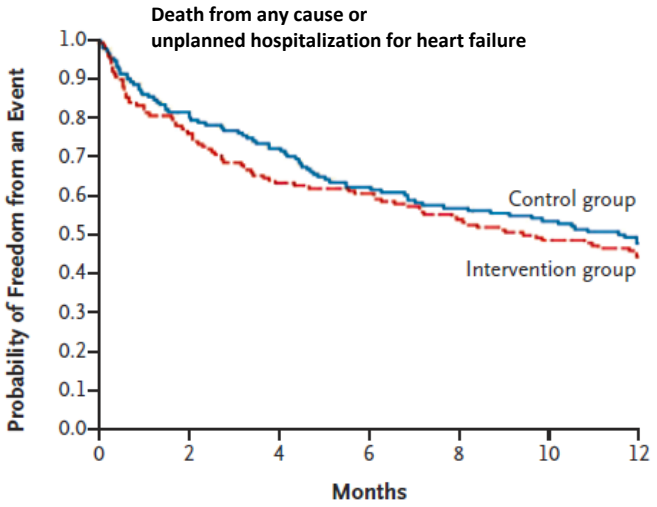
Randomized Controlled Trials on MitraClip in secondary MR

ESC European Society of Cardiology

ORIGINAL ARTICLE

Percutaneous Repair or Medical Treatment for Secondary Mitral Regurgitation

J.-F. Obadia, D. Messika-Zeitoun, G. Leurent, B. Iung, G. Bonnet, N. Piriou, T. Lefèvre, C. Piot, F. Rouleau, D. Carrié, M. Nejjari, P. Ohlmann, F. Leclercq, C. Saint Etienne, E. Teiger, L. Leroux, N. Karam, N. Michel, M. Gilard, E. Donal, J.-N. Trochu, B. Cormier, X. Armoiry, F. Boutitie, D. Maucort-Boulch, C. Barnel, G. Samson, P. Guerin, A. Vahanian, and N. Mewton, for the MITRA-FR Investigators*

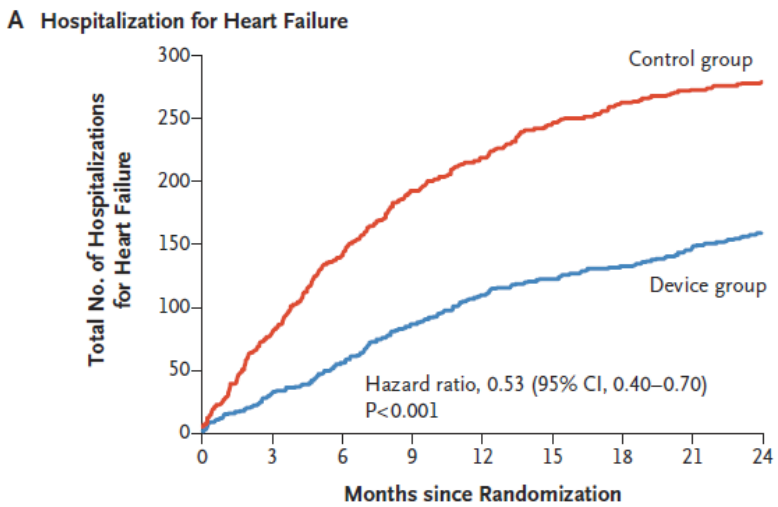


No. at Risk							
Control group	152	123	109	94	86	80	73
Intervention group	151	114	95	91	81	73	67

ORIGINAL ARTICLE

Transcatheter Mitral-Valve Repair in Patients with Heart Failure

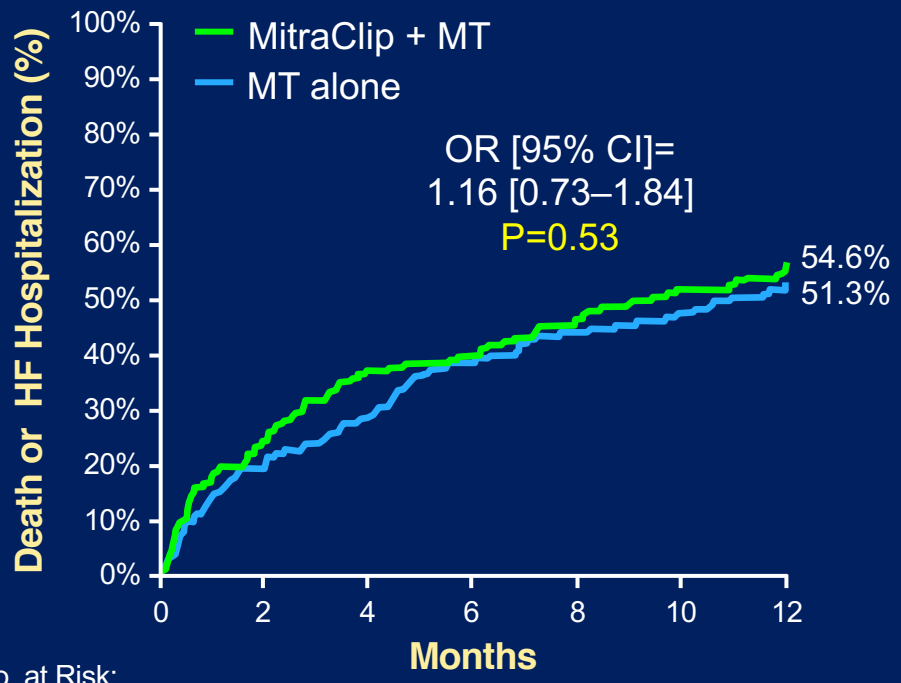
G.W. Stone, J.A. Lindenfeld, W.T. Abraham, S. Kar, D.S. Lim, J.M. Mishell, B. Whisenant, P.A. Grayburn, M. Rinaldi, S.R. Kapadia, V. Rajagopal, I.J. Sarembock, A. Brieke, S.O. Marx, D.J. Cohen, N.J. Weissman, and M.J. Mack, for the COAPT Investigators*



No. at Risk									
Control group	312	294	271	245	219	176	145	121	88
Device group	302	286	269	253	236	191	178	161	124

COAPT vs. MITRA-FR: 12-Month Death or HF Hosp

MITRA-FR

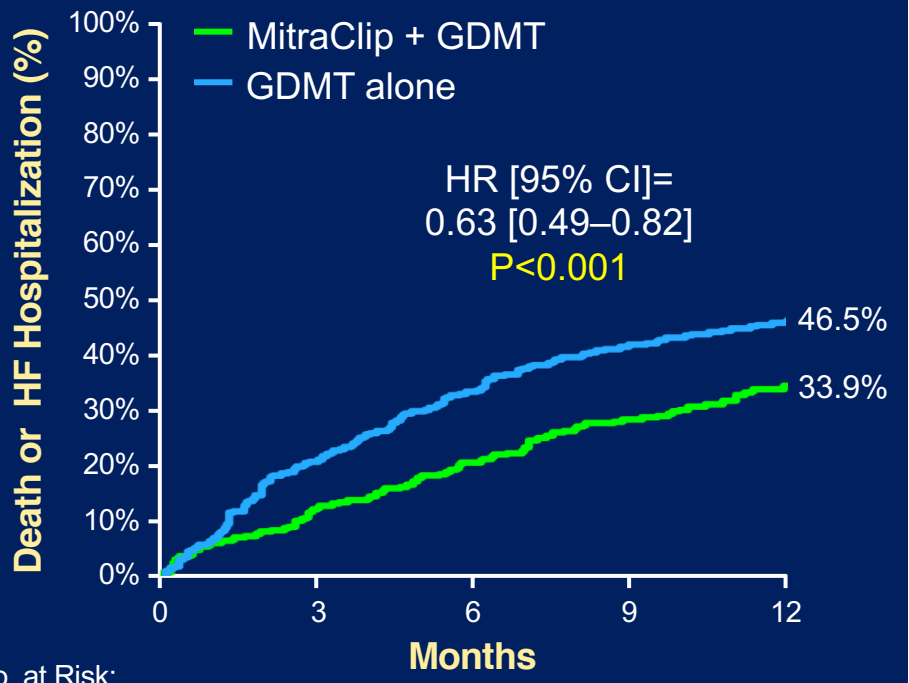


No. at Risk:

Control Group	152	123	109	94	86	80	73
Device Group	151	114	95	91	81	73	67

Obadia JF et al. NEJM. 2018 Aug 27. doi: 10.1056/NEJMoa1805374

COAPT



No. at Risk:

Control Group	312	244	205	174	153
Device Group	302	264	238	215	194

Stone GW et al. NEJM. 2018 Sept 23.

Key differences between both trials: why is the outcome so different

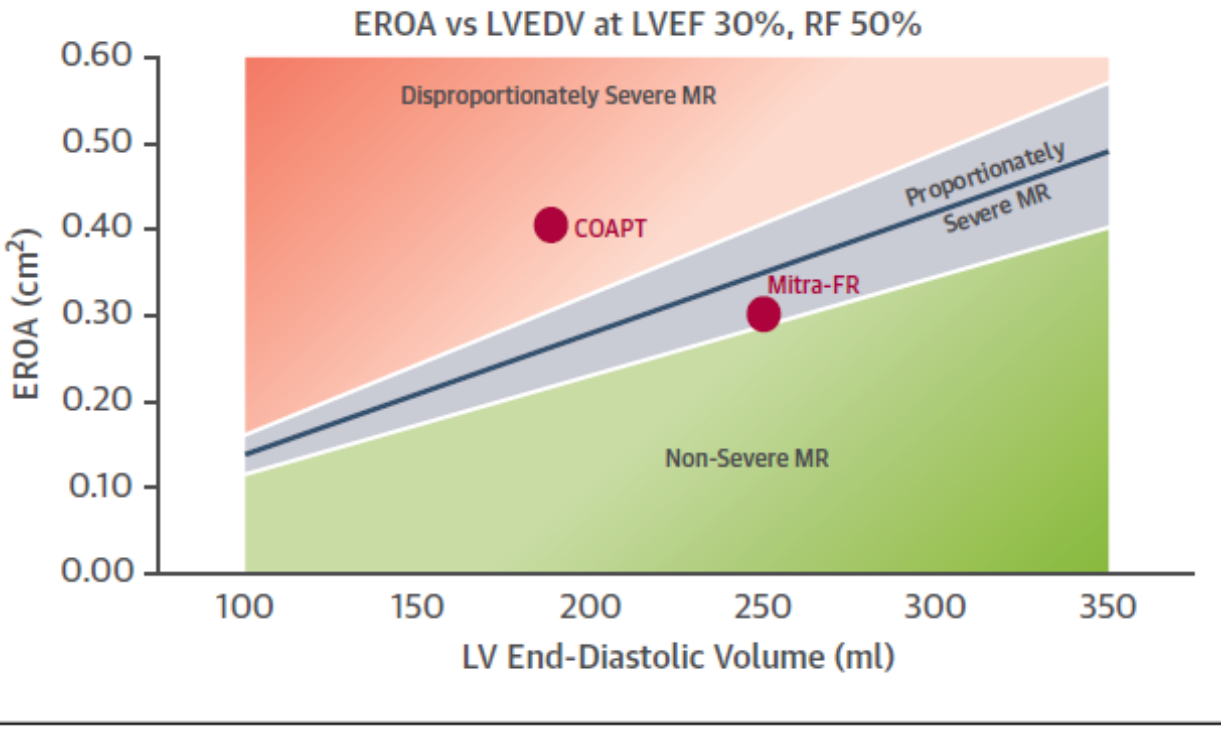
ESC European Society of Cardiology

	MITRA-FR (n=304)	COAPT (n=614)
Severe MR entry criteria	Severe FMR by EU guidelines: EROA >20 mm^2 or RV >30 mL/beat	Severe FMR by US guidelines: EROA >30 mm^2 or RV >45 mL/beat
EROA (mean ± SD)	31 ± 10 mm^2	41 ± 15 mm^2
LVEDV (mean ± SD)	135 ± 35 mL/m^2	101 ± 34 mL/m^2
GDMT at baseline and FU	Receiving HF meds at baseline – allowed variable adjustment in each group during follow-up per "real-world" practice	CEC confirmed pts were failing maximally-tolerated GDMT at baseline – few major changes during follow-up
Acute results: No clip / ≥3+ MR	9% / 9%	5% / 5%
Procedural complications*	14.6%	8.5%
12-mo MitraClip ≥3+ MR	17%	5%

GW Stone, presentation at TCT 2018

MITRA FR
COAPT

´Heterogenous group´



- Patients enrolled in the COAPT trial had approximately 30% higher EROA with LV volumes approximately 30% smaller
- "We hypothesize that the ratio of EROA to LVEDV is likely to be useful in **individual clinical decision-making**,

  that is, patients with **proportionate MR** might be highly likely to respond to optimization of medical therapy,

  whereas those with **disproportionate MR** would be most likely to benefit from additional transcatheter repair"

Grayburn et al. JACC Cardiovasc Imaging. 2018.

Leaflets

- Edge-to-Edge
- Leaflet ablation
- Space occupier

Leaflet ablation

Device:

Thermocool catheter

Status:

Animal models

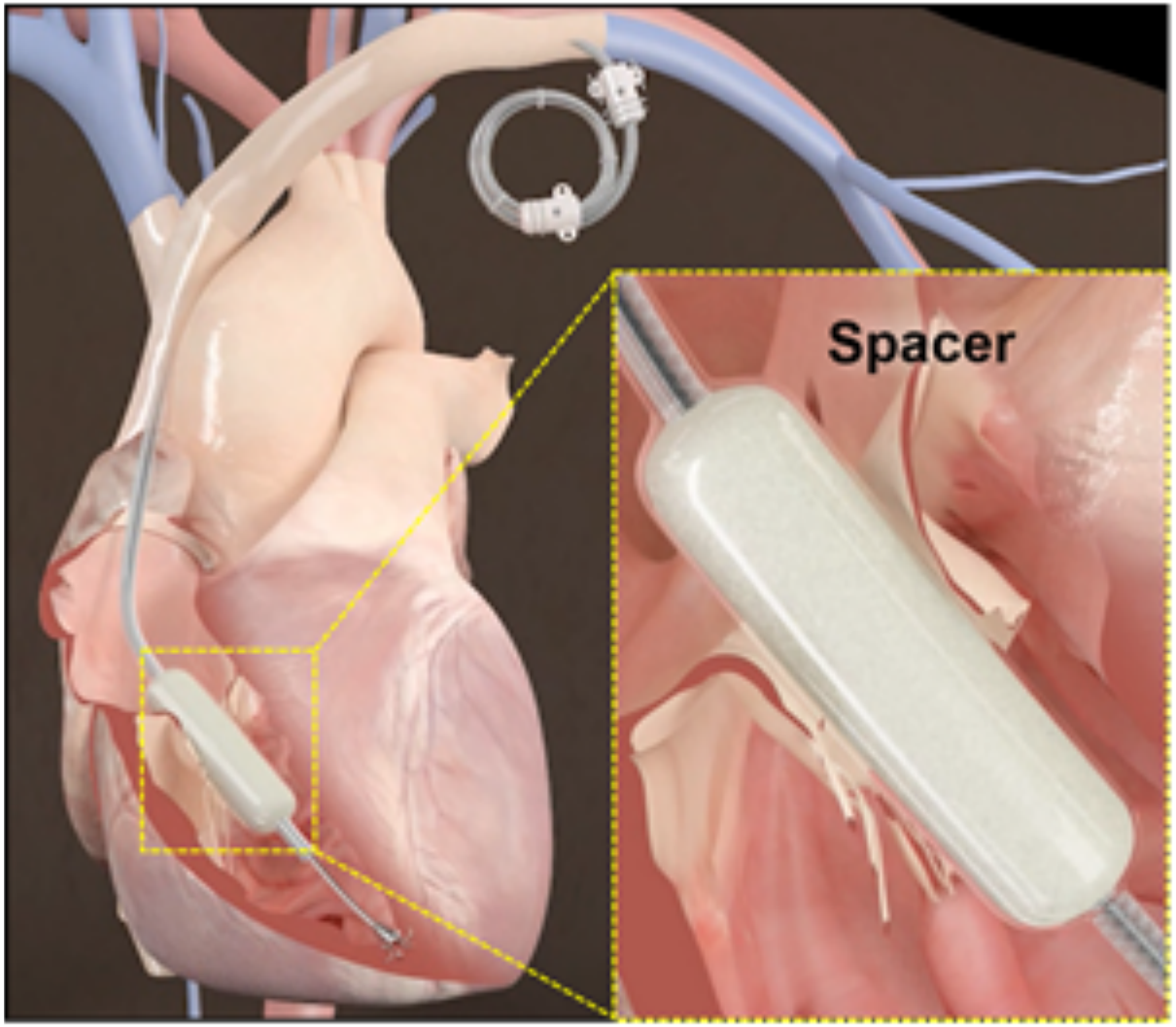
Principle:

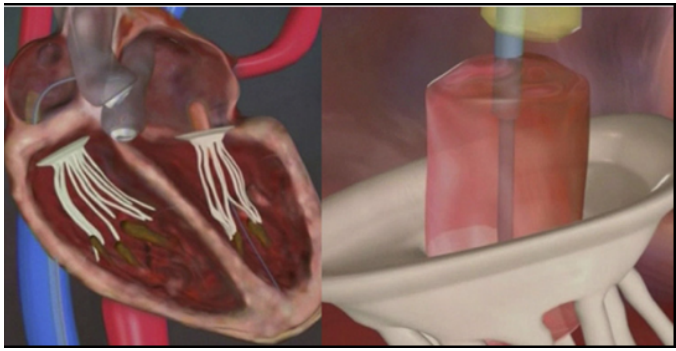
Radiofrequency energy is delivered retrograde from the LV to the leaflet(s) to cause scarring and fibrosis and functional (reduced leaflet motion) alterations

Limitations:

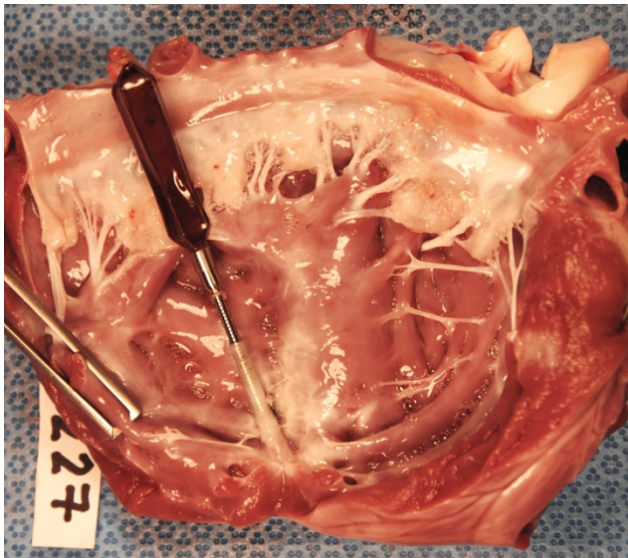
- Only for DMR
- RF ablation not precise
- Leaflet perforation
- Damage to the adjacent cardiac structures

Williams JL et al. J Interv Cardiol. Dec 2008;21(6):547-54.





