Mitral Valve Regurgitation: 2014 Best Practice

The Interventionalist's View – "Soon, I will Remodel Your Valve"

Ted Feldman, M.D., MSCAI FACC FESC

Evanston Hospital

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NorthShore University HealthSystem
Evanston Hospital

Ted Feldman MD, *MSCAI FACC FESC*

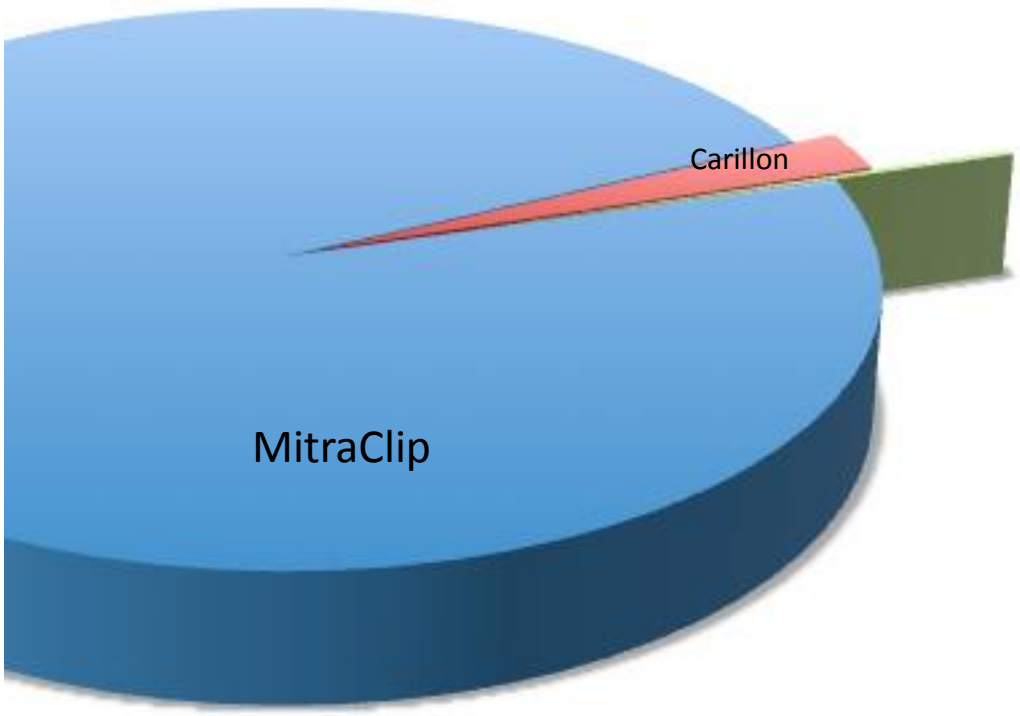
Disclosure Information

The following relationships exist:

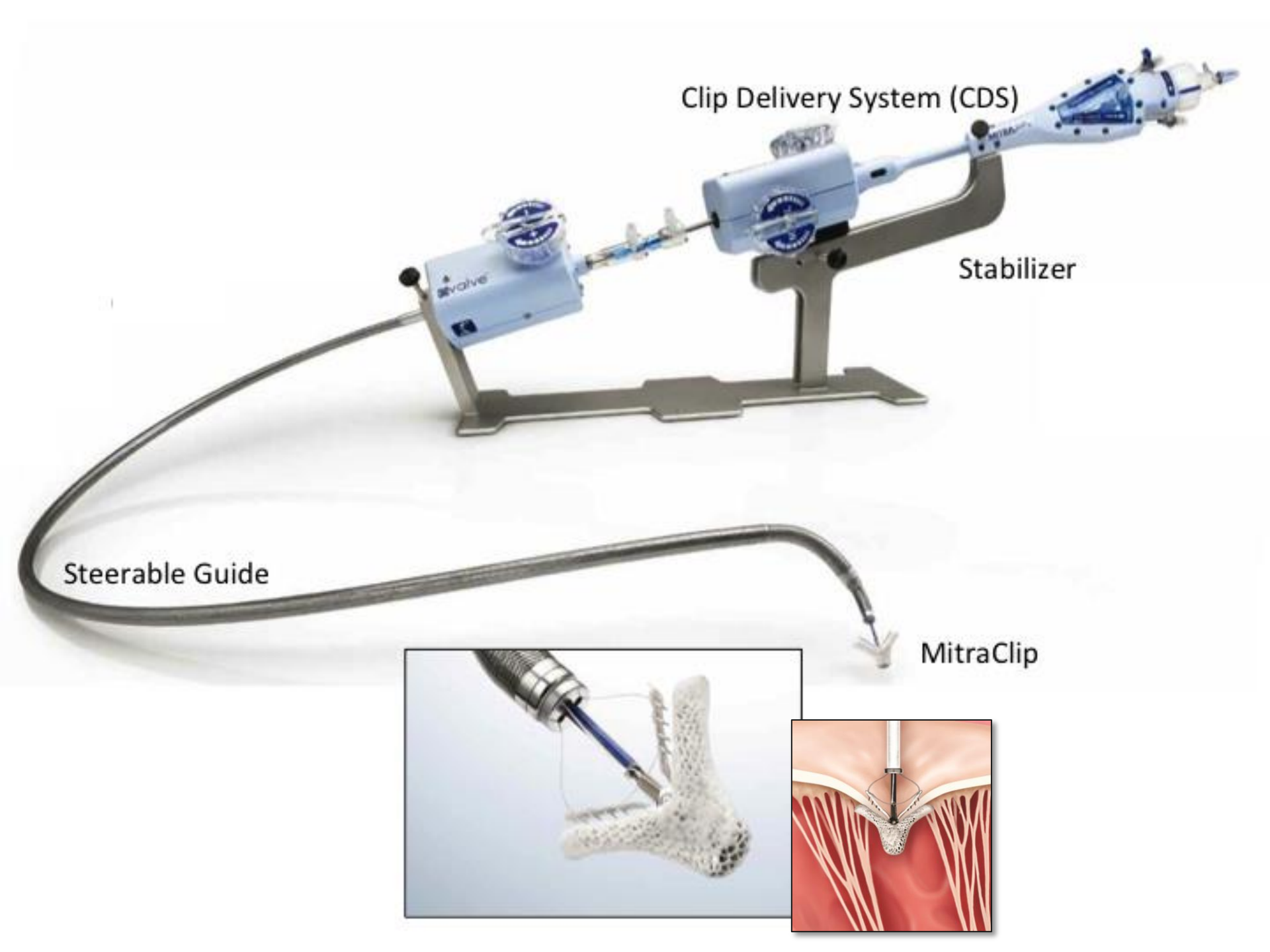
Grant support: Abbott, BSC, Edwards, WL Gore
Consultant: Abbott, BSC, Coherex, Edwards, JenaValve, Diiachi Sankyo-Lilly, WL Gore

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

Treated Patients



MitraClip	>15,000
Carillon	300
Mitralign	50
Cardioband	40
Replacement	20


Clip Delivery System (CDS)
Stabilizer
Steerable Guide
MitraClip

Improved Functional Status and Quality of Life in Prohibitive Surgical Risk Patients With Degenerative Mitral Regurgitation After Transcatheter Mitral Valve Repair

D. Scott Lim, MD,* Matthew R. Reynolds, MD, MSc,†‡ Ted Feldman, MD,§ Saibal Kar, MD,‖
Howa
Paul G

METHODS A prohibitive-risk DMR cohort was identified by a multidisciplinary heart team that retrospectively evaluated high-risk DMR patients enrolled in the EVEREST (Endovascular Valve Edge-to-Edge Repair Study) II studies.

