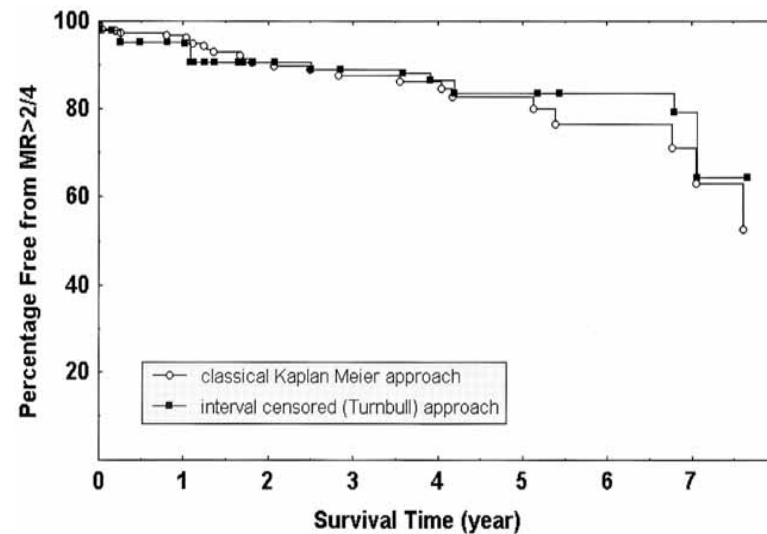
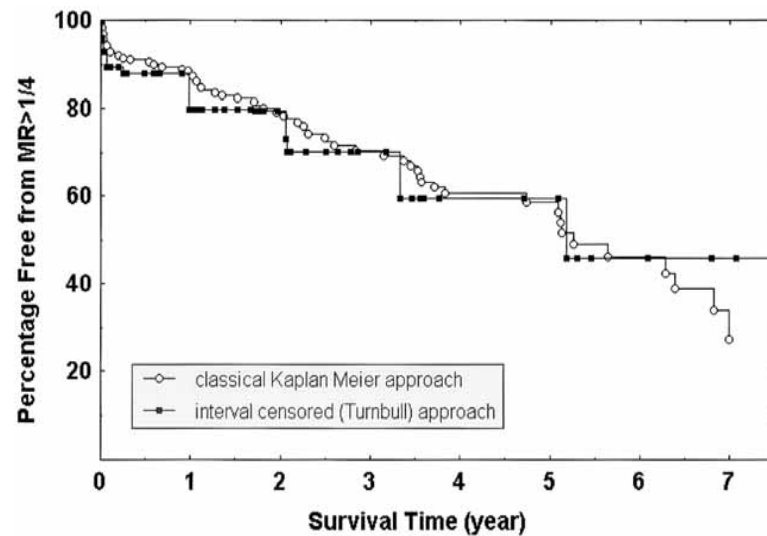


Edge-to Edge Mitral Repair with the Evalve Mitra-clip **EVEREST TRIAL UPDATE**

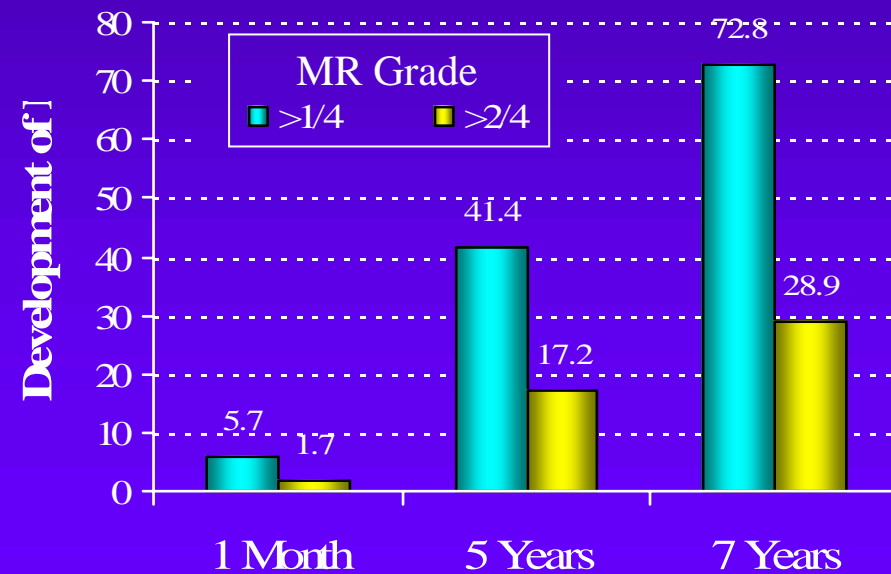
Ted Feldman MD, FACC, FSCAI

April 29th, 2005

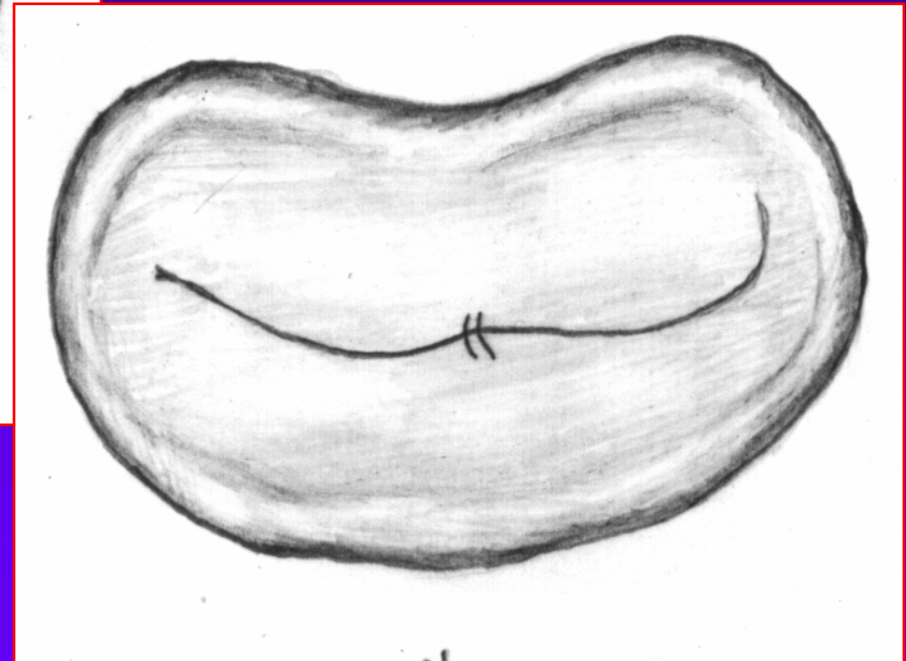
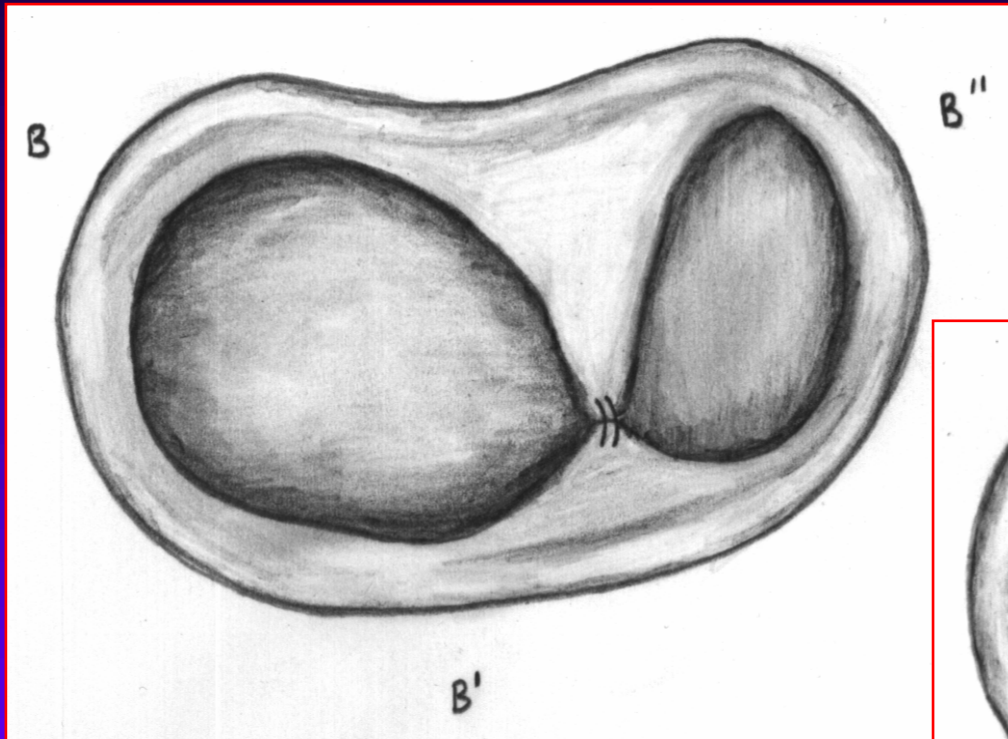
Recurrence of Mitral Valve Regurgitation After Mitral Valve Repair in Degenerative Valve Disease