MV orifice to provide a
g MR
anchored at the apex



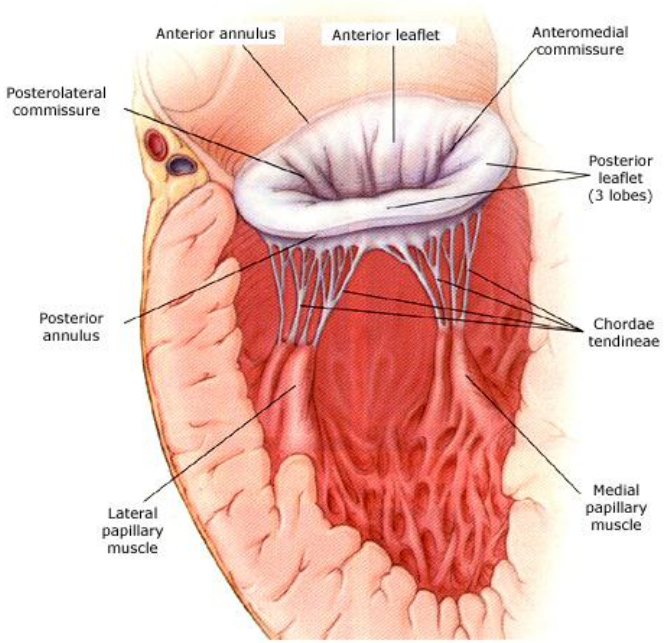
FORMA Repair System. The Forma Repair System (Edwards Lifesciences,
CA, USA) positioned at the level of the tricuspid valve annulus, anchoring
the right ventricular apex, and excess device length coiled into a subcuta
pocket. Image adapted with permission from Edwards Lifesciences, Irvine

C
D
Cleveland Clinic, USA

Transcatheter Mitral Valve Devices Mechanism of Action

Annulus

- **Indirect annuloplasty**
  - Coronary sinus approach
  - Asymmetrical approach
- **Direct annuloplasty**
  - Mechanical cinching
  - Energy mediated cinching
  - Hybrid



Leaflets

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Left Ventricle

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MV replacement

- Right mini-thoracotomy
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- Transseptal

Otto *N Engl J Med* 2001:345:740-746

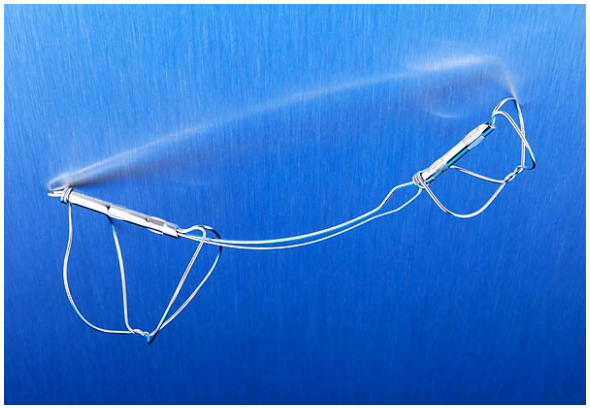
Annulus

- Indirect annuloplasty
  - Coronary sinus approach
  - Asymmetrical approach
- Direct annuloplasty
  - Mechanical cinching
  - Energy mediated cinching
  - Hybrid

Indirect annuloplasty – Coronary sinus approach

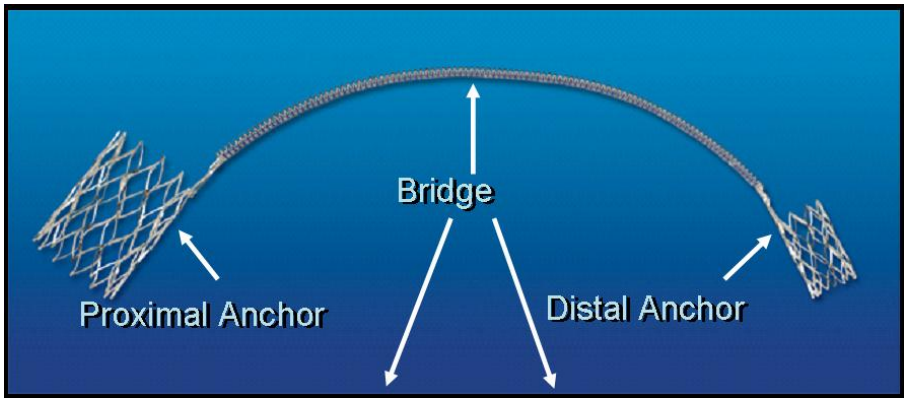
Device:

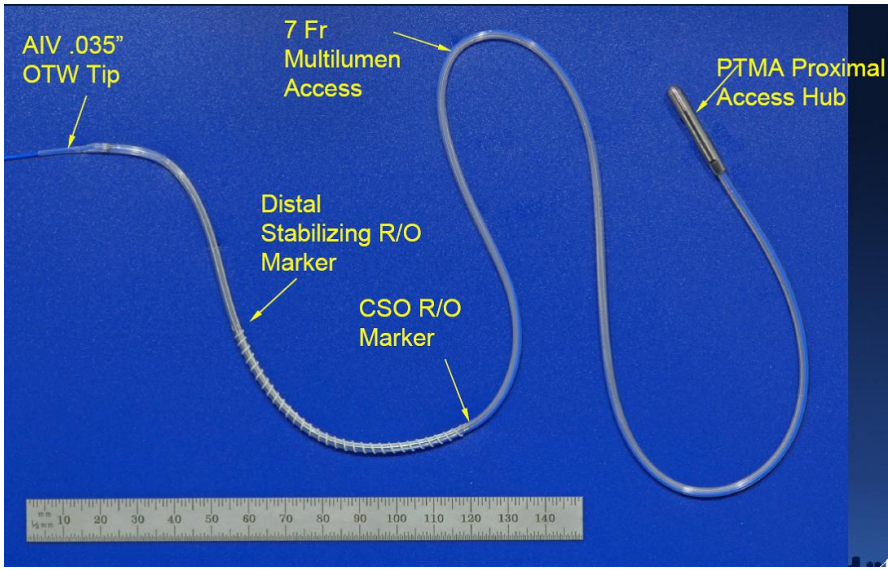
Carillon / (Monarc/Viking) / (Viacor)



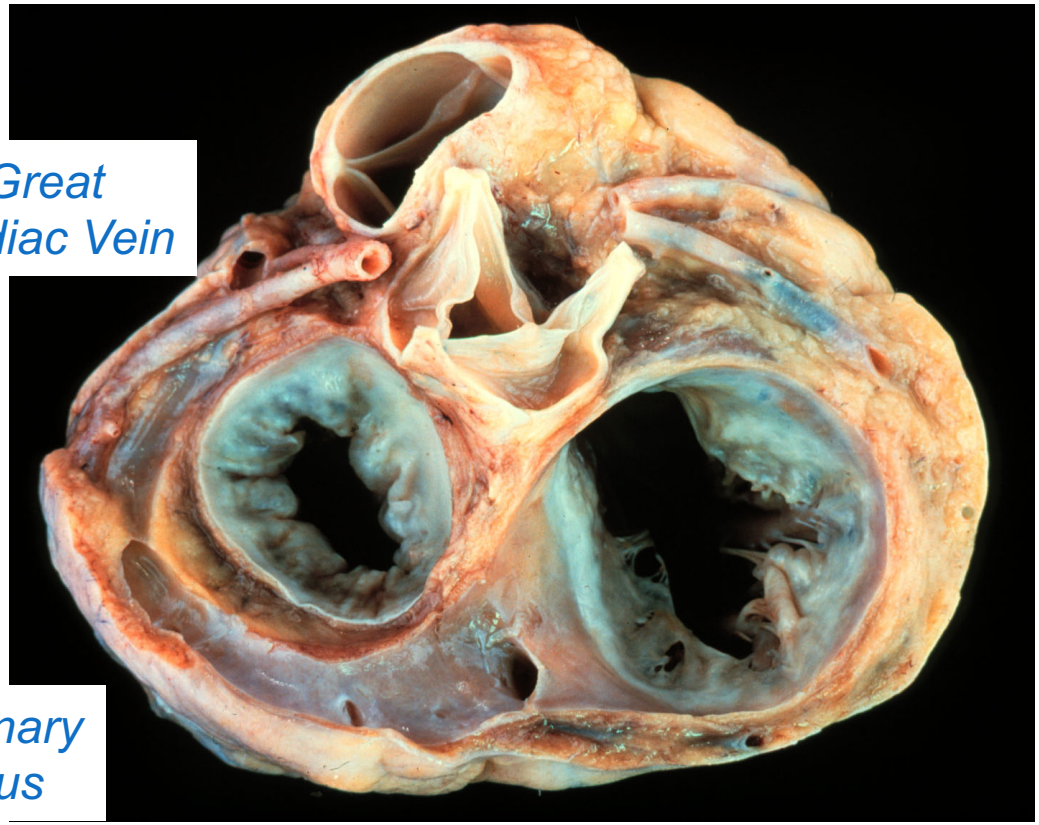
- Status:

Enrollment in multicentre, randomized clinical trial (REDUCE FMR Trial)





Indirect annuloplasty
Coronary sinus approach



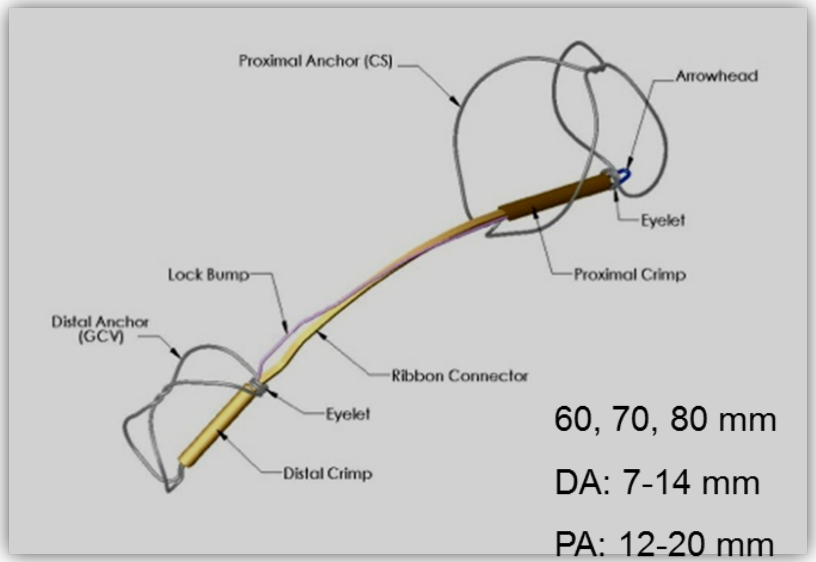
Principle:

- Implantation of devices within the CS with the aim of "pushing" the posterior annulus anteriorly, thereby reducing the septal-lateral (anterior-posterior) dimension of the mitral annulus

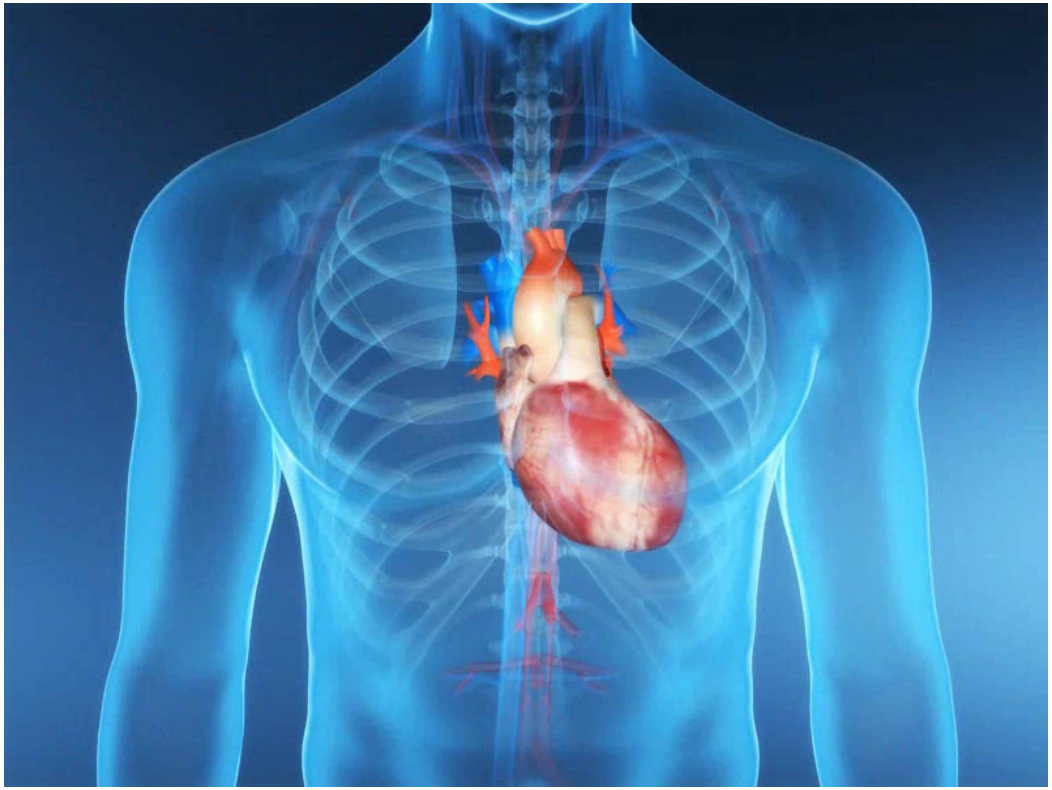
- This has been demonstrated in surgical data to improve leaflet coaptation and decrease MR

Timek TA et al. *J Thorac Cardiovasc Surg*. May 2002;123(5):881-8.