RESULTS A total of 141 high-risk DMR patients were consecutively enrolled; 127 of these patients were retrospectively identified as meeting the definition of *prohibitive risk* and had 1-year follow-up (median: 1.47 years) available. Patients were elderly (mean age: 82.4 years), severely symptomatic (87% New York Heart Association class III/IV), and at prohibitive surgical risk (STS score: 13.2 ± 7.3%). TMVR (MitraClip) was successfully performed in 95.3%; hospital stay was 2.9 ± 3.1 days. Major adverse events at 30 days included death in 6.3%, myocardial infarction in 0.8%, and stroke in 2.4%. Through 1 year, there were a total of 30 deaths (23.6%), with no survival difference between patients discharged with MR ≤1+ or MR 2+. At 1 year, the majority of surviving patients (82.9%) remained MR ≤2+ at 1 year, and 86.9% were in New York Heart Association functional class I or II. Left ventricular

including decreases in rehospitalization, functional improvements, and favorable ventricular remodeling, at 1 year.
(Real World Expanded Multi-center Study of the MitraClip System [REALISM]; NCT01931956)

TMVR in prohibitive surgical risk patients is associated with safety and good clinical outcomes, including decreases in rehospitalization, functional improvements, and favorable ventricular remodeling, at 1 year.

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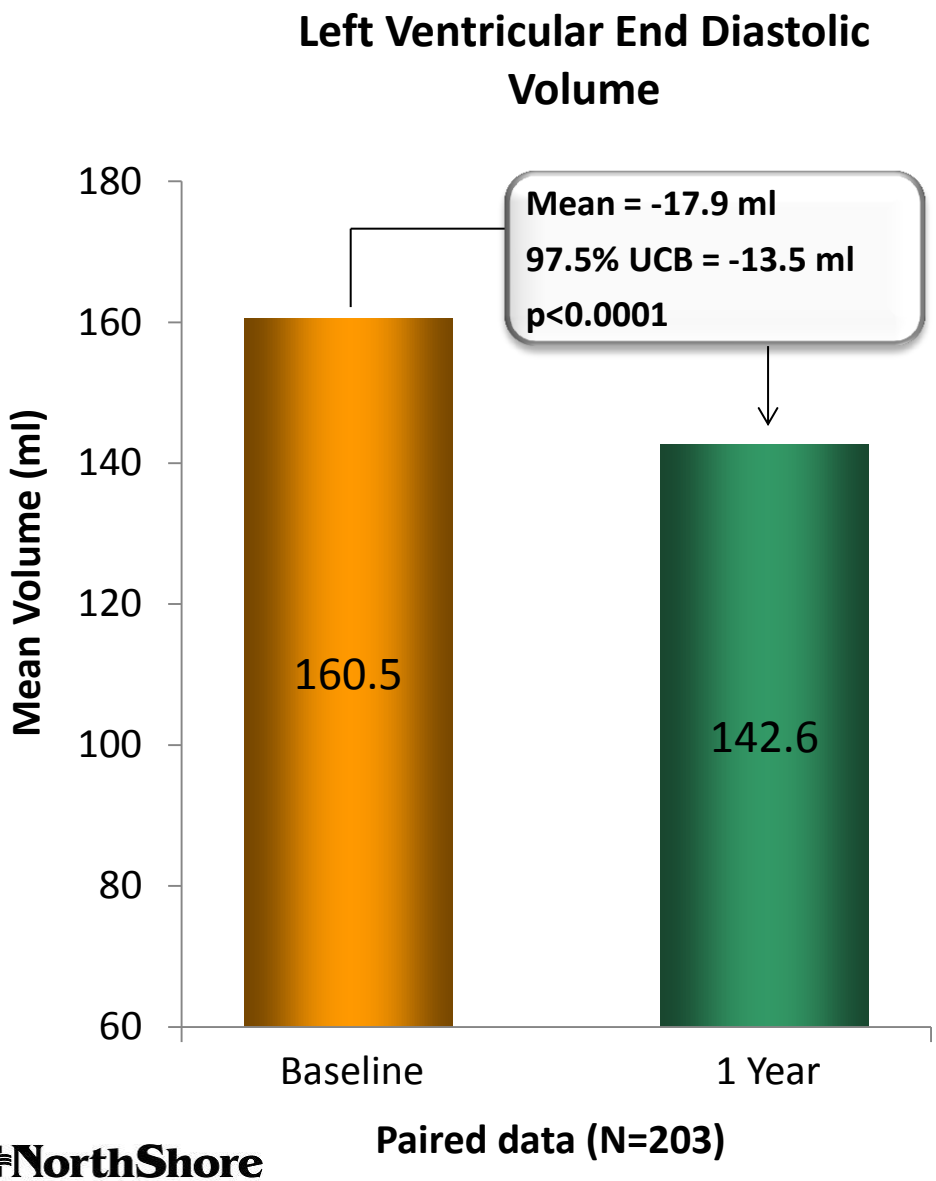
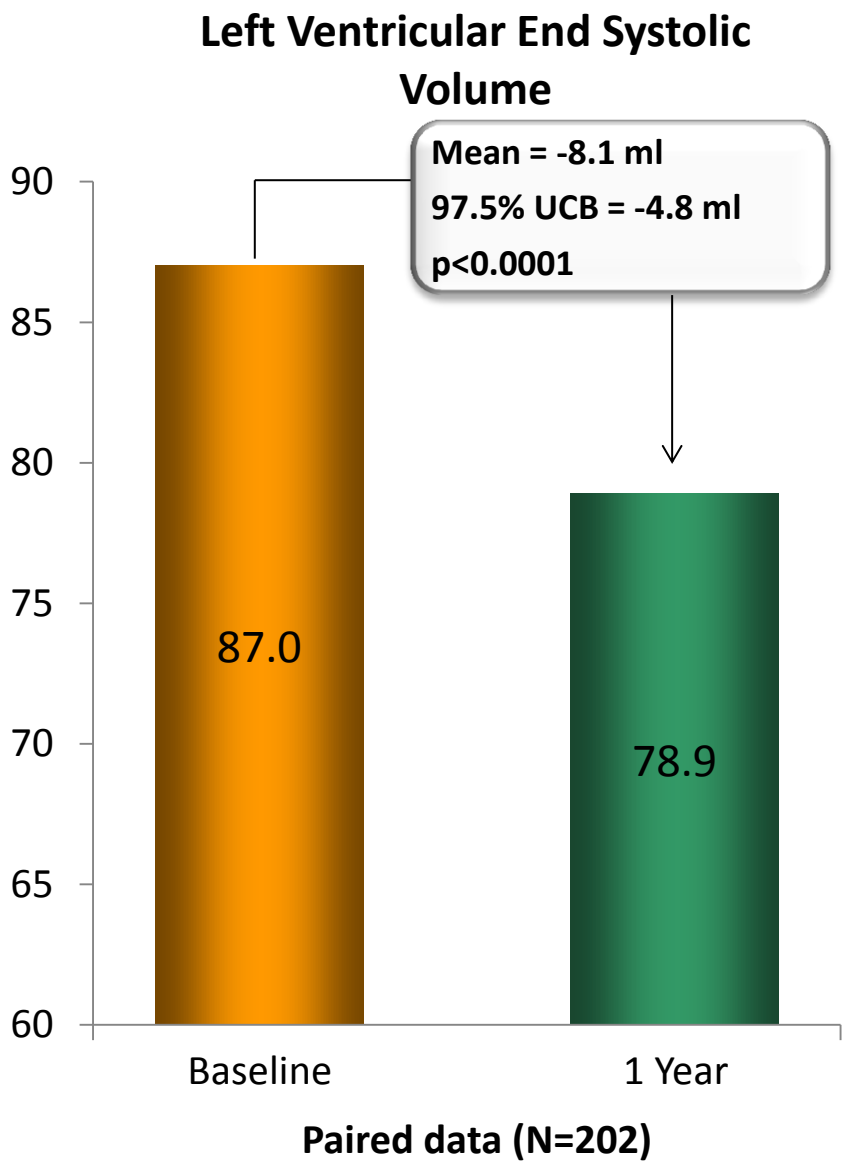
J Am Coll Cardiol 2014;64:182–92

