Transcatheter tricuspid valve repair devices and data

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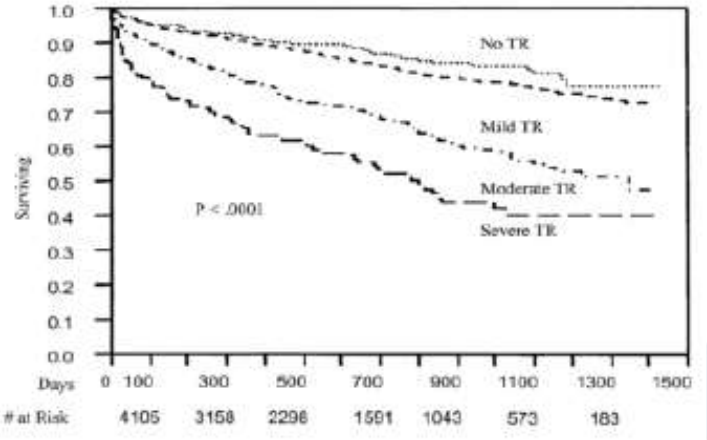
Heart Lung Institute

The Prince Charles Hospital

Background

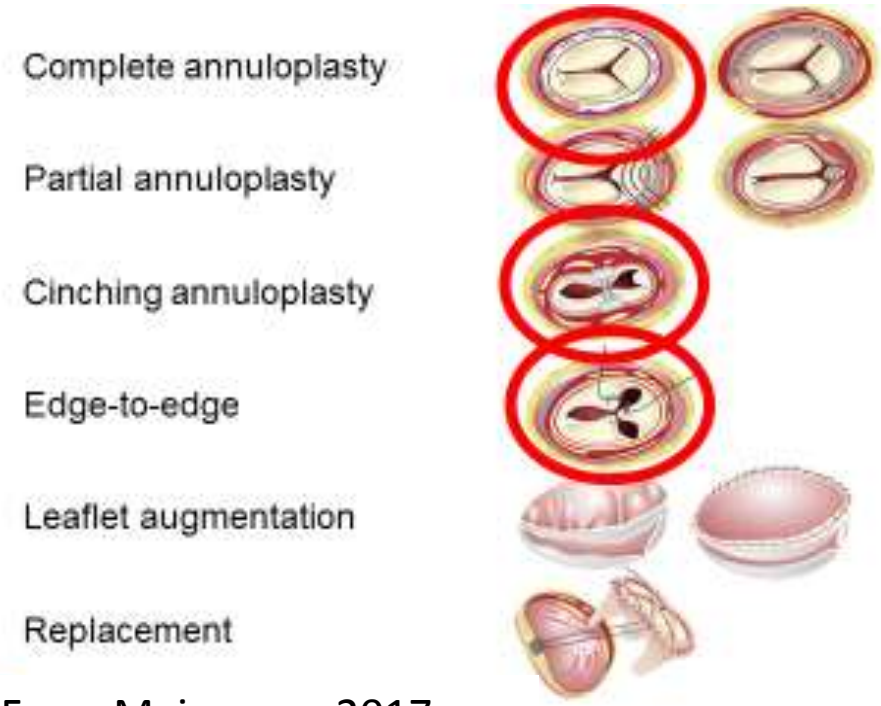
- Population studies 15-18% at least mild while 1.2% severe COMMON
- There is an independent (LVEF/PAP) effect on survival of significant TR
  - There is a 4X increased late mortality in patient with functional TR
  - 50% increase in mortality in first year post Mitraclip if severe TR
- Moderate to severe TR is an under-treated condition
- More frequent indications for combined tricuspid surgery
  - Inherent risk of subsequent dysfunction of tricuspid repair or replacement
- Redo tricuspid valve surgery is often associated with high morbidity-mortality rates (15-35%)
- Increased in patients with co morbidities



Stuge and Liddicoat. J Thorac Cardiovasc Surg. 2006;132:1258-61
Nath et al. J Am Coll Cardiol. 2004;43:405–9
Kim et al. Circulation. 2009;120:1672-78
McCarthy PM,et al. J Thorac Cardiovasc Surg 2004;127:674-85.
Pfannmuller B,et al J Thorac Cardiovasc Surg 2013;146:841-7

Background

- A number of pipeline technologies for TV repair
  - Mitralign, Mitraclip, Tricinch, Millipede, Forma



From Maissanno 2017

Novel Interventions

- The TriCinch System™
- Mitraclip
- Edwards FORMA Repair System
- Cardioband
- Millipede
- Trialign
- Triapta
- Caval Valve

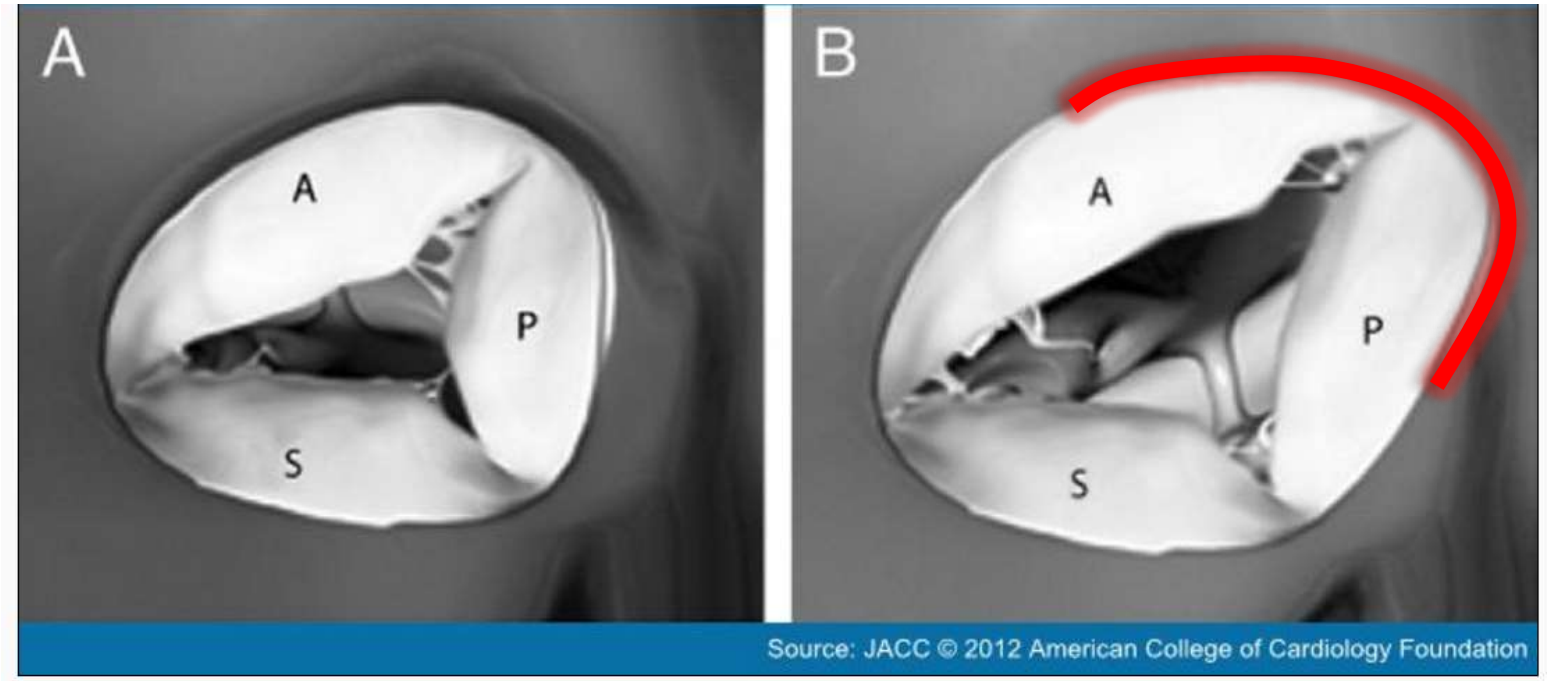
Feasibility Study of the Percutaneous 4Tech TriCinch Coil Tricuspid Repair System

17 April 2017

Functional TR is a Result of Annular Dilatation

Normal Tricuspid Valve

Antero-Posterior Dilatation of Tricuspid Annulus

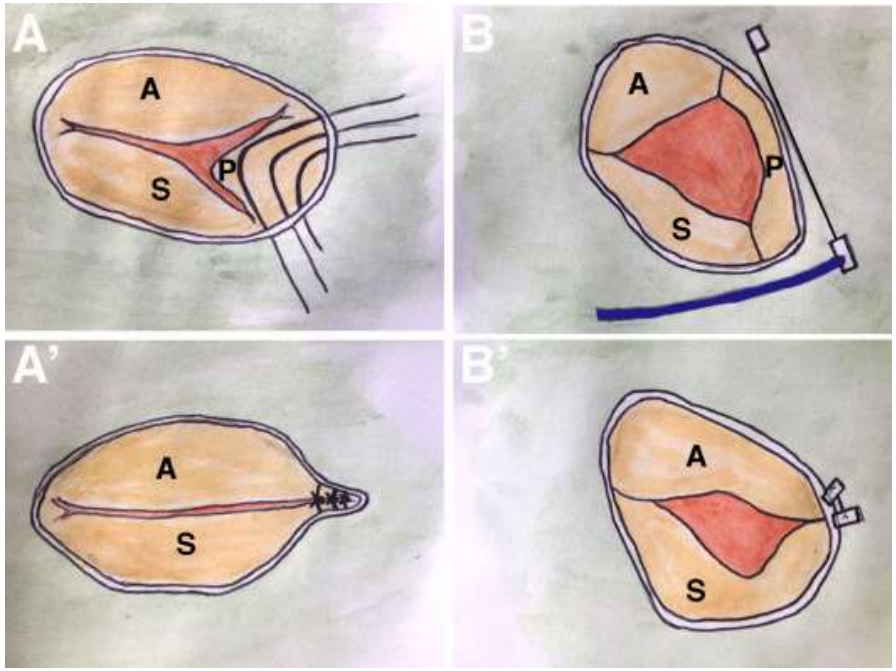


A = Anterior leaflet; P = Posterior leaflet; S = Septal leaflet

- FTR is primarily due to tricuspid antero-posterior dilatation[1]
- FTR is often secondary to left-sided heart disease[1]
- Approx. 30% - 50% of patients with MR have significant FTR[1]

