Synthetic Leaflets:
Don’t Believe the Hype vs. the Future is Here

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Disclosures

- No disclosures

Novel Biopolymer Heart Valve Goals

Address longstanding conundrum of tissue valve limited durability vs. mechanical valve lifetime anticoagulation

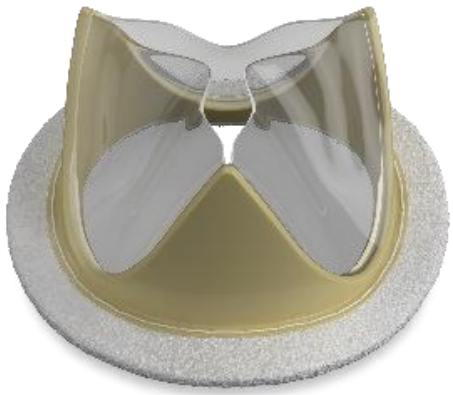
Create the future of heart valves

- Superior durability
- Superior hemodynamics
- No long-term anticoagulation
- Precision manufacturing
- Potential lifetime valve

New Biopolymer Specifically for Heart Valve Function*

Patented Silicone Poly(urethane urea) Formulation

- Formulated to exceed functional stresses of human heart valves
- Enabled computer optimized design
- Not limited by constraints & variability of animal tissue



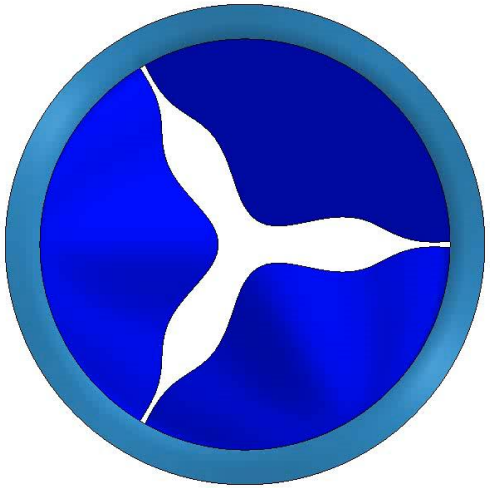
- Thinner, lighter leaflets than tissue - less inertia, lowest opening/closing resistance
- Stronger material - highly fatigue, tear resistant
- Biostable, biocompatible
- Non-calcific#

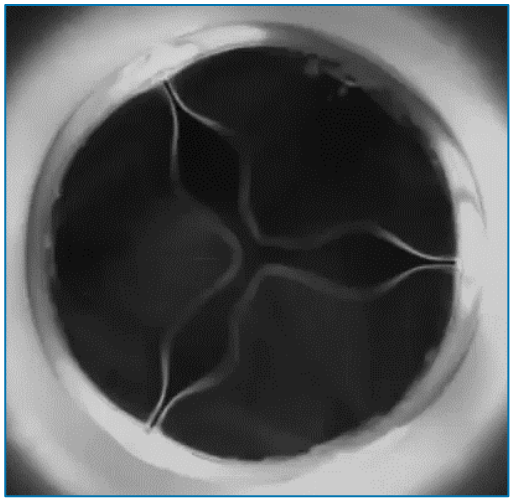
*Assessment of a Siloxane Poly(urethane-urea) Elastomer Designed for Implantable Heart Valve Leaflets. Chris Jenney, et al. Adv. NanoBiomed Res. 2020, 2000032

In sheep studies

Computer Model Design

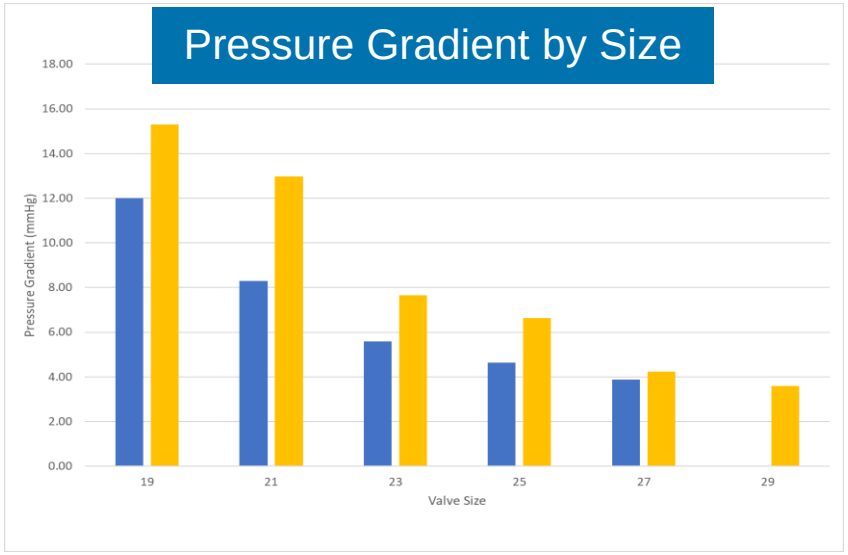
- Polymer valve can be predictably modeled
- Optimized leaflet shape to minimized leaflet stress profile
- Polymer valve eliminates performance variability associated with tissue valves
- Applicable to both surgical & transcatheter valves