Left Ventricular Volumes





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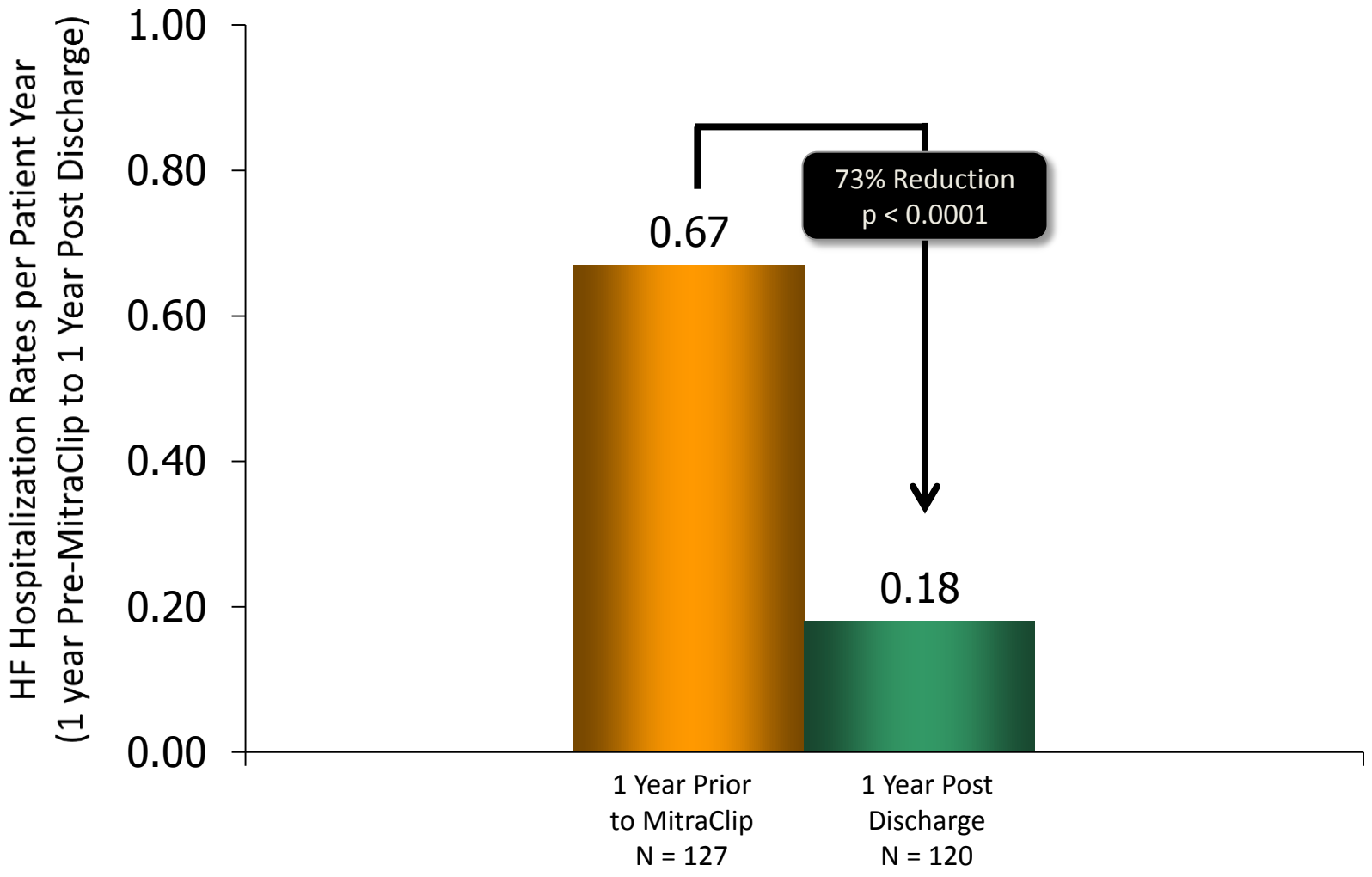
Hospitalizations For Heart Failure



MitraClip Clip Delivery System

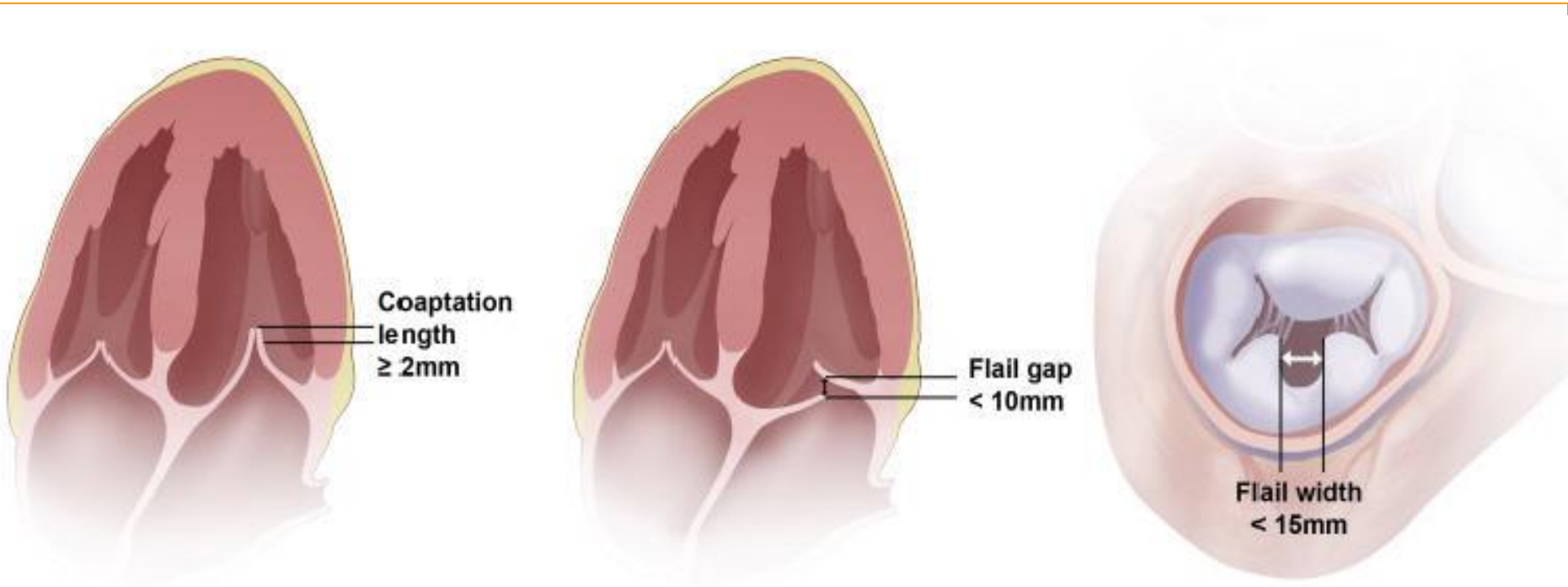
Approved October 24, 2013

Indication for Use:

The MitraClip Clip Delivery System is indicated for the percutaneous reduction of significant **symptomatic** mitral regurgitation (MR ≥ 3+) due to primary abnormality of the mitral apparatus [**degenerative MR**] in patients who have been determined to be at **prohibitive risk for mitral valve surgery by a heart team**, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the **expected benefit** from reduction of the mitral regurgitation.

