

TCT AP
Seoul, Korea, April 26-29, 2016

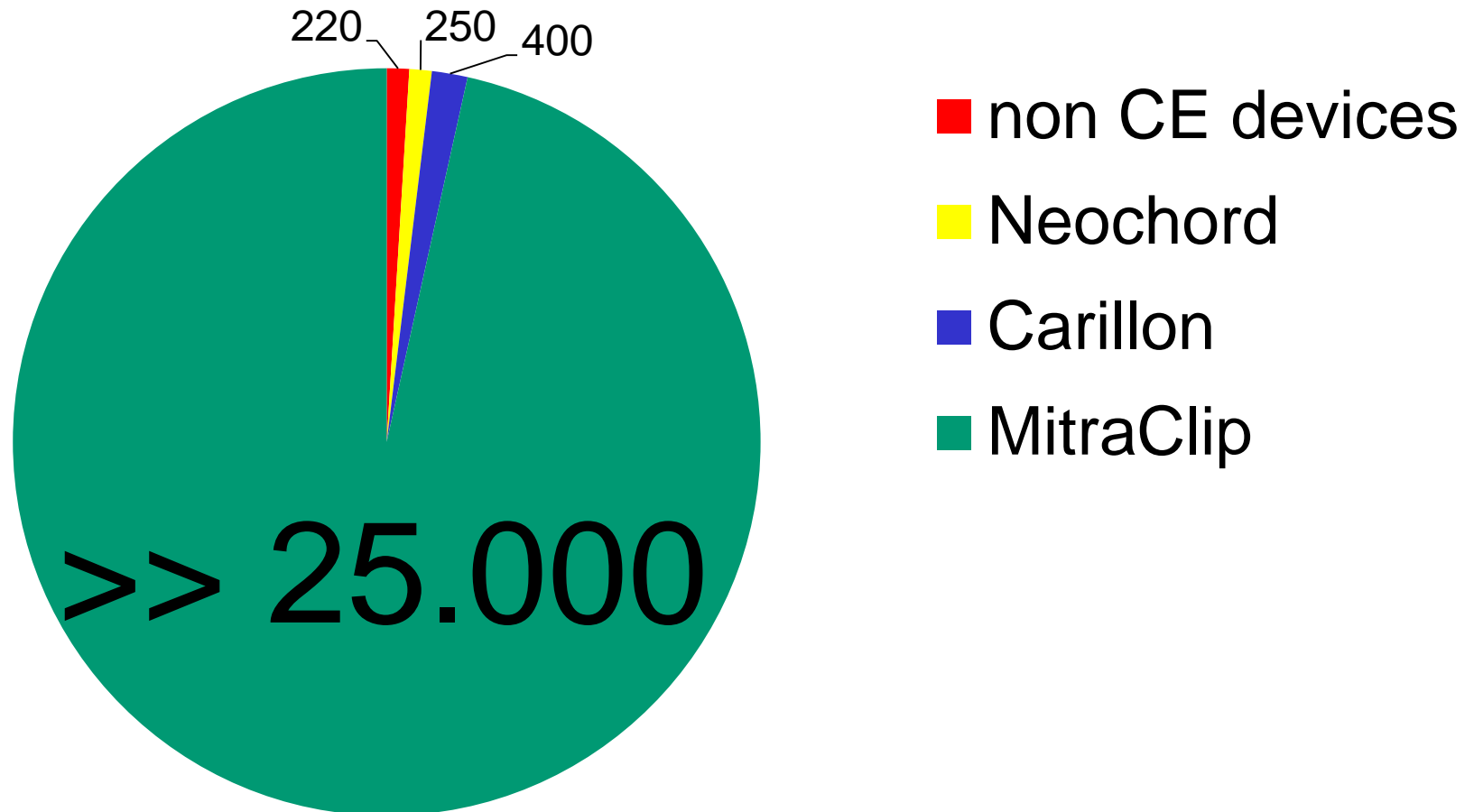
Transcatheter Mitral Valve Replacement Beyond Repair: New Paradigm Changes or Not Yet?

