

An Innovative Robotically Manufactured Polymer Valve Establishes Promising Early Clinical Results

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Disclosures

Within the prior 24 months, I have had a relevant financial relationship with a company producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients:

Nature of Financial Relationship

Consultant Fees/Honoraria
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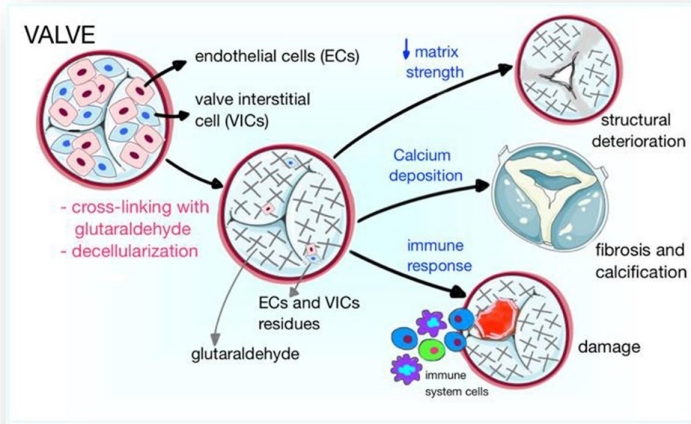
Ineligible Company

Edwards Lifesciences
Boston Scientific
Medtronic

All relevant financial relationships have been mitigated.

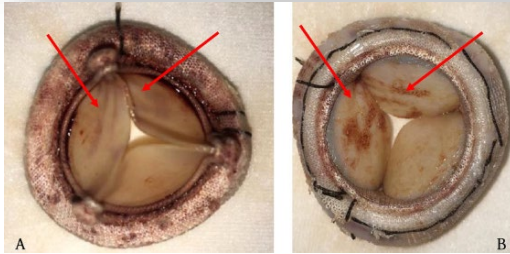
Faculty disclosure information can be found on the app

Current Tissue Valve Failure Mechanisms



Focus is on material science innovation

- Edwards RESILIA™ tissue valve
- Anteris DurAVR transcatheter valve



Typical calcification on bioprosthetic leaflets



New Polymer Formulated Specifically for Heart Valves

Limitations of Tissue



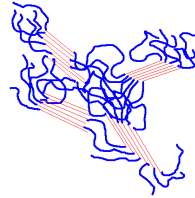
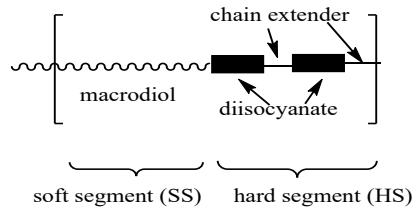
LifePolymer™ Development Criteria

- Mechanical property specifications (threshold, dynamic modulus)
- Biostability
- Creep resistance
- Blood compatibility
- Non-calcifying
- Biocompatible, non-toxic, no leachables, full spectrum ISO 10993
- Manufacturing stability, manageable supply chain



New Leaflet Designs: TRIA™ Valve + Computational Design + Robotic Manufacturing

Polyurethane

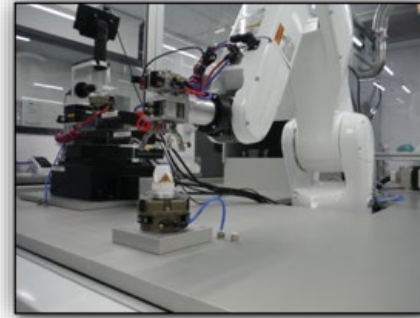
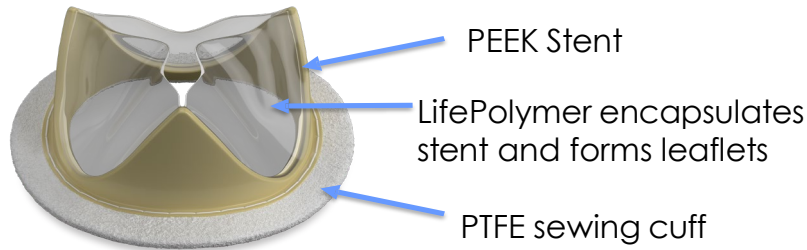


