MVRx ARTO System (Septam Sinus Shortening) and the MAVERIC Trial

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Disclosures of Conflict of Interest

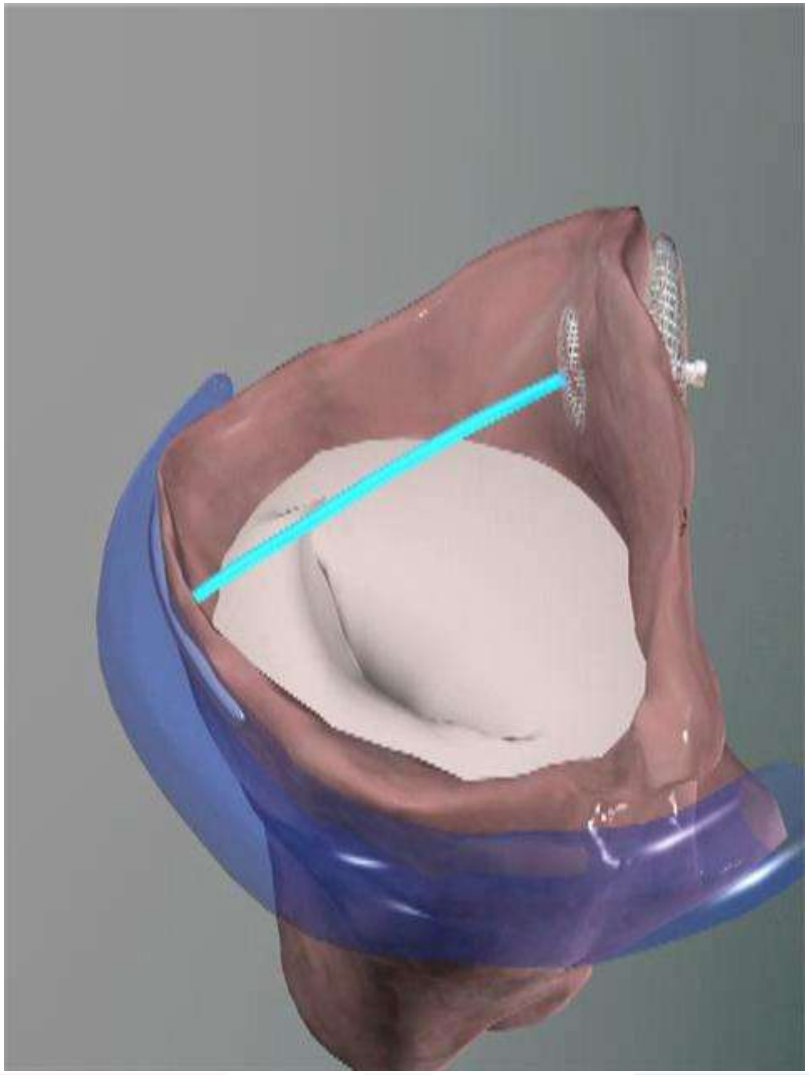
Speaker's name: Andrejs Erglis

☑ **I have the following** potential conflicts of interest to report:

☑ Research contracts (Abbott Vascular, Boston Scientific)
☑ Consulting, Speakers Bureau (Abbott Vascular, Boston Scientific, Medtronic, Cordis J&J, Biosensors, MVRx)
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

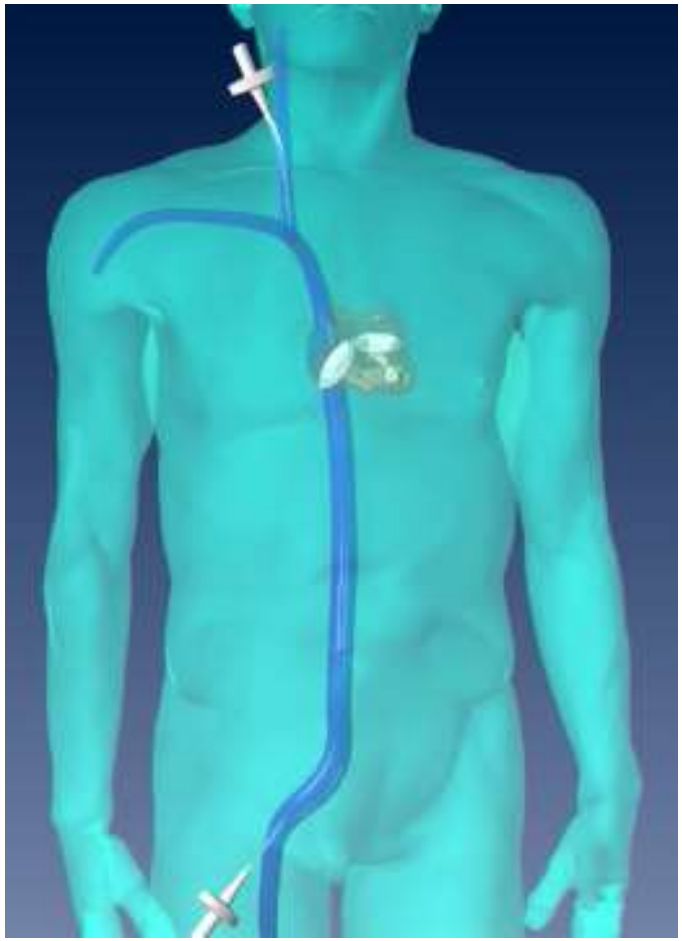
☐ **I do not have any potential conflict of interest**

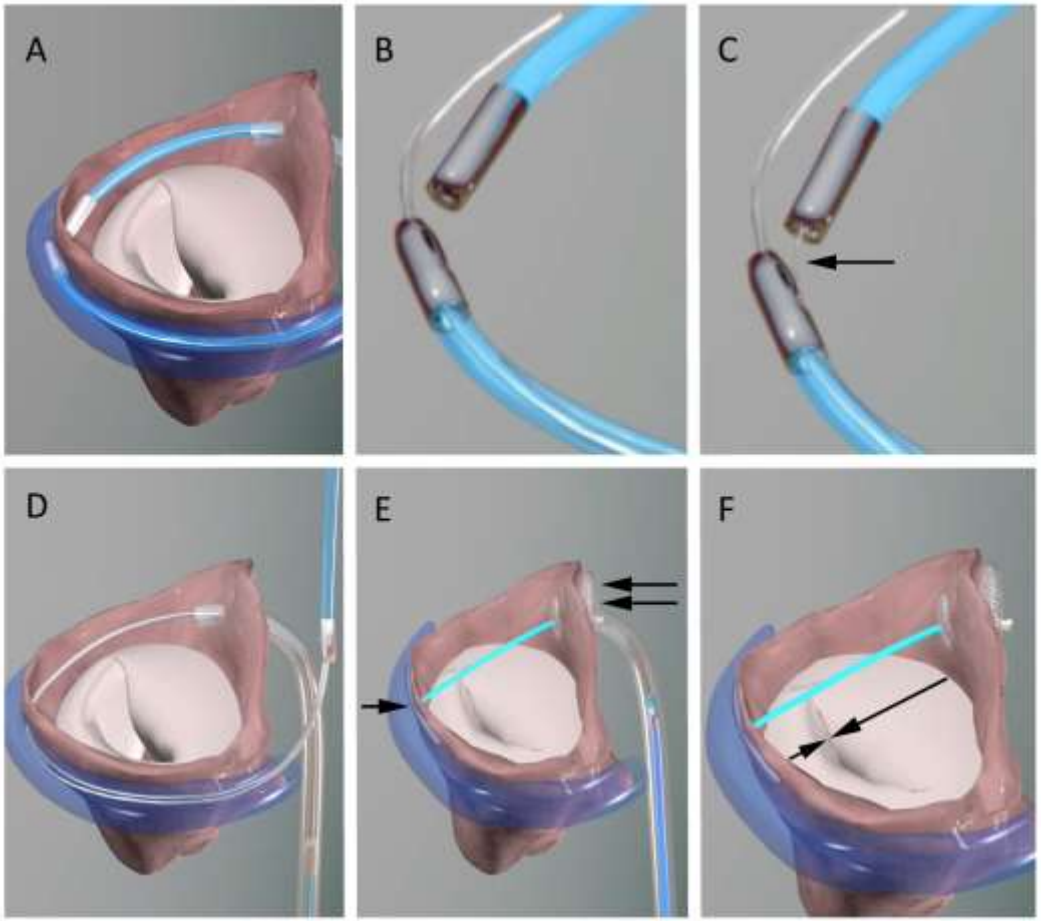
The ARTO™ System



- **Direct A-P Diameter Shortening to Treat FMR**
- **Venous Based Delivery Under Fluoroscopic Imaging**
- **Customizable to Anatomy**
- **Acutely Reversible or Removable**
- **12 Fr Delivery System**
- **No residual ASD, no trauma to native MV leaflets or cords**
- **Little Impact to Potential Future Therapy**

