



Milano 21 Marzo 2016

# La MitraClip:

# I presupposti teorici, il fissaggio ed il risultato del posizionamento del device in vitro.

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# DISCLOSURE

- No financial relationship
- No stock option holder
- No interventional cardiologist
- CARDIOVASCULAR SURGEON





EDGE TO EDGE TECHNIQUE

#### **ALFIERI STITCH**

#### 1991

successfully treat a patient with anterior leaflet prolapse. At that time, anterior leaflet repair was considered challenging, and most patients would undergo replacement. The day before, Alfieri had operated on another patient for correction of atrial septal defect who had, as a concomitant asymptomatic condition, a perfectly competent congenital double-orifice valve. Initially the technique was applied only



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Viewpoin

#### The Evolution From Surgery to Percutaneous Mitral Valve Interventions

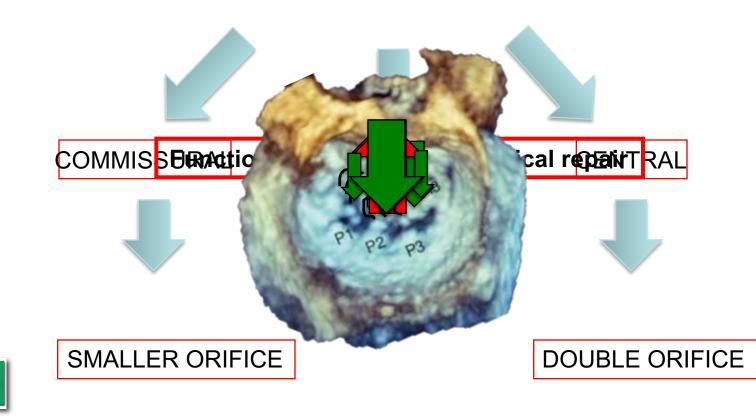
The Role of the Edge-to-Edge Technique

Francesco Maisano, MD, Giovanni La Canna, MD, Antonio Colombo, MD, Ottavio Alfieri, MD Milano, Italy

# EDGE TO EDGE TECHNIQUE

BASIC CONCEPT:

mitral regurgitation can be corrected simply by suturing the free edge of the diseased leaflet to the corresponding edge of the opposing leaflet exactly where the regurgitant jet is located





### EDGE TO EDGE TECHNIQUE

## INDICATIONS:

- Bileaflets prolapse
- Anterior mitral leaflet prolapse
- Commissural prolapse
- SAM (prevention / treatment)
- "Rescue" technique for suboptimal mitral valve repair





## EDGE TO EDGE TECHNIQUE



- Simple and Reproducible
- Short Cross Clamp
- Ensures a fixed area of coaptation during systole without disturbing the subvalvular and annular function

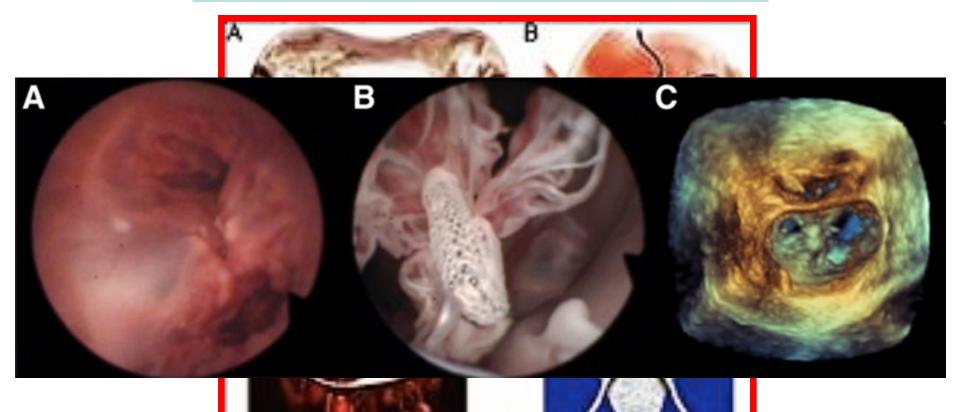
# Best long term results when associated with annuloplasty

- Risk of stenosis
- Impairment of leaflets motions
- Changes in hemodynamics ?





