

# From Biologic Limits to Polymeric Possibilities

## *Surgical and Transcatheter Valves*

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**TCT**®

TRANSCATHETER  
CARDIOVASCULAR  
THERAPEUTICS®

# Disclosure of Relevant Financial Relationships

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

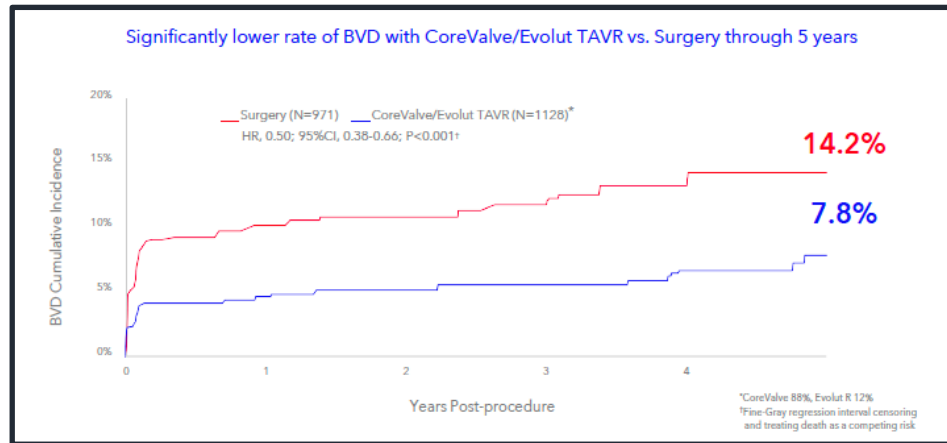
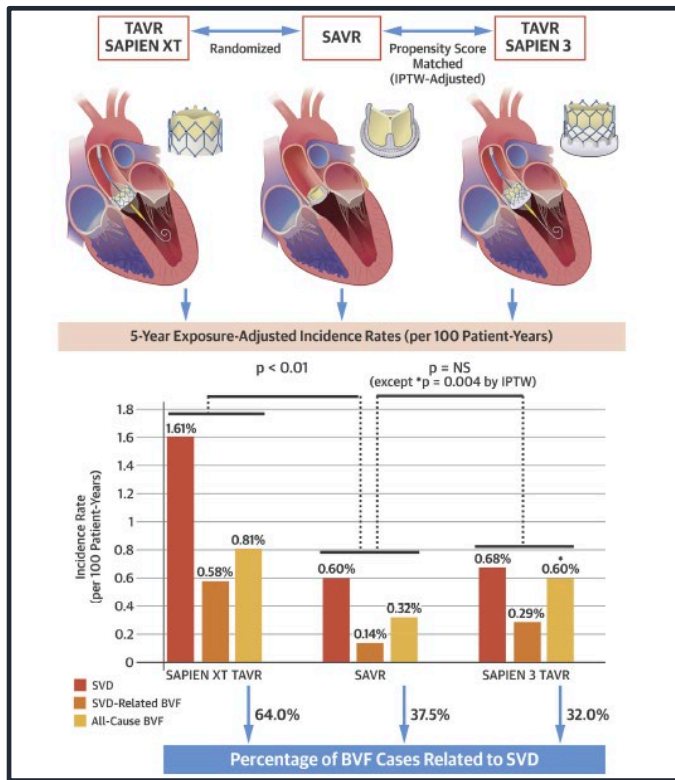
## Nature of Financial Relationship

