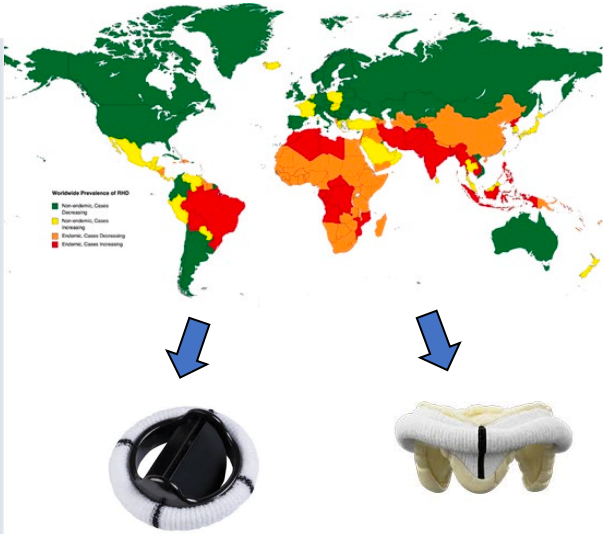
Sustained Performance: One-Year Outcomes of the TRIA™ Mitral Valve

Background

- Mitral valve disease, including RHD, affects more than 24 million people globally[1]
- Mechanical valves are challenging to manage in childbearing women
- Bioprosthetic valves suffer from poor durability in younger patients
- Synthetic polymer leaflet materials may be a promising alternative to tissue and mechanical valves

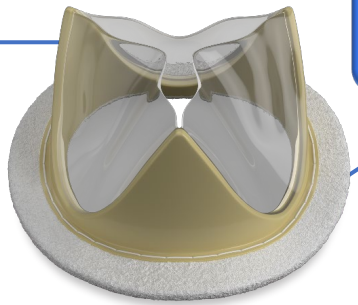


[1]Coffey et al. Nat Rev Cardiol. 2021; 18:853-864.

Objective

To report 1-year safety and performance of a novel polymeric leaflet TRIA™ Mitral Valve in patients undergoing surgical mitral valve replacement for symptomatic moderate-to-severe or severe mitral valve disease

TRIA™ Mitral Valve with LifePolymer™



- Siloxane + PU
- Biocompatible and designed to resist calcification
- Three flexible polymer leaflets are dip-cast as a single piece external to frame (unibody)

Site Map and Study Oversight

- **Clinical Evaluation**
  - 67 patients
  - 8 centers across India
- **Prospective, single-arm, multicenter study**
- **Trial Oversight**
  - Central Screening Committee
  - Echocardiography Core Laboratory
  - CT Core Laboratory
  - Clinical Events Committee (CEC)
  - Data Safety Monitoring Board (DSMB)

Inclusion & Exclusion Criteria

Inclusion Criteria

- Age ≥18 years
- Candidate for mitral valve replacement with bypass
- Mod-severe/severe mitral valve disease
- No contraindication for anticoagulation
- Ability to comply with the protocol

Selected Exclusion Criteria

- Requires other valve replacement
- Requires concomitant CV procedures (except LAAL)
- Active endocarditis or myocarditis
- LVEF <20%
- Aortic aneurysm >4.5 cm
- Life expectancy <12 months
- Serum creatinine ≥2.0 mg/dL or ESRD requiring chronic dialysis

Primary Safety & Performance Endpoints

Primary Safety

- All-cause death
  - Valve-related death
- Thromboembolic events
  - Valve thrombosis
  - Ischemic stroke
- Major bleeding
- Paravalvular leak
- Endocarditis
- SVD / NSVD
- Valve reintervention

Primary Performance

- Hemodynamic
  - Mean gradient
  - Effective orifice area (EOA)
  - Valvular regurgitation
- Functional
  - ΔNYHA from baseline to FU

Key Secondary Endpoints

- Ischemic stroke or hemorrhagic stroke
- Transient ischemic attack
- ICU LOS
- Ventilation time
- Post-operative LOS

- Kansas City Cardiomyopathy Questionnaire
- Six-Minute Walk Test

Consort Diagram

Patients Screened: 115

Excluded: 48
Most common reasons:
- Neo-LVOT <200 mm^2,
- Need for non-LAAC concomitant procedure,
- poor imaging quality

Total Implanted: 67

1 in-hospital death
(procedural but not valve-related)