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Repair or Replacement?

Catheter Mitral Valve Repair = MitraClip

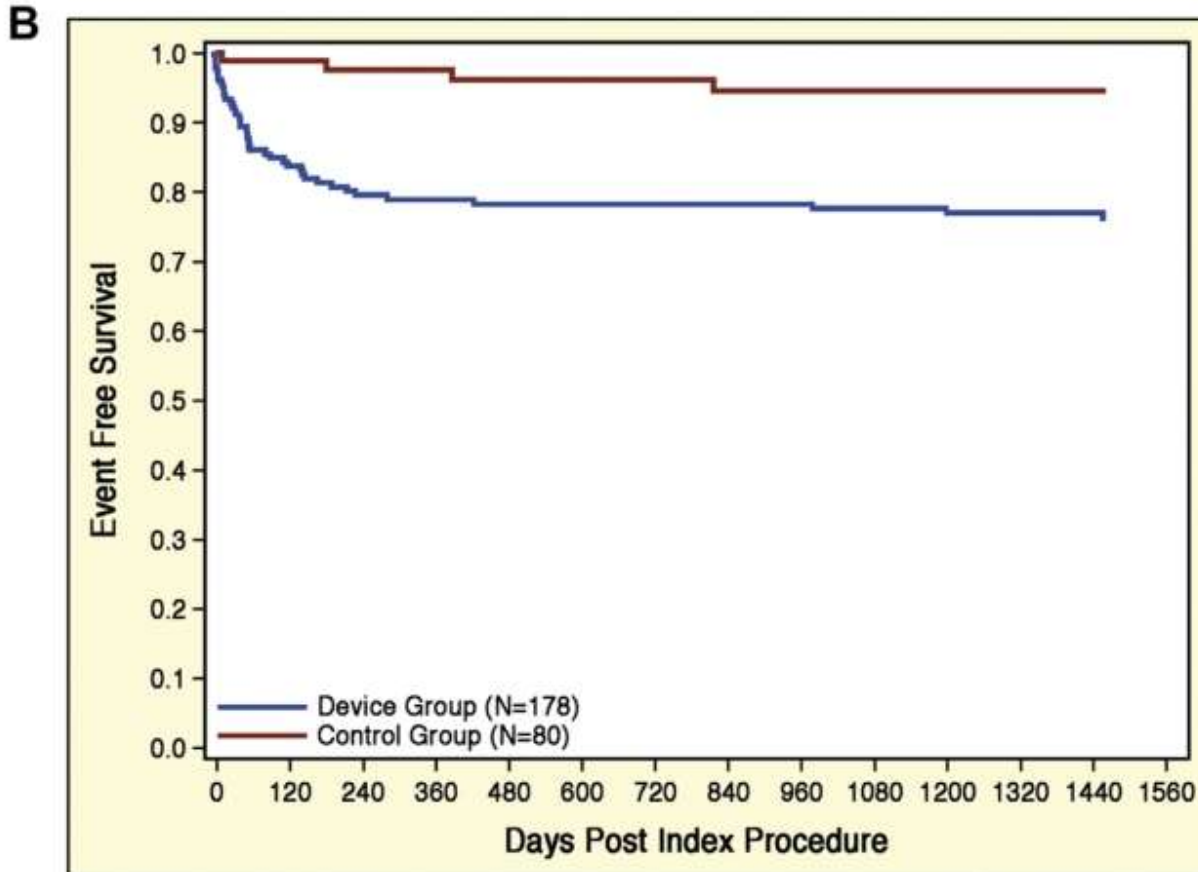
2003 - 2015



MitraClip

- Works very well in many patients
- Takes 1-2 hours
- "Has become a routine procedure in our lab"
- But sometimes
 - it is not that easy
 - it takes much more time
 - the result could be better

MitraClip 4-Year Results



Functional result of MitraClip is not as good as surgery

"Let's forget repair!"

