

Percutaneous Mitral Valve Repair (PMVR):

From Science to Practice

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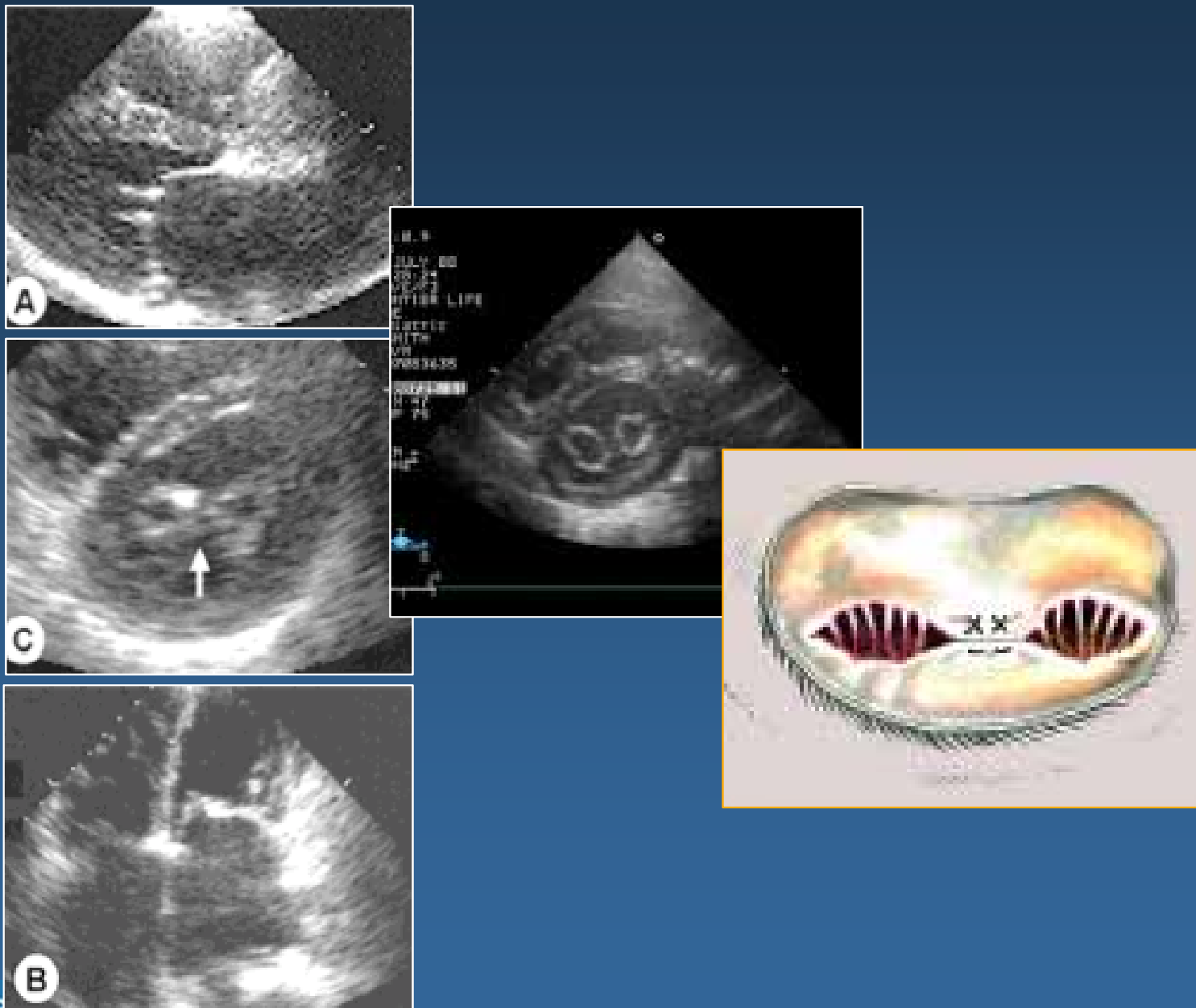
Disclosure Information

The following relationships exist:

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

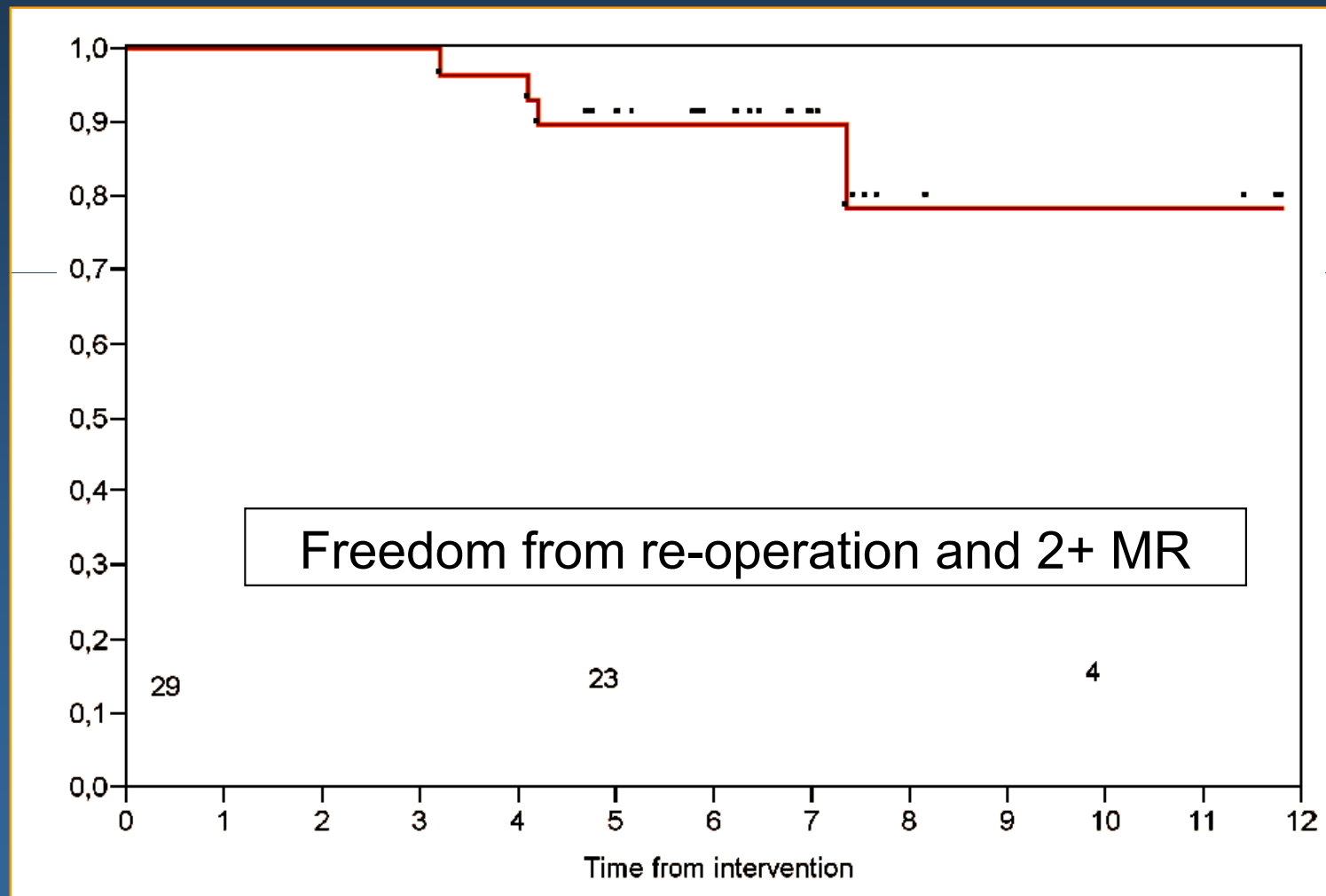
*Off label use of products and investigational devices
will be discussed in this presentation*

Congenital Double Orifice Mitral Valve



Surgical isolated edge-to-edge mitral repair without annuloplasty

clinical proof of principle for an endovascular approach



The edge-to-edge technique: a simplified method to correct mitral insufficiency¹

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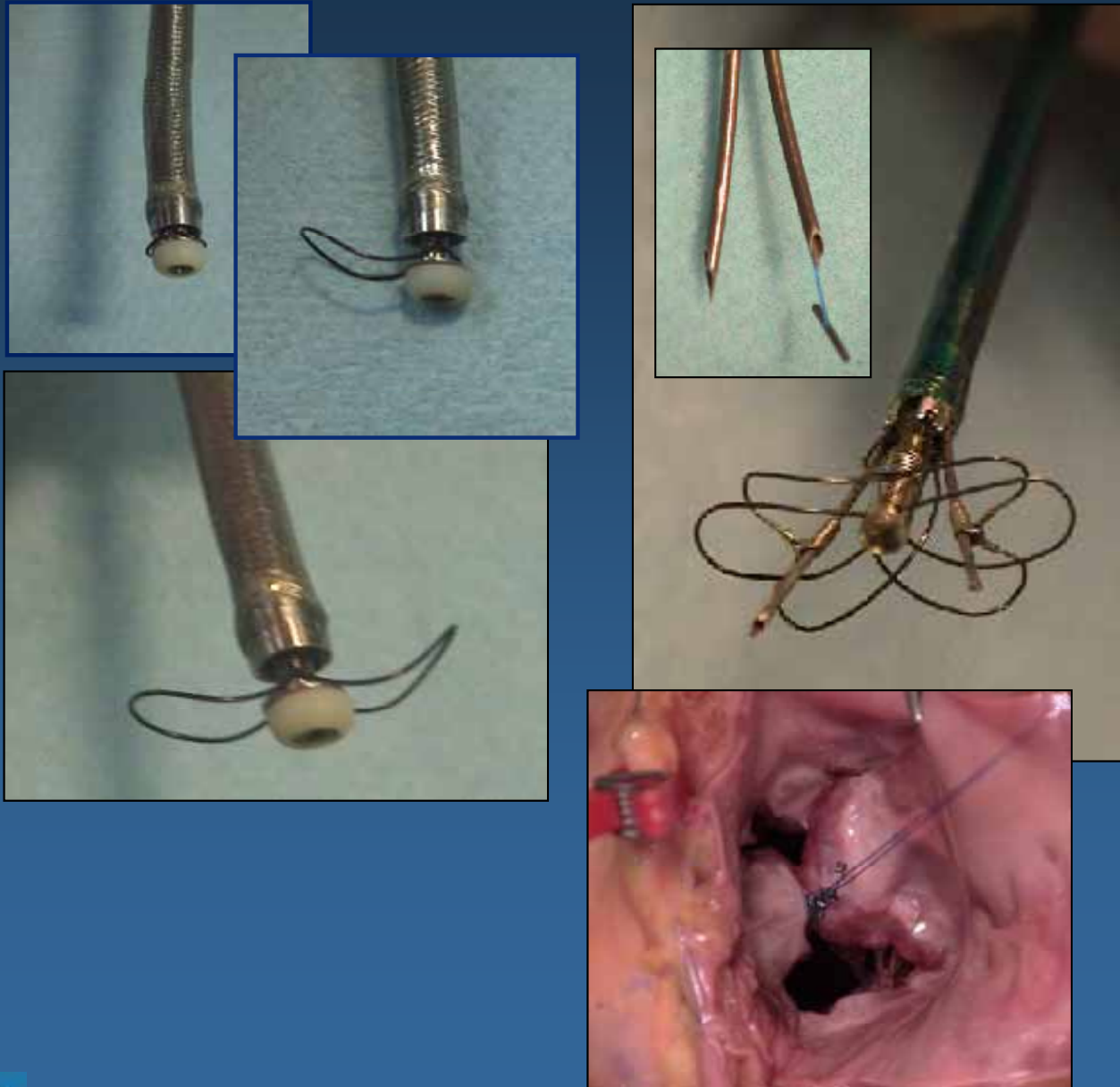


Cardio-thoracic Surgery 13 (1998) 240–246

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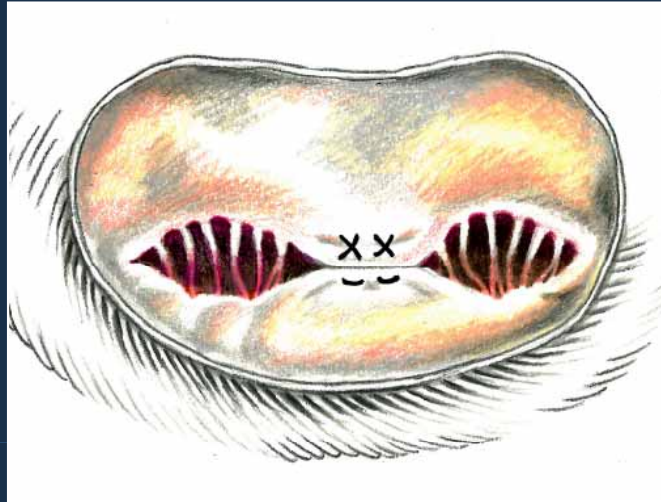
The E-to-E repair is applicable to lesions of any etiology and it is effective not only when MR is due to leaflet prolapse, but also with other types of valve dysfunction. Due to its intrinsic simplicity, the E-to-E repair could be the technique of choice when exposure is difficult or when the repair is carried out through a port access. Eventually, the concept introduced by this type of repair can open the perspective of percutaneous correction of MR. Longer follow-up period is needed to confirm long term expectations with this promising alternative technique of valve repair.

