APPAC
6/7/8 JUIN 2018
Palais des Congrès
BIARRITZ
20e édition

La mitrale est elle l'avenir du cardiologue interventionnel ?

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CHU Nantes

APPAC
6 Juin 2018

l'Institut du thorax

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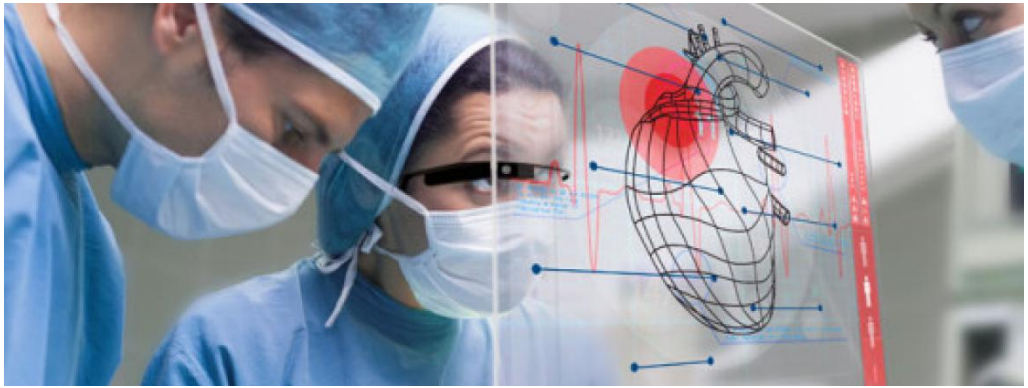
• Intellectual Property Rights	
• Other Financial Benefit	

La mitrale est elle l'avenir du cardiologue interventionnel ?

- RM ?
- IM secondaire ?
- IM primitive ?
- Conclusion



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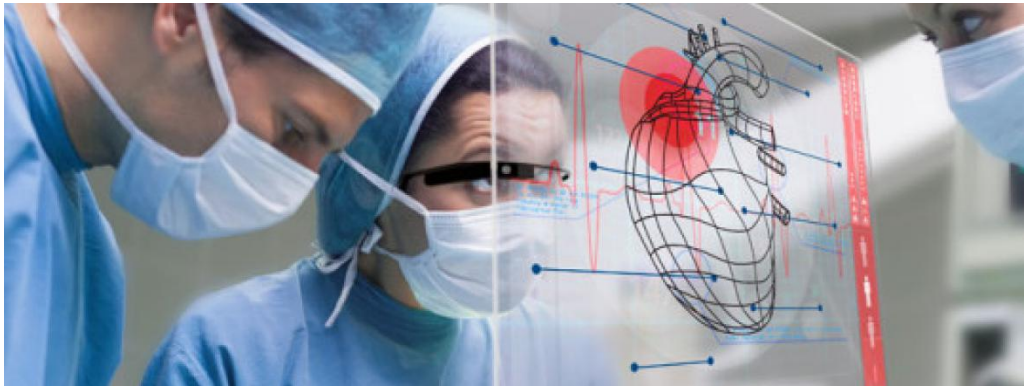

Quid du RM rhumatismal…

European Heart Journal (2012) **33**, 2451–2496
doi:10.1093/eurheartj/ehs109

ESC/EACTS GUIDELINES

Guidelines on the management of valvular heart disease (version 2012)

The Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

« Surgery is preferable in patients who are unsuitable for PMC »

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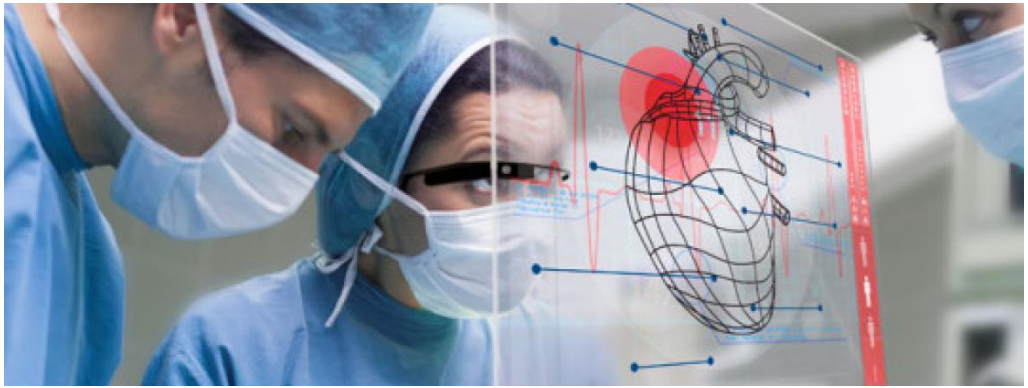
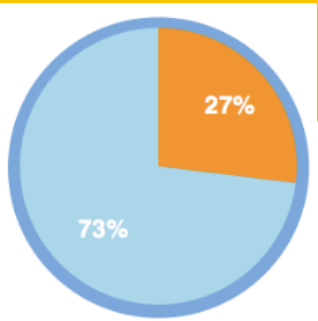
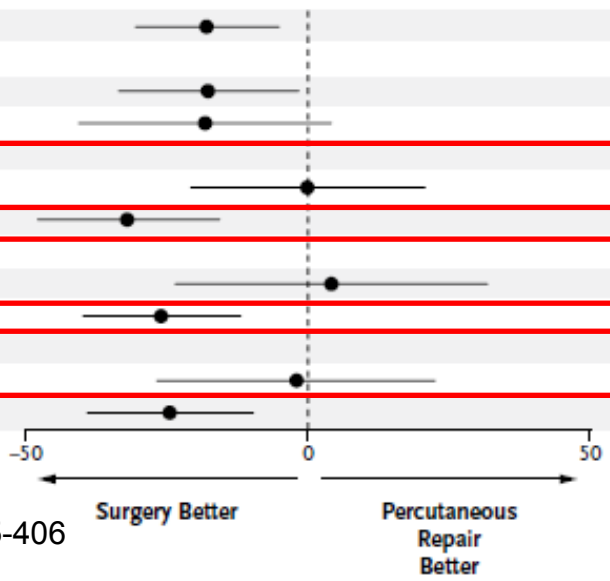


- **EVEREST II**



Subgroup	Percutaneous Repair	Surgery	P Value for Interaction
	no. of events/total no. (%)		
All patients	100/181 (55)	65/89 (73)	
Sex			0.97
Male	63/114 (55)	43/59 (73)	
Female	37/67 (55)	22/30 (73)	
Age			0.009
≥70 yr	52/86 (60)	23/38 (61)	
<70 yr	48/95 (51)	42/51 (82)	
MR			
Functional	26/48 (54)	12/24 (50)	0.02
Degenerative	74/133 (56)	53/65 (82)	
LVEF			0.06
<60%	35/68 (51)	15/28 (54)	
≥60%	64/111 (58)	50/61 (82)	



Feldman et al. , NEJM 2011; 364:1395-406

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The ESC guidelines: indications for FMR percutaneous treatment

Recommendations	Class[b]	Level[c]
Surgery is indicated in patients with severe secondary mitral regurgitation undergoing CABG and LVEF >30%.	I	C
Surgery should be considered in symptomatic patients with severe secondary mitral regurgitation, LVEF <30% but with an option for revascularization and evidence of myocardial viability.	IIa	C
When revascularization is not indicated, surgery may be considered in patients with severe secondary mitral regurgitation and LVEF >30% who remain symptomatic despite optimal medical management (including CRT if indicated) and have a low surgical risk.	IIb	C
When revascularization is not indicated and surgical risk is not low, a percutaneous edge-to-edge procedure may be considered in patients with severe secondary mitral regurgitation and LVEF >30% who remain symptomatic despite optimal medical management (including CRT if indicated) and who have a suitable valve morphology by echocardiography, avoiding futility.	IIb	C
In patients with severe secondary mitral regurgitation and LVEF <30% who remain symptomatic despite optimal medical management (including CRT if indicated) and who have no option for revascularization, the Heart Team may consider a percutaneous edge-to-edge procedure or valve surgery after careful evaluation for a ventricular assist device or heart transplant according to individual patient characteristics.	IIb	C

