

Percutaneous pulmonary valve implantation (PPVI): Indications and outcome

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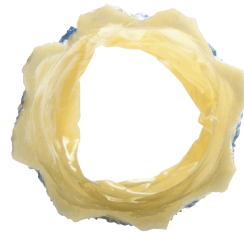
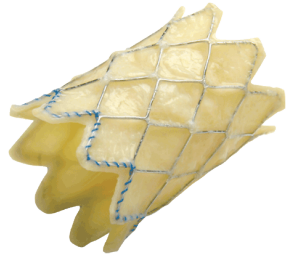
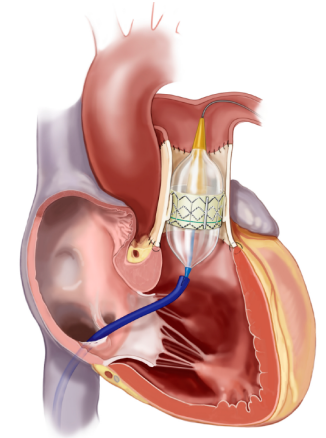
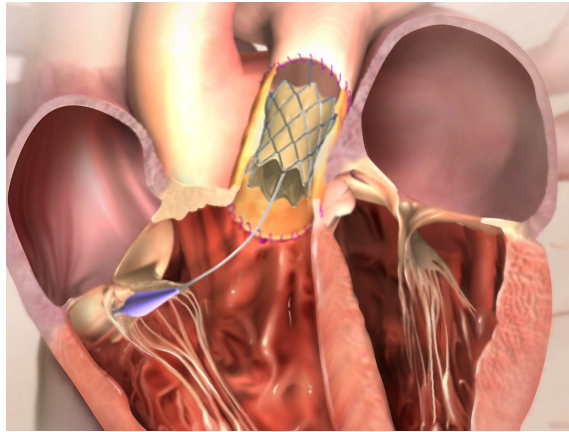
Transcatheter valve implantations

