

# Single-operator Implantation of the New Generation Vitaflow Liberty valve for Efficient Transcatheter Aortic Valve Implantation: The SINGLE-TAVI Study

*Filippo Pensotti, MD; Yan Wang, MD, Julio Ruiz Ruiz, MD; Bin Wang, MD, Matias Stejfman, MD, Mario García-Gómez, MD; Marcelo Rodriguez, MD; Akash Jain, MD; Mauricio Zúñiga, MD; Luis Llamas-Fernández, MEng; Sofía Campillo, MSc; Alberto Campo, MD; Ana Serrador, MD; Alberto San Román, MD; Ignacio Jesús Amat Santos MD, PhD*

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Hospital Clínico  
Universitario de  
Valladolid

# Disclosure of Relevant Financial Relationships

I, Filippo Pensotti, DO NOT have any financial relationships to disclose.

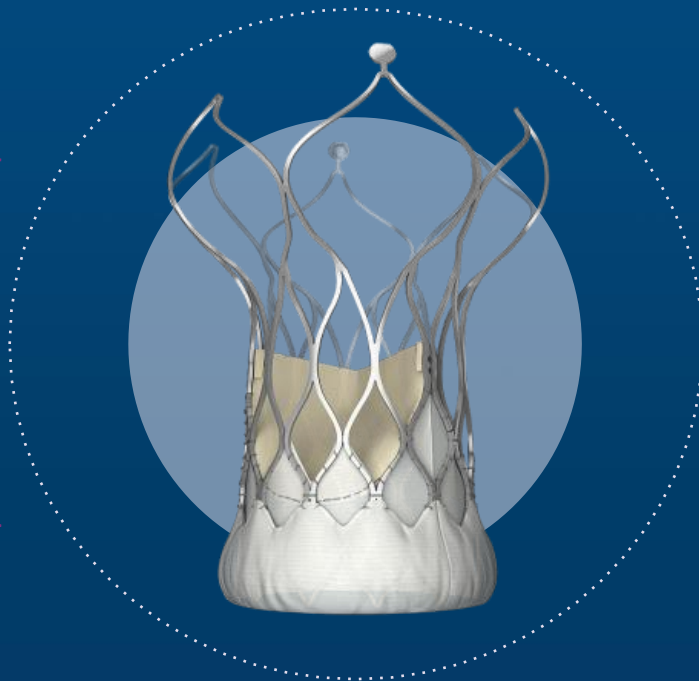
# Background: VitaFlow Liberty TAV

## *Supra-annular design*

- *Preserves annulus circularity*
- *Large EOAs and low gradients*

## *Tubular Shaped Frame*

- *Large EOA*



## *PET double layer skirt design*

- *Reducing perivalvular leakage*

## *Bovine pericardial leaflets*

# Background: VitaFlow Liberty Delivery System

## *Motorized delivery system*

### *Motorized handle*

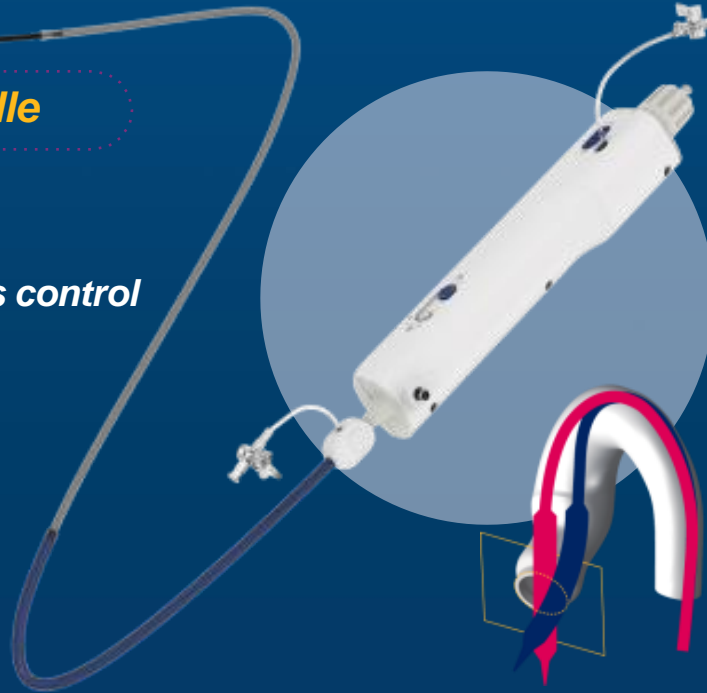
- *Stable position during deployment*
- *Allows simultaneous control of guidewire during deployment*