Siloxane polyurethane



Similar structure used in pacing leads for over 15 years

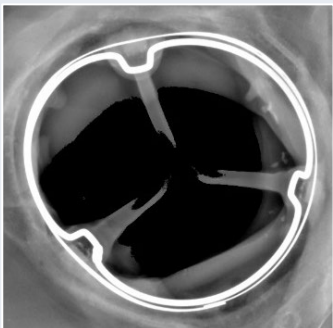
Tria valve



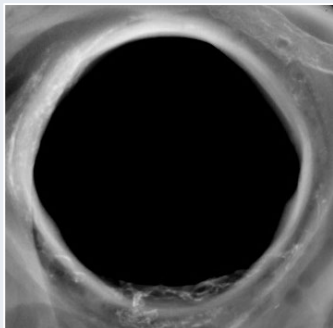
Chronic Sheep Study Results: No Calcification on TRIA™ Valves

X-ray Image

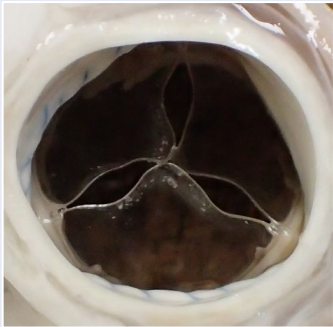
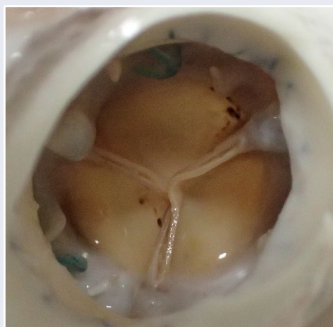
Pericardial Valve



TRIA™ Valve

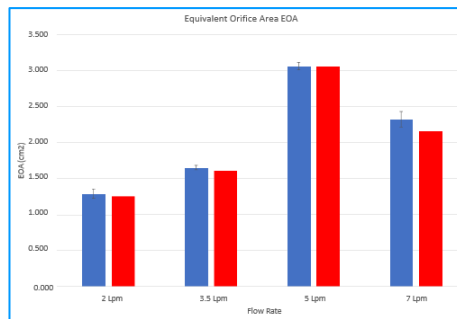


Explant Image



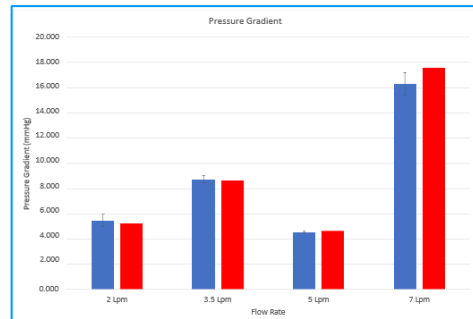
Pulse Duplicator Hydrodynamics

EFFECTIVE ORIFICE AREAS



23mm TRIA™ v. 25mm EW PERIMOUNT™
EOA by Flow Rate at 200M Cycles

PRESSURE GRADIENTS



23mm TRIA™ v. 25mm EW PERIMOUNT™
Pressure Drop by Flow Rate at 200M Cycles



TRIA™ - India Surgical Mitral Valve Trial:

67 Patients, 8 Centers

Objective: to report the clinical and echocardiographic outcomes of the TRIA™ Surgical Mitral Valve at 30 days for symptomatic patients with moderate to severe mitral valve stenosis and/or regurgitation.

Inclusion Criteria:

- 18 - 80 years of age
- Candidate for mitral valve replacement due to symptomatic:
 - Moderate to severe mitral valve stenosis
 - Moderate to severe mitral valve regurgitation, or
 - Moderate to severe mixed mitral stenosis/regurgitation

Exclusion Criteria:

- LVEF < 30% or LVEDD > 7 cm
- Concomitant procedures other than LAA closure
- severe TR
- Active endocarditis or active myocarditis
- Recent MI or CVA
- End-stage renal disease requiring chronic dialysis



Patient Demographics

PATIENT DEMOGRAPHICS	N=67
Age (years)	42
BMI (Kg/m ²)	22.7
BSA (cm ²)	1.6
NYHA Class III or IV	54%
STS Score (%)	1.4%
Cr (mg/dL)	0.97+/- 0.6
BNP (pg/mL)	760 +/- 1078
Atrial fibrillation	42%
On AC (n)	54%
Rheumatic HD	73%

- 64% were Female
- Of those, >60% = women of childbearing age



Medication Regimen

AC therapy protocol:

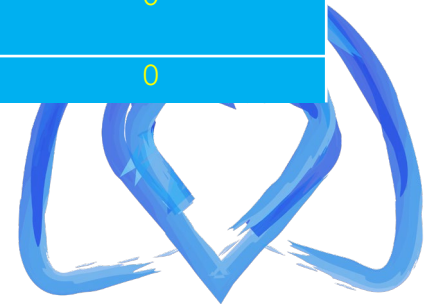
- All patients continue warfarin for first 12 months post-procedure
- Target INR: 2.0-2.5
- Patient compliance
 - Approximately 50% of patients remained in INR range of 2.0-3.0 during first 30 days
- Discontinuation protocol at 12 months: TTE, CTA, and labs followed by clinical decision-making by site PI



Safety: 30-Day Follow-Up

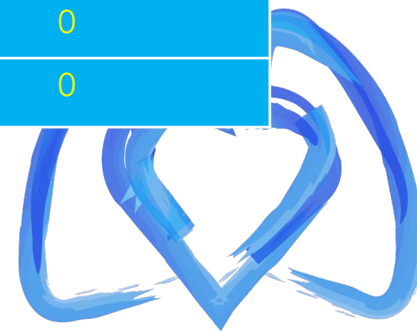
30-Day Follow-Up	TRIA Surgical Mitral (India Clinical Trial) N=67	30-Day Follow-Up	TRIA™ Surgical Mitral (India Clinical Trial) N=67
All-Cause Mortality (%)	1.4% (1)	Endocarditis	0
Valve Related Mortality	0	All Bleeding	1.4%. (1)
Valve Reintervention/Reoperation	0	Major Bleeding	1.4% (1)
Study Valve Explant	0	Hemolysis	0
Thromboembolism	0	Non-Structural Valve dysfunction	0
Ischemic Stroke	1.4% (1)	Structural Valve deterioration	0
Hemorrhagic Stroke	0	Hospital Readmission	2 (CVA, Pl. Effusion)
TIA	0	New Atrial Fibrillation	0
Valve Thrombosis	0	New Pacemaker	0

- One unrelated-to-valve death on Day 0 Post-implant



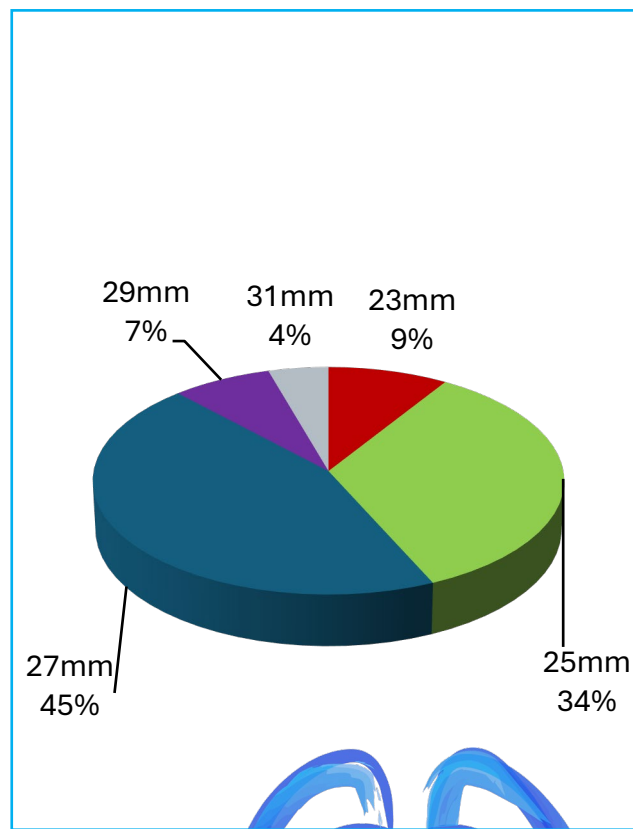
Comparison to Other Trials

30-Day Follow-Up	TRIA Surgical Mitral (India Clinical Trial) N=67	Edwards MITRIS™ (Commence Study) Heimansohn, et. al N=82	Meril Life Sciences Dafodil™ Valve Hiremath et. al N=30
All-Cause Mortality	1.4% (%)	1 (1.2%)	3 (10%)
Valve reintervention	0	0	Not Reported
Thromboembolism	1.4% (1)	2 (2.4%)	Not Reported
All Bleeding	1.4% (1)	1 (1.2%)	0
Endocarditis	0	0	Not Reported
Hemolysis	0	0	0
Valve Dysfunction	0	0	0



