MyVal – Balloon Expandable THV Science and Clinical Update

Imrankhan Lohani
Meril Life Science Pvt. Ltd.
India

MyVal – Balloon Expandable THV Design Philosophy

Meril

MyVal THV has been indigenously developed by Meril Life Sciences, Vapi, India

Hybrid Honeycomb Cell Design Concept

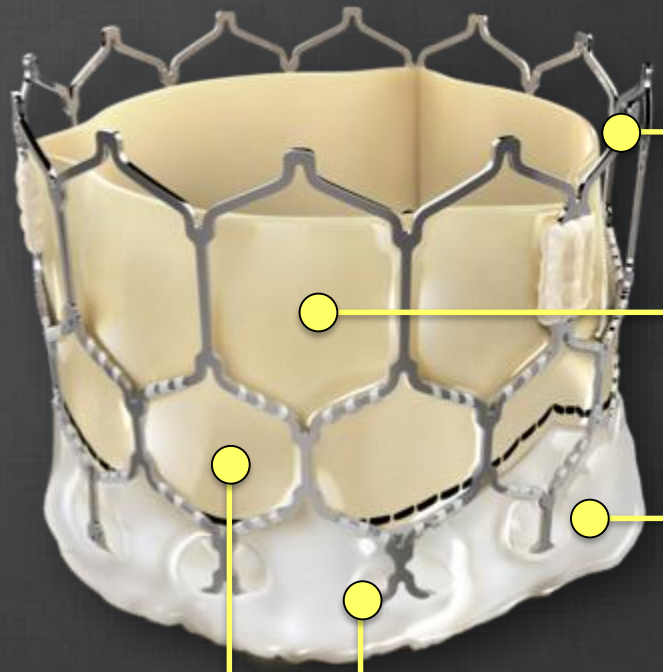
Open cells on upper half to ensure un-jailing of coronary ostia

Closed cells on lower half for high radial strength

≈ 53%

≈ 47%

Frame height 17-20 mm



Nickel Cobalt alloy frame for high radial strength & RO

Bovine pericardium Tri-leaflet valve

External PET buffing to minimize para-valvular leaks

Internal PET sealing cuff for lower profile & puncture resistance

Ø – 20 mm, 23 mm, 26 mm, 29 mm#
21.5 mm 24.5 mm 27.5 mm#
30.5 mm 32 mm XL*

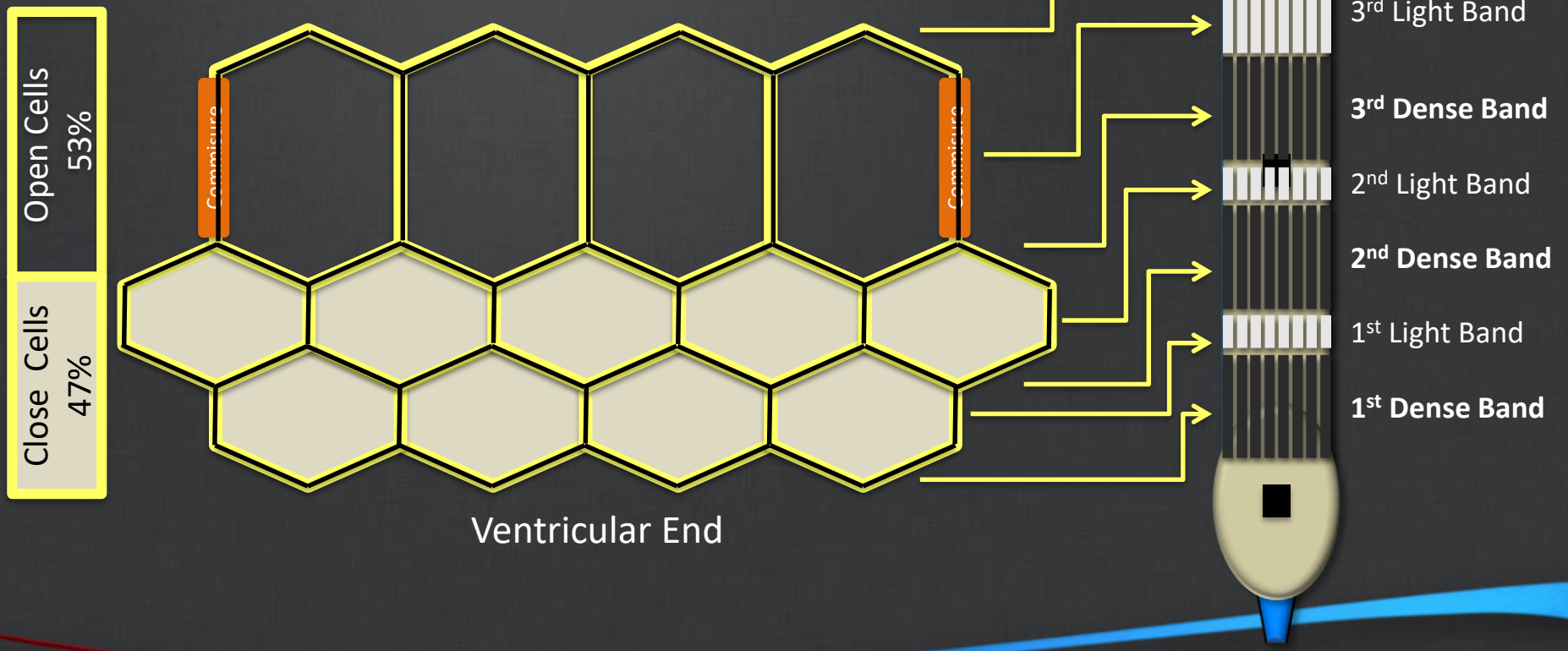
- Sizes available now
* - Sizes coming soon

Approved in India Oct 2018
CE Marked April 2019

MyVal – Precise Deployment

Upon Crimping-

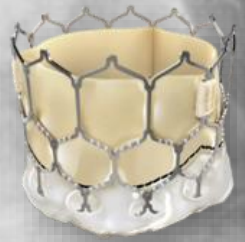
- ***V-shaped hinges*** on hexagonal frame fold, generating the dense bands on fluoroscopy
- ***Vertical connectors*** **|** give rise to light bands
- Alternating V-folds & vertical connectors give MyVal a unique appearance on fluoro for ease of positioning



MyVal – Precision Placement Technique

Meril

Schematic of Crimped MyVal on Navigator Balloon



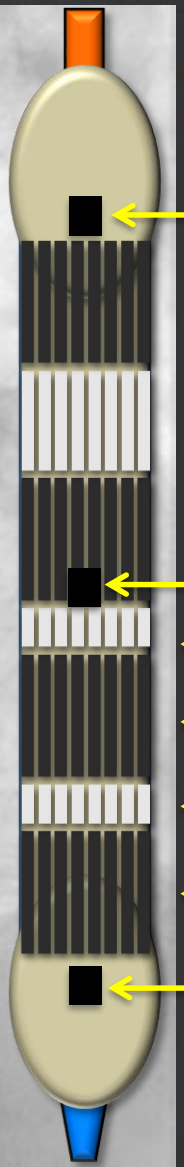
2nd Dense Row Landing Zone

Annular Plane

Upon Crimping-

- Alternating V-folds & vertical connectors give MyVal a unique appearance on fluoro for ease of positioning

Distal End
Towards Ventricle



Prox. balloon marker

Mid balloon marker

2nd Light Band

2nd Dense Row

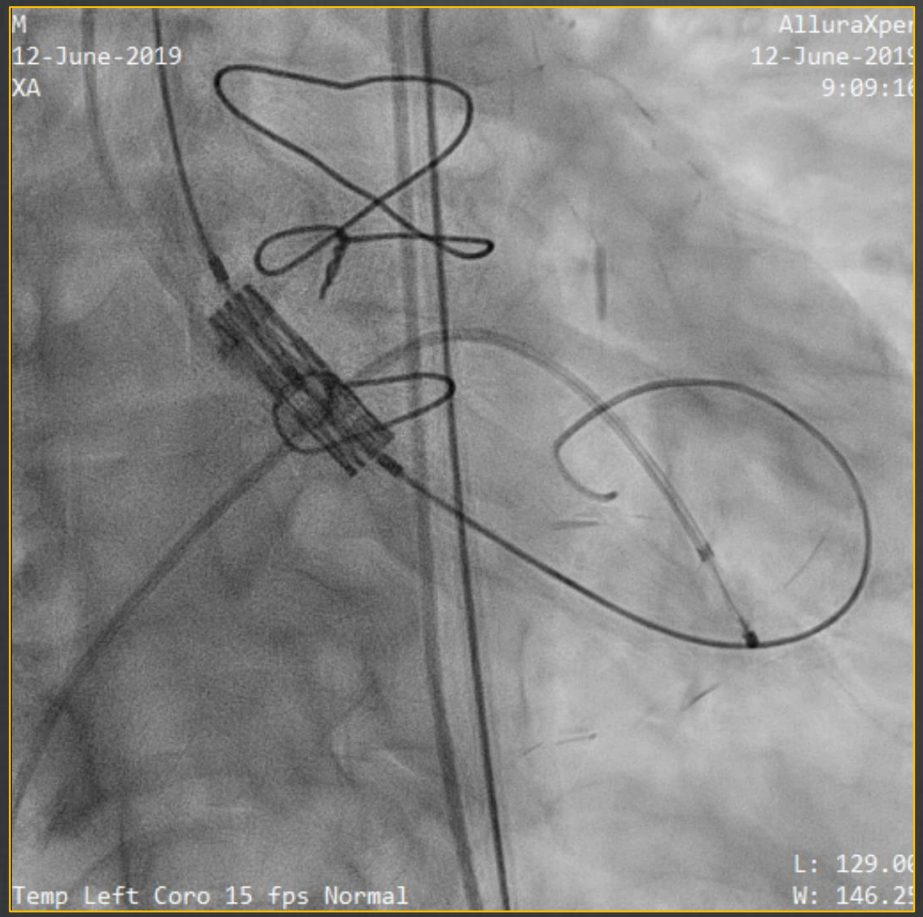
1st Light Band

1st Dense Row

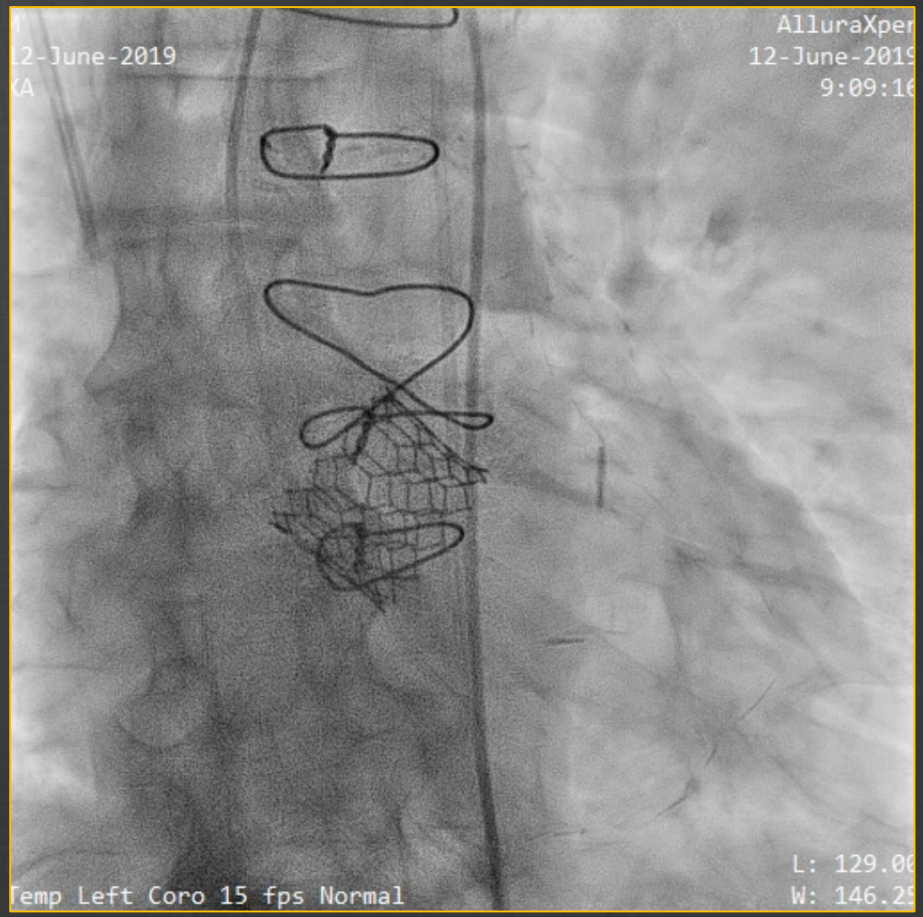
Dist. balloon marker

Myval 24.5 mm Deployment

24.5mm Myval Deployment



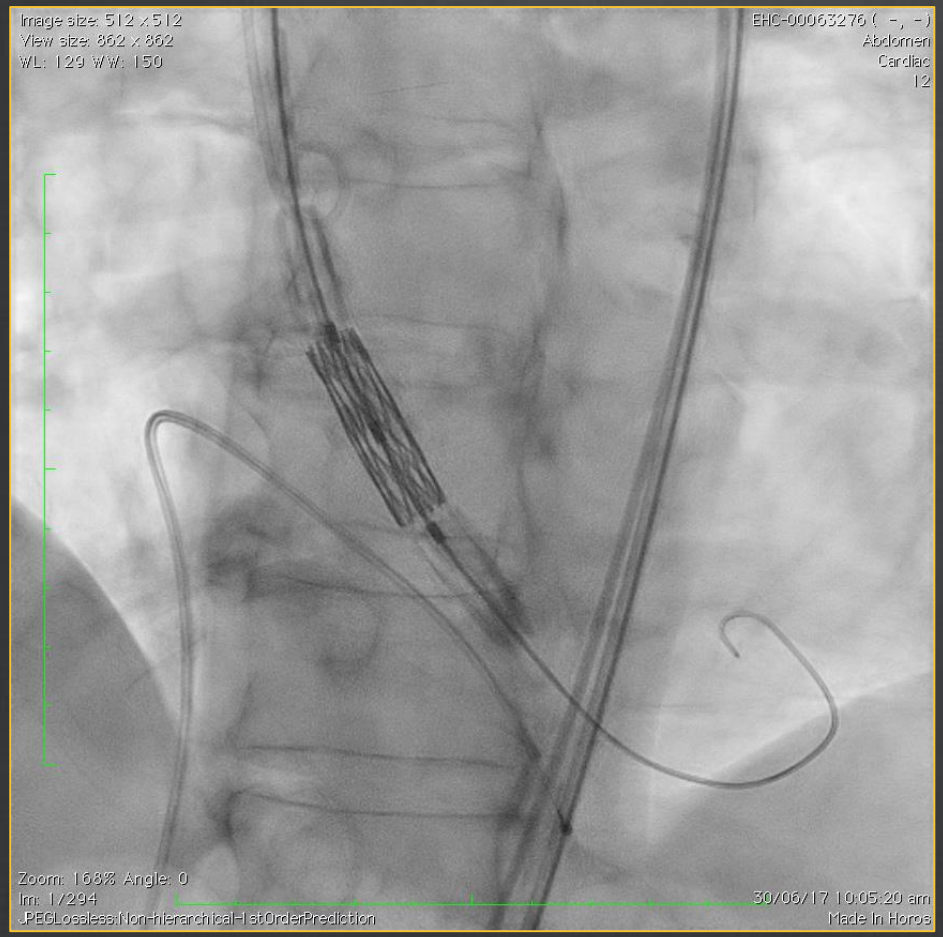
24.5mm Myval



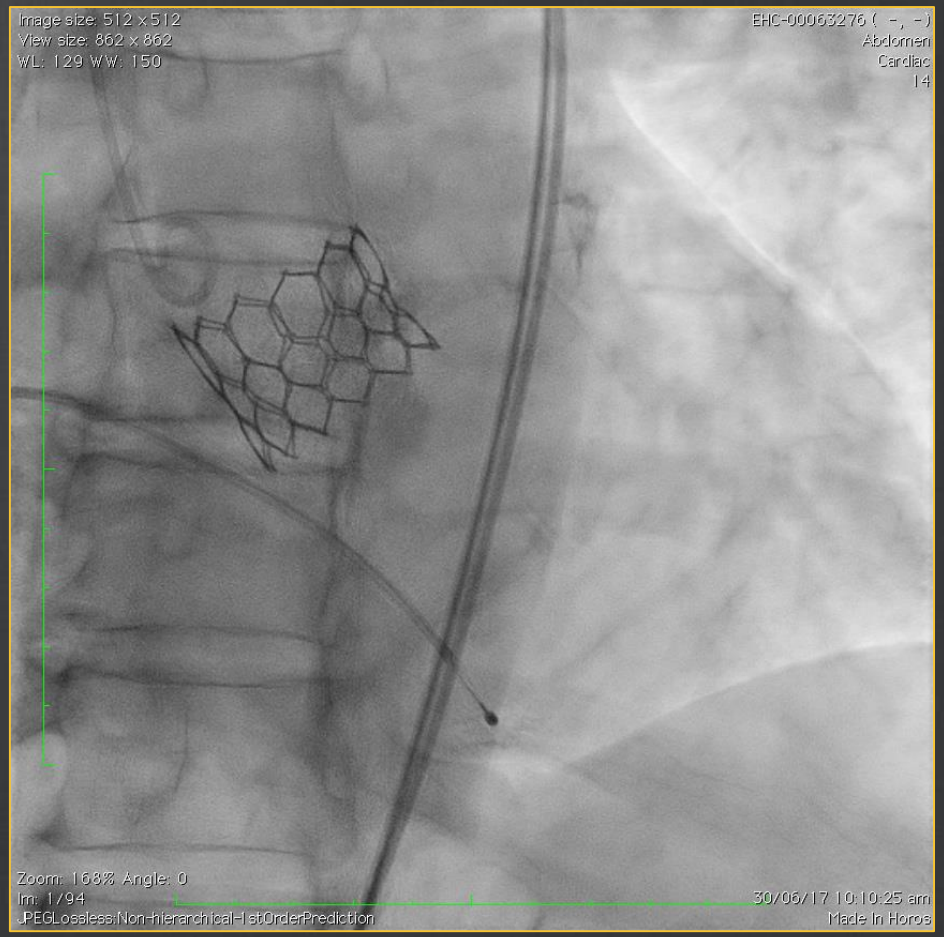
Clinical case, images and videos courtesy Dr. Jagdish Parikh / Dr. Ravinder Singh Rao, S. R. Mehta Hospital, Mumbai, India

