

Percutaneous mitral valve repair: current techniques and results

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EVANSTON
NORTHWESTERN
HEALTHCARE

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Disclosure Information

The following relationships exist:

Grant support: Abbott, Atritech, BSC, Cardiac Dimensions, Cordis, Evalve, EV3, St Jude, .

Consultant: BSC, Cardiac Dimensions, Cordis, Edwards, Myocor

Speaker: Boston Scientific

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

Percutaneous Mitral Repair Approaches

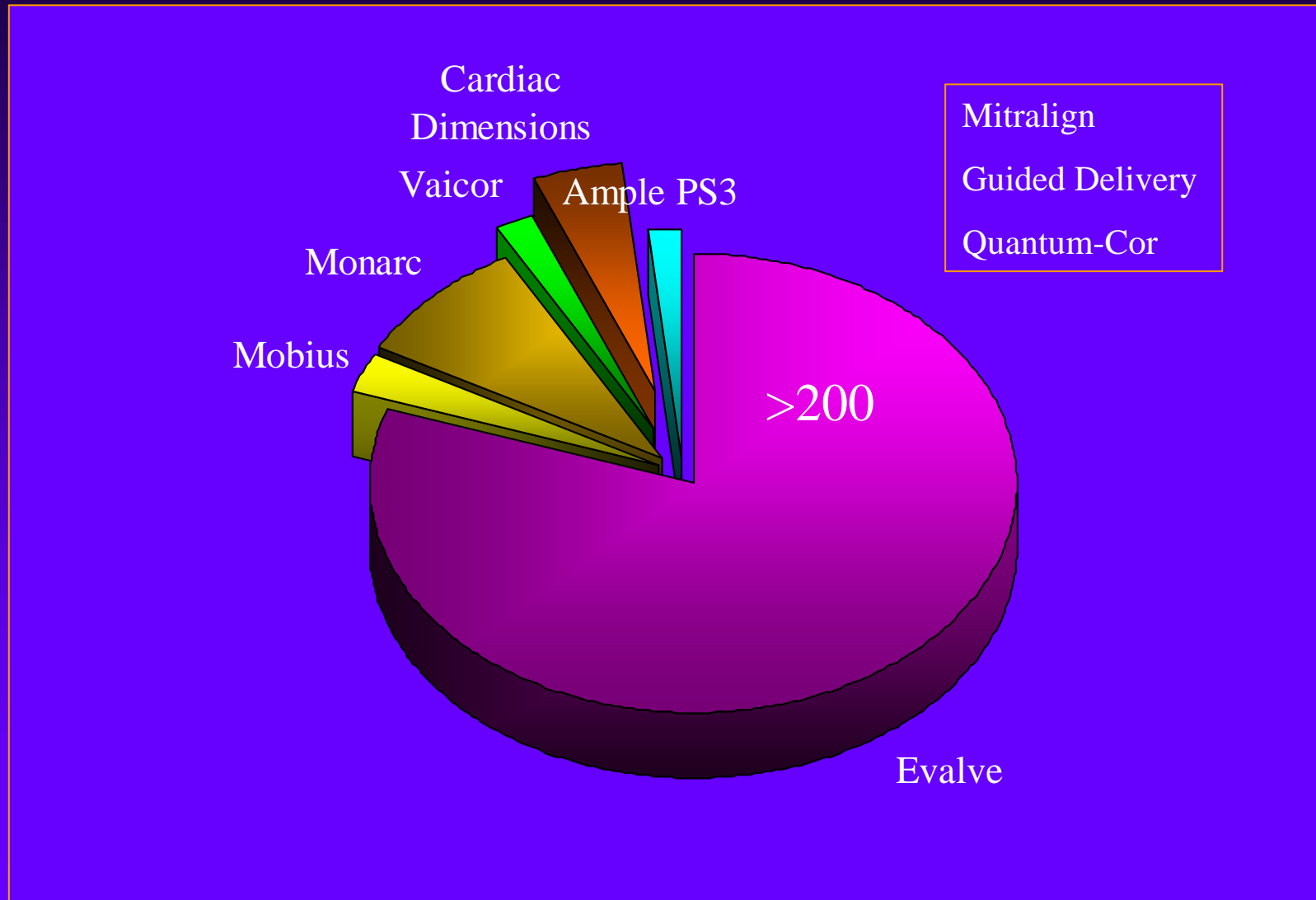
- **Coronary sinus annuloplasty**
 - Edwards Monarc
 - Cardiac Dimensions Carillon
 - Viacor Shape Changing Rods
 - St. Jude Annulus Reshaping

- **Direct annuloplasty**
 - Mitralign Suture-Based Plication
 - Guided Delivery Anchor-Cinch Plication
 - QuantumCor RF Annulus Remodeling
 - MiCardia variable size ring