### EDGE TO EDGE TECHNIQUE







#### MitraClip System

The MitraClip System performs **percutaneous mitral valve repair** by creating a vertical line of coaptation, forming a double–orifice valve.

- Beating heart procedure—no cardiopulmonary bypass
- Allows for real-time positioning and repositioning to optimize MR reduction
- Designed to preserve surgical options

The Clip Delivery System and Steerable Guide Catheter are designed to fit co-axially to accurately position and reposition multiple implants with the use of one guide.



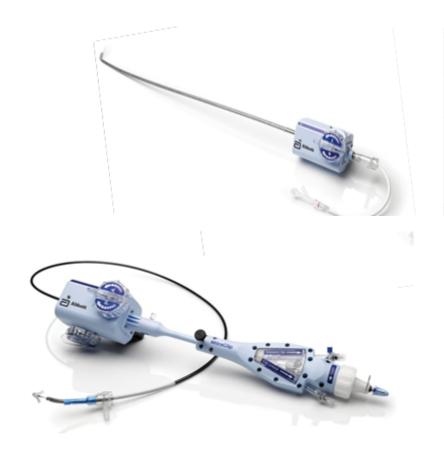


#### **Steerable Guide Catheter**

- 24 French steerable catheter
- Percutaneous venous access

#### **Clip Delivery System**

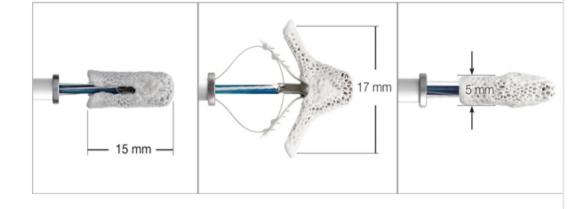
Contains the Implant attached to a highly manueverable delivery catheter with all controls at the proximal end.



#### MitraClip Device (Implant)

- Cobalt chromium construction
- Polyester cover designed to promote tissue growth
- Magnetic resonance conditional to 3 Tesla\*

\* Static magnetic field up to 3 Tesla; maximum spatial gradient in static field of 2500 gauss/cm or less; maximum whole–body averaged specific absorption rate (SAR) of 3.0 W/kg for 15 minutes of scanning.



### Equipment

The MitraClip System can be used in a standard cath-lab or hybrid room.

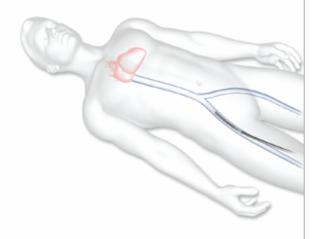
#### Equipment required:

- Fluoroscopy
- Slave monitors (one for echocardiography, one for fluoroscopy)
- General anesthesia
- Echocardiography machine equipped with TEE probe
- Sterile system preparation station



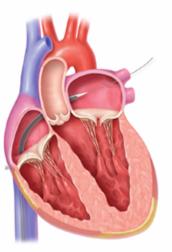
### **Procedural Overview**

#### Patient and System Preparation



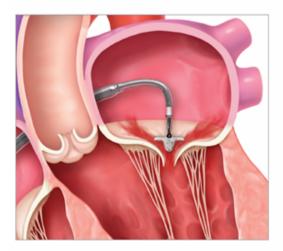
- The following considerations should be accounted for:
  - TEE probe will be in place for an extended period of time
  - Intubation under general anesthesia
  - 24 French sheath in right femoral vein
  - Bladder/urinary catheter in place
  - Heparinization during procedure to ACT > 250
- System is prepared by removing all the air in the lumens of the Clip Delivery System and Steerable Guide Catheter
- System is functionally tested prior to use

#### Transseptal Crossing and Guide Insertion



A transseptal procedure is performed to gain access from the right atrium to the left atrium. The Steerable Guide Catheter (Guide) and Dilator are then carefully advanced into the left atrium over a wire. Once the Guide is in place and secured, the wire and Dilator are removed leaving the Guide in the left atrium.