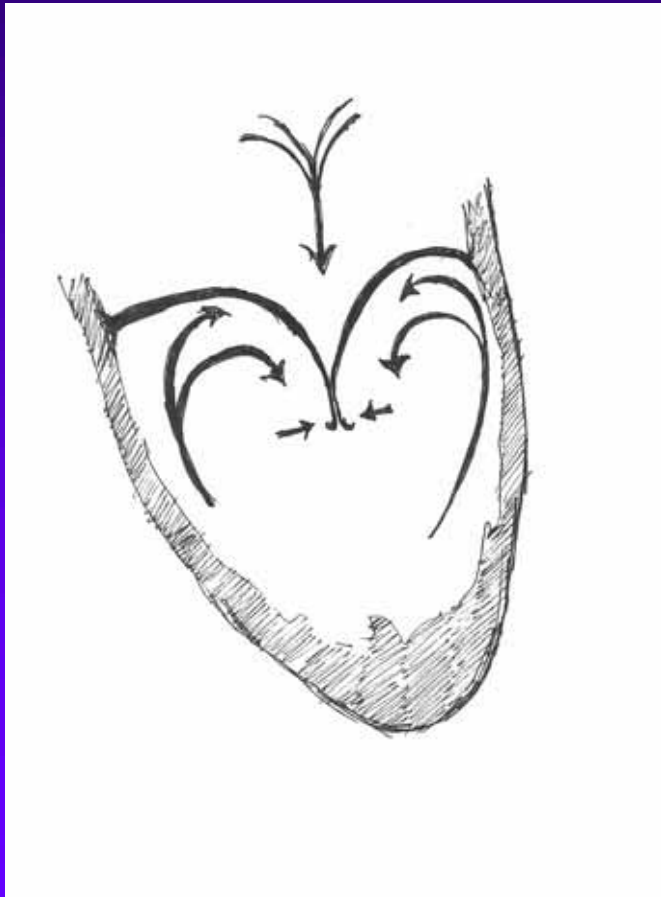
- n=242
- Degenerative MR
- 91% survival
- 94% freedom from re-operation
- Linearized recurrence rate
 - >1/4 8.3%/year
 - >2/4 3.7%/year



“Bow - Tie” Repair



Flow Dynamics Support the Edge-to-Edge Repair

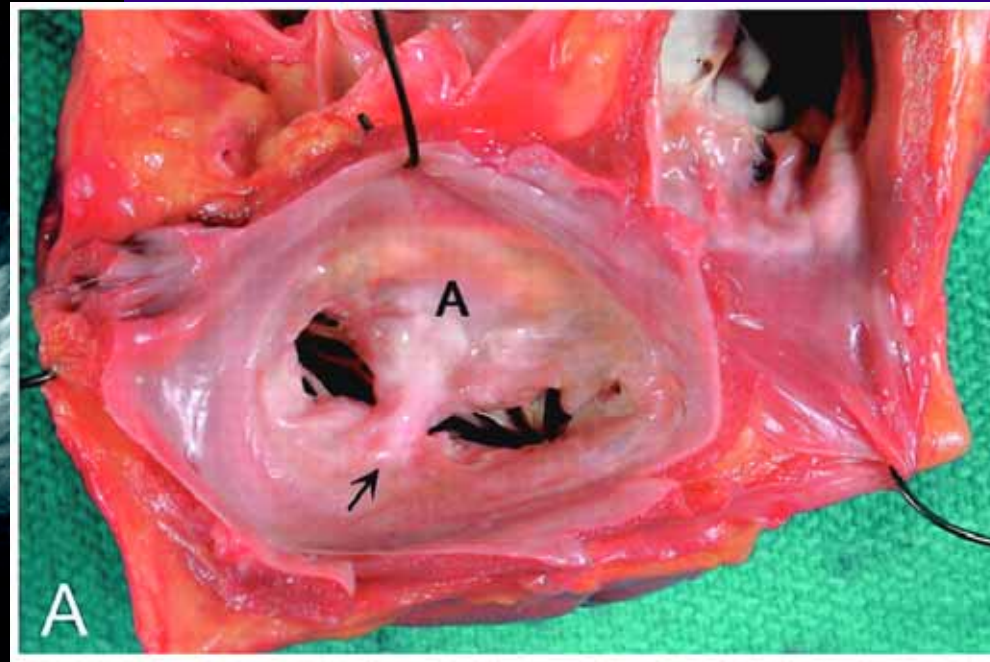
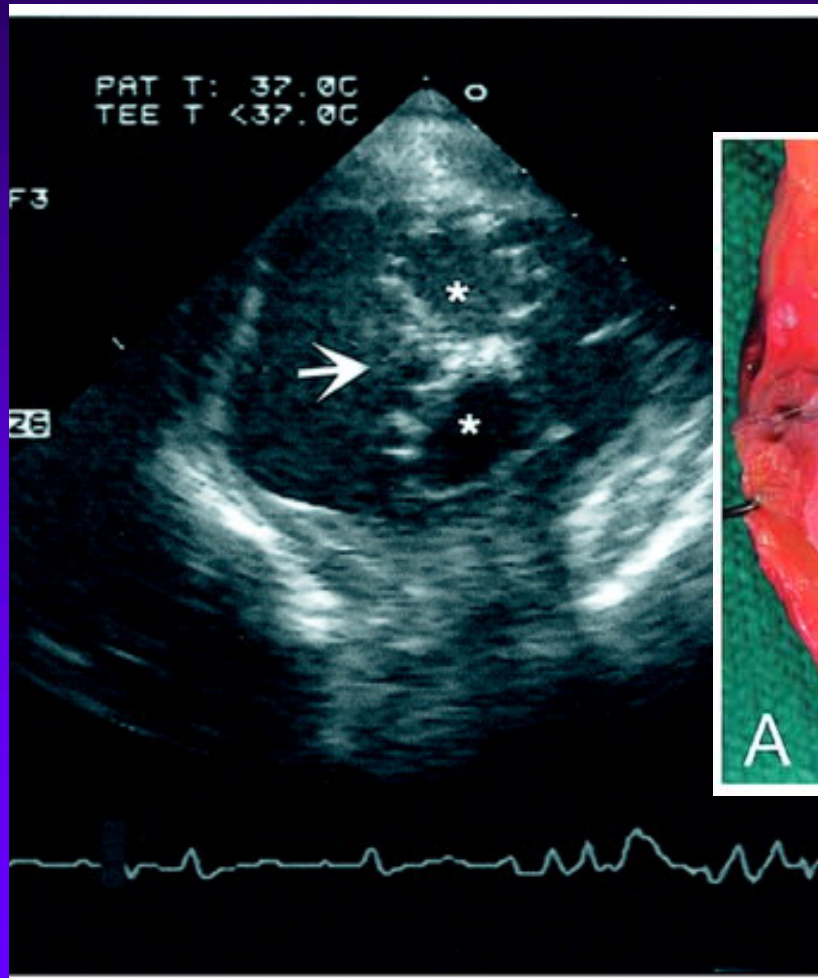