From Science to Practice: Prototype

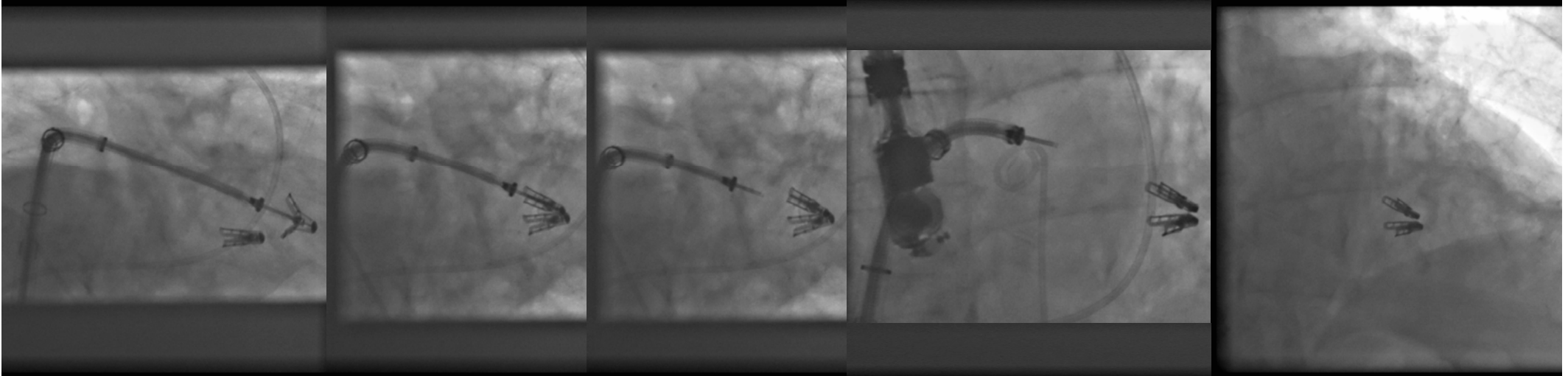
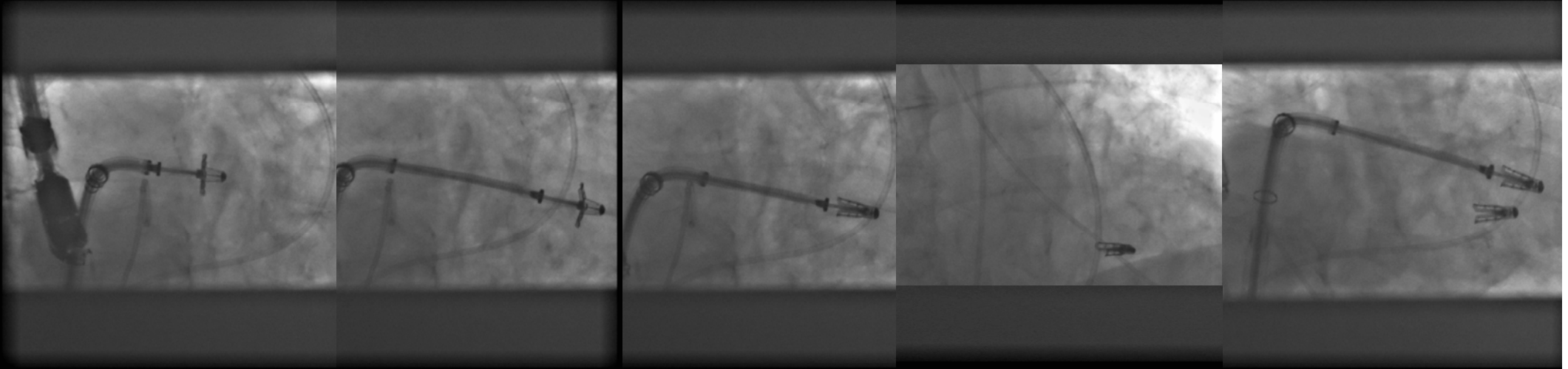


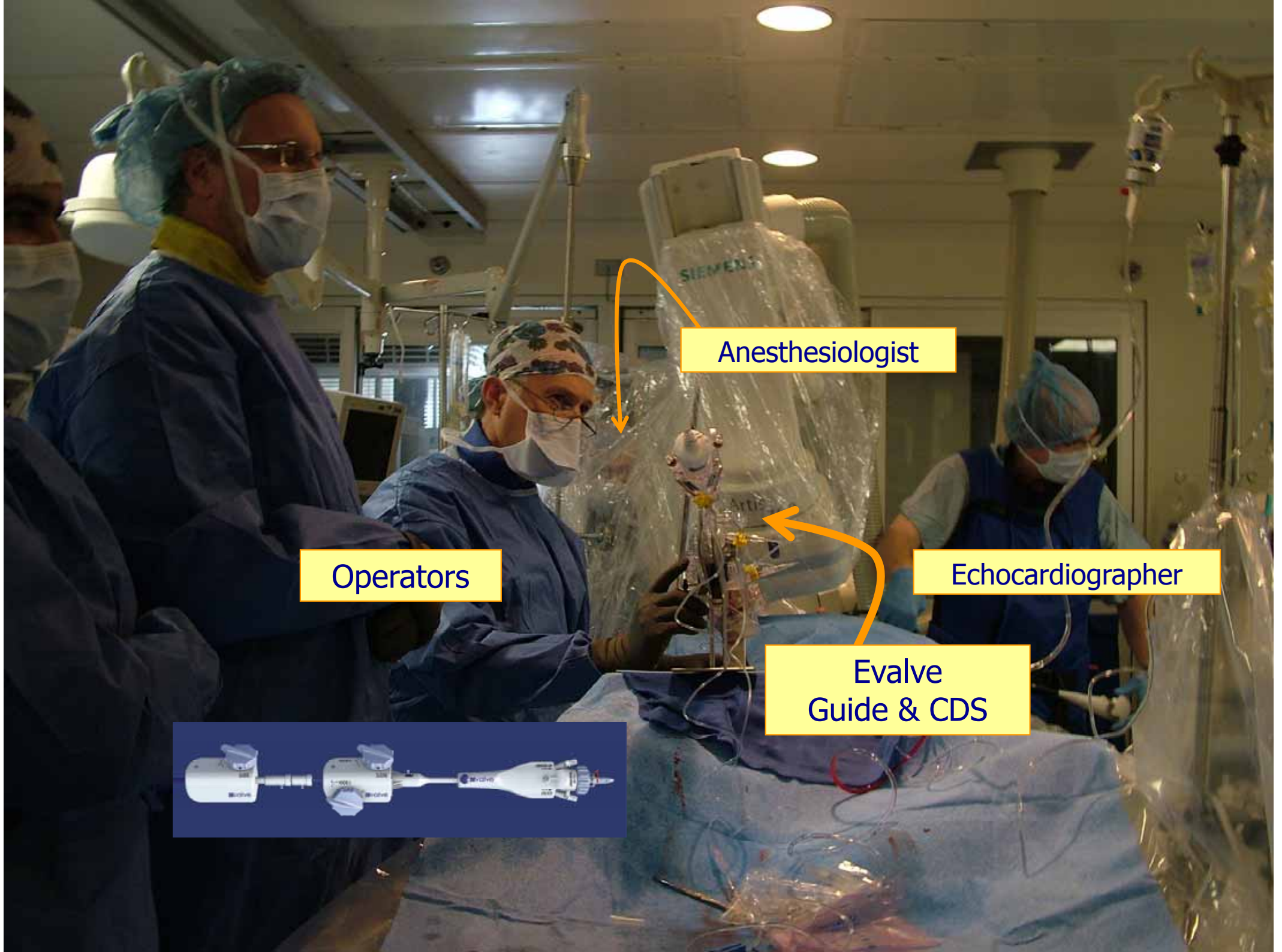
Catheter-Based Mitral Valve Repair

MitraClip® System



Investigational Device only in the US; Not available for sale in the US





Anesthesiologist

Operators

Echocardiographer

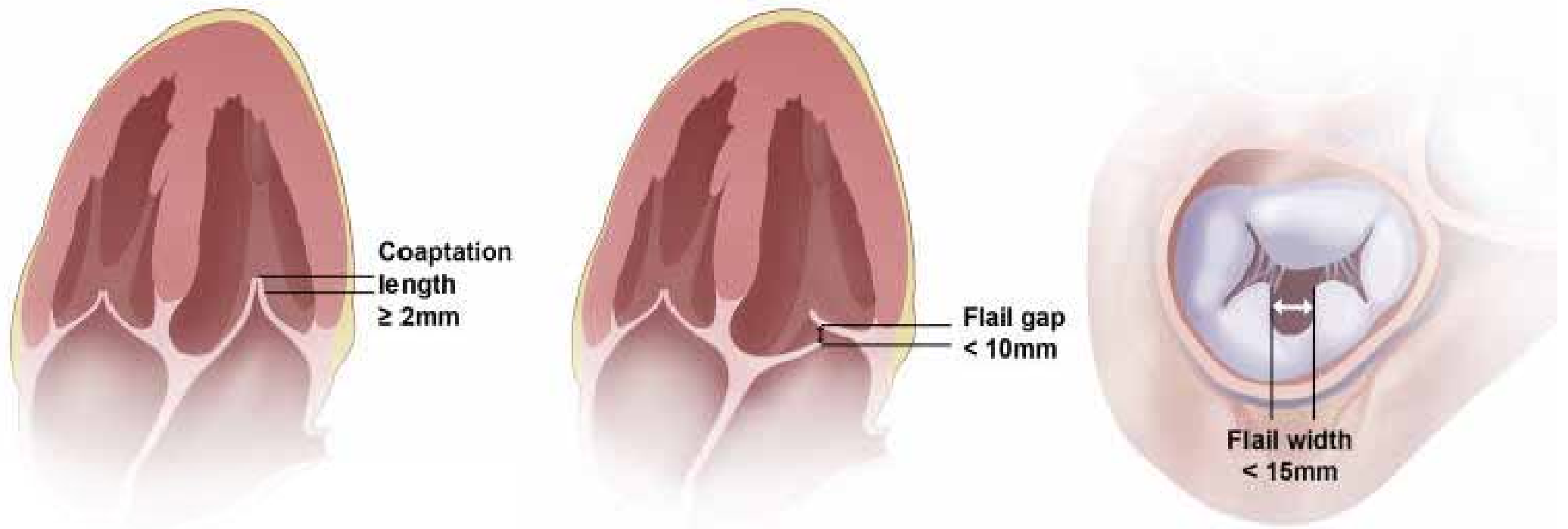
Evaluate
Guide & CDS





Anatomic Eligibility

Leaflet mal-coaptation resulting in MR



Non-rheumatic/endocarditic valve morphology; LVIDs $\leq 55\text{mm}$; MVA $\geq 4\text{cm}^2$

Feldman T, Kar S, Rinaldi M, Fail P, Hermiller J, Smalling R, Whitlow PL, Gray W, Low R, Herrmann HC, Lim S, Foster E, Glower D
Percutaneous Mitral Repair with the MitraClip System: Safety and Midterm Durability in the Initial EVEREST Cohort

J Am Coll Cardiol 54:686-694, 2009

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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



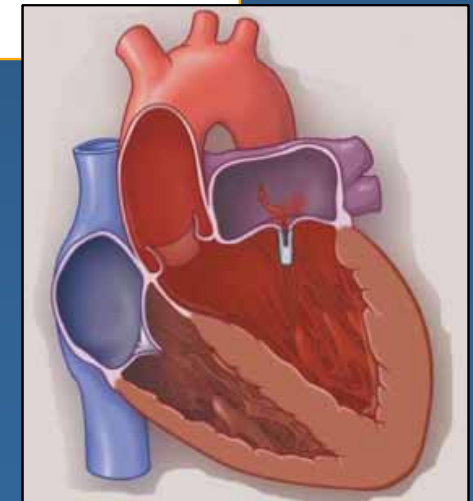
CONCLUSIONS

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.

