Mitraclip : actualités

Autour de la mitrale

DÉCLARATION DE LIENS D'INTÉRÊT AVEC LA PRÉSENTATION

Intervenant : Patrice GUERIN, Nantes

☑ J'ai les conflits d'intérêt suivant à déclarer

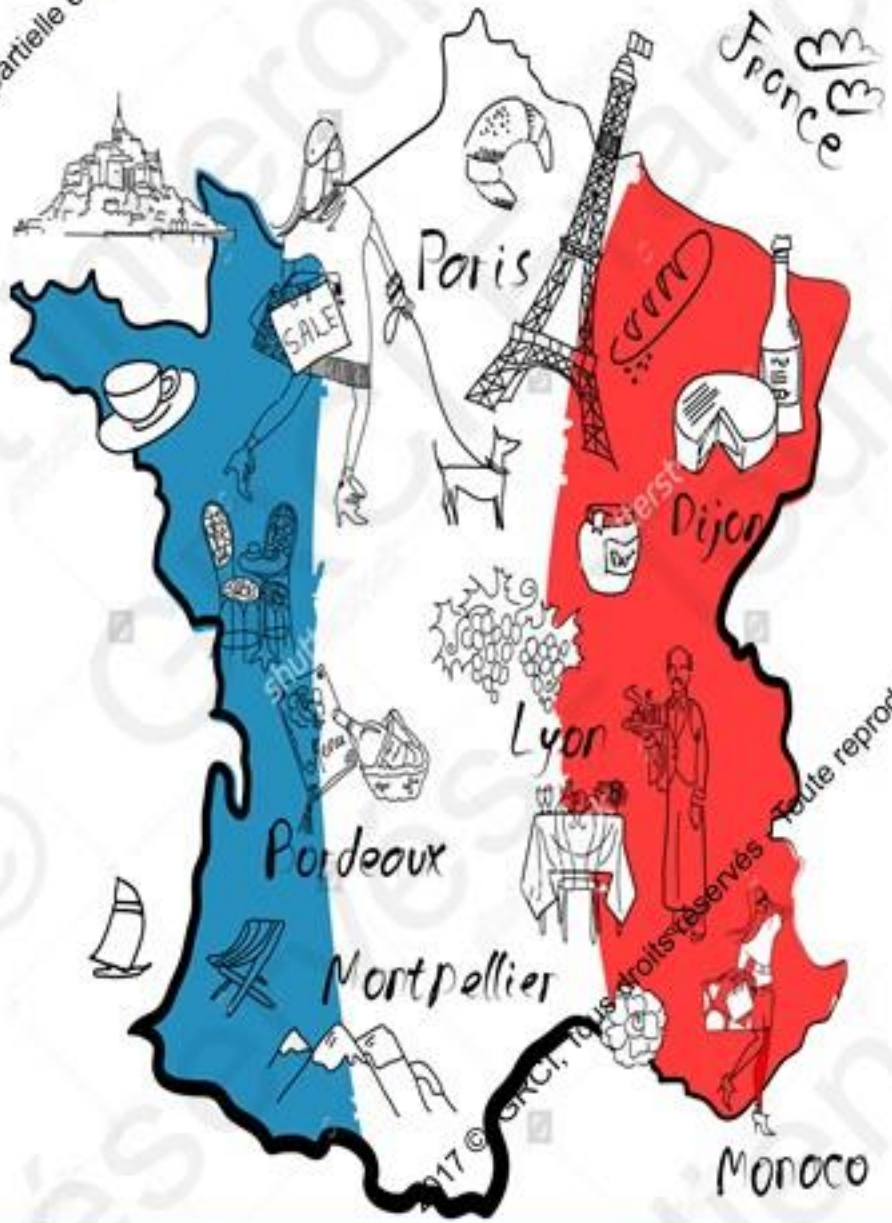
Grant/Research Support: Abbott Vascular, Boston scientific, Biotronic

Consulting Fees/Honoraria: Abbott Vascular, AstraZeneca, Lilly, Actelion

GRCI 2017
France

6 AU 8 DÉCEMBRE 2017
Novotel Paris Tour Eiffel

Passion Communication Education



Mitraclip en France

- IM secondaires :
  - PHRC MitraFr : Inclusions terminées
  - Période blanche…
  - RDV à Munich 2018
- IM primitives :
  - Contre indiqués à la chirurgie : Remboursement
  - Haut risque opératoire : PHRC Mitra HR

HAS

HAUTE AUTORITÉ DE SANTÉ

COMMISSION NATIONALE D'EVALUATION DES DISPOSITIFS MEDICAUX ET DES TECHNOLOGIES DE SANTE

AVIS DE LA CNEDiMTS

24 mars 2015

CONCLUSIONS

MITRACLIP, clip de réparation mitrale bord à bord

Demandeur : ABBOTT France SAS (France)

HAS

- Patients avec insuffisance mitrale sévère, d'origine dégénérative, symptomatique malgré une prise en charge médicale optimale, non éligibles à la chirurgie et répondant aux critères échographiques d'éligibilité.

- Tous ces critères et en particulier la contre-indication chirurgicale doivent être validés par une équipe multidisciplinaire ad hoc.

- Les patients ayant une espérance de vie inférieure à un an compte tenu de facteurs extracardiaques (comorbidités) ne sont pas éligibles à la technique (non indication).

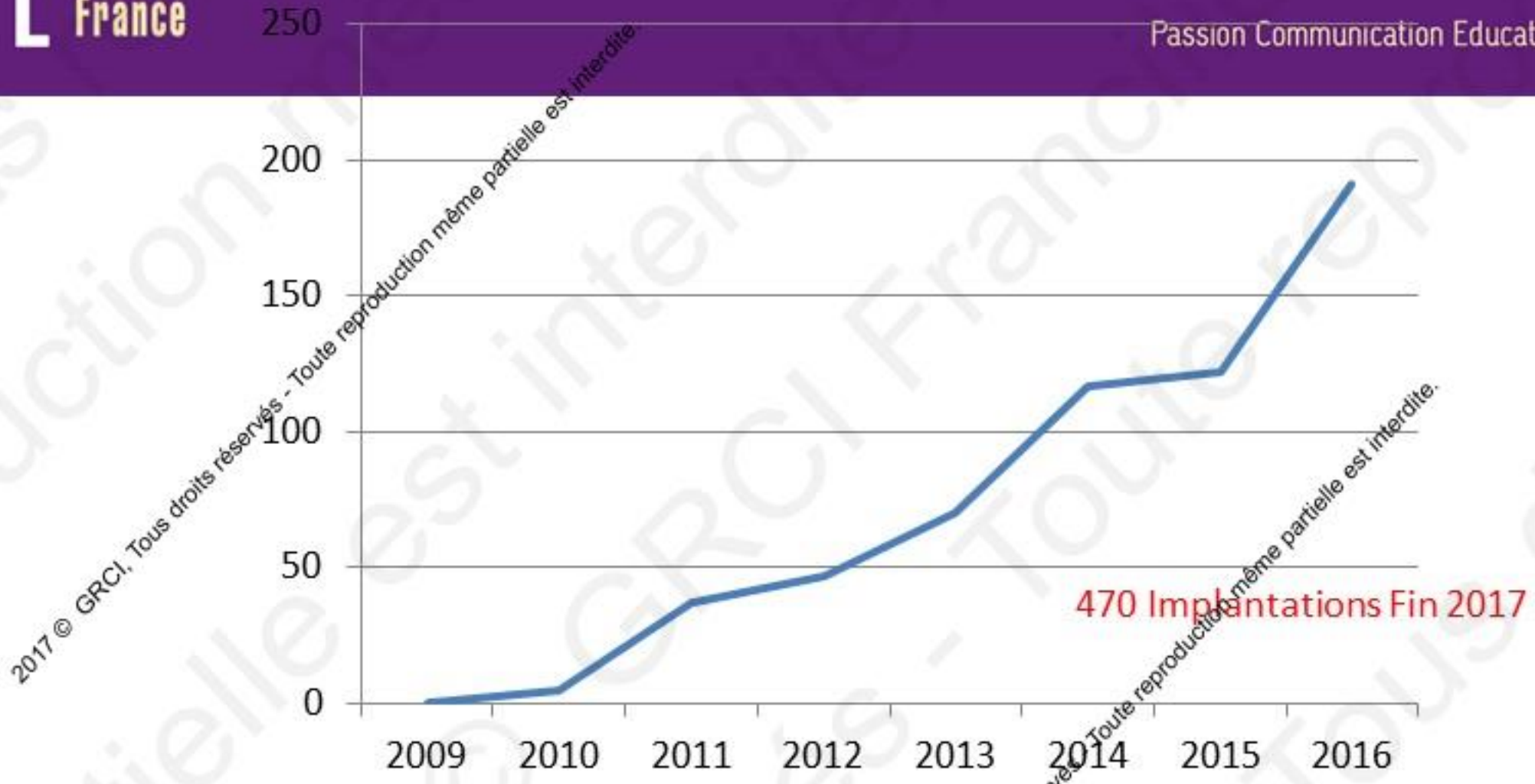
ASA II (amélioration importante)