"Replacement is the future!"

Mitral valve implantation

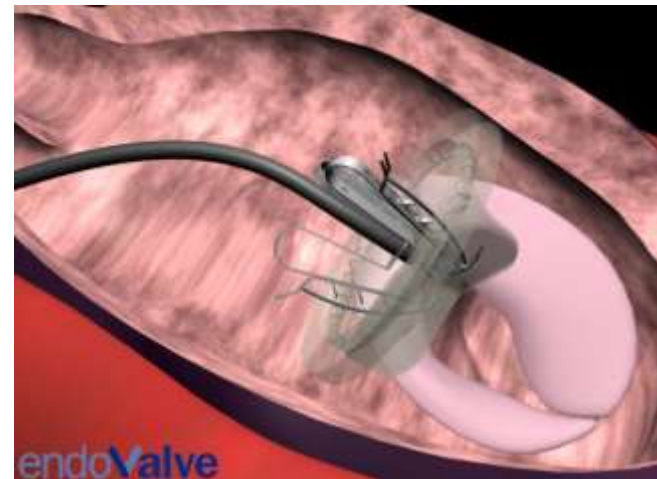
- Is in an early stage
 - Worldwide
 - < 400 valve in valve
 - < 80 in calcified mitral valve stenoses
 - < 70 worldwide in native valves with MR
- Highly selected patients with severe comorbidity
 - Compassionate use
 - High morbidity and mortality

Why is the mitral more difficult than the aortic?

- The mitral valve is larger than the aortic
- Percutaneous access is more difficult
- More complex structure
 - No calcium to grab
 - Not a round valve but saddle-shaped (→ leaks)
 - Orientation may be important
- Paravalvular leak likely less well tolerated
- LVOT obstruction is a concern
- Subvalvular apparatus should be preserved
 - Makes anchoring difficult

EndoValve-Herrmann Prosthesis

- First mitral valve implantation in animals
- Direct approach via mini-thoracotomy and the right atrium
- Working on a modified version
trans-apical
with anchors



CardiAQ Valve Technologies

Transcatheter Mitral Valve Implantation



NEWS RELEASE

FOR IMMEDIATE RELEASE

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CardiAQ™ Valve Technologies reports cardiovascular medicine milestone: first-in-human nonsurgical percutaneous implantation of a bioprosthetic mitral heart valve

Nearly 50% of patients suffering from a diseased mitral heart valve with severe, symptomatic regurgitation are denied open-heart surgery because it is considered too risky; in the future, Transcatheter Mitral Valve Implantation (TMVI) may offer new hope for these patients.

IRVINE, Calif., June 14, 2012—CardiAQ Valve Technologies (CardiAQ), which has developed the world's first self-conforming and self-anchoring technology for nonsurgical Transcatheter Mitral Valve Implantation (TMVI), today announced that the Company has achieved a cardiovascular medicine milestone: a bioprosthetic mitral heart valve was successfully implanted as a compassionate treatment into an 86-year-old male suffering from severe mitral regurgitation (MR 4+). The breakthrough TMVI procedure was performed on **June 12, 2012**, at The Heart Centre, Rigshospitalet University Hospital, Copenhagen, Denmark, by interventional cardiologists Lars Søndergaard, M.D., and Olaf Franzen, M.D., cardiovascular surgeon Susanne Holme, M.D., anesthesiologist Peter Bo Hansen, M.D., and echocardiographer Nikolaj Ihlemann, M.D.

