### **Degenerative MR:**

### Where the Interventionalist stops

### And the Surgeon begins



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### **Disclosure Statement of Financial Interest**

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

#### **Affiliation/Financial Relationship**

#### Company

Major Stock Shareholder/Equity

Coremedic AG

# The landscape of valve surgery and interventions



# The expanding portfolio of transcatheter mitral repair and replacement



## MitraClip is an example of the natural evolution of a surgical technique into a percutaneous intervention



----- Video assisted ------

zcho-guided

### Young patients with no comorbidities, go for surgery!!!





# In hospital data USZ, 400 MICS mitral repairs

ICU stay (d)	1	0-96
Ventilation time (h)	6.6	0-460
Hospital stay (d)	8	3-61
No transfusion needed	323	80.7%
Infection	9	2.3%
30-day mortality	2	0.5%
Myocardial infarction	2	0.5%
Permanent stroke	9	2.3%
Reoperation	6	1.2%

## Follow up

- 22 months (1-55), 337 patients (84%)
  - 95.5+/-1.2% survival
  - 96.8+/-1.2% MACCE free survival
  - 94.8+/-0.1% freedom from reoperation





### SL, 83 yo

### A difficult decision in a patient with borderline risk profile

#### **Retired farmer**

recent worsening of symptoms,

no major comorbidites,

STS score 2

Normal LV function

Normal coronary angiogram

P2 prolapse, monosegment, short flail gap (Ideal EVEREST candidate)



### Final outcome....0 MR, mean Gradient 2 mmHg, no residual prolapse





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tional surgery for repair or replacement of the mitral valve. The primary compo-

### CONCLUSIONS

Perc

Although percutaneous repair was less effective at reducing mitral regurgitation than conventional surgery, the procedure was associated with superior safety and similar improvements in clinical outcomes.

## No 3D echo No previous experience Learning curve

#### CONCLUSIONS

Although percutaneous repair was less effective at reducing mitral regurgitation than conventional surgery, the procedure was associated with superior safety and similar improvements in clinical outcomes. (Funded by Abbott Vascular; EVEREST II ClinicalTrials.gov number, NCT00209274.)

Feldman T et al., J Am Coll Cardiol 2009;54:686–94

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### Kaplan-Meier 5 Year Freedom From MV Re-intervention



### Building the Evidence for MitraClip therapy

EVEREST	<ul> <li>Surgery (Repair /Replacement) vs MitraCLip</li> <li>FMR, DMR, No risk threshold</li> </ul>
RESHAPE	<ul><li>OMT (including CRT) vs MitraClip</li><li>FMR</li></ul>
FRANCE MR	<ul><li>OMT (including CRT) vs MitraClip</li><li>FMR</li></ul>
COAPT	<ul><li>OMT (including CRT) vs MitraClip</li><li>FMR</li></ul>
MATTERHORN	<ul> <li>Surgery (Repair /Replacement) vs Mitraclip</li> <li>FMR</li> </ul>
HIRIDE	<ul> <li>Surgery (Repair /Replacement) vs Mitraclip</li> <li>DMR high-intermediate risk (but operable) pts</li> </ul>

### **Study Design**

*Two-arm, multi-centre, randomized prospective study* comparing MitraClip to Surgical therapy in high and intermediate risk patients. 1:1 randomization) to be enrolled in up to **15** sites and 3 countries in **Europe**.

CO-PI: F. Maisano, A. Vahanian

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## Safety: 30-day safety superiority of MitraClip as compared to surgery (ITT analysis)

All-cause death, Prolonged ventilation (>48h), Renal failure, Stroke, Need for non-elective cardiovascular or thoracic surgery

## Efficacy: 12-month efficacy non-inferiority (ITT analysis)

• All-cause death, NYHA Functional Class improvement (at least one), Heart failure (HF) Hospitalization

Modern MitraClip therapy

- With experience, anatomical indications are becoming wider
- Palliative approach should be acceptable only in inoperable patients
- In treating high risk but operable patients the quality bar needs to be raised

## Kaplan-Meier Estimate of Freedom From All-Cause Mortality by Discharge MR



## **FCR** Kaplan-Meier Estimate of Freedom From All-Cause Mortality by Discharge MR



## Edge-to-edge surgical mitral valve repair in the era of MitraClip: what if the annuloplasty ring is missed?



Mechanism of MR:

- bileaflet prolapse in 46%
- anterior leaflet prolapse in 18%
- posterior leaflet in 36%

The omission of annuloplasty was due to important annular calcification in 59%.

