MAVERIC: 6-Month Outcomes of Transcatheter MV Repair in Patients With Severe Secondary Mitral Regurgitation

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Potential conflicts of interest

Speaker's name: Stephen Worthley

❑ ***I have no potential conflict of interest to report***

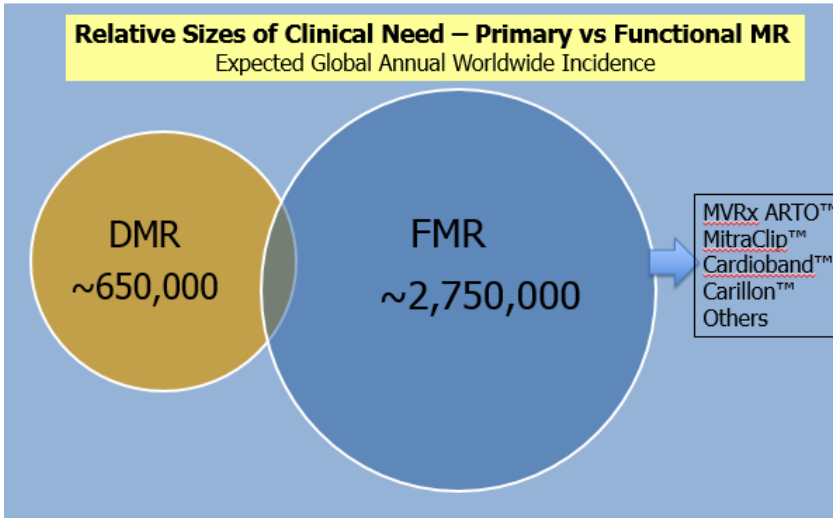
X I have the following potential conflict(s) of interest to report:

Type of affiliation / financial interest:

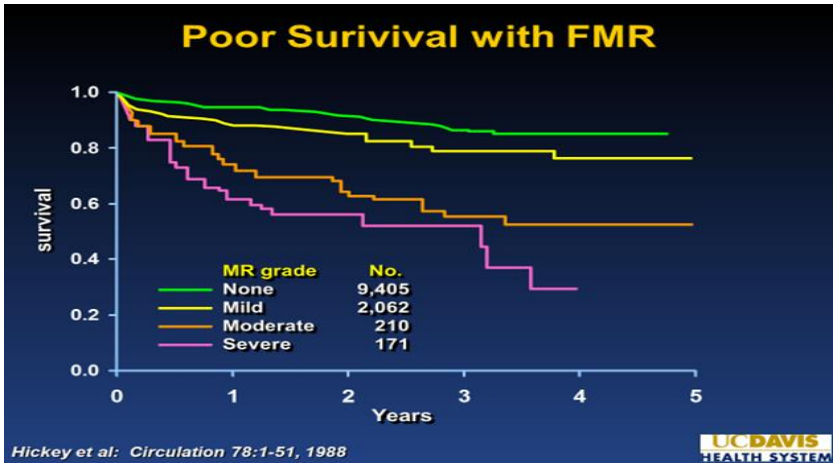
- ***Receipt of honoraria or consultation fees*** ***Medtronic and Abbott***

Functional Mitral Regurgitation: The Clinical Problem

- **The global annual incidence of FMR is estimated to be >2,500,000**



- **Left untreated, the 3 year survival rate for those with mod/severe MR is ~ 55%**



