

# The DurAVR® Biomimetic TAVR System in Patients with Small Aortic Annuli: 1-Year Clinical & Hemodynamic Outcomes

Rishi Puri, MD, PhD, FRACP  
Cleveland Clinic



# 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

Consultant Fees/Honoraria

Equity

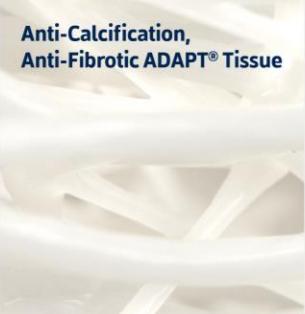
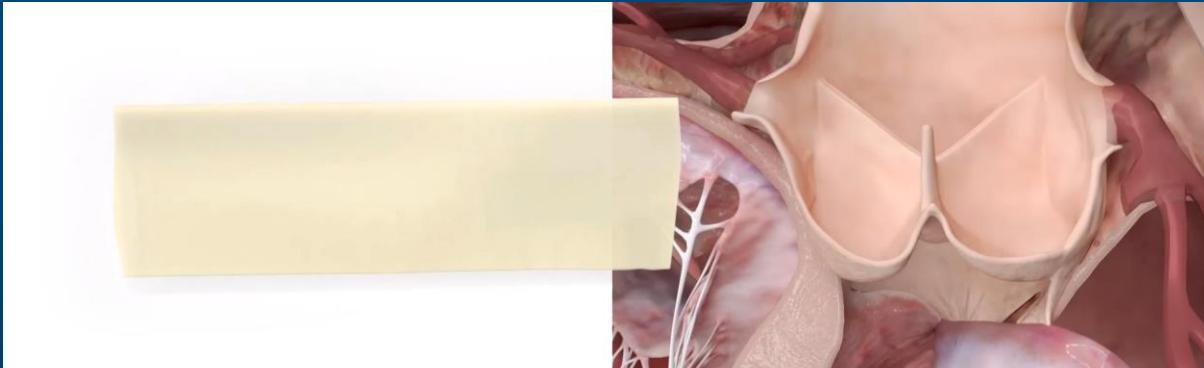
## Ineligible Company

Centerline Biomedical, Medtronic, Abbott, P&F, Shockwave Medical, Vdyne, VahatiCor, AdvNanoT, NuevoSono, Alleviant Medical, Protembis, GE Healthcare, Pi-Cardia, AngioWave, T45 Labs, HRT, Anteris, Nyra Medical

Centerline Biomedical, VahatiCor, NuevoSono, Synkopi

# DurAVR® THV : A New Class of TAVR

*Single piece, native-shaped biomimetic design  
built to mimic the performance of a healthy aortic valve*



