



Pulmonary valve replacement: experience using the Venus P-Valve

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Disclosure information

Lecture title:

***Pulmonary valve replacement:
experience using the Venus P-Valve***

Alejandro Peirone MD, FSCAI

***As a faculty member for this program, I disclose the following relationships
with industry:***

None

Background

- *Percutaneous PVR is a recognized alternative to repeated surgery after development of - significant PR
 - RV dilation
 - and / or RV dysfunction.*
- *The overall safety and effectiveness of the interventional procedure has compared favourably with surgical repair.*
- *Nevertheless, limitations for PVR using the current valves available exist mainly due to - large RVOT
 - native outflow tracts.*

Background

- *Clinical experience to date with transcatheter PVR has been limited to two balloon expandable systems: **Melody Valve** (Medtronic Inc, Minneapolis, MN) **Sapien Valve** (Edwards Lifesciences, Irvine, CA).*
- *Both have undergone clinical trials with good medium-term valve durability.*
- *In the majority of pts requiring PVR, these balloon expandable systems are not large enough to maintain stable valve position within the dilated native RVOT.*
- *Therefore more recent efforts have concentrated on a self-expanding system to provide valve competence despite significant dilation of the native RVOT in a wide variety of post-operative anatomical variants.*

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RVOTO anomalies (@ 20.1% of all CHD pts)

Tetralogy of Fallot

Truncus Arteriosus

Transposition Great Arteries

Others

With Pulm Stenosis

With Pulm Stenosis/Atresia

Surgical correction of RVOT (non-conduit)

Right Ventricle to Pulmonary Artery (RV - PA) Conduit

RV - PA Conduit

RV - PA Conduit

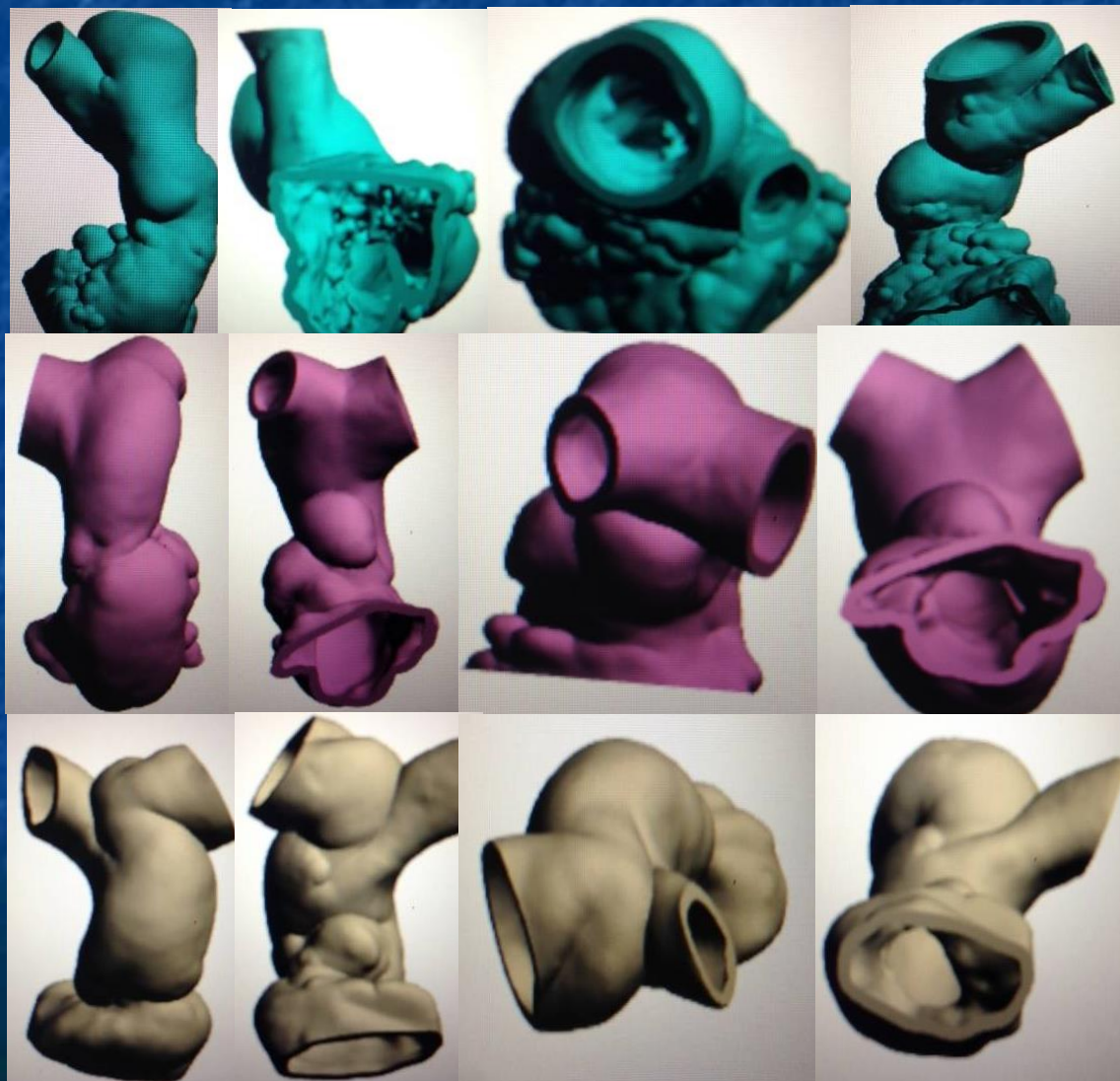
RV - PA Conduit

~85% of RVOT pts

~15% of RVOT pts

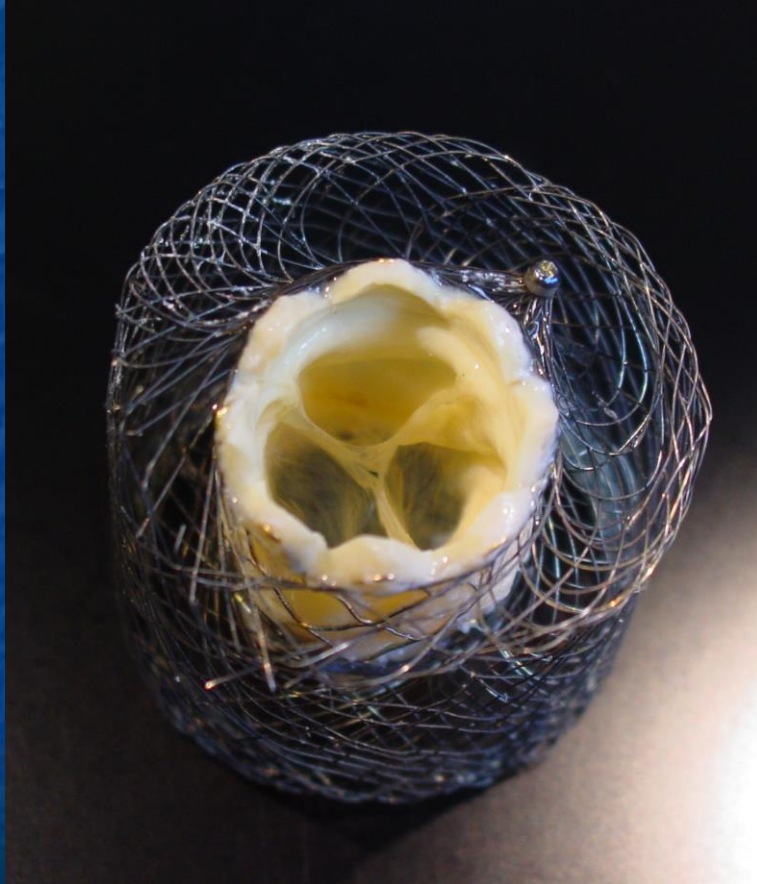
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MRI and different anatomies of RVOT

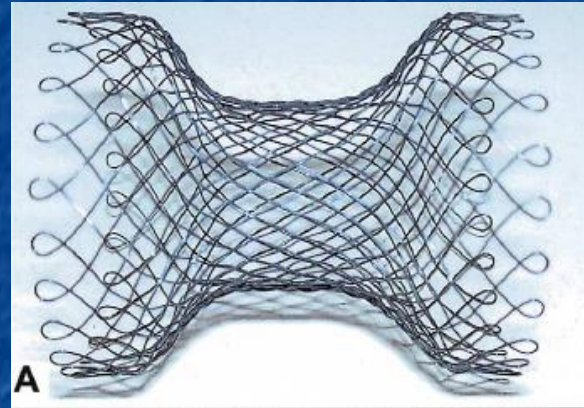


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Early attempts of RVOT “reducers”



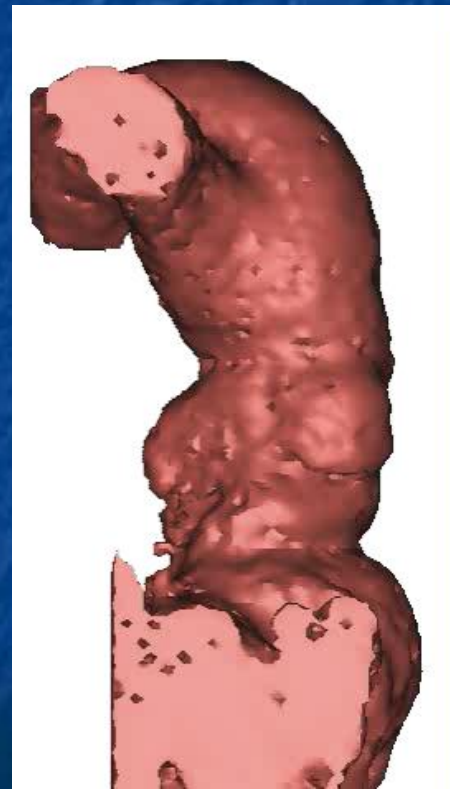
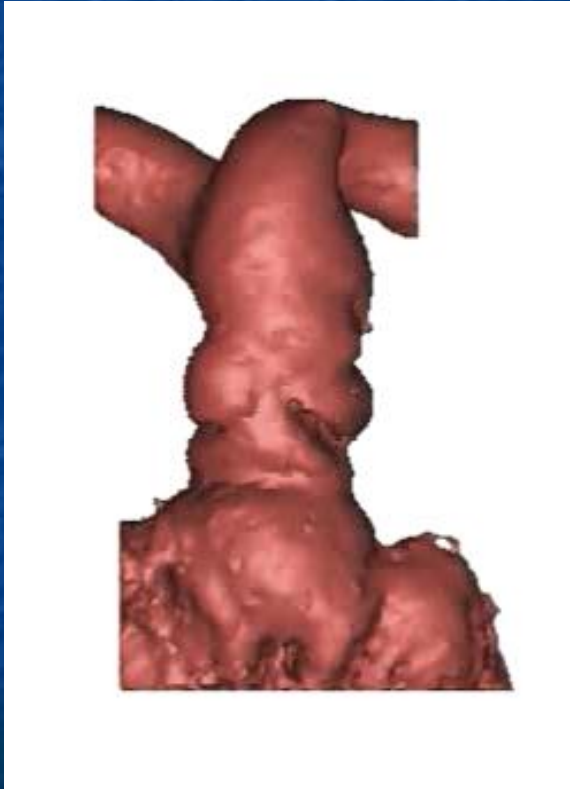
Dr. K. Amplatz



Dr. P. Bonhoeffer

Venus P-Valve

*Custom patient experience. 42 yo male.
January 2009 - Pre implant CT evaluation*



