REDUCTION PERCUTANEE DE L'INSUFFISANCE MITRALE FONCTIONNELLE

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APPAC
ACTUALISATIONS ET PERSPECTIVES EN PATHOLOGIE CARDIOVASCULAIRE
15e édition

POLE SANTE
REPUBLIQUE
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Nous n’avons pas de conflit d’intérêt

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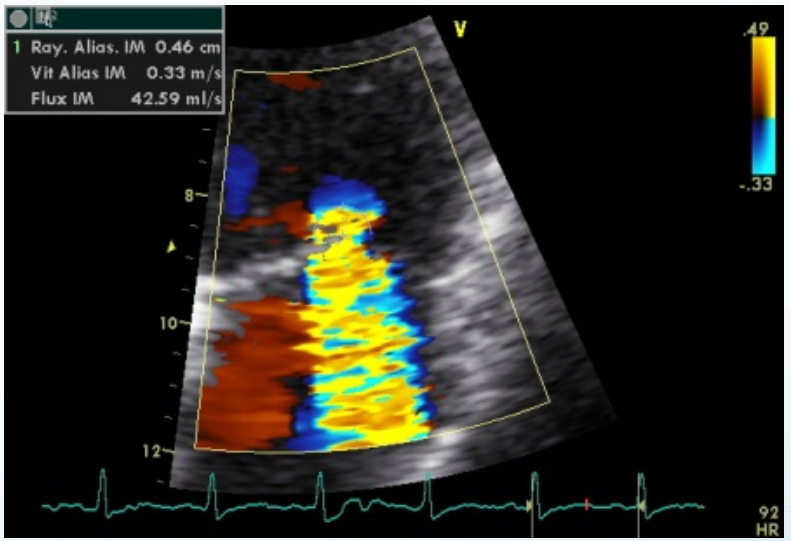
Prévalence de l' IM fonctionnelle

- IM fonctionnelle et IC systolique

grade II ou + 60% des patients

grade III ou + 40% des patients

après un IdM 30% des patients



…malgré le traitement pharmacologique optimal

Di Salvo TG, J Am Coll Cardiol 2010, Rossi A, Heart 2011

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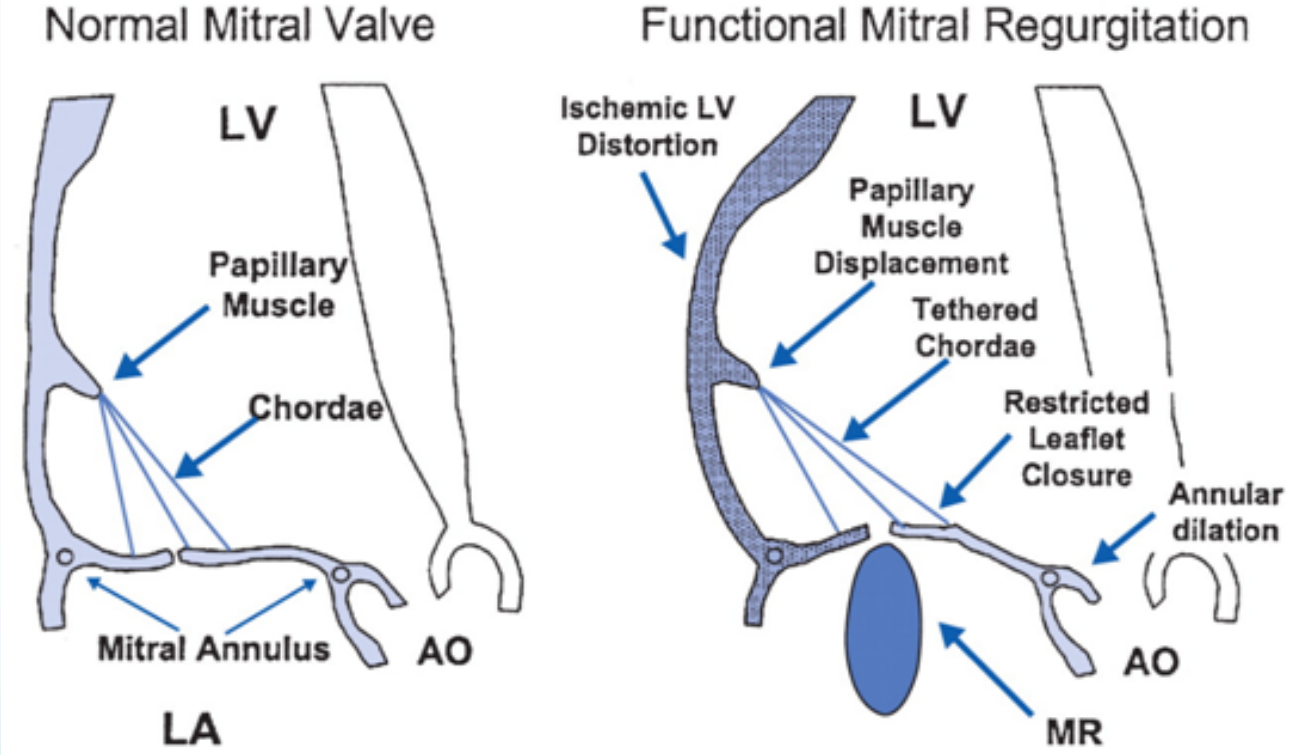
Mécanisme de l'IM fonctionnelle



Processus auto-aggravant

Remodelage ventriculaire

Déplacement des muscles papillaires

Dilatation de l'anneau

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Mécanisme de l'IM fonctionnelle

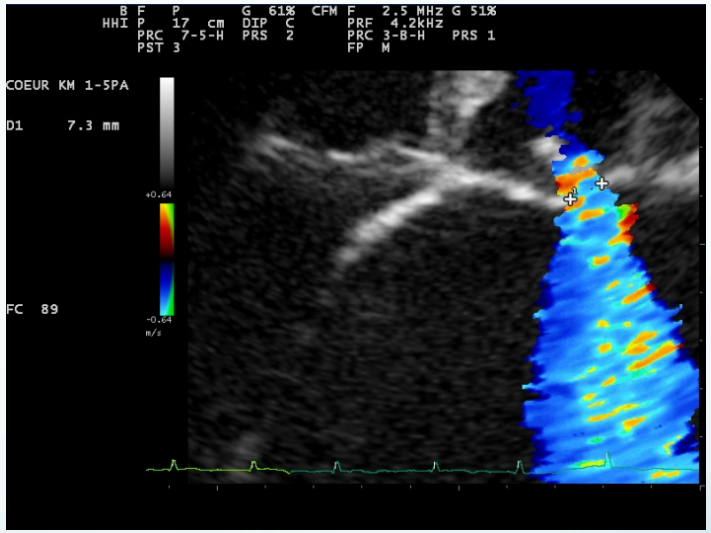
- Caractère dynamique
- **30% - 70% aggravation à l'effort**
- Corrélation avec l'augmentation de la mortalité