...percutaneous repair group and 75% in the surgery group ($P=0.007$). The respective rates 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.)

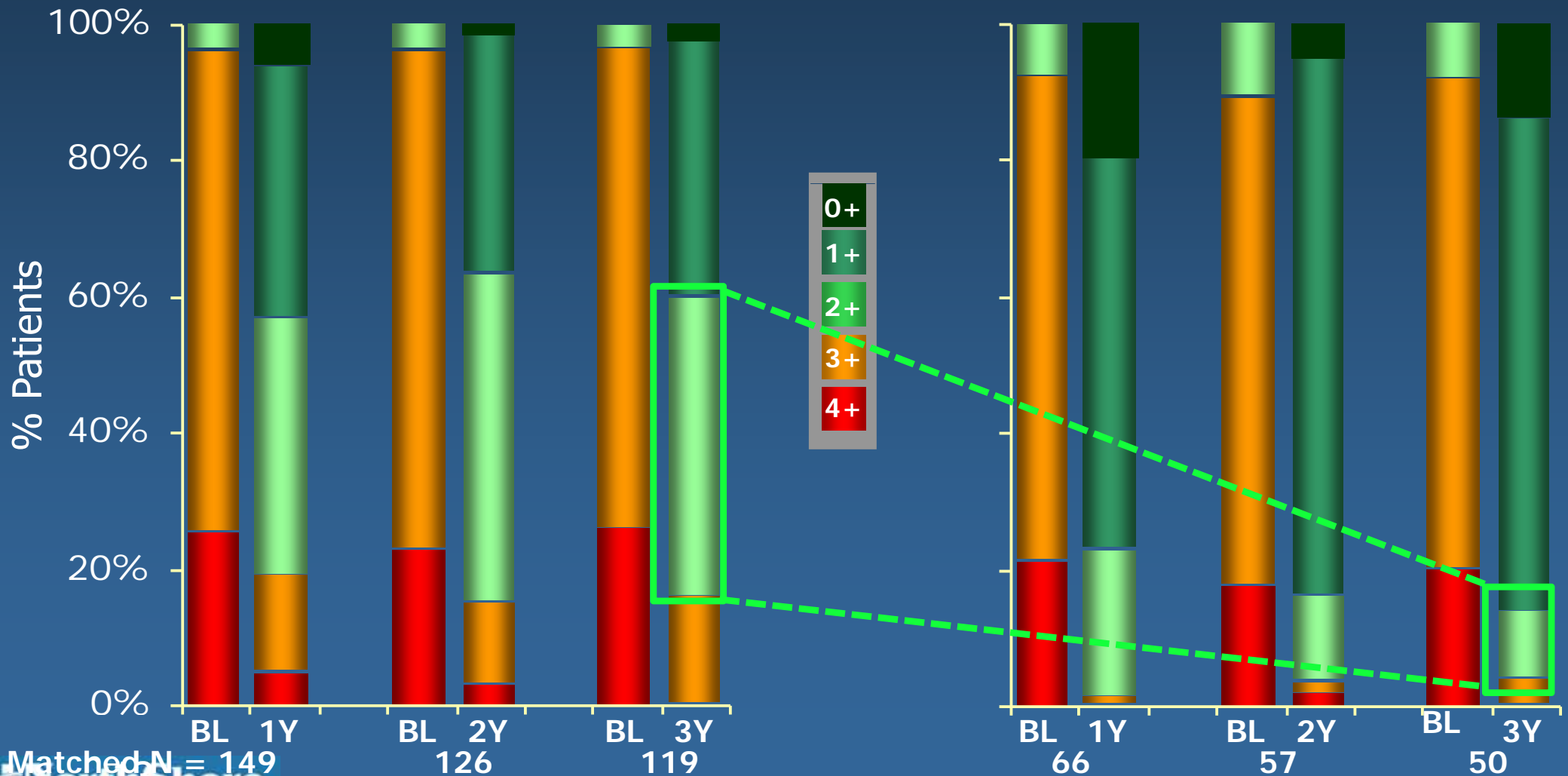


Mitral Regurgitation Severity

MitraClip (N=178)
84% MR ≤ 2+ at 3 Years

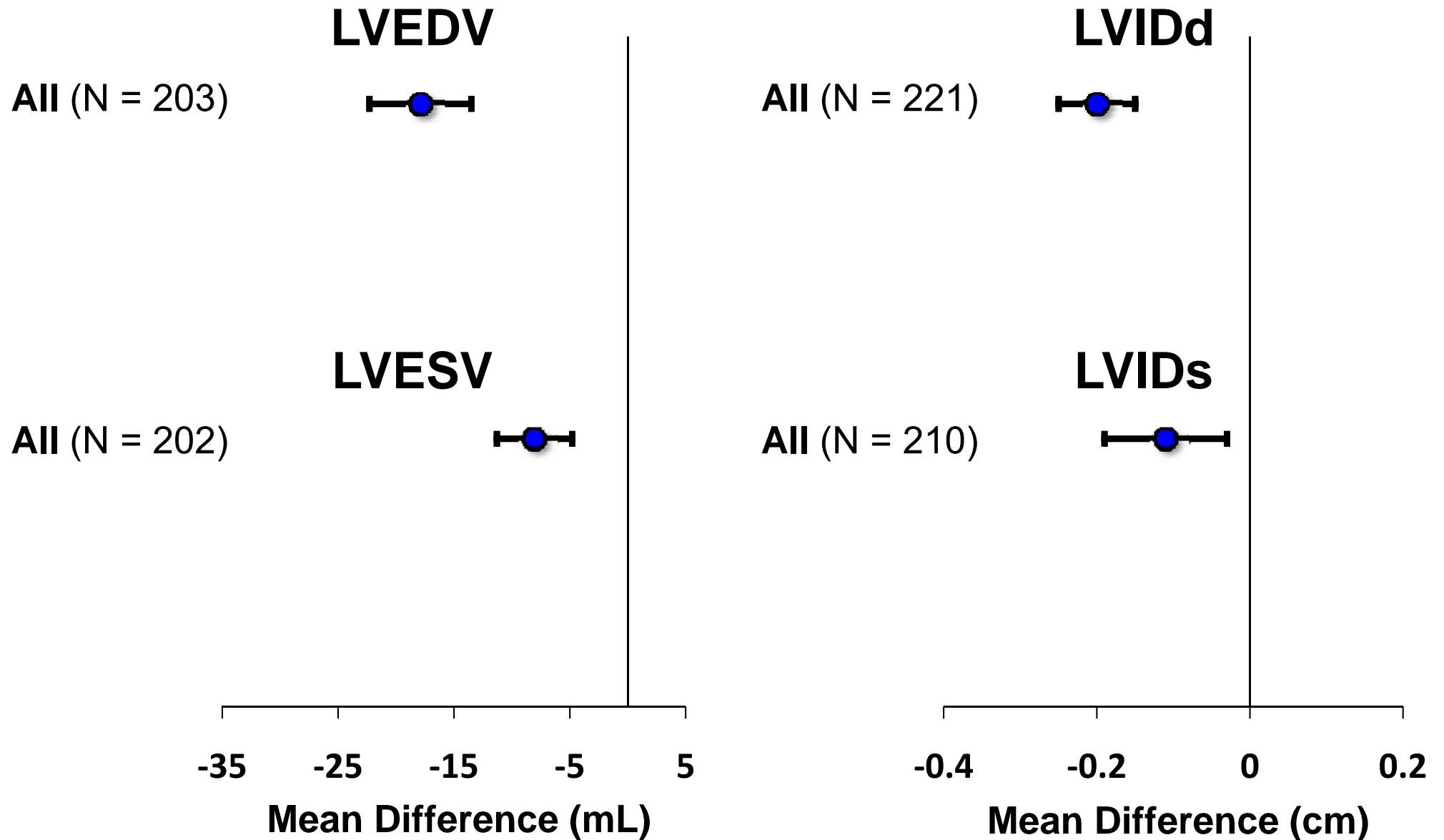
Matched Patients (N=258)

Surgery (N=80)
96% MR ≤ 2+ at 3 Years



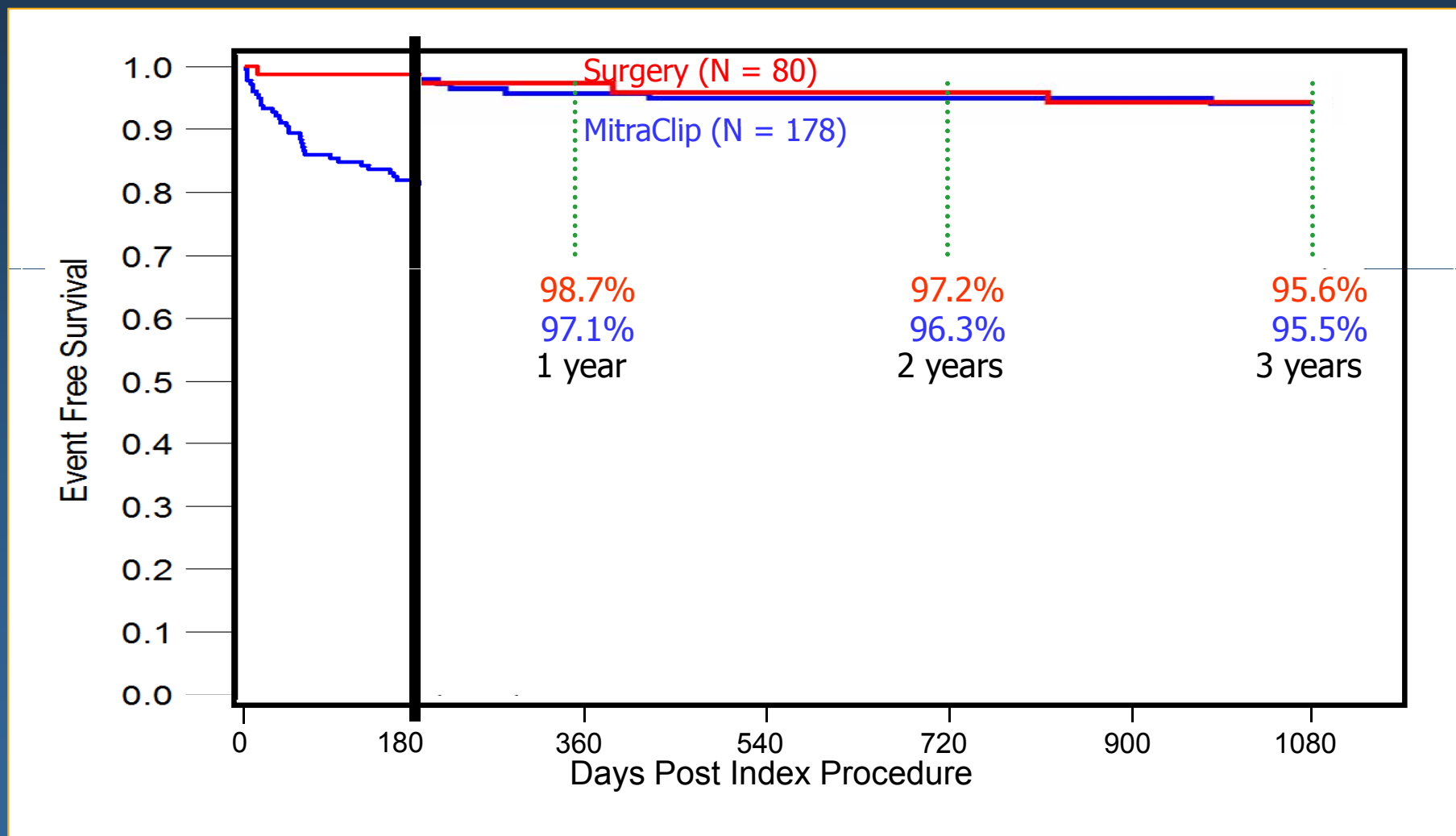
Effectiveness: Reduction in LV Size at 1 Year