MyVal 29 mm Deployment

Precise placement & deployment



Final – Orthotopic Deployment



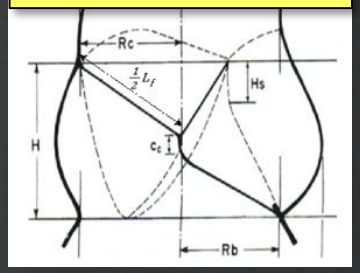
Clinical case, images and videos courtesy Dr. Samin Sharma & Dr. Ravinder Singh Rao, EHCC, Jaipur, India

Myval – Sizing Rationale

Meril

- Precision sizing during TAVR is most crucial
  - Ideally TAVR sizing has been in the range of 10-15% over the CT derived annulus diameter
  - This is in correlation with other cross-sectional measurements - AAo | STJ | SOV | LVOT | Height of coronary ostia | Valve anatomy (tricuspid/bicuspid) | Ca^{2+} score & dispersion across the root complex
  - For a particular implant geometry, the ideal design characteristics are determined based on several anatomical features that lead to optimal valve performance & a long term fatigue free failure; simultaneously minimizing risk for anatomical trauma

Preserve Geometry

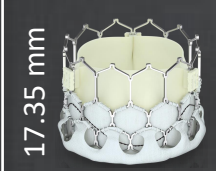
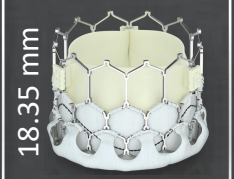


Respect Anatomy

  - Traditionally B/Ex-TAVR sizes have been 20, 23, 26 & 29 mm diameters
    - This limited size matrix necessitates adjustments in nominal volume in order to over/under expand to ensure a proper fit of the prosthetic valve to patient's area derived annulus diameter and to prevent any procedural trauma to the aortic root complex
  - This empirical adjustment to fit the '*Patient to the Prosthesis*' is unnecessary & sub-ideal; may lead to change in implant design geometry or lead to procedural trauma
  - Myval size matrix has been developed to address this important unmet clinical need
  - With large matrix of *Traditional* + new *Intermediate* sizes now one can fit the '*Prosthesis to the Patient*' without concern for over/under expansion and ensure ideal valve geometry for optimal trauma free procedure & long term fatigue free valve performance

MyVal – Size Matrix

Meril

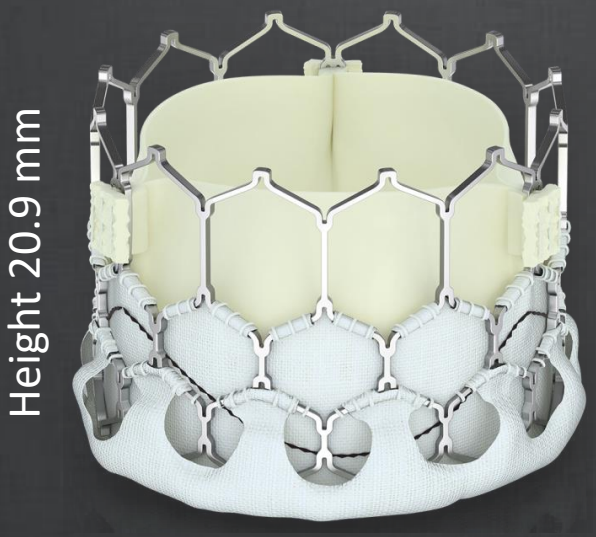
MyVal Size Matrix & Technical Specs.	Area 314 mm²  20 mm	Area 363 mm²  21.5 mm	Area 415 mm²  23 mm	Area 471 mm²  24.5 mm	Area 531 mm²  26 mm	Area 594 mm²  27.5 mm	Area 661 mm²  29 mm
Perimeter	62.83 mm	67.54 mm	72.26 mm	76.97 mm	81.68 mm	86.39 mm	91.11 mm
Python Expandable Introducer Sheath	14 Fr	14 Fr	14 Fr	14 Fr	14 Fr	14 Fr	14 Fr
Native Annulus Area (CT Derived)	270 – 330 mm²	314 – 380 mm²	360 – 440 mm²	410 – 500 mm²	460 – 560 mm²	510 – 630 mm²	570 – 700 mm²
Area-derived diameter	18.5 – 20.5 mm	20.0 – 22.0 mm	21.4 – 23.7 mm	22.8 – 25.2 mm	24.2 – 26.7 mm	25.5 – 28.3 mm	26.9 – 29.9 mm
Native Annulus Size by TEE	16 – 19 mm	17.5 – 20.5 mm	18 – 22 mm	19.5 – 23.5 mm	21 – 25 mm	22.5 – 26.5 mm	24 – 28 mm

Sizing of Myval-THV should be in correlation with cross-sectional CT images/measurement of AAo | STJ | SOV | Annulus | LVOT | Coronary ostia heights | Valve anatomy (tricuspid/bicuspid) | Ca^{2+} score & dispersion across the root complex during the heart team meeting prior to procedure.

Large Annulus? No Worries!!

Myval – XL sizes soon to be available

Area 731 mm^2



Dia - 30.5 mm

Area 804 mm^2

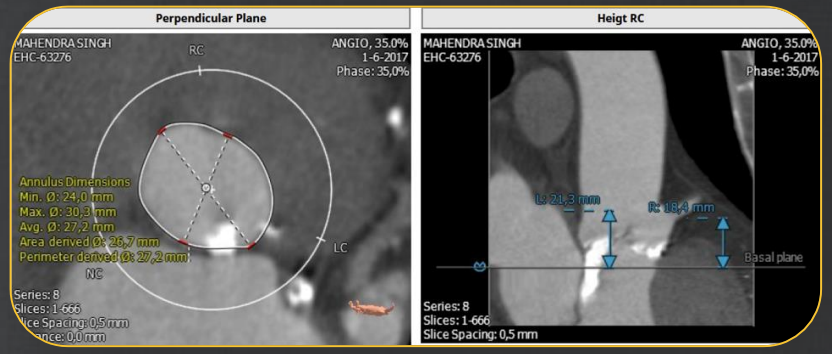
Dia 32.0 mm

Myval – XL 30.5 and 32 mm are currently not CE marked and not available for sale.

MyVal – Sizing Rationale Example

Meril

- For an area of 561.2mm^2; 26.7 mm diameter annulus, traditionally 29mm Myval would have 17.5% over size
- Ideal valve sizing may be in the range of 10-15% higher than area derived annulus diameter to have a good valve apposition
- Large Ca^{2+} at the LCC running towards LVOT is a potential risk for trauma. In such situation with traditional sizing, 2cc less volume of contrast : saline is considered prudent



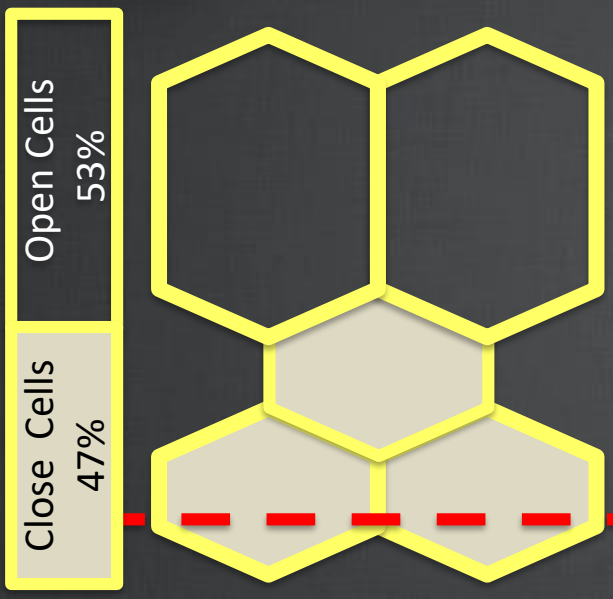
3D Annular area mm^2		480	490	500	510	520	530	540	550	561.2	570	580	590
3D area derived diameter mm		24.7	25.0	25.2	25.5	25.7	26.0	26.2	26.5	26.7	26.9	27.2	27.4
% Annular area over/under using different Myval sizes													
Not ideal	20 mm	-34.6%	-35.9%	-37.2%	-38.4%	-39.6%	-40.7%	-41.8%	-42.9%	-44.0%	-44.9%	-45.8%	-46.8%
Not ideal	21.5 mm	-24.4%	-25.9%	-27.4%	-28.8%	-30.2%	-31.5%	-32.8%	-34.0%	-35.3%	-36.3%	-37.4%	-38.5%
Not ideal	23 mm	-13.4%	-15.2%	-16.9%	-18.5%	-20.1%	-21.6%	-23.1%	-24.5%	-26.0%	-27.1%	-28.4%	-29.6%
Not ideal	24.5 mm	-1.8%	-3.8%	-5.7%	-7.6%	-9.3%	-11.0%	-12.7%	-14.3%	-16.0%	-17.3%	-18.7%	-20.1%
Sub ideal	26 mm	10.6%	8.4%	6.2%	4.1%	2.1%	0.2%	-1.7%	-3.5%	-5.4%	-6.9%	-8.5%	-10.0%
Most ideal	**27.5 mm**	**23.7%**	**21.2%**	**18.8%**	**16.5%**	**14.2%**	**12.1%**	**10.0%**	**8.0%**	**5.8%**	**4.2%**	**2.4%**	**0.7%**
Sub ideal	29 mm	37.6%	34.8%	32.1%	29.5%	27.0%	24.6%	22.3%	20.1%	17.7%	15.9%	13.9%	12.0%

Preserve Geometry, Respect Anatomy

Clinical case images courtesy Dr. Samin Sharma & Dr. Ravinder Singh Rao, EHCC, Jaipur, India

MyVal Sizing – Coronary Height Cut-Offs

Meril



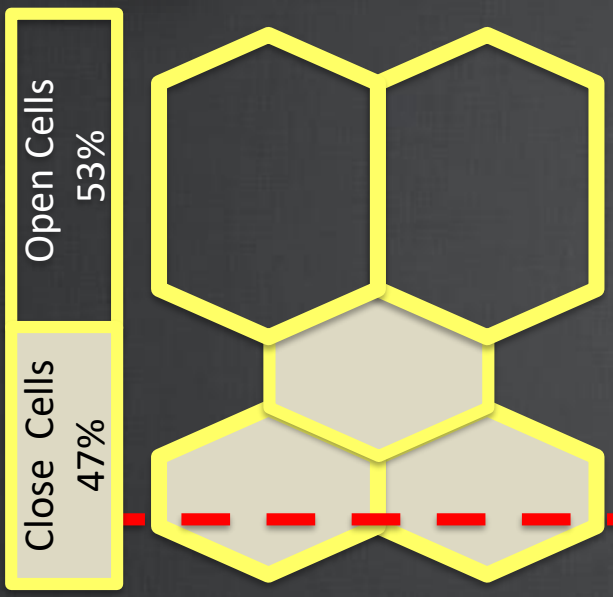
MyVal Sizes	20 mm	23 mm	26 mm	29 mm
MyVal Total Height	17.35 mm	17.85 mm	18.85 mm	20.35 mm
MyVal Open Cells 53%	9.19 mm	9.46 mm	9.99 mm	10.87 mm
MyVal Close Cells 47%	8.16 mm	8.39 mm	8.86 mm	9.48 mm
MyVal Infra-annular height	3.05mm	2.85 mm	3.05 mm	3.35 mm
Supra-annular height of close cells	5.11 mm	5.54 mm	5.81 mm	6.13 mm
Consider Coronary Protection	10 mm	10 mm	10 mm	10 mm

Largest circumscribable diameter in Open Cell

- Check Sinus of Valsalva lengths for each cusp
- Consider coronary protection if height ≤ 10mm with DES

MyVal Sizing – Coronary Height Cut-Offs

Meril



Largest circumscribable diameter in Open Cell

MyVal Sizes (mm)	21.5	24.5	27.5	30.5	32
MyVal Total Height (mm)	18.35	18.75	19.25	20.90	21.14
MyVal Open Cells 53% (mm)	9.73	9.94	10.20	11.08	11.21
MyVal Close Cells 47% (mm)	8.62	8.86	9.05	9.82	9.94
MyVal Infra-annular height (mm)	3.20	3.05	3.15	3.45	3.55
Supra-annular height of close cells (mm)	5.42	5.81	5.90	6.37	6.39
Consider Coronary Protection	10 mm	10 mm	10 mm	10 mm	10 mm

- Check Sinus of Valsalva lengths for each cusp
- Consider coronary protection if height ≤ 10mm with DES

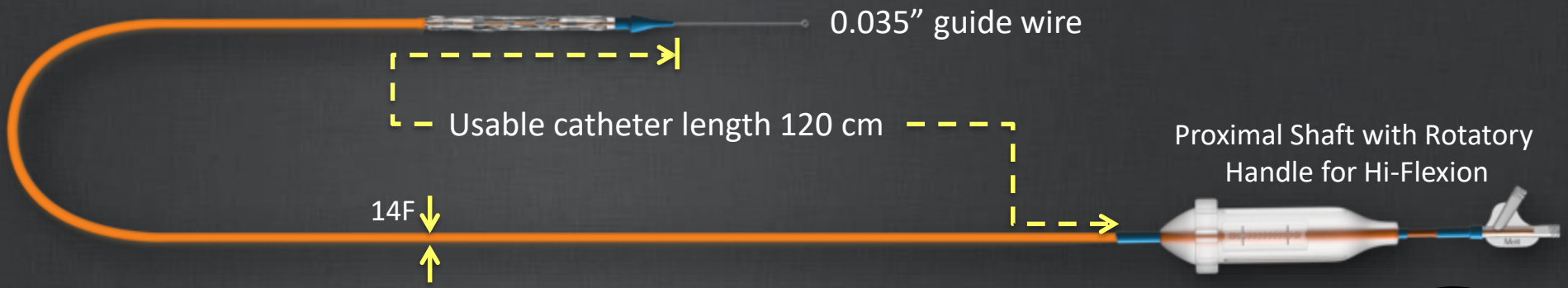
Delivering TAVI Made Easy

- MyVal THV device is recommended to be crimped directly across the balloon
- The crimped valve with delivery system is then loaded through 14Fr Python – Expandable Sheath

- Navigator balloon delivery system has a set of proximal and distal *Stoppers* which ensure that valve crimping is precise and snug.
- Visual confirmation of crimped valve can be had before entering the sheath to avoid any crimping errors/defects.
- The *Stoppers* prevent inadvertent migration of the valve & ensure there is no risk of valve dislodgement (embolization) during entry through the sheath or while negotiating the loaded delivery system across the aorta.
- MyVal THV direct crimping on the balloon makes TAVI delivery simple, intuitive and eliminates unwarranted procedural steps.

Navigator THV Delivery System

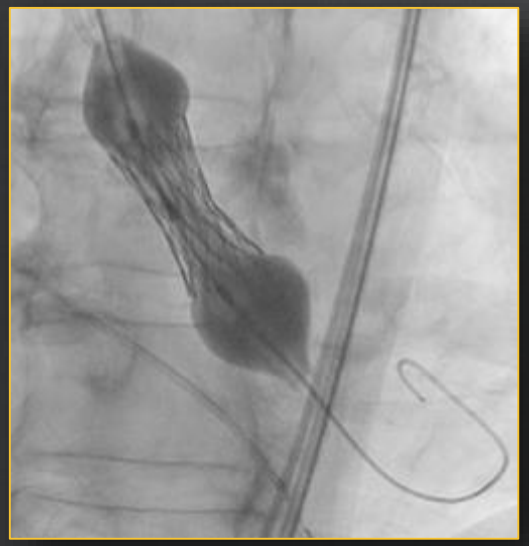
Navigator – THV Delivery System has been indigenously developed by Meril Life Sciences Pvt. Ltd.