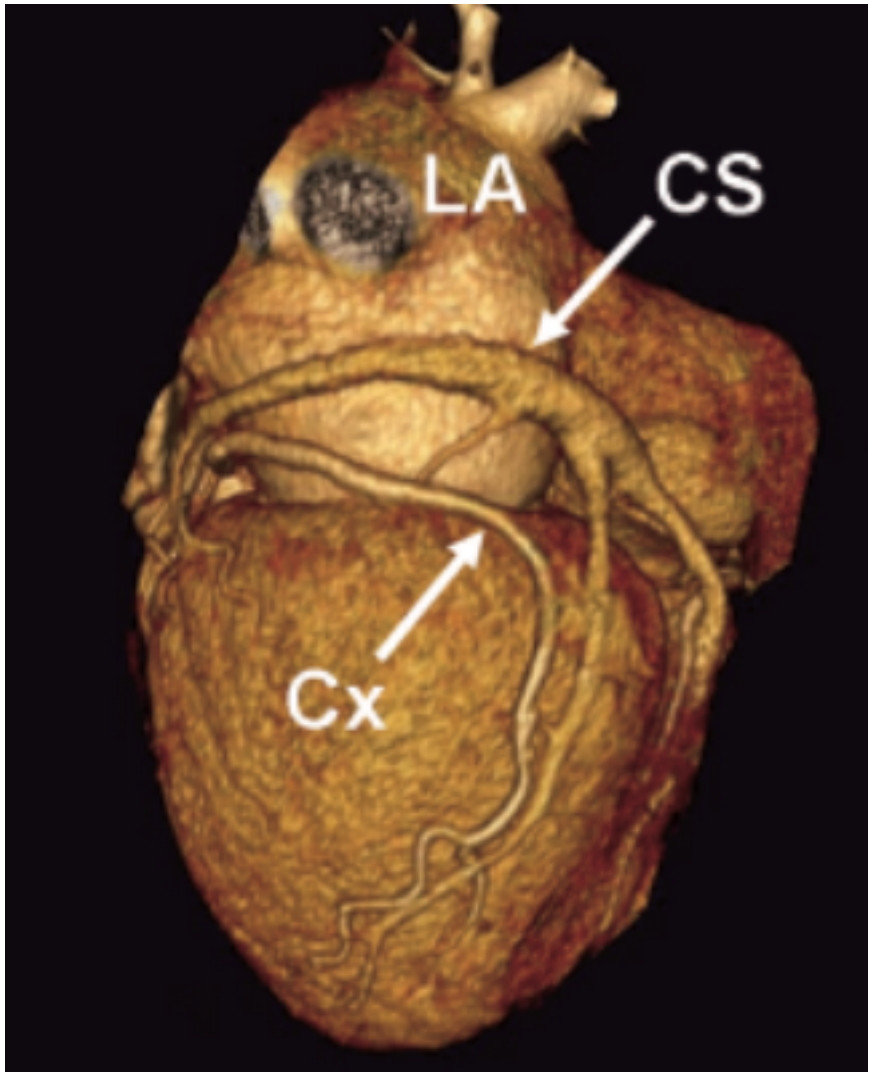
CARILLON Mitral Contour System



Device Deployment

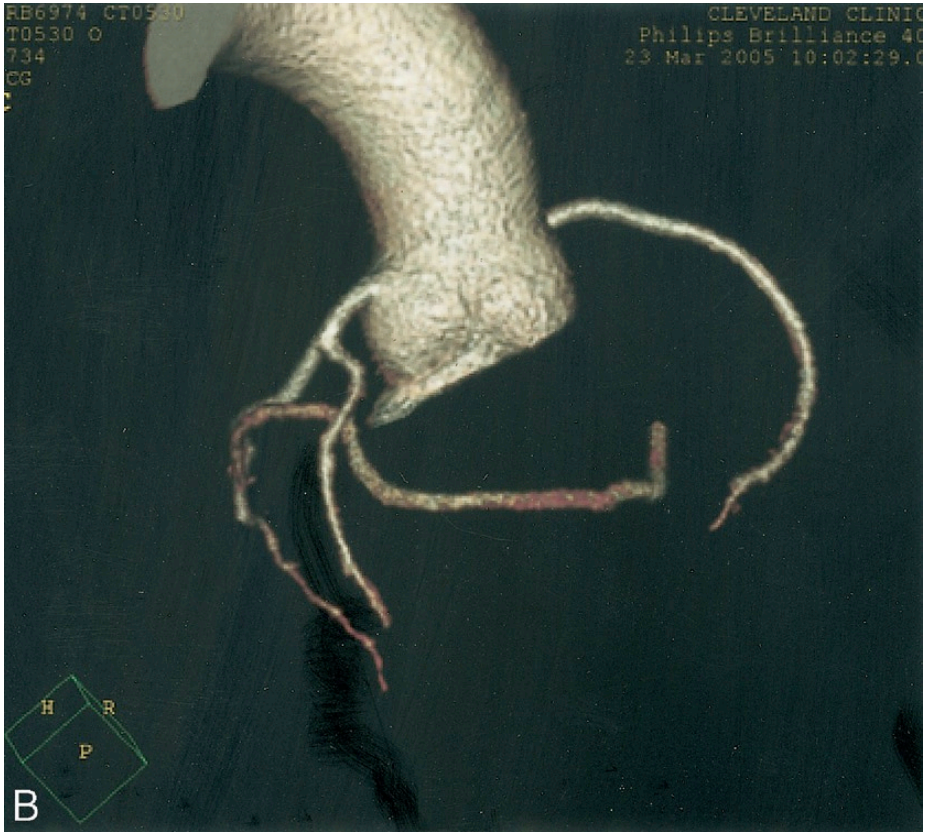


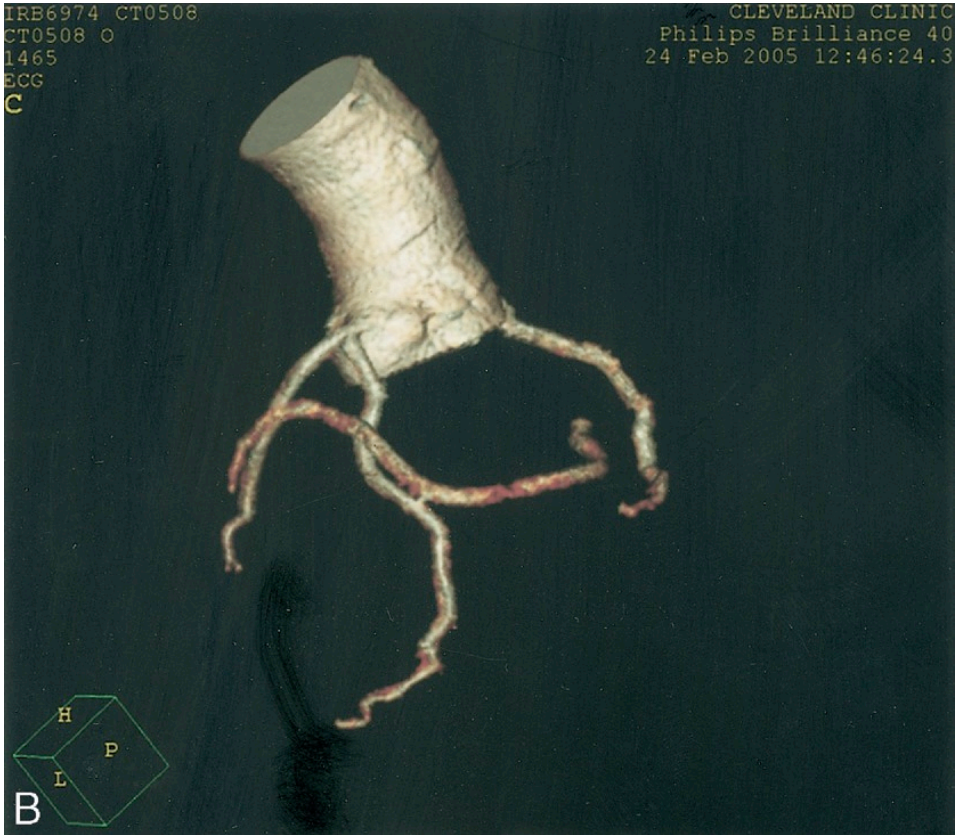
Relation coronary sinus – MV annulus



Courtesy to Dr.Lederman
National Institutes of Health
Bethesda, MD, USA

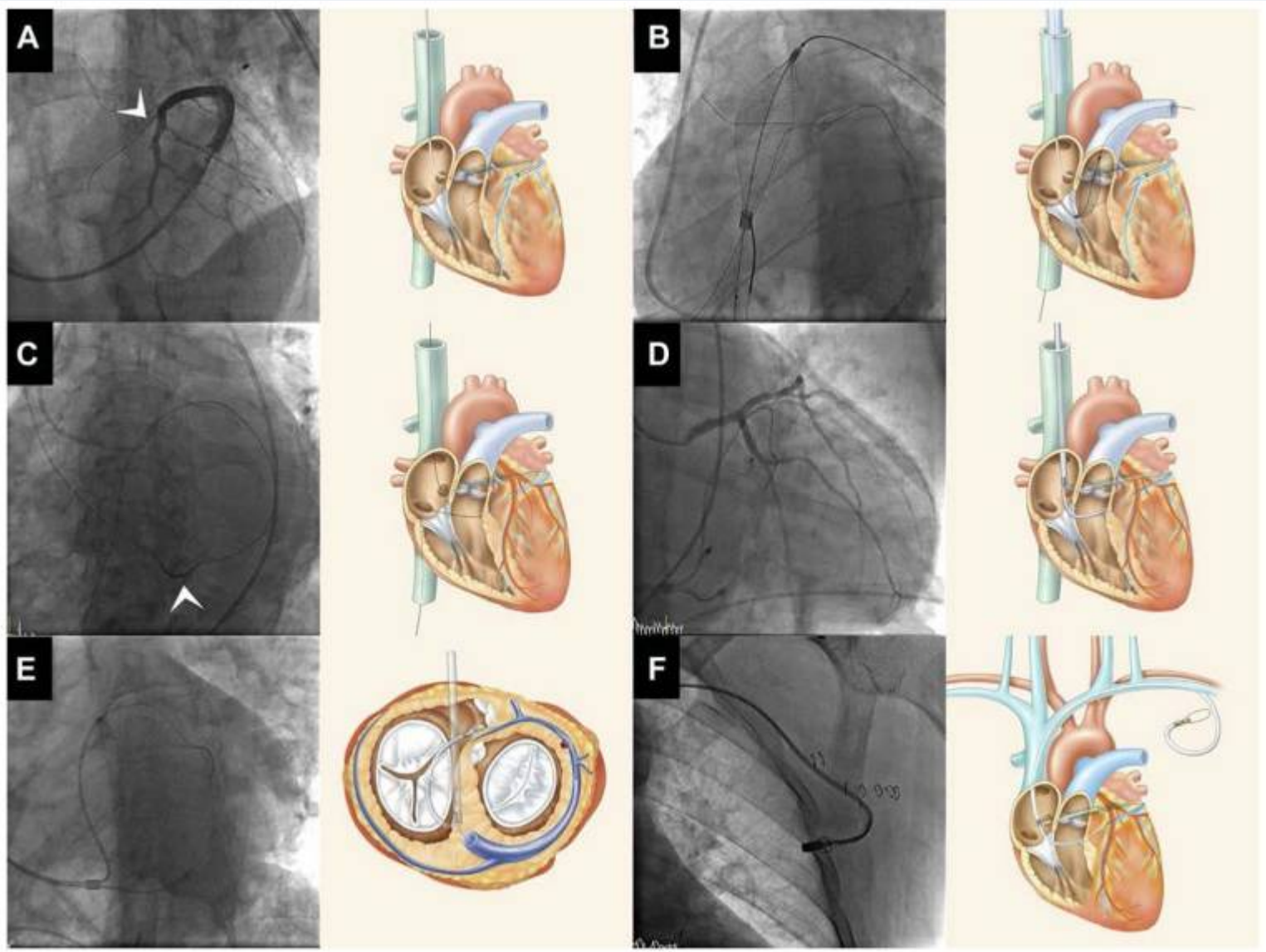
Relation coronary sinus - circumflex artery

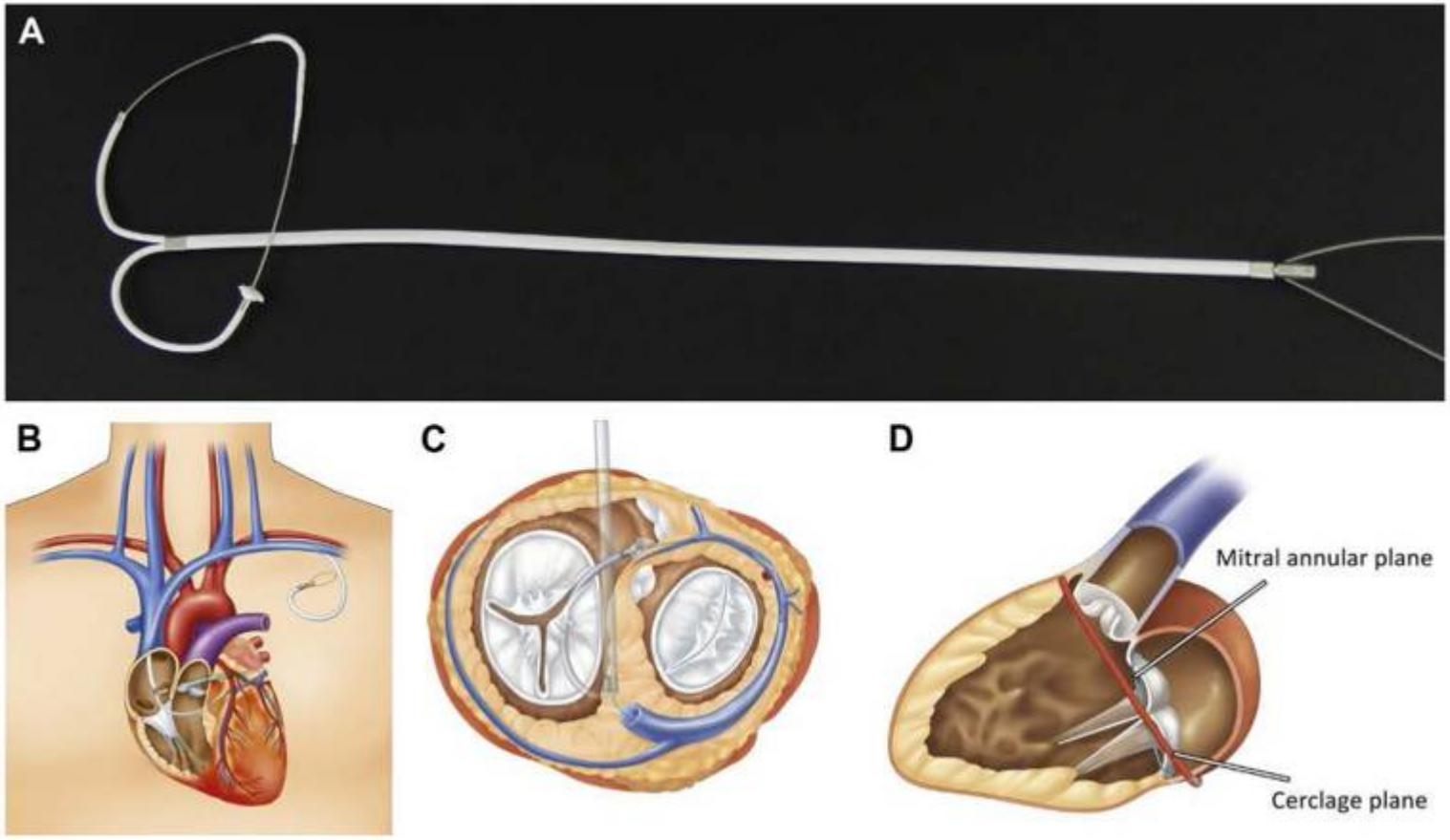




Courtesy to Dr.Kapadia, Cleveland Clinic, USA
Choure AJ et al. JACC 2006

mitral loop cerclage catheter system (Tau-PNU Medical Co, Ltd, Pusan, Korea)




A
B
C
D
Mitral annular plane
Cerclage plane

Coronary Sinus-Based Approach to Mitral Regurgitation

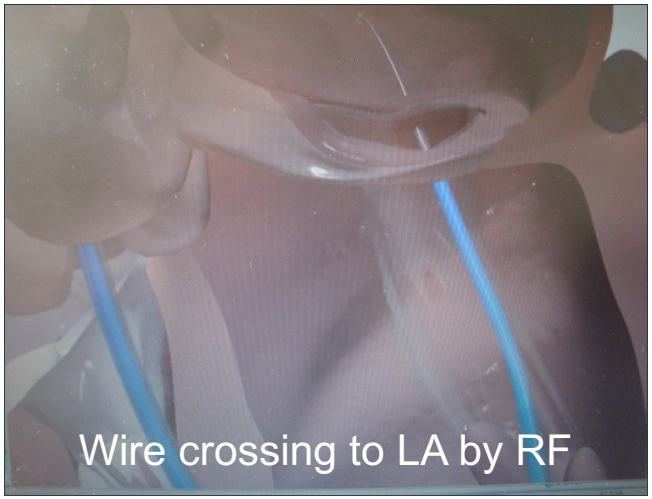
Steven L. Goldberg, MD[a,b,*],
Christoph Hammerstingl, MD