Dr. P. Bonhoeffer

Venus P-Valve

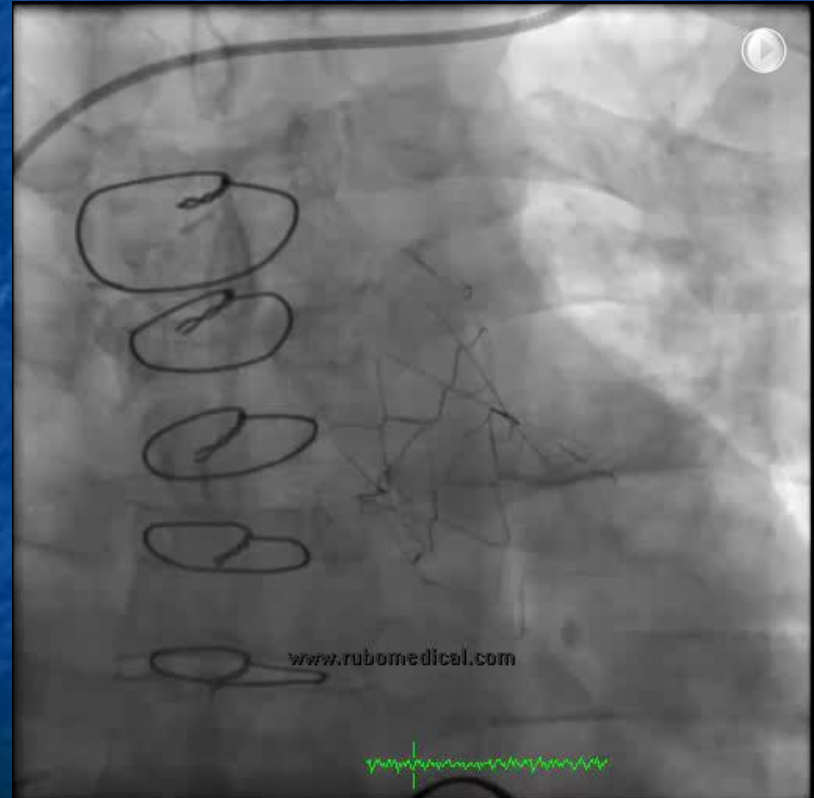
***Custom patient experience. 42 yo male.
Implantation date: January 2009
The device***



Dr. P. Bonhoeffer

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**Custom patient experience. 42 yo male.
January 2009 – The device**



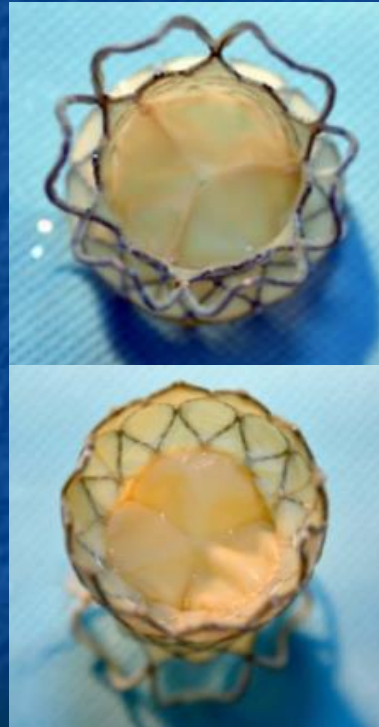
Dr. P. Bonhoeffer

History

- ***Developed by Dr. Qi-Ling Cao & Venus MedTech Team.***
- ***First in-man implantation: female pt in 2011 in Hanoi.
Vietnam Heart Institute.***
- ***First pt in China: 14 yo girl in 2013 in Shanghai.
Shanghai Zhongshan Hospital.***
- ***Trial in China started in 2013 and enrolled @ 45 pts.***
- ***First pt in LATAM: Pontificia Universidad Católica de Chile
Dr. F. Garay & team. March 2016.***

Venus P-Valve

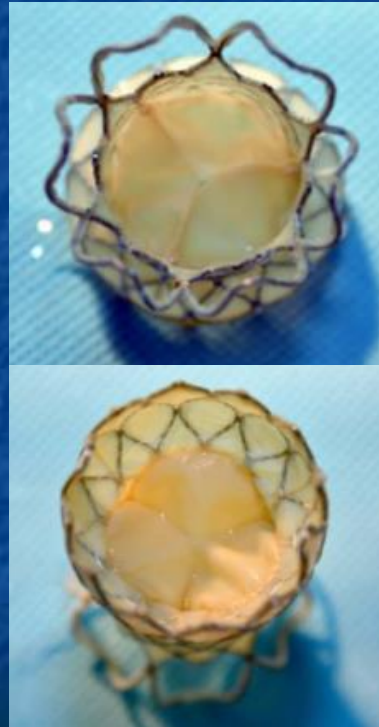
The valve:



- *Self-expandable Nitinol multi-level support frame.*
- *Tri-leaflet porcine pericardial tissue.*
- *Preserved in low-concentration solutions of buffered gluteraldehyde .*
- *19–24 Fr catheter delivery system.*
- *The entire stent is covered (except the distal cells) by hand-sewn porcine pericardial tissue.*

Venus P-Valve

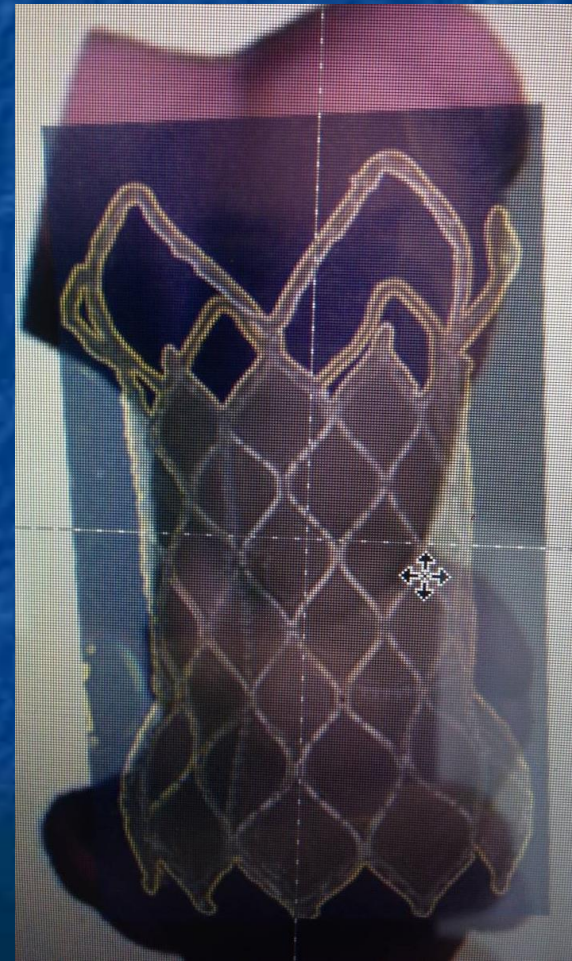
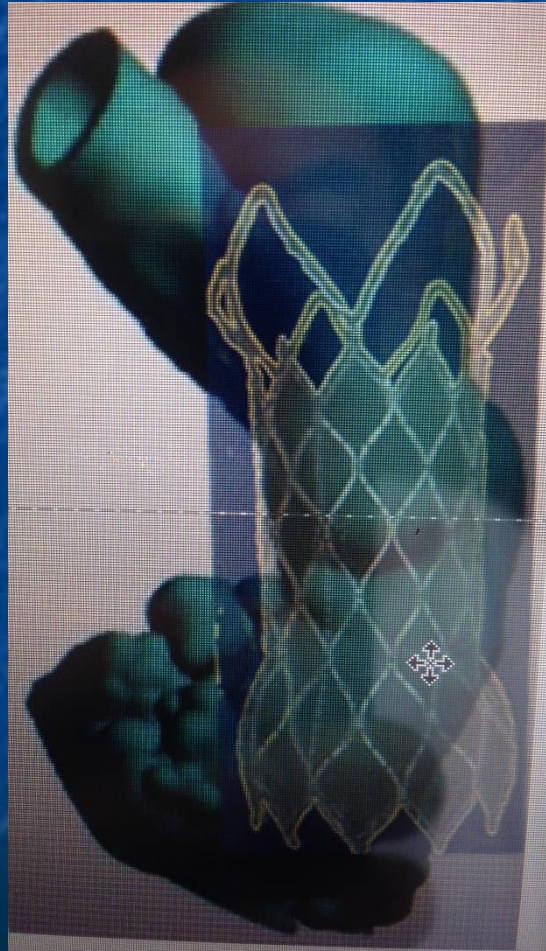
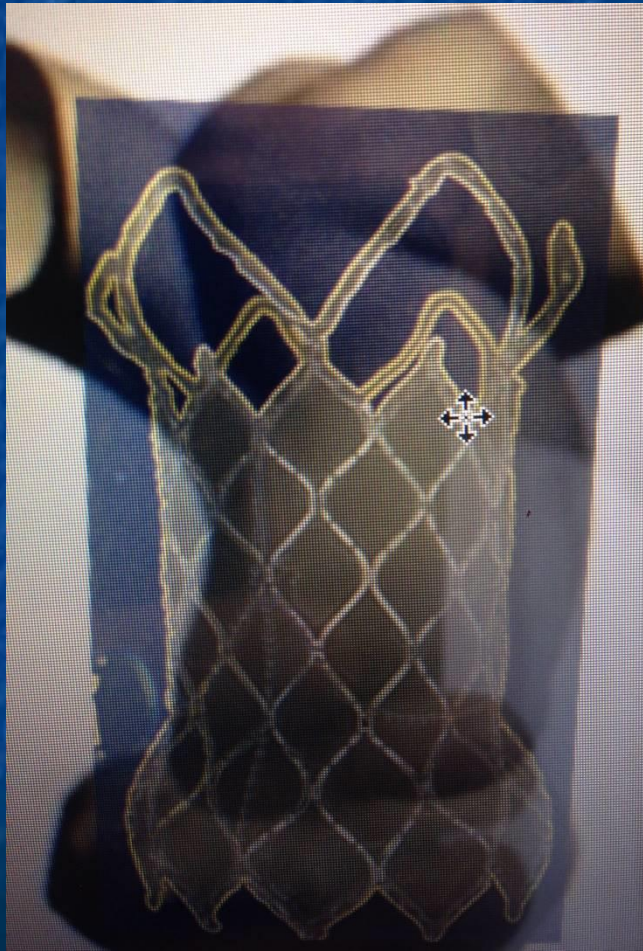
The valve:



- *Flared uncovered distal end secures anchoring at PA bifurcation with radiopaque markers .*
- *Flared covered proximal end allowing conformability with the dilated RVOT with two “ears”.*
- *Stent valve diameters range from 20 to 34 mm (in 2 mm increments) with each diameter available in 20, 25 and 30 mm straight sections lengths. Add 10 mm in diameter & length for each flared end.*