1. Dreyfus, G. (2015). Functional Tricuspid Regurgitation. JACC Vol 65, Issue 21

Kay repair



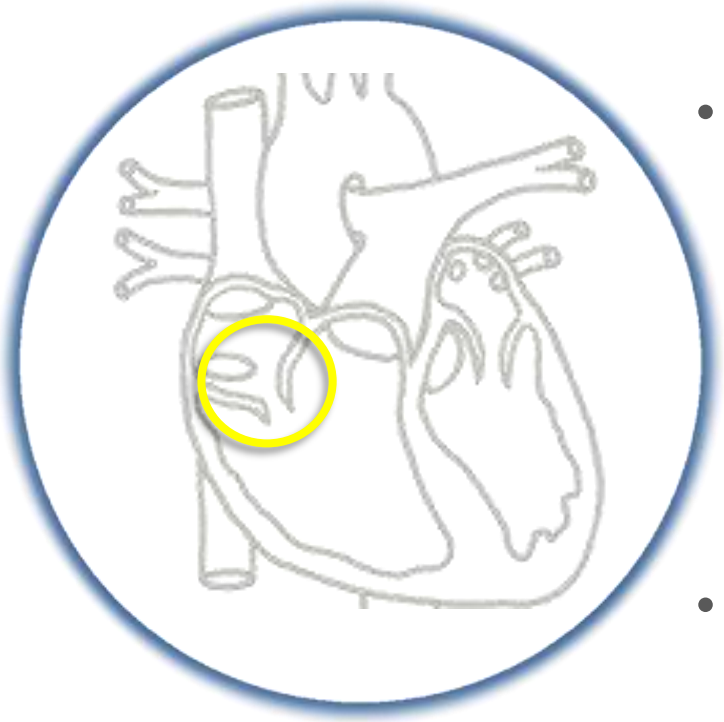
Kay Repair Technique (A and A') and corresponding percutaneous approach using the Mitralign system™ (Mitralign Inc., Tewksbury, MA, USA) (B and B'). A. Tricuspid valve bicuspidization is accomplished by plicating the annulus along the posterior leaflet

Claire Bouleti, Jean-Michel Juliard, Dominique Himbert, Bernard Iung, Eric Brochet, Marina Urena, Marie-Pierre Dilly, Phalla Ou, Patrick Nataf, Alec Vahanian

Tricuspid valve and percutaneous approach: No longer the forgotten valve!

Archives of Cardiovascular Diseases, Volume 109, Issue 1, 2016, 55–66

Interventional TVT for the tricuspid valve
4 Tech Device



- FTR is a complex disease that requires a **dedicated** device
  - Innovative solution should be **simple**, easy to use, **reproducible**, **effective** in the long term
- TriCinch was developed with **simplicity** to treat the FTR patients of today with the future in mind

In the **Structural Heart Toolkit** there is a rising need for a **dedicated** percutaneous TV repair device

The Tricinch system

Antero-posterior annuloplasty solution for treating FTR

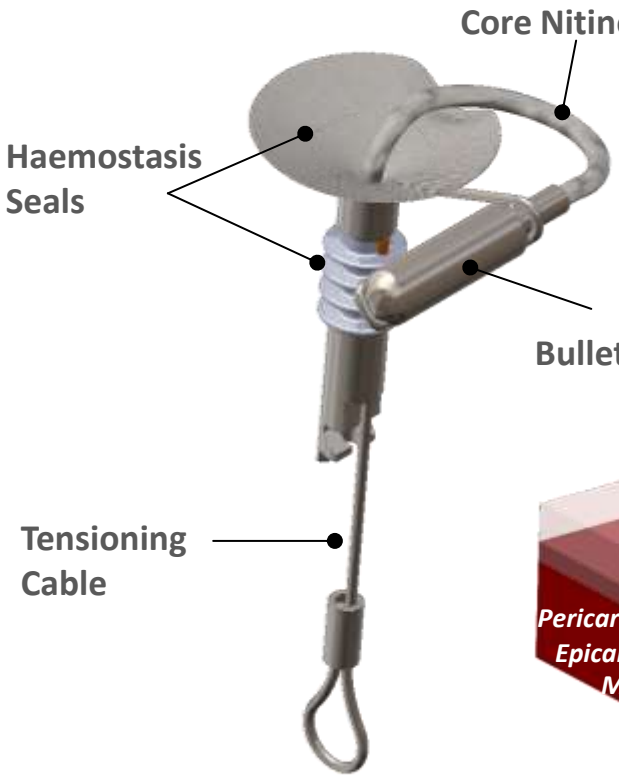
TriCinch Coil Implant

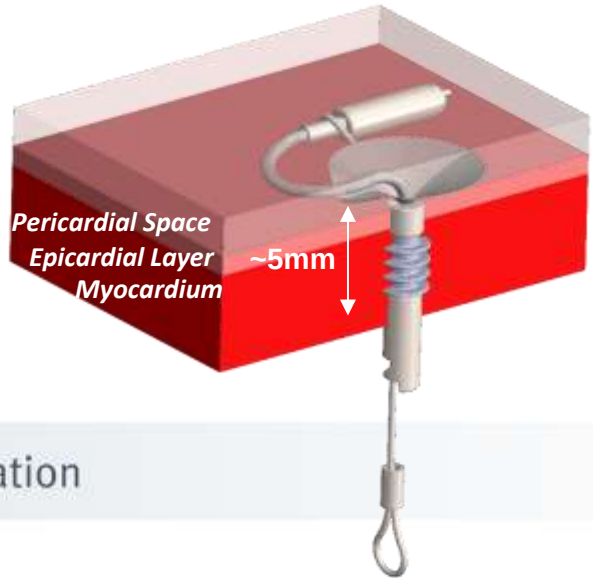
Single Delivery System

- *Simple controlled venous based delivery*
- *Secure, small profile anchor covering large surface area*
- *Restores leaflet coaptation*

Coil Anchor Overview

Coil anchor design provides significant surface area to distribute tensioning force





Coil Anchor Phases

Wire Exposed → Wire begins to coil → Hemi-spiral shaped anchor

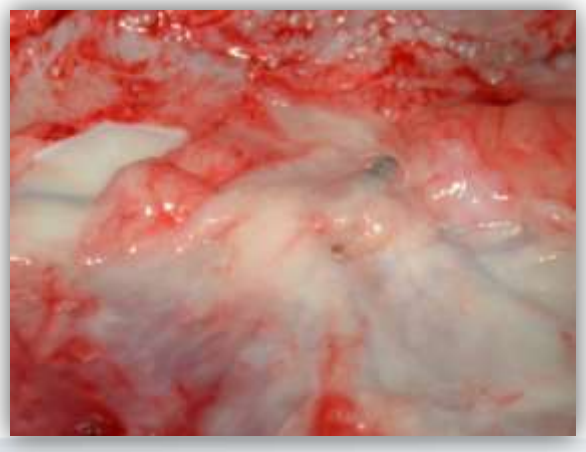
PreClinical Test: Hemostatic Sealing

20+ Chronic Pigs

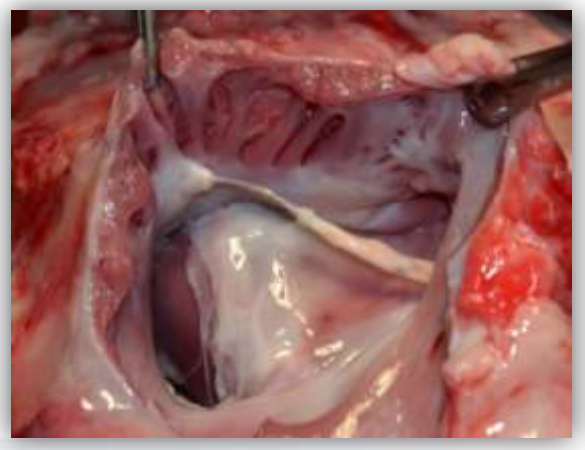
- ✓ Observed at 30, 60 and 90 days
- ✓ All animals survived
- ✓ No bleeding was found
- ✓ No severe complications were found
- ✓ At explant, the tissue healed

30+ Acute Pigs

- ✓ "In Wall" stacked ePTFE disk self-retained & sealed without tether tension
- ✓ No bleeding immediately after coil anchor delivery
- ✓ Pigs kept under observation for ≥ 30 mins and no bleeding was observed



Coil Endothelialized



Tensioning Band Endothelialized

Stable stent position at 90 days

innovation and collaboration

Feasibility Study Design

Study Design:

- Clinical feasibility safety and performance study, multi-center, prospective, single-arm, non-randomized study

Study Objectives:

- Evaluate feasibility safety and performance for the 4Tech TriCinch Coil System

Study Centers:

- Up to 7 centers in Australia & Europe

Study Population:

- The TriCinch Coil System is intended to repair and/or reconstruct pathological tricuspid valves in symptomatic patients suffering from significant functional tricuspid regurgitation with annular dilatation

