

DurAVR Biomimetic THV: First-In-Human Study Results Update

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Disclosure of Relevant Financial Relationships

Within the prior 24 months, I have had a relevant financial relationship(s) with an ineligible company(ies) listed below.

<u>Nature of Financial Relationship</u>	<u>Ineligible Company</u>
Chef Medical Officer	Anteris Technologies
Grant/Research Support	Boston Scientific
Consultant Fees/Honoraria	Abbott Alleviant Medical Boston Scientific Cardiovalve Vdyne xDot Medical

All relevant financial relationships have been mitigated.
Faculty disclosure information can be found on the app

DurAVR™ A New Class of TAVR

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



ADAPT®
ANTI-CALCIFICATION
TECHNOLOGY



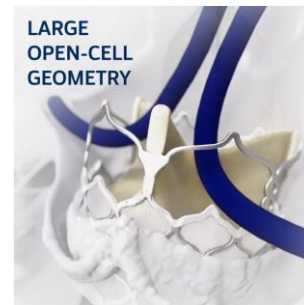
BALLOON
EXPANDABLE
PRECISION



COMMISSURE
ALIGNMENT
TECHNOLOGY

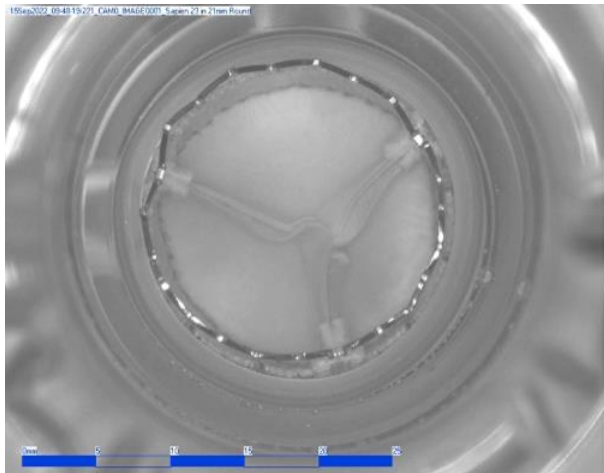


LARGE
OPEN-CELL
GEOMETRY



Biomimetic Design for Improved Hemodynamics & Flow

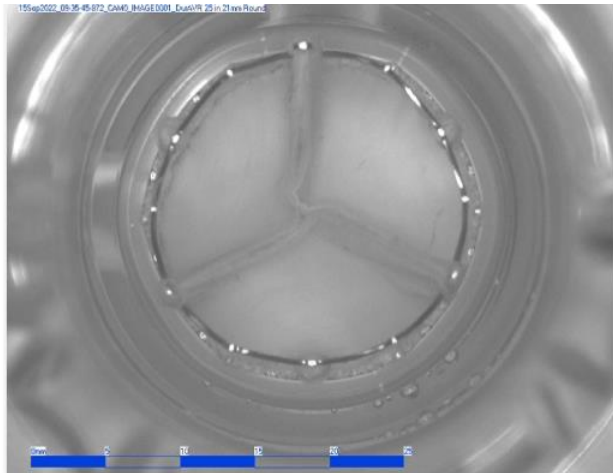
Hydrodynamic Bench Test



Sapien 3

EOA: 2.30 cm²

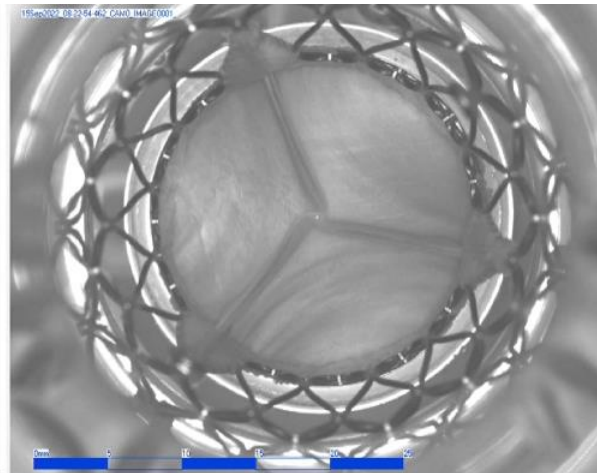
Gradient: 8.8 mmHg