Venus P-Valve

Initial modeling work



Venus P-Valve

Initial modeling work



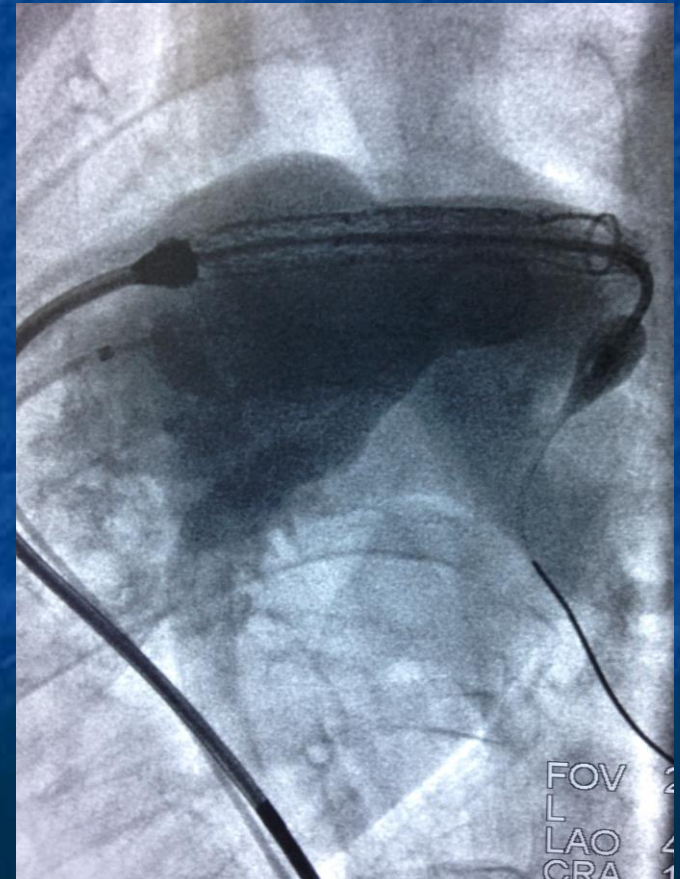
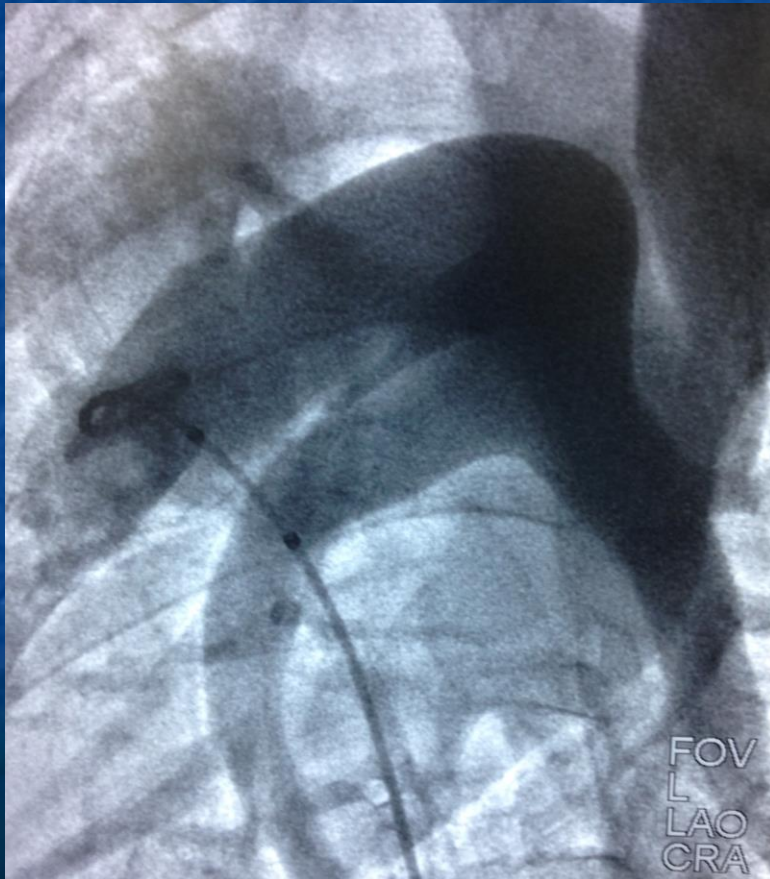
Venus P-Valve

Initial animal lab experience



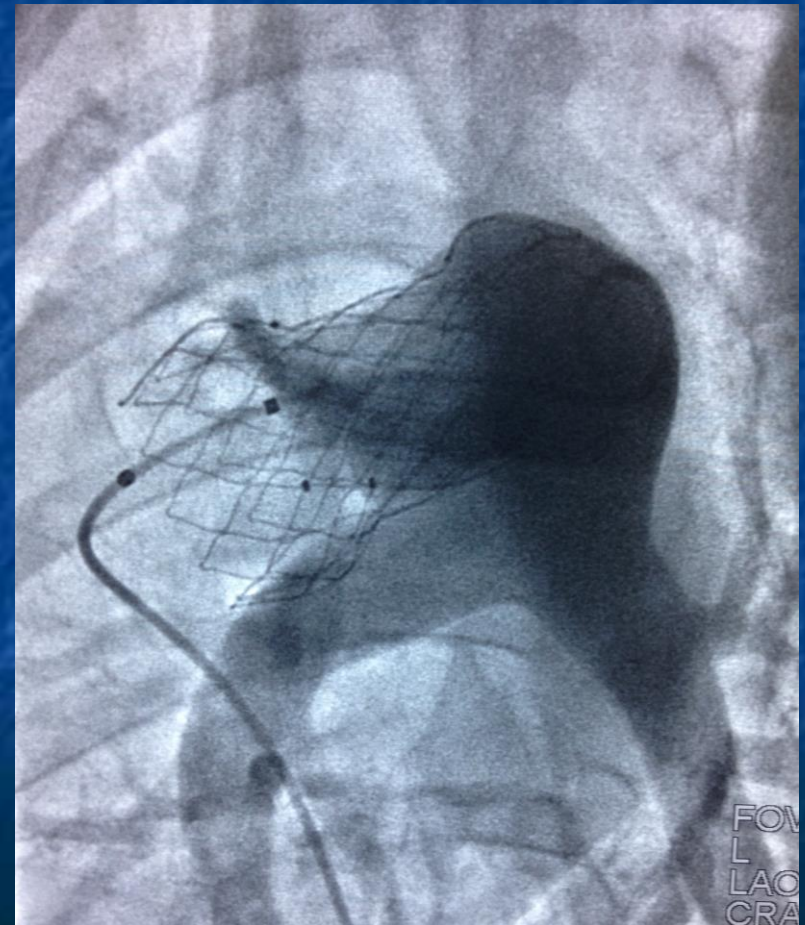
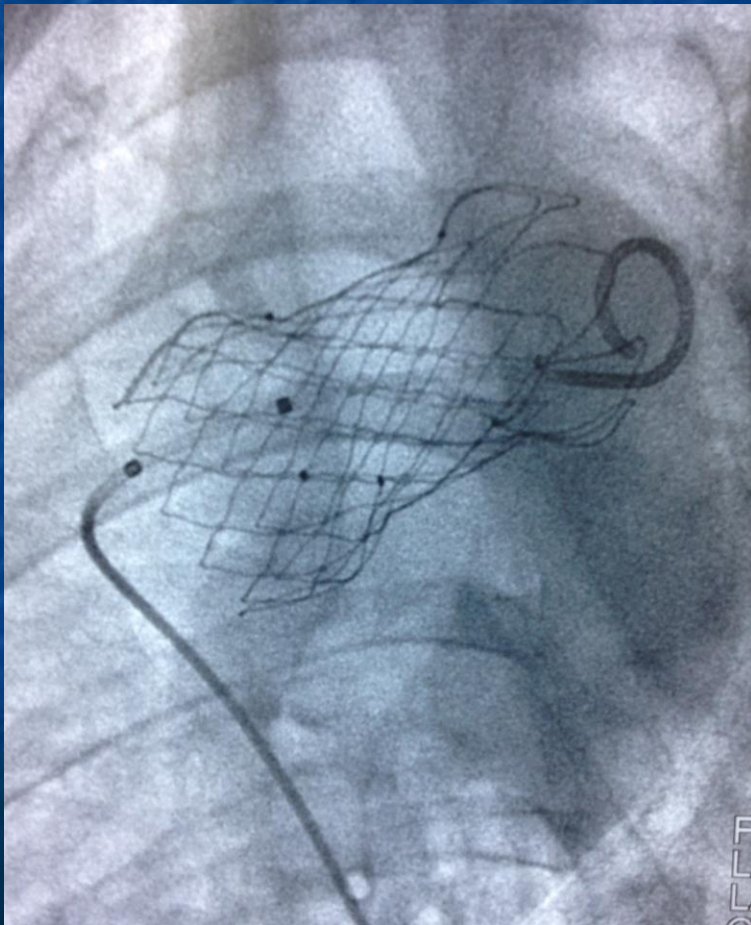
Venus P-Valve

Initial animal lab experience



Venus P-Valve

Initial animal lab experience



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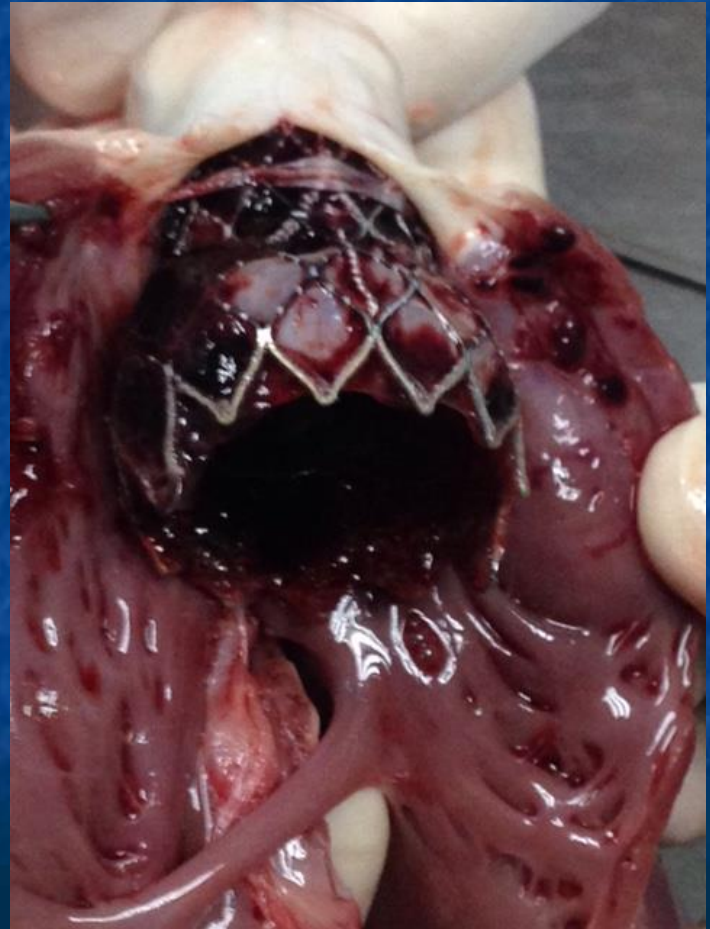
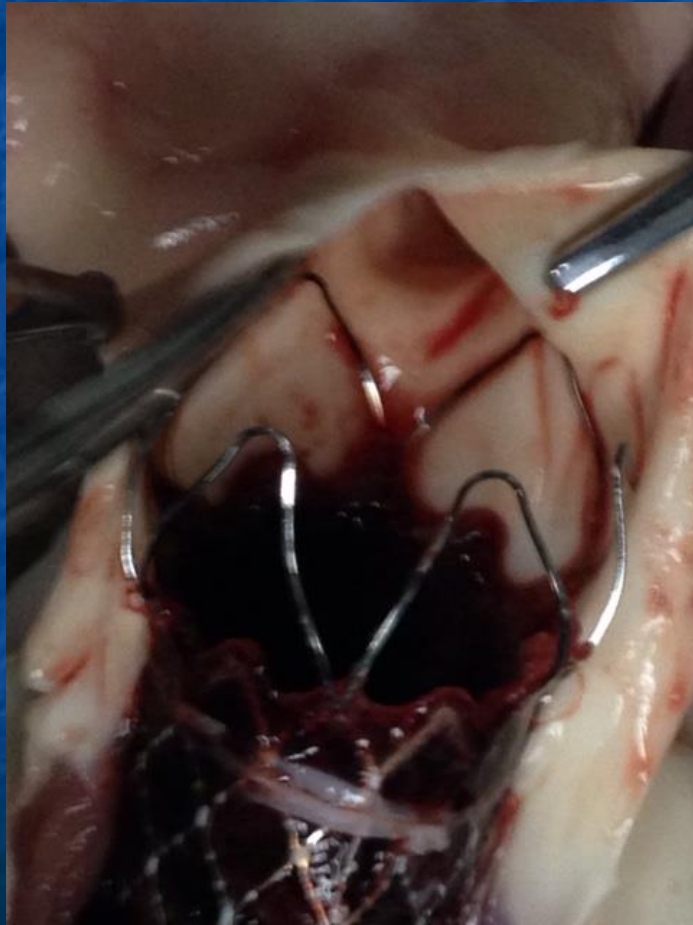
Venus P-Valve