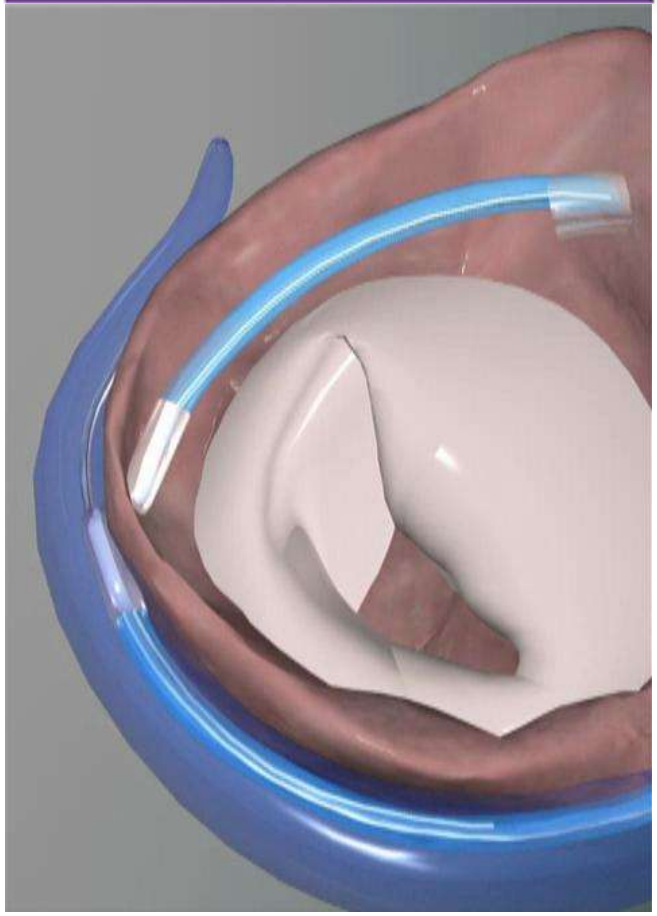
Deployment Procedure

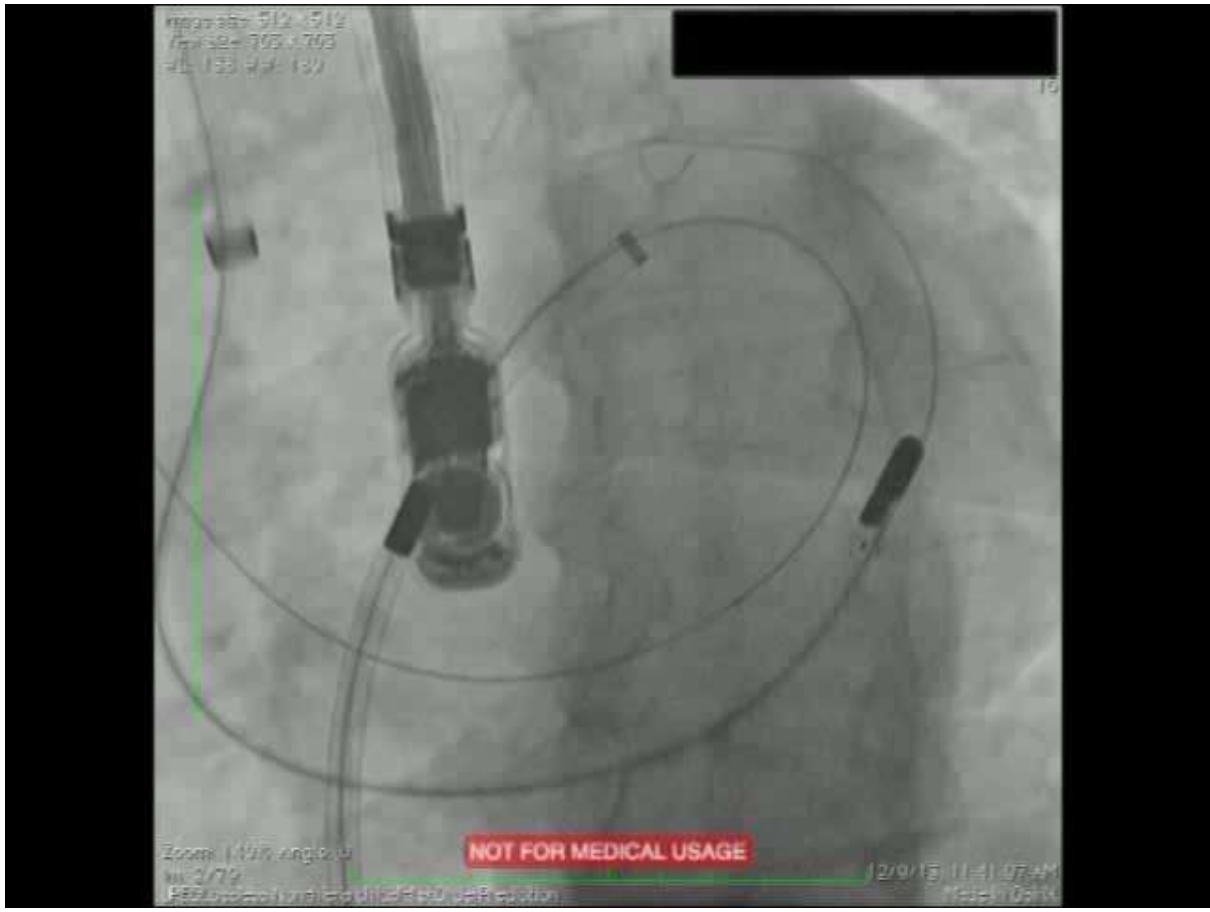




Magnet Tipped Catheters

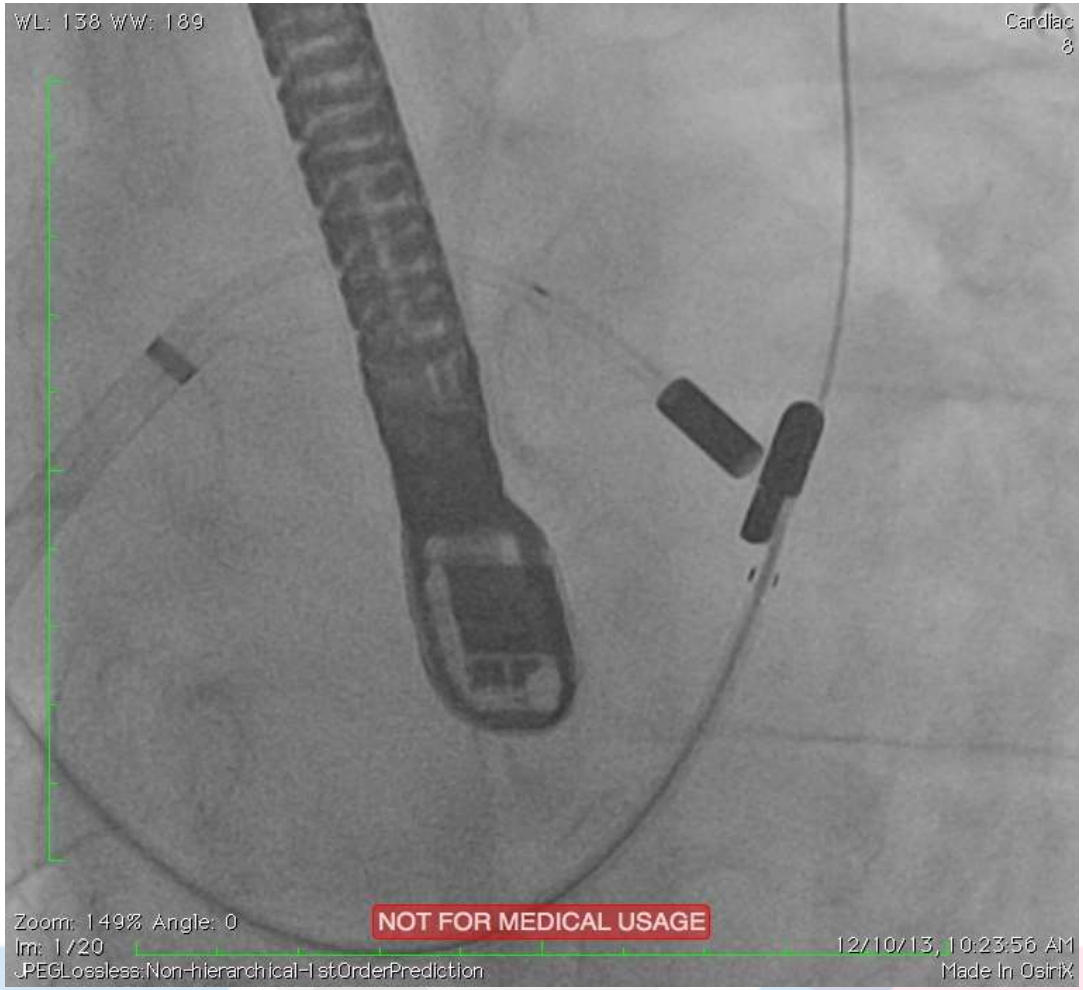
MagneCath™ Delivery



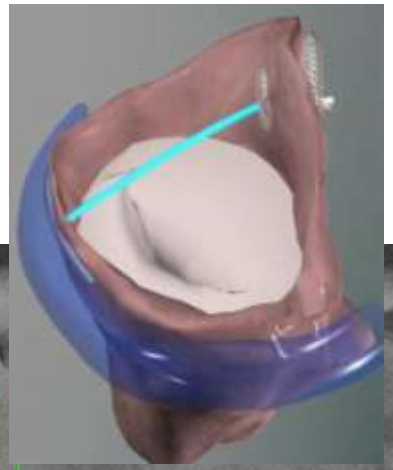


Magnet Tipped Catheters

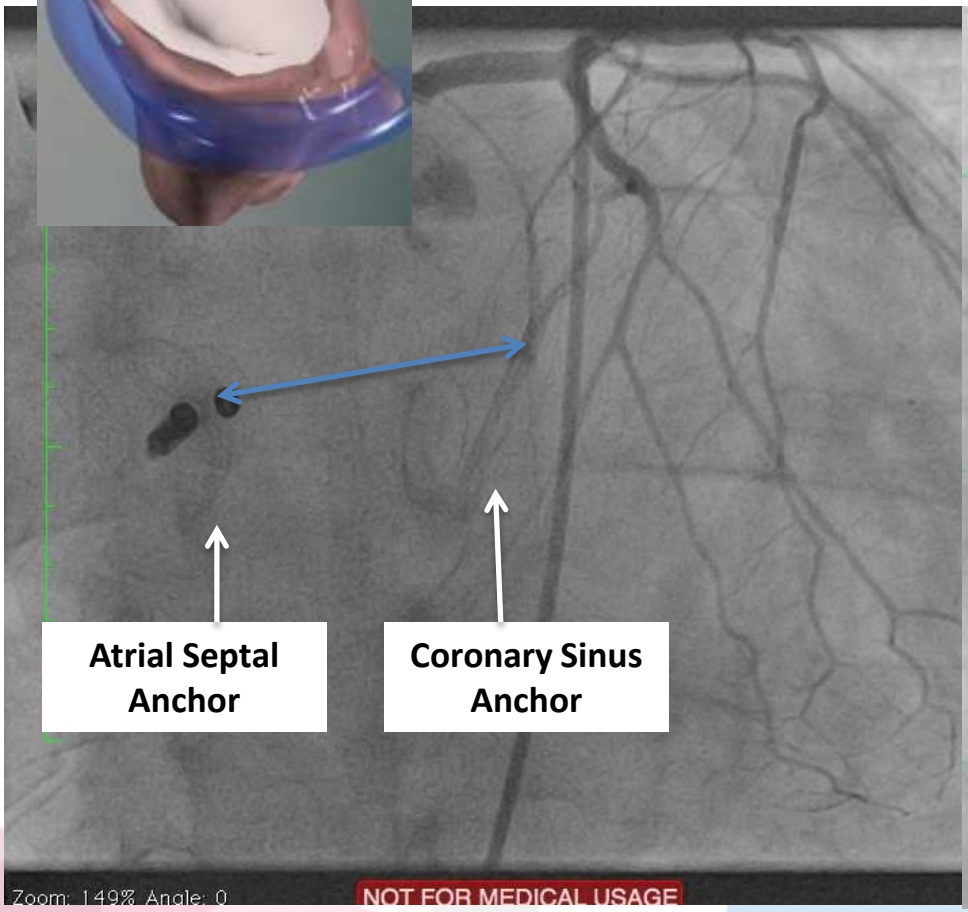
Catheter tipped with magnet connection enables safe creation of venous to venous loop between coronary sinus and the atria

