MiRus Siegel™ TAVR

EFS Results

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Presented on behalf of:
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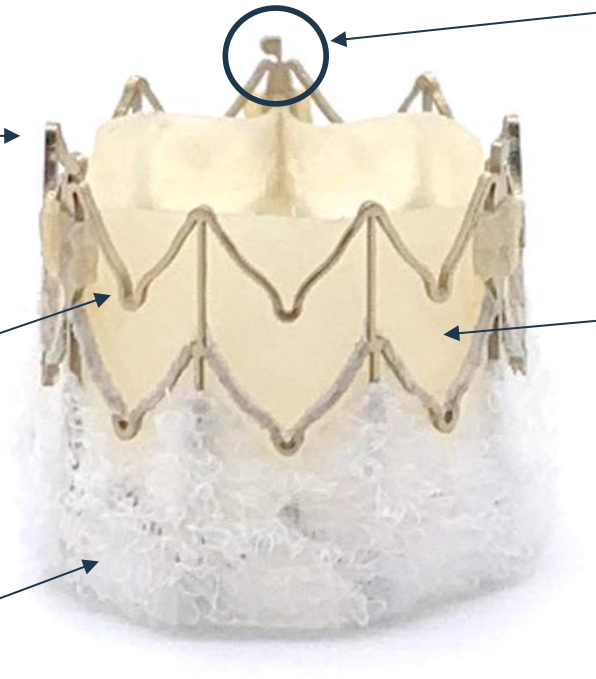
Disclosure of Relevant Financial Relationships

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	Ineligible Company
Grant/Research Support	Edwards Lifesciences, Abbott, Medtronic, Boston Scientific, Jena Valve, HighLife, Innovalve, Trisol, Laplace, Croi, TriCare, MiRus
Consultant Fees/Honoraria	Edwards Lifesciences, Abbott, Boston Scientific, Medtronic
Individual Stock(s)/Stock Options	Dasi Simulations, Excision Medical
Royalties/Patent Beneficiary	
Executive Role/Ownership Interest	
Medical Advisory Board	Dasi Simulations, Trisol, TriCare, PiCardia, Excision Medical

All Relevant Financial Relationships have been mitigated.
Faculty disclosure information can be found on the app

Siegel: A Revolutionary THV System



Commissural Alignment Flags

Rhenium Frame
Nickel Free

Leaflets
Dry Porcine
Anti-calcification

Nitride Oxide Coating

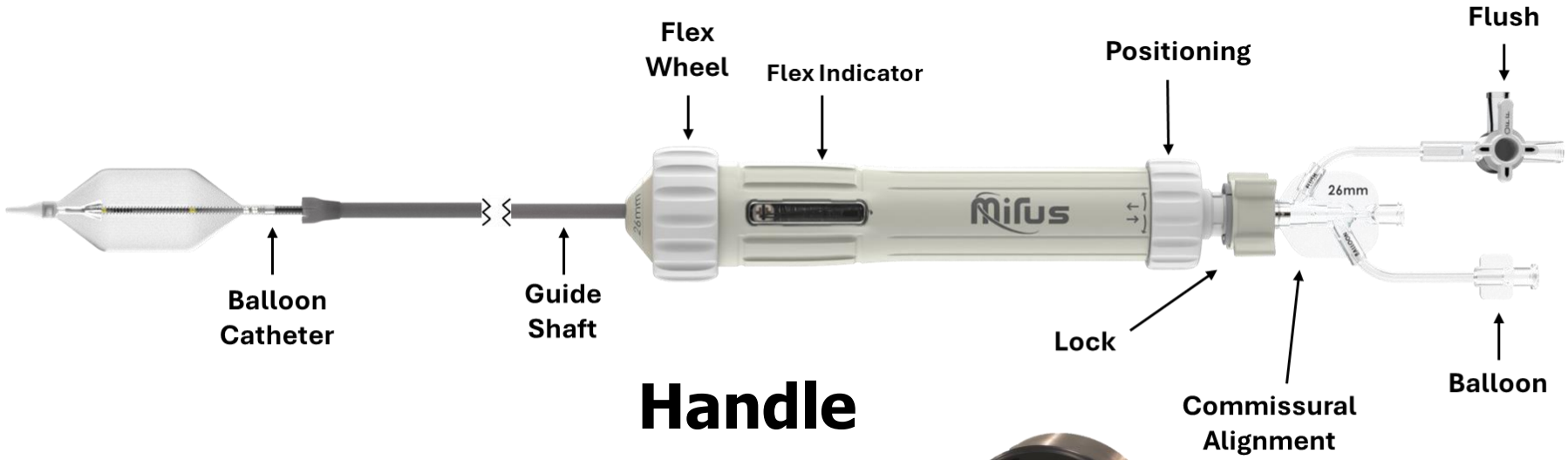
Conformable PVL skirt

Delivered Crimped On Balloon Through 8 Fr Expandable Sheath

Delivery System

More Flexion

mSheath
8 Fr



Handle

- Small Profile
- 1:1 Torque → Precise commissural alignment
- Crimped on Balloon prior to insertion through sheath

Crimper

Early Feasibility Study

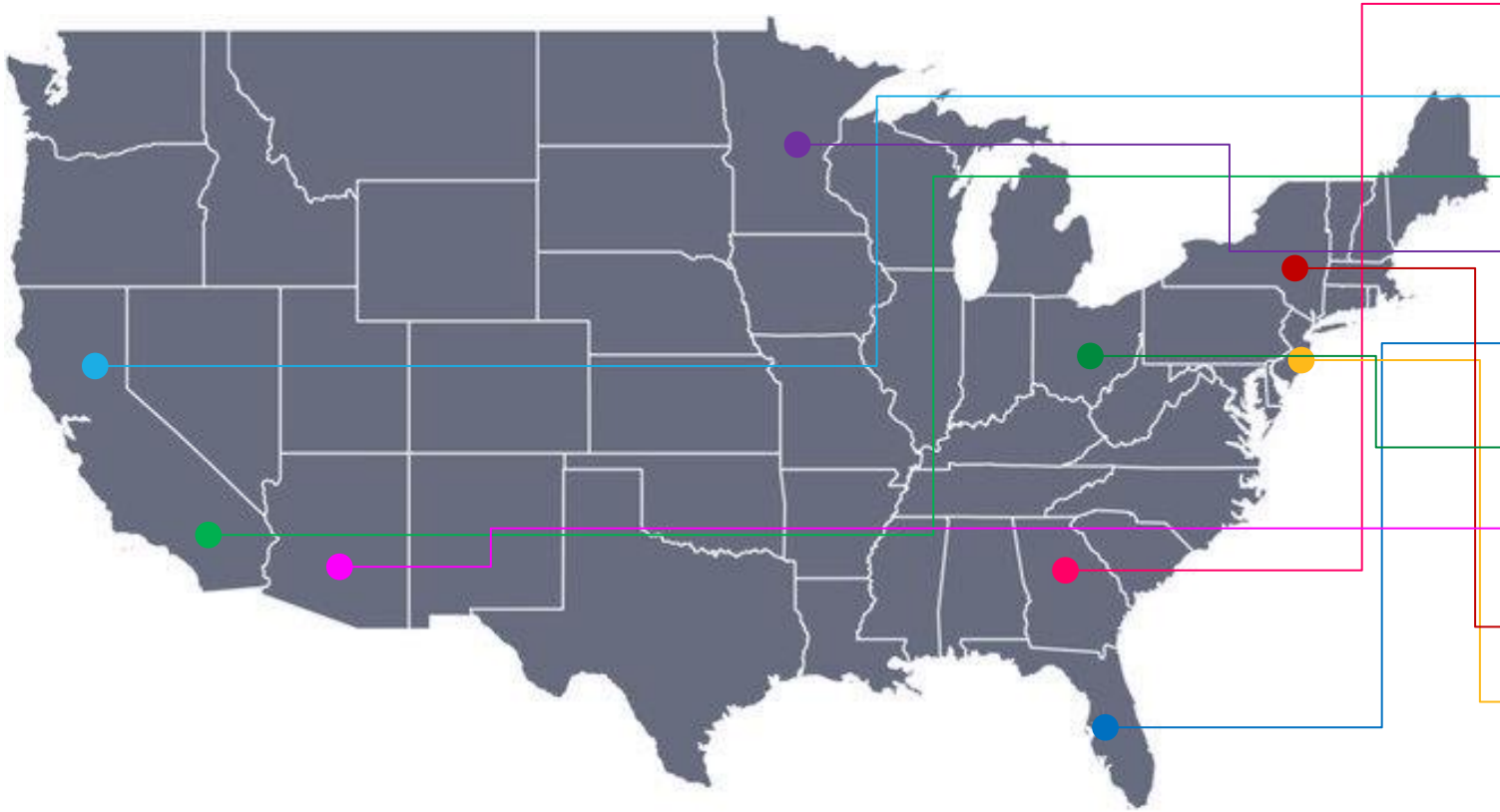
Objective: Safety and efficacy of Siegel TAVR system in patients with symptomatic severe aortic stenosis, all surgical risks