- Systolic flow occurs at high ventricular pressure and drives leaflets closed
- Diastolic flow occurs at low ventricular pressure and drives leaflets open
- Low stress at the E-2-E apposition point

Images in Cardiovascular Medicine

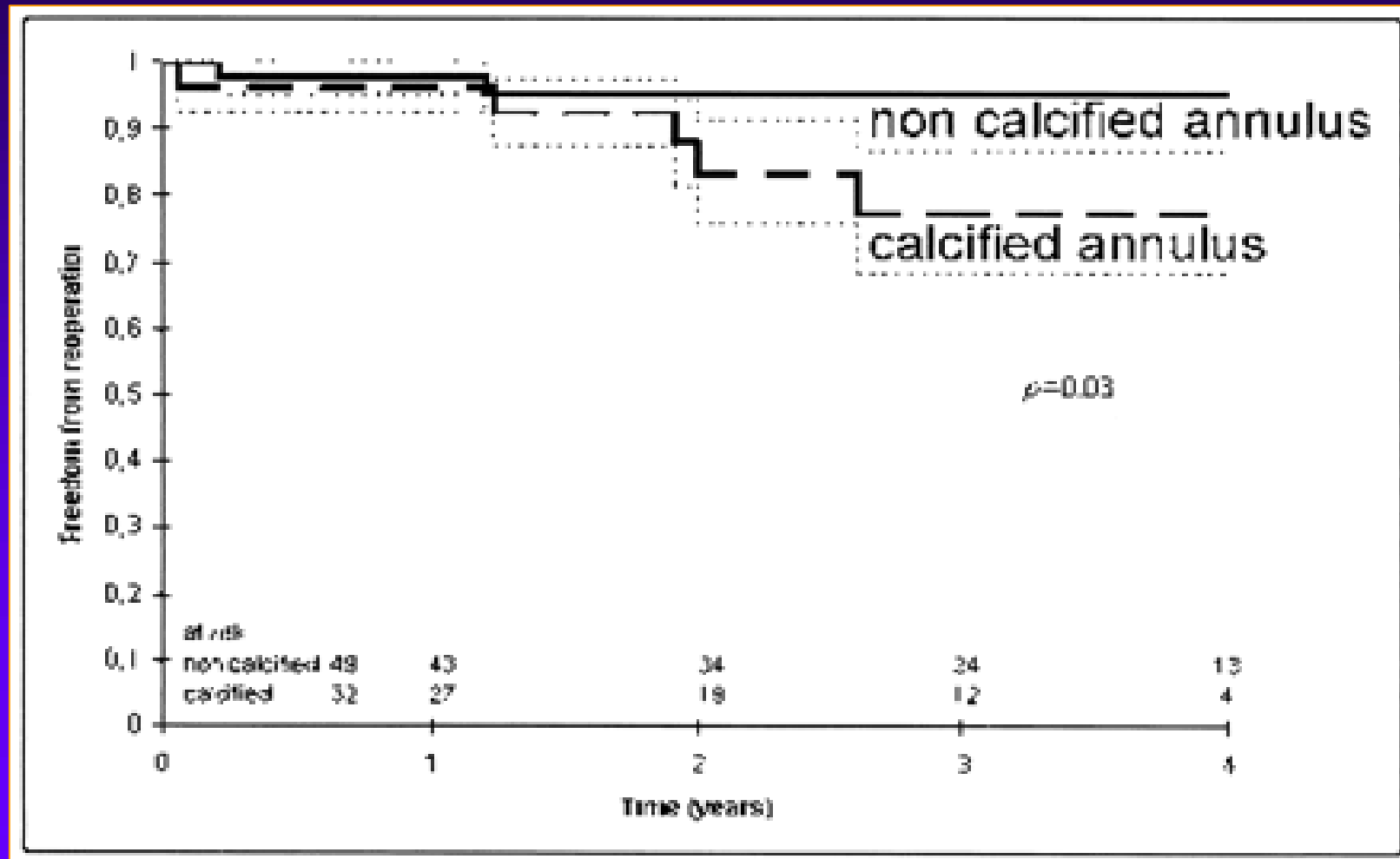
Alfieri Mitral Valve Repair

Clinical Outcome and Pathology



Double Orifice Technique

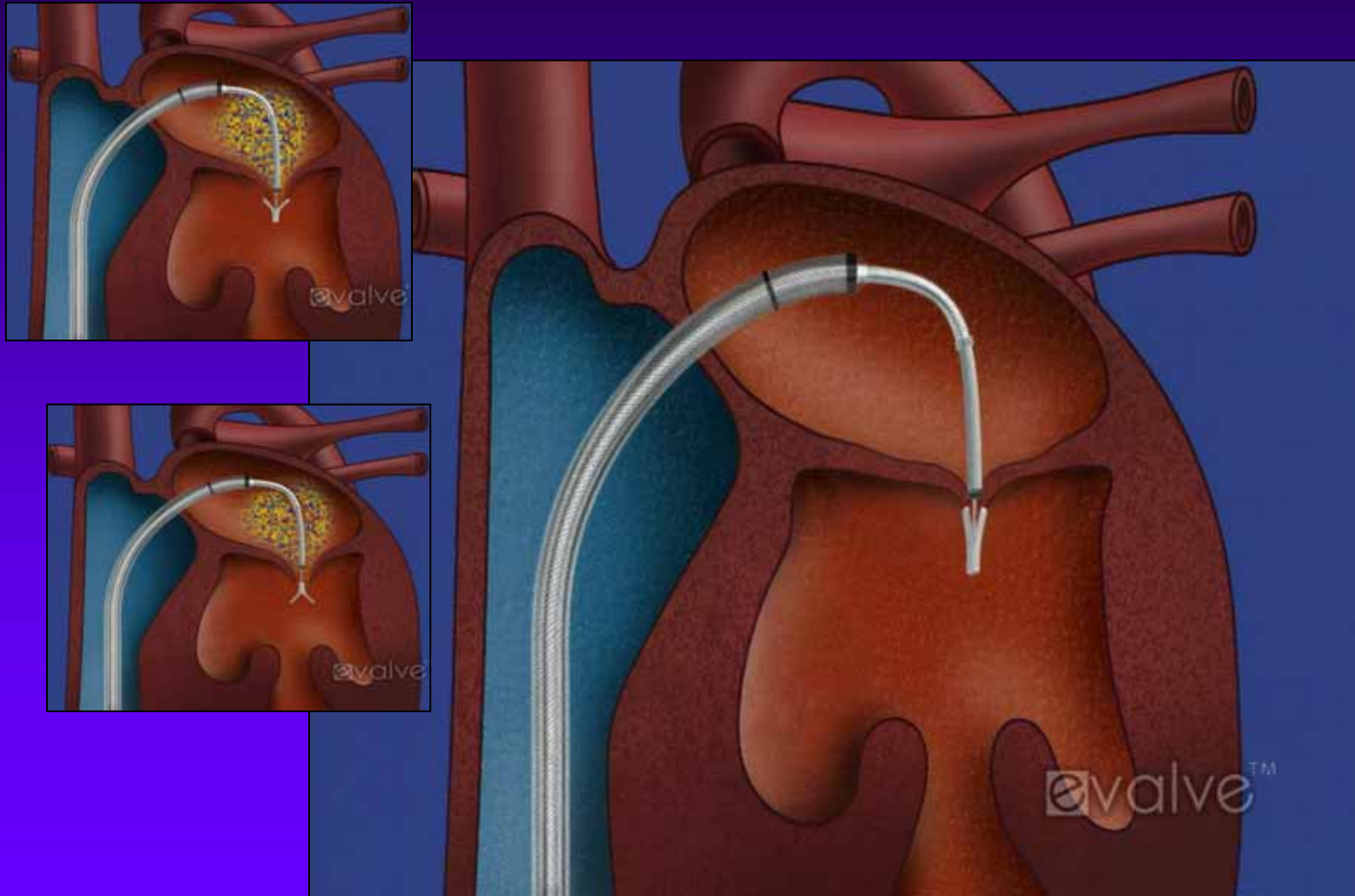
Without annuloplasty n=160

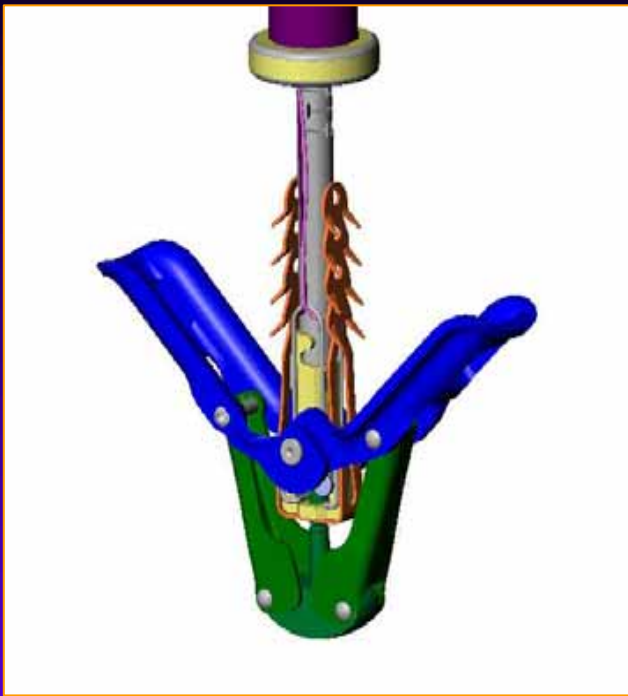


Apples Oranges