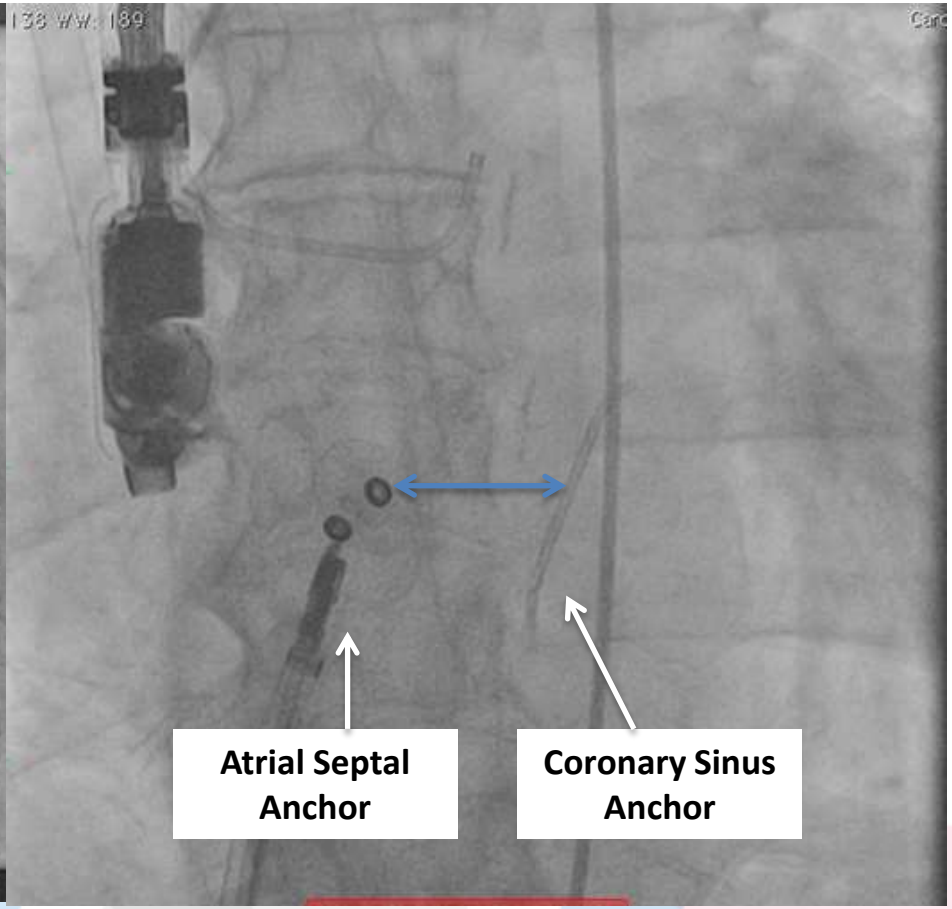


Shortening the A-P Diameter

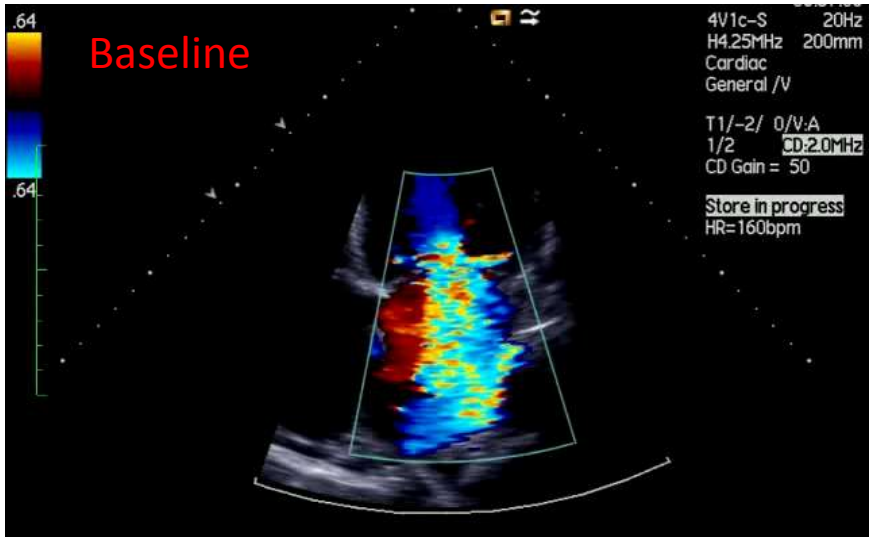


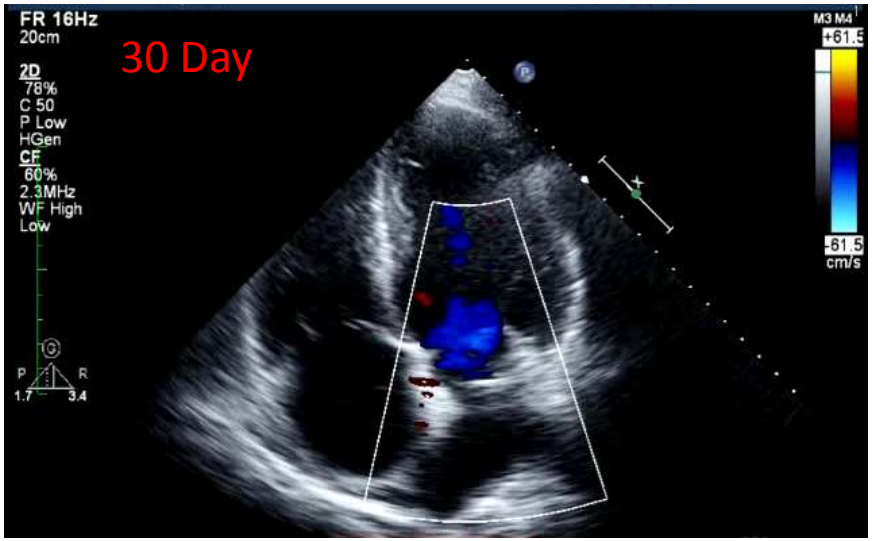
AP diameter shortened by tightening cord and locked into position