Anti-Calcification,  
Anti-Fibrotic ADAPT® Tissue



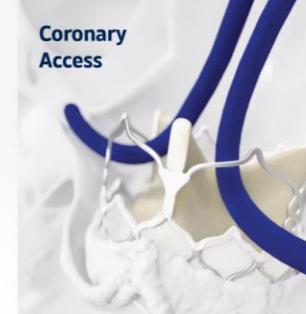
Long Coaptation  
To Reduce Stress



Balloon Expandable  
Precision



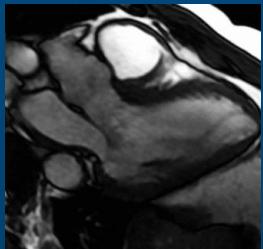
Commissure Alignment  
Technology



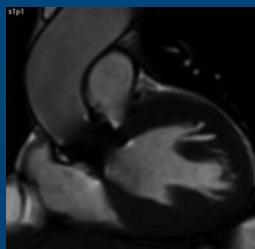
Coronary  
Access

# DurAVR® THV Demonstrates Restoration of Physiologic Laminar Flow

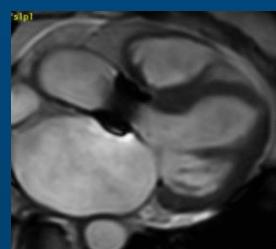
Healthy Aortic Valve



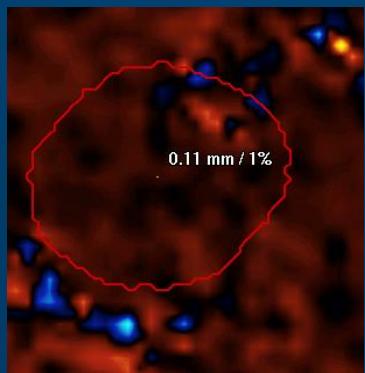
Post DurAVR® THV



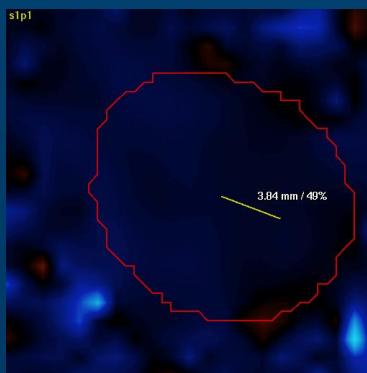
Post Sapien 3



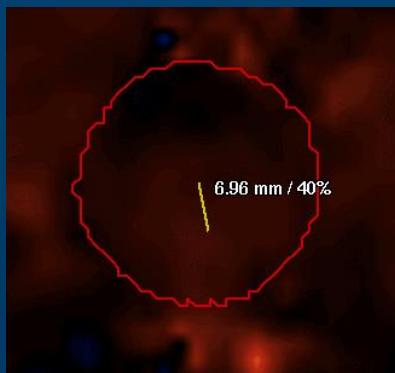
Post Evolut R



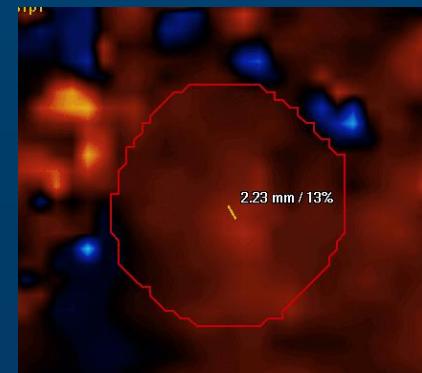
FD = 10% FRR = 1%



FD = 14% FRR = 4%



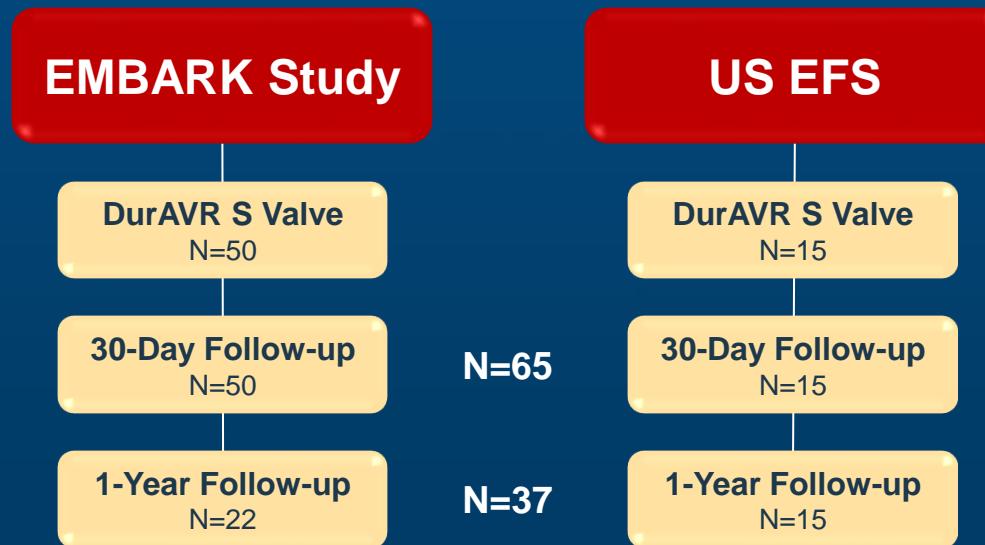
FD = 48% FRR = 35%



FD = 25% FRR = 4%

# DurAVR® THV Small Aortic Annuli Pooled Cohort

## Symptomatic Severe Native Aortic Stenosis



## DurAVR® THV Small Aortic Annuli (SAA) Pooled Cohort

# Baseline Characteristics

## Demographics

DurAVR SAA  
(n = 65)

Age (years)	76.3 ± 7.1
Gender – Female	76.9%
STS-PROM Score (%)	4.1 ± 3.3
NYHA Class III or IV	55.4%
Prior CABG	7.7%
Prior PCI	43.1%
Diabetes	35.4%
Renal Insufficiency or Failure	53.8%
Permanent Pacemaker or ICD	4.6%
Atrial Fibrillation	16.9%

