Percutaneous Mitral &Tricuspid Repair

State-of-the Art and Future directions

Ted Feldman, M.D., MSCAI FACC FESC

Evanston Hospital

CardioVascular Summit-TCTAP 2017

April 25th-27th 2017

Seoul

NorthShore University HealthSystem
Evanston Hospital

Ted Feldman MD, *MSCAI FACC FESC*

Disclosure Information

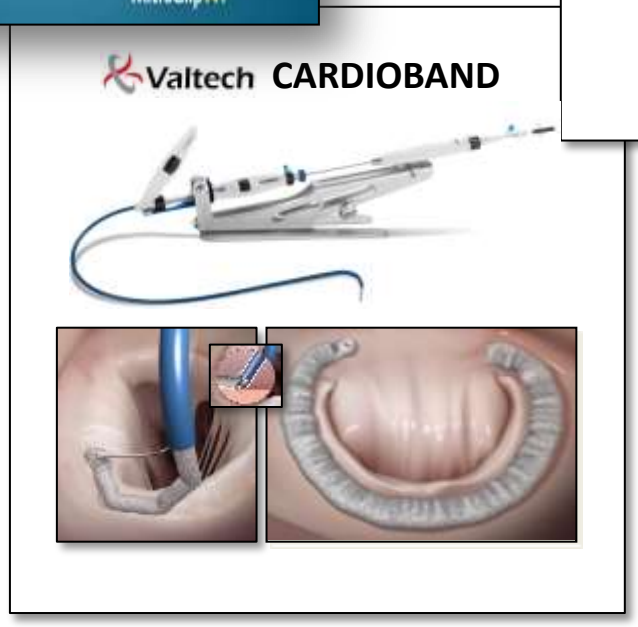
The following relationships exist:

Grant support: Abbott, BSC, Cardiokinetics, Corvia, Edwards, WL Gore
Consultant: Abbott, BSC, Edwards, WL Gore
Stock Options: Mitralign

Off label use of products and investigational devices will be discussed in this presentation

Percutaneous Mitral Repair

Approved or In Commercial Use



Surgical & Interventional Therapy for MR

	Degenerative	**Functional**
Low Surgical Risk	Surgical Mitral Repair	
High Surgical Risk	Commercial MitraClip	International Practice- **COAPT** **Mitra-Fr**

Clinical Outcomes Assessment of the MitraClip Percutaneous Therapy for High Surgical Risk

COAPT TRIAL

>610 patients enrolled at 100 US sites

Significant FMR ≥3+ core lab; EF<50%; CHF hospitalization or BNP>300

High risk for mitral valve surgery- Local Heart Team

Specific valve anatomic criteria

Randomize 1:1

MitraClip

Control group Standard of care

Safety: Composite death, stroke, worsening renal function, LVAD implant, heart transplant at 12 months

Effectiveness: Recurrent heart failure hospitalizations

1st COAPT patient randomized on Dec 27, 2012

NorthShore University HealthSystem
Evanston Hospital

Multicentre Study of Percutaneous Mitral Valve Repair MitraClip Device in Patients With Severe Secondary MR (MITRA-FR)

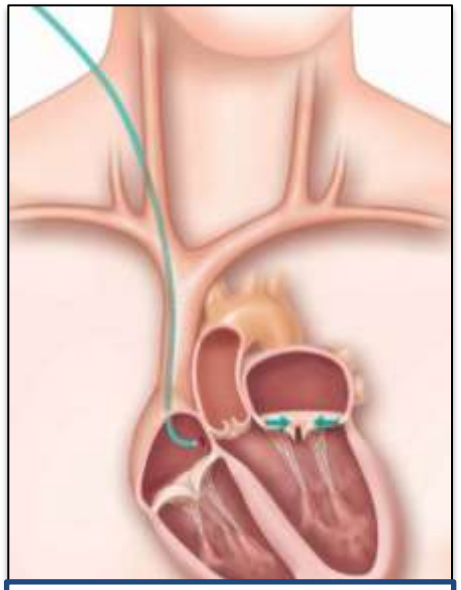
- **MitraClip vs optimal therapy alone**
- Estimated Enrollment: 288 at 22 sites- >290 enrolled as of Jan 2017
- Primary Outcome Measures: All-cause mortality and unplanned hospitalizations for heart failure 1 year
- Inclusion Criteria
  - Age > 18 years old
  - Severe secondary mitral regurgitation confirmed by the Echocardiography Core Laboratory Characterized by a regurgitation volume > 30 mL/beat or a regurgitant orifice area > 20 mm2
  - New York heart Association Class≥ II.
  - Left ventricular ejection fraction between 15% and 40%
  - Minimum of 1 hospitalization for heart failure within 12 months preceding randomization
  - Assessed by the investigator to be on optimal standard of care therapy for heart failure
  - Assessed by the heart team to be not eligible to a mitral surgery intervention

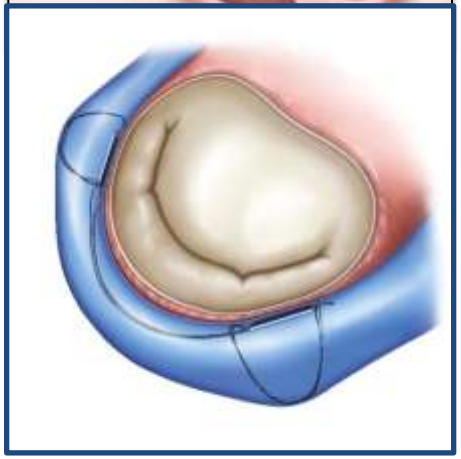
Profs. Obadia and Vahanian
NCT01920698
https://clinicaltrials.gov/ct2/show/NCT01920698?intr=Mitraclip&cntry1=EU%3AFR&rank=1

Cardiac Dimensions Carillion

Indirect annuloplasty with nitinol device anchored into the coronary sinus to reduce annulus dimensions
Transjugular approach

- 700 pts treated for commercial use
- 113 pts implanted in prospective trials
- FMR
- Safe (Death @30d 0% device related)
- Results @12 mo
  - 1 grade of MR reduction
  - 1 NYHA Class improvement (from III to II)
- indirect CS approach
- annular reduction around 15-20%

