

# Long Term Safety and Durability of MitraClip for Primary or Functional MR

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# Disclosure Statement of Financial Interest

## *Saibal Kar, MD, FACC*

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

### •Affiliation/Financial Relationship

- Grant/Research Support
- Consulting Fees/Honoraria
- Other Financial Benefit

### •Company

- Abbott Vascular, Boston Scientific, Mitralign
- Abbott Vascular, Boston Scientific,

# Introduction

- > 30,000 patients have undergone percutaneous transcatheter mitral valve repair using the MitraClip
- It is safe, and effective in both high and moderate surgical risk non rheumatic mitral regurgitations with suitable anatomy
- Data on long term durability of this procedure is evolving



# Key MitraClip Data

- Safety
  - Impeccably safe in experienced hands
  - No early or late safety events
- Effective
  - Selected patients with both degenerative or functional MR
- Long term data
  - New data supports durability .



# EVEREST II 5 year data

## Randomized Comparison of Percutaneous Repair and Surgery for Mitral Regurgitation



### 5-Year Results of EVEREST II

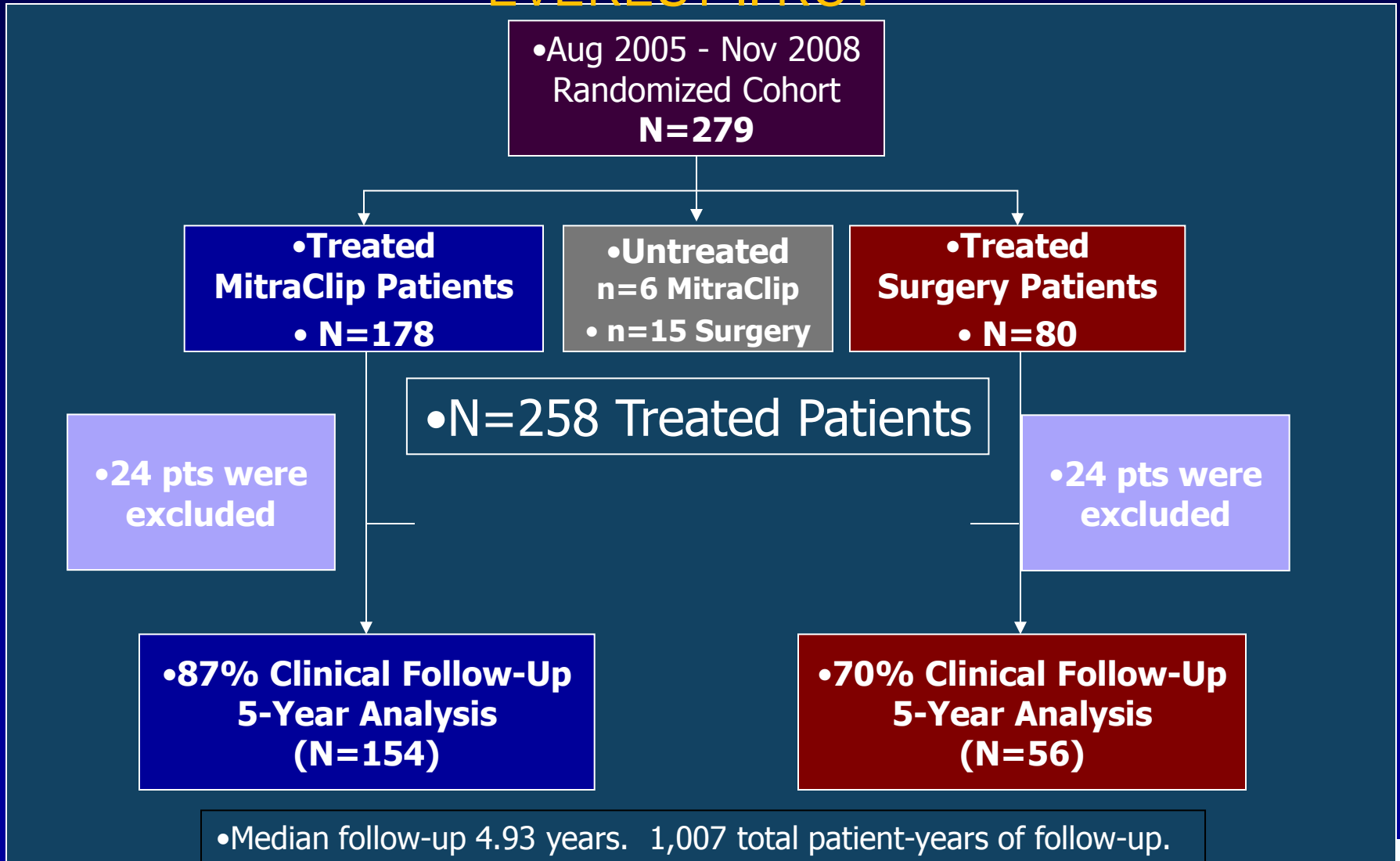
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• *J Am Coll Cardiol* 2016;66:2844-2854



