Current Status of Transcatheter Therapies for Mitral Regurgitation

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Seoul
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NorthShore University HealthSystem
Evanston Hospital

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Disclosure Information

The following relationships exist:

Grant support: Abbott, BSC, Edwards, WL Gore
Consultant: Abbott, BSC, Coherex, Edwards, JenaValve, Diiachi Sankyo-Lilly, WL Gore

Off label use of products and investigational devices will be discussed in this presentation

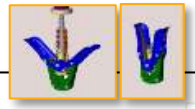
Percutaneous Mitral Repair Devices

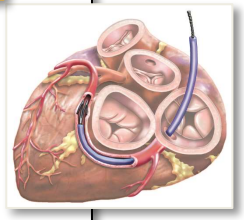
Already gone

- PTMA
- Monarc
- Mobuis leaflet repair
- Recor RF annular remodeling
- Coapsys

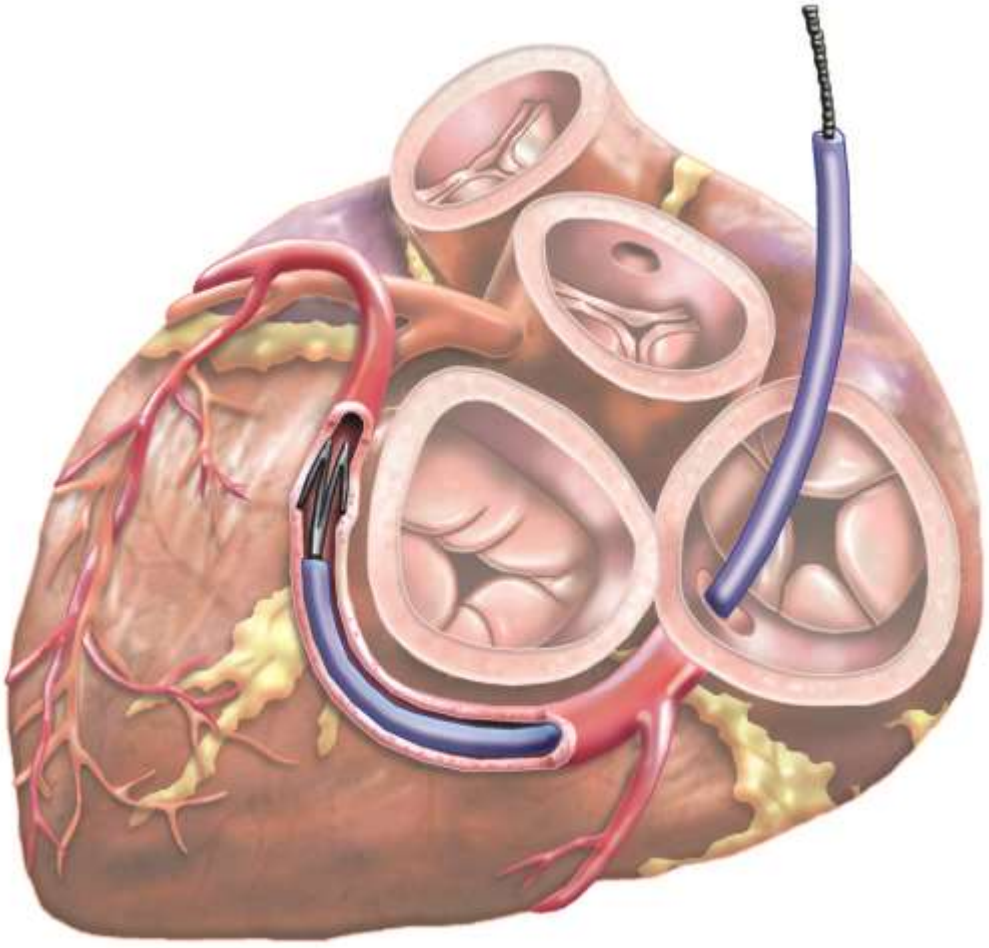
Still developing

- Leaflet repair
- CS annuloplasty
- Direct annuloplasty
- Cerclage
- Mitral spacer
- Midle Peak
- Chordal replacement
- Valve replacement





Coronary Sinus- Indirect Annuloplasty



CARILLON Mitral Contour System

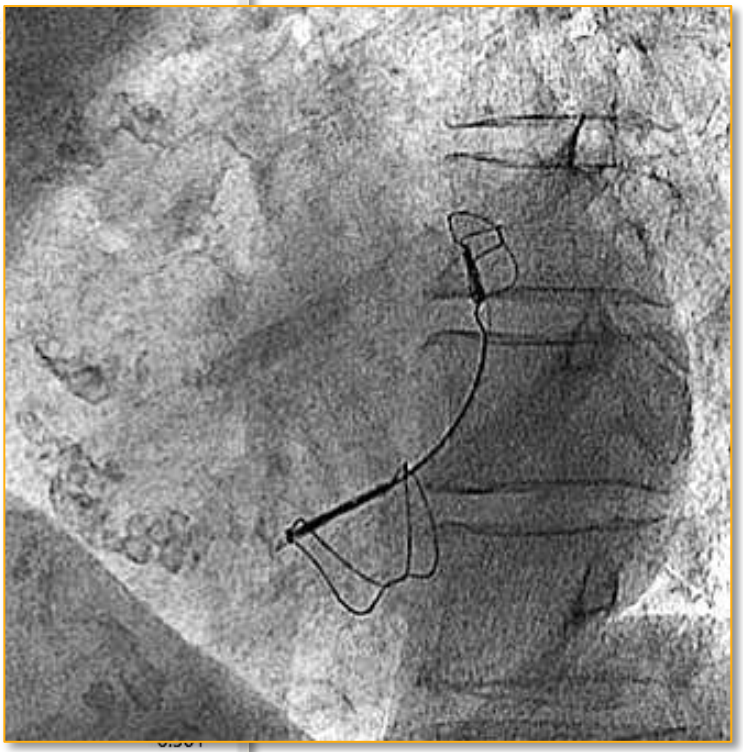

PHILIPS

Treatment of functional mitral regurgitation by percutaneous annuloplasty: results of the TITAN Trial

