Hospices Civils de Lyon

Percutaneous Mitral Plasty techniques

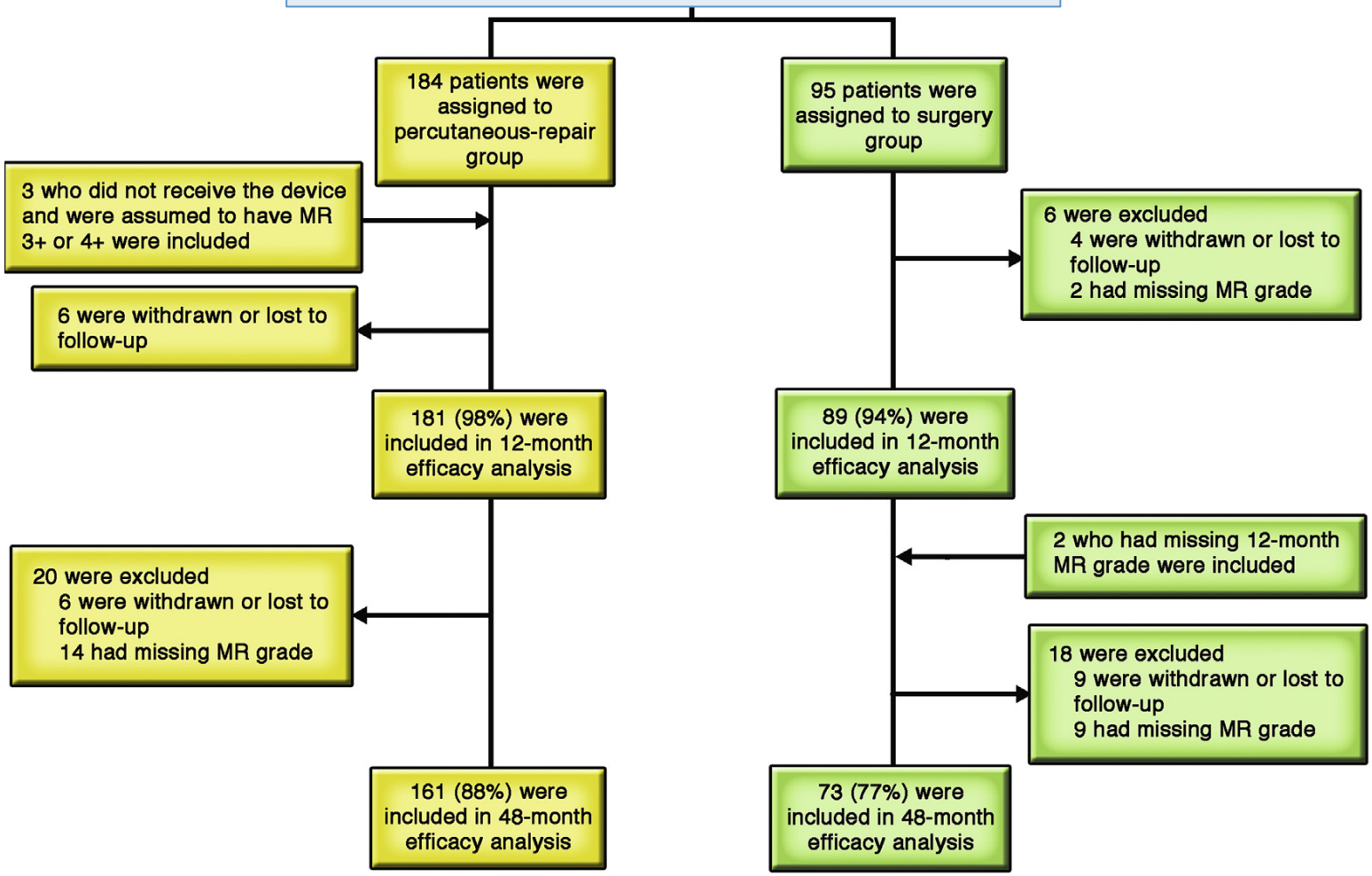
Jean-François OBADIA

Cardiothoracic and Vascular Surgery Department
Hôpital Louis Pradel
LYON - France

Percutaneous Mitral Plasty Techniques

Approach	Commercial	In Development	Abandoned
Edge-to-Edge Repair	Abbott Vascular	St. Jude Medical	
Direct Annuloplasty		Kardium, Valcare, mitralis, Guided Delivery Systems, Mitralign, millipede llc., Valtech	QuantumCor, ReCor Medical
Indirect Annuloplasty	Cardiac Dimensions		St. Jude Medical, Viacor, Edwards
Chordal Repair	neoCHORD	Valtech	
Ventricular Remodeling		CardioKinetix Inc., MARDIL MEDICAL, BioVentrix	Myocor, Acorn
Enhanced coaptation		middle peak, cardiosolutions, Mitralix, MitrAssist	
MV Replacement		Medtronic, endoValve, neovasc, Valtech, twelve, Cassion, CardiAO, Highlife, Braile, Edwards, Tendyne, NaviGate	

EVEREST II 279 patients

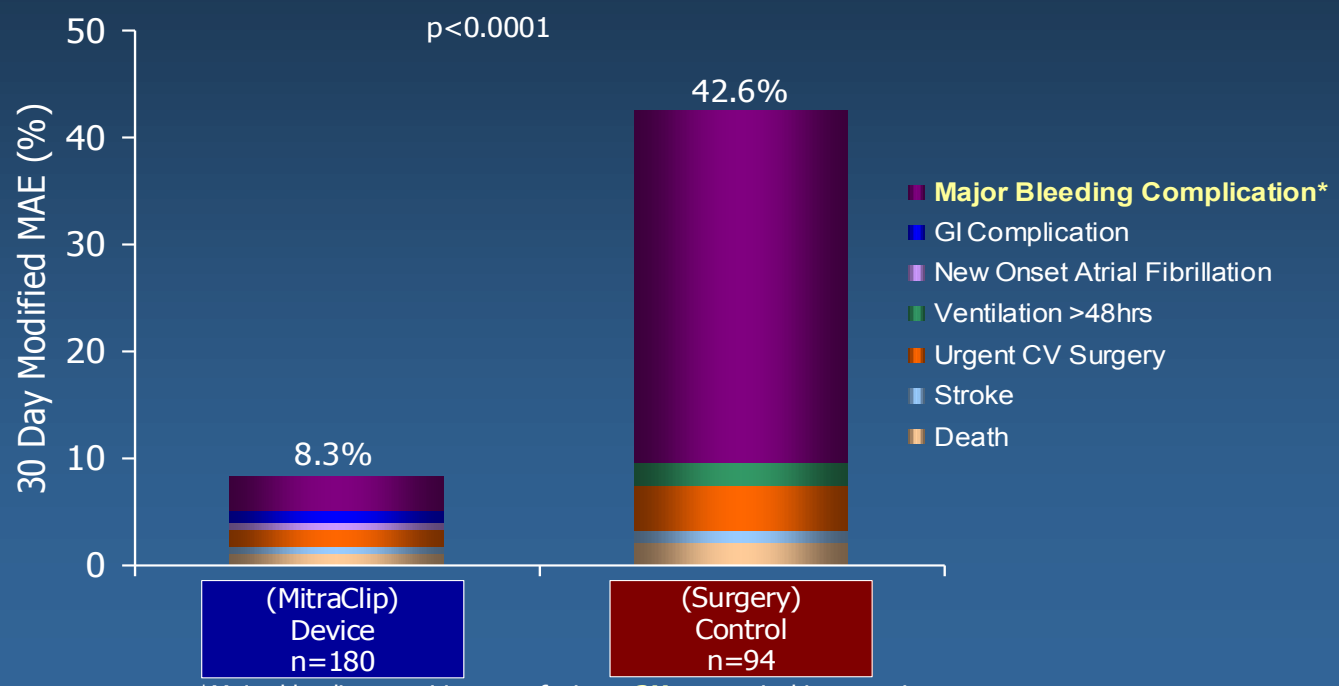


MitraClip > Surgery "*Safety*"

30 Day Modified * MAE

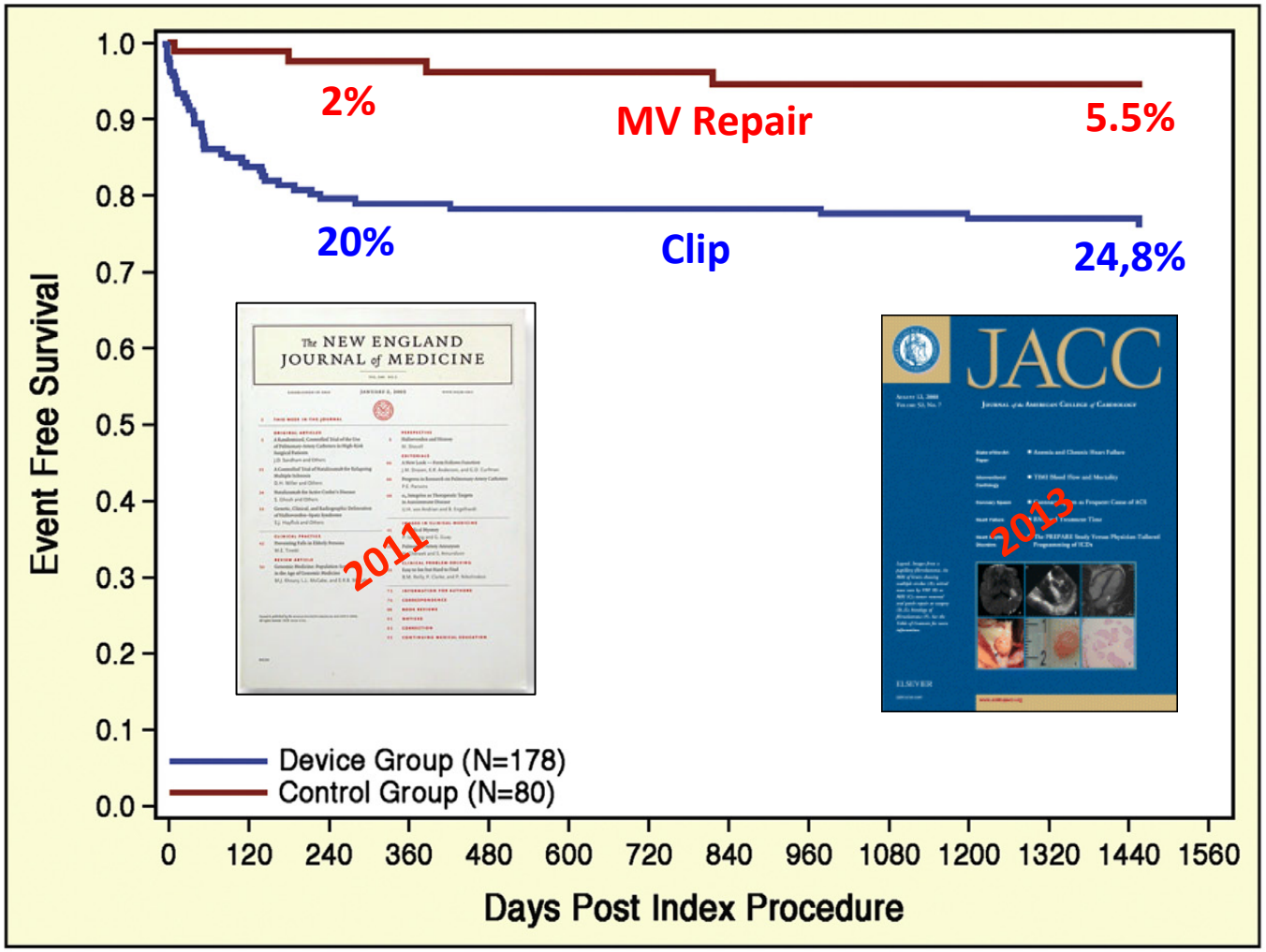
Intent to Treat, Hierarchical Events

Safety endpoint met with a wide margin



*Major bleeding requiring transfusion **= 2U**, or surgical intervention.