### *Accurate repositioning*

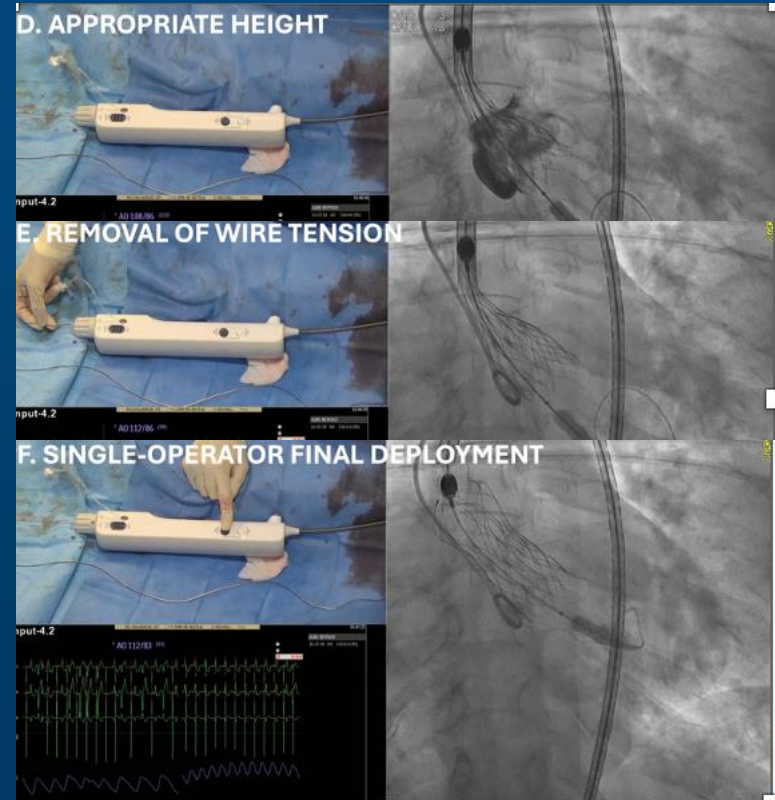
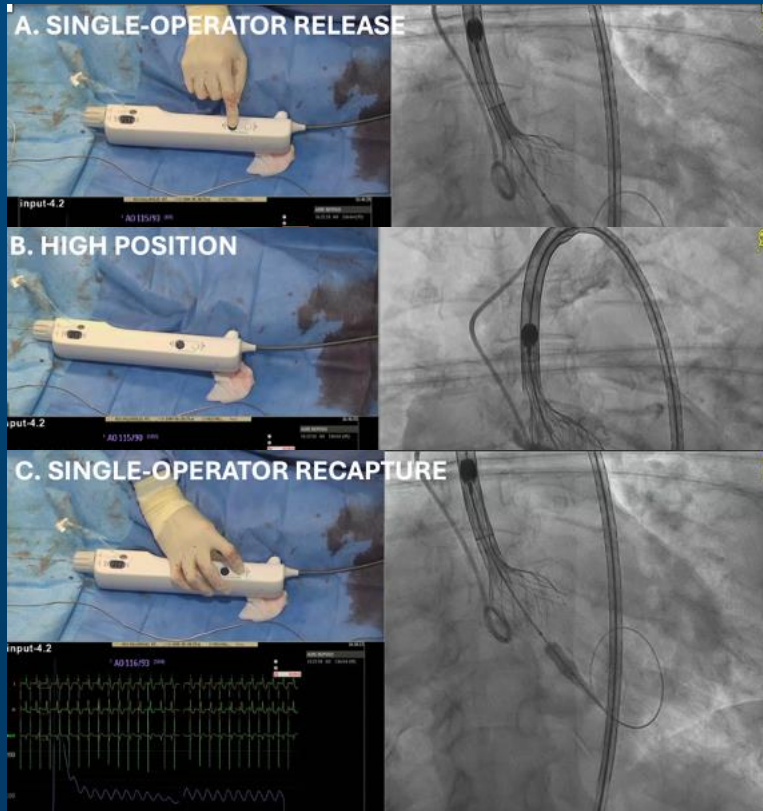
- *Recapturable and repositionable to 75%*