First pulmonary valve 2000
Bonhoeffer, Paris



First aortic valve
2002, Cribier, Rouen

18, 20, and 22 mm
double Balloons



**23 mm
SAPIEN**



**26 mm
SAPIEN**



Melody TPV n >5500

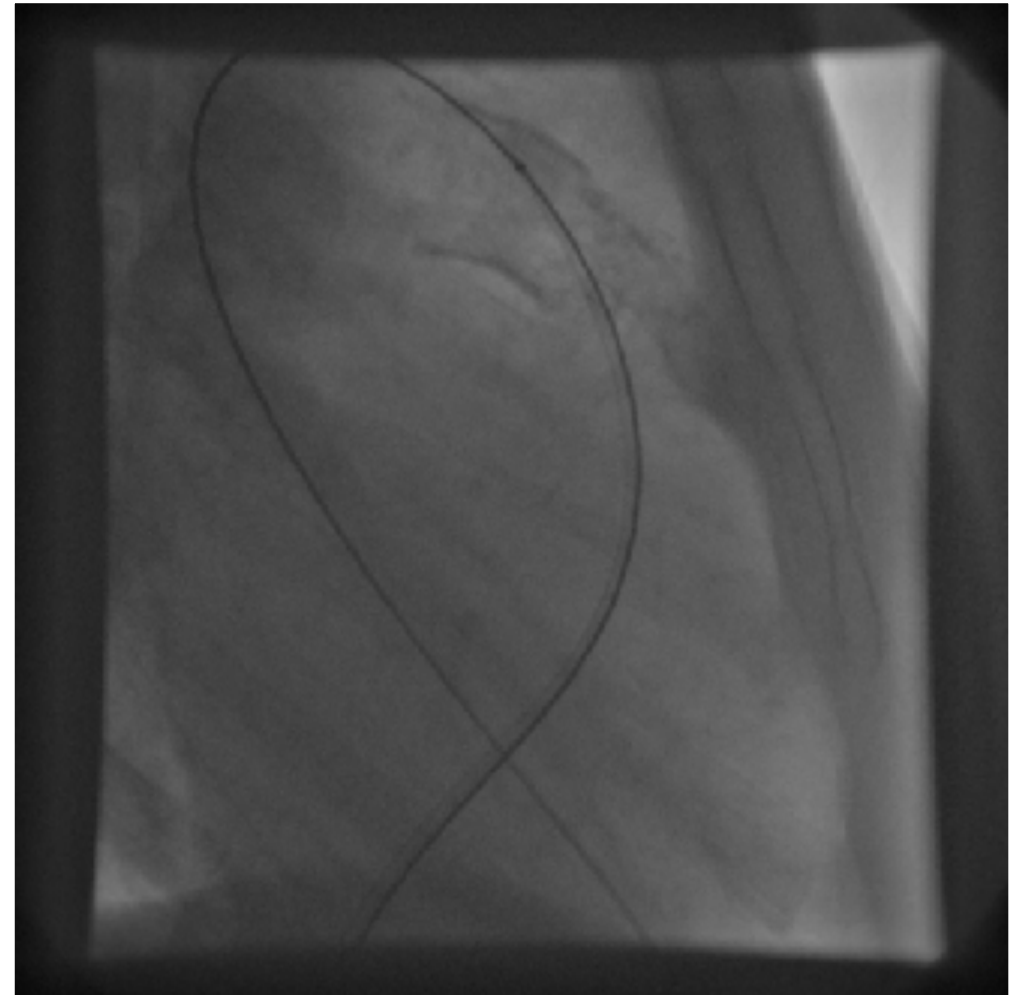
Edwards Sapien valves n >300

Actual DHM Patient Selection for PPVI

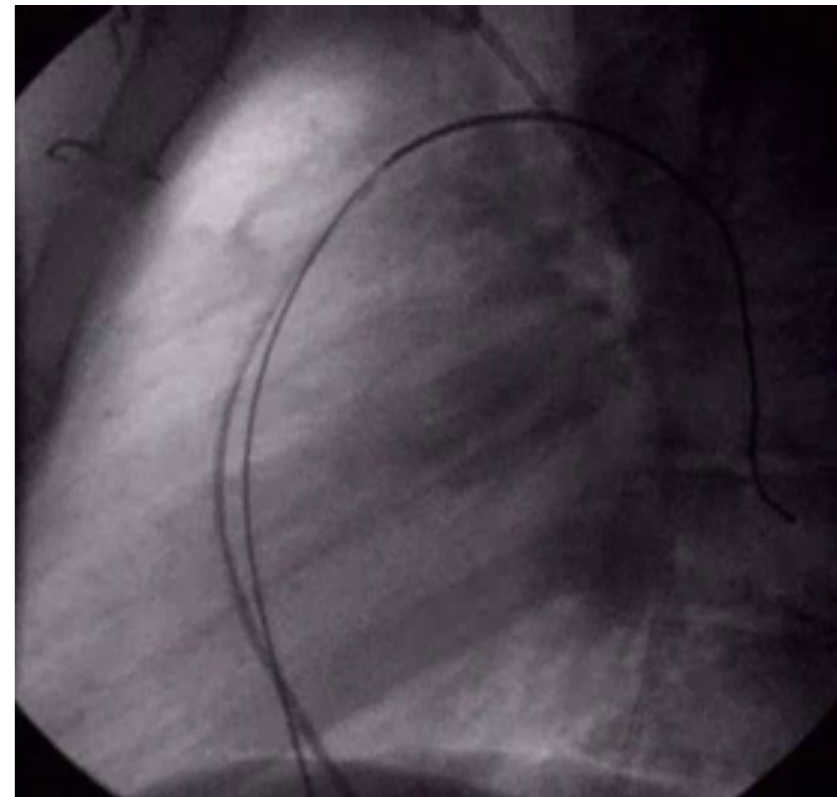
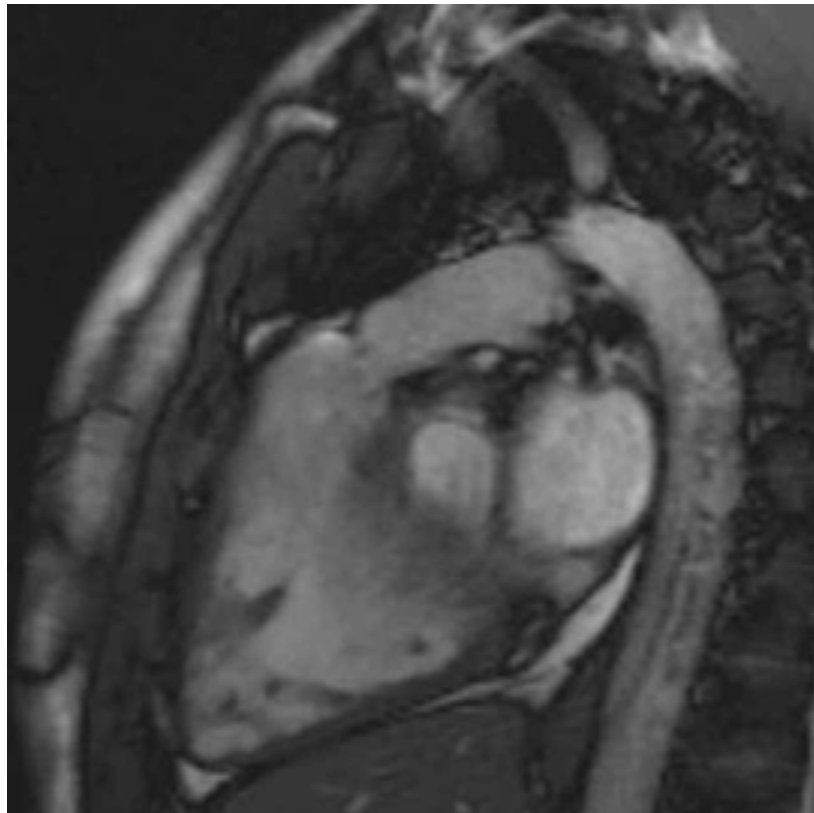
- increased RV-pressure ($> 2/3$ systemic pressure, Echo peak-gradient > 80 mmHg)
- pulmonary regurgitation leading to a MRI-RVED-volume index > 150 ml/m²,
reduced and declining RV function in cardiac MR
- a combination of stenosis and regurgitation with RV- dysfunction and dilatation
- ?symptomatic? patients with declining exercise tolerance ($< 65\%$ of normals)
- no clear lower age limit, looping of stiff delivery system is limited in small patients
- conduits or RV outflow tracts which can accomodate a covered stent to be dilated to at least 18 mm