Navigator Balloon Ø	20 mm	21.5 mm	23 mm	24.5 mm	26 mm	27.5 mm	29 mm	30.5 mm	32 mm
Balloon Length	30 mm					35 mm			
Balloon RBP	6 atm								
Ratio of 3:1 Saline : Contrast to achieve stated balloon Ø	12 mL	15 mL	18 mL	20 mL	23 mL	26 mL	30 mL	33 mL	36 mL

Navigator Balloon Expansion

- Navigator balloon with dual expansion ports at each end ensures rapid, simultaneous, controlled expansion (dog-boning) of distal and proximal ends
- This typical dog bone pattern of inflation steadies the Valve during expansion phase, ensure its precision annular position and deployment without any risk of valve migration or embolization
- Rapid balloon inflation using a inflation device is possible with controlled palm thrust
- Rapid balloon deflation 3-5 sec ensures procedure safety and compliance

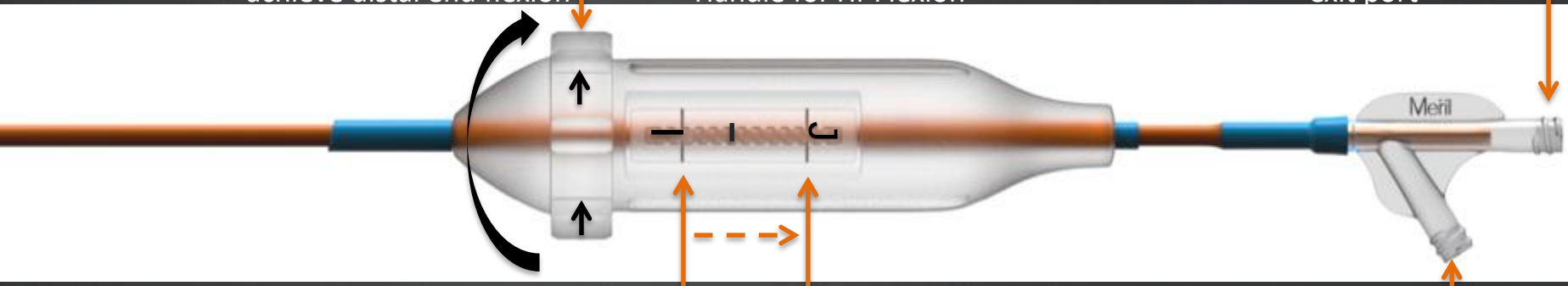


Navigator – Proximal Assembly

Clock-wise rotation to achieve distal end flexion

Proximal Shaft with Rotatory Handle for Hi-Flexion

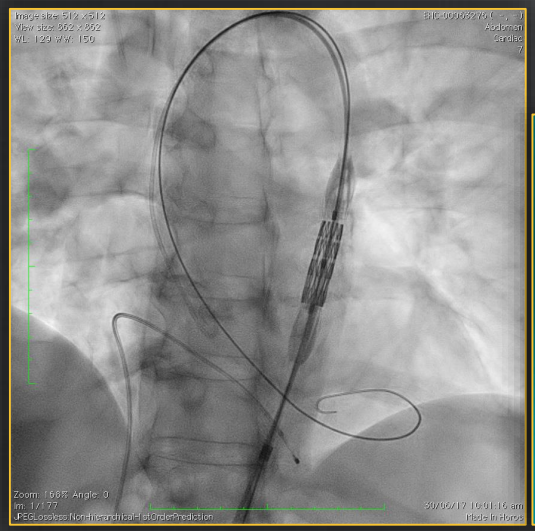
0.035” Guide wire exit port



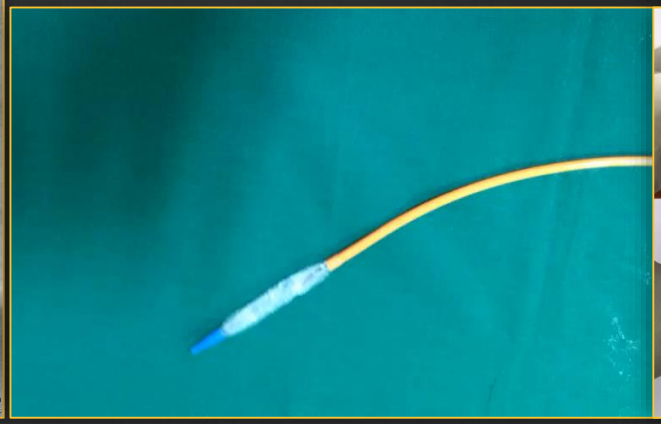
Un-deflected Catheter position (straight)

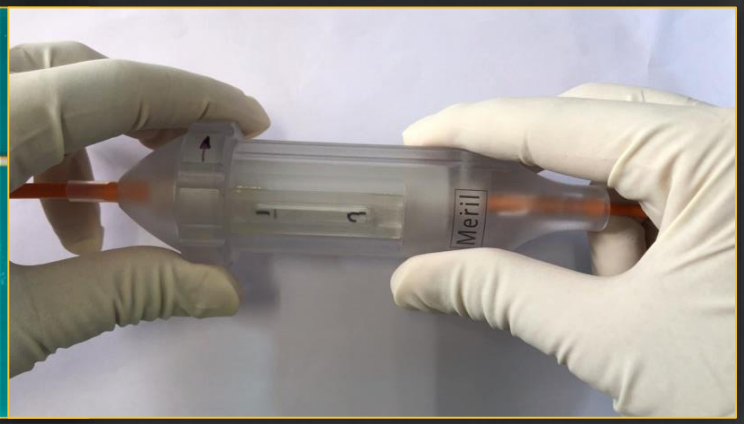
Maximum deflection catheter position

Balloon inflation port



Note the horizontal band – migration from straight to J symbol denoting distal flexion



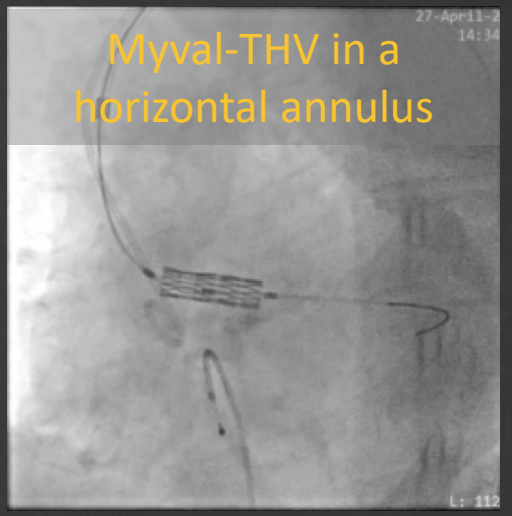


Caution : Always remember to fully un-flex the Navigator system while withdrawing

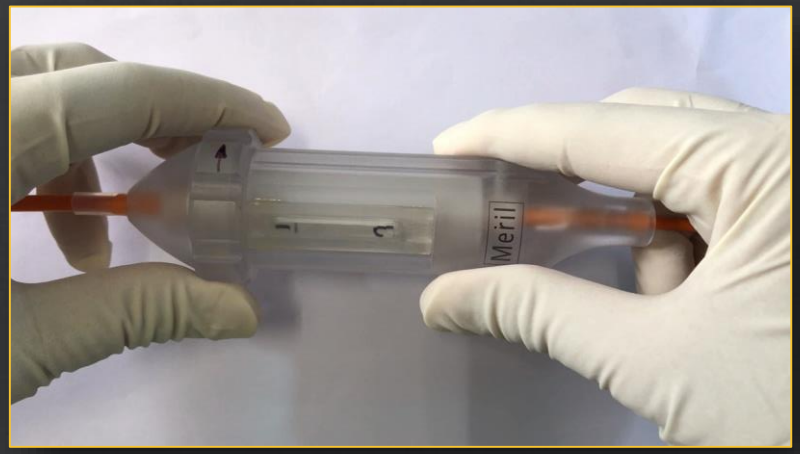
Navigator – Deep-Flexion

Horizontal annulus

Deep flexion is possible



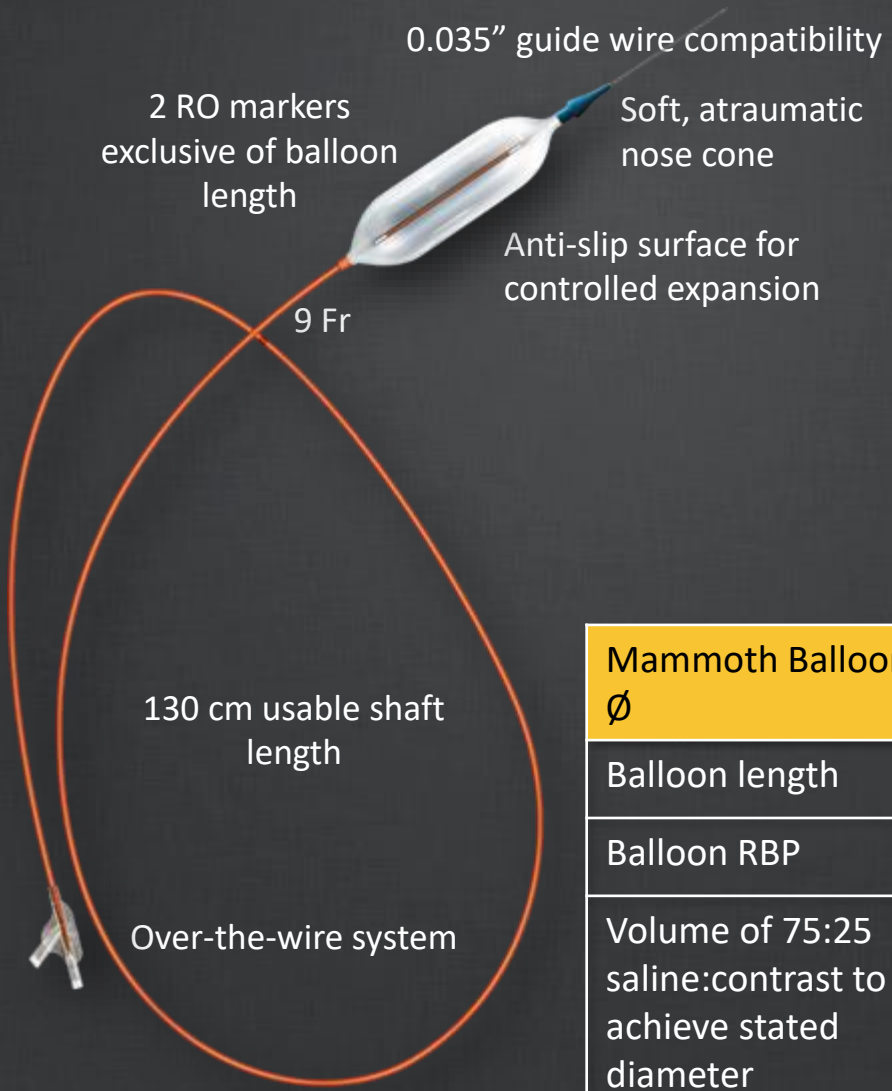
Turn proximal flexion knob & advance system

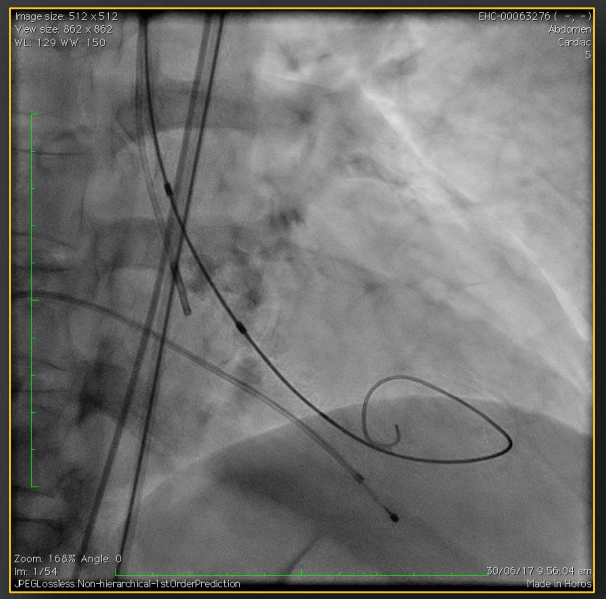


Caution : Always remember to fully un-flex the Navigator system while withdrawing

Mammoth OTW Balloon

Mammoth – Balloon Catheter has been indigenously developed by Meril Life Sciences Pvt. Ltd.





Mammoth Balloon Ø	14 mm	16 mm	18 mm	20 mm	23 mm	25 mm
Balloon length	← 40 mm →					
Balloon RBP	← 6 atm →					
Volume of 75:25 saline:contrast to achieve stated diameter	7 mL	10 mL	13 mL	18 mL	23 mL	30 mL

Python – 14Fr Expandable Introducer Sheath

Meril

Sheath expands momentarily (like a python swallowing prey)
to allow passage of THV crimped balloon catheter

A separate loading tube ensures temporary opening of sheath valve allowing smooth passage of crimped Myval-THV

Atraumatic, 14 Fr Distal Entry Profile
Allows for percutaneous access

RO distal tip

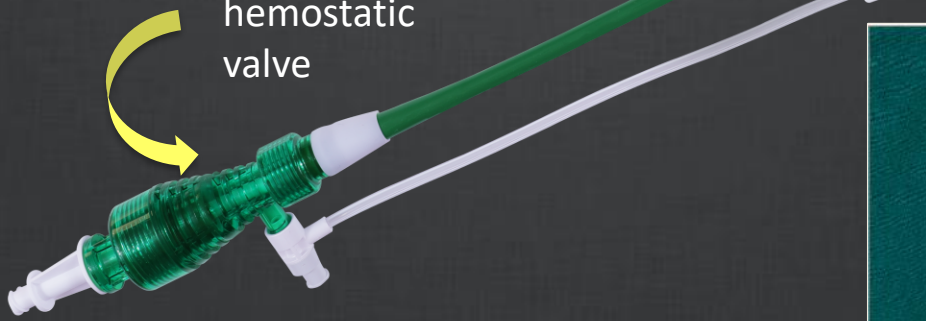
Seamless transition from dilator to distal tip

14 Fr Profile for all Myval diameters
Ø 20, 23, 26, 29 mm

Lubricious, hydrophilic shaft coating

30 cm usable length

One-way hemostatic valve

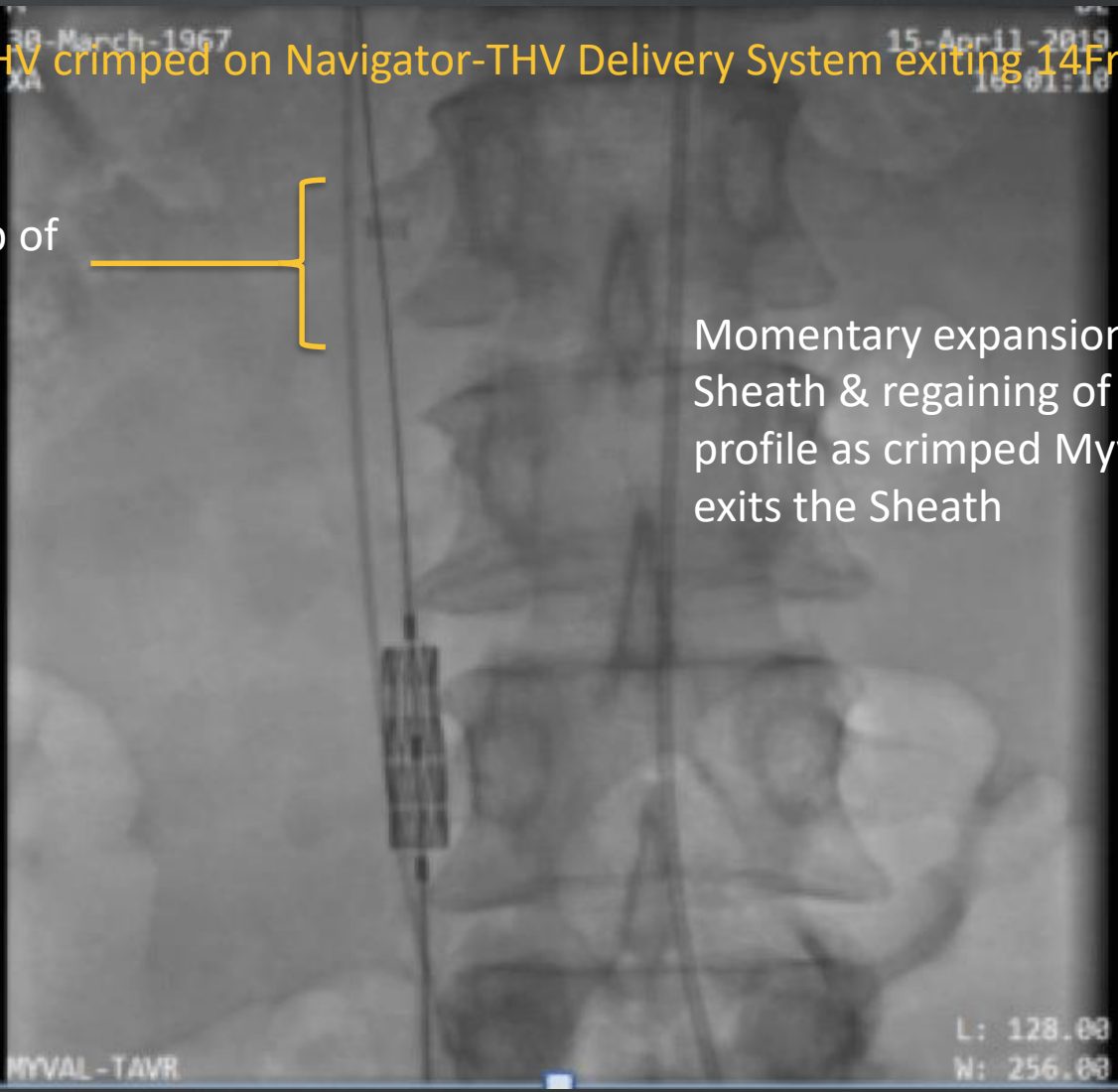


Proximal Entry Port
Allows for smooth valve loading

Python Expansion

26mm Myval-THV crimped on Navigator-THV Delivery System exiting 14Fr Python Sheath

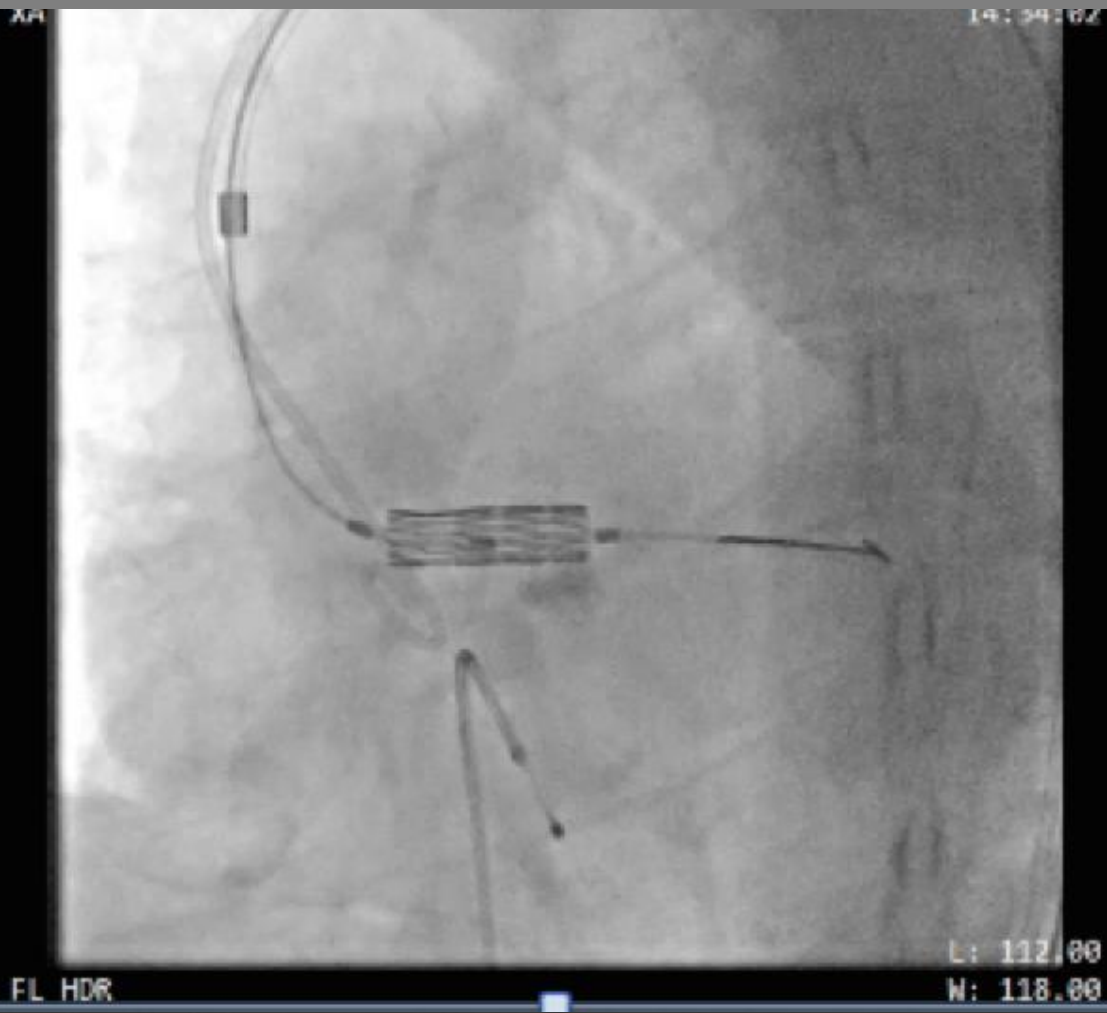
Distal RO marker tip of Python Sheath



Momentary expansion of Python Sheath & regaining of original profile as crimped Myval-THV exits the Sheath