DurAVR™ THV

EOA: 2.83 cm²

Gradient: 5.9 mmHg



Evolut

EOA: 2.41 cm²

Gradient: 8.3 mmHg

DurAVR™ FIH Study Design



Design

Prospective, non-randomized, single-arm, single-center (Tbilisi, Georgia)



Purpose

Evaluate the safety and feasibility of the DurAVR™ THV System (Anteris technologies, USA)



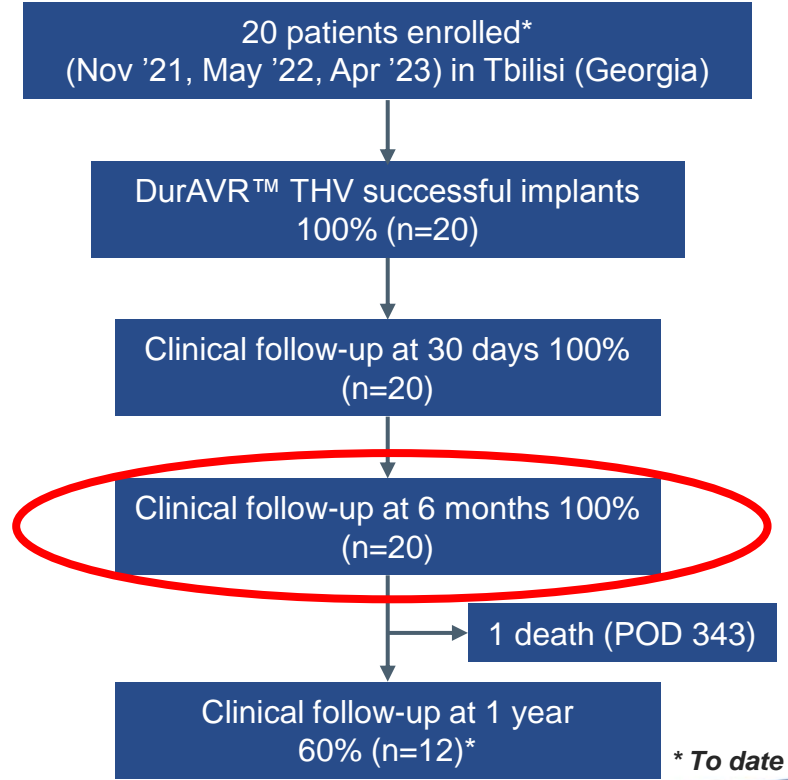
Population

20 subjects with severe symptomatic AS enrolled *



Follow-up

Clinical, echo, MDCT, CMR performed. Follow-up to 1 year.



Baseline and Procedural Characteristics

Baseline characteristics	n = 20
Age (years)	74.25 ± 5.72
Gender (female)	16 (80)
STS Prom (%)	2.25 ± 0.90
Area-derived annulus diameter (mm)	22.73 ± 1.25
NYHA class	
II	16 (80)
III	4 (20)
Risk factors	
CAD	15 (75)
Conduction disturbances	11 (55)
Renal insufficiency	5 (25)
Past MI	4 (20)
Obesity	4 (20)
Diabetes type II	4 (20)
Prior PCI	11 (55)
Permanent pacemaker	1 (5)

Data presented as mean ± SD or n (%)

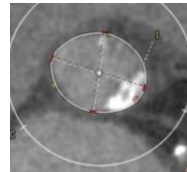
Procedural characteristics	n = 20
Approach	
Transfemoral (TF)	14 (70)
Transaortic (TAo)*	5 (25)
Transcarotid (TC)	1 (5)
General anesthesia	20 (100)
Pre-BAV	20 (100)
Post-BAV	16 (80)