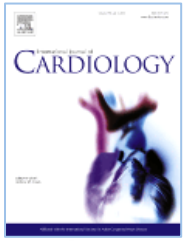
Reoperation at 1 and 4 years



After Everest : *Cohorts & Registries ?*

Percutaneous Mitral Valve Edge-to-Edge Repair

In-Hospital Results and 1-Year Follow-Up of 628 Patients of the 2011-2012 Pilot European Sentinel Registry



Long-term survival after MitraClip® therapy in patients with severe mitral regurgitation and severe congestive heart failure: A comparison among survivals predicted by heart failure models

Thomas Schau (MD)[a,1,*], Akihiro Isotani (MD)[a,1], Michael Neuss (MD)[a], Maren Schöpp (MD)[a], Martin Seifert (MD)[a], Christin Höpfner (MD)[a], Daniel Burkhoff (MD, PhD)[b], Christian Butter (MD)[a]

[a] *Heart Center Brandenburg in Bernau, Bernau, Germany*
[b] *Columbia University, New York, NY, USA*

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Percutaneous Mitral Valve Repair for Mitral Regurgitation in High-Risk Patients

Results of the EVEREST II Study

Donald D. Glower, MD,* Saibal Kar, MD,† Alfredo Trento, MD,† D. Scott Lim, MD,‡ Tanvir Bajwa, MD,§‖ Ramon Quesada, MD,¶ Patrick L. Whitlow, MD,# Michael J. Rinaldi, MD,** Paul Grayburn, MD,†† Michael J. Mack, MD,†† Laura Mauri, MD,‡‡§§ Patrick M. McCarthy, MD,‖‖ Ted Feldman, MD¶¶

Predictors of clinical outcomes after edge-to-edge percutaneous mitral valve repair

Davide Capodanno, MD, PhD,[a,c] Marianna Adamo, MD,[b,c] Marco Barbanti, MD,[a] Cristina Giannini, MD,[c] Maria Luisa Laudisa, MD,[d] Stefano Cannata, MD,[a] Salvatore Curello, MD,[b] Sebastiano Immè, MD,[a] Diego Maffeo, MD,[b] Francesco Bedogni, MD,[d] Anna Sonia Petronio, MD,[c] Federica Ettori, MD,[b] Corrado Tamburino, MD, PhD,[a] and Carmelo Grasso, MD[a], on behalf of the GRASP-IT Investigators *Catania, Brescia, Pisa, and Milan, Italy*

Association of tricuspid regurgitation with clinical and echocardiographic outcomes after percutaneous mitral valve repair with the MitraClip System: 30-day and 12-month follow-up from the GRASP Registry

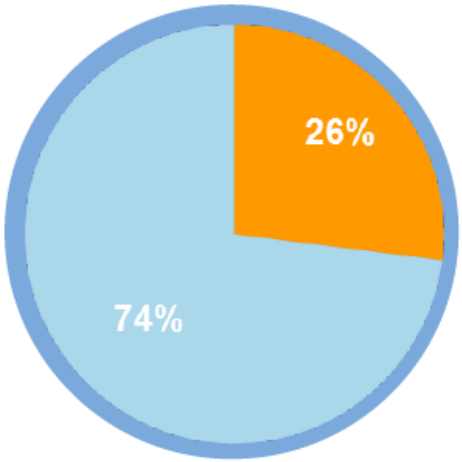
Yohei Ohno[1,2†], Guilherme F. Attizzani[1,3,4†], Davide Capodanno[1,5], Stefano Cannata[1] Fabio Dipasqua[1], Sebastiano Immé[1], Marco Barbanti[1], Margherita Ministeri[1], Anna Caggegi[1], Anna M. Pistritto[1], Marta Chiarandà[1], Giuseppe Ronsivalle[1], Sandra Giaquinta[1], Silvia Farruggio[1], Sarah Mangiafico[1], Salvatore Scandura[1], Corrado Tamburino[1,5], Piera Capranzano[1,5☆], and Carmelo Grasso[1‡*]

Meta-Analysis of the Usefulness of Mitraclip in Patients With Functional Mitral Regurgitation

Fabrizio D'ascenzo, MD[a], Claudio Moretti, MD[a], Walter Grosso Marra, MD[a], Antonio Montefusco, MD[a], Pierluigi Omede, MD[a], Salma Taha, MD[a,b,*], Davide Castagno, MD[a], Oliver Gaemperli, MD[c], Maurizio Taramasso, MD[d], Simone Frea, MD[a], Stefano Pidello, MD[e], Volker Rudolph, MD[f], Olaf Franzen, MD[g], Daniel Braun, MD[h], Cristina Giannini, MD[i], Huseyin Ince, MD[j], Leor Perl, MD[k], Giuseppe Zoccai, MD[l], Sebastiano Marra, MD[a], Maurizio D'Amico, MD[a], Francesco Maisano, MD[m], Mauro Rinaldi, MD[a], and Fiorenzo Gaita, MD[a]

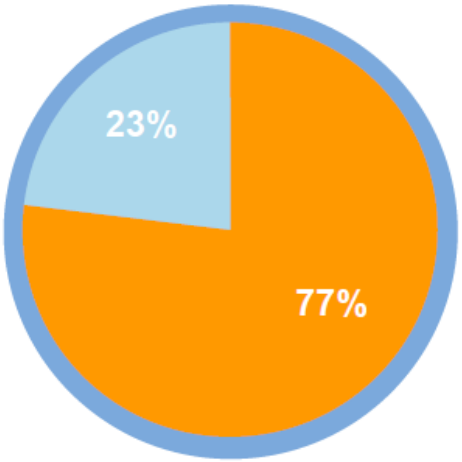
1) Indications : ➔ Shift towards Secondary MR

EVEREST II
(Randomized Controlled Trial)



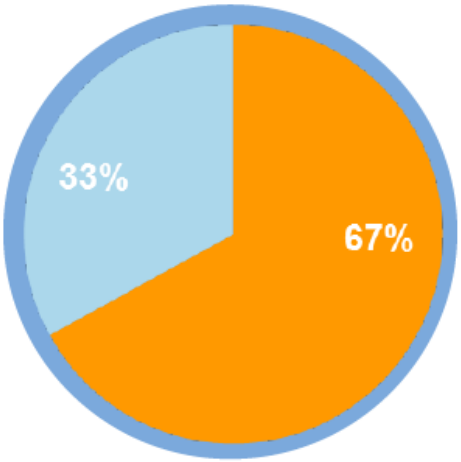
- 178 patients

ACCESS EU
(Europe)



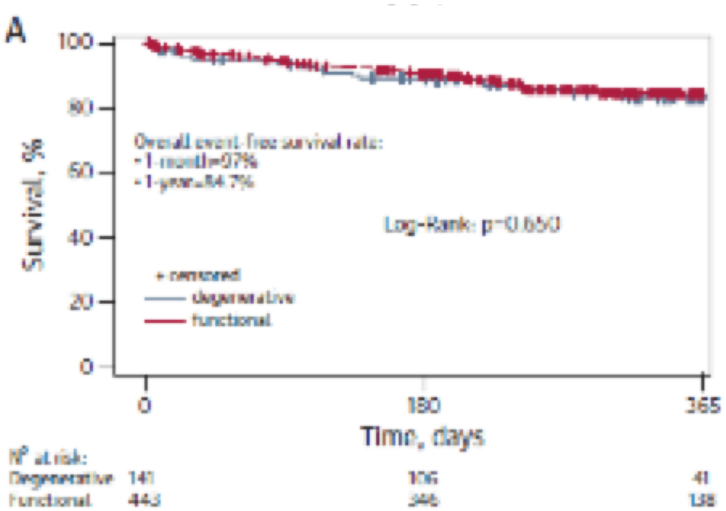
- 567 patients

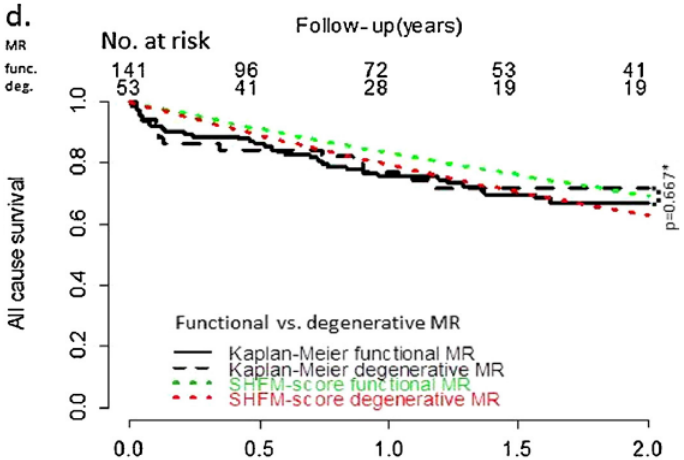
Commercial
(APJ, CALA, Europe, US)



- 10,614 patients

2) Questionable : Impact on mortality ?





Percutaneous Mitral Valve Edge-to-Edge Repair

In-Hospital Results and 1-Year Follow-Up of 628 the 2011-2012 Pilot European Sentinel Registry

Georg Nickenig, MD, PhD,* Rodrigo Estevez-Loureiro, MD, PhD,† Olaf Franzen, MD,‡ Corrado Tamburino, MD, PhD,§

- 628 patients in Europe (25 centers, 8 countries)
- FU for secondary and primary MR
- 1 year echo assessement

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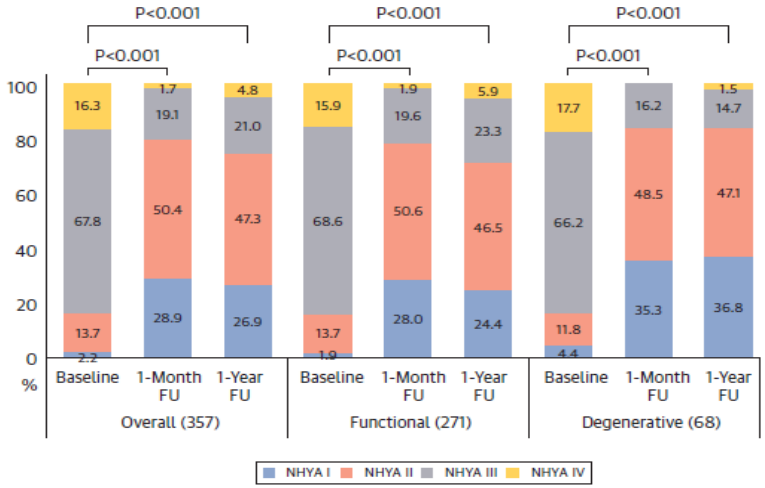
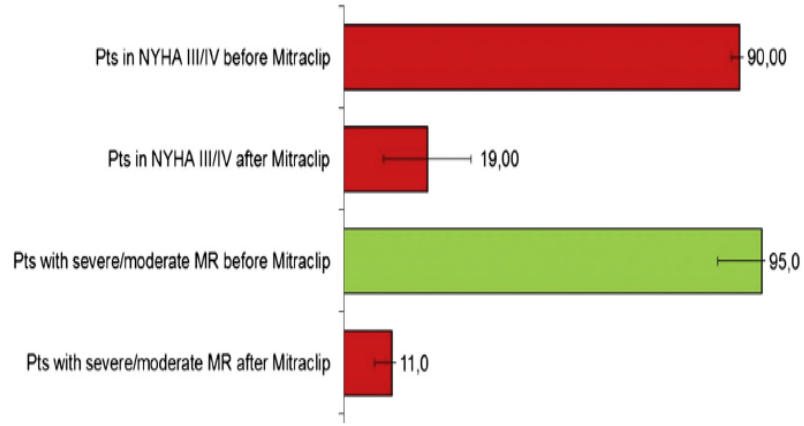
[a] Heart Center Brandenburg in Bernau, Bernau, Germany
[b] Columbia University, New York, NY, USA