Animal lab experience



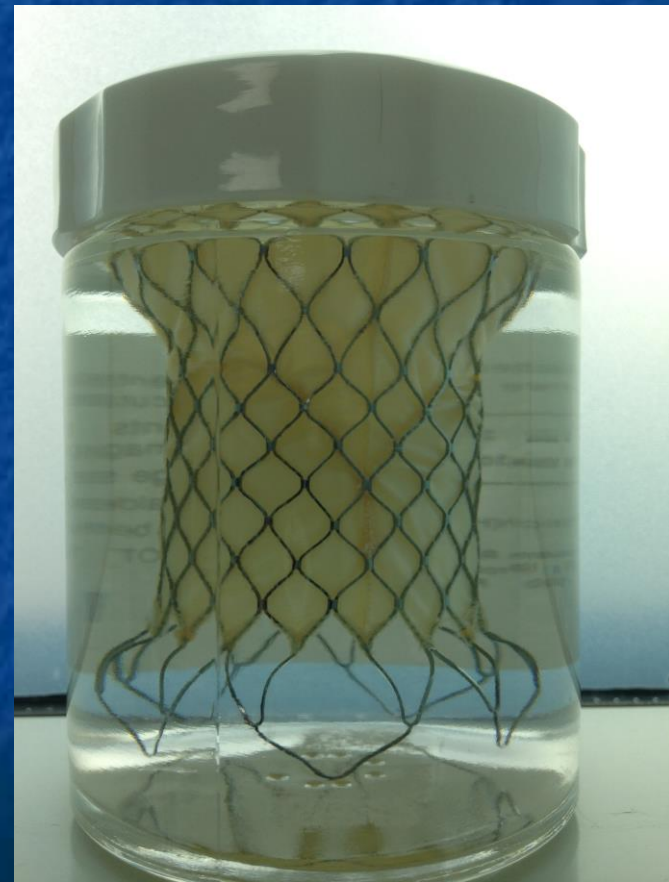
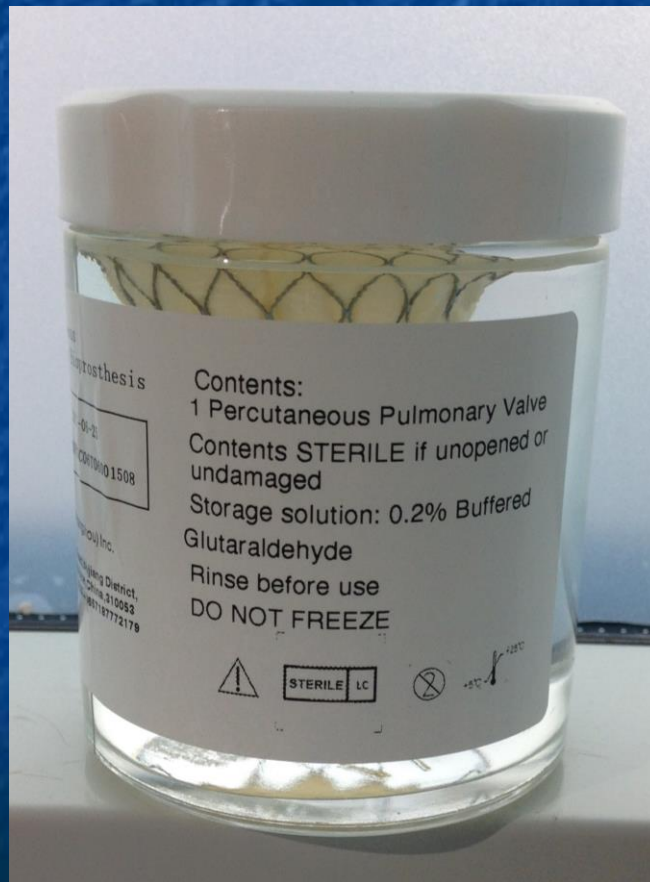
Venus P-Valve

Animal lab experience



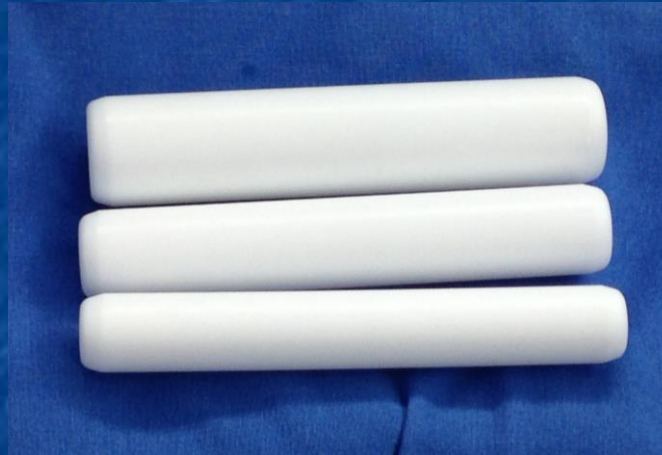
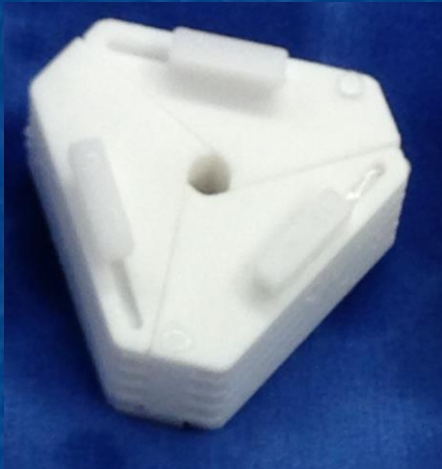
Venus P-Valve

The valve:

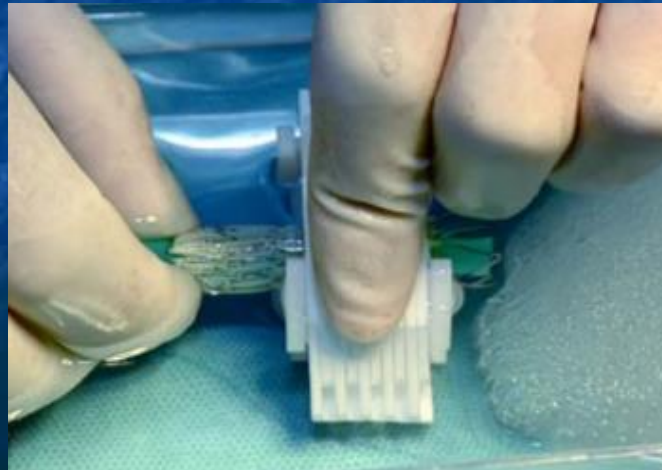
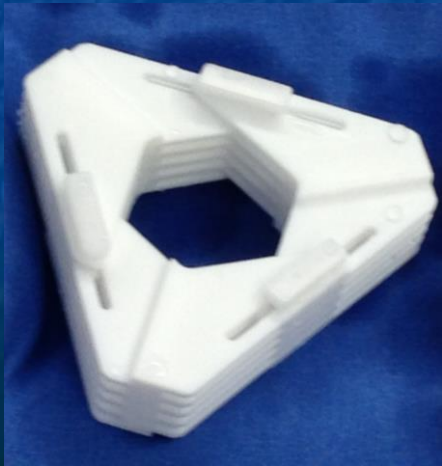


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The valve: Valve crimper



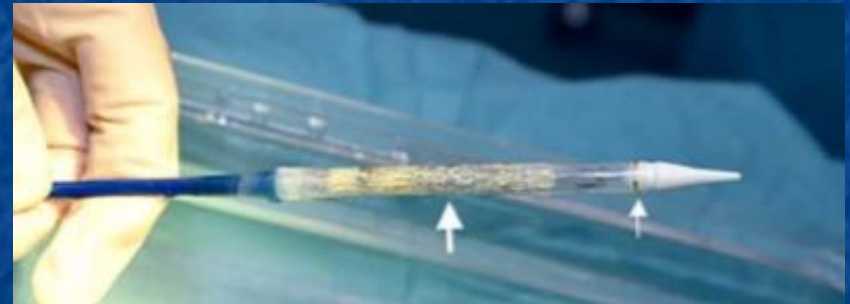
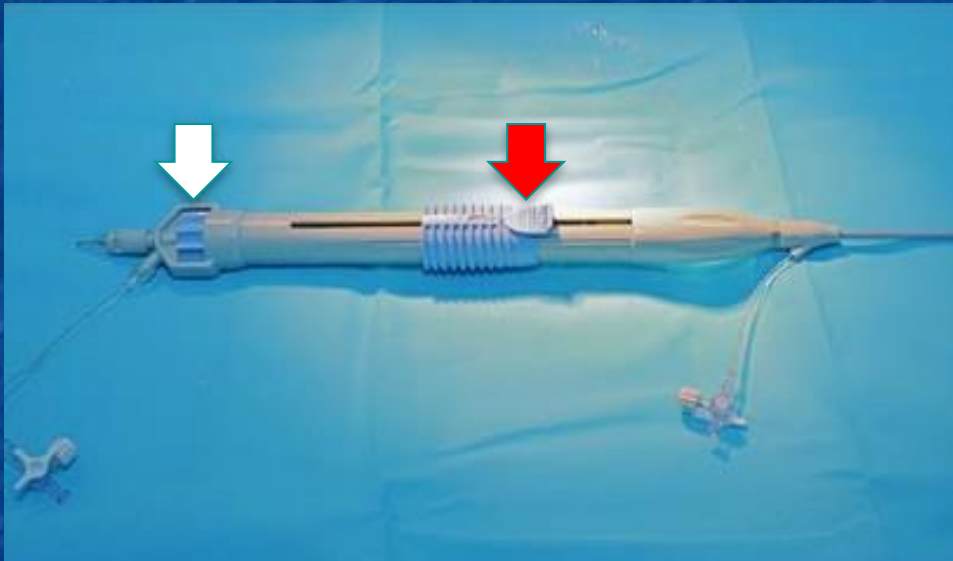
➤ *The crimper is a non-patient contacting compression device .*



➤ *Symmetrically reduces the diameter/profile of the valve when loaded inside the catheter .*