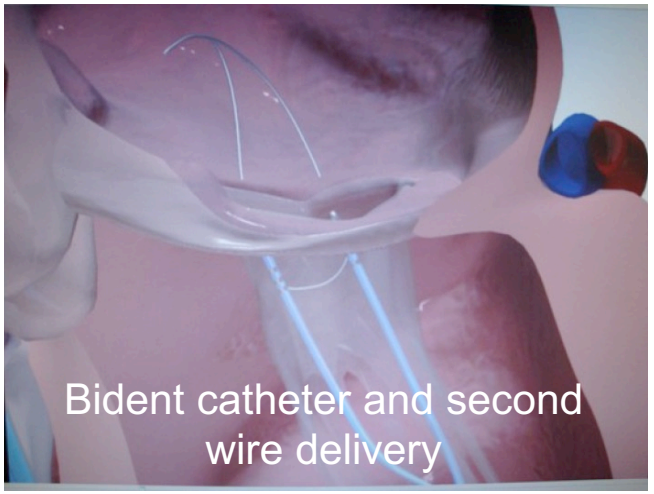
A double blind randomized trial is currently ongoing comparing the Carillon device against
optimal medical therapy

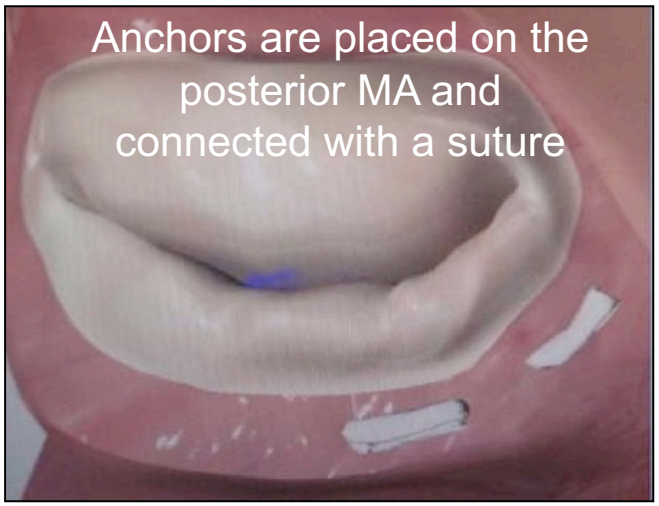
Interv Cardiol Clin 2016

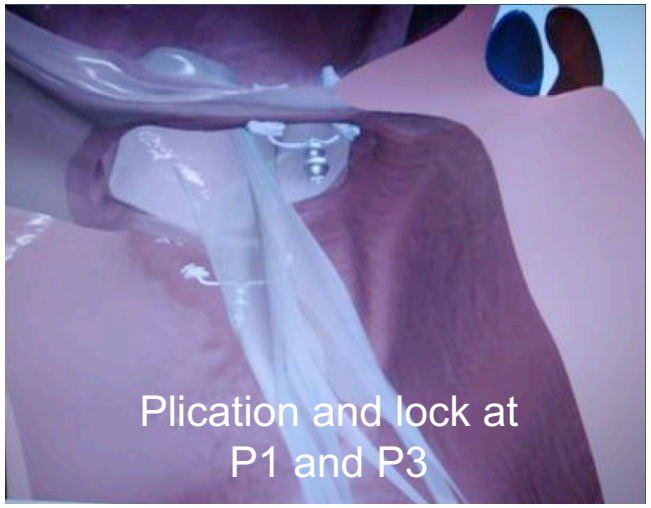
Direct Annuloplasty - Mechanical

Mitralign Device





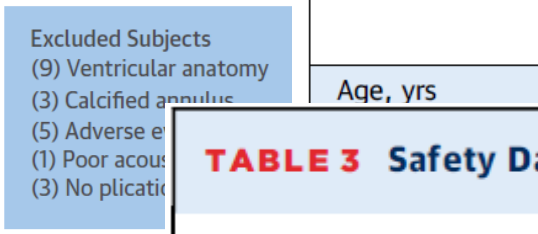


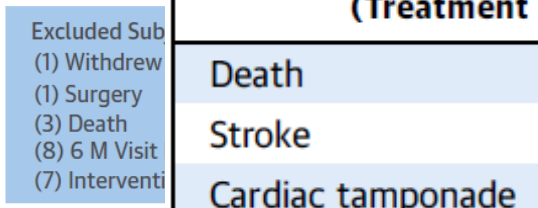


Mimics surgical suture annuloplasty of Paneth and Burr

Aybek et al., JTCS. 2006;
Burr LH, Paneth M, et al. JTCVS 1977:73:589

FIGURE 2 Study Enrollment Chart





6 M = 6 month; 6MWD = 6-

TABLE 2 Baseline Characteristics of the Study Population

	All Patients (N = 71)	Treatment Group (Implant With Plication) (n = 45)
Age, yrs	67.7 ± 11.3	67.9 ± 12.5
Nitrates	38 (53.5)	19 (42.2)

Values are mean ± SD or n (%). *Calculated for mitral valve repair.
ACEI = angiotensin-converting enzyme inhibitor; CABG = coronary artery
:tion fraction; NYHA = New York Heart
intervention; STS = Society of Thoracic

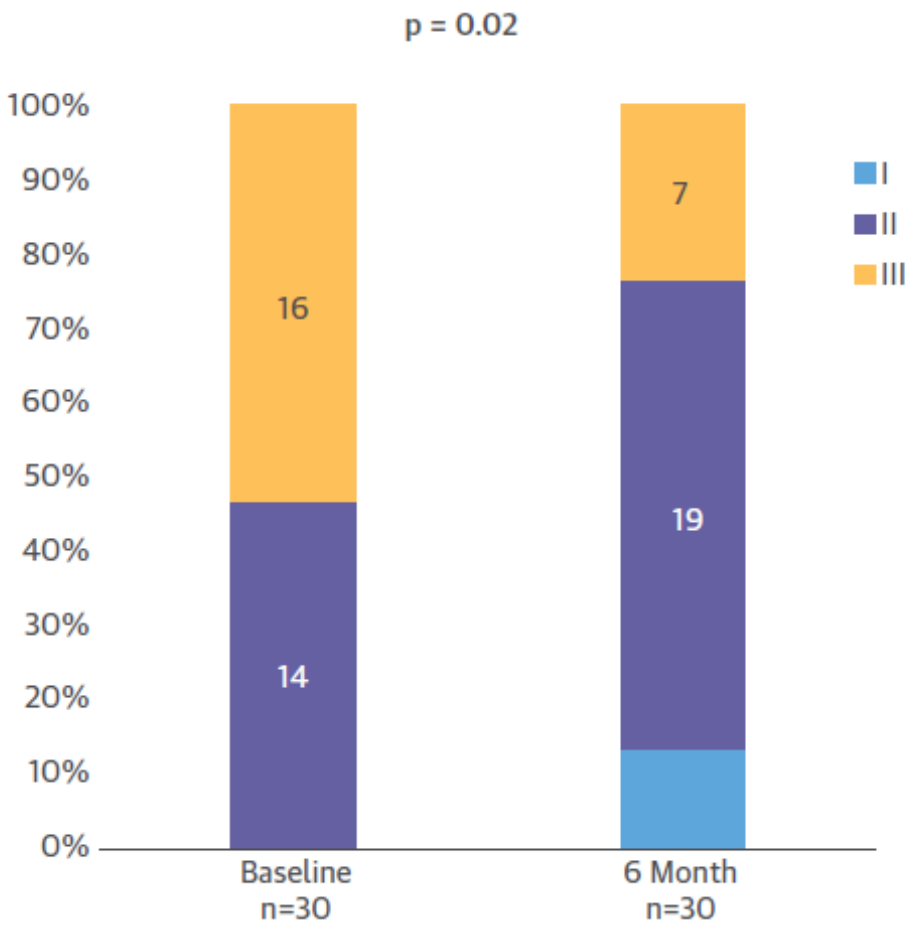
TABLE 3 Safety Data 30 Days and 6 Months After the Procedure

Major Adverse Events (Treatment Group)	30 Days (n = 45)	6 Months (n = 41)
Death	2 (4.4)	5 (12.2)
Stroke	2 (4.4)	2 (4.9)
Cardiac tamponade	4 (8.9)	4 (9.8)
Myocardial infarction	0 (0.0)	0 (0.0)
Urgent surgery/intervention	0 (0.0)	0 (0.0)
Nonurgent mitral valve intervention	2 (4.4)	7 (17.1)
Nonurgent mitral valve surgery	0 (0.0)	1 (2.4)

Values are n (%).

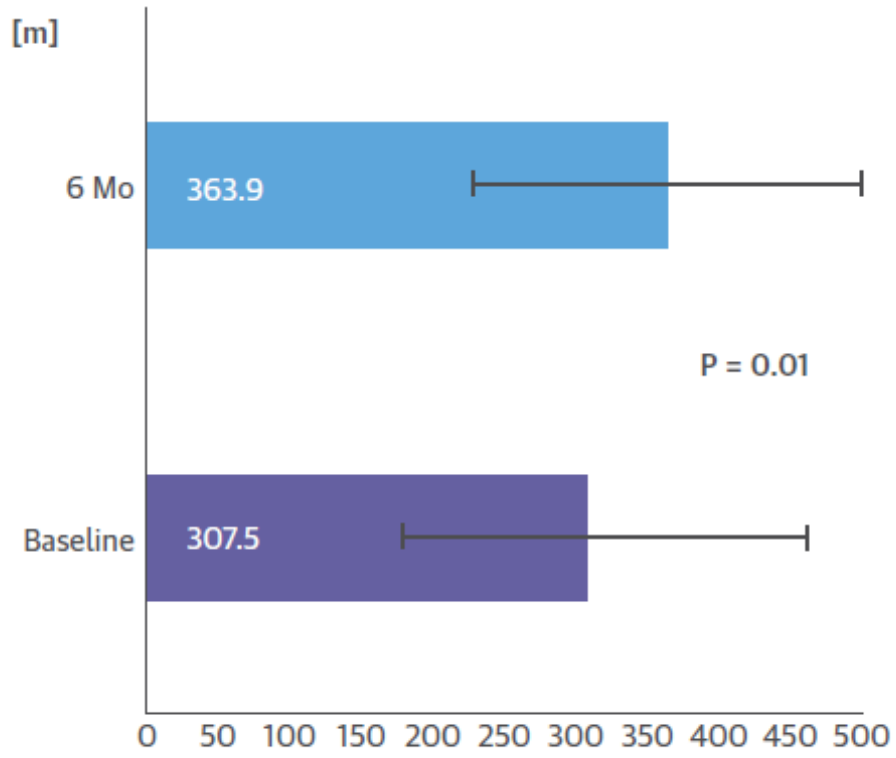
Nickenig, G. et al. J Am Coll Cardiol. 2016;67(25):2927-36.

FIGURE 4 NYHA Functional Classification of Treated Patients



Stacked columns showing New York Heart Association (NYHA) functional class of treated patients at baseline and after 7 months of follow-up.

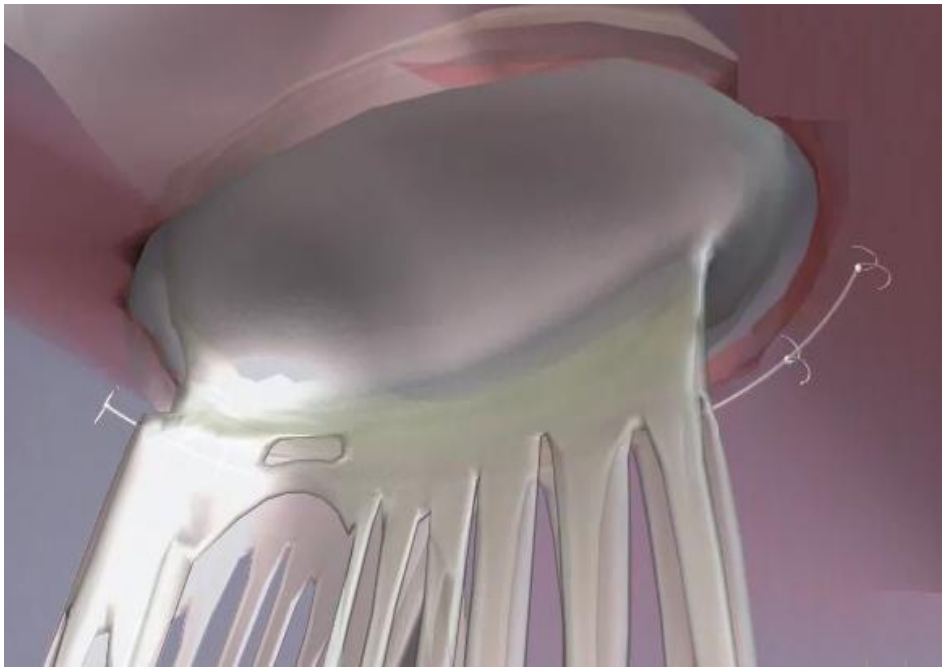
FIGURE 5 Changes in 6MWT After 6 Months

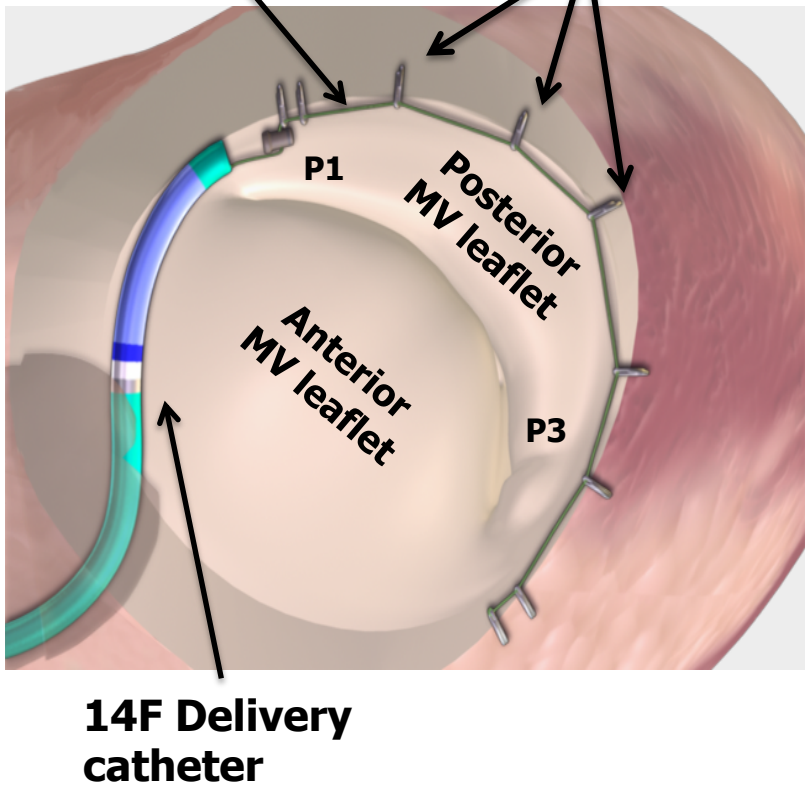


6MWT = 6-min walking test.