Sous – estimation de l'impact de l'IM fonctionnelle

Bigi R. Cardiovascular Ultrasound 2009, Izumo M. Europ J Echocardiography 2011, Lancellotti Circulation 2003

Impact sur la mortalité et la morbidité

- **VC > 0.4 cm -> HR x 2**
- VC > 0.7 cm -> survie à 4 ans 55%
- VC 0.3-0.69 cm -> survie à 4 ans 57%
- VC >0.2 cm -> HR X 6.72 (cardiopathie ischémique)



Rossi A, Heart, 2011, Agricola E,
Eur J Heart Failure 2009, Szymanski C, Am J Cardiol 2011

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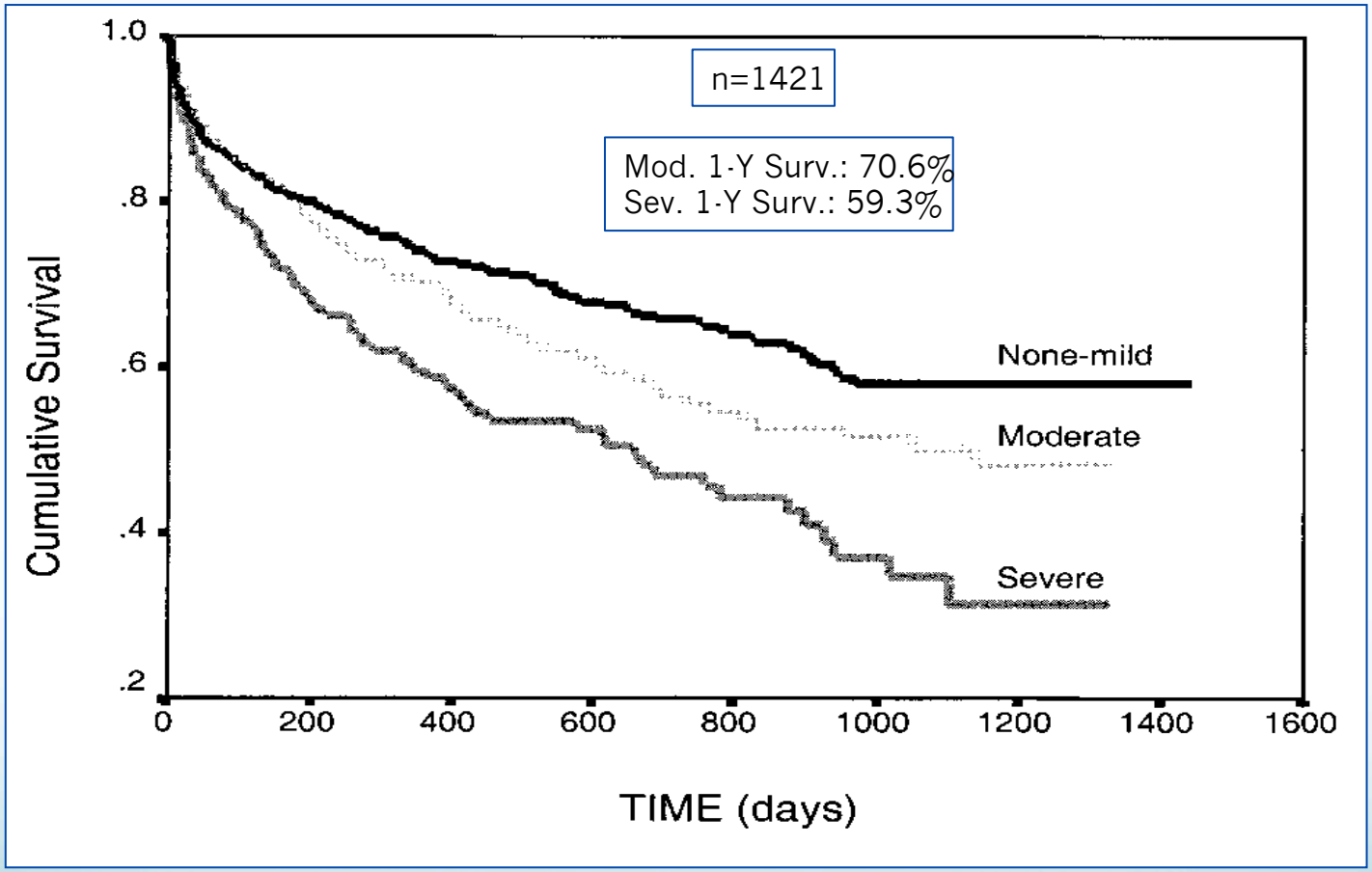
Effect of MR Grade on Cumulative Survival Rate for Patients with LVSD



Koelling TM, American Heart Journal, 2002:144;524-9.

Trichon BH, Am J Cardiol 2003;91:538-543.

Réduction de l'IM fonctionnelle
=
Amélioration du pronostic

- **Réduction ≥ 1 grade => amélioration de la survie à 36 mois**

  (HR 0.35, CI 0.13-0.94, p=0.04)

- **Réduction ≥ 11% du VR => remodelage inverse**

  (sensibilité 90%, spécificité 80%, AUC 0.85)

- **Réduction ≥ 1 grade => remodelage inverse dans 71 % des cas**

  (6% de risque d'aggravation d'IC vs 57%)

Liang Y-J. Eur Heart J 2010, van Bommel
RJ Circulation 2011, Takeda K Circulation 2010

Réduction de l’ IM fonctionnelle

- Traitement pharmacologique optimal
- Chirurgie cardiaque
- Resynchronisation
- Valvuloplastie percutanée