Current Therapies Do Not Adequately Address Treatment for FMR

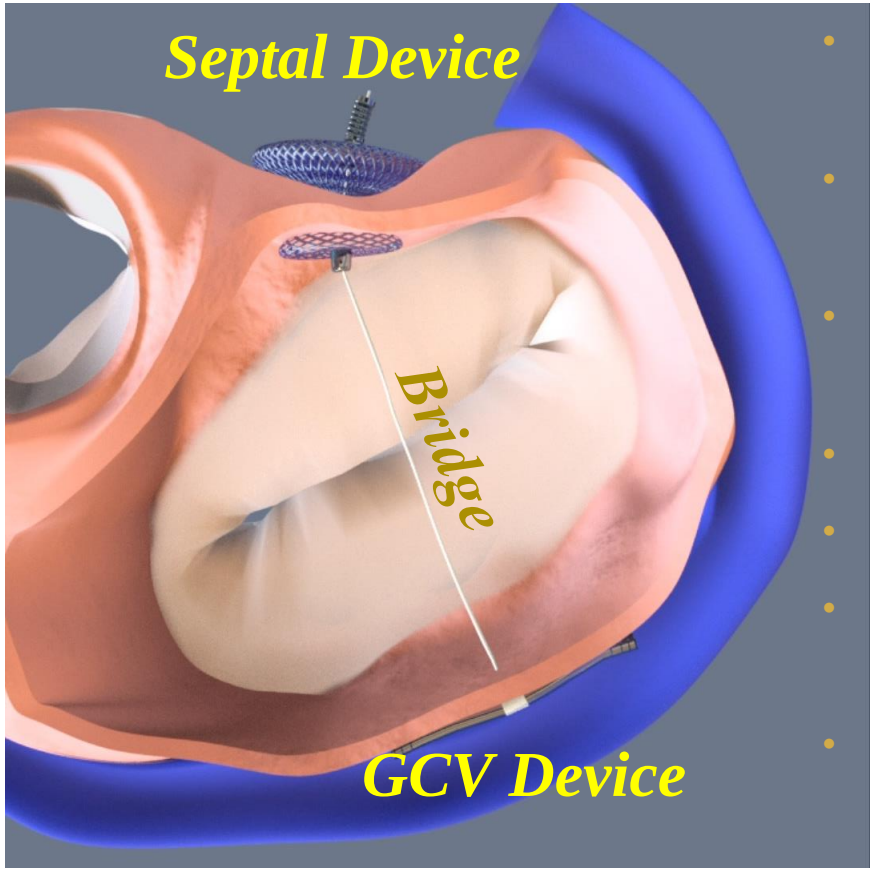
- **Guideline Directed Medical Therapy**

- **Mitral Valve Surgery**
  - may be reasonable for those undergoing CABG (IIb/B)
  - Considered for severely symptomatic: NYHA III/IV IIb/B
  - MV repair considered with moderate MR for those undergoing other cardiac surgery (IIb/C)

- **Reality for Stand Alone FMR:**

  Duke Database: Only 11% of patients with isolated FMR are offered surgery and only 6% when LV function is between 20 and 30.

The ARTO™ System
Transcatheter Annular Reduction Therapy (TART)



Immediate and Direct A-P Diameter Shortening to Treat FMR

No compression of LCX or other coronary artery

Venous Based Delivery **Under Fluoroscopic Imaging**

Acutely **Reversible or Removable**

12 Fr Delivery System

No residual ASD, no trauma to native MV leaflets or chords

Ample room for *future* septal access

Procedure generally takes <90 mins

MAVERIC STUDY DESIGN

Multi-Centre, Single Arm 45 Patient Safety and Efficacy Study

30 day, 6 month, 1, 2 and 3 year clinic/echo visit follow-up

Primary Outcome Measures:

- **Safety: Major Adverse Events at 30 days**
- **Efficacy: Mitral Regurgitation Grade at 30 days**

Secondary Outcome Measures

- **NYHA Class**
- **HF Hospitalization**
- **Device success measures**

Major Inclusion Criteria:

- **MR Grade ≥ 2+**
- **NYHA Class II-IV**
- **Optimized medical therapy**

Major Exclusion Criteria:

- **Significant structural abnormality of the mitral valve**
- **Known need for any cardiac surgery**
- **Life expectancy <1 year**

Echo Core Lab: CERC

Study Mgmt: CERC

All Events CEC Adjudicated

MAVERIC Clinical Sites

MAVERIC Currently approved on 4 continents and 7 countries

Participating Centres/Investigators:

St Andrews, Adelaide, AU – S Worthley
Pauls Stradins, Riga, LV – A Erglis
St Thomas', London, UK – S Redwood
Brighton & Sussex, Brighton, UK – D Hildick-Smith
Welsey Hospital, Brisbane, AU – T Rafter
HeartCare Victoria, Melbourne, AU -M Horrigan
HeartCare W AU, Perth, AU - A Wheelan
San Donato, Milan, IT – F DeMarco
UC Davis, Sacramento, USA –R Low
Univ of Pisa, Pisa, IT – A Petronio
San Raffaele, Milan, IT – A Colombo
HPCG, Massy, FR – P Garot
Univ of Catania, Catania, IT - C Tamburino
Sunninghill Hosp, J'burg, SA - F Hellig
Bristol Heart Instit, Bristol, UK – M Turner

Baseline Characteristics

Characteristic	All Patients (N=45)
Age (mean, std)	69.6 ± 12.4
Male Gender (%)	60.0
STS Score (mortality)	3.8 ± 3.4
HF Hospitalizations Prior 2 Years (mean,std)	0.7 ± 0.8
LVEF %	40.4 ± 9.0
Hypertension (%)	46.7
Prior MI (%)	37.8
Previous PCI (%)	33.3
Previous CABG (%)	13.3
Atrial Fibrillation (%)	44.4
Mod/Severe Renal Insuff(%)	55.8
COPD (%)	21.4
Mod/Severe Pulm HTN (%)	47.7

30 day Safety Outcomes- Reduced MR, Safe and 100% Device Success

Primary Safety and Technical	N=45 n(%)
Safety Composite*	**2(4.4)**
Death, Stroke, MI	**0**
Device Technical Success (MVARC)	**45 (100)**

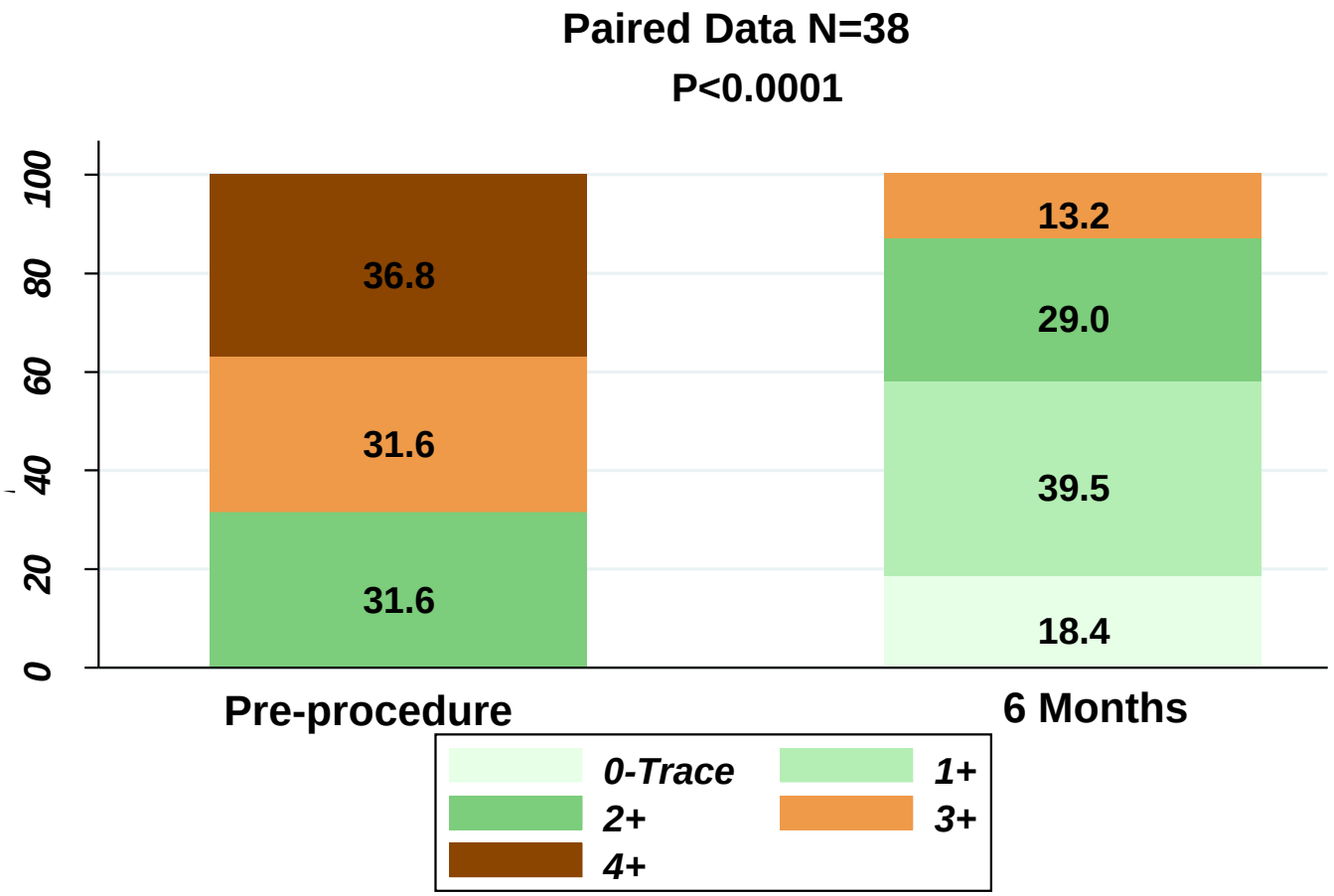
Death, Stroke, MI, cardiac tamponade, device related cardiac surgery, renal failure