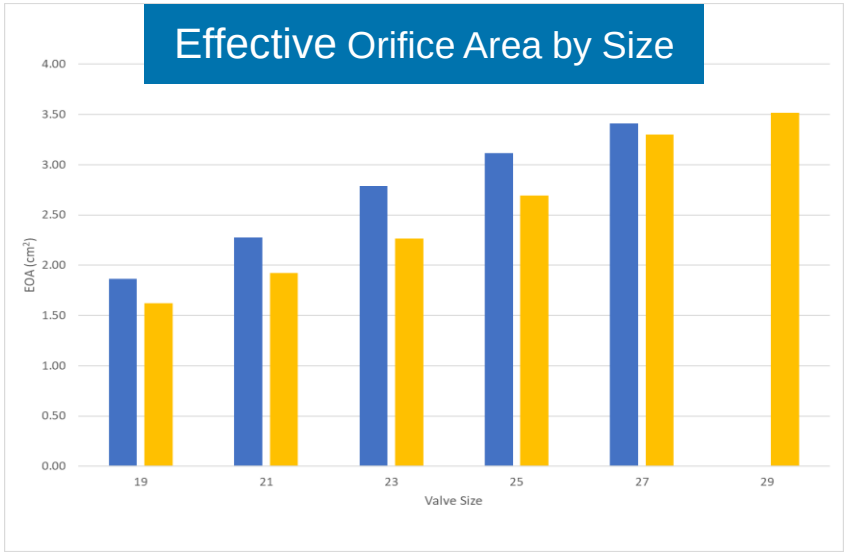




In-Vitro Hemodynamics

Superior to Pericardial Valves across size range for ΔP and EOA = one size better