When revascularization is not indicated and surgical risk is not low, a percutaneous edge-to-edge procedure may be considered in patients with severe secondary mitral regurgitation and LVEF >30% who remain symptomatic despite optimal medical management (including CRT if indicated) and who have a suitable valve morphology by echocardiography, avoiding futility.	IIb	C
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Volkmar Falk et al. European Heart Journal (2017) 38, 2739–2791

The ESC guidelines classify indications for FMR surgery in 3 groups

Indications for surgery in Secondary MR

Recommendations	Class[b]	Level[c]
Surgery is indicated in patients with severe secondary mitral regurgitation undergoing CABG and LVEF >30%	I	C
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Volkmar Falk et al. European Heart Journal (2017) 38, 2739–2791

MR severity

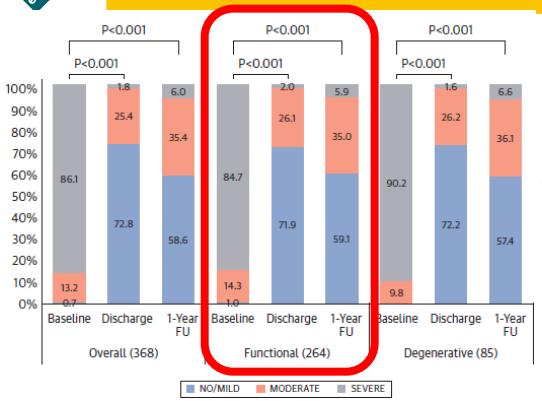


FIGURE 4 Severity of Mitral Regurgitation at Baseline and Follow-Up (Discharge and 1-Year Follow-Up) After TMVR

NYHA class

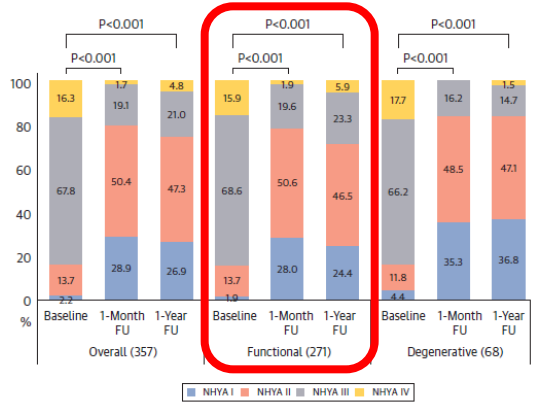
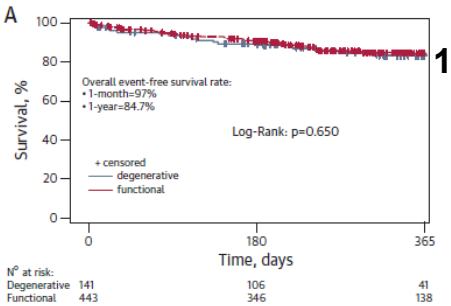


FIGURE 3 NYHA Functional Class at Baseline and at 1-Month and 1-Year Follow-Up

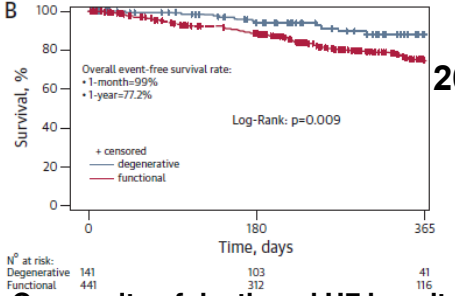
Nickenig et al. JACC 2014; 64:875-84 2011–2012 Pilot European Sentinel Registry (FMR 72.0%)

Death



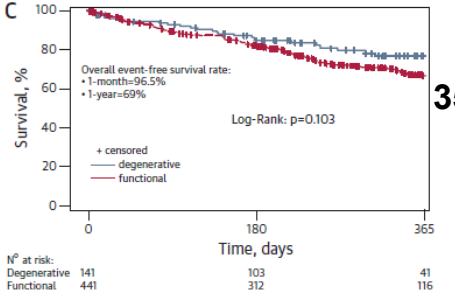
15 %

HF hospitalization



26 %

Composite of death and HF hospitalization



35 %

SMR ?

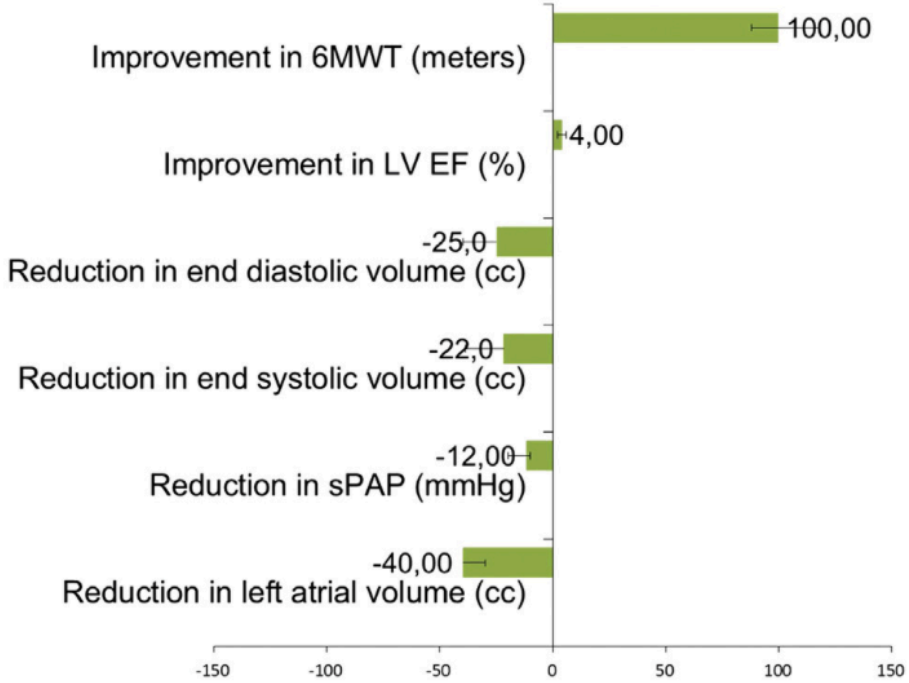
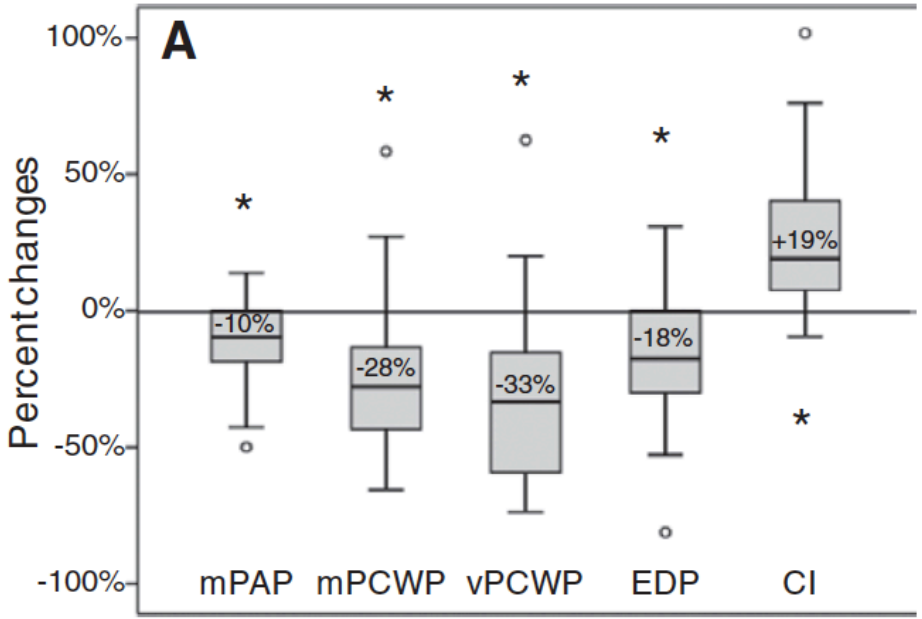


Figure 4. Change of functional and echocardiographic data at follow-up.