Venus P-Valve

The valve: Delivery system



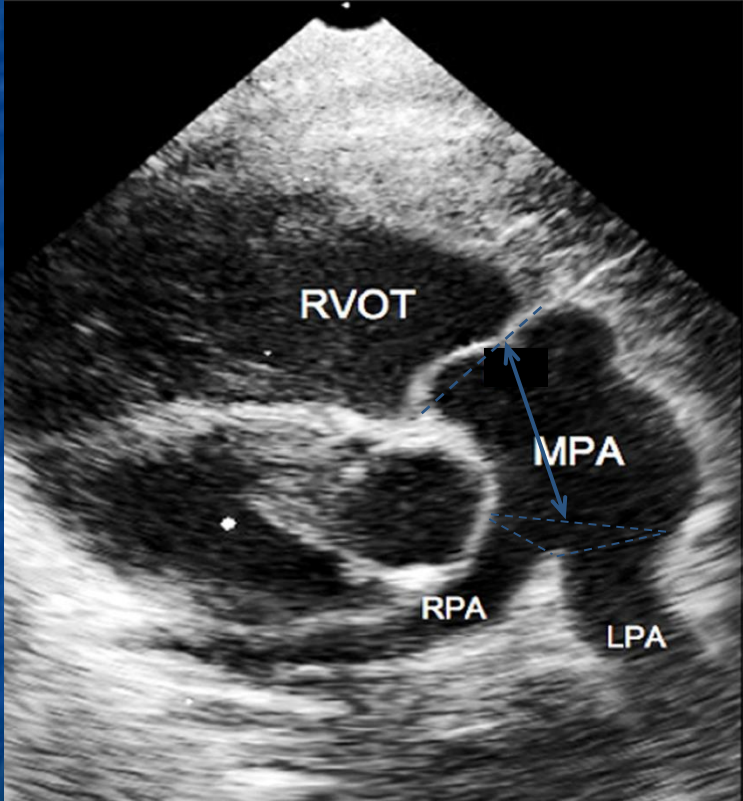
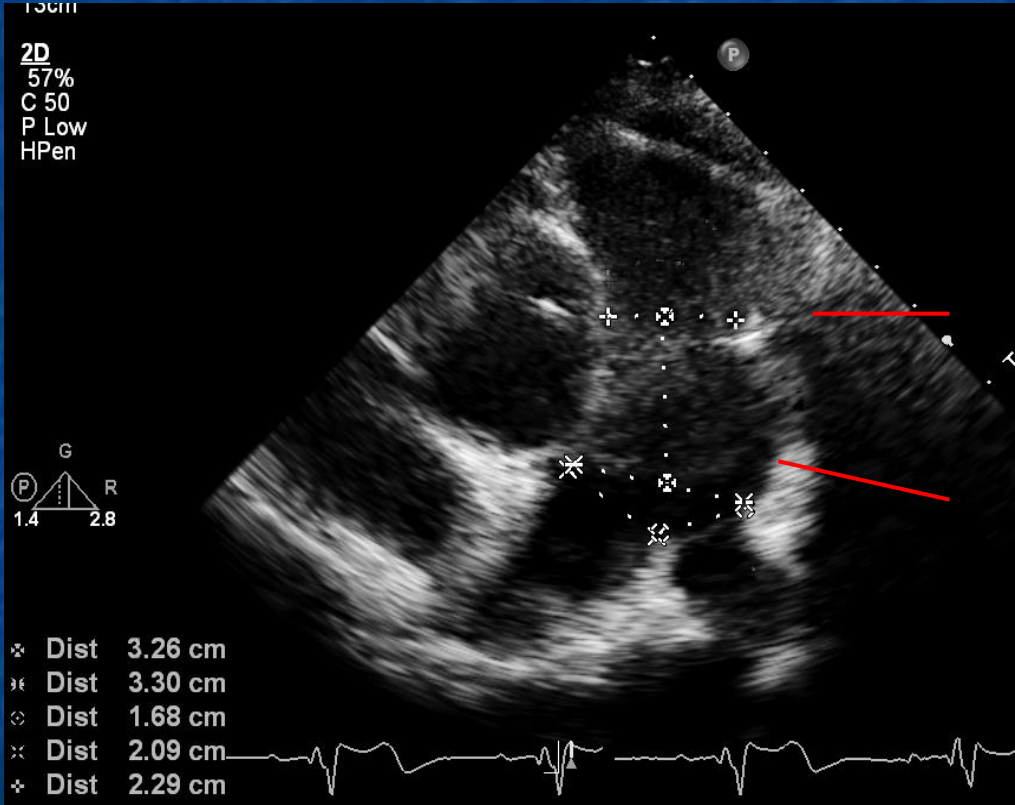
The delivery system consists of a 20–22 Fr capsule and a 16 Fr 100 cm long shaft, with a rotating handle for deployment of the valve with a slow (white arrow) and fast valve (red arrow) deployment

Patient selection criteria:

- 1. Age: ≥ 10 years/old; Weight: ≥ 18 Kg***
- 2. Severe PR: TTE $\geq 3+$; MRI $> 30\%$, PRRF $> 40\%$***
- 3. Dilated RV & RA size (TTE & MRI)
RV EDV $130 \text{ ml/m}^2 \leq \text{index} \leq 160 \text{ ml/m}^2$;
RV EF $< 40\%$ (MRI)***
- 4. Non significant structure narrowing of RVOT, MPA
and branch of PA (RPA & LPA) (TTE, MRI & CT)***
- 5. During catheterization sizing balloon determined
no coronary artery compression***
- 6. Maximal RVOT diameter 30-32 mm (balloon sizing)***

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Selection criteria:



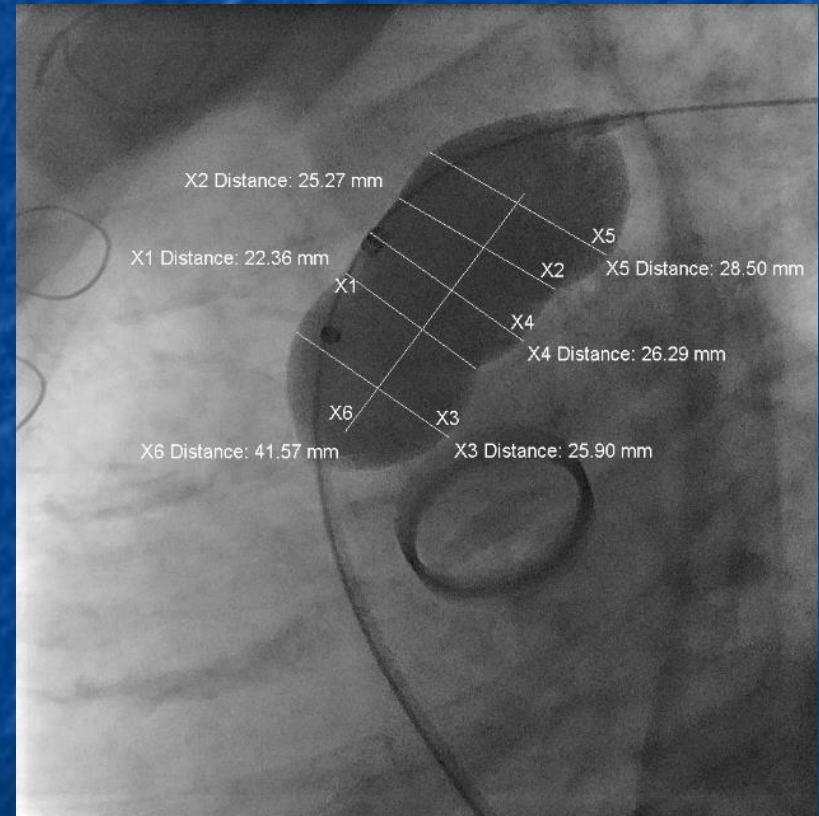
TT echocardiography is very important!!

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The procedure:



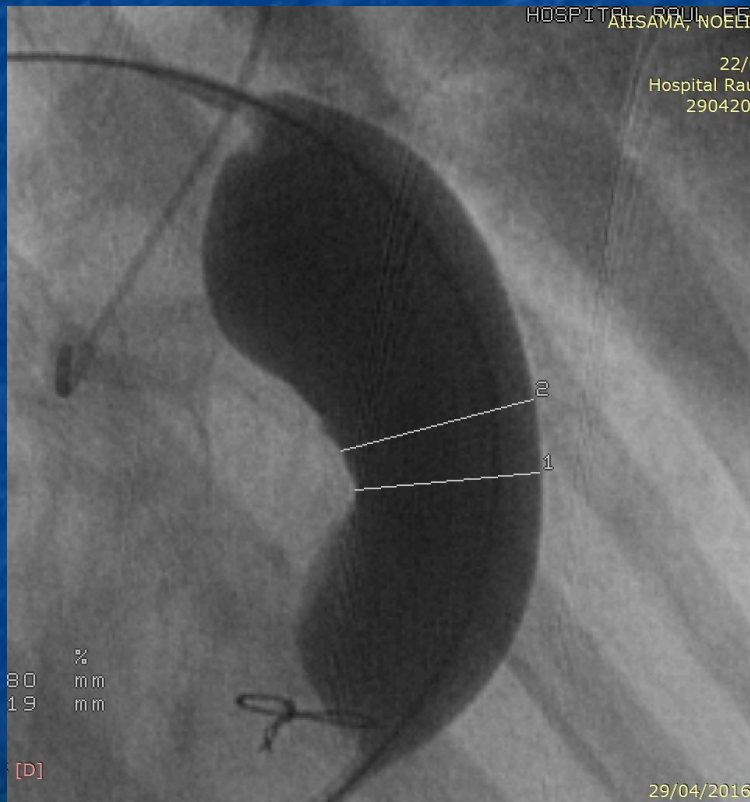
MRI



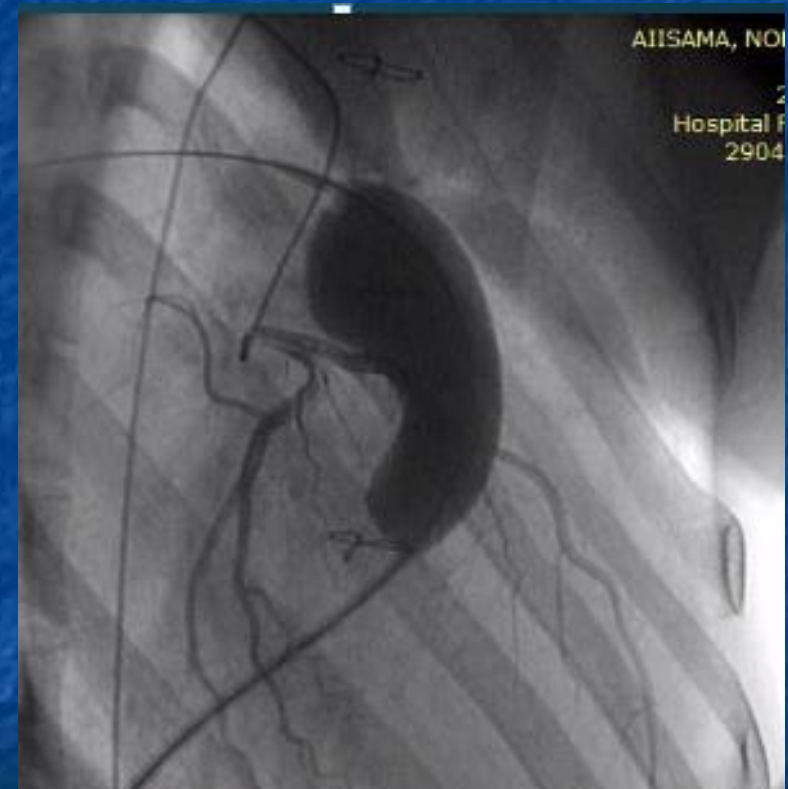
Balloon sizing

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The procedure:



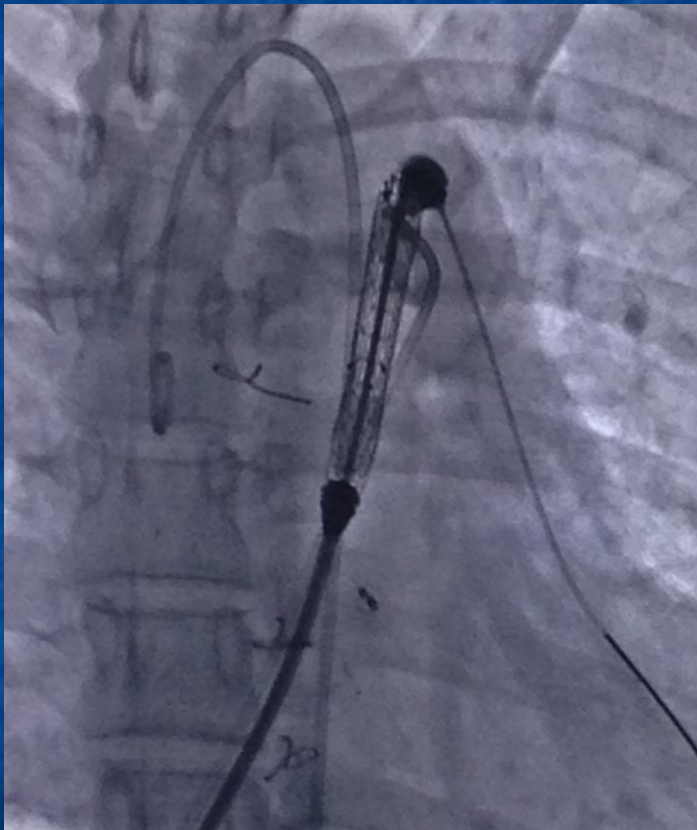
Balloon sizing



LCA angiography

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The procedure:



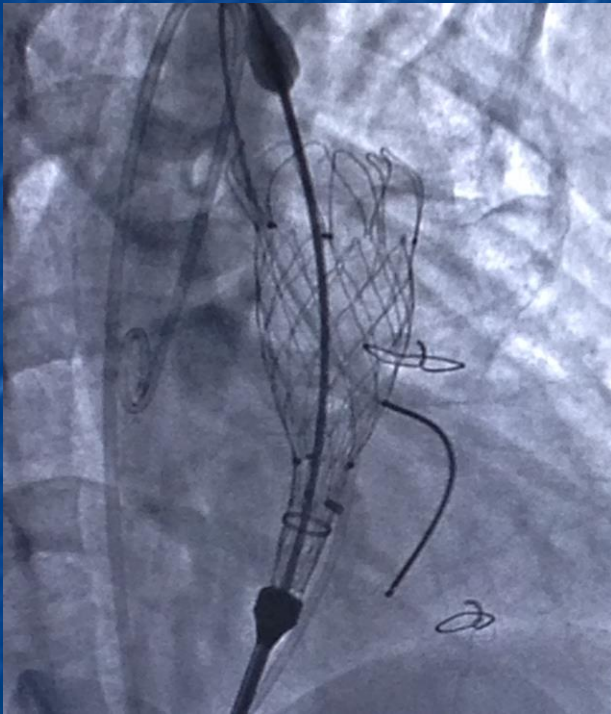
Initial LPA position



Early deployment

Venus P-valve

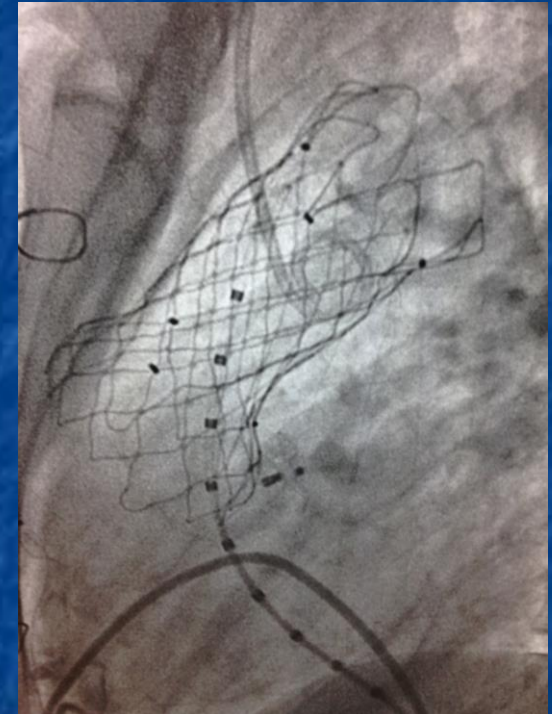
The procedure:



Partial deployment



Full deployment & final position



Initial data:

Early Clinical Experience With a Novel Self-Expanding Percutaneous Stent-Valve in the Native Right Ventricular Outflow Tract

Qi-Ling Cao,¹ MD, Damien Kenny,¹ MB, MD, Daxin Zhou,² MD, Wenzhi Pan,² MD, Lihua Guan,² MD, Junbo Ge,² MD, PhD, and Ziyad M. Hijazi,^{1*} MD, MPH

Catheterization and Cardiovascular Interventions 2014; 84: 1131–1137

5 pts

Median age 33 years

Mean body weight 54.8 kg

Initial data:

Original Article

Percutaneous pulmonary valve implantation with the Venus P-valve: clinical experience and early results

Worakan Promphan,¹ Pimpak Prachasilchai,¹ Suvipaporn Siripornpitak,³ Shakeel A. Qureshi,² Thanarat Layangool¹

¹*Pediatric Heart Center, Queen Sirikit National Institute of Child Health, College of Medicine, Rangsit University;*

²*Department of Radiology, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand;*

³*Department of Paediatric Cardiology, Evelina London Children's Hospital, Guy's and St Thomas' NHS Foundation Trust, London, United Kingdom*

Cardiology in the Young 2016; 26: 698-671

6 pts

Median age 18.5 years

Mean body weight 53.8 kg

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Venus P- Valve China Clinical Trial

Updated April 2016.

Data provided by Dr. Z. Hijazi & Venus MedTech team.

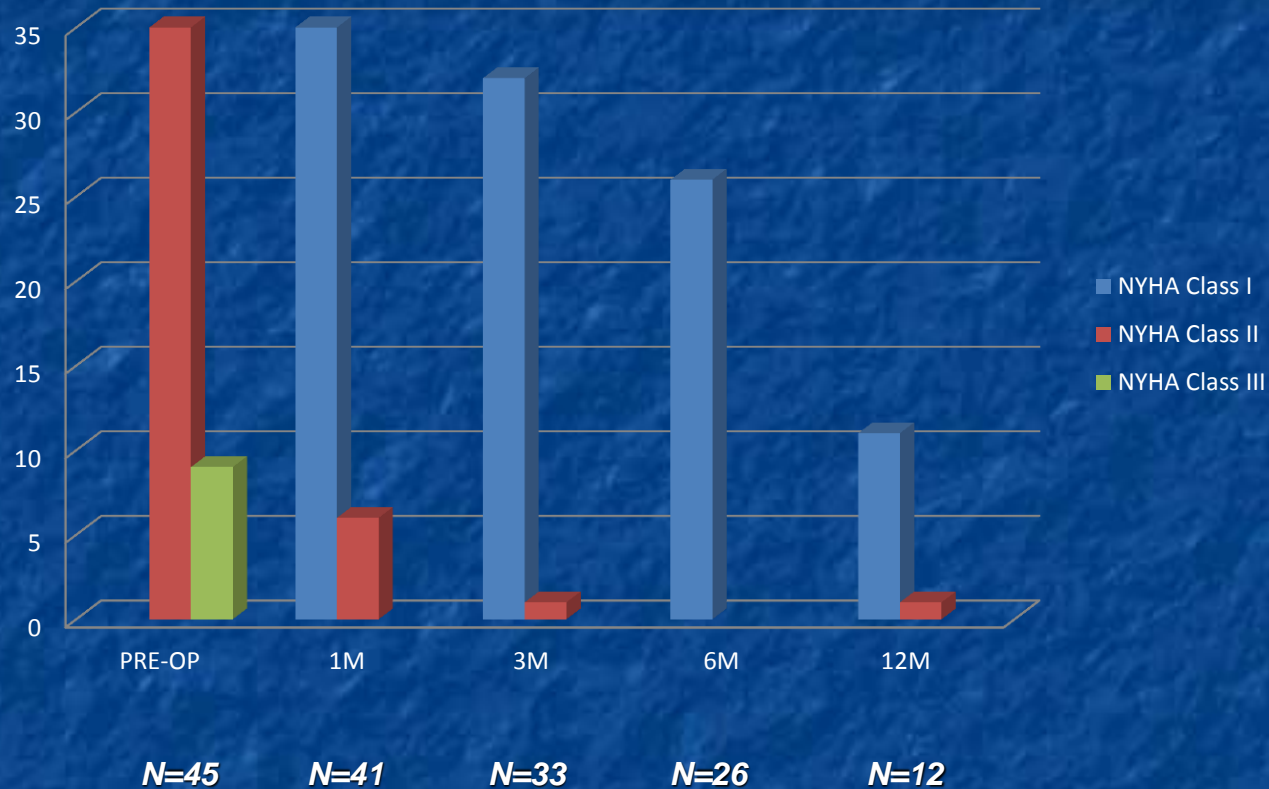
Demographics

Characteristics	N= 45
Age	29.1±12.0
Female Gender	73% (33)
Weight (kg)	53.7±8.2
Height (cm)	161.8±6.2
Age of 1st TOF repair (yrs)	14.0±11.6
Time from 1st TOF repair to PPVI.	15.1±8.7
NYHA Class III	20%
NYHA Class II	80%
PR grade 4 (severe)	64%
LV EF	60.8±10.8

Pre-Procedural data

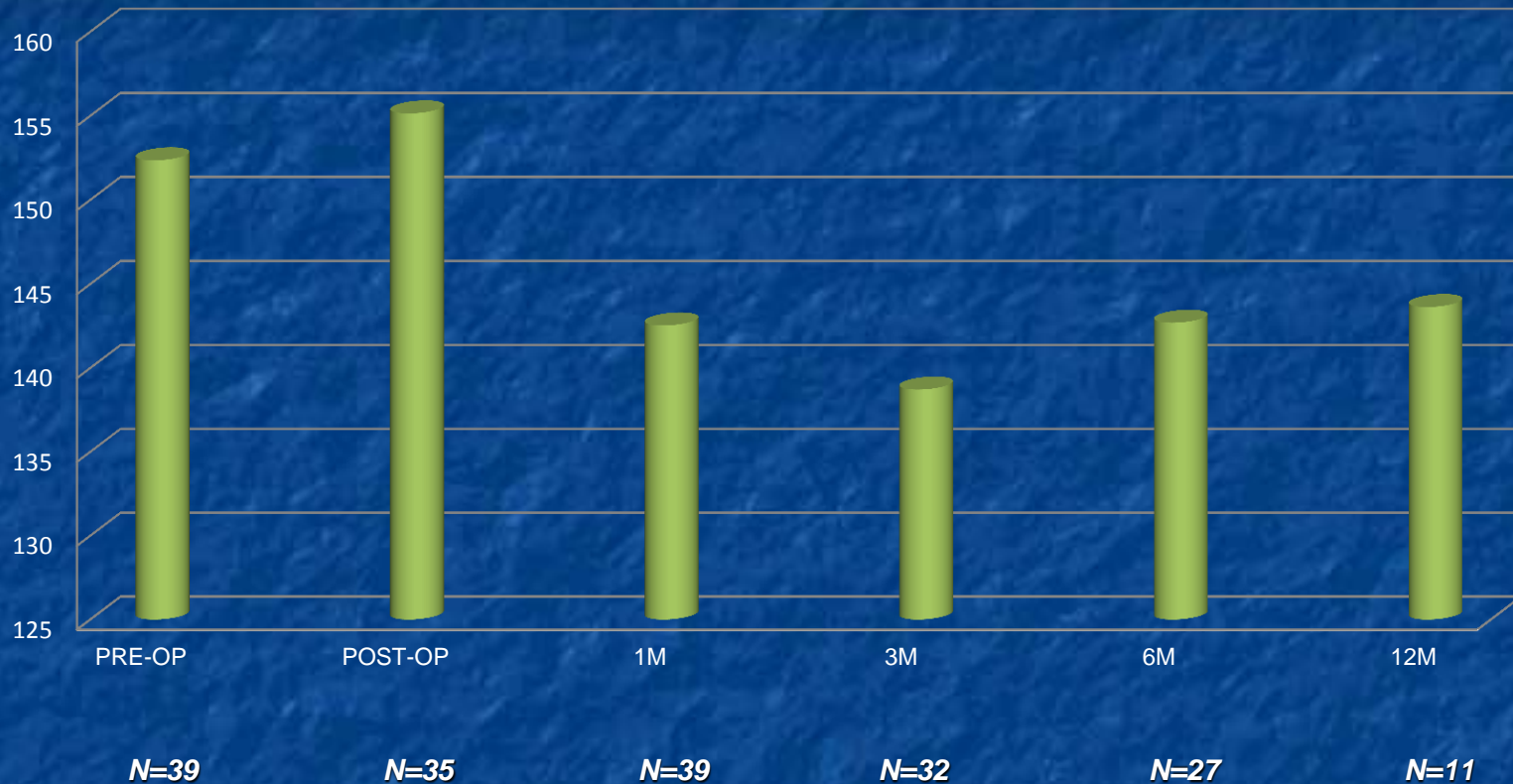
Characteristics	Value (N)
RVOT diameter , Mean± SD (mm)	
<i>Echo</i>	30.5±5.5 (36)
Annular Diameter , Mean± SD (mm)	
<i>Echo</i>	23.3±4.9 (39)
<i>CT</i>	27.4±4.9 (42)
Mid-MPA diameter , Mean± SD (mm)	
<i>Echo</i>	24.1±4.1 (44)
Narrow -MPA diameter , Mean± SD (mm)	
<i>CT</i>	24.7±3.4 (30)
RPA Diameter , Mean± SD (mm)	
<i>CT</i>	19.7±5.3 (39)
LPA Diameter , Mean± SD (mm)	
<i>CT</i>	17.7±4.6 (39)