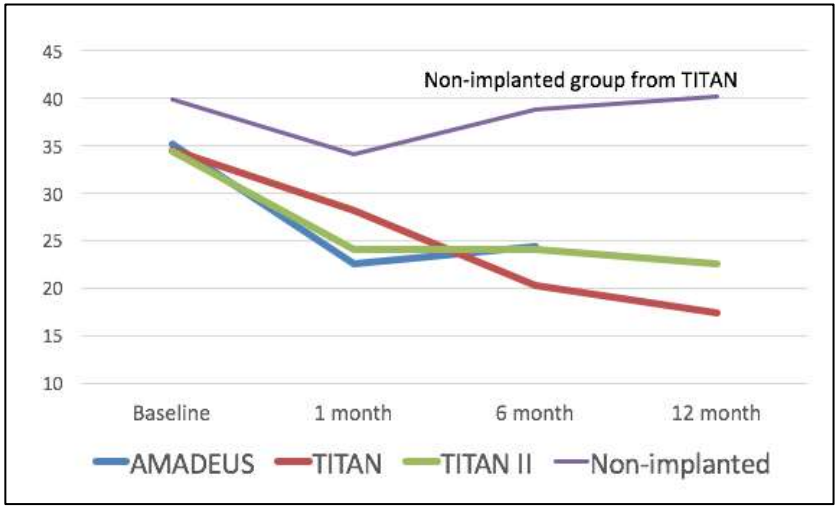




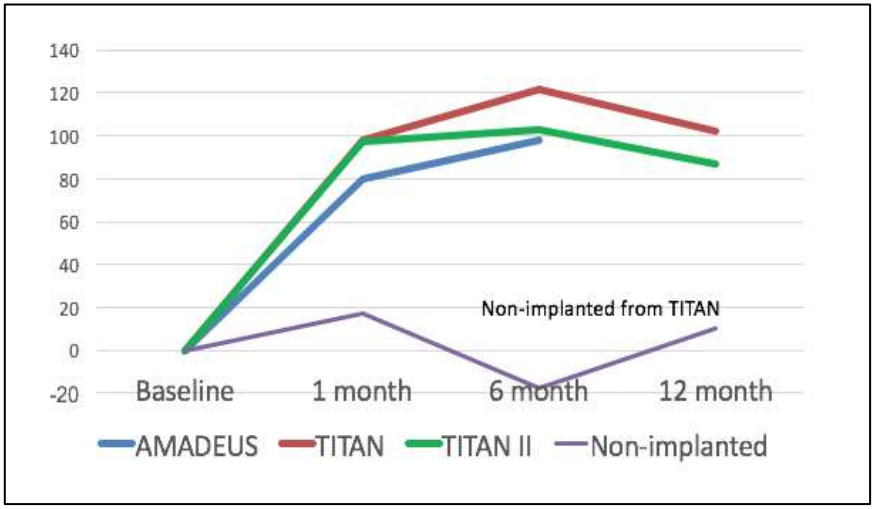
NorthShore University HealthSystem
Evanston Hospital

Carillon Clinical Trials

Regurgitant volume



6 minute walk test



NorthShore University HealthSystem
Evanston Hospital

Carillon Pivotal FDA IDE Trial

- 400 patient trial in 50 sites in US, Canada, Europe and Australia
- Blinded, sham-controlled
- 2:1 randomization
- Co-Primary Efficacy Endpoints
  - 1st Primary endpoint: Hierarchical Endpoint
    - Death, Heart Failure, 6 minute walk-test at 12 months
  - 2nd Co-Primary Efficacy Endpoint
    - Reduction in Regurgitant Volume at 12 months in treatment group compared to control group