Data presented as n (%)

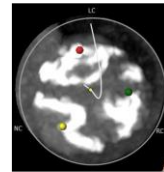
* Performed prior to development of the ComASUR™ TF Delivery System

Challenging anatomies treated (Baseline MDCT)

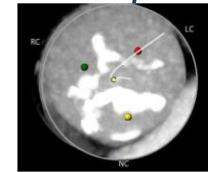
Severe annular calcium



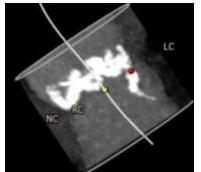
Extreme leaflet calcium



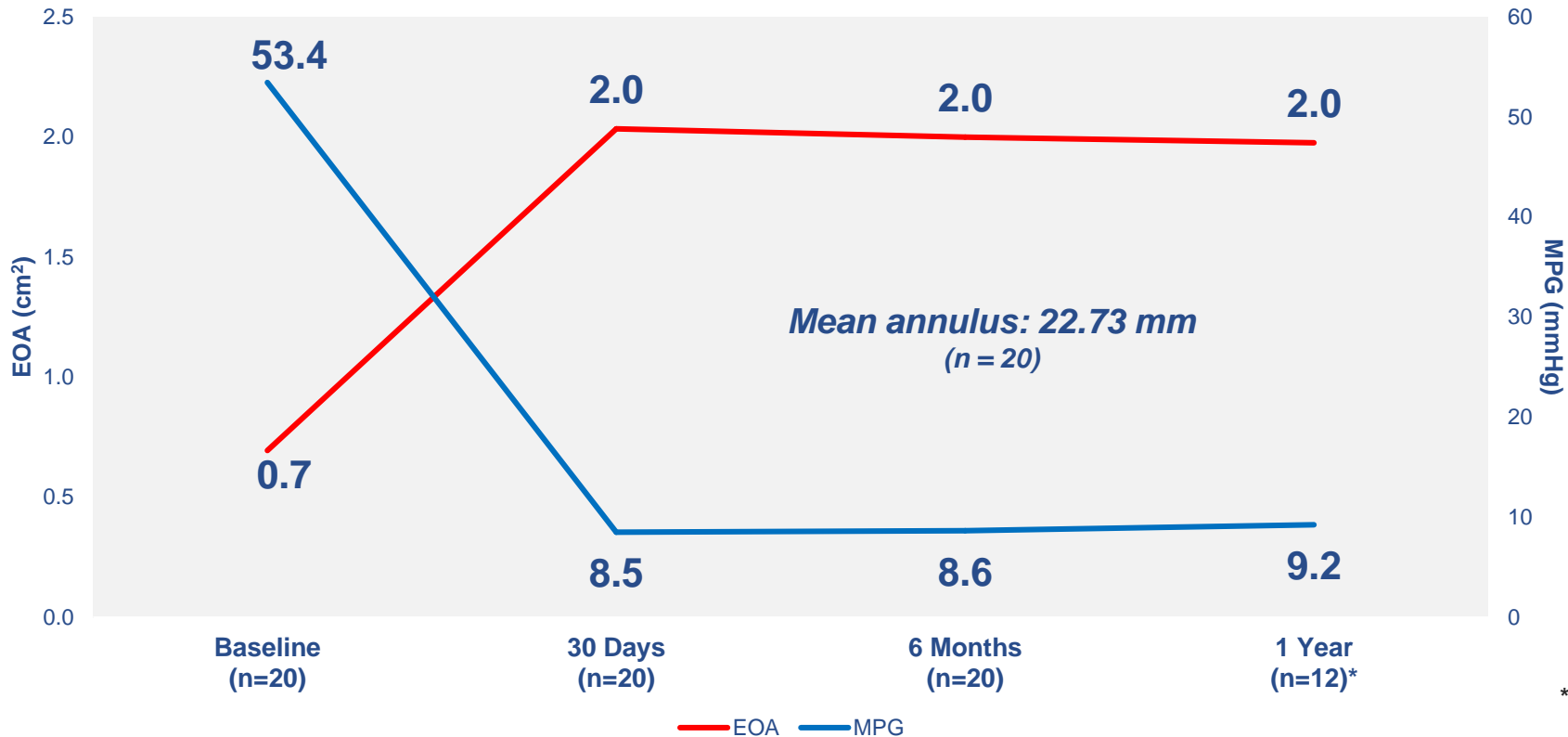
Type 1 bicuspid



