Surgical Management for Severe Heart Failure

-Alternative to Heart Transplantation-

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Yonsei

Congestive Heart Failure in USA

- Heart transplantation
  - Most effective therapy (~90% / 1 yr ; 50% /10 yr)
  - Scarcity of organs (2500 donors)
  - Transplantation related problems
    - infection
    - rejection
    - post-transplant lymphoproliferative disease
    - accelerated coronary artery disease

Ventricular Remodeling in CHF

- This process is characterized by a progressive change in shape of the LV and a progressive increase of LV muscle mass. The remodeling process may be the primary mechanism for a reduction in LV wall motion that accompanies a reduced LVEF. Thus, the systolic dysfunction described above may often result not from a primary deficit of contraction but rather an enlargement of the chamber as a results of remodeling.

Jay N. Cohn, 2000

The Structure and Function of the Heart

The Structure and Function of the Healthy Helical and Failing Spherical Heart. Overview: The Ventricular Band and Its Surgical Implications

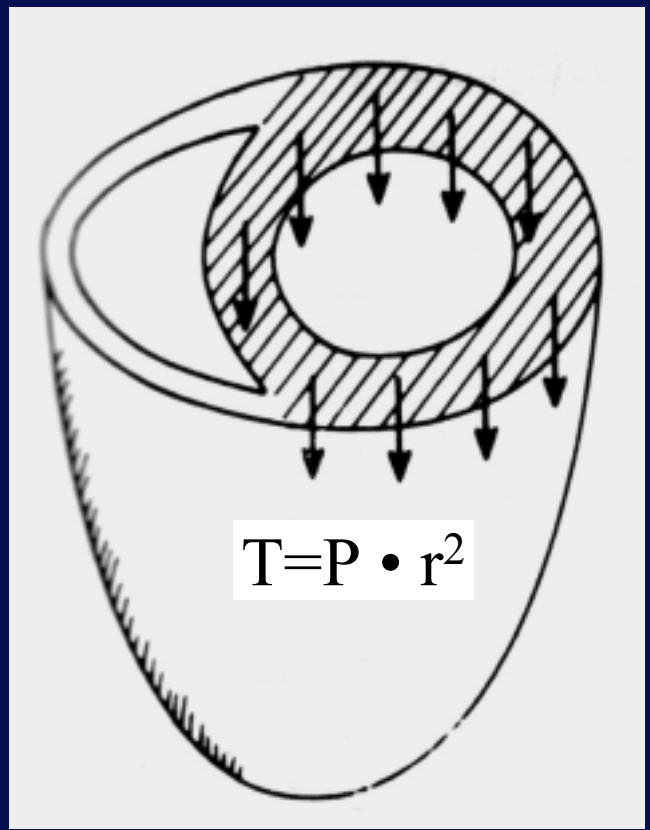
Gerald D. Buckberg

The fundamental principle of surgery is the alteration of structure to improve function. This requires understanding normal [illegible] and recognizing how it is [illegible]. This concept cor[illegible] that, "no phy[illegible] it giv[illegible] points of str[illegible] cuses on a spect[illegible] conical shape of the v[illegible] ration of muscles, shortening a[illegible] the base on the structurally fixed but moveable

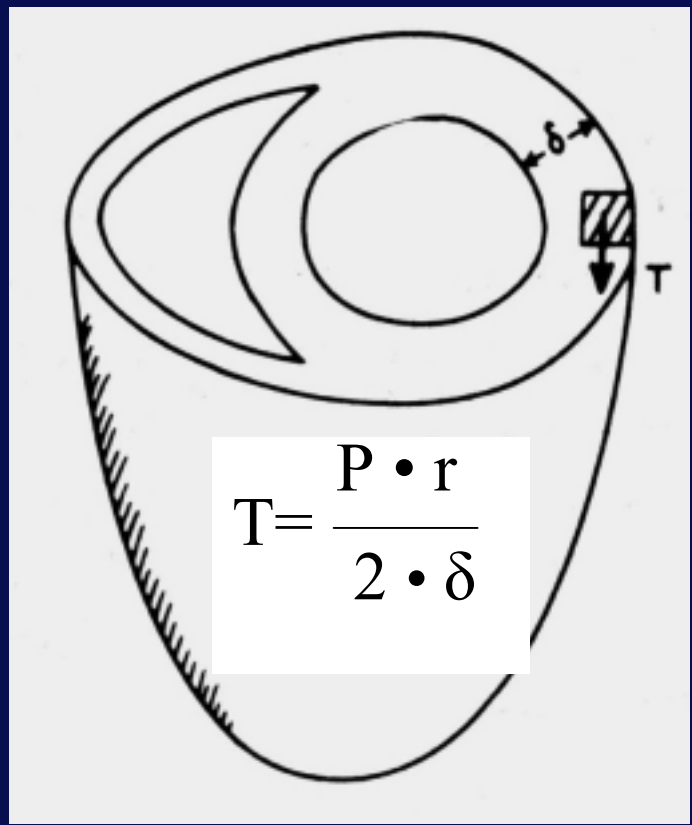
monary artery at its beginning, to the aorta at its end. The ventricular band contains a transverse descending segment that proceeds [illegible]ding segment [illegible]hese [illegible] in [illegible] apical vortex with fibers on the outside moving inside.[4] This

The fundamental principle of surgery is the alteration of structure to improve function.

The Law of Laplace



T = force across the total cross-sectional area



T = force per unit cross-sectional area of muscle

Badeer HS, AHJ 1963

Background

Normal Helical Shape Heart

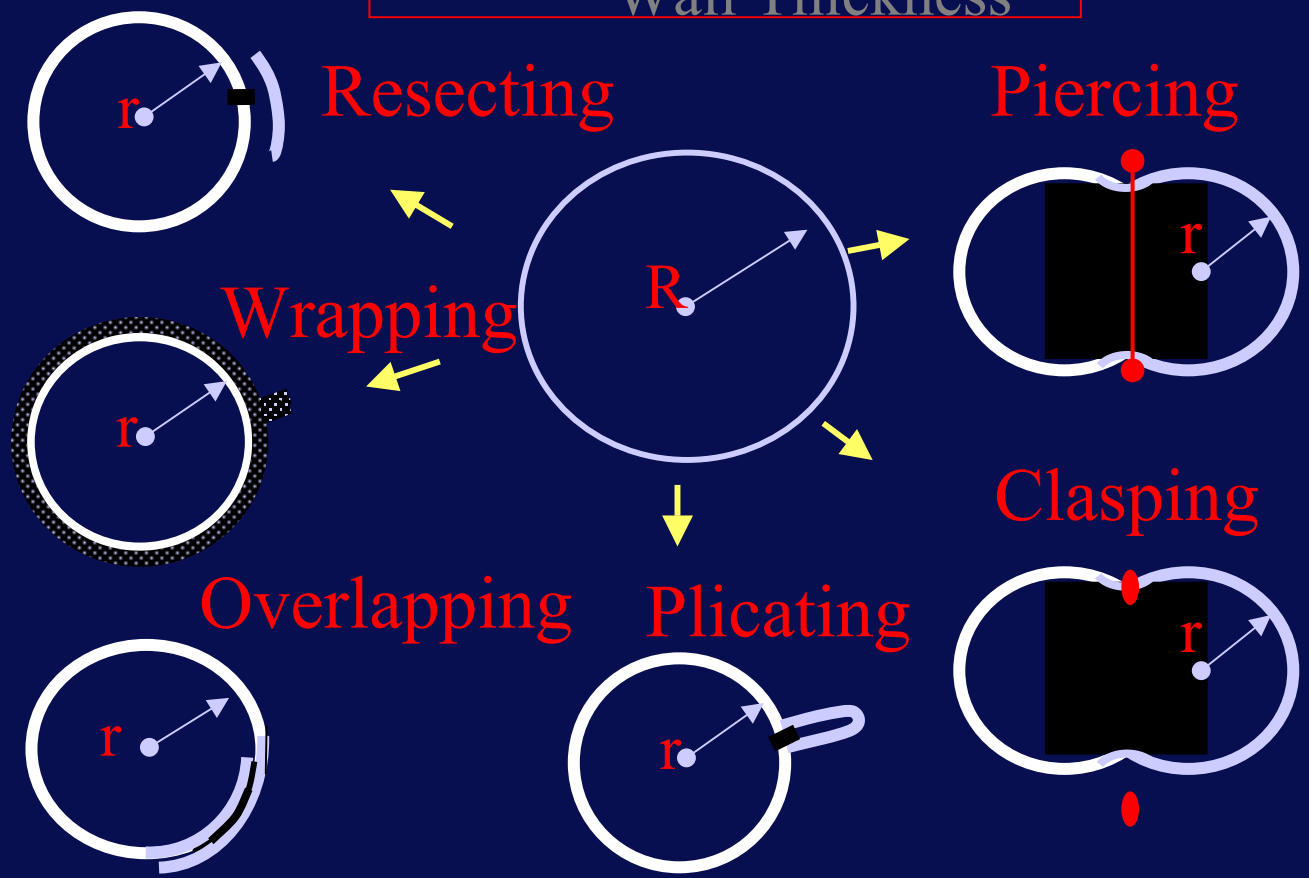
Spherical Shape Failing Heart

Less Wall Tension and Effective Outflow

Surgical Concept

Spherical Shape Failing Heart Normal Helical Shape Heart

$$\text{Stress} = \frac{\text{Pressure} \times \textbf{Radius}}{\text{Wall Thickness}}$$



From A. Kawaguchi

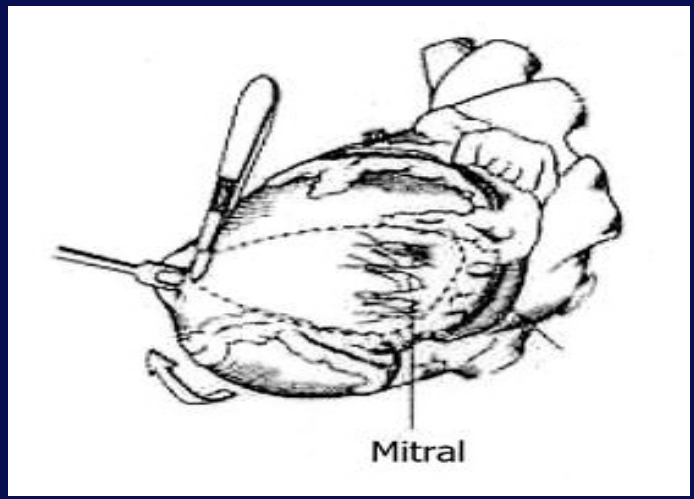
Yonsei

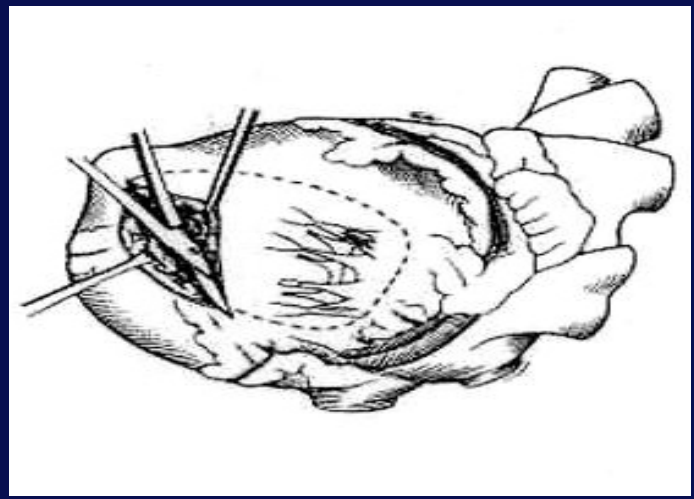
Alternatives to Heart Transplantation

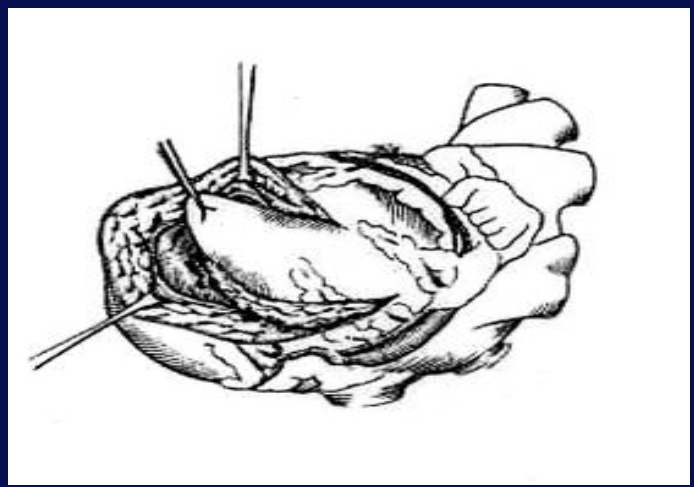
- **LV Volume reduction surgery**

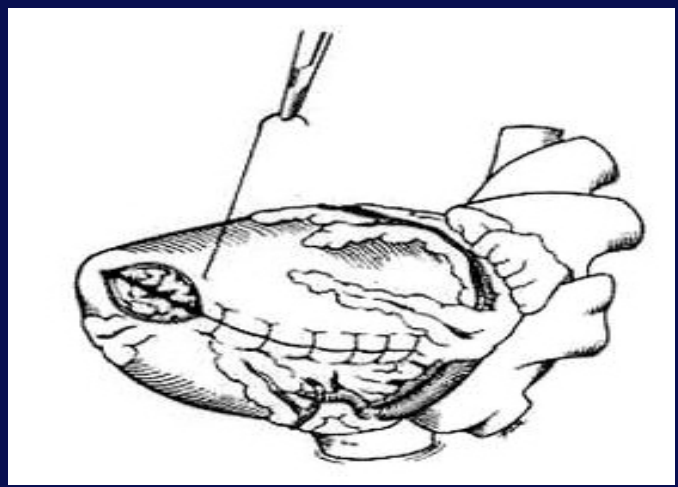
  (Batista, MyoSplint, Acorn…..)
- **Mitral annuloplasty (Bolling)**
- **Cardiomyoplasty**
- **Implantable LVAD (REMATCH trial)**
- **Artificial heart (AbioCor, 2001)**
- **Xeno-transplantation (?)**

Batista procedure
-Partial Left Ventriculectomy-









Partial Left Ventriculectomy (Batista Procedure)

Nations	Institutes	Cases
USA	5	67
Brazil	1	670
France	1	2
Germany	1	88
Italy	3	35
Netherland	1	6
Yugoslavia	1	38
Japan	35	245
Korea	5	25
Philippines	1	9
Taiwan	2	11
Thailand	1	14
Turkey	1	29
13	58	1239