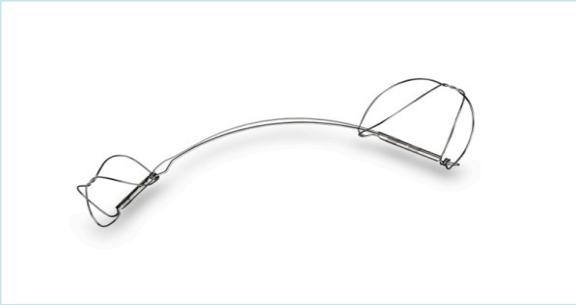
VALVULOPLASTIE MITRALE PERCUTANÉE

- Directe

MITRA-CLIP

- Indirecte

CARILLON



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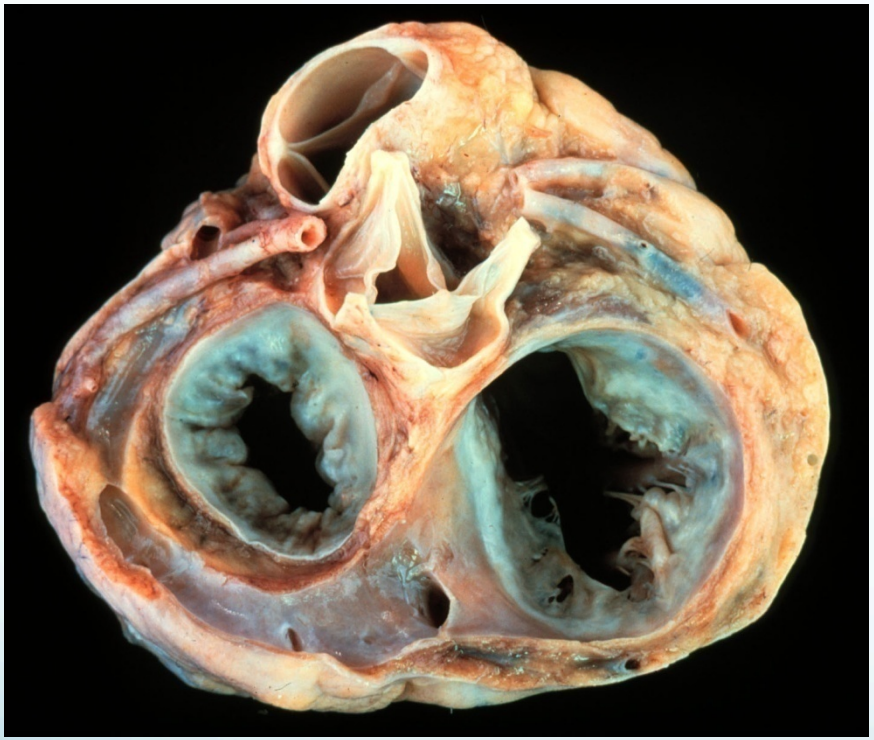
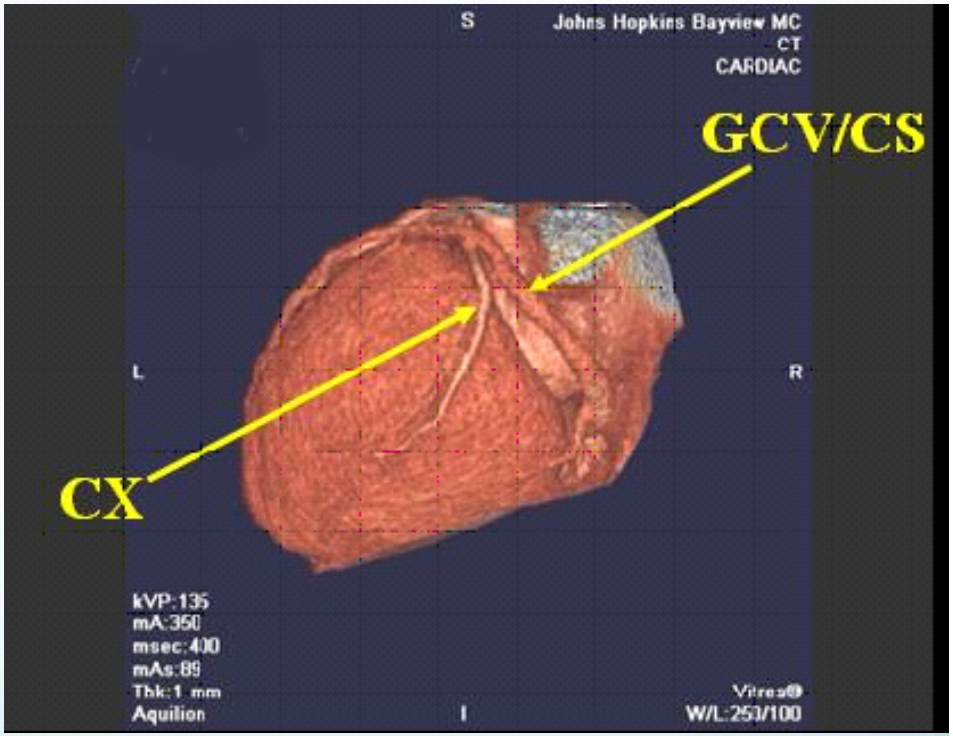
Pertinent Anatomical Relationships for Percutaneous Annuloplasty Device



CS Anatomy Conducive to Percutaneous Rx



Anatomical Challenges:

1. CS / LCx relationship
2. Superior CS position

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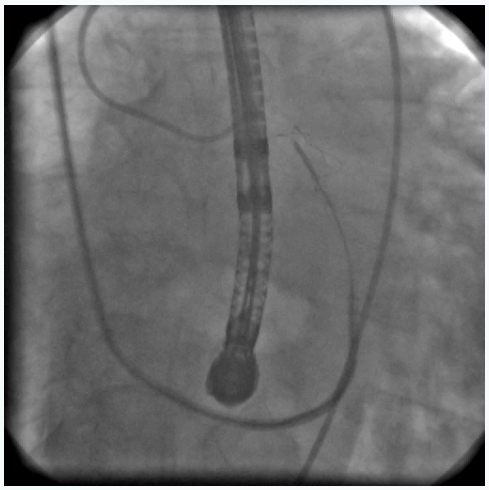
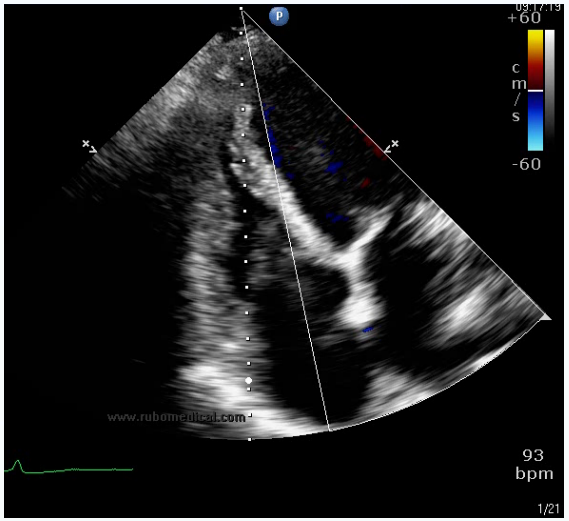
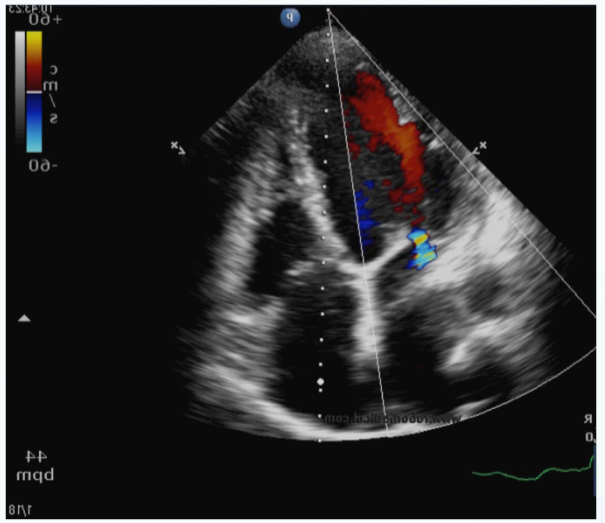
Animated Procedure Overview