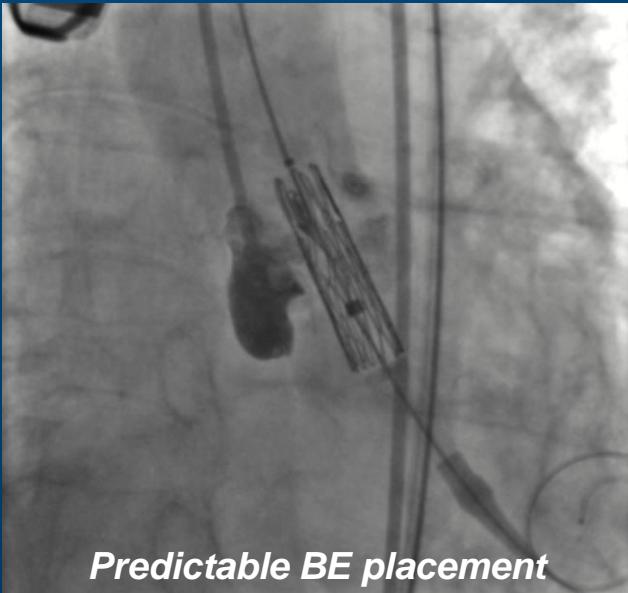
# Baseline Echocardiography

Characteristic	DurAVR SAA (n = 65)
Annulus Area (mm <sup>2</sup> )	396 ± 37
Annulus Diameter (mm)	22.4 ± 1.1
AV Area (cm <sup>2</sup> )	0.77 ± 0.18
AV Mean Gradient (mmHg)	46.0 ± 17.4
LV Ejection Fraction (%)	57 ± 7

# Procedural Success Across Variety of Anatomies

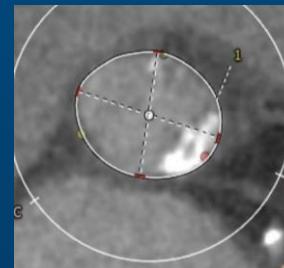
Technical success: 94%

Device success: 92%

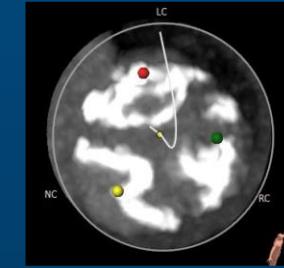


Challenging anatomies treated

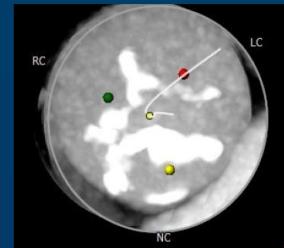
Severe annular calcium



Extreme leaflet calcium



Type 1 bicuspid



Extreme LVOT calcium



# 30-Day & 1-Year Outcomes

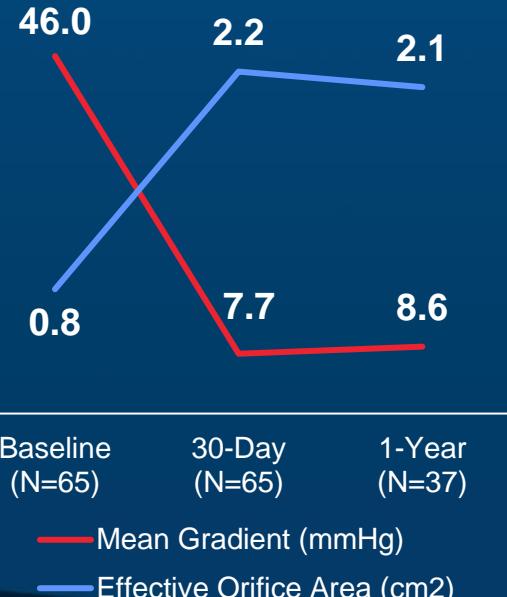
DurAVR® THV Outcomes (N=65)	30-Day	1-Year
All-Cause Mortality	0%	4.6% <sup>1</sup>
Cardiovascular Mortality	0%	0%
Disabling Stroke	0%	1.5%
Endocarditis	0%	1.5% <sup>2</sup>
Acute Kidney Injury Stage 2 or 3	0%	0%
Cardiovascular Hospitalizations	3.1%	6.2%

\* Not all DurAVR subjects reached 1 year follow up. Rates were calculated to the longest follow up available (Mean Follow Up 293 days)