STEP 2

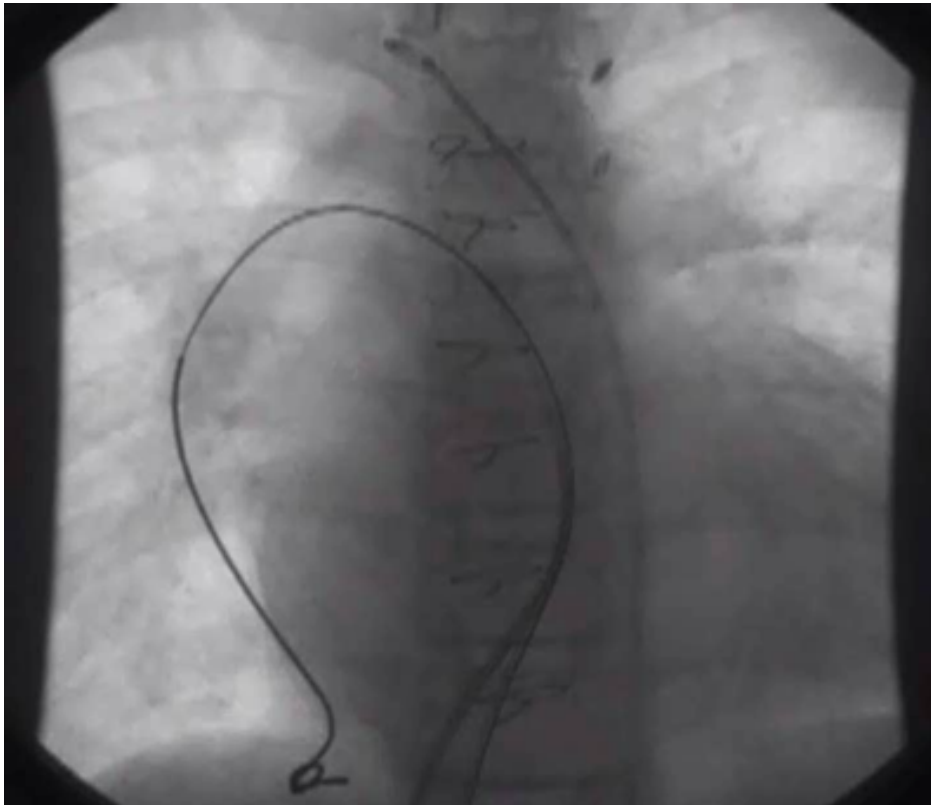
Verify that the patient meets the morphological criteria:



Compare angiograms with pre-imaging informations MRI / CT

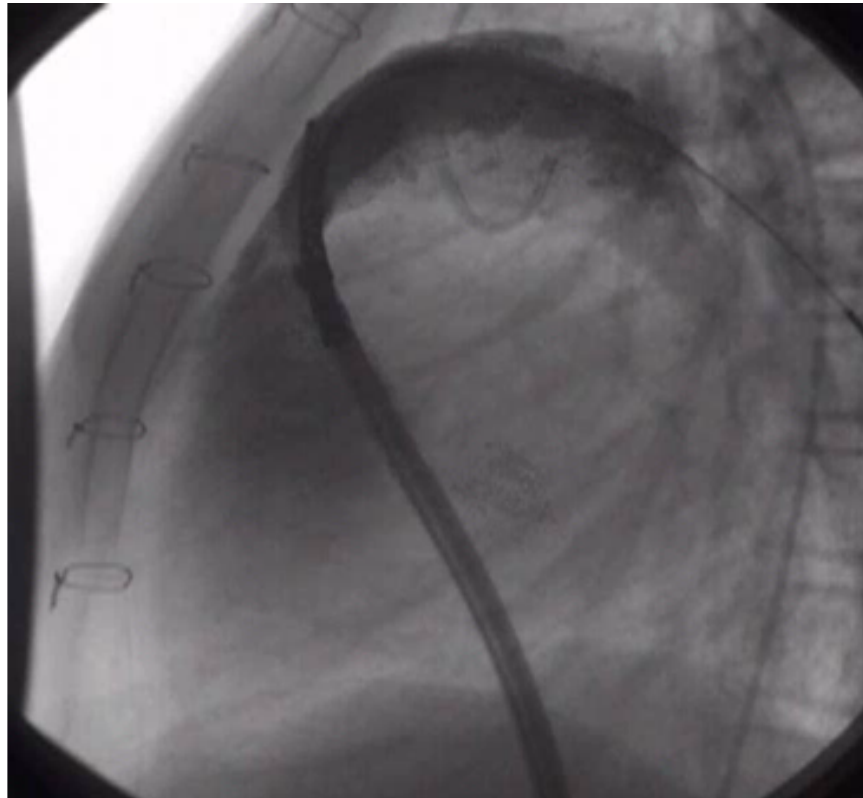


STEP 4



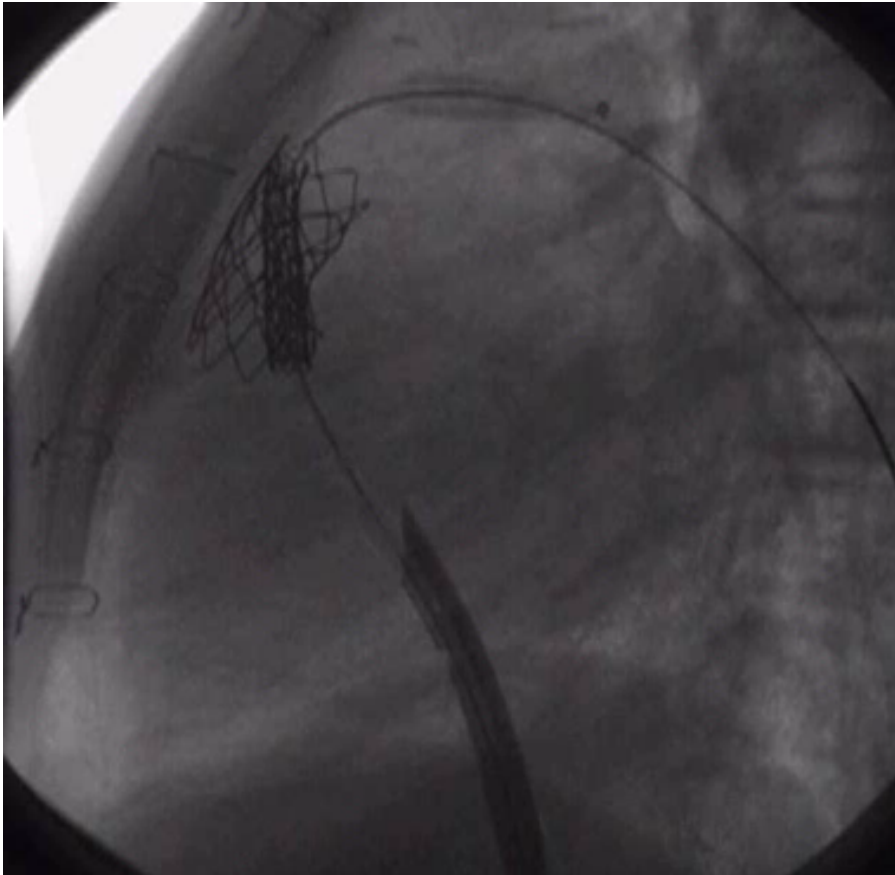
Pre-dilatation & Coronary Angio:
RVOT balloon inflation and
simultaneous coronary
angiography in AP and
lateral projection:

- To evaluate conduit distensibility
- Potential compression of coronary arteries



STEP 5

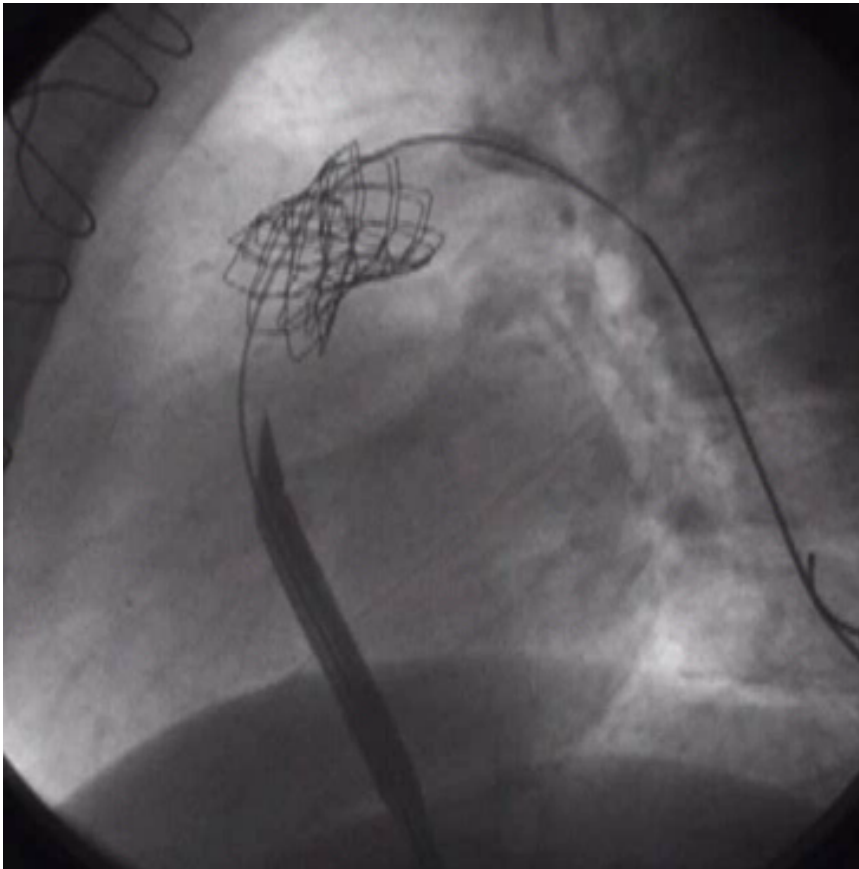
Pre-stenting*



STEP 6

Melody® TPV Implant

STEP 7



Melody[®] TPV implantation
Residual gradient $\geq 25\text{mmHg}$

STEP 8



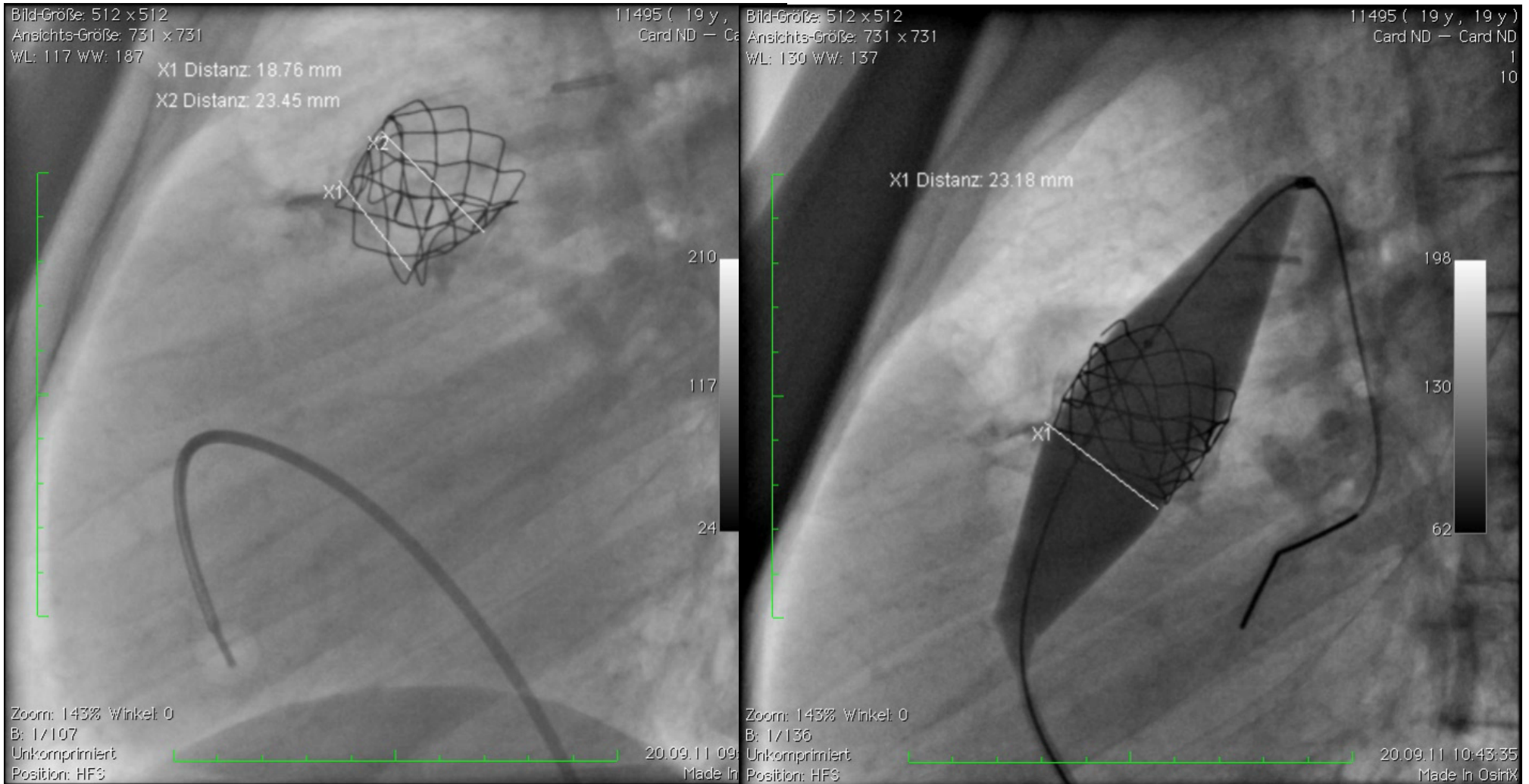
Post dilatation with HIGH PRESSURE BALLOON

Patients 10/2013 n = 157 - 161 valves

median age (y)	18.9 (4.1-54,5)
median weight (kg)	60.8 (17.7-176)
gender	f = 57, m = 100
previous OP	2 (1-6)