Cardioband procedure: Major Steps

Pre-Procedure Planning

1 Transseptal Puncture

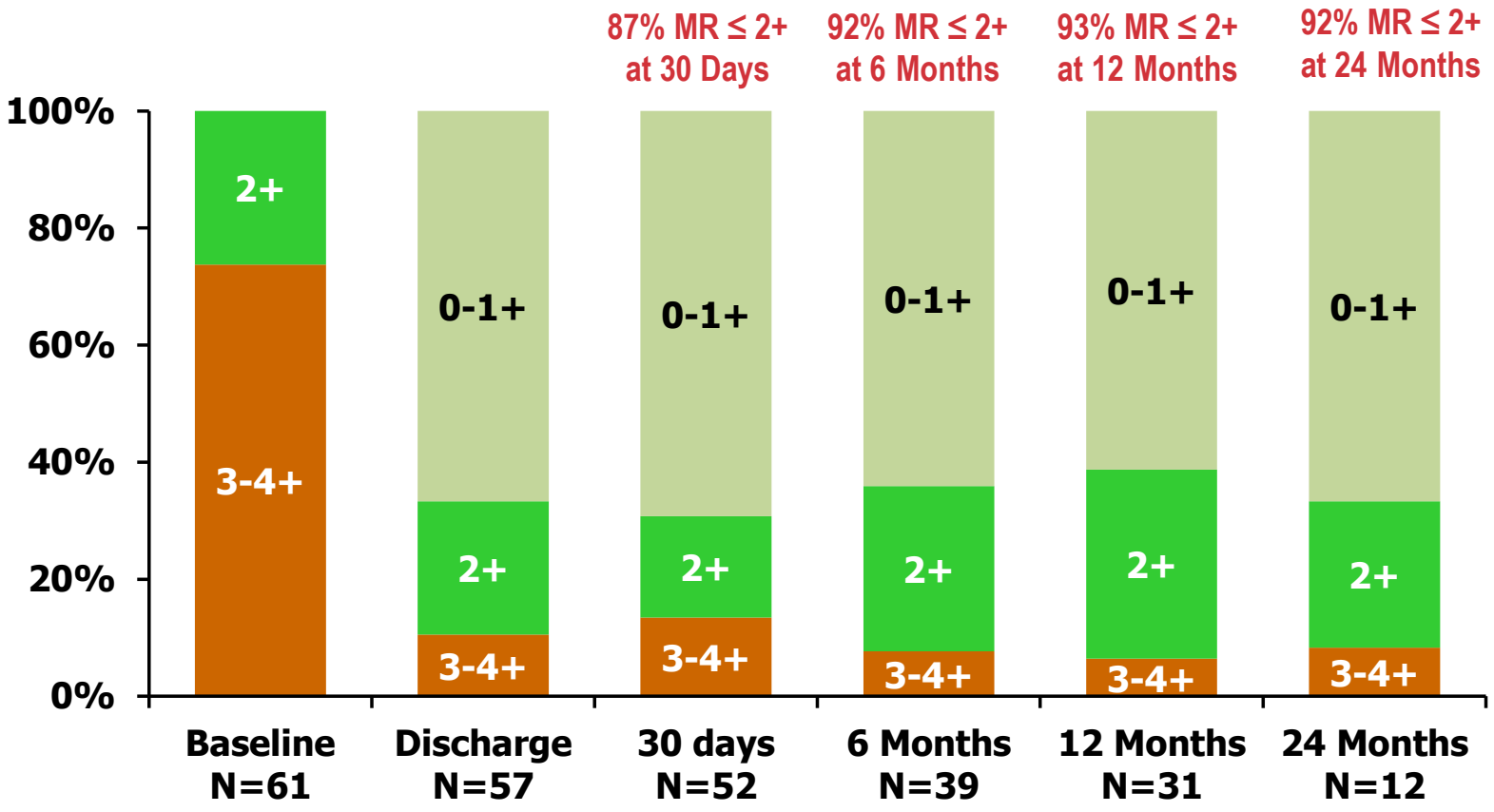
2 System Insertion

3 Implant Deployment

4 Implant Size Adjustment

NorthShore University HealthSystem
Evanston Hospital

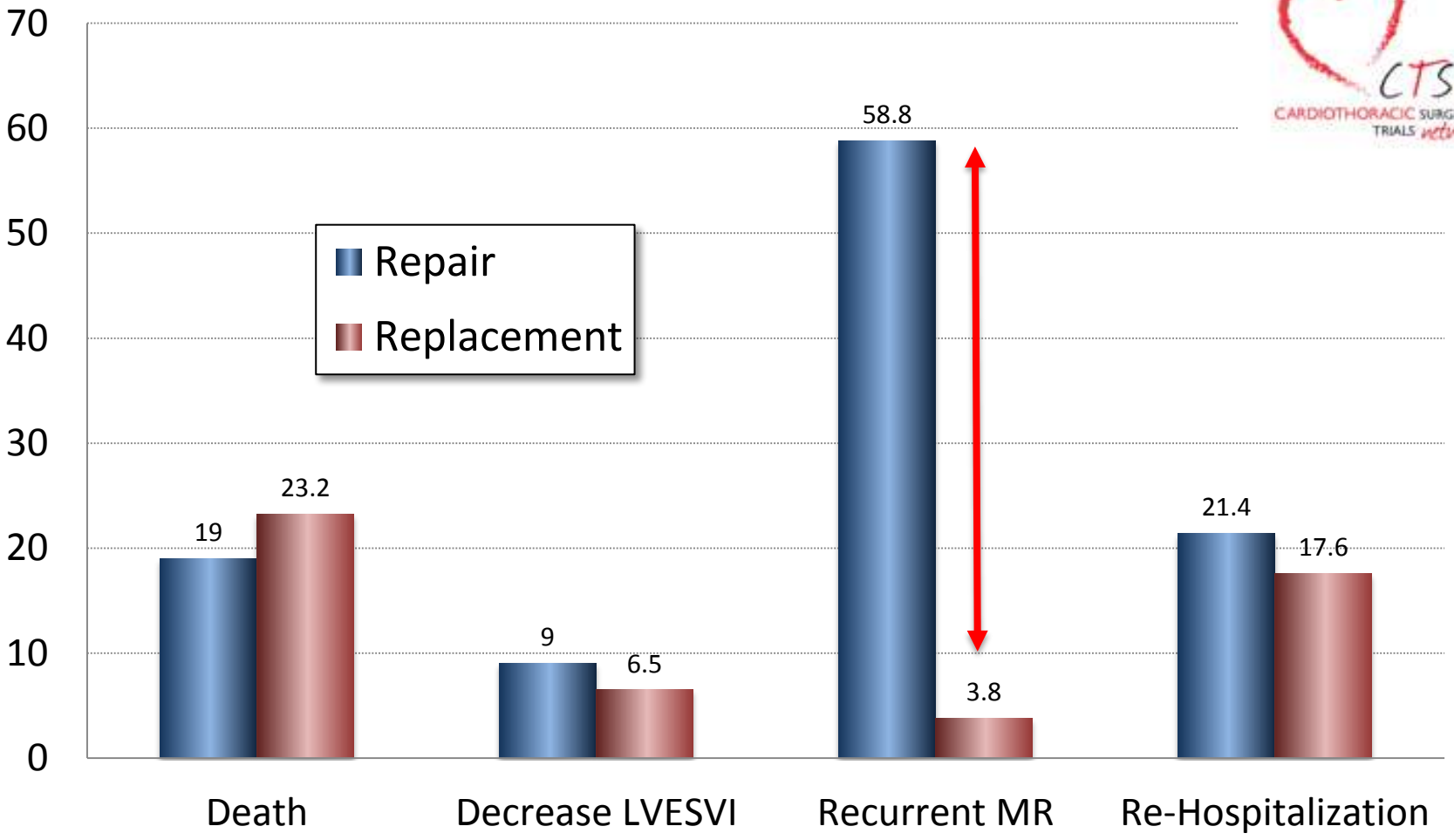
92% patients with MR≤2+ At 24 Months By Core Lab*



*Dr. Paul Grayburn – Baylor University

NorthShore University HealthSystem Evanston Hospital

Two-Year Outcomes of Surgical Treatment of Severe Ischemic MR



CTSN
CARDIOTHORACIC SURGICAL TRIALS network

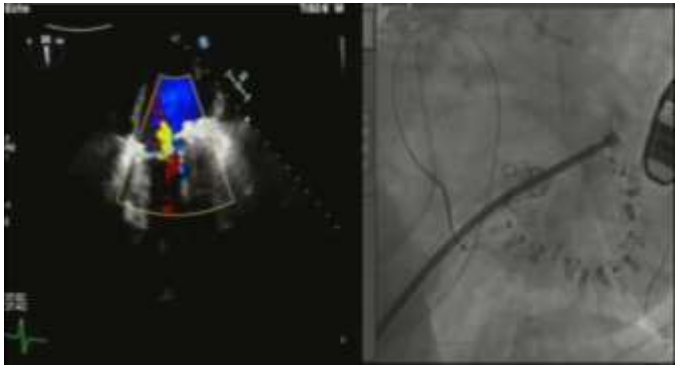
NorthShore University HealthSystem
Evanston Hospital

n=251

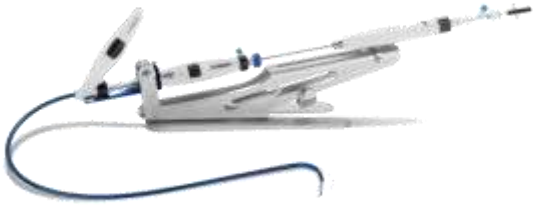
Goldstein D et al. N Engl J Med 2016;374:344-353