Safety at 6 months

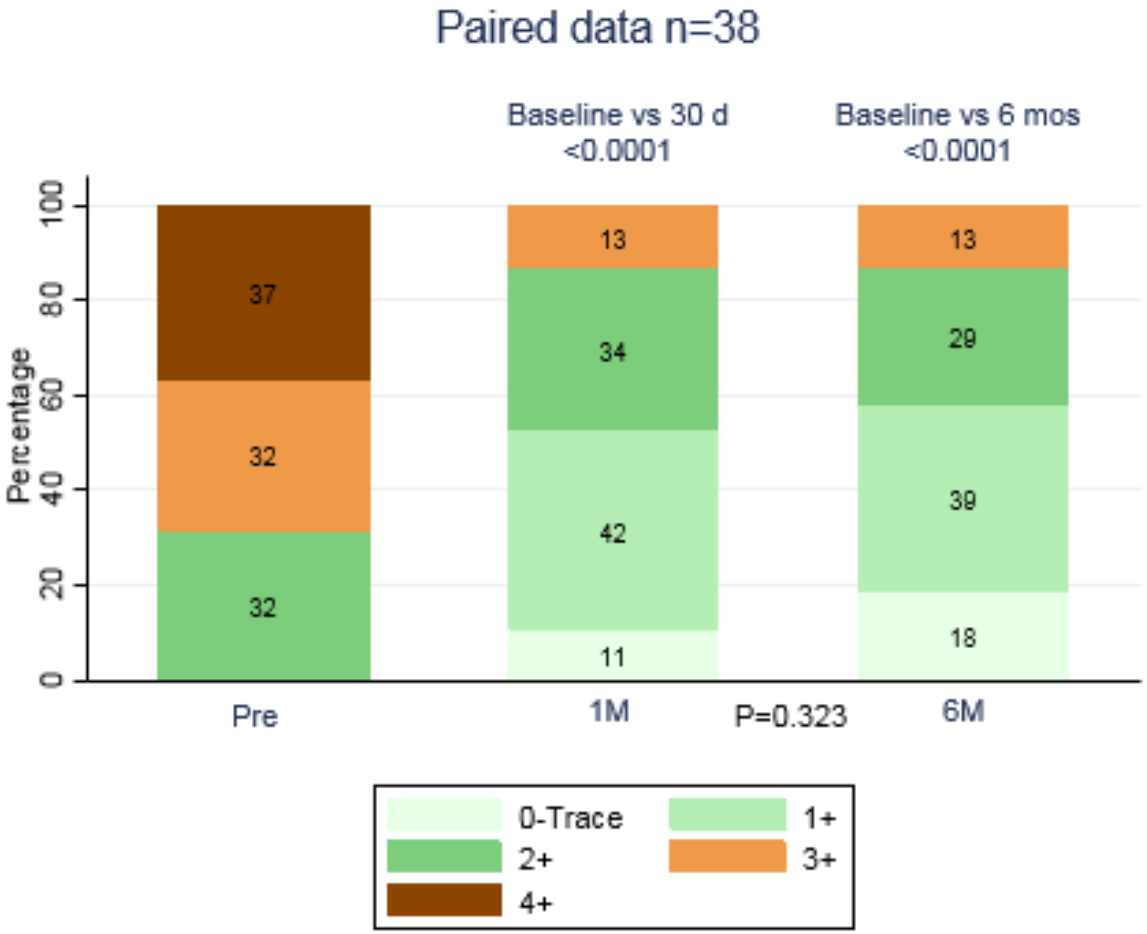
CEC Adjudicated Event	30 days N=45 N(%)	6 months N=42 N(%)
Safety Composite Endpoint at 6 months*	2(4.4)	7(16.0)
Death	0	3(7.2)
Cardiovasc	0	3(7.2)
Non-cardiovasc	0	0
Stroke	0	1(2.3)
Myocardial Infarction	0	0
Mitral Operation/Intervention	0	1(2.3)
Cardiac Tamponade	1(2.2)	1(2.2)
Renal Failure	1(2.2)	3(6.9)