CardiAQ → Edwards



- Supra annular valve leaflets
- Tapered outflow to limit LVOT obstruction

- Symmetric
 - No rotation required
- Atrial **anchors**
 - Axial stability
- **Ventricular anchors**
 - Leaflet capture
- Nitinol frame
- Bovine leaflets
- **One size**
- Annular skirt for sealing

CardiAQ: Supra/Intra Annular Position

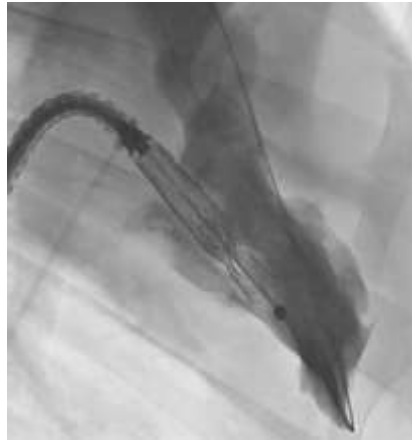


CardiAQ TMVI Procedures (TF & TA)

TMVI-Trans-femoral Procedure Sequence



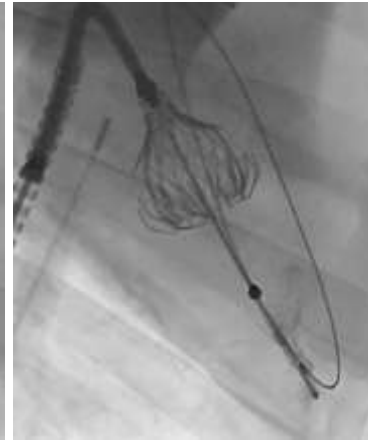
Track into LV



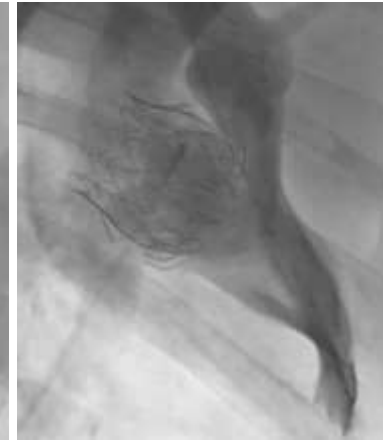
Establish Depth



Flip LV Anchors



Engage + Expand



Confirm + Release

TMVI-Trans-apical Procedure Sequence



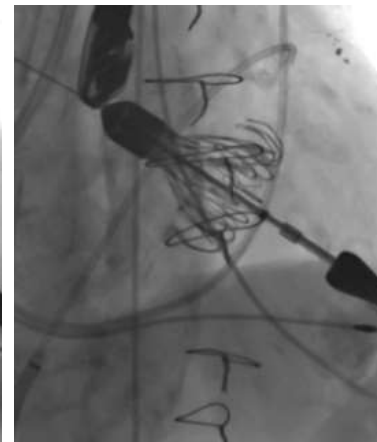
Insert into LV



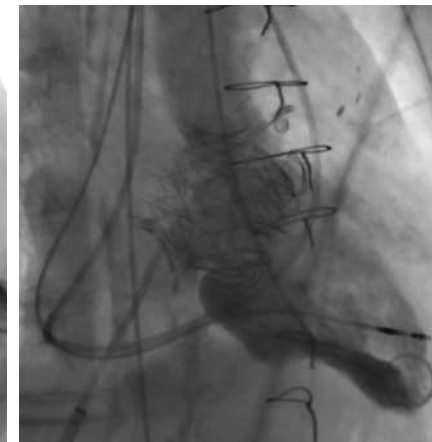
Establish Depth



Flip LV Anchors



Engage + Expand



Confirm + Release

CardiAQ - Current status

- FIM transseptal 2012
- 9 compassionate cases
 - 1 trans-femoral Gen1 + 8 trans-apical Gen2
 - 2 device/procedure related deaths
- Clinical trial is planned with trans-apical approach
 - 50 patients

In Humans

Valve	Company	Access	n
CardiAQ	Edwards	TA/TF	8
Fortis	Edwards	TA	13+7
Tiara	Neovasc	TA	4
Tendyne	Abbott	TA	12
Twelve	Medtronic	TA	4

Fortis (Edwards)

Compassionate use

- Nitinol
- Bovine leaflets
- Atrial flange
- Paddles for leaflet capture and anchoring
- Transapical, 32 F
- Repositionable