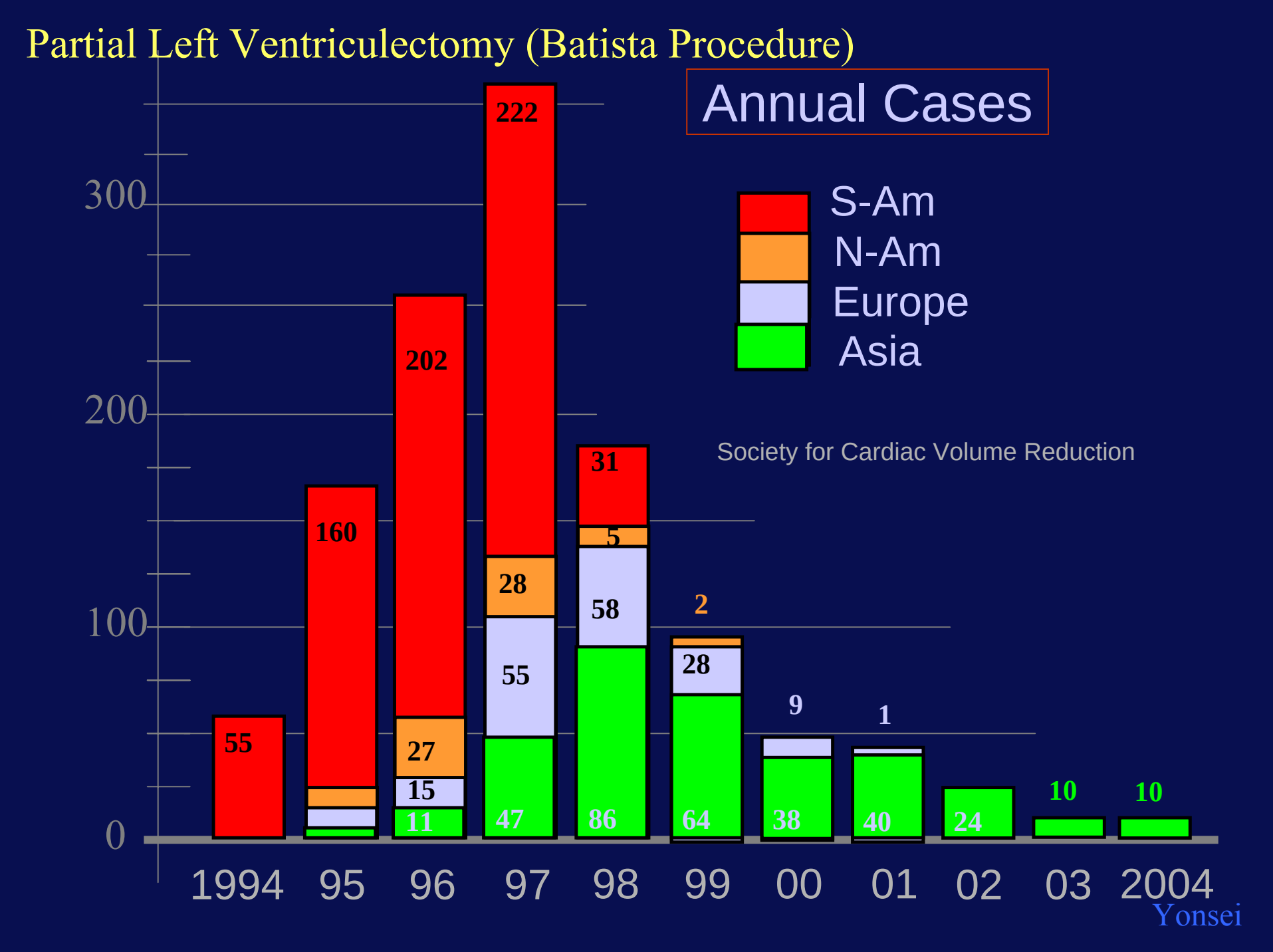
USA

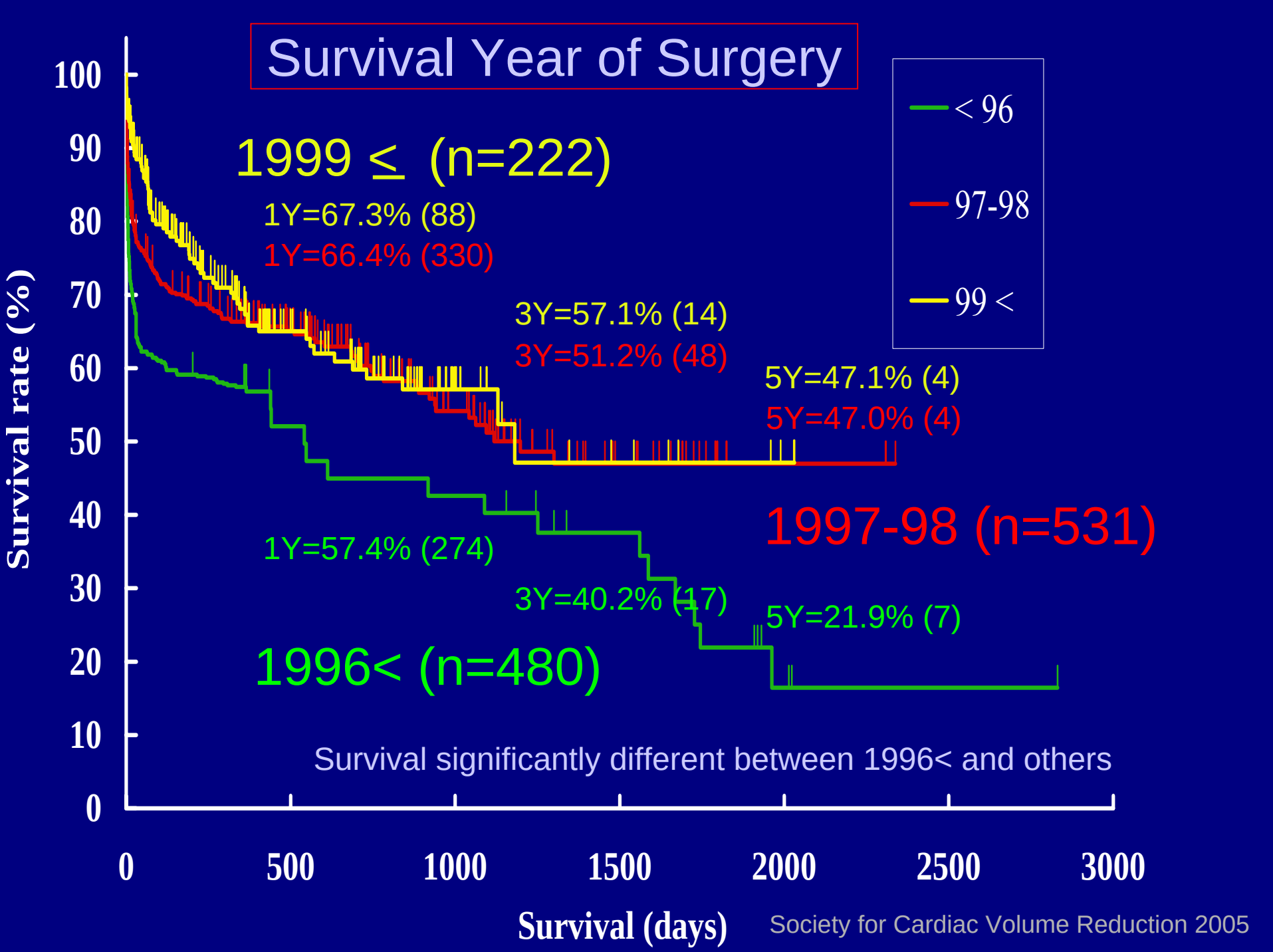
Brazil

Europe
n=168

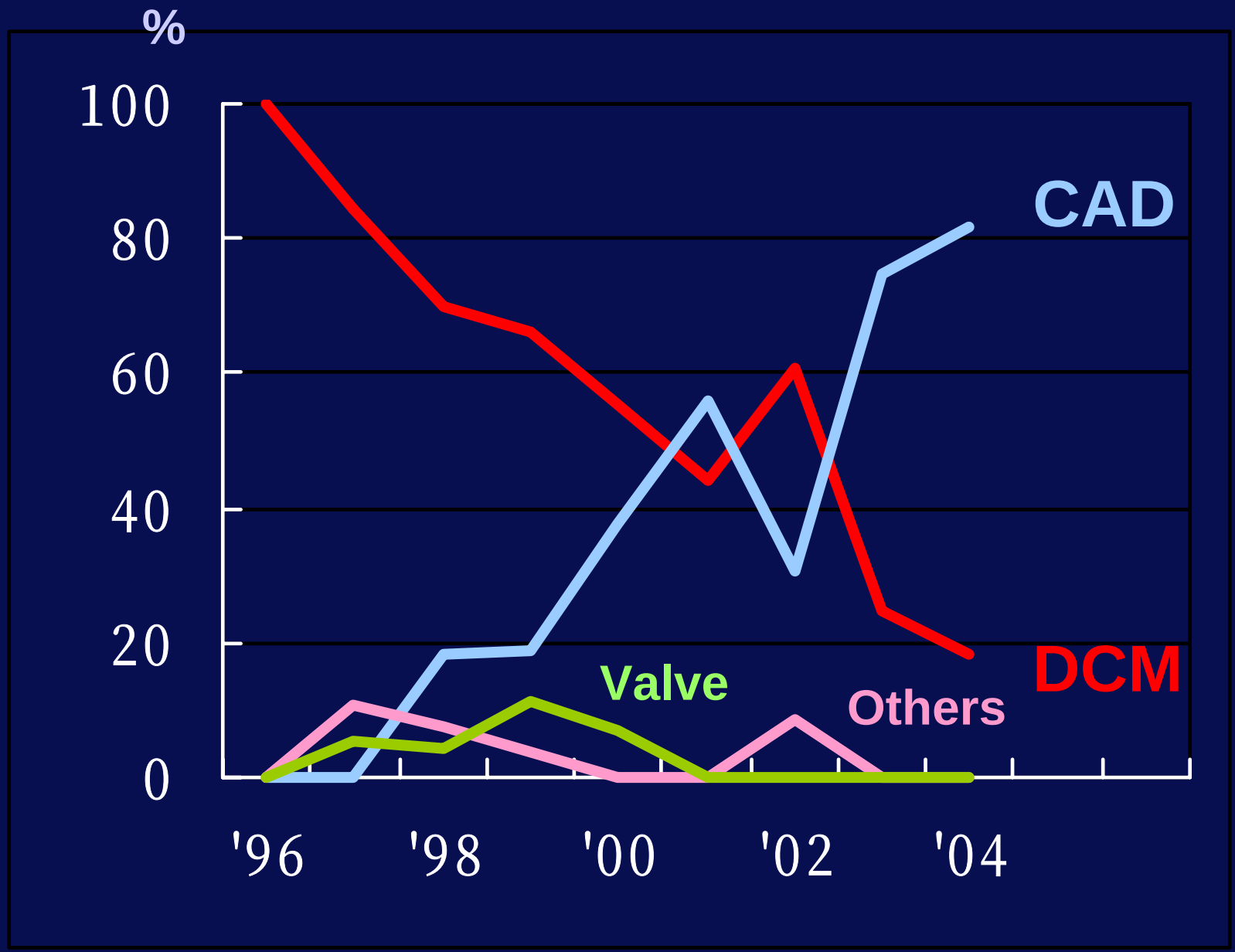
Asia
n=328

Partial Left Ventriculectomy (Batista Procedure)




Survival Year of Surgery
< 96
97-98
99 <
1999 ≤ (n=222)
1Y=67.3% (88)
1Y=66.4% (330)
3Y=57.1% (14)
3Y=51.2% (48)
5Y=47.1% (4)
5Y=47.0% (4)
1997-98 (n=531)
1Y=57.4% (274)
3Y=40.2% (17)
5Y=21.9% (7)
1996< (n=480)
Survival significantly different between 1996< and others
Survival rate (%)
100
90
80
70
60
50
40
30
20
10
0
0
500
1000
1500
2000
2500
3000
Survival (days)
Society for Cardiac Volume Reduction 2005

Partial Left Ventriculectomy (Batista Procedure)



Myosplint for Dilated Cardiomyopathy and Coapsys for Functional Mitral Regurgitation

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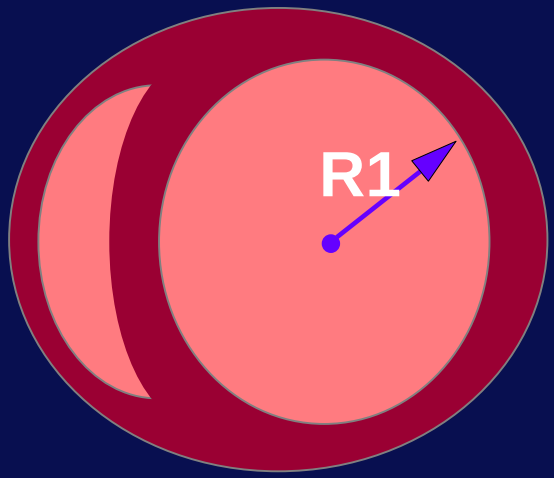
Cardiovascular Dynamics Laboratory
Department of Biomedical Engineering
Lerner Research Institute

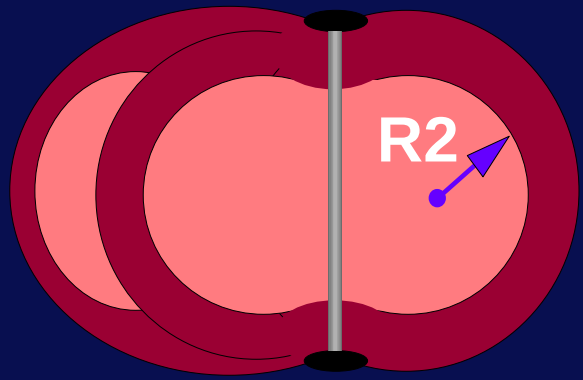
The Cleveland Clinic Foundation
Cleveland, OH, U.S.A.

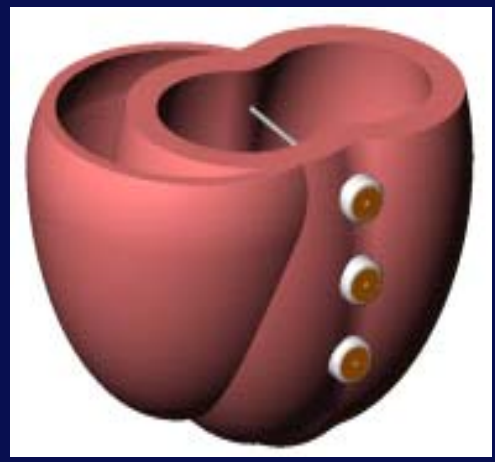
Myosplint ® Concept

Dilated Heart

Myosplint ®







Dilated Radius

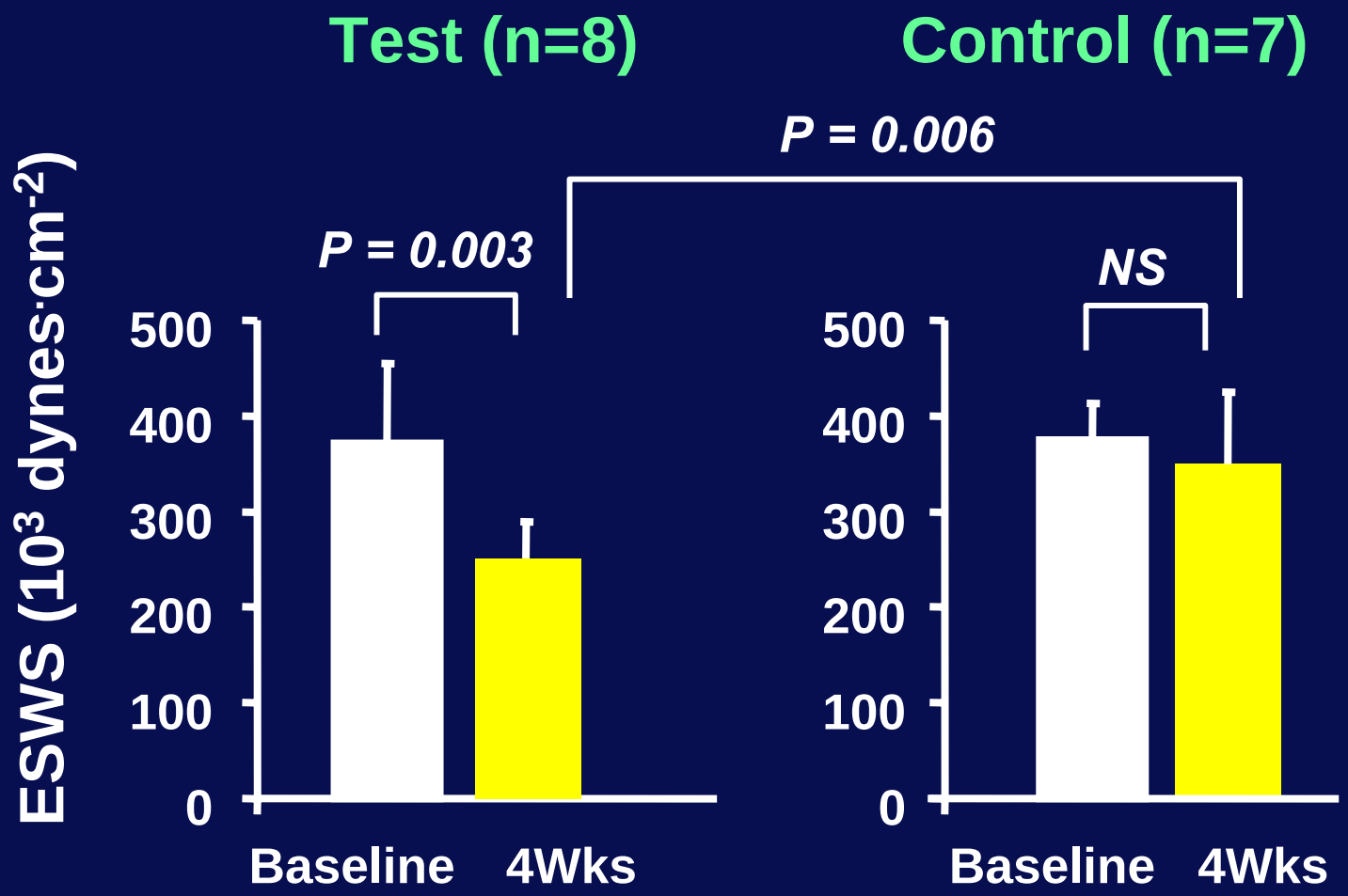
$$T = \frac{P \times R1}{h}$$

Modified Radius

$$T = \frac{P \times R2}{h}$$

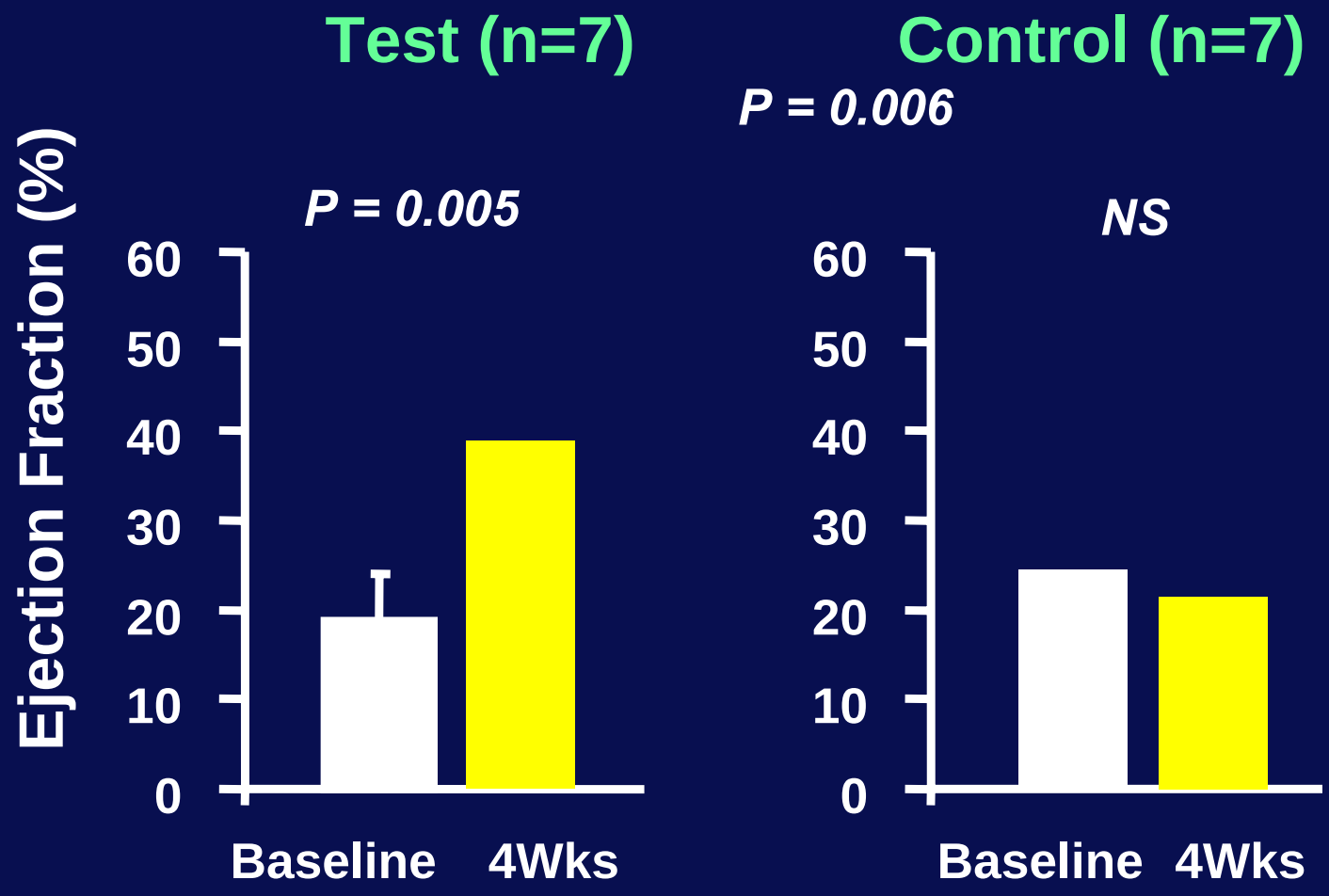
End-systolic Wall Stress

Pacing induced, canine HF model



Ejection Fraction (3D Echo)

Pacing induced, canine HF model



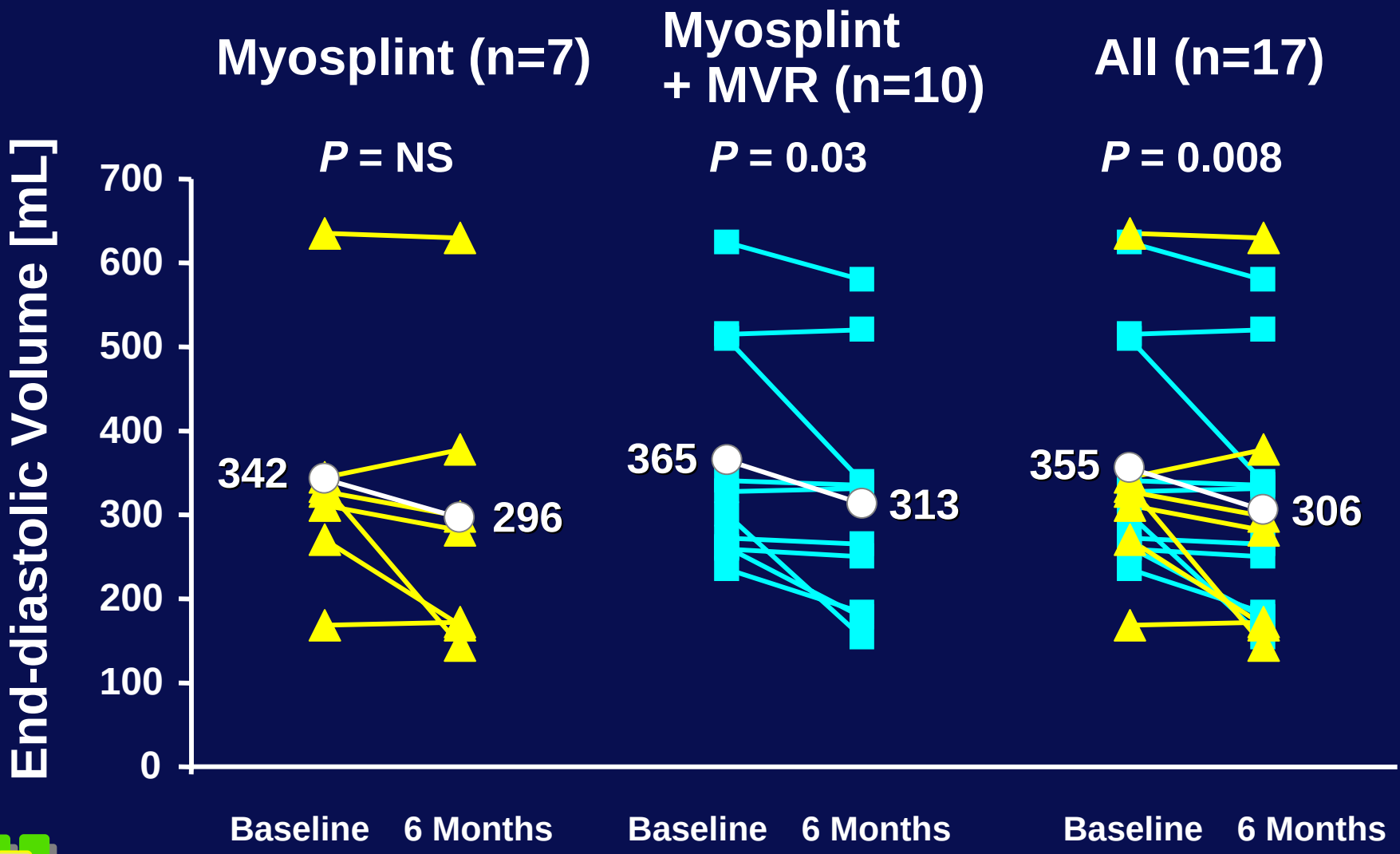
Myosplint Clinical Trial

- **Institutions**
  - Leipzig Heart Center, Leipzig, Germany
  - University Hospital Munich-Grosshadern, Munich, Germany
  - The Cleveland Clinic Foundation, Cleveland, U.S.A.
- **Primary Objective**
  - To assess the intraoperative and perioperative safety.
- **Secondary Objective**
  - To gather preliminary device efficacy data through assessments of NYHA functional class, LVEDV, LVEF, and MR grade at enrollment and during follow-up.