Paired Analysis



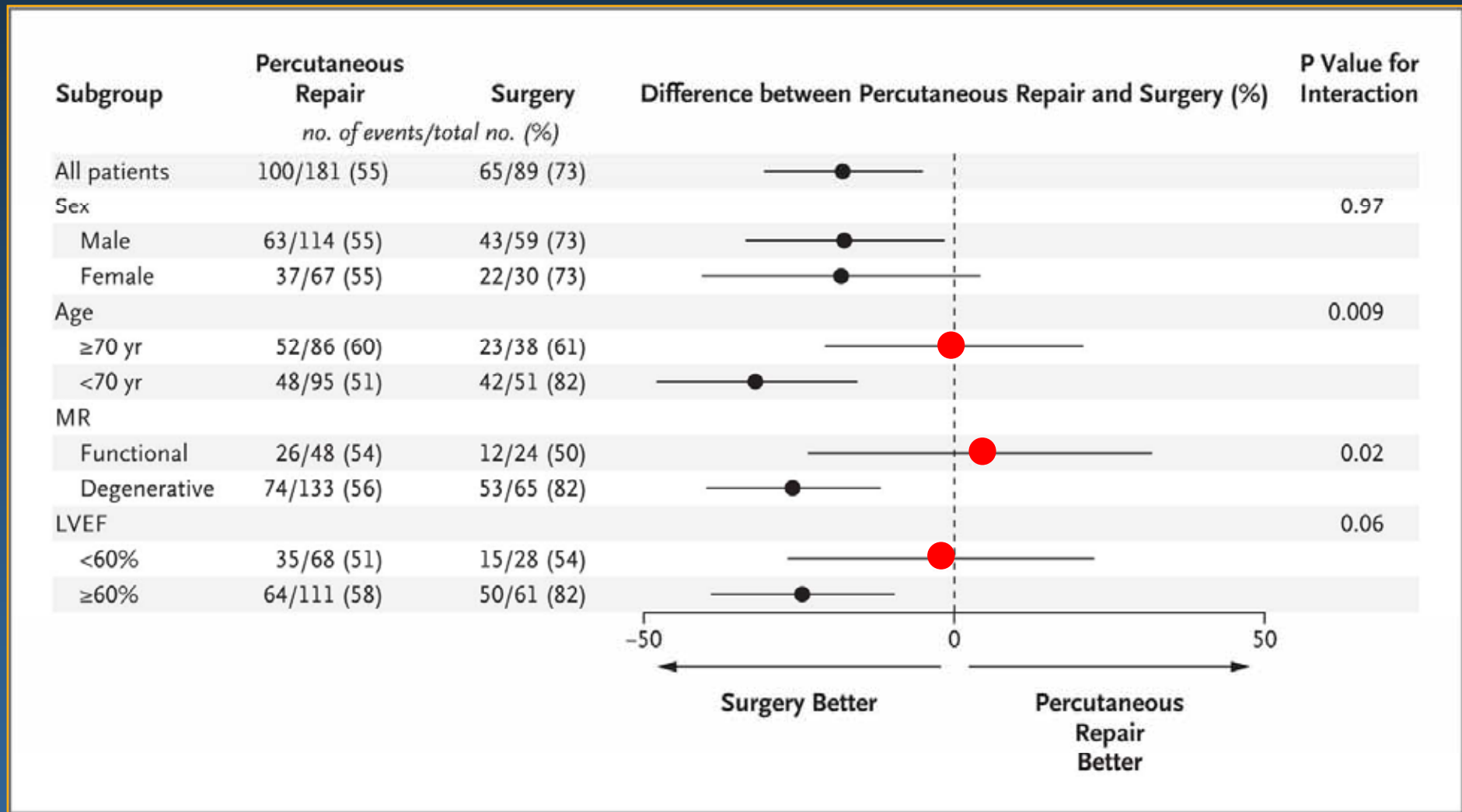
Kaplan-Meier Freedom from MV Surgery in MitraClip group or Re-operation in Surgery group

All Treated Patients (N = 258)



TCT 2012

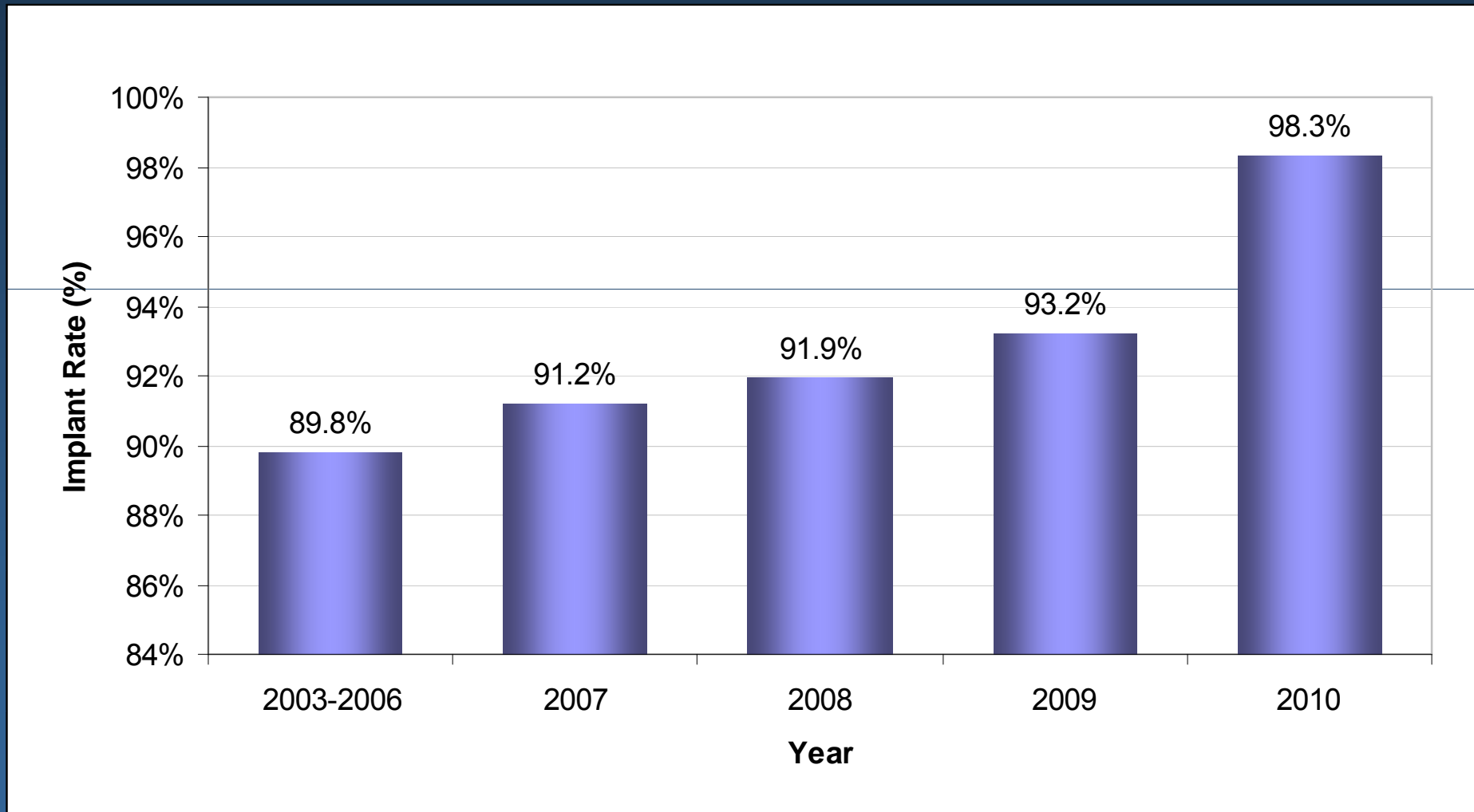
Endovascular Valve Edge-to-Edge REpair STudy