Fortis - Procedural and 30 day outcomes

		N = 13
	Procedural success	10 (76.9%)
	Conversion to open heart surgery	2 (15.4%)
	In hospital mortality	4 (30.8%)
30 day results		
	Mortality	5 (38.5%)
	Probable prosthesis thrombosis	1 (?)
	Major bleeding	2 (15.4%)
Echo at discharge		N=9
	LVEF (%)	31 ± 12
Mitral regurgitation		
	None/trace	8
	Mild	1

Fortis

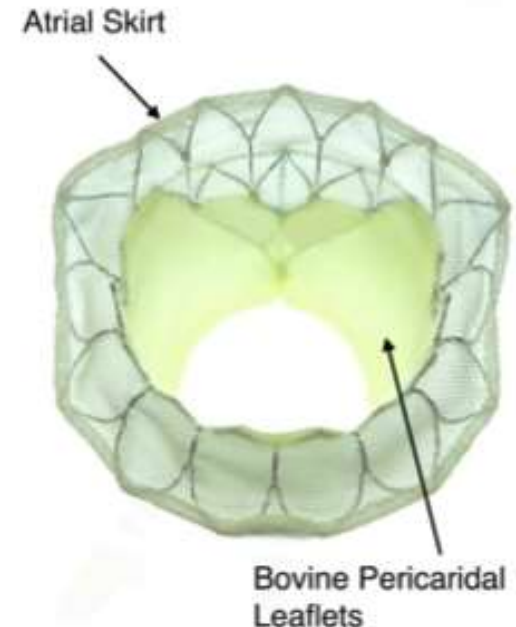
EDWARDS PAUSES ENROLLMENT IN EARLY STAGE MITRAL PROGRAM

IRVINE, Calif., May 19, 2015 – Edwards Lifesciences Corporation (NYSE: EW), the global leader in the science of heart valves and hemodynamic monitoring, today announced that in consultation with trial investigators, **the company has voluntarily implemented a temporary pause on enrollment** in its FORTIS clinical program. We observed evidence of valve thrombosis that we believe warrants additional investigation.

Program stopped because of valve thrombosis

Neovasc - TIARA™

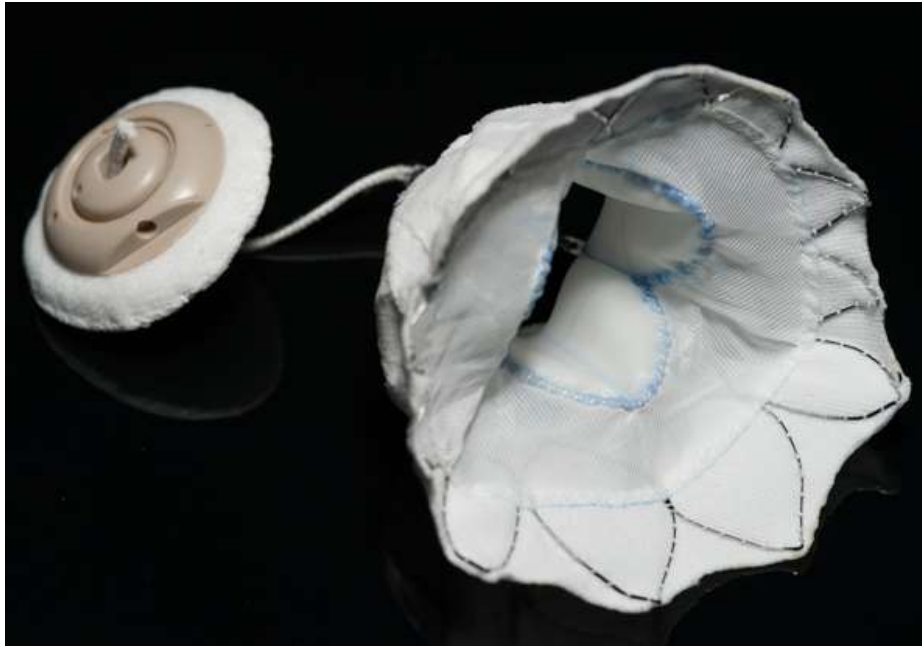
- Nitinol frame, **D-shaped**, with anchors (not relying on native leaflets)
- bovine leaflets
- trans-apical approach, 42F
- repositionable until final release