Patient Demographics

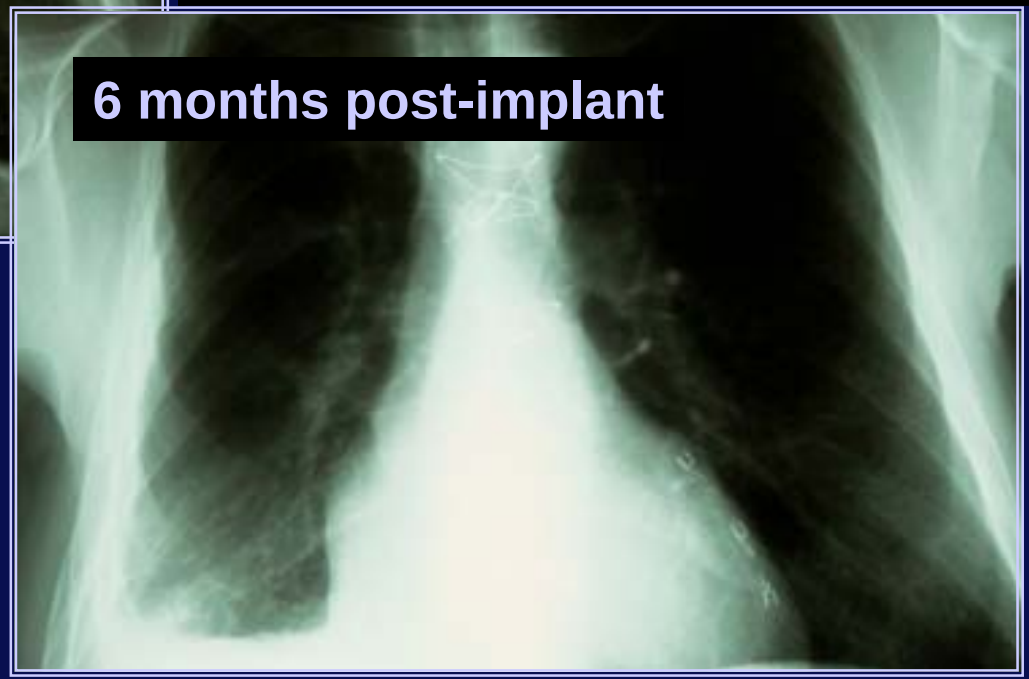
	Myosplint	Myosplint + MVR	All patients
Number	N = 9	N = 17	N = 26
Age	52.8 ± 7.0	52.8 ± 12.5	52.4 ± 10.8
Gender			
Male	7 (78%)	12 (71%)	19 (73%)
Female	2 (22%)	5 (29%)	7 (27%)
Years with HF	3.8 ± 2.0	8.4 ± 4.7*	6.9 ± 4.5

LV End-diastolic Volume



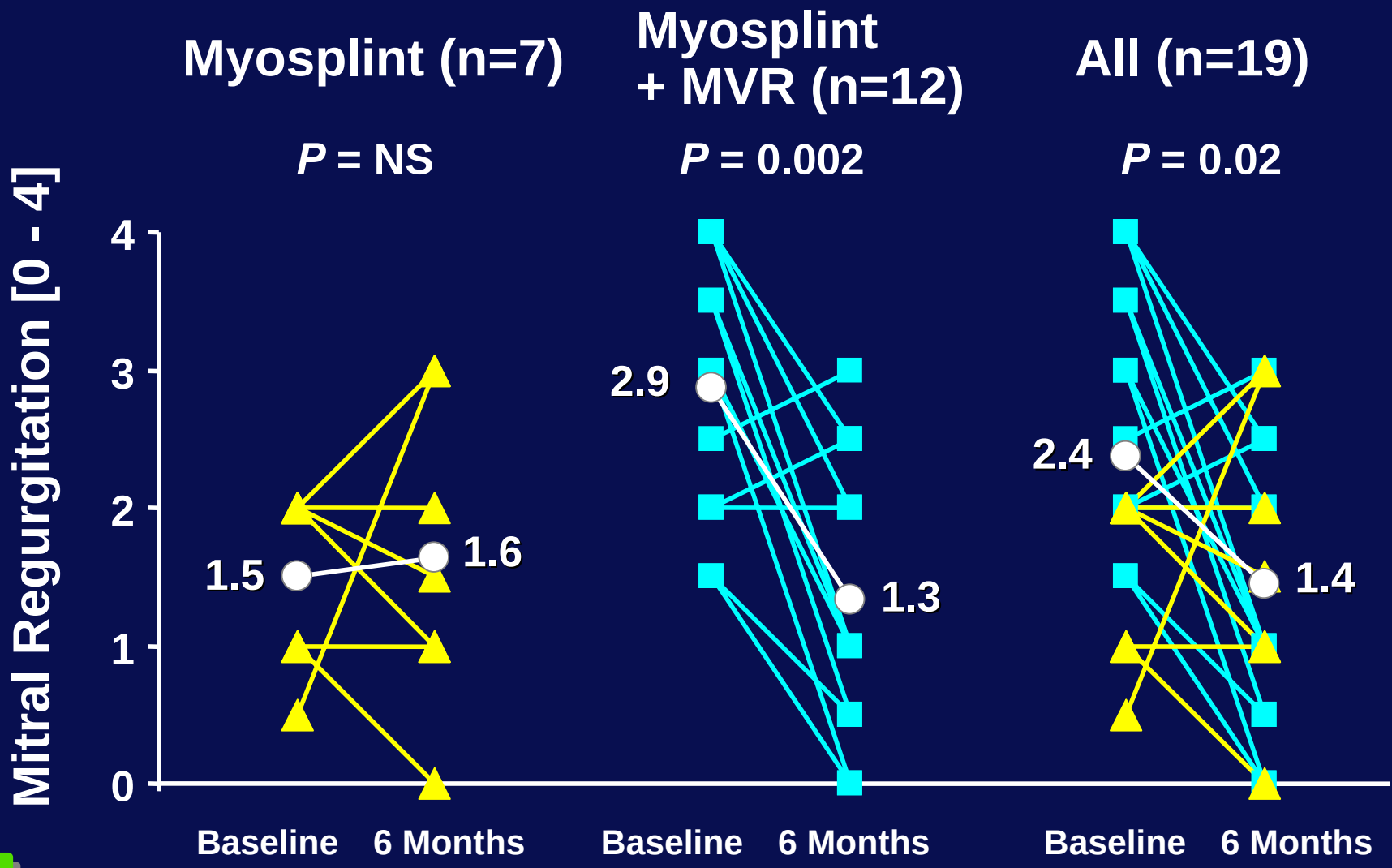
Myosplint Patient

	LVEF (%)	EDV (ml)	MR Grade
Baseline	14	334	2
6 month	37	145	1
18 month	40	80	Trace
24 month	40	100	0

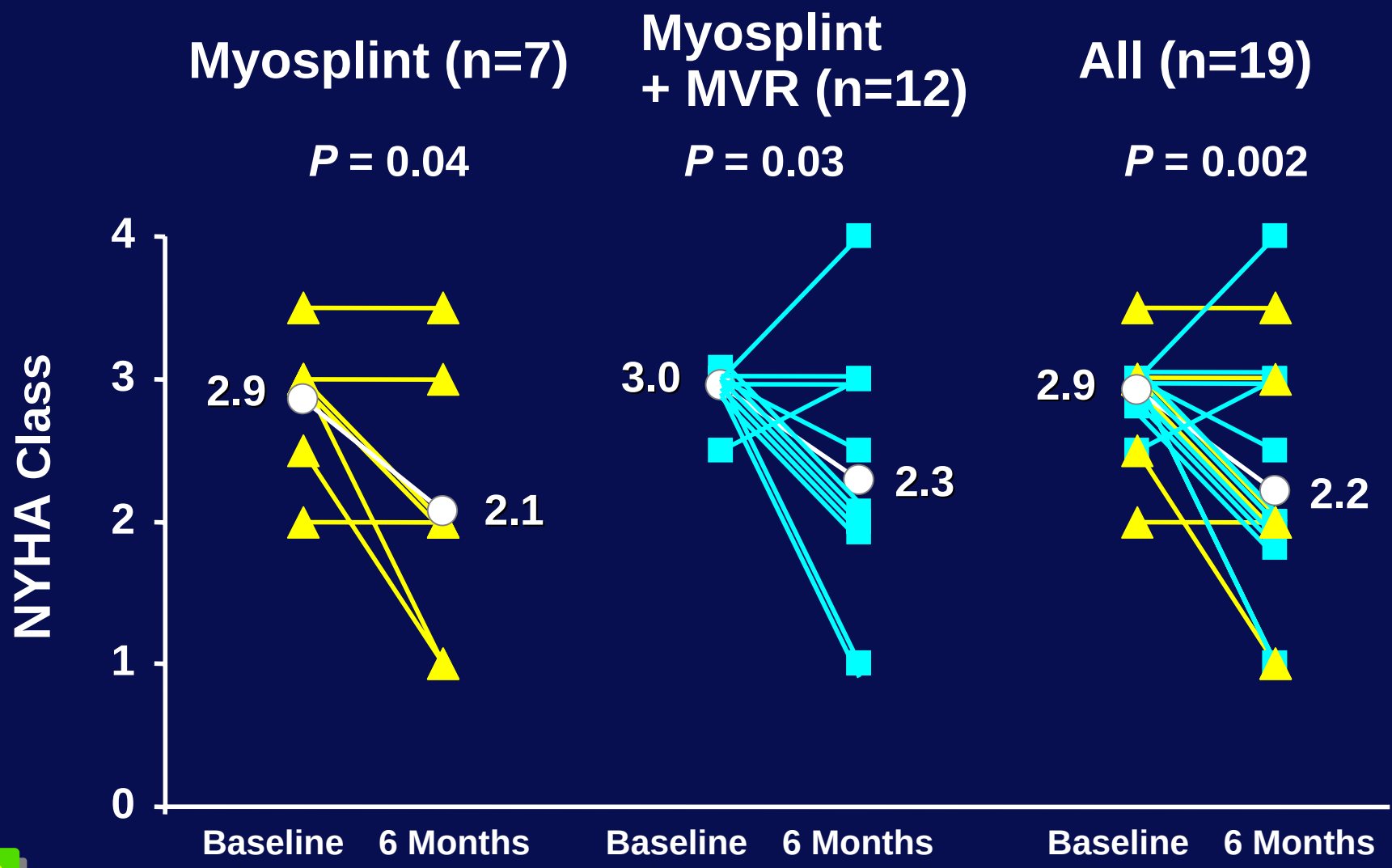


Photographs courtesy of
Professor Friedrich Mohr,
University of Leipzig.

Mitral Regurgitation



NYHA Functional Class



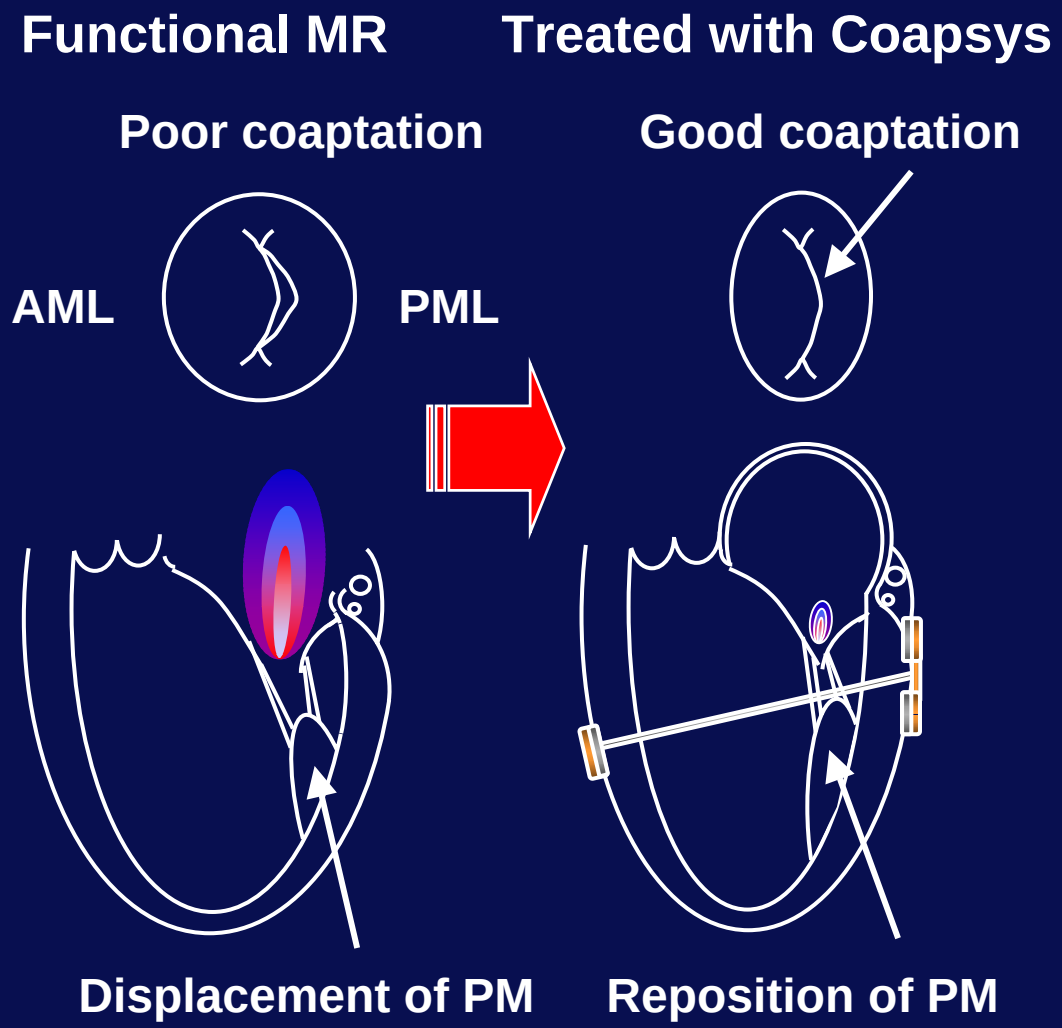
Clinical Status

- **3 patients died during follow-up**
  - **2 patients from sepsis**
  - **1 patient from a sudden ventricular tachyarrythimia**
- **2 patients underwent heart transplantation**
- **The MR grade had a significant linear relationship with the NYHA functional class (NYHA = 0.285 × MR + 1.97. *P* = 0.002)**

Surgical Concept

Coapsys™ Therapeutic

- Draws mitral leaflets together to increase valve ***coaptation***
- Repositions papillary muscles

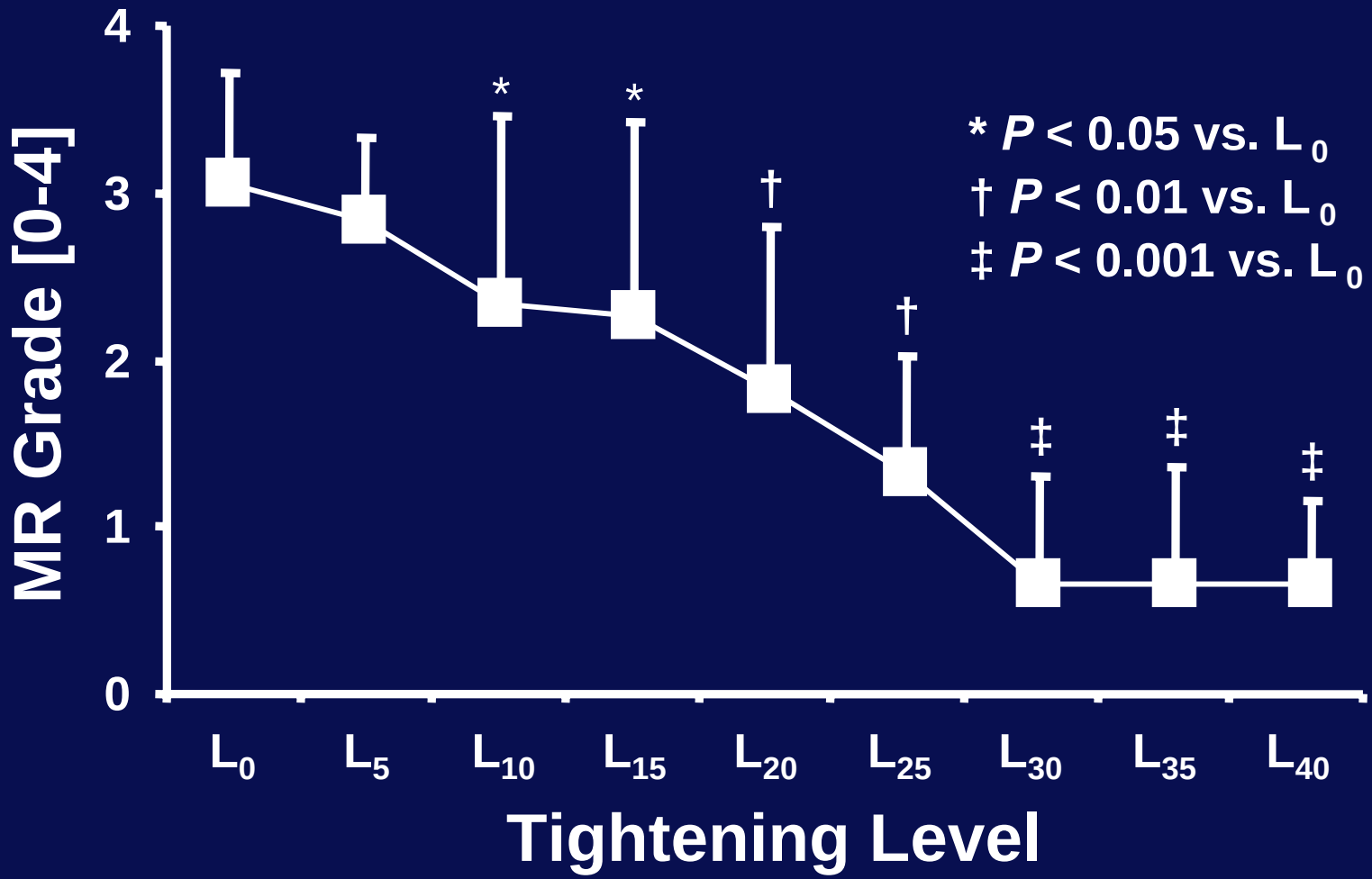


Advantages

- **Ability to affect both the mitral annulus and the papillary muscle.**
- **Off-Pump: Elimination of cardiopulmonary bypass. No atriotomy. Immediate evaluation.**
- **Technically simple. Reversible implantation.**
- **Potential for a more stable repair which does not interfere with annular dynamics.**

Mitral Regurgitation

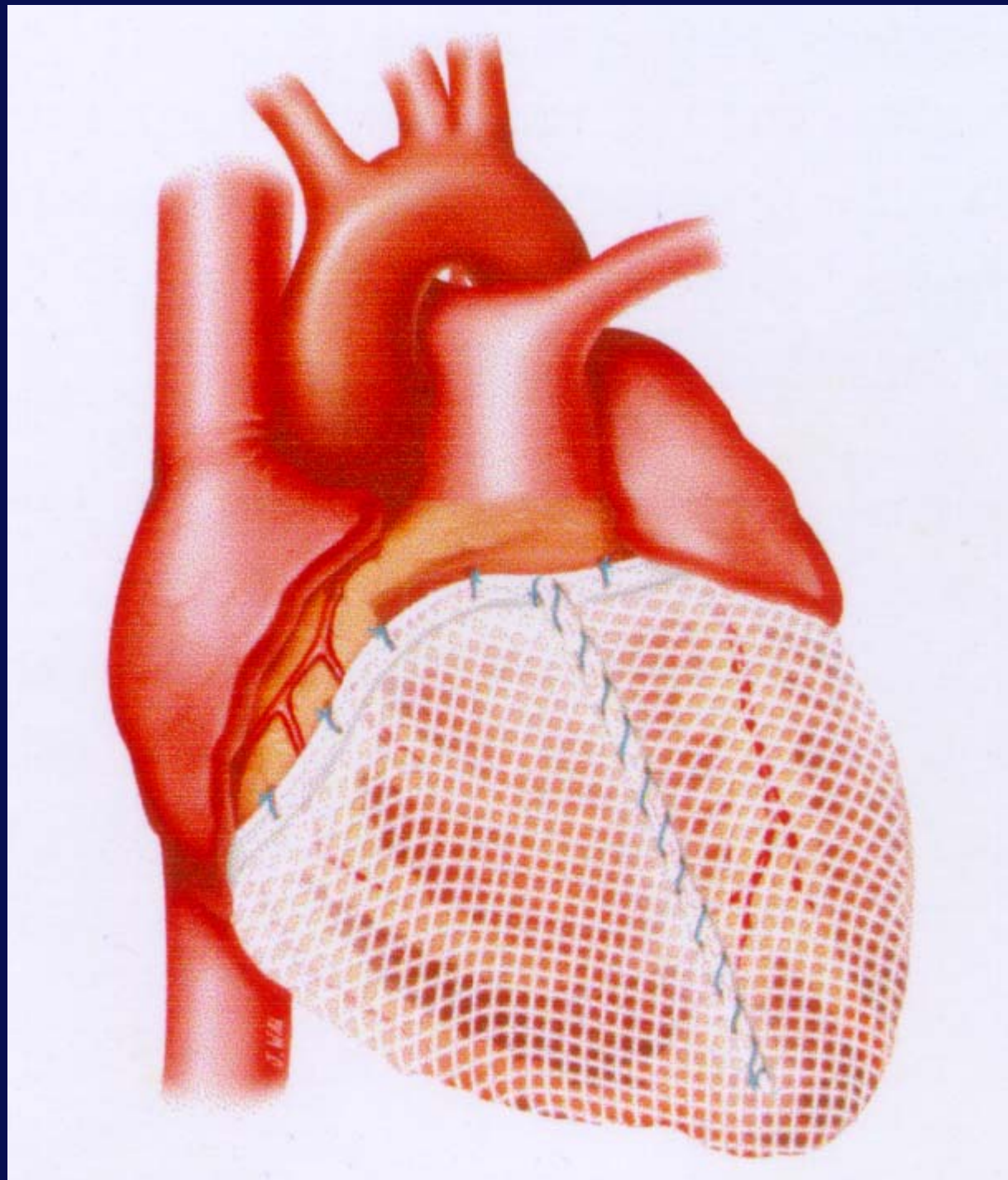
Average ± SD (7 animals)