Anatomic Eligibility

Leaflet mal-coaptation resulting in MR



Non-rheumatic/endocarditic valve morphology; LVIDs ≤55mm; MVA ≥4cm^2

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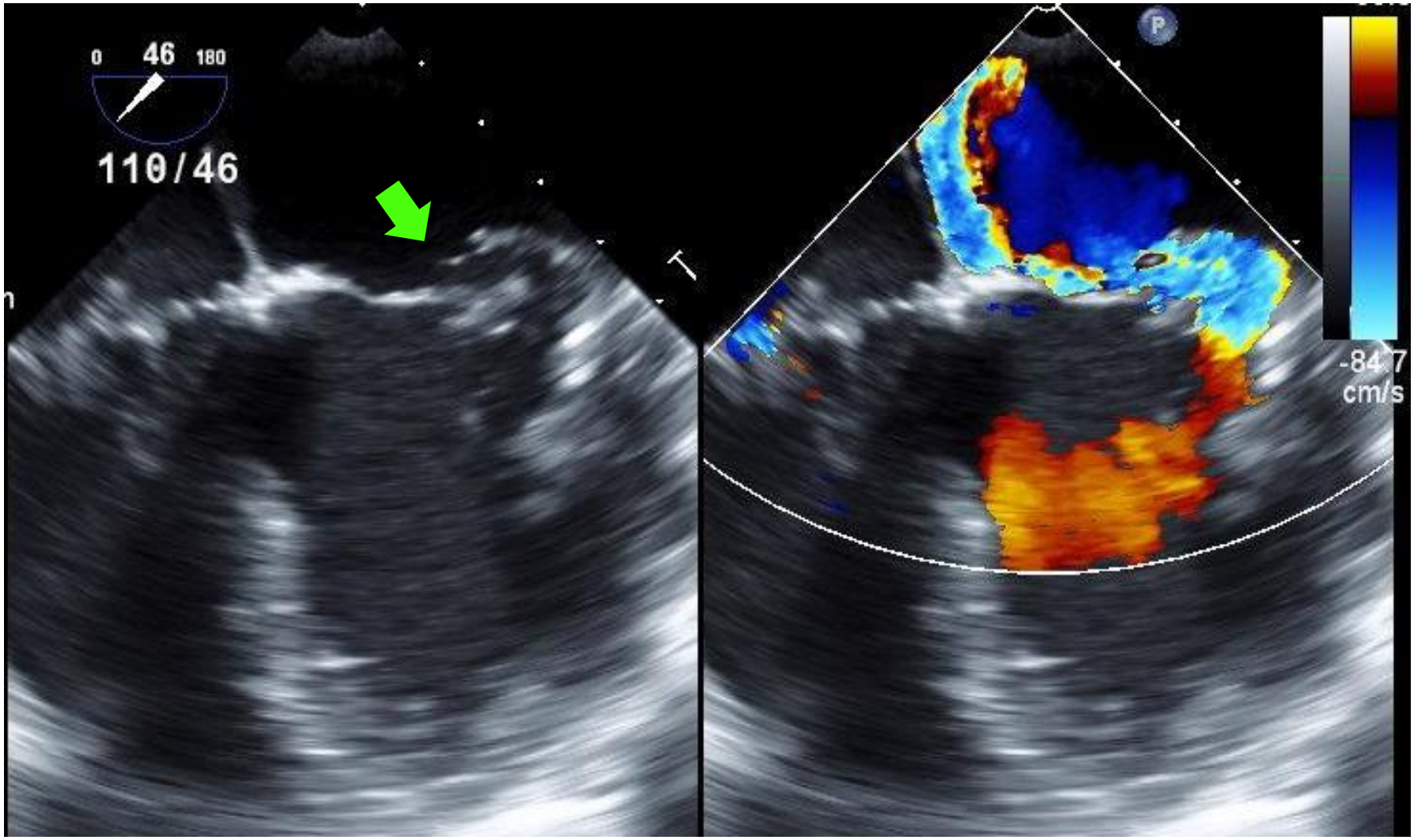
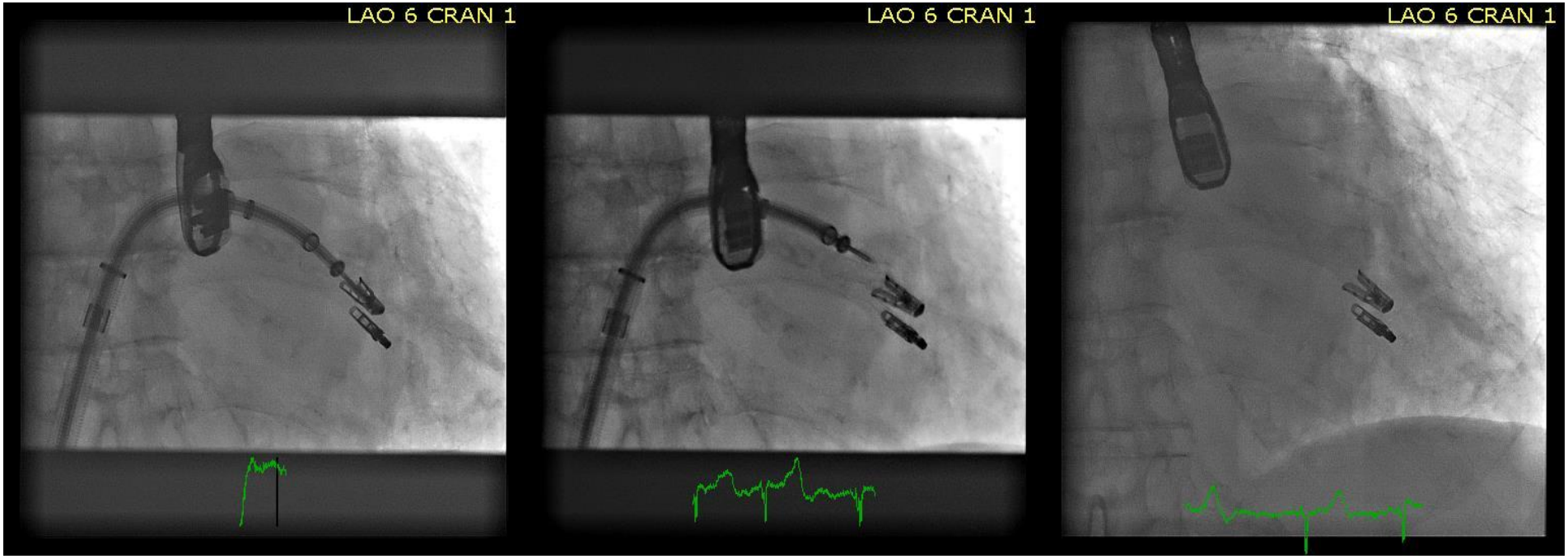
Feldman- J Am Coll Cardiol 2011;57:529–37

DMR Case Example

- 87M
- Multiple hospitalizations for CHF
- EF 70-75%
- NYHA Class III
- PASP 50mmHg
- STS
  - Repair 7.5%
  - Replace 11%