Real time monitoring of MR reduction

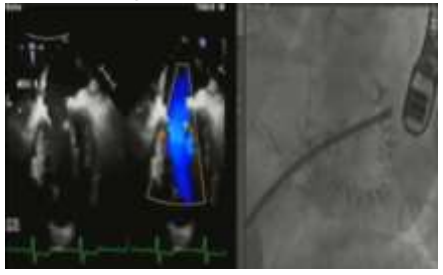
Pre Adjustment



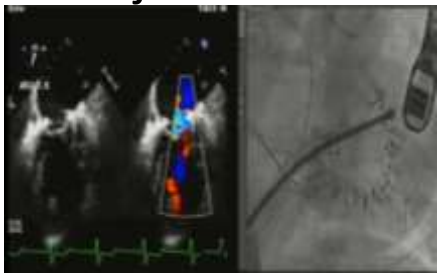
Valtech



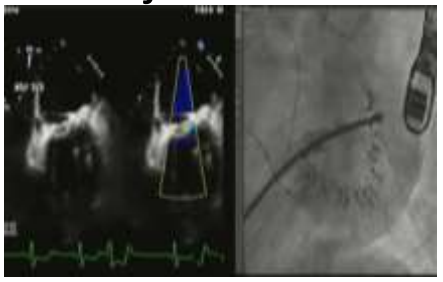
Adjustment 1



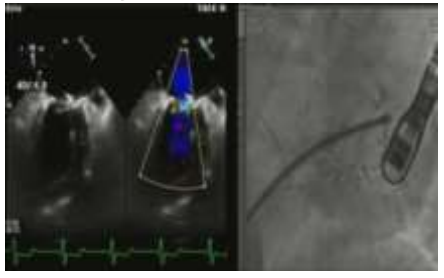
Adjustment 2



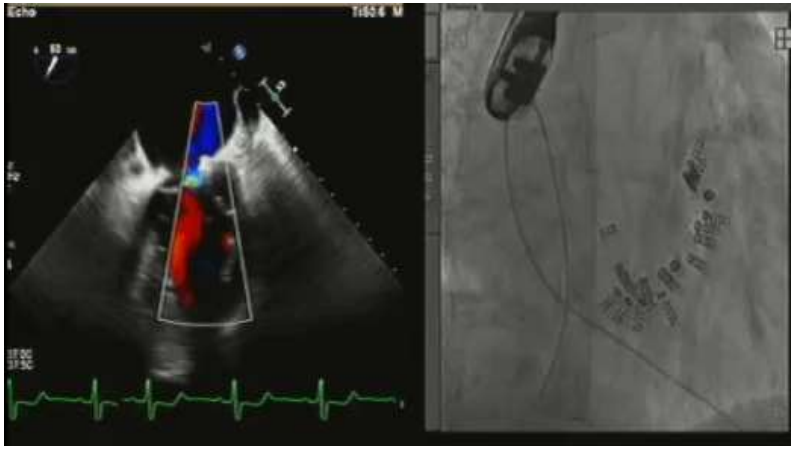
Adjustment 3



Adjustment 4

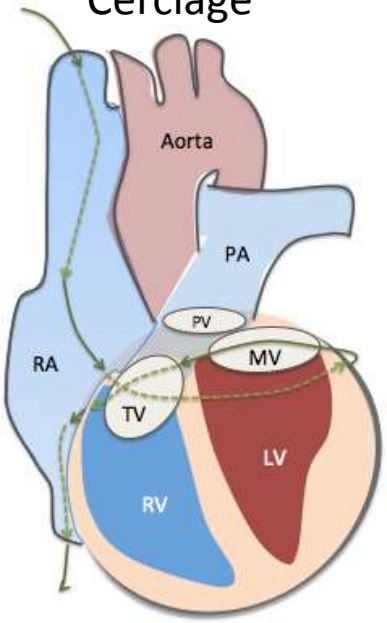


Post procedure



NorthShore University HealthSystem
Evanston Hospital

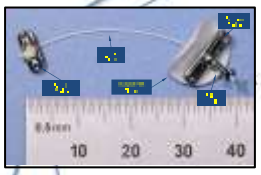
Cerclage

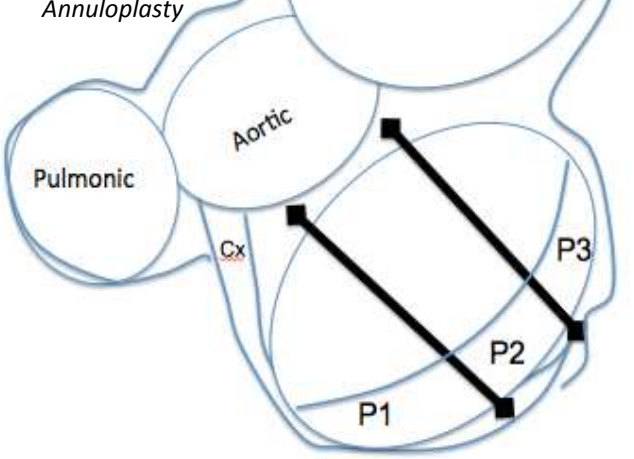


Millipede

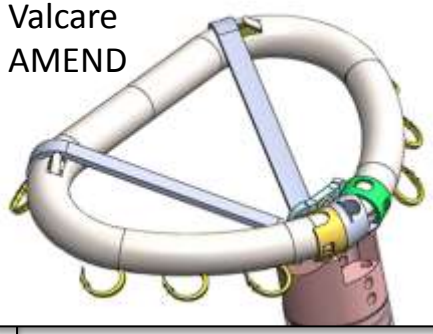
TASRA

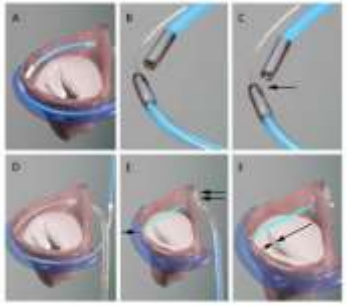
Trans-Apical Segmental Reduction Annuloplasty





Valcare AMEND

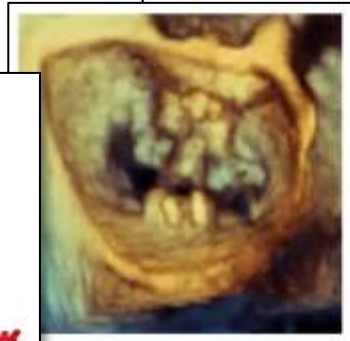




Arto

VenTouch

MR reduction + LV remodeling

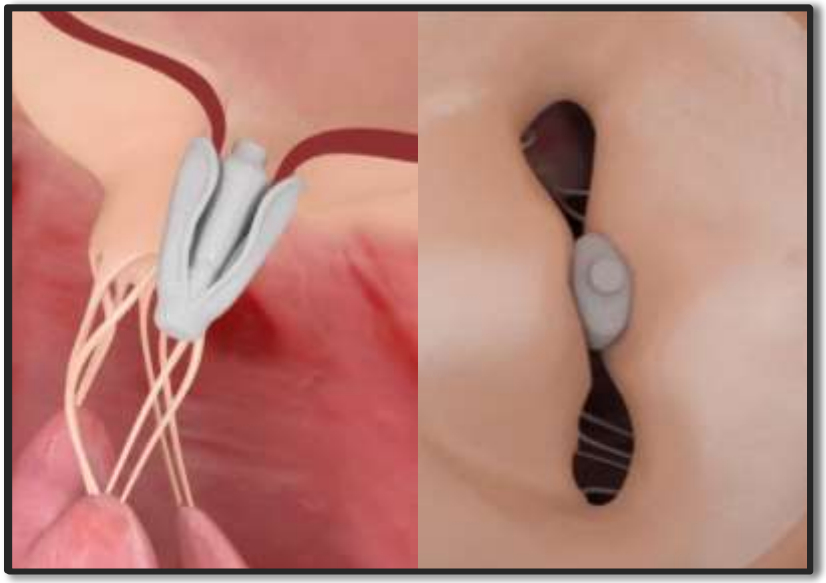


Mitral Bridge

NorthShore University HealthSystem
Evanston Hospital

Edwards PASCAL Repair System

- Spacer is clasped between both Mitral Valve leaflets
- Independent leaflet clasping
- Simple “Commander-like” delivery system
- Conventional transfemoral/transseptal approach