Myval THV Recapture in Python

Myval-THV being retrieved from a severely Ca2+, bicuspid, horizontal annulus

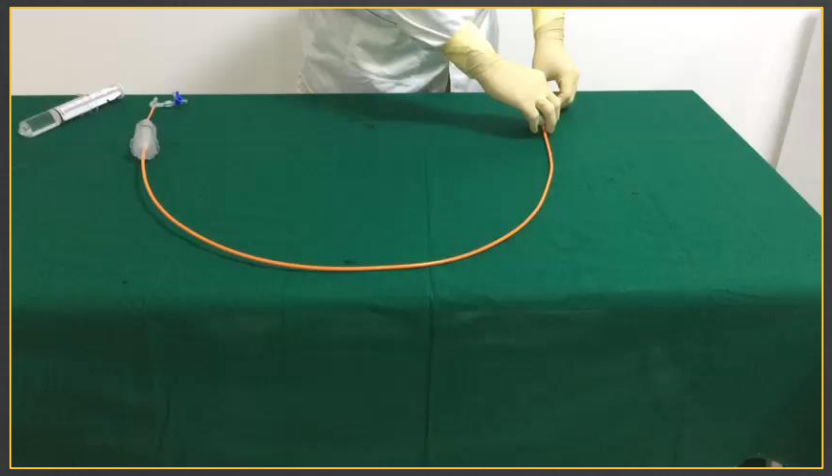


Caution : Always remember to fully un-flex the Navigator system while withdrawing

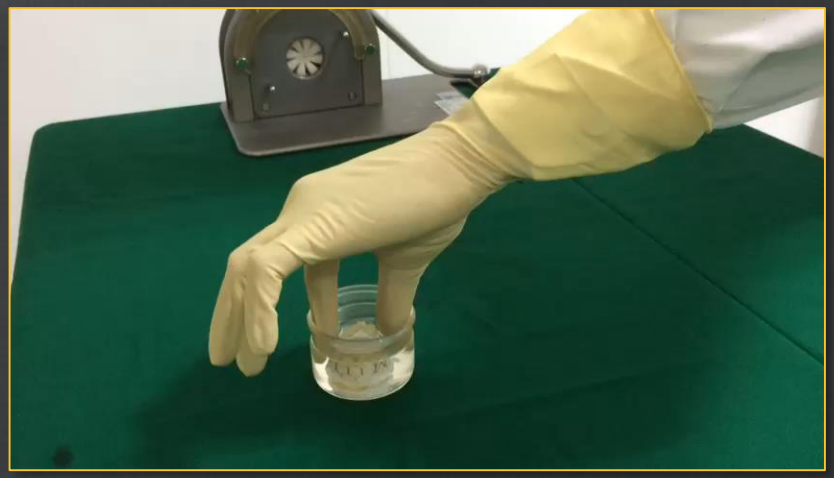
MyVal + Navigator Preparation

CrocoDial – Heart Valve Crimping Tool has been indigenously developed by Meril Life Sciences Pvt. Ltd.

A. Flushing guide wire lumen with saline

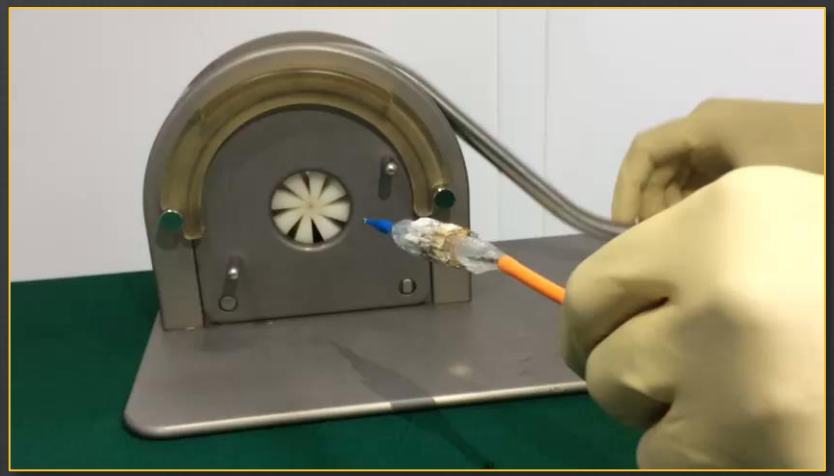


B. Partial crimping of the valve



C. Initial crimping of valve on balloon

D. Final crimping of the valve



MyVal – Global Clinical Program

2000 Pts

MyVal-1[1] (n=30/30)
FiM Pilot Study. Intermediate to high surgical risk subjects.
20 Indian Sites

MyVal-1[2] (n=70)
Extended to 100 subjects in India. Intermediate to high risk.
26 Indian Sites.

LANDMARK RCT[3] **(N=544)**
2:1:1 RCT Myval : EDW : MDT
Low, Intermediate to High surgical risk subjects. EU/Brazil/ANZ/SK. 50+ participating sites.

MyVal Global[4] (n=1,000)
Low, Intermediate to High surgical risk subjects. Real world registry.
100 participating sites.

MyVal-China[5] (n=110)
High surgical risk subjects
10 participating sites

1. **Primary endpoint achieved. 1-Y f/up @ EuroPCR 2019**
2. **Enrollment complete. 1m f/up N=100 @ TCT 2019**
3. **Initiated. FPFV First Patient First Visit expected Nov 2019.**
4. **Initiated. FPFV First Patient First Visit expected Dec 2019.**
5. **Pre-study activities initiated.**

Investigating Sites

30 Subjects, 14 Investigating Sites

Investigator Name	Site Name and City	# Enrollment
Dr. Ashok Seth	Fortis Escorts, New Delhi	3
Dr. Praveen Chandra	Medanta, Gurugram	1
Dr. Ravinder Singh Rao	Eternal Heart, Jaipur	7
Dr. Amit Kumar Chaurasia	BLK Hospital, Delhi	1
Dr. Pravin Kumar Goel	SGPGI, Lucknow	4
Dr. Rishi Sethi	Lari Cardio, Lucknow	1
Dr. Prashant Bharadwaj	MHCTC, Pune	4
Dr. Ajaykumar U. Mahajan	Sion Hospital, Mumbai	2
Dr. C N Manjunath	Sri Jayadeva, Bengaluru	1
Dr. Sanjay Mehrotra	NH, Bengaluru	1
Dr. George Joseph	CMC, Vellore	2
Dr. G. Sengottuvelu	Apollo Hospital, Chennai	1
Dr. Rajpal K Abhaichand	GKNM, Coimbatore	1
Dr. Ajith Kumar	Sree Chitra, Kerala	1
	Total	30

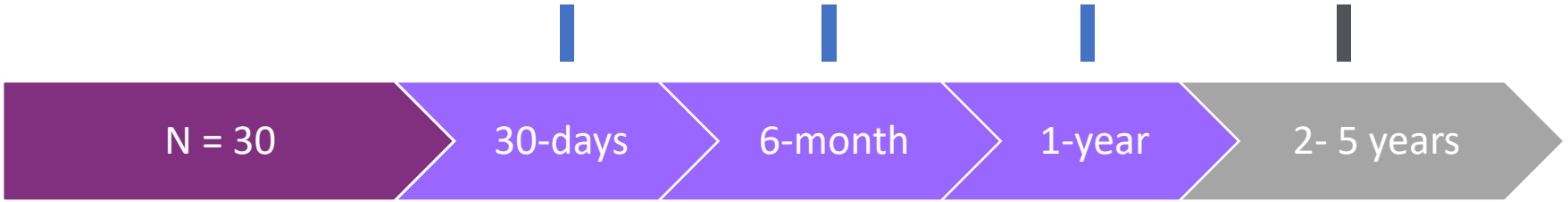
Presented by Dr. Ashok Seth at TCT 2018, San Diego, USA

MyVal-1 Study Design & Overview

MyVal-1 study: FiH prospective, multicentre, single-arm, open label study of Myval THV in the treatment of severe symptomatic native aortic valve stenosis

Total number of patients: 30

CTRI/2016/11/007512



Clinical Follow-up	30	30	30	30
MACCRE	30	30	30	30
ECHO TTE or TEE	30	30	30	30
6-minutes walk test	30	30	30	-

Echo Core Lab – CRF, NY, USA

Dr. Samin Sharma – Chairman
Dr. Ashok Seth – PI
Dr. Praveen Chandra – Coordinating PI
Dr. Ravinder S. Rao – Co-PI

MyVal-1 Study Endpoints

- **Safety Endpoint**: **Survival** at 30 days, 6 and 12 months
- **Efficacy Endpoints:**
  - Improvement in **NYHA Class** at 30 days, 6 and 12 months
  - **Effective orifice area** at 30 days, 6 and 12 months
  - **Six-minute walk test** at 30 days, 6 and 12 months
- **Other Endpoints:**
  - **Quality of life** and evidence of **prosthetic valve dysfunction** (hemolysis, infection, thrombosis, severe **paravalvular leak**, or migration) at 30 days, 6 and 12 months
  - Additionally, **freedom from MACCRE** was measured at respective follow-up time periods (planned annually to a minimum of 5 years)

Key Eligibility Criteria

Inclusion Criteria

- Patients >18 years
- Senile degenerative aortic valve stenosis with echo-cardiographically derived criteria : mean gradient > 40mmHg or jet velocity greater than 4.0 m/s or an aortic valve area (AVA) of < 0.8 cm2
- Must have co-morbidities such that the heart team concur that the **predicted risk of operative mortality was ≥15% and/or a minimum Society of Thoracic Surgeons (STS) score of ≥ 4**
- Patients were symptomatic from aortic valve stenosis as demonstrated by New York Heart Association (NYHA) Functional Class ≥II

Exclusion Criteria

- Acute myocardial infarction (AMI) ≤ 1 month prior to Tx
- Unicuspid, **bicuspid** or non-calcified
- Mix aortic valve disease (AS+AR) with **AR >3+**
- Pre-existing **prosthetic heart valve (HV)** in any position, prosthetic ring
- Untreated **significant coronary artery disease** (CAD) requiring revascularization
- Hemodynamic instability
- Left ventricular ejection fraction **(LVEF) <20%**
- Native aortic annulus <18mm or >28mm by echo
- Renal insufficiency, end-stage renal disease (ESRD), dialysis

Baseline Demographics

Characteristics	N=30
Age (Years) (mean±SD)	**75.5±6.7**
Male, n (%)	22 (73.33)
STS Score (mean±SD), (%)	**6.4±1.8**
New York Heart Association functional class, n (%)	
NYHA Class II	9 (30.0)
NYHA Class III	**16 (53.3)**
NYHA Class IV	**5 (16.7)**
Previous intervention and history, n (%)	
COPD	**14 (46.7)**
Coronary artery disease	13 (43.3)
CABG	5 (16.7)
Pulmonary hypertension	5 (16.7)
Percutaneous coronary intervention	4 (13.3)
Previous myocardial infarction	4 (13.3)
Peripheral vascular disease	3 (10.0)
Cerebral vascular disease	1 (3.3)

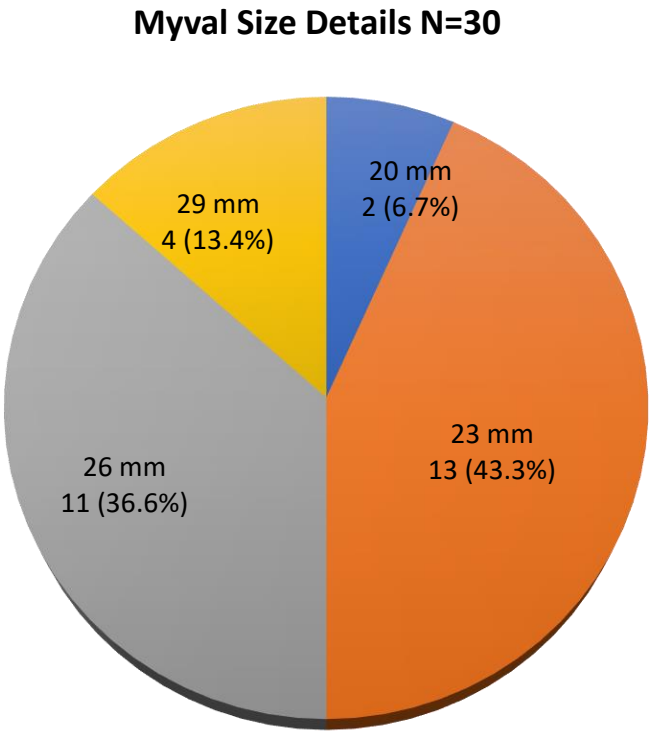
Aortic Root Analysis

Characteristics	N=30
Aortic Annulus diameter, (mm)	
Perimeter derived	23.9±1.9
Area derived	23.6±1.9
Sinus of Valsalva Diameter, (mm)	
Left	28.7±1.8
Right	28.7±1.5
Non	31.1±2.4
Height of Coronary Ostia, (mm)	
LCA	13.6±1.3
RCA	12.9±1.6
Sinotubular junction, (mm)	29.3±2.4
Ascending aorta, (mm)	34.9±3.4
Horizontal annulus, n (%)	2 (6.9)

Values are n (%) or mean±SD

Analysis done using CT images and 3mensio software

Device & Treatment Details
Pre-dilatation encouraged



Study procedure details, n (%)	N=30
Femoral access	
Right common femoral artery	22 (73.3)
Left common femoral artery	8 (26.7)
Procedural anaesthesia	
General anaesthesia	18 (60.0)
Conscious deep sedation	12 (40.0)

Patient Enrollment & Follow-up

Successful Enrolment

- N= 30 Patients

30 Day Follow-up

- N=29 Patients
- Patient death due to renal failure

6 Month Follow-up

- N=28 Patients
- Patient death due to septicaemia

12 Month Follow-up

- N=26 Patients
- Patient death due to Hypertension and CAD along with a Non Cardiac death reported

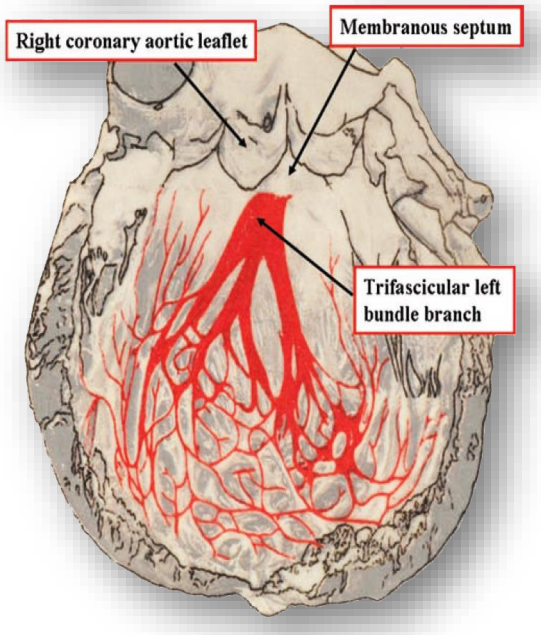
Clinical outcomes till 12-month follow-up

Events	Post-procedure (n=30)	30-day FU (n=29)	6-month FU (n=28)	12-month FU (n=26)
SURVIVAL	**30 (100 %)**	**1 (96.6 %)**	**$28 (92.8 %)**	**^ 26 (84.6 %)**
Stroke	**0 (0.00)**	**0 (0.00)**	**0 (0.00)**	**0 (0.00)**
Kidney dysfunction	1 (3.33)	0 (0.00)	0 (0.00)	0 (0.00)
Prosthetic valve dysfunction				
Hemolysis	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Infection	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Thrombosis	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Valve migration	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Device associated and/or procedure-associated adverse cardiac events	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Myocardial infarction	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Major vascular complications	2 (6.67)	0 (0.00)	0 (0.00)	0 (0.00)
Repeat hospitalization	0 (0.00)	*3 (10.34)	0 (0.00)	0 (0.00)
New permanent pacemaker	**0 (0.00)**	**0 (0.00)**	**0 (0.00)**	**0 (0.00)**

Values are n (%).*1 patient reported gastroenteritis, 1 patient had access site complications and 1 patient reported fracture in left femur. #Patient died due to renal failure, $Patient died due to septicemia, ^1 patient died due to coronary artery disease with hypertension and another one died due to non-cardiac event

Post Procedure Re-intervention

- Unique crimping geometry of MyVal ensures precise orthotopic device placement without any deep throating into the LVOT
- Precise annular placement ensures that there is no conduction system disturbances thus eliminating need for a new pace maker as seen with previous technologies.