Number of Subjects:

- ≤ 44 patients total (2 max. roll-in per site)

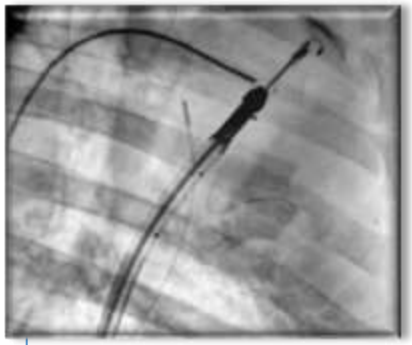
Study Period:

- Approx. 18 months (6 months enrolment + 12 months follow-up)

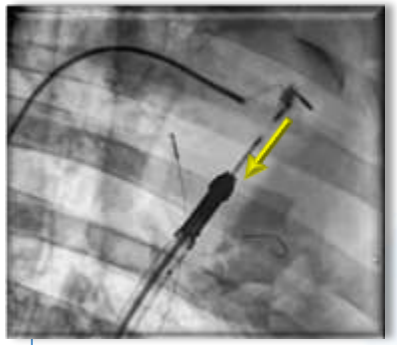
TriCinch Coil System - Procedural Steps

4 procedural steps to deploy the TriCinch Coil System

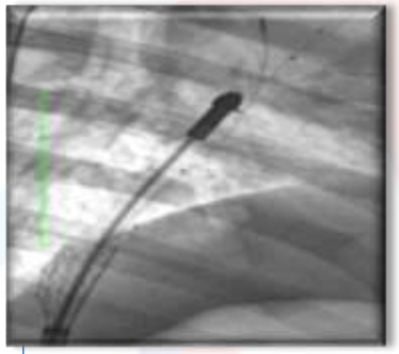
1 Position & puncture APC region



2 Deploy Coil anchor in pericardial space

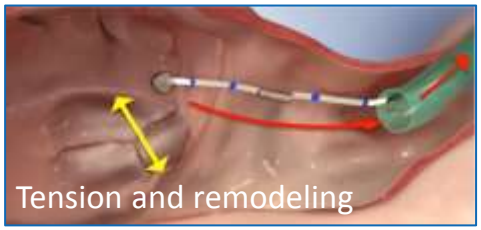


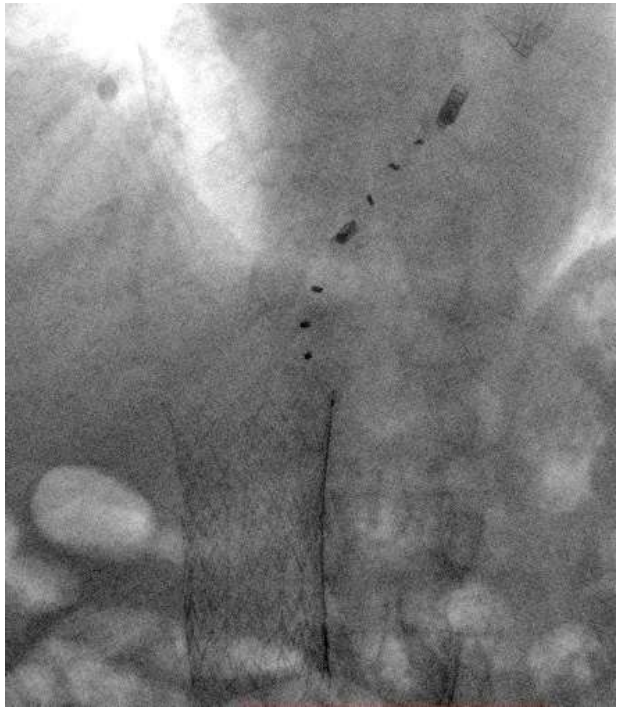
3 Tension applied

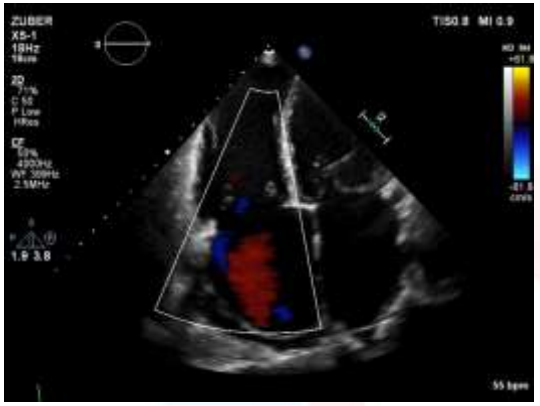


4 Stent deployment in IVC

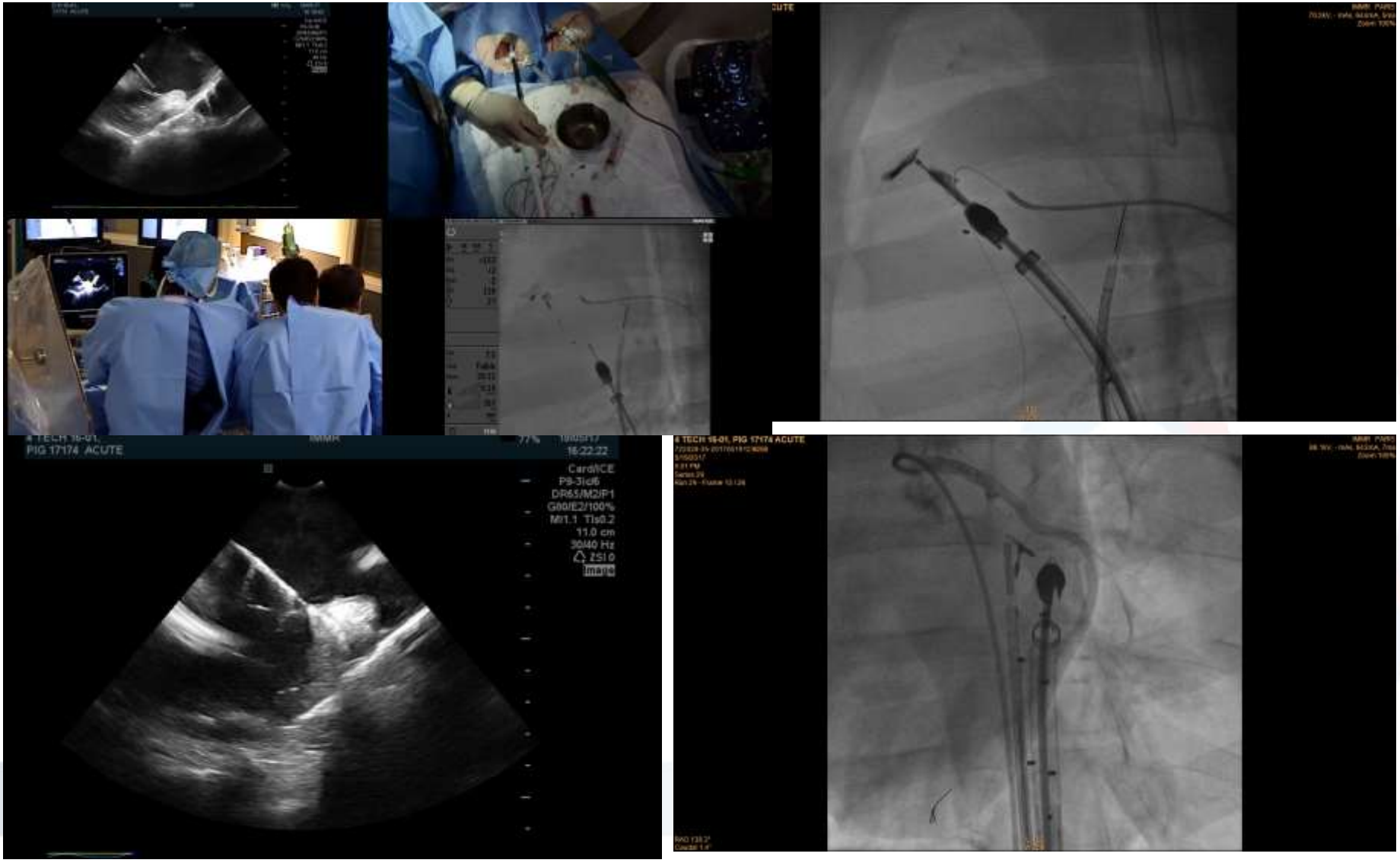
4TECH TriCinch: septo-anterior cinching







4TECH TriCinch: septo-anterior cinching



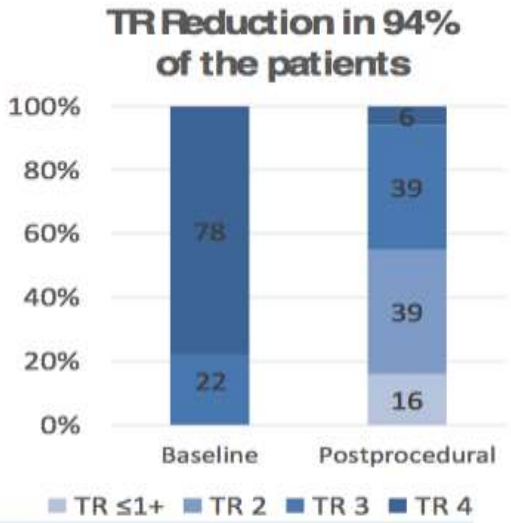
Early Clinical outcomes from TriCinch™ Gen 1

Baseline characteristics - Patients Enrolled: **24**

- Age	71±7yo
- NYHA class ≥ III	17 [71%]
- LogES	median 12
- Signs of right HF	24 [100%]