HAS

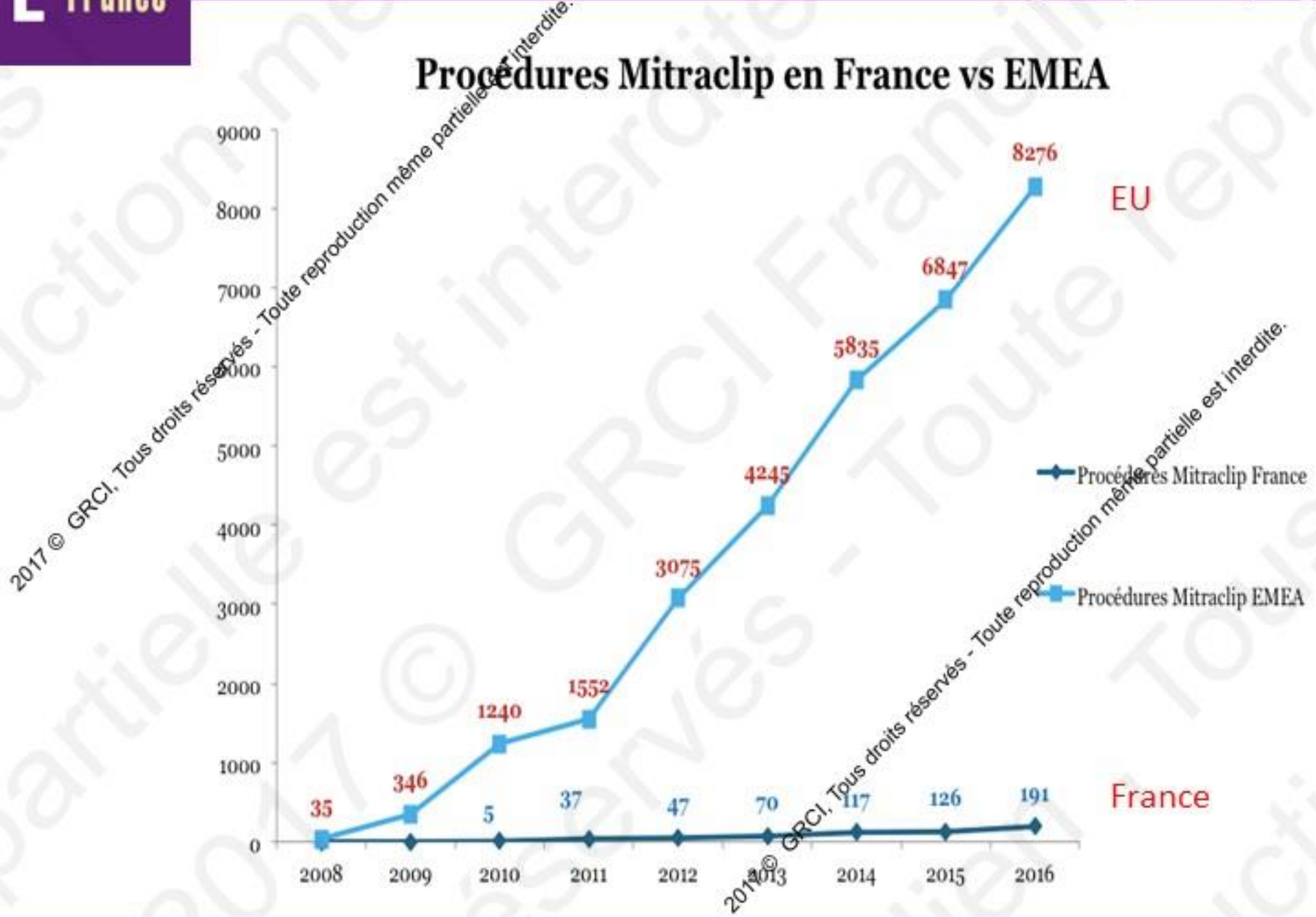
- La sélection des patients éligibles doit être réalisée lors de la réunion multidisciplinaire ad hoc impliquant :
  - un chirurgien cardio-vasculaire et thoracique,
  - un cardiologue interventionnel
  - un cardiologue clinicien
  - un échocardiographiste
  - un anesthésiste-réanimateur
  - L'obtention de l'avis d'un gériatre est très fortement recommandée.

- Des spécialistes cliniques du laboratoire Abbott Vascular peuvent être consultés pour vérifier la compatibilité de l'anatomie valvulaire à la pose du dispositif.

Activité en France



Année	2008	2009	2010	2011	2012	2013	2014	2015	2016
France	0	0	5	37	47	70	117	122	191
EMEA	35	346	1240	1552	3075	4245	5835	6847	8283



Quid des patients opérables mais à risque opératoire intermédiaire à élevé ?

Etude multicentrique randomisée de non infériorité comparant dans une population à risque opératoire élevé MITRACLIP® vs chirurgie

Objectifs : comparer, en cas de fuite mitrale sévère primitive, le Mitraclip à la chirurgie conventionnelle (à 12 mois) chez les patients **à risque opératoire élevé mais non prohibitif** (heart team) :

- Efficacité
- Sécurité

Etude multicentrique randomisée de non infériorité comparant dans une population à risque opératoire élevé MITRACLIP® vs chirurgie

- Objectif principal :
  - Démontrer la non-inferiorité du MitraClip® en comparaison au traitement chirurgical à 12 mois
- Objectifs secondaires :
  - Meilleurs sécurité du MitraClip® à 30 jours en comparaison au traitement chirurgical

Etude multicentrique randomisée de non infériorité comparant dans une population à risque opératoire élevé MITRACLIP® vs chirurgie

La population :

Comment définir un risque opératoire élevé ?

Etude multicentrique randomisée de non infériorité comparant dans une population à risque opératoire élevé MITRACLIP® vs chirurgie

Clinical Trial Design Principles and Endpoint Definitions for Transcatheter Mitral Valve Repair and Replacement: Part 1: Clinical Trial Design Principles

A Consensus Document From the Mitral Valve Academic Research Consortium

Gregg W. Stone, MD,*† Alec S. Vahanian, MD,‡ David H. Adams, MD,§ William T. Abraham, MD,‖ Jeffrey S. Borer, MD,¶ Jeroen J. Bax, MD, PhD,# Joachim Schofer, MD,** Donald E. Cutlip, MD,†† Mitchell W. Krucoff, MD,‡‡ Eugene H. Blackstone, MD,§§ Philippe Généreux, MD,*‖‖ Michael J. Mack, MD,¶¶ Robert J. Siegel, MD,## Paul A. Grayburn, MD,¶¶ Maurice Enriquez-Sarano, MD,*** Patrizio Lancellotti, MD, PhD,††† Gerasimos Filippatos, MD,‡‡‡ Arie Pieter Kappetein, MD, PhD,§§§ for the Mitral Valve Academic Research Consortium (MVARC)

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Stone, Vahanian et al.. European heart journal 2015;36:1851-77.

Stone, Vahanian et al.. European heart journal 2015;66: 308–21.