Individual Stock(s)/Stock Options

## Ineligible Company

Foldax®

# SVD Remains a Persistent Problem with all TAVR (and SAVR)

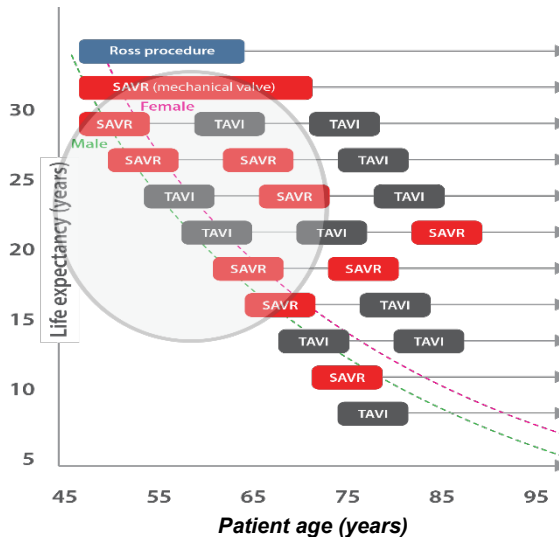


JACC Vol. 85, NO. 13, 2025  
APRIL 2025: 1419-30

JACC Vol. 76, NO. 16, 202  
OCTOBER 20, 2020: 1830-43

# Unmet Need: Patient Reintervention Burden Caused by Bioprosthetic Structural Valve Deterioration

Strategies for Lifetime Management According to Patient's Life Expectancy



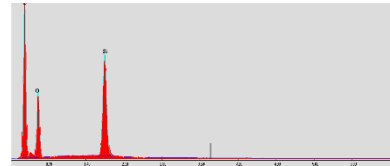
- Valve replacement treatment options remain sub-optimal
- Valve durability is increasingly important as TAVI expands to **lower risk and younger populations** with longer life expectancy
- Creates complex lifetime management decision making

# Innovative Novel Polymer Developed Specifically for Degradation-Resistant Heart Valve Leaflets

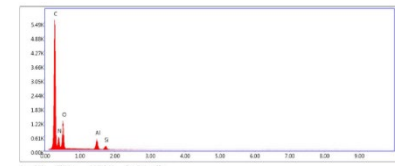
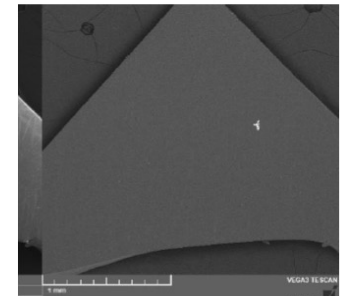
- LifePolymer™ SiPU(Elast-Eon) as base
- Incorporates urea groups, linked macrodiol + 2nd chain extender to optimize biomechanical leaflet properties
- Resists calcification and degradation, biostable and biocompatible

## No Calcium Detected

Subcutaneous  
In-vivo Test<sup>1</sup>



Clinical Findings  
at 3 Years



<sup>1</sup>Jenny, et. al. *Advanced NanoBiomed Research*, 1, 2000032 (2021).

# Technology Leveraged in Surgical and TAVR Valves

## Computationally Modeled & Optimized



### TRIA™ Mitral Valve

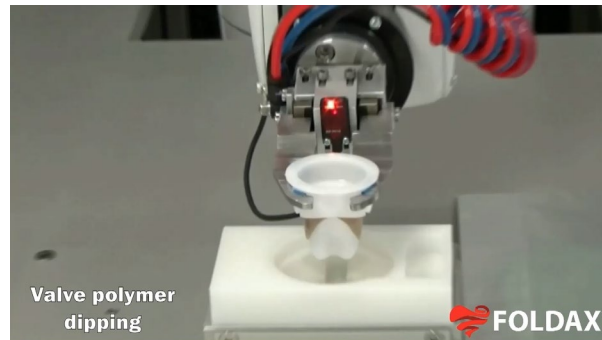
Implantable  
grade PEEK  
radiopaque  
frame



Porous PTFE  
sewing ring

Three flexible polymer leaflets are dip-cast  
as a single piece (unibody)