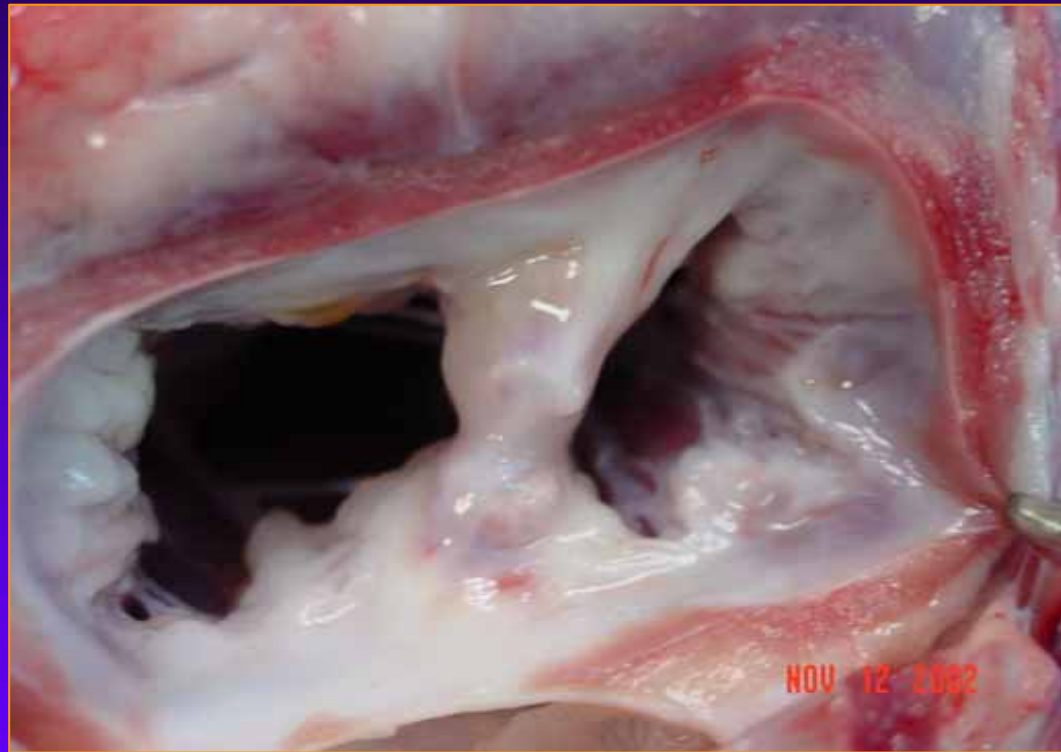


Endovascular CVRS for E2E Repair (Cardiovascular Valve Repair System)





Off-pump Edge-to-Edge Mitral Valve Technique Using a Mechanical Clip in a Chronic Model



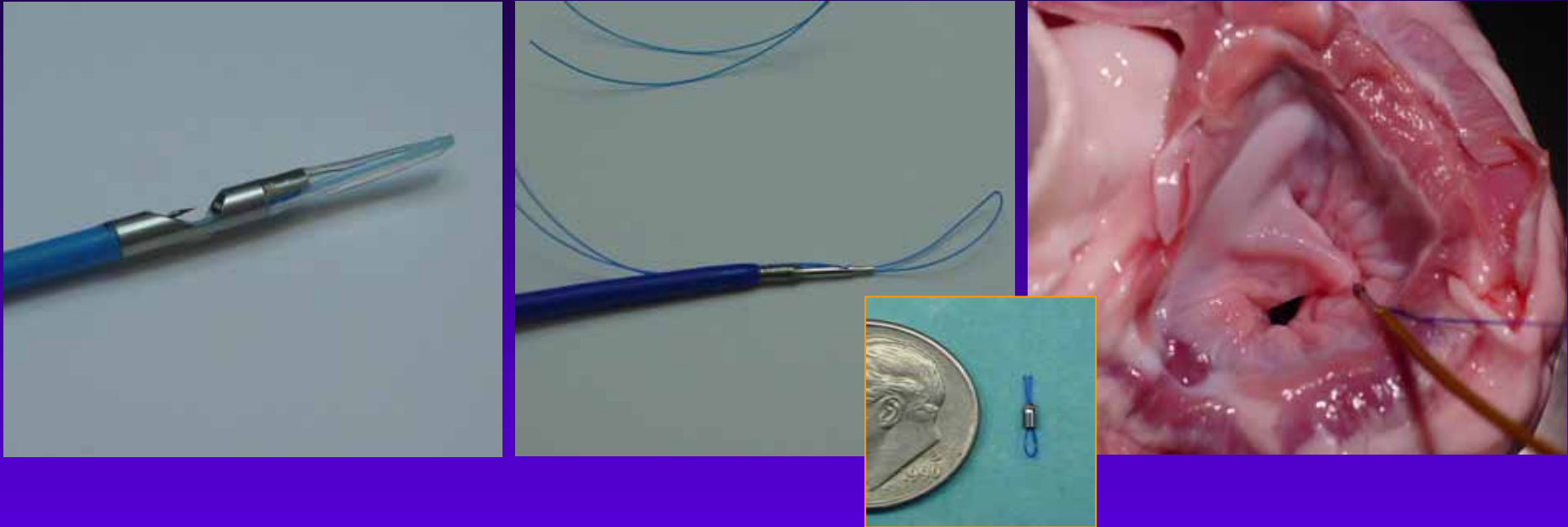
Clip repair in porcine heart (6 mos post repair)

Fann JJ, St Goar FG, Komtebedde J, Oz MC, Block PC, Foster E, Butany J, Feldman T, Burdon TA:

Beating heart catheter-based-edge-to-edge mitral valve procedure in a porcine model; efficacy and healing response.