2015

- 194 patients (brandeburgh, New york)
- Mortality versus Seattle HF model

3) Likely : Improved Symptoms / decreased MR





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- 628 patients in Europe (25 centers, 8 countries)
- FU for secondary and primary MR
- 1 year echo assessement

- Meta analysis
  - 9 studies
  - 875 patients

4) Complex : Echographic analysis

Percutaneous Mitral Valve Edge-to-Edge Repair

In-Hospital Results and 1-Year Follow-Up of 628 Patients of the 2011-2012 Pilot European Sentinel Registry

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- 628 patients in Europe (25 centers, 8 countries)
- FU for secondary and primary MR
- 1 year echo assessement
- 15 centers with > 90% FU ➔ 368 echo at 1 year

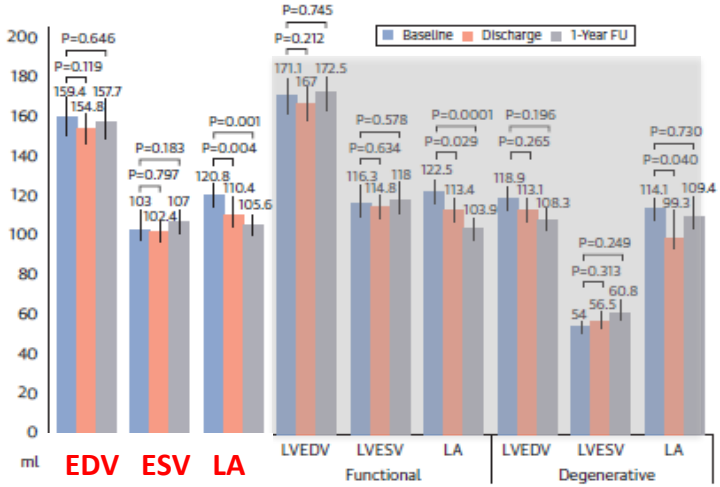


FIGURE 5 Echocardiographic Measurement of Left Ventricular and Left Atrial Volumes at Baseline, Discharge, and 1-Year Follow-Up After TMVR (Paired Data From 368 Patients)

In the overall cohort, a nonsignificant reduction in left ventricular end-diastolic volume (LVEDV) was observed, with a significant reduction in left atrial volume (LA). In functional mitral regurgitation, left ventricular volumes remained stable during follow-up, although a significant reduction in LA was noted. In degenerative mitral regurgitation, the most relevant finding was a reduction in LVEDV over time (nonsignificant). LVESV = left ventricular end-systolic volume; TMVR = transcatheter mitral valve repair.

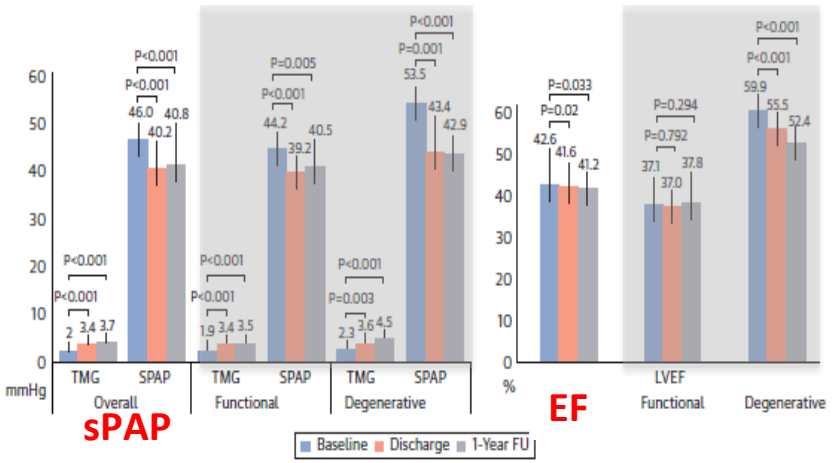
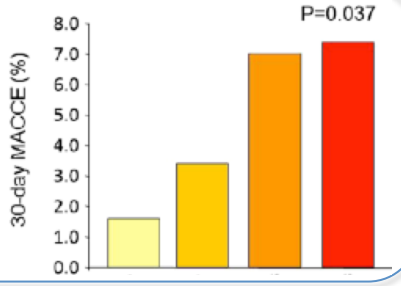


FIGURE 6 Echocardiographic Measurement of Transmitral Pressure Gradient, SPAP, and Ejection Fraction, at Baseline, Discharge, and 1-Year Follow-Up

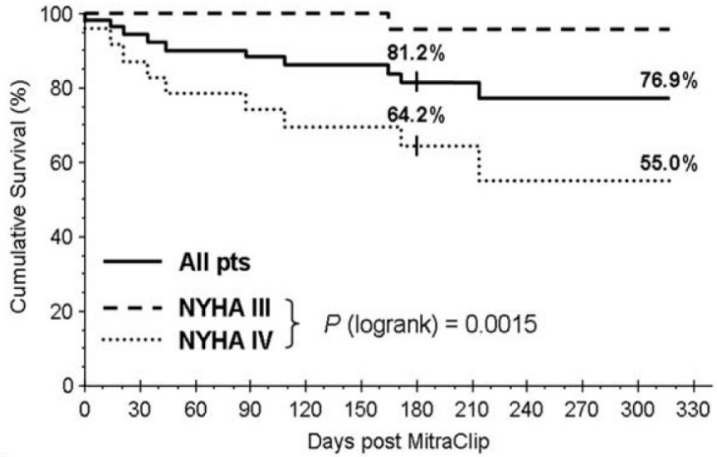
Significant and persistent reductions in systolic pulmonary artery pressure (SPAP) were observed. After transcatheter mitral valve repair, transmitral pressure gradient (TMG) (mm Hg) increased significantly, although no cases of severe mitral stenosis were reported. LVEF = left ventricular ejection fraction (%).

Influence of non-cardiac comorbidities on outcome after percutaneous mitral valve repair: results from the German transcatheter mitral valve interventions (TRAMI) registry

Influence of extra-cardiac comorbities ➔



MitraClip® therapy in patients with end-stage systolic heart failure

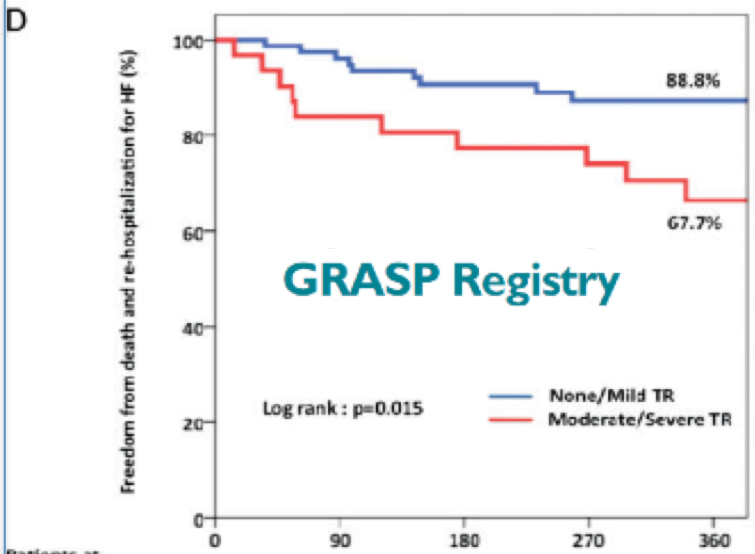


At risk:

All pts	50	47	45	44	43	38	30	19	11	10	9
NYHA III	27	27	27	27	27	24	19	12	8	7	6
NYHA IV	23	20	18	17	16	14	11	7	3	3	3

Franzen O. Eur J Heart Failure 2011; 13: 569–576

Association of tricuspid regurgitation



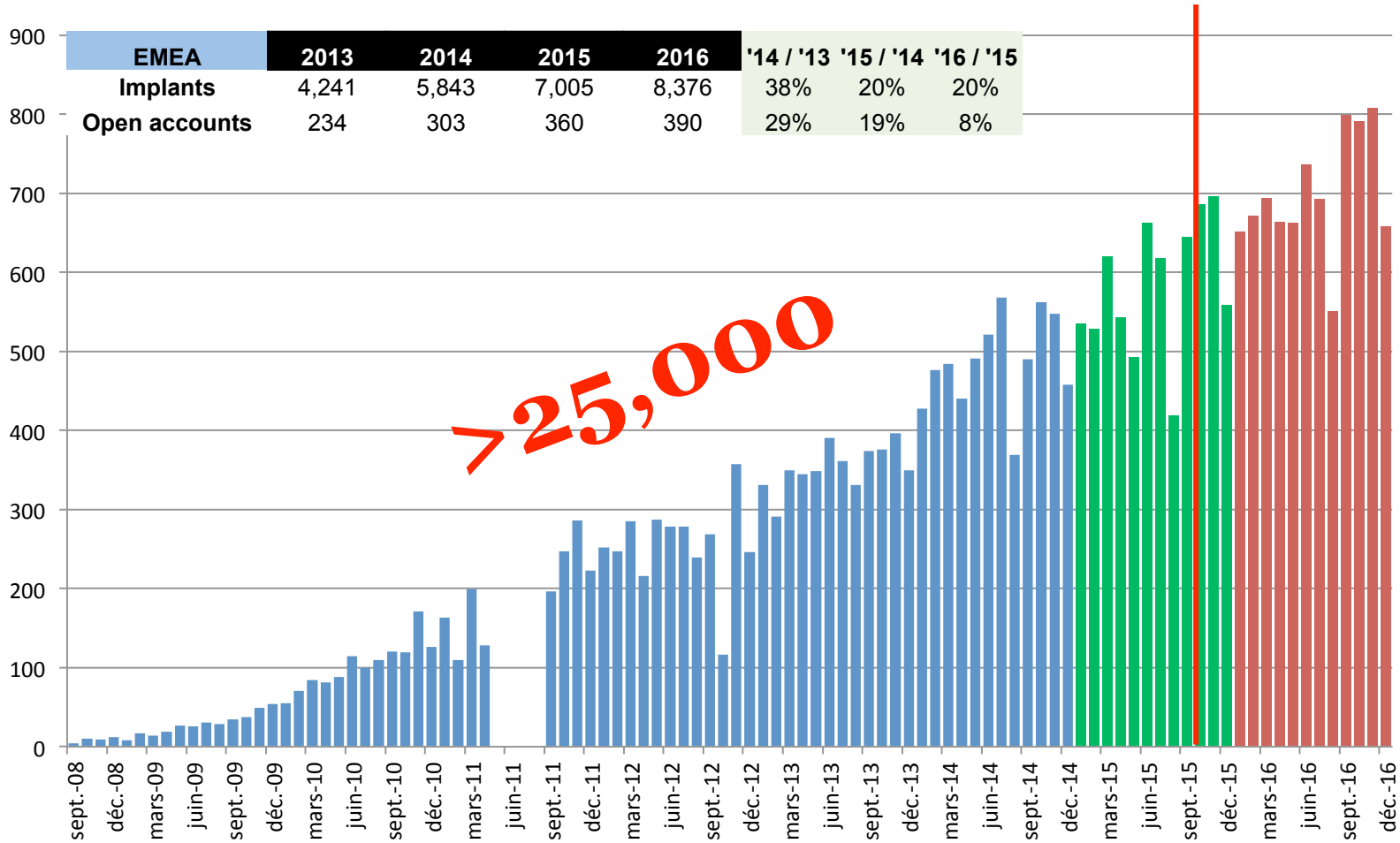
Patients at Risk :

