Structural Spotlight 10: Newer Versions of Current TAVR Systems
Innovation III: Innovation in Transcatheter Aortic Valve Replacement
Featured Technological Trends: Next Generation TAVR Systems

DurAVR™ A New Class of TAVR. US Early Feasibility Study Results

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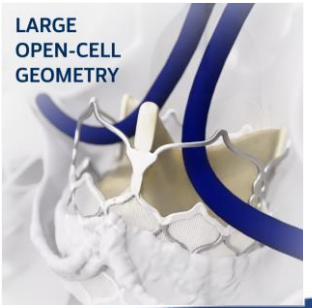
Disclosure Statement of Financial Interest

Within the past 24 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	*Company*
• ***Grant/Research Support***	Medtronic, Edwards Lifesciences, Philips, Abbott, Boston Scientific
• ***Consulting Fees/Honoraria*** • ***Scientific Advisory Board***	*Medtronic, Edwards Lifesciences, Shifamed, Philips, Abbott Vascular, CorFlow, Neochord, V-dyne, Boston Scientific, Bolt Medical, Advanced NanoTherapies, Centerline Biomedical*
• ***Equity Interest***	*Shifamed, Neochord, Vvital, NuevoSono, Centerline Biomedical, Coramaze*

DurAVR™ A New Class of TAVR

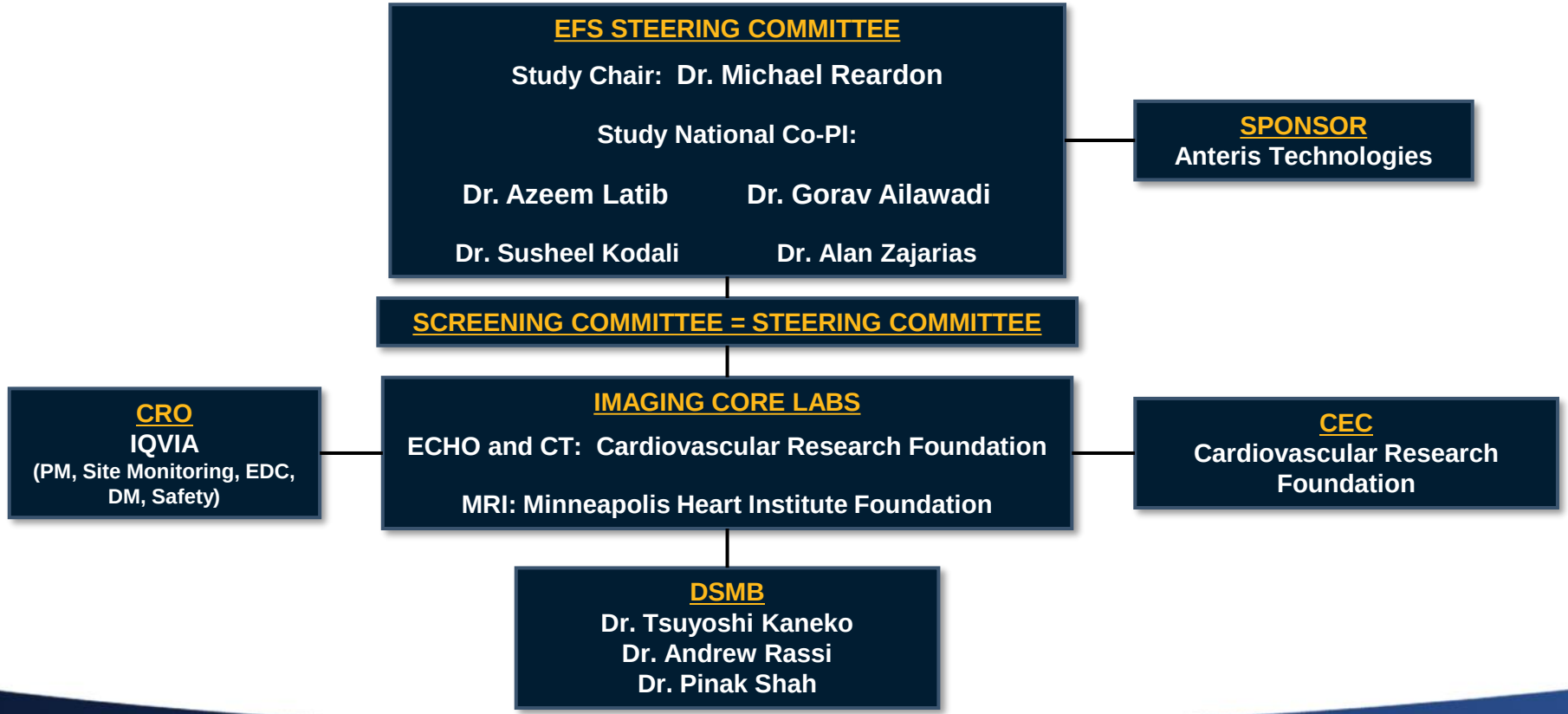
Single-piece, native-shaped biomimetic design built to mimic the performance of a healthy aortic valve.