TABLE 7 Recommended Major Inclusion and Exclusion Criteria for Transcatheter Device Trials in Patients with Mitral Regurgitation

Inclusion Criteria
Age ≥18 yrs
Degree of MR: Severe (or 3+ and 4+)*
LVEF >20% (primary MR) or ≥20% to ≤60% (secondary MR)†‡
Symptom status: NYHA functional class II to IVa§
Treatment and compliance with optimal guideline-directed medical therapy for heart failure for at least 30 days (preferably 90 days)
MR mechanism/anatomy: Appropriate to the design specifications of each device
Surgical risk: Specific STS risk score criteria and/or the presence of high-risk features or comorbidities, depending on the specific trial aims
Completion of required functional tests (e.g., 6-min walk) and/or quality-of-life assessments

Exclusion Criteria
Life expectancy <1 yr due to noncardiac conditions
NYHA functional class IVb or ACC/AHA stage D heart failure
Hypotension (systolic pressure <90 mm Hg) or requirement for inotropic support or mechanical hemodynamic support
UNOS status 1 heart transplantation or prior orthotopic heart transplantation
Hypertrophic cardiomyopathy, restrictive cardiomyopathy, constrictive pericarditis, or any other structural heart disease causing heart failure other than dilated cardiomyopathy of either ischemic or nonischemic etiology
Fixed pulmonary artery systolic pressure >70 mm Hg‖
Physical evidence of right-sided congestive heart failure with echocardiographic evidence of moderate or severe right ventricular dysfunction.
Mitral valve anatomy which may preclude proper device treatment
Mitral valve area <4.0 cm^2 (if new device therapy may further decrease the mitral orifice area)
Any prior mitral valve surgery or transcatheter mitral valve procedure
Stroke or transient ischemic event within 30 days before randomization
Modified Rankin Scale ≥4 disability
TAVR within 1 month before randomization
Severe symptomatic carotid stenosis (>70% by ultrasound).
Need for emergent or urgent surgery for any reason or any planned cardiac surgery within the next 12 months
Absence of CRT with Class I indication criteria for biventricular pacing
Implant or revision of any rhythm management device (CRT or CRT-D) or implantable cardioverter-defibrillator within 1 month before randomization
Untreated clinically significant coronary artery disease requiring revascularization
Any percutaneous cardiovascular intervention, cardiovascular surgery, or carotid surgery within 30 days
Tricuspid valve disease requiring surgery or severe tricuspid regurgitation
Aortic valve disease requiring surgery
Need for any cardiovascular surgery (other than for MV disease)
Echocardiographic evidence of intracardiac mass, thrombus, or vegetation
Active endocarditis
Active infections requiring current antibiotic therapy
Subjects in whom transesophageal echocardiography is contraindicated or high risk
Any condition making it unlikely the patient will be able to complete all protocol procedures (including compliance with guideline directed medical therapy) and follow-up visits
Patient (or legal guardian) unable or unwilling to provide written, informed consent before study enrollment

Mitra HR

population à haut risque ?

TABLE 8 Risk Assessment in Valvular Heart Disease, Combining Society of Thoracic Surgery Risk Estimates, Frailty, Major Organ System Dysfunction, and Procedure-Specific Impediments for Intervention

	Low Risk (ALL Criteria in This Column Must Be Present)	Intermediate Risk (At Least 1 Criterion in This Column Must Be Present)	High Risk (At Least 1 Criterion in This Column Must Be Present)	Prohibitive Risk (Any 1 Criterion in This Column Must Be Present)
STS PROM*	<4%	4%-8%	>8%	Predicted risk with surgery of death or major morbidity (all-cause)
Frailty†	None	1 index (mild)	≥2 indexes (moderate to severe)	>50% at 1 yr
Major organ system compromise not to be improved post-operatively‡	None	1 organ system	No more than 2 organ systems	≥3 organ systems
Procedure-specific impediment§	None	Possible procedure-specific impediment	Possible procedure-specific impediment	Severe procedure-specific impediment

*Use of the STS predicted risk of mortality (PROM) to predict risk in a given institution with reasonable reliability is appropriate only if institutional outcomes are within 1 SD of STS average observed/expected ratio for the procedure in question. †Seven frailty indexes: Katz Activities of Daily Living (independence in feeding, bathing, dressing, transferring, toileting and urinary continence) and independence in ambulation (no walking aid or assist required for 5-m walk in <6 s). Other scoring systems can be applied to calculate no, mild, or moderate-to-severe frailty. ‡Examples of major organ system compromise: Cardiac: severe LV systolic or diastolic dysfunction or RV dysfunction, or fixed pulmonary hypertension; CKD stage 3 or worse; pulmonary dysfunction with FEV1 <50% or $DLCO_2$ <50% of predicted; CNS dysfunction: dementia, Alzheimer's disease, Parkinson's disease, or CVA with persistent physical limitation; GI dysfunction: Crohn's disease, ulcerative colitis, nutritional impairment, or serum albumin <3.0; cancer: active malignancy; and liver: any history of cirrhosis, variceal bleeding, or elevated INR in the absence of VKA therapy. §Examples: tracheostomy present, heavily calcified ascending aorta, chest malformation, arterial coronary graft adherent to posterior chest wall, or radiation damage. Adapted with permission from Nishimura et al. (1).

CKD = chronic kidney disease; CNS = central nervous system; CVA = cerebrovascular accident (stroke); $DLCO_2$ = diffusion capacity for carbon dioxide; FEV1 = forced expiratory volume in 1 s; GI = gastrointestinal; INR = international normalized ratio; LV = left ventricular; PROM = predicted risk of mortality; RV = right ventricular; STS = Society of Thoracic Surgeons; VKA = vitamin K antagonist.

population à haut risque ?

High Risk (At Least 1 Criterion in This Column Must Be Present)

- >8%
- ≥2 indexes (moderate to severe)
- No more than 2 organ systems
- Possible procedure-specific impediment

Thoracic Surgery Risk Estimates, Frailty, Major Organ System Dysfunction, and

	...ate Risk ...Criterion in ...st Be Present)	High Risk (At Least 1 Criterion in This Column Must Be Present)	Prohibitive Risk (Any 1 Criterion in This Column Must Be Present)
STS		>8%	Predicted risk with surgery of death or major morbidity (all-cause)
Frail		≥2 indexes (moderate to severe)	>50% at 1 yr
Majo		No more than 2 organ systems	≥3 organ systems
Proc	...dure-specific ...t	Possible procedure-specific impediment	Severe procedure-specific impediment

*Use... ...ble reliability is appropriate only if institutional outcomes are within 1 SD of STS average observed/expected ratio... ...endence in feeding, bathing, dressing, transferring, toileting and urinary continence) and independence in amb... ...applied to calculate no, mild, or moderate-to-severe frailty. ‡Examples of major organ system compromise: Card... ...ension; CKD stage 3 or worse; pulmonary dysfunction with FEV1 <50% or $DLCO_2$ <50% of predicted; CNS dysf... ...mitation; GI dysfunction: Crohn's disease, ulcerative colitis, nutritional impairment, or serum albumin <3.0; canc... ...n the absence of VKA therapy. §Examples: tracheostomy present, heavily calcified ascending aorta, chest malf... ...pted with permission from Nishimura et al. (1).

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Mitra HR

population à haut risque ?

-Adult patients judged eligible for mitral valve surgery by the local heart team but at high surgical risk defined as:

age ≥ 75 years and STS score ≥ 6 % or one frailty index or one major organ system compromise or one possible procedure-specific impediment (using MVARC definitions)

or age < 75 years and STS score > 8 % or at least one other high-risk criterion following the MVARC definitions

TAB… Thoracic Surgery Risk Estimates, Frailty, Major Organ System Dysfunction, and Proc…

	…iate Risk …Criterion in …st Be Present)	High Risk (At Least 1 Criterion in This Column Must Be Present)	Prohibitive Risk (Any 1 Criterion in This Column Must Be Present)
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Frailty ?

- Frailty indexes:
  - Katz Activities of Daily Living (independence in feeding, bathing, dressing, transferring, toileting and urinary continence) and independence in ambulation (no walking aid or assist required for 5-m walk in <6 s). Other scoring systems can be applied to calculate no, mild, or moderate-to-severe frailty.
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- Procedure-specific impediment :
  - tracheostomy present, heavily calcified ascending aorta, chest malformation, arterial coronary graft adherent to posterior chest wall, or radiation damage

Sélection échographique des patients

Easy to do	Doable	Hard or impossible to do
Optimal valve morphology	**Conditionally suitable valve morphology**	**Unsuitable valve morphology**
Central pathology in Segment 2	Pathology in segment 1 or 3	Perforated MV leaflet or Cleft
No leaflet calcification	Mild calcification outside of the grip-zone, ring calcification, post anuloplasty	Severe calcification in the grip-zone
MVOA > 4cm²	MVOA >3cm² with good residual leaflet mobility	Hemodynamically significant mitral stenosis (MVOA <3cm²; MPG≥ 5mmHg)
Mobile length of PML ≥ 10mm	Mobile length of PML 7- <10mm	Mobile length of PML < 7mm
Coaptation depth <11mm	Coaptation depth ≥ 11 mm	Rheumatic leaflet thickening and restriction in systole and diastole (Carpentier IIIa)
Normal leaflet strength and mobility	Leaflet restriction in systole (Carpentier IIIB)	Barlow`s syndrome with multisegment flail leaflets
Flail width < 15mm	Flail width > 15mm only with large ring width and the option for multiple Clips	
Flail gap <10mm		

Boekstegers et al. Clin Res Cardiol. 2013

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Boekstegers et al. Clin Res Cardiol. 2013

Etude multicentrique randomisée de non infériorité comparant dans une population à risque opératoire élevé MITRACLIP® vs chirurgie

Critères de jugement ?