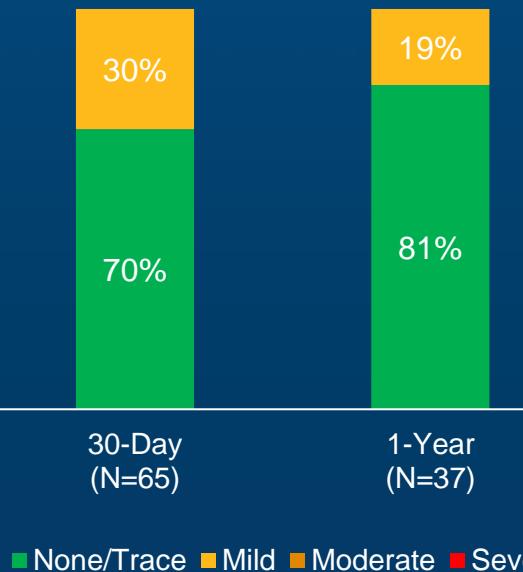
1. Mortality related to car accident (n=1) and sepsis of non-cardiac origin (n=2)
2. Endocarditis resulting in valve explantation

# Favorable Hemodynamics Through 1-Year

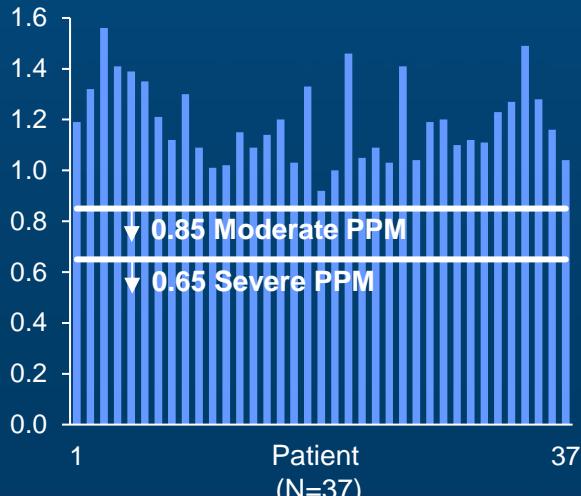
Single-digit mean gradient  
and large effective orifice  
area



No moderate or severe  
paravalvular leak



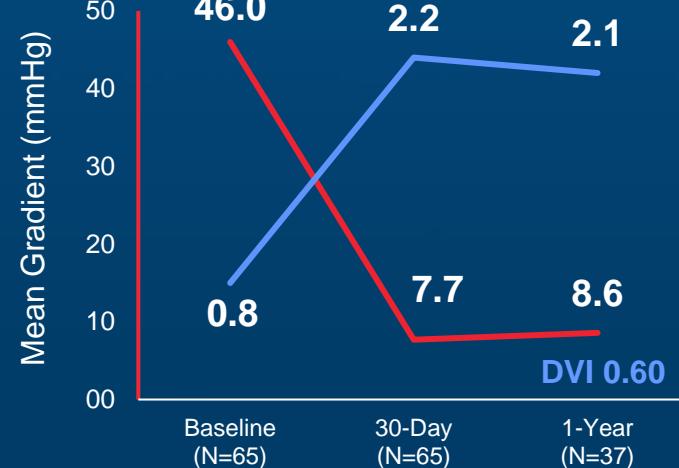
No moderate or severe  
prosthesis-patient  
mismatch



# Favorable Hemodynamics in Small Aortic Annuli

## DurAVR

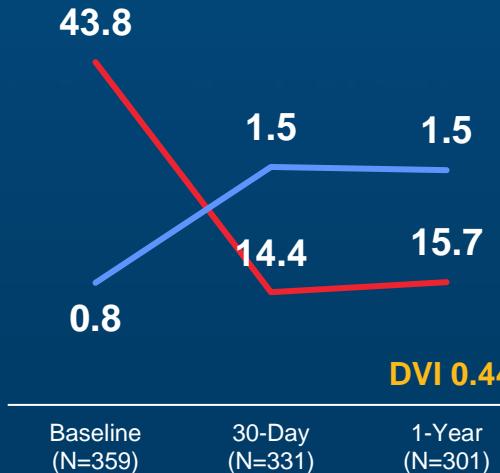
Aortic annulus area:  $395.8 \pm 37.3 \text{ mm}^2$



1.5% moderate or severe  
PPM at 30 days

## BEV (SMART)<sup>1,2</sup>

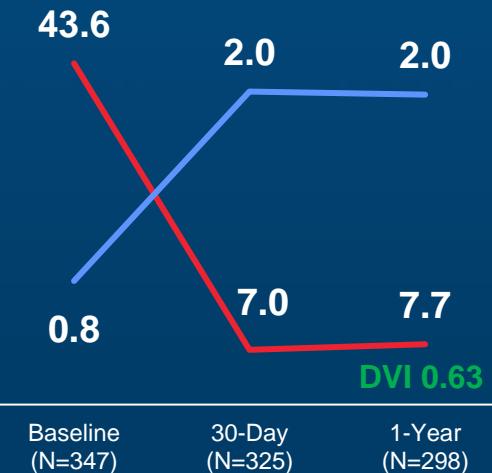
Aortic annulus area:  $382.8 \pm 33.9 \text{ mm}^2$