Direct Annuloplasty - Mechanical

GDS Accucinch

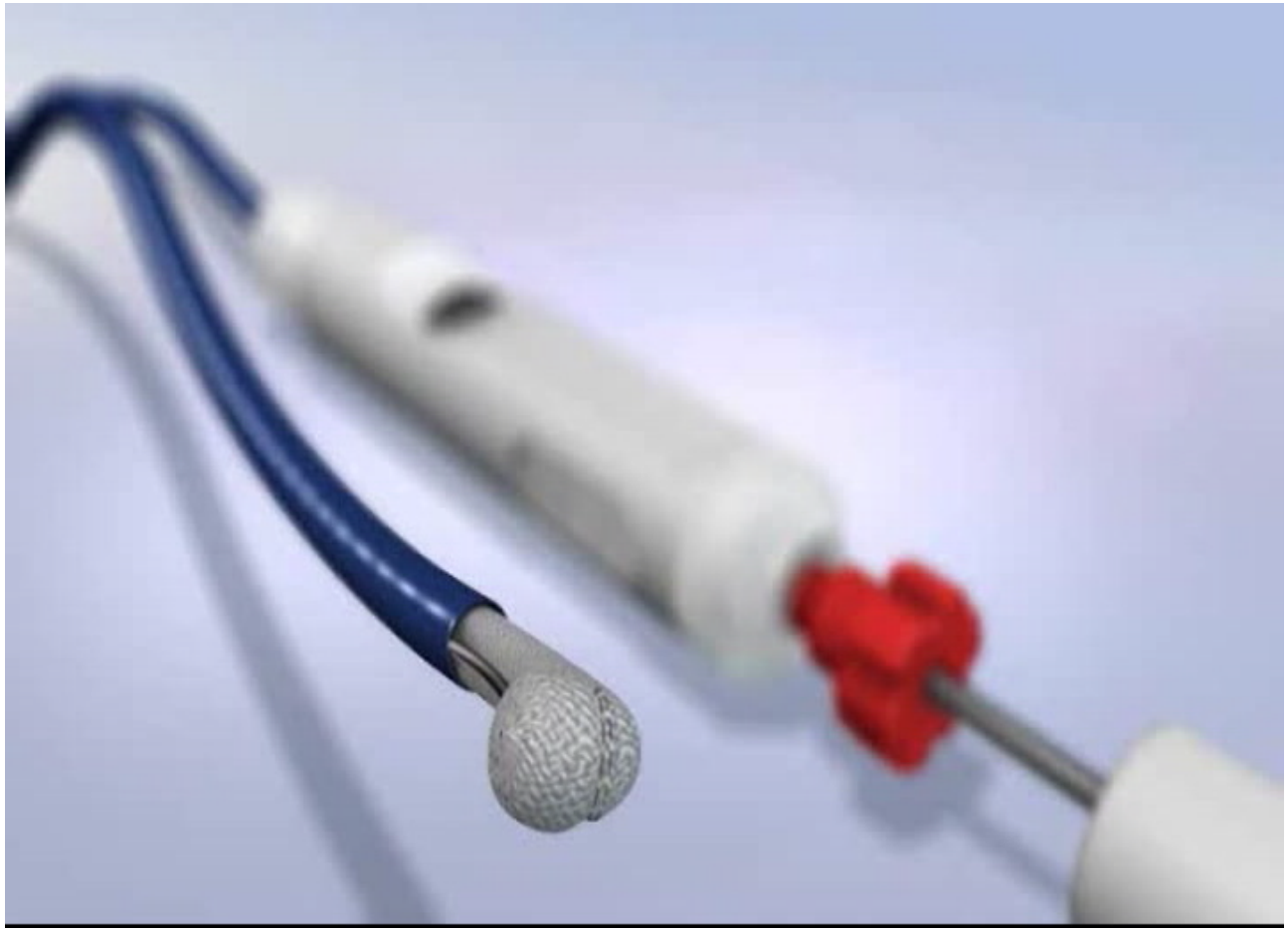




Sub-valvular placement of anchors and a cinching cable along the posterior LV wall via a retrograde trans-femoral approach

Direct Annuloplasty – Mechanical

Valtech Cardioband



- Fully percutaneous procedure based on surgical principles
- Off-pump adjustment of leaflet coaptation
- Innovative multi-functional catheter system
- Based on technology that is tested surgicaly in current clinical study

Courtesy to Dr.Maisano
San Raffaele Hospital
Milan, Italy

JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 9, NO. 19, 2016

ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER
http://dx.doi.org/10.1016/j.jcin.2016.07.005

STRUCTURAL

Transcatheter Mitral Annuloplasty in Chronic Functional Mitral Regurgitation

6-Month Results With the Cardioband Percutaneous Mitral Repair System

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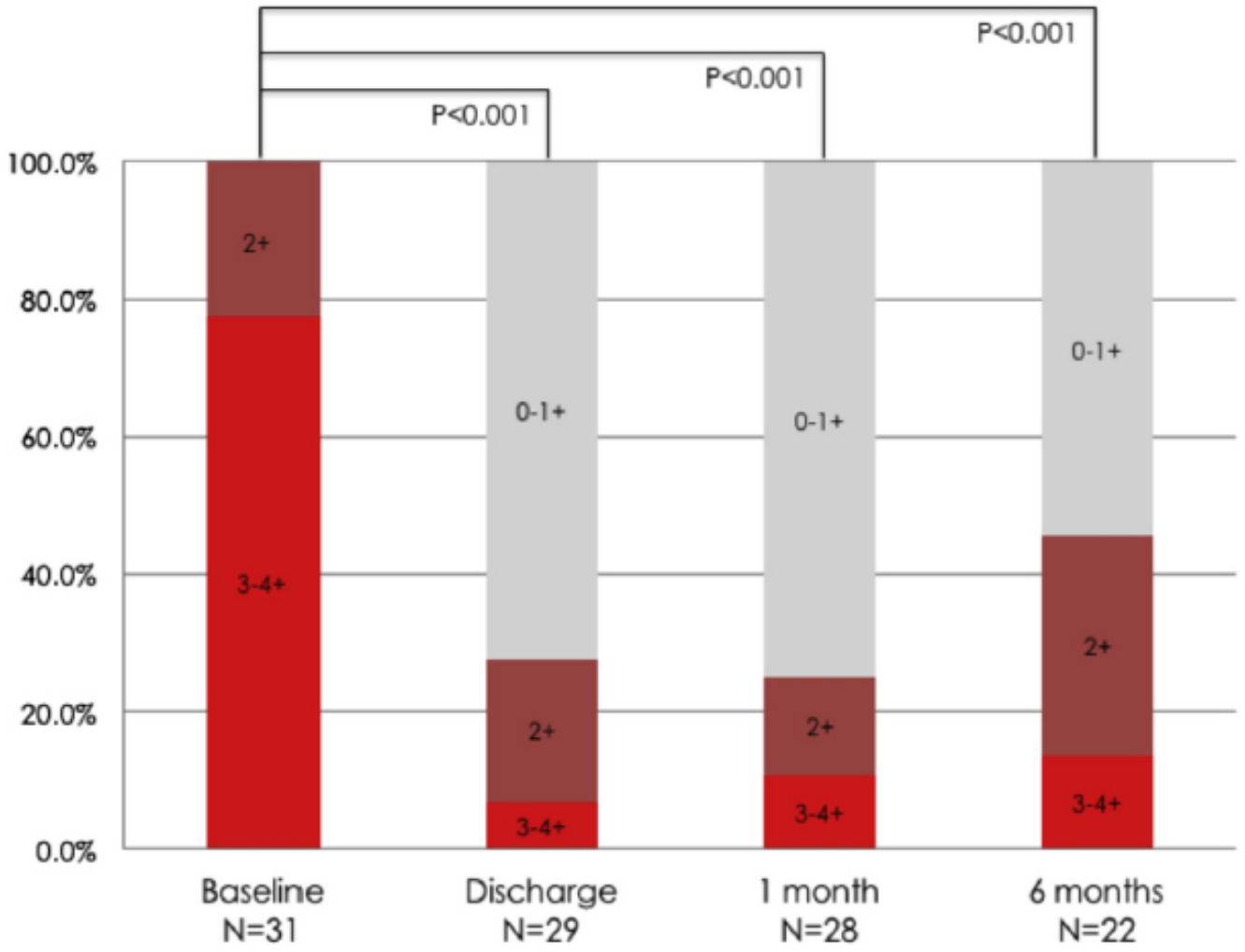
From the [a]Department of Cardiology, Heart Center Bonn, University Hospital Bonn, Bonn, Germany; [b]The Tel-Aviv Sourasky Medical Center, Tel-Aviv, Israel; [c]Baylor Health, Dallas, Texas; [d]Bichat Claude Bernard Hospital-Paris VII University, Paris, France; [e]Heart Center, University of Cologne, Cologne, Germany; [f]San Raffaele University Hospital, Milan, Italy; [g]Interventional Cardiology Unit, EMO-GVM Centro Cuore Columbus, Milan, Italy; and the [h]Interventional Cardiology Unit, San Raffaele Scientific Institute, Milan, Italy; [i]Department of Cardiology, Asklepios Klinik St. Georg Hospital, Hamburg, Germany; [j]Valve Clinic, University Heart Center, University Hospital Zürich, Zürich, Switzerland; and the [k]Cardiovascular Research Foundation and Columbia University, New York, New York. Dr. Hammerstingl has received speaker honoraria from Valtech Cardio. Dr. Topilsky has served

TABLE 1 B

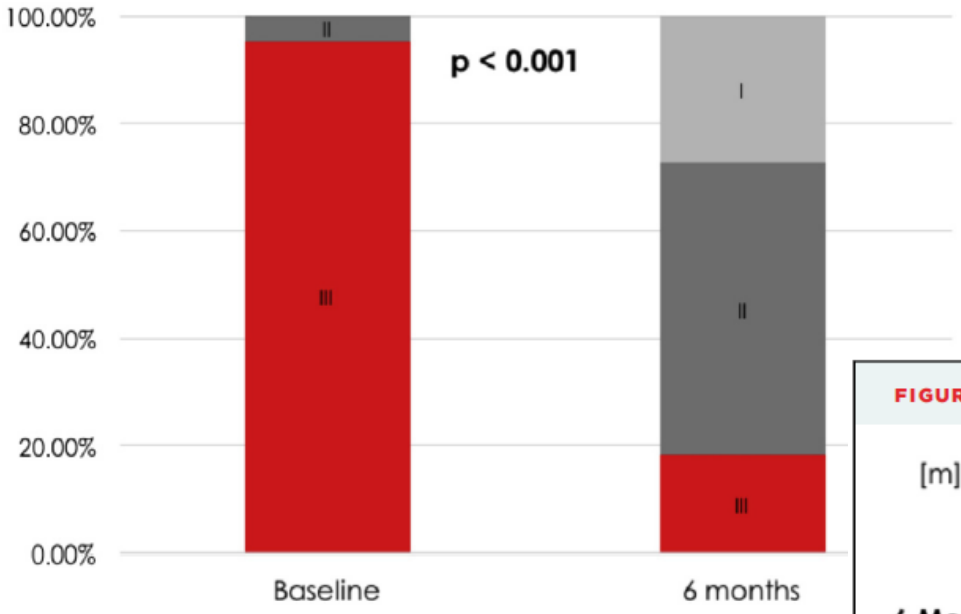
Age, yrs
Male
Medical hist
EuroSCOR
EuroSCOR
NYHA fun
EF, %
MR etiolo
Ischemi
Nonisch
Systemic I
Diabetes
Dyslipiden
Renal insu
Moderat
Severe
Moderate
Arrhythmias
AFib
AFL
VT
Prior cardiac
CABG
PCI
ICD implar
PM implar
CRT impla

FIGURE 3 MR Severity From Baseline to 6 Months



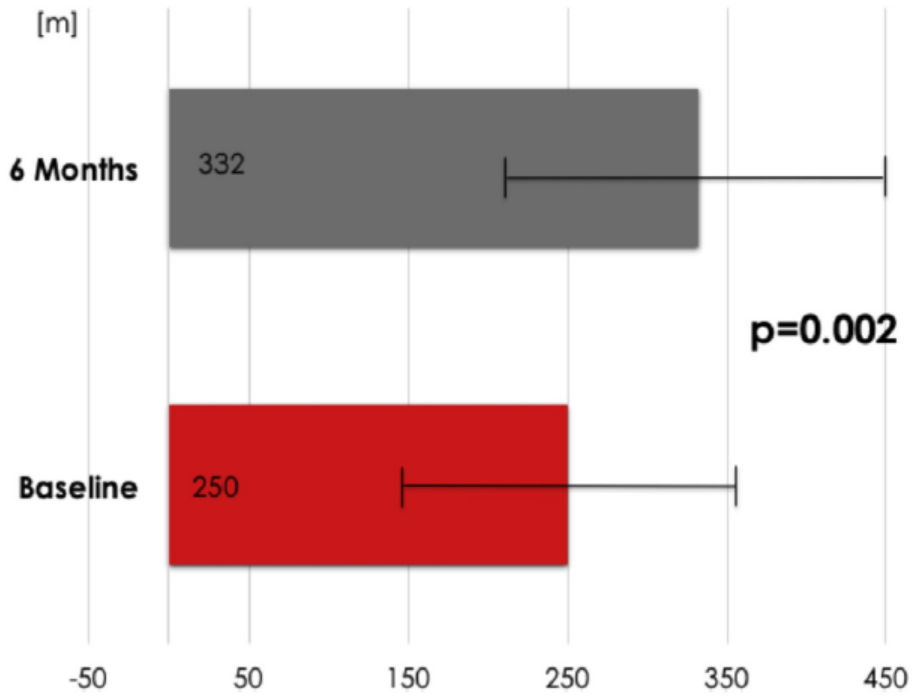
MR = mitral regurgitation.

FIGURE 4 Stapled Columns of NYHA Functional Classification Before Treatment and After 6 Months



NYHA = New York Heart Association.

FIGURE 5 6MWT Before Annuloplasty and After 6 Months

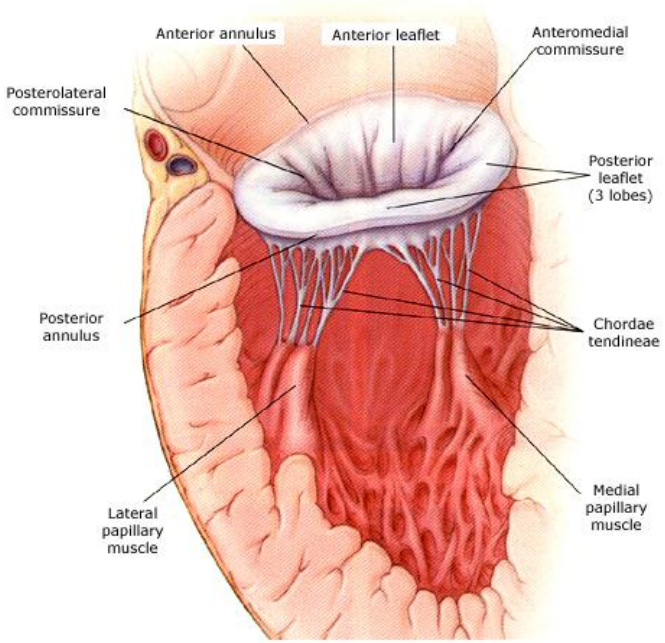


m = meters; 6MWT = 6-min walking test.

Transcatheter Mitral Valve Devices Mechanism of Action

Annulus

- **Indirect annuloplasty**
  - Coronary sinus approach
  - Asymmetrical approach
- **Direct annuloplasty**
  - Mechanical cinching
  - Energy mediated cinching
  - Hybrid



Leaflets

- Edge-to-Edge
- Leaflet ablation
- Space occupier

Left Ventricle

- LV (and MA) remodeling

Chordal implants

- Transapical
- Transapical-Transseptal

MV replacement

- Right mini-thoracotomy
- Transapical
- Transseptal

Otto *N Engl J Med* 2001:345:740-746

Chordal implantation

- Transapical (Neochord/Valtech Vchordal/Mitralflex)
- Transapical-Transseptal (Babic)

Chordal Implantation

Device: Neochord / Valtech Vchordal / (Babic-device) / (Mitraflex)

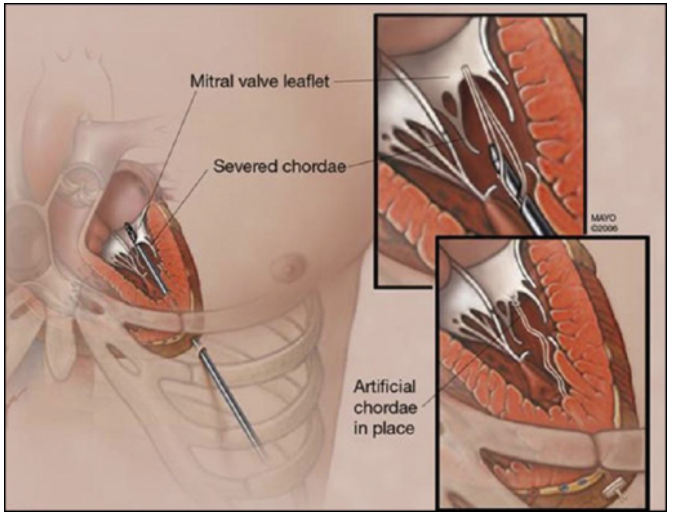
Status: Pre-clinical development /FIM

Principle:

- Synthetic chords or sutures are implanted either from a transapical or transseptal approach and anchored onto the LV myocardium at one end, with the leaflet at the other.
- The length of the chord is then adjusted to achieve optimal leaflet coaptation and reduce MR.