TMVR

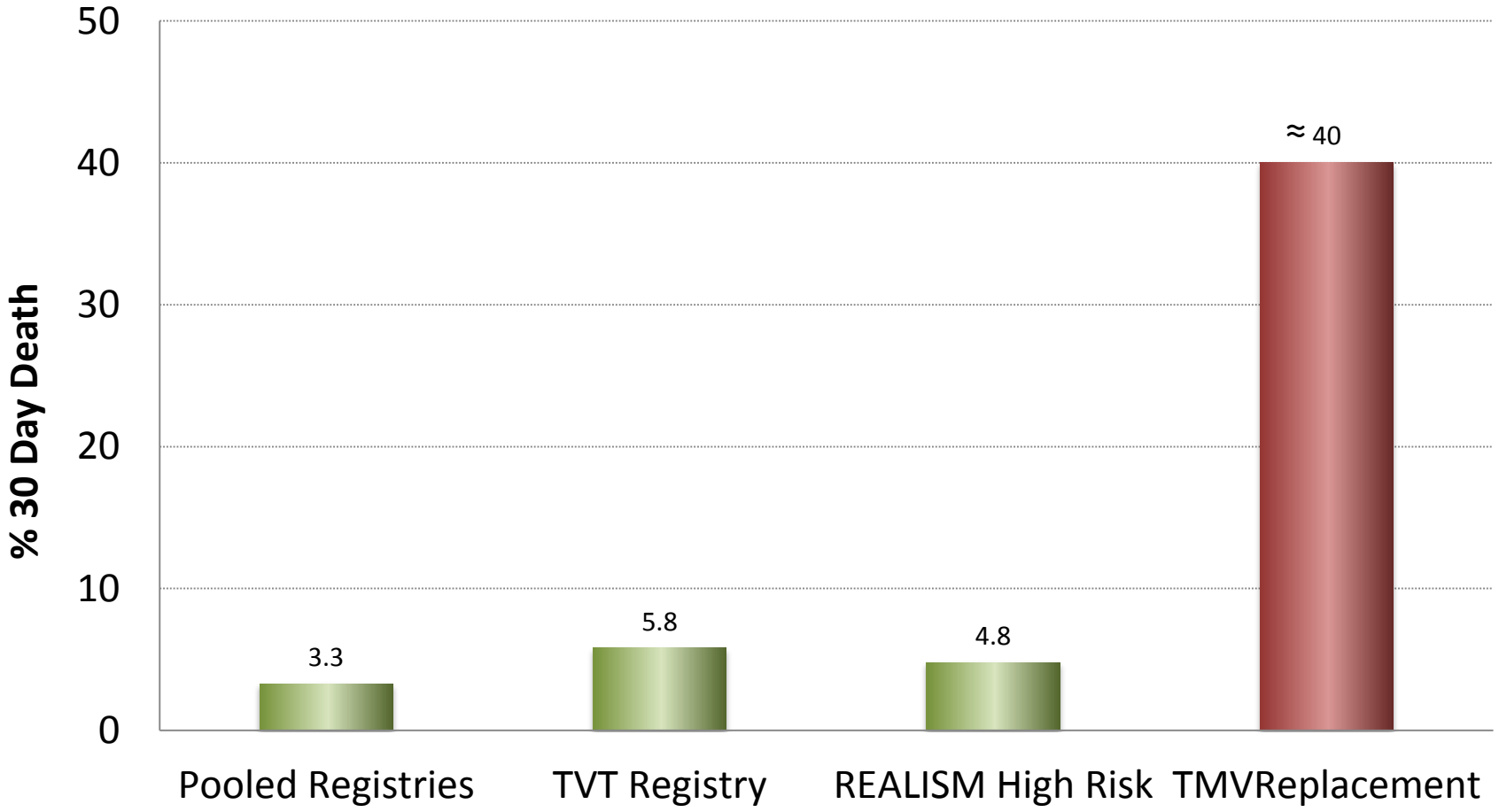
Tendyne-Abbott

CardiAQ-Edwards

TWELVE-Medtronic

Mitral Repair vs Repalcement

30 Day Mortality



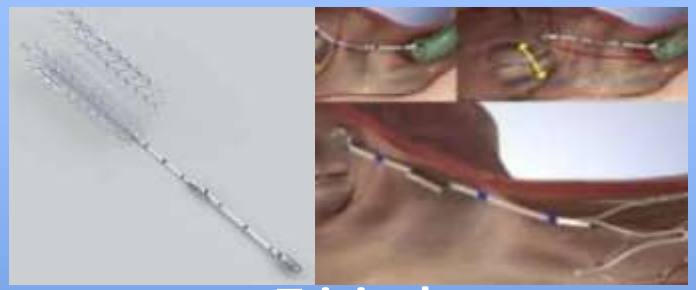
CCI 2014;84:581
n=3198

JACC 2016;67:1129-40
n=564

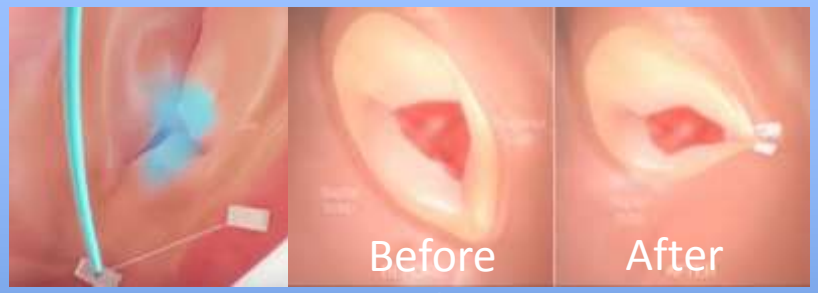
JACC 2014;64:172–81
n=351

NorthShore University HealthSystem
Evanston Hospital

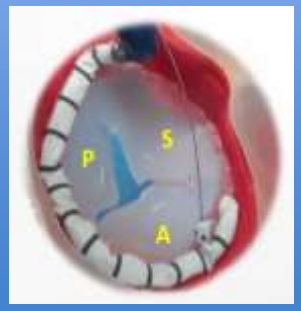
Annular modification



Tricinch

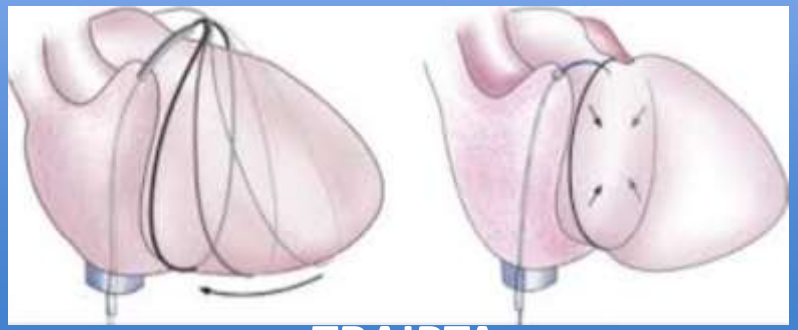