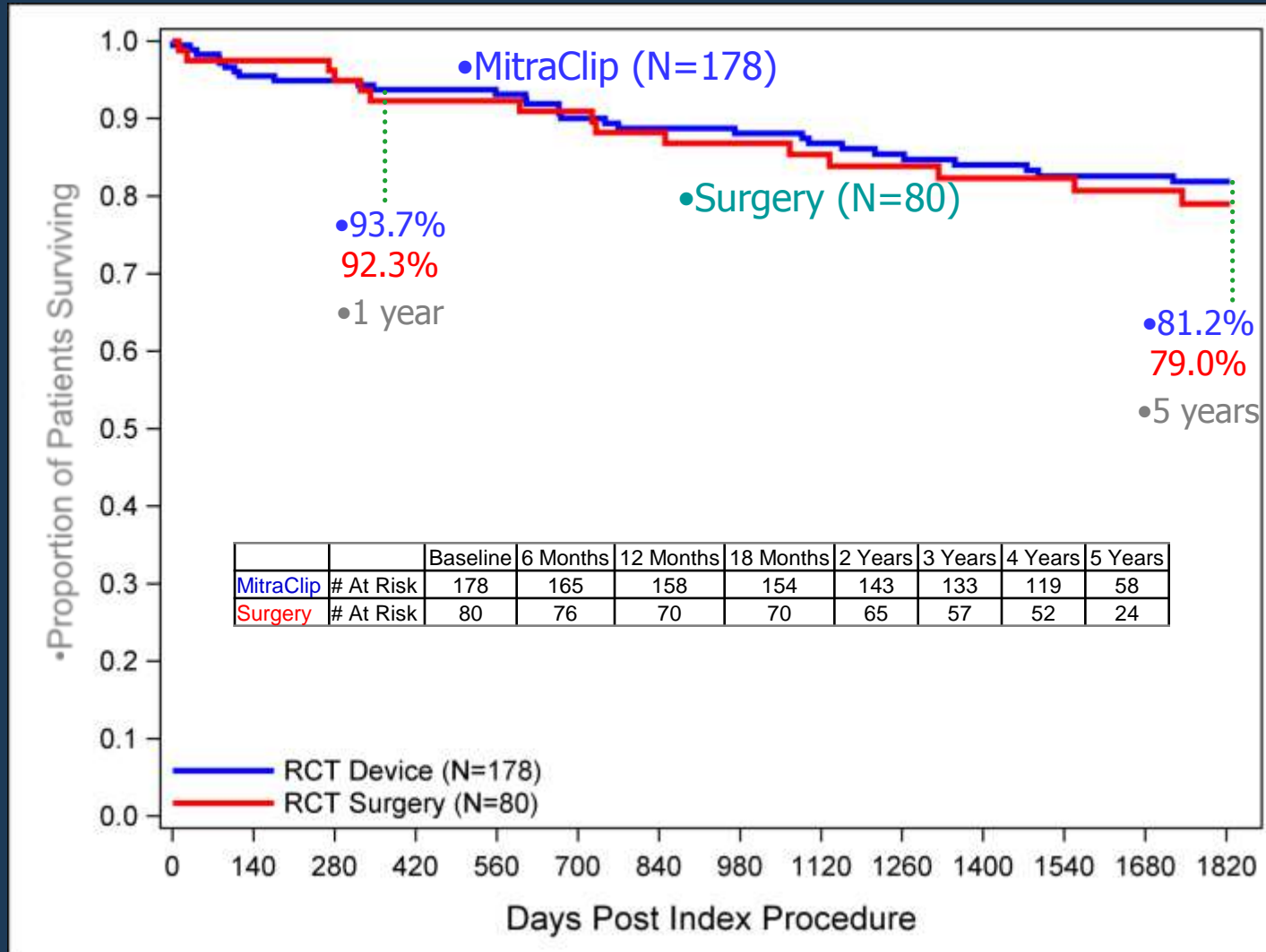
# Clinical Follow-Up

## EVEREST II RCT



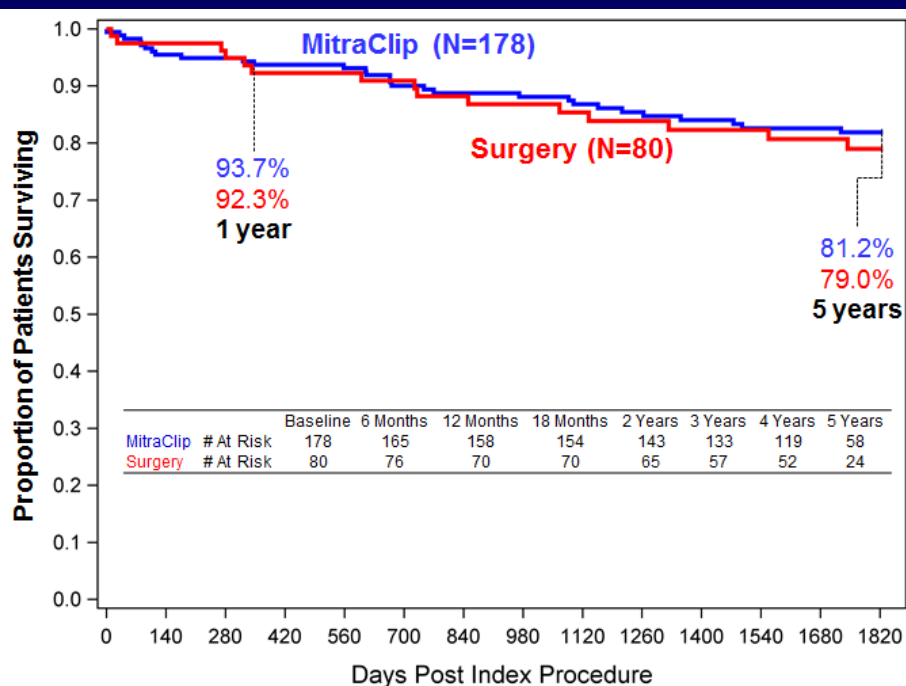
# •Kaplan-Meier Freedom From Mortality

## •EVEREST II RCT

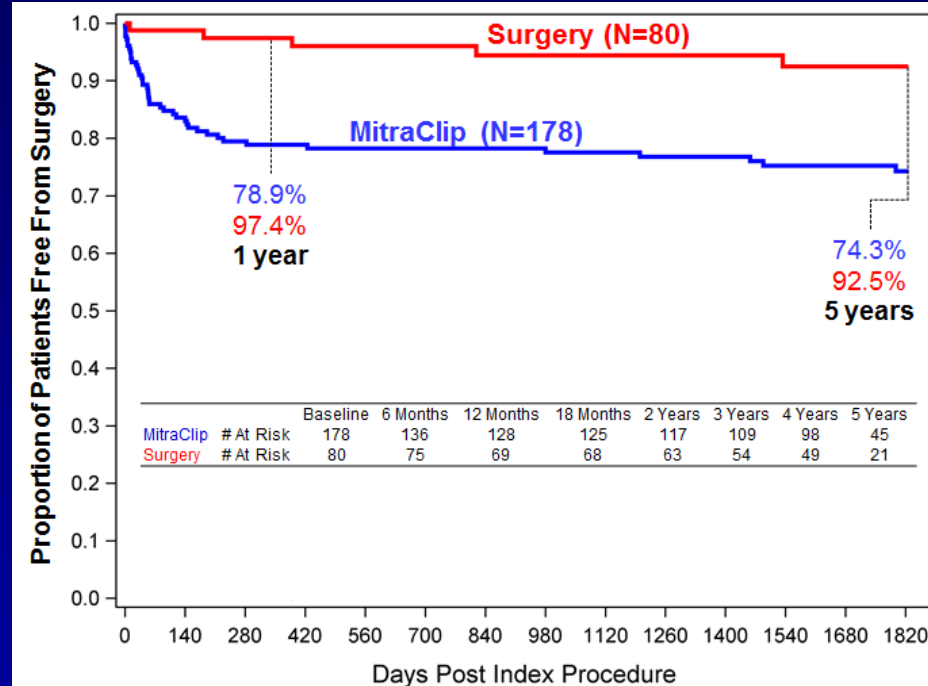