FMR :
Median follow-up of 9 months (6 to 12)

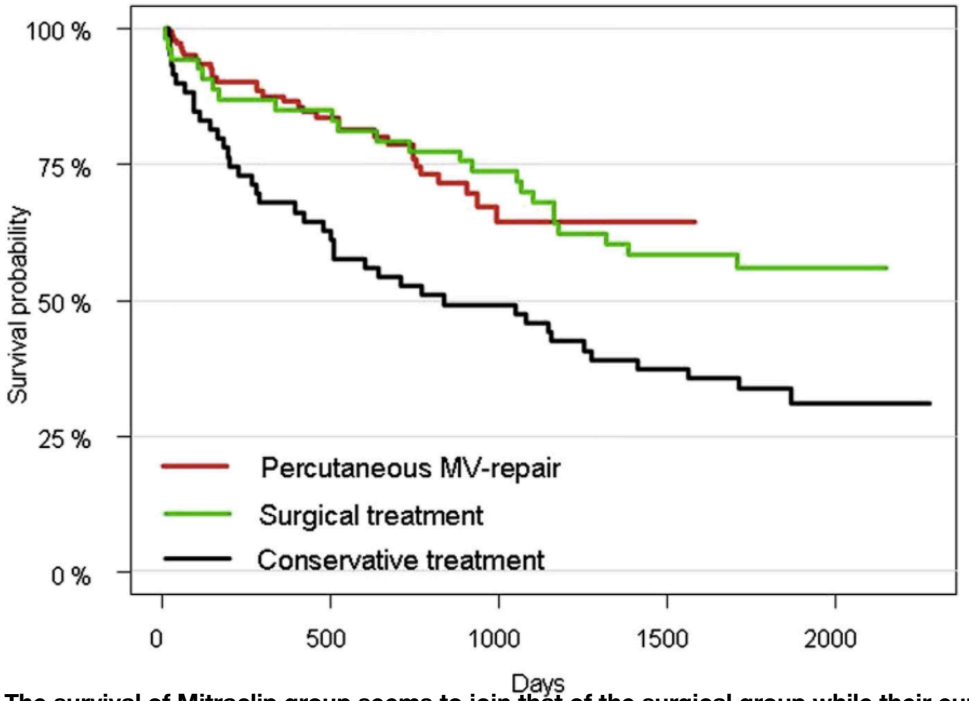
Fabrizio D'Ascenzio et al. , Am J Cardiol 2015; 116:325-331

SMR ?



Gaemperli et al. Circulation. 2013;127:1018-1027
Frantisek Bednar et al. BioMed Research International 2016

SMR ?



Survival of Transcatheter Mitral Valve Repair Compared With Surgical and Conservative Treatment in High-Surgical-Risk Patients

EuroSCORE:

Mitraclip (23.9±16.1%)
Surgery (14.2±8.9%)
Conservative (18.7±13.2%)

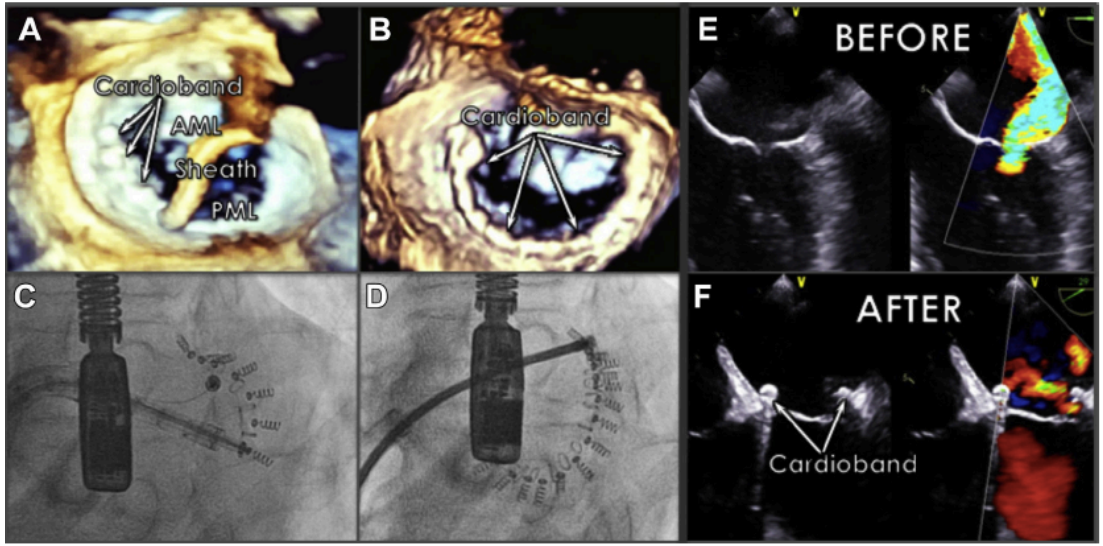
p < 0.0001)

The survival of Mitraclip group seems to join that of the surgical group while their eurosc̀ore is significantly higher

Swaans et al. , JACC intervention 2014; 7:875-81

SMR ?

FIGURE 2 Stepwise Deployment of the Cardioband Device and Acute Reduction of MR After Cinching



No effect on mitral annulus ? But it is not an annuloplasty
Keep in mind that Mitraclip therapy is not the only one percutaneous treatment for FMR

- Nickenig et al. J A C C CardioVascular Interv 2016, 19.

SMR ?

FIGURE 3 MR Severity From Baseline to 6 Months

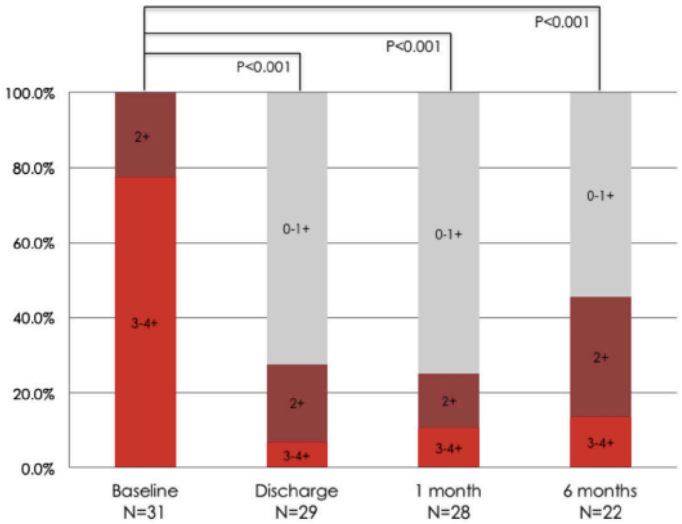
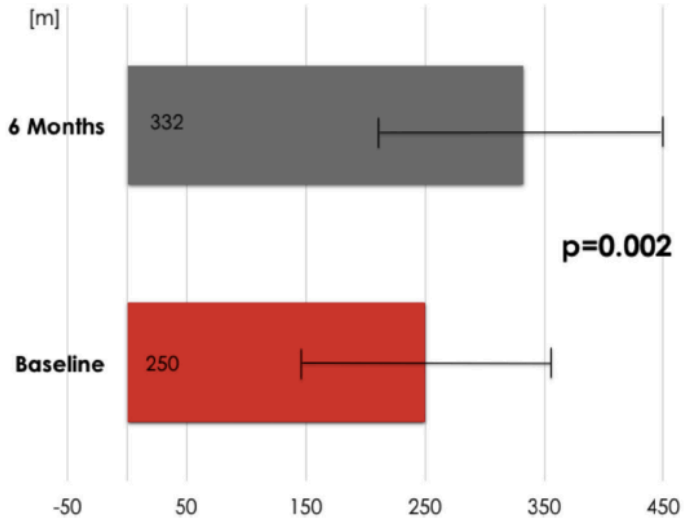


FIGURE 5 6MWT Before Annuloplasty and After 6 Months



- A-P diameter of the FMR mitral orifice was greatly decreased at 6 months (stable).
- Patients with grade 3 or 4 mitral regurgitation was significantly reduced (from 77% to 11%)
- NYHA ssociat functional class, 6-minute walk test, and Minnesota QOL were also improved

- Nickenig et al. J A C C CardioVascular Interv 2 0 1 6, 19.

SMR ?