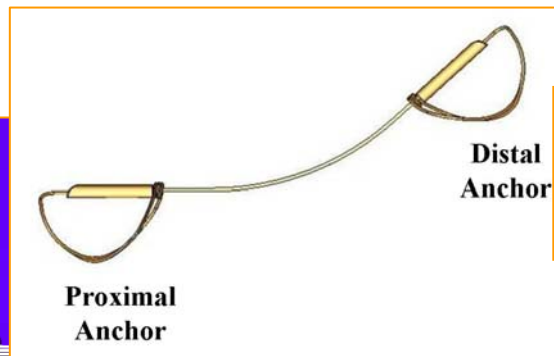
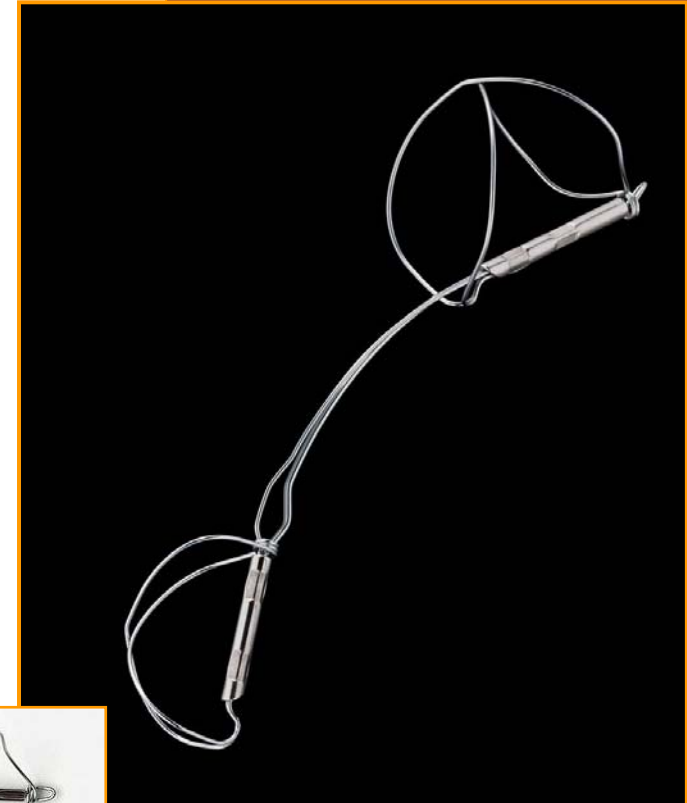
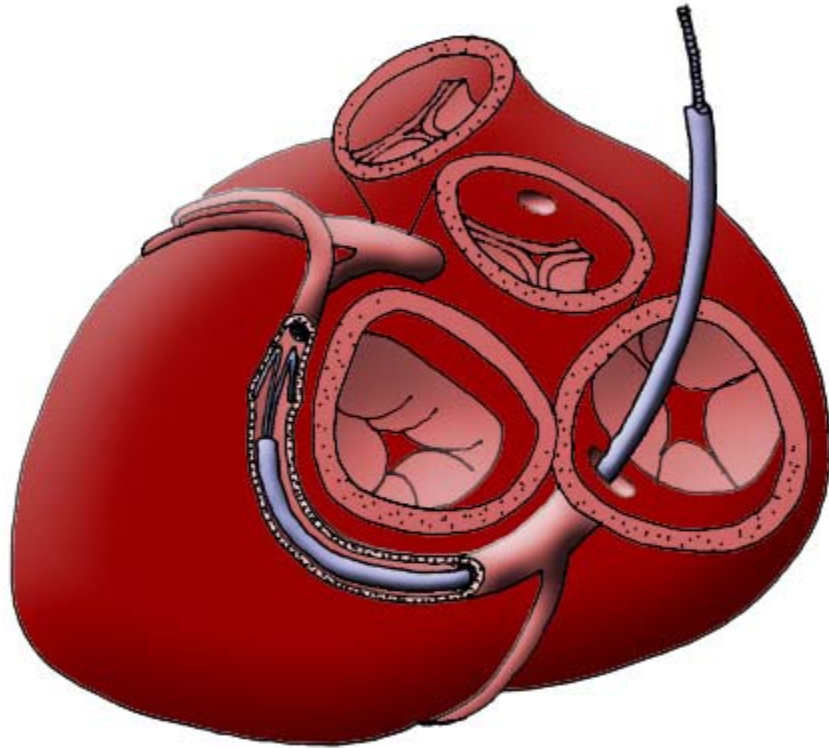
- **Leaflet repair**
 - EValve Mitraclip
 - Edwards Mobius stitch