# of patients: 30

# of sites: Up to 10 sites in the United States

Independent Core Laboratories CT Analysis, Echo Analysis

Investigational Sites



PIEDMONT	**Pradeep Yadav, MD** **Vinod Thourani, MD**
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STANFORD	**Rahul Sharma, MD**
MAYO CLINIC	**Kim Holst, MD**
NAPLES	**Robert Cubeddu, MD**
CLEVELAND CLINIC	**Samir Kapadia, MD**
TUCSON MEDICAL CENTER	**Tom Waggoner, MD**
MT. SINAI	**Sahil Khera, MD** **Gilbert Tang, MD**
MORRISTOWN	**Philippe Genereux, MD**

EFS Baseline Clinical Characteristics

Characteristic	n = 30
Age (year)	76 ± 6.21
Male	17/30 (57%)
NYHA Class ≥II	15/30 (100%)
AVA (Vmax) cm^2	0.73
Mean Gradient (mmHg)	40.36
Velocity (m/s)	4.18
DVI	0.23
LVEF (%)	61
STS Score	2.81%
Low	24/30 (80%)
Intermediate/High	6/30 (20%)

Characteristic	n = 30
HTN	20/30 (67%)
DM	7/30 (23%)
CKD	3/30 (10%)
AFib	7/30 (23%)
CAD	20/30 (67%)
LBBB	1/30 (3%)
Permanent Pacemaker	1/30 (3%)
Severe Nickel Allergy	3/30 (10%)

EFS Procedural Results

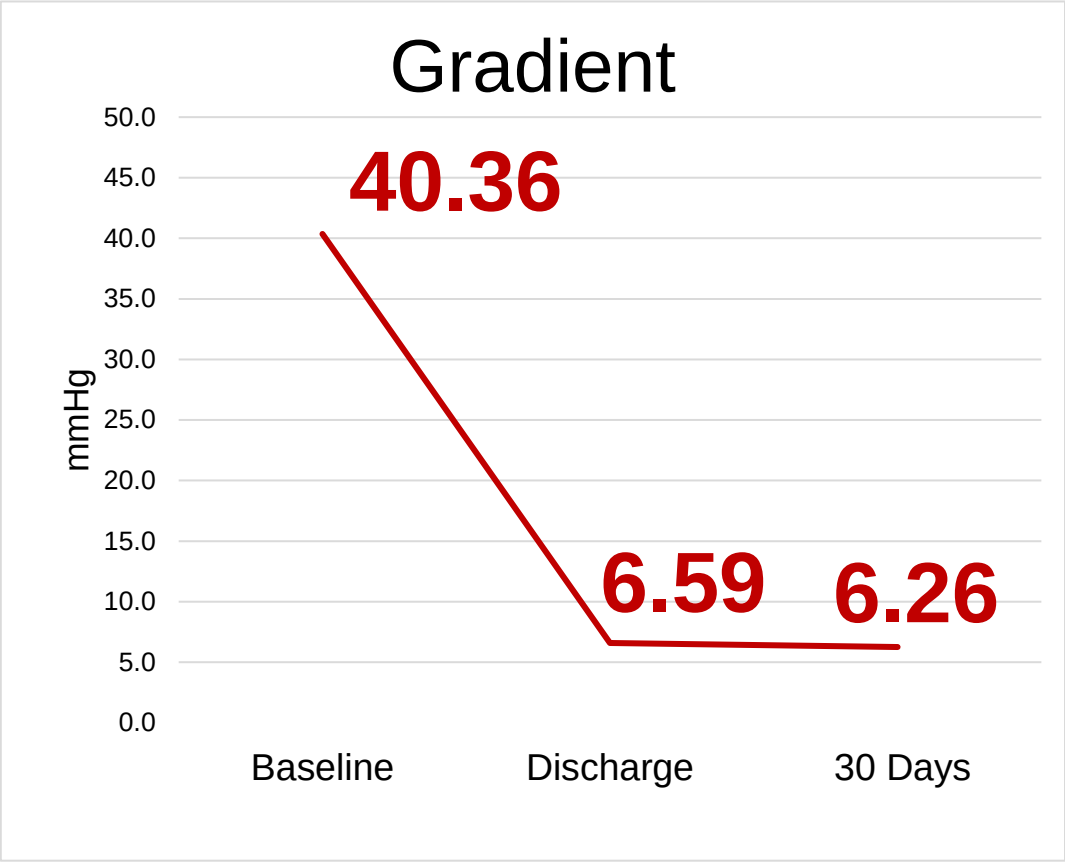
Procedural		N = 30
General Anesthesia & TEE		2/30 (7%)
Percutaneous Transfemoral Access		30/30 (100%)
Dilation:	Pre Post	6/30 (20%) 10/30 (33%)
Aortic 90% / Ventricular 10% Position or Higher		30/30 (100%)
Commissural Alignment		30/30 (100%)
Sheath insertion to valve deployment time		15 minutes

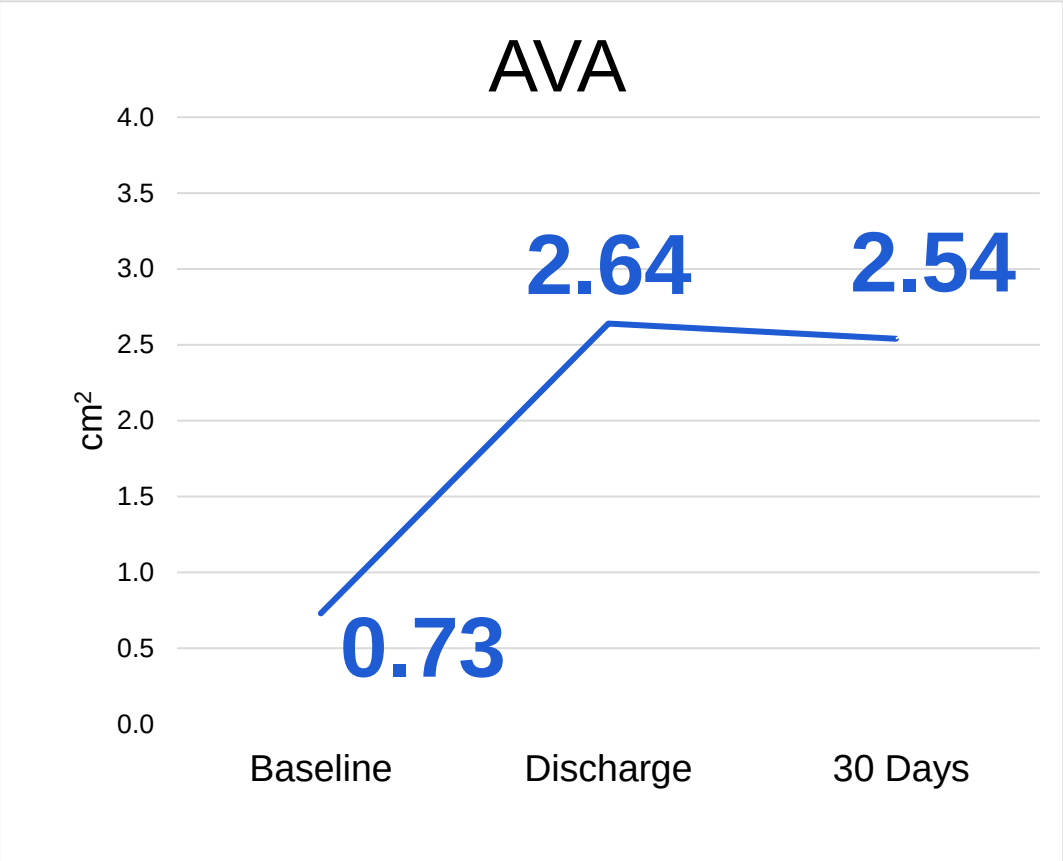
FIH (5) and EFS (30): Clinical Outcomes at 30 Days N=35