Delivering the implant

Echo and fluoro to guide tissue plication







- Goal:
  - Optimize efficacy and implant success
  - Minimize impact on coronary arteries
  - Minimize frequency of recapture (with associated contrast use / venous trauma)
- Technique:
  - Pull the proximal anchor toward the CS target location guided by echo and then check position with Fluoro. Simultaneous use is not recommended.
  - Confirm adequate coronary artery flow and optimal FMR reduction prior to deploying proximal anchor

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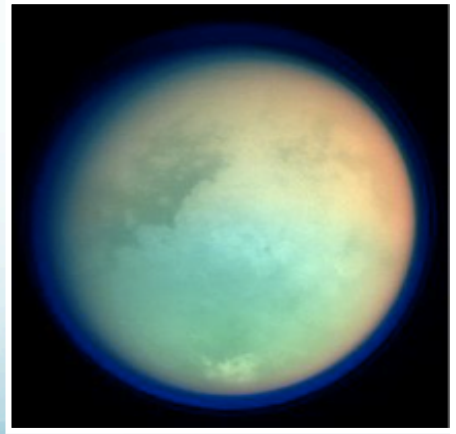
Completed EU Multi-Centre Studies with the Carillon device

- **AMADEUS – published in *Circulation*[1]**
  - Feasibility study of Carillon system.
  - 30 patients implanted across 6 centers with 6-month f/u.
  - Feasibility established with improvement in MR, functional status and quality of life.

- **TITAN – published in *Eur J. Heart Failure*[2]**
  - Safety and efficacy trial w/ non-blinded, non-randomized comparison group.
  - 36 patients implanted across 7 centers with 2-year f/u.



1 Schofer J, Siminiak T, Haude M, et.al., *Circulation*. 2009;120:326-33.
2 Siminiak T, Wu JC, Haude M, Hoppe UC, Sadowski J, et.al, *EuJHF* 2012: 14(8): 931-8.

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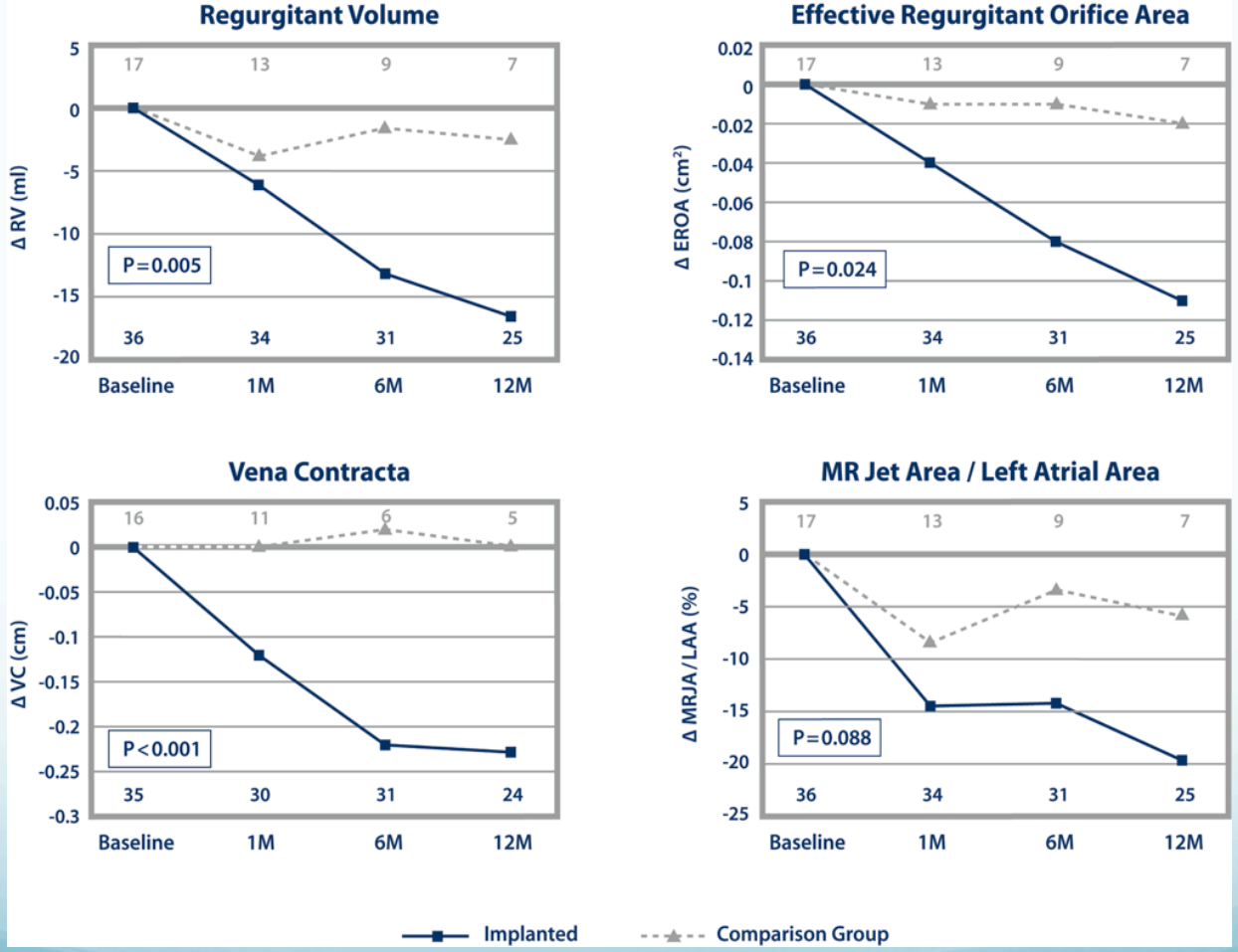
EFFICACITÉ DU SYSTÈME CARILLON