- **Chamber + annular remodeling**
 - Myocor iCoapsys
 - Ample PS3

Percutaneous Mitral Valve Therapies

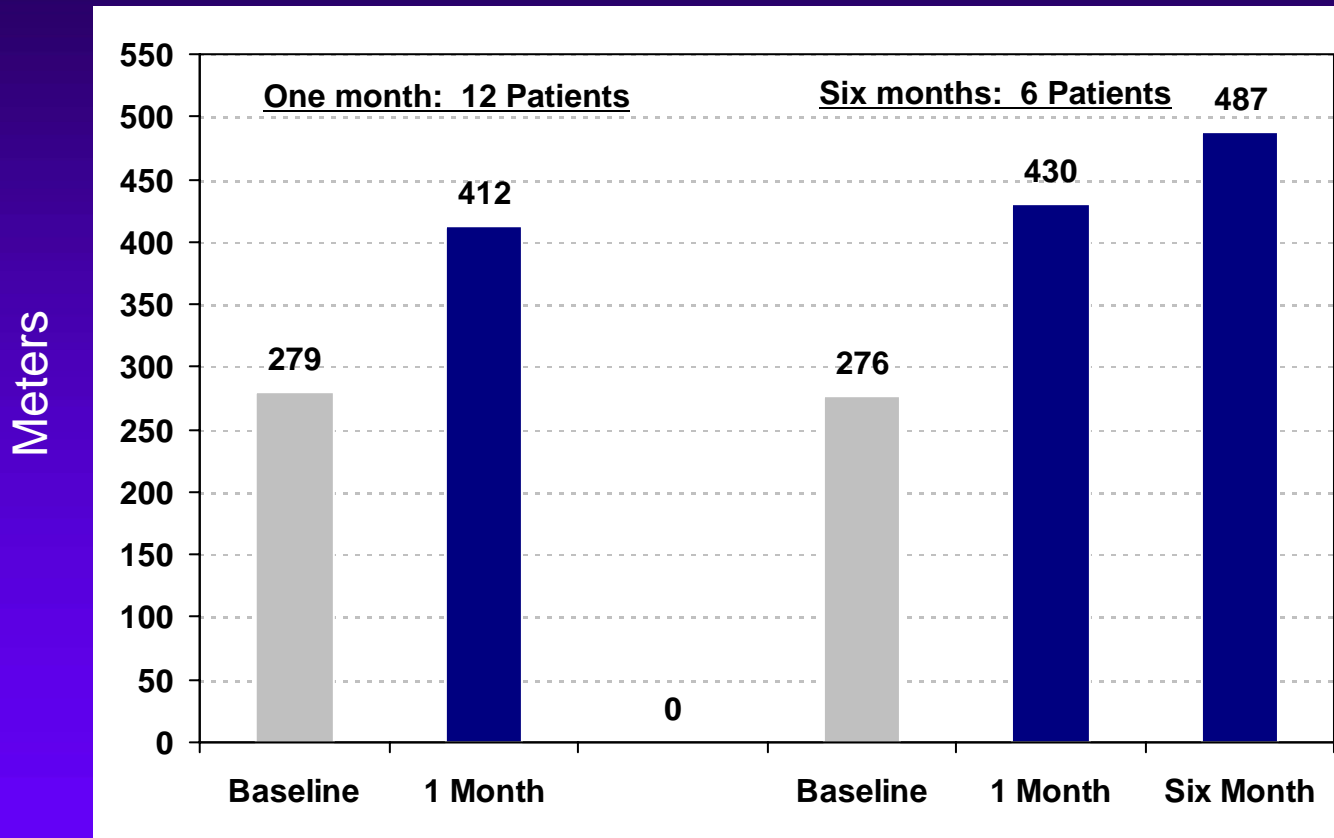


CARILLON Mitral Contour System



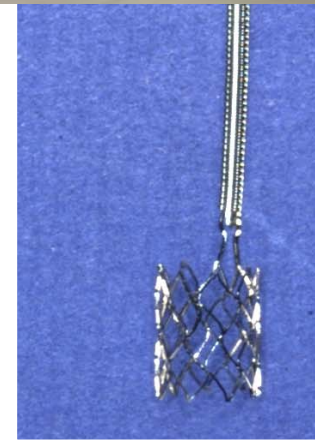
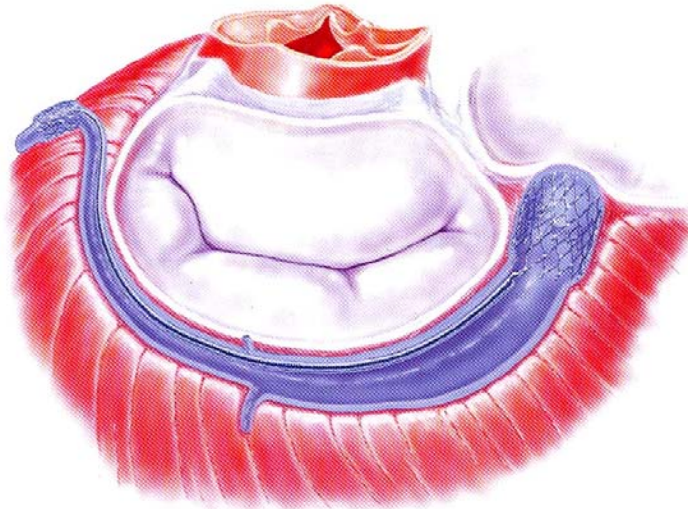
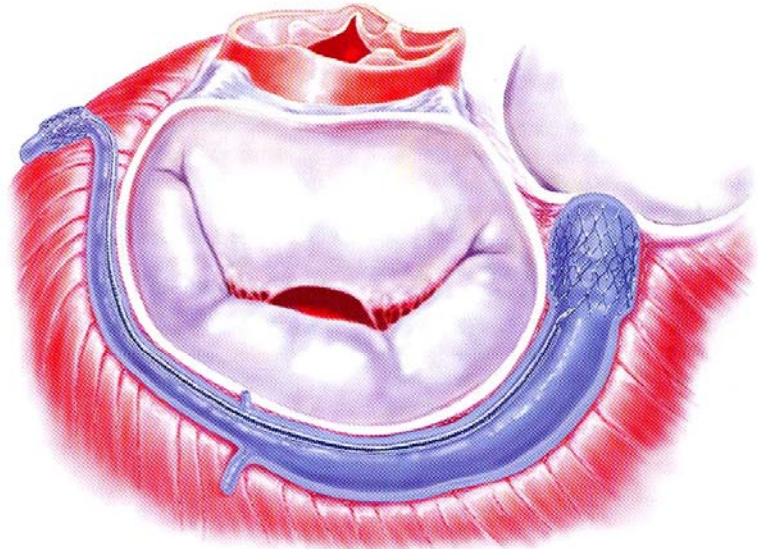
Average Exercise Improvement CARILLON Implants

Six Minute Walk Test

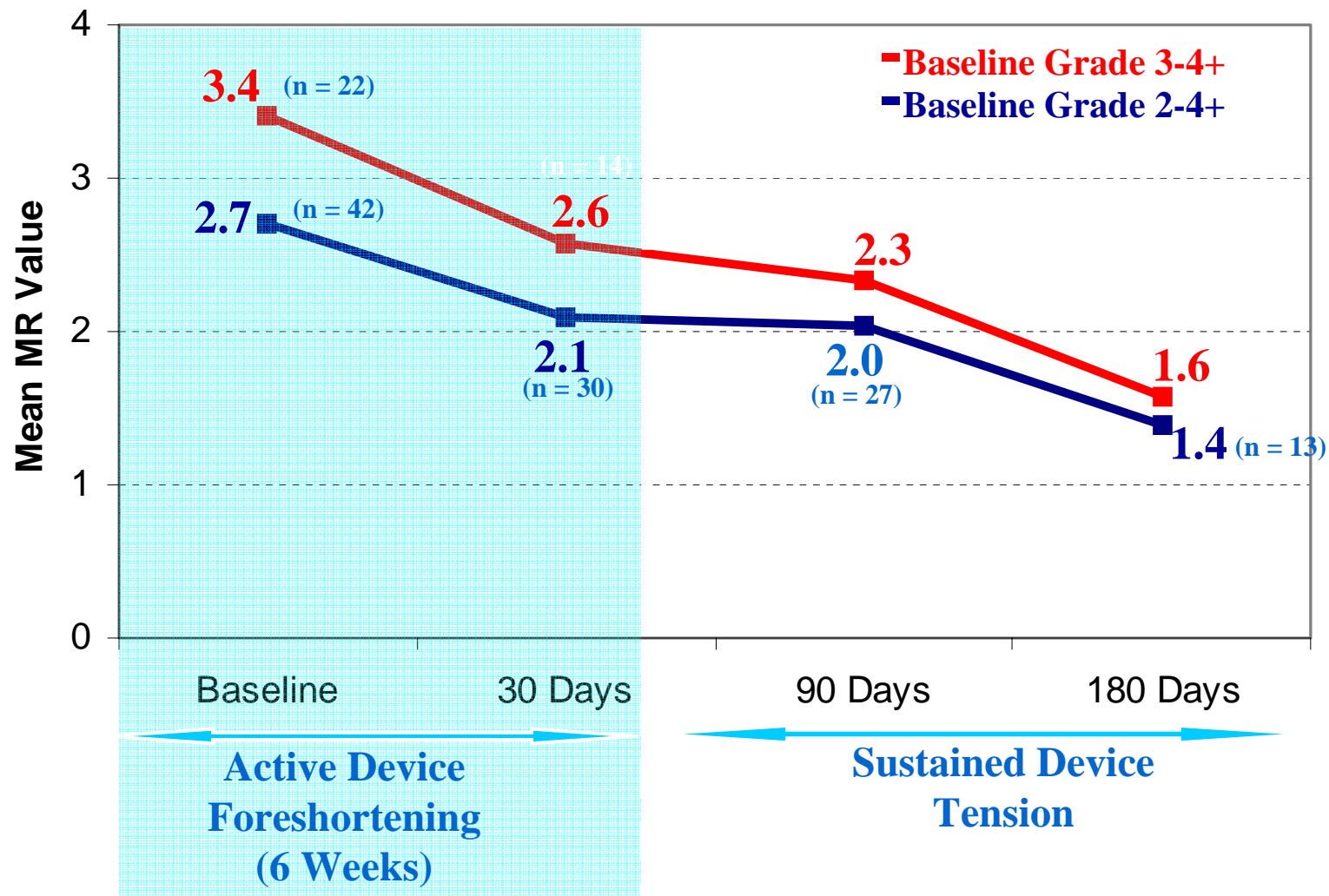


Average improvement: 1 month (n=12) 133 meters or 48%
6 months (n=6) 211 meters or 77%