Tiara - Procedural Outcomes

- N = 7
- No procedural complications
- MR grade reduced to
 - none in 5 pts
 - trivial in 2 pts
- Two deaths out 69 and 157 days post
 - Functioning prosthesis confirmed at day 60 and day 150 respectively

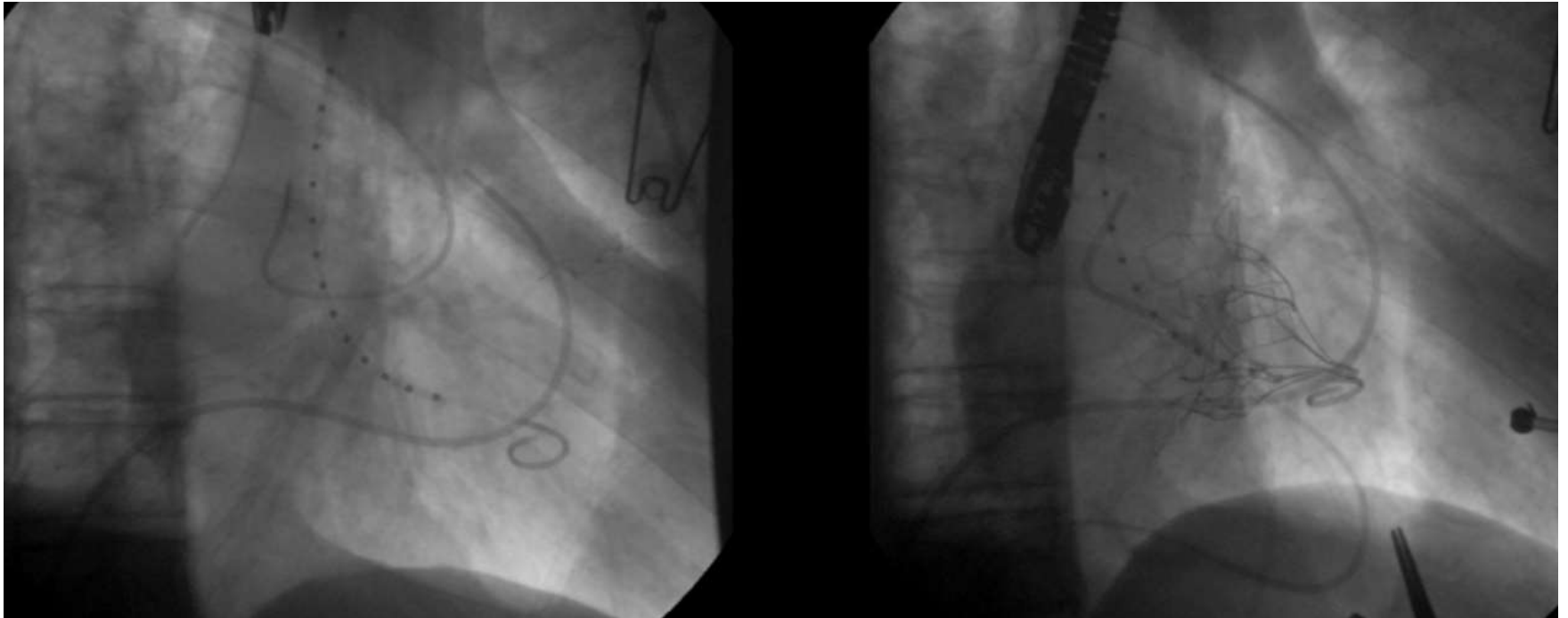
Tendyne Transapical Mitral Valve



- Fully retrievable and repositionable

- Nitinol frame, saddle shaped
- 20 different sizes
- porcine pericardium
- Left ventricular apical tether, anchor outside LV
- FIM 2013