Subgroup Analyses for the Primary End Point at 12 Months

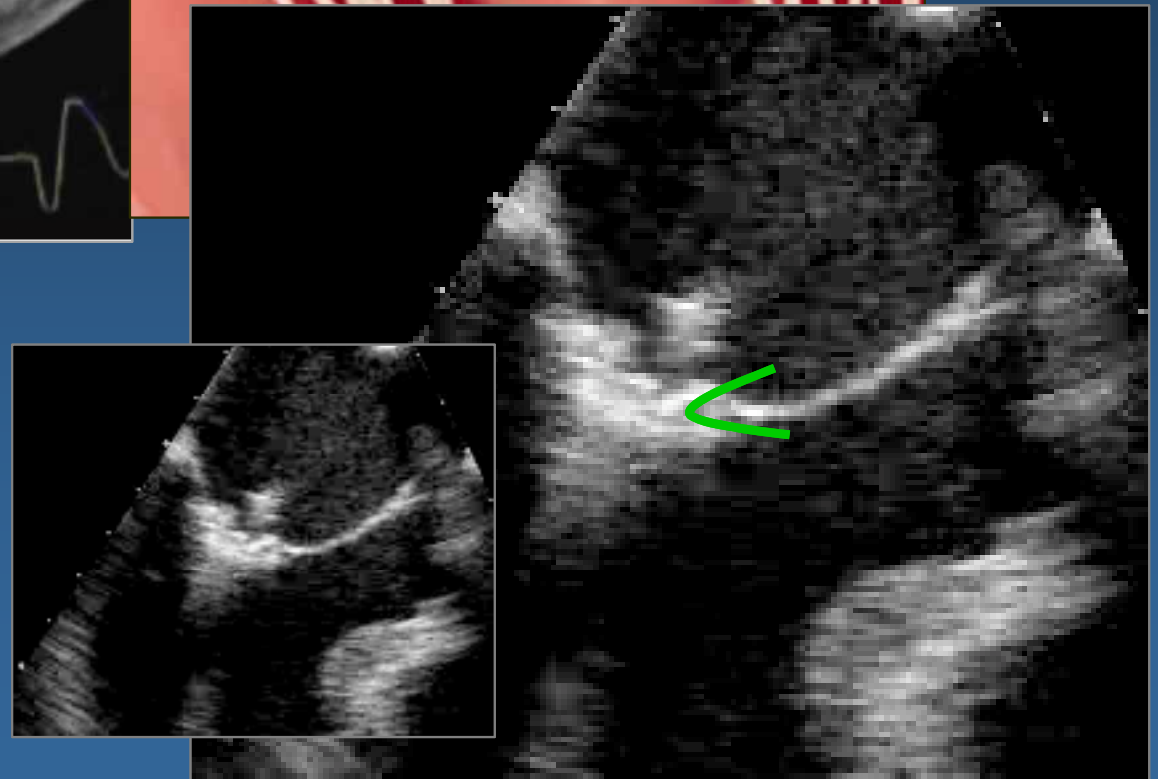
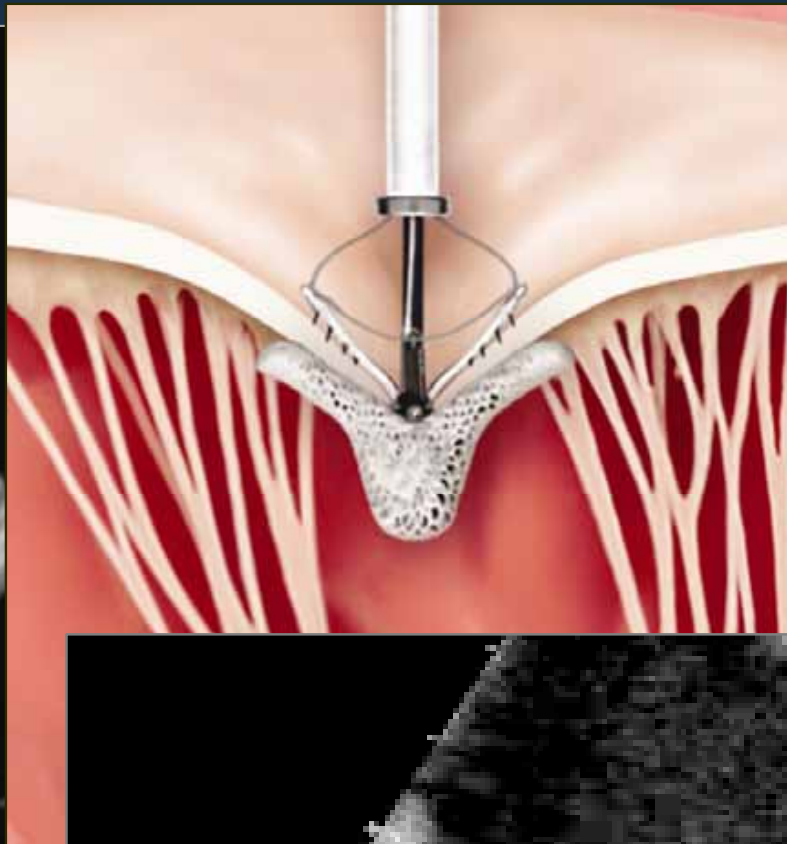
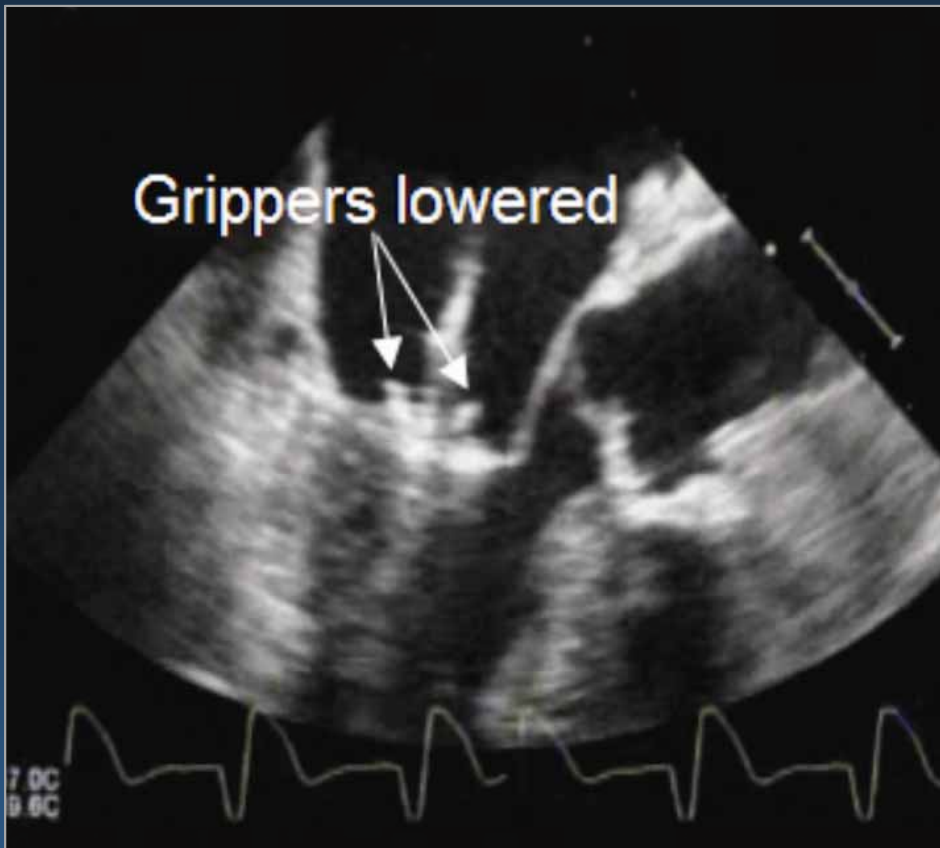
Device Implant Rate

EVEREST Trials



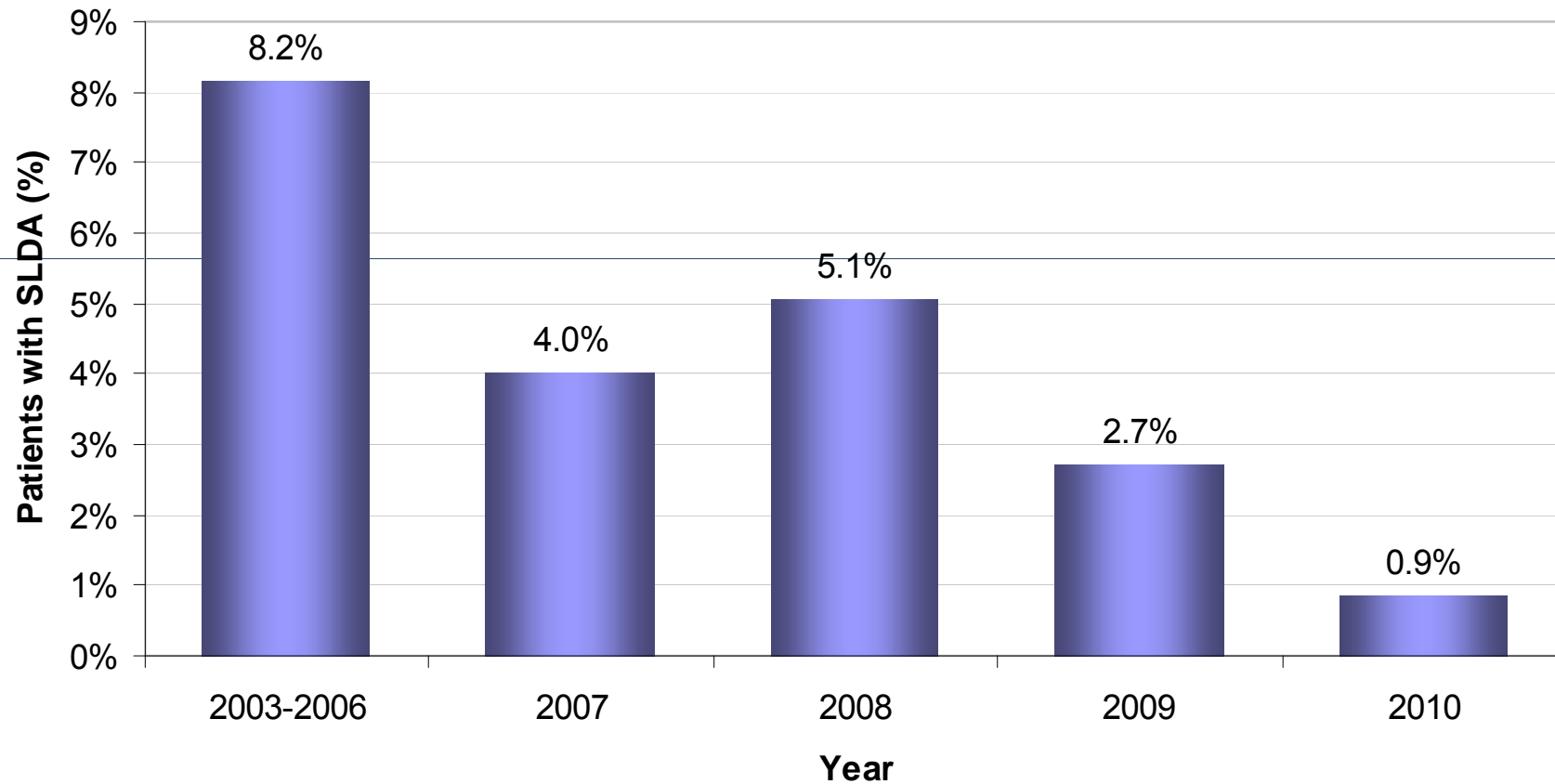
N=710

July 2003- Nov 2010



Single Leaflet Device Attachment

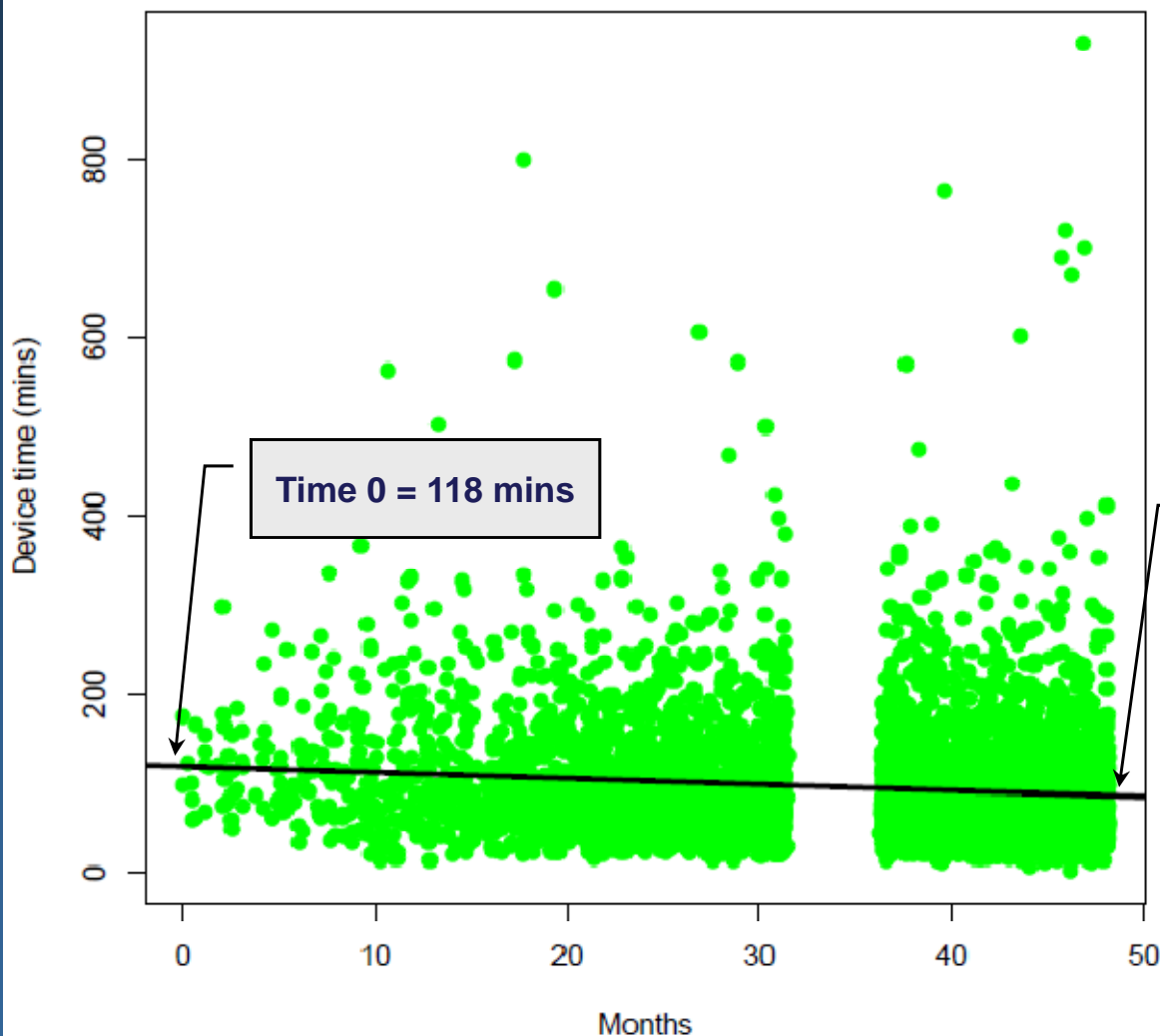
EVEREST Trials



Loss of insertion of a single ongoing insertion of the opposing leaflet

European Use Device Time

Reduction of 32 minutes in the mean Device Time ($p < 0.0001$)



Time 49 months = 86.1 mins

Acute and 12-Month Results With Catheter-Based Mitral Valve Leaflet Repair

The EVEREST II (Endovascular Valve Edge-to-Edge Repair) High Risk Study

Patrick L. Whitlow, MD,* Ted Feldman, MD,† Wes R. Pedersen, MD,‡ D. Scott Lim, MD,§

Robert Kipp

Howard C.