The MONARC system Delayed Release-*in situ*

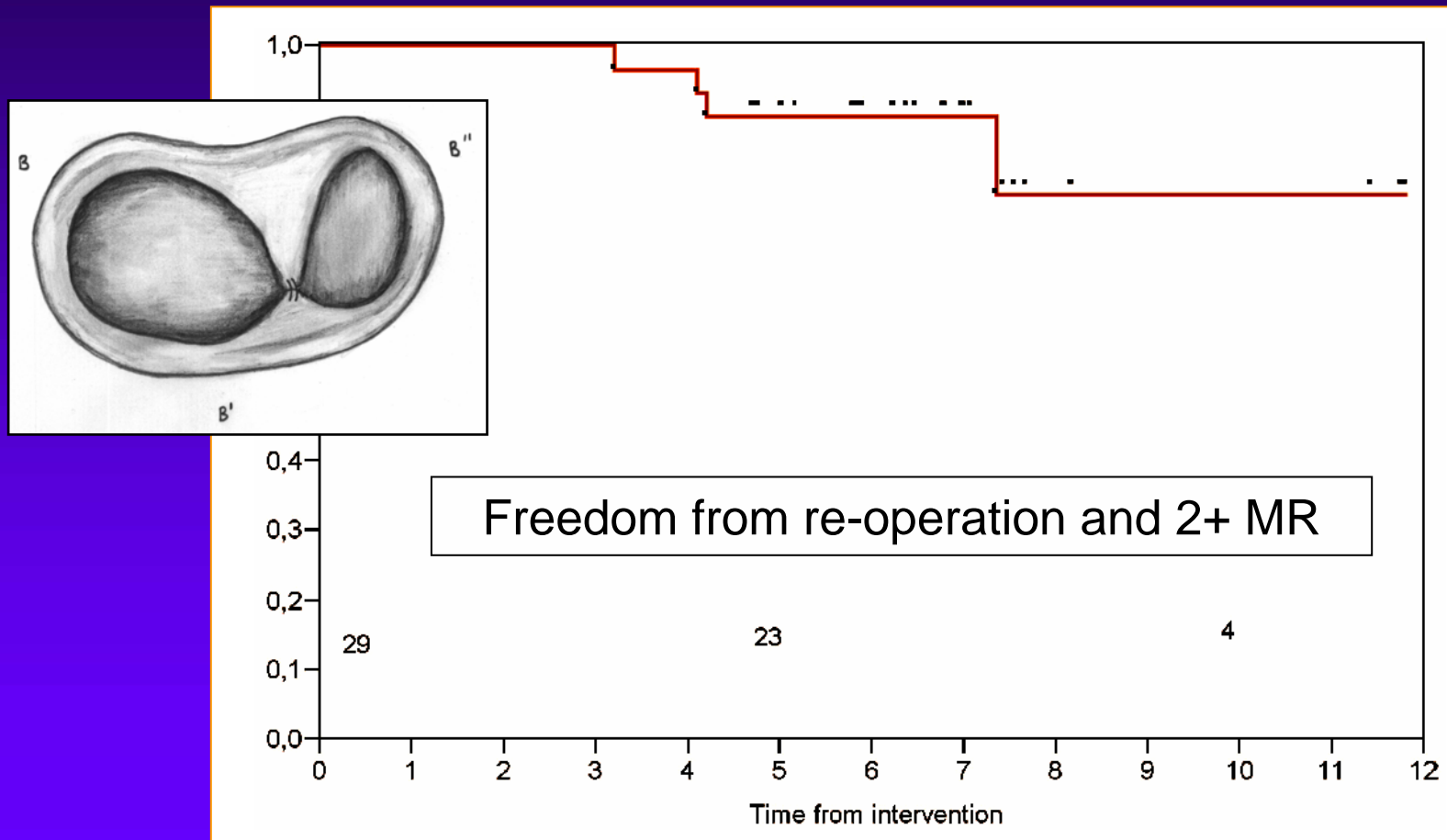


EVOLUTION study interim performance data



Surgical isolated edge-to-edge mitral repair without annuloplasty

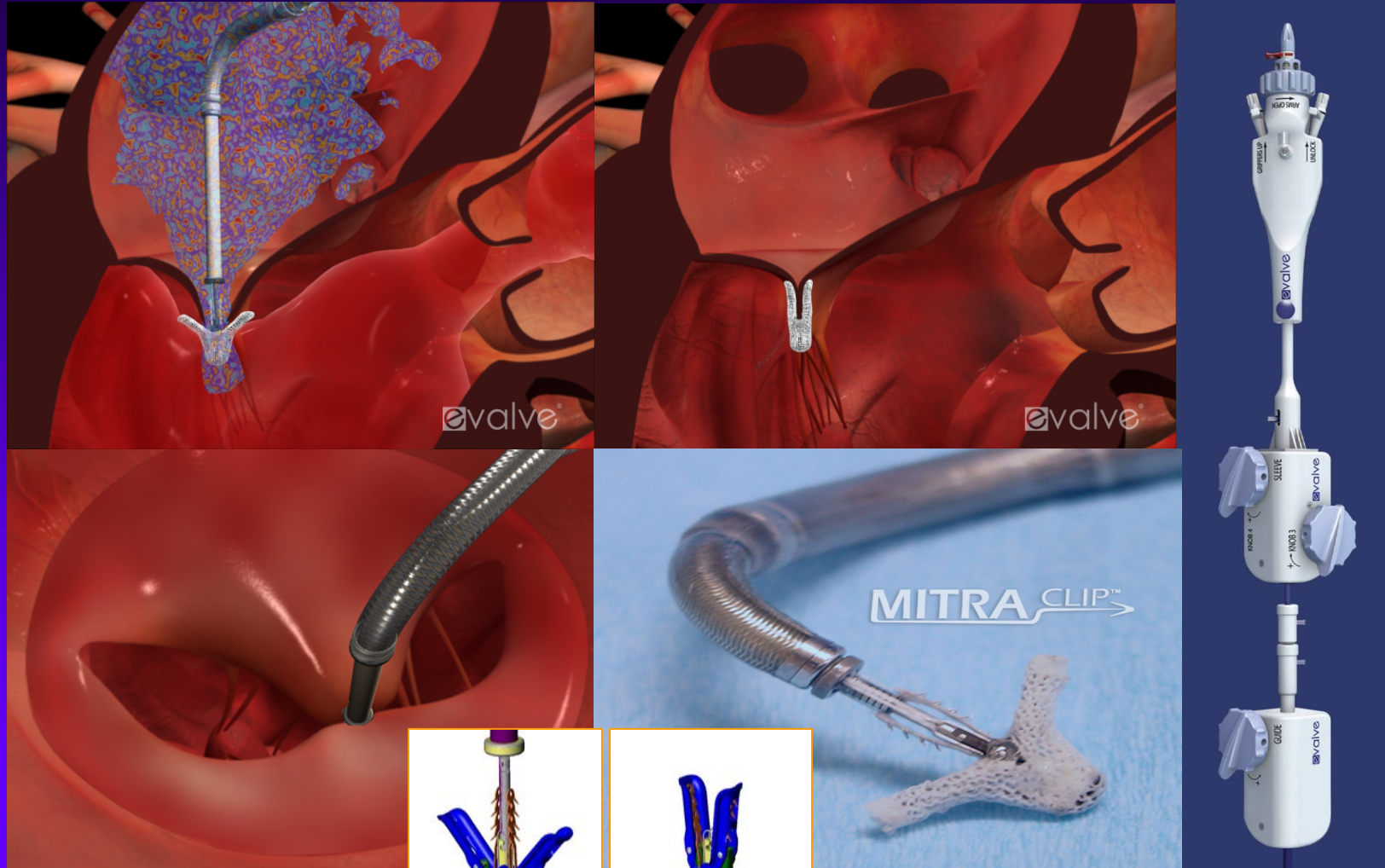
clinical proof of principle for an endovascular approach