NYHA Functional Class



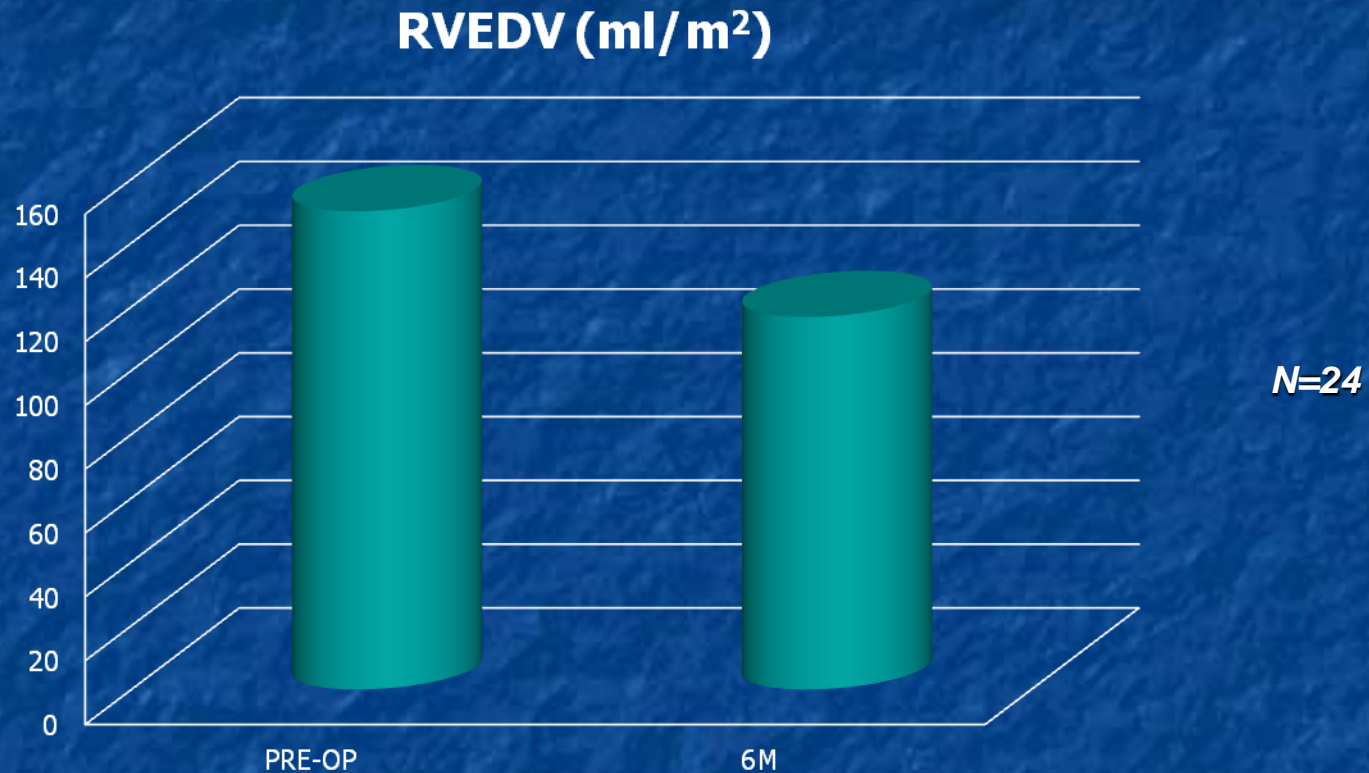
In 26 pts their NYHA class improved from class III to class II or I during the 6m follow-up

EKG - QRS duration (msec)



QRS wave duration narrowed down by 5.3% for 26 pts during 6m follow-up

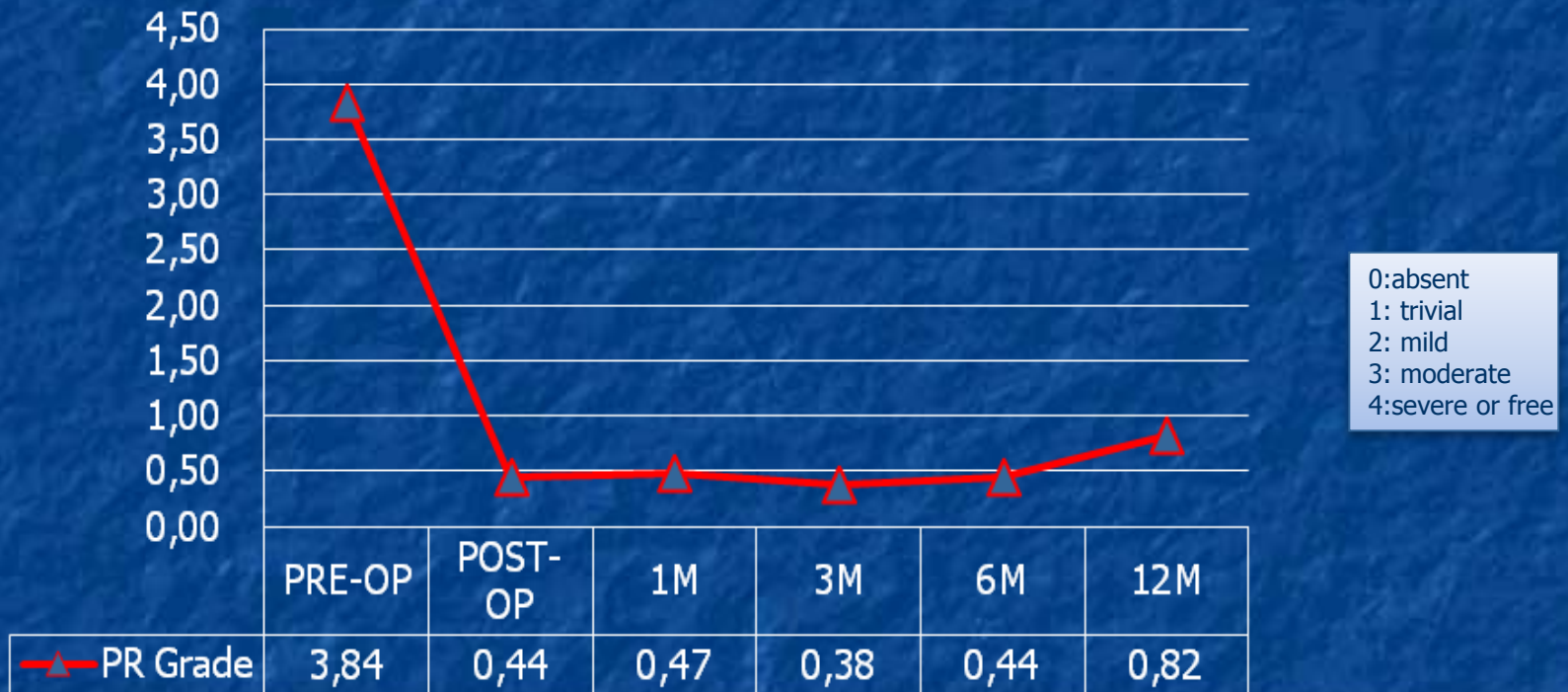
RVED volume - Primary End Point



RVEDVI has significantly decreased in 24 patients during 6m follow-up (RVEDV: 150 \pm 37 vs 117 \pm 31, $p < 0.01$)

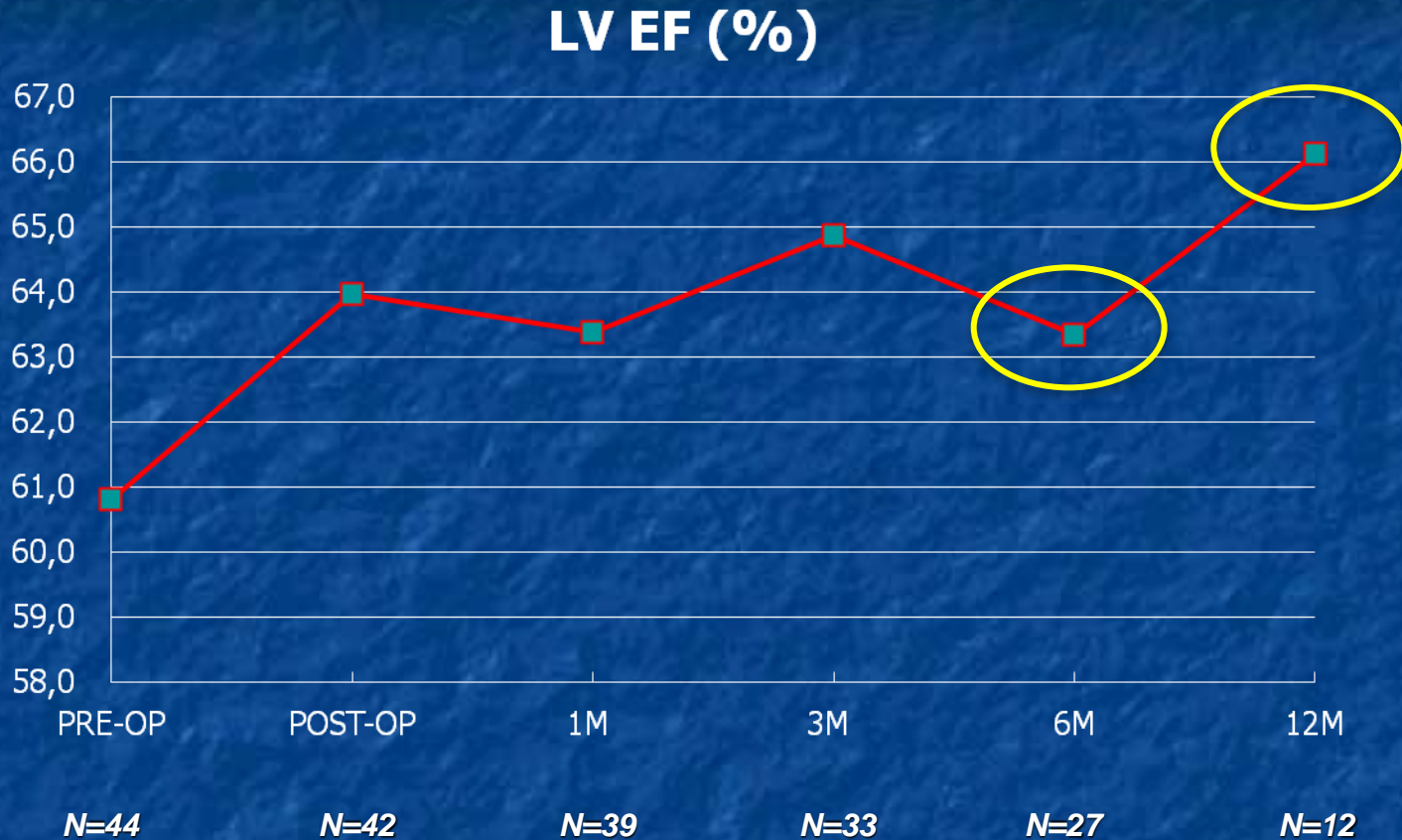
Pulmonary valve regurgitation (grade)