Procedural and post-procedure

Patient Treated (successful implantation)	**18** [75%]
Perioperative complications	
hemopericardium	2 [8%]
Post-operative complications	
annulus anchor late detachment	4 [17%]
(no SAE/AE related to detachment)	
30-day all-cause mortality	**0 [0%]**



6 Months Follow-up data (n=4)

Accumulated implant time	**43 months**
Median follow-up time	1 month [1-6]
NYHA class	**I - II** 75% **III** 25% **IV** 0%
Quality of Life Improvement	**6MWT** (m) **+53%** - **MLHFQ +38%** - **SF36-physical +42%**
All-cause mortality	0 [**0%**]

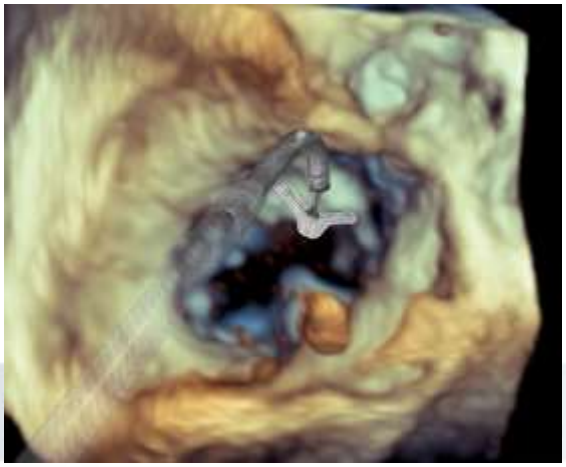
tct2016

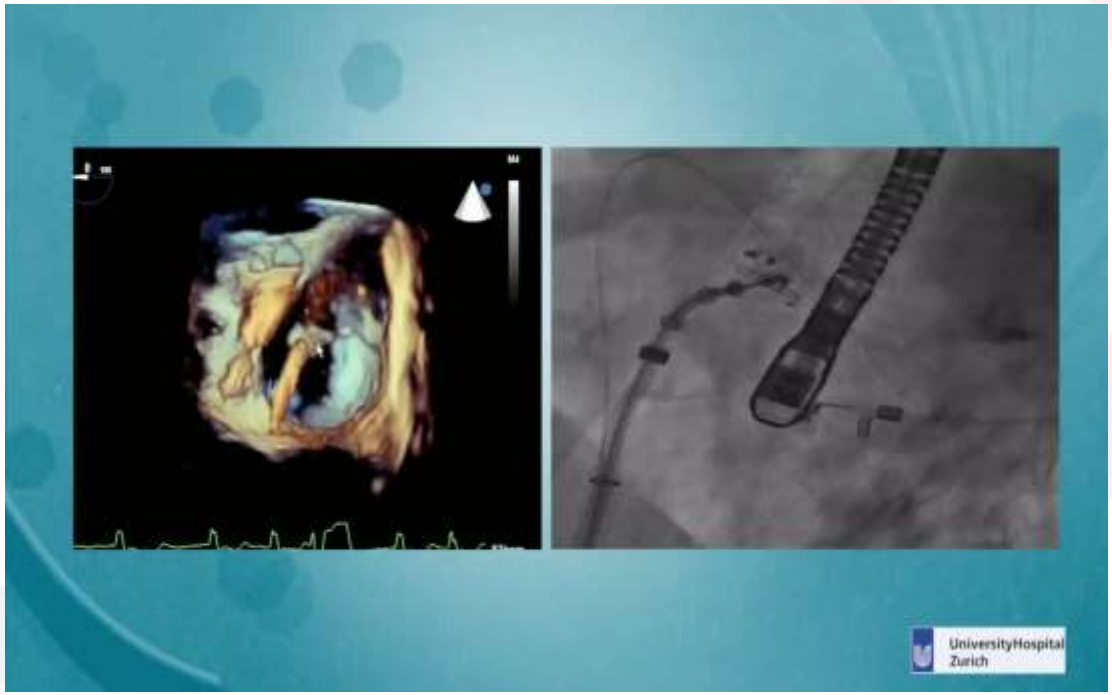
Cardiovascular Research Foundation

UniversityHospital Zurich

Mitra Clip in the tricuspid position

- Adapted from Mitral technology
- Trans-jugular and more popular transfemoral access
- Tricuspid leaflets have different tissue proprieties than the mitral (durability) and no double orifice outcome
- - Challenging intraprocedural echo guidance





Mitra clip in tricuspid position

- >400 cases worldwide
- 1-2 clips for septal leaflet
- Imaging challenging TOE vs ICE
- Friable leaflets
- No double orifice result
- Not designed for the tricuspid

Circulation

American Heart Association.

ORIGINAL RESEARCH ARTICLE

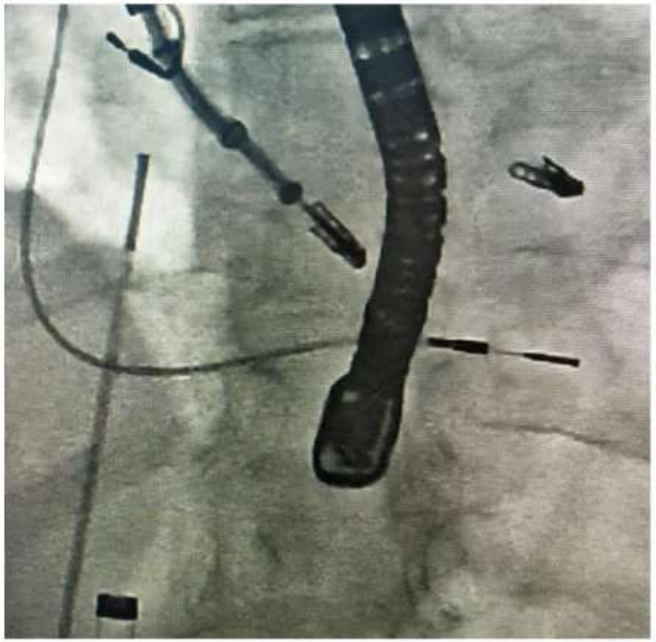
Transcatheter Treatment of Severe Tricuspid Regurgitation With the Edge-to-Edge MitraClip Technique

Georg Nickenig, Marek Kowalski, Jörg Hausleiter, Daniel Braun, Joachim Schofer, Ermela Yzeiraj, Volker Rudolph, Kai Friedrichs, Francesco Maisano, Maurizio Taramasso, Neil Fam, Giovanni Bianchi, Francesco Bedogni, Paolo Denti, Ottavio Alfieri, Azeem Latib, Antonio Colombo, Christoph Hammerstingl, Robert Schueler

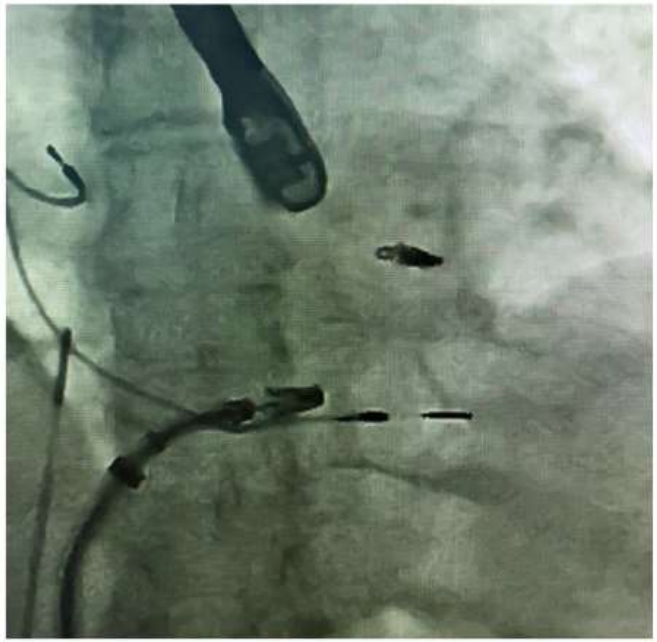
https://doi.org/10.1161/CIRCULATIONAHA.116.024848
Circulation. 2017;135:1802-1814
Originally published March 23, 2017