Outcome	Discharge
	Siegel 26mm & 23mm
All-cause Mortality	0/35 (0%)
Major Stroke	0/35 (0%)
Annular Rupture	0/35 (0%)
Need for 2nd Valve	0/35 (0%)
Surgery or intervention related to the device, including aortic valve reintervention [d]	0/35 (0%)
Major Vascular Complications[a]	0/35 (0%)
VARC-3 Type 2-4 Bleeding[c]	0/35 (0%)
Moderate or severe aortic regurgitation	0/35 (0%)
Acute Kidney Injury[b]	0/35 (0%)
New pacemaker	2/35 (5.7%)

[a] Vascular Complications is defined as major vascular, access-related, or cardiac structural complication according to VARC-3 Guidelines
[b] Renal failure is defined as stage III acute kidney injury: Increase in serum creatinine to ≥ 300% (3 x increase compared with baseline) or serum creatinine of ≥ 4 mg/d (≥ 354 µmol/L) with an acute increase of at least 0.5 mg/dl (44 µmol/L)
[c] VARC-3 Type 2-4 Bleeding: Fatal bleeding OR bleeding in a critical area or organ, such as intracranial, intraspinal, intraocular, or pericardial necessitating pericardiocentesis, or intramuscular with compartment syndrome OR bleeding causing hypovolemic shock or severe hypotension requiring vasopressors or surgery OR overt source of bleeding with drop in hemoglobin of ≥ 5 g/dL or whole blood of packed red blood cells (RBC) transfusion ≥ 4 units
[d] Cardiac reintervention includes any intervention that repairs, alters or replaces a previously operated valve OR balloon aortic valvuloplasty OR Surgical aortic valve replacement OR valve in valve
CEC adjudicated data