0
46
180
110/46
P
-84.7
cm/s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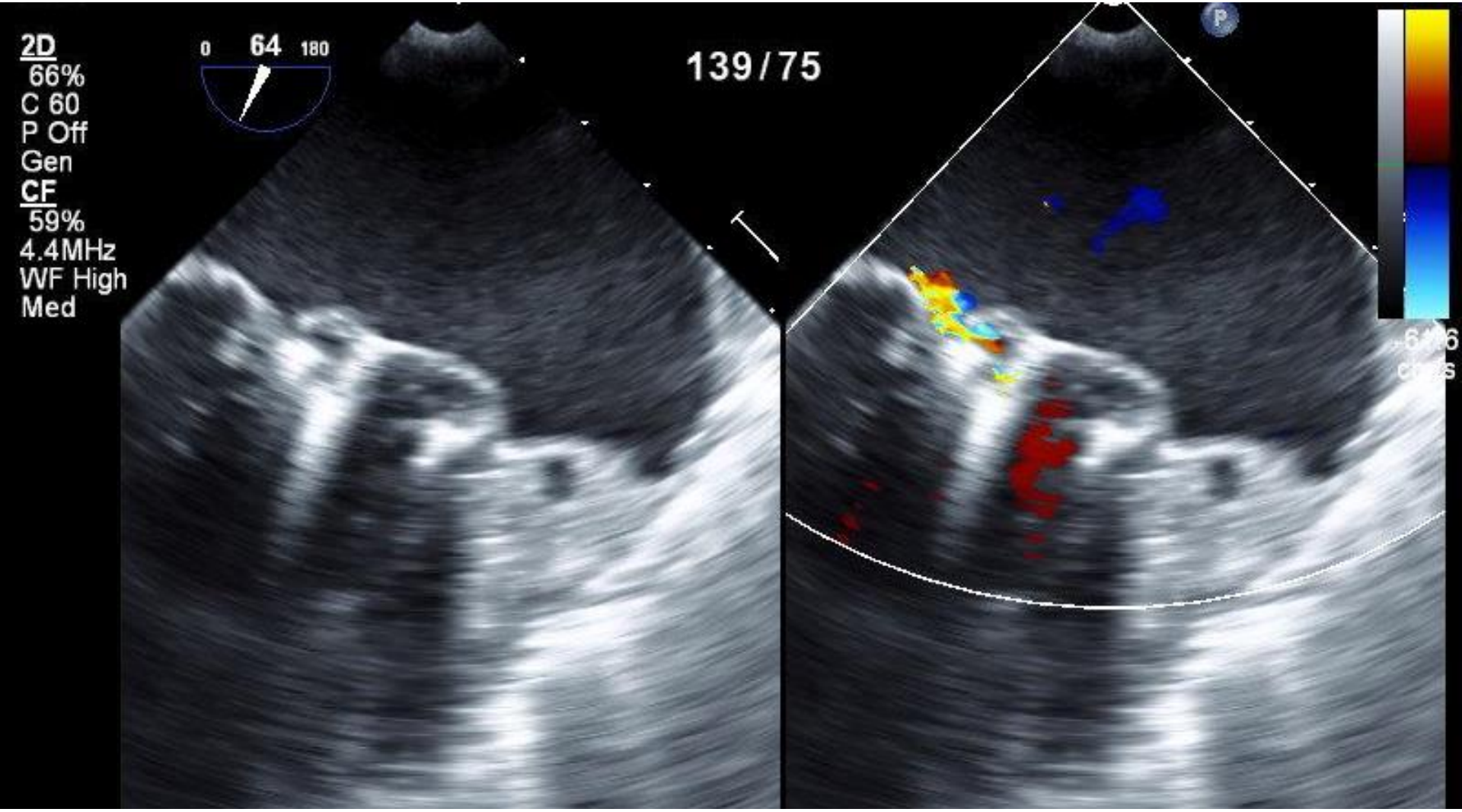
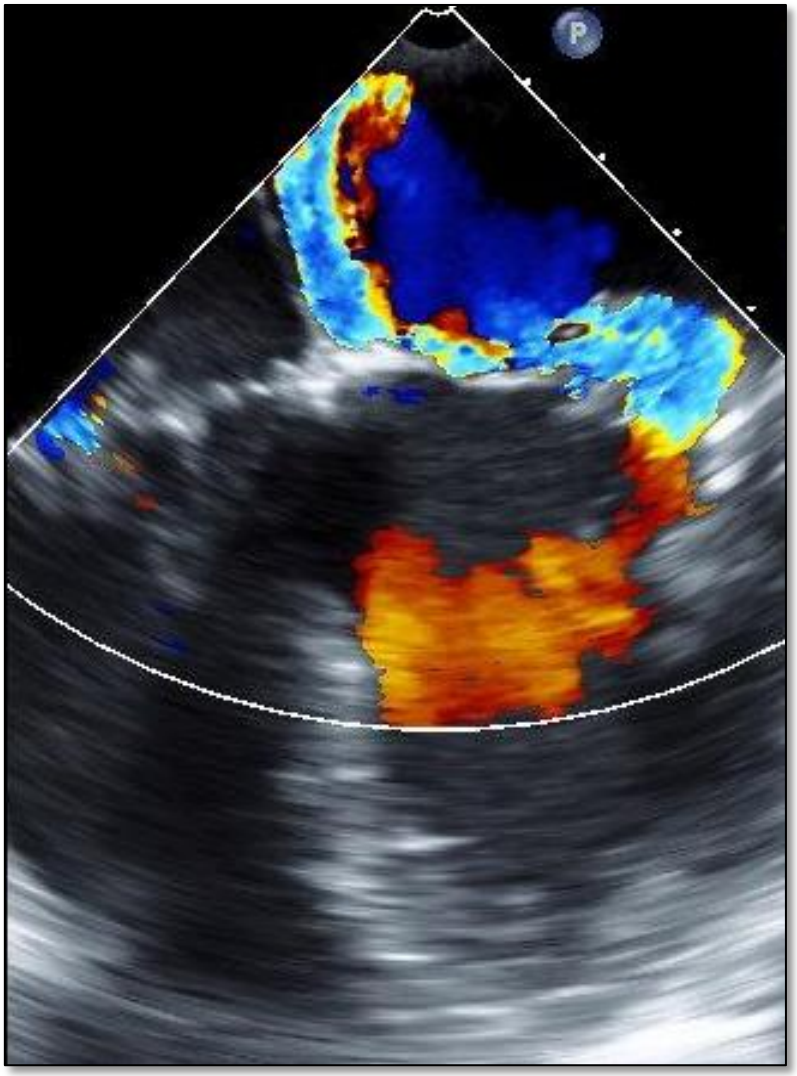
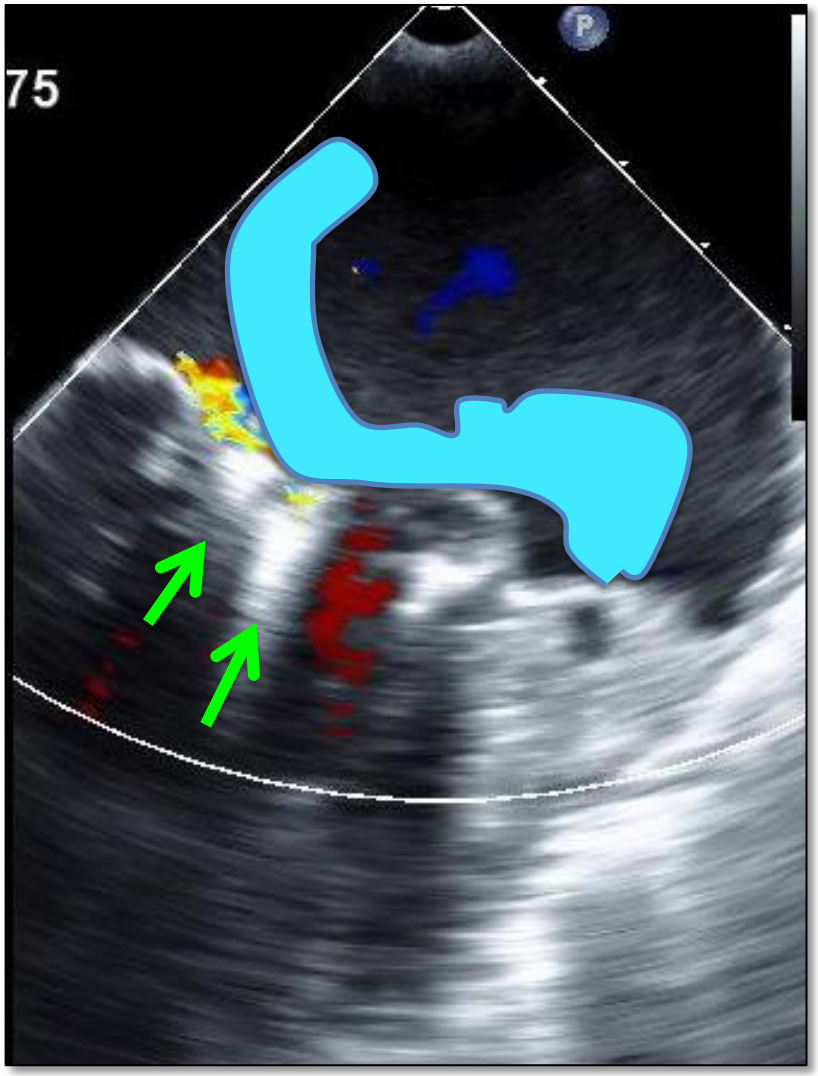

2D
66%
C 60
P Off
Gen
CF
59%
4.4MHz
WF High
Med
0
64
180
139/75

Pre vs Post 2 Clips





The EVEREST II Randomized Clinical Trial: 5 Year Outcomes By MR Etiology

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 APRIL 14, 2011 VOL. 364 NO. 15

Percutaneous Repair or Surgery for Mitral Regurgitation

Ted Feldman, M.D., Elyse Foster, M.D., Donald G. Glower, M.D., Saibal Kar, M.D., Michael J. Rinaldi, M.D., Peter S. Fail, M.D., Richard W. Smalling, M.D., Ph.D., Robert Siegel, M.D., Geoffrey A. Rose, M.D., Eric Engeron, M.D., Catalin Loghin, M.D., Alfredo Trento, M.D., Eric R. Skipper, M.D., Tommy Fudge, M.D., George V. Letsou, M.D., Joseph M. Massaro, Ph.D., and Laura Mauri, M.D., for the EVEREST II Investigators*