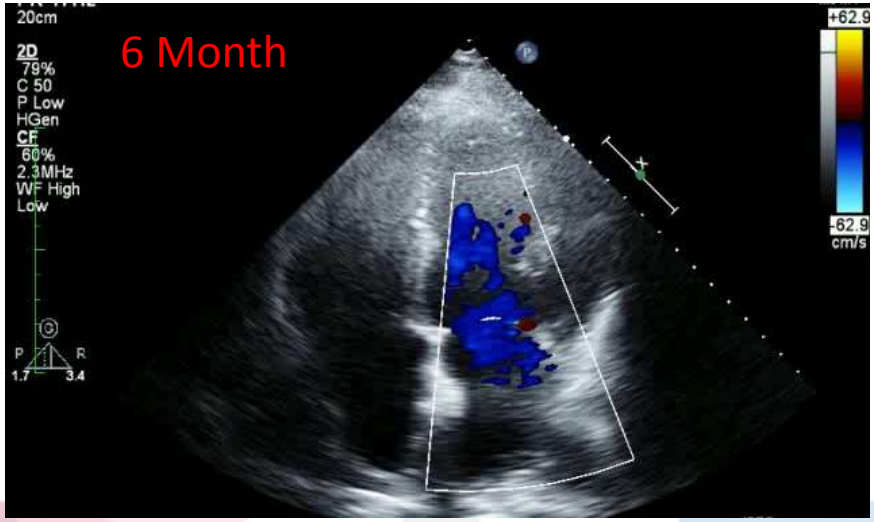


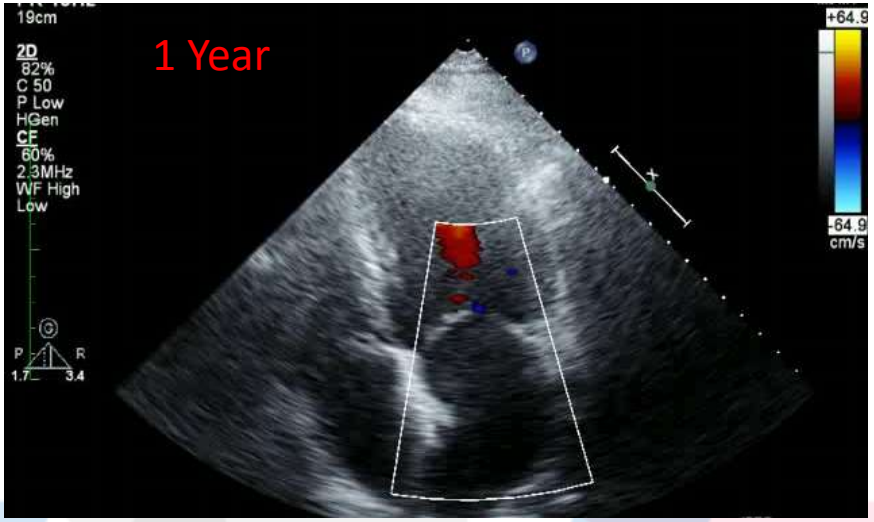


MAVERIC Case Example

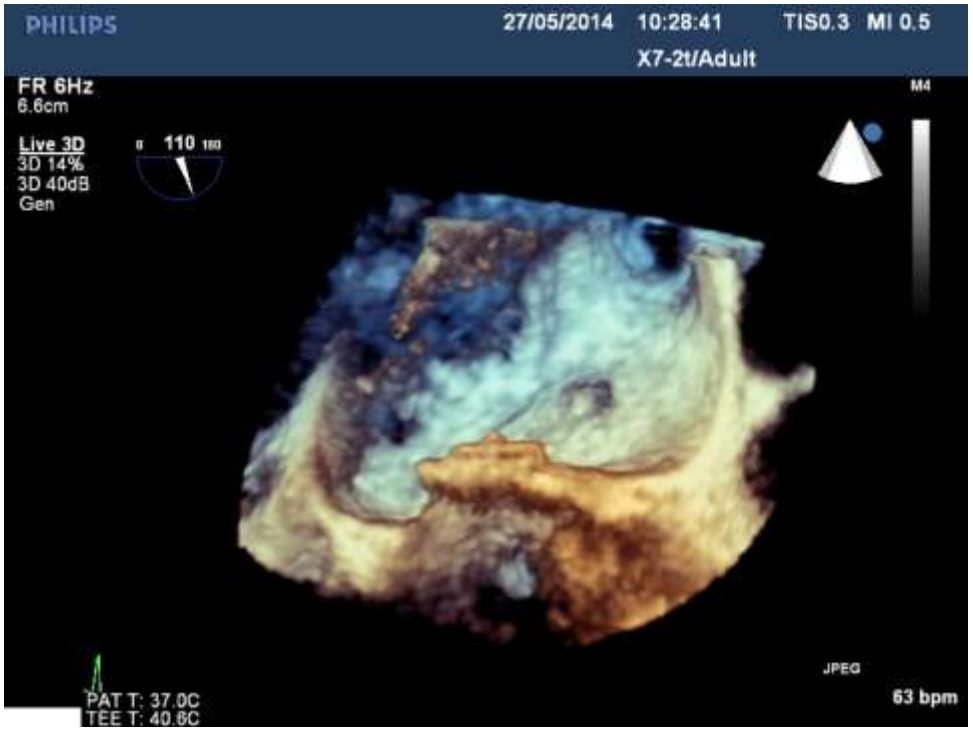


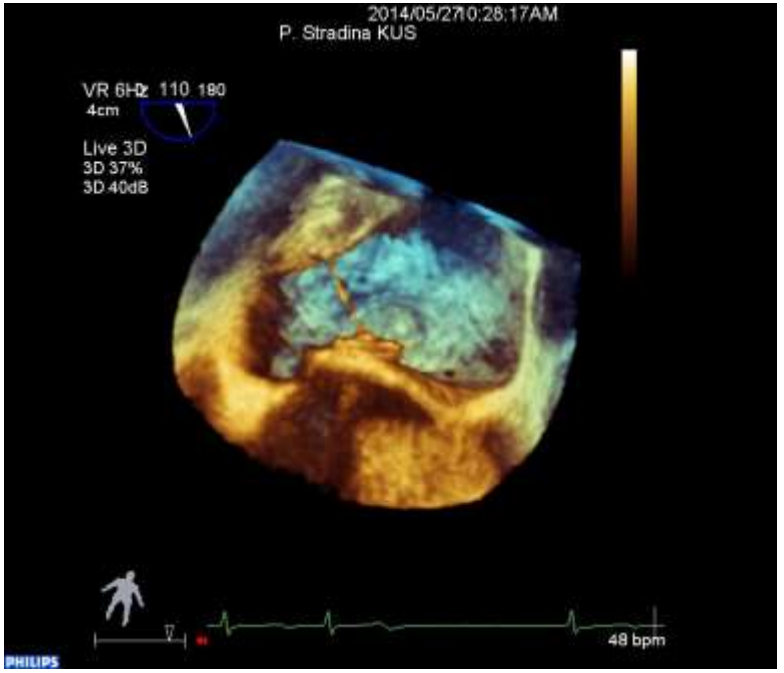






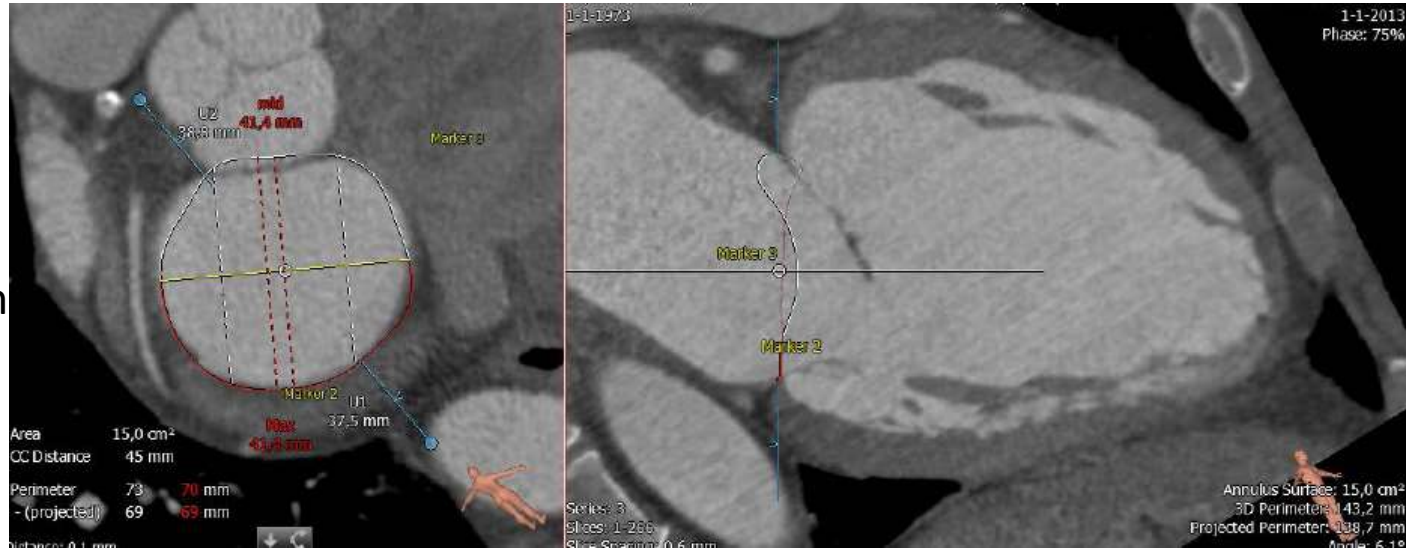
3D Echo


PHILIPS
27/05/2014 10:28:41 TIS0.3 MI 0.5
X7-2t/Adult
FR 6Hz
6.6cm
Live 3D
3D 14%
3D 40dB
Gen
110
M4
JPEG
63 bpm
PAT T: 37.0C
TEE T: 40.6C


2014/05/27 10:28:17AM
P. Stradina KUS
VR 6Hz 110 180
4cm
Live 3D
3D 37%
3D 40dB
48 bpm
PHILIPS

MAVERIC Case Example 2

<u>Pre-Procedure</u>
Area: 14 cm^2
Perimeter: 138 mm



<u>6 Month</u>
Area: 11 cm^2
Perimeter: 126 mm

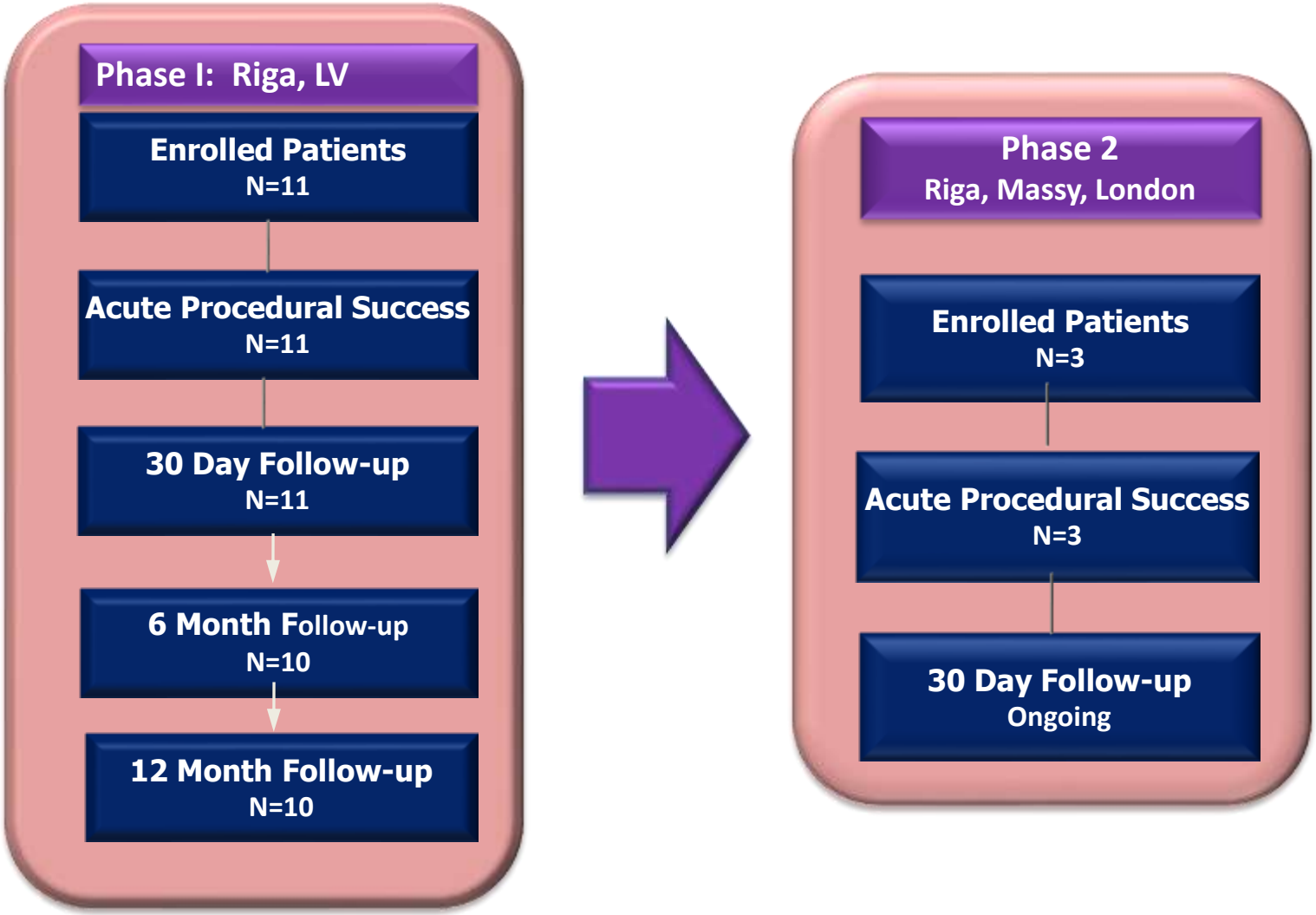
MAVERIC Trial
MitrAl ValvE RepaIr Clinical Trial

- **Objective:**
  - Evaluate Feasibility and Safety of the MVRx ARTO System in treating FMR patients who were refused MV surgery
- **Primary Outcome Measures**
  - Major Adverse Event Rate to 30 Days
  - Reduction of mitral regurgitation at 30 Days
- **Secondary Outcome Measures**