Mitral Clip

Internal Jugular Approach



Common Femoral Approach




12/18/2014 12:32:09 PM
Cardiac / IntraCardiac* / AcuNav V
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General
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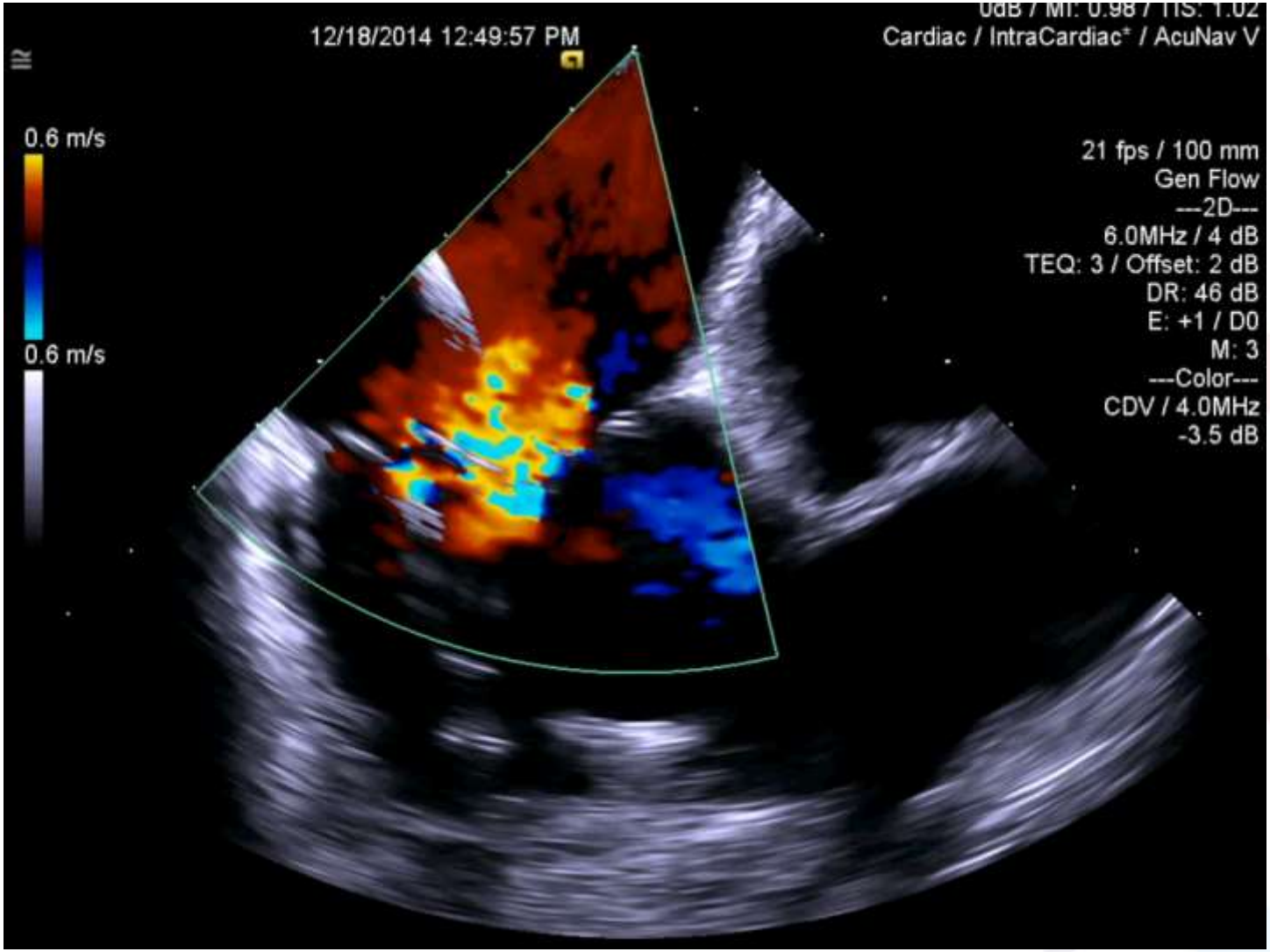
6.0MHz / 5 dB
TEQ: 3 / Offset: 3 dB
DR: 46 dB
E: +1 / D0
M: 3


12/18/2014 12:49:57 PM
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0.6 m/s
21 fps / 100 mm
Gen Flow
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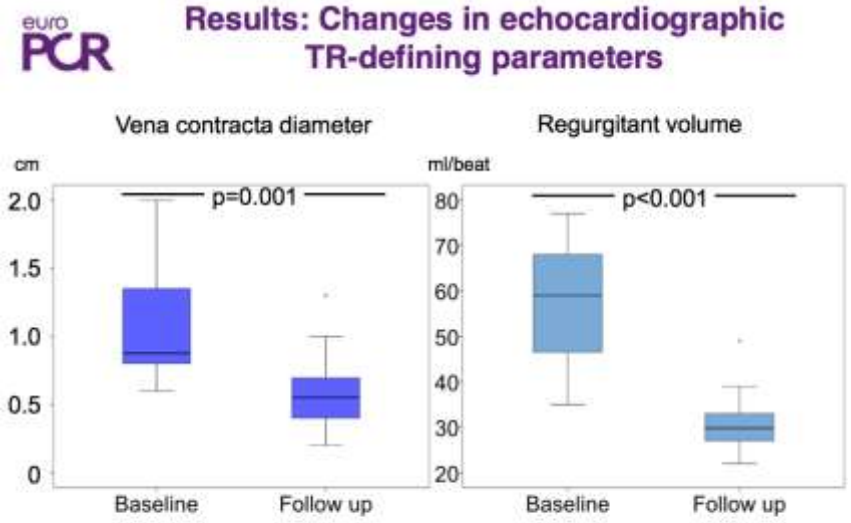
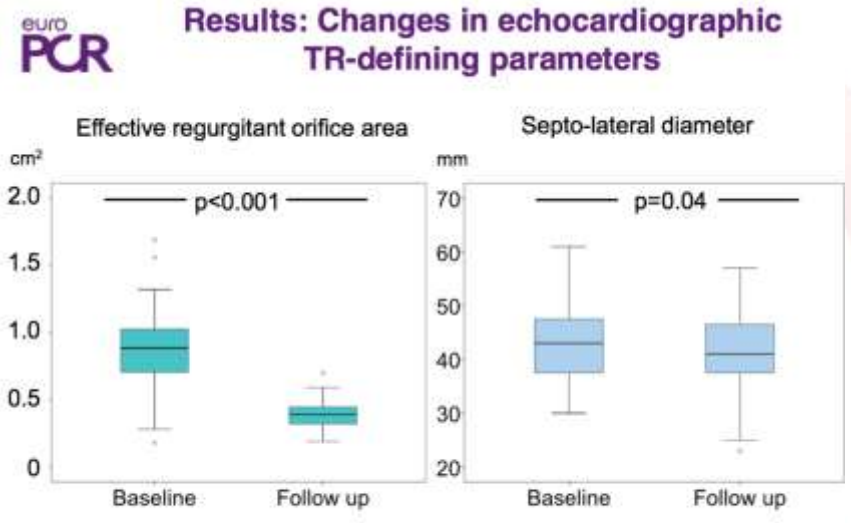
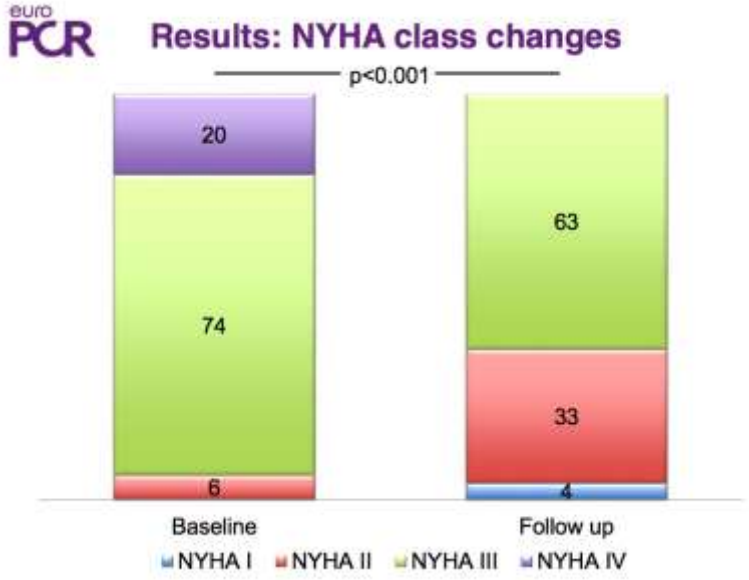
6.0MHz / 4 dB
TEQ: 3 / Offset: 2 dB
DR: 46 dB
E: +1 / D0
M: 3
---Color---
CDV / 4.0MHz
-3.5 dB

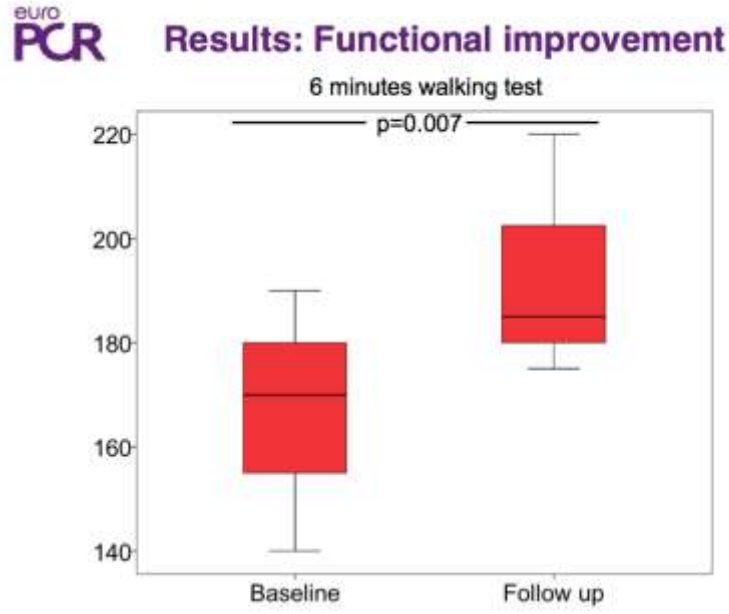
TR Reduction





Clinical improvement



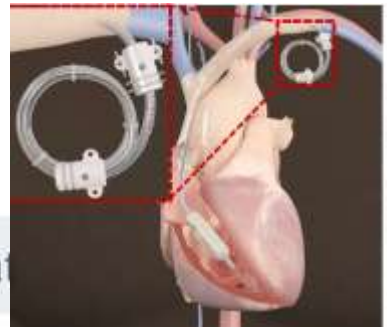


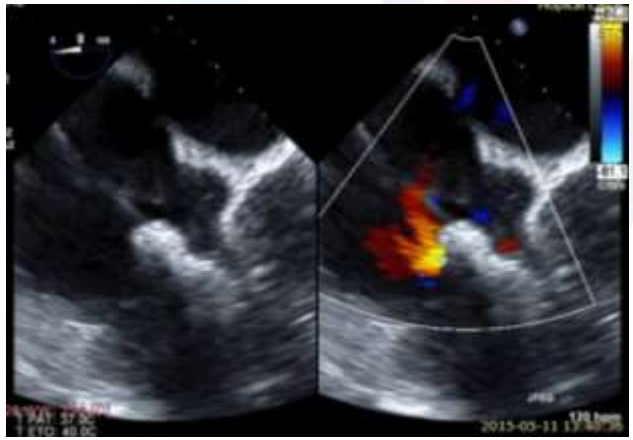
Edwards FORMA Repair System

Designed to restore leaflet coaptation

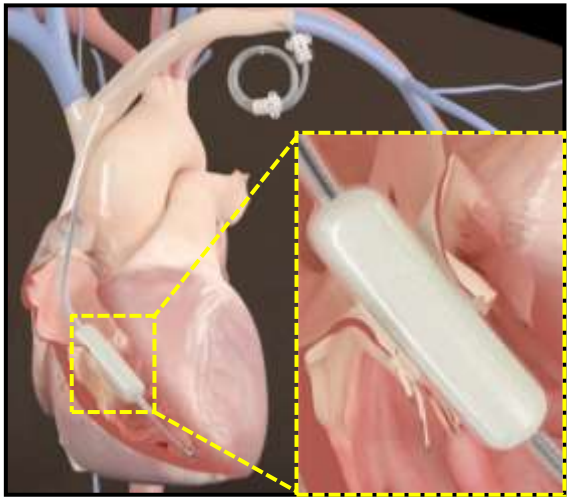
FORMA Repair System consists of:

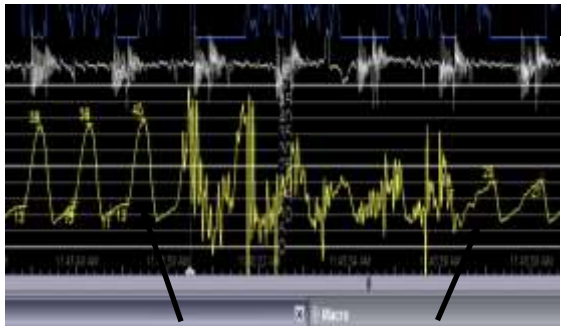
1. **Spacer**
   - Positioned into the regurgitant orifice
   - **Creates a platform for native leaflet coaptation**
2. Rail
   - Tracks Spacer into position
   - Distally and proximally anchored





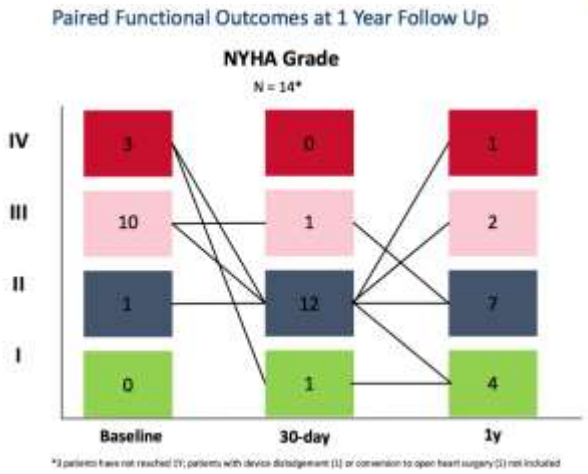
Forma Early results

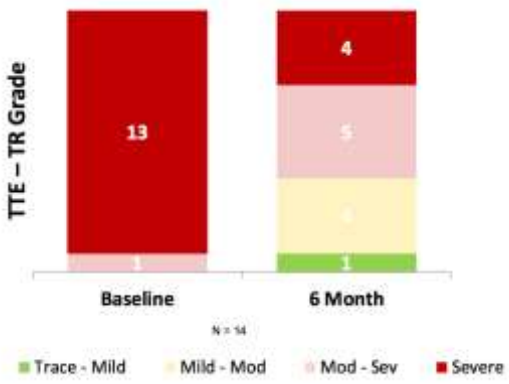


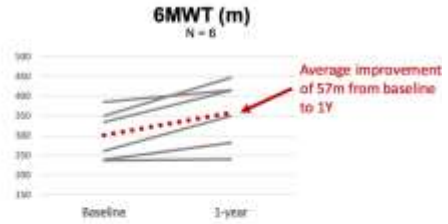


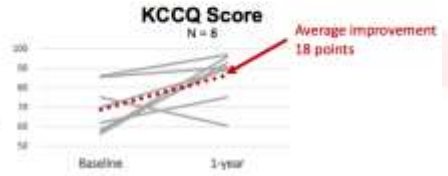
Pull back from Right Ventricle

To Right Atrium







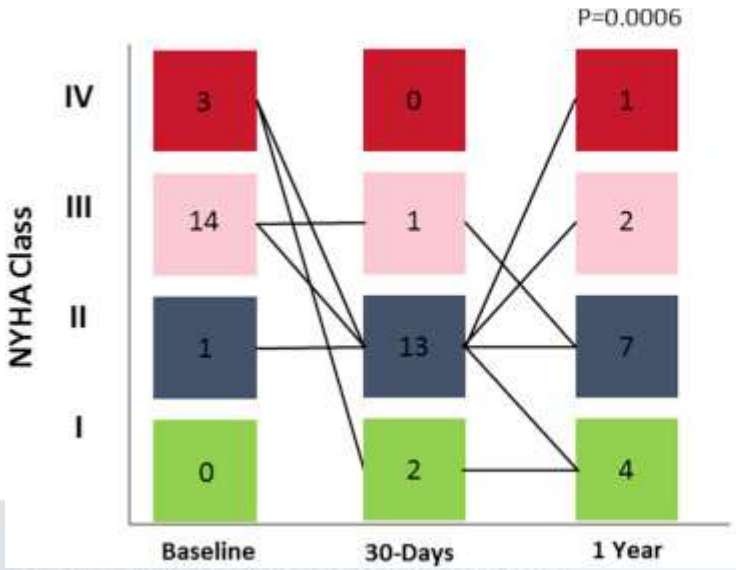


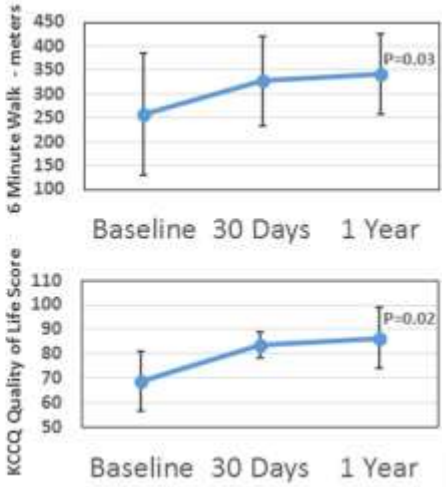
courtesy of F Praz

Transcatheter Tricuspid Valve Repair With a New Transcatheter Coaptation System for the Treatment of Severe Tricuspid Regurgitation

1-Year Clinical and Echocardiographic Results

Gidon Perlman, MD,[a,b] Fabien Praz, MD,[c] Rishi Puri, MBBS, PhD,[d,e,f] Hadass Ofek, MD,[a] Jian Ye, MD,[a] Francois Philippon, MD,[d] Thierry Carrel, MD,[c] Philippe Pibarot, DVM, PhD,[d] Adrian Attinger, MD,[a] Nay Min Htun, MBBS, PhD,[a] Danny Dvir, MD,[a] Robert Moss, MD,[a] Francisco Campelo-Parada, MD,[d] Elisabeth Bédard, MD,[d] David Reineke, MD,[c] Aris Moschovitis, MD,[c] Sandra Lauck, PhD,[a] Philipp Blanke, MD,[a] Jonathon Leipsic, MD,[a] Stephan Windecker, MD,[c] Josep Rodés-Cabau, MD,[d] John Webb, MD[a]

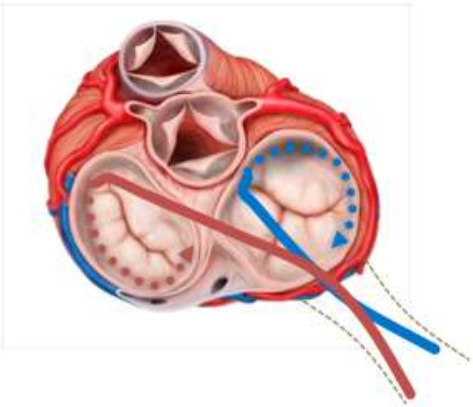


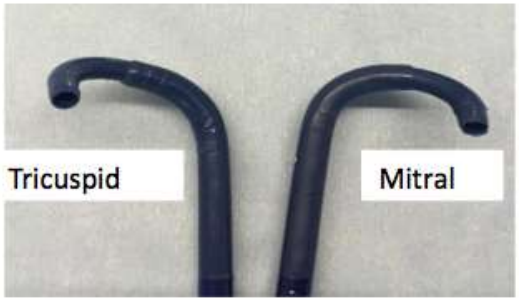


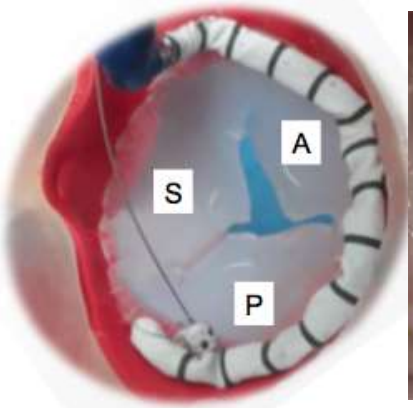
Available online 2 August 2017

Cardioband Tricuspid

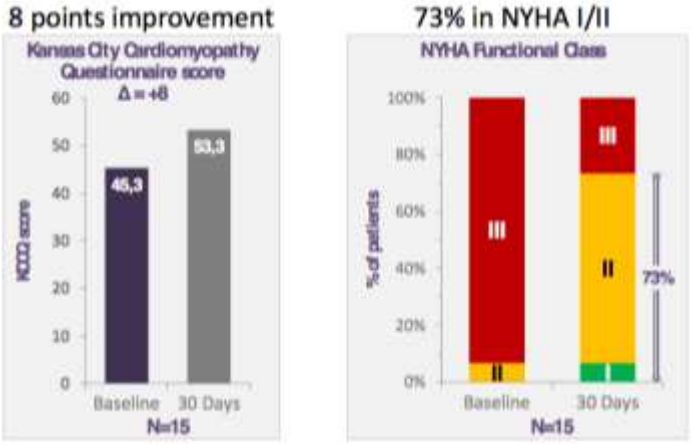
- Cardioband Tricuspid is an adjusted Cardioband Trans Femoral (CBTF – CE approved for mitral regurgitation treatment).
- Proven safety and performance with over 90 mitral patients.
- Quick learning curve to CBTF users.
- Applying the surgical gold standard with a trans femoral approach.