### *Capsule with 360° range of motion*

- *Flexibility for coaxial alignment and valve positioning*



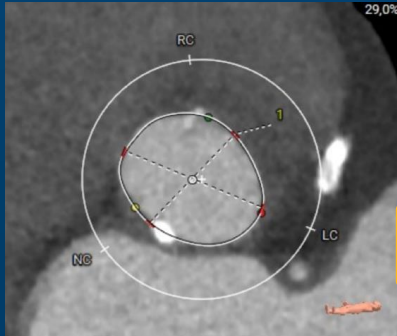
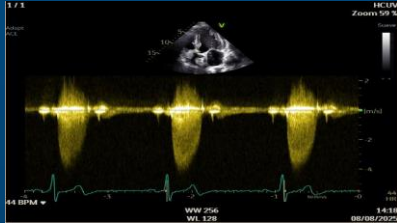
# The single operator technique



# Baseline characteristics

Variable	Global study population N=103
<b>CLINICAL CHARACTERISTICS</b>	
Age (years)	80.5 ± 5.9
Female sex	40 (38.8%)
Weight (kg)	72.0 ± 11,2
Height (m)	1.62 ± 0.12
EuroSCORE II (%)	3.4 ± 2.2
STS PROM (%)	3.8 ± 2.1
NYHA III-IV	23 (22.3%)
Angina CCS III-IV	7 (6.8%)
Previous Syncope	9 (8.7%)
Dialysis	9 (8.7%)
History of cancer	8 (7.8%)
Atrial fibrillation	47 (45.6%)
Peripheral artery disease	10 (9.7%)
Prior stroke	13 (12.6%)
Previous Right Bundle Branch block	20 (19.4%)
Prior pacemaker	9 (8.7%)
Prior CABG	3 (2.9%)
Prior PCI	12 (11.7%)
Prior valve surgery (ViV candidate)	2 (1.9%)

# TTEcho and CT features



## Variable

Global study population  
N=103

### ECHOCARDIOGRAPHIC CHARACTERISTICS

LVEF (%)	53.1 ± 13
Mean gradient (mmHg)	44.4 ± 11.6
AVA (cmq)	0.78± 0.19
Aortic Regurgitation III-IV	30 (19.1%)
Mitral Regurgitation III-IV	28(27.2%)
Tricuspid Regurgitation III-IV	11 (10.7%)

### COMPUTED TOMOGRAPHY CHARACTERISTICS

Aortic annular perimeter (mm)	76.4± 9.5
Perimeter Derived Diameter (mm)	23.9± 3.2
Aortic annular area (mm2)	458.6 ± 114
Maximum Annulus Diameter (mm)	26.0 ± 3.3
Minimum Annulus Diameter (mm)	21.8 ± 3.1
Mean Annulus Diameter (mm)	23.5± 2.8
Maximum Sinuses of Valsalva Diameter (mm)	33.6± 5.1
Minimum Sinuses of Valsava Diameter (mm)	31.4± 4.7
Agatston units	3138 ± 1743
Bicuspid valve	37 (35.9%)
Left main height (mm)	14.6± 2.8
Right coronary artery height (mm)	15.4± 3.5
Mean Right Femoral Artery (mm)	8.1± 0.9
Mean Left Femoral Artery (mm)	7.9± 1.1