  - MAE Rate & MR reduction at 6 Months
  - Successful device placement
- **Key Inclusion Criteria**
  - NYHA Class II-IV of any etiology
  - Symptomatic with MR grade ≥ 2+
  - Refused for MV surgery

MAVERIC Trial

- **Multi-Center Trial of up to 30 Patients**
  - ***Phase I: Complete***
    - Riga, Latvia - Andrejs Erglis (PI)
    - 11 patients enrolled
  - ***Phase II: Commenced***
    - Riga, Latvia - Andrejs Erglis (PI)
    - London, UK - Simon Redwood (PI)
    - Massy, France – Philippe Garot (PI)
- **Trial Management**
  - Study management: CERC
  - Core lab: CERC

MAVERIC Patient Flow



MAVERIC Patient Demographics

Parameter	Phase I Patients (N=11)	Phase II Patients (N=3)
Age (years)	60.6 ± 10.6	61.3 ± 14.8
Logistic EuroScore (%)	6.5 ± 4.6	TBC
HF Hospitalizations Prior 2 Years	1.1 ± 0.7	0.0
Male Gender (%)	82	100
Current Smoker (%)	46	100
Hypertension (%)	27	33
COPD (%)	27	100
Previous PCI (%)	45	66
Previous CABG (%)	18	0
Atrial Fibrillation (%)	82	66
Pacemaker/ICD (%)	9	0