# Freedom From Mortality and MV Surgery/Re-operation

•Kaplan-Meier Freedom From Mortality



•Kaplan-Meier Freedom From Mitral Valve Surgery/Re-operation



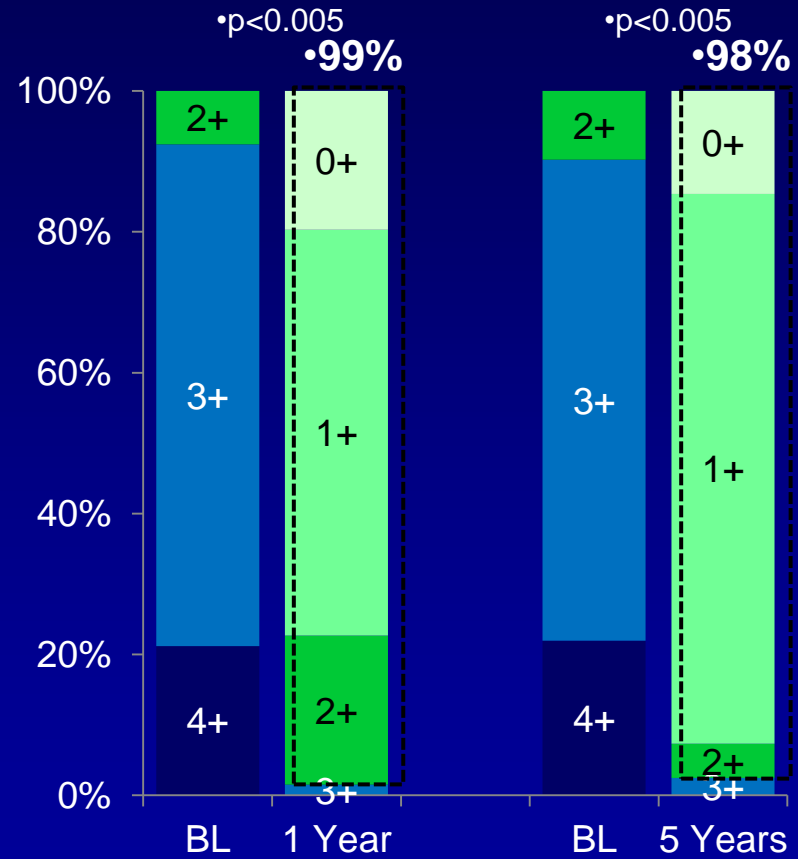
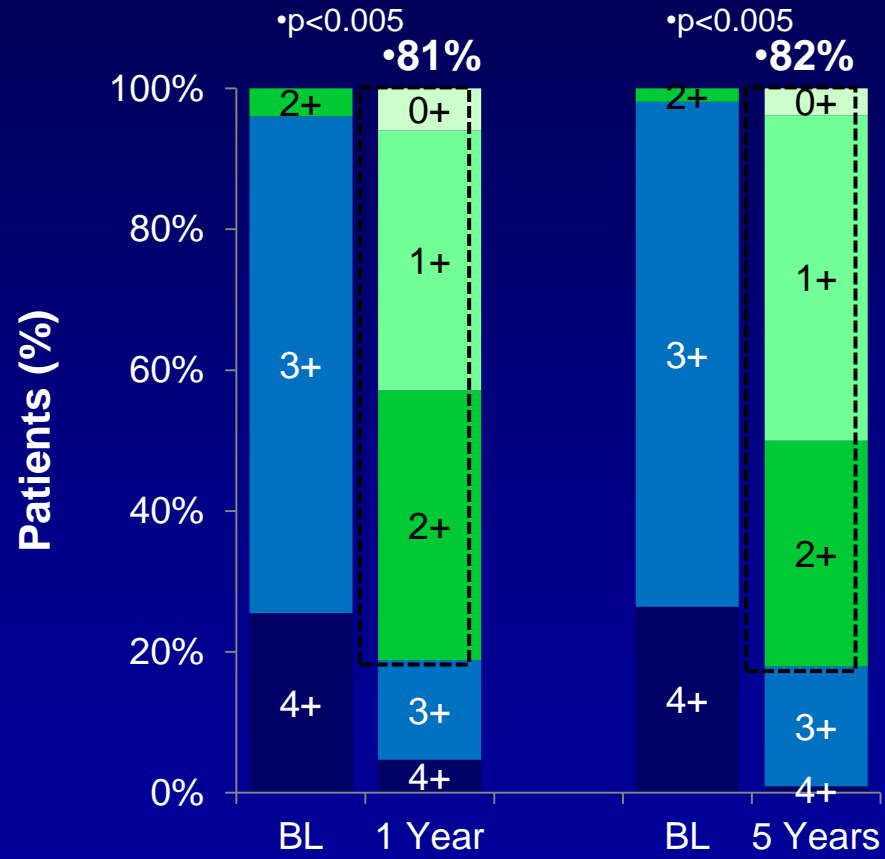
•Feldman et al ACC 2014