Discharge
Clinical FU: 66
ECHO FU: 66

1 withdrawal

Day 30
Clinical FU: 65
ECHO FU: 65

5 deaths
(0 valve-related)

Day 365
Clinical FU: 60
ECHO FU: 60
CT FU: 58

Percent FU Available

Discharge
Clinical FU: 100%
ECHO FU: 100%

Day 30
Clinical FU: 98.5%
ECHO FU: 98.5%

Day 365
Clinical FU: 98.5%
ECHO FU: 98.4%
CT FU: 95.1%

Baseline Characteristics

	N = 67
Age (years)	**42 ± 12 [19-67]**
Sex, female **Women of childbearing age**	**64%** **48%**
STS Risk Score (%)	**1.4 ± 0.8**
Prior valve surgery or procedure	7%
Government/Public Hospital	**49%**
Rheumatic heart disease	**73%**
Diabetes mellitus	2%
Atrial fibrillation	**42%**
On chronic anticoagulation	19%
NYHA Class III or IV	**54%**

Data presented as mean ± SD [range] or %

Baseline Echo Characteristics

	N = 67
LVEF (%)	**63 ± 11**
Mitral regurgitation (MR)	12%
Mitral stenosis (MS)	12%
Mixed MR/MS	**76%**
Mitral mean gradient (mmHg) • Mean gradient >10	9.7 ± 5.6 39%
EOA (cm^2)	0.9 ± 0.5
PASP (mmHg)	36 ± 15

Data presented as mean ± SD or %

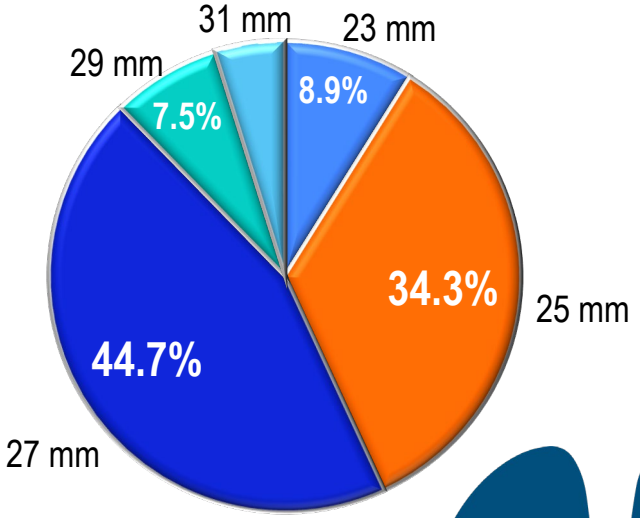
Intraoperative Surgical Metrics and Hospital Course

Procedural Details

	N = 67
Complete sternotomy	100%
Total procedure time (min)	205 ± 54
Bypass (min)	93 ± 24
Cross clamp (min)	63 ± 26
Concomitant LAA closure (suture)	100%
ICU time (days)	5 ± 3
Length of stay (days)	9 ± 4

Data presented as mean ± SD or %

Valve Sizing Distribution



Anticoagulation

Anticoagulation Therapy:

- Patients started on VKA + ASA 75 mg postoperatively
- Target INR: 2.0-3.0
- All patients remained on AC therapy for 12 months post-procedure

Primary Safety: Clinical Outcomes

	30-Day*	1-Year†
All-cause mortality‡	1 (1.5%)	6 (9.1%)
Valve-related mortality	0 (0%)	0 (0%)
Valve reintervention/reoperation	0 (0%)	0 (0%)
Structural valve deterioration (SVD)	0 (0%)	0 (0%)
Non-structural valve deterioration (NSVD)	1 (1.5%)	1 (1.6%)
Endocarditis	0 (0%)	0 (0%)

*absolute frequency (%); †number of events (KM rate)
‡ Causes of death = Intraop surgical complication, unknown x 3, aspiration, sepsis

***Note**: 5 deaths occurred >30 d with echo demonstrating normal valve function in 4/5 pts*

Primary Safety: Thromboembolic Events

	30-Day*	1-Year†
Thromboembolism	1 (1.5%)	5 (7.5%)
Ischemic stroke‡	1 (1.5%)	3 (4.9%)
Hemorrhagic stroke	0 (0%)	0 (0%)
Transient ischemic attack (TIA)	0 (0%)	0 (0%)
Valve thrombosis	0 (0%)	2 (4.3%)