Table 4 Predictors of the combined event (primary endpoint: combination of all-cause mortality, left ventricular assist device implantation, mitral valve surgery, unsuccessful implantation) in univariate and multivariate analysis (Cox model)

Parameter	Univariate analysis		Multivariate analysis: optimized model	
	HR (95% CI)	P-value	HR (95% CI)	P-value
NT-proBNP >10 000 pg/mL	4.6 (2.6–8.2)	<0.001	3.5 (1.9–6.7)	<0.001
Age >80 years	1.8 (1.0–3.3)	0.046	2.2 (1.2–4.2)	0.008
Serum creatinine >150 mmo/L	2.4 (1.4–4.3)	0.002		
NYHA class IV	2.1(1.2–3.7)	0.008	1.7(1.0–3.2)	0.049
TAPSE <15 mm	3.2 (1.8–5.6)	<0.001	1.9(1.0–3.6)	0.038
TR grade >2+	2.0 (1.0–4.0)	0.052		

CI, confidence interval; HR, hazard ratio; TAPSE, tricuspid annular plane systolic excursion; TR, tricuspid regurgitation.

Neuss M. et al., Eur J Heart Failure (2013) 15, 786–576795

Table 3
Predictors for 2-year survival in univariate and multivariate analyses (Cox model).

	Outcome		Univariate analysis		Multivariate analysis	
	n	Death, %	HR (95% CI)	p-Value	HR (95% CI)	p-Value
Male gender	43	33	1.7 (0.7–4.2)	0.2		
Age > 80 years	39	31	1.6 (0.7–3.6)	0.3		
NYHA functional class IV	12	42	2.2 (0.8–6.0)	0.1		
LVEF < 30%	24	29	1.2 (0.5–2.8)	0.7		
Functional etiology	45	24	0.8 (0.3–1.8)	0.6		
NT-proBNP >5000 μg/L	10	50	3.4 (1.2–9.2)	0.02	5.4 (1.8–16.2)	0.003
Previous valve surgery	8	75	4.8 (1.9–12.2)	0.001	4.5 (1.7–12.2)	0.003
TR > grade 2	24	42	2.6 (1.1–6.0)	0.03	2.8 (1.2–6.8)	0.02
Absence of MR reduction (graded)[a]			1.9 (1.1–3.3)	0.03	2.1 (1.2–3.8)	0.01

HR: hazard ratio; CI: confidence interval; NYHA: New York Heart Association; LVEF: left ventricular ejection fraction; TR: tricuspid regurgitation; MR: mitral regurgitation.
[a] Graded by 0 grade/1 grade/2 grade/3 grade reduction of MR after MitraClip implantation.

Boerlage-vanDijk. et al., Int J of Cardiology 2015;238-243

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Volkmar Falk et al. European Heart Journal (2017) 38, 2739–2791

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Volkmar Falk et al. European Heart Journal (2017) 38, 2739–2791

SMR ?

Recommendation for the type of revascularization (CABG or PCI) in patients with SCAD with suitable coronary anatomy for both procedures and low predicted surgical mortality

Recommendations according to extent of CAD	CABG		PCI		
	Class[a]	Level[b]	Class[a]	Level[b]	Ref[c]
One or two-vessel disease without proximal LAD stenosis.	IIb	C	I	C	
One-vessel disease with proximal LAD stenosis.	I	A	I	A	107,108,160, 161,178,179
Two-vessel disease with proximal LAD stenosis.	I	B	I	C	108,135,137
Left main disease with a SYNTAX score ≤ 22.	I	B	I	B	17,134,170
Left main disease with a SYNTAX score 23–32.	I	B	IIa	B	17
Left main disease with a SYNTAX score >32.	I	B	III	B	17
Three-vessel disease with a SYNTAX score ≤ 22.	I	A	I	B	17,157,175,176
Three-vessel disease with a SYNTAX score 23–32.	I	A	III	B	17,157,175,176
Three-vessel disease with a SYNTAX score >32.	I	A	III	B	17,157,175,176

CABG = coronary artery bypass grafting; LAD = left anterior descending coronary artery; PCI = percutaneous coronary intervention; SCAD = stable coronary artery disease.
[a]Class of recommendation.
[b]Level of evidence.
[c]References.

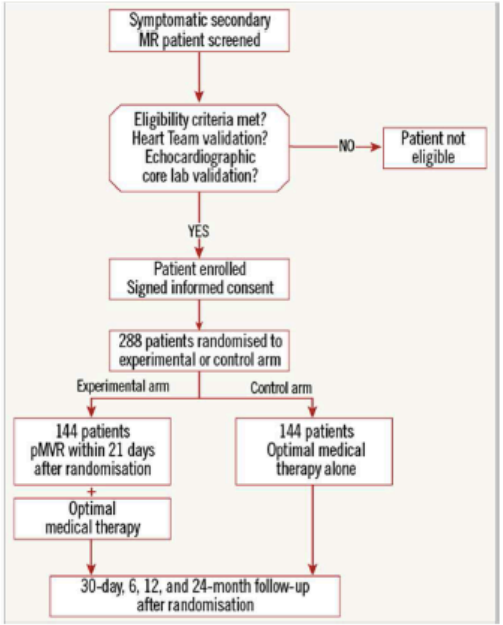
ESC Guidelines 2014

The MITRA-FR study: design and rationale of a randomised study of percutaneous mitral valve repair compared with optimal medical management alone for severe secondary mitral regurgitation

Jean-François Obadia[1,2*], MD, PhD; Xavier Armoiry[3,4], PharmD, PhD; Bernard Iung[5], MD, PhD; Thierry Lefèvre[6], MD; Nathan Mewton[7], MD, PhD: David Messika-Zeitoun[5], MD, PhD; Bertrand Cormier[6], MD; Julien Berthiller[3], MSc; Delphine Maucort-Boulch[8], MD, PhD; Florent Boutitie[8], PhD; Bernadette Vaz[7], PharmD, MSc; Jean-Noël Trochu[9], MD, PhD; Alec Vahanian[5], MD, PhD

EuroIntervention

2015 Mar;10(11):1354-60



- Coapt
- Reshap

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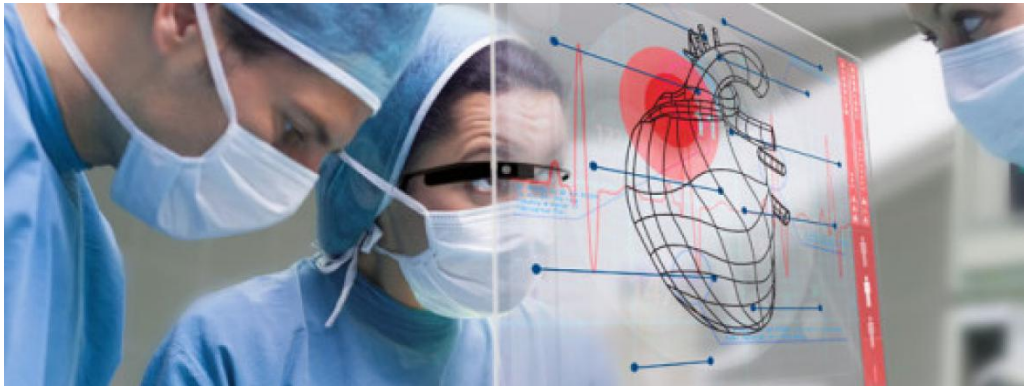


PMR ?