diagnoses	TOF/PA 71 TAC 31; TGA 10, AoVS 12, other 25
conduit	Homograft 119, none 10, Hancock 5, Shelhigh 2, Matrix 1, Contegra 8, other 12
valve Position	PaV 148, TrV 9
valve	Melody 144, Sapien 23 n = 1 Sapien 26 n = 7; Sapien 29 n = 5

14J. 48 kg, TOF, ap shunt, corr. Surg. 20 mm homograft, Melody on 18 mm BiB
Pre: RV 57, PA 20, Ao 89; post: RV 32, PA 20, Ao 95





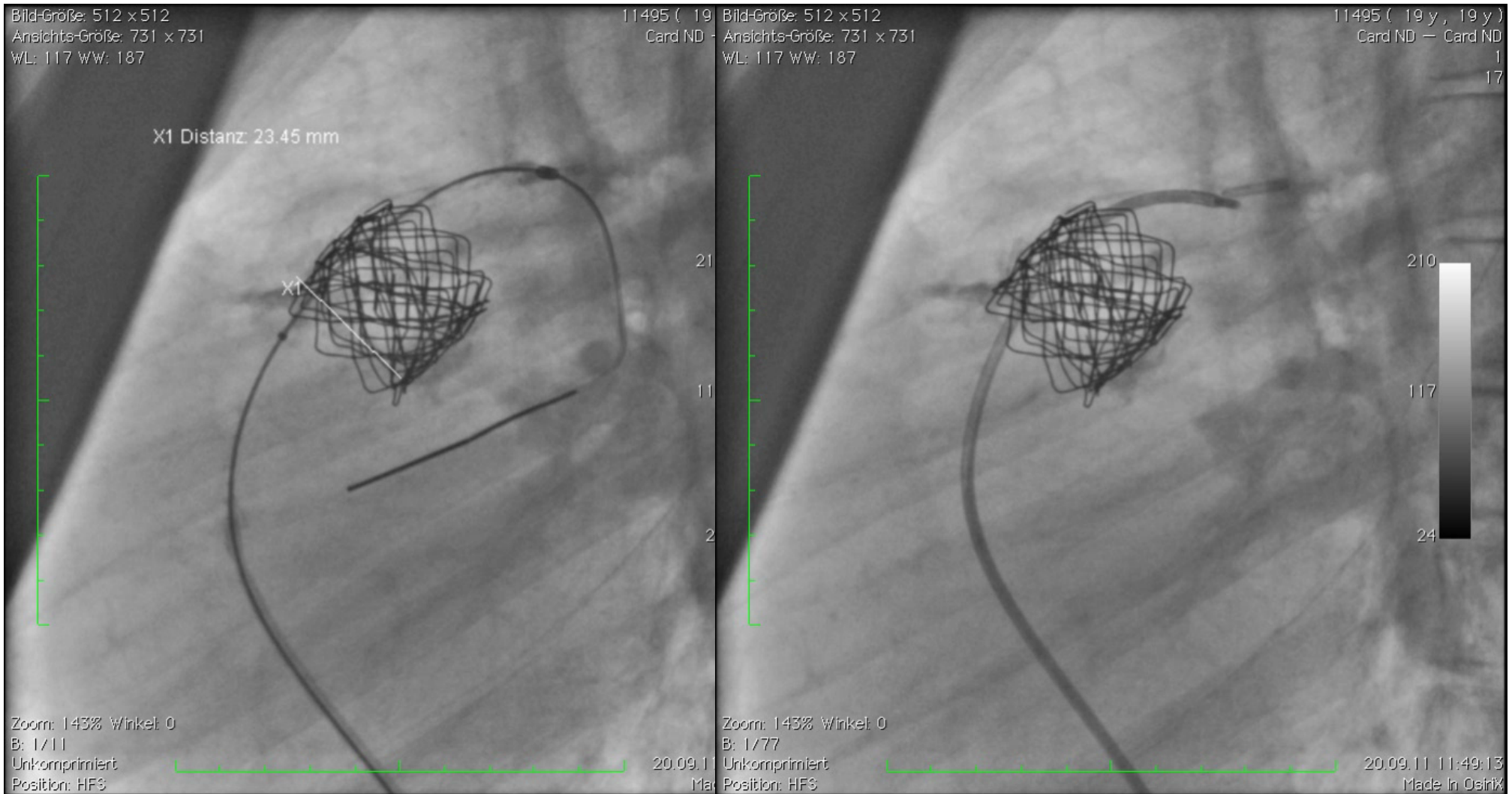
gradient RV-PA 40 mmHg, Echo mean grad. 50 mmHg
peak syst. Doppler 90 mmHg