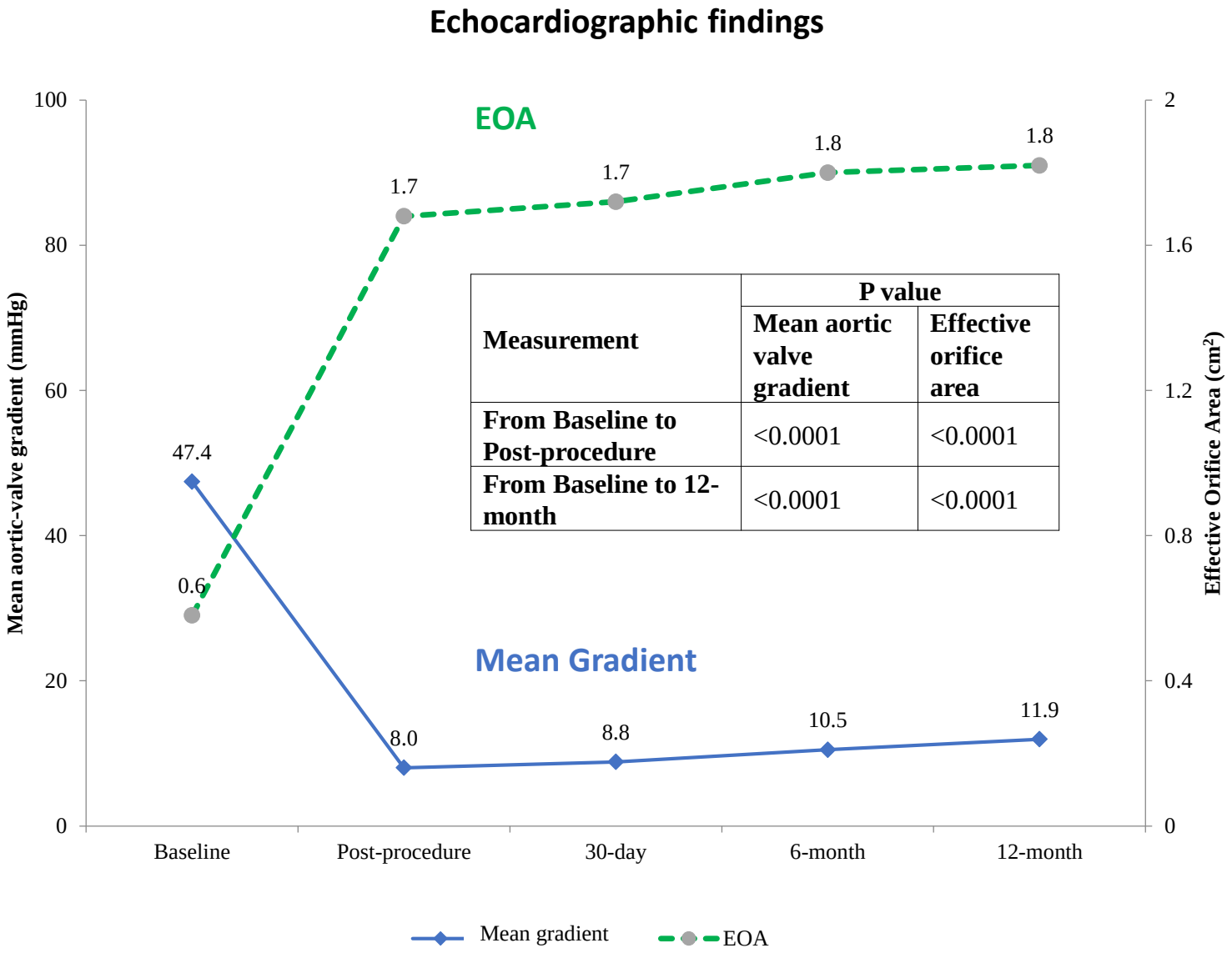


Tawara shows how easily a prosthesis inserted too low within the outflow tract can impinge directly on the LBB, with obvious implications for induction of conduction abnormalities.

Reintervention	Post-Procedure (N=30)	30 Days (N=29)	1 Year (N=26)
Balloon aortic valvuloplasty	0	0	0
Repeat TAVI	0	0	0
Aortic-valve replacement	0	0	0
Endocarditis	0	0	0
New atrial fibrillation	0	0	0
New pacemaker	0	0	0
Open surgical HV replacement	0	0	0

Tawara et al. JACC CardioVascular Interventions 2008; 1:310-316

Sustained low mean gradients post procedure and ~1.8cm² large EOA at 12-month follow-up



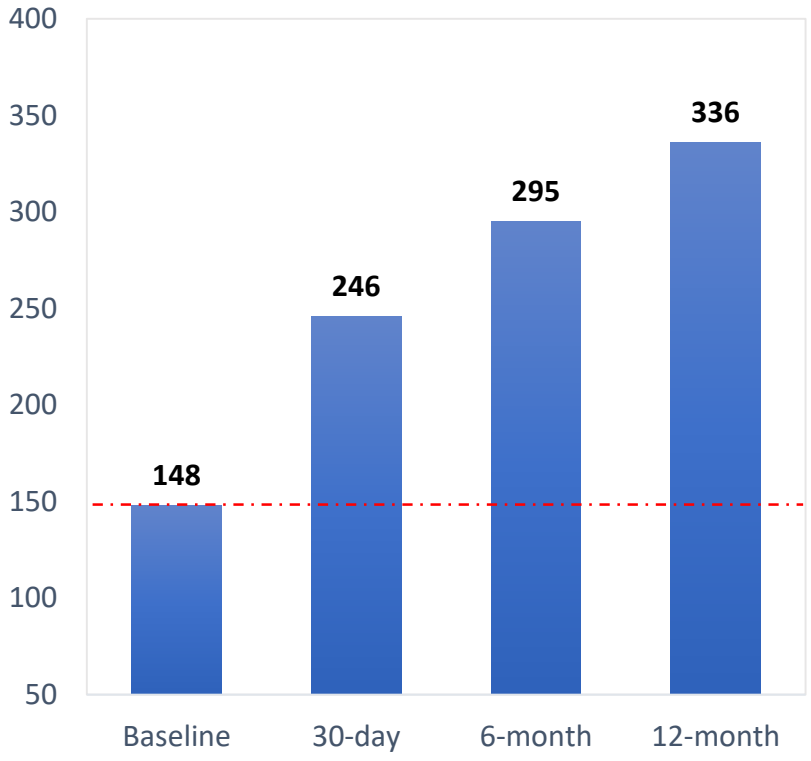
Measurement	P value	
	Mean aortic valve gradient	Effective orifice area
From Baseline to Post-procedure	<0.0001	<0.0001
From Baseline to 12-month	<0.0001	<0.0001

Echocardiographic findings at 12-month follow-up

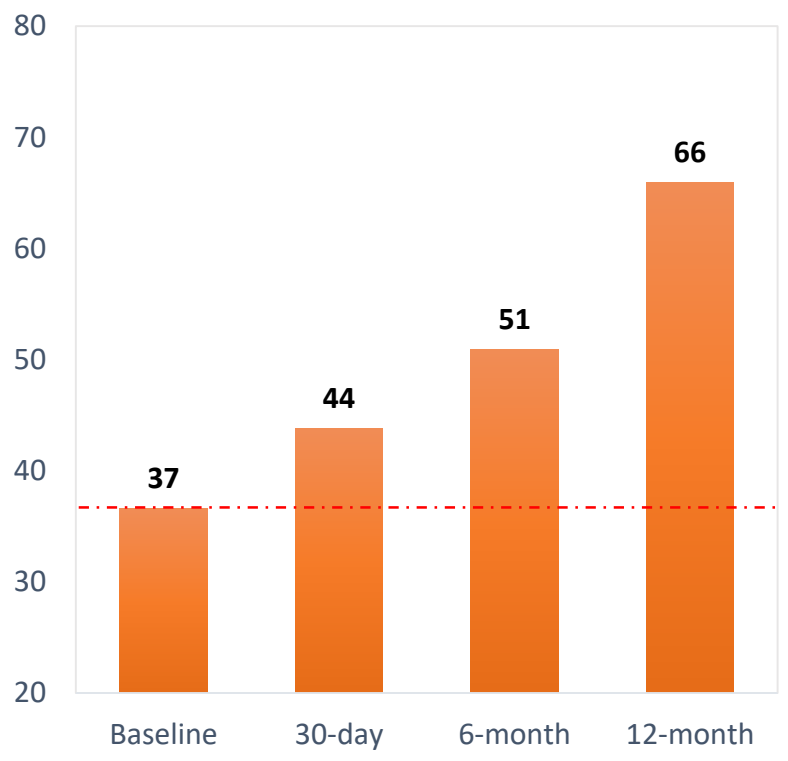
Parameters	Baseline	Post-procedure	30-day FU	6-month FU	12-month FU
Effective orifice area, (cm^2)	**0.56±0.1**	**1.7±0.3**	**1.8±0.5**	**1.8±0.5**	**1.8±0.3**
Mean aortic-valve gradient, (mmHg)	**47.4±8.8**	**8.0±2.7**	**8.8±2.5**	**10.5±2.6**	**11.9±3.3**
Peak aortic-valve gradient, (mmHg)	71.7±13.0	14.4±2.4	15.7±2.8	17.9±2.9	20.3±5.9
Trans-aortic velocity, (m/s)	4.5±0.4	1.9±0.4	1.8±0.4	1.8±0.3	2.2±0.4
Mean LVEF, (%)	**45.5±11.5**	**47.8±11.1**	**48.6±8.9**	**48.8±8.0**	**48.9±9.8**
Mild paravalvular leak, (n)	-	2	0	0	0
Moderate or severe mitral Regurgitation, (n)	2	0	0	0	0
Aortic regurgitation, (n)	-	0	0	0	0

Values are mean ±SD (n) or % (n); FU: follow-up, LVEF: left ventricular ejection fraction

Marked improvement in Quality of Life (QoL) parameters

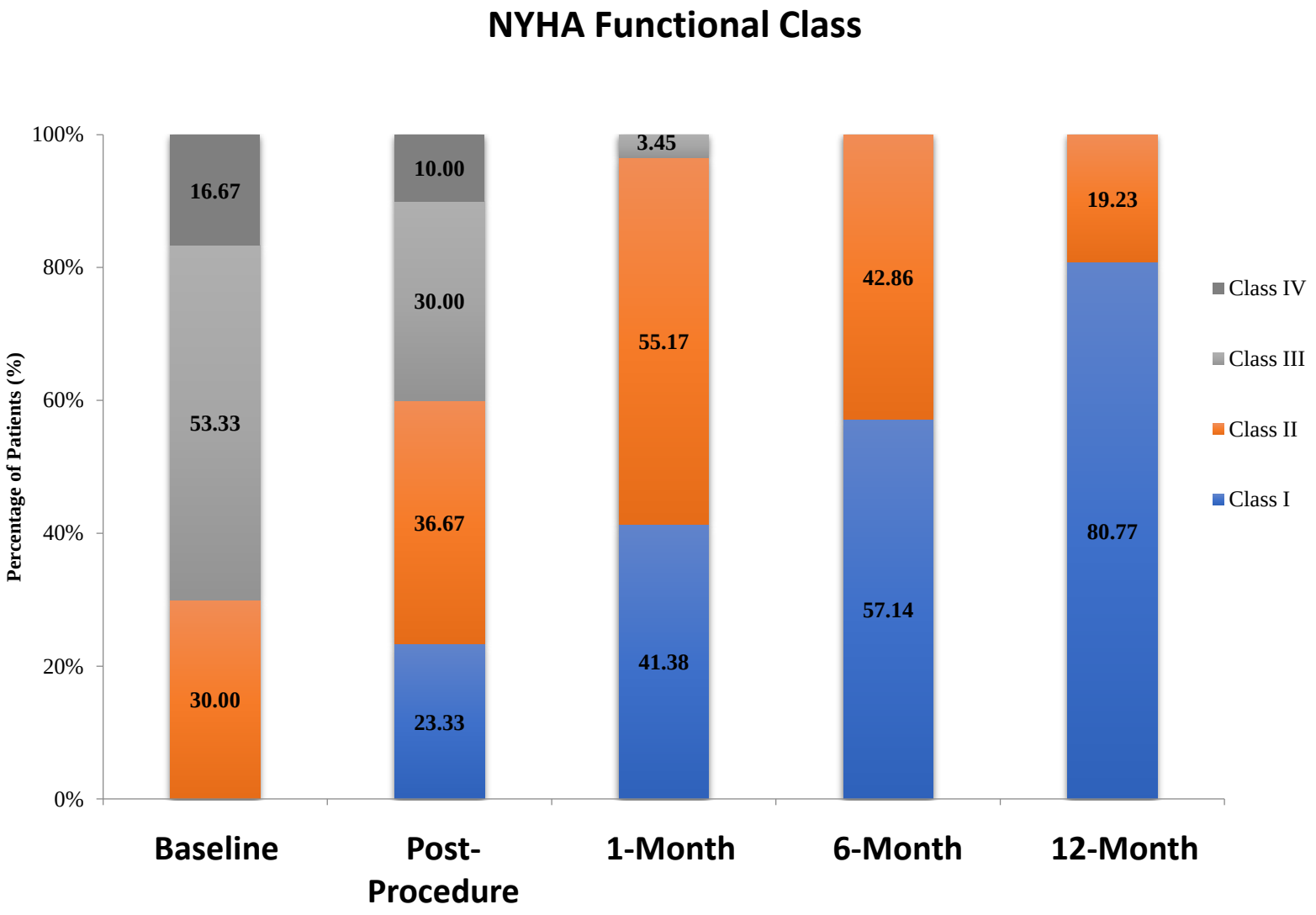


Significant improvement from baseline to 12month Follow-up



Significant improvement from baseline to 12month Follow-up

Marked improvement in Quality of Life (QoL) parameters



FiH MyVal-1 Study met the Primary end-point of Safety & Effectiveness

FiH MyVal-1 study successfully achieved the primary endpoint indicating acceptable safety at 12-month follow-up driven by:

- 100% procedural success
- No device related mortality
- No new pacemaker implantations, strokes or Paravalvular leaks
- Maintained Echo Parameters upto 12 months follow up

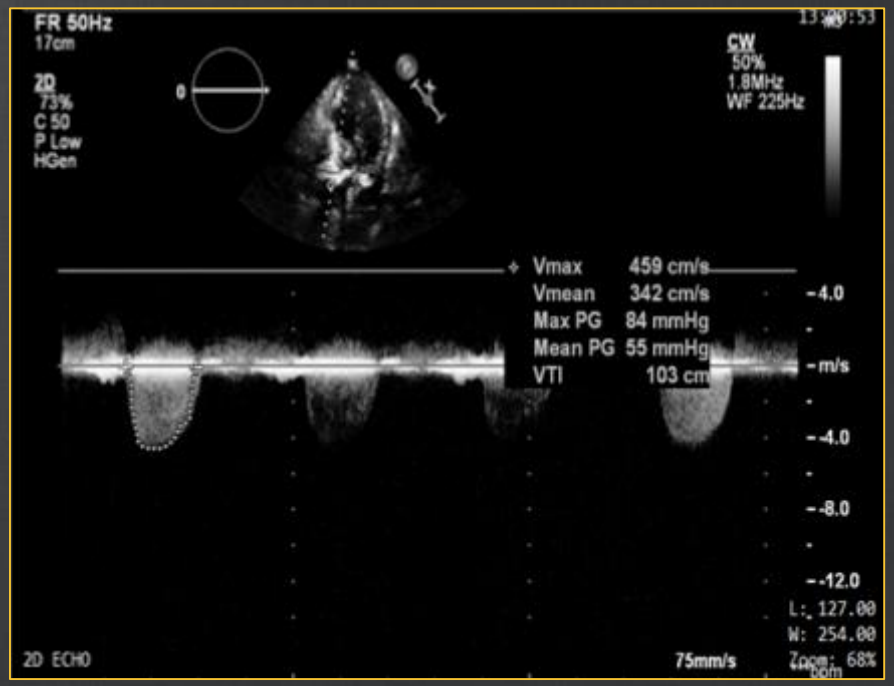
  Significant improvement in NYHA functional class

- **Based on these encouraging Results of the FIH study ,Further studies are being planned in a larger population and geographical locations**

MyVal – Interesting Case

71 Year/Male | Symptomatic AS | NYHA class IV | LVEF 25 % | Normal Renal Function |Hypertensive, AF on treatment | Moderate Pulmonary Disease |STS Score 7.97%

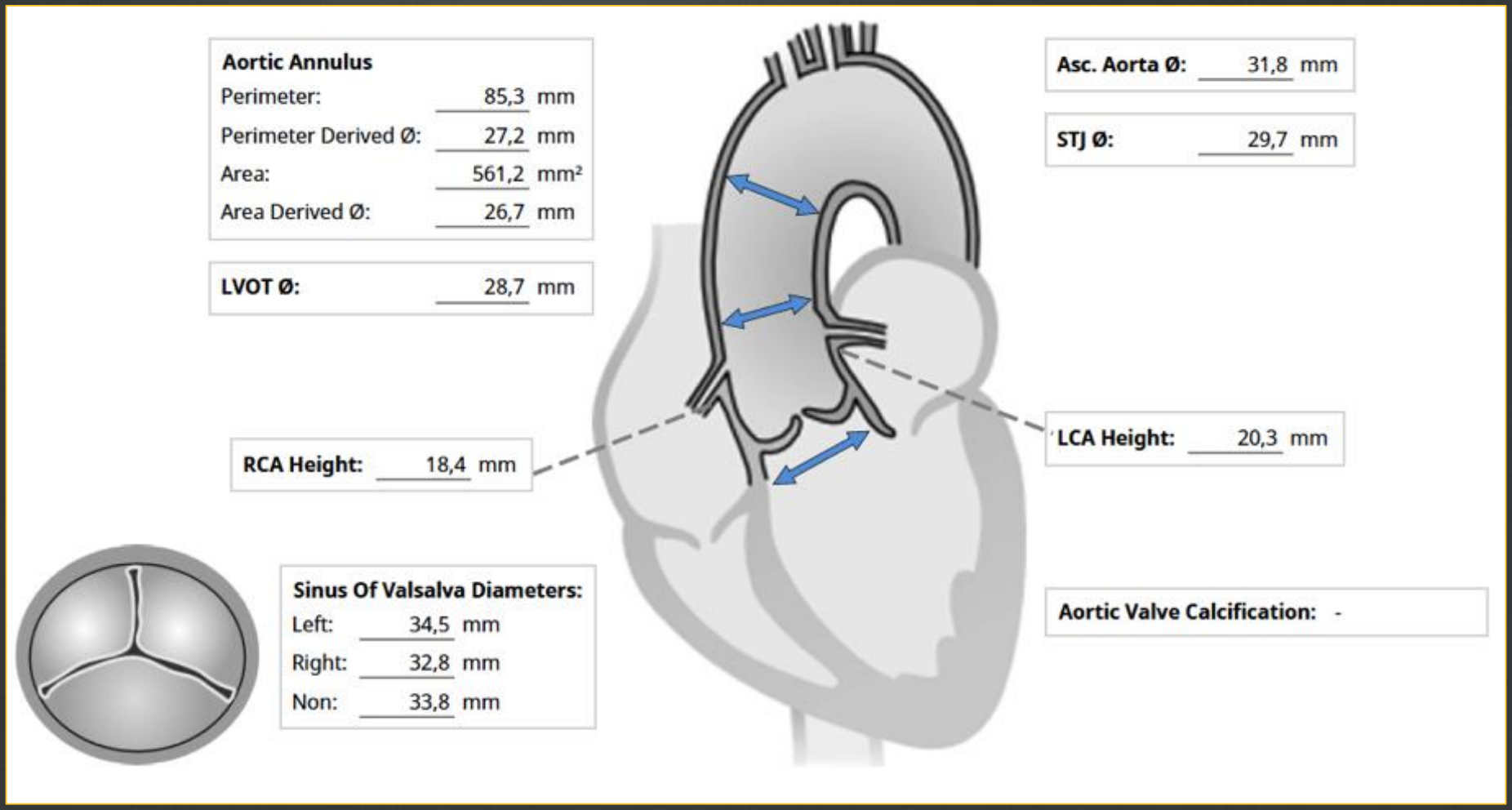
Parameters	Values
Valve Type	Tri-leaflet
Peak Trans-aortic Velocity	4.59 m/s
Mean Trans-aortic Gradient	**55 mmHg**
Peak Gradient	**84 mmHg**
Calculated EOA	**0.5 cm^2**
Severity of AR	Mild
Severity of MR	No
Ejection Fraction	**25 %**