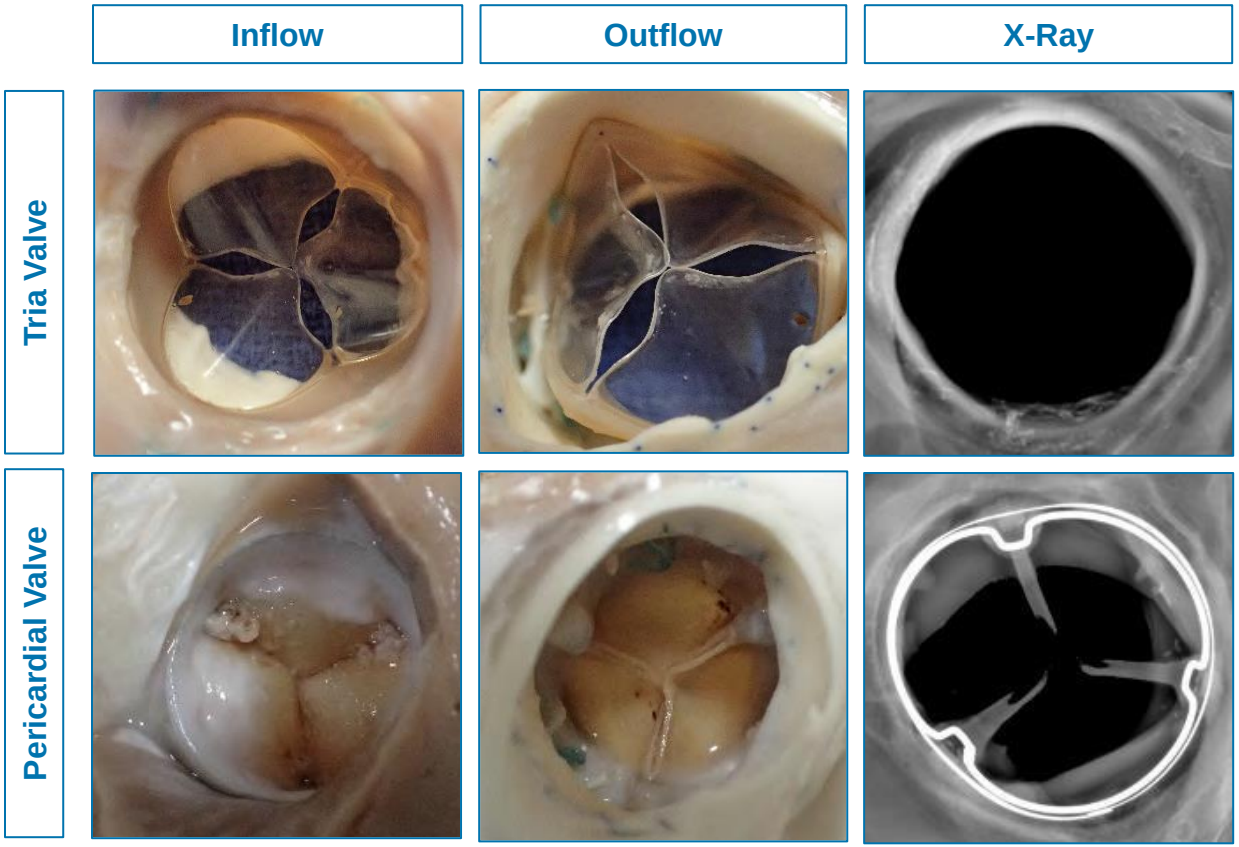




Tria LifePolymer

Edwards Perimount

In-Vivo Sheep Aortic Study



Tria valves show:

- No calcification
- No pannus formation

EFS Clinical Experience*

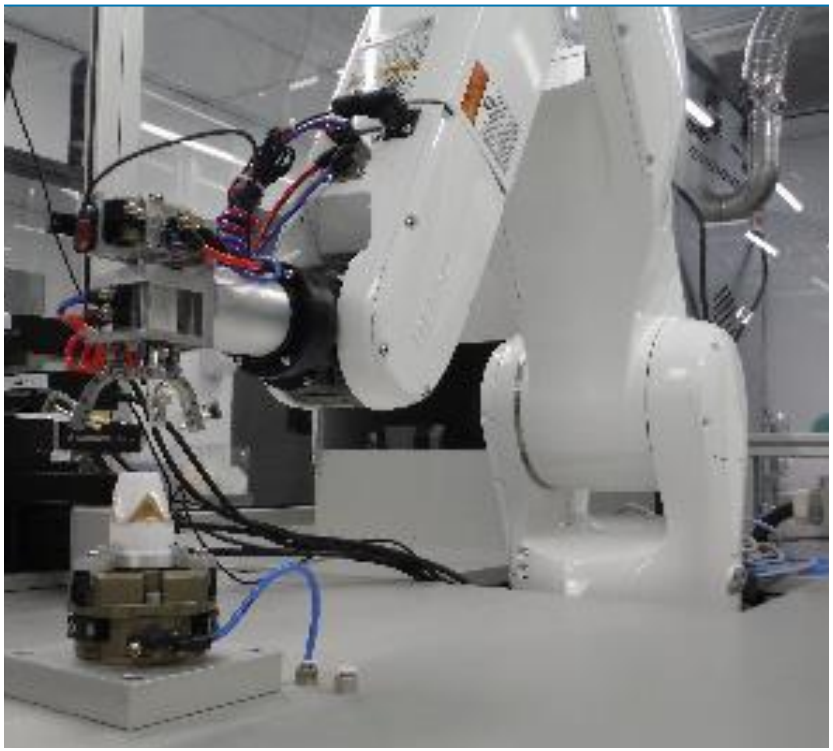
*1st polymer heart valve FDA approved for clinical study

- Currently conducting Early Feasibility Studies (EFS) for surgical aortic and mitral valves
- >30 aortic valves implanted to date
- Early results are encouraging

* 1-year publication in development

Robotic Manufacturing

- High precision
  - Single digit micron tolerances
- Consistent, repeatable process
- No human assembly
  - No COVID impact on manufacturing
- Enabled by polymer



Conclusions

- Polymer formulated for heart valve function – thinner, lighter leaflets
- Computer modeling optimizes hemodynamics & durability
- Bench & animal hemodynamics - Tria superior to pericardial valves
- Robotics ensure precise & repeatable manufacturing of each valve
- Encouraging early clinical results

1st polymer valve approved by FDA for clinical study & successfully implanted in clinical trial

THE FUTURE IS HERE!