# Procedural and In-Hospital outcomes



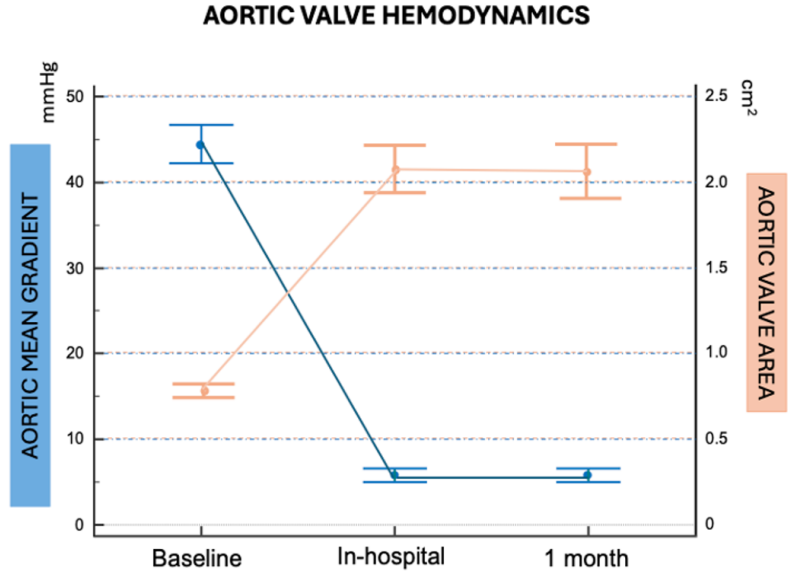
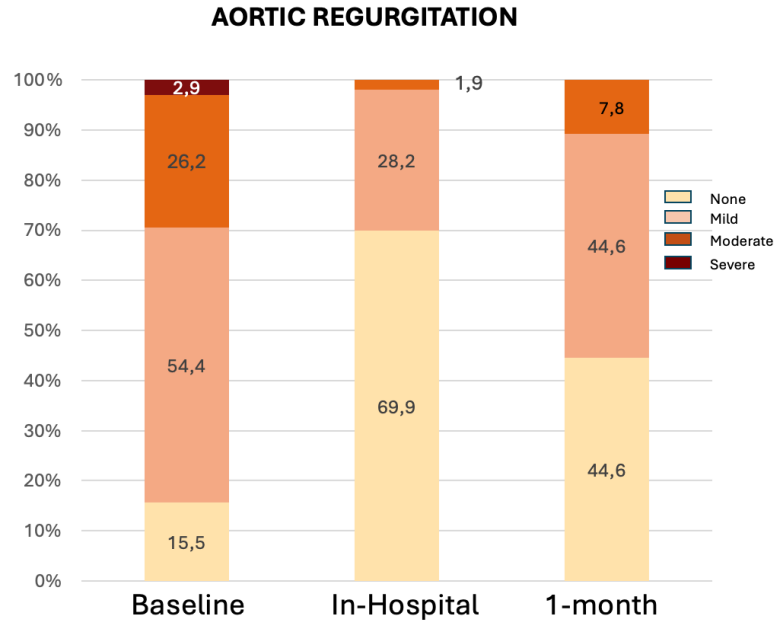
## PROCEDURAL CHARACTERISTICS

<b>Femoral Access</b>	103 (100%)
<b>Pre-Dilatation (Yes)</b>	69,9%
<b>Valve Size</b>	
24 mm	39 (37.8%)
27 mm	34 (33%)
30 mm	31(29.1%)
<b>Need for Second Operator Bailout</b>	8 (7.8%)
<b>Post-Dilatation (Yes)</b>	11 (10.7%)
<b>Annulus Rupture (Yes)</b>	0 (0%)
<b>Coronary Occlusion (Yes)</b>	0(0%)
<b>Valve Embolization (Yes)</b>	5 (4.9%)
<b>Minor Vascular Complications (Yes)</b>	10 (9.7%)
<b>Minor Intraprocedural Bleeding (Yes)</b>	9 (8.7%)
<b>Technical Success (Yes)</b>	98 (95,1%)
<b>Procedure Duration (min)</b>	64.7± 42.1

## IN-HOSPITAL OUTCOMES

<b>In-Hospital Death</b>	0 (0%)
<b>Permanent Pacemaker Implantation (Yes)</b>	23 (22.3%)
<b>Acute Kidney Injury (Yes)</b>	10 (9.7%)
<b>Cerebrovascular Events (Yes)</b>	0 (0%)
<b>LVEF (%)</b>	53.5± 12.3
<b>Mean gradient (mmHg)</b>	5.8 ± 3.9
<b>AVA (cmq)</b>	2.0± 0.6
<b>Aortic Paravalvular Regurgitation III-IV</b>	2 (1.9%)
<b>Mitral Regurgitation III-IV</b>	21 (20.4%)
<b>Tricuspid Regurgitation III-IV</b>	8 (7.8%)
<b>TAPSE</b>	18.2± 3.3

# 30-day Outcomes and Valve Performance



# Take Home Messages

- Single-operator TAVR is feasible and safe with the VitaFlow Liberty system
- Excellent valve performance with low gradients and minimal paravalvular leak
- Streamline the procedure, reduce its complexity, and optimize resource utilization, “PCI”-like procedure