Tomasz Siminiak , Justina C. Wu , Michael Haude , Uta C. Hoppe , Jerzy Sadowski , Janusz Lipiecki , Jean Fajadet , Amil M. Shah , Ted Feldman , David M. Kaye , Steven L. Goldberg , Wayne C. Levy , Scott D. Solomon , and David G. Reuter

Table 1 Baseline patient characteristics

	Intent-to-treat population (n = 53)	Permanent implant population (n = 36)	Device recaptured population (n = 17)	P-value
Demographic factors				
Age (years)	62.44 ± 12.69 (53)	62.37 ± 12.67 (36)	62.59 ± 13.11 (17)	
Gender				
Male	77.4% (41/53)	75.0% (27/36)	82.4% (14/17)	
Female	22.6% (12/53)	25.0% (9/36)	17.6% (3/17)	
NYHA class	3.0 ± 0.24 (53)	3.1 ± 0.23 (36)	2.9 ± 0.24 (17)	
6 min walk distance (m)	314 ± 77.9 (53)	302 ± 73.6 (36)	338 ± 83.4 (17)	
Echocardiographic characteristics				
Baseline MR grade				
Moderate (2+)	17.0% (9/53)	19.4% (7/36)	11.8% (2/17)	
Moderate–severe (3+)	56.6% (30/53)	55.6% (20/36)	58.8% (10/17)	
Severe (4+)	26.4% (14/53)	25.0% (9/36)	29.4% (5/17)	
LVEDD (cm)	6.7 ± 0.82 (53)	6.6 ± 0.85 (36)	6.7 ± 0.77 (17)	
LVESD (cm)	5.8 ± 0.95 (53)	5.8 ± 1.01 (36)	5.7 ± 0.80 (17)	
LVEDV (mL)	217.8 ± 75.2 (53)	208.5 ± 62.0 (36)	237.4 ± 96.8 (17)	
LVESV (mL)	160.1 ± 70.3 (53)	151.8 ± 57.1 (36)	177.7 ± 91.9 (17)	
LVEF (%)	28.1 ± 7.56 (53)	28.66 ± 7.49 (36)	26.99 ± 7.80 (17)	
Cardiovascular history				
Ischaemic aetiology to HF	64.2% (34/53)	66.7% (24/36)	58.8% (10/17)	
HF admission in past 12 months	77% (41/53)	75% (27/36)	82% (14/17)	
History of ICD	15.1% (8/53)	16.7% (6/36)	11.8% (2/17)	
History of diabetes	20.8% (11/53)	16.7% (6/36)	29.4% (5/17)	



European Journal of Heart Failure
doi:10.1093/eurjhf/hfn076

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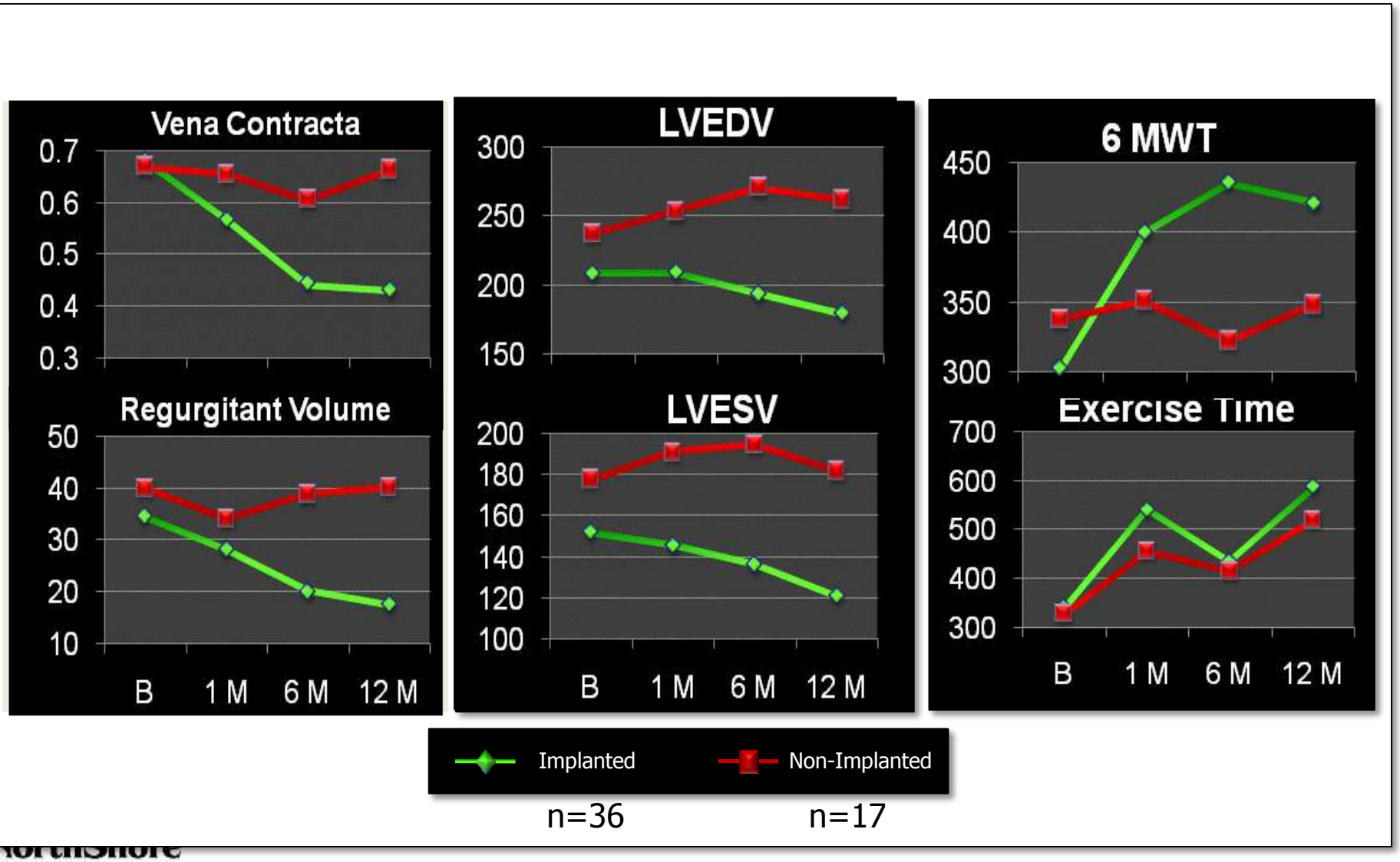
TITAN Trial