***Death, Stroke, MI, cardiac tamponade, device related cardiac surgery, renal failure**

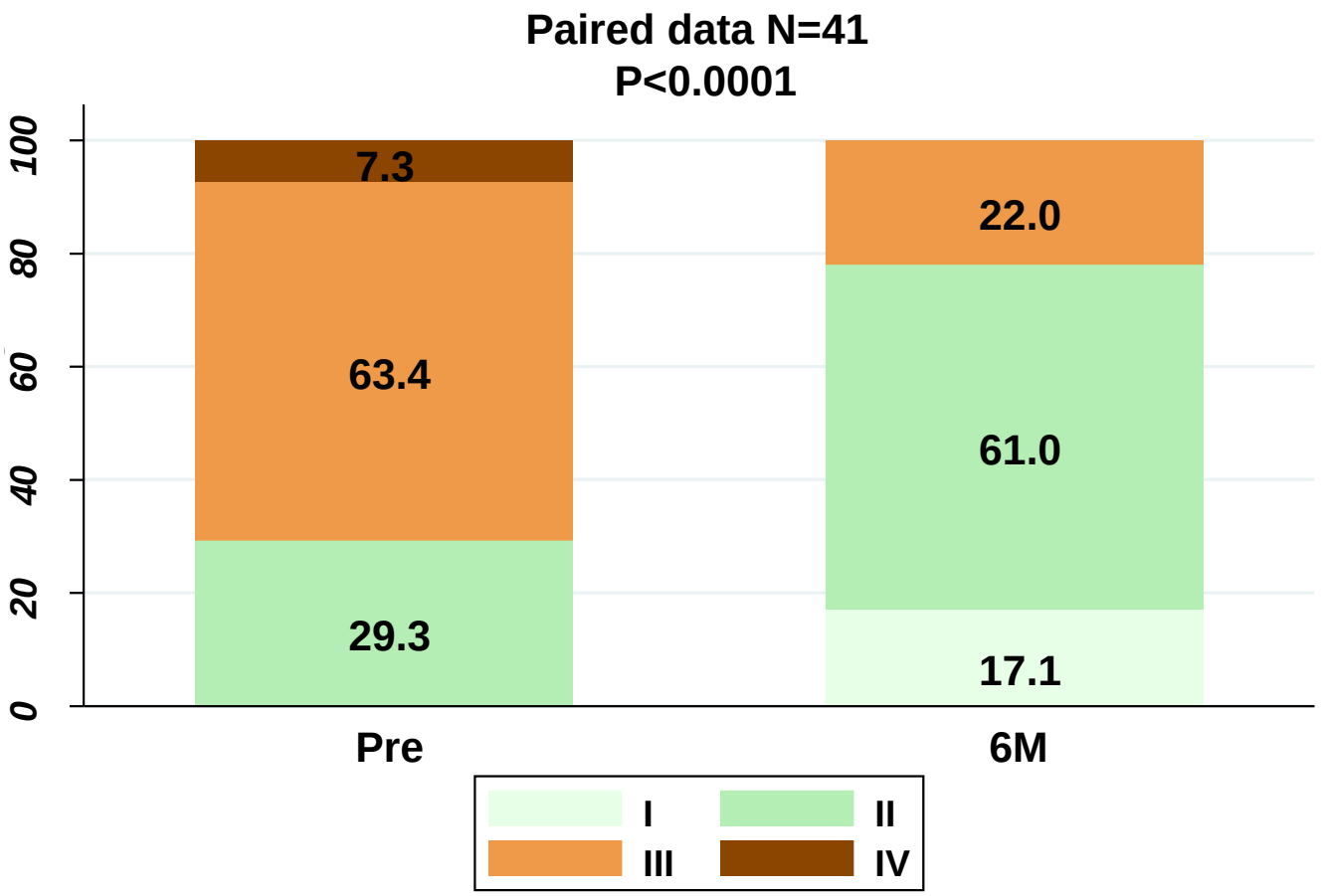