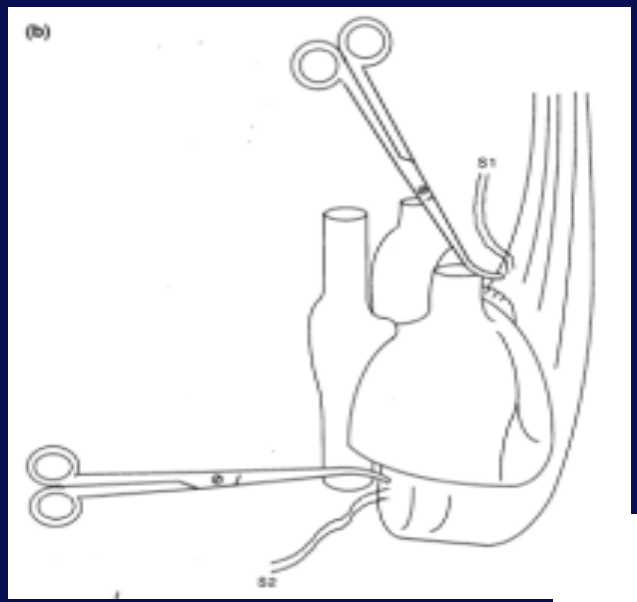
TRACE Summary

- The Coapsys device was safe and effective in significantly reducing MR in the beating heart.
- The device significantly reduced
  - S-L annular diameter
  - Interpapillary muscle distance
  - Posterior papillary muscle to intervalvular fibrosa distance
  - Tenting area
- Thus, restoring MV geometry appears to be responsible for the clinical effects of the device
- MR reduction is sustained at 12 months follow up

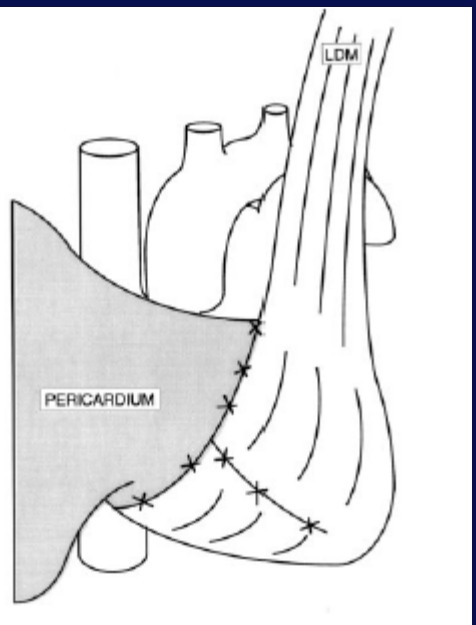
Acorn Device



Dynamic Cardiomyoplasty



LDM transposition and cardiac wrapping

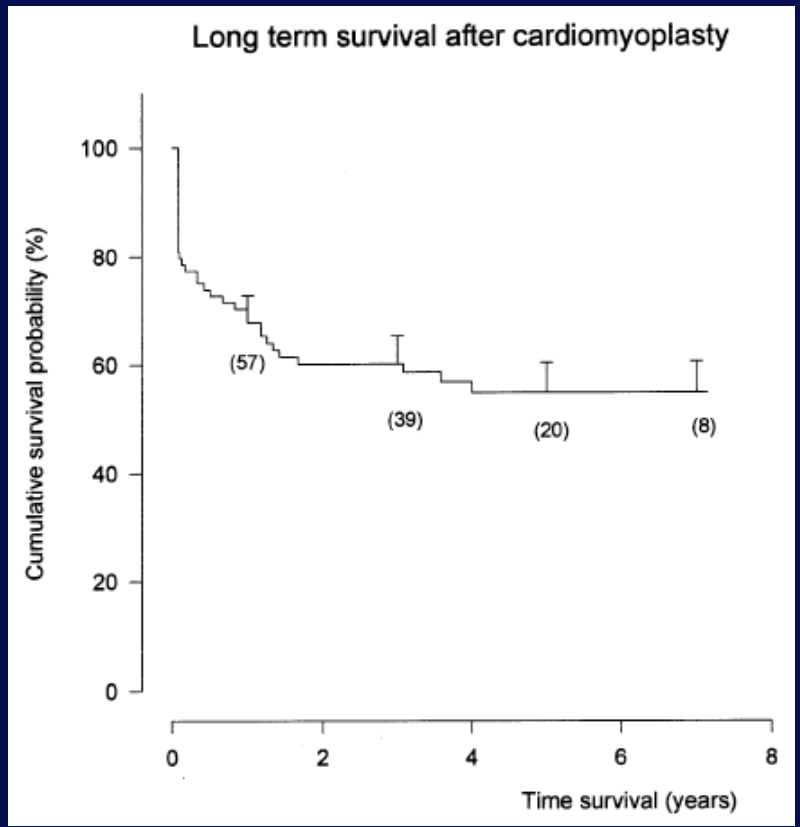


1. Systolic assist
2. limitation of ventricular dilatation
3. Reduction in ventricular wall stress
4. Ventricular remodeling with an active girdling effects
5. Angiogenesis
6. Neurohormonal effects

Chachques JC ,1997,

Eur J Cardiothorac Surg

Dynamic Cardiomyoplasty
-long term results-



7-year survival ; 54%

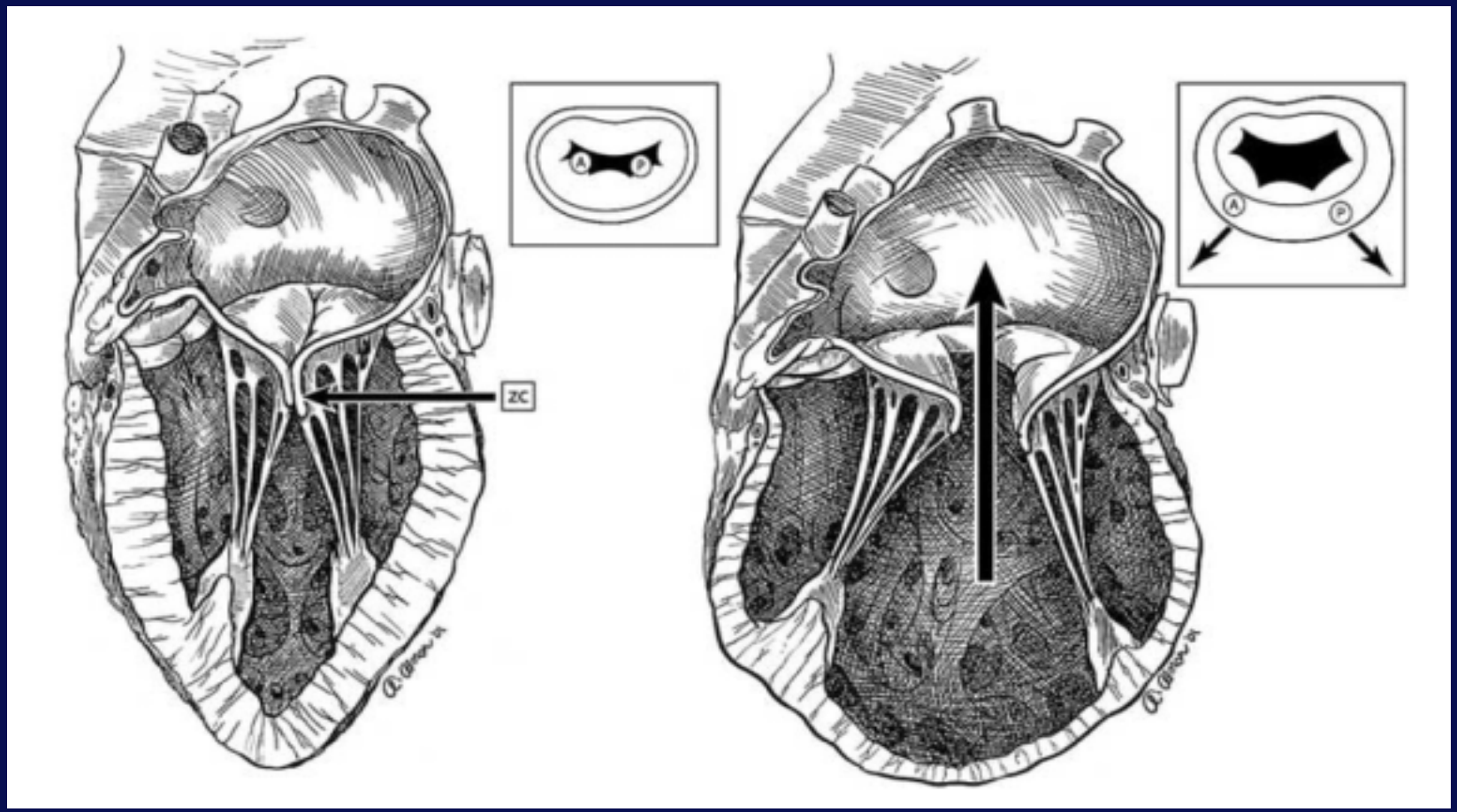
Causes of long-term mortality

- Heart failure(41%)
- Sudden death(30%)
- MI, GI bleeding, cancer(7%)

Six patients underwent heart transplantation after CMP.

Chachques JC ,1997, Eur J Cardiothorac Surg

Mitral annuloplasty



Bolling SF , 2004, J Card Surg

Yonsei

Mitral annuloplasty

-Long Term Results-

- 1994-2003 ; 200 patients with end stage cadiomyopathy underwent mitral valve repair with undersized flexible annuloplasty ring
- F/U peroid ; 49months(1-74)
- ***All patients showed improvement in EF (preop ; 16±5%→postop ; 26±8%), cardiac output, end-diastolic volume with reduction in spherical index and regurgitant fraction.***

Bolling SF , 2004, J Card Surg

Impact of Mitral Valve Annuloplasty on Mortality Risk in Patients With Mitral Regurgitation and Left Ventricular Systolic Dysfunction

Audrey H. Wu, MD, MPH,* Keith D. Aaronson, MD, MS,* Steven F. Bolling, MD, FACC,†
Francis D. Pagani, MD, PhD, FACC,† Kathy Welch, MS, MPH,‡ Todd M. Koelling, MD, FACC*

- 1995-2002 ; 126 patients with MR (moderate to severe) and LV dysfunction (LVEF<30%) underwent Mitral valve annuloplasty
- Risk factors ; coronary artey disease, blood urea nitrogen, cancer, digoxin use
- Favorable factors ; ACE use, beta-blockers, higher mean arterial pressure, higher serum sodium

Bolling SF, 2005, JACC

Impact of Mitral Valve Annuloplasty on Mortality Risk in Patients With Mitral Regurgitation and Left Ventricular Systolic Dysfunction

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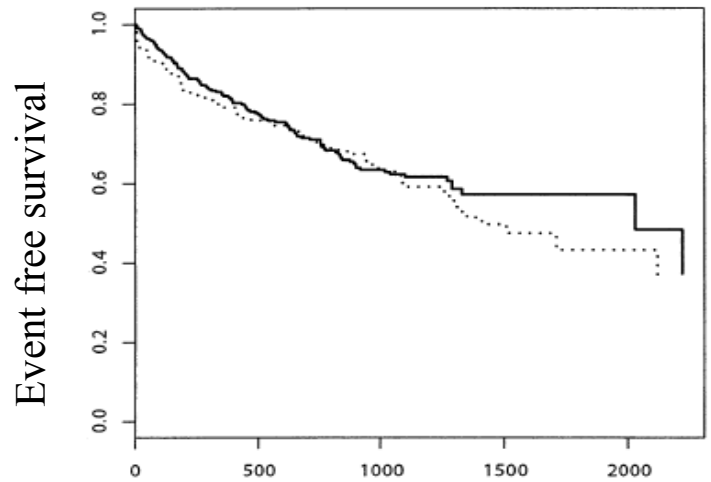


Figure 1. Event free survival for non-MAP (solid) and MVA (dotted line)

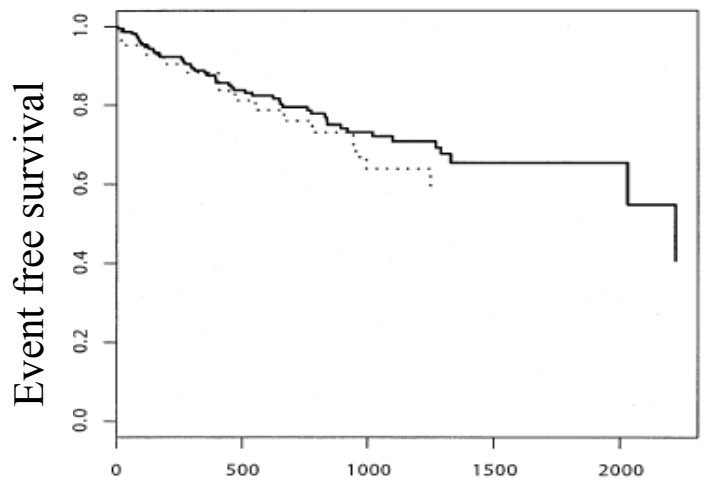


Figure 2. Event free survival in patients without CAD.

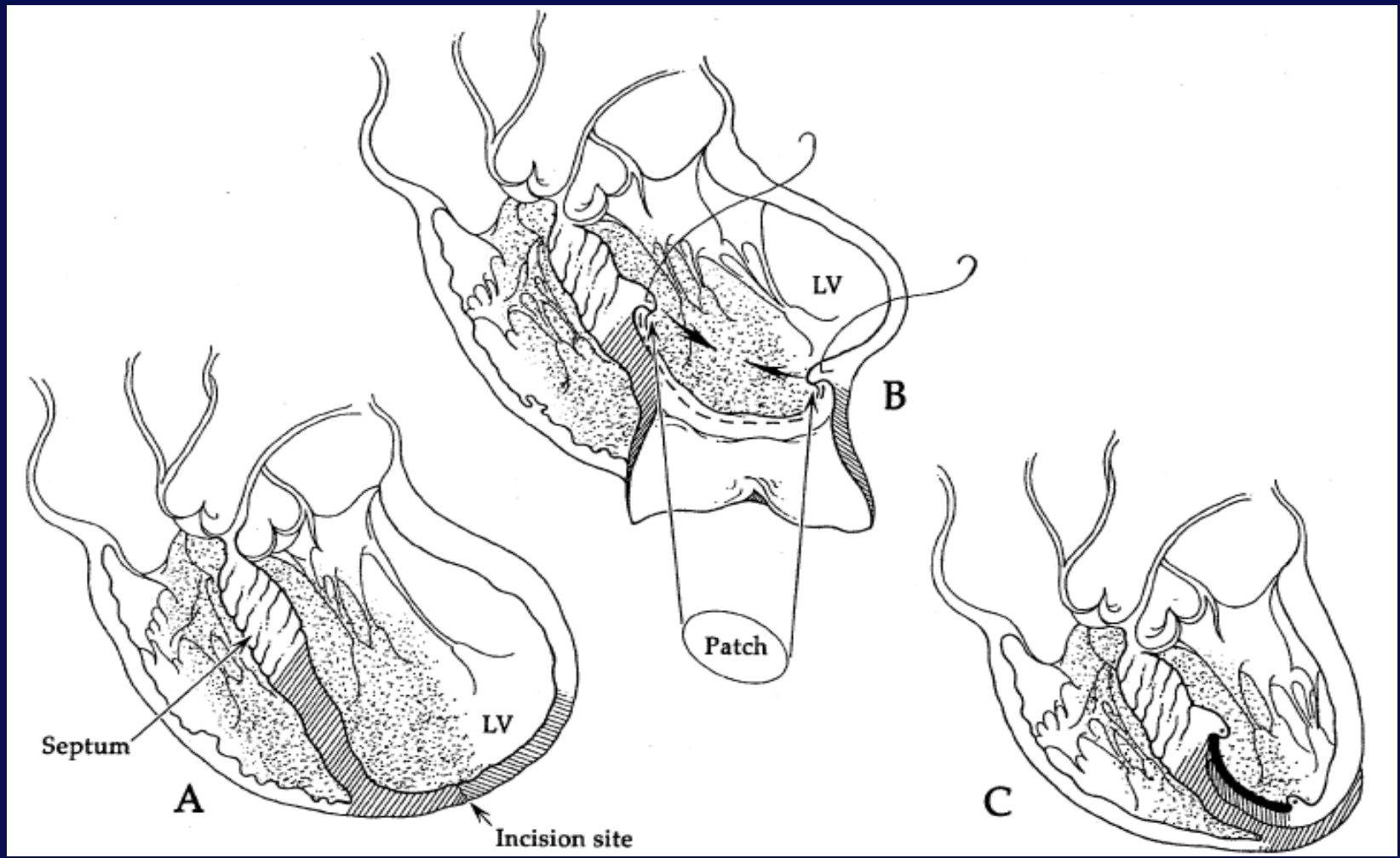
CONCLUSIONS In this analysis, there is no clearly demonstrable mortality benefit conferred by MVA for significant M[illegible] severe LV dysfunction. A prospective randomized control trial is warranted for further study of mortal[illegible]
2005;45:38[illegible]7) © 2005 by the Am[illegible]

No clearly demonstrable mortality benefit conferred by MVA

Bolling SF, 2005, JACC

Yonsei

Surgical Ventricular Restoration

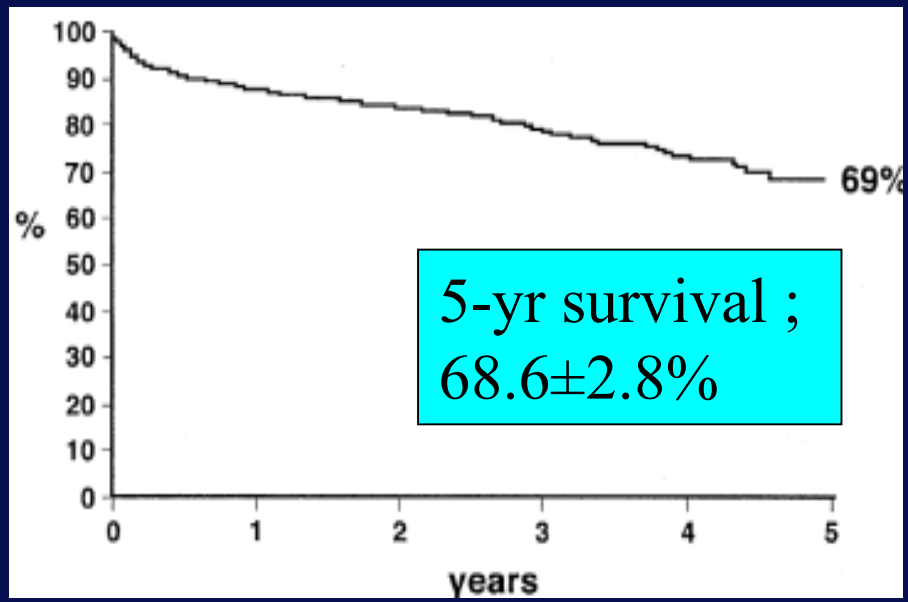


Athanasuleas et al, RESTORE group, 2004, JACC

Yonsei

Surgical Ventricular Restoration in the Treatment of Congestive Heart Failure due to Post-Infarction Ventricular Dilatation

- 1998-2003 ; 1,198 pts with post-infarction CHF
- SVR improved LVEF(29.6±11.0%→39.5±12.3%) and reduced LVESVI(80.4±51.4ml/m^2→56.6±34.3ml/m^2)[2].