The NEW ENGLAND JOURNAL of MEDICINE

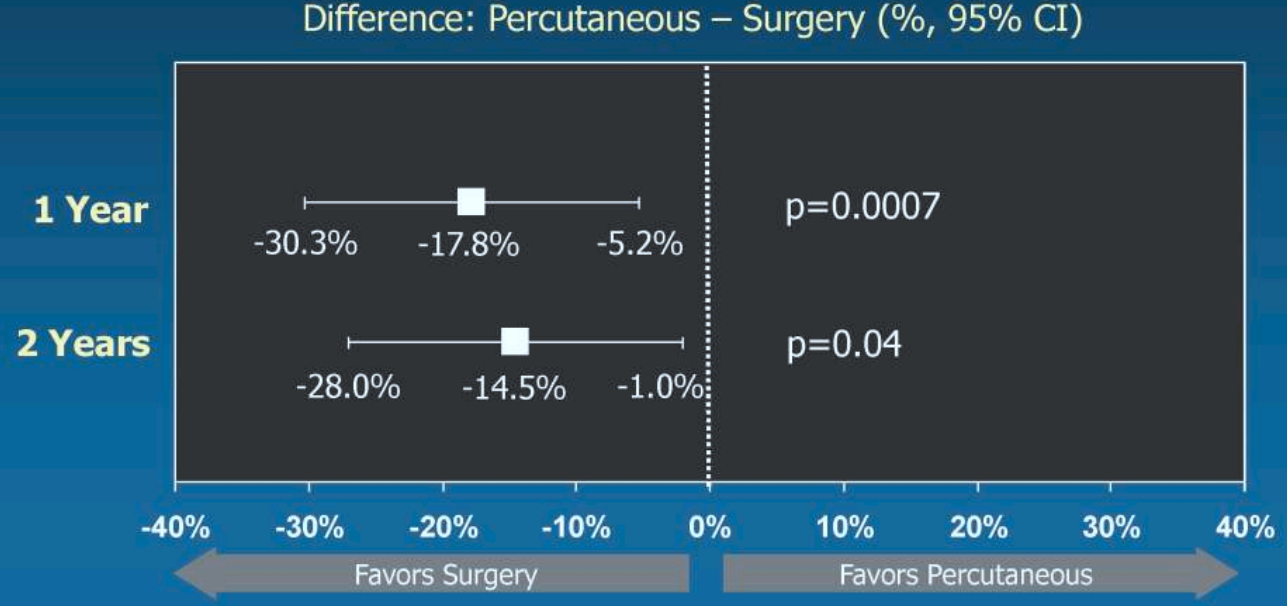
Percutaneous Repair or Surgery for Mitral Regurgitation

Ted Feldman, M.D., Elyse Foster, M.D., Don Glower, M.D., Saibal Kar, M.D., Michael J. Rinaldi, M.D., Peter S. Fail, M.D., Richard W. Smalling, M.D., Ph.D., Robert Siegel, M.D., Geoffrey A. Rose, M.D., Eric Engeron, M.D., Catalin Loghin, M.D., Alfredo Trento, M.D., Eric R. Skipper, M.D., Tommy Fudge, M.D., George V. Letsou, M.D., Joseph M. Massaro, Ph.D., and Laura Mauri, M.D., M.Sc., for the EVEREST II Investigators*

Feldman et al. , NEJM 2011; 364:1395-406

EVEREST DEUX
LA CHIRURGIE FAIT MIEUX !!!!!!

Primary Effectiveness:
Freedom from death, MV surgery/re-operation or 3+ or 4+ MR



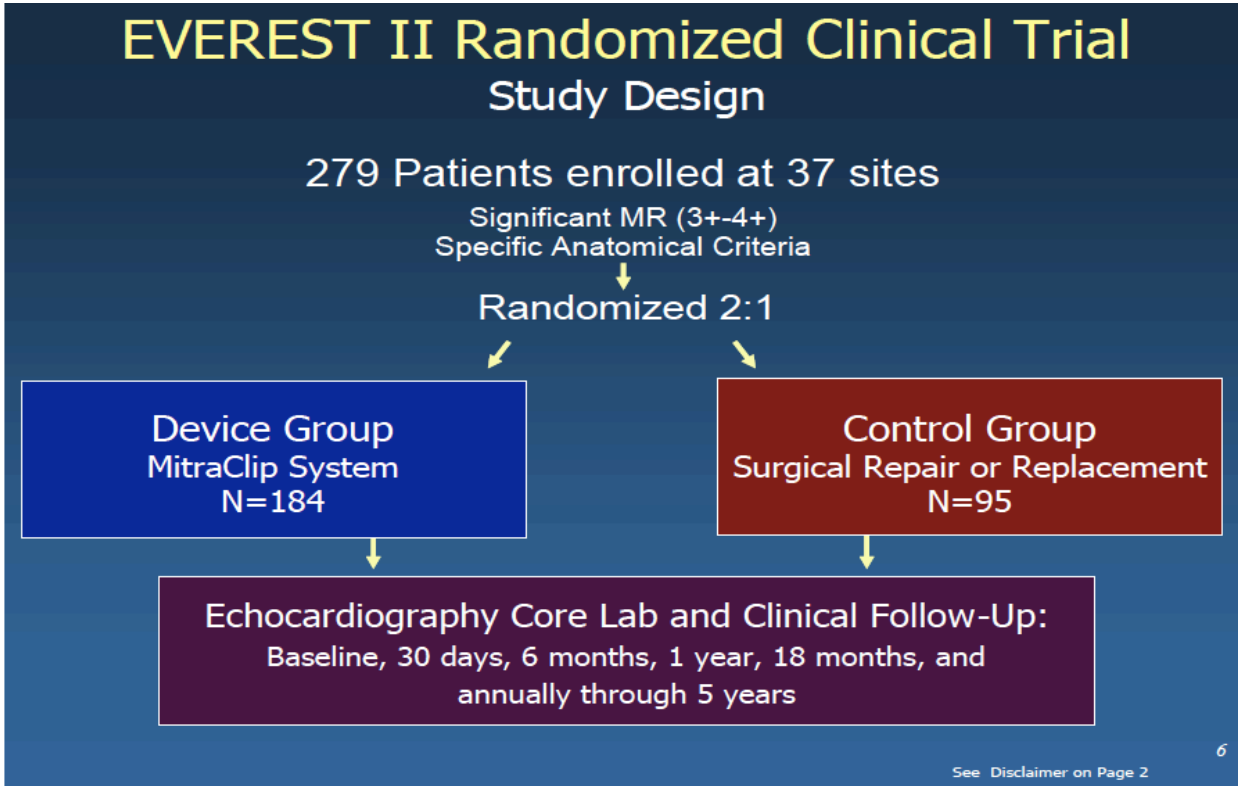
Superiority of surgery compare to Mitraclip

NorthShore University HealthSystem Evanston Hospital

EVEREST II RCT – ACC 2011

Investigational Device only in the U.S. Not available for sale in the U.S.

PMR ?


EVEREST II Randomized Clinical Trial
Study Design
279 Patients enrolled at 37 sites
Significant MR (3+-4+)
Specific Anatomical Criteria
Randomized 2:1
Device Group
MitraClip System
N=184
Control Group
Surgical Repair or Replacement
N=95
Echocardiography Core Lab and Clinical Follow-Up:
Baseline, 30 days, 6 months, 1 year, 18 months, and annually through 5 years
6
See Disclaimer on Page 2

Safety Endpoint: 30 Day MAE
Intention to Treat

30 Day MAE	# (%) Patients experiencing event	
	Percutaneous (N=180)	Surgery (N=94)
Death	2 (1.1%)	2 (2.1%)
Major Stroke	2 (1.1%)	2 (2.1%)
Re-operation of Mitral Valve	0	1 (1.1%)
Urgent / Emergent CV Surgery	4 (2.2%)	4 (4.3%)
Myocardial Infarction	0	0
Renal Failure	1 (0.6%)	0
Deep Wound Infection	0	0
Ventilation > 48 hrs	0	4 (4.3%)
New Onset Permanent Atrial Fib	2 (1.1%)	0
Septicemia	0	0
GI Complication Requiring Surgery	2 (1.1%)	0
Transfusions ≥ 2 units	24 (13.3%)	42 (44.7%)
TOTAL % of Patients with MAE	**15.0%**	**47.9%**
	Difference (Percutaneous – Surgery) = -32.9%	
	p<0.001; (95% CI: -20.7%, -45.0%)	