# EVEREST II 5 year: Sustained reduction of MR

•MitraClip (N=178)  
•MR ≤ 2+ at 1 and 5 Years

•Surgery (N=80)  
•MR ≤ 2+ at 1 and 5 Years



•N=149  
•Feldman et al ACC 2014

•N=106

•N=66

•N=41

# Reduction in LV Measurements

•LV Volumes

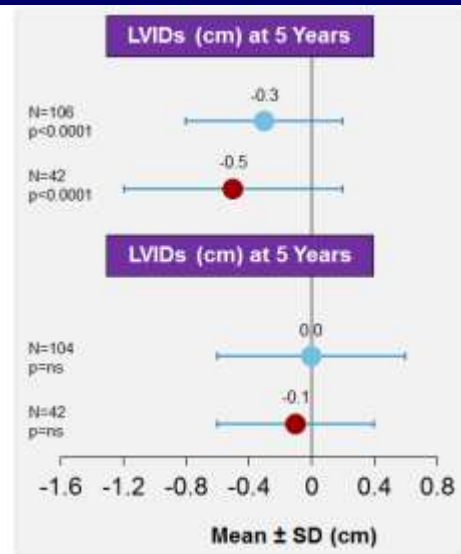
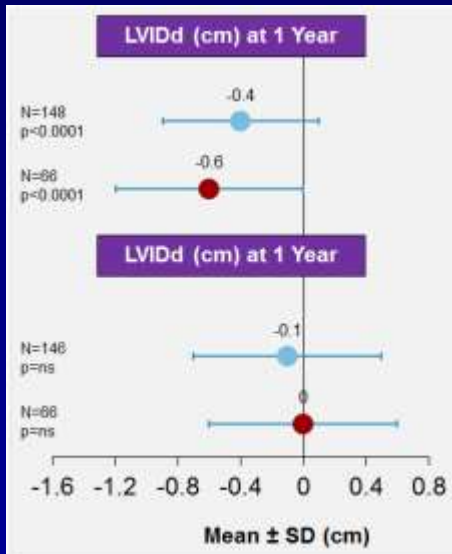
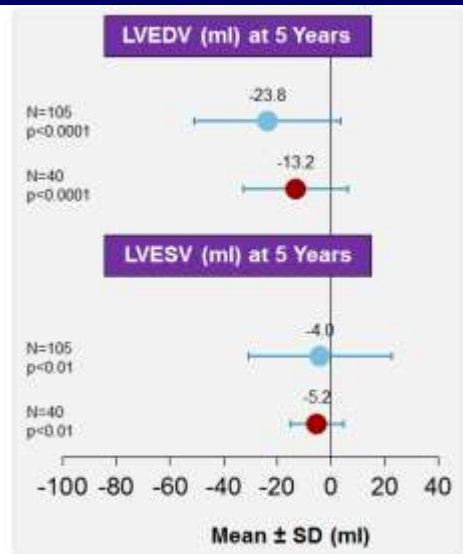
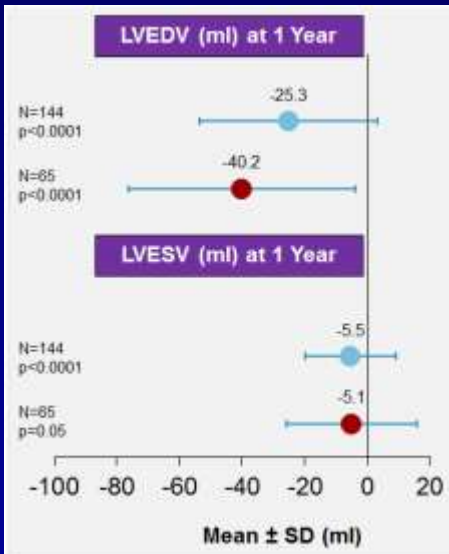
•LV Dimensions

•1 Year

•5 Years

•1 Year

•5 Years



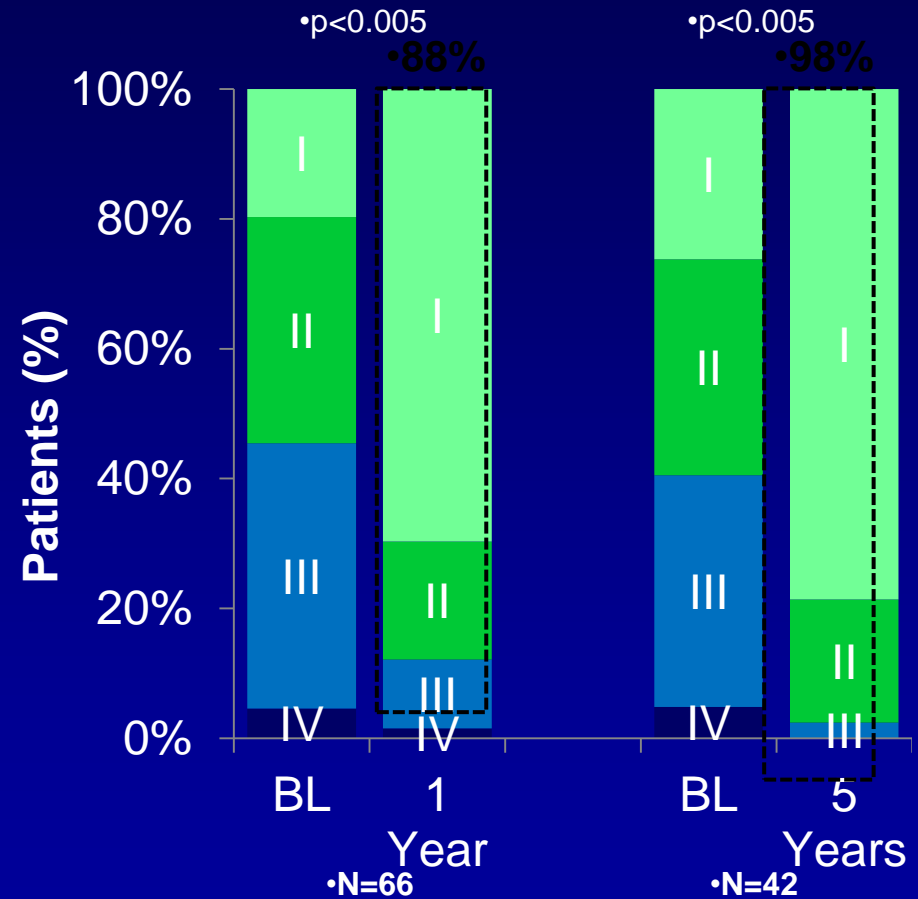
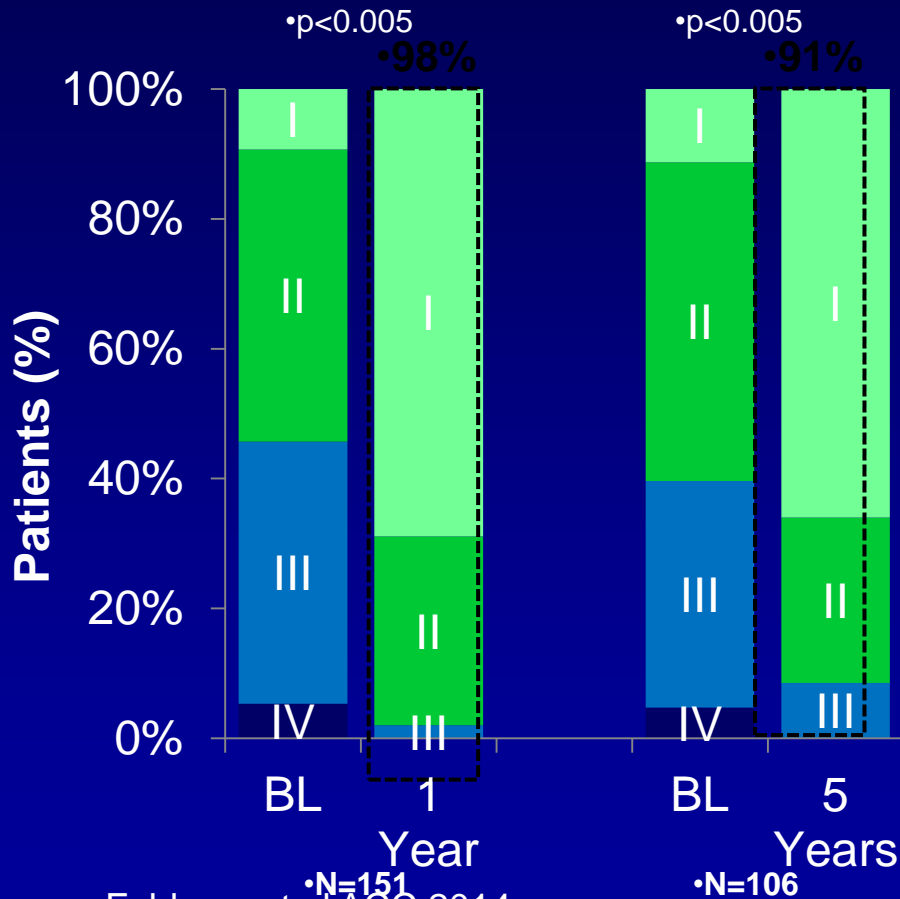
Legend: ● MitraClip ● Surgery