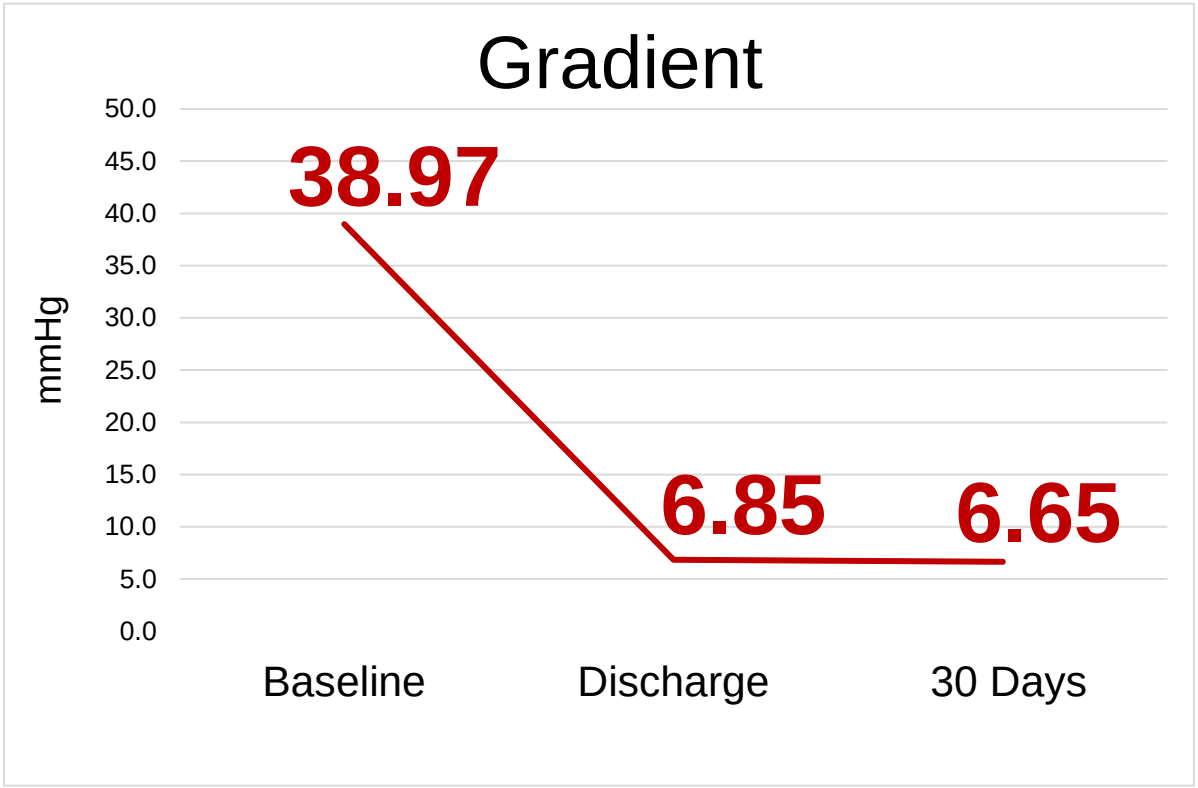
EFS Siegel TAVR Hemodynamics N=30

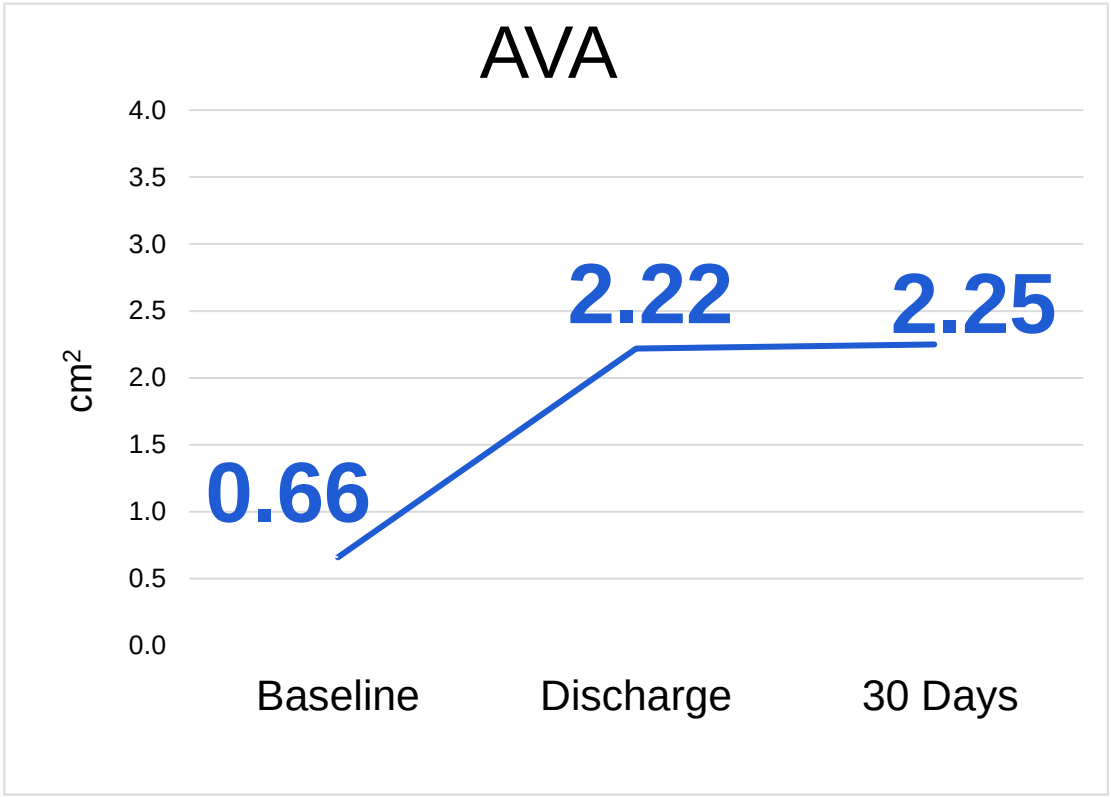




*Corelab assessment

EFS Hemodynamics
N=11
23mm Valve



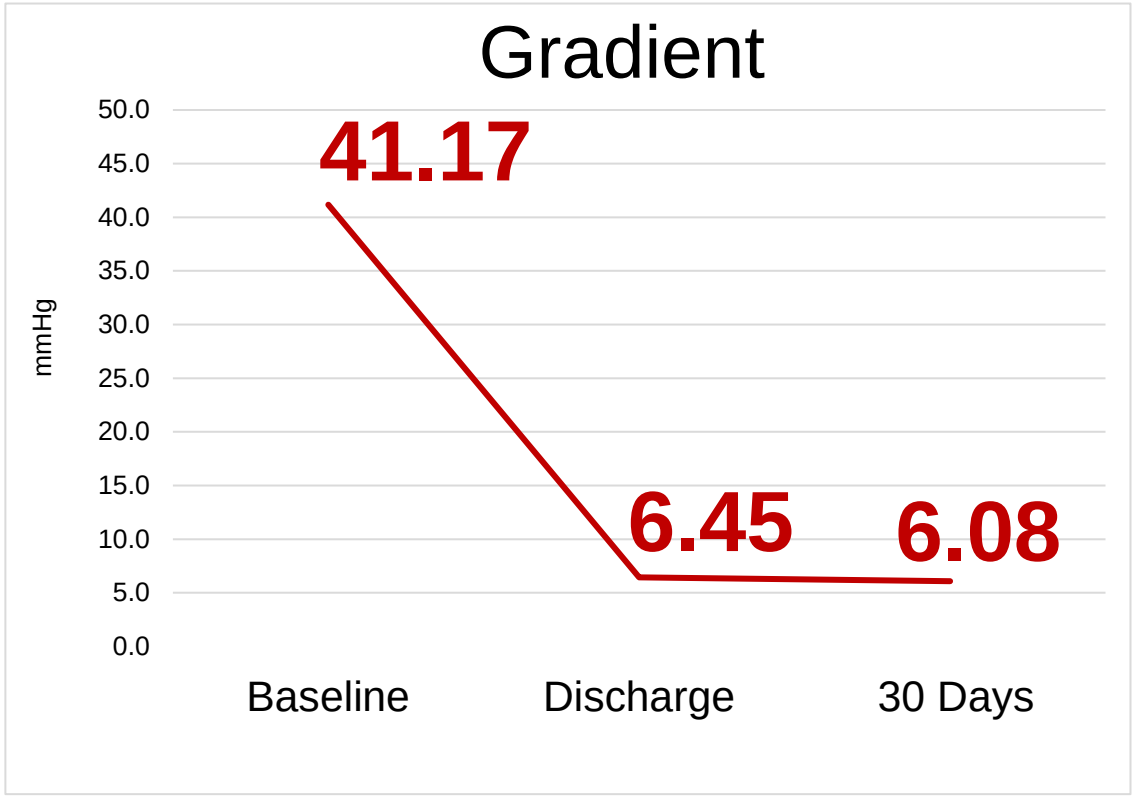


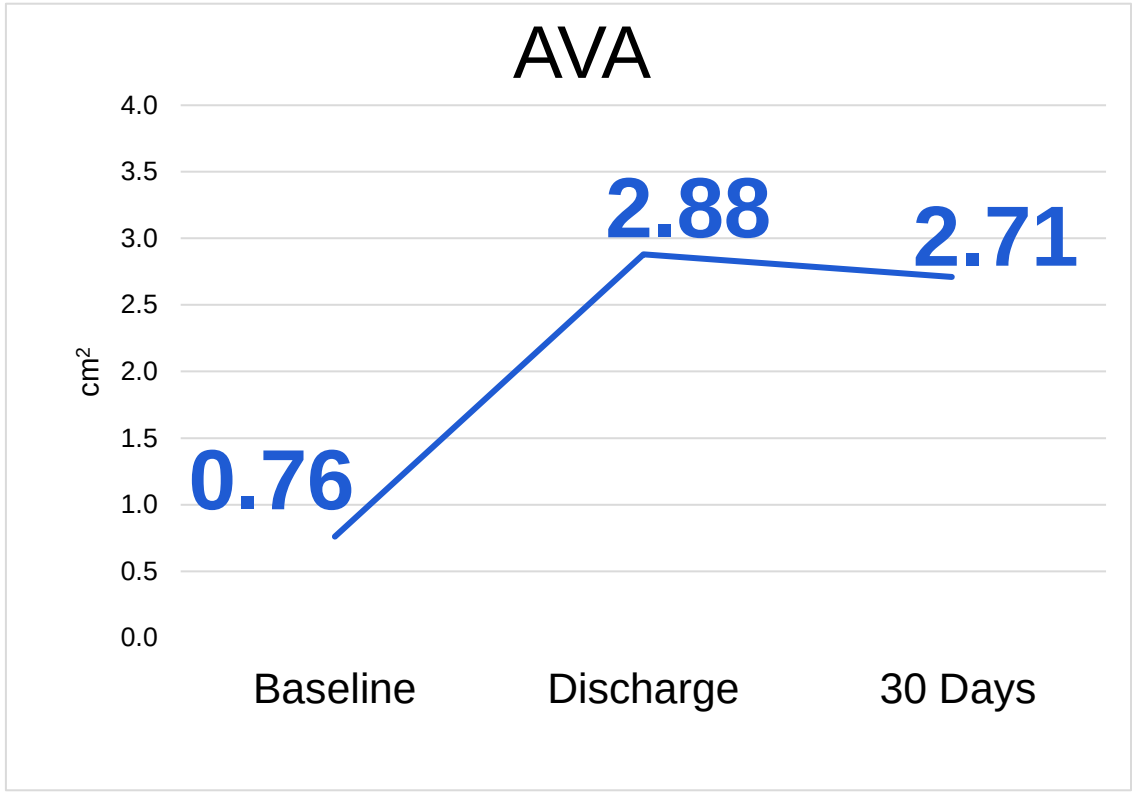
*Corelab assessment

n=11 n=11 n=11

EFS Hemodynamics
N=19

26mm Valve

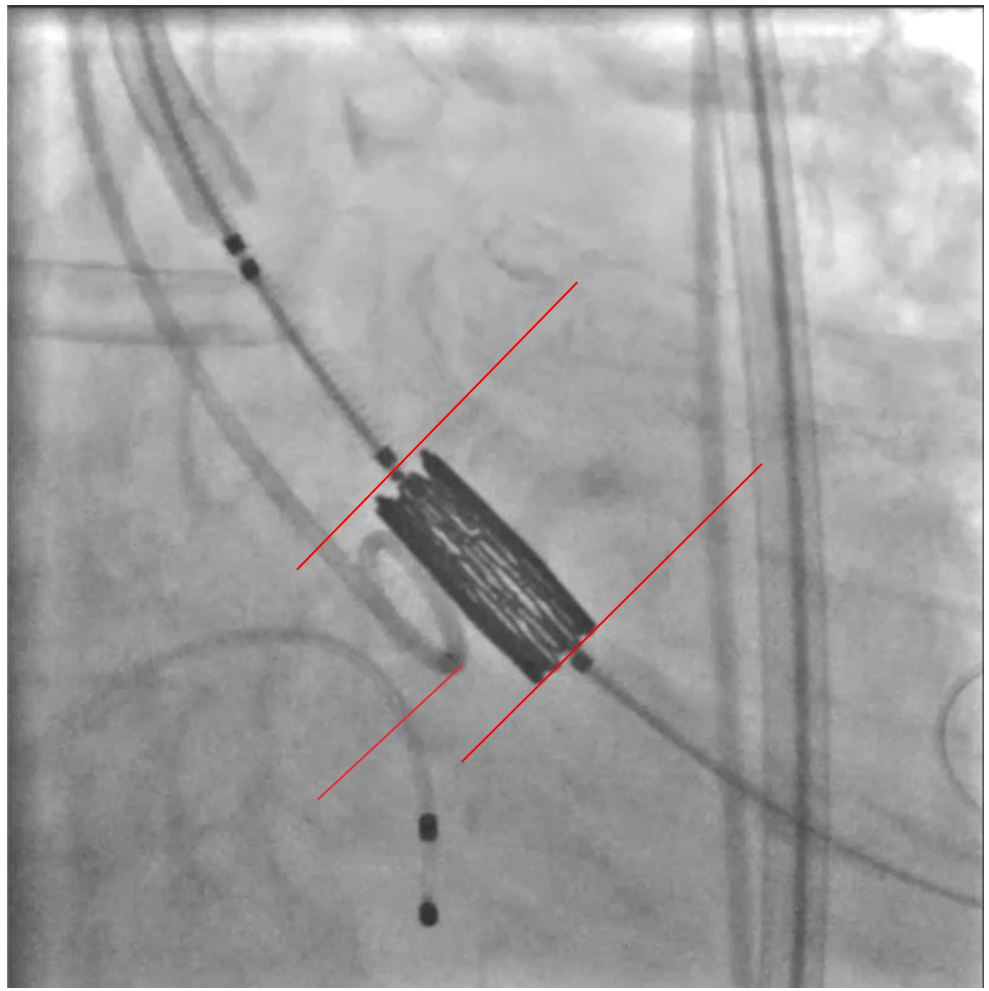




*Corelab assessment

n=19 n=19 n=17

Siegel TAVR Deployment



No Foreshortening Allows Consistent Higher Placement

+

Shorter Balloon in LVOT

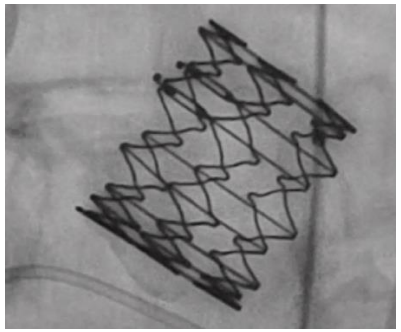
+

Less recoil /need for oversizing

↓

Should Reduce Conduction System Injury

Case 1



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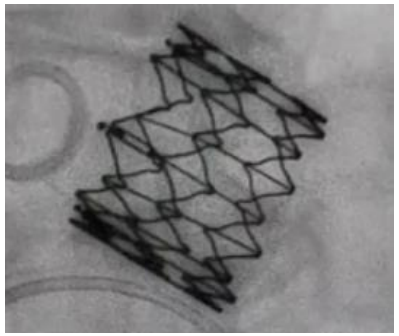