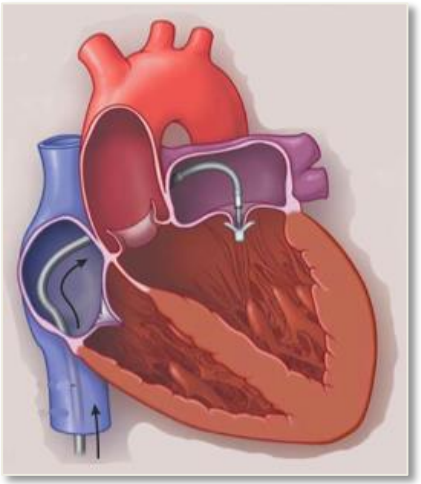
BACKGROUND

Mitral-valve repair can be accomplished with an investigational procedure that involves the percutaneous implantation of a clip that grasps and approximates the edges of the mitral leaflets at the origin of the regurgitant jet

of the components of the primary end point were as follows: death, 6% in each group; surgery for mitral-valve dysfunction, 20% versus 2%; and grade 3+ or 4+ mitral regurgitation, 21% versus 20%. Major adverse events occurred in 15% of patients in the percutaneous-repair group and 48% of patients in the surgery group at 30 days ($P<0.001$). At 12 months, both groups had improved left ventricular size, New York Heart Association functional class, and quality-of-life measures, as compared with baseline.

CONCLUSIONS

Although percutaneous repair was less effective at reducing mitral regurgitation than conventional surgery, the procedure was associated with superior safety and similar improvements in clinical outcomes. (Funded by Abbott Vascular; EVEREST II ClinicalTrials.gov number, NCT00209274.)



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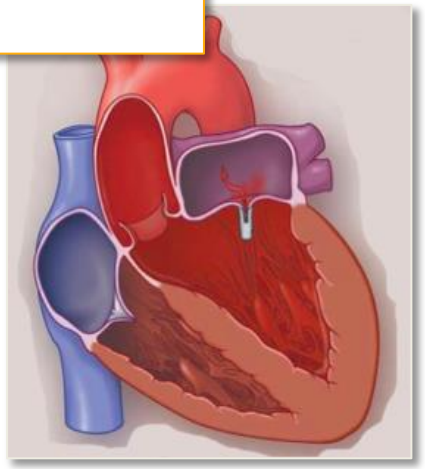

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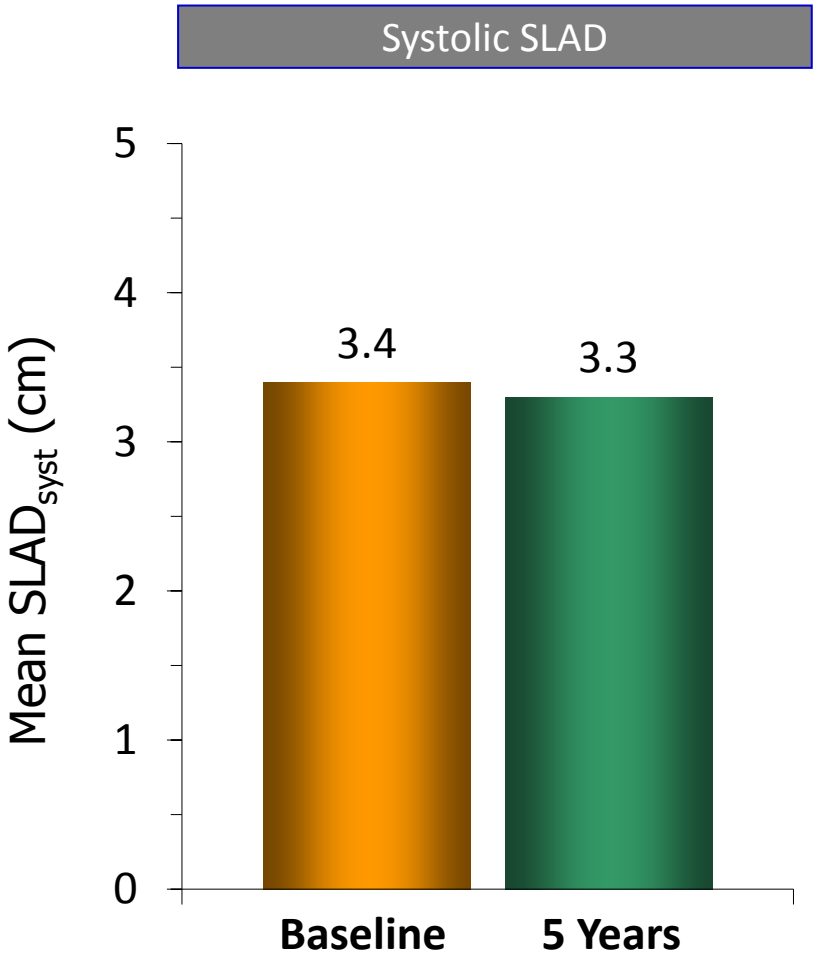
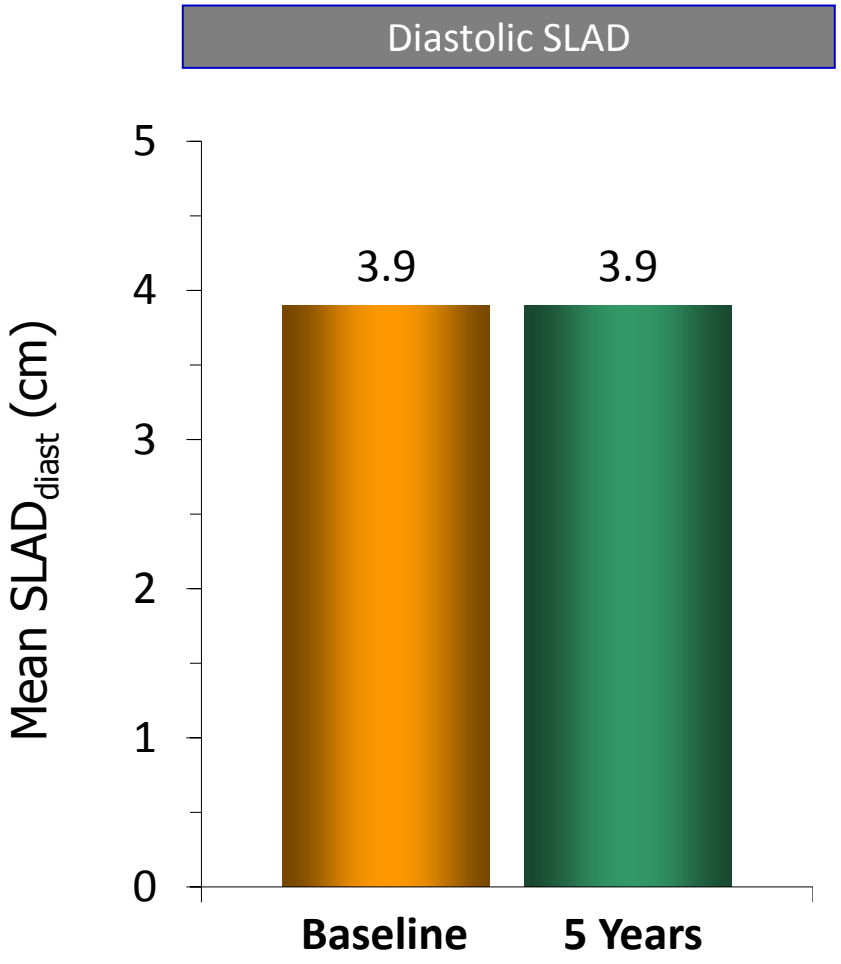
Septal Lateral Annular Dimensions

EVEREST II RCT All Treated Patients - MitraClip Group (N=178)