•Feldman et al ACC 2014

# NYHA Functional Class

•MitraClip (N=178)  
•NYHA I/II at 1 and 5 Years

•Surgery (N=80)  
•NYHA I/II at 1 and 5 Years



•Feldman et al ACC 2014

# EVEREST II RCT

## 5-Year Results Summary

- Surgery has greater reduction of MR on follow up
- MitraClip shows long term safety and durable reduction of MR at 5 years
  - Beyond 1 year worsening or MV surgery was rare in both groups
- The stable improvement of symptoms and LV size mitigates concerns of residual MR and absence of annuloplasty ring in MitraClip arm
- Functional MR was an independent predictor of mortality in both groups



# **MitraClip in High Risk patients**

**Final 5 Year Results of the  
EVEREST II High Risk Registry**



# Baseline Characteristics

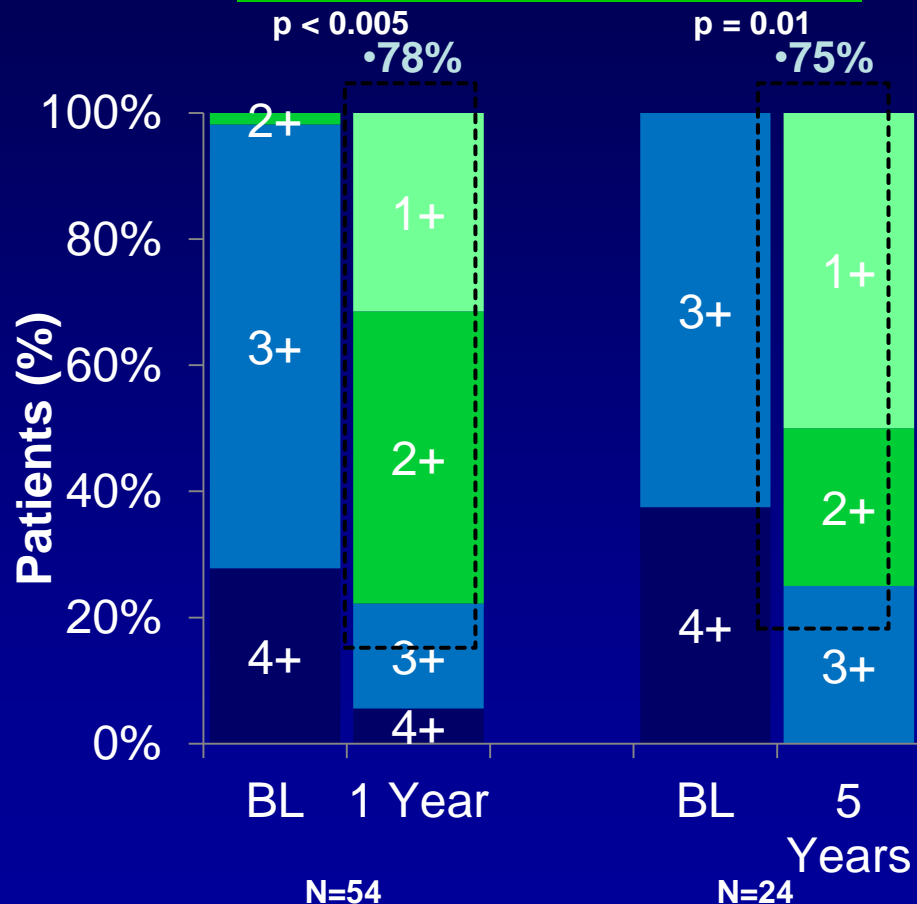
Baseline Characteristics	EII – HRR (N=78)	Euro Heart Survey*	
		Not Operated (N=193)	Operated (N=203)
Age (mean)	77	69	63
Gender, male (%)	63	47	53
NYHA Class III or IV (%)	90	70	65
History Coronary Artery disease (%)	85	60	38
<b>Prior Cardiac Surgery (%)</b>	<b>59</b>	<b>7</b>	<b>3</b>
Prior MI (%)	56	28	18
Hypertension (%)	90	53	47
Diabetes Mellitus (%)	41	21	10
COPD / Chronic Lung Disease (%)	35	21	11
Moderate to Severe Renal Failure (%)	23	n/a	n/a
Atrial Fibrillation (%)	62	36	32
Ejection Fraction, % (mean)	54	48	56
LVIDs, cm (mean)	3.9	4.1	4.0

•Kar et al ACC 2014

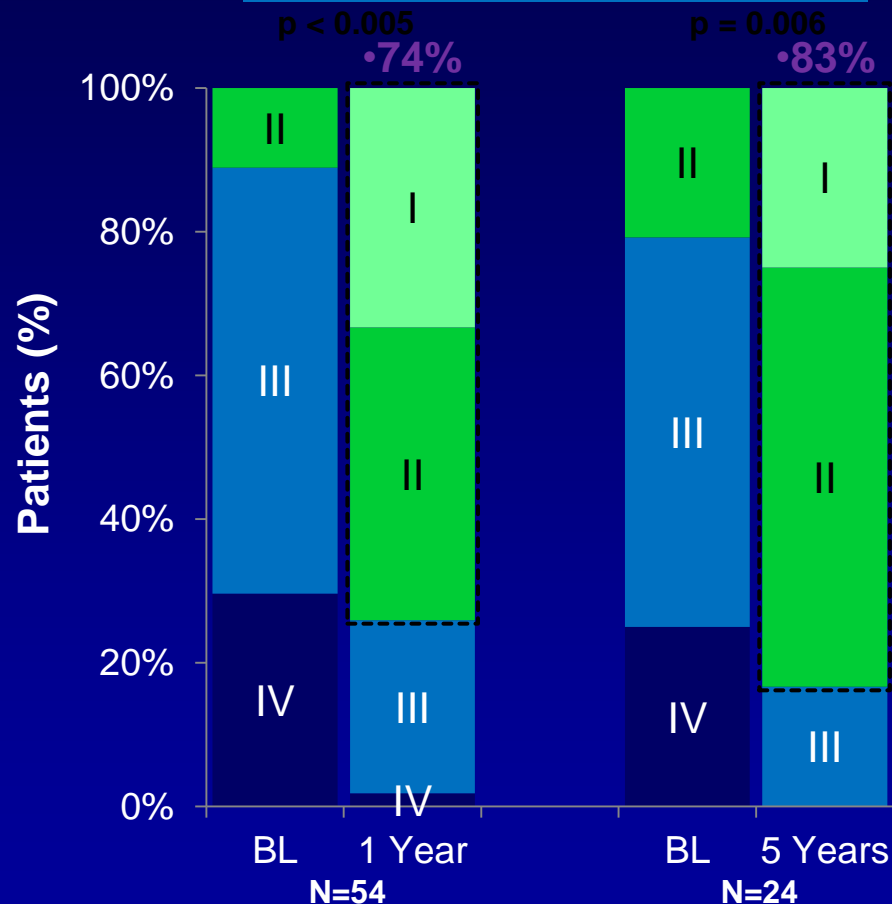
\*Mirabel et al. European Heart Journal 2007;28:1358-65

