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#

# 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 $\Delta P$ and EOA = one size better

Pressure Gradient by Size

Effective Orifice Area by Size

Tria LifePolymer  Edwards Perimount
In-Vivo Sheep Aortic Study

Tria valves show:
- No calcification
- No pannus formation
EFS Clinical Experience*

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

*1st polymer heart valve FDA approved for clinical study

* 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!