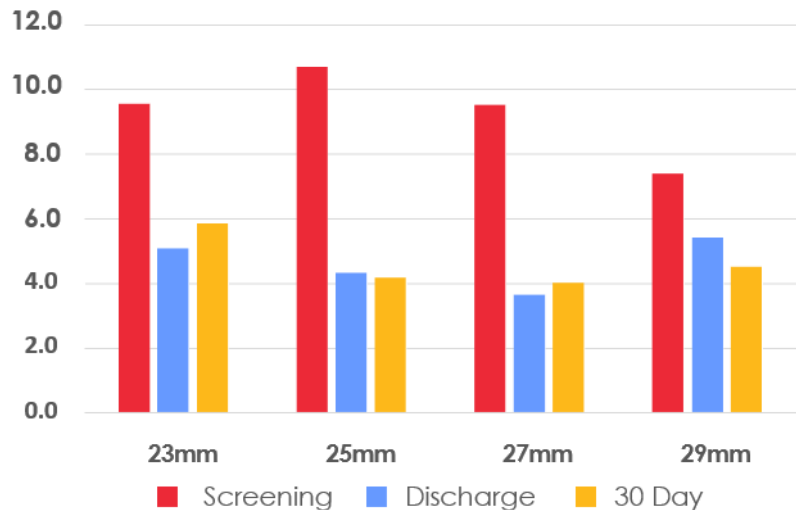
30-Day Echocardiography Results

Echo Parameter	Baseline	30-day FU
Mean Gradient (mmHg)	9.5	4.3
Peak Gradient (mmHg)	19.8	9.6
EOA (cm ²)	0.9	1.7
EOAI	0.6	1.1
Cardiac Output (l/min)	4.6	5.1
Paravalvular Leak		
None/Trace	NA	60
Mild	NA	2
Moderate	NA	1

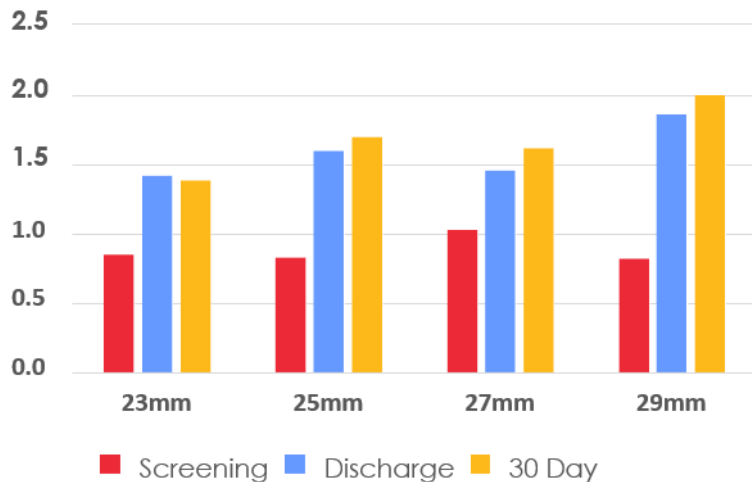


Mean Gradient and EOA by Valve Size

Mean Gradients (mmHg)



EOA (cm²)



Conclusions

- In patients with symptomatic moderate to severe mitral valve stenosis and/or regurgitation, the TRIA™ Surgical Mitral Valve 30-day follow-up demonstrated:
 - A low mortality rate and low thromboembolism rate
 - Valve function stable by echocardiography
 - Qualitative echo review shows excellent hemodynamics

This data will be submitted for approval to DCGI for TRIA™ valve approval in India later this year and serve as the basis for a US clinical trial.



A LifePolymer™ Portfolio of Valves That May Change the Treatment Paradigm for all valvular disease

- TRIA™ incorporates next-generation LifePolymer™ material and design that enables robotic manufacturing
- TRIA™ has the most human clinical experience of any polymer valve = More than 250 patient life years
- Early clinical evaluation demonstrates safety and excellent/stable hemodynamics
- Tolerance for short-term sub-therapeutic INRs and potential for no long-term AC therapy
- Promising for young patients, especially women of childbearing age



Foldax Investigators and Advisors