Risk factors

EF≤30%,

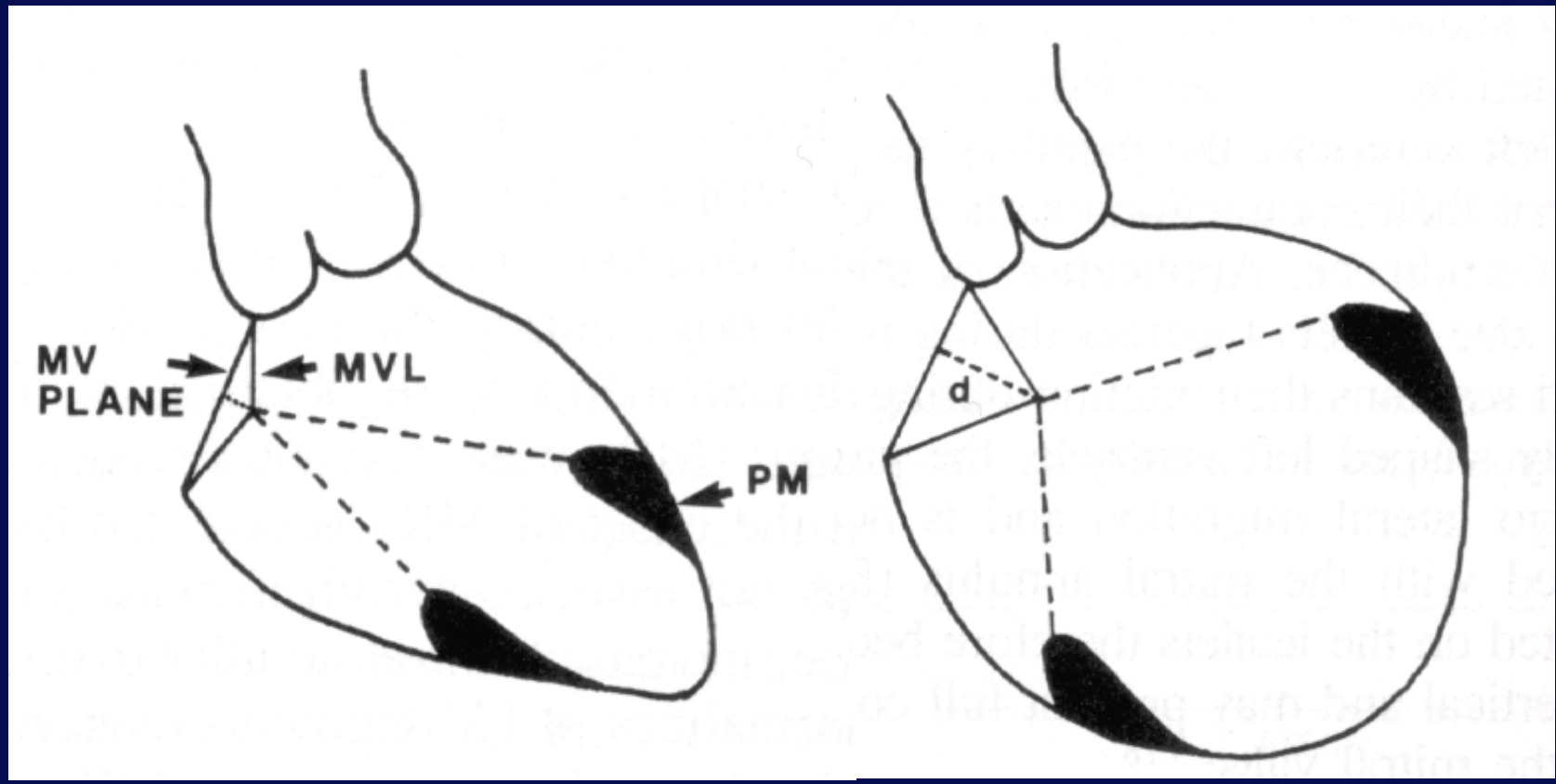
LVESVI≥80ml/m^2

Advanced NYHA class

Age≥75years

Athanasuleas et al, RESTORE group, 2004, JACC

Mechanism of MR in d-CMP



Normal LV

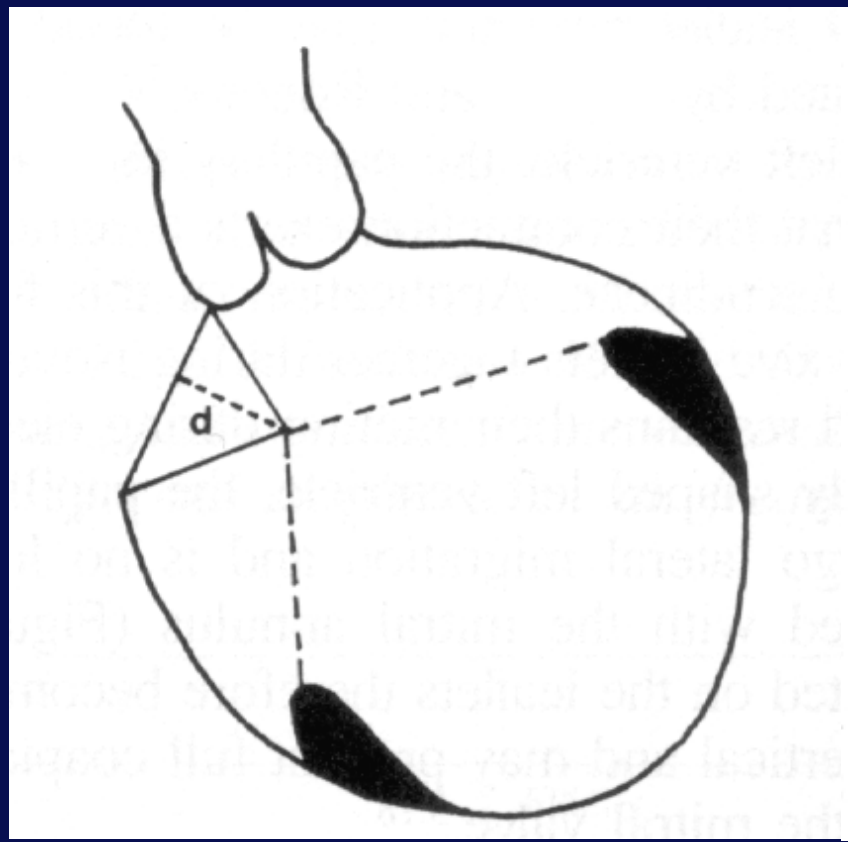
Spherical LV with MR

Sabbah HN et al AJC 1993

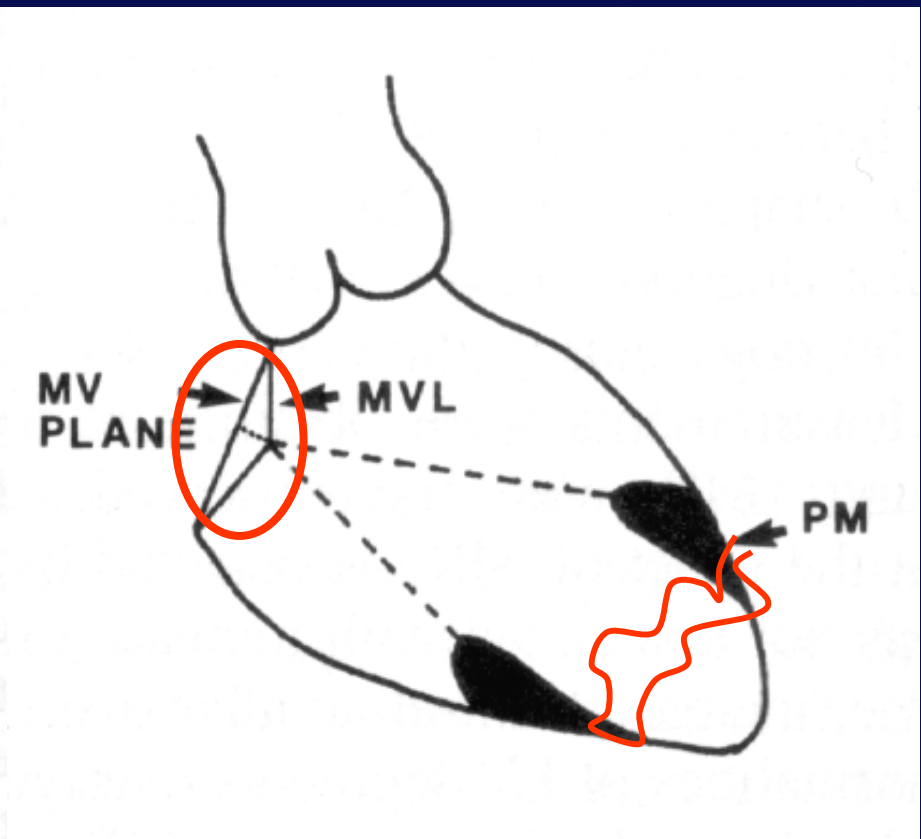
Hypothesis

Left Ventriculoplasty and Mitral Annuloplasty

in Patients of d-CMP and MR



Spherical LV with MR

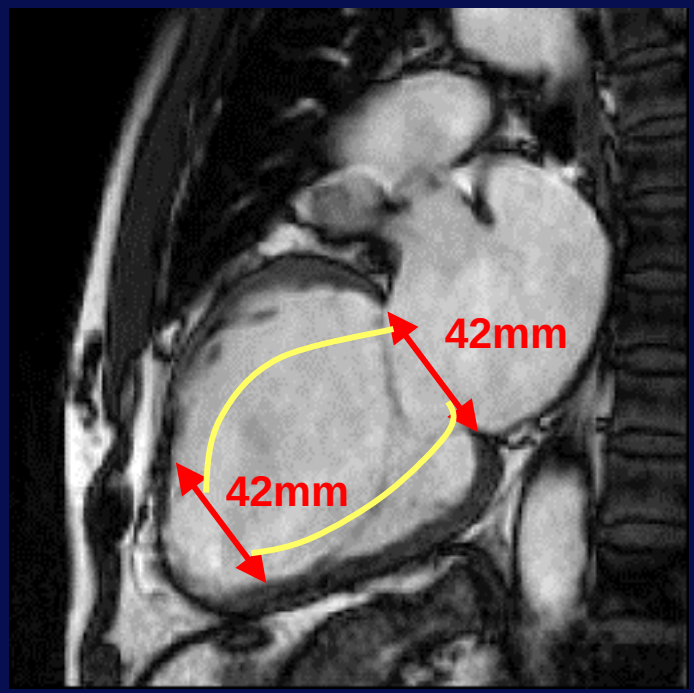


LVP with MAP

Chang BC et al J Cardiac Surg 2001

Hypothesis

Left Ventriculoplasty and Mitral Annuloplasty
in Patients of CMP and MR



M/56 Pre-OP. Cine-MRI:
LVEF:29.1%, LVEDV 265.3ml,
SV 77.2ml, MR vol: 46.3 ml

Left Ventriculoplasty and/or Mitral Annuloplasty in Severe Heart Failure

- We reviewed early and long-term clinical outcome after mitral annuloplasty and/or left ventriculoplasty in severe heart failure.

- To evaluate the functional changes of left ventricle before and after MAP and/or left Ventriculoplasty.

Patient Profiles

- **Periods: November, 1997 – June, 2005**
- **Patients: 34**

  male: 24, female: 10
- Mean age: 60.0 ± 9.4 (37 - 76) years
- Causes of Operation

  ischemic CMP: 18

  dilated CMP: 14

  valvular: 2

Preop. Profiles

- Preop. NYHA class

  III: 13 IV: 15, dobutamine dependent: 6

- Preop. Rhythm

  NSR : 18, Atrial Fib. : 16

- Preop. MR grade

  < I : 5, II : 8, III : 10, IV : 11

Surgical Procedures

- Mitral Annuloplasty(n=28)
  - only: 5
  - CABG: 9
  - modified Dor. Procedure: 6
  - modified Dor. Procedure and CABG: 6
  - Aortic valve replacement: 2
- Modified Dor Procedure(n=6)
  - only: 1
  - CABG: 5

Postop. Results

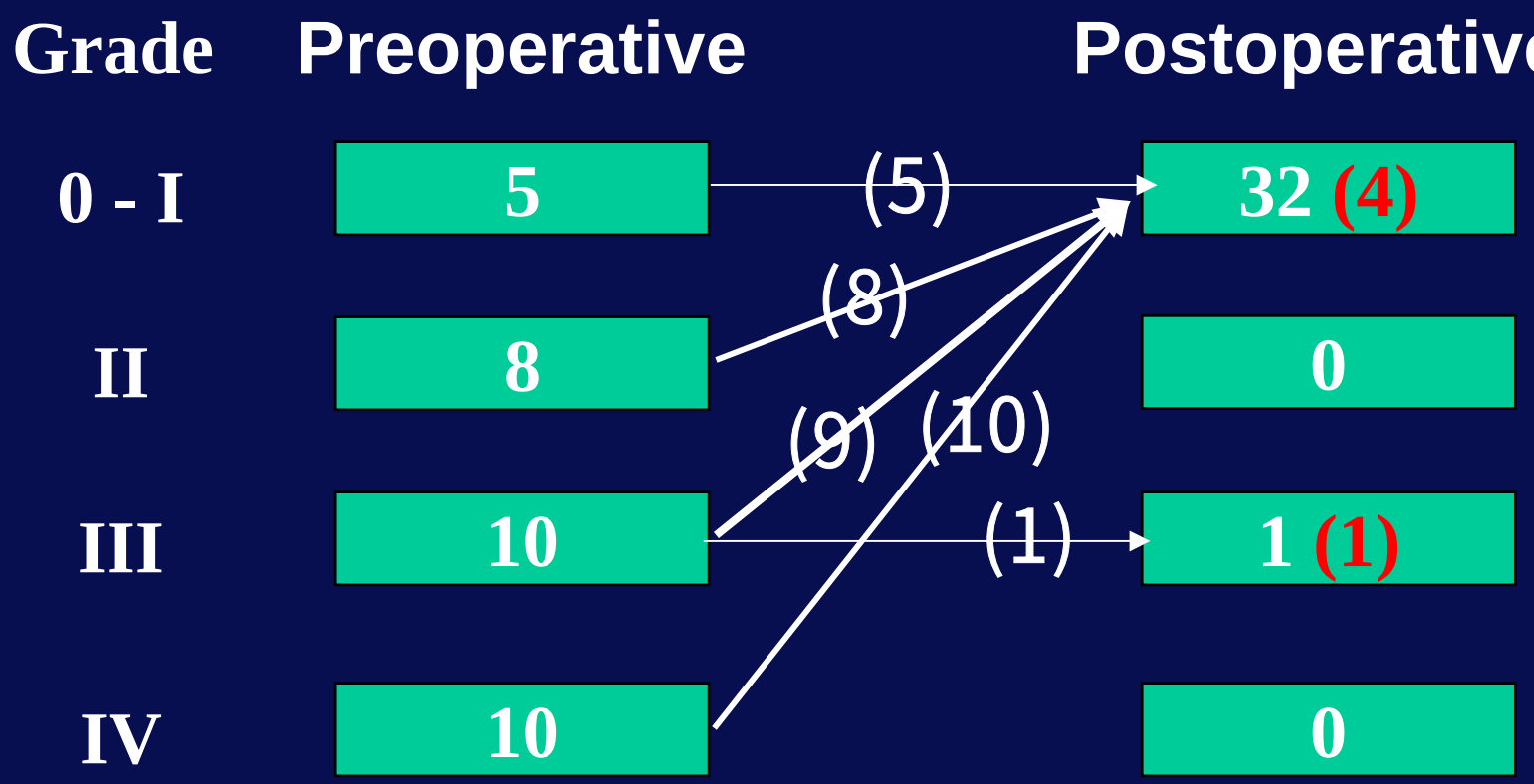
- **Early results**
  - operative death: 1 with sepsis
  - bypass weaning failure: 1
    implantable LVAD for 502 days (HeartMate®)
    → heart transplantation
- **Late results:**
  - late death: 5
    heart failure (POD # 8, 9 months) in 2
    sudden death (POD # 4, 5, 65 months) in 3

Echocardiography Results

Mean	Preop.(n=34)	Postop.(n=34)
*LVEF(%)	25.6 ± 6.3	34.2 ± 15.0
range	15 – 39	13 - 76
* LAD(mm)	53.2 ± 8.5	48.1 ± 7.8
range	41 – 70	37 - 66
* LVESD(mm)	59.1 ± 9.3	50.8 ± 12.2
range	45 – 77	25 - 79
* LVEDD(mm)	69.0 ± 9.4	61.7 ± 9.8
range	46 – 85	43 – 85