CARILLON Mitral ystem for FunContour Sctional MR

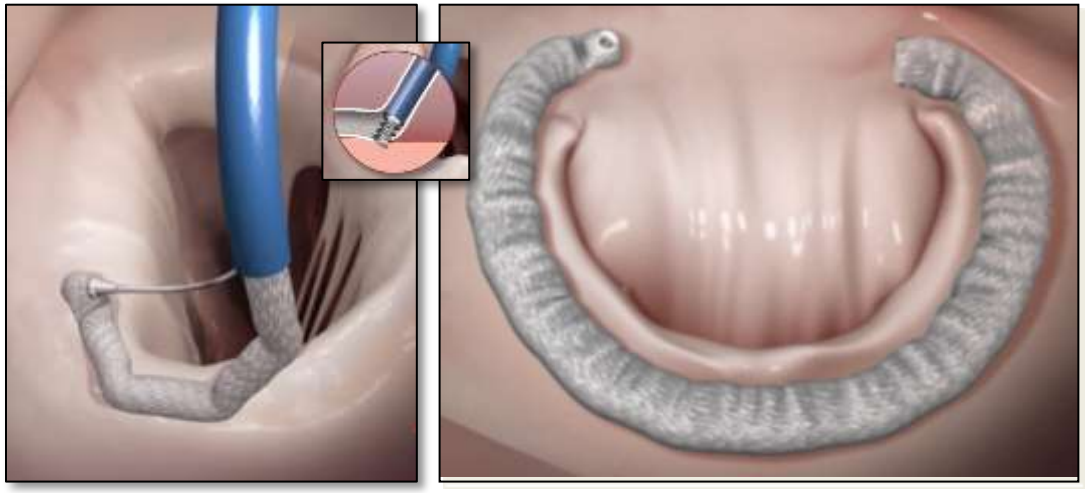


Eur J Heart Fail. 2012 Aug;14(8):931-8

CARILLON Current Status

- REDUCE FMR
  - Randomized trial of Carillon versus sham
  - Europe and Australia
- CLINCH
  - Investigator driven pilot study of Carillon versus MitraClip
- Commercialized
  - Germany, Saudi Arabia, Turkey and expanding