# MR Grade and NYHA Functional Class

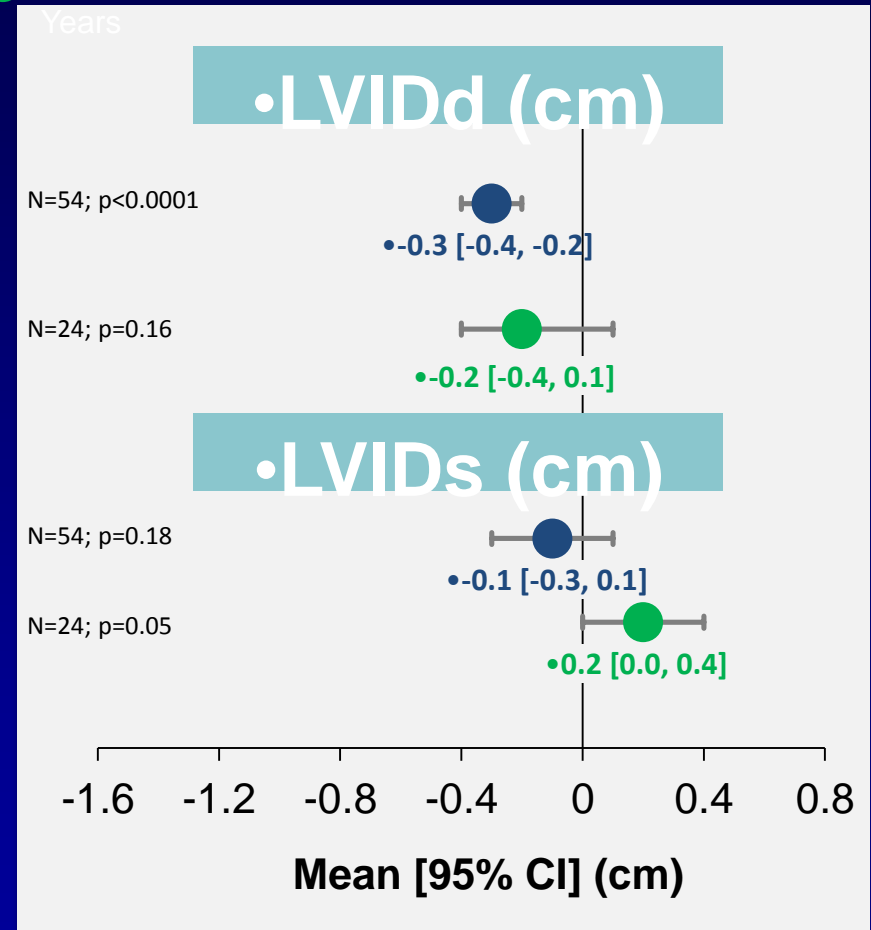
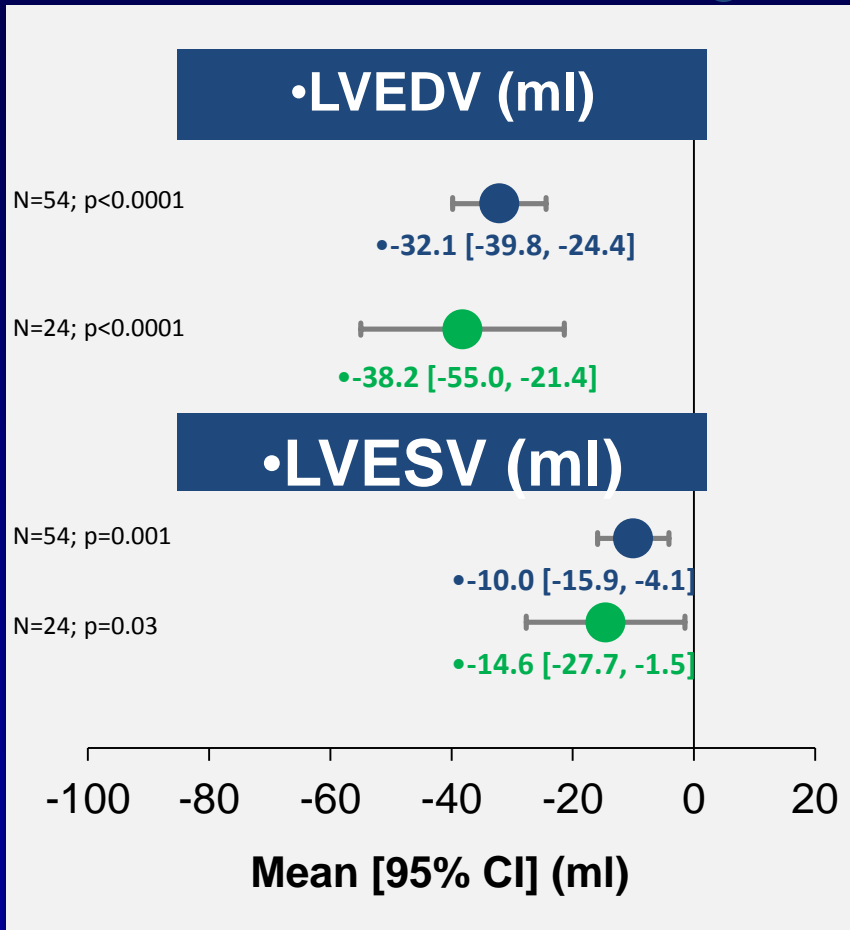
## •Mitral Regurgitation Grade