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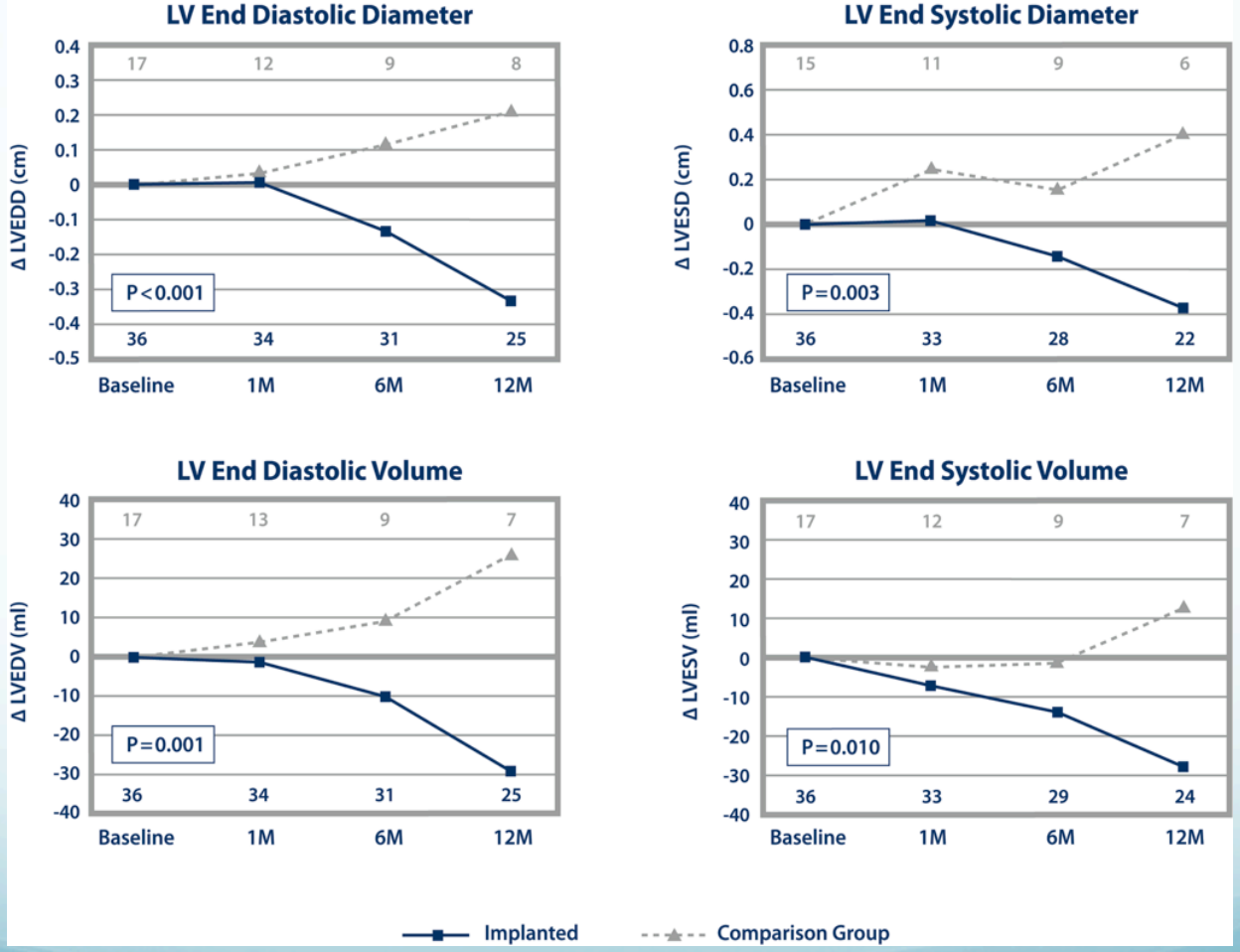
EFFICACITÉ DU SYSTÈME CARILLON



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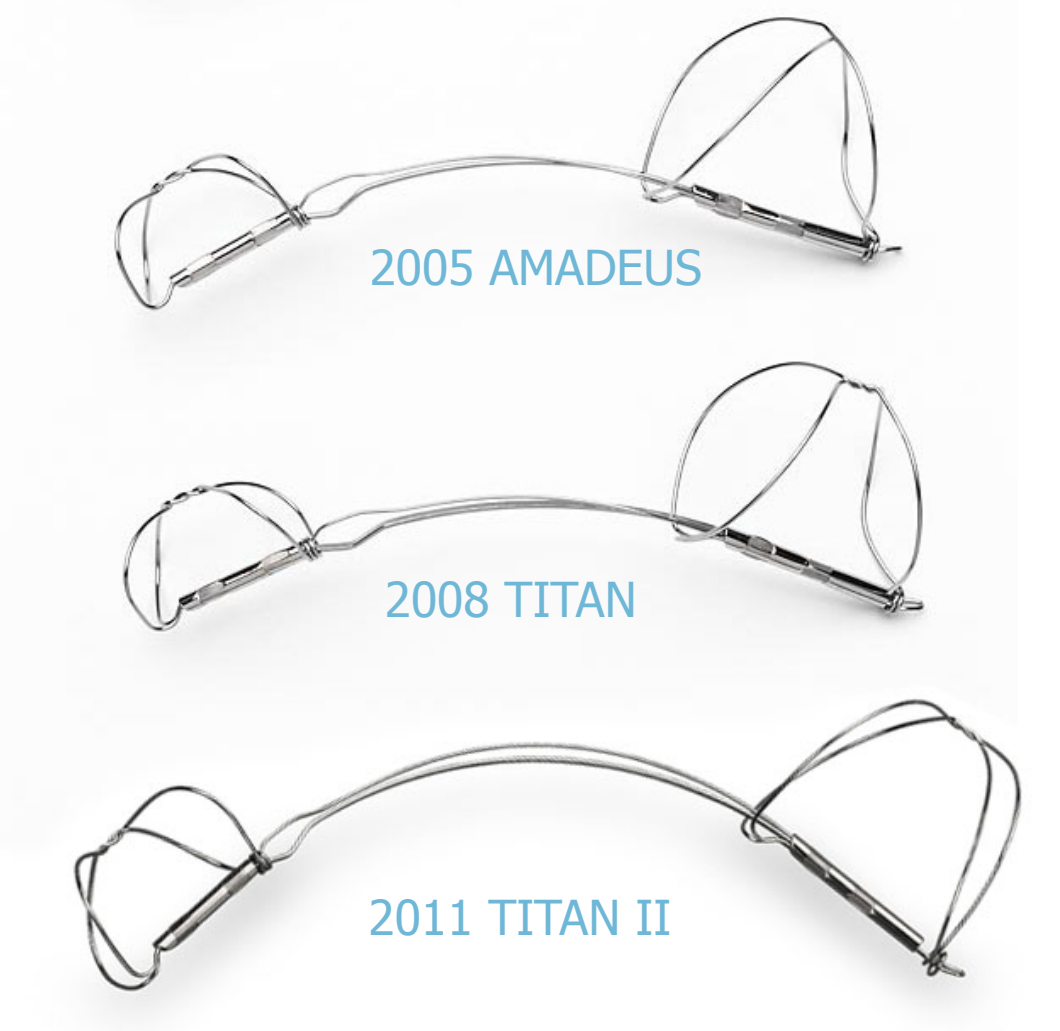
Carillon Device Evolution