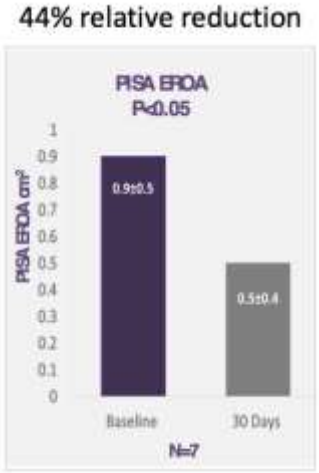


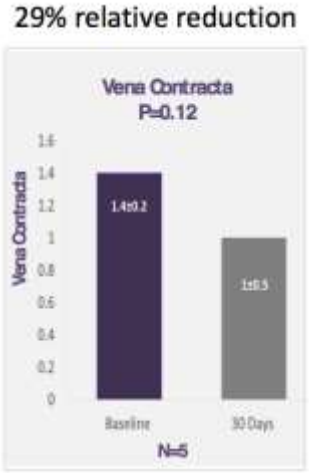




TRI-REPAIR study: Efficacy



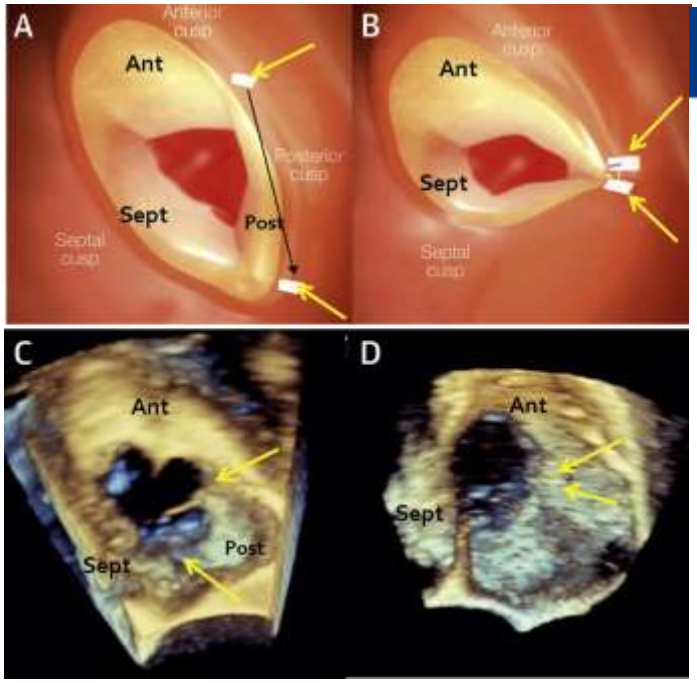




Clinical Improvements at 30 days

30 days TR reduction (core-lab)

Trialign



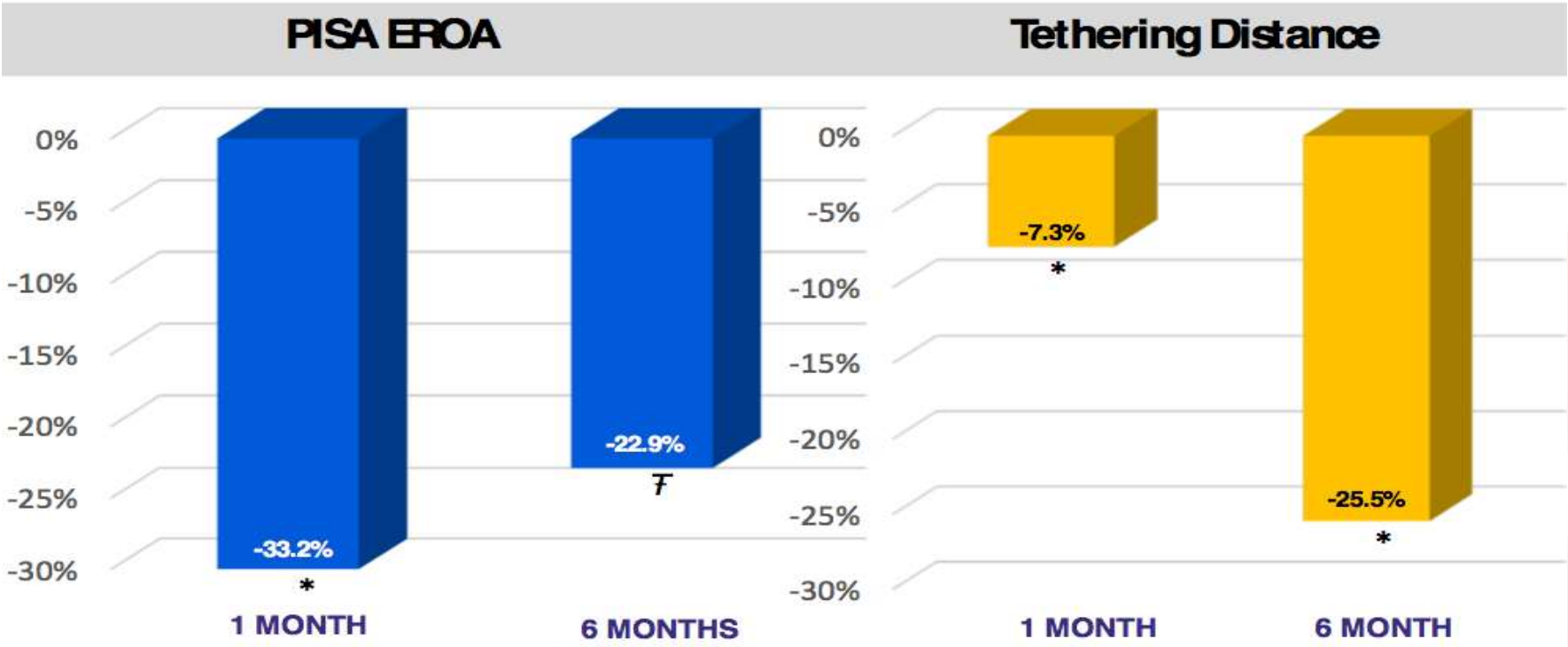
SCOUT I

trialign™

	n/N	(%)
Acute Procedure		
Implant Success	15/15	100%
Unplanned intervention	1/15	7%
Intraprocedural stenting of RCA		
30 Day Follow Up		
Freedom from death	15/15	100%
Technical Success	12/15	80%
3 single pledget dehiscence		
Major Adverse Events	0/15	0%