Murat Tuzcu

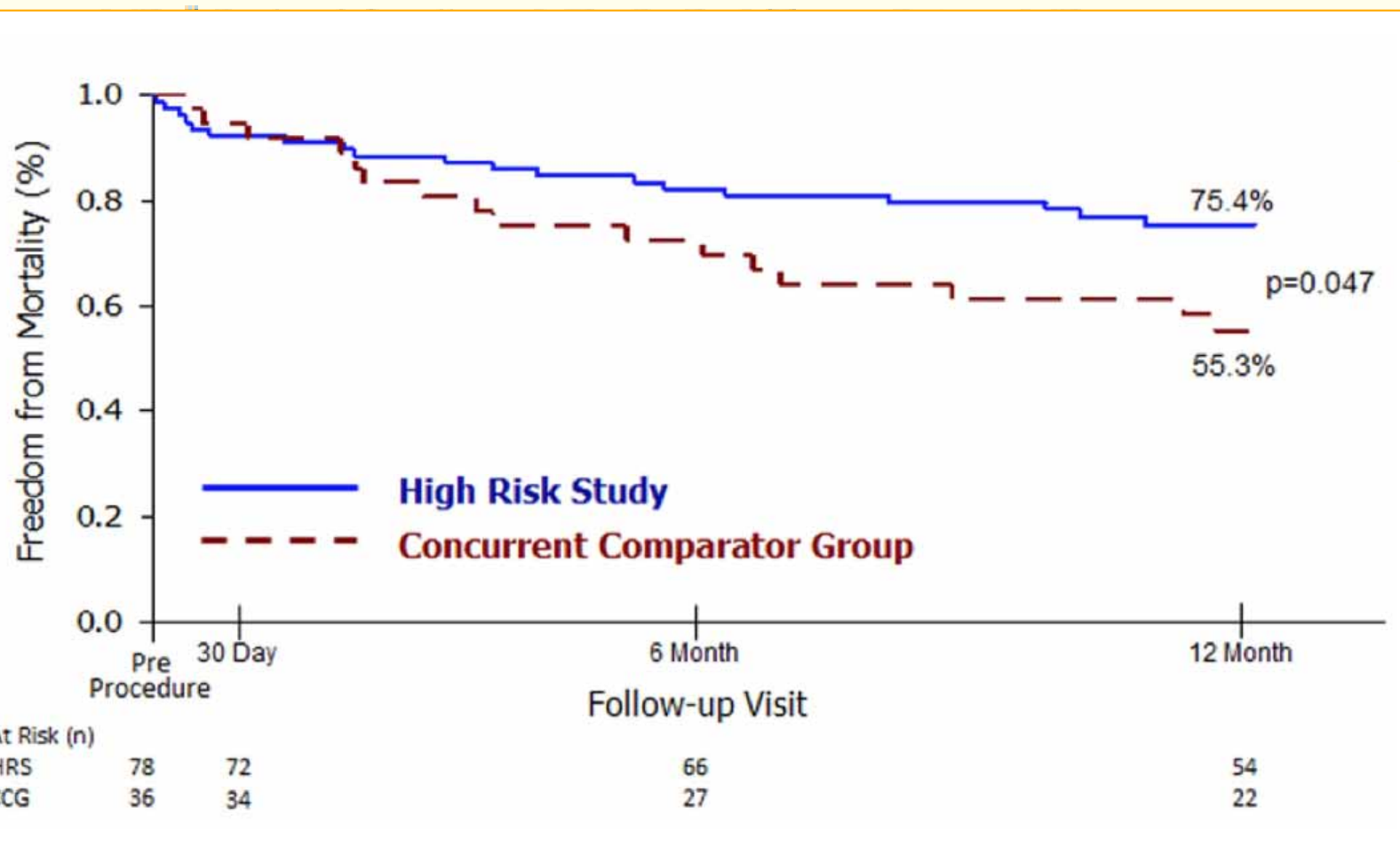
Elyse Foster

on behalf of

Cleveland, C

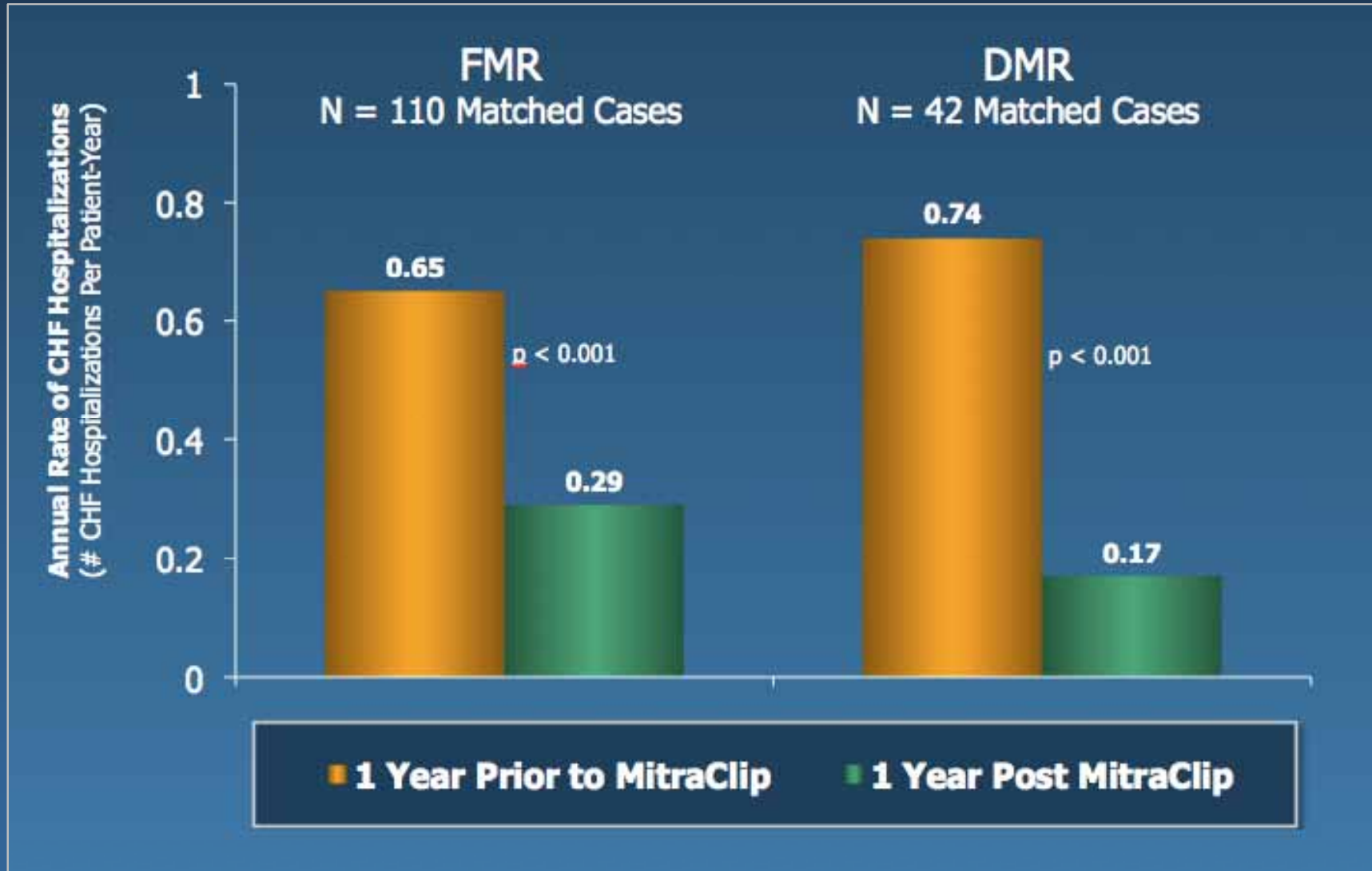
Oklahoma; E

Los Angeles



Hospitalizations for CHF

EVEREST II High Surgical Risk Cohort



Hemodynamic Data

Height, cm: 160 Weight, kg: 65.7 BSA: 1.69 m²
O₂ Consumption, ml/m²: 161.61; Hemoglobin, mg%:

State: 1: Rest

Pressures

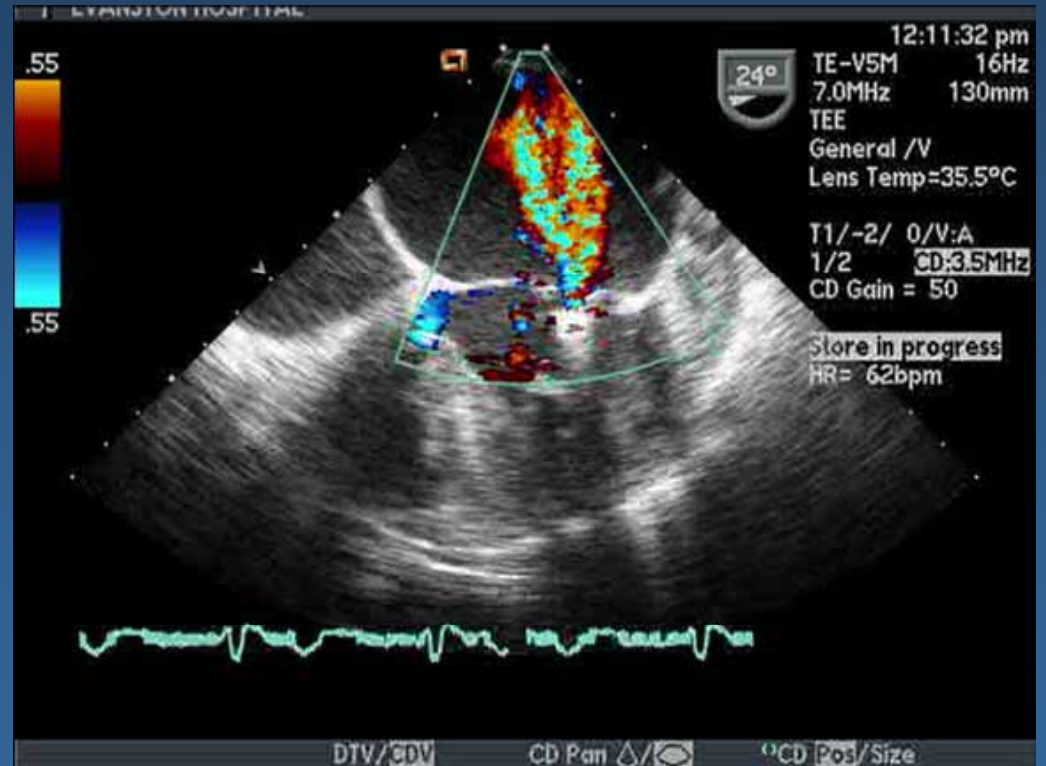
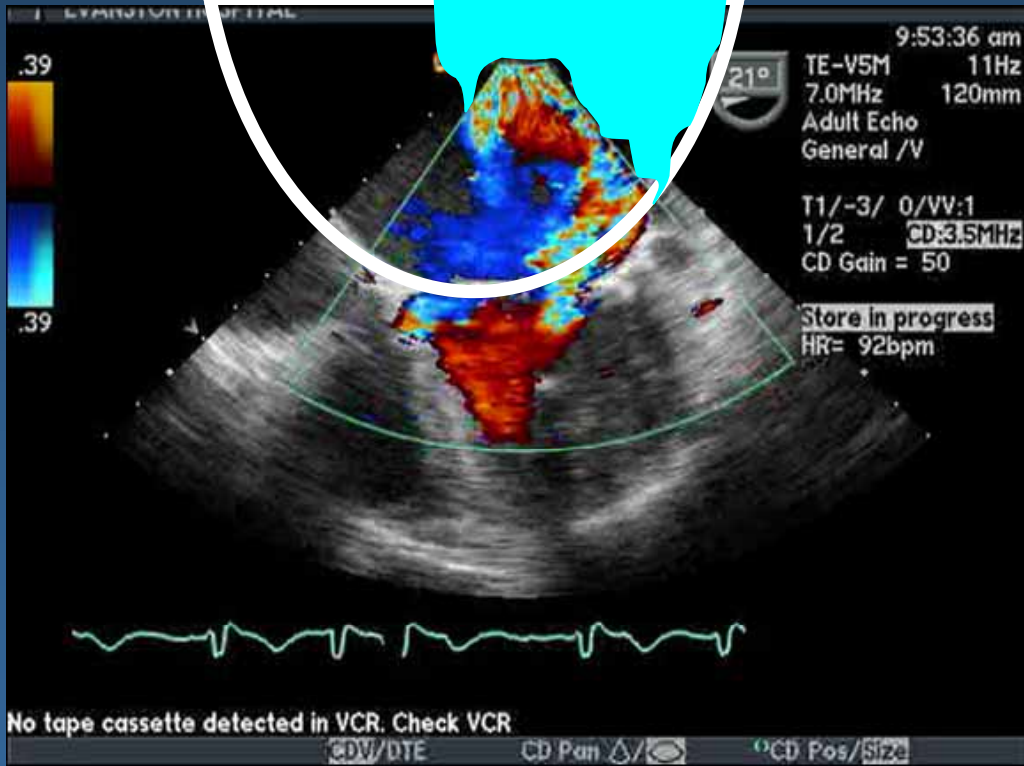
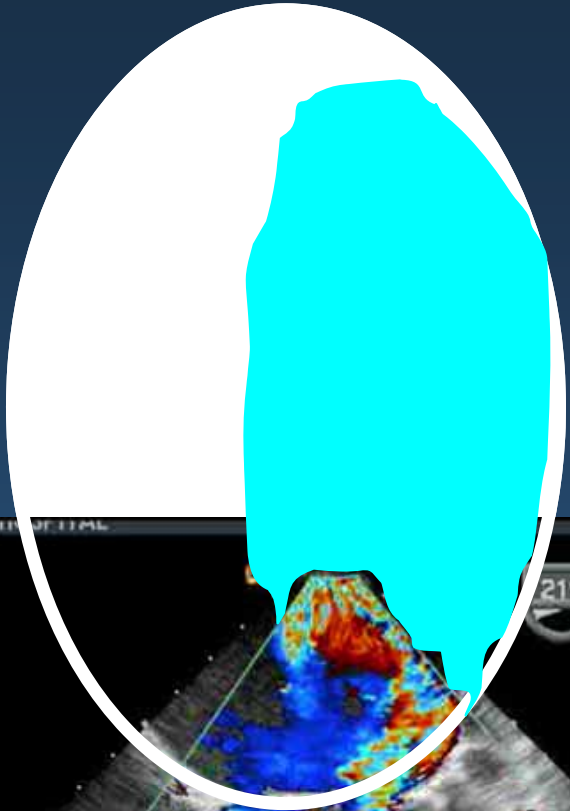
<u>Site</u>	<u>Pressures, mm Hg</u>	<u>HR</u>
RA	21/16/14	88
RV	76/14/19	88
PA	79/32/52	87
PCW	29/33/21	88
LV	168/18/23	92
AO	163/73/107	87