Cardioband TRANS FEMORAL



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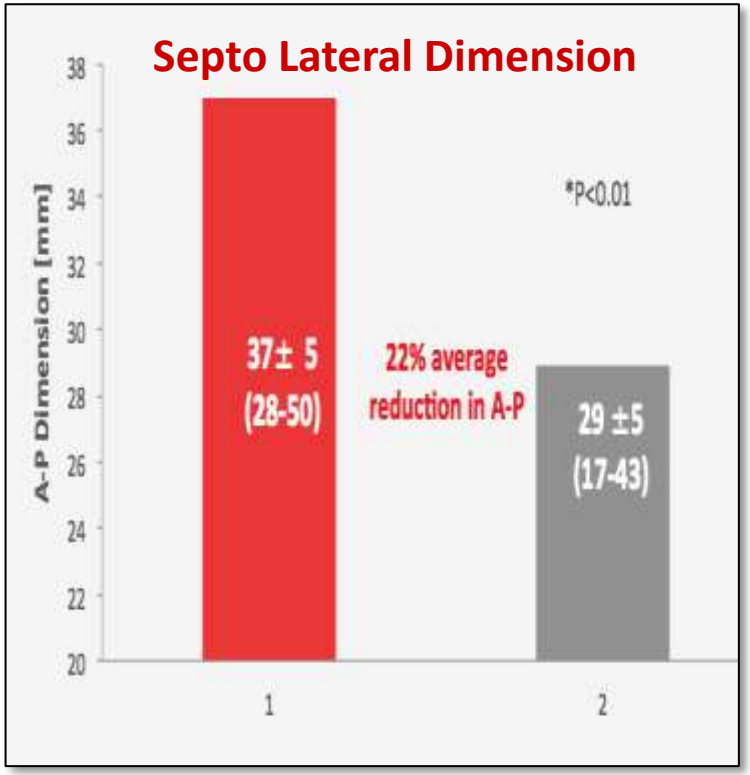
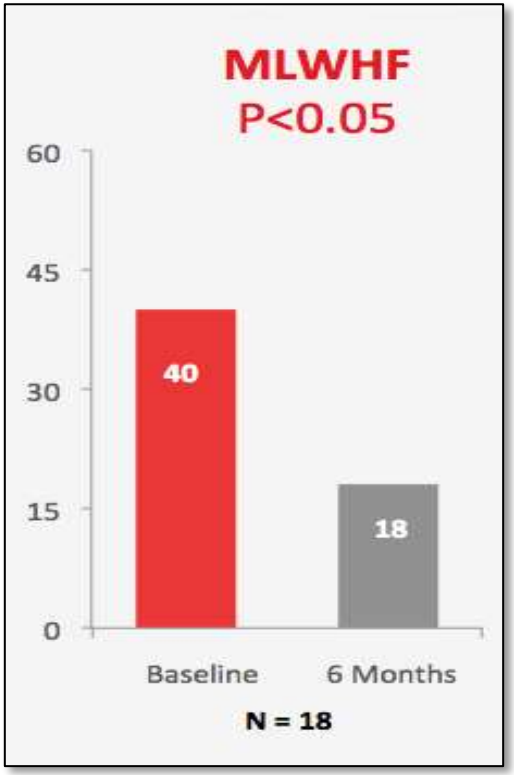
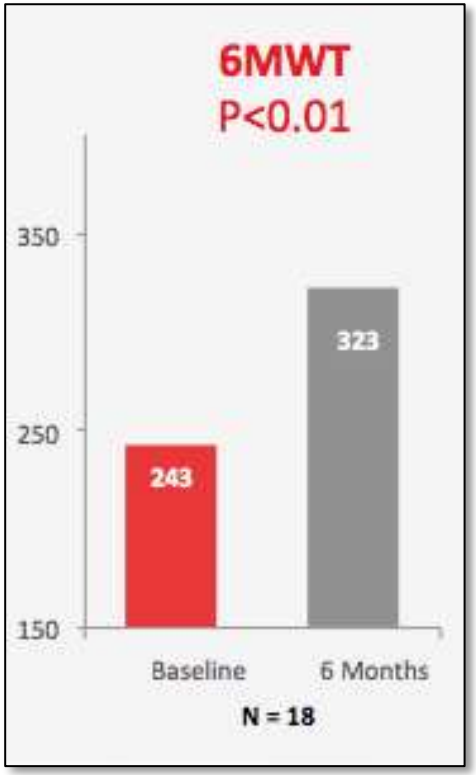
Update from European CARDIOBAND Trial

35 patients results 2/3/2015







24/33 Patients with MR ≤Mild at 6 Months FU

Mean Age 72 (56-81)

STS Repair 7 (1-34)

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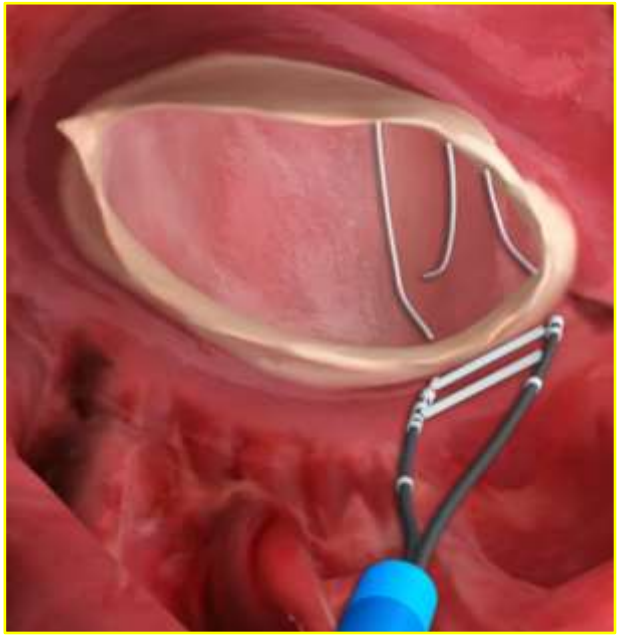
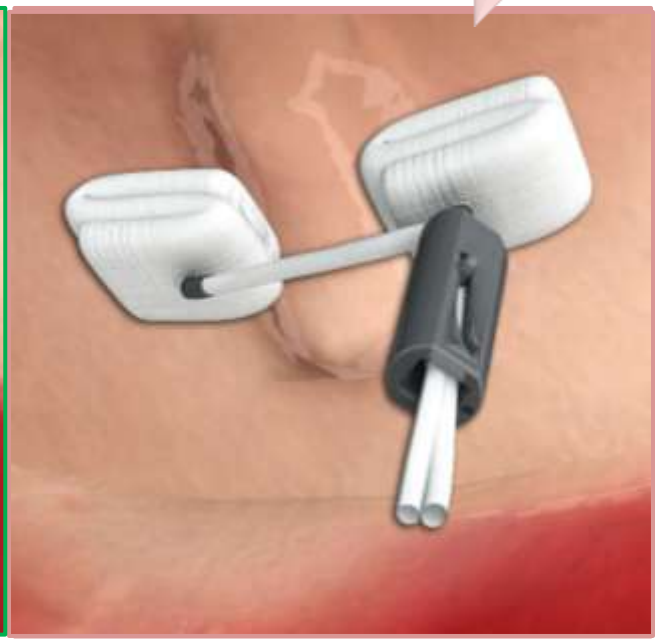
DIRECT ANNULOPLASTY
Mitralign Procedure Steps