35.3% moderate or severe  
PPM at 30 days

## SEV (SMART)<sup>1,2</sup>

Aortic annulus area:  $380.9 \pm 34.2 \text{ mm}^2$

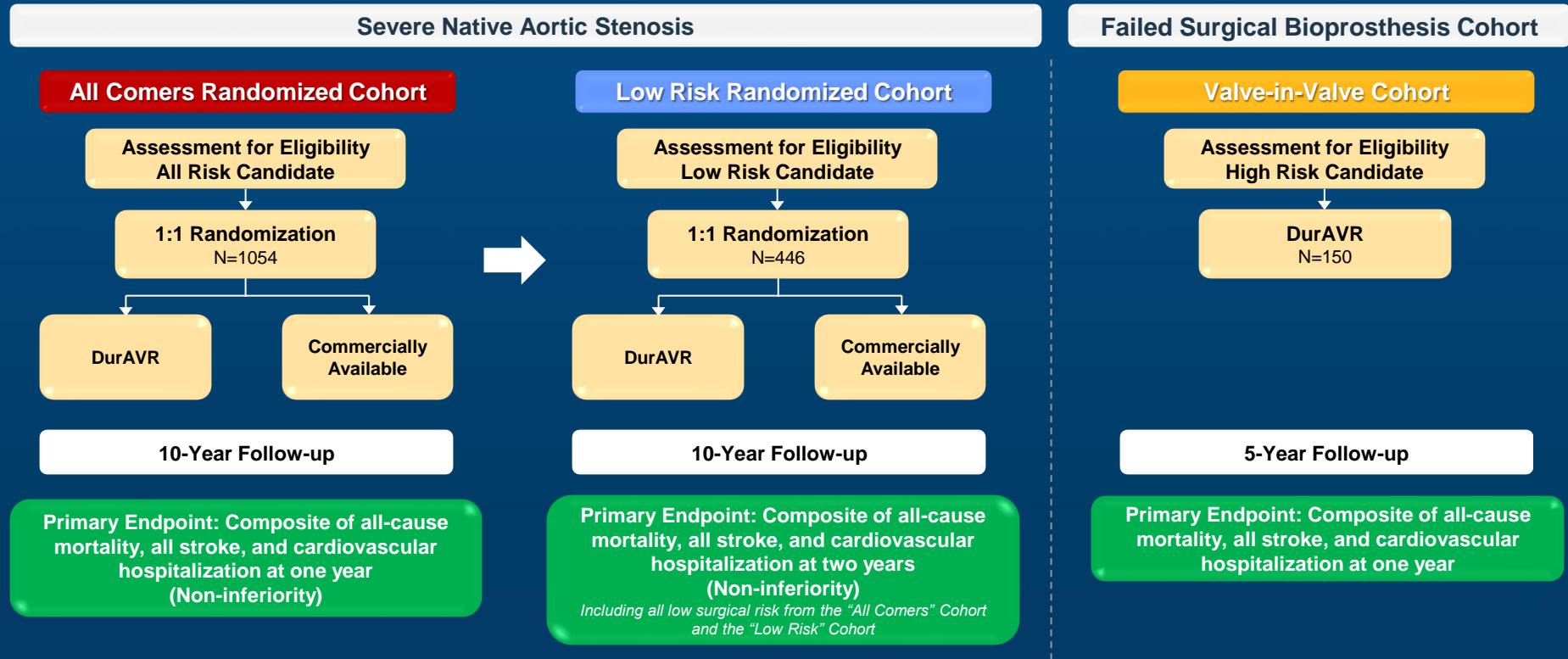


11.2% moderate or severe  
PPM at 30 days

PPM: prosthesis-patient mismatch

1. Hermann HC et al. NEMJ. 2024;390:1957-71. 2. Herrmann HC oral presentation, SCAI May 2024, Long Beach, CA USA.

# PARADIGM Trial Design



# Summary

- Over 100 SAA patients implanted with DurAVR® THV
- 1-year: no valve related mortality in a SAA cohort
- Excellent hemodynamics through 1-year, single digit mean gradient, large EOAs, no  $\geq$  moderate PVL
- Very low prosthesis-patient mismatch rate



PARADIGM Trial has started!