## Robotically Manufactured



### ELEVARE™ BE TAVR Valve

Competitive  
profile

Nanofiber mesh  
sealing skirt

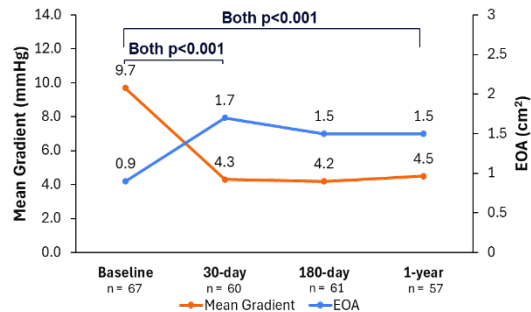


Large open  
cell design



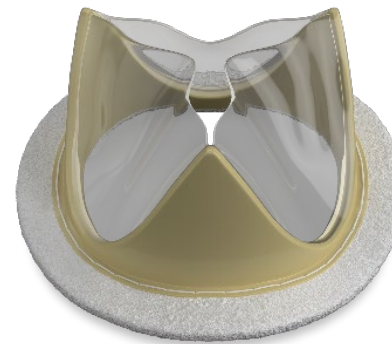
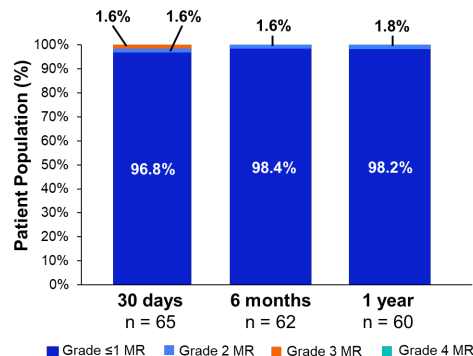
# TRIA™ Mitral Valve Performance at 1 Year: N =67

## Echocardiography: EOA & Mean Gradient

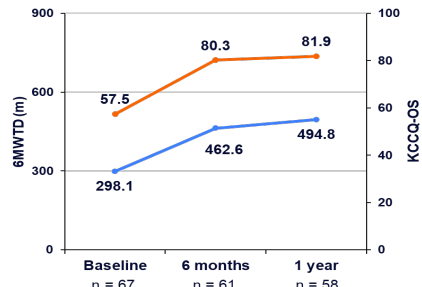
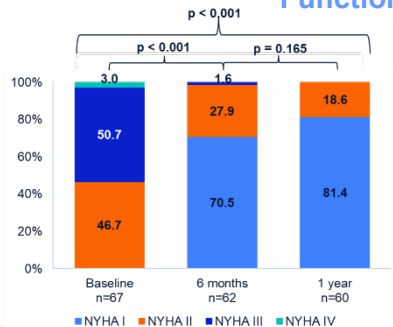


Graph shows all available echo data at each timepoint, but p-value is calculated using paired values only

## Residual MR



## Functional & Health Status Outcomes



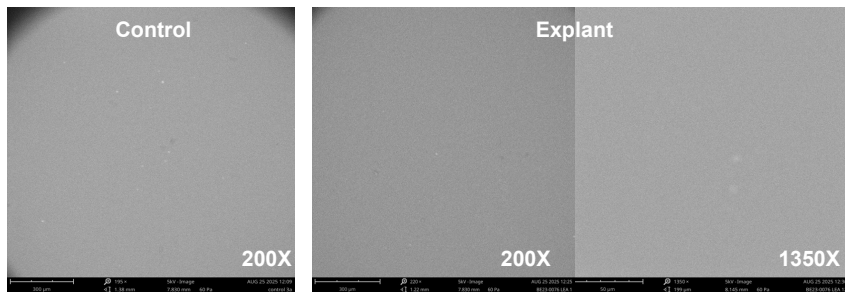
■ 6 Minute Walk Test Distance ■ KCCQ Overall Score

- No valve-related mortality or reintervention
- 50% reduction in mean gradient
- 24-point improvement in KCCQ
- 65% improvement in quality-of-life

Source: George, I, Rao, D, Jain, A. et al. 1-Year Results From a Multicenter Trial of a Polymer Surgical Mitral Valve: Insights Into New Technology. JACC. 2025 Aug, 86 (7) 515–526. <https://doi.org/10.1016/j.jacc.2025.06.017>

# Successful ELEVARE™ BE TAVR Simulated Use

- 16Fr expandable sheath
- Accurate deployment without frame/leaflet injury
- In-vitro hydrodynamic characterization meets ISO standard performance criteria (5 L/min, 70 bpm, 35% systolic duration, per ISO5840-3)
- Performance comparison



*SEM Images: No leaflet tear/structural damage on valve leaflets that have had catheter passed through*

	Foldax® ELEVARE 23mm BE TAV	EW Sapien 3 Ultra, 23mm [1]
Mean Gradient	9.10 mmHg	10.56 mmHg