None/Mild TR	80	72	61	49	42
Moderate/Severe TR	31	26	24	21	14

Ohno Y. Eur Heart Journal 2014; 15: 51246-55

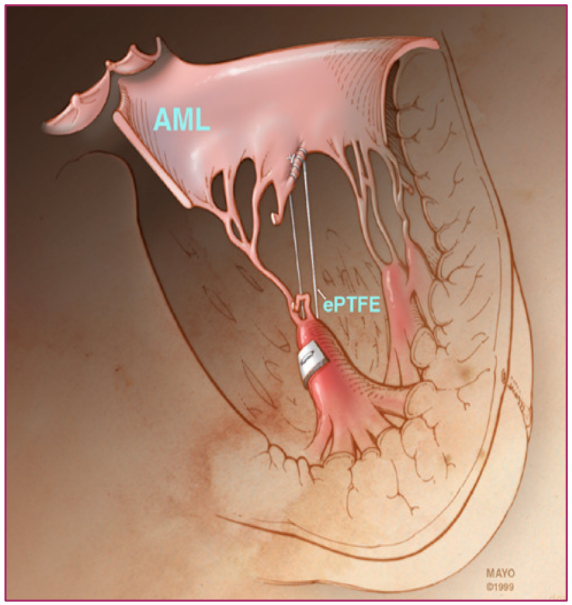
Transcatheter techniques : *From Mitraclip to prostheses*

EMEA	2013	2014	2015	2016	'14 / '13	'15 / '14	'16 / '15
Implants	4,241	5,843	7,005	8,376	38%	20%	20%
Open accounts	234	303	360	390	29%	19%	8%



	COAPT	RESHAPE-HF	MITRA.fr
Sponsor	Abbott Vascular	Abbott Vascular	PHRC / Abbott
Méthodology	Prospective, randomized	Prospective, randomized	Prospective, randomized
Comparison	Optimal Medical Medicatio	Optimal Medical Medication	Optimal Medical Medication
MR etiology	Secondary MR	Secondary MR	Secondary MR
Ejection Fraction	> 30%	15 to 40%	15 to 40%
Hospitalisation HF < 12 months ?		100%	100%
High Risk Patients	Surgical CI (heart team)		Surgical CI (heart team)
NHYA	II, III, IV	III, IV	II, III, IV
Principal Criteria	Safety et efficacy (hospit pour CHF)	% all deaths or rehospitalisation rate HF	% all deaths + % rehospitalisation HF
Hypothesis		18 vs 14 % death and 0,6 vs 0,45 hospit	20 vs 35%
Lost pats		15%	10%
Number of inclusions	430 patients 85 centers 368	400 x 2	280 patients 26 centers 146
Number of centres	9	75	18