Limitations:

- Mainly for DMR
- Residual leaflet prolapse / Leaflet restriction
- Residual MR
- Device thrombus formation



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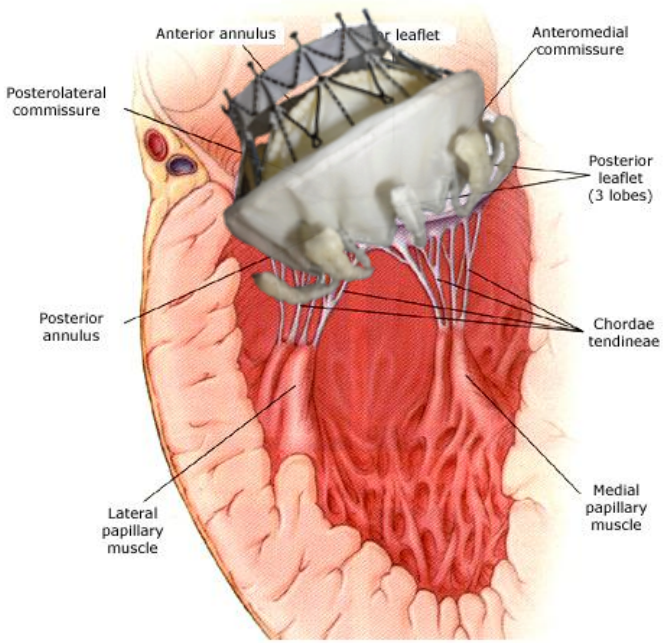

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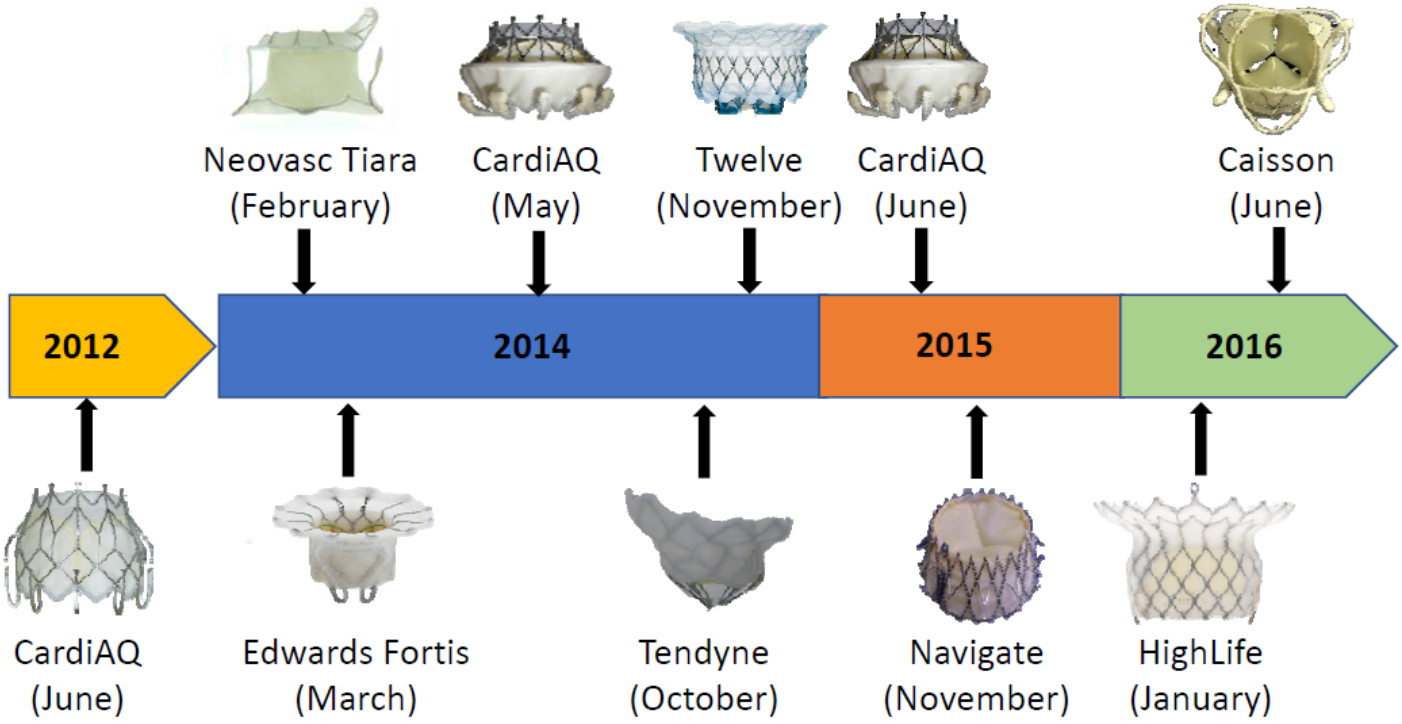
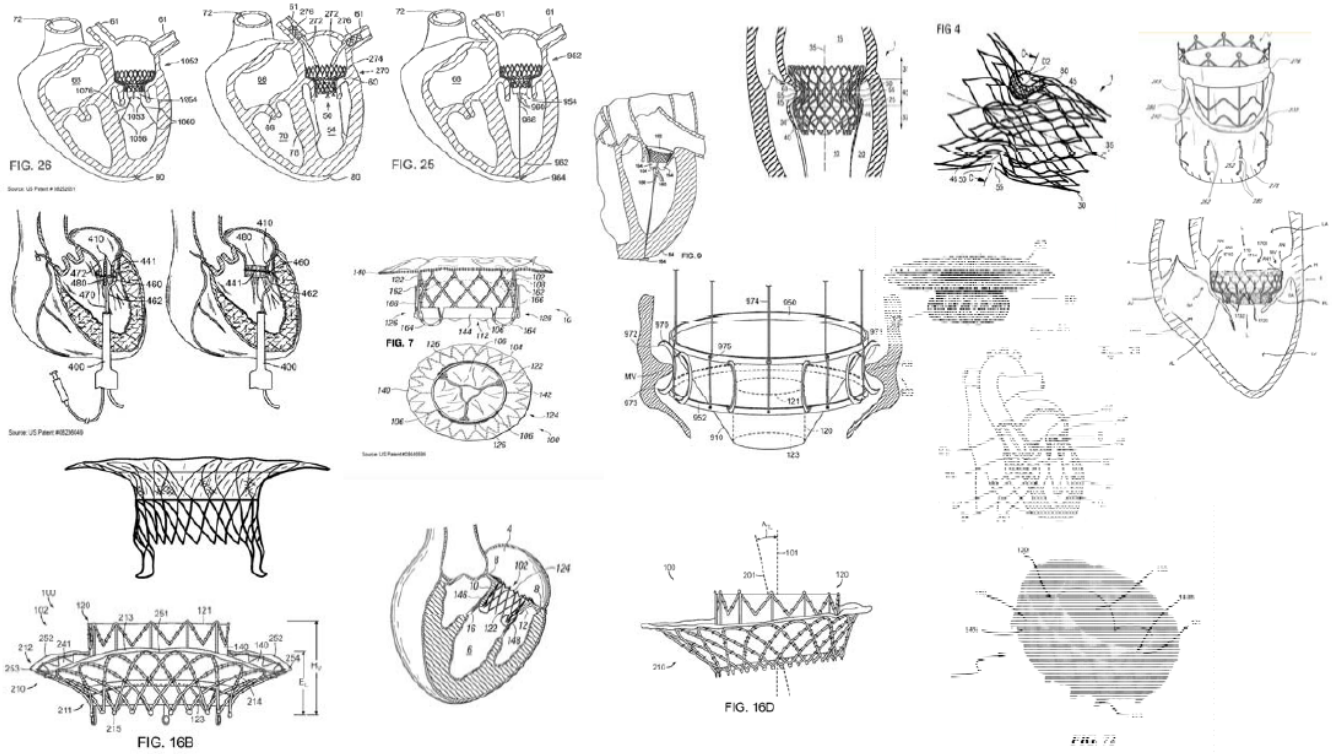
Transcatheter Mitral Valve Implantation (TMVI)

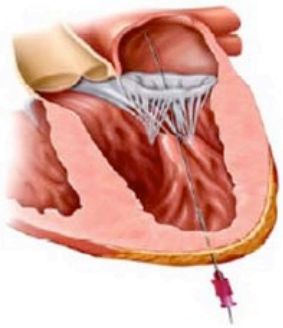
First-in-human timeline for TCMV replacement



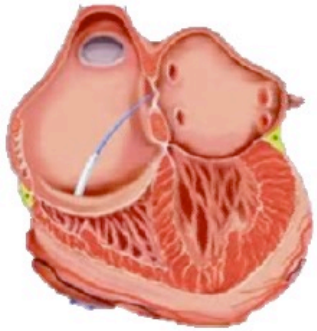
Crowded space of intellectual property



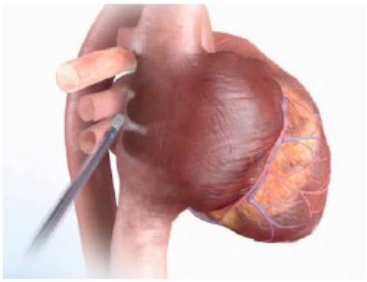
Access routes for TCMV replacement



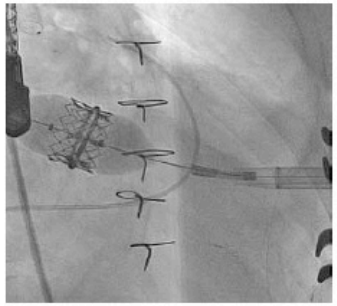
Transapical

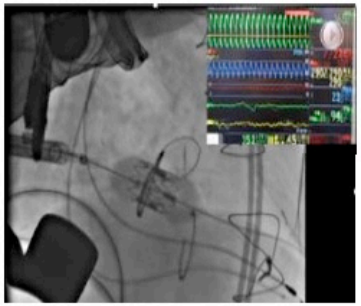


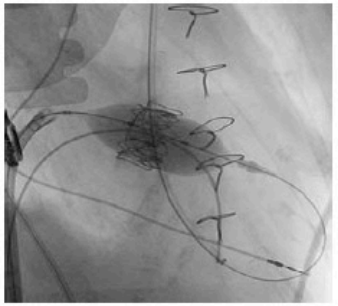
Transseptal



Transatrial



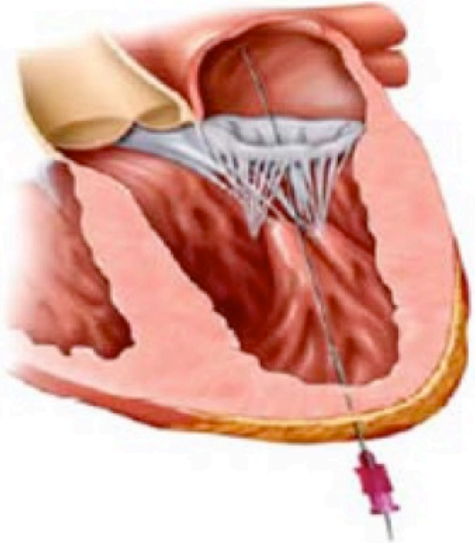




Transapical approach

Pros

- Straight shot
- TAVR experience



Cons

- LV dysfunction / large bore catheters (>30F)
- Retrograde approach (subvalvular apparatus entanglement)
- Thoracotomy (invasive)

Prognostic Value Of Impaired Left Ventricular Function In Patients Undergoing Transapical Versus Transfemoral TAVI

TCT2014

VJ Nijenhuis, MD[1]; MJ Swaans, MD[1]; R.H. Heijmen, MD[2]; T.L. de Kroon, MD[2]; J van der Heijden, MD, PhD[1]; B.J.W.M. Rensing, MD, PhD[1]; J.M. ten Berg, MD, PhD[1].

[1] St. Antonius Hospital, [2]

INTRODUCTION

An impaired left ventricular ejection fraction (LVEF) severely affects prognosis and peri-operative risk in patients undergoing surgical aortic valve replacement. Also in patients undergoing transcatheter aortic valve implantation (TAVI), an impaired LVEF seems to affect prognosis, although contradictory findings exist. We analyzed the effects of an impaired LVEF on prognosis in patients undergoing transfemoral versus transapical TAVI.

METHODS

Patients. All patients undergoing a transfemoral or transapical TAVI in our centre from June 2007 to December 2013, were prospectively enrolled.

Procedure. Transthoracic echocardiography was routinely performed before TAVI. The LVEF was assessed using the biplane Simpson method. An impaired LVEF was defined as <50%.

RESULTS (1)

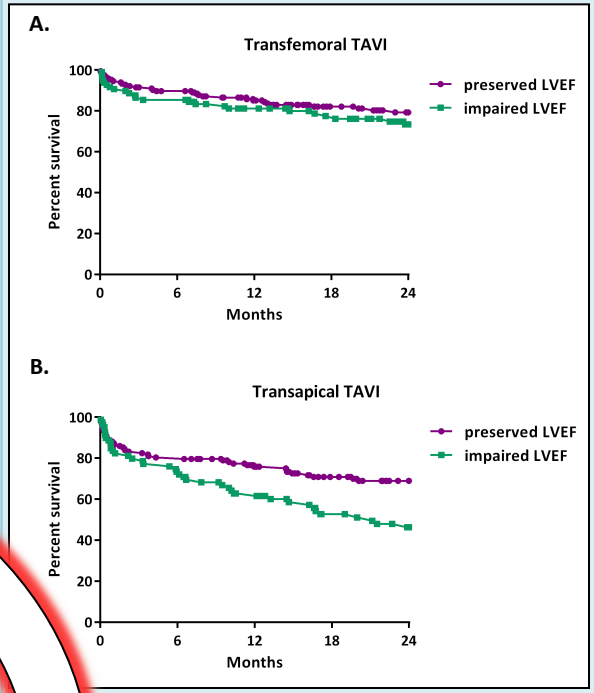
In total, 488 patients were included of whom 263 underwent transfemoral (age 81.6 ± 7.5 years, 153 female, STS score 6.0 ± 3.7%) and 225 (46%) tran TAVI (age 80.1 ± 6.5 years, 122 (54%) female, ST 6.2 ± 3.5%). An impaired LVEF was present in 178 patients. Baseline parameters are shown in ta

Uni- and multivariate Cox regression analysis showed t an impaired LVEF was associated with all-cause mortalit at 2 years (HR 1.49, 95% CI 1.05 to 2.11, p=0.03). After 30 days, an impaired LVEF does not play a role in transfemoral patients (HR 1.34, 95% CI 0.75 to 2.37, p=0.32) whereas it continues to affect survival in transapical patients (HR 1.67, 95% CI 1.07 to 2.60, p=0.02).

RESULTS (2)

	LVEF <50%	LVEF≥50%	P
Transfemoral	N=97	N=166	
Age (years)	79.6 ± 8.0	82.8 ± 6.8	<0.01
Female gender	37 (38)	116 (70)	<0.01
LVEF (%)	35.5 ± 9.6	64.7 ± 9.0	<0.01
		57.8	
	12 (12)	11 (7)	0.1
COPD	29 (30)	29 (18)	0.02
AF	37 (38)	62 (37)	0.90
Diabetes	25 (26)	30 (18)	0.14
	49 (50)	93 (56)	<0.01
	61.6 ±	62.4 ±	
PAD			0.51

RESULTS (3)



Kaplan–Meier survival analysis. A. Survival in transfemoral patients according to left ventricular ejection fraction (LVEF)

CONCLUSIONS

An impaired LVEF before TAVI seems to play no significant role in transfemoral patients whereas it continues to affect survival in transapical patients at 2 years. The LVEF may be considered in deciding the most appropriate approach for TAVI.

CONTACT

Further information please contact Vincent J Nijenhuis@antoniusziekenhuis.nl or scan the QR

DECLERATION OF INTEREST

No declare.

RESEARCH & DEVELOPMENT
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Prognostic Value Of Impaired Left Ventricular Function In Patients Undergoing Transapical Versus Transfemoral TAVI

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INTRODUCTION

An impaired left [illegible] severely aff[illegible] patients u[illegible] Also in pa[illegible] implantati[illegible] prognosis, analyzed t[illegible] patients u[illegible]

conclusions

An impaired LVEF before TAVI seems to play no significant role in transfemoral patients whereas it continues to affect survival in transapical patients at 2 years. The LVEF may be considered in deciding the most appropriate approach for TAVI.

Patients. transapic[illegible] Decembe[illegible]

Procedure performed biplane Si[illegible] as <50%.

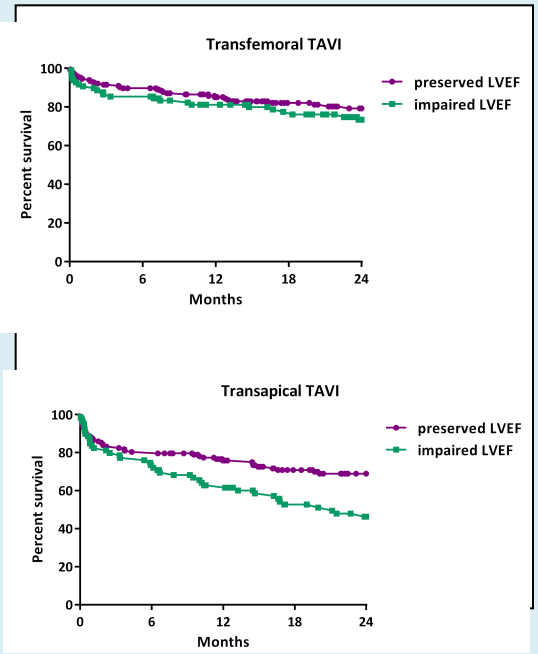
In total, 48[illegible] underwent[illegible] female, ST[illegible] TAVI (age[illegible] 6.2 ± 3.5%). An impaired LVEF was present in 178 (37%) patients. Baseline parameters are shown in table 1.

