

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

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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

Consultant Fees/Honoraria

Equity

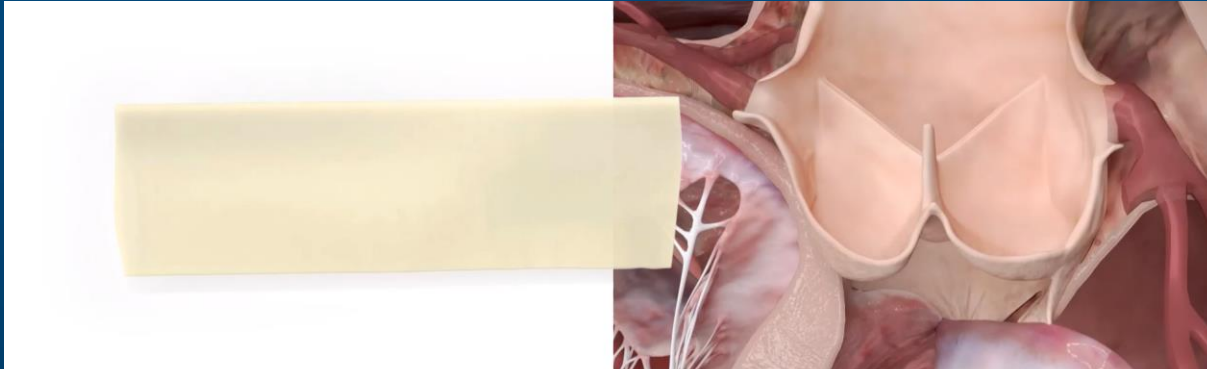
Ineligible Company

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

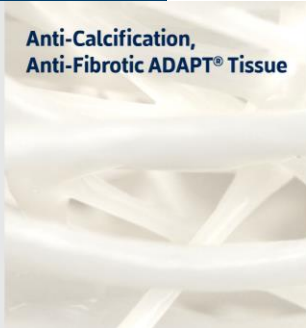
Centerline Biomedical, VahatiCor, NuevoSono, Synkopi

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



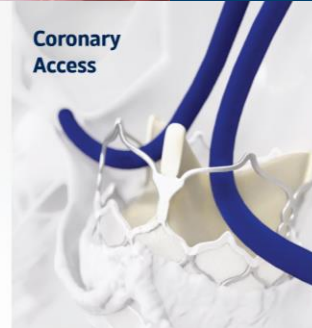
Balloon Expandable
Precision



Commissure Alignment
Technology

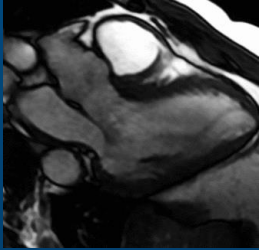


Coronary
Access

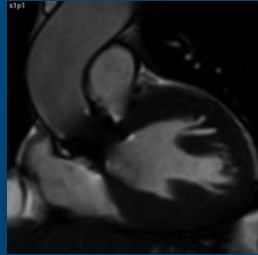


DurAVR[®] THV Demonstrates Restoration of Physiologic Laminar Flow

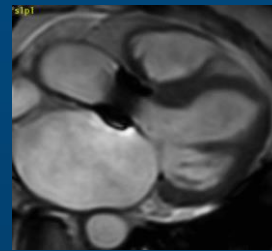
Healthy Aortic Valve



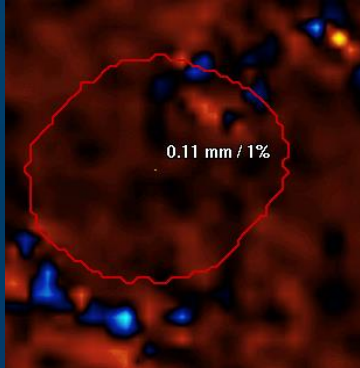
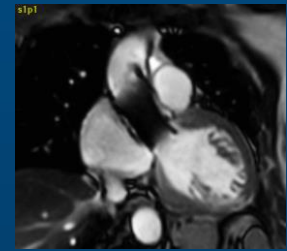
Post DurAVR[®] THV



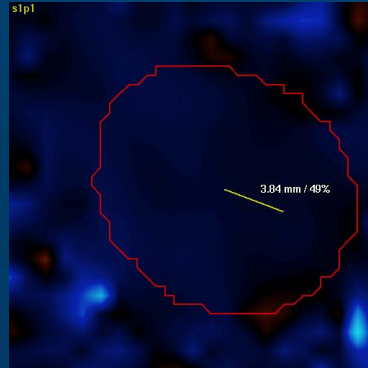
Post Sapien 3



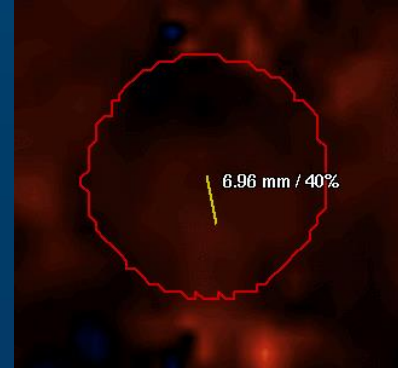
Post Evolut R



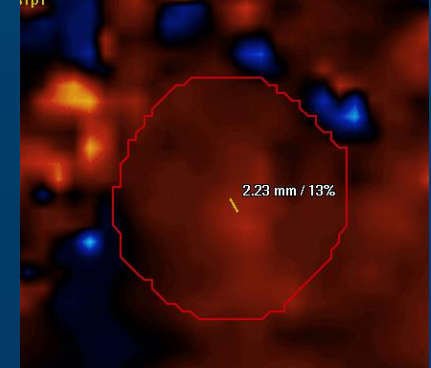
FD = 10% FRR = 1%



FD = 14% FRR = 4%



FD = 48% FRR = 35%



FD = 25% FRR = 4%

DurAVR® THV Small Aortic Annuli Pooled Cohort

Symptomatic Severe Native Aortic Stenosis

EMBARK Study

DurAVR S Valve
N=50

30-Day Follow-up
N=50

1-Year Follow-up
N=22

N=65

N=37

US EFS

DurAVR S Valve
N=15

30-Day Follow-up
N=15

1-Year Follow-up
N=15

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%

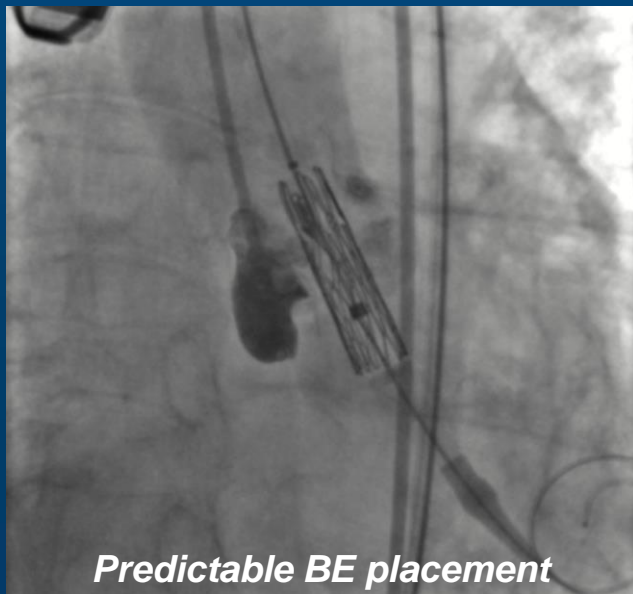
Baseline Echocardiography

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

Procedural Success Across Variety of Anatomies

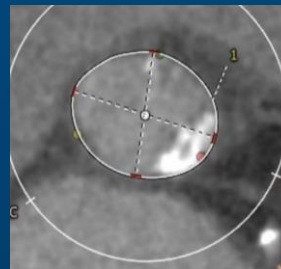
Technical success: 94%

Device success: 92%

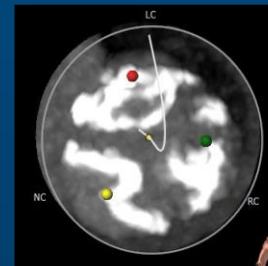


Challenging anatomies treated

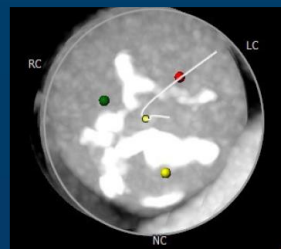
Severe annular calcium



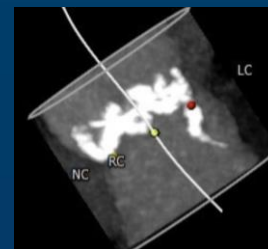
Extreme leaflet calcium



Type 1 bicuspid



Extreme LVOT calcium



30-Day & 1-Year Outcomes

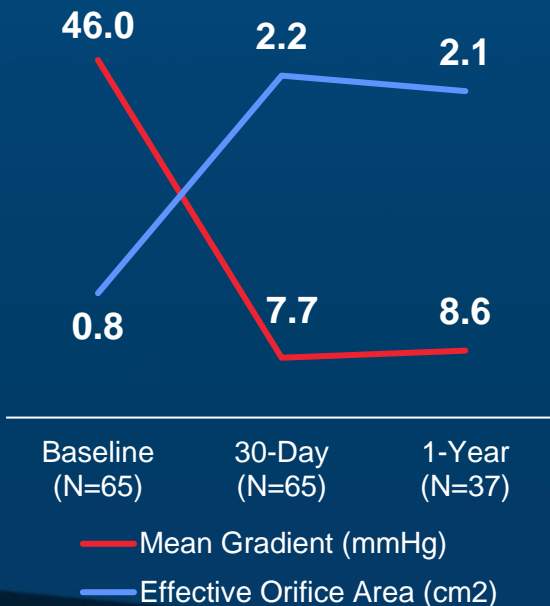
DurAVR® THV Outcomes (N=65)	30-Day	1-Year
All-Cause Mortality	0%	4.6% ¹
Cardiovascular Mortality	0%	0%
Disabling Stroke	0%	1.5%
Endocarditis	0%	1.5% ²
Acute Kidney Injury Stage 2 or 3	0%	0%
Cardiovascular Hospitalizations	3.1%	6.2%

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

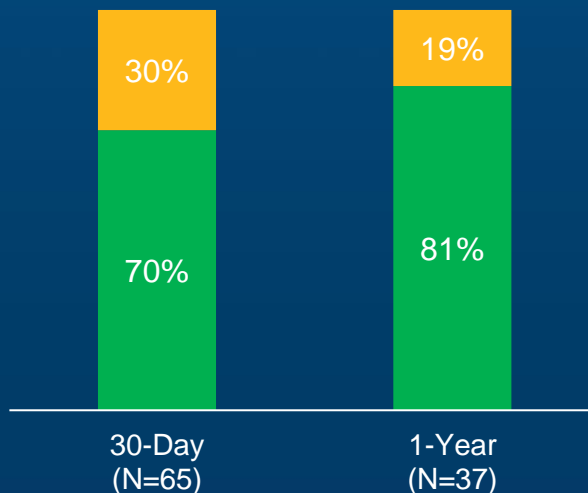
1. Mortality related to car accident (n=1) and sepsis of non-cardiac origin (n=2)
2. Endocarditis resulting in valve explanation

Favorable Hemodynamics Through 1-Year

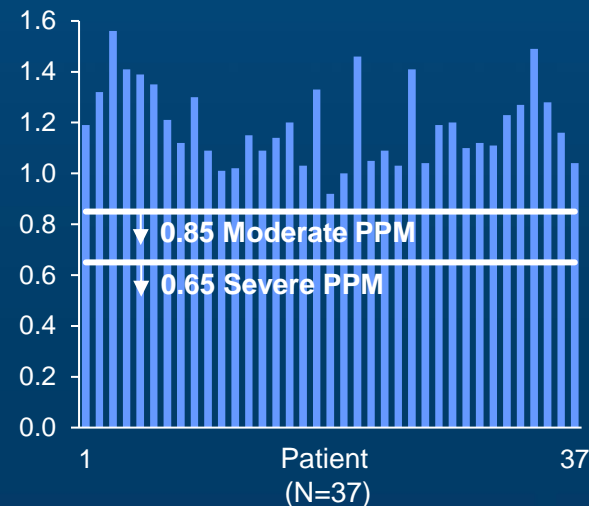
Single-digit mean gradient
and large effective orifice
area



No moderate or severe
paravalvular leak



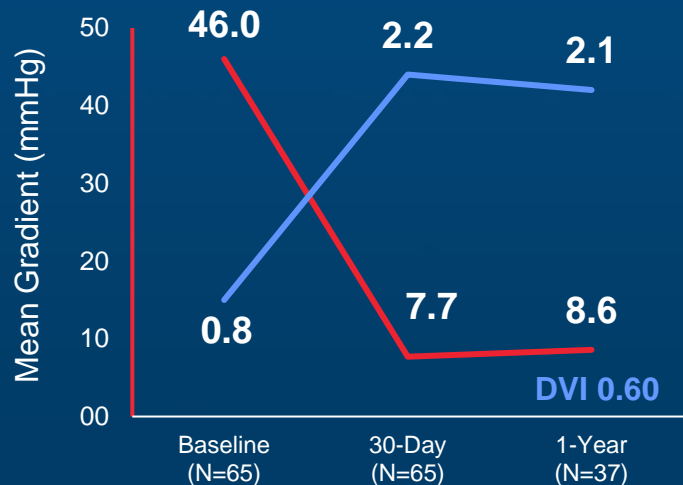
No moderate or severe
prosthesis-patient
mismatch



Favorable Hemodynamics in Small Aortic Annuli

DurAVR

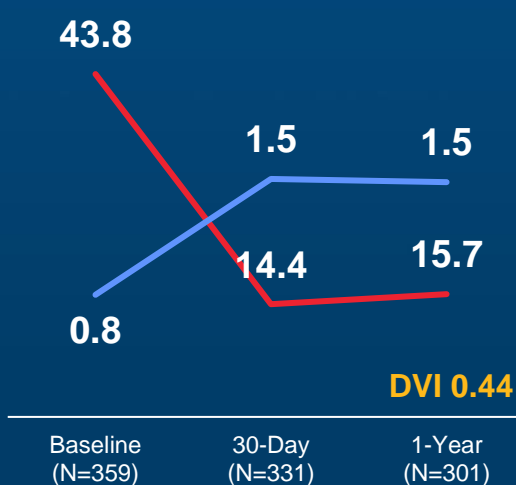
Aortic annulus area: $395.8 \pm 37.3 \text{ mm}^2$



1.5% moderate or severe PPM at 30 days

BEV (SMART)^{1,2}

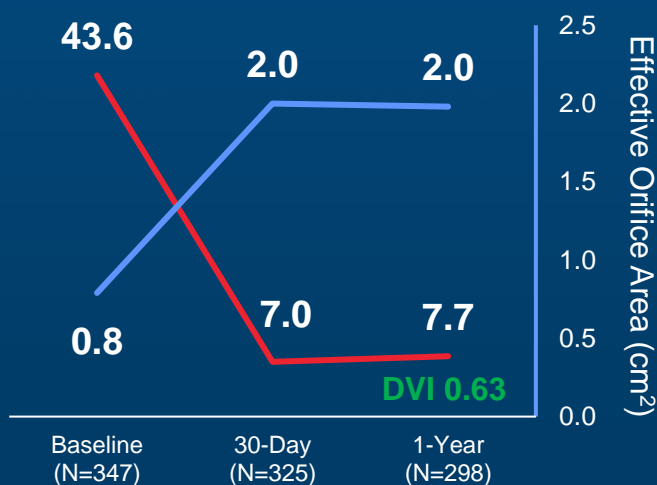
Aortic annulus area: $382.8 \pm 33.9 \text{ mm}^2$



35.3% moderate or severe PPM at 30 days

SEV (SMART)^{1,2}

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. Hermann HC oral presentation, SCAI May 2024, Long Beach, CA USA.

PARADIGM Trial Design

Severe Native Aortic Stenosis

All Comers Randomized Cohort

Assessment for Eligibility
All Risk Candidate

1:1 Randomization
N=1054

DurAVR

Commercially
Available

10-Year Follow-up

Primary Endpoint: Composite of all-cause mortality, all stroke, and cardiovascular hospitalization at one year
(Non-inferiority)

Low Risk Randomized Cohort

Assessment for Eligibility
Low Risk Candidate

1:1 Randomization
N=446

DurAVR

Commercially
Available

10-Year Follow-up

Primary Endpoint: Composite of all-cause mortality, all stroke, and cardiovascular hospitalization at two years
(Non-inferiority)
Including all low surgical risk from the "All Comers" Cohort and the "Low Risk" Cohort



Failed Surgical Bioprosthesis Cohort

Valve-in-Value Cohort

Assessment for Eligibility
High Risk Candidate

DurAVR
N=150

5-Year Follow-up

Primary Endpoint: Composite of all-cause mortality, all stroke, and cardiovascular hospitalization at one year

MRI and CT Sub-Studies

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!