Extreme LVOT calcium

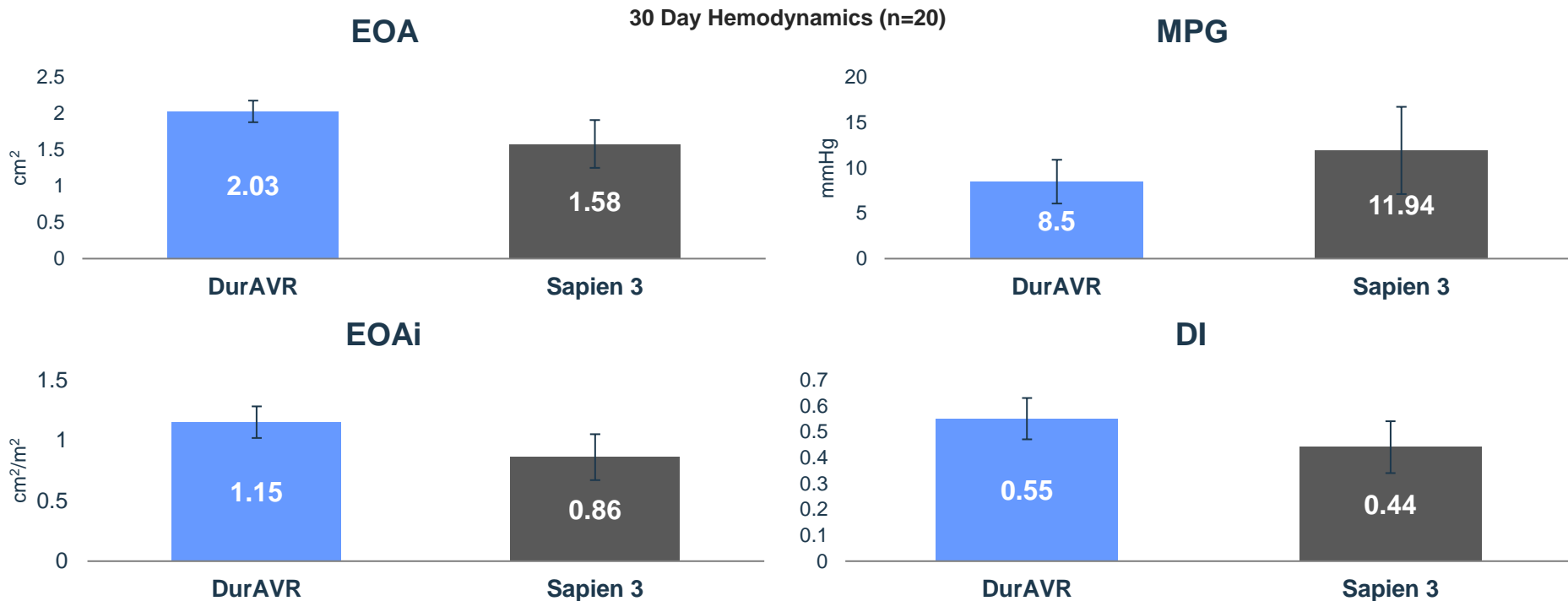


Consistent Excellent Hemodynamic Results up to 1 Year



DurAVR shows Superior Hemodynamics vs BE TAVR

Comparison with benchmark studies in subjects with similar baseline native aortic valve area*



*Hahn RT et al., Comprehensive Echocardiographic Assessment of Normal Transcatheter Valve Function. JACC CV Imag. 2019;12(1):25-34.