post AP Atlas 24 grad. 25 mmHg, PR grade 2-3,
fracture of 3 Struts



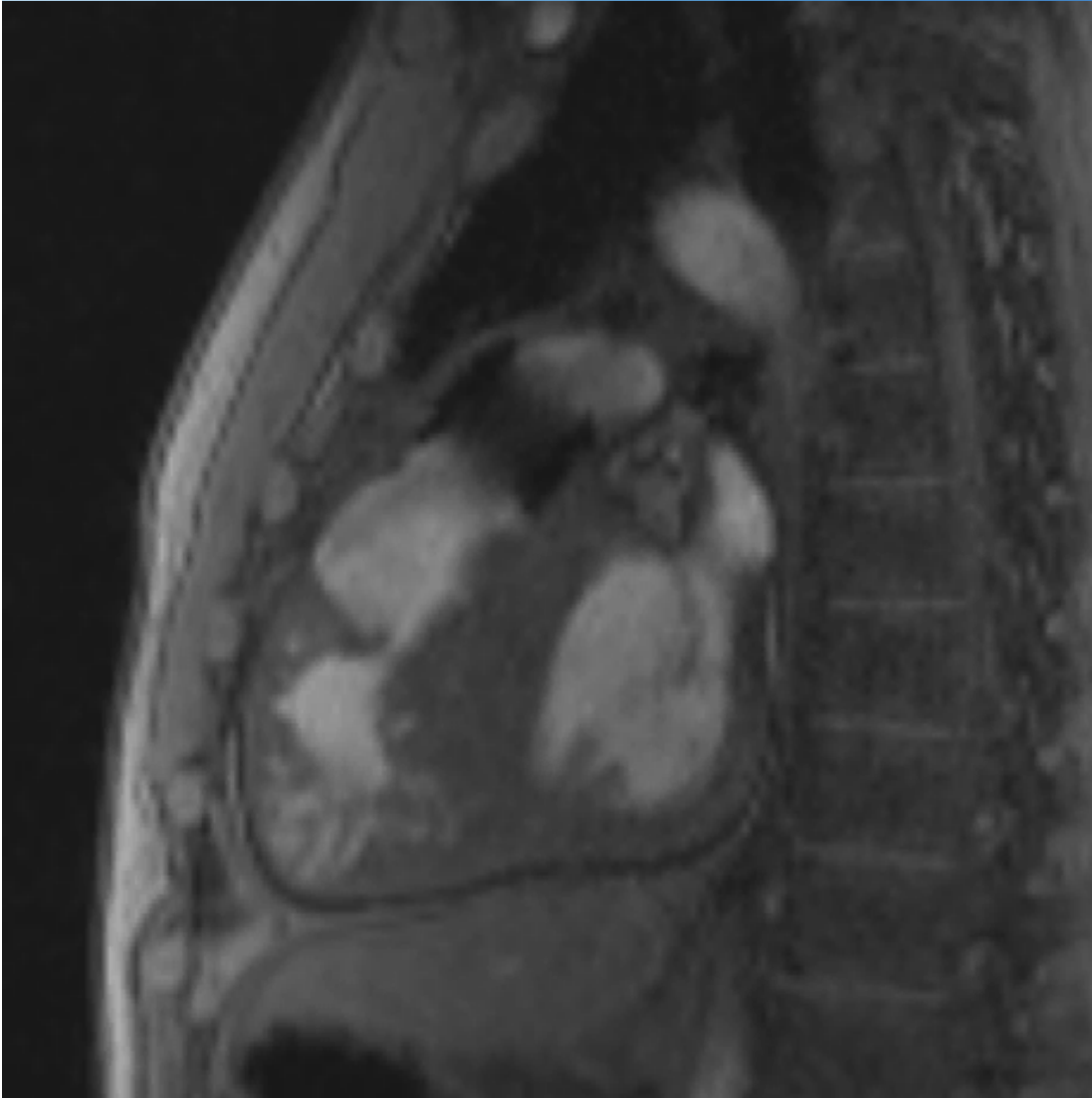
34 mm cp covered on 24 BiB

Melody on 22 BiB



valve-in-valve post AP with 24 mm Atlas

final result, res. gradient 12 mmHg



MRI one day post valve-in-valve; PR: 9%

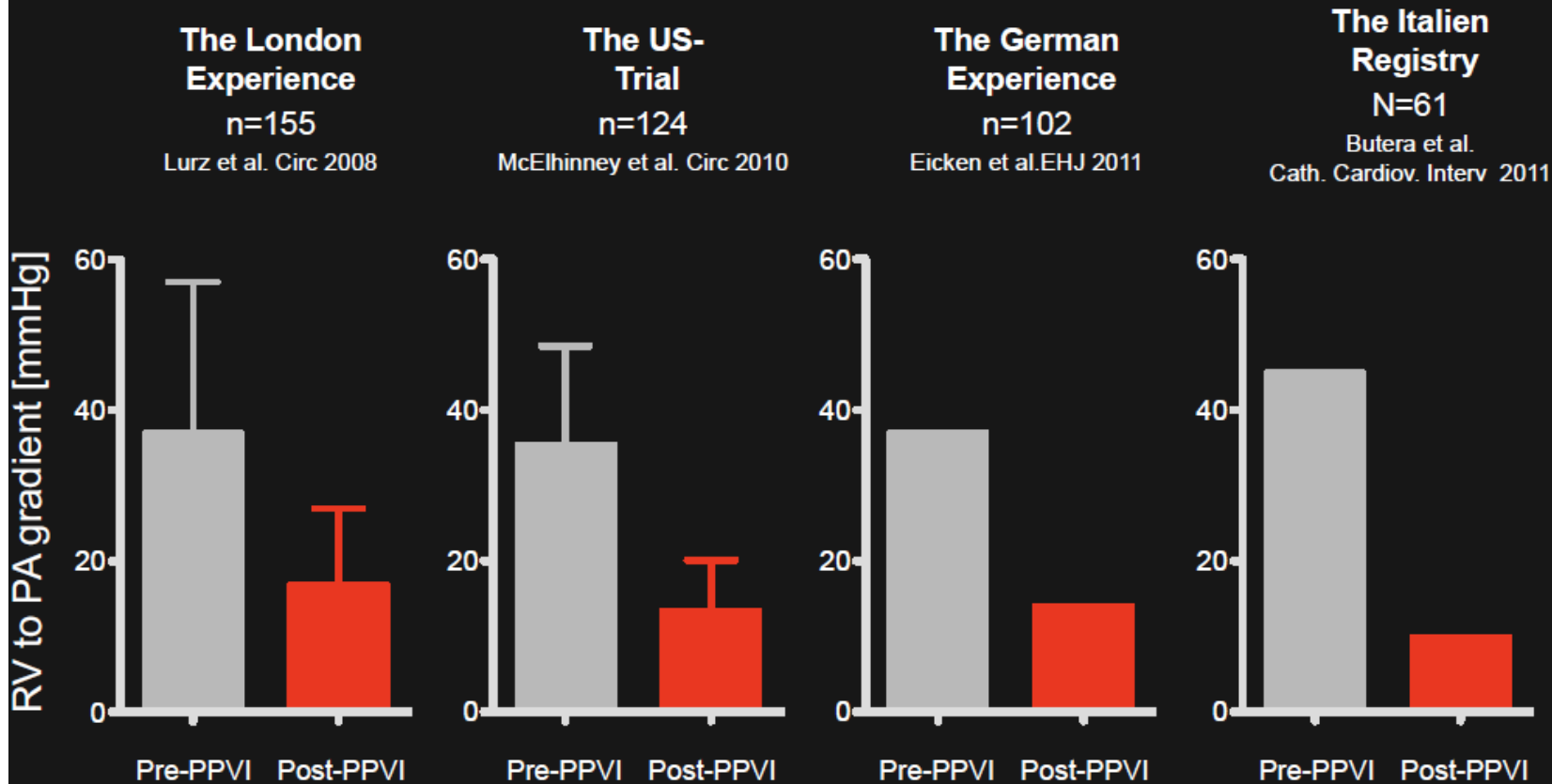
What did we learn since our initial patient?

- „homograft rupture“ occurs -> covered stent implantation