#### Clip Delivery System Insertion and Steering in the Left Atrium



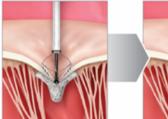
To introduce the Clip, the Clip Delivery System (CDS) is advanced through the Guide into the left atrium. A series of steering maneuvers and manipulations with the Guide and CDS are required to align the Clip perpendicular to the mitral valve plane, and the Clip Arms perpendicular to the line of coaptation. These maneuvers are done under echocardiographic and fluoroscopic guidance.

### **Procedural Overview**

#### Advancing into Left Ventricle and Leaflet Grasping



After the Clip is aligned over the regurgitant jet in the left atrium, the System is then advanced into the left ventricle to begin the grasping procedure. Leaflet grasping is done by slowly retracting the System back towards the left atrium to allow the leaflets to come to rest on the Clip Arms and then dropping the Grippers.





Clip Arms closed to 120°

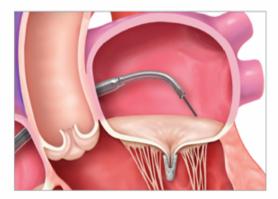
Clip Arms closed to 20°

Leaflet Insertion Assessment and Hemodynamic Measurements



Prior to Clip closure and deployment, a leaflet insertion and hemodynamic assessment must be performed. The leaflet insertion assessment ensures both leaflets are fully inserted and secure into the Clip. In addition, the MR reduction and pressure gradients are assessed to ensure regurgitation reduction without stenosis.

#### **Deployment and System Removal**



Once the assessments are positive, the Clip can be fully closed and deployed in a multistep process. The physician may also decide to place a second Clip to optimize MR reduction. The System is removed by releasing deflections on the catheter and slowly removing from the patient. Groin management and continued medical therapy are recommended per the institution's guidelines.

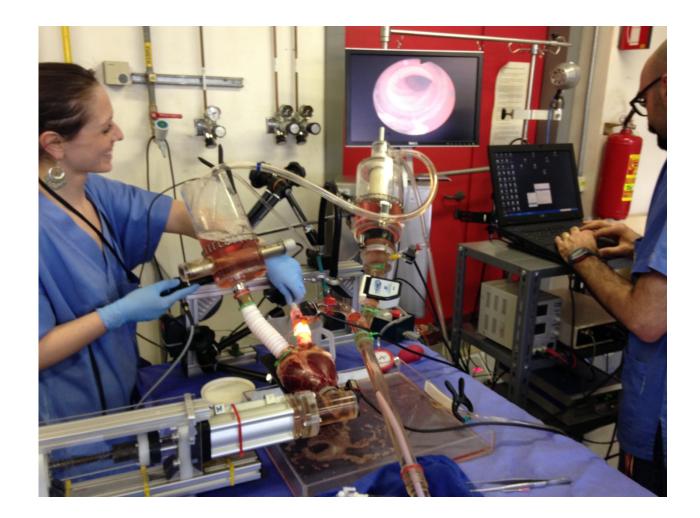


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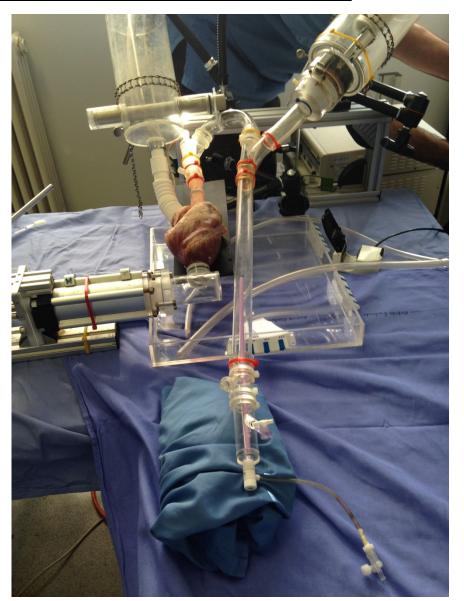
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### Transcatheter Valve Platform

**TAVI** (transfemoral, direct aortic, transapical)

**Mitral** (transeptal, transapical, direct atrium)

LAA closure Tricuspid (right)



# Pratice In Silico Abbott Model

- Ing. Fabio Simone
- Ing. Daniele Guzzetti