Wire Delivery

Pledget Delivery

Plication & Lock





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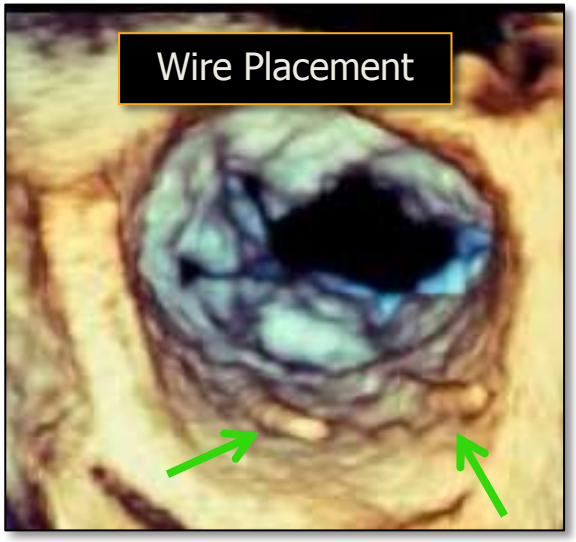
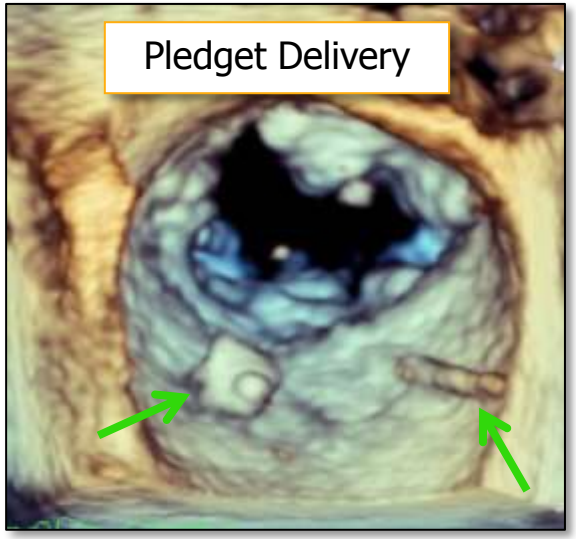
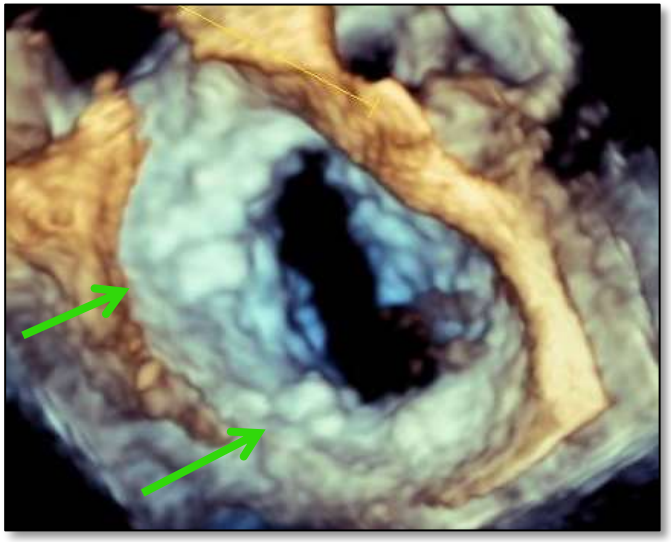
Direct Annuloplasty - Transventricular Approach

Mitralign System







CE Mark Study

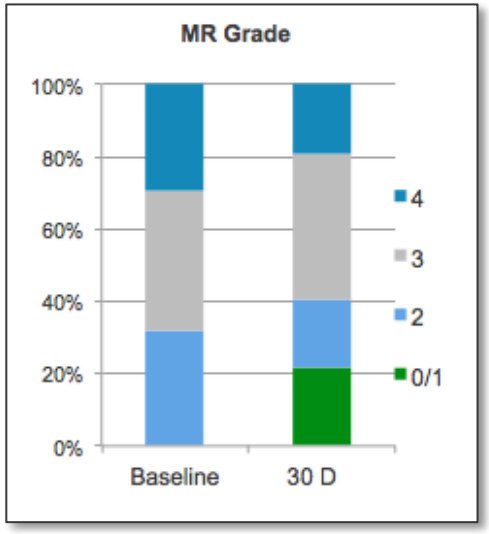
30-Day Performance: Core Lab Adjudicated

Ventricular Changes

	Baseline (n)	30 Day (n)	30 Day Change Paired (n)	30 Day Change P-Value
LVIDd (cm)	6.35 (44)	6.10 (38)	**-0.21 (36)**	**0.004**
LVIDs (cm)	5.37 (44)	5.15 (38)	**-0.21 (35)**	**0.079**
LVEDv (ml)	186.4 (44)	169.0 (38)	**-20.1 (31)**	**< 0.001**
LVESv (ml)	122.8 (44)	110.5 (38)	**-13.1 (31)**	**0.008**

Annular Changes

	Baseline (n)	30 Day (n)	30 Day Paired Change (n)	P-Value
A-P Dia. (cm)	3.58 (44)	3.27 (38)	**-0.39 (31)**	**< 0.001**
S-L Dia. (cm)	3.55 (44)	3.34 (38)	**-0.26 (33)**	**< 0.001**