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Stone, Vahanian et al.. European heart journal 2015;36:1851-77.
Stone, Vahanian et al.. European heart journal 2015;66: 308–21.

Etude multicentrique randomisée de non infériorité comparant dans une population à risque opératoire élevé MITRACLIP® vs chirurgie

- <u>Critère de jugement principal :</u>
  - Critère composite incluant la mortalité toutes causes, la ré-hospitalisation pour raison CV et la ré intervention sur la valve mitrale (à 12 months)
- <u>Critères de jugement secondaires :</u>
  - Critère composite de sécurité (MVARC)

- **We believe that the primary composite endpoint**, non-inferior in surgery and MitraClip® arm associated with MR is high; 1-year rate are about 20%.

- The clinically relevant non-inferiority margin is fixed to 13%, power equal to 80% and the alpha risk=2.5%.

- With this hypothesis, we need to randomize 300 patients to show the non-inferiority of MitraClip® to surgery

- The total required randomized sample size is 330 patients (165 MitraClip®, 165 surgery) to account for loss of follow-up (10%).

Etude multicentrique randomisée de non infériorité comparant dans une population à risque opératoire élevé MITRACLIP® vs chirurgie

Centre :

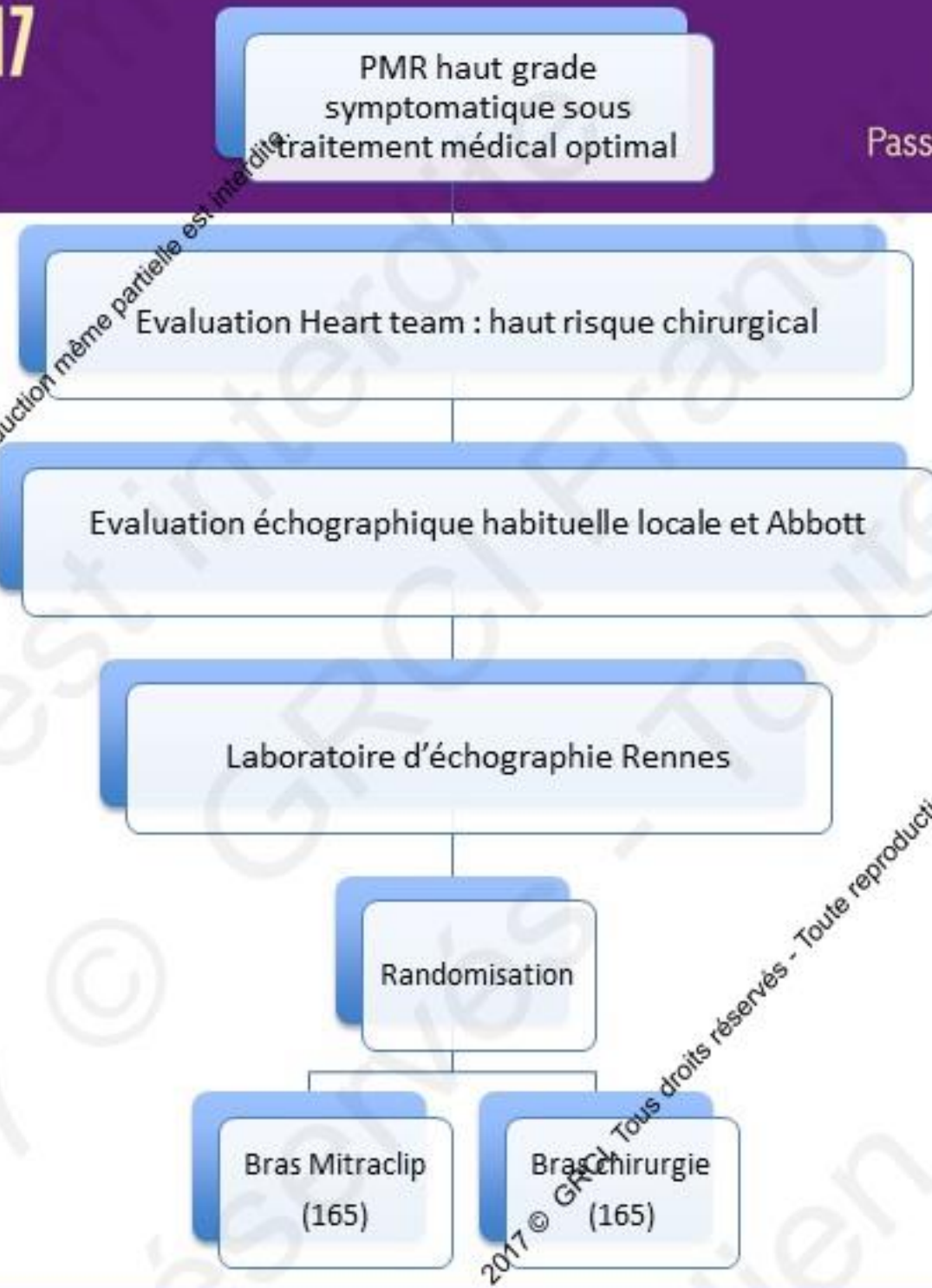
- KT : expérience > ou = 10 Mitraclips (dont deux NT)
- Chirurgie : > 50 mitrales opérées/an

n=330 patients

Bras MitraClip®

Bras chirurgie (plastie ou remplacement)

Durée totale de l'étude 63 month (enrollement sur 3 ans)



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6 AU 8 DÉCEMBRE 2017
Novotel Paris Tour Eiffel

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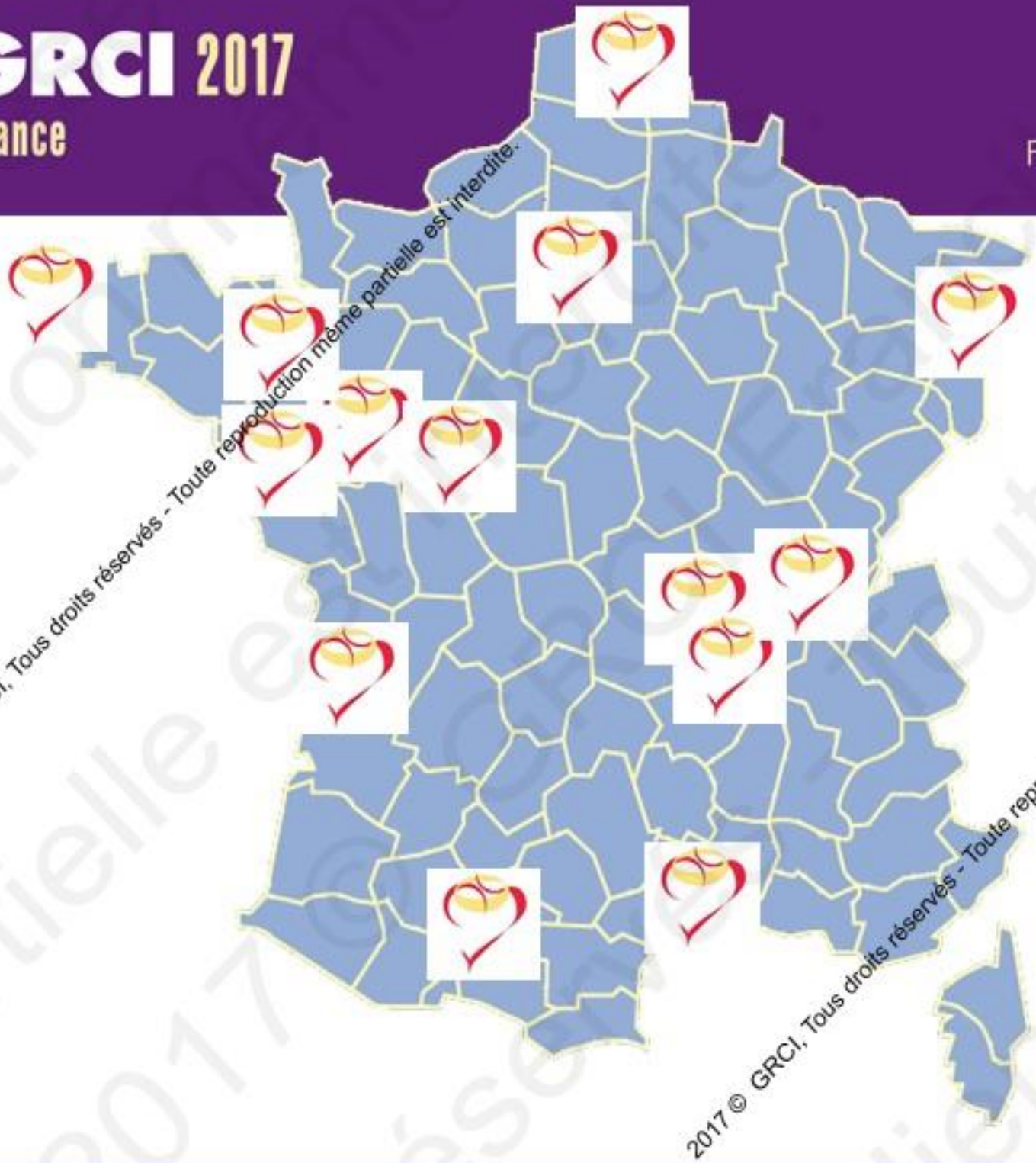