In the remaining patients, annuloplasty was intentionally avoided because of the presence of only mild annular dilatation/ deformation.

Freedom from reoperation & recurrence of MR 3-4+ with initial residual MR 0-1+ at discharge.

### Beyond

- Chasing surgical results with
  - combination therapies
  - Annuloplasty
  - Mitral replacement

## Combination of MitraClip and Annnuloplasty: towards surgical standards





- Improve long term durability
- Improve MR reduction in FMR and DMR











### **Anatomical complexity**

**simple anatomy** A2P2, single segment, (EVEREST candidate)

> complex anatomy Barlow's, post-endocarditis, calcified leaflet, multilesion

### We believe in repair!!!





## Chordal replacement with PTFE sutures for mitral valve repair: A 25-year experience



## **Mitral- Panorama**

Approach	Commercial	In Development	Abandoned
Edge-to-Edge Repair	Abbott Vascular	ST. JUDE Medical MITRAFLEX	E Edwards Lifesciences
Direct Annuloplasty	<b>&amp;Valtech</b> Cardioband	Kardium Alcare mitralign Millipede IIc Kvaltech GDS Accucinch MiCardia	ReCor Medical
Indirect Annuloplasty			ST. JUDE MEDICAL V/ACOR Edwards Lifesciences
Chordal Repair	neochord	CoreMedic straight to the heart	
Ventricular Remodeling		CARDIOKINETIX Phoenix Cardiac MARDIL MEDICAL Sin DioVentrix	MYOCOR CARDIOVASCULAR
Enhanced Coaptation		cardiosolutions middle peak MitrAssist Assisting the Mitral Valve	
Mitral Valve Replacement		Edwards Medtronic Cares Caisson Mederonic Caisson Mede	E Edwards Lifesciences

### ChordArt™ Chordae replacement respecting anatomy



Repair with ChordArt<sup>™</sup> can not be distinguished from *natural anatomy* and *does not burn any bridges* for standard surgical procedures

#### ChordArt<sup>™</sup> :

-Does NOT use *large implants* -Does NOT create *irreparable damage* 

-Does NOT target incorrect anatomical or physiological sites

### ChordArt™ The Implant

The **Implant** consist of three basic components:

- (1) Distal anchor
- (2) Proximal anchor
- (3) Suture (artificial chordae)



This implant is delivered through



### ChordArt™ Delivery Systems

#### ChordArt S ™



#### ChordArt C ™



### ChordArt S ™ Animation



### ChordArt C ™ Animation



### ChordArt™ The GLP preclinical 6 months chronic study



N=5 Sheep, 60-70 kg	Acute Chorda Rupture Model Beating Heart with ECC support
Procedural Success	100%
Early Safety	Procedural 30-day mortality = 0%
<b>Clinical Efficacy</b>	Survival at 6 months = 100% Normal growing of all animals
Time-related valve safety	MR < 2+ = 100% Mean Gradient = 0.5 ± 0.5 mmHg
	NO disruption or malfunction of the implant at 6 months NO annular or ventricular dilatation

### ChordArt<sup>™</sup> The GLP preclinical 6 months chronic study





### ChordArt™ The preclinical transcatheter direct access study



### ChordArt™ The preclinical transcatheter direct access study



### ChordArt™ Transcatheter direct access with Heart Navigator



### ChordArt™ Transcatheter direct access with Heart Navigator



### Surgical vs transcatheter interventions



# Surgical rescue after interventional failures, interventional rescue after surgical failures









## **Evolution of interventions**

Surgery is the only treatment

Surgery is the gold standard treatment

Surgery is the preferred treatment for low and intermediate risk patients

Transcatheter interventions are performed in intermediate risk patients

Surgery is performed in patients with contraindication to transcatheter approach





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