MAVERIC Phase I Safety Events

Event	Event Timing			
	Procedure N=11	1 to 30 Days N=11	31-180 Days N=11	1 year N=10
Death	0	0	0	0
Stroke	0	0	0	0
Myocardial Infarction	0	0	0	0
Mitral Operation/Intervention	0	0	1	0
Bleeding Complication	0	0	0	0
Renal Failure	0	0	0	0
Pericardial Effusion	0	1	0	0

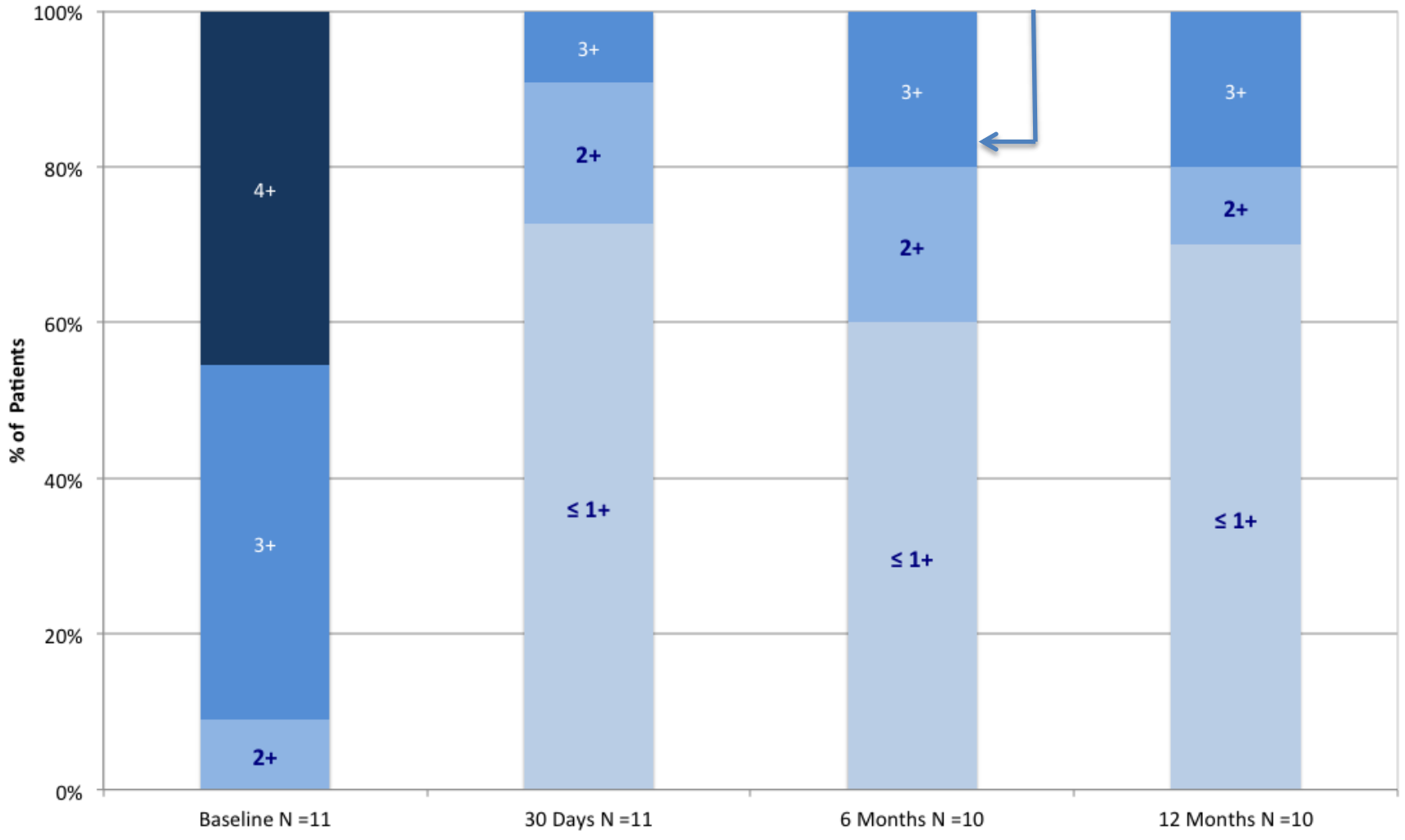
MAVERIC Phase II Safety Events

Event	Event Timing	
	Procedure N=3	Sub-Acute N=3
Death	0	0
Stroke	0	0
Myocardial Infarction	0	0
Mitral Operation/Intervention	0	0
Bleeding Complication	0	0
Renal Failure	0	0
Pericardial Effusion	0	0

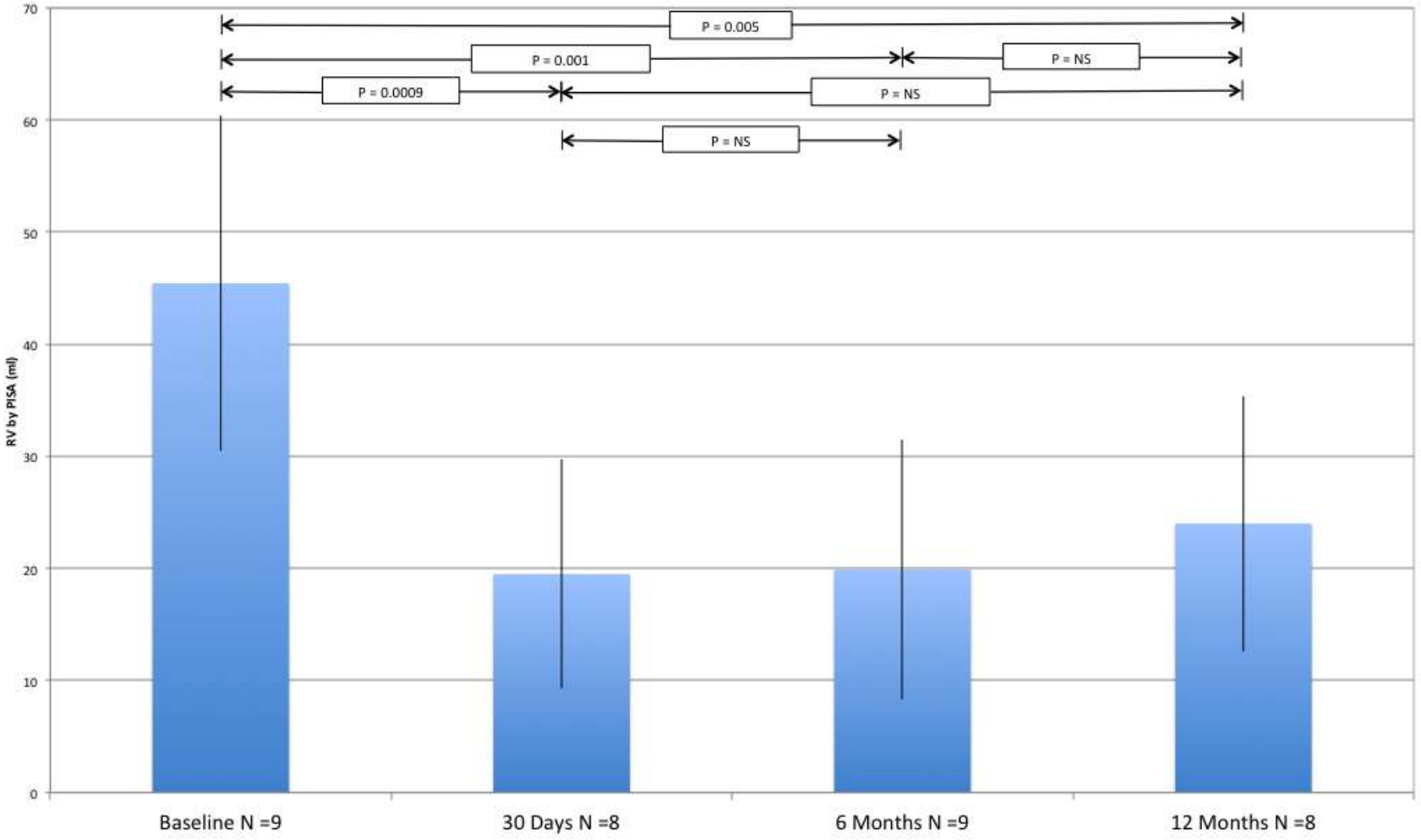
Phase I MR Improvement

- **Observed MR grade improvement maintained at 1 year FU**
- **Important to adhere to HF therapy**