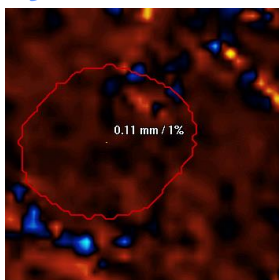
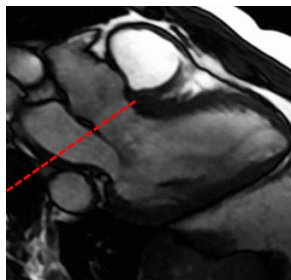
Favorable Safety Profile in All Patients at Latest Follow-up

- ✓ **One non-cardiac death (car accident) on POD 343**
- ✓ **One access site complication (resolved on POD 1)**
- ✓ **One new pacemaker in a patient with baseline RBBB and LAFB (POD 6)**
- ✓ **No stroke**
- ✓ **No minor or major bleeding**
- ✓ **No reoperation or reintervention**
- ✓ **No moderate or severe prosthesis-patient mismatch**
- ✓ **PVL at 1 year: 75% none, 25% mild**

AR = Aortic Regurgitation, LAFB = Left Anterior Fascicular Block, POD = Post Operative Day, RBBB = Right Bundle Branch Block

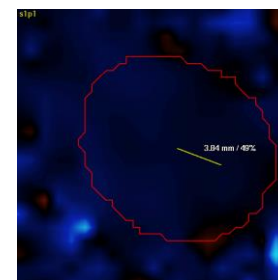
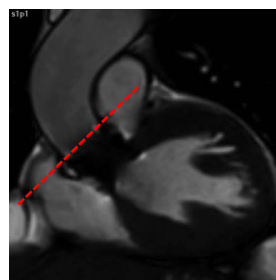
DurAVR™: the First-In-Class Biomimetic THV To Restore Normal Aortic Flow

Healthy Aortic Valve



FD = 10%
FRR = 1%
(n=5)

Post DurAVR™ THV

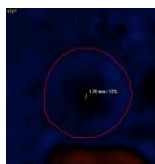
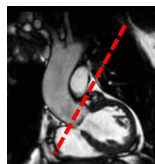


FD = 14%
FRR = 4%
(n=5)

Normal Valve flow vs DurAVR™: **No significant difference** in flow ($p > 0.05$)

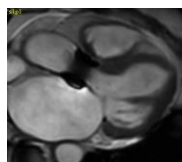
Impaired Aortic Flow

Severe AS



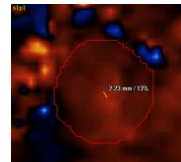
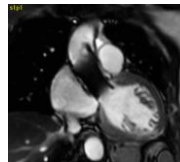
FD = 46% FRR = 23%

Sapien 3



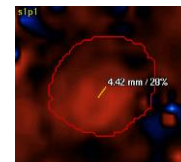
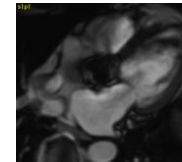
FD = 48% FRR = 35%

Evolut R



FD = 25% FRR = 4%

CEP Magna Ease



FD = 27% FRR = 30%

Normal Valve flow vs: TAVR $p < 0.05$ SAVR $p < 0.01$

DurAVR™ a New Class of TAVR

- DurAVR™ biomimetic valve provides sustained outstanding hemodynamic performance
- DurAVR™ FIH study confirms excellent safety profile
- DurAVR™ THV demonstrates restoration of normal aortic flow
- DurAVR™ EFS discharge data to be presented later today
- DurAVR™ EFS 30d data to be presented at PCR London Valve Late Breaking Clinical Trials session