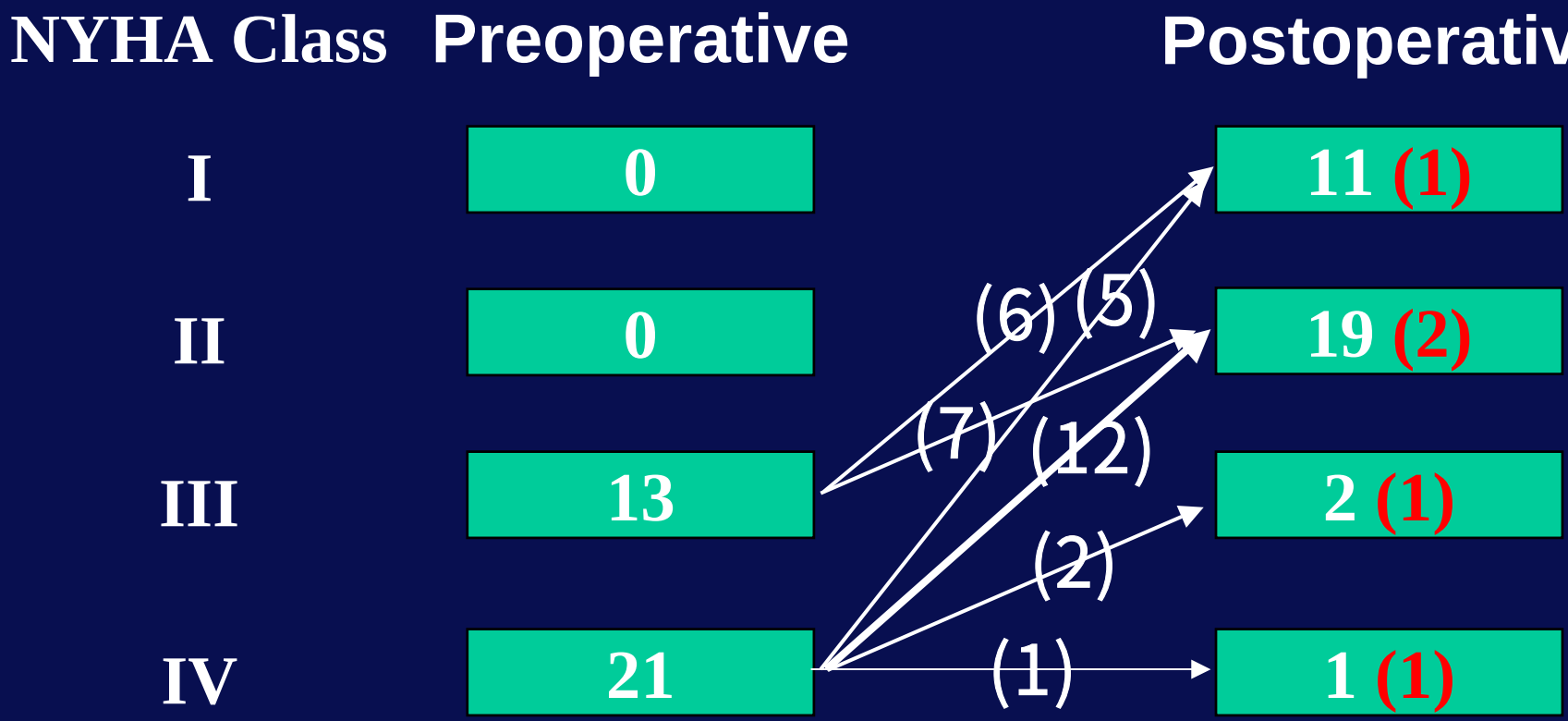
*: $p<0.05$

Changes of MR



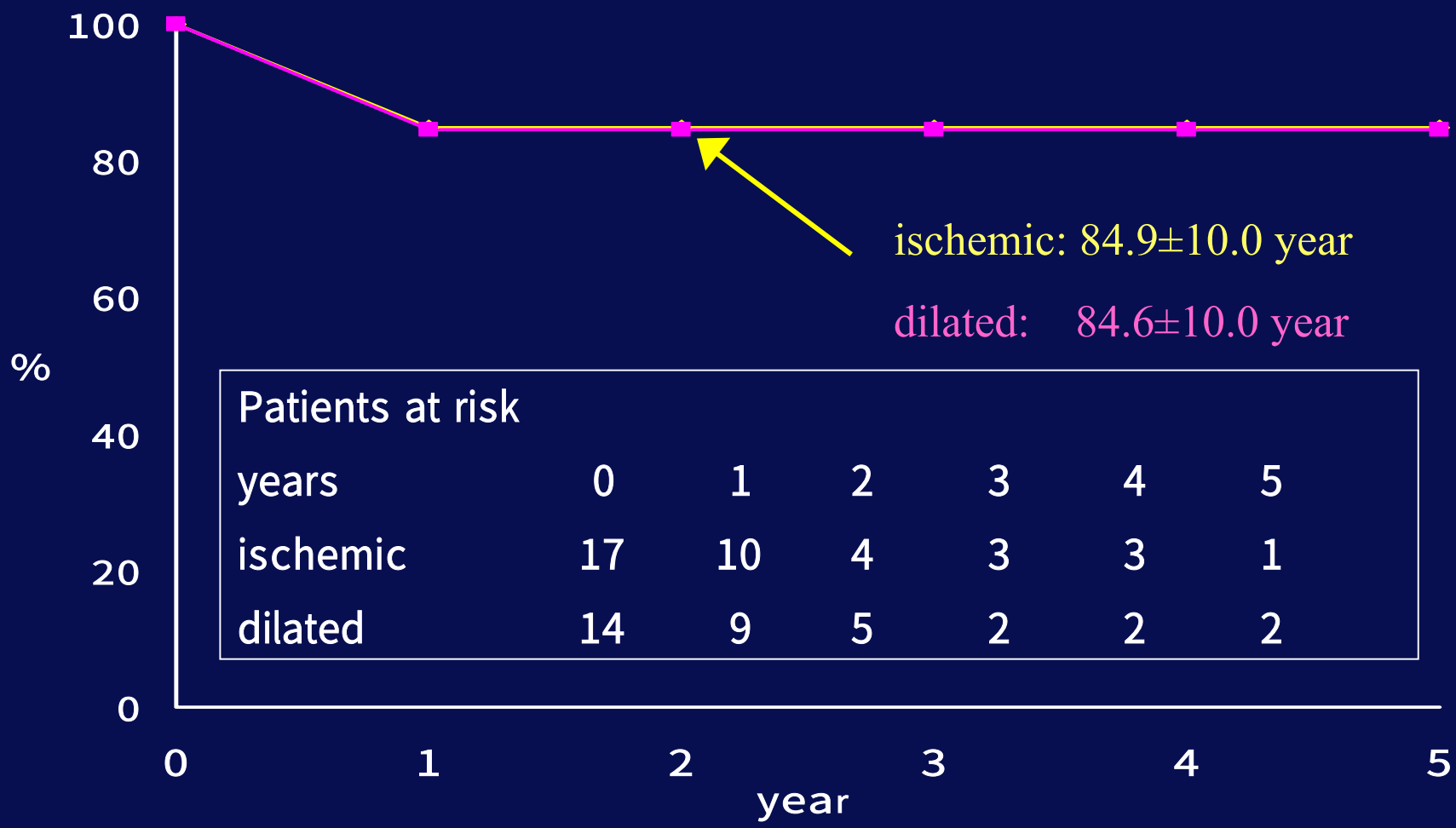
( ): Number of death

Changes of NYHA Class



( ): Number of death

Kaplan-Meier Survival

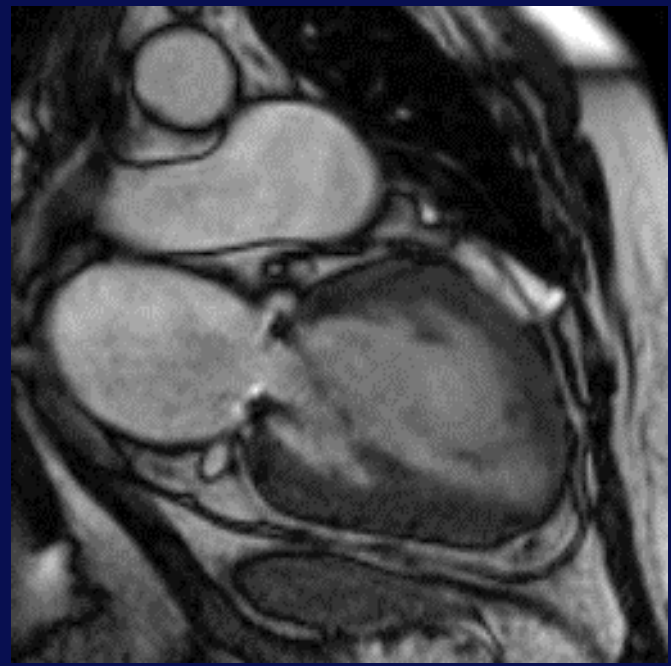


Pre and Postop cine-MRI
MV annuloplasty & CABG (2003-3-17)

Echo; EF 25%->31%, LV dimension 83 to 64mm

Choi YR, M/63

Preop. 2003-3-3



Postop. 2003-4-10

Yonsei

Analysis of LV geometry & function in modified Dor procedure and MVA using MRI

Yonsei

Analysis of LV geometry & function in modified Dor procedure and MVA using MRI

- **Materials: 21 cases of MAP and/or LVP**
- **Analysis**
  - **Short-axis cine images: 1cm thickness slices from mitral valve plane toward apex**
  - **Measurement of pre- & postoperative cross-sectional area at End-diastole & End-systole**
  - **Comparison of changes of cross-sectional area at ED, ES & segmental EF**

Group I (Dor + MVA)

7 cases

Case 1: Chung CS	4106326	MVA, CABG, Dor
Case 2: Park NS	2736259	MVA, Dor
Case 3: Choi YN	2261126	MVA,CABG, Dor
Case 4: Kim JY	4126445	MVA, CABG, Dor
Case 5: Choi JH	3032390	MVA, CABG, Dor
Case 6: Shin MC	1905478	MVA, CABG, Dor
Case 7: Kim JK	2983777	MVA, CABG, Dor

Group II (Dor)

8 cases

Case 8: Jang OH	1604921	Dor, CABG
Case 9: Lee WS	2286574	Dor, CABG
Case 10: Kim TW	4029029	Dor, CABG
Case 11: Lee JH	3333027	Dor, CABG
Case 12: Park SW	4227617	Dor, CABG
Case 13: Kim KH	4254598	Dor, CABG, AVR
Case 14: Kwon HY	2753298	Dor, Tricuspid A
Case 15: Jung JS	3014199	Dor, CABG

Group III (MVA)

6 cases

Case 16: Jang IN	2372250	MVA only
Case 17: Hyun PA	2600789	MVA + CABG
Case 18: Chun NM	4135787	MVA + CABG
Case 19: Kim SB	4142017	MVA + CABG
Case 20: Ka JH	4073802	MVA + CABG
Case 21: Whang	4093979	MVA only

Group I

1905478 Shin MC, Male/54

Preop	Postop 11d	Postop 9 m
2003-12-15	2003-12-30	2004-9-10

Group II (SAVER)

3333027 Lee JH Male/53

Preop 2002-8-13

Postop 2002-10-7

Yonsei

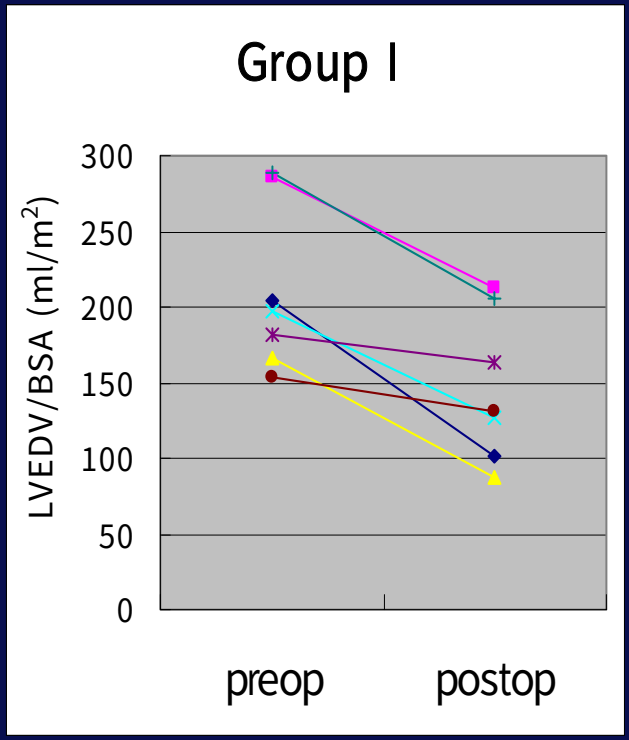
Group III

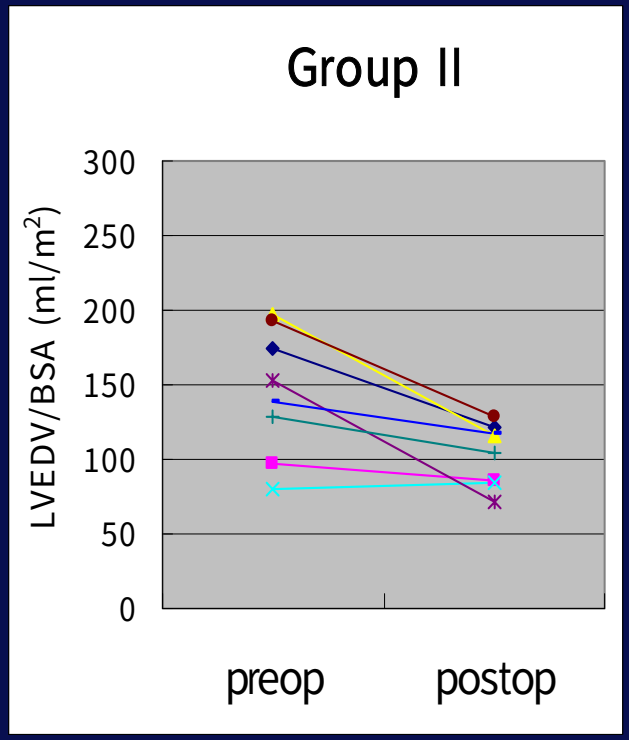
4135787 Chun NM
Male/40
MAP and CABG

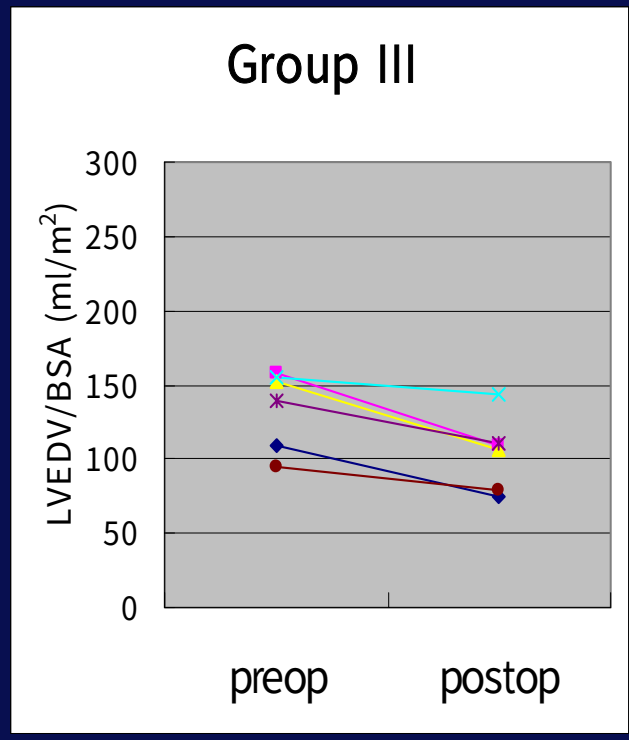
Preop 2003-11-13

Postop 2004-1-5

Changes of LVEDV



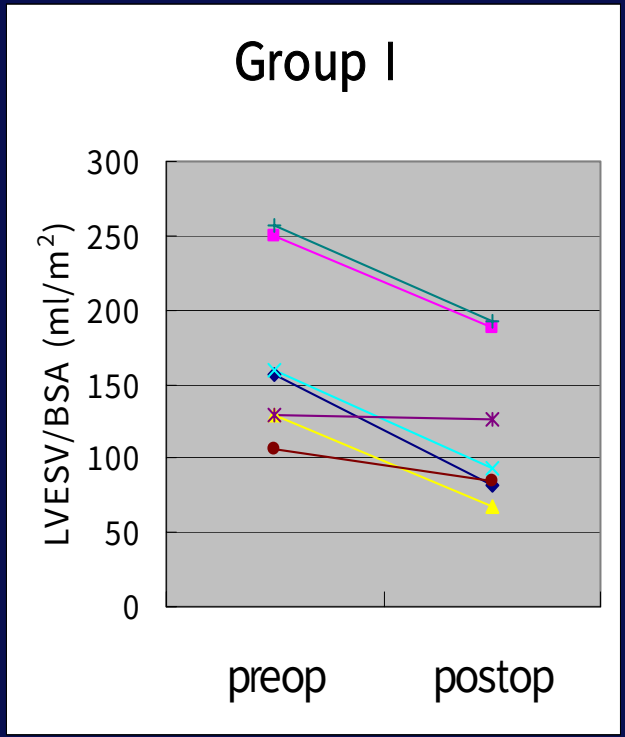


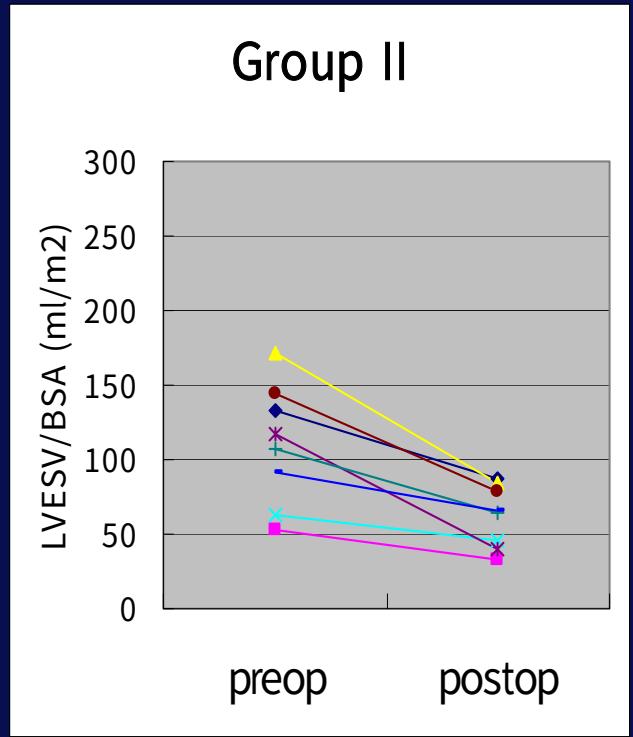


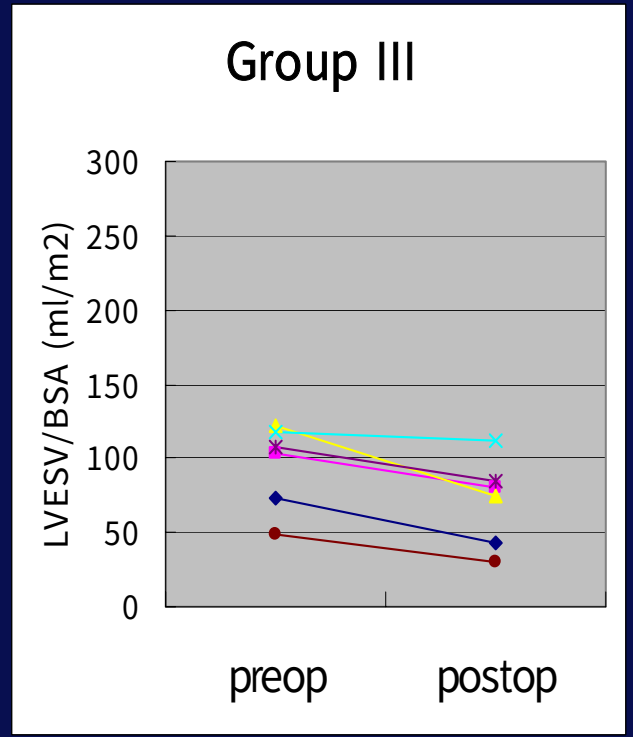
LVEDVI;		P=0.0018	P=0.0090	P=0.0042
Preop.		211.2±54.9	145.1±78.4	134.5±61.2
Postop.		146.9±48.9 1	103.5±20.7	104.0±24.8

Yonsei

Changes of LVESV



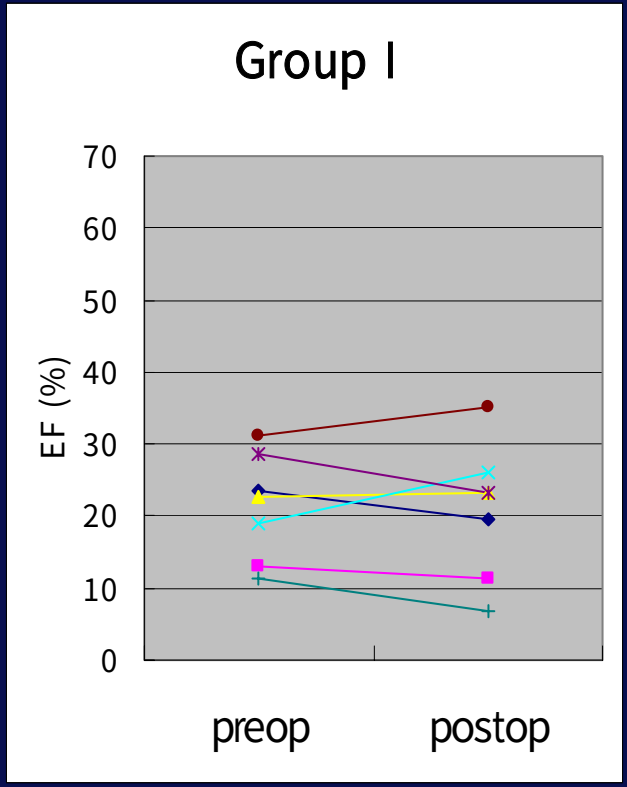




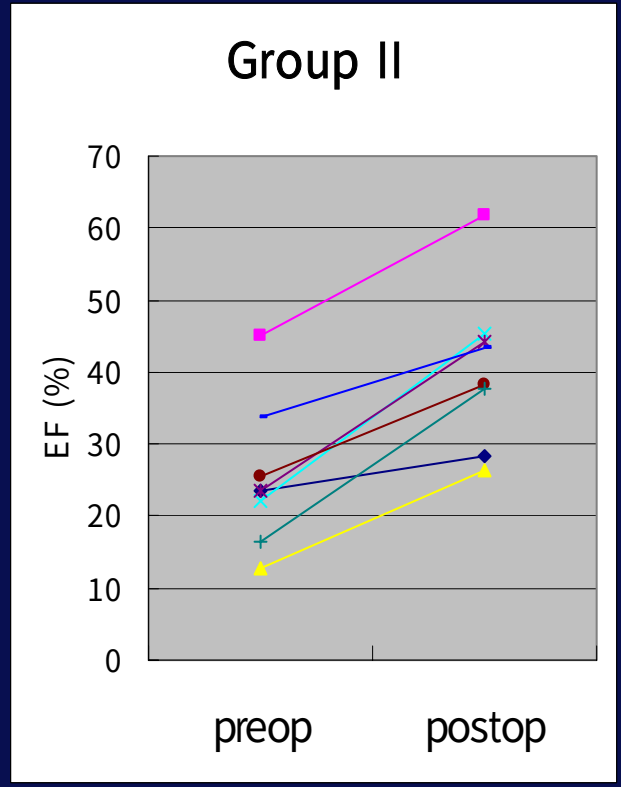
LVESVI;	P=0.0026	P=0.0015	P=0.0076
Preop.	169.4±59.9	110.0±40.3	95.3±28.1
Postop.	111.0±51.7	62.6±20.9	71.0±29.9