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MITRACLIP THERAPY CURRENT GLOBAL ADOPTION

Treating Centers	777
Patients (clinical and commercial)	Over 40,000
Implant Rate[2]	97%
Functional MR[3]	64%
Degenerative MR[2,3]	22%
Mixed	14%

1. First-time procedures only. Includes commercial patients, ACCESS I and ACCESS II patients
2. OUS Commercial Experience
3. Etiology not inclusive of U.S. cases as of 14/04/2014

Data As of November 30, 2016. Source: Data on file at Abbott Vascular

GLOBAL MITRACLIP EXPERIENCE

1. Includes clinical and commercial procedures as of 31/07/2016. Source: Data on file at Abbott Vascular

MitraClip in the treatment of FMR

Management of Valvular Heart Disease

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)

Authors/Task Force Members: Alec Vahanian (Chairperson) (France)*, Ottavio Alfieri (Chairperson)* (Italy), Felicita Andreotti (Italy), Manuel J. Antunes (Portugal), Gonzalo Barón-Esquivias (Spain), Helmut Baumgartner (Germany), Michael Andrew Borger (Germany), Thierry P. Carrel (Switzerland), Michele De Bonis (Italy), Arturo Evangelista (Spain), Volkmar Falk (Switzerland), Bernard Iung (France), Patrizio Lancellotti (Belgium), Luc Pierard (Belgium), Susanna Price (UK), Hans-Joachim Schäfers (Germany), Gerhard Schuler (Germany), Janina Stepinska (Poland), Karl Swedberg (Sweden), Johanna Takkenberg (The Netherlands), Ulrich Otto Von Oppell (UK), Stephan Windecker (Switzerland), Jose Luis Zamorano (Spain), Marian Zembala (Poland)

Indication for primary MR

"Percutaneous edge-to-edge procedure may be considered in patients with symptomatic severe primary MR who fulfill the echo criteria of eligibility, are judged inoperable or at high surgical risk by a 'heart team', and have a life expectancy greater than 1 year (recommendation class IIb, level of evidence C)." *page 21*

Indication for secondary MR

"The percutaneous mitral clip procedure may be considered in patients with symptomatic severe secondary MR despite optimal medical therapy (including CRT if indicated), who fulfill the echo criteria of eligibility, are judged inoperable or at high surgical risk by a team of cardiologists and cardiac surgeons, and who have a life expectancy greater than 1 year (recommendation class IIb, level of evidence C)." *page 25*

MitraClip in the treatment of FMR

Indication for secondary MR

(ESC Guidelines 2012)

"The percutaneous mitral clip procedure may be considered in patients with symptomatic severe secondary MR despite optimal medical therapy (including CRT if indicated), who fulfill the echo criteria of eligibility, are judged inoperable or at high surgical risk by a team of cardiologists and cardiac surgeons, and who have a life expectancy greater than 1 year (recommendation class IIb, level of evidence C)." *page 25*

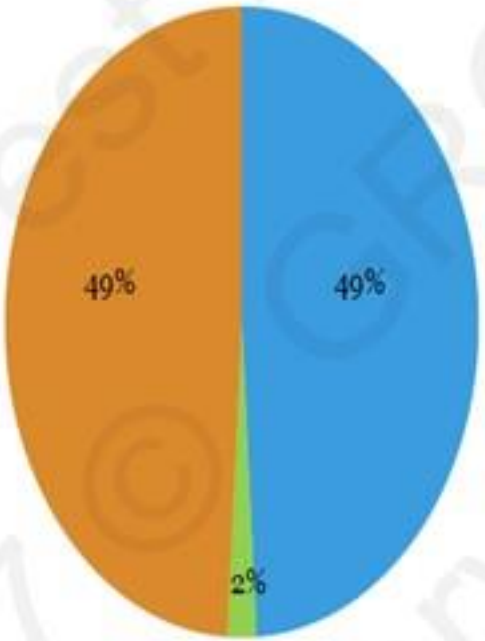
In patients with HF **with moderate-severe, secondary mitral** regurgitation who are **judged inoperable or at high surgical risk, percutaneous mitral valve intervention (percutaneous edge-to-edge repair) may be considered in order to improve symptoms and quality of life**, although no RCT evidence of improvement has been published, only registry studies

ESC Guidelines 2016

Quelle impact sur l'activité chirurgicale

Patients éligibles ou non à la chirurgie ?

Nearly 50% of MR patients are not considered appropriate for Mitral Valve Surgery



- Surgical Candidates
- Surgical Patients
- High-Risk Patients

Of surgical candidates, up to 50% of patients are not referred to surgery even if a surgical indication exists.

High-risk is defined as patients with LVEF <35% and/or age >75. Factors prohibiting surgery include impaired LVEF, high operative risk, multiple comorbidities and advanced age.

N= 1,740,000 (US Population)