Circulation 110:988-993, 2004

Edwards Delivery System

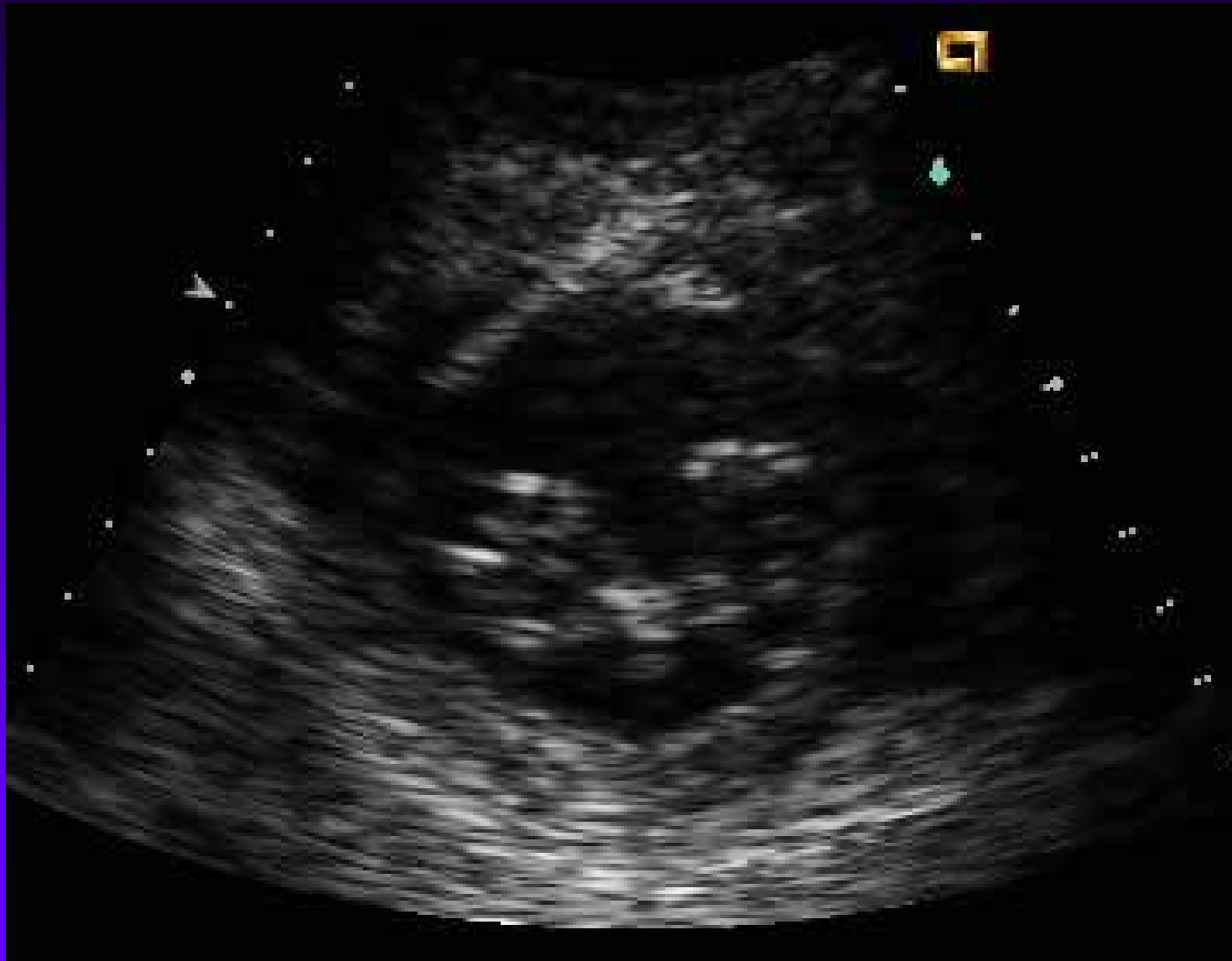


- Therapy catheter – 10F
- Percutaneous deflectable guide catheter

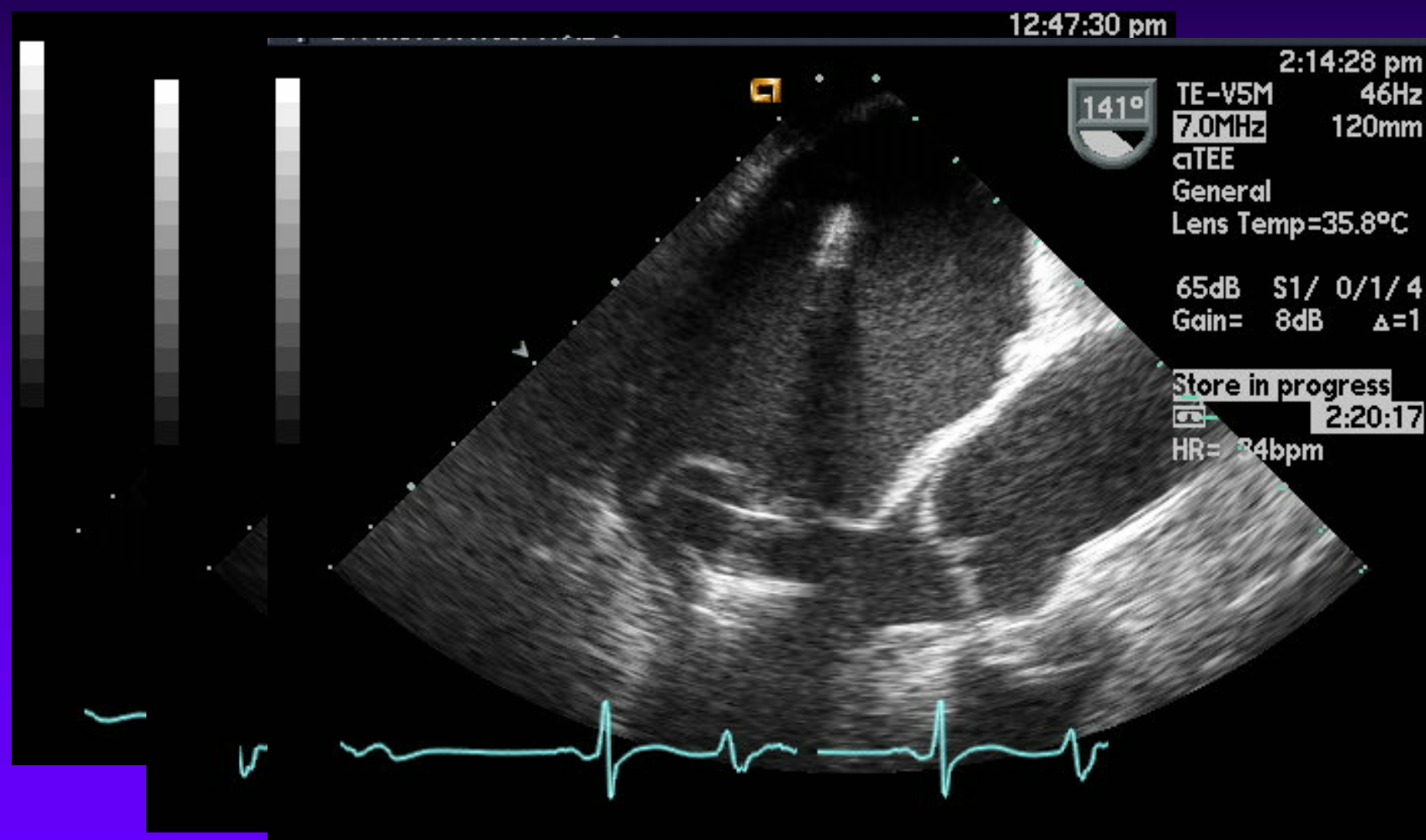
- Fastener catheter – 6F
 - Low profile
 - Flexible