Clinical case, images and videos courtesy Dr. Samin Sharma & Dr. Ravinder Singh Rao, EHCC, Jaipur, India

Aortic Root Analysis

Meril



Analysis done using CT images and 3mensio software

Clinical case, images and videos courtesy Dr. Samin Sharma & Dr. Ravinder Singh Rao, EHCC, Jaipur, India

MyVal – Detailed Sizing Guide

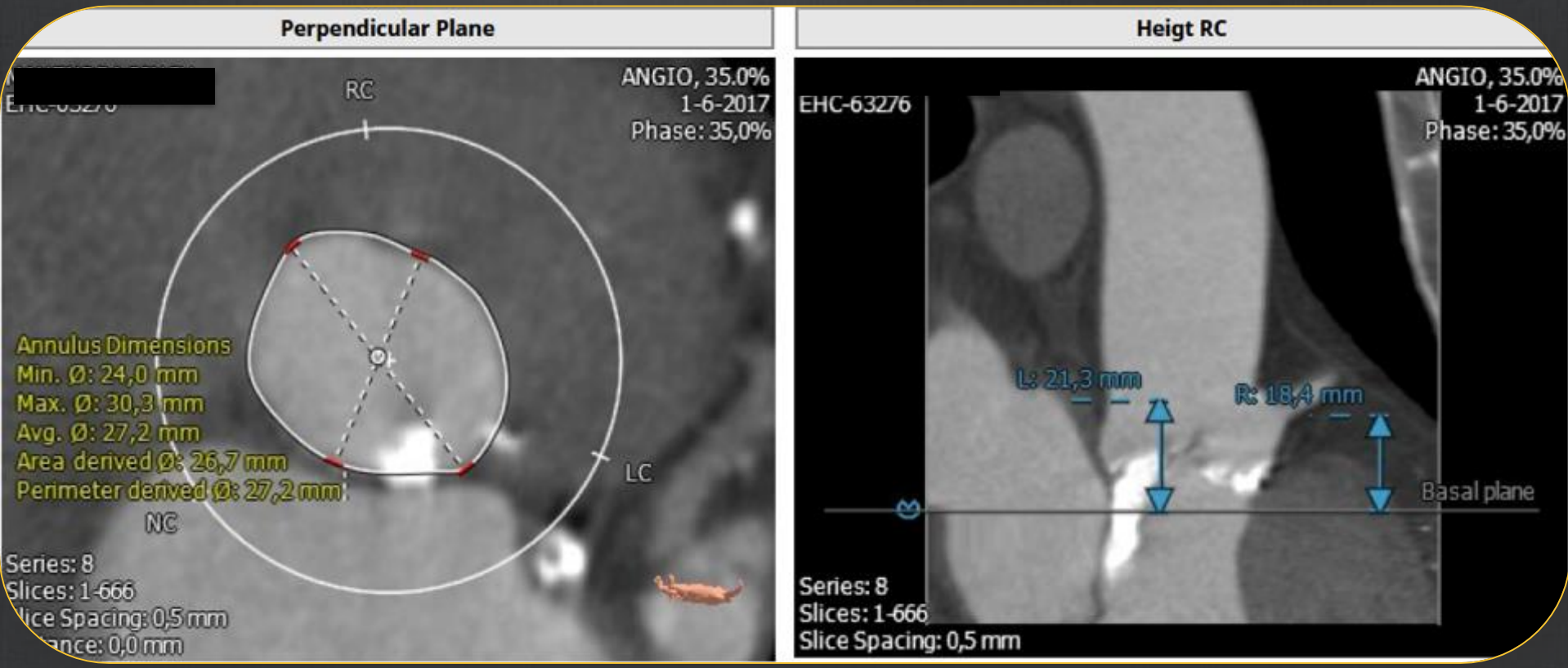
Meril

- Ideal valve sizing may be in the range of 10-15% higher than area derived annulus diameter to have a good valve apposition
- For an area of 561.2mm^2, a 29mm MyVal would have 17.5% over size
- Considering there is a large Ca^{2+} at the LCC running towards LVOT, it was considered to us 2cc less volume of contrast and saline during inflation

3D Annular area mm^2		**546**	**550**	**560**	**570**	**580**	**590**	**600**	**610**	**615**	**620**	**630**	**640**	**650**	**660**	**670**	**680**	**690**	**700**	**710**	**720**
3D area derived diameter mm		26.4	26.5	26.7	26.9	27.2	27.4	27.6	27.9	28.0	28.1	28.3	28.5	28.8	29.0	29.2	29.4	29.6	29.9	30.1	30.3
29mm % Annular area over/under	20 mm	-42.7%	-43.1%	-44.1%	-45.1%	-46.0%	-46.9%	-47.8%	-48.7%	-49.1%	-49.5%	-50.3%	-51.1%	-51.8%	-52.6%	-53.3%	-54.0%	-54.6%	-55.3%	-55.9%	-56.5%
	23 mm	-24.2%	-24.7%	-26.1%	-27.4%	-28.6%	-29.8%	-31.0%	-32.1%	-32.7%	-33.2%	-34.3%	-35.3%	-36.3%	-37.3%	-38.2%	-39.1%	-40.0%	-40.9%	-41.7%	-42.5%
	26 mm	-3.1%	-3.8%	-5.5%	-7.2%	-8.8%	-10.3%	-11.8%	-13.3%	-14.0%	-14.7%	-16.0%	-17.3%	-18.6%	-19.8%	-21.0%	-22.2%	-23.3%	-24.4%	-25.5%	-26.5%
	29 mm	**20.5%**	**19.6%**	**17.5%**	**15.4%**	**13.4%**	**11.5%**	**9.7%**	**7.9%**	**7.0%**	**6.1%**	**4.4%**	**2.8%**	**1.2%**	**-0.3%**	**-1.8%**	**-3.2%**	**-4.6%**	**-6.0%**	**-7.3%**	**-8.6%**

Clinical case, images and videos courtesy Dr. Samin Sharma & Dr. Ravinder Singh Rao, EHCC, Jaipur, India

Aortic Root Analysis



Analysis done using CT images and 3mensio software

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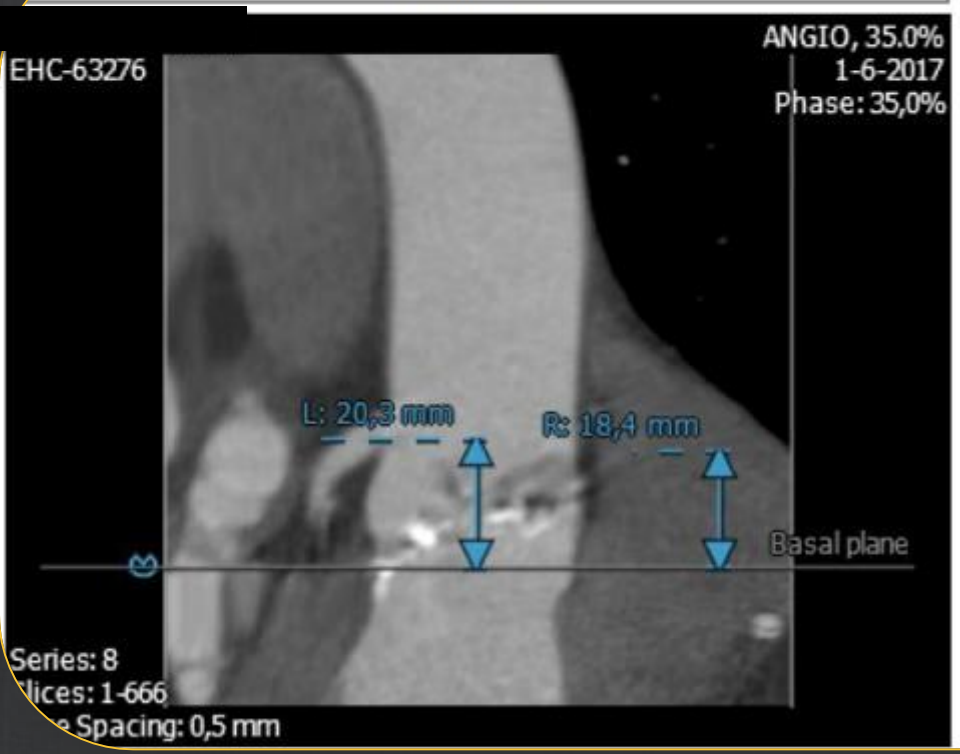
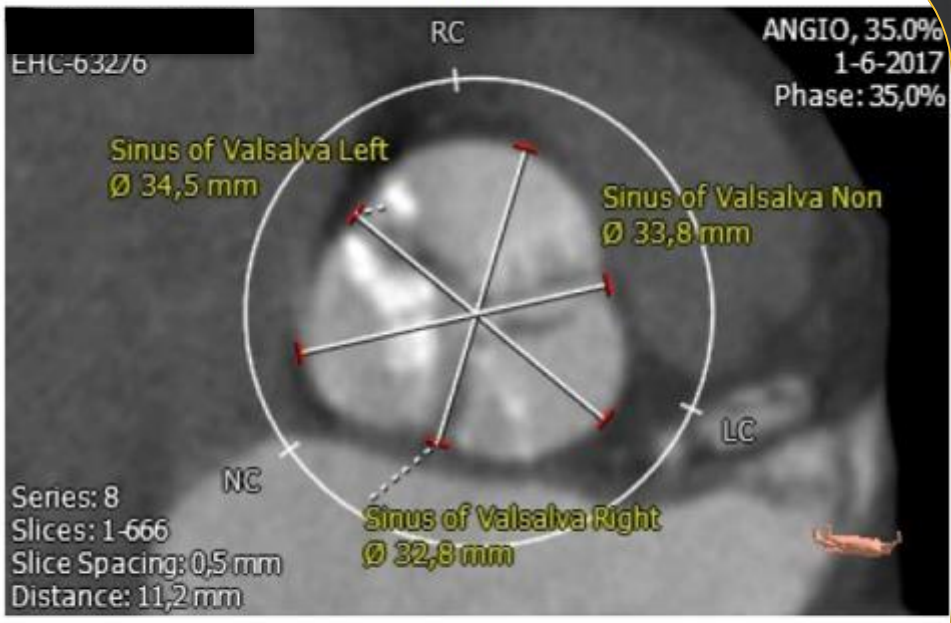
Aortic Root Analysis

Meril

Height LC



SOV Diameter



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Aortic Root Analysis

Meril

Analysis done using CT images and 3mensio software

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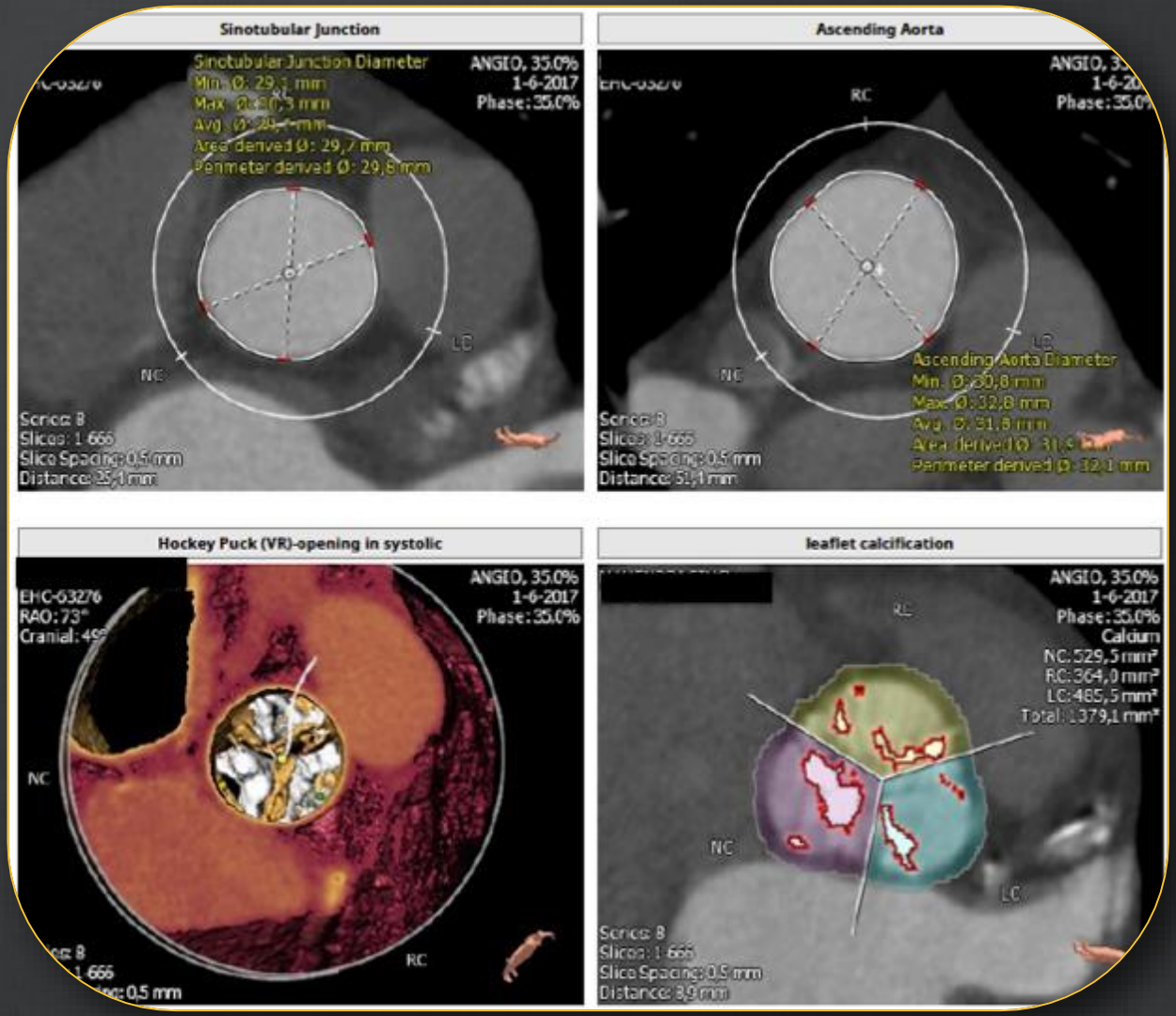
Aortic Root Analysis

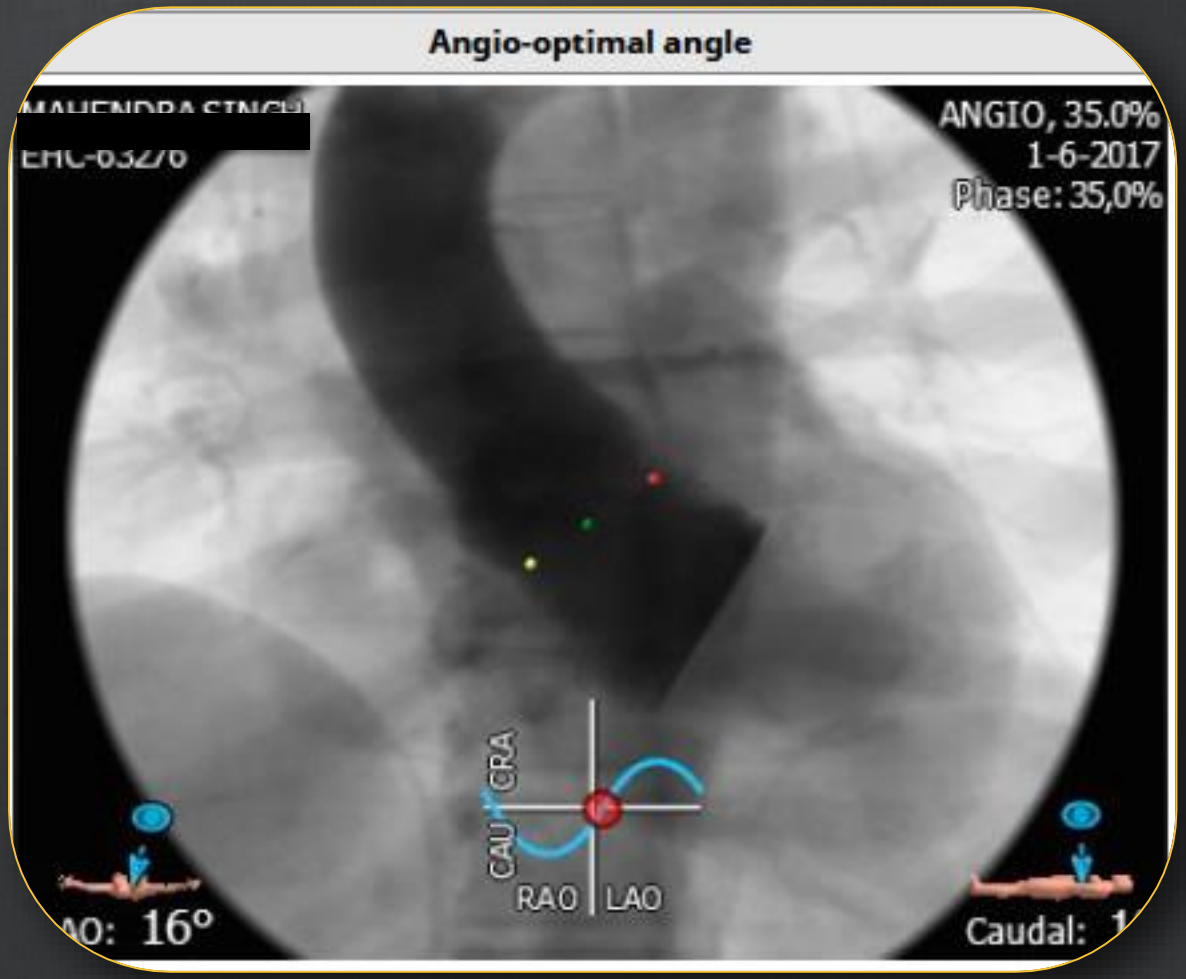


Analysis done using CT images and 3mensio software

Clinical case, images and videos courtesy Dr. Samin Sharma & Dr. Ravinder Singh Rao, EHCC, Jaipur, India