UNIVERSITÄTSmedizin. MAINZ

Zentrum für Kardiologie

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

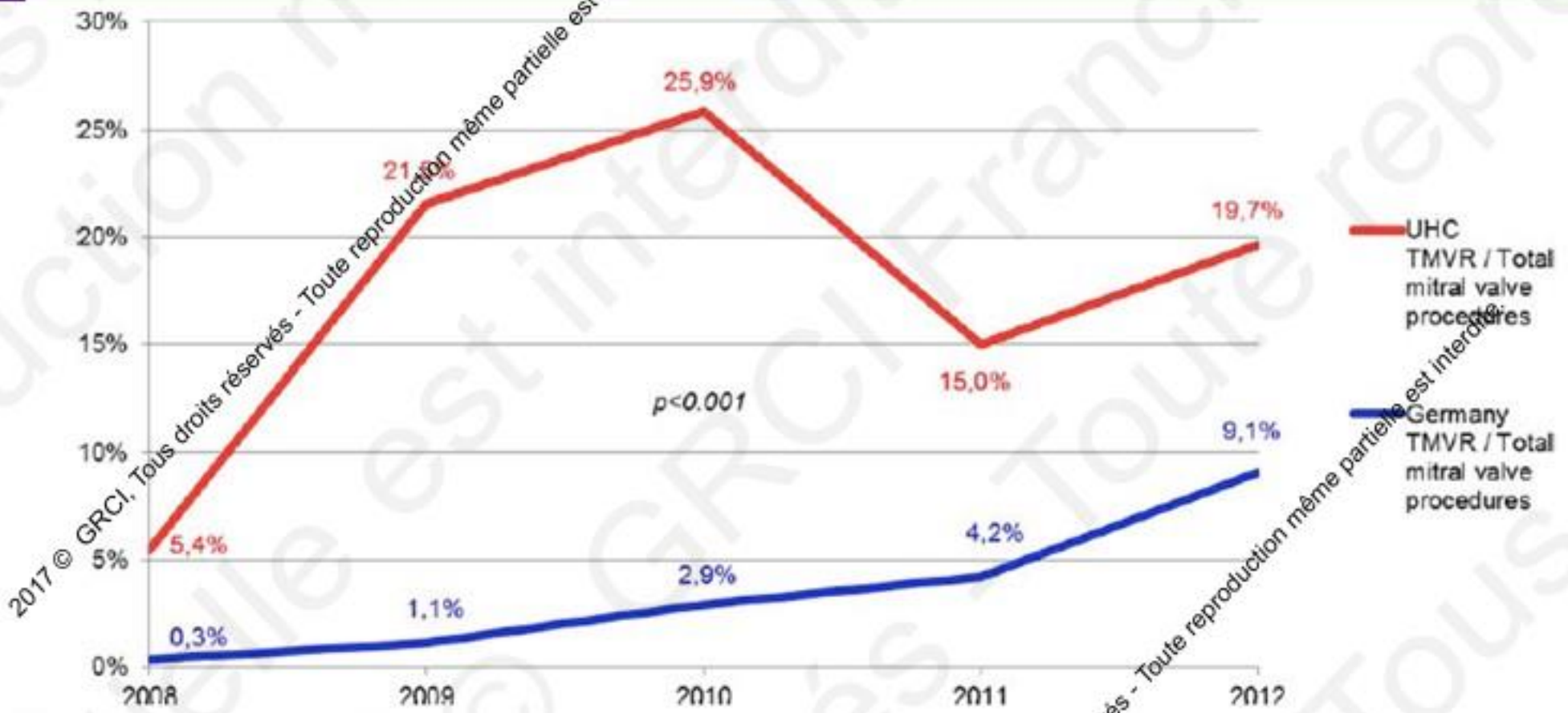
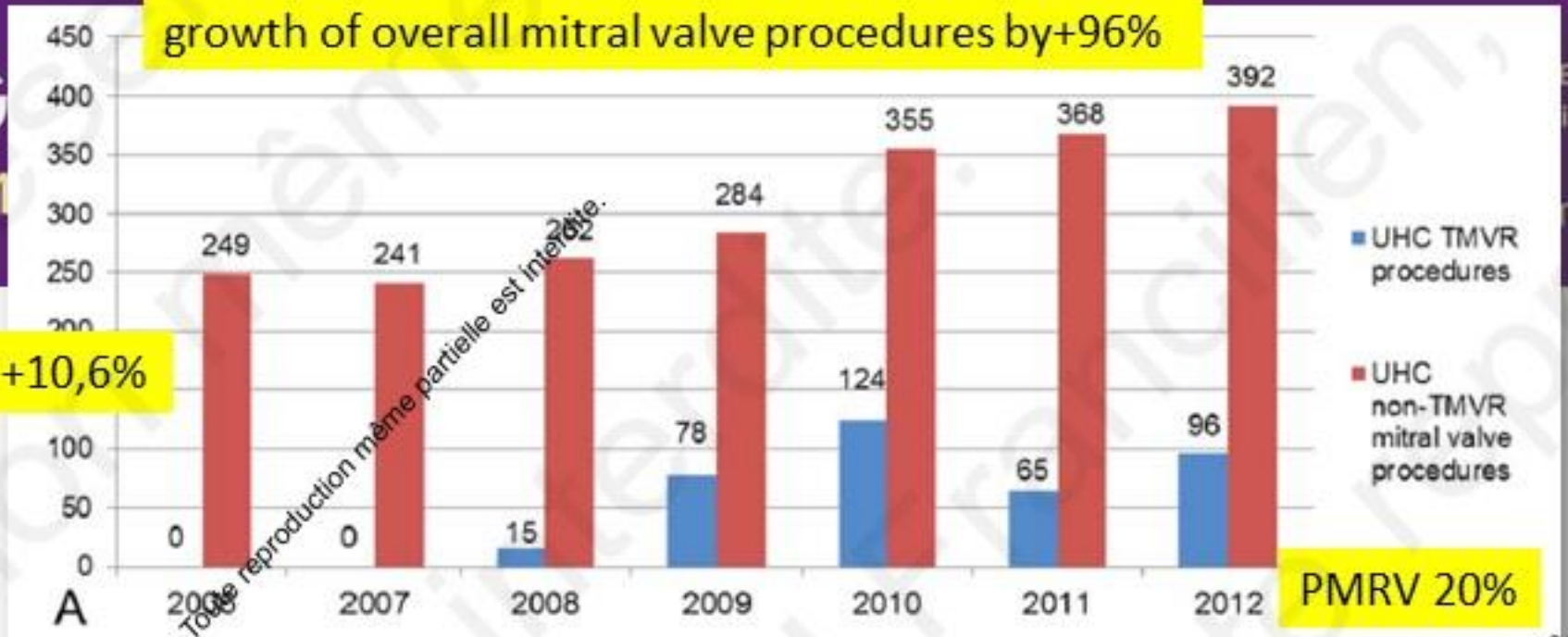


Fig. 2. Share of TMVR procedures of overall mitral valve procedures. *P* value relates to complete time frame 2008–2012. TMVR, transcatheter mitral valve repair.

Conradi et al., Catheterisation and Cardiovascular Interventions, 2015

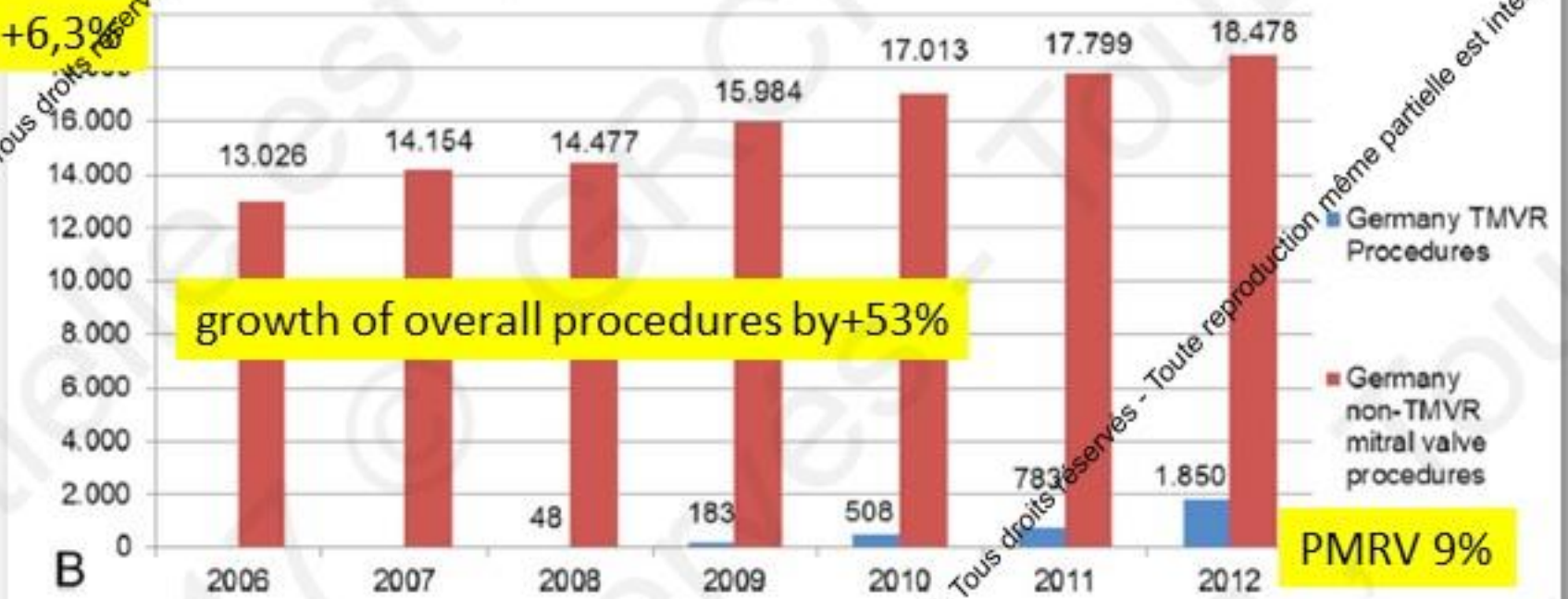
growth of overall mitral valve procedures by+96%

Surgery +10,6%



PMRV 20%

Surgery +6,3%



growth of overall procedures by+53%

PMRV 9%

Fig. 1. TMVR and non-TMVR procedure volumes at UHC Hamburg and in Germany 2006–2012. TMVR, transcatheter mitral valve repair.