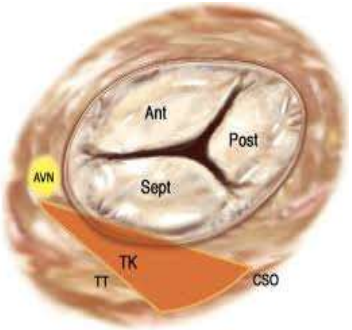


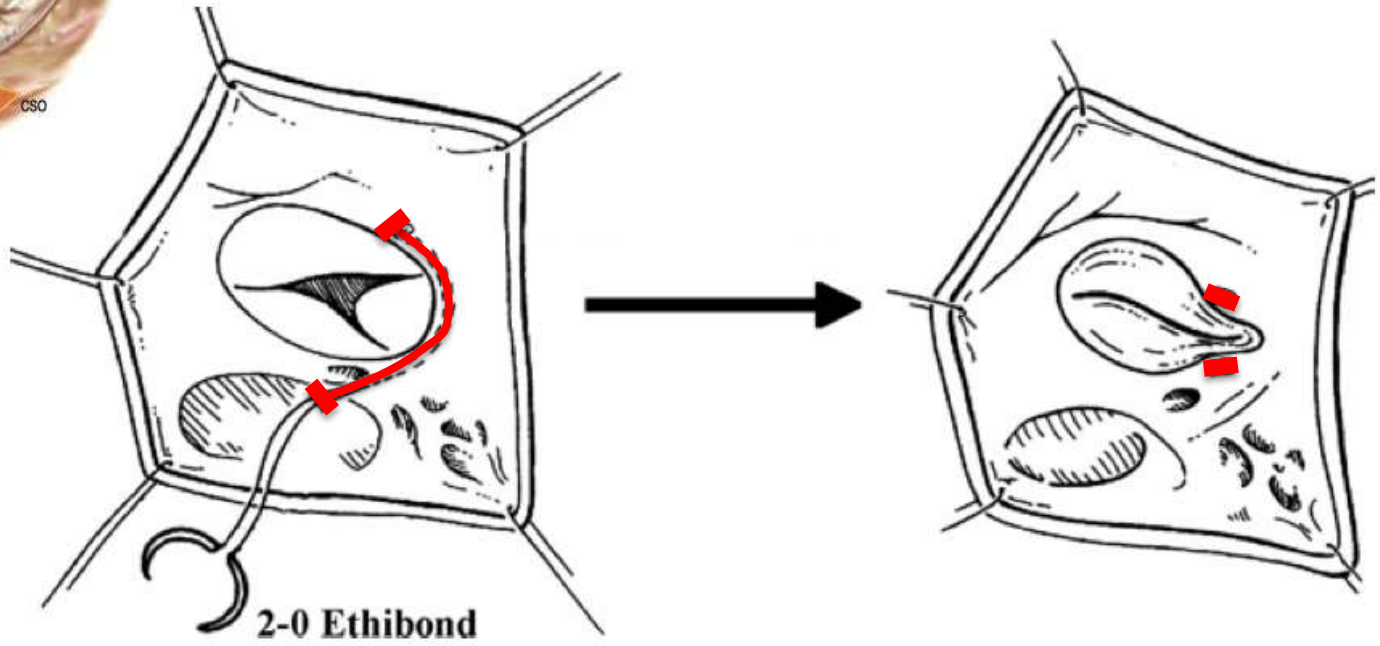
N=64

Investigational Device Only: Not Available in the EU or US

Suture bicuspidization of the tricuspid valve vs ring annuloplasty for functional tricuspid regurgitation

Midterm results of 237 consecutive patients





Suture bicuspidization is performed by placement of a 2-0 pledget-supported mattress suture from the antero-posterior to the posteroseptal commissures along the posterior annulus.

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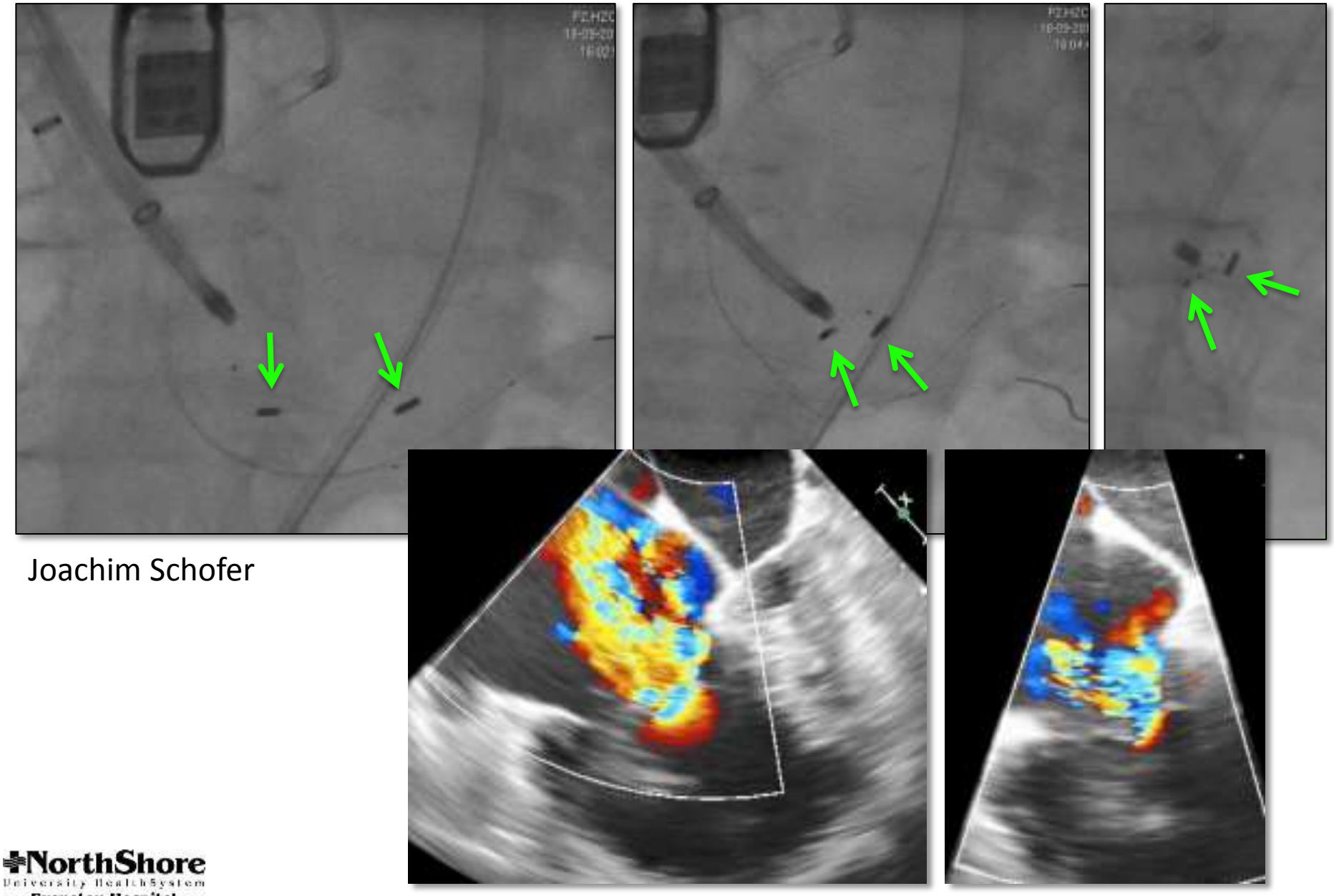
J Thorac Cardiovasc Surg 2007;133:117-126