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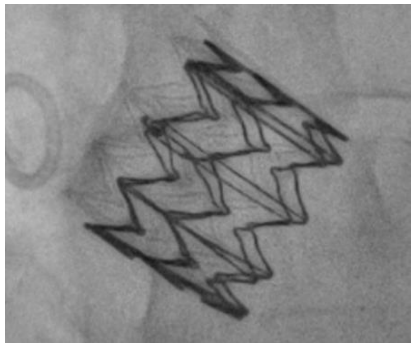

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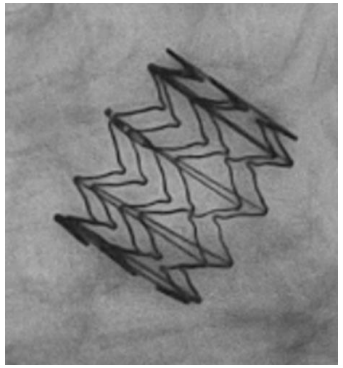

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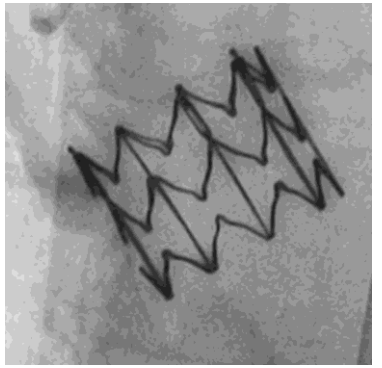

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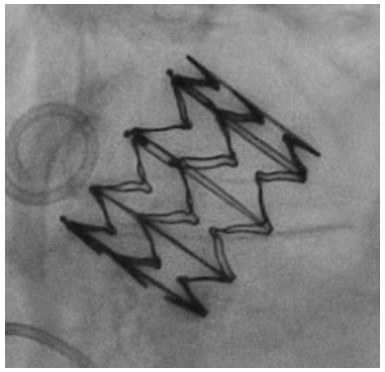

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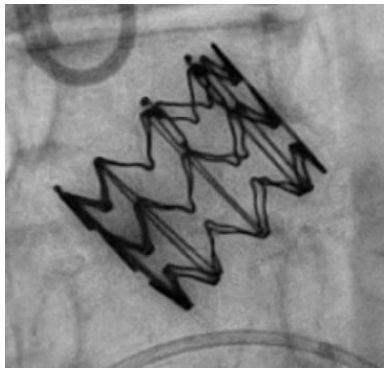

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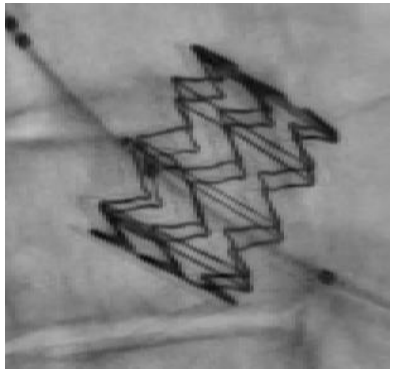

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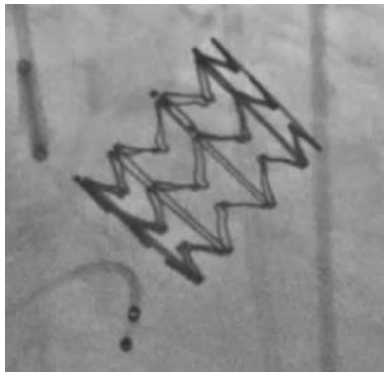

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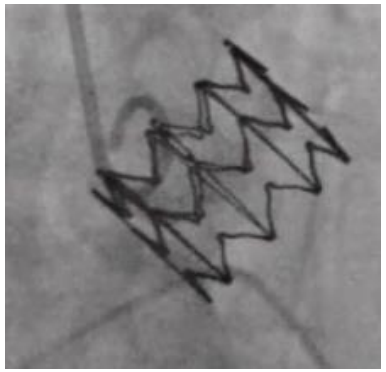