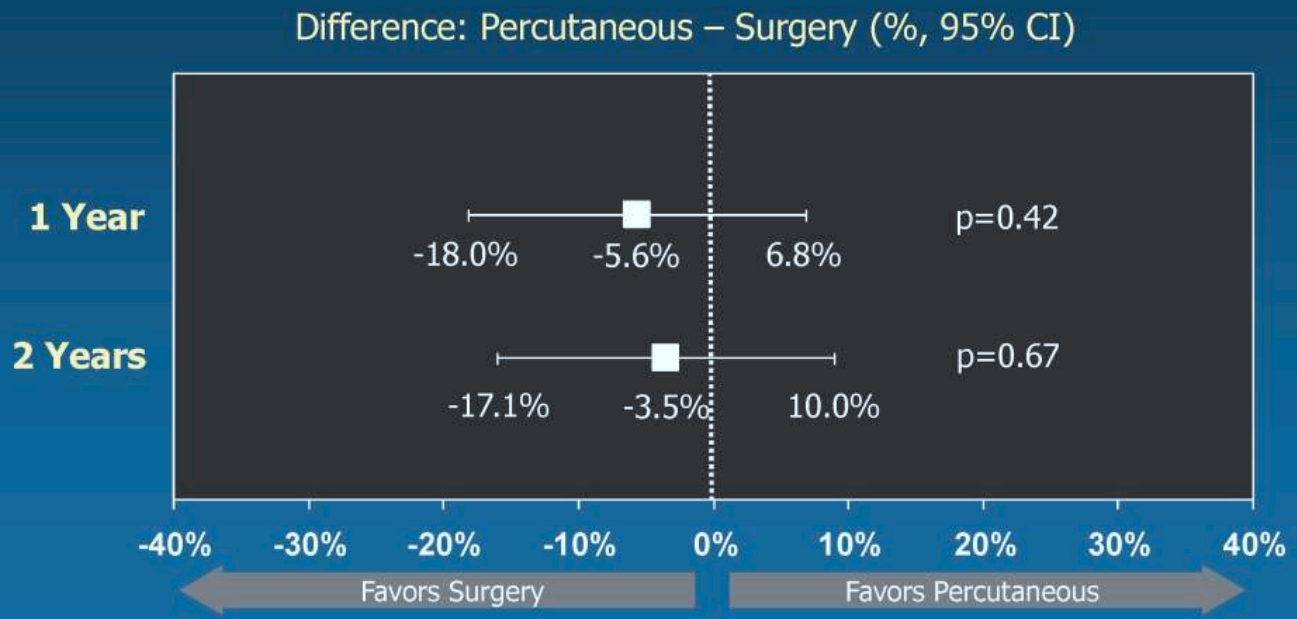
Investigational Device only in the U.S. Not available for sale in the U.S.

Primary Effectiveness Endpoint

- Effectiveness defined as freedom from death, MV surgery/re-operation or 3+ or 4+ MR
- Two analyses performed:
  1. Intention to Treat
     - Any mitral valve surgery following percutaneous repair was considered an "endpoint" event
  2. Comparison of Treatment Strategies
     - Mitral valve surgery following unsuccessful in-hospital percutaneous repair is not considered an "endpoint" event

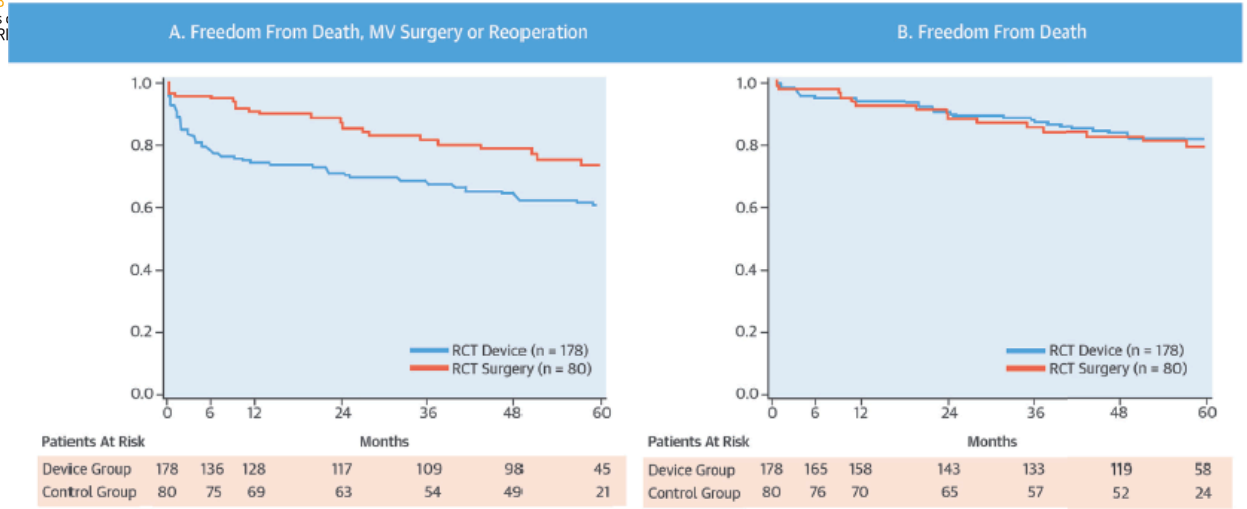
Investigational Device only in the U.S. Not available for sale in the U.S.

Primary Effectiveness Analyses at 1 and 2 Years
Difference Between Percutaneous & Surgery
Comparison of Treatment Strategies Analysis
Primary Effectiveness:
Freedom from death, MV surgery/re-operation or 3+ or 4+ MR



Equivalence between surgery and Mitraclip

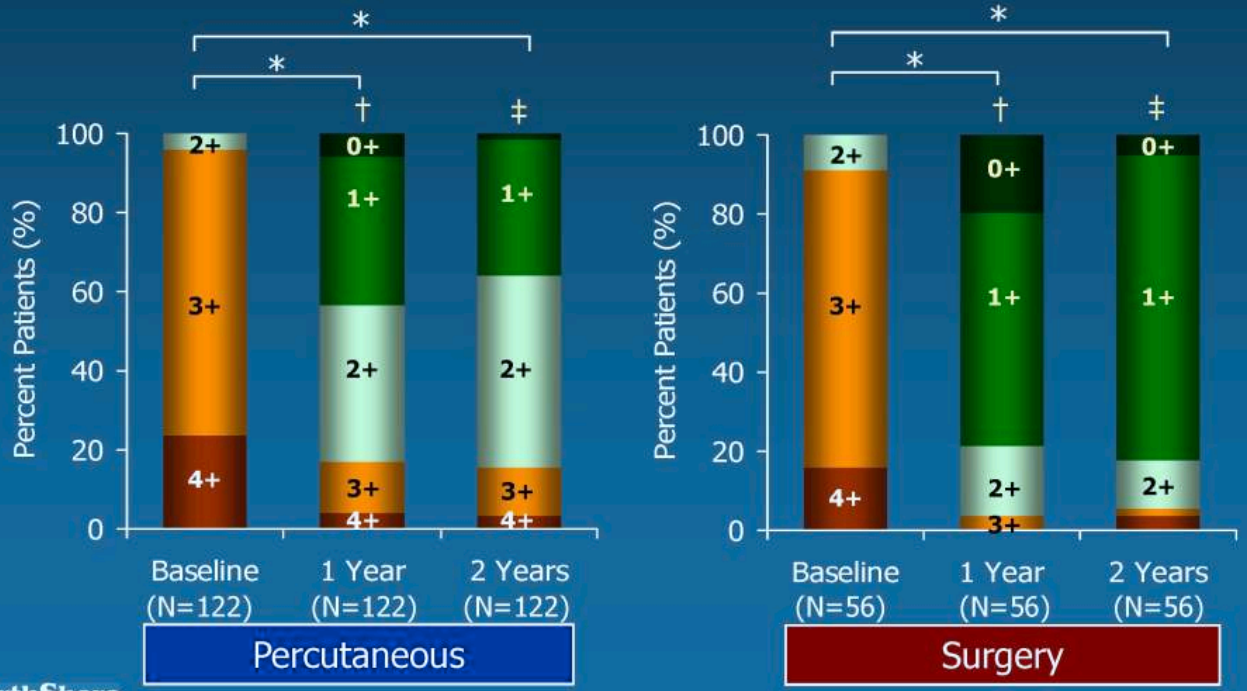
CENTRAL ILLUSTRATION **5-Year Clinical Outcomes: Percutaneous Repair and Surgery for Mitral Regurgitation**