First Human Report on Percutaneous Repair for Functional Tricuspid Regurgitation with the Mitralign System



Joachim Schofer

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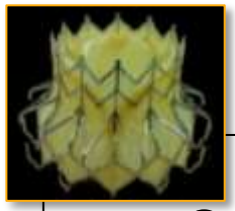
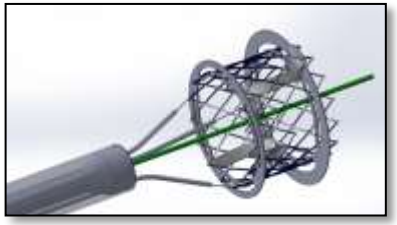
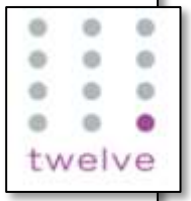
Mitral Replacement Technologies



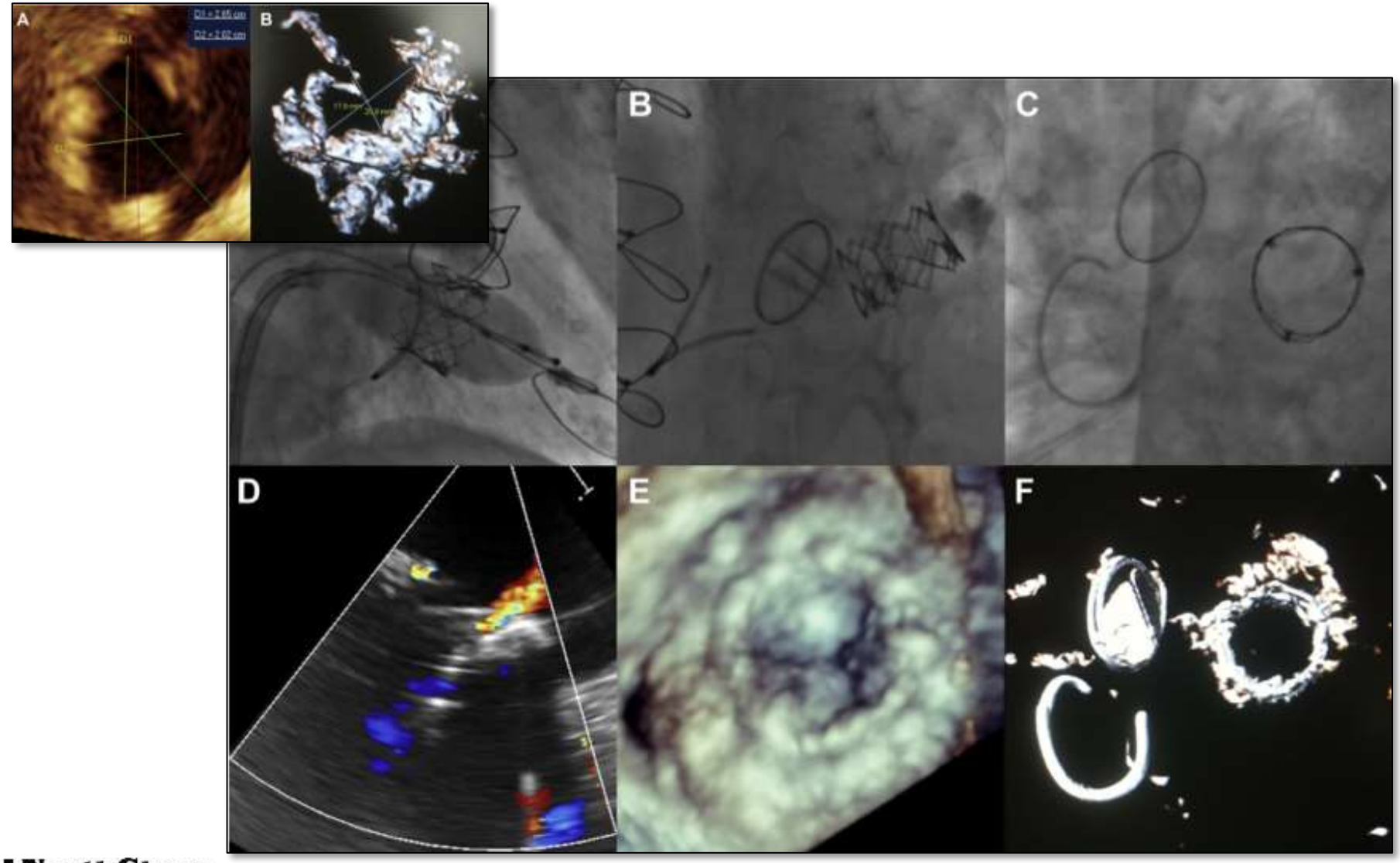
- CardiaAQ
- Neovasc TIARA
- Tendyne
- Edwards FORTIS
- Endovalve
- M-Valve
- Medtronic



- Valtech
- Lutter
- MitrAssist
- Caisson
- MitraSeal
- Twelve
- HighLife
- Others….