Uni- and multivariate Cox regression analysis showed that an impaired LVEF was associated with all-cause mortality at 2 years (HR 1.49, 95% CI 1.05 to 2.11, p=0.03). After 30 days, an impaired LVEF does not play a role in transfemoral patients (HR 1.34, 95% CI 0.75 to 2.37, p=0.32) whereas it continues to affect survival in transapical patients (HR 1.67, 95% CI 1.07 to 2.60, p=0.02). Survival curves are provided in figure 1A and B.

RESULTS (2)

Female	[illegible]	116	
	37.9 ±	65.4 ±	
LVEF (%)	9.9	9.2	<0.01
	[illegible]	[illegible]	
PAD	42 (52)	68 (47)	0.51
COPD	36 (32)	33 (23)	0.13
AF	33 (41)	47 (33)	0.22
Diabetes	24 (30)	40 (28)	0.77

RESULTS (3)



ure 1. Kaplan–Meier survival analysis. A. *Survival in transfemoral ated patients according to left ventricular ejection fraction (LVEF) 0.32). B. Survival in transapical treated patients according to LVEF*

DECLERATION OF INTEREST

None to declare.

CONTACT

For further information please contact Vincent J Nijenhuis, v.nijenhuis@antoniusziekenhuis.nl or scan the QR code.

RESEARCH & DEVELOPMENT

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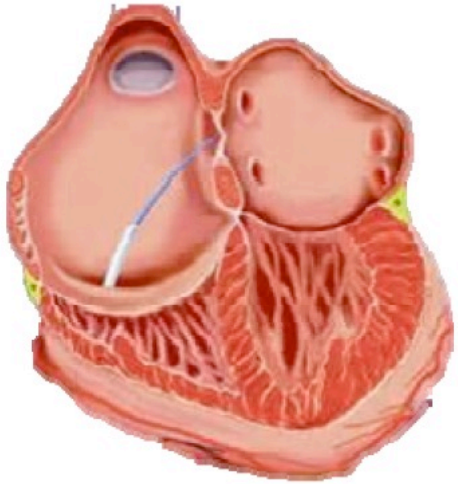
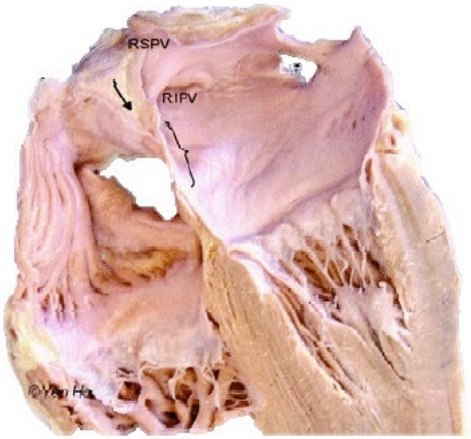
Transseptal approach

Pros

- Direct antegrade approach
- Avoids LV puncture
- Transseptal puncture



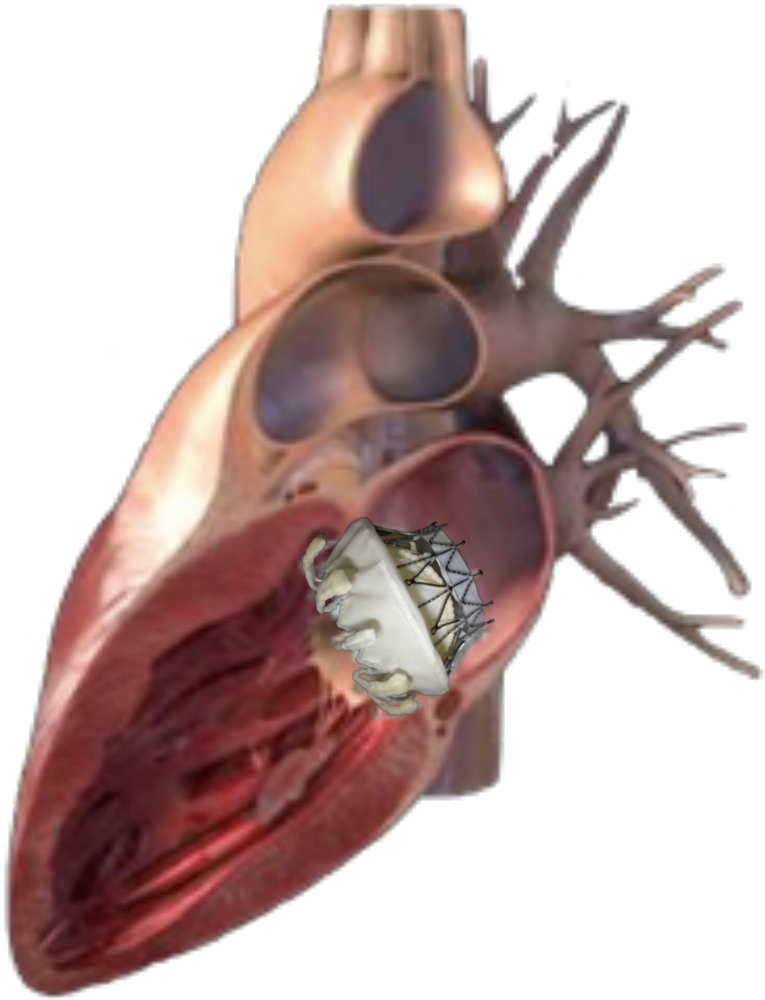


Cons

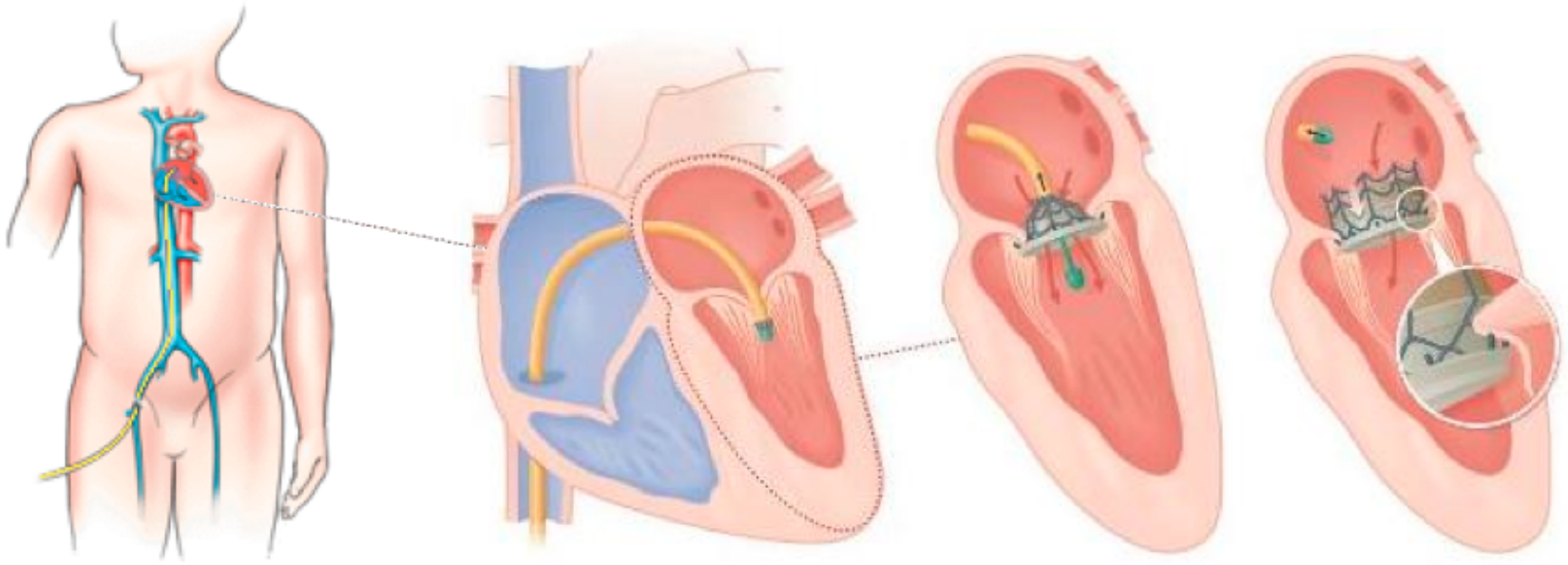
- Navigation and steering more than transatrial
- Veno-arterial access (submitral apparatus)
- Atrial septal defect / large catheter OD

CardiAQ™ TMVI System

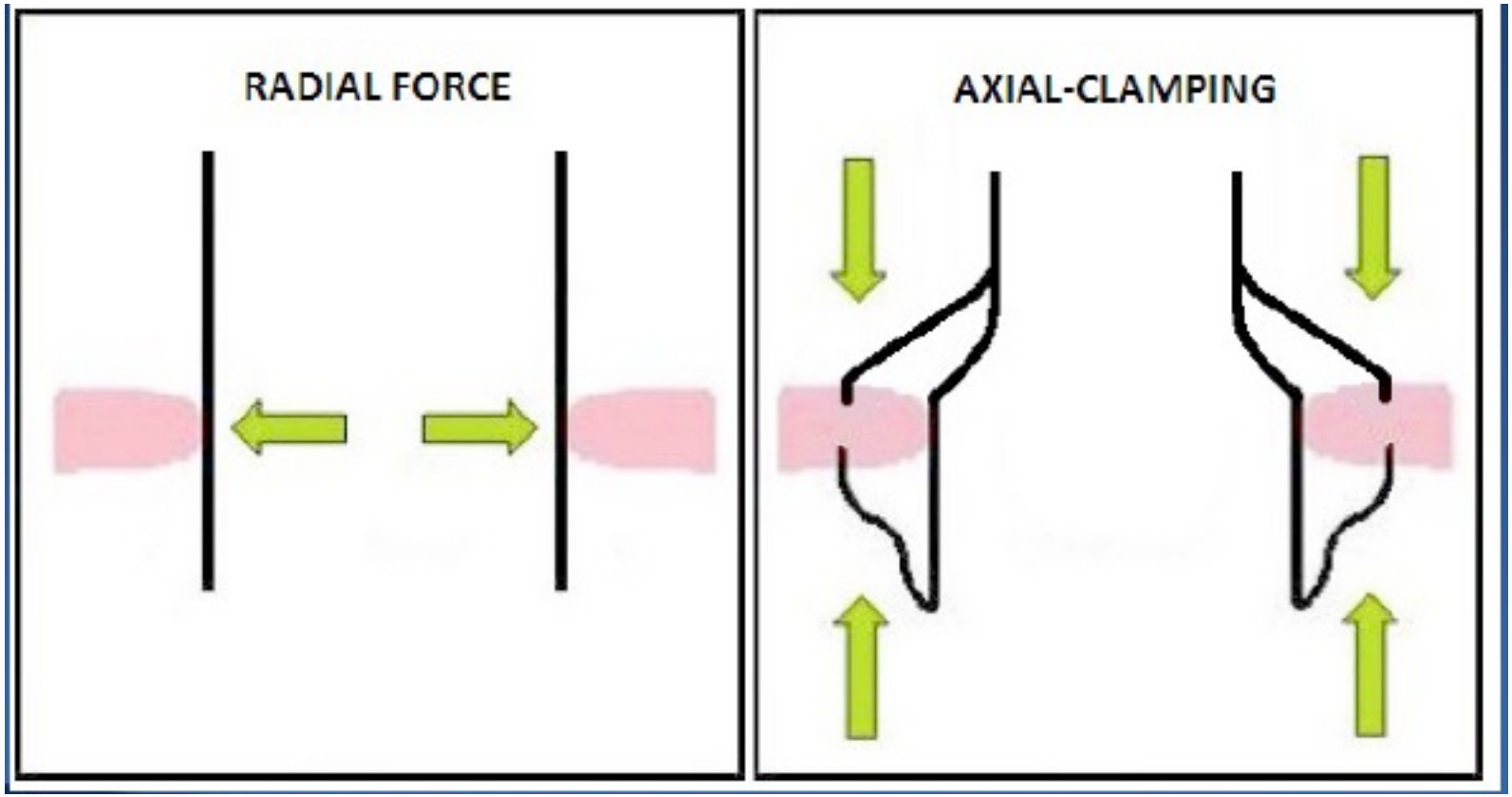
- **MULTIPLE ACCESS ROUTES**
  - **TF** – Trans-Femoral vein, trans-septal, antegrade approach
  - **TA** – Trans-Apical, retrograde approach
- **POSITIONING & CONTROL**
  - Multi-stage controlled deployment
  - Intra/Supra annular placement
  - Self-positioning within native valve annulus
- **ANCHORING**
  - Unique frame designed for annular attachment **without radial force**
  - Preserves chords and uses native leaflets
  - Load distribution between chords and annulus



CardiAQ TMVI Procedure Overview

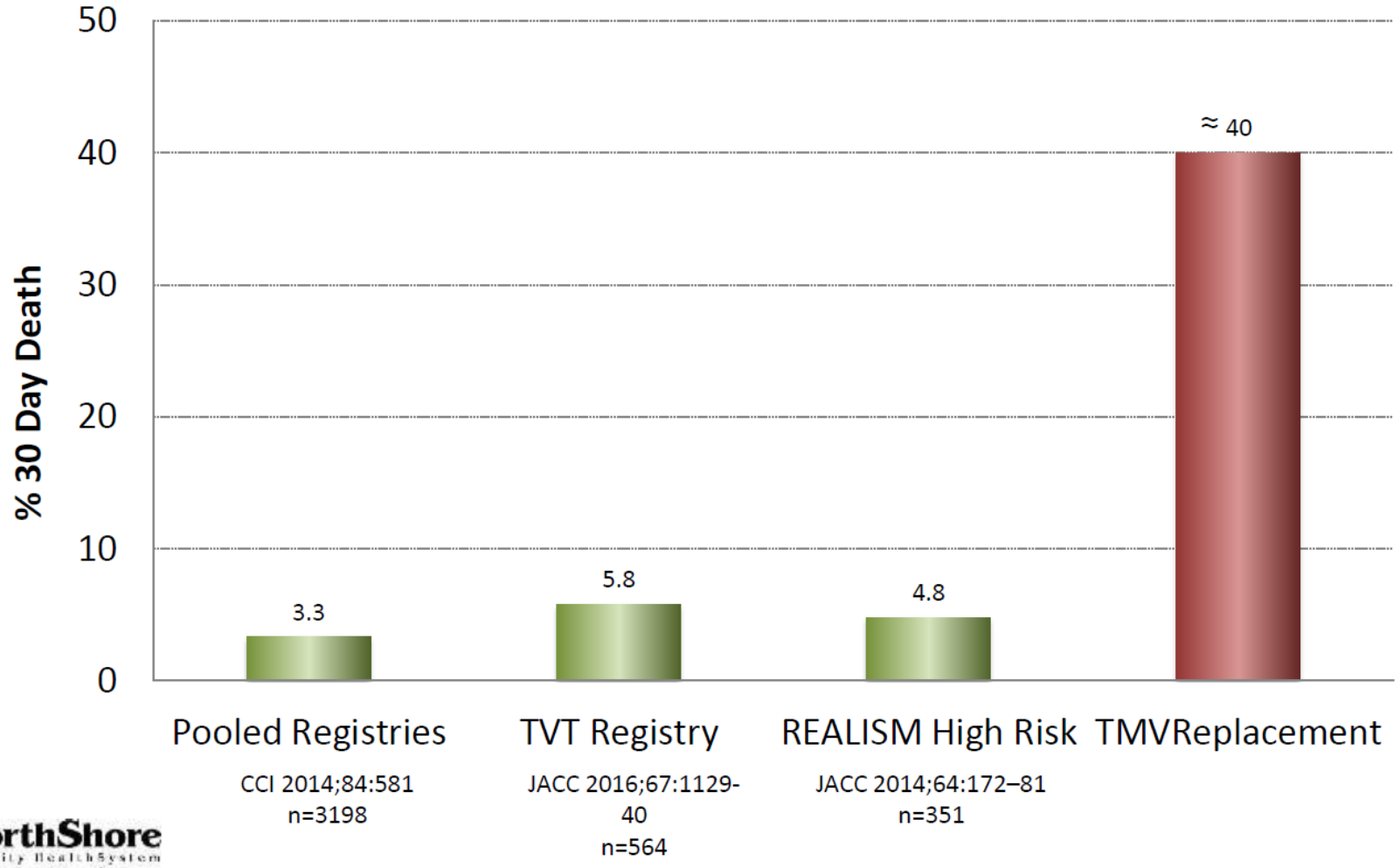


For illustration only - the devices depicted are not an accurate reflection of the CardiAQ TMVI technology