Feldman JACC 2015

Mitral Regurgitation Grade
Baseline, 1 and 2 Years (matched)
Intention to Treat

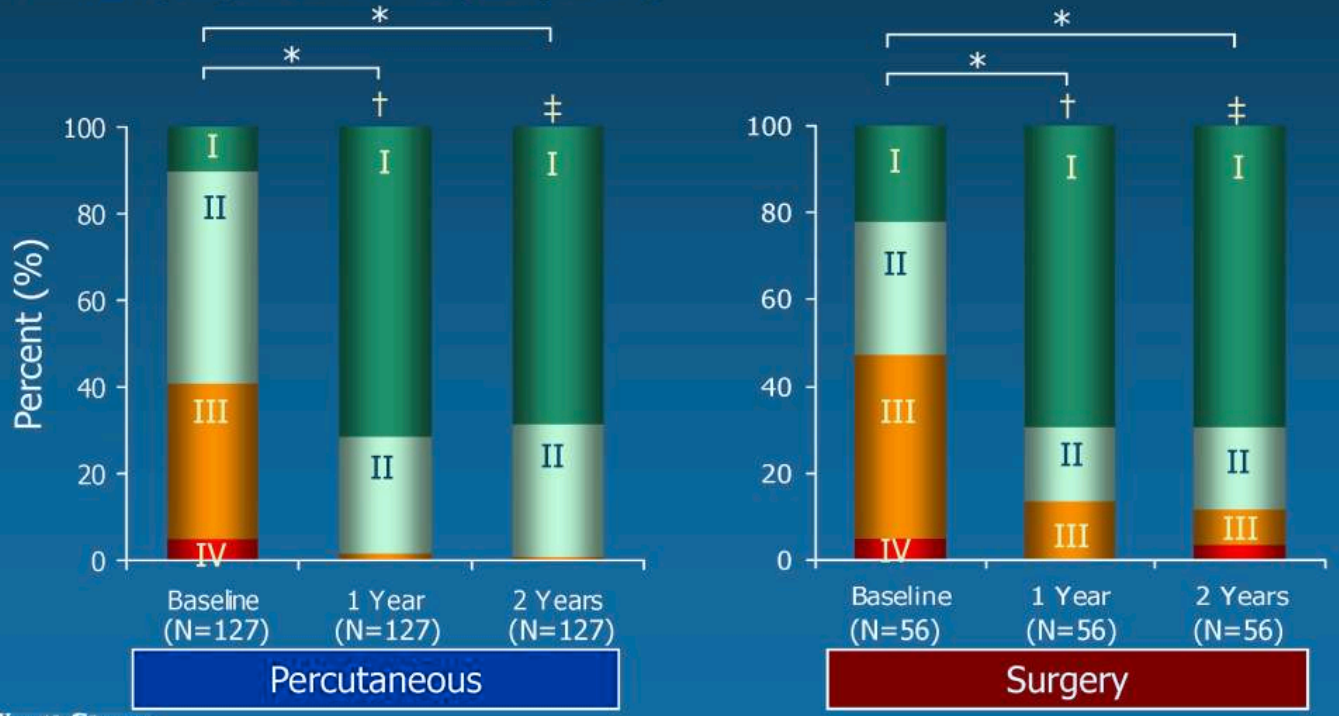
* Within group difference (p<0.05)
† Between group difference at 1 year (p<0.05)
‡ Between group difference at 2 year (p<0.05)



Investigational Device only in the U.S. Not available for sale in the U.S.

NYHA Functional Class
At Baseline, 1 and 2 Years (matched)
Intention to Treat

* Within group difference (p<0.05)
† Between group difference at 1 year (p<0.05)
‡ Between group difference at 2 year (p<0.05)



NorthShore University HealthSystem Evanston Hospital

EVEREST II RCT – ACC 2011

Investigational Device only in the U.S. Not available for sale in the U.S.

La mitrale est elle l'avenir du cardiologue interventionnel ?

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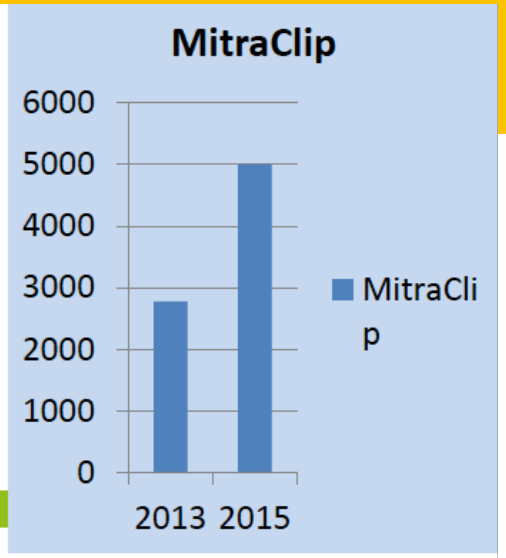
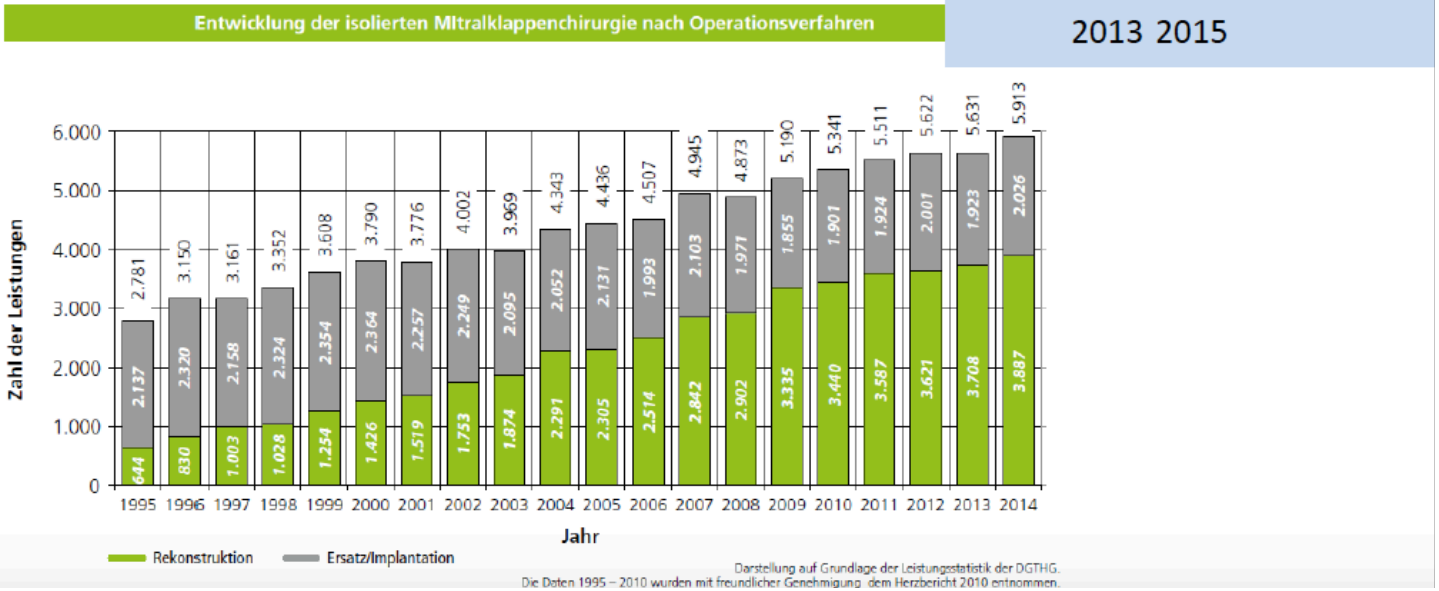
UNIVERSITÄTSmedizin.
MAINZ
Zentrum für Kardiologie