Yonsei

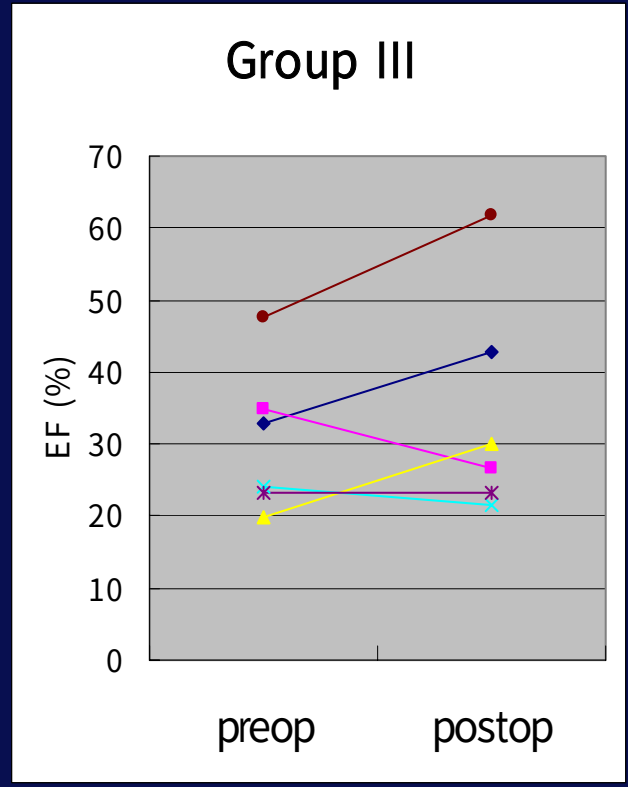
Changes of LVEF



Preop EF(%): 21.32 ± 2.8
Postop EF(%): 20.78 ± 3.6
P=0.7717

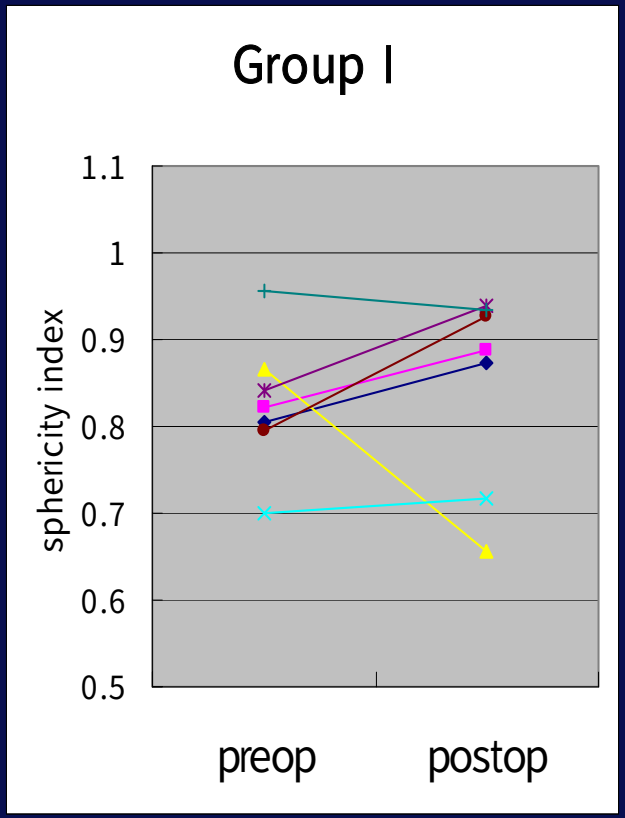


Preop EF(%): 25.37 ± 3.6
Postop EF(%): 40.71 ± 3.9
P=0.0002

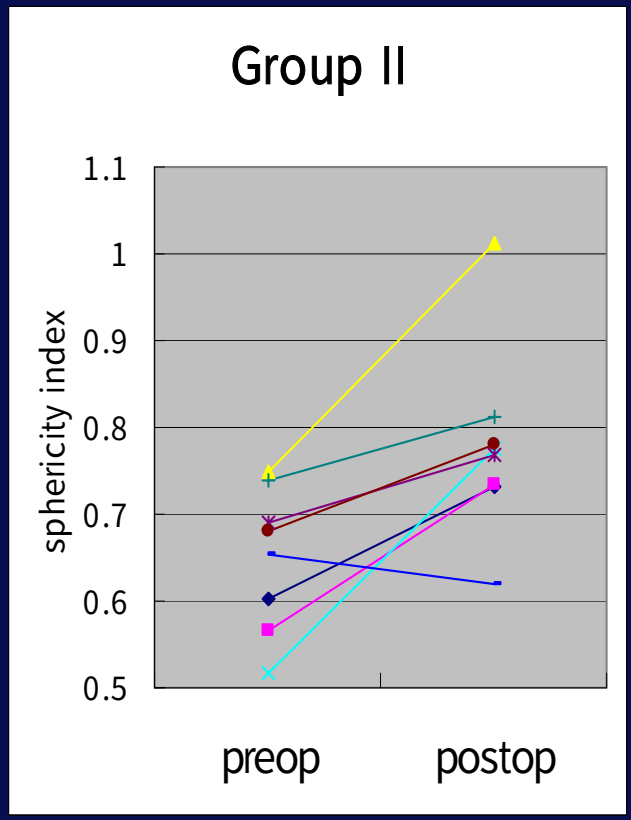


Preop EF(%): 30.41 ± 4.2
Postop EF(%): 34.32 ± 6.3
P=0.3266

Changes of Sphericity Index

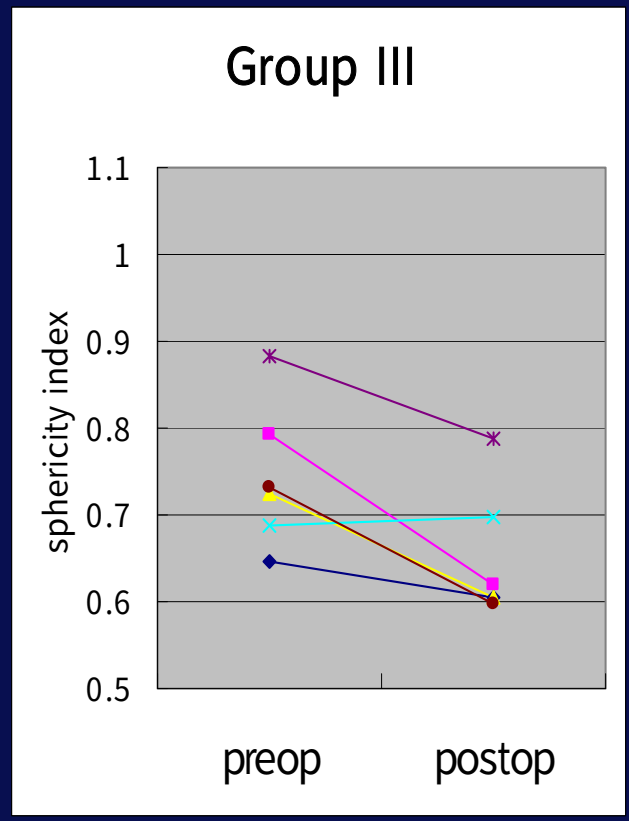


Preop SI: 0.8268 ± 0.0292
Postop SI: 0.8478 ± 0.0433
P=0.6444



Preop SI: 0.6496 ± 0.0291
Postop SI: 0.7793 ± 0.0392
P=0.0082

Sphericity ↑

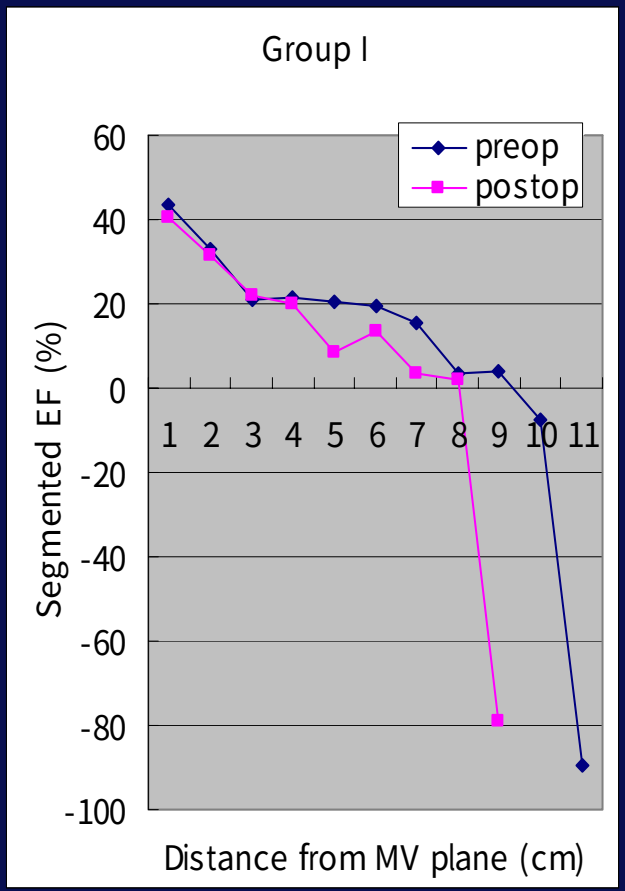


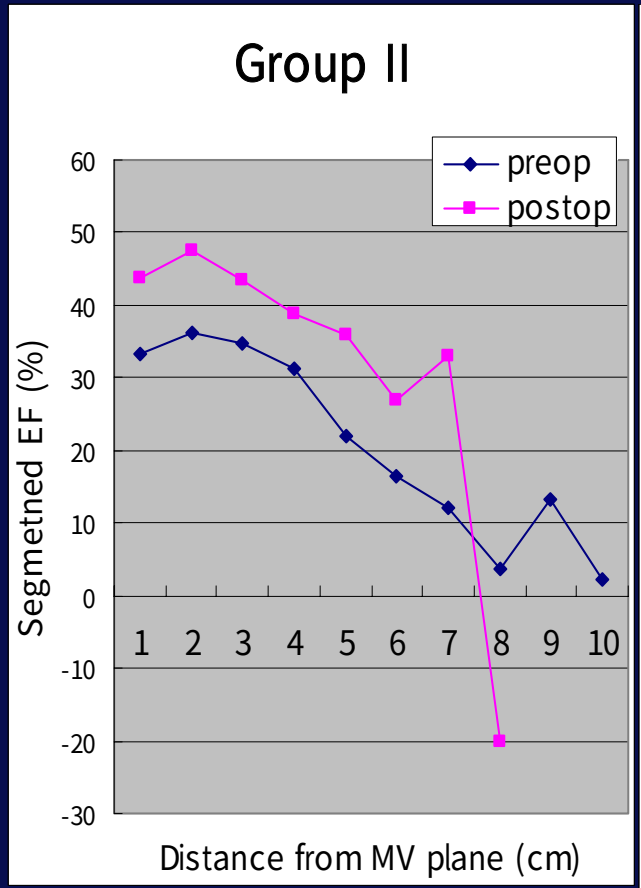
Preop SI: 0.7445 ± 0.0341
Postop SI: 0.6519 ± 0.0308
P=0.0180

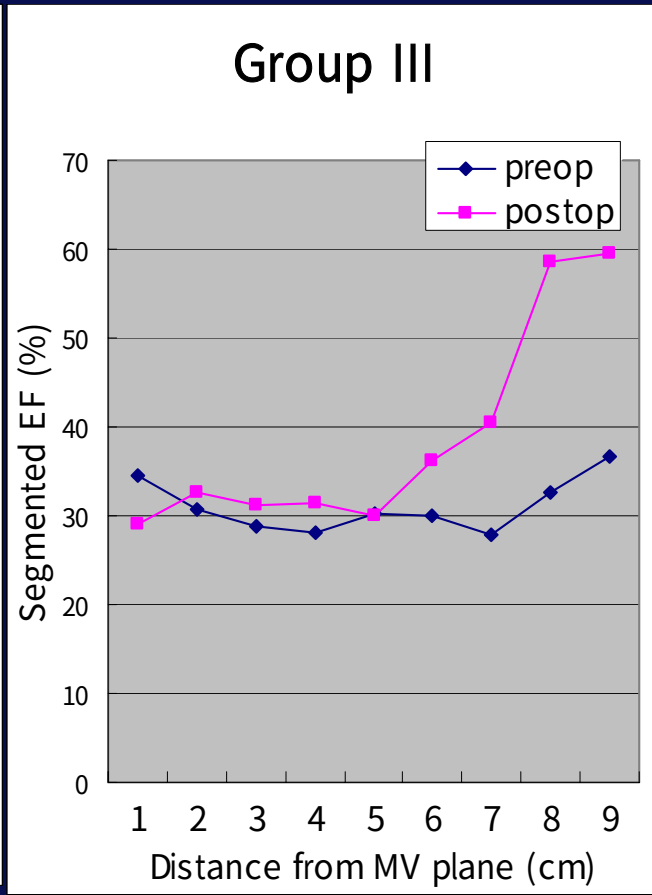
Sphericity ↓

Yonsei

Changes of Segmental EF







Conclusion(1)

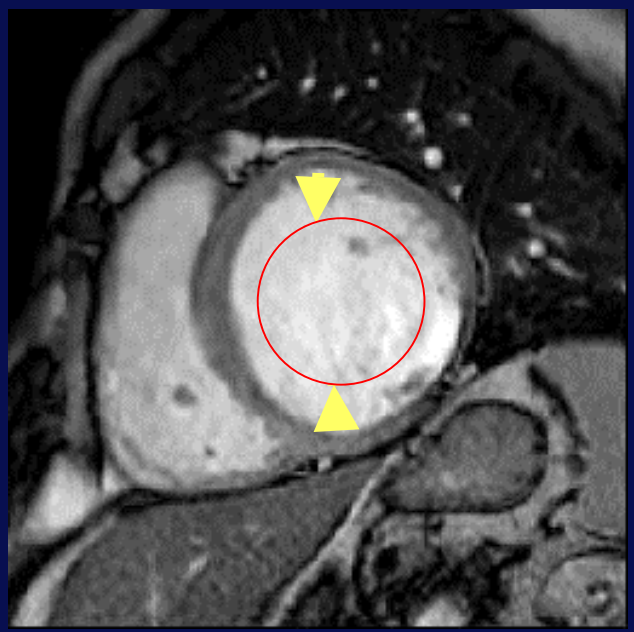
- **In patients with severe left heart failure with significant mitral regurgitation, mitral annuloplasty c/s left ventriculoplasty improved morphological and functional status of LV.**
- **Long-term results of mitral annuloplasty c/s left ventriculoplasty appeared to be good and can be performed in patients of end-stage heart failure, not indicated for heart transplantation.**

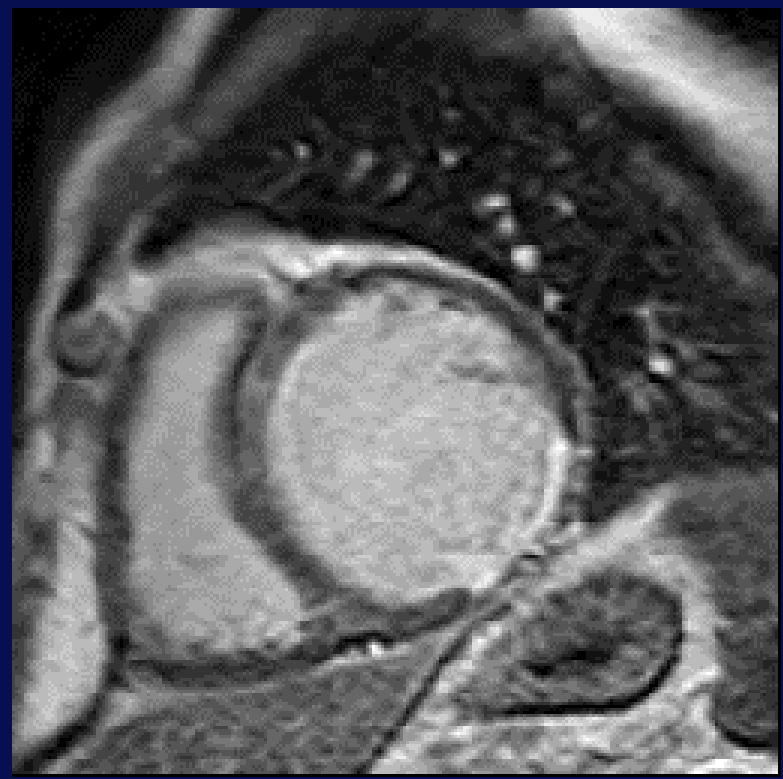
Conclusion(2)

- **Pre and Postoperative MRI revealed that LV Volumes are decreased significantly during End- diastole and End-systole.**
- **Postoperative segmental LVEFs were increased significantly from 5 cm from of mitral plane in Group 1 and 3. However segmental LVEFs were increased in all segment in Group 2.**
- **With these results, it appeared that earlier surgical approach is important in improving LV function before irreversible myocardial damage.**
- **However, these results are limited with small numbers, and with heterogeneous data.**

Mitral Annuloplasty and Apical Left Ventriculoplasty in I-CMP

Choi JH, 56/M





Pre-op: SV=293.1-215.3=77.8ml, EF=26.5%

Simulation: SV=151-99=52ml, EF=34%

Post-op: SV=54.1ml, EF 32% (Echo)

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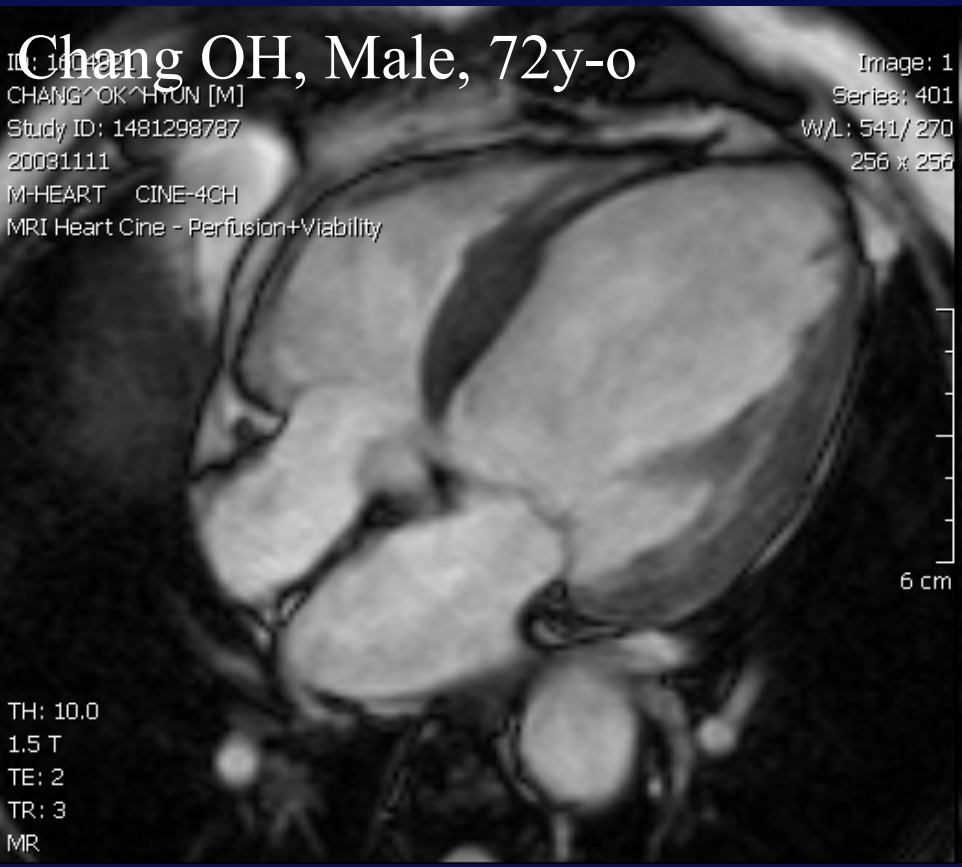
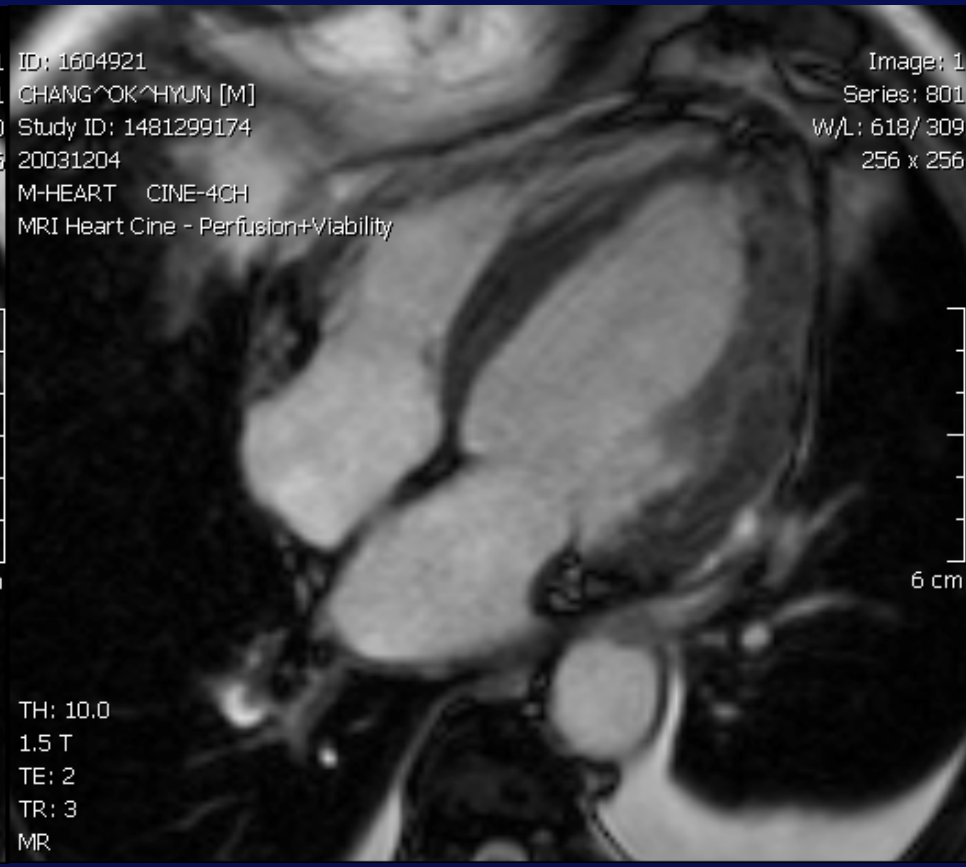
Changes of LV Dynamic Morphology before and after LVPlasty