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ETUDE TITAN II

- Prospective, multi-center (5), single-arm.
- Inclusions / exclusions similar to TITAN.
- 30 patients implanted.
- One-year follow up period.
- Endpoints similar to TITAN.
  - Safety; Hemodynamics; Functional Status; QoL.

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TITAN II Study Design

- Inclusion criteria

  Dilated Ischemic or Non-ischemic Cardiomyopathy

  - FMR moderate to severe (2 + to 4 +)
  - EF < 40%
  - NYHA Class II – IV
  - 6 minute walk distance between 150 to 450 meters
  - Stable on heart failure meds

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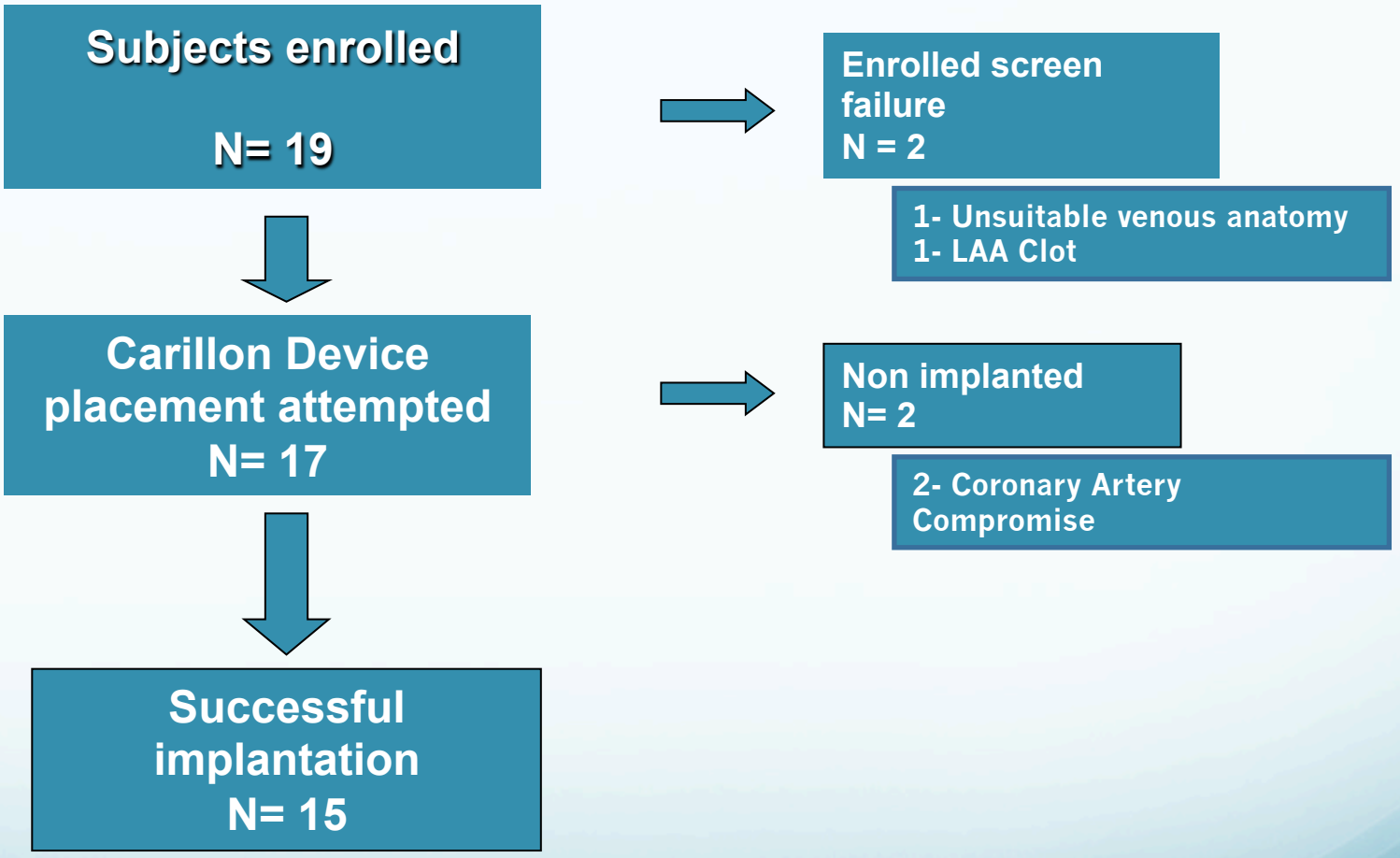
PSR Clermont-FD Implant Rate



Implant Rate = 88%

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Implanted Patients - Baseline Demographics

Age (years)	71.9 (58-79)
Gender	M = 60%
Ischemic	7 (47%)
Non-Ischemic	8 (53%)
NYHA Class	
III	13 (92%)
IV	2 (8%)
MR Grade	
2+	9 (60%)
3+	6 (40%)
History of CABG/PCA	7 (47%)
History of MI	7 (47%)
Atrial Fibrillation	6 (40%)

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Procedural Data (N=17)

Procedure length (min)	**69.0 ±32.5**
Contrast dye (ml)	**170.1 ±66.8**
Cx artery crossing	**10/17 (59%)**
Cx artery compromise	**2/17 (12%)**
Device Recaptured	**4/17 (24%)**

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Procedural Safety Issues

MI	0%
Cardiac perforation	0%
Device embolization	0%
Surgery or PCI related to the procedure	0%
MAE Rate	0%
Transient AF	2 (13%)
Vein dissection	3 (20%)