Maisano F, Vigano G, Blasio A, Columbo A, Calabrese C, Alfieri O

Eurointervention 2:181-186, 2006

Percutaneous Mitral Repair



Caution: Investigational

Not for Sale (US) Law to Investigational Use

Key Eligibility Criteria

- Age 18 years or older
- Moderate to severe (3+) or severe (4+) MR
 - *Symptomatic*
 - *Asymptomatic with LVEF <60% or LVESD >45mm*
ACC/AHA Task Force Guidelines JACC 1998;32:1486
- MR originates from A2-P2 mal-coaptation
- Core lab echo assessment
ASE Guideline - JASE 2003;16:777-802
- Candidate for mitral valve surgery including CPB
- Transseptal deemed feasible
- Key Exclusions
 - *EF < 25% or LVESD > 55 mm*
 - *Renal insufficiency*
 - *Endocarditis, rheumatic heart disease*

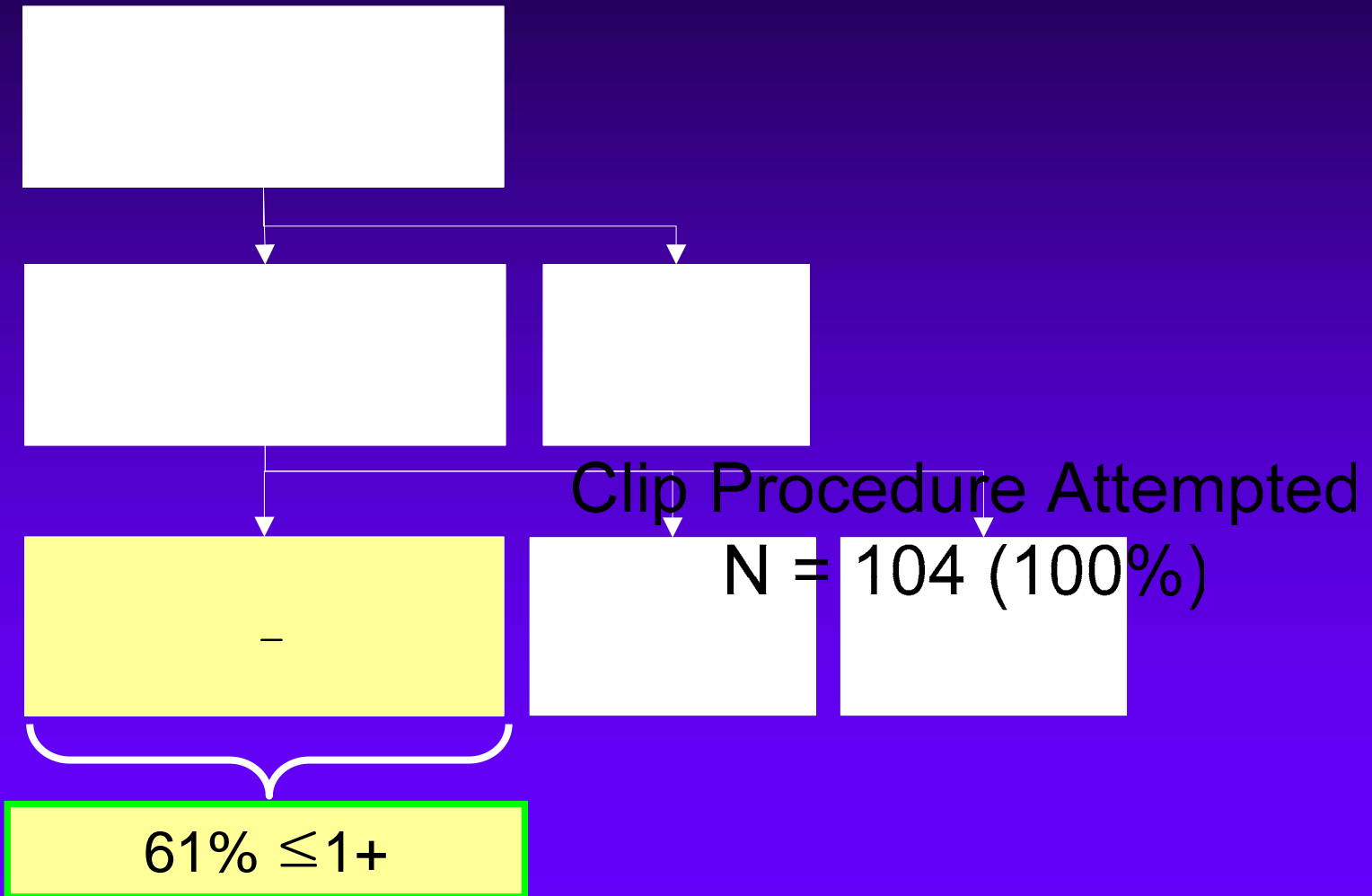
Clinical Features

(N = 104)

	EVEREST Registry	STS Database 2002	
		Repair	Replacement
Median Age (range)	71 (26 – 88)	59	64
≥ age 65	61 %	37%	48%
Male gender	63 %	58%	41%
Diabetes mellitus	19 %	9%	15%
Hypertension	68 %	47%	53%
COPD	11 %	13%	21%
History CHF	50 %	40%	56%
Atrial Fibrillation	38 %	n/a	n/a
Median EF	63 %	55%	55%
NYHA III or IV	45 %	43%	60%