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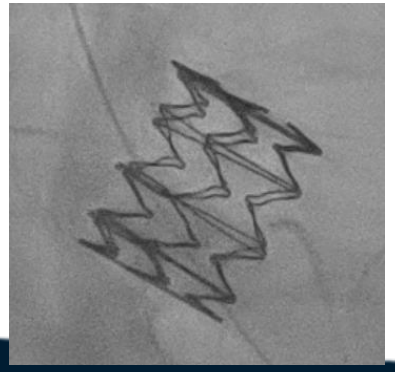

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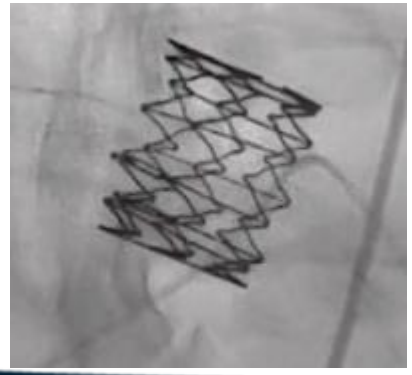

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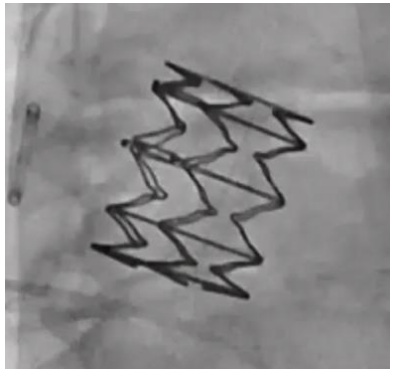

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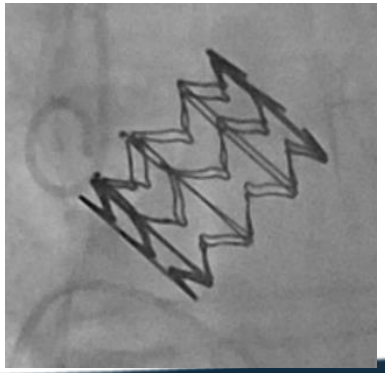

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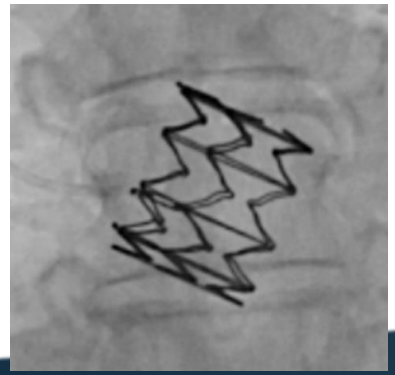

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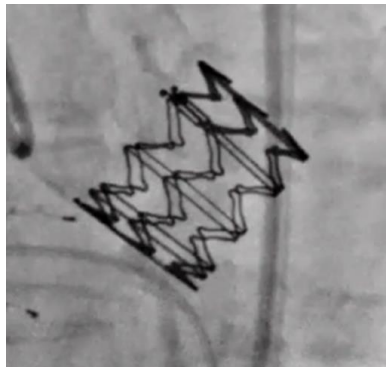
Case 16



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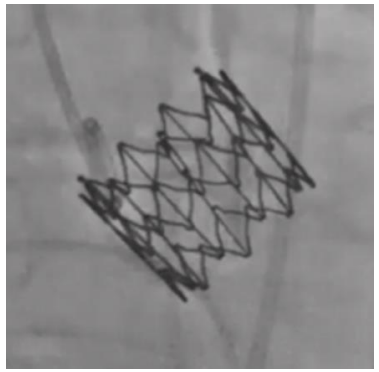

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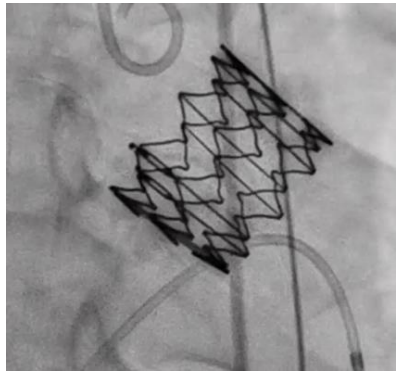

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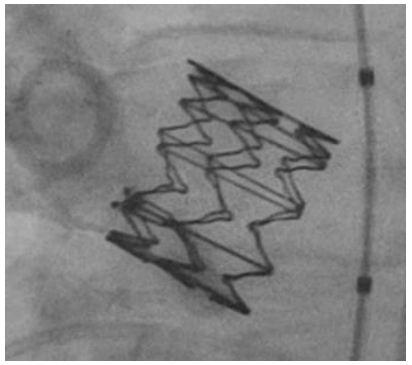

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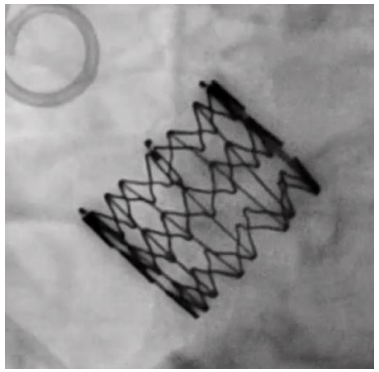

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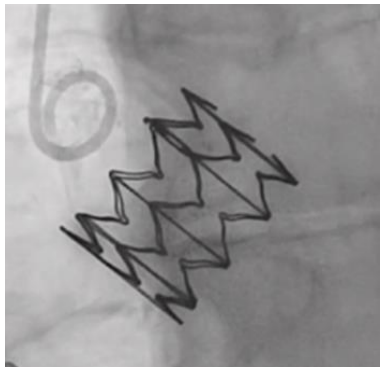

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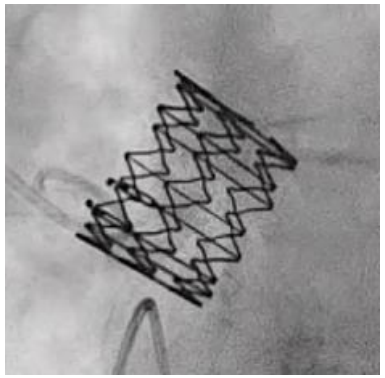

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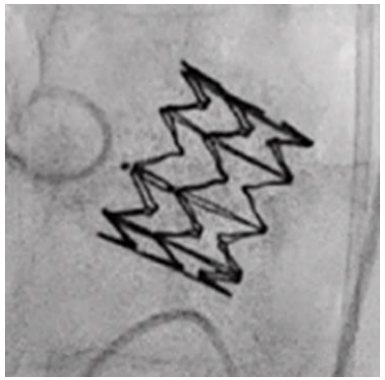

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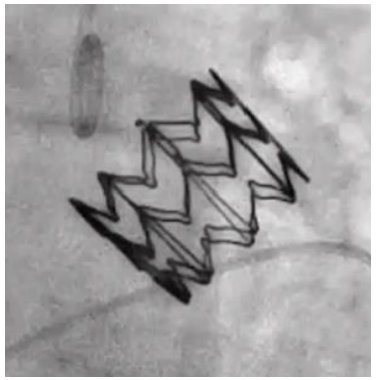

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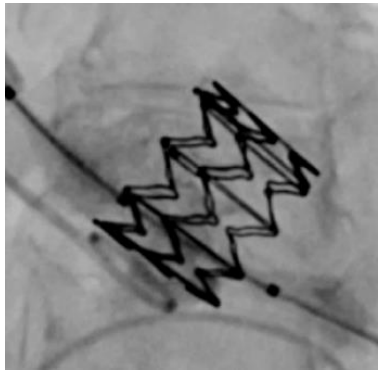