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1 Month Follow-up

Survival Rate

100%

Device Integrity

100%

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Functional Data

	Baseline	1 Month	% Change
NYHA class N=15	3.13 ±0.35	2.13 ±0.52	-33.3%
6MWD (m) N=14	298.6 ±92	375.7±115	+ 25.8%

All patients improved at least 1 NYHA class

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Echo Data – FMR parameters

	Baseline	1 Month	% Change
MR Grade N = 6	2.33 ±0.52	1.66 ±1.03	**- 30.6%**
VC (cm) N = 4	0.67 ±0.19	0.49 ±0.27	**- 23.8%**
RV (ml) N = 4	22.6 ±9.7	11.0 ±10.8	**- 58.0%**
EROA (cm^2) N = 4	0.17 ±0.09	0.08 ±0.08	**- 61.2%**
MRJA/LAA (%) N = 6	32.9 ±8.1%	22.3 ±16.7	**- 36.2%**

Corelab analysed data

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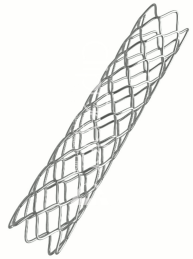
Conclusions 1

- L'IM fonctionnelle:
  - est un facteur aggravant le pronostic de l'Insuffisance cardiaque
  - est sous estimée par l'évaluation échographique de repos.
  - n'est pas une fatalité mais peut être réduite par différentes méthodes dont la valvuloplastie percutanée par le dispositif CARILLON®

Conclusions 2

- Le dispositif CARILLON ®
  - Donne des résultats encourageants sur la faisabilité et la sécurité
  - Améliore le statut fonctionnel de tous les patients implantés.
- Les résultats de TITAN II
  - Doivent confirmer le maintient de la réduction de l'IM et l'amélioration fonctionnelle à un an
  - Doivent être confrontés au traitement pharmacologique par une étude comparative



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EFFICACITÉ DU SYSTÈME CARILLON

European Journal of Heart Failure
doi:10.1093/eurjhf/hfs076

Treatment of functional mitral regurgitation by percutaneous annuloplasty: results of the TITAN Trial

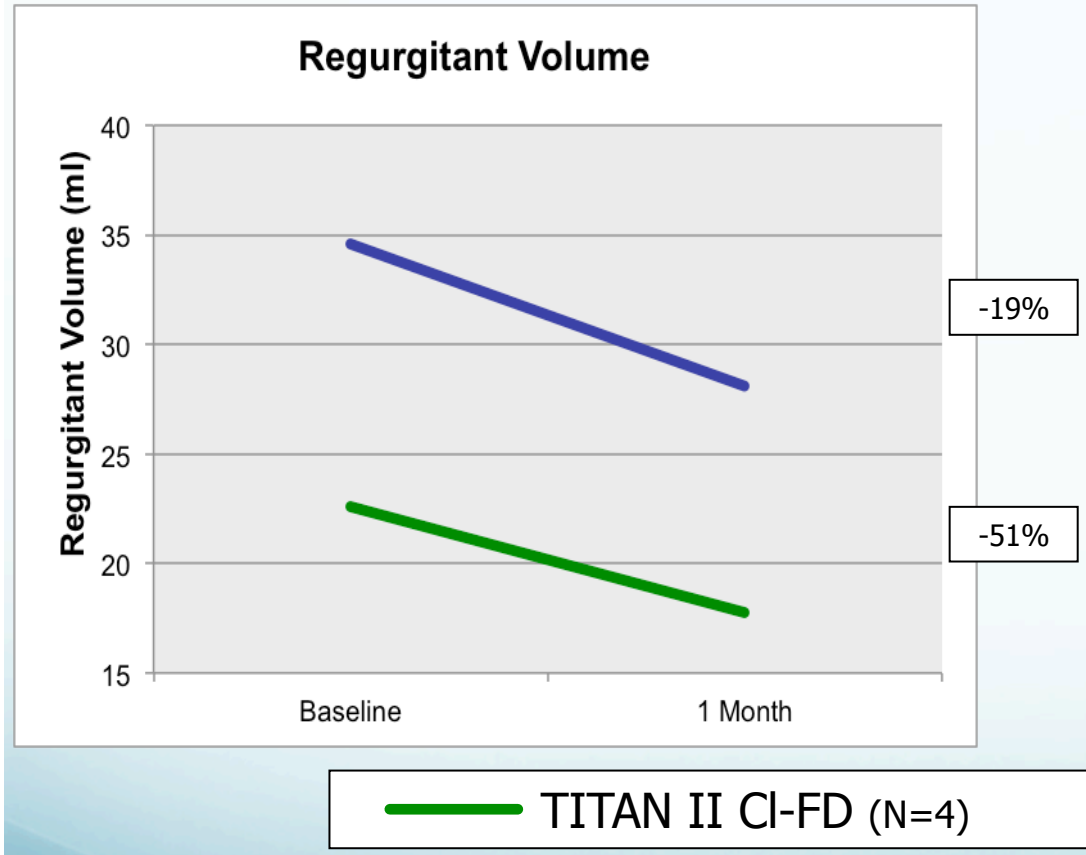
Tomasz Siminiak[1], Justina C. Wu[2], Michael Haude[3], Uta C. Hoppe[4], Jerzy Sadowski[5], Janusz Lipiecki[6], Jean Fajadet[7], Amil M. Shah[2], Ted Feldman[8], David M. Kaye[9], Steven L. Goldberg[10†], Wayne C. Levy[10], Scott D. Solomon[2], and David G. Reuter[11†*]

[1]Department of Cardiology, Poznan University, Poznan, Poland; [2]Department of Cardiovascular Medicine, Brigham and Women's Hospital, Boston, MA, USA; [3]Medical Clinic I, Städtische Kliniken Neuss, Neuss, Germany; [4]Department of Cardiology, Paracelsus Medical University, Salzburg, Austria; [5]Department of Cardiac Surgery, John Paul II Hospital, Krakow, Poland; [6]Department of Cardiology, University Hospital, Clermont-Ferrand, France; [7]Department of Cardiology, La Clinique Pasteur, Toulouse, France; [8]Cardiology Division, Northshore University Health System, Evanston, IL, USA; [9]Division of Heart Failure Research, Alfred Hospital, Melbourne, Australia; [10]Department of Cardiology, University of Washington, Seattle, WA, USA; and [11]Division of Pediatric Emergency Medicine, Seattle Children's Hospital, Seattle, WA, USA