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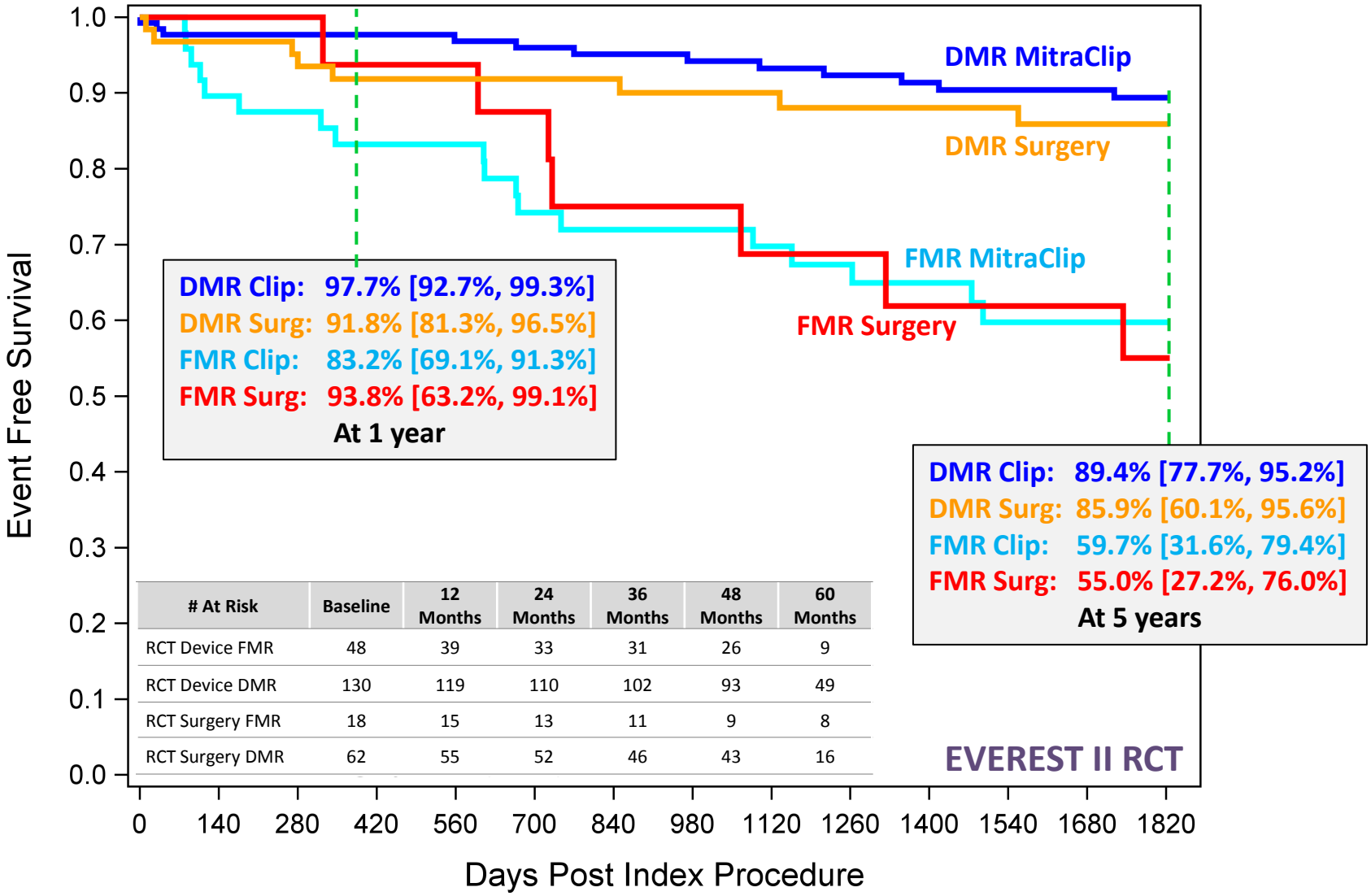
Freedom From Mortality & Reintervention



# At Risk	Baseline	12 Months	24 Months	36 Months	48 Months	60 Months
RCT Device FMR	48	39	33	31	26	9
RCT Device DMR	130	119	110	102	93	49
RCT Surgery FMR	18	15	13	11	9	8
RCT Surgery DMR	62	55	52	46	43	16

Kaplan-Meier estimate

Therapy for MR

	Degenerative	**Functional**
Low Surgical Risk	Surgical Mitral Repair	?
High Surgical Risk	Commercial MitraClip	COAPT

Clinical Outcomes Assessment of the MitraClip Percutaneous Therapy for High Surgical Risk

COAPT TRIAL

~430 patients enrolled at up to 75 US sites

Significant FMR ≥3+ core lab; EF<50%; CHF hospitalization or BNP>300

High risk for mitral valve surgery- Local Heart Team

Specific valve anatomic criteria

Randomize 1:1

MitraClip

Control group Standard of care

Safety: Composite death, stroke, worsening renal function, LVAD implant, heart transplant at 12 months

Effectiveness: Recurrent heart failure hospitalizations

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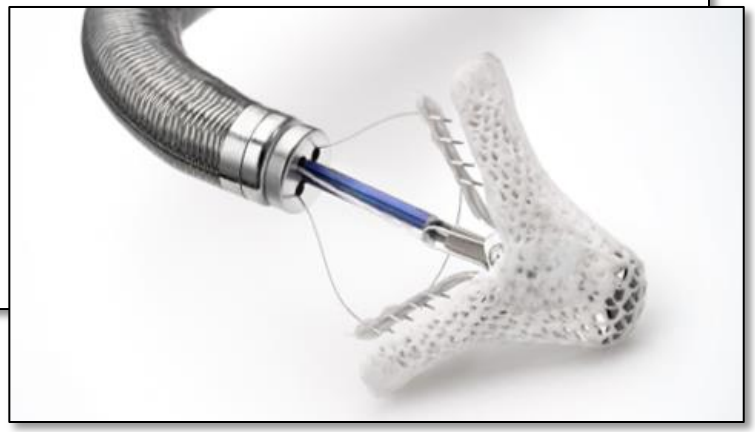
MitraClip Status

- 17,095 total implants
- 411 global sites in 35 countries
- 69 commercial US sites
  - 1000 US commercial implants
- 69 active COAPT sites
  - 142 patients randomized



Abbott Vascular updated November 7th 2014

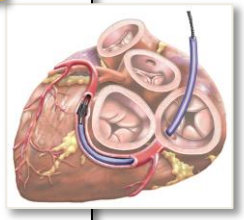
Percutaneous Mitral Repair Devices

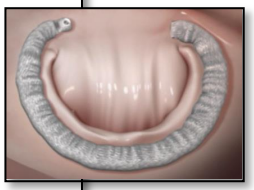
Already gone

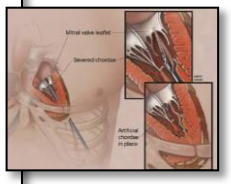
- PTMA
- Monarc
- Mobuis leaflet repair
- Recor RF annular remodeling
- Coapsys

Still developing

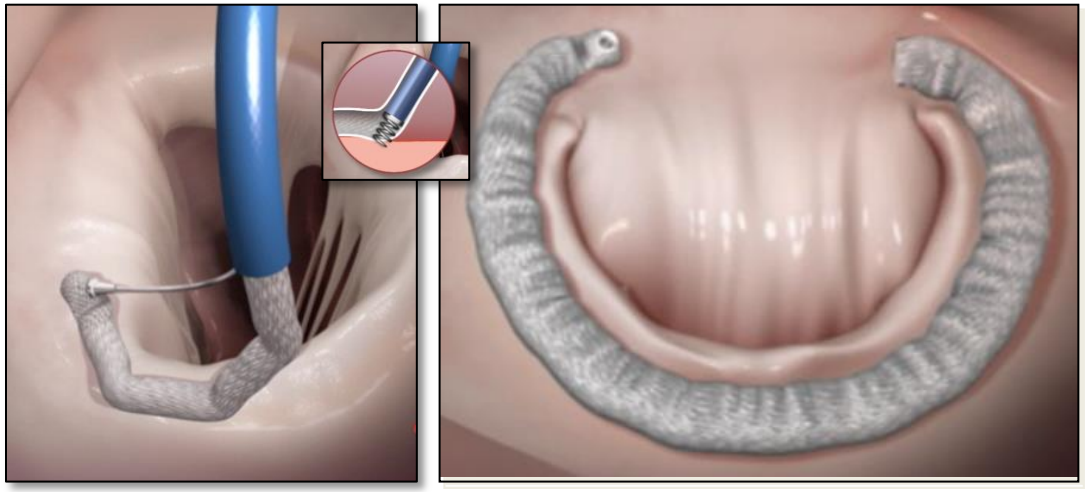
- Leaflet repair
- CS annuloplasty
- Direct annuloplasty
- Cerclage
- Mitral spacer
- Midle Peak
- Chordal replacement
- Valve replacement