Overall EF 40-45% with no regional wall motion abnormalities.
There is 4+ MR.

Left Anterior Descending:

60-70% stenosis proximal to the 1st diagonal and 50-60%
stenosis 2-3cm distal to the 1st diagonal

- Adenosine negative



State: 2: Post Mitral Valve Repair

Pressures

Site	Pressures, mm Hg	HR
RA	7/6/5	83
PA	55/22/33	83
LA	14/13/9	75
LV	98/9/9	81
AO	97/36/59	81

Estimated Fick

Flows and Resistance

Thermal

CO/CI 5.72/3.34

SVR 755.91

PAR 335.96

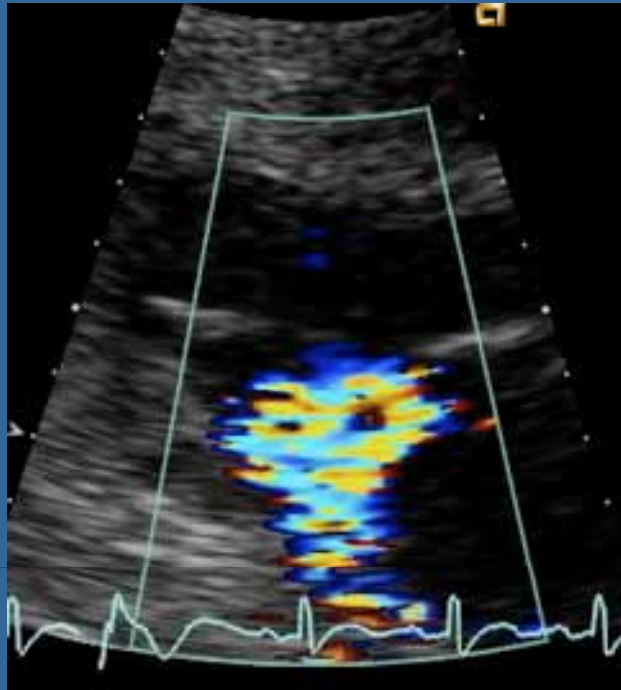
Valve parameters

	Aortic Valve	Mitral valve
Mean Grad, mm Hg	4	2
Valve Area, cm ²	2.68	

Pre

5 Years Post

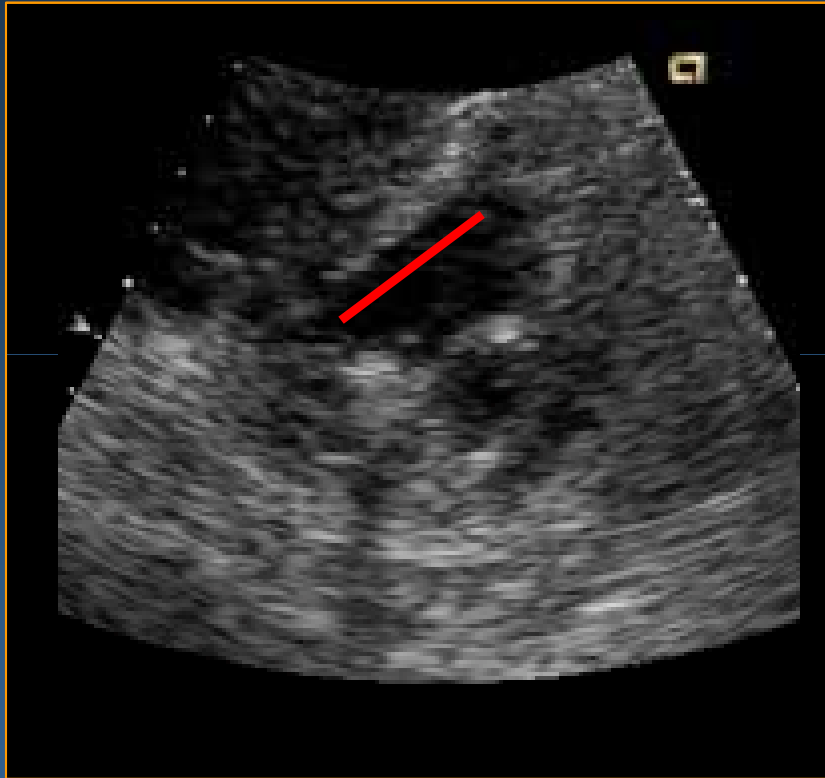
Long Axis



4 Chamber

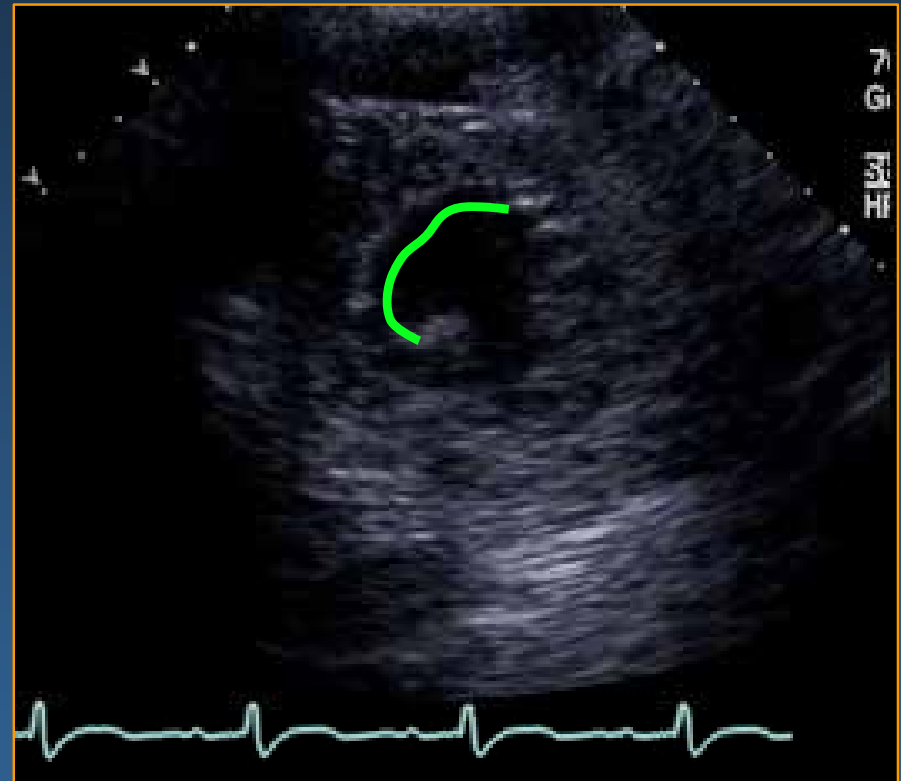


1 Day Post



PASP already down
from 79mm to 55mm

5 Years Post



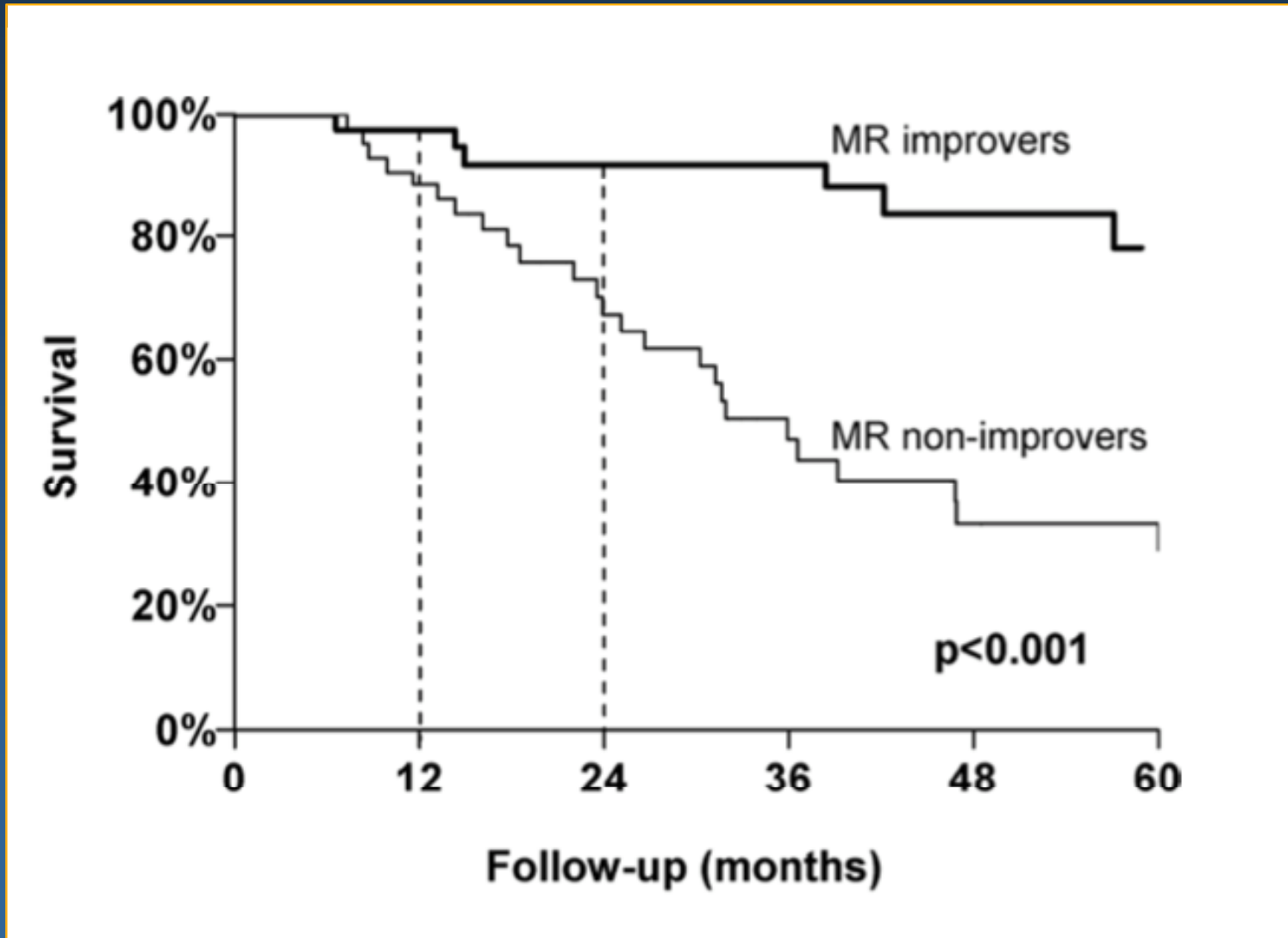
Correction of Mitral Regurgitation in Nonresponders to Cardiac Resynchronization Therapy by MitraClip Improves Symptoms and Promotes Reverse Remodeling