- „pre stenting“ („covered stent“?); is very effective; the ideal landing zone does not show recoil (sometimes > one stent necessary)
- a strong guide wire is very helpful (for example Lunderquist)
- valve-in-valve is possible if re-stenosis occurs or stentfracture occurs during re-dilatation

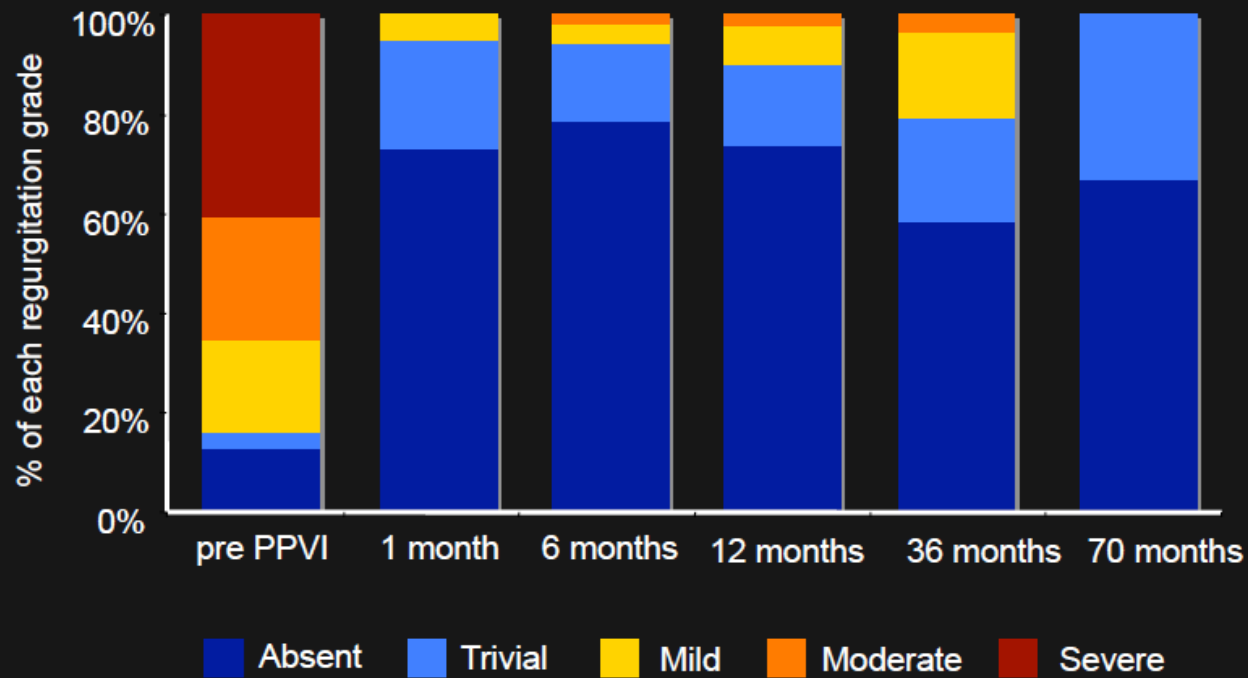
What did we learn since our initial patient?