Transseptal Transcatheter Mitral Valve Implantation for Severely Calcified Mitral Stenosis



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JACC: CARDIOVASCULAR INTERVENTIONS, VOL. 7, NO. 6, 2014 JUNE 2014:696–7

The MITRAL Trial

Mitral **I**mplantation of **TRA**nscatheter va**L**ves in native mitral stenosis

The safety and feasibility of the SAPIEN XT TM Transcatheter Heart Valve with NovaFlex and Ascendra delivery systems in patients with symptomatic severe calcific mitral stenosis who are not candidates for mitral valve Surgery

- Cedars-Sinai Medical Center (Co- Principal Investigators: Saibal Kar, MD; Rajendra Makkar, MD)
- Columbia University (Co-Principal investigators: Susheel Kodali, MD; Martin Leon, MD)
- Evanston Hospital (Co- Principal Investigators: Mayra Guerrero, MD; Ted Feldman, MD)
- Henry Ford Hospital (Principal investigator: William O'Neill, MD)
- Massachusetts General Hospital (Principal Investigator: Igor Palacios, MD)
- Mayo Clinic (Principal Investigator: Charanjit RIhal, MD)

Principal Investigator Mayra Guerrero, MD

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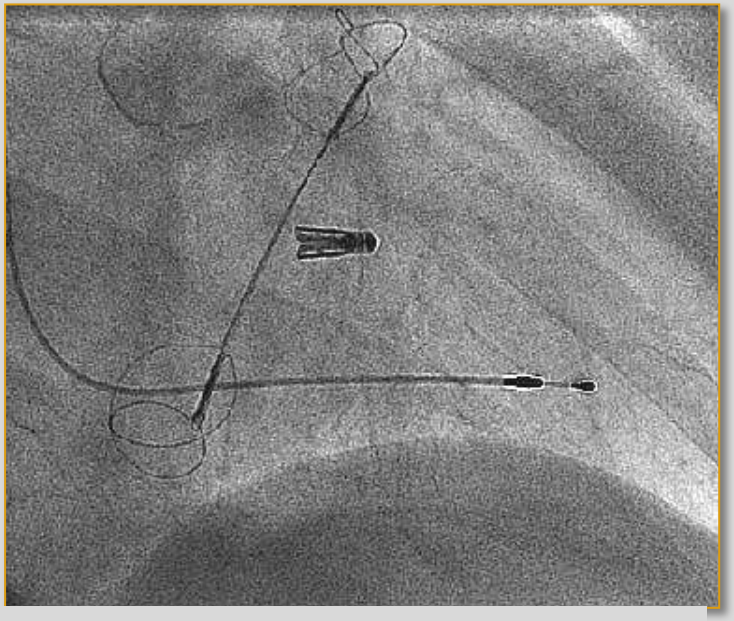
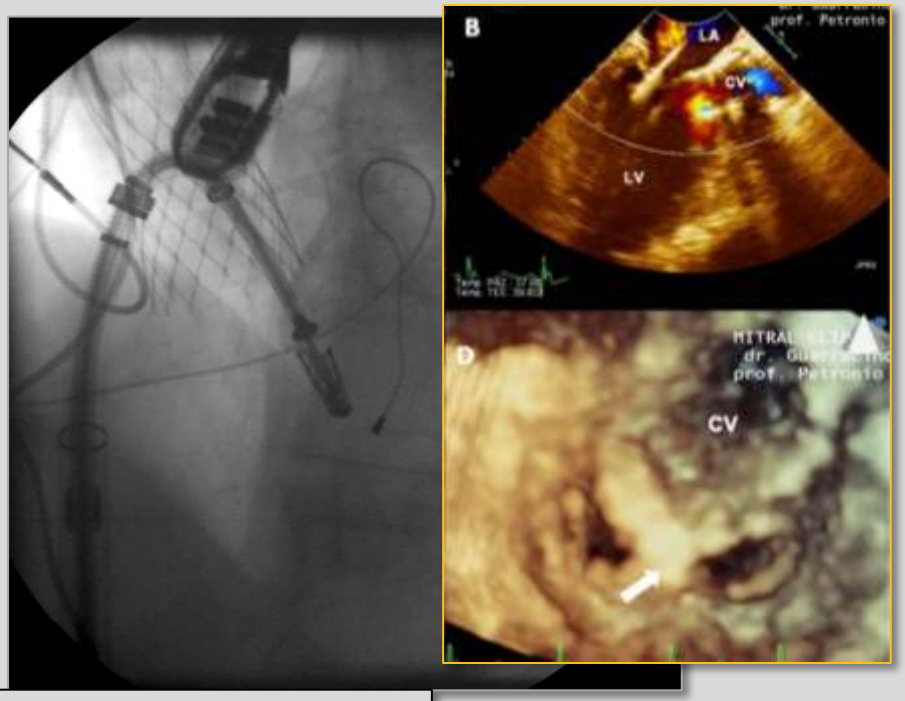


Coronary Sinus Annuloplasty and MitraClip Repair

Joachim Schofer

Staged CoreValve and MitraClip Repair

Sonia Petronio



CoreValve and MitraClip Repair

C Tamburino

CCI 78:650–655 (2011)

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