Trialign by Mitralign

courtesy of R. Hahn



*p≤ 0.05 Paired t-test versus Baseline

Ŧp= 0.0535 Paired t-test versus Baseline

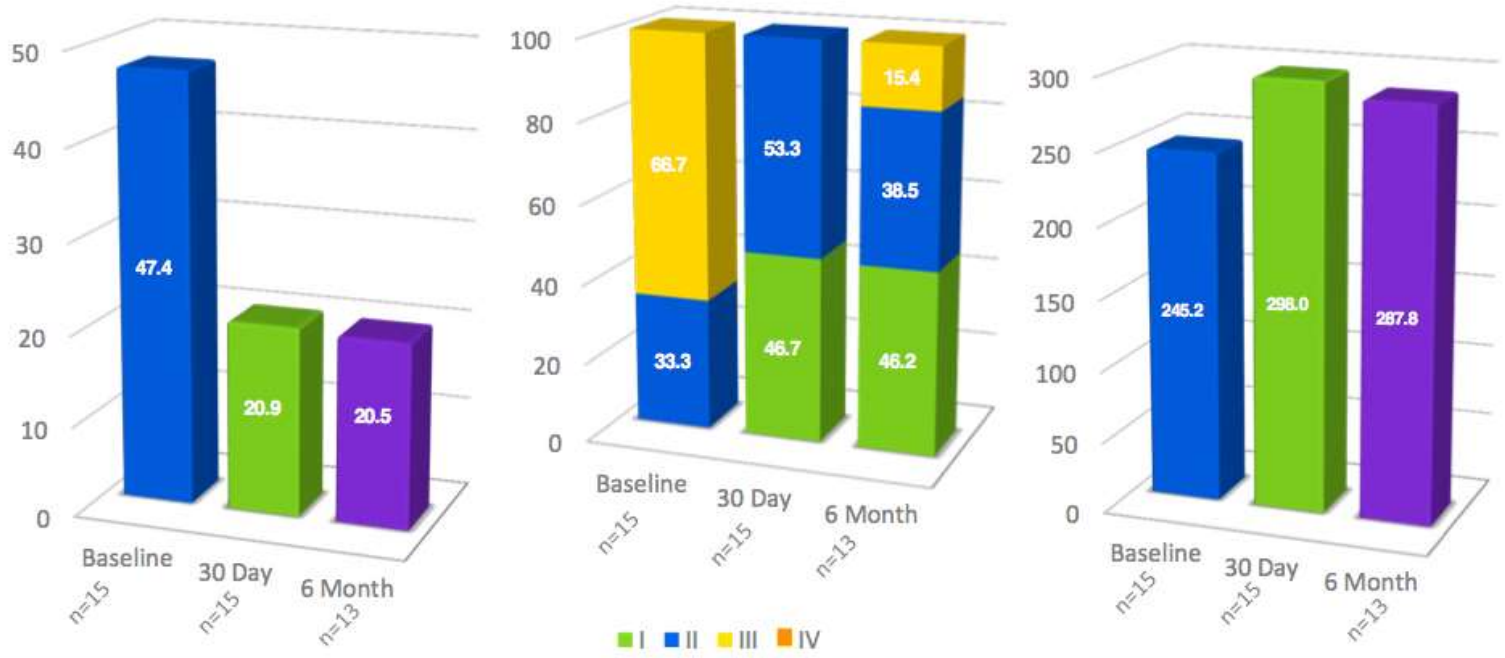
† Per Protocol

Trialign by Mitralign

SCOUT I

trialign™

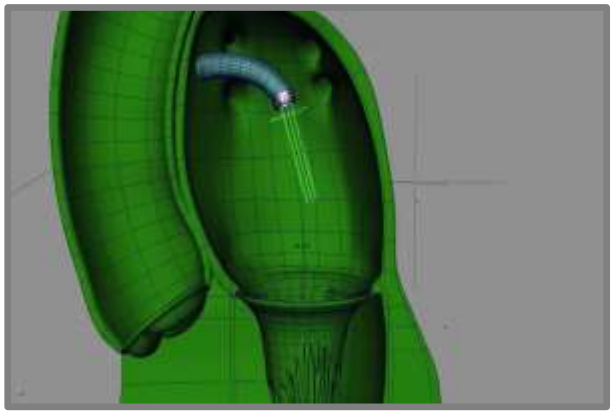
MLWHF	NYHA Classification	6 MWT (m)



‡ Information for all patients available through follow up

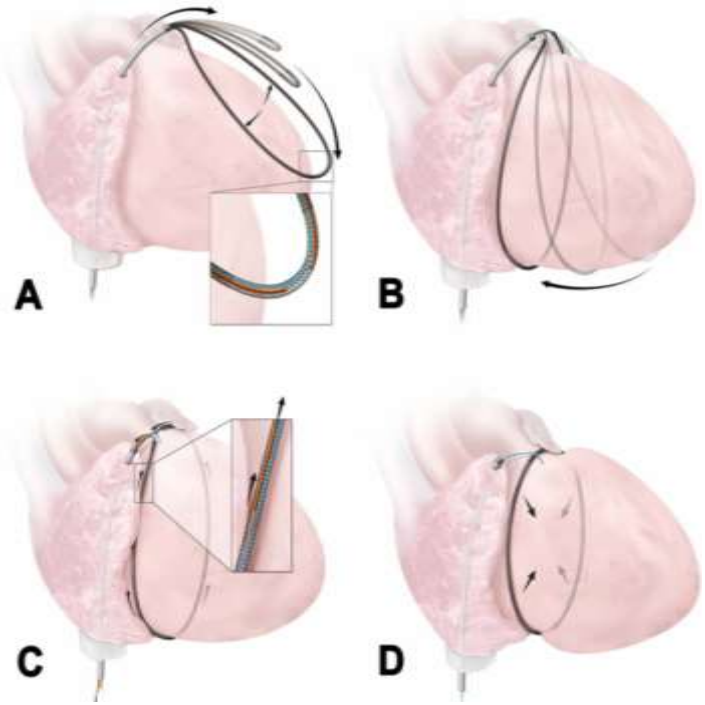
Trialign by Mitralign

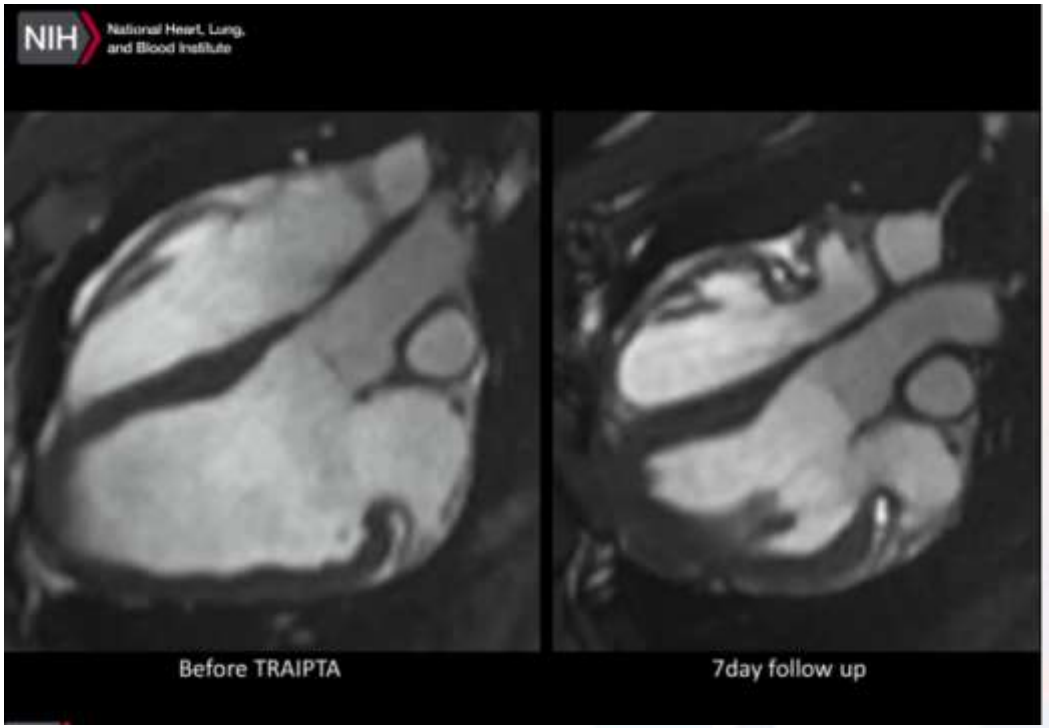
Millipede




PHILIPS
JM MILLIPEDE FOLLOW UP
02/08/2016 07:47:38AM TIS0.6 MI 1.4
10410720160209
S5-1/Adult
FR 45Hz
18cm
22
65%
C 50
P Low
HGain
M3
JPEG
bpm

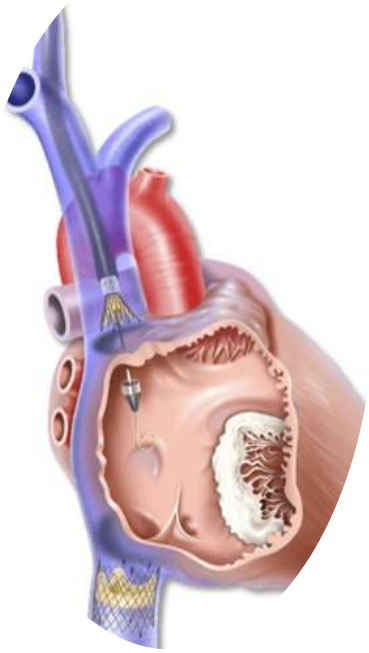
The TRAIPTA concept

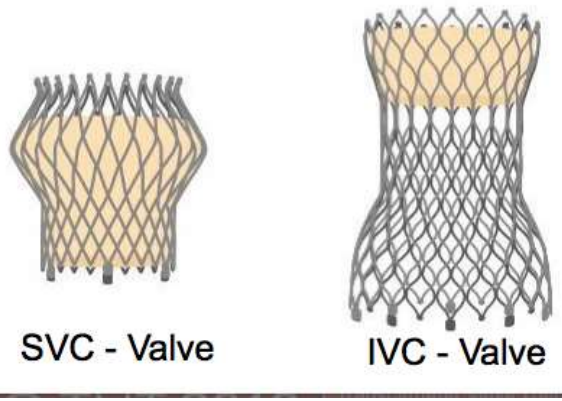




Rogers et al, JACC Cardiovasc Interv. 2015 Mar; 8(3): 483–491.

Eterotopic implantation: the CAVI concept





Summary Tricuspid data

Device	Primary Use	Trial Status	Experience
Mitraclip[1]	Mitral	Registry	~400
Tricinch[2]	Tricupsid	Gen 1 FIM Gen 2 Feasibilty	24
Cardioband	Mitral	Feasibility FIM	15
Millipede	Mitral	Feasibility Animal	0
Trialign[3]	Mitral	Feasibility FIM	15
Forma[4]	Tricuspid	Feasibility FIM	16
Triapta	Tricuspid	Feasibility Animal	0
Caval stent	Aortic	Feasibility FIM	10

1.Nickenig G, et al Circulation. 2017 May 9;135(19):1802-1814.
2.Calen C, et al. JACC Cardiovasc Interv. 2017 Apr 24;10(8):e75-e77.
3.Hahn RT et al. J Am Coll Cardiol. 2017 Apr 11;69(14):1795-1806.
4.Perlman G, et al . JACC Cardiovasc Interv. 2017 Jul 27. pii: S1936-8798(17)31312-2.

Conclusion

- Percutaneous interventions have an increasing place in the treatment of :
  - Functional tricuspid regurgitation
- Multiple new devices being trialled
  - Some are purposefully designed
  - Other adapted from the mitral valve intervention
  - Preliminary results are encouraging