* absolute frequency (%); † number of events (KM rate)
‡ all strokes were non-disabling

Thromboembolic Event Details

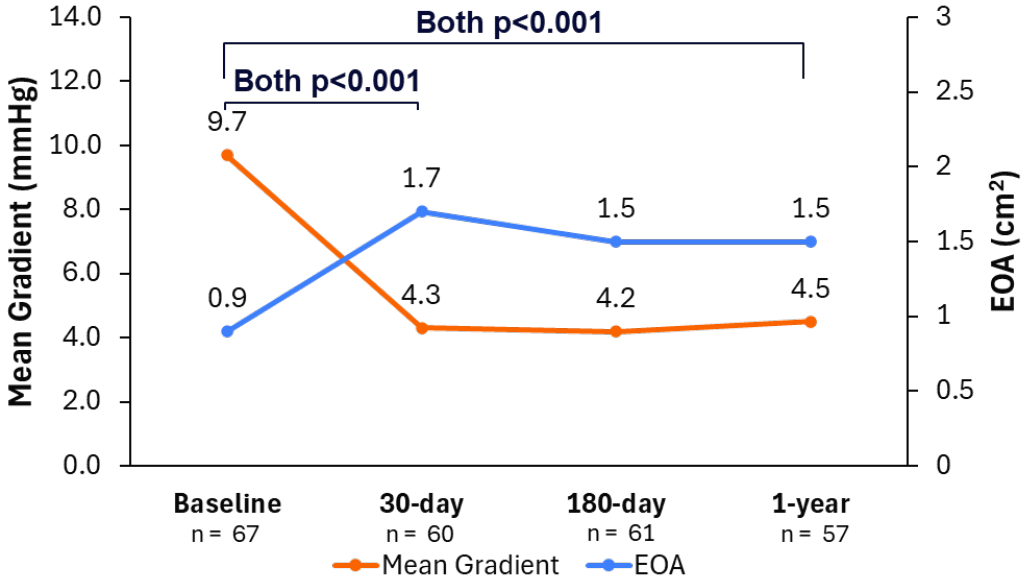
POD	Event Type	Event Details
24	Stroke	MRI+; Echo: **valve functioning well, no thrombus**; Tx thrombolysis; Resolved (LOS 6 days).
93	Valve Thrombosis	90-day follow-up Echo: ↑ gradient, **thrombus on ventricular side**. Tx thrombolysis; Resolved (LOS 8 days)
241	Stroke	CT+; Echo: valve in-situ functioning well, **LV apical clot** (1.5*0.9 cm). Tx antiplatelets, VKA, supportive tx; Resolved (LOS 2 days).
319	Stroke	MRI+; Echo: valve w/ mild MR, **layered clot on the roof of LA**; Tx IV Heparin, VKA dose adjusted; Resolved (LOS 5 days).
360	Valve Thrombosis	1-yr follow-up Echo: **thickening of valve leaflets suggestive of thrombus**. Tx with thrombolysis; Resolved (LOS 3 days)

Other Events

	30-Day*	1-Year†	Probability event-free at 1 year*
All bleeding			
Major bleeding	1 (1.5%)	1 (1.5%)	98.5%
Hemolysis	0 (0%)	0 (0%)	100%
Kidney failure	0 (0%)	0 (0%)	100%
Newly diagnosed AF or other arrhythmias	0 (0%)	1 (1.6%)	98.4%
New pacemaker	0 (0%)	0 (0%)	100%
New or worsening heart failure	1 (1.5%)	1 (1.6%)	98.4%