Transapical Off Pump MV Repair

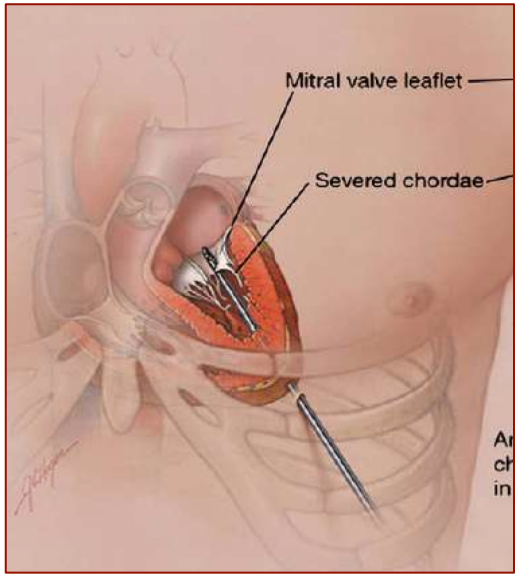


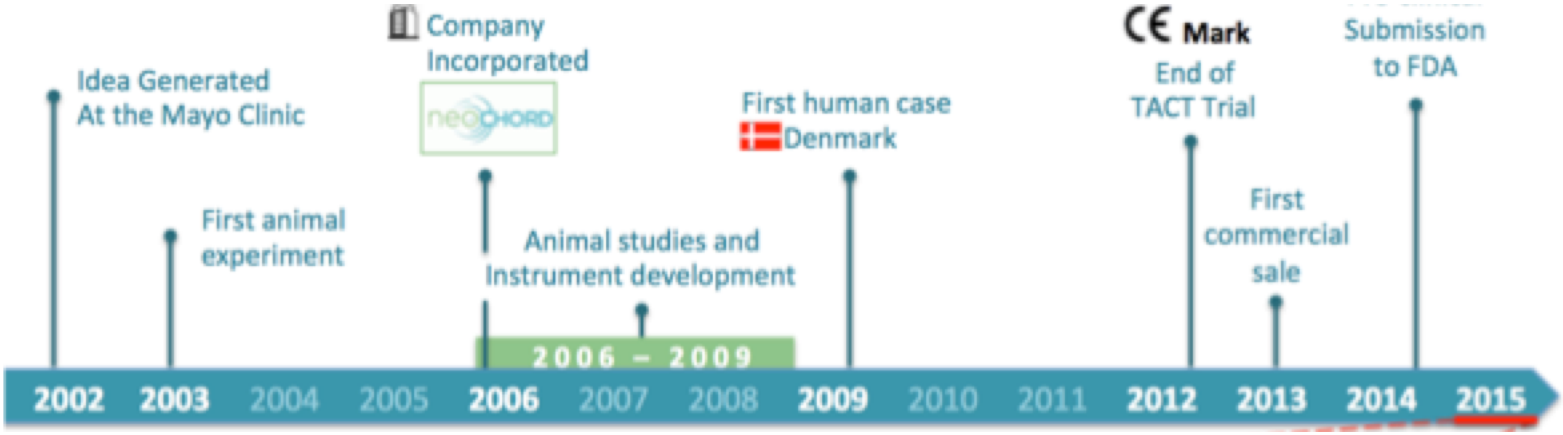
2009 : 1er patient

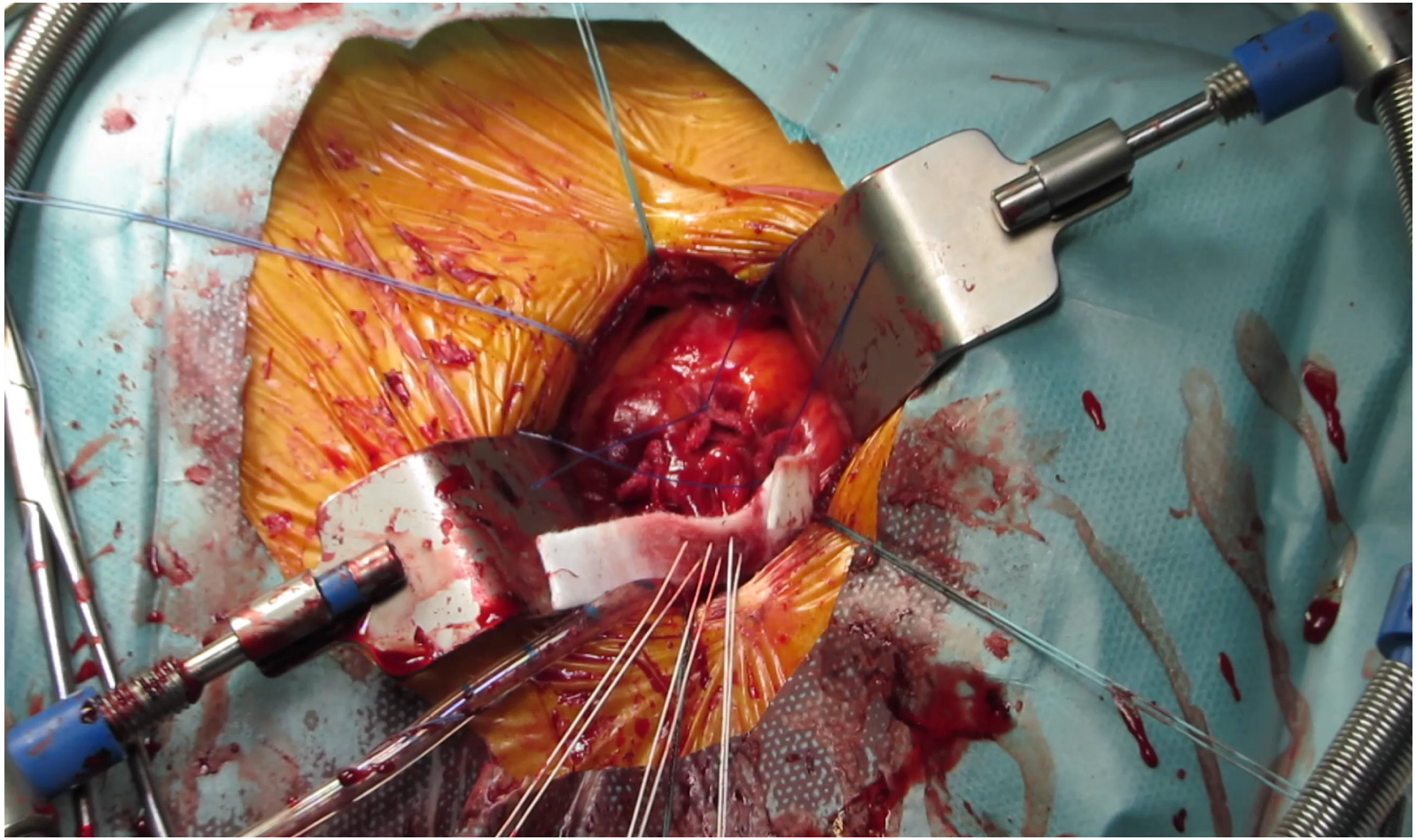
2013 : CE mark

2014 : 100 Pts

2015 : 265 Pts





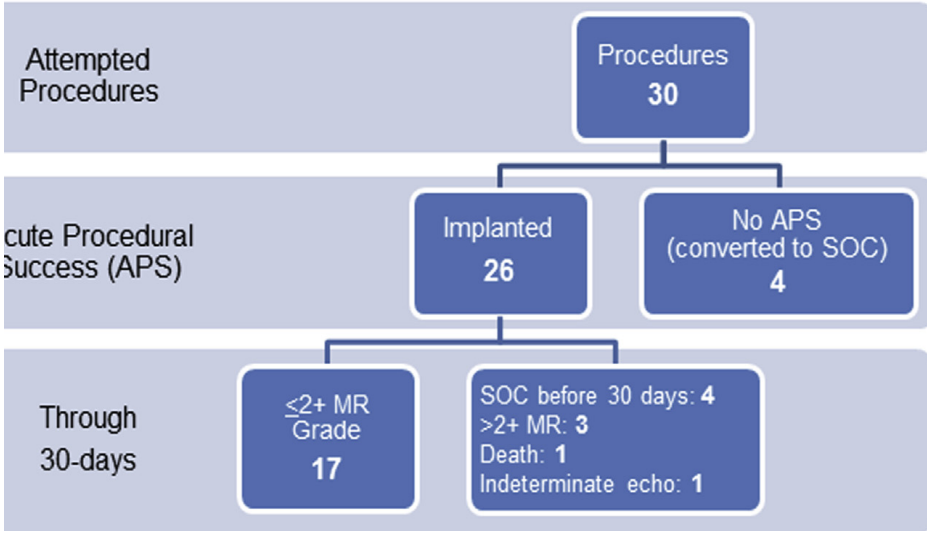


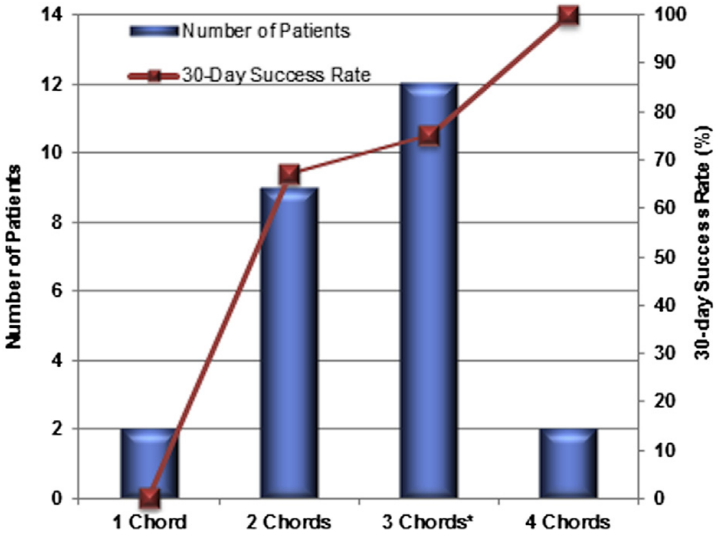
Off-Pump Transapical Implantation of Artificial Neo-Chordae to Correct Mitral Regurgitation

The TACT Trial (Transapical Artificial Chordae Tendinae) Proof of Concept

Joerg Seeburger, MD, PHD,* Mauro Rinaldi, MD, PHD,† Sten Lyager Nielsen, MD,‡ Stefano Salizzoni, MD,† Ruediger Lange, MD, PHD,§ Markus Schoenburg, MD,‖ Ottavio Alfieri, MD, PHD,¶ Michael Andrew Borger, MD, PHD,* Friedrich Wilhelm Mohr, MD, PHD,* Audrius Aidietis, MD, PHD#

Leipzig, Munich, and Bad Nauheim, Germany; Turin and Milan, Italy; Aarhus, Denmark; and Vilnius, Lithuania





Acute safety and efficacy of the NeoChord procedure†

Padova and Vilnius → Interactive CardioVascular and Thoracic Surgery 2015

Andrea Colli[a,*], Erica Manzan[a], Kestutis Rucinskas[b], Vilius Janusauskas[b], Fabio Zucchetta[a], Diana Zakarkaitė[b], Audrius Aidietis[b] and Gino Gerosa[a]

Table 2: Procedural results

Variable	N = 63 Median (IQR I, III)
NeoChords attempted (*n*)	4 (4–5)
NeoChords left (*n*)	4 (3–4)
Two neochords	2 (3.2%)
Three neochords	20 (32%)
Four neochords	28 (44%)
Five neochords	10 (16%)
Six neochords	2 (3%)
Seven neochords	1 (2%)
Operative time (min)	130 (117.5–150)
Intensive care unit stay (h)	24 (24–24)
≤24	50 (80%)
25–48	7 (11%)
>48	6 (9%)
Mechanical ventilation time (h)	3 (2–5)
0 (extubation in the operation theatre)	7 (11%)
≤3	33 (52%)
4–6	17 (27%)
>6	6 (9%)
Hospital stay (days)	8 (6–11)
Discharge at home	9 (14%)
Discharge at a cardiac rehabilitation centre	54 (86%)

Safety

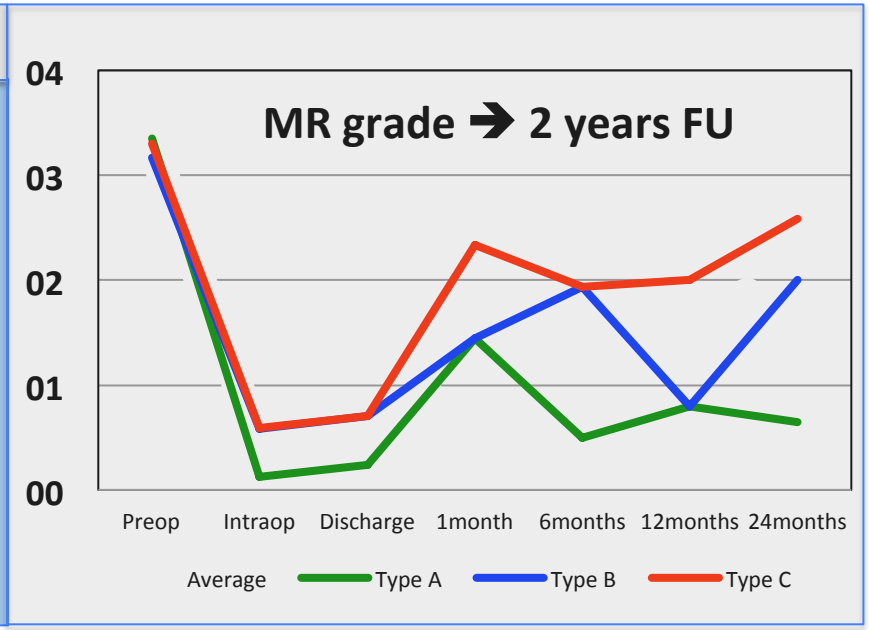
Perioperative complications (*n*)	
Ventricular fibrillation	3 (5%)
CPB/ECMO	1 (2%)
Bleeding requiring >2 blood units	3 (5%)
Surgical revision for bleeding	0
Apex bleeding or rupture	0
Conversion to conventional surgery	0
Major adverse events (*n*)	
Death	0
Stroke	0
Acute myocardial infarction	1 (2%)
Septicaemia	2 (3%)

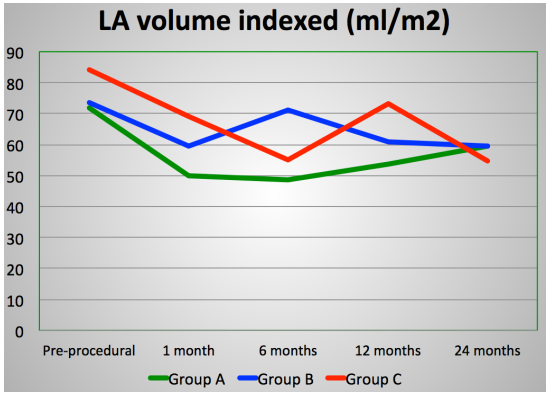
Efficacy

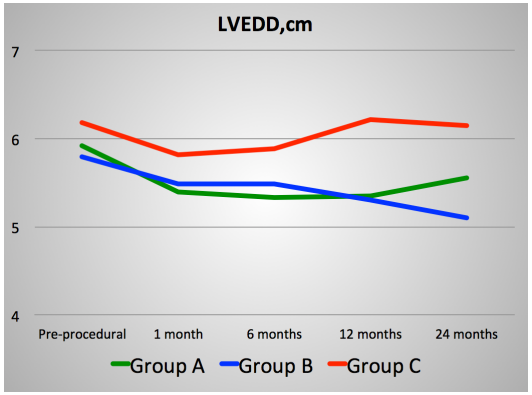
Residual MR at 30 days (*n*)	
0+	29 (46%)
1+	16 (25%)
2+	10 (16%)
3+	7 (11%)
4+	1 (2%)
NYHA Class at 30 days (*n*)	
I	55 (87%)
II	4 (6%)
III	4 (6%)

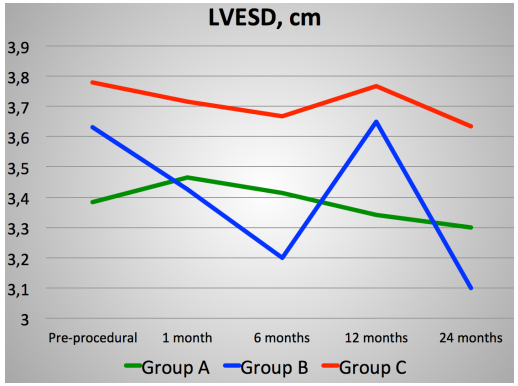
77 % grade ≤ 2

Type A	Type B	Type C
• Eccentric regurgitant jet • Central P2 prolapse, extension up to 50% of entire PML. No pericommissural involvement. • No anterior leaflet prolapse or tethering • No severe LV dilatation	• Eccentric regurgitant jet • Extension of prolapse to include the portions of P1 or P3 adjacent to P2 • Or may have more than one prolapsing segment (P1+P2, P2+P3)	• Prolapse extending towards the commissures, involvement of anterior leaflet • LV dilatation with initial tethering of AL (gullwing sign) • Central component to regurgitant jet (lack of central coaptation) • Calcified leaflet segments