Conradi et al., Catheterisation and Cardiovascular Interventions, 2015

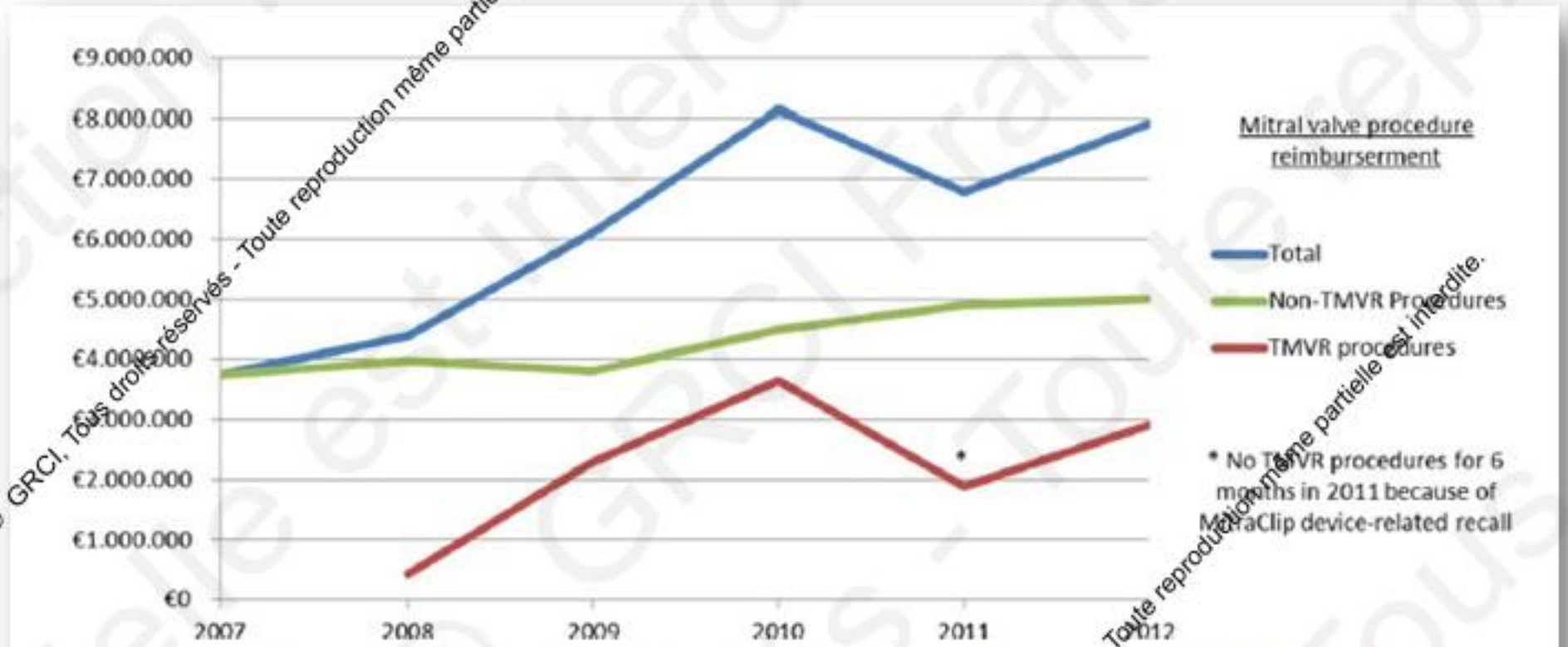


Fig. 4. Development of mitral valve procedure reimbursement revenues stratified by overall, surgical, and endovascular reimbursement 2007–2012. TMVR, transcatheter mitral valve repair.

Conradi et al., Catheterisation and Cardiovascular Interventions, 2015

MitraClip dans le Futur

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MitraClip NT 2ème Génération

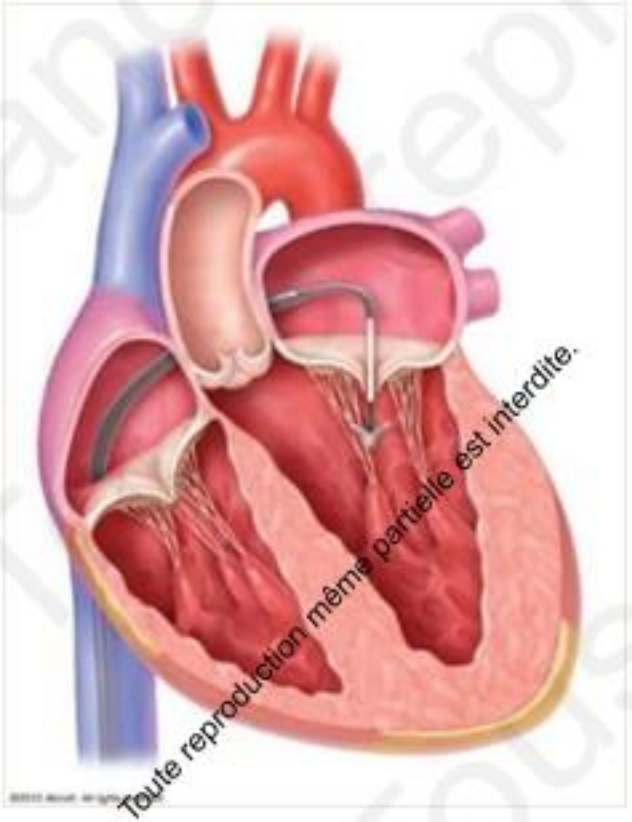
PRODUCT CHANGE	BENEFIT
New CDS and SGC Packaging	More robust Packaging
Delivery Catheter and Steerable Sleeve enhancements[1]	More responsive and consistent steering[1]
Gripper material change from Elgiloy to Nitinol[1]	Facilitates more efficient leaflet capture on the first attempt[1]
Radiopaque Ring Self-Centering Technology[1]	Easier clip retraction[1]

Note: Other than packaging, no further changes to SGC

References: 1. Tests performed by and data on file at Abbott Vascular.

MitraClip NTR 3ème Génération

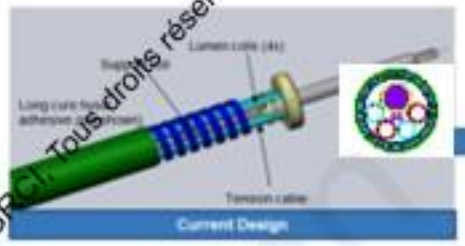
France → Fin 2018

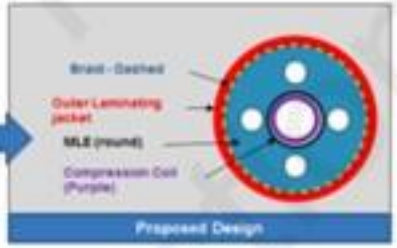


Delivery Catheter Shaft Design Improvement

Improve Usability and Predictability

- ✓ Minimize clip rotation and provide straighter advancement into the valve plane and left ventricle for a more predictable path
- ✓ Ability to keep the clip unlocked throughout the procedure





* Currently in development at Abbott Vascular. Not available for sale.