Angelo Auricchio, MD, PhD,* Wolfgang Schillinger, MD,† Sven Meyer, MD,‡
Francesco Maisano, MD,§ Rainer Hoffmann, MD,|| Gian Paolo Ussia, MD,¶
Giovanni B. Pedrazzini, MD,* Jan van der Heyden, MD,# Simona Fratini, MD, PhD,**
Catherine Klersy, MD, MSc,†† Jan Komtebedde, DVM,* Olaf Franzen, MD,‡
on behalf of the PERMIT-CARE Investigators

*Lugano, Switzerland; Göttingen, Hamburg, and Aachen, Germany;
Milan, Catania, L'Aquila, and Pavia, Italy; and Nieuwegein, the Netherlands*

Objectives	This study evaluated the safety, efficacy, and effect of MitraClip treatment on symptoms and left ventricular (LV) remodeling in nonresponders to cardiac resynchronization therapy (CRT).
Background	Moderate to severe functional mitral regurgitation (FMR) frequently persists after CRT, contributing to reduced or no response to CRT. Percutaneous repair with the MitraClip has been proposed as an additional therapeutic option in select patients with significant FMR.
Methods	Fifty-one severely symptomatic CRT nonresponders with significant FMR (grade ≥ 2 , 100%) underwent MitraClip treatment. Changes in New York Heart Association functional class, degree of FMR, LV ejection fraction (EF), and LV end-diastolic/end-systolic volumes (EDV/ESV) before and after (3, 6, and 12 months) MitraClip implantation were recorded. Mortality data, including cause of death, were collected.
Results	MC treatment was feasible in all patients (49% 1 clip, 46% 2 clips). There were 2 periprocedural deaths. Median follow-up was 14 months (25th to 75th percentile: 8 to 17 months). New York Heart Association functional class improved acutely at discharge (73%) and continued to improve progressively during follow-up (regression model, $p < 0.001$). The proportion of patients with significant residual FMR (grade ≥ 2) progressively decreased during follow-up (regression model, $p < 0.001$). Reverse LV remodeling and improved LVEF were detected at 6 months, with further improvement at 12 months (regression model, $p = 0.001$, $p = 0.008$, and $p = 0.031$ for ESV, EDV, and LVEF, respectively). Overall 30-day mortality was 4.2%. Overall mortality during follow-up was 19.9 per 100 person-years (95% confidence interval: 10.3 to 38.3). Nonsurvivors had more compromised clinical baseline conditions, longer QRS duration, and a more dilated heart.
Conclusions	FMR treatment with the MitraClip in CRT nonresponders was feasible, safe, and demonstrated improved functional class, increased LVEF, and reduced ventricular volumes in about 70% of these study patients. (J Am Coll Cardiol 2011;58:2183-9) © 2011 by the American College of Cardiology Foundation

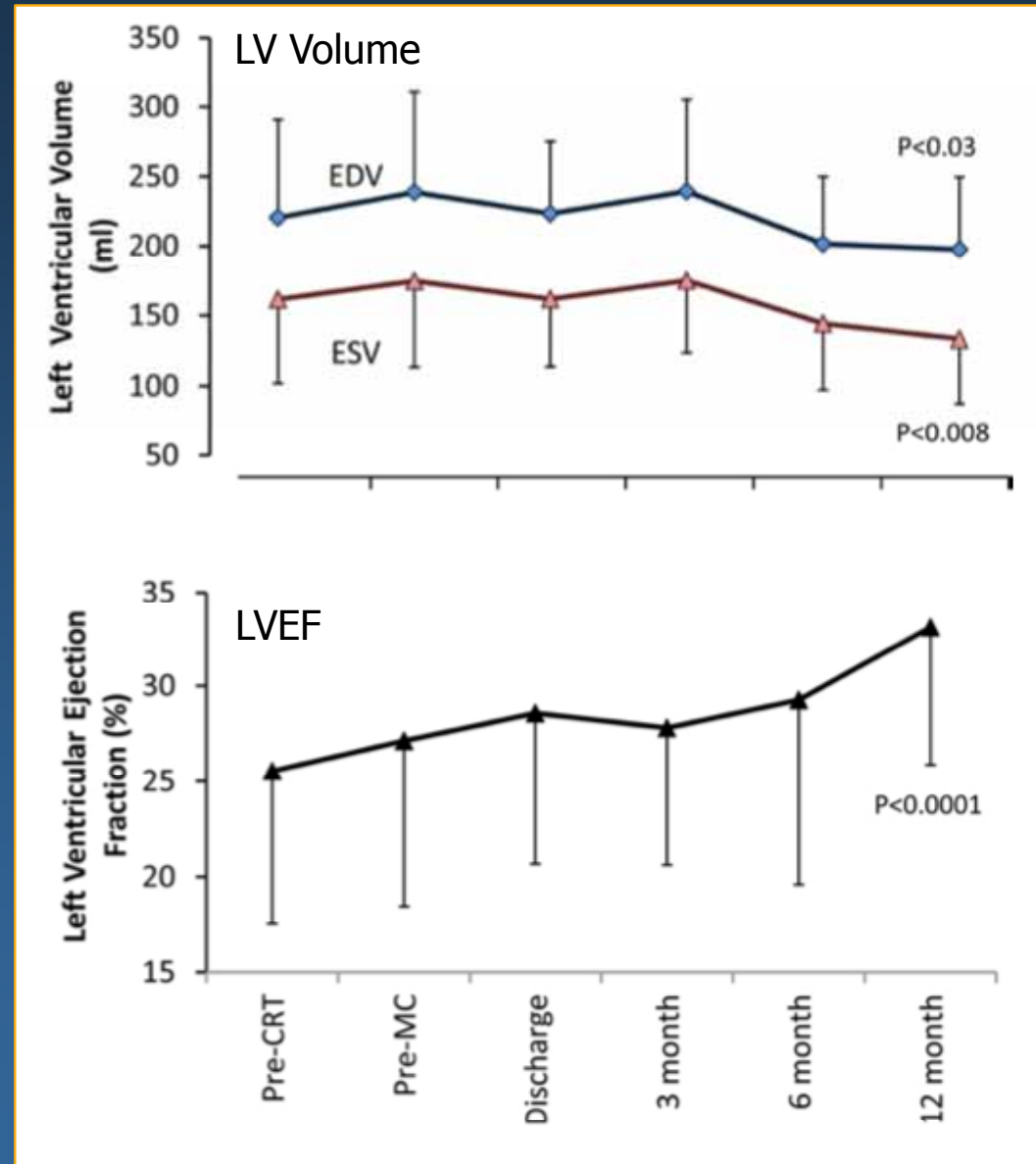
CRT in Patients With Moderate-Severe Functional MR and High Operative Risk



Correction of MR in Non-responders to CRT

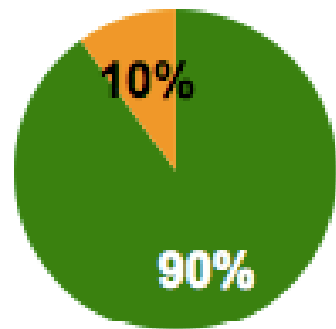
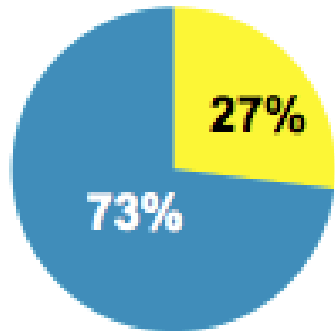
MitraClip Improves Symptoms and Promotes Reverse Remodeling

Table 1	Demographic Characteristics (N = 51)
Age (yrs)	70.26 ± 9.16
Male	44 (86)
Etiology (%)	
Ischemic cardiomyopathy	37 (73)
Nonischemic cardiomyopathy	14 (27)
Previous interventions (%)	
CABG or PCI	24 (47)
Valve surgery	4 (8)
New York Heart Association functional class	
III	32 (63)
IV	17 (35)
Previous CRT-D (%)	47 (92)
CRT-P	4 (8)
Comorbidities	
Previous stroke	8 (16)
Diabetes	11 (22)
COPD	15 (29)
Renal insufficiency	36 (70)
Logistic EuroSCORE	29.7 ± 19.4
STS score	13.9 ± 14.6



EVEREST II

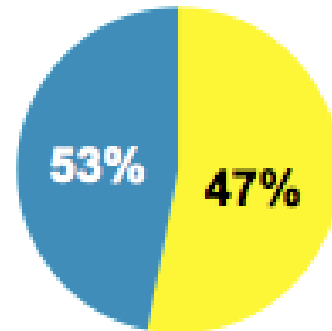
(Randomized Controlled Trial)



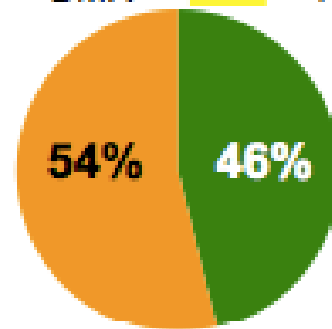
- 178 patients
- Implant rate – 89%

REALISM

(Continued Access Registry)



■ = DMR¹ ■ = FMR¹

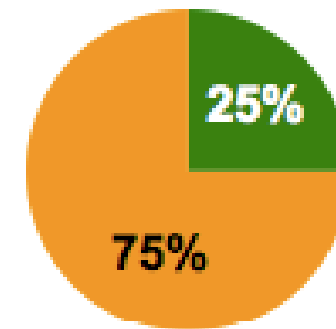
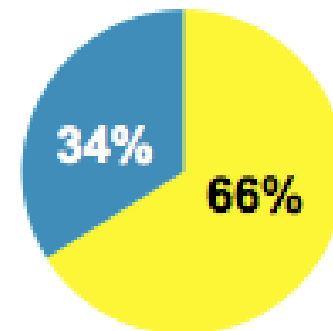


■ = Standard Risk² ■ = High Risk²

- 571 patients
- Implant rate – 94%

Commercial

(Europe, Canada, Asia, Australia)



- 2,472 patients
- Implant rate – 95%

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

~420 patients enrolled at up to 75 US sites

Significant FMR $\geq 3+$ core lab
High risk for mitral valve surgery
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

Percutaneous Mitral Leaflet Repair



Edited by
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Forewords by Ferolyn T. Powell and Mehmet Oz

Preface by Alfieri Ottavio

informa
healthcare

NorthShore
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