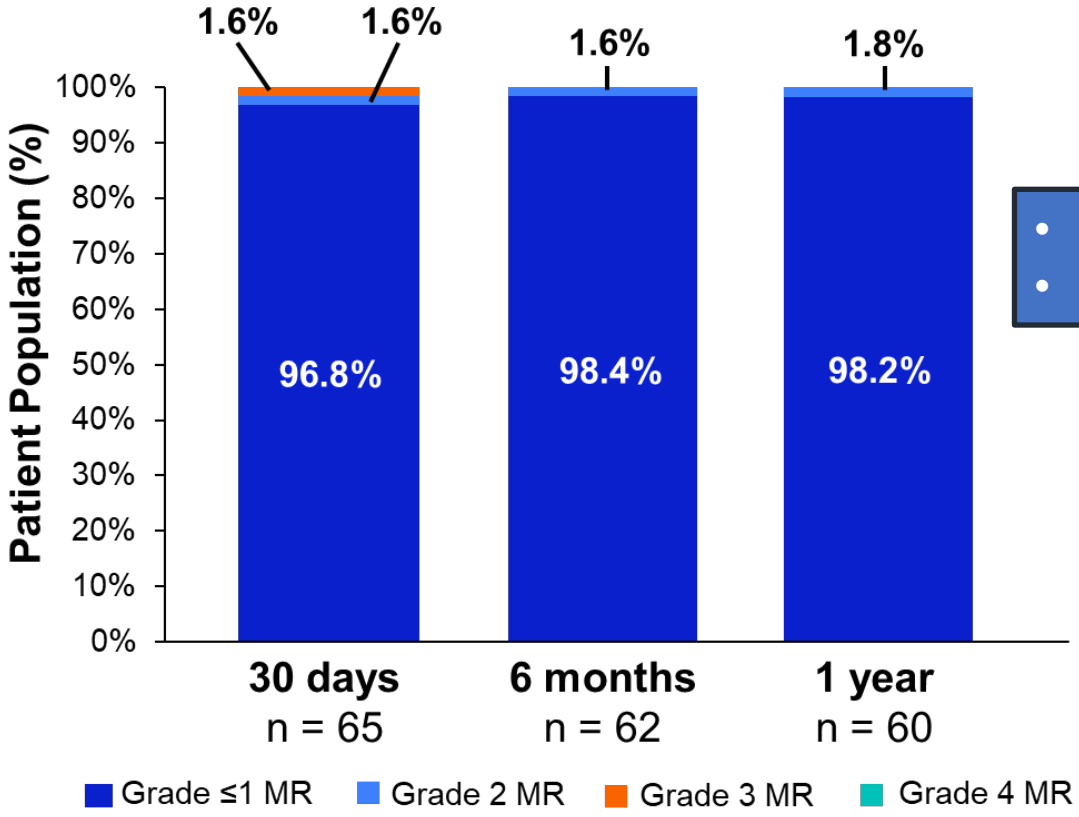
*absolute frequency (%); † number of events (KM rate)

Echocardiography: EOA and Mean Gradient



Graph shows all available echo data at each timepoint, but p-value is calculated using paired echos only