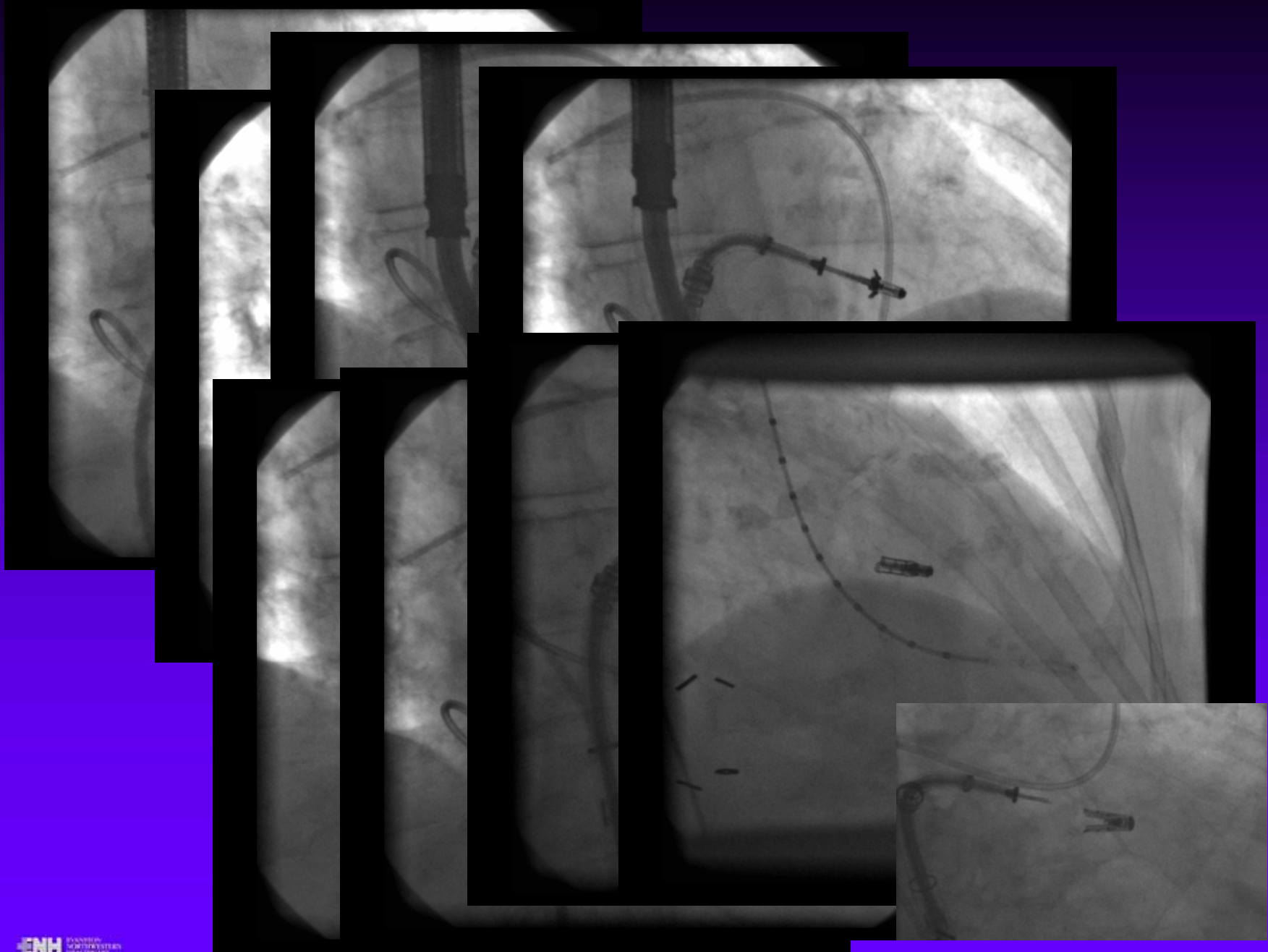
Moderate to Severe (3+) or Severe (4+) Mitral Regurgitation

- Symptomatic or
- Asymptomatic with
 - LVEF < 60% and/or LVESD 50-55, or
 - LVEF 50-60 and LVESD < 45 mm, or
 - LVEF >60 and LVESD 45-55