FIM Ventriculogram



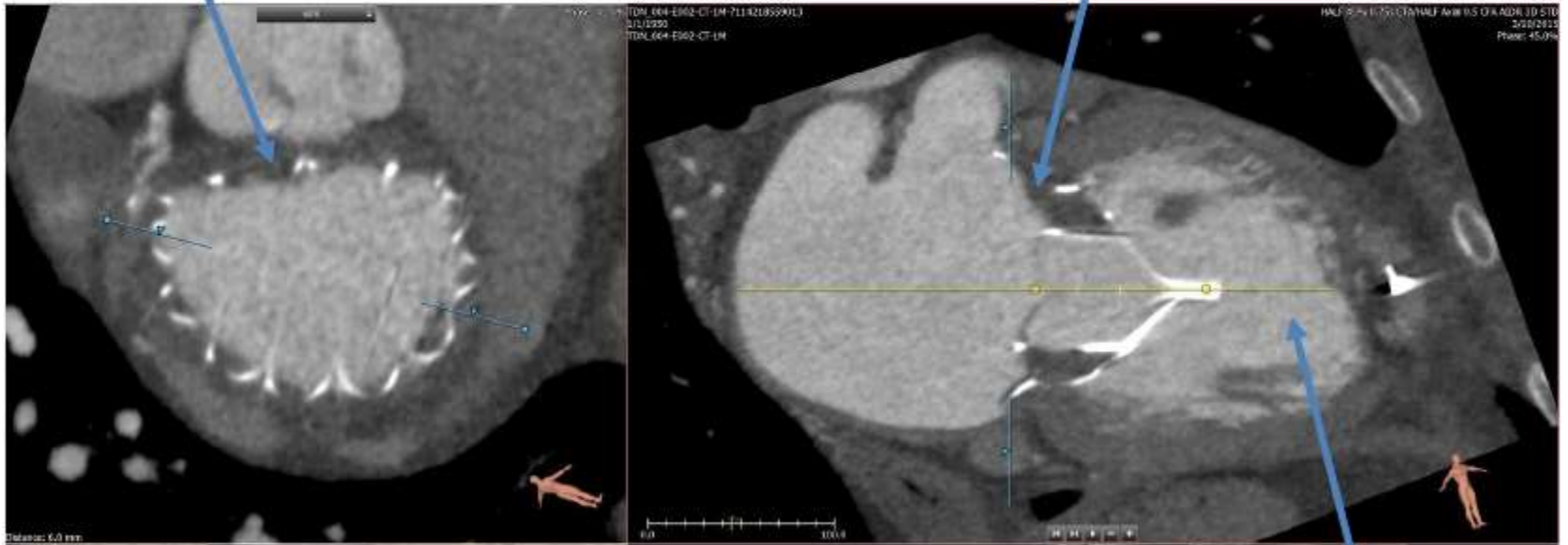
Baseline

Post Tendyne

Day 30 CT: systole

Circumferential apposition of atrial skirt

Seated well at annulus/atrioventricular junction



Tether perpendicular to plane of annulus

Tendyne - Procedural Outcomes

- Twelve (12) patients with severe MR
- One valve was successfully retrieved
- No deaths
- 9/10 : 0 PVL leak 1/10 : mild PVL

There is no question, that mitral valve implantation has a great future...

- ... but currently we see more limitations than we would like to see
 - Most valves require a transapical access
 - LVOT obstruction is a big problem for more or less all valves
 - this limits the number of suitable patients
 - Very high mortality in some series
- Nevertheless, the future has never been closer

Thank you!

LIVE CASES

JUNE 22–25, 2016 | FRANKFURT, GERMANY

CSI 2016 – CONGENITAL, STRUCTURAL
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