Procedural Results

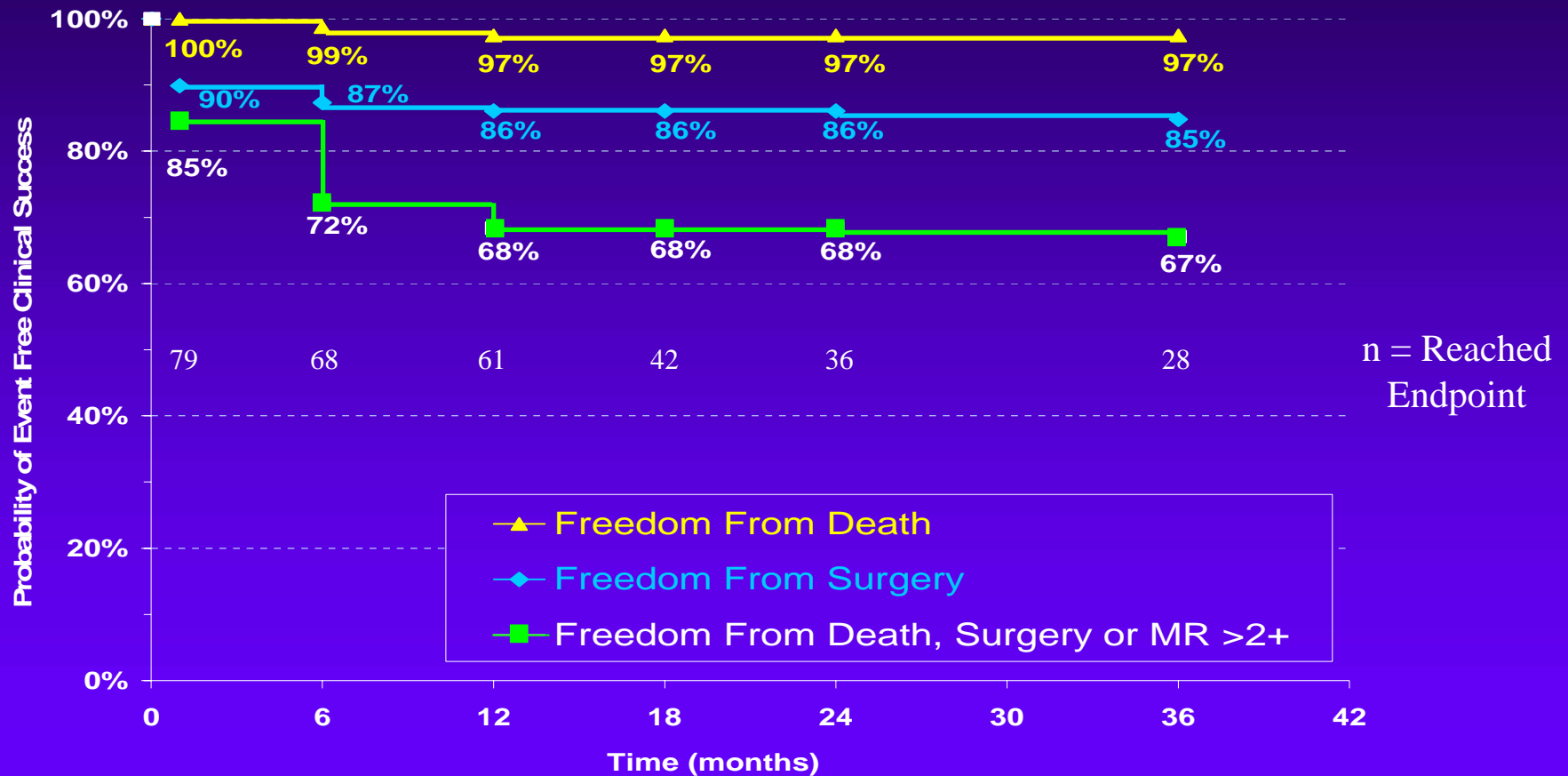
(N = 104)



Event Free Clinical Success Kaplan-Meier

Patients with Acute Procedural Success

n = 79



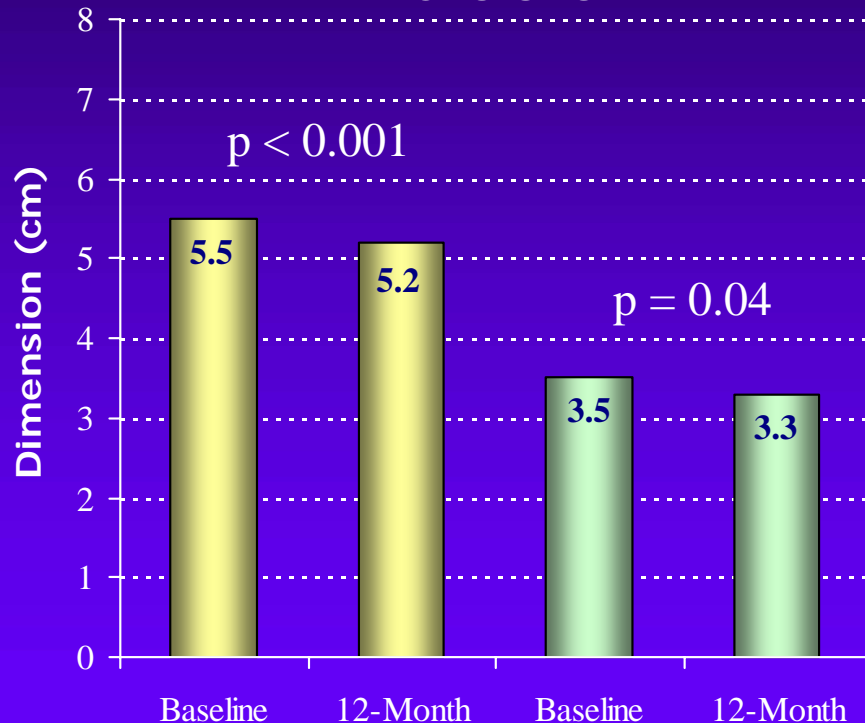
Freedom from death, mitral valve surgery, & MR>2

Reverse LV Remodeling

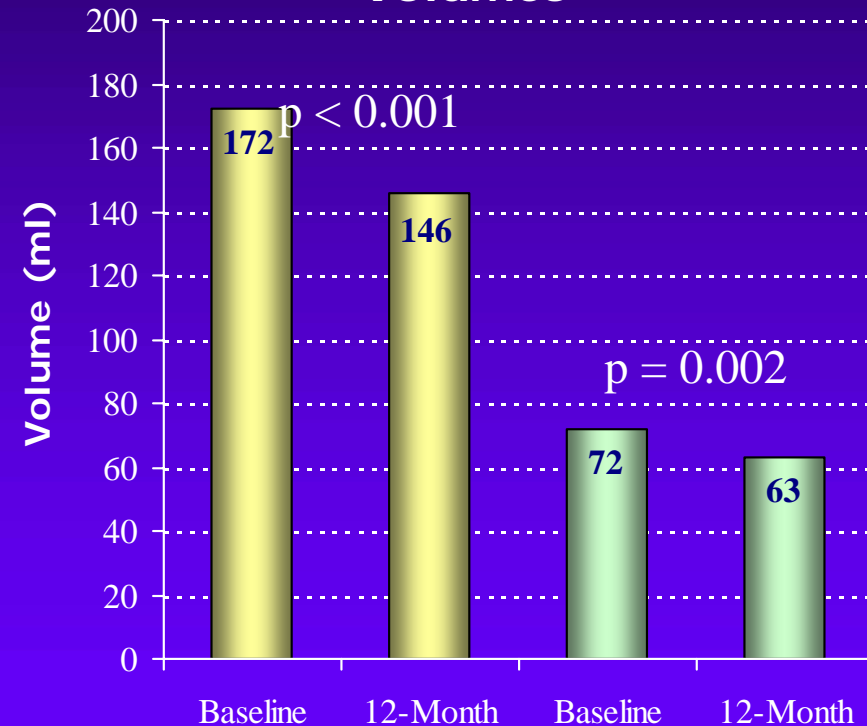
Matched Data, Acute Procedural Success Patients

n = 46

LV End Diastolic & Systolic Dimensions



LV End Diastolic & Systolic Volumes



■ Diastolic ■ Systolic

Surgery Following Clip Procedure

(N = 104)