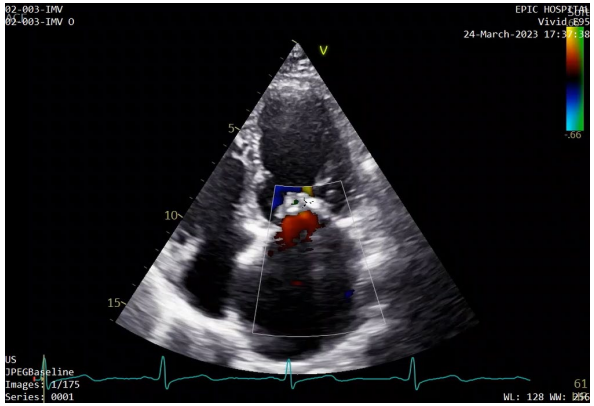
Residual MR



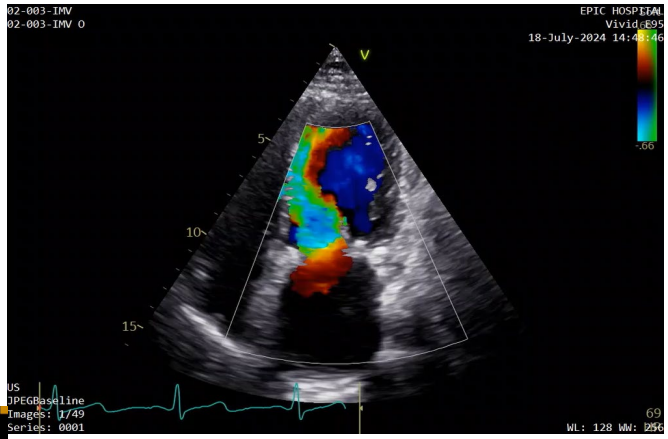
- No Severe PVL
- 1 Moderate PVL

Sample Patient

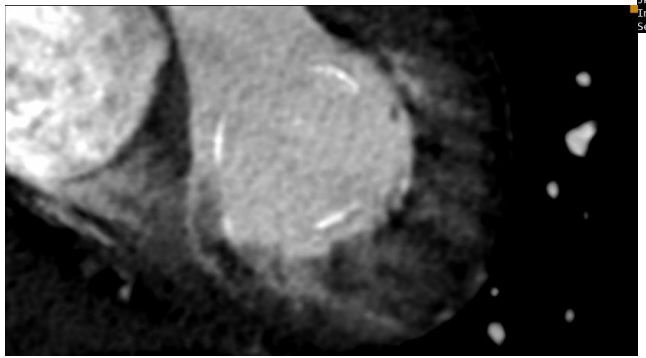
Baseline



1 Year Echo

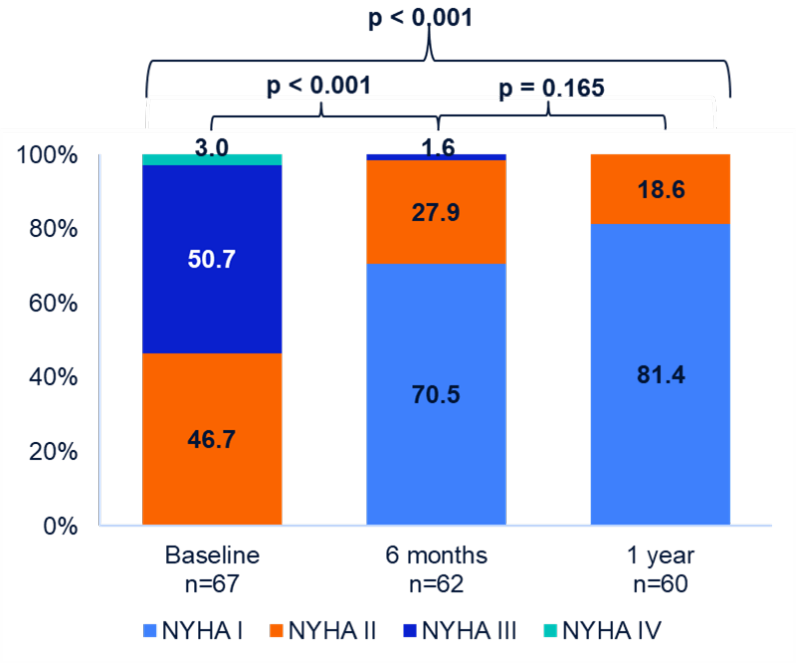


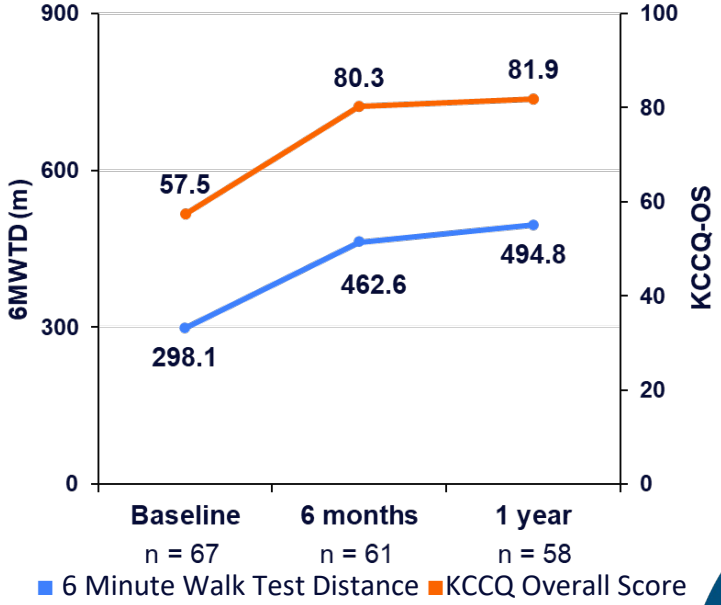
1 Year CT



No calcification or gross valve thrombus was seen on any patient at 1 year (n=58)

Functional and Health Status Outcomes





Conclusions

In young patients with symptomatic moderate to severe mitral valve stenosis and/or regurgitation, the TRIA Polymer Surgical Mitral Valve 1-year follow-up demonstrated:

- Acceptable safety profile, with thromboembolic events complicated by a developing country, rheumatic disease, and suboptimal anticoagulation
- Stable 1-year hemodynamic valve performance
- Significant improvements in functional outcomes and health status

Further investigation to establish longer term durability and implement anticoagulation reduction protocols are necessary and are underway