- during re-dilatation of a secondary stenotic Melody valve serial fractures may occur, or the valve may become severely incompetent, in this event valve-in-valve is an option
- even dilatation up to 24 mm may result in a good Melody valve function
- coronary arterial compression and conduit rupture are the major hazards of this procedure

Reduction in RV to PA Gradient



Valvar performance



Lurz et al. Circ 2008

Procedural complications

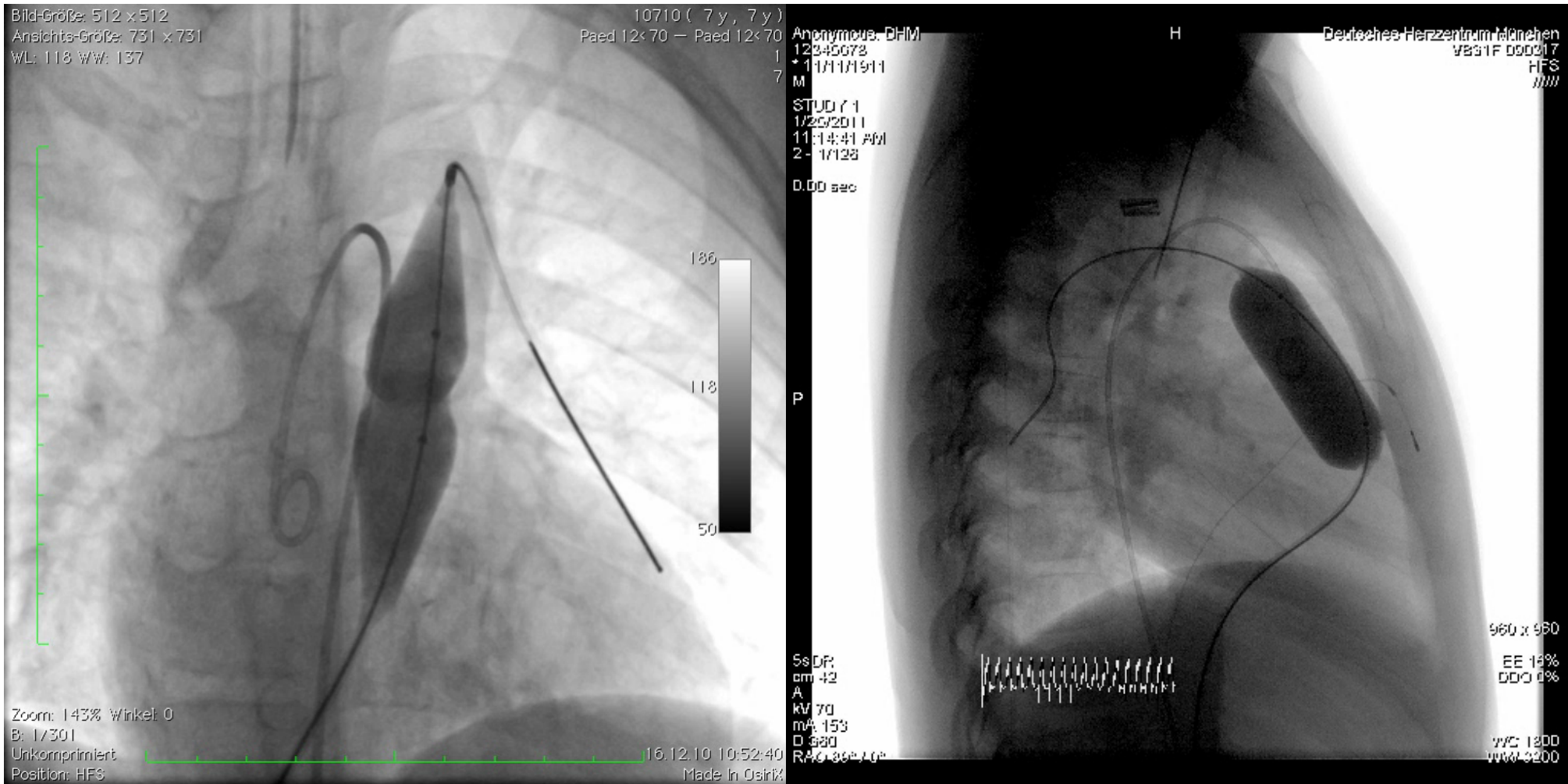
Major Complications in 