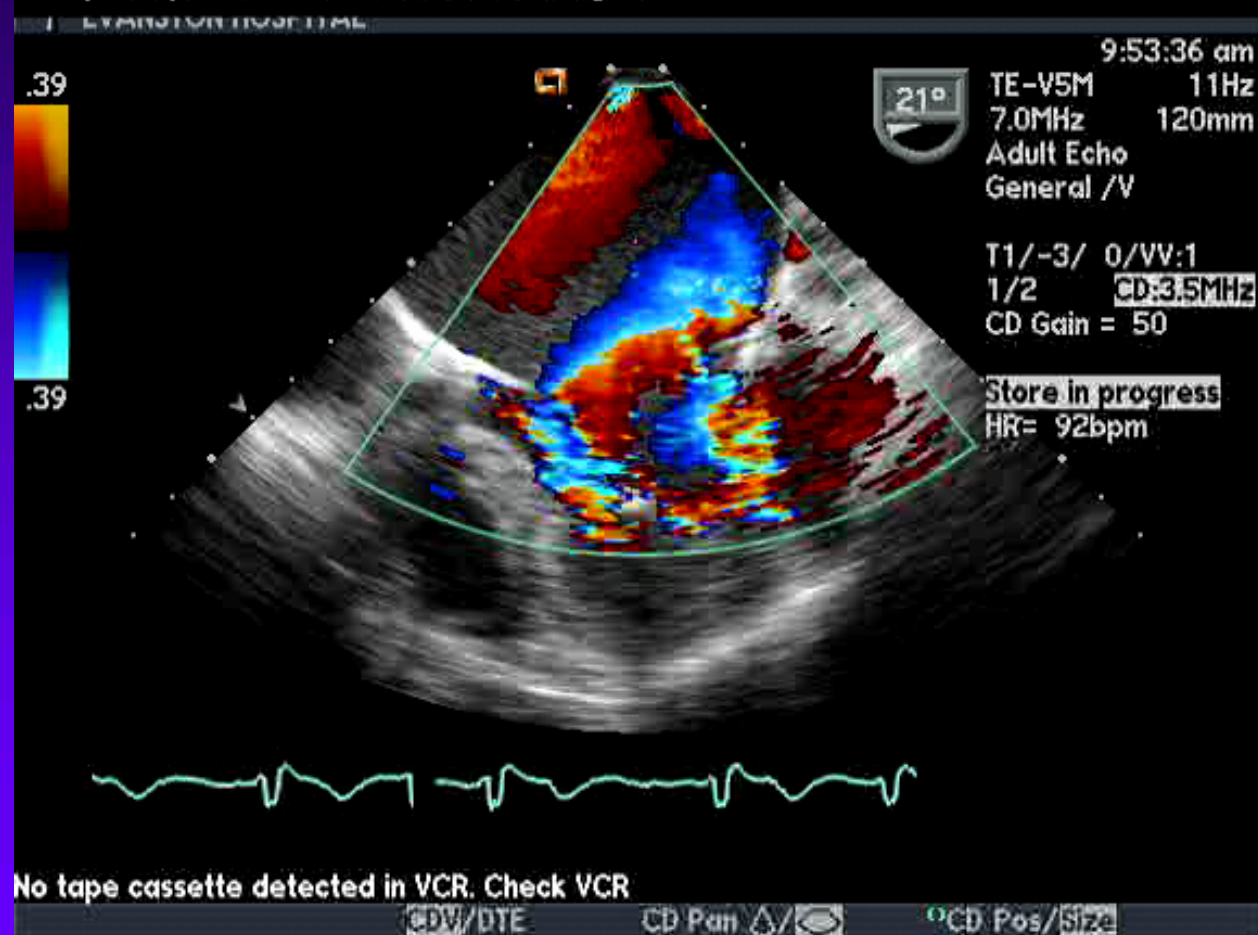
Intra-procedure echo guidance



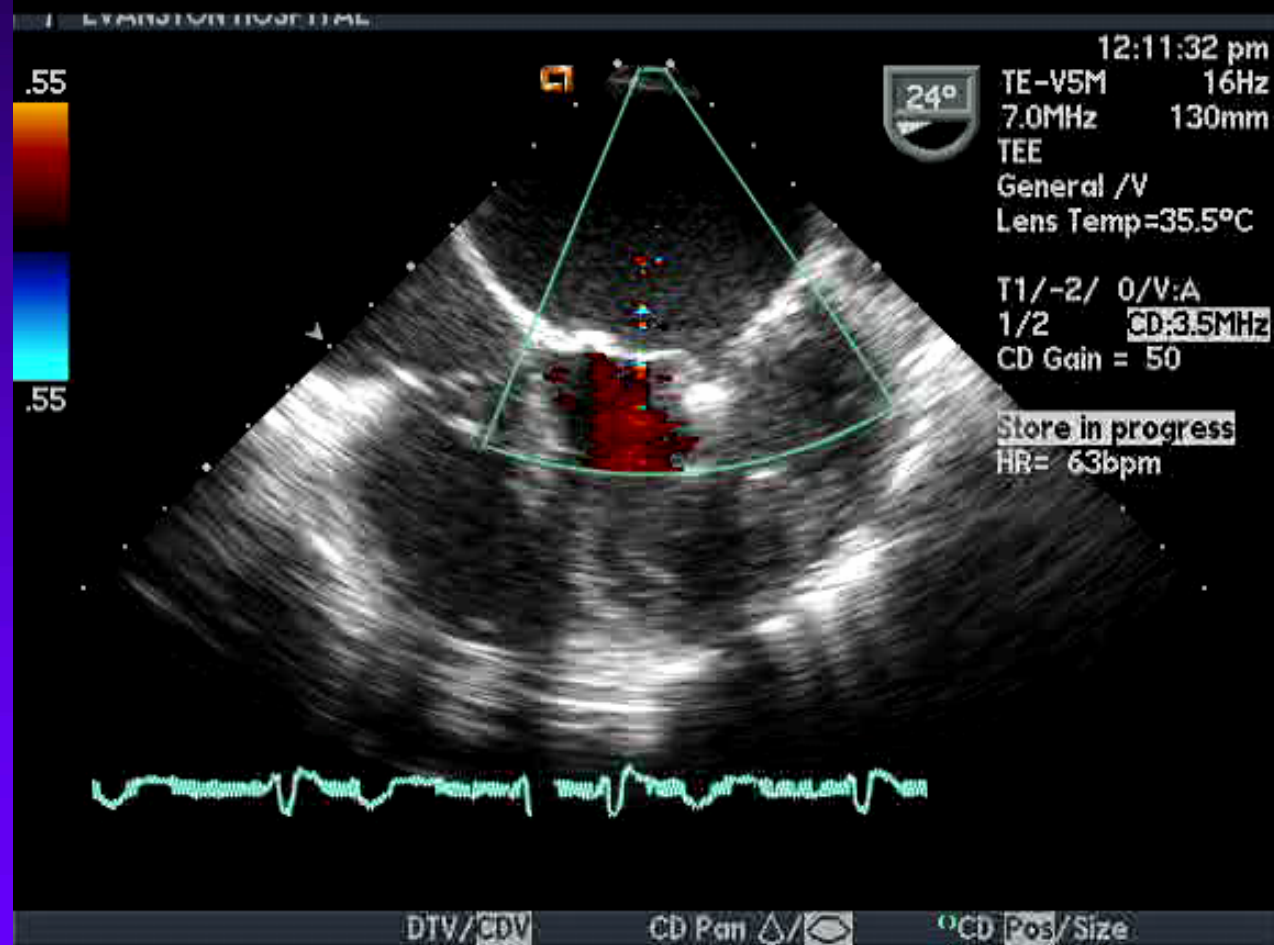


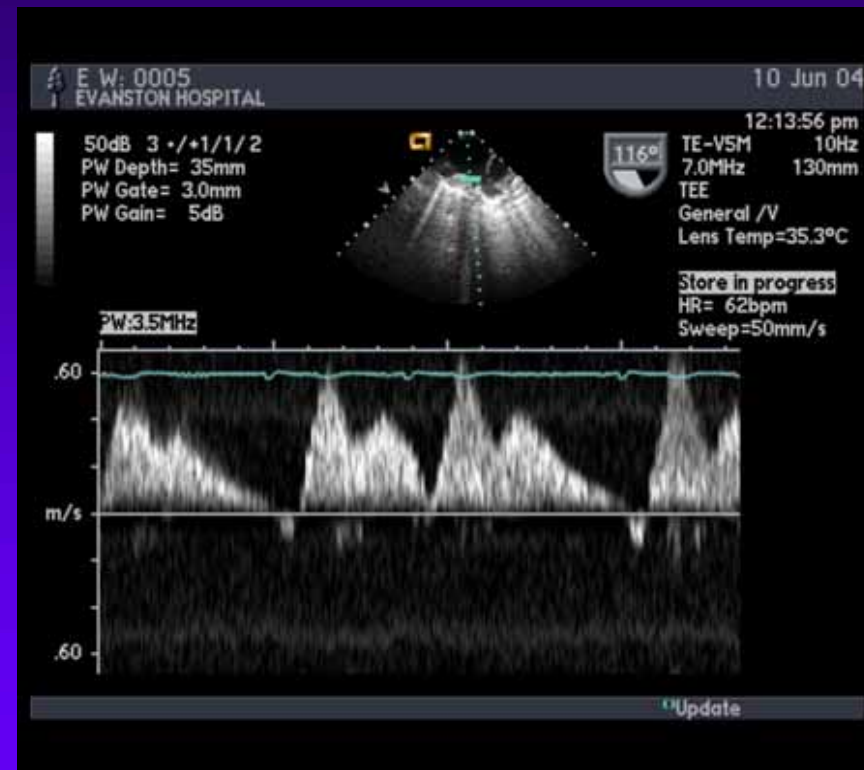


Lossy compression - not intended for diagnosis

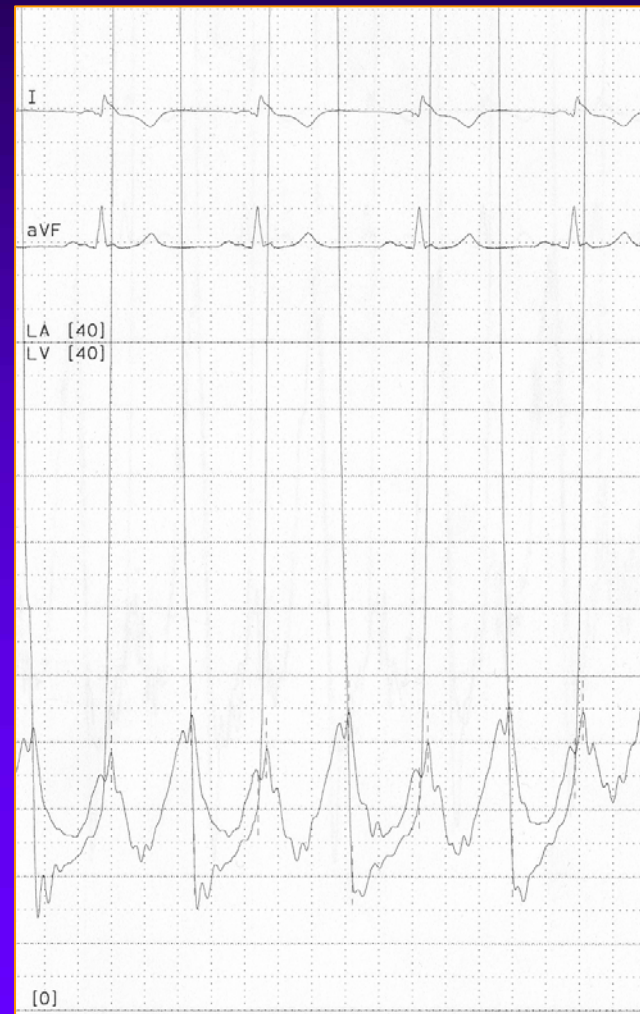
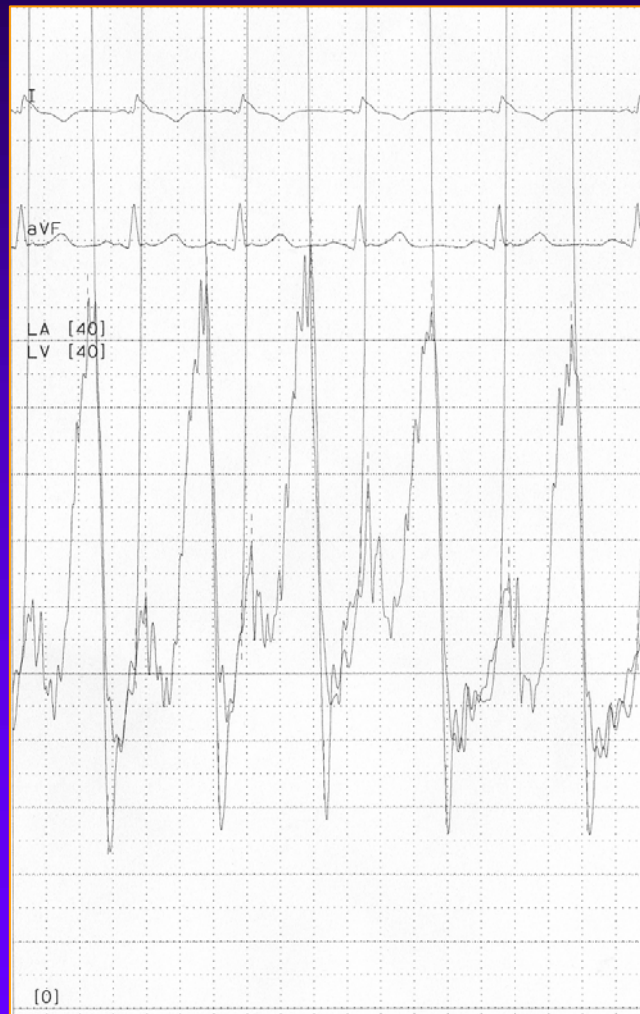


Lossy compression - not intended for diagnosis





Hemodynamic Results



Clinical Features

n = 27

Age (mean)	68.6 years
Male gender	59%
Diabetes mellitus	15%
Hypertension	63%
COPD	18%
History CHF	59%
Atrial Fibrillation	41%
NYHA III/IV	44%

MR Etiology

n=27

Degenerative	25 (93%)
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P2 Prolapse/Flail	14 (56%)
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Bi-leaflet Prolapse/Flail	10 (40%)