## •NYHA Functional Class



# Reduction in LV Volumes and Dimensions



•Kar et al ACC 2014



# EVEREST II High Risk Registry

## 5-Year Results Summary

- The EVEREST II High Risk Registry is the longest prospective follow-up of a high surgical risk cohort treated for severe MR
- Clinical benefits provided by MitraClip are durable in high risk patients surviving through 5 years
  - Sustained improvements in functional status and MR severity
- No new or ongoing safety concerns through 5 years in this high risk population

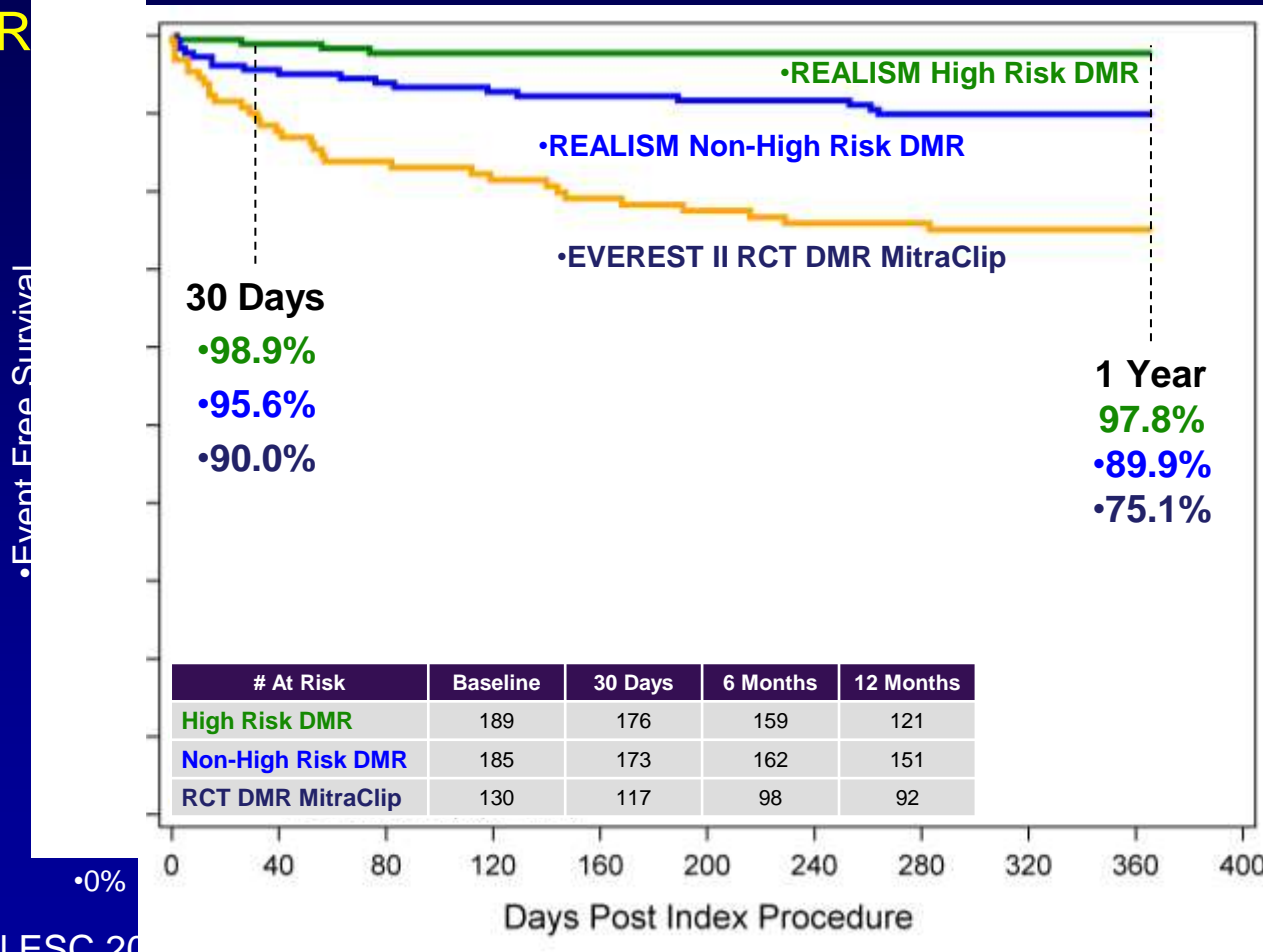
# REALISM ( degenerative MR Cohort)



# Freedom From MV Surgery in DMR:

EVEREST

High Risk



• Kar et al ESC 2016

# What about Functional MR



# MitraClip for functional MR

- > 20,000 treated worldwide
- Evidence of safety, efficacy,
- No proof of survival benefit
- No data from randomized trials available
- Ongoing clinical trials in US
  - COAPT study in North America