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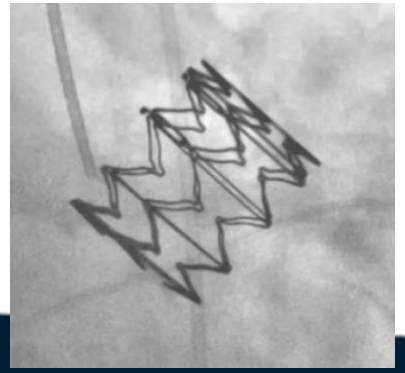

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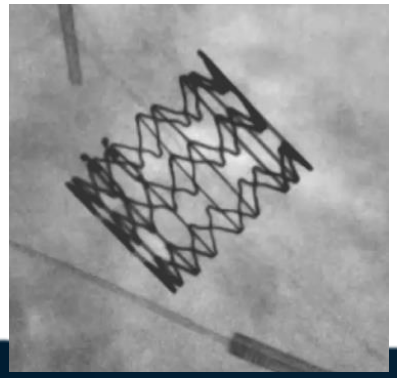

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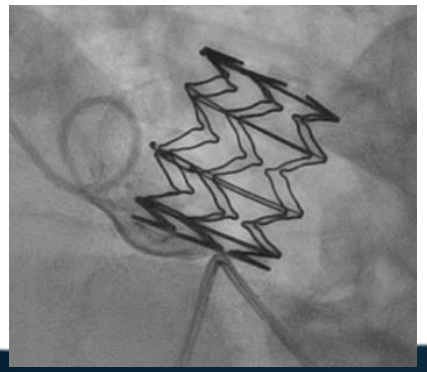

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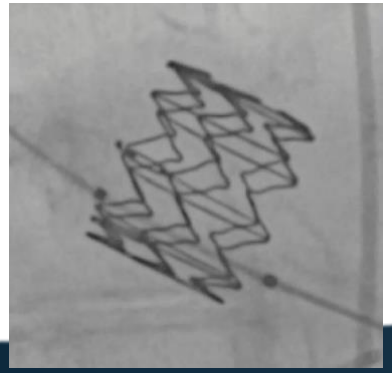

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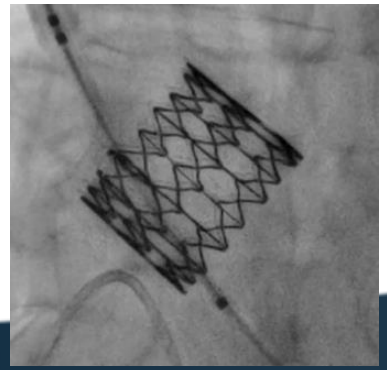

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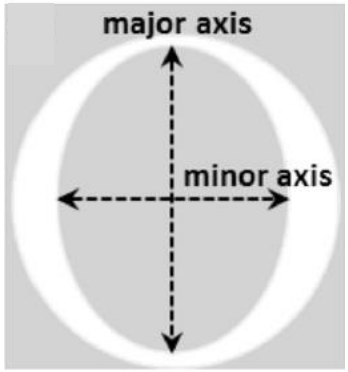
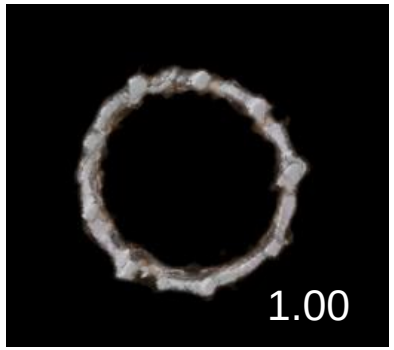
Siegel TAVR: Ellipticity Ratio