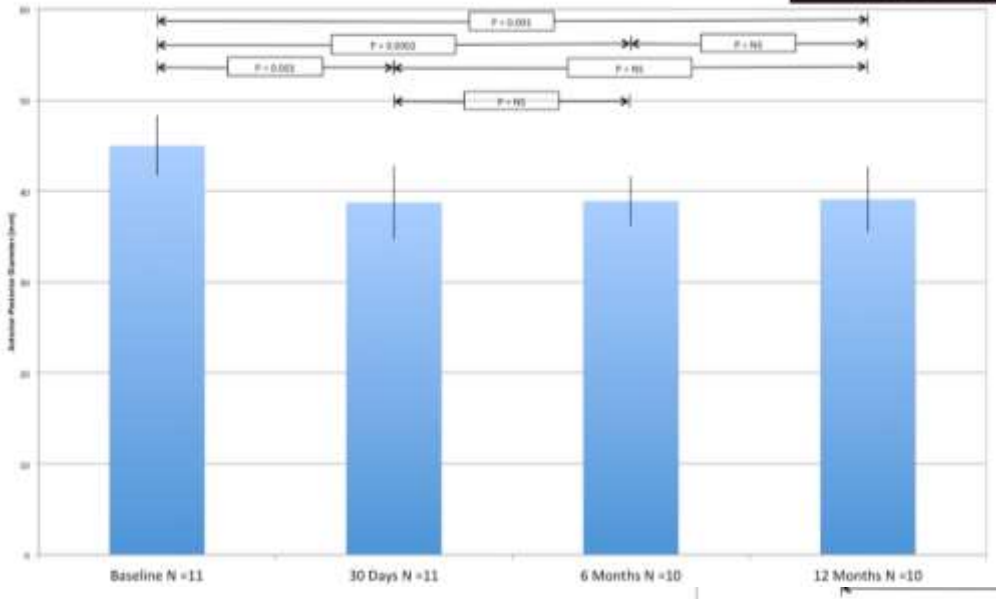
Pt. 010 – from 1+ to 3+
Stopped all HF meds at 6 mon.