# *Trial design*



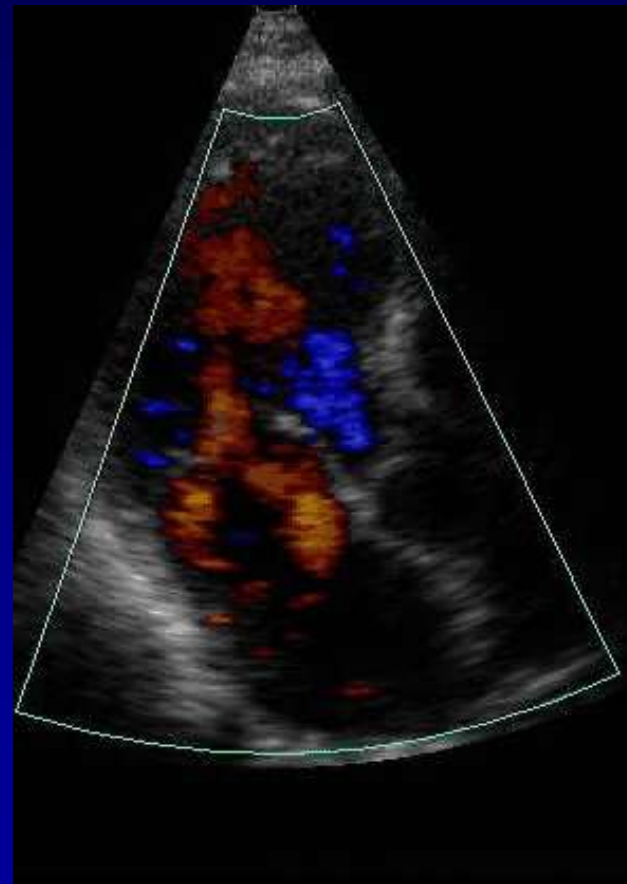
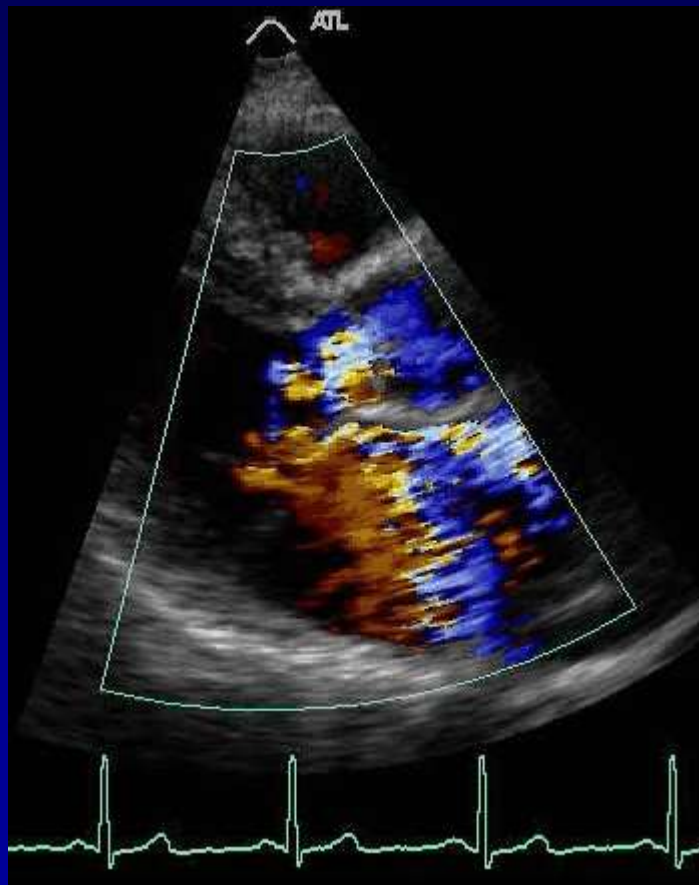
- 430 patients enrolled at up to 85 US sites
  - Significant FMR ( $\geq 3+$  by core lab) treated per standard of care
    - Deemed not suitable for mitral valve surgery
    - Specific valve anatomic criteria
  - Randomize 1:1

• *398 Randomized 32 pts to go*

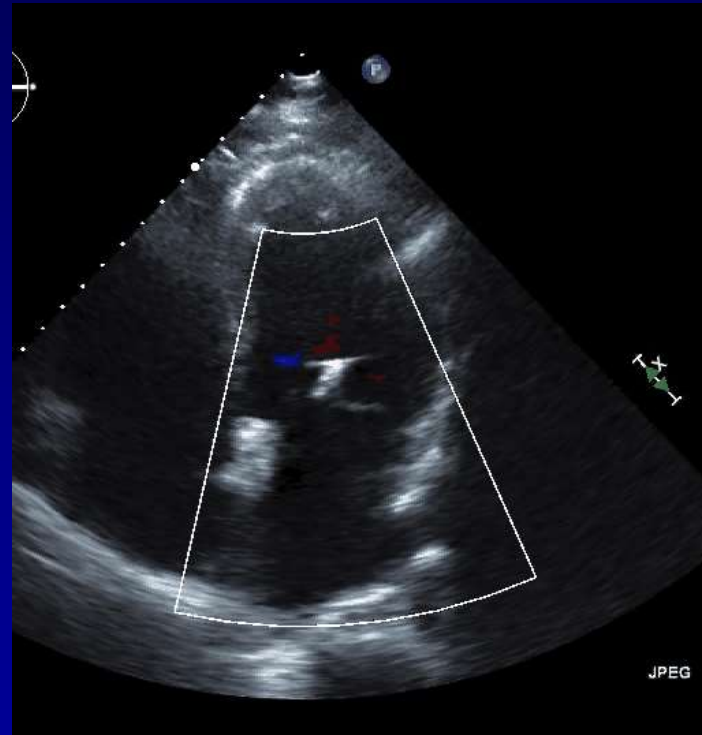
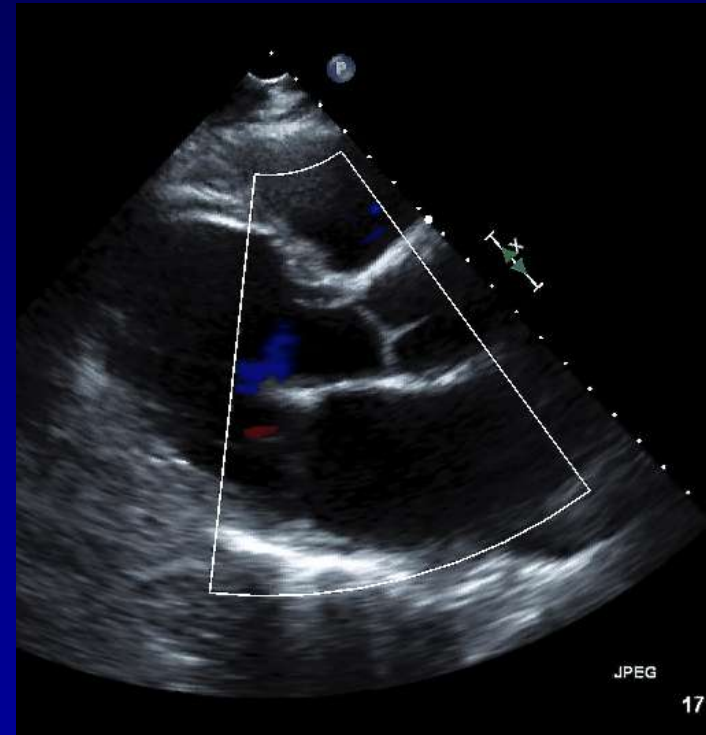
- 
- Clinical and TTE follow-up:  
• 1, 6, 12, 18, 24, 36, 48, 60 months
- The diagram consists of a red rectangular box containing the text "• 398 Randomized 32 pts to go". Two grey arrows point downwards from the bottom corners of this box to a grey rounded rectangular box below it. This second box contains the text "• Clinical and TTE follow-up:" followed by a list of time points: "• 1, 6, 12, 18, 24, 36, 48, 60 months".



# 62 yr old male with flail P2 treated with MitraClip in May 2006



# 9years later NYHA I





# Summary

- MitraClip is a safe and effective treatment option for patients with significant MR who are not suitable for surgery.
- New data suggests the durability of repair
- Ongoing randomized clinical trials will address the role of MitraClip in patients with significant FMR
- Future trials should study the role of Clip in intermediate to low risk patients



# *Conclusions*

- Is MitraClip an effective and durable treatment option for intermediate risk degenerative MR patients

*Probably yes*

*In the right patient*

*In the right hands*

*In the right time*