Ellipticity Ratio =
Major axis / Minor axis

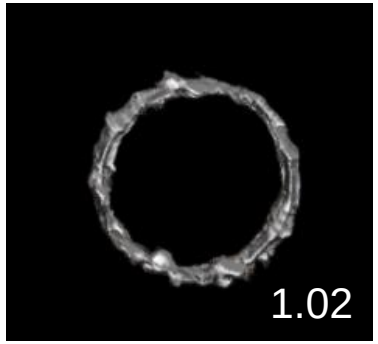


	Tricuspid	Bicuspid
Siegel	1.02	1.03
Sapien	1.09	1.12
Evolut	1.2	1.3

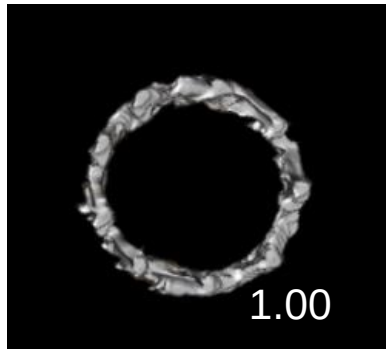
Case 1



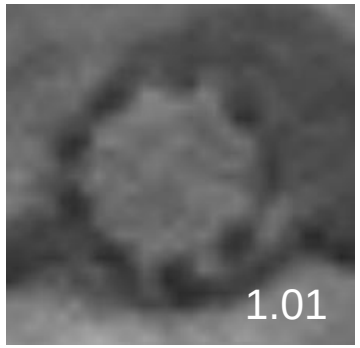
Case 2



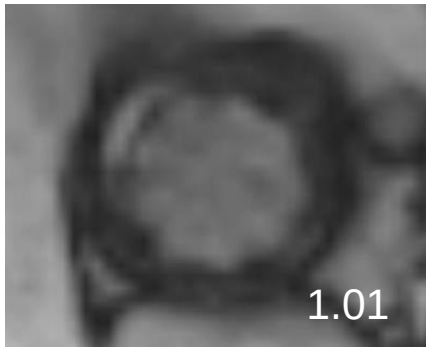
Case 3



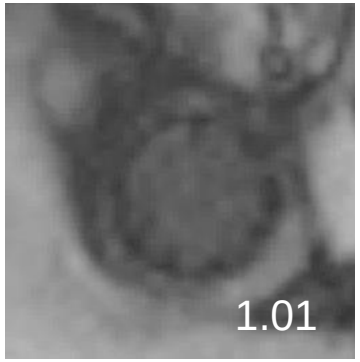
Case 4



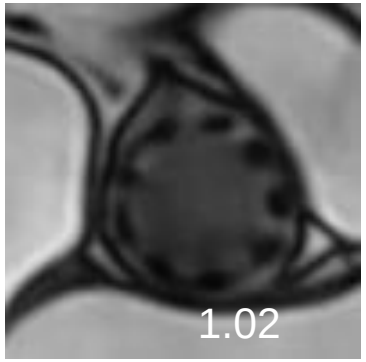
Case 5



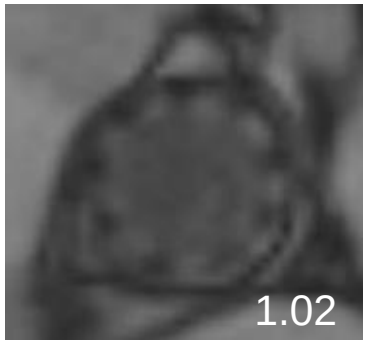
Case 6



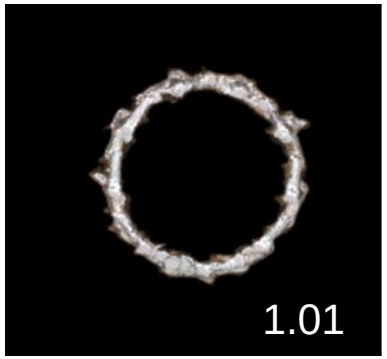
Case 7



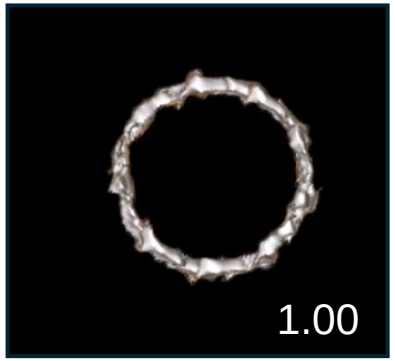
Case 8



Case 9



Case 10

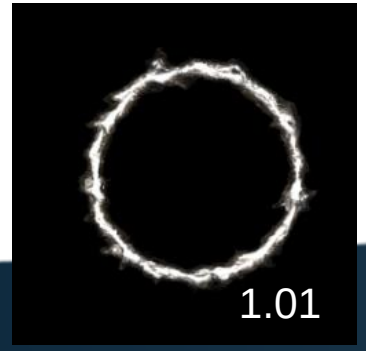


Case 11

Case 12

Case 13

Case 14

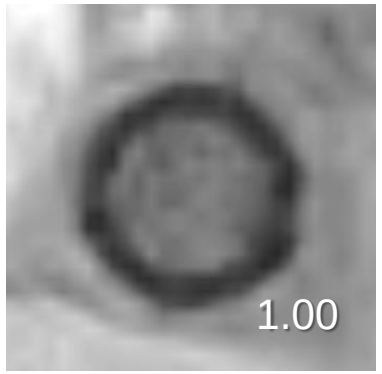


Case 15

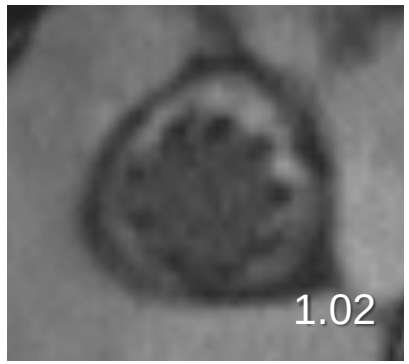
Tchetche D., de Biase C. Bicuspid Aortic Valve Anatomy and Relationship with Devices: The BAVARD Multicenter Registry. Circ Cardiovasc Interv. 2019;12:e007107: 1-10.

Case 16

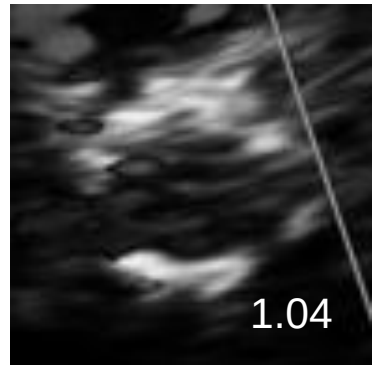
Case 17



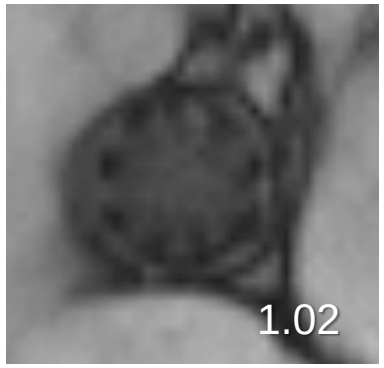
Case 18



Case 19

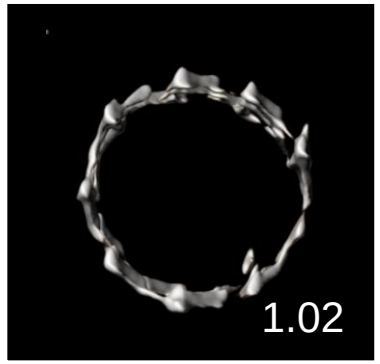


Case 20

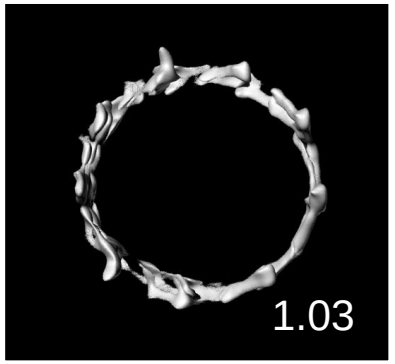


Case 21

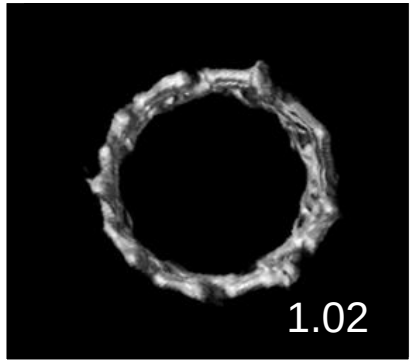
Case 22



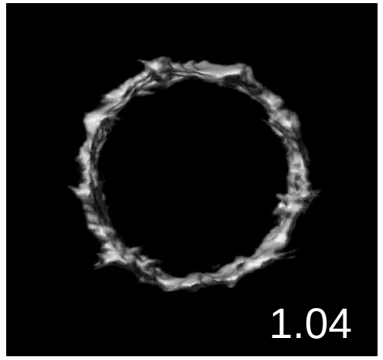
Case 23



Case 24



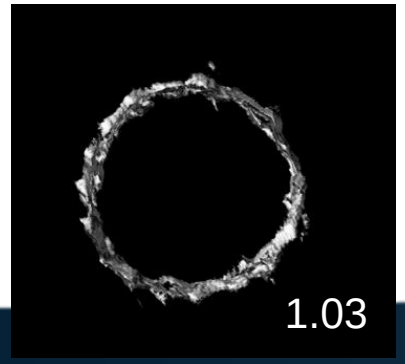
Case 25



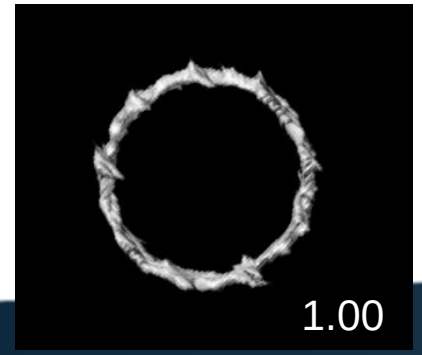
Case 26

Case 27

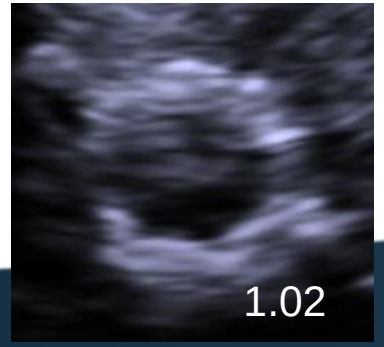
Case 28



Case 29



Case 30



CRF® TCT®

SIEGEL TAVR

+ Biocompatibility

Valve	Material
SIEGEL™	**Nickel Free**
Market Leader	Nickel, Cobalt

+ Pro-healing

Valve	Pro-healing	Surface
SIEGEL™	**+++**	**Nitride Oxide Coating**
Market Leader	− − −	Nickel, Cobalt

Ø Foreshortening

Valve	Foreshortening
SIEGEL™	**0%**
Market Leader	27%

↓ Access Profile

Valve	Sheath Profile
SIEGEL™	**8 Fr**
Market Leader	14 & 16 Fr

↑ Radial Force

Valve	Radial Force
SIEGEL™	**70 N**
Market Leader	35 N

+ Tissue

Valve	Tissue
SIEGEL™	**Dry Porcine**
Market Leader	Dry Bovine

+ Hemodynamics

Benchtop

Valve	EOA	Gradient
26mm SIEGEL™	**3.0 cm^2**	**5.4 mmHg**
26mm Market Leader	2.4 cm^2	9.2 mmHg

Conclusions – MiRus Siegel Valve

1-year followup of 5 FIH

30-day followup of 30 US Early Feasibility Study patients

The elegant, precise balloon expandable Siegel TAVR showed promising results in the US EFS:

- No Nickel
- 8 Fr access – crimped on balloon
- No foreshortening ---> precise, high placement
- Low pacemaker rate

Hemodynamics are superior and valve is circular – which likely will result in better durability

All risk categories, pivotal randomized control trial is starting soon