MitraClip XTR

Elargissement de la Gamme

Longer Clip Arms

France → Fin 2018

Design Goals: **Grasping Enhancements**

- ✓ Increased ease of grasping in challenging cases
- ✓ Increased ease of grasping in treating TR
- ✓ Potentially greater MR and TR reduction

MitraClip Next Gen
4ème Génération

France → 2020

Improve Usability

- ✓ Simplify procedure
  - Provide intuitive controls
  - Facilitate single operator system
  - Reduce number of procedural steps
- ✓ Reliable delivery catheter movement
- ✓ Controlled stabilizer movements

Platform Technology

- ✓ Technology can be used to deliver future therapies in adjacent and new spaces

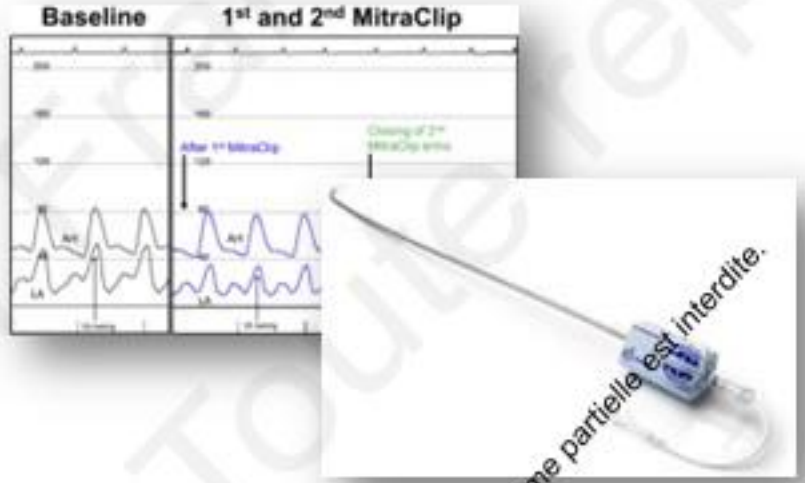
Momentum

* Currently in development at Abbott Vascular. Not available for sale.

Fonctionnalités Futures?

- LA Pressure Measurement
- Independent Arm Closing
- Leaflet Grasping Indicator

LA Pressure Measurement*



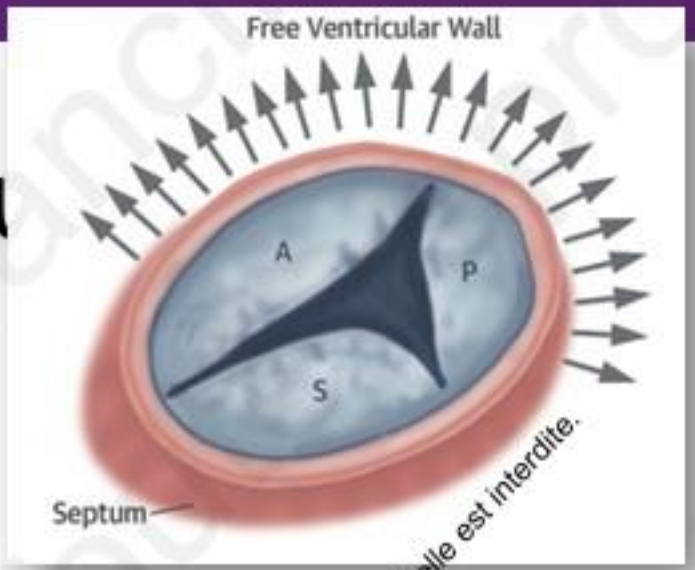
Design Goals: **Improved Procedural Outcomes**

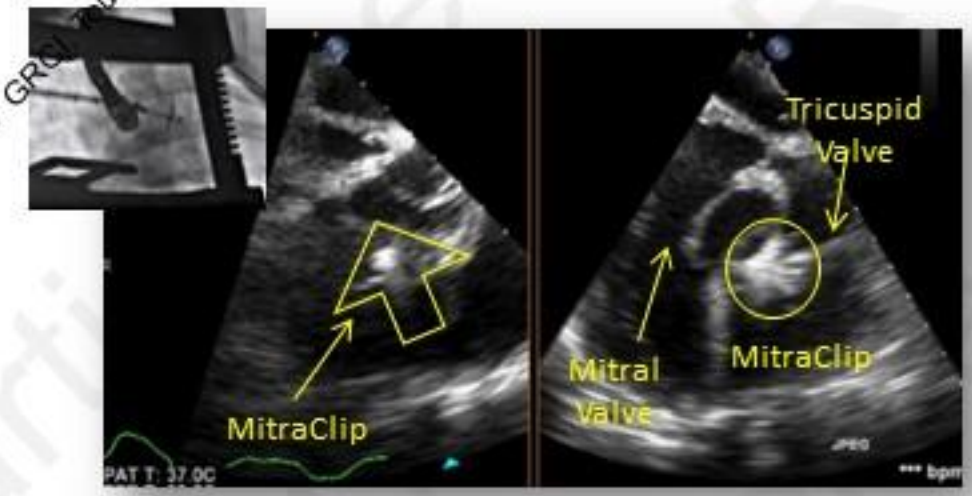
- ✓ Reduce reliance on color Doppler as an effectiveness measure
- ✓ Potentially greater MR reduction and QoL improvements due to continuous LA pressure measurement capability in the SGC

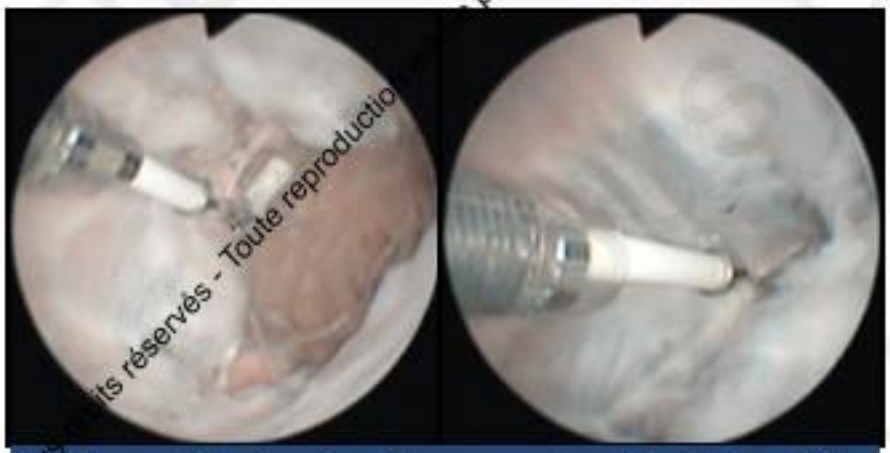
*Currently in development at Abbott Vascular. Not available for sale.

Développement d'un système de réparation Bord à Bord pour la valve Tricuspide

- ✓ Utilisation de la technique éprouvée de MitraClip
- ✓ Des résultats cliniques préliminaires favorables permettent d'envisager la faisabilité d'un traitement Bord à Bord pour la régurgitation Tricuspide **







Tricuspid edge to edge repair with MitraClip

* Currently in development at Abbott Vascular. Not available for sale.

** Testing performed by and data on file at Abbott Structural Heart

Conclusions

- L'Europe est leader
- La France rattrape son retard
- La France mène des études

- PMR :
  - CI à la chirurgie : remboursement
  - Risque élevé non CI : MitraHR

- SMR : attendre MitraFR

  - En attendant, sur un budget propre :
    - Patients dans les recommandations de l'ESC

  - Avenir ? Tout ou rien ?

GRCI 2017 France

6 AU 8 DÉCEMBRE 2017
Novotel Paris Tour Eiffel

Passion Communication Education

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Mitra HR

- ***Mortality :*** litterature :
- mortality for MV replacement in a global population was 3.8% versus 1.4% for repair (65).
- Everest II randomized study (mean age of 62 years ; 27% SMR, 33% PMR ; MV replacement 14%), one year global mortality rate after mitral valve surgery was 5% (3).
- In octogenarians, postoperative 30-day mortality associated with MVR were calculated to be 13%
- In another study with octogenarians patients (Logistic EuroSCORE * 5.77 [3.5—63]), 1-year survival after mitral replacement was 81.3% (36).
- we estimated the one year mortality rate after surgery for PMR to be close to 8-10%.

- ***Reintervention rate for severe MR***:

- At one year, in the surgical group of the Everest II study, the rate of recurence of severe MR is 20.2%, and the rate of reintervention is about 2.2% (3).

- Hence, in our high surgical risk population with only PMR, we estimate the theorical risk of reintervention for severe MR to be close to 2%.

- ***Unplanned rehospitalization for cardiavasular reasons:*** Datas are poorer.
- The national PMSI give a rehospitalization rate of 25% after surgery for all grades primary MR (67).
- In the study of Trochu et al., when considering reasons for hospital stay, 3.2% were :
  - directly related to valvular surgery, 4.7%
  - to coronary artery disease (angioplasty, stent or ACS),
  - 4.6% to endocarditis,
  - 30.2% to arrhythmias and electrophysio-logical disorders,
  - 18.8% to heart failure and

  - We estimated the one year risk of rehospitalization for CV reasons in our high surgical risk population to be close to 8-10%.