Functional Mitral Regurgitation Requires Both a Mitral and a Ventricular Solution

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Functional MR is a VENTRICULAR Disease!

In Nonischemic and ischemic cardiomyopathies, geometric perturbations in the left ventricle (LV) result in dysfunction of the Mitral Valve and secondary (functional) mitral regurgitation (FMR).

An increase in the interpapillary distance, annular dilation, and enhanced leaflet tethering contribute to secondary MR.

THE VALVE ARCHITECTURE IS NORMAL.
Surgery for FMR

Mitral Valve Replacement or Repair (annuloplasty)

56 years of experience
Which Ring is better (Best)? Does size matter, does Shape?
Surgical Therapy and Functional Improvement

Cosgrove 2000
Improved NYHA from 2.8 to 1.2
Reduced Readmissions for Heart Failure
Patients tolerated higher doses of Medical Therapy

Badwar and Boling 2002
4+ MR and Low EF (mean 14%)
NYHA 3.9 to 2.0

Romano and Boling 2004
Over 200 patients
Improved NYHA Class from 3.2 to 1.8

De Bonis, Alfieri 2005
Improved NYHA 3.4 to 1.4

Acker (Acorn Trial) 2006
Better Functional Class, MLHF, Short-form 36, 6 minute walk

NO Survival Benefit
What is the Impact of mitral valve annuloplasty on mortality risk in patients with mitral regurgitation and left ventricular systolic dysfunction?


Event-free survival for non-mitral-valve annuloplasty (MVA) group (solid line) and MVA group (dotted line).

Lack of Survival Benefit!
What is the impact of mitral valve annuloplasty on mortality risk in patients with mitral regurgitation and left ventricular systolic dysfunction?


Event-free survival for patients without coronary artery disease in non-mitral-valve annuloplasty (MVA) group (solid line) and MVA group (dotted line).
Double-orifice technique: A simple solution for complex problems

Ottavio Alfieri, MD, Francesco Maisano, MD, Michele De Bonis, MD, Pier Luigi Stefano, MD, Lucia Torracca, MD, Michele Oppizzi, MD, Giovanni La Canna, MD

The Journal of Thoracic and Cardiovascular Surgery
Volume 122, Issue 4, Pages 674-681 (October 2001)
Freedom from recurrence of MR of grade 3 to 4+ in the edge-to-edge and in the ring-only groups.

Is the MitraClip different than the Alfieri Stitch?
From: Randomized Comparison of Percutaneous Repair and Surgery for Mitral Regurgitation: 5-Year Results of EVEREST II


A. Freedom From Death, NY Surgery or Resection

B. Freedom From Death

C. Freedom From MV Surgery or Resection

D. Landmark Analysis of Freedom From MV Surgery or Resection Beyond 6 Months

COAPT Trial design overview

**Primary endpoints**

**Efficacy**
- Recurrent heart failure (HF) hospitalizations

**Safety**
- Composite of Single Leaflet Device Attachment (SLDA), device embolizations, endocarditis requiring surgery, Echocardiography Core Laboratory confirmed mitral stenosis requiring surgery, and any device related complications requiring non-elective cardiovascular surgery at 12 months

**Secondary endpoints**

**Efficacy**
- Mitral regurgitation severity at 12 months
- Change in 6-minute walk test at 12 months
- Change in quality of life at 12 months
- Change in Left Ventricular end-diastolic volume at 12 months
- NYHA functional class I/II at 12 months
- Hierarchical composite of death and recurrent HF hospitalization
- Recurrent hospitalizations — all-cause

**Safety**
- Composite of all-cause death, stroke, MI, or non-elective cardiovascular surgery for device related complications at 30 days post-procedure in the MitraClip group

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**430** patients enrolled at up to 75 U.S. sites

**RANDOMIZE 1:1**

**DEVICE GROUP** (MitraClip® device)

**CONTROL GROUP** (No device)

**CLINICAL AND ECHO FOLLOW-UP**

- **30 days**
- **1 week** (post-treatment phone contact)
- **Annually thereafter, for a total of 5 years**
- **6, 12, 18, 24 months**

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*TEST: 6MWT, QoL, NYHA functional class, TTE, BNP, NT-pro BNP level, modified Rankin Scale

* For COAPT Protocol Rev. 5.1

**Snapz Pro X**
Two-Year Outcomes of Surgical Treatment of Severe Ischemic Mitral Regurgitation (MV Repair vs Replacement)


N Engl J Med
Volume 374(4):344-353
January 28, 2016
Time-to-Event Curves for Death.

Hazard ratio, 0.79 (95% CI, 0.46–1.35)
P = 0.39

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Time-to-Event Curves for Major Adverse Cardiac or Cerebrovascular Events (MACCE).

Hazard ratio, 0.97 (95% CI, 0.66–1.42)
P=0.88

No. at Risk

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Quality-of-Life Scores.

Cumulative Failure of Mitral-Valve Repair or Replacement.

Novel Device Strategies... outside the box

Mitra l Bridge™ Concept

Transvalvular Bridge in SL dimension with centered infra annular curvature

Direct nonplanar reduction in SL diameter

Preserves the leaflet curvature
Shortens the papillary muscle to leaflet distance

Leaflet Restraint below the annular plane

Current device is adaptable for transcatheter delivery via 16 Fr Catheter
Subvalvular Solutions to improve durability of MVRepair in FMR: Chordal Cutting, PPM Relocation ... or PPM Sling (internal restraint)

Papillary muscle sling: a new functional approach to mitral repair in patients with ischemic left ventricular dysfunction and functional mitral regurgitation
Ulrik Hvass, Michel Tapia, Frank Baron, Bruno Pouzet and Abdel Shafi
Ann Thorac Surg 2003;75:809-811
How about pMVR plus LV Reduction or Stabilization?
How about pMVR and LV Assist?
Those Unfamiliar with History are doomed to Repeat it?

Ruiz et al, JACC Online, 2015
In FMR

Pathophysiology: Ventricular Disease

Surgical Mitral Valve Repair or Replacement improve Quality of life NOT Quantity of Life!!

Replacement better than repair!

(Except Coapsys Device)

Improved survival will require a ventricular solution!