2015 German Heart Report: Treatment of TMVR with MitraClip passed surgical volume



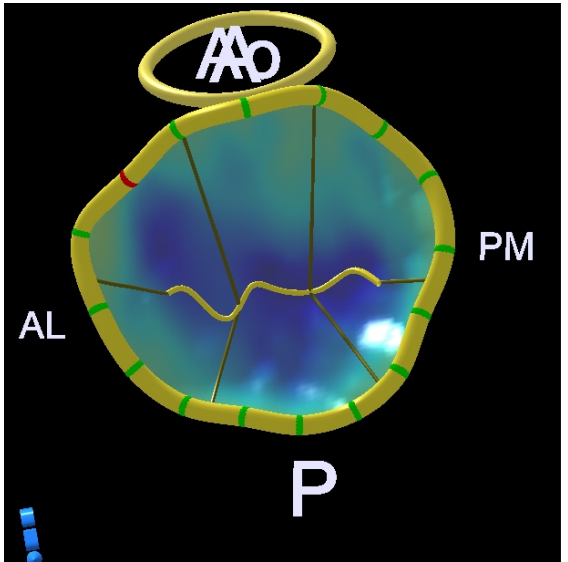


Mitral valve annulus repair

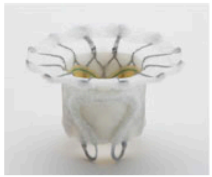
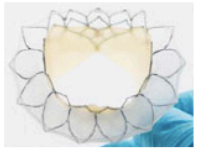
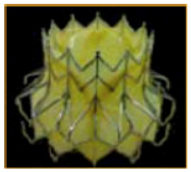
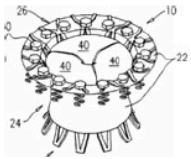
- ***Indirect annuloplasty (Coronary sinus annuloplasty):***
- **Edwards Monarc**
- **Carillon**
- **Viacor Shape Changing Rods**
- **St. Jude Annulus Reshaping …**

- ***Direct annuloplasty***
- **Mitralign.**
- **Guided Delivery Anchor-Cinch Plication**
- **QuantumCor RF Annulus Remodeling.**
- **MiCardia variable size ring…**

- ***Left ventricle annulplasty***
- **Myocor iCoapsys, Ample PS3 …**

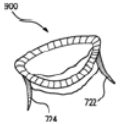
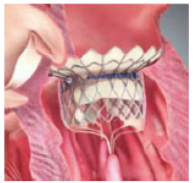
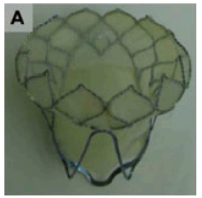
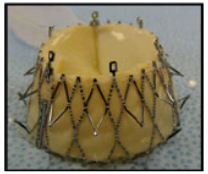


Percutaneous mitral valve replacement

Fortis (Edwards Lifesciences)		First-in-man study underway	– Mitral valve replacement technology designed to minimize *para*-valvular leak – Initial version being studied in first-in-man has a transapical delivery system
Tiara (Neovasc)		First-in-man study underway	– Self-expanding bovine pericardial, D-shaped trileaflet mitral valve implanted using a transapical delivery system – It is anchored to the mitral annulus – A transfemoral delivery system is also in development
TMVI-TA (CardiAQ)		First-in-man study completed	– Self-positioning, self-anchoring, and self-conforming system for transcatheter mitral valve implantation through transapical approach
TMVI-TF (CardiAQ)		First-in-man study completed	– Self-positioning, self-anchoring, and self-conforming system for transcatheter mitral valve implantation – 2nd-generation device has been developed; this profile covers transfemoral version
Caisson TMVR (Caisson)		Preclinicals underway	– Mitral valve replacement system with a transfemoral delivery system

Maisano et al (review). Eur J Cardiothorac Surg. 2012 Sep;42(3):524-9

Percutaneous mitral valve replacement

MitraCath (Emory University)		In development	– Technology that enables the placement of a stent-mounted bioprosthetic heart valve in the mitral position
HighLife Mitral Valve Replacement (HighLife)		Preclinicals underway	– Percutaneous mitral valve replacement technology with a transatrial delivery system
Medtronic TMVR (Medtronic)		Preclinicals underway	– Self-expanding nitinol scaffold and a bovine pericardium valve with three cusps – Designed for fixation with the native mitral annulus
MitrAssist Valve (MitrAssist)		Preclinicals underway	– A mitral valve that fits into the existing mitral valve – Delivered through a small-diameter catheter – For all forms of mitral regurgitation
Navigate TMVR (NCSI)		Clinical implants have occurred	– Self-expandable mitral valve replacement device featuring a nitinol stent and dehydrated tissue for treatment of functional mitral regurgitation – Transatrial, transapical, and transseptal versions are also in development

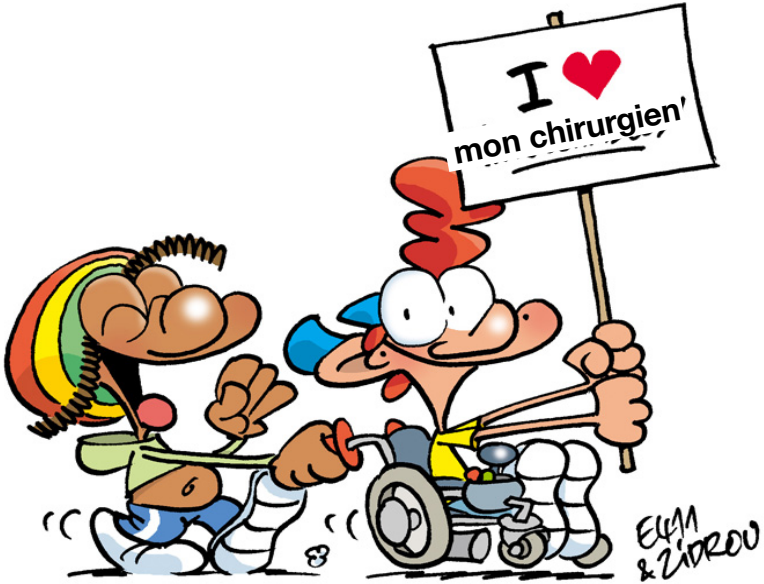
Maisano et al (review). Eur J Cardiothorac Surg. 2012 Sep;42(3):524-9

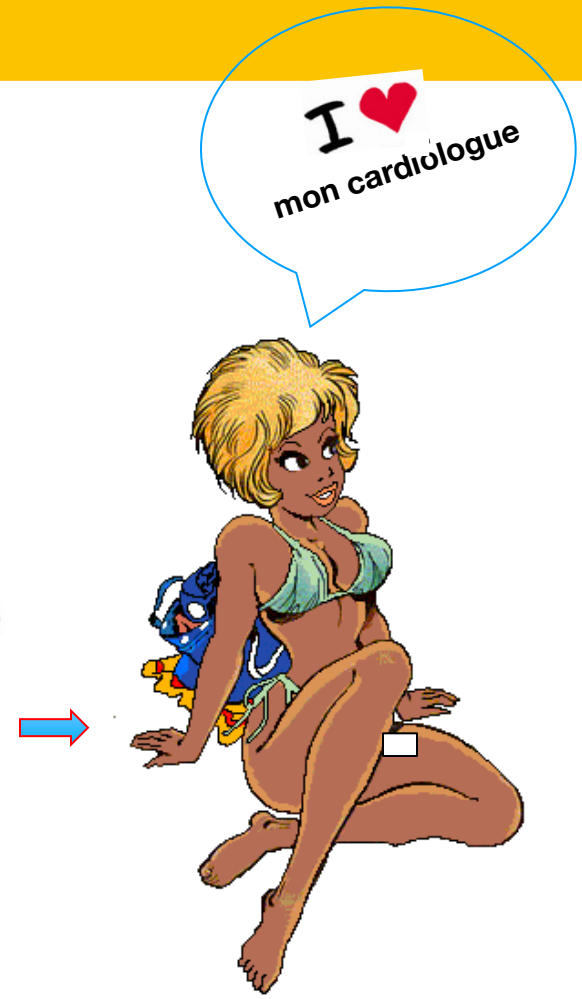
"le futur du traitement percutané de la valve mitrale"

Ce qui paraît certain :
•La fuite mitrale est la première valvulopathie
•50% des IM ne sont pas opérées
•nous sommes sur la route du traitement percutané de la mitrale : c'est parti !
•Va t'on vers le remplacement valvulaire mitral percutané ou plutôt vers la réparation comme l'ont fait les chirurgiens avant nous ? (Associations de gestes (Ex : Mitraclip et anneau mitral ?)

•L'imagerie sera un élément clé et décisif, potentiellement limitant.

Ce qui n'est pas clair :
•SMR ? MitraFr, Coapt, Reshape ?
•PMR ? MitraHR





Merci pour votre attention