Optimal Deployment Angle

Adjust the final deployment angles as per cusp separation on fluoroscopy



Analysis done using CT images and 3mensio software

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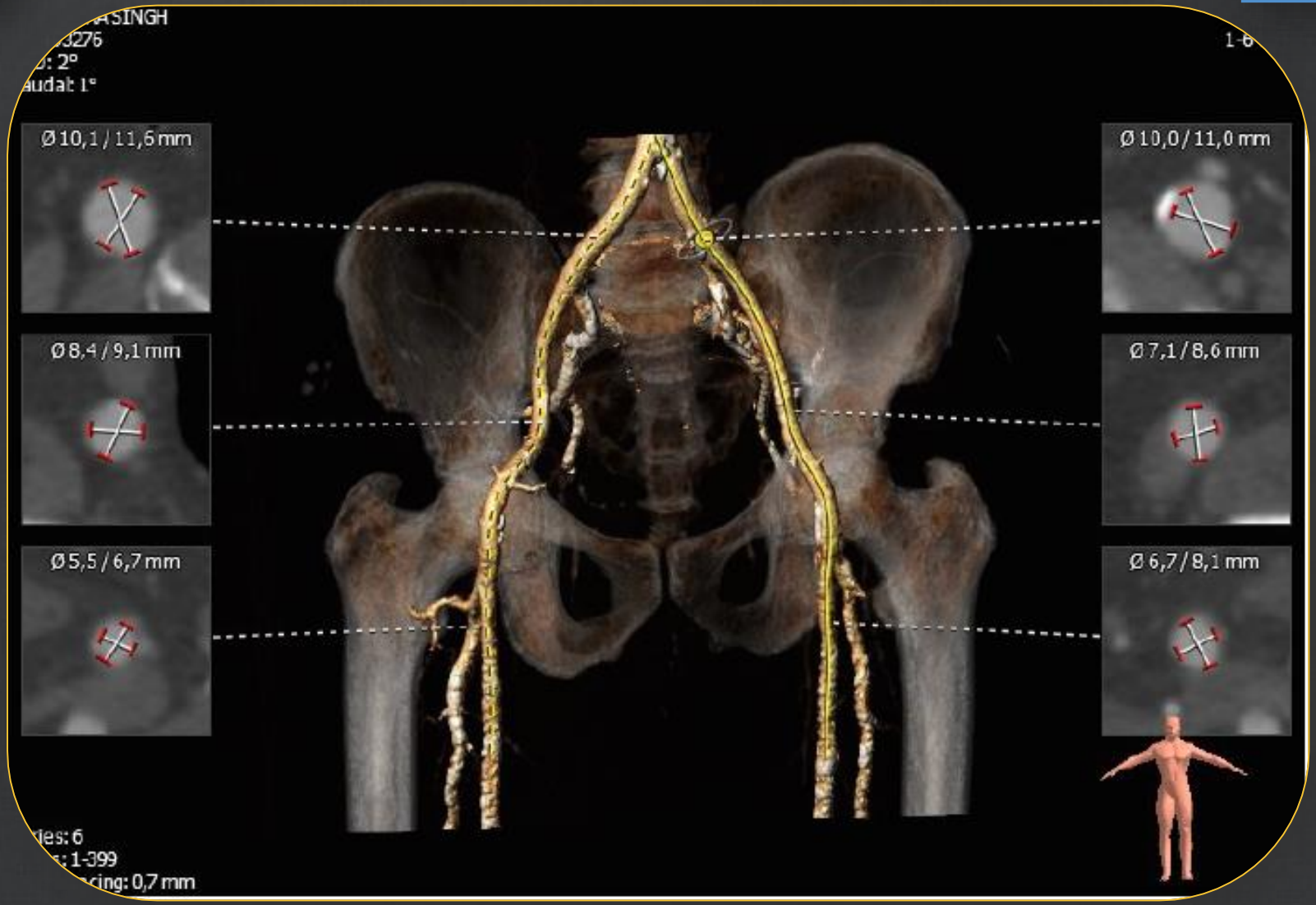
Iliofemoral Analysis



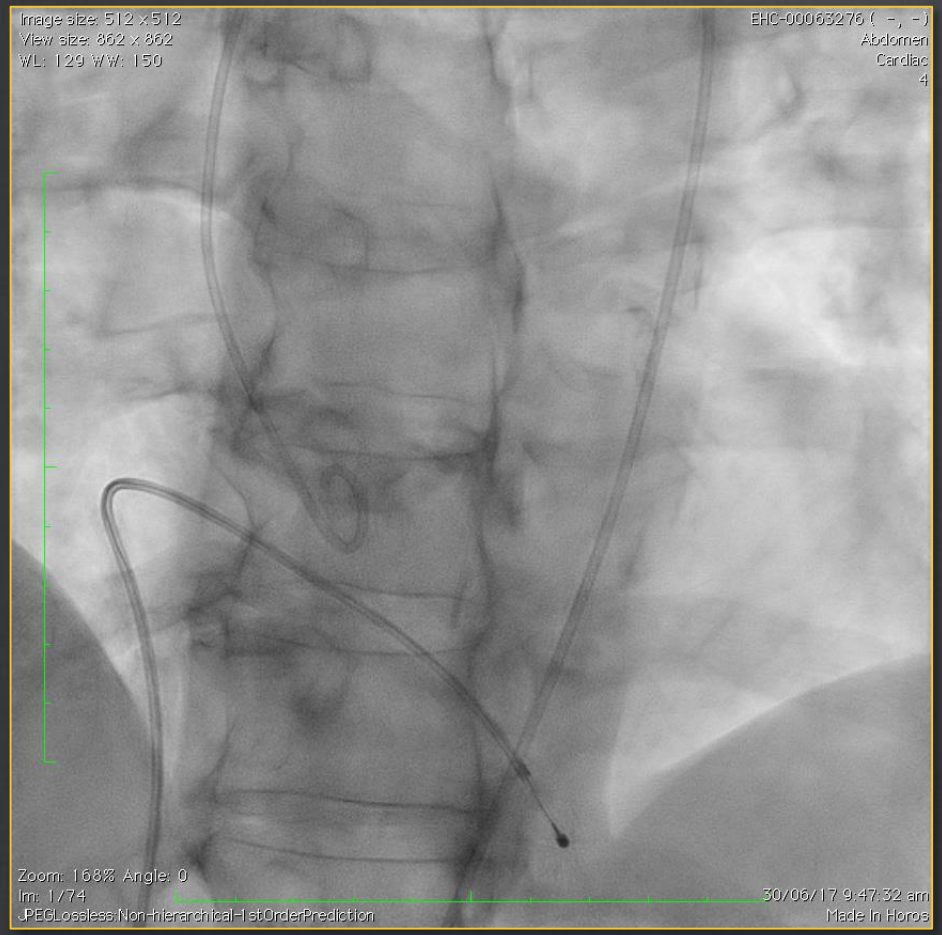
Analysis done using CT images and 3mensio software

Clinical case, images and videos courtesy Dr. Samin Sharma & Dr. Ravinder Singh Rao, EHCC, Jaipur, India

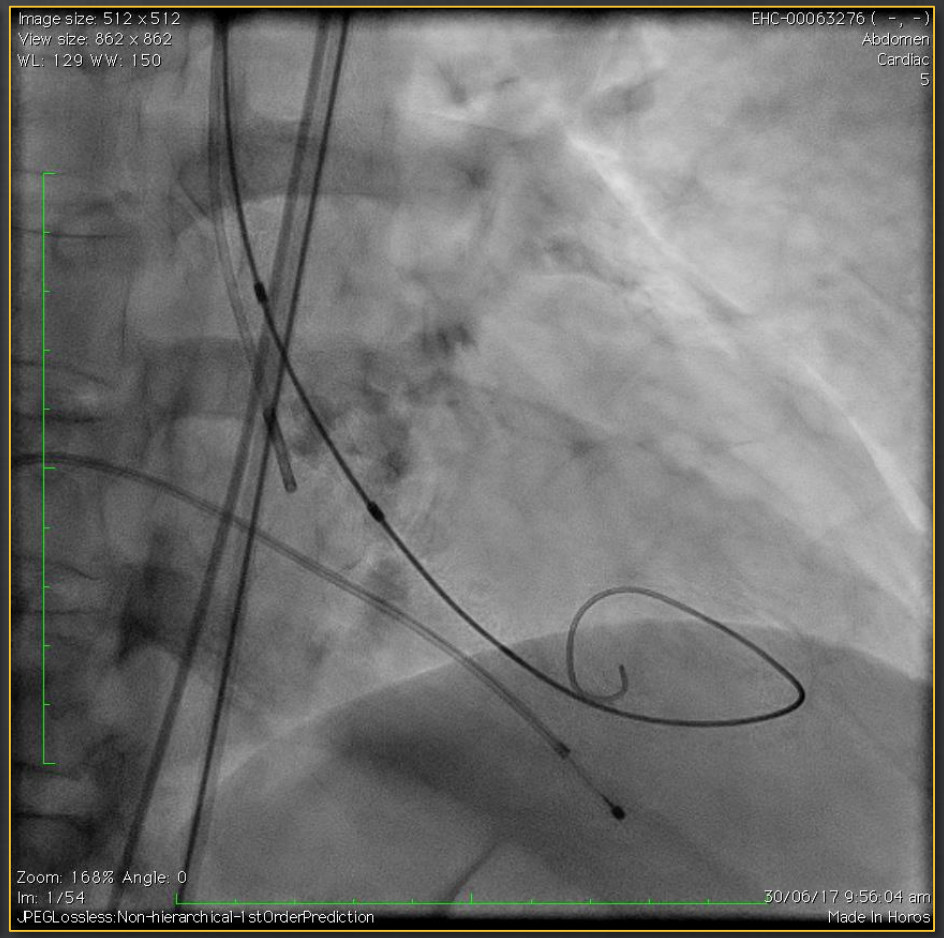
Baseline & Predilatation

Procedure done under conscious sedation

Baseline Aortogram

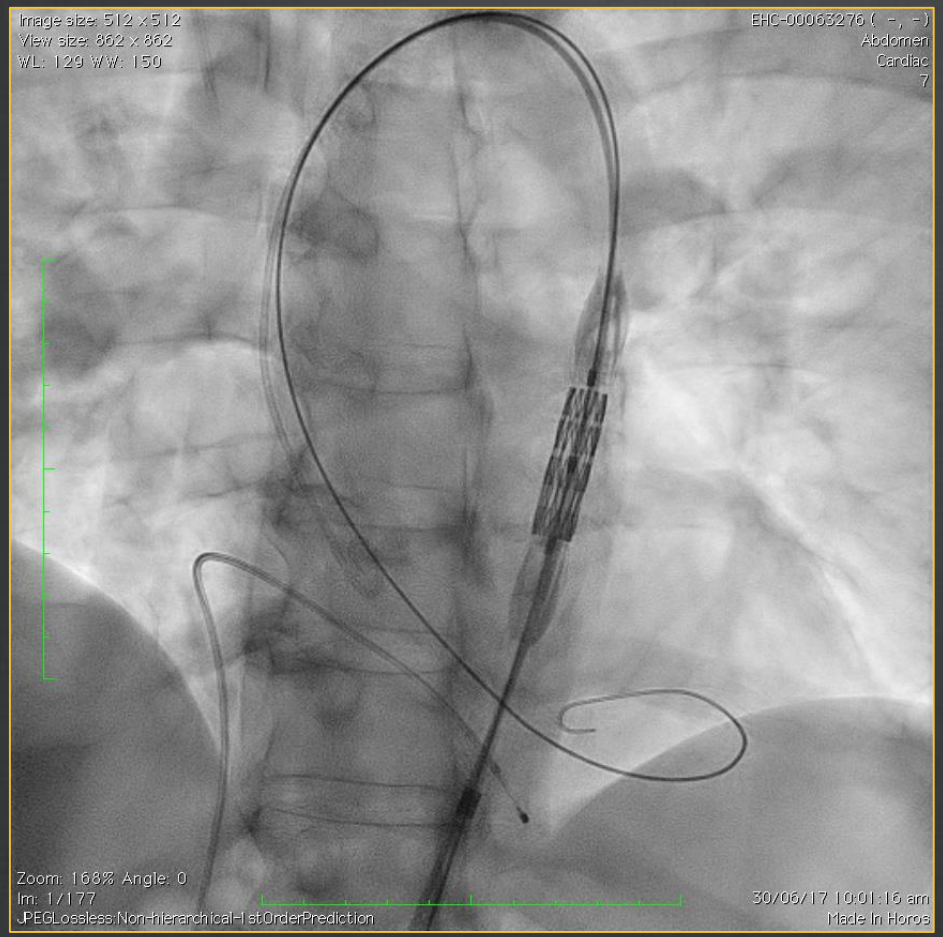


25mm Mammoth Balloon (30 mL)