Trialign



Cardioband

Millipede



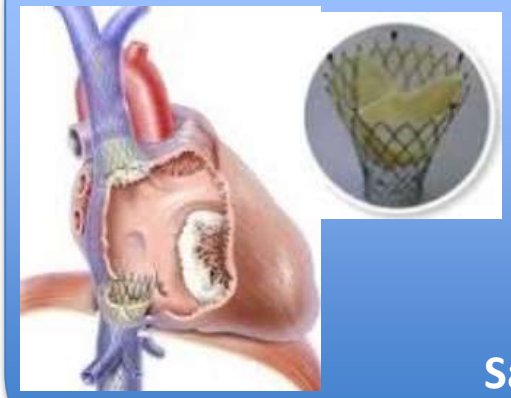
TRAIPTA

Leaflet apposition

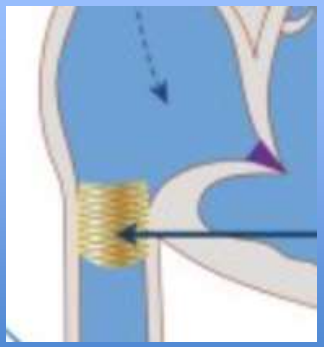
Forma Device

MitraClip

Caval Valve Implantation

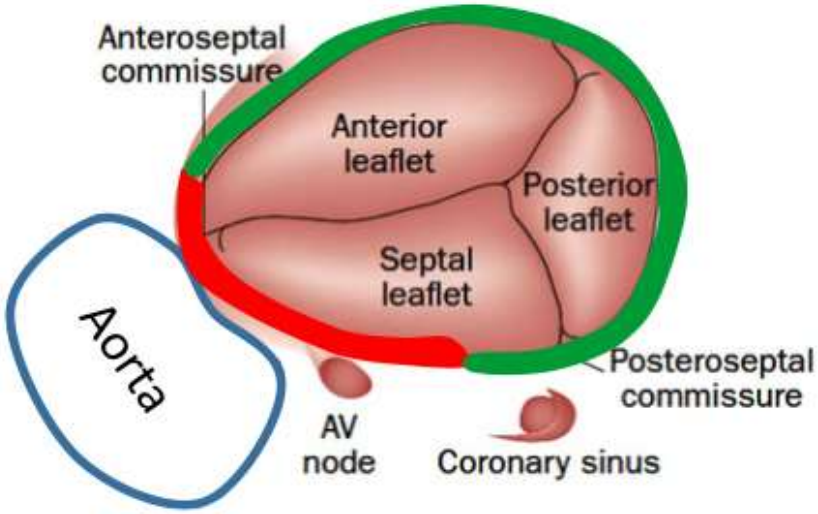


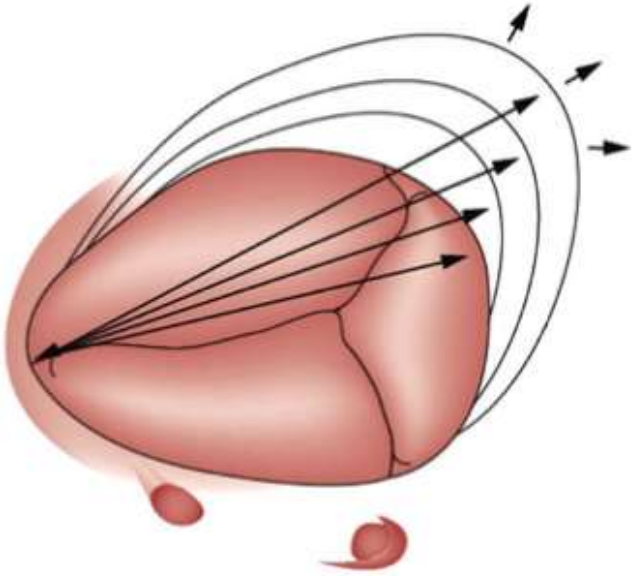
TricValve



Sapien Valve implanted in the inferior cava vein

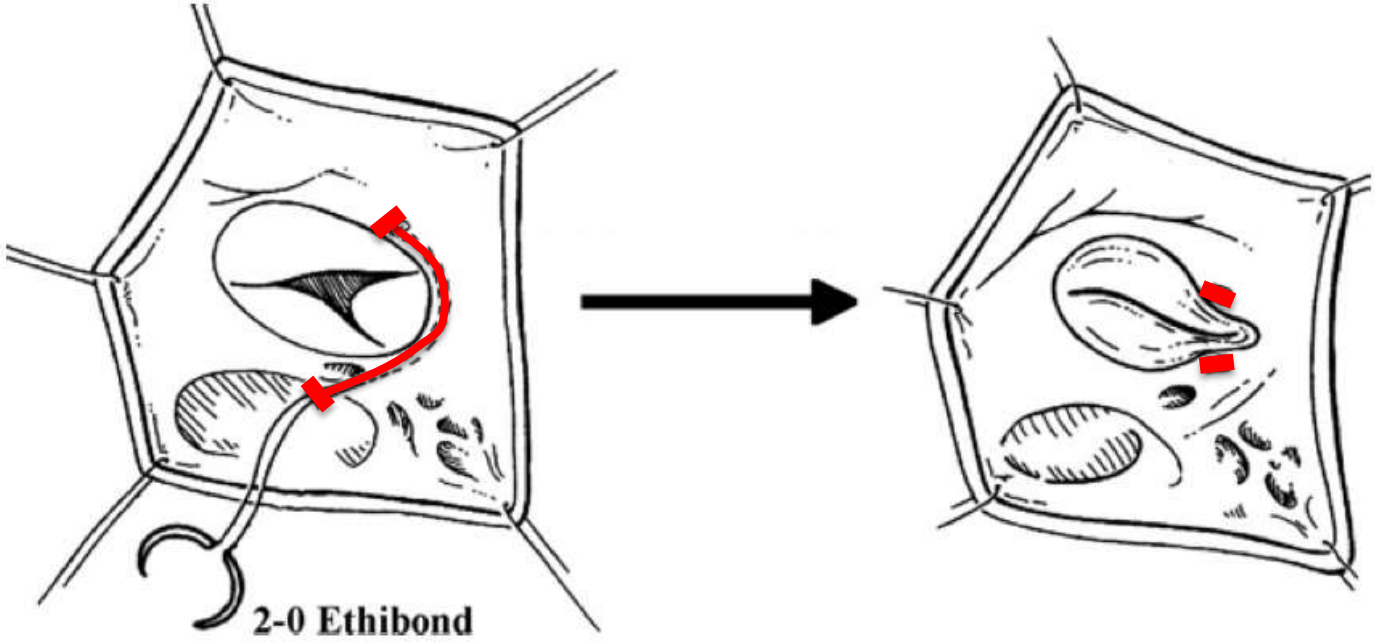
Functional TR is the Result of Anterior Dilatation