Cardioband TRANS FEMORAL



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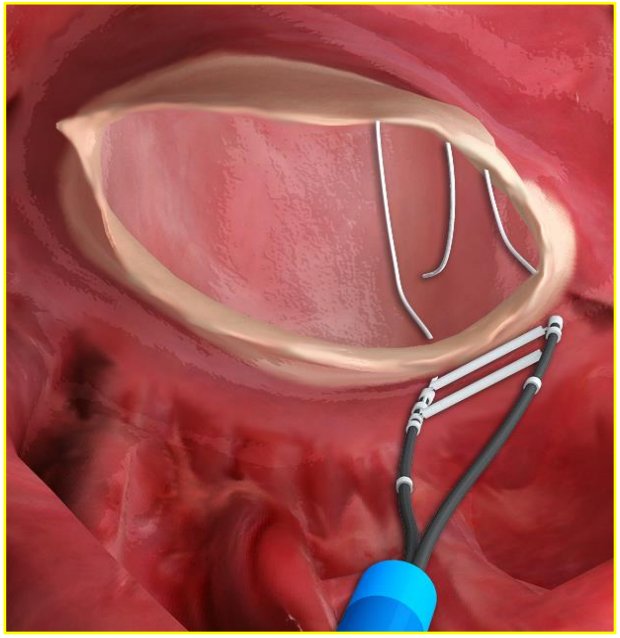
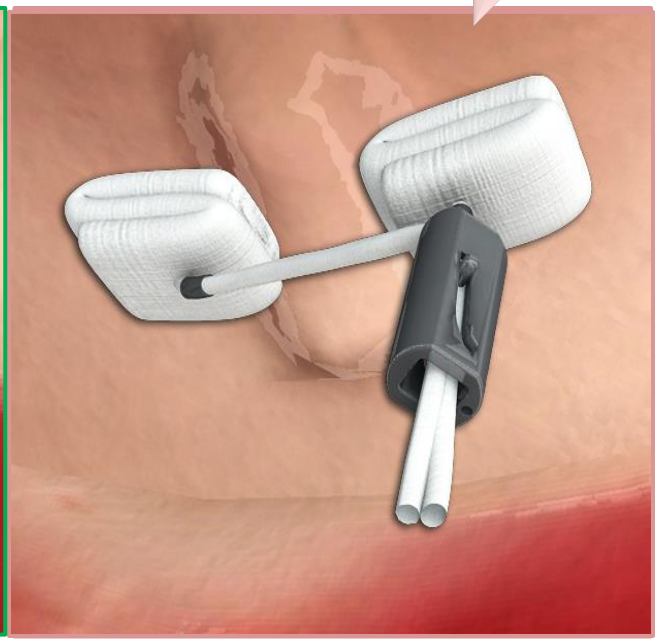
DIRECT ANNULOPLASTY
Mitralign Procedure Steps

Wire Delivery

Pledget Delivery

Plication & Lock





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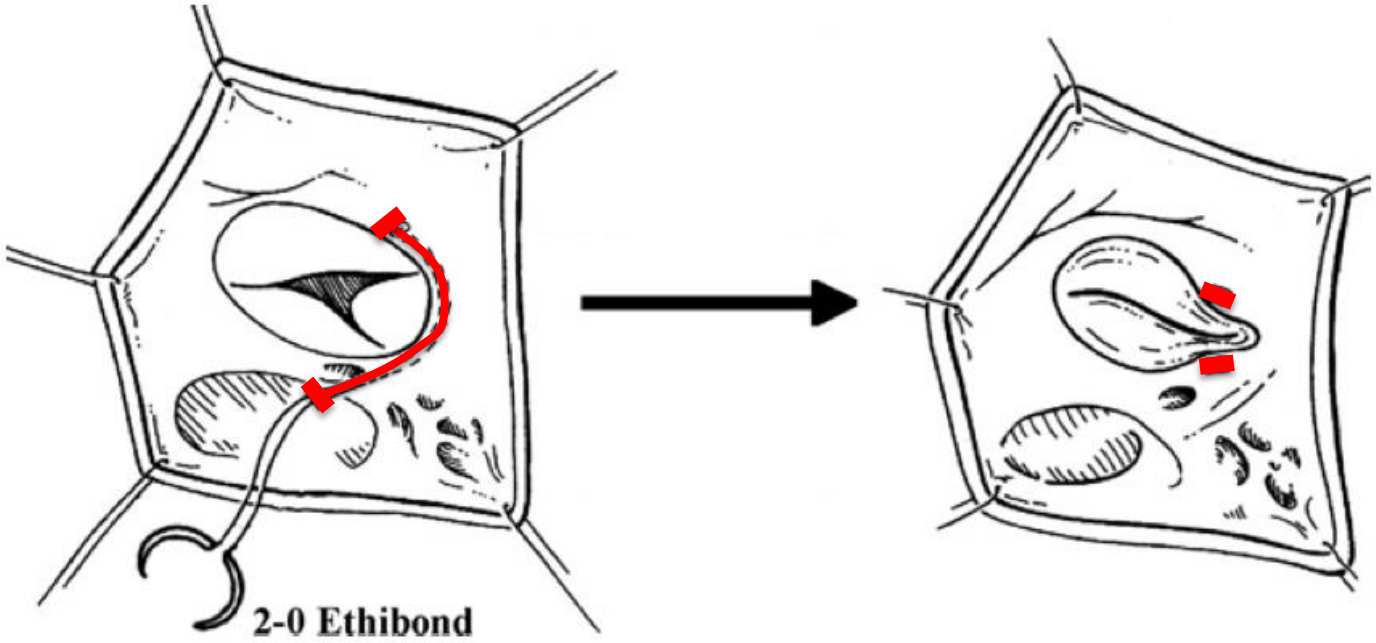
Suture bicuspidization of the tricuspid valve vs ring annuloplasty for functional tricuspid regurgitation

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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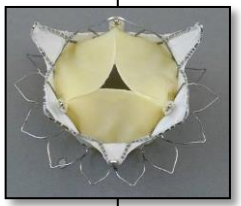
J Thorac Cardiovasc Surg 2007;133:117-126

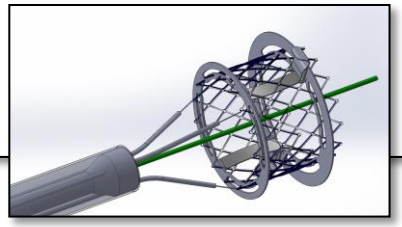
Mitral Replacement Technologies

- CardiaAQ



- Neovasc TIARA
- Tendyne

- Edwards FORTIS
- Endovalve
- M-Valve



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

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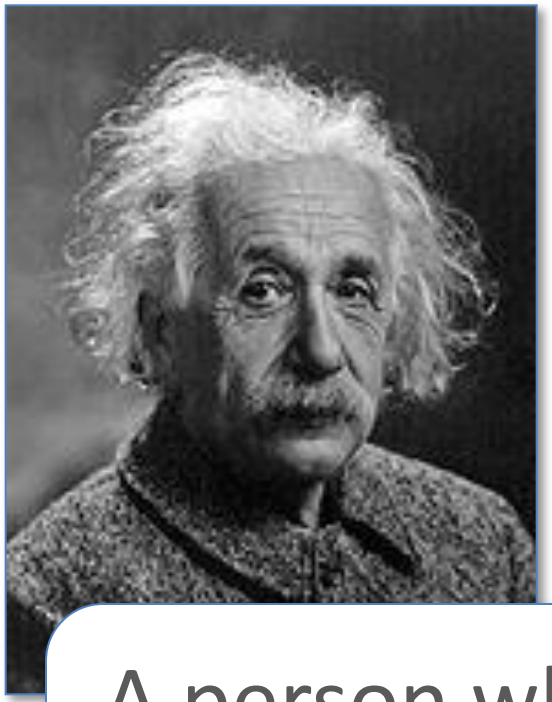

A person who never made a mistake never tried anything new.