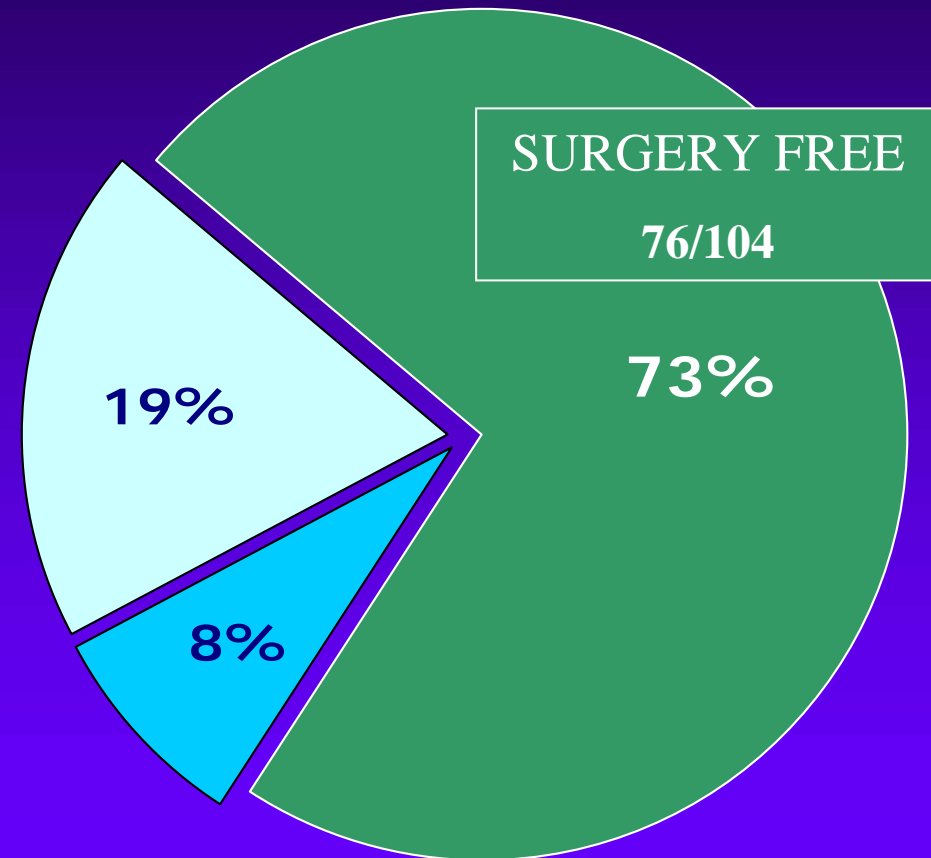
Surgery After Clip Implanted (n = 20)

- 15 (75%) Repairs (0 - 562 days)
- 5 (25%) Replacements

71% Repaired

Surgery After No Clip (n = 8)

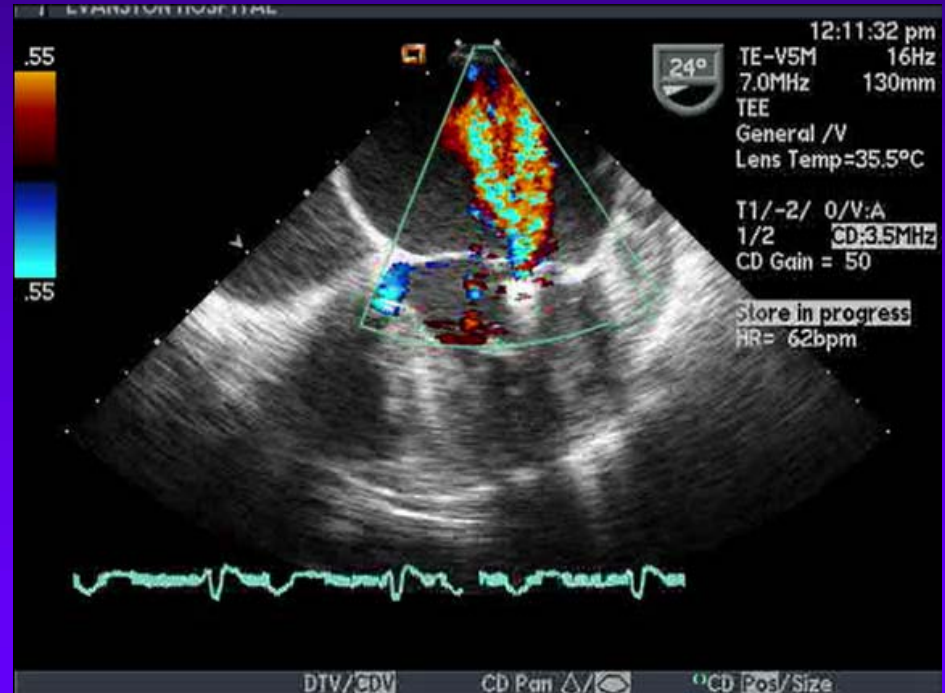
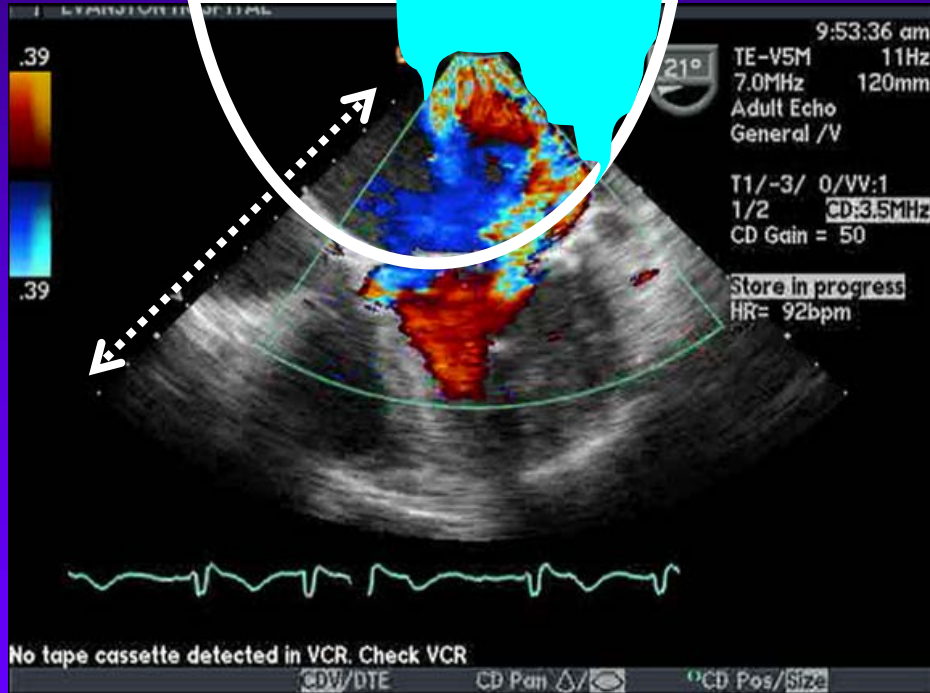
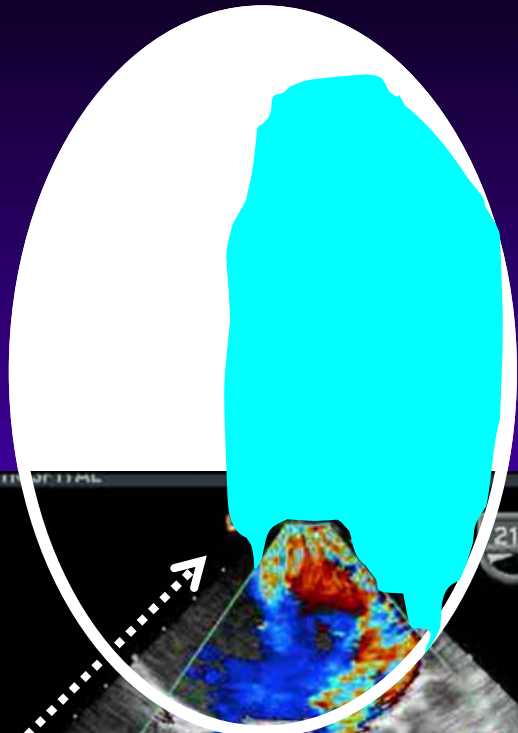
- 5 (63%) Repairs
- 3 (37%) Replacements