MR Grade Reduction at 6 months



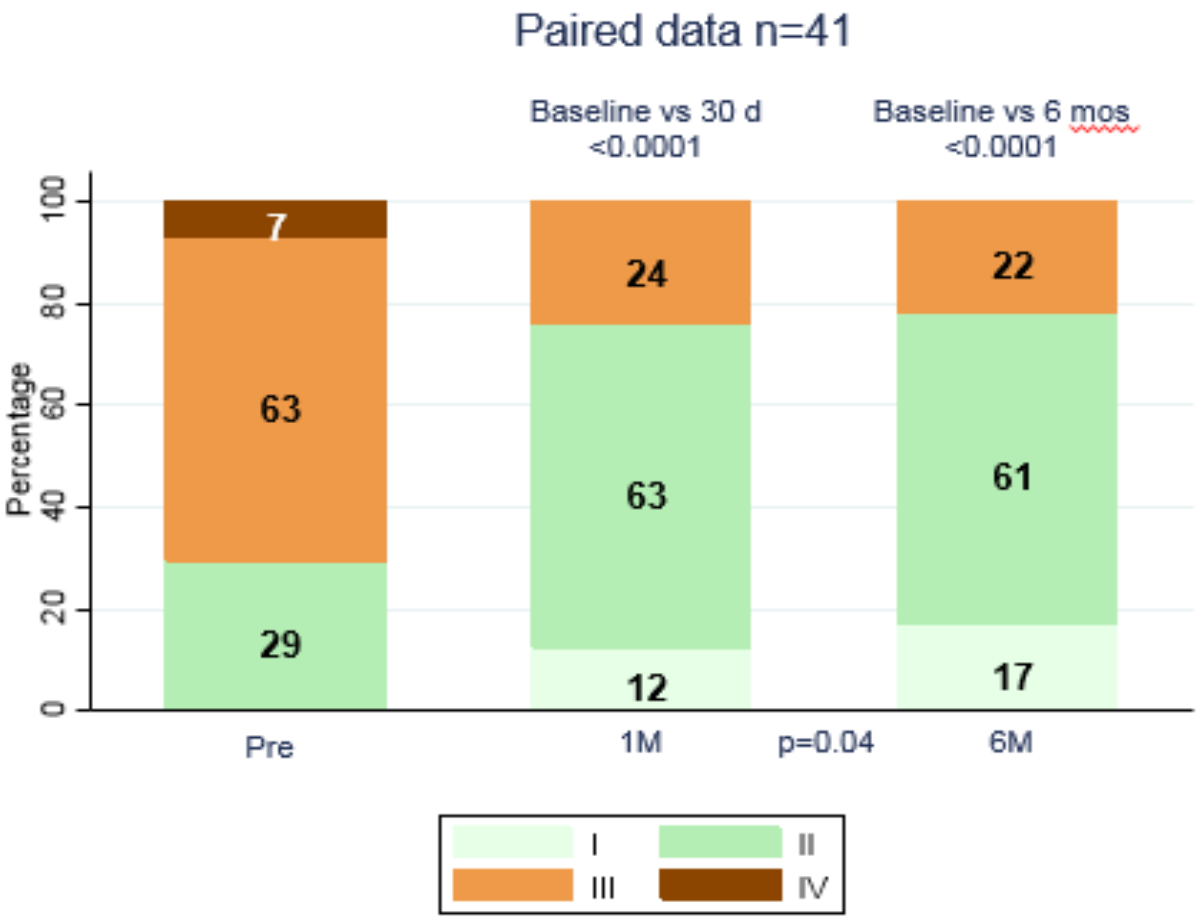
MR Reduction at 30 days maintained at 6 months