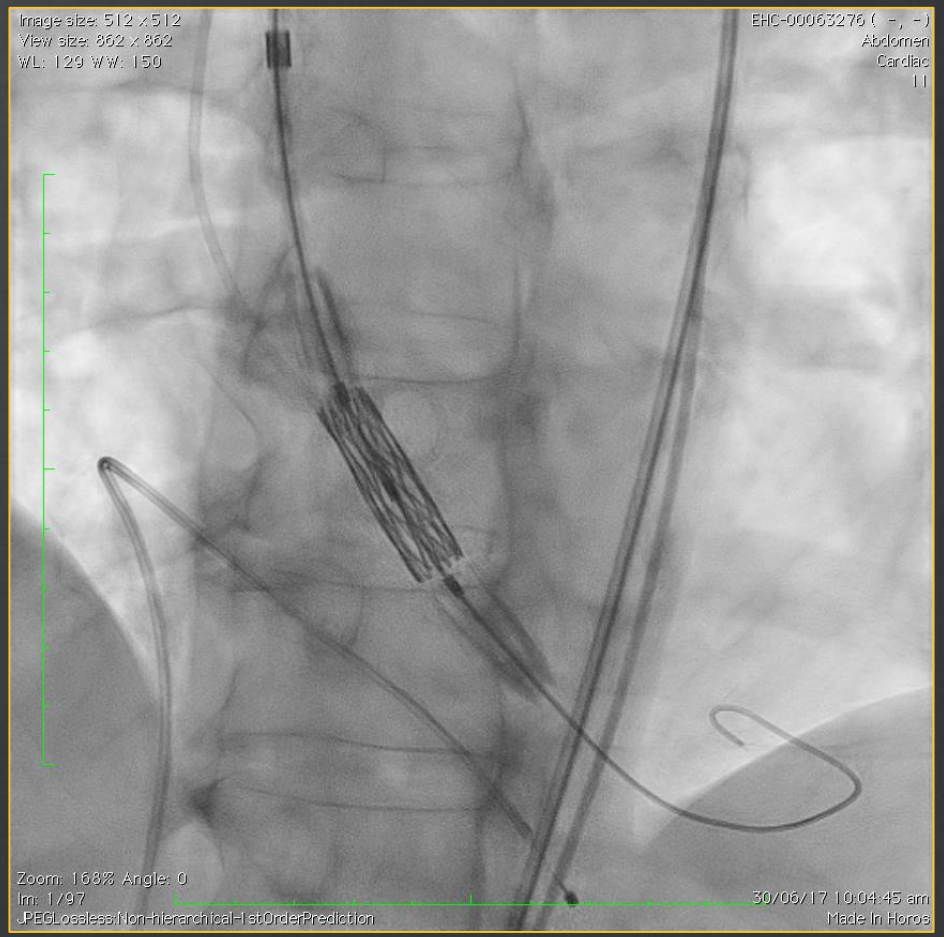


Navigator Delivery System Across Aortic Arch

Navigator flexion avoids scrapping against contralateral arch wall

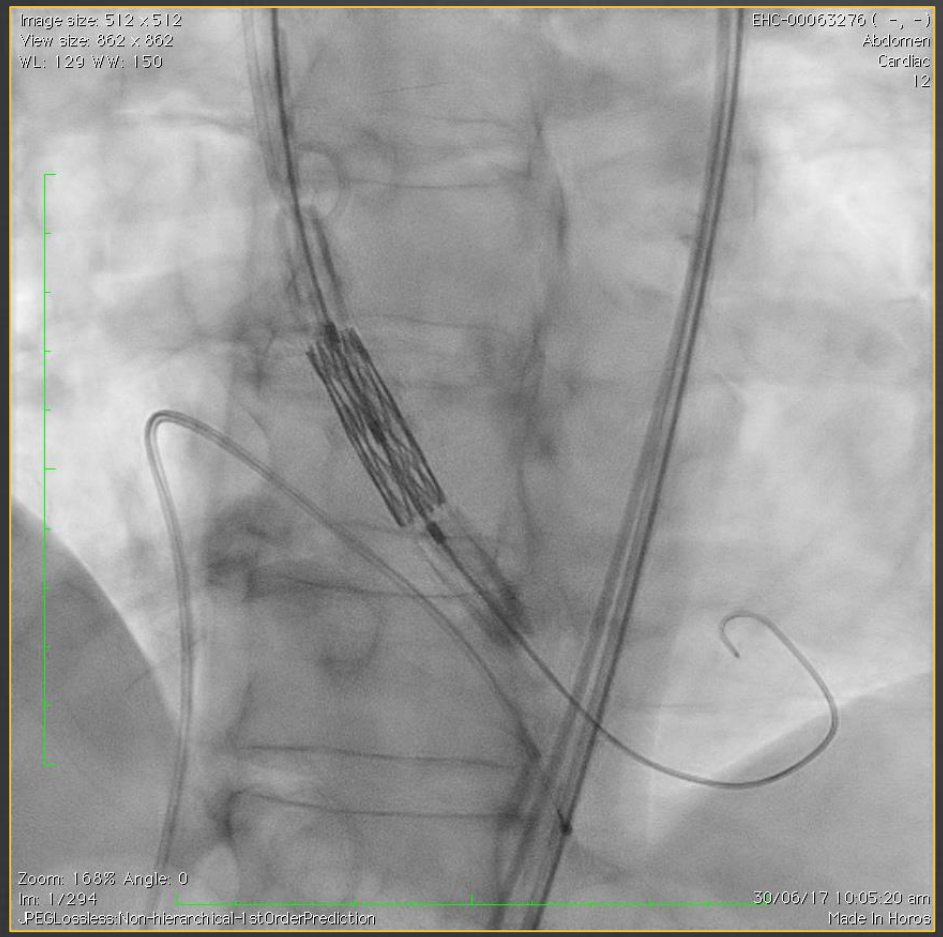


29 mm MyVal THV

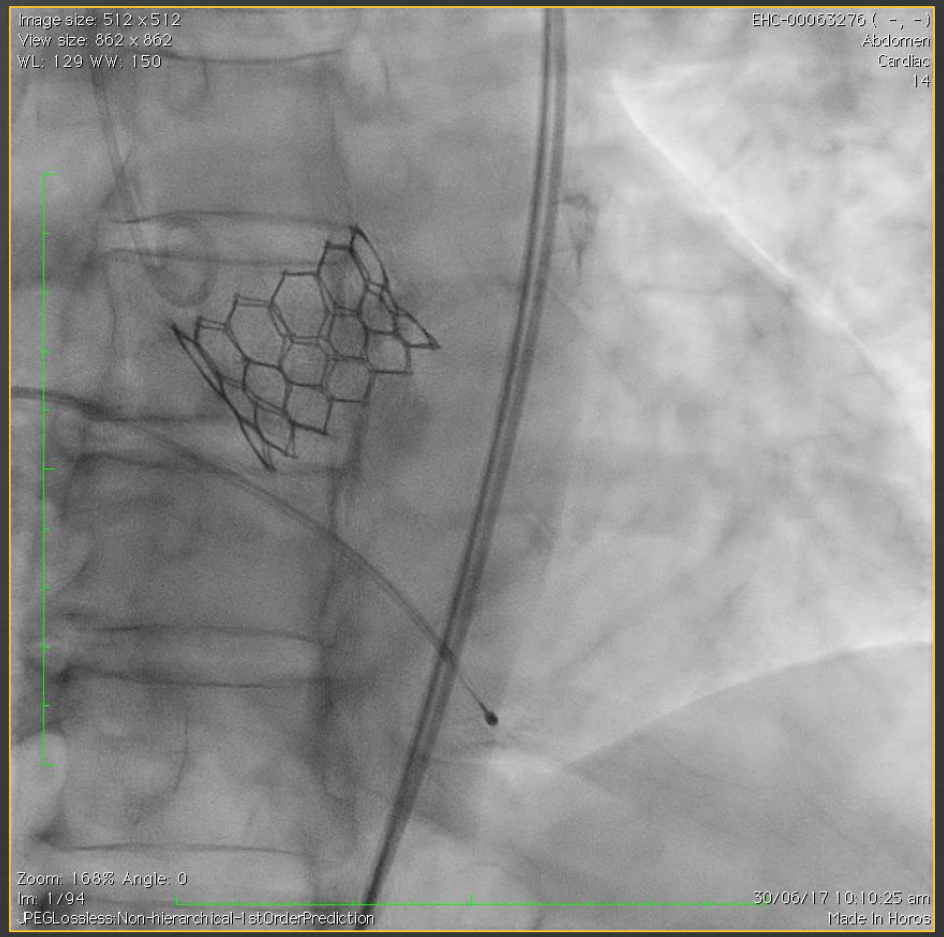


MyVal 29 mm Deployment

Precise placement & deployment

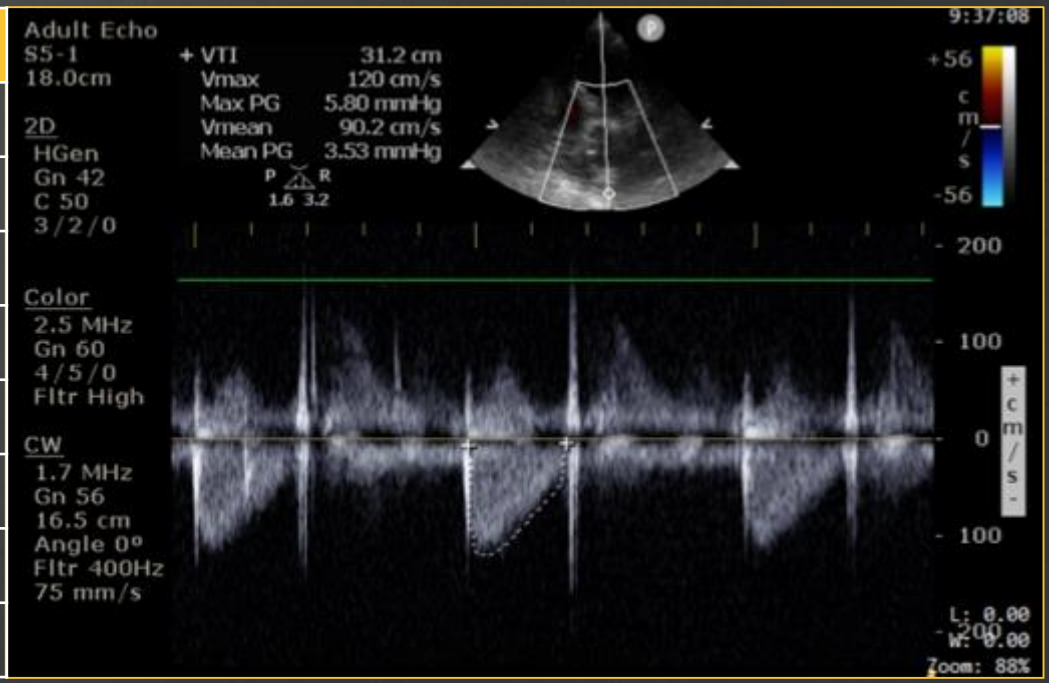


Final – Orthotopic Deployment



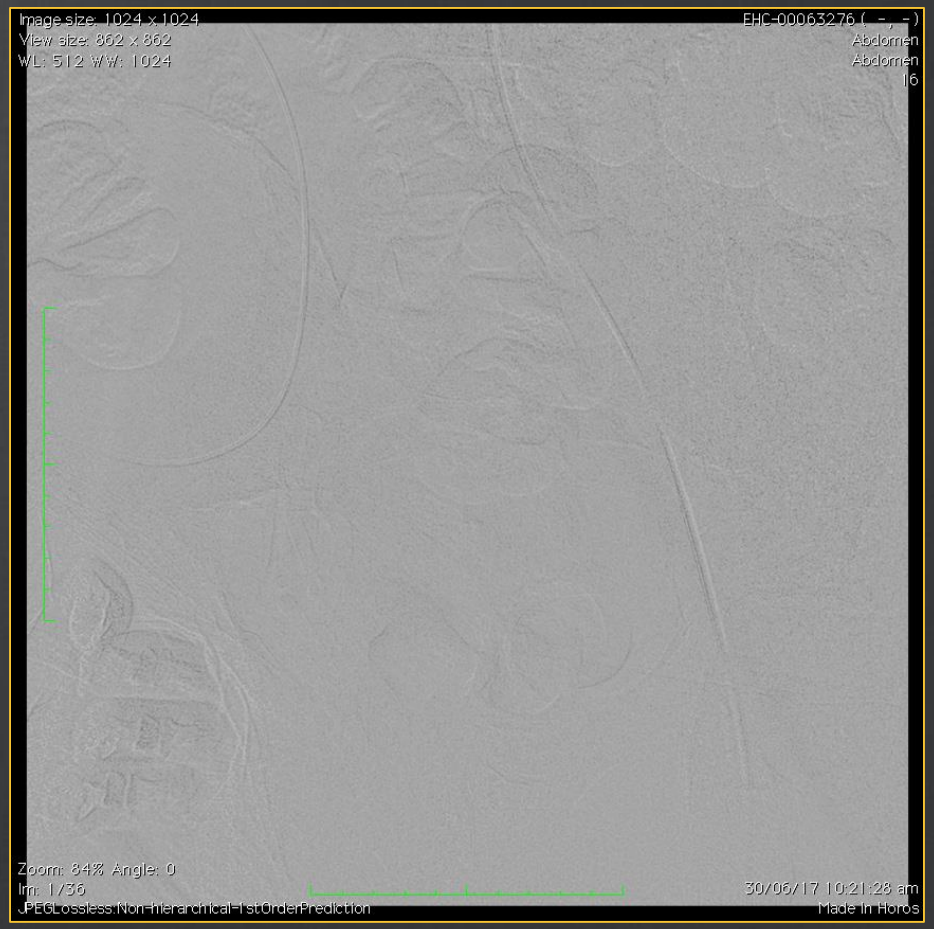
Post Procedure Echo Readings

Parameters	Values
Valve Type	Tri-leaflet
Peak Trans-aortic Velocity	1.20 m/s
Mean Trans-aortic Gradient	3.53 mmHg
Peak Gradient	5.80 mmHg
Calculated EOA	>1.0 cm^2
Severity of AR	No
Severity of MR	No
Ejection Fraction	25 %



Successful Femoral Closure – DSA

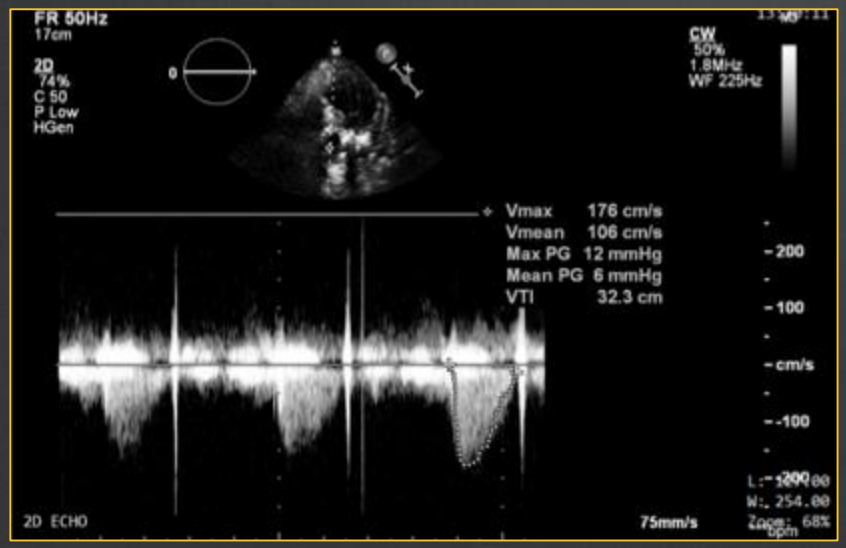
- Procedure date 30-June-2017
- Patient discharged within 48 hours
- No pace maker required
- No access site complications
- No cerebrovascular accident
- DAPT for 3 months
- **No AE >2 years post procedure**

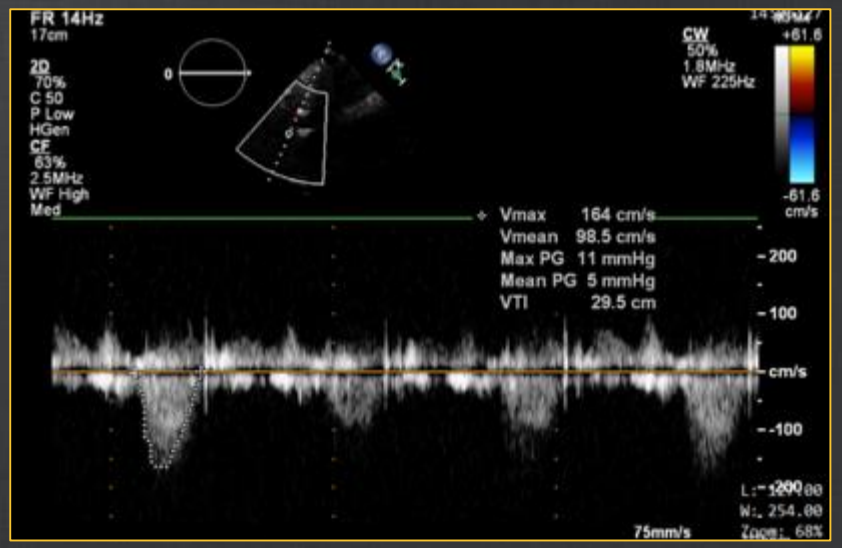


Clinical Follow-up 1 & 6 Months

Parameters @ 1 month	Values
Peak Trans-aortic Velocity	1.76 m/s
Mean Trans-aortic Gradient	6.0 mmHg
Peak Gradient	12.0 mmHg
Calculated EOA	>1.0 cm^2

Parameters @ 6 months	Values
Peak Trans-aortic Velocity	1.64 m/s
Mean Trans-aortic Gradient	5.0 mmHg
Peak Gradient	11.0 mmHg
Calculated EOA	>1.0 cm^2





MyVal-1 Key Learning

Meril

- All cases have been extremely positive in terms of device and procedural success
  - The unique hybrid geometry of valve scaffold incorporating the novel honey-comb structure allows for precise placement of the valve at annular plane (orthotopic position)
  - Shorter height of the MyVal THV frame ensures unjailing of the coronary ostia
  - Direct crimping of MyVal THV over its Navigator delivery system eliminates un-necessary maneuvering of the device in descending aorta that is required in first generation balloon expandable THV
  - The Navigator delivery system with its ability to flex while crossing over the arch allows for minimal injury to arch anatomy
  - Dual nose cone on Navigator balloon ensures flawless crimping, precise positioning and predictable deployment of MyVal THV
- Novel 14 Fr Python sheath opens up the possibility of atraumatically treating patients with ilio-femoral diameters of ≥6.5mm
- Availability of intermediate sizes (Ø 21.5, 24.5, 27.5 mm) ensure preservation of valve geometry and respect for patient's anatomy

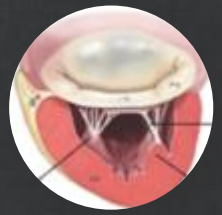
SHD Portfolio – Beyond MyVal THV

Meril

Technology Segments: Low, Medium, Premium

Pre-Clin	Clinical	Commercial	Pre-Clin	Commercial	Commercial
Miltonia	Daffodil AV Daffodil MV	MyVal B/Ex MyVal S/Ex*	Mytral	Mammoth Mboss Mammoth Plain	Floret NiTi Floret BRO*
Mechanical	Surgical Tissue	TAVI	PMVI	Valvuloplasty	Occluders



3D-Echo, Skirball Lab, NY. * Currently in pre-clinical stage.

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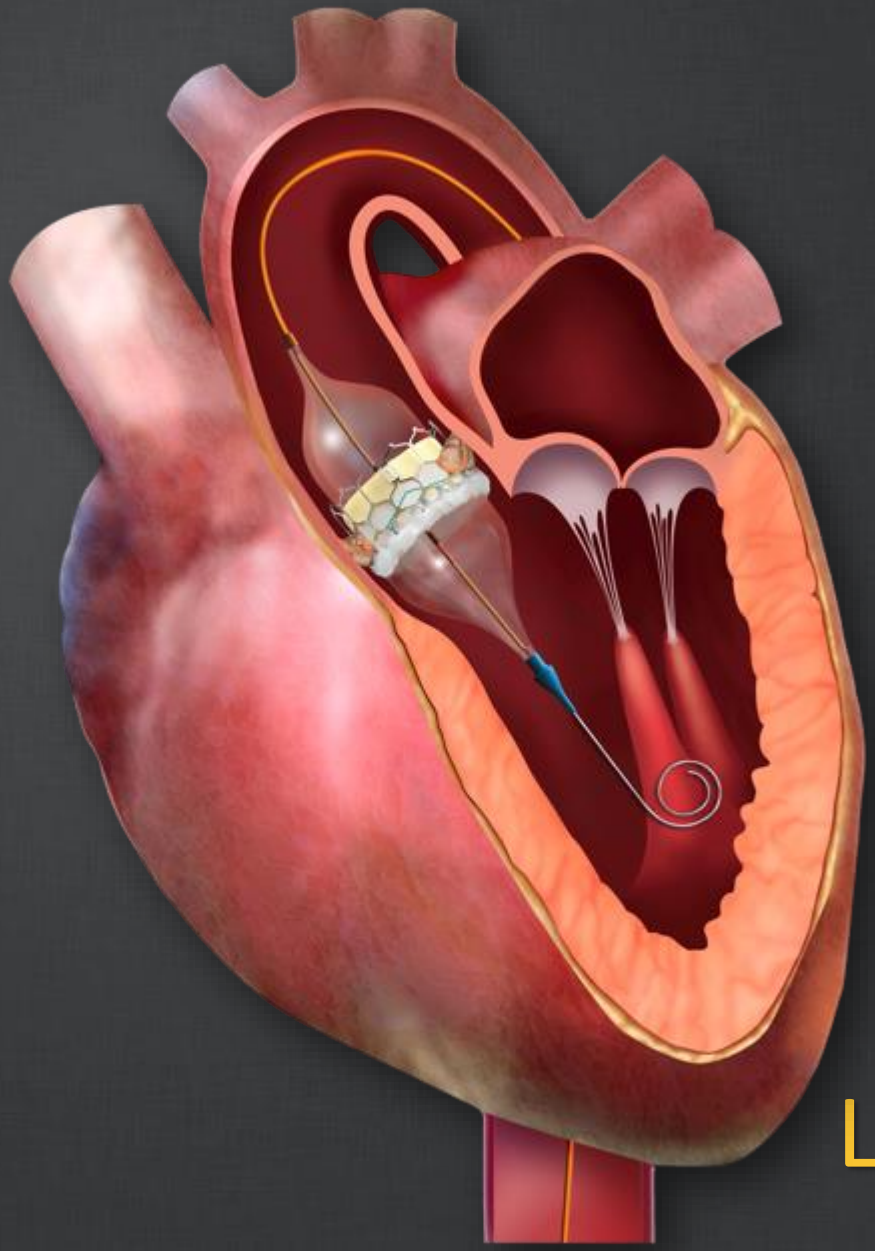

Let’s TAVI…