Received 26 April 2012; accepted 27 April 2012

TITAN vs TITAN II
MR Improvement

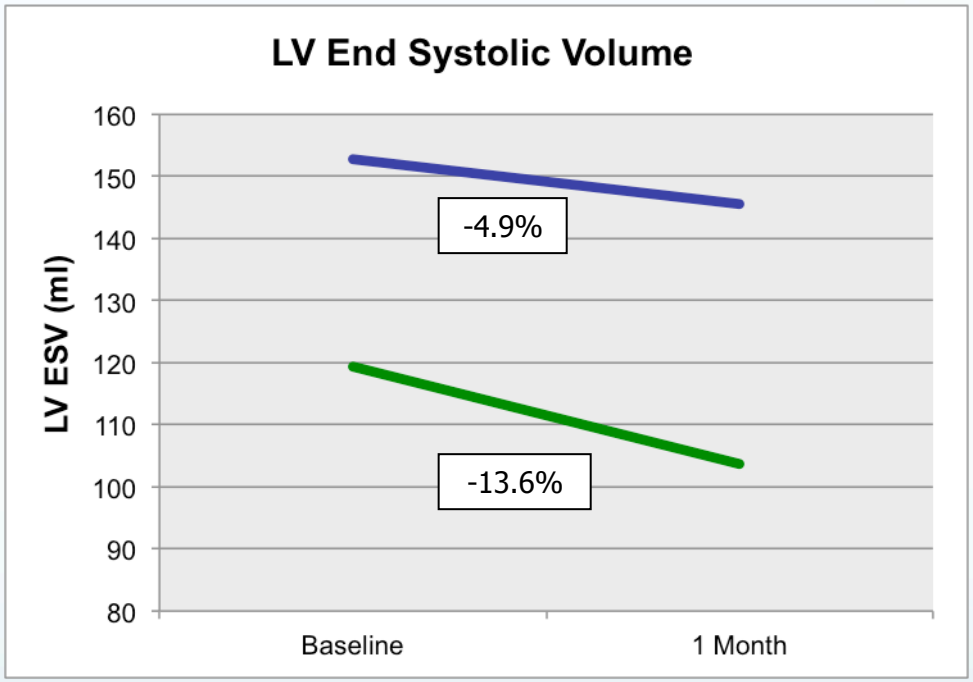
Trend toward better improvements in reducing MR



Corelab analysed data

TITAN vs TITAN II
Reverse Remodeling

Trend toward better improvements in Reverse Remodeling



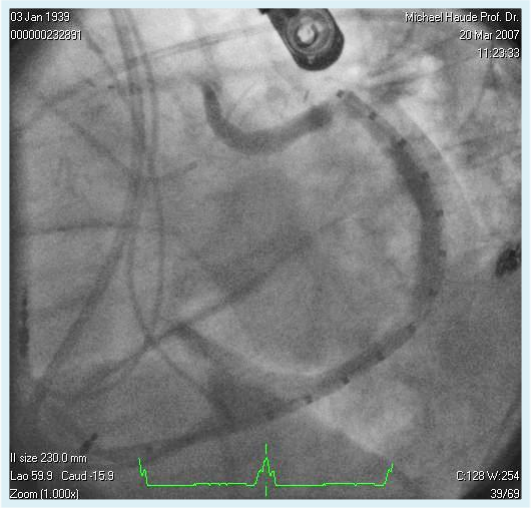
Corelab analysed data

Hemodynamic Data – LV assessment

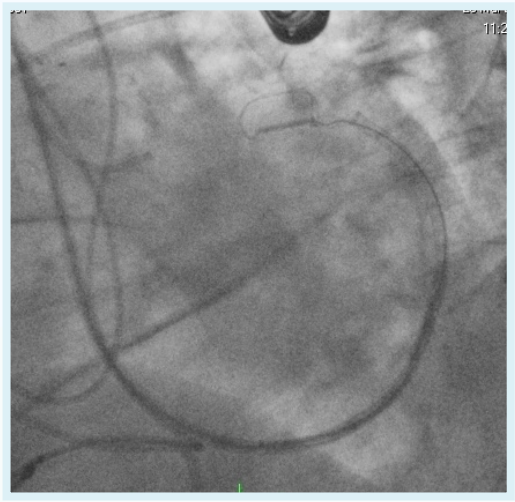
	Baseline	1 Month	% Change
LVEDV (ml) N = 6	147.3 ±37.0	137.8 ±35.5	**-5.1**
LVESV (ml) N = 5	119.3 ±39.0	103.1 ±37.9	**-12.5**
LVEF (%) N = 5	27.2 ±10.0	31.9 ±8.3	**22.1**

Corelab analysed data

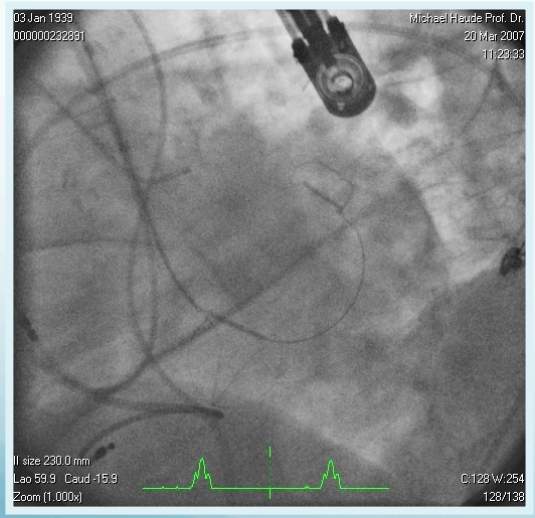
Procedure Overview and Highlights



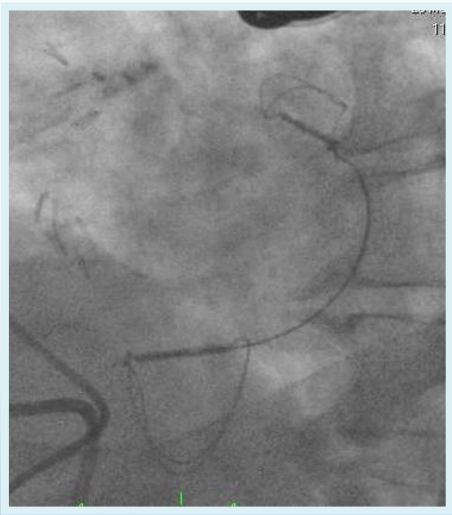
Perform Venogram



Deploy Distal Anchor



Apply Tension to Plicate Tissue



Release Device

CARILLON® Mitral Contour System®

Therapy Highlights

- **Coronary Sinus Position**
  - Straightforward Access
- **Adjustable**
  - Accomodates Variable Anatomy
- **Recapturable**
  - Real-Time MR Assessment
  - Real-Time Coronary Assessment

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