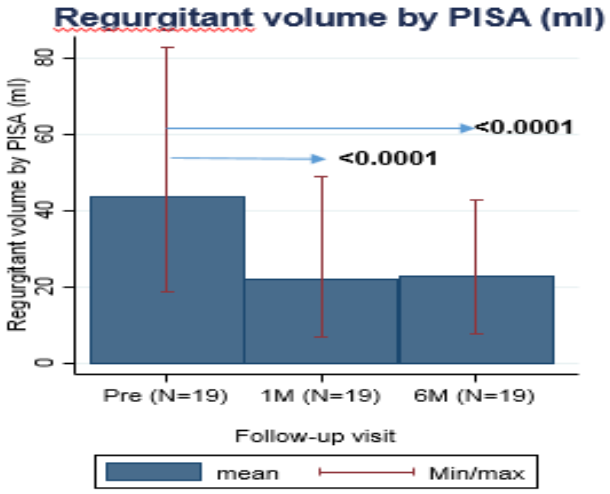
NYHA Class Improvement at 6 months

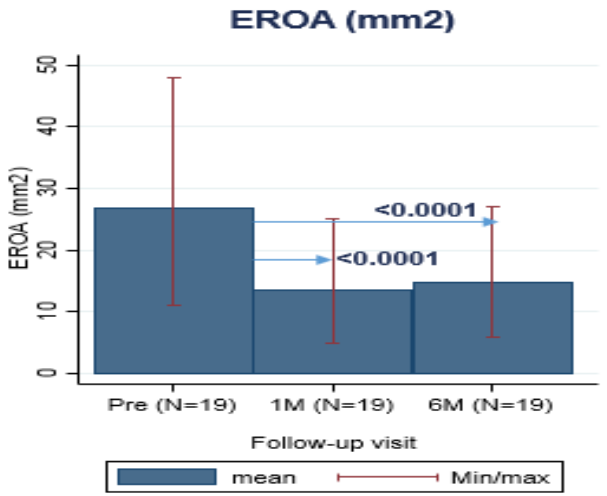


NYHA improvement at 30 days maintained at 6 months

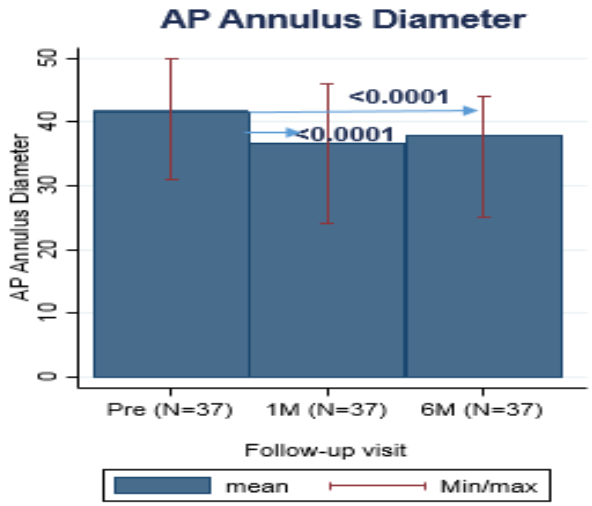


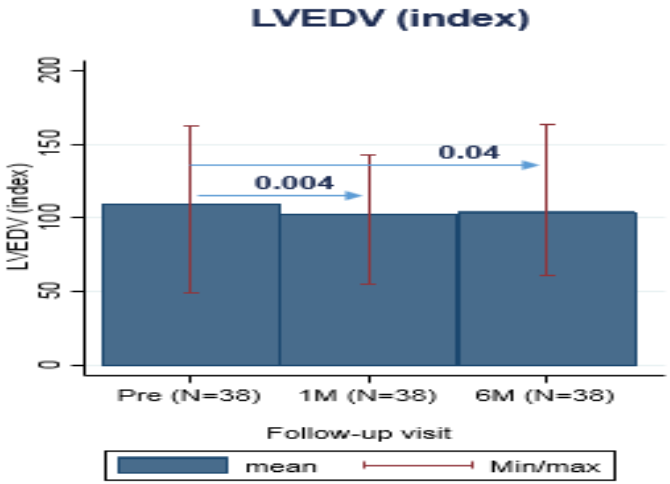
MAVERIC: Reduced Volumes and Indices at 6 months





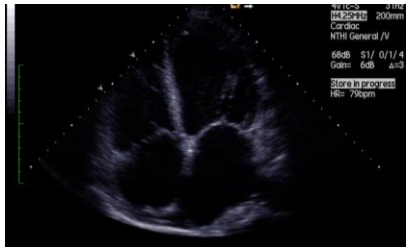
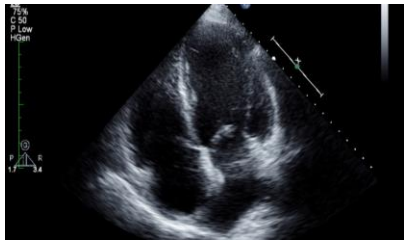
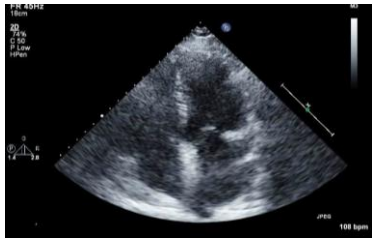
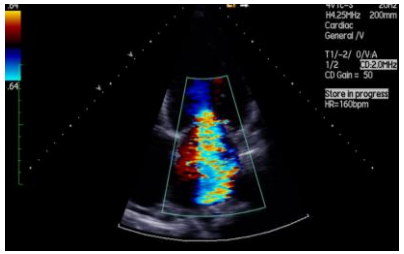
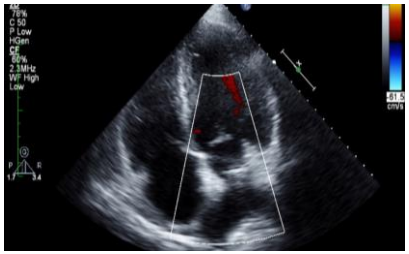
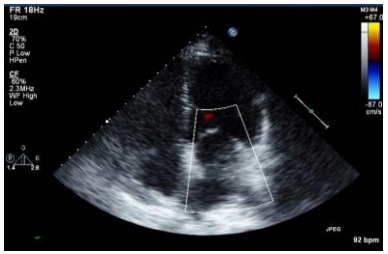
Paired data





MAVERIC ARTO –Transcatheter Annular Reduction Therapy (TART)

Baseline **30 day** **3 years**

RVol/A-P Dia 74 ml/48 mm ***RVol/A-P Dia 20 ml/37mm*** ***RVol/A-P Dia 4 ml/38 mm***

MAVERIC CONCLUSIONS

- MR Grade, AP Diameter, NYHA Class and RVols after the ARTO procedure were all significantly reduced at 6 months and improvements evident and maintained from 30 day outcomes

- The primary safety composite endpoint was low at 16%, as was mortality (7.2%) with no deaths attributed to the device or procedure

- Importantly, the rate of hospitalization for heart failure and heart failure or death were both low at 9.3% and 16.2% respectively

- This study demonstrates the 6 month efficacy and safety of the ARTO System for the treatment of FMR