[1] J Mech Behav Biomed Mater . 2022 Mar;127:105092

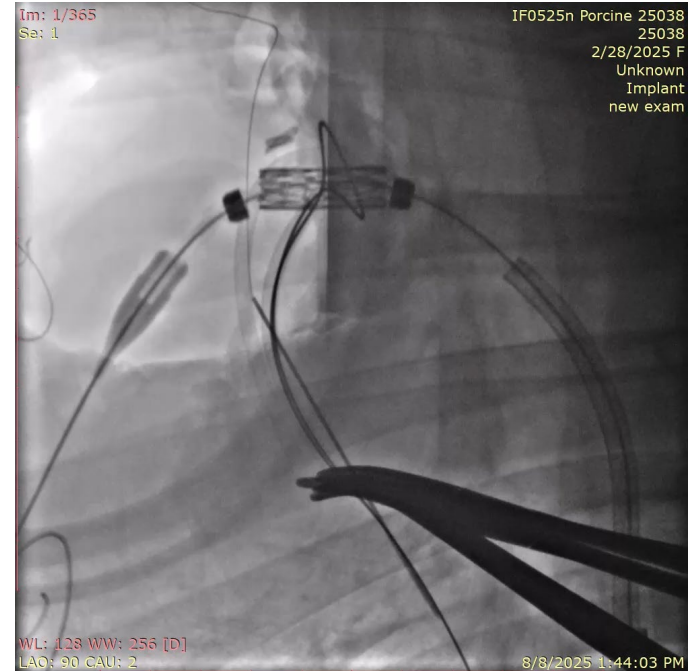


# Acute Animal Study: Precise Deployment and Damage-Free Delivery

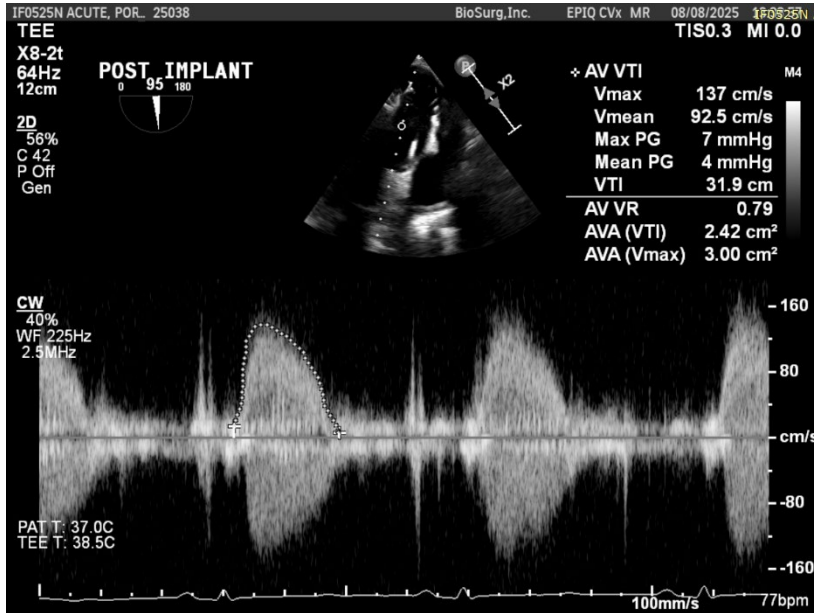
- Porcine model with surgical band
- Valve delivered by steerable balloon catheter
- 100% technical success (VARC-3)
  - 2 cases



*No gross or microscopic leaflet damage with repeated wire crossings*



# Acute Animal Study: Favorable Hemodynamics



- No PVL in 100% of implants
- Mean gradient: 3mmHg
- AVA 2.4cm<sup>2</sup>

# Transformative Potential to Meet Lifetime Patient Needs

- **LifePolymer™:** designed to resist calcification and degeneration
- **Platform Precision:** Computationally optimized, robotically manufactured for consistency and accuracy
- **Clinical Proof:** TRIA™ Mitral Valve: first commercial polymer valve, demonstrating strong outcomes at 1 year
- **Pipeline Momentum:** ELEVARE™ BE TAVR Valve advancing toward first-in-human analysis in 2026