Suture bicuspidization of the tricuspid valve vs ring annuloplasty for functional tricuspid regurgitation

Midterm results of 237 consecutive patients

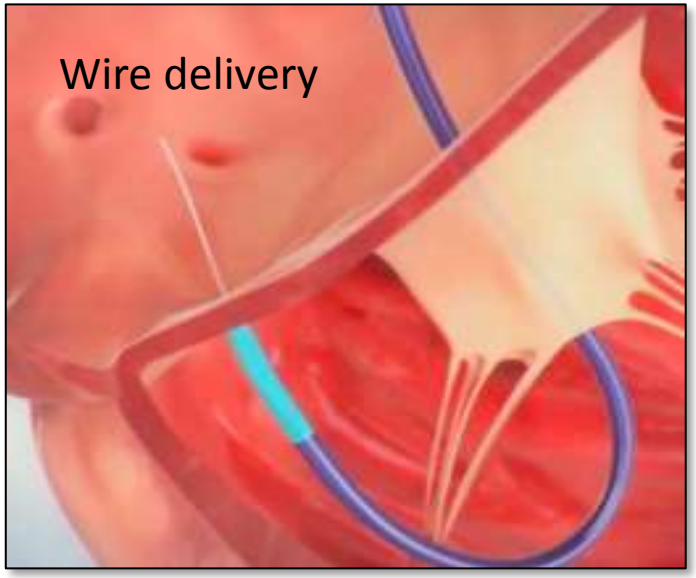


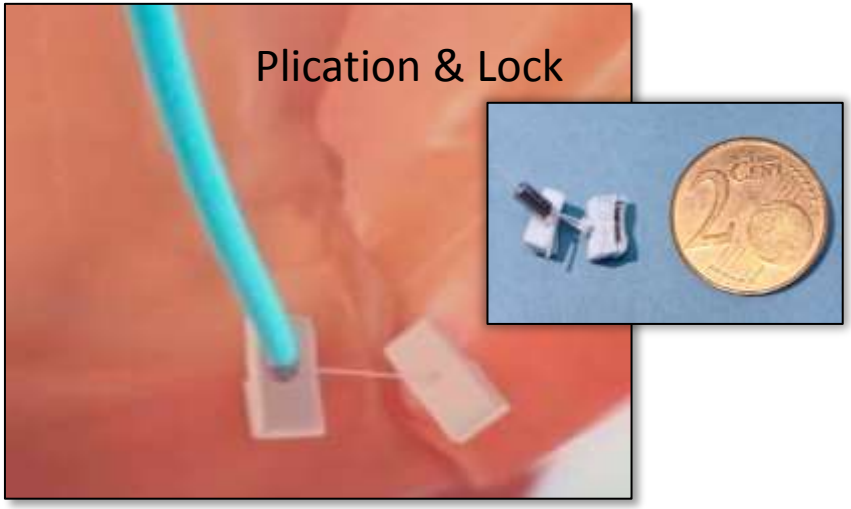
Suture bicuspidization is performed by placement of a 2-0 pledget-supported mattress suture from the antero-posterior to the posteroseptal commissures along the posterior annulus.