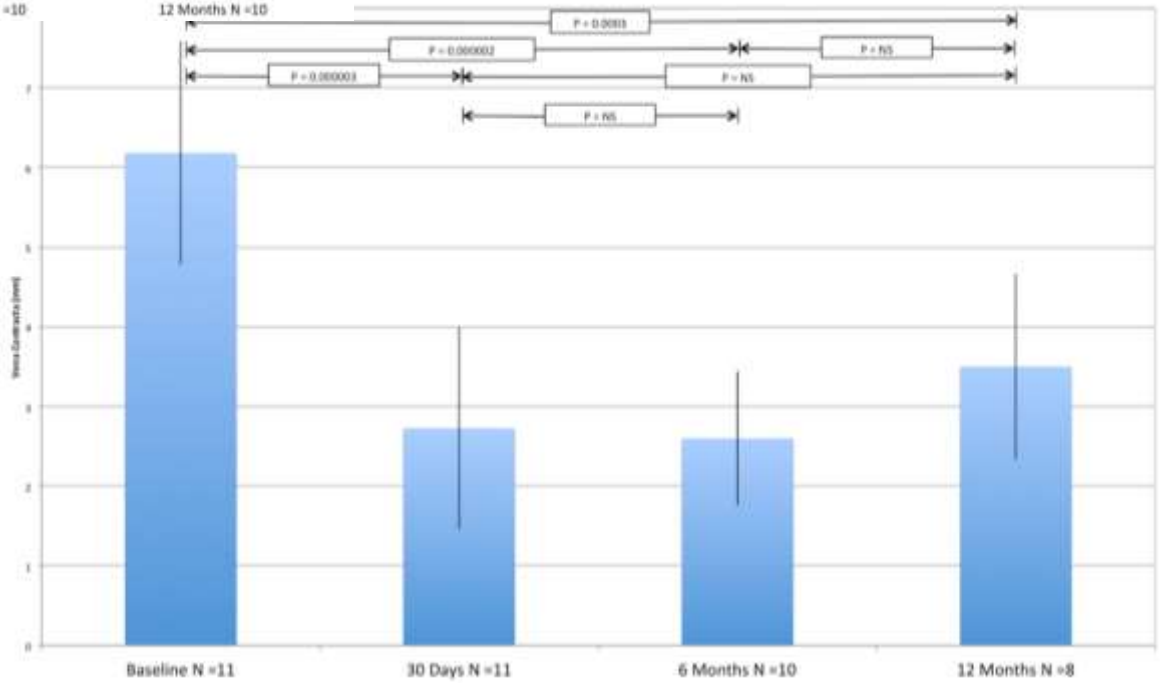
Reduced Regurgitant Volume



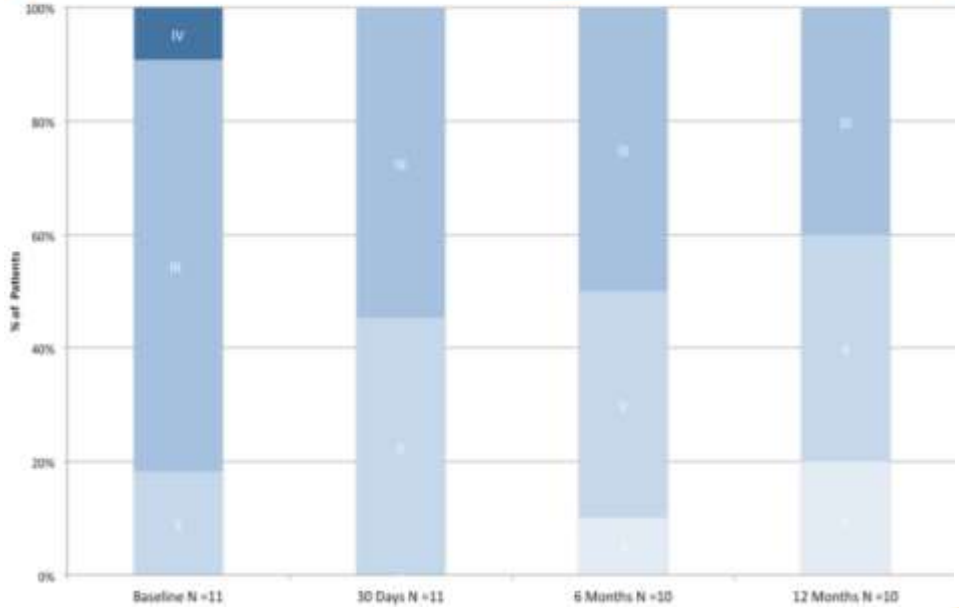
A-P Diameter Reduced



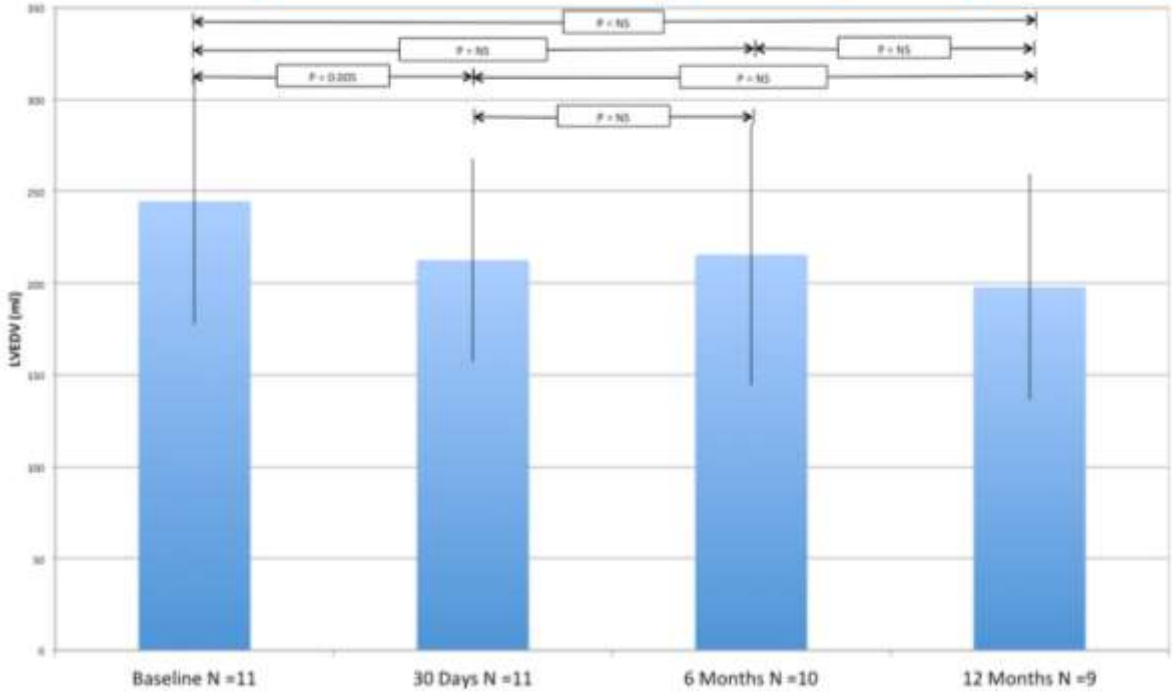
Improved Vena Contracta



Phase I NYHA Improvement

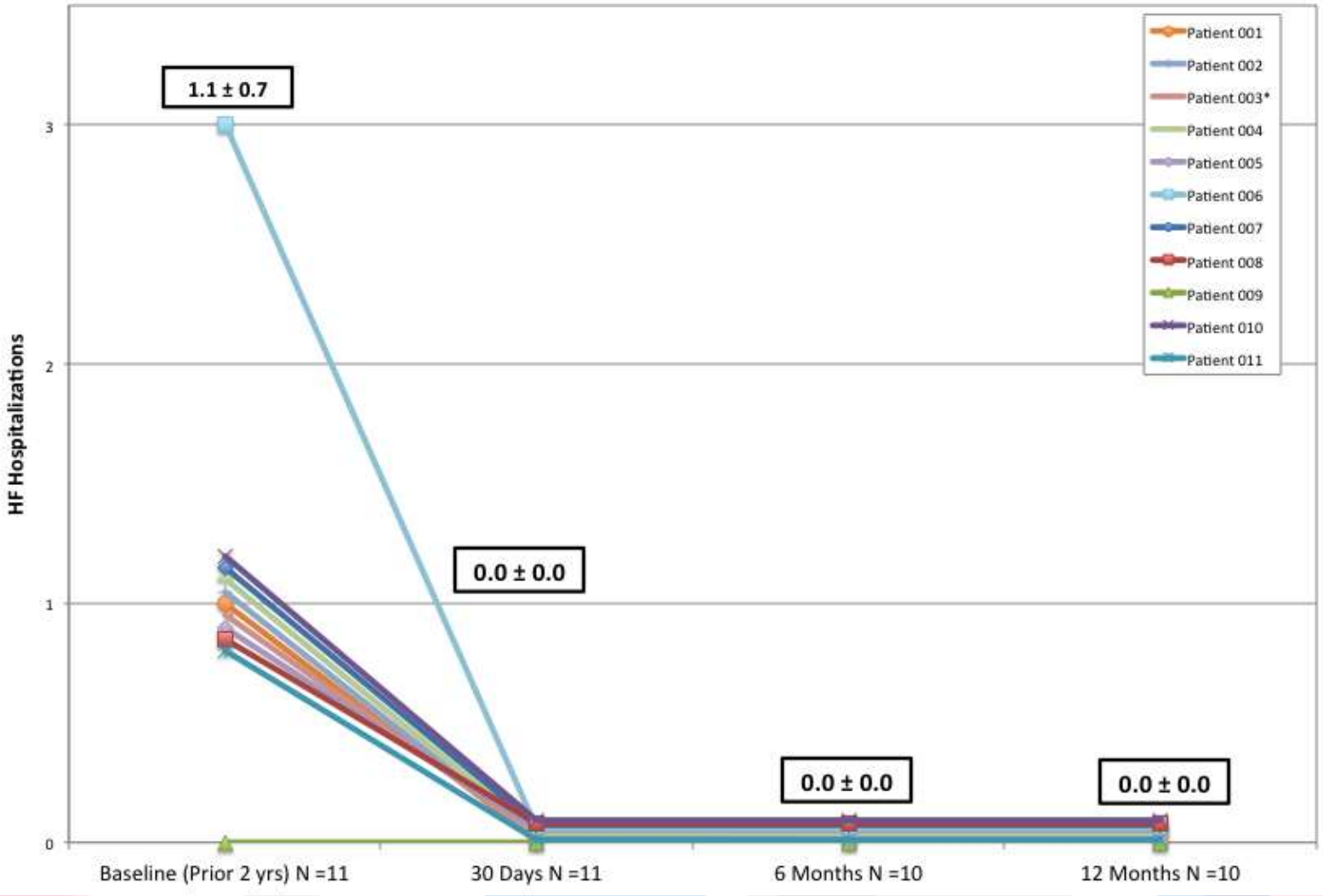


Left Ventricle (LVEDV) Improved

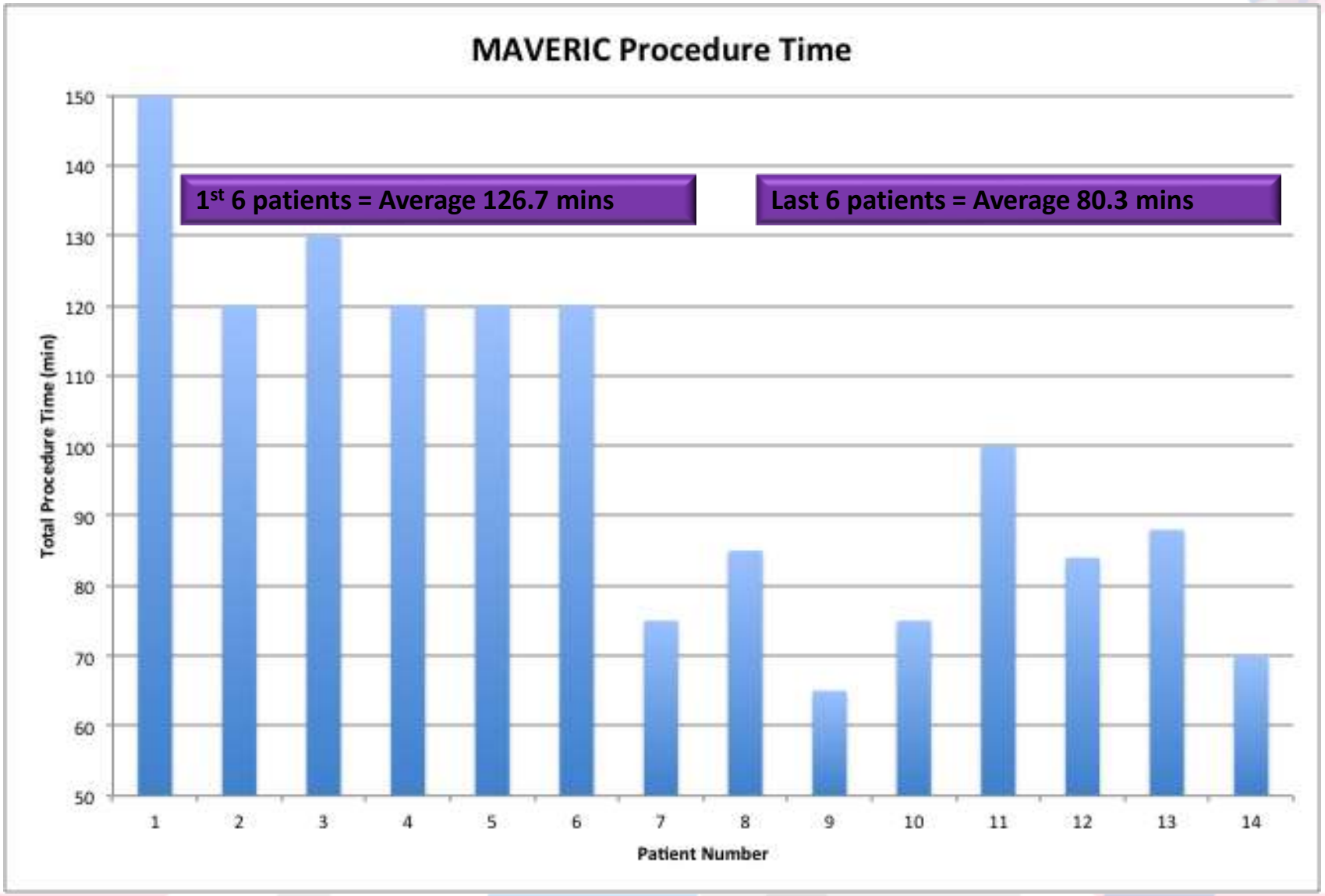


Heart Failure Hospitalizations

No Heart Failure Hospitalizations in 1 Year Follow-up Period



Procedure Learning Curve



MAVERIC Program Summary

- Clinical Feasibility with the MVRx Arto System Established
  - Quick Learning Curve
  - Safe, Reliable, and Repeatable procedure
  - Strong and Durable Efficacy
- Long term data suggests clinical efficacy and safety maintained at 1 year FU
- Phase II Multi-centre study underway