RADIAL FORCE
AXIAL-CLAMPING

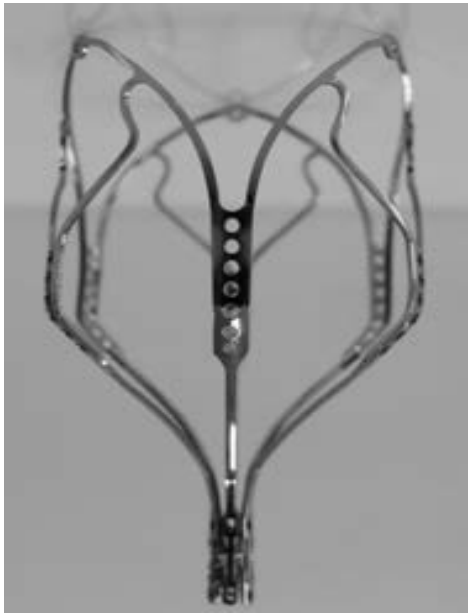
Mitral Repair vs Repalcement

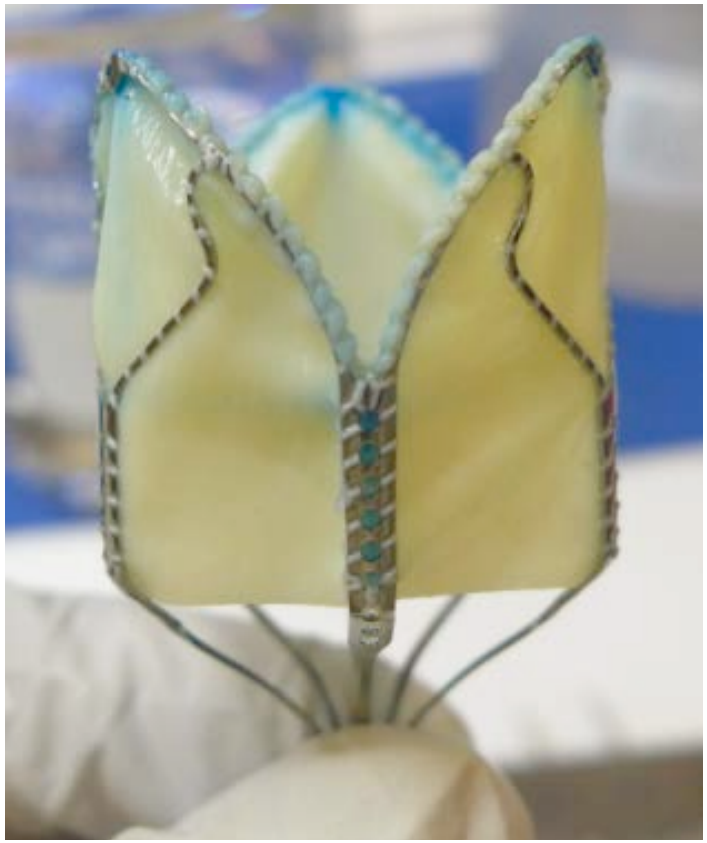
30 Day Mortality



NorthShore University HealthSystem
Evanston Hospital

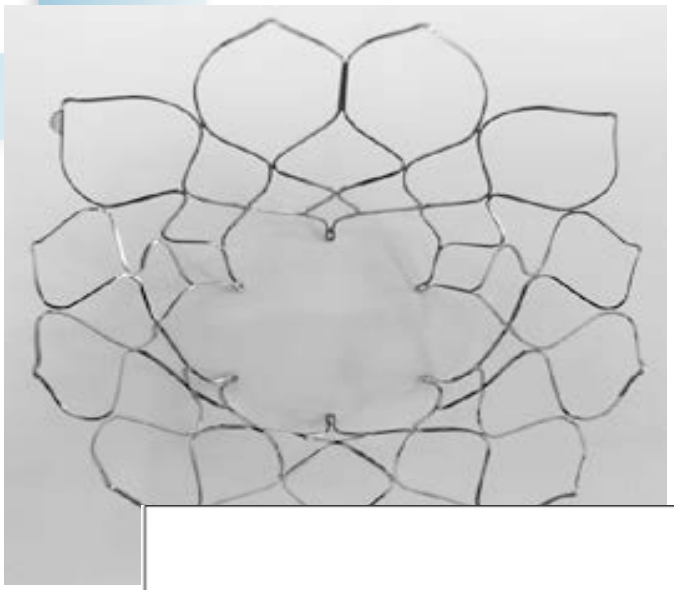
TENDYNE (Abbott)

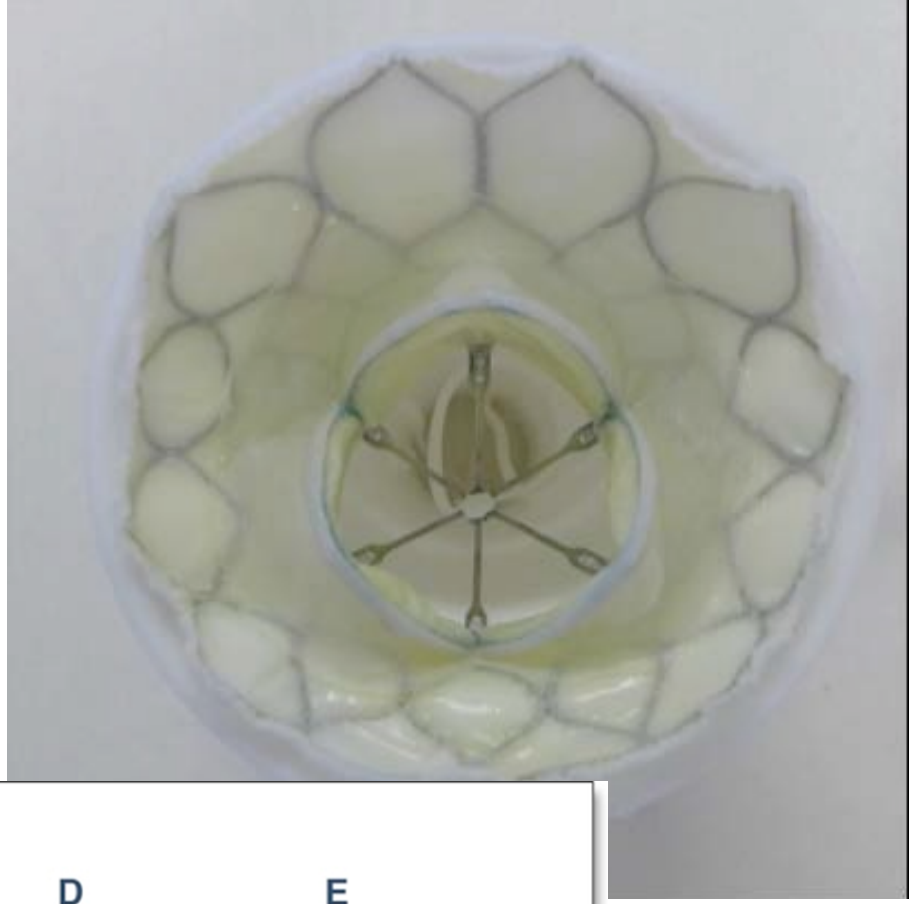


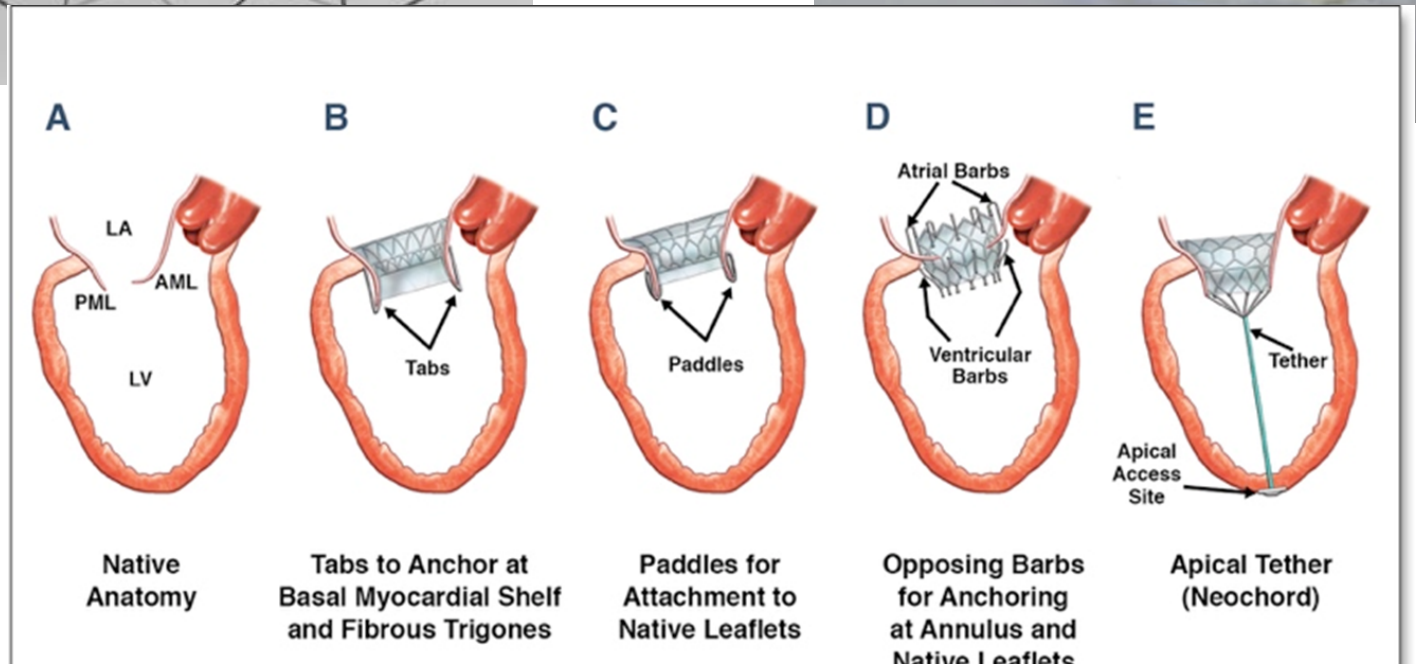


Early safety and feasibilty trial USA/Canada Zurich/Nieuwegein
N=40 (+6 compasioned use)

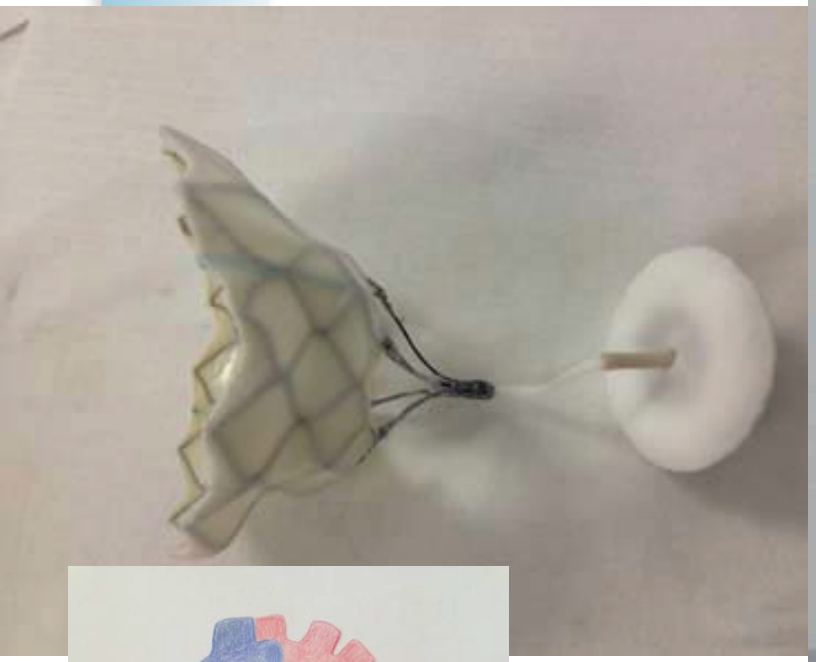
TENDYNE (Abbott)

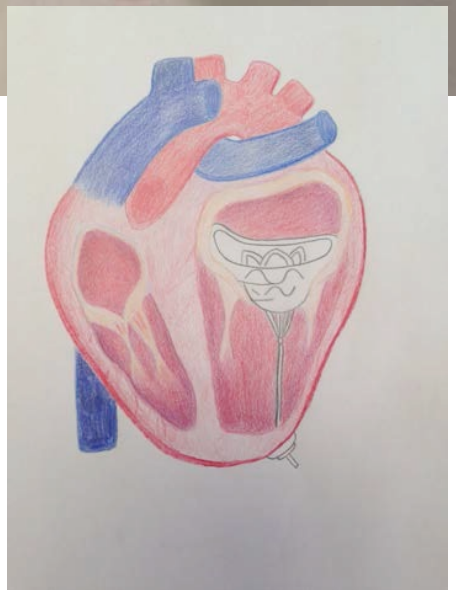




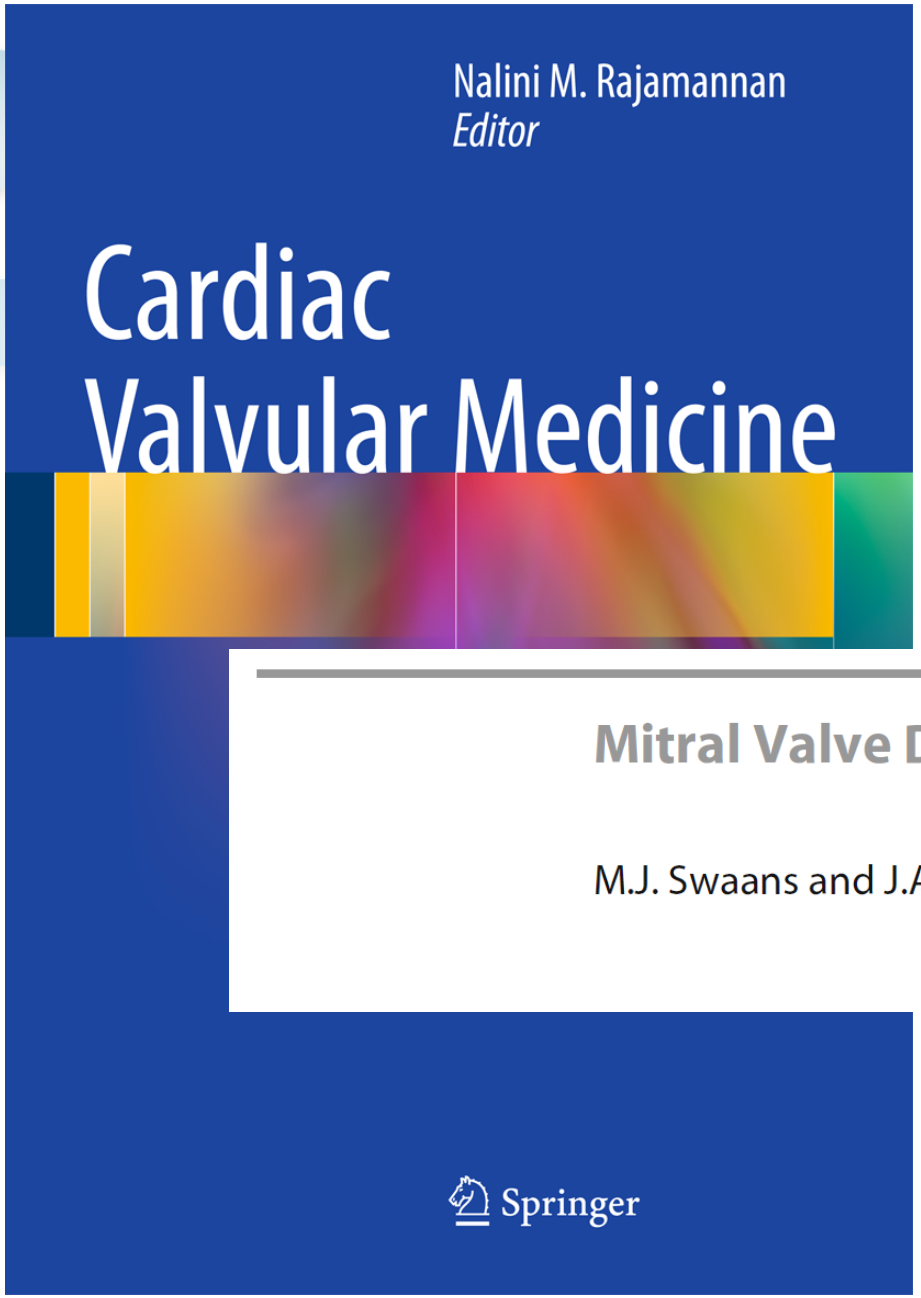


TENDYNE (Abbott)





Cephea 2020
TS TMVR



Mitral Valve Devices

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M.J. Swaans and J.A.S. van der Heyden

"This really is an innovative approach, but I'm afraid we can't consider it. It's never been done before."

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