NorthShore University HealthSystem
Evanston Hospital

J Thorac Cardiovasc Surg 2007;133:117-126

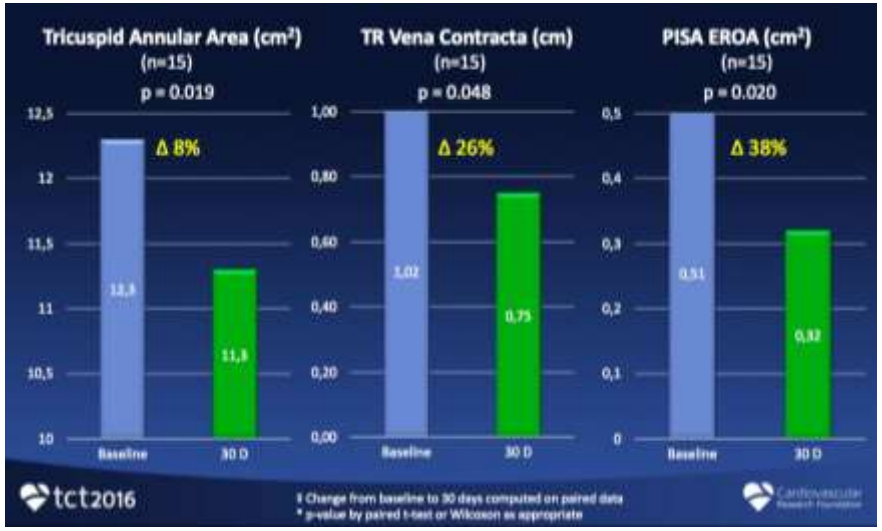
Trialgn Device

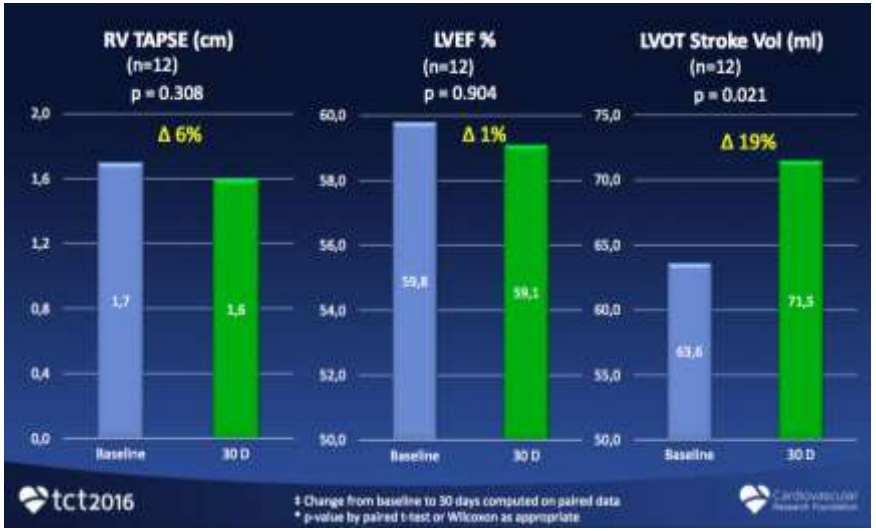


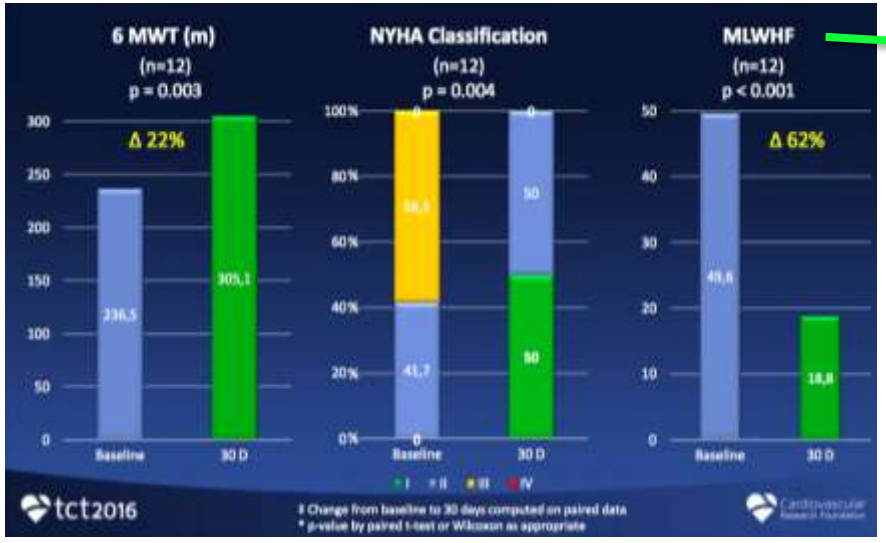


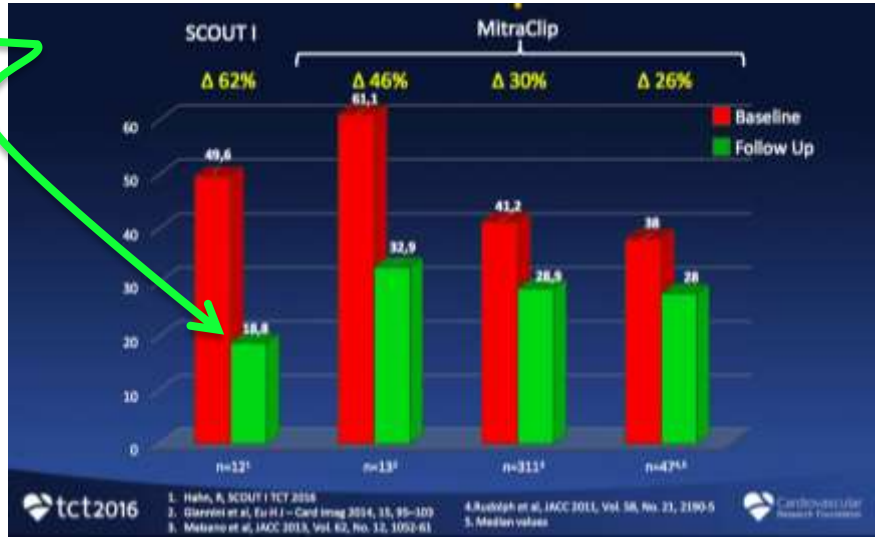
NorthShore University HealthSystem
Evanston Hospital

SCOUT 30 Day As-Treated

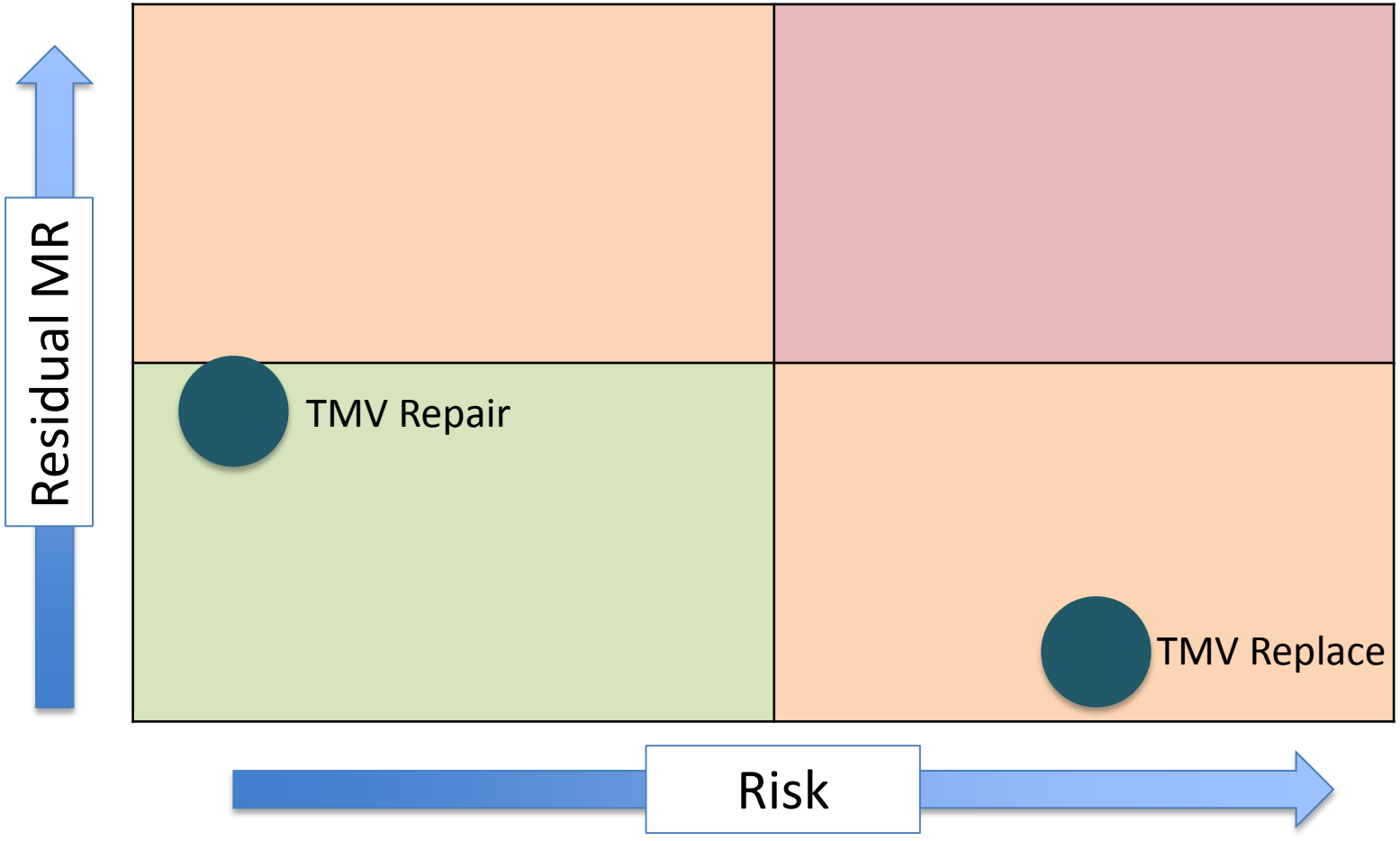








NorthShore University HealthSystem
Evanston Hospital



NorthShore University HealthSystem
Evanston Hospital