Pulmonary Regurgitation



**27 pts showed mild or none PR during 6m follow up
(mild # 12, none # 15)**

TT Doppler Echocardiography



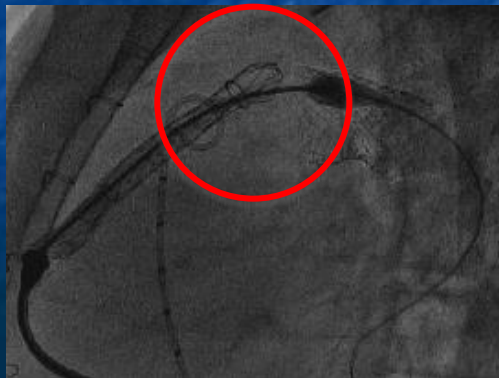
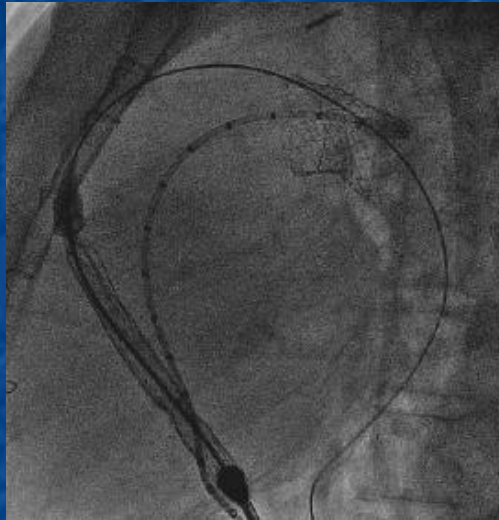
LVEF increased by 6.9% in 27 pts during 6m follow-up and improved by 10.4% in 12 pts during 12m follow-up

Sudden Adverse Events

SAE	Cases	Treatment	Outcome
Death	1	-	1 month after intervention. Transit accident.
Endocarditis	1	Antibiotic and surgical removal	Healed without sequence
Fever	2	Antibiotic	Healed without sequence
Migration	1	Surgical intervention for fixation	Healed without sequence
Arrhythmia	1	Electrical conversion	Healed without sequence

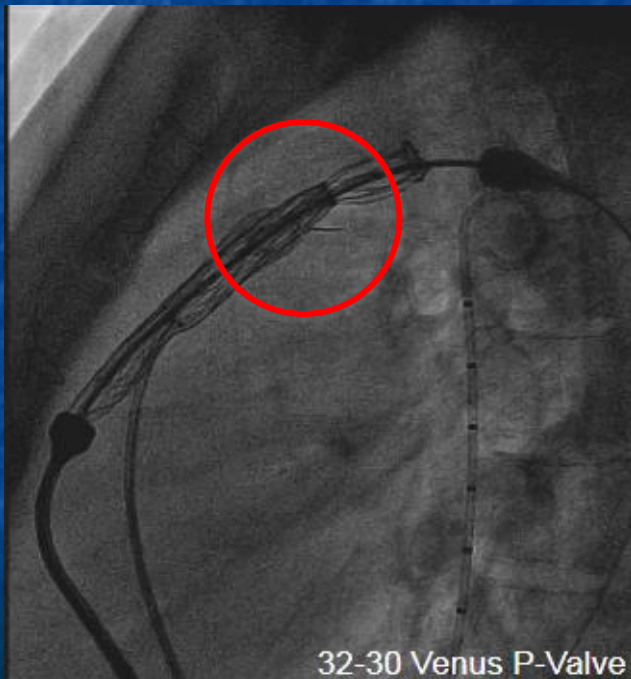
Delivery system malfunction:

Aborted case. Breaking of the capsule

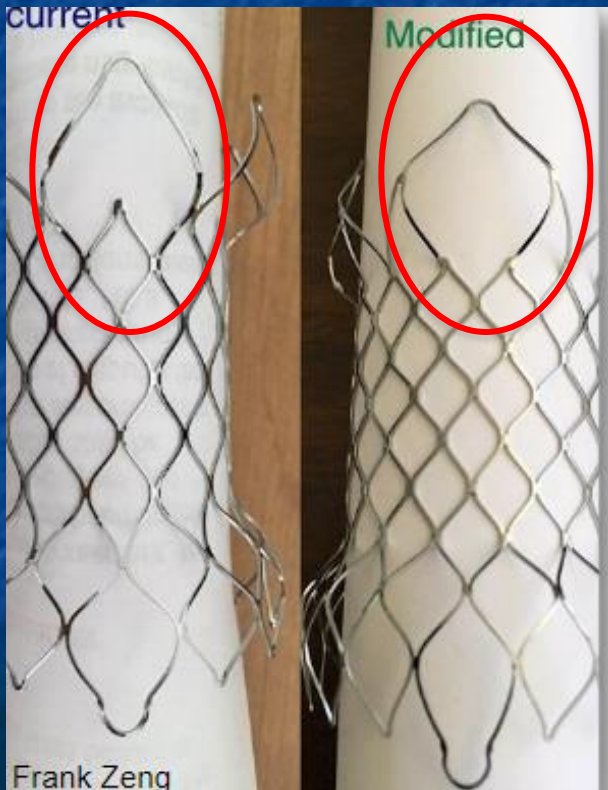


Delivery system malfunction:

Piercing of the stent strut out of the capsule while uncovering the sheath



Delivery system and valve modifications:

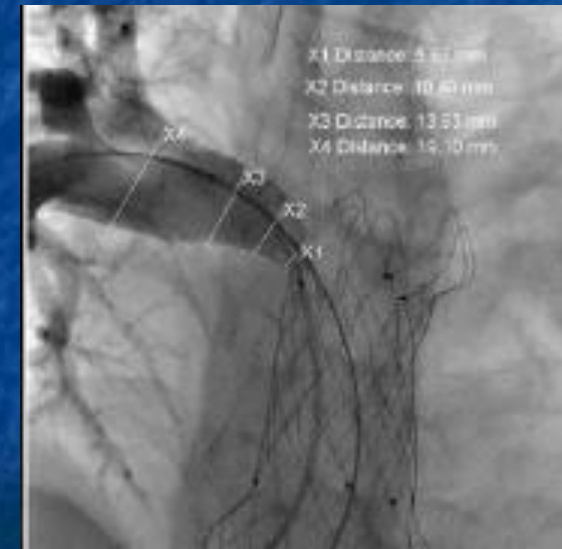
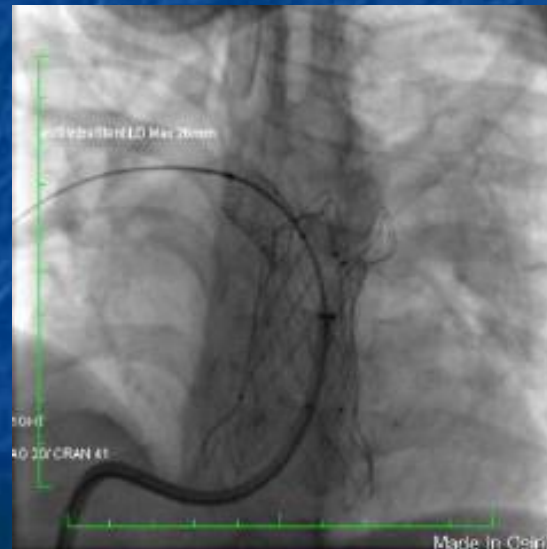


Delivery system modifications

1. Braiding/thickened capsule
2. Longer and softer carrot
3. Seamless carrot-capsule connection

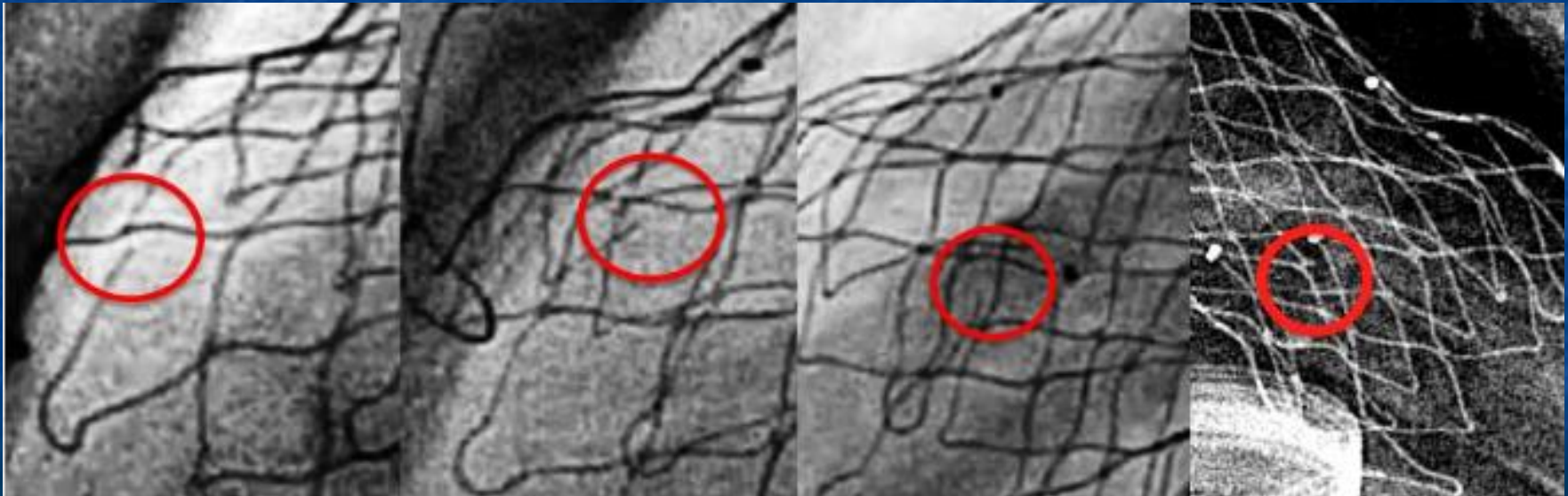
Valve complication: RPA occlusion

Prior RPA stenosis occluded by Venus P-valve needing stenting (Max LD 26 mm in length on a 15 x 30 mm Crystal balloon)



Fluroscopy follow-up:

*Single wire fracture 4 cases (earliest @ 3 months)
w/o hemodynamic consequences*



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Worldwide experience: 36 pts

Global Compassionate Implantation, As of March, 2016			
City/Country	Case No.	Hospital	Program Leader
London, UK	8	<u>Evelina</u> Children's Hospital	Dr. <u>Shakeel A Qureshi</u>
Dublin, Ireland	1		Dr. Kevin Walsh
Hanoi, Vietnam	1	Hanoi Medical University Hospital	Dr. Nguyen <u>Lan Hieu</u>
Bangkok, Thailand	13	Queen <u>Sirikit</u> National Institute of Child Health	Dr. <u>Worakan Promphan</u>
Jakarta, Indonesia	1	Harapan Kita National Cardiovascular Center	Dr. <u>Indriwanto Atmosudigdo</u>
Kochi, India	2	Amrita Institute of Medical Sciences	Dr. Raman Krishna Kumar
Chennai, India	6	The MADRAS MEDICAL MISSION	Dr. K. <u>Sivakumar</u>
Hyderabad, India	1	Care Hospital	Dr. <u>Nageswara Rao</u>
Santiago, Chile	3	<u>Pontificia</u> Universidad <u>Católica</u> de Chile	Dr. Francisco <u>Garay</u>

Next step...

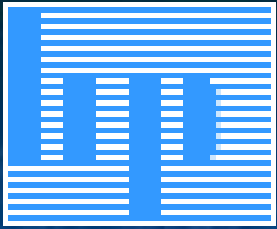
The Venus P-Valve[®] System for Conduit RVOTs

- A straight body self-expanding Nitinol frame with a tri-leaflet porcine pericardial tissue valve
- A 19-24 French catheter delivery system
- A disposable loading system with a crimper



Venus P Valve[®]

Straight body for
pre-stented conduit
Max diameter 30 mm

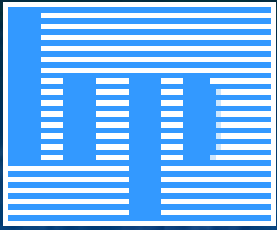


Venus P-Valve



Conclusions:

- *The Venus P-Valve can be implanted successfully and effectively in pts with severe PR and a large RVOT after transannular patch surgery.*
- *The valve restores early, sustained pulmonary competence with RV remodeling and improvement in clinical symptoms.*
 - *Early results with this valve are encouraging.*
- *More extensive clinical trials are in progress and will likely provide more robust longer-term data on the valve functionality and durability.*



Venus P-Valve



Acknowledgments



Gracias!