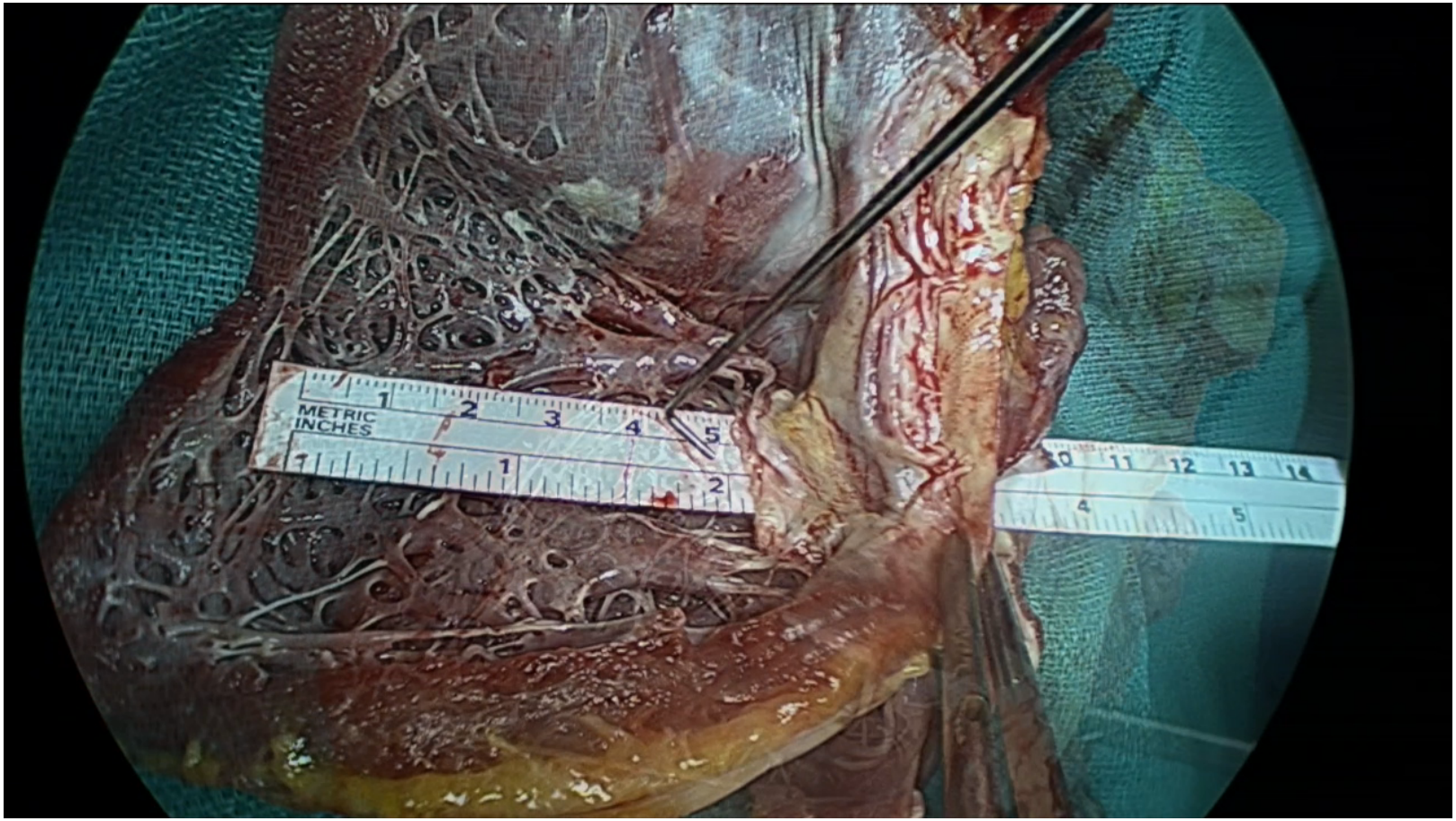




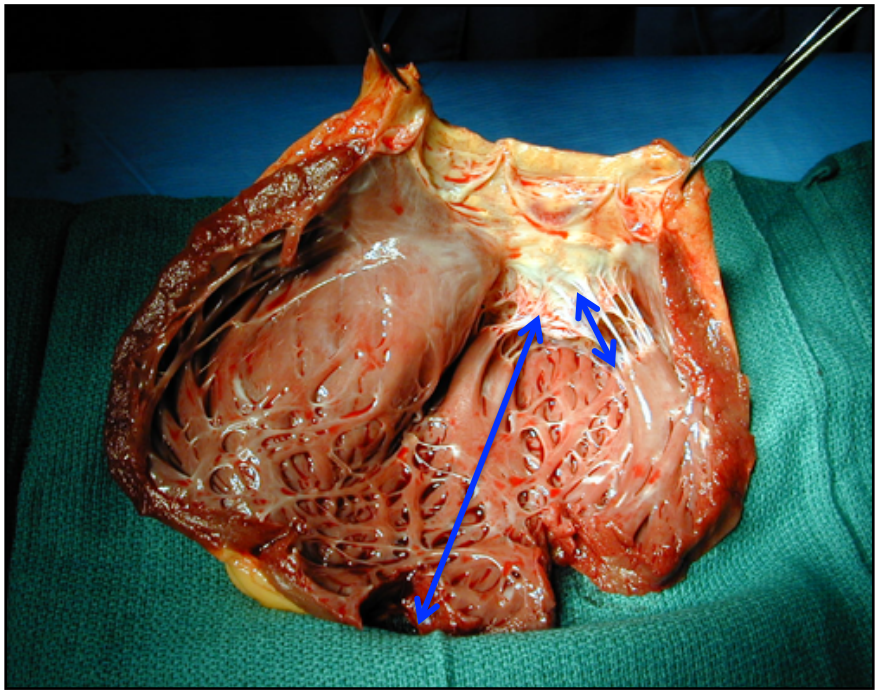
Vilniaus universiteto ligoninės SANTARIŠKIŲ KLINIKOS

2 years Vilnius Experience, K. Rucinskas Vilnius, Lithuania

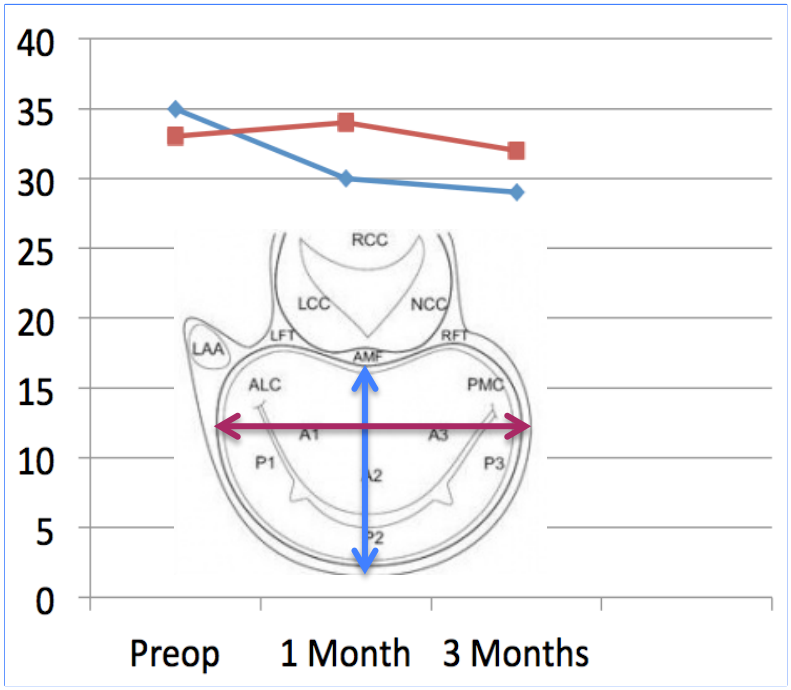
Chordae dimensions ?



Chordae dimensions ?



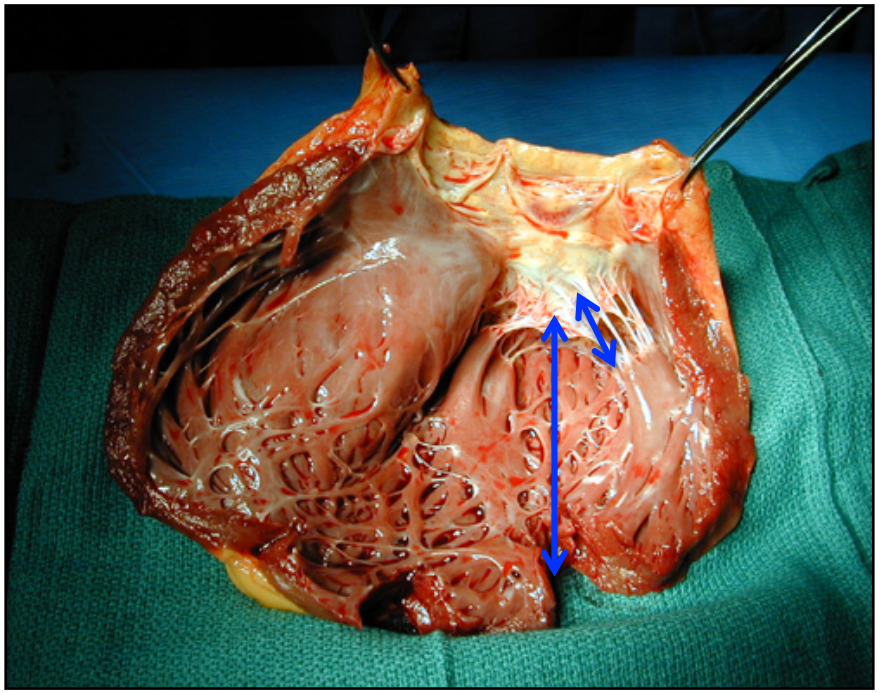
Annulus dimensions ?



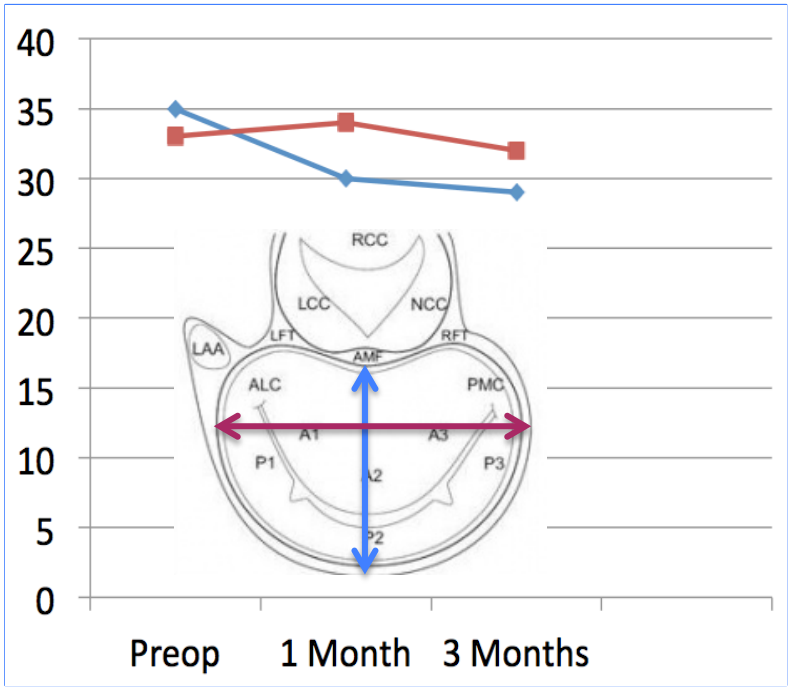
Risk of Reoperation ?

Early surgery ?

Chordae dimensions ?



Annulus dimensions ?



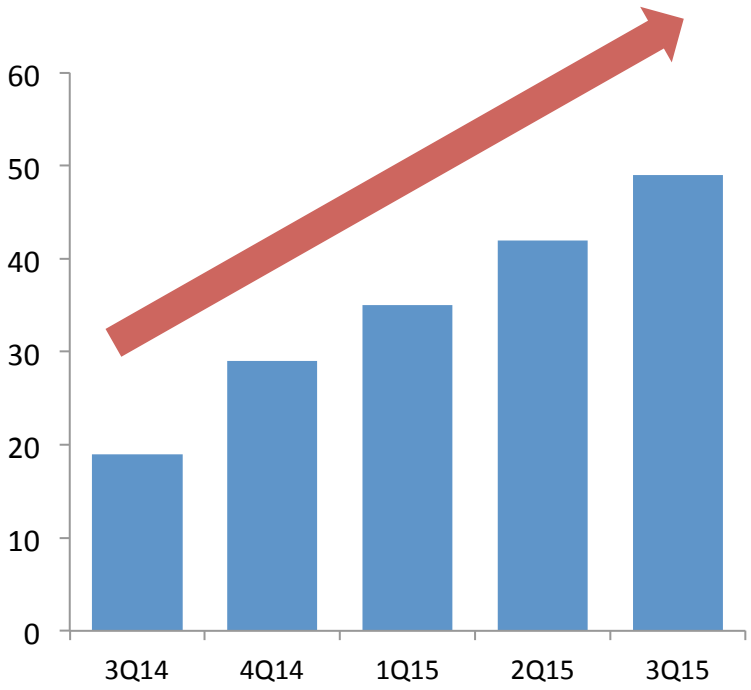
Risk of Reoperation ?