Preop (LVEF=24%)



Postop 10 days

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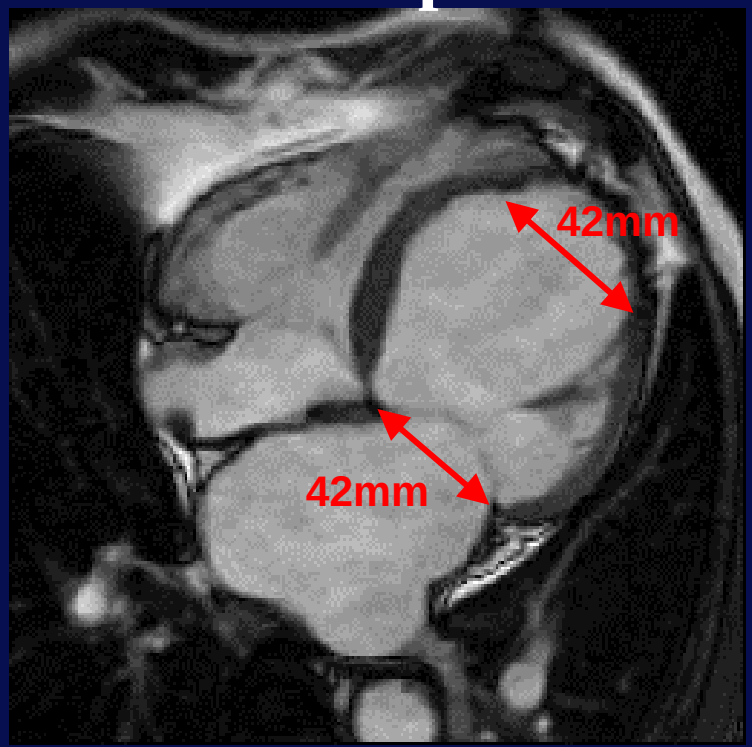
Mitral Annuloplasty and Apical Left Ventriculoplasty in I-CMP

Choi JH, 56/M

Preop

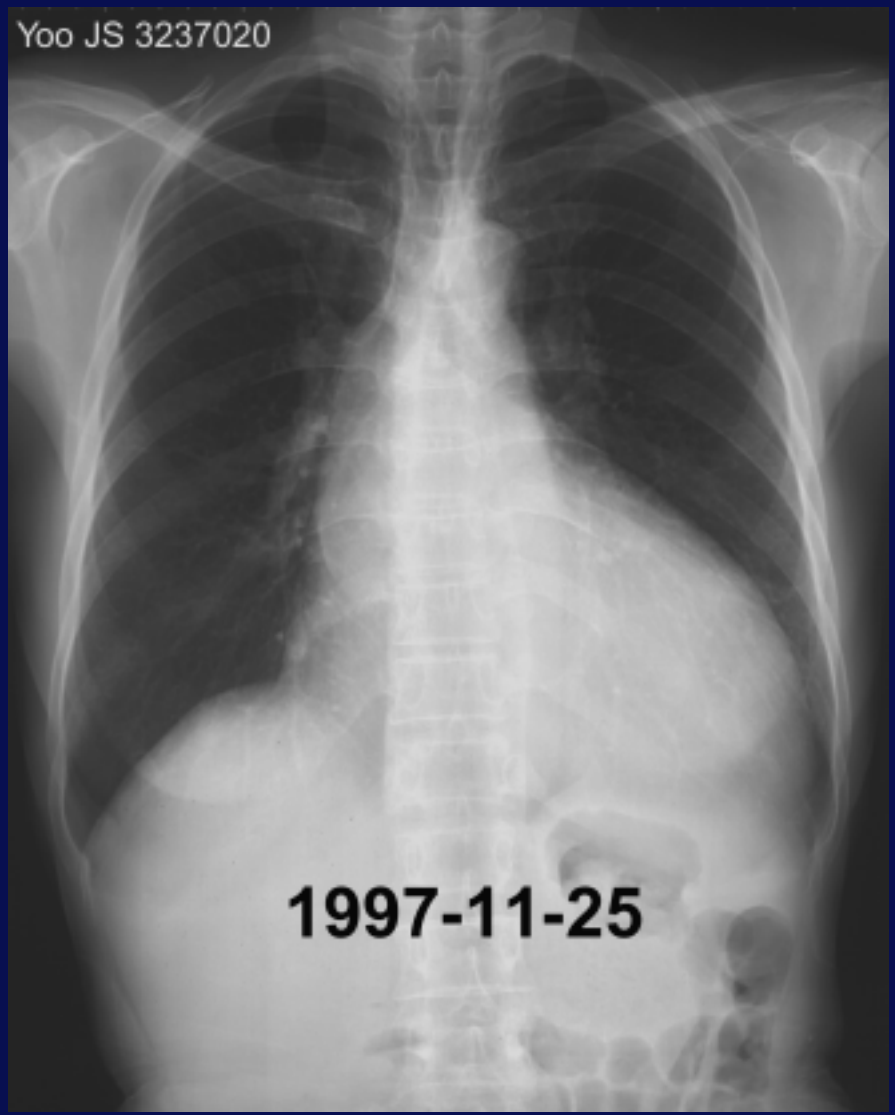


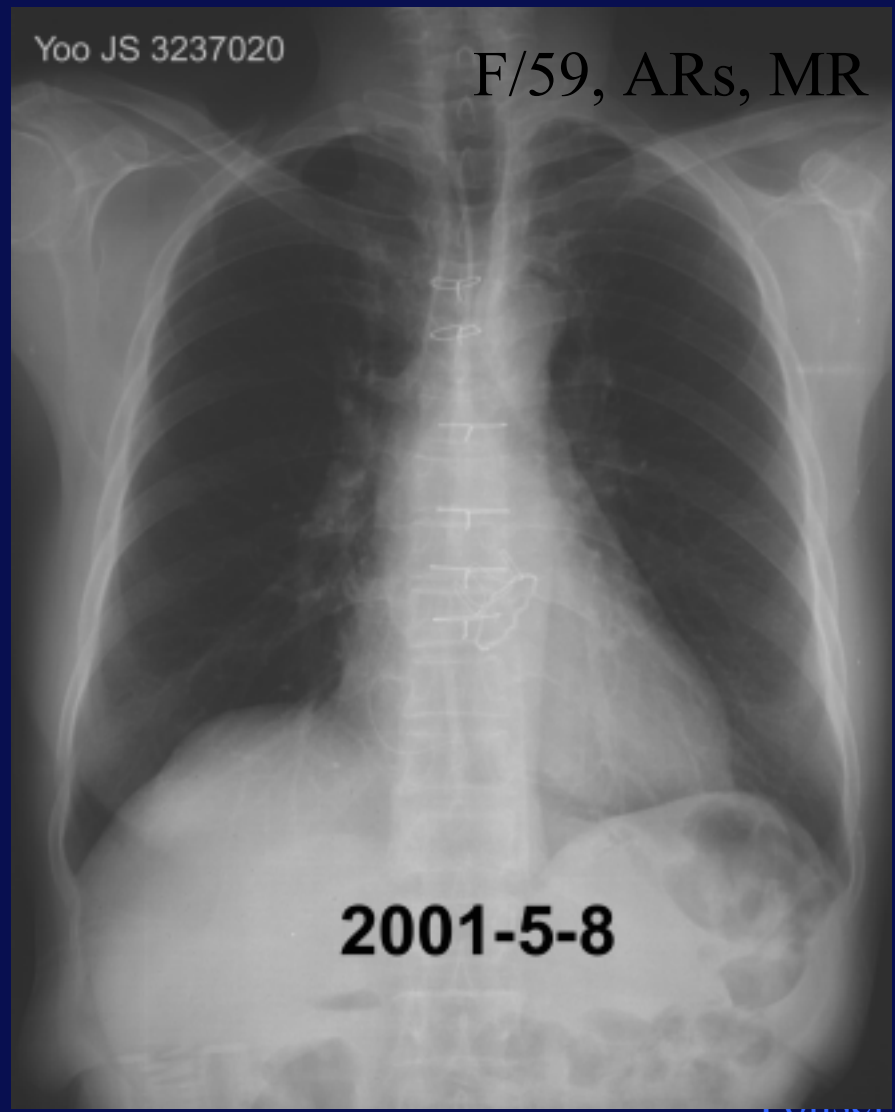
Postop

Pre-OP. : LVEF:29.1%, LVEDV 265.3ml, SV 77.2ml

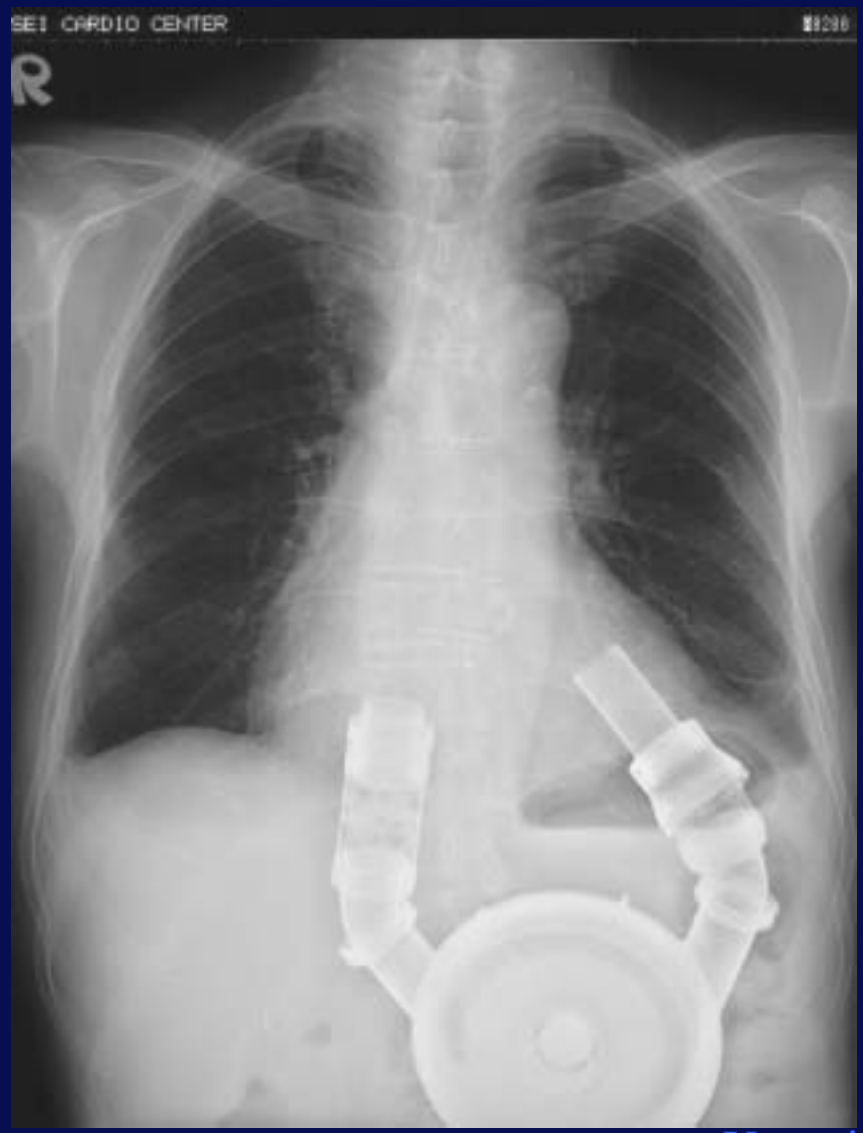
Yonsei

Pre and Postop. Chest P-A





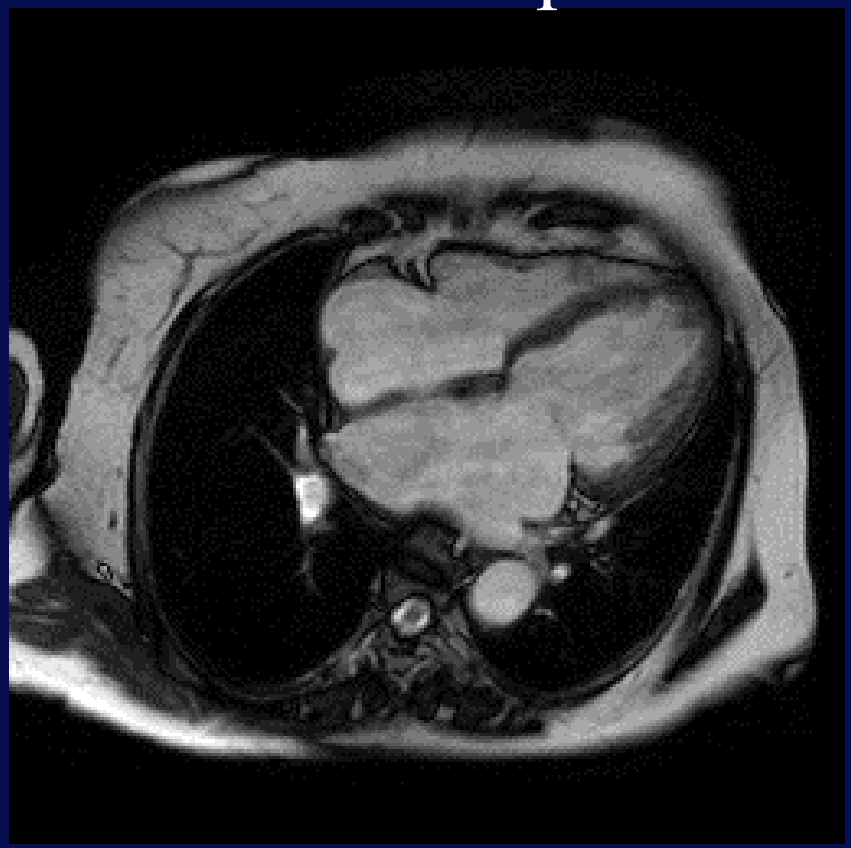
HeartMate LVAS for BTT



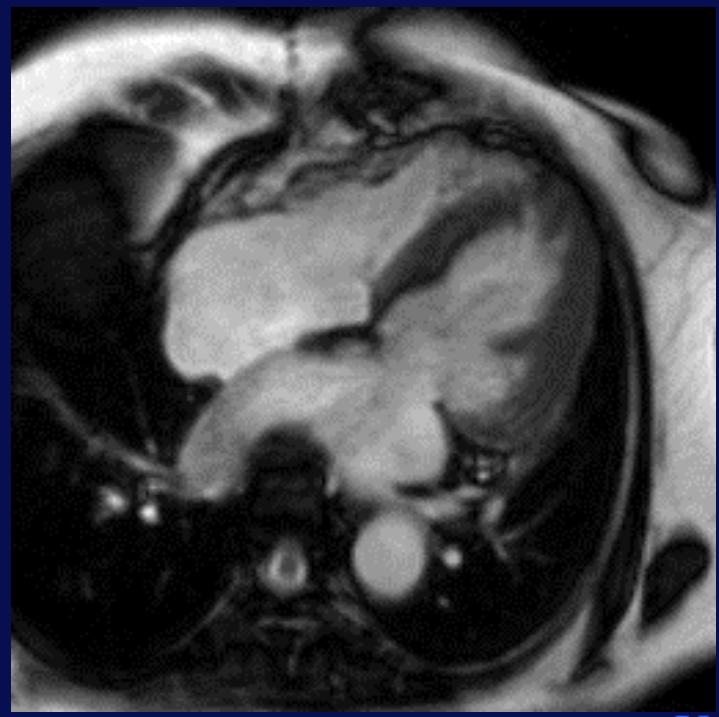
Yonsei

Changes of LV Dynamic Morphology before and after MAP

Preop

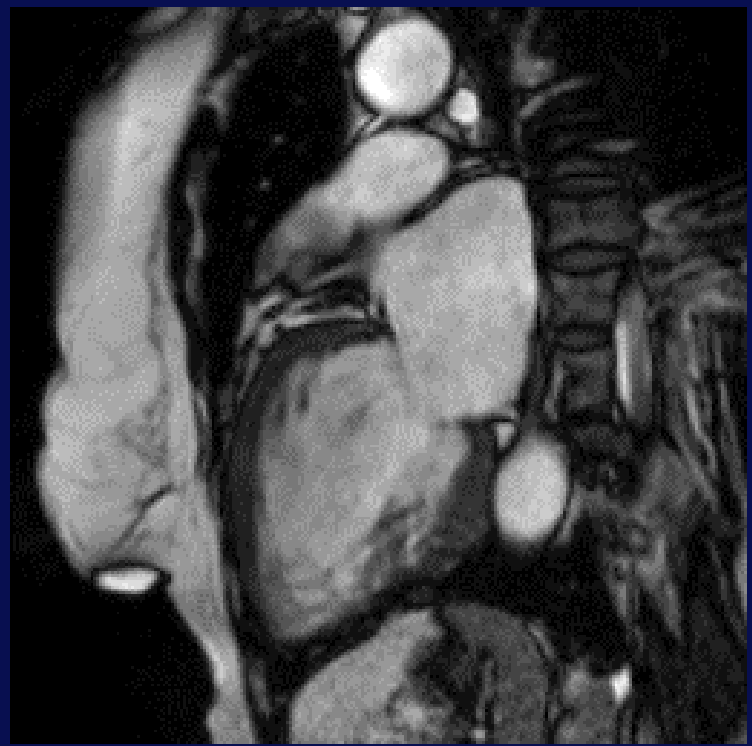


Postop

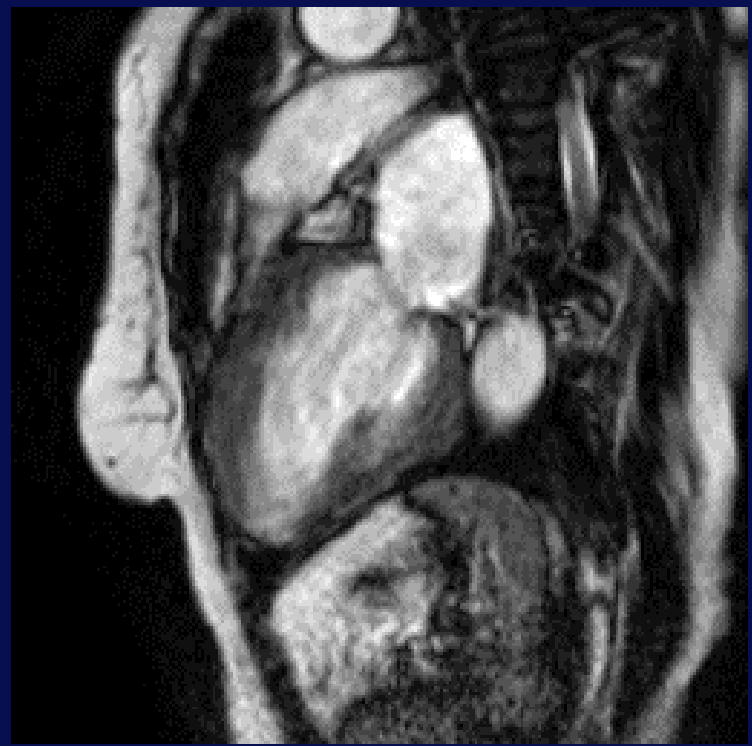


Changes of LV Dynamic Morphology before and after MAP

Preop



Postop



Changes of LV Dynamic Morphology before and after MAP