---------------------------	----------

A2 Prolapse/Flail	1 (4%)
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Ischemic	2 (7%)
----------	--------

Primary Endpoint

30 Day Major Adverse Events

n= 27

FREEDOM FROM 30-DAY MAE

85%

Death

0

Permanent Stroke

1

Cardiac Surgery for failed clip

0

Partial Clip Detachment

3

Clip Embolization

0

Myocardial Infarction

0

Cardiac Tamponade

0

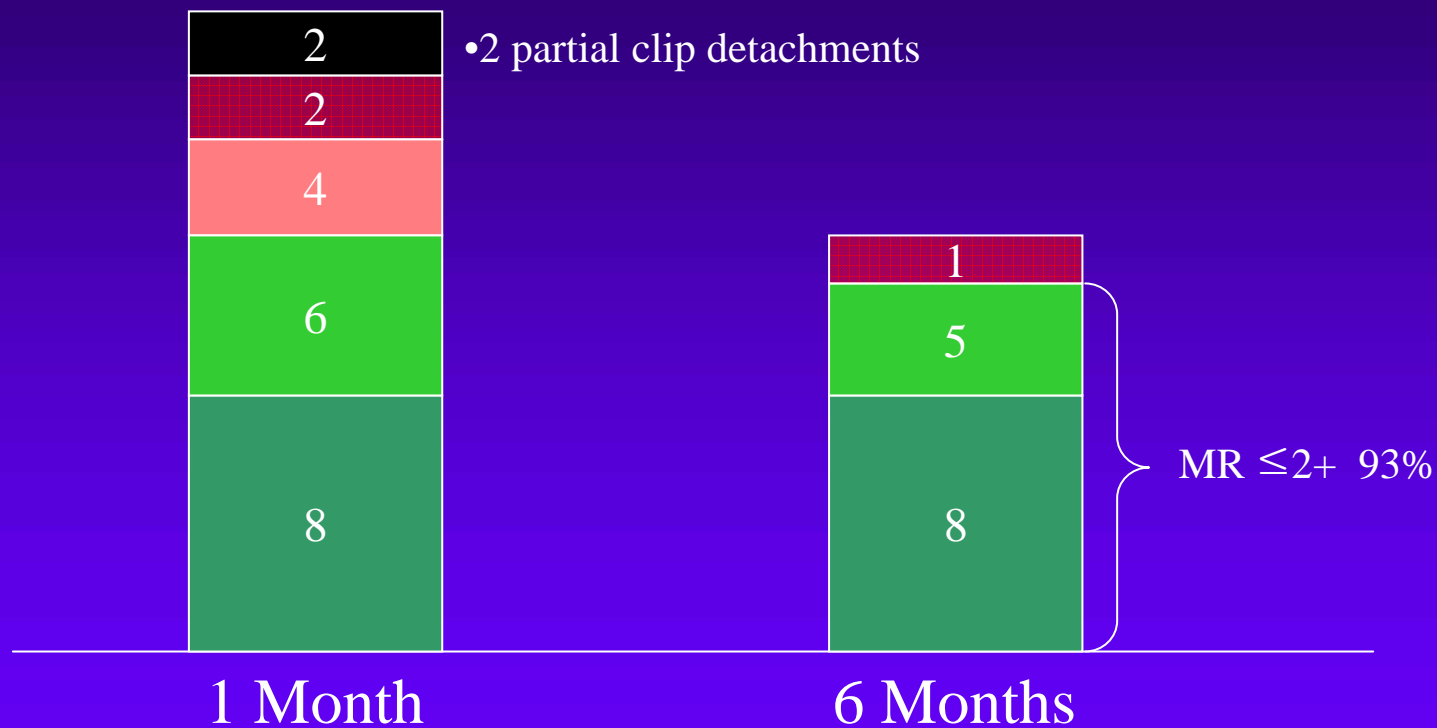
Septicemia

0

4/27 (15%)

Patients Discharged with a Clip

MR $\leq 2+$ at One Month was
Maintained at 6 Months in 93% of Patients



MR Severity

4	3	2	1
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EVEREST II Study Design

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