EVEREST II Study Design

- Prospective, randomized, multi-center study
 - Control: surgical mitral valve repair or replacement
 - Patients randomized 2:1
- Primary Effectiveness Endpoint: non-inferiority
 - Freedom from surgery for Valve Dysfunction, death, and moderate to severe (3+) or severe (4+) mitral regurgitation at 12 months
- Primary Safety Endpoint: superiority
 - Freedom from MAE at one month



High Risk :Inclusion Criteria

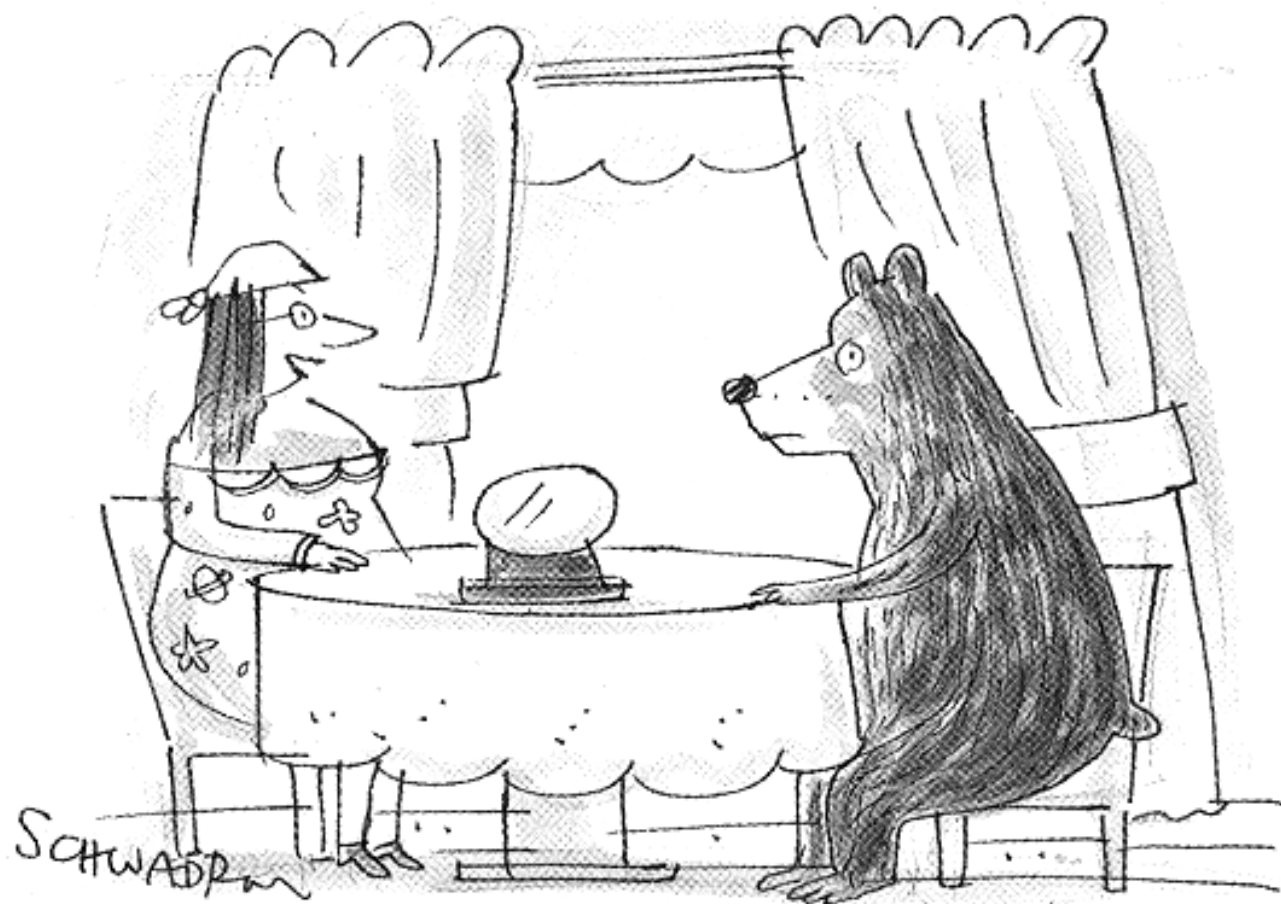
- STS surgical risk calculator $\geq 12\%$
- *or* judgment of surgeon investigator the patient is considered high risk due to one of the following:
 - Porcelain aorta or mobile ascending aortic aneurysm
 - Post-radiation mediastinum
 - Previous mediastinitis
 - Functional MR with EF<40
 - Over 75 years old with EF<40
 - Re-operation with patent grafts
 - Two or more prior chest surgeries
 - Hepatic cirrhosis
 - Three or more of the following STS high risk factors:
 - Creatinine > 2.5 mg/dL
 - Prior chest surgery
 - Age over 75
 - EF<35

EVEREST I & II Enrollment

(4/23/07)

Enrollment	Population	n
EVEREST I Feasibility (completed)	Registry patients	55
EVEREST II	Roll-in	50
Randomized n=97	Randomized Clip	65
	Randomized Surgery	32
EVEREST II	High Risk Registry	6
Total enrolled		208

- 30 sites



*“You will spend many years in a luxurious mansion
sprawled in front of a warm fireplace.”*