Early surgery ?

265 patients Worldwide

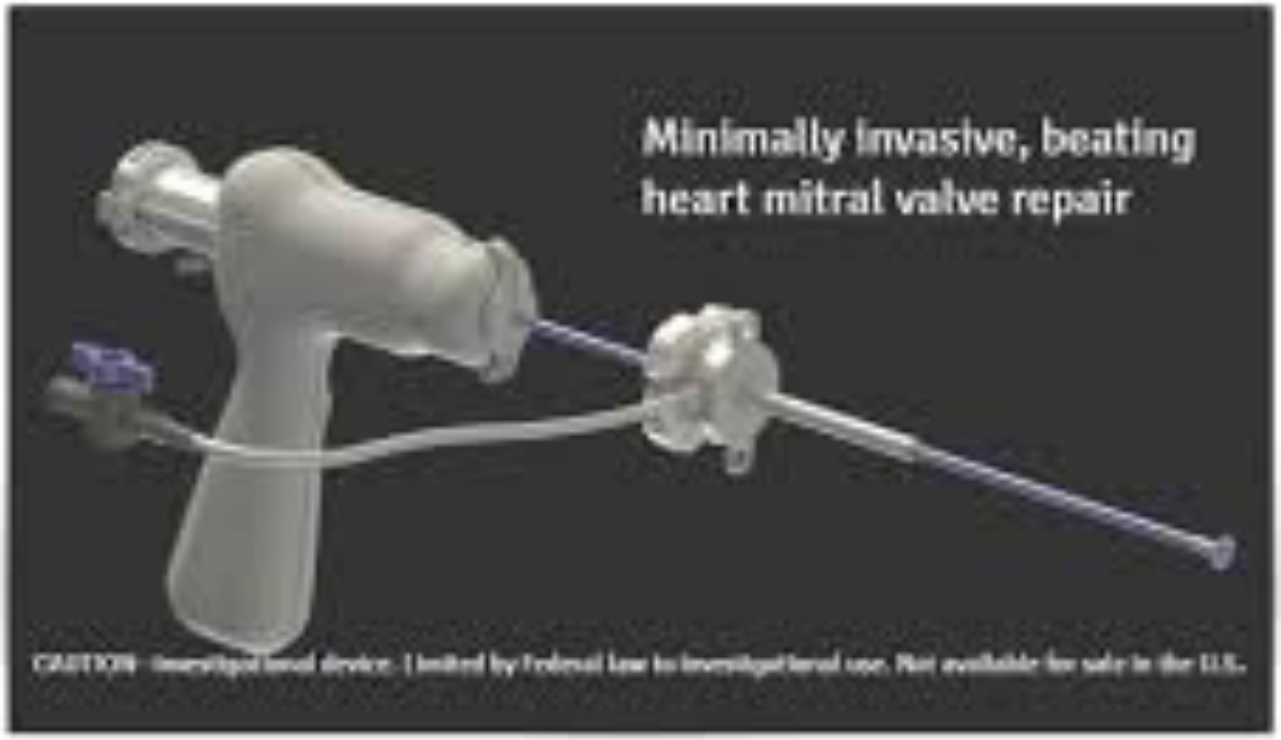
Currently selling in 10 markets

Consistent QOQ Growth in cases

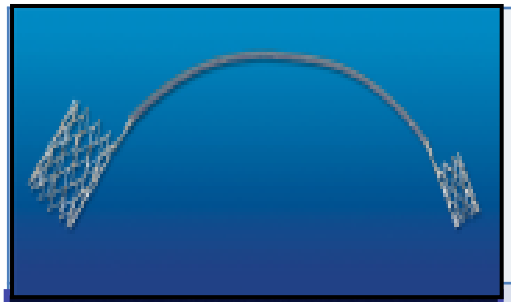
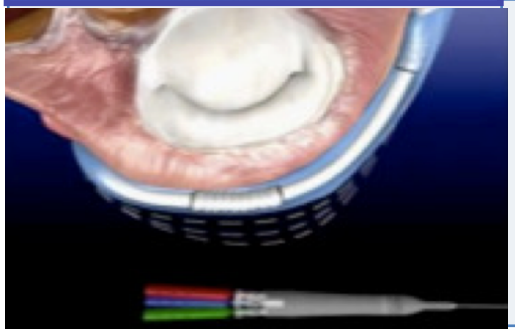


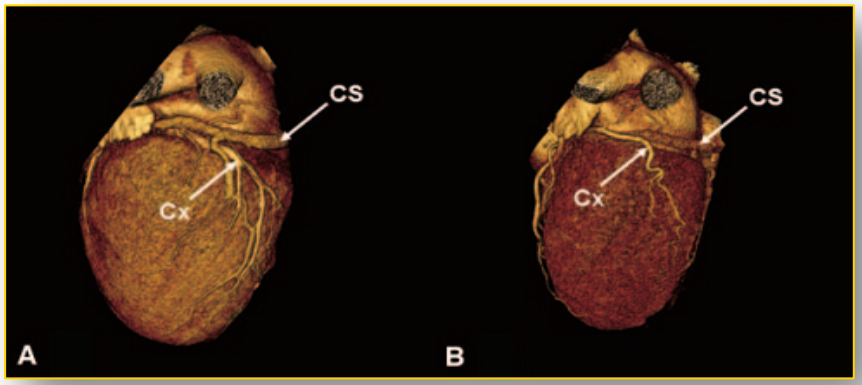
HARPOON MEDICAL

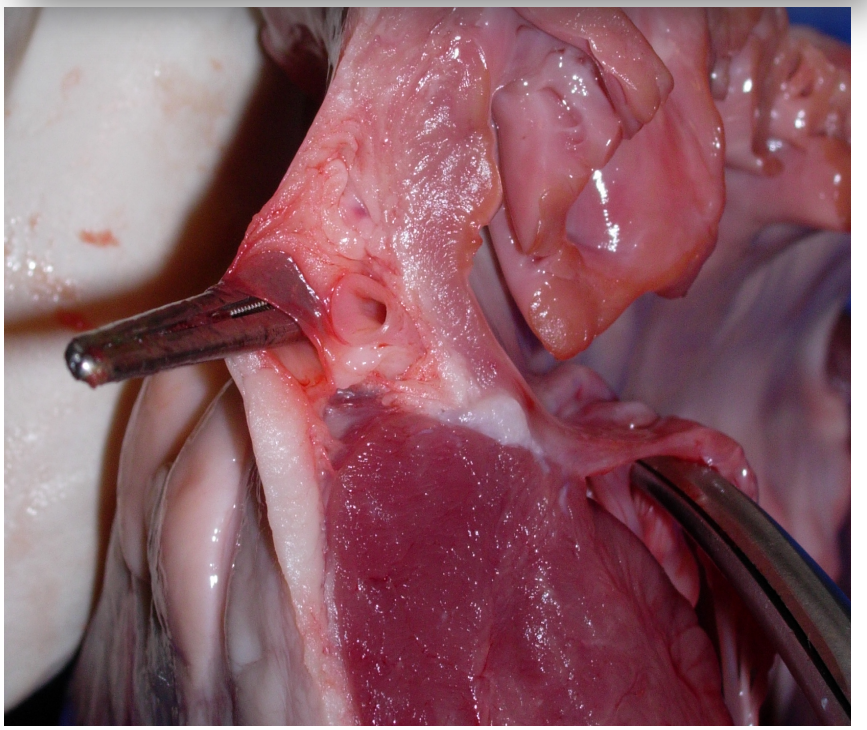
➔ **10 patients**

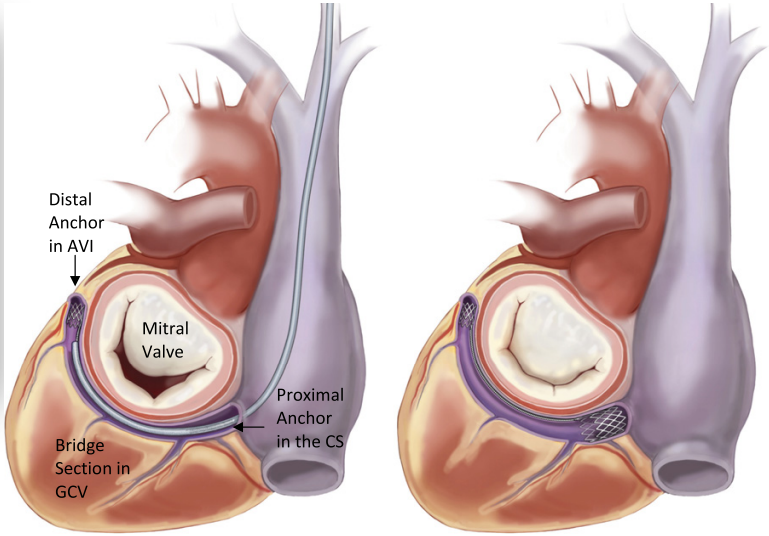


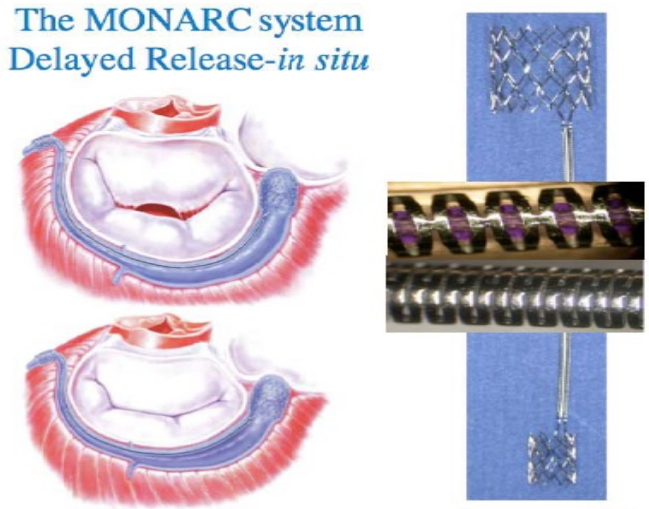
INDIRECTE Annuloplasty
- coronary sinus -

	MONARC (Edwards Lifesciences LLC)	Two-anchor design with chronic reshaping (6weeks) by a foreshortening bridge	EVOLUTION trial (72 pts 82% success)
	CARILLON (Cardiac Dimensions Inc)	Acute reshaping device acting in P2P3, repositionable, retrievable	AMADEUS trial (113 pts 58 % success)
	PTMA (Viacor Inc)	Tri-lumen catheter, reshapable, possibility of multiple long term adjustment	PTOLEMY (31 pts 29 % success)





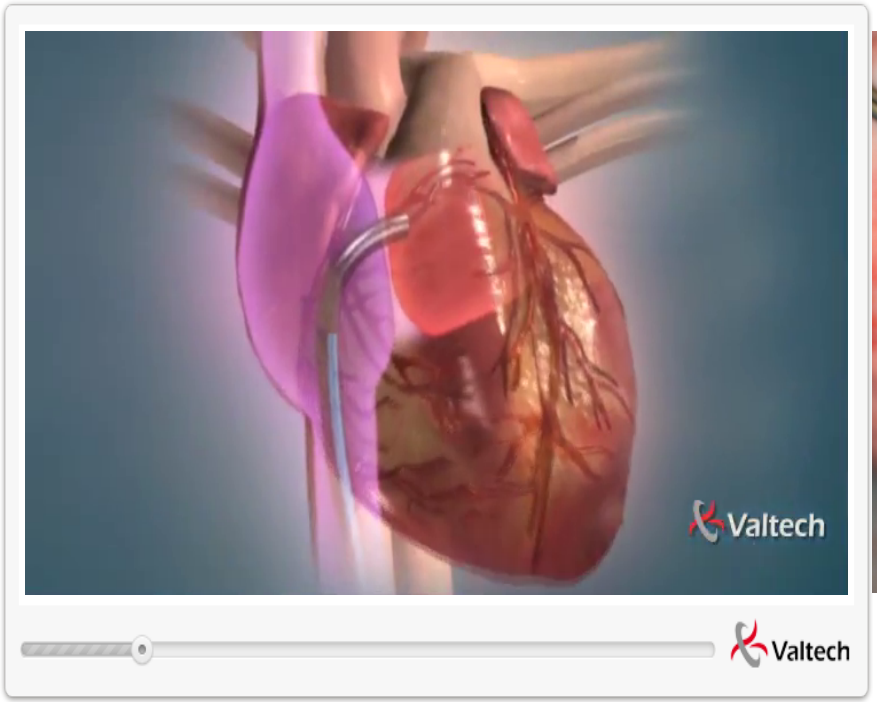


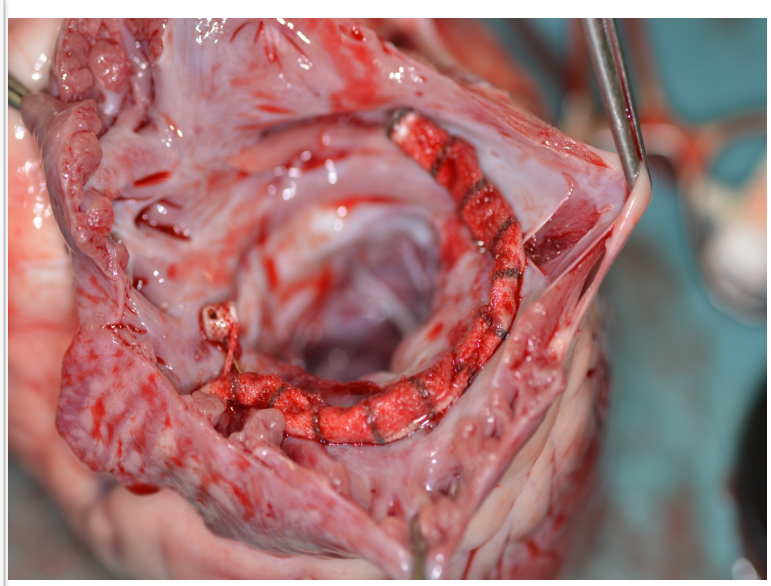


Webb et al Circulation 113:851-855, 2006

Valtech Cardio – CARDIOBAND

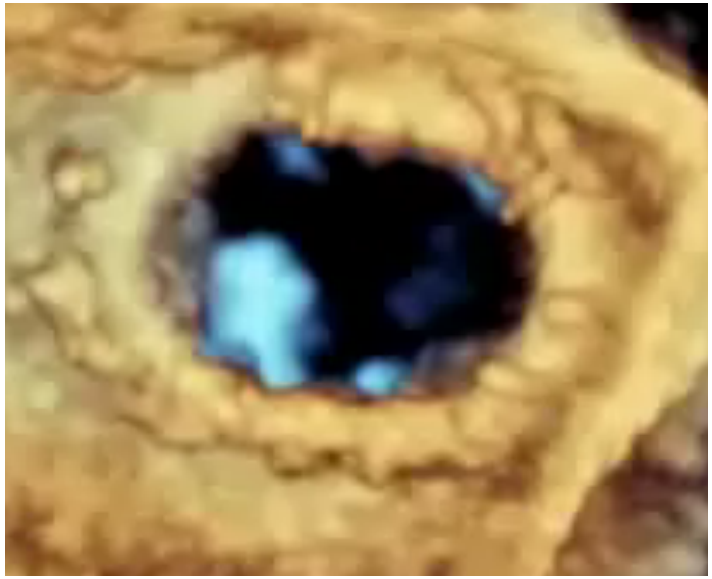
First in man in 2013



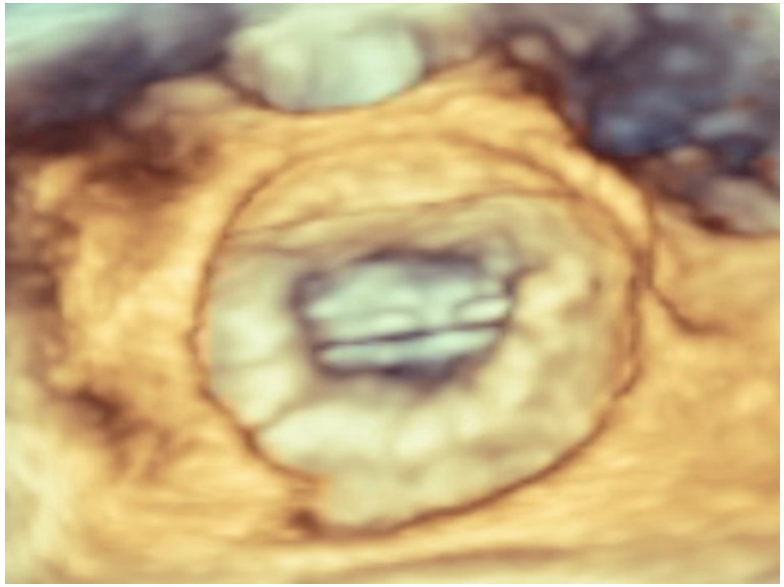


Courtesy of Francesco MAISANO

Which is surgical ? Percutaneous ?



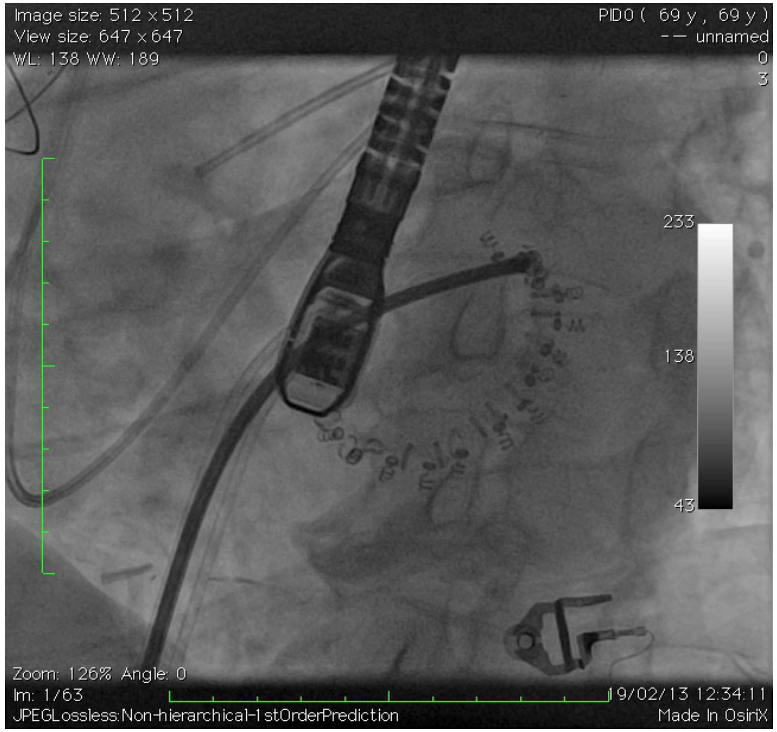
Surgical Ring

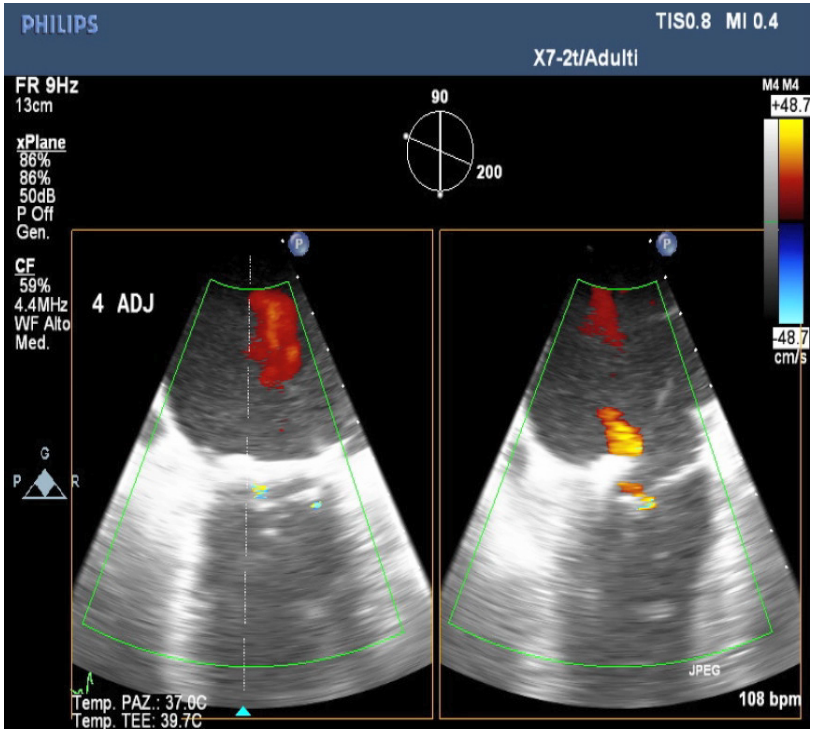


Cardioband

Courtesy of Francesco MAISANO

Valtech Cardio – CARDIOBAND





Courtesy of Francesco MAISANO

Cardioband European Study Early Outcomes (N=30)

Courtesy of Francesco MAISANO

Procedure

- Implants successfully deployed on annulus (30/30)
- Average reduction of septolateral diameter 20%

Effectiveness

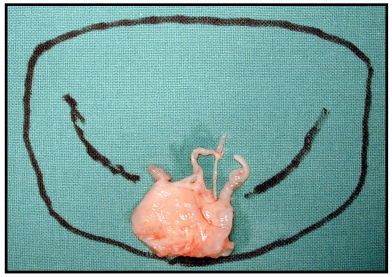
- MR ≤ 2+ in 1 month follow up (N=27) 89%
- MR ≤ 2+ in 6 month follow up (N=16) **88%**

Safety

- Procedural mortality 0/30
- 30 days Mortality (according to VARC) 2/30

No Device Related Major Adverse Events as adjudicated by independent committee

Surgical MV Repair



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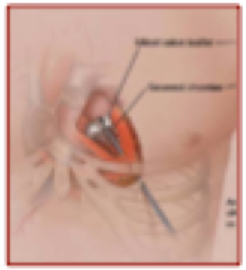
Carpentier French Correction

Percutaneous Mitral Plasty techniques



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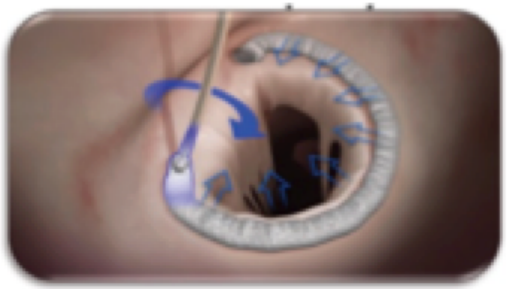

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Fully percutaneous Mitra valve repair