DurAVR™ EFS: Study Design

Design	Prospective, non-randomized, single-arm, at up to 7 US clinical centers
Purpose	Evaluate the safety and feasibility of the DurAVR™ THV System
Population	15 subjects with symptomatic severe native aortic stenosis
Follow-up	Clinical, echo, MDCT, optional CMR. Follow-up to 10 years.
Key Study Methods	Central screening committee confirmed patient eligibility Core laboratory assessed echocardiographic, CT imaging, CMR External Clinical Event Committee and Data Safety Monitoring Board

DurAVR™ EFS: Study Organization



Study Enrollment Complete

n=15

Top Enrolling Sites

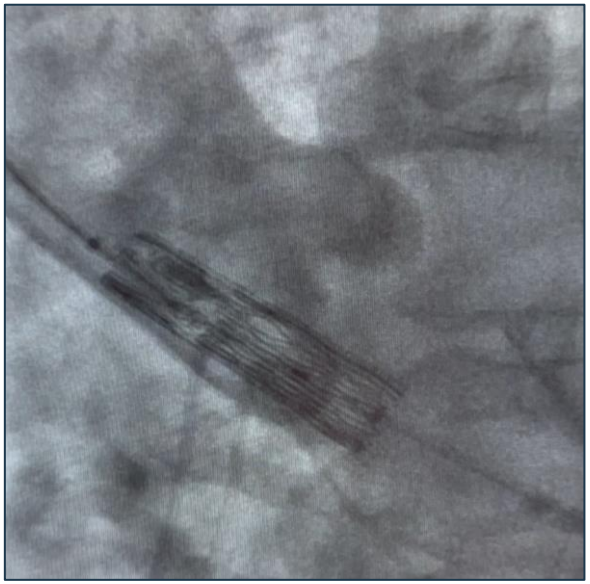
- Cleveland Clinic Foundation (n = 8)
  (Dr. A. Krishnaswamy, Dr. R Puri, Lydia Sweeney)
- Montefiore Medical Center (n = 3)
  (Dr. Azeem Latib, Kara Booth, Donellie Edwards)
- University of Michigan (n =2)
  (Dr. S. Chetcuti, Dr. G. Ailawadi, Jessica Frizzell)
- Tucson Medical Center (n= 2)
  (Dr. T. Waggoner, Dr. A. Eshan, Mary Marsh)

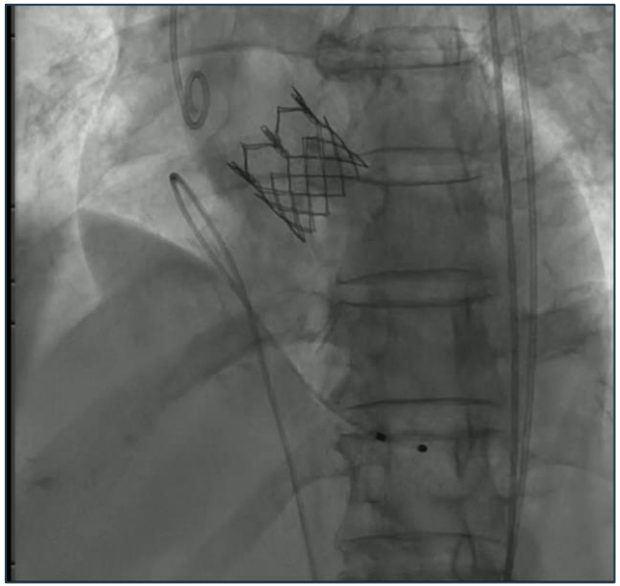
Baseline Characteristics: High Risk Patients with Small Annuli

Baseline Characteristics	n = 15
Age, years (avg)	81
Gender – Female (%)	**64**
STS Prom (%)	6.1
NYHA Class II (%)	53
Ejection Fraction (%)	56
Prior PCI (%)	14
Prior CABG (%)	0
Prior Conduction Disorder (%)	50
Prior Pacemaker or ICD (%)	0
CAD (%)	43
Native Annulus Diameter (mm)	**22.2**

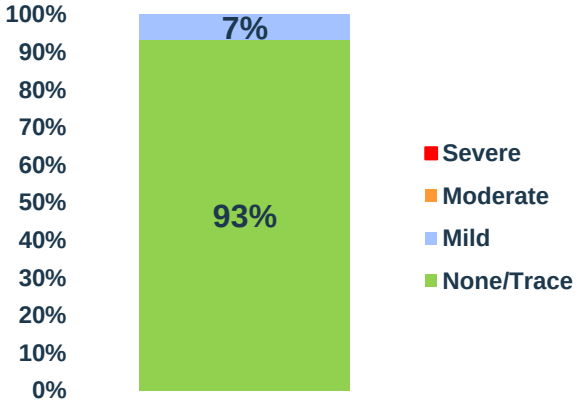
Easy to Deliver and Precise Placement

n=15





100%
successful delivery



Excellent Safety Profile

- ✓ No death
- ✓ No stroke
- ✓ No permanent pacemaker
- ✓ No major bleeding/vascular complications
- ✓ No re-interventions or re-operation

Paradigm Shifting Hemodynamic Results*

(Discharge, N=15)

Mean Annulus size: 22.2 mm

EOA
(Effective Orifice Area)

2.36

cm^2

MPG
(Mean Pressure Gradient)

7.8

mmHg

DVI
(Doppler Velocity Index)

0.71

Invasive MPG **1.78 mmHg**
(n=11)

EOAi **1.36 cm^2/m^2**

CRF TCT

***Echo Core Lab Analysis**

DurAVR™ A New Class of TAVR

- DurAVR™ biomimetic valve provided outstanding hemodynamic performance in independent core lab adjudicated data
- Delivery System was intuitive and easy to use, even with first time users
- DurAVR™ EFS results demonstrated excellent safety profile
- 30-day EFS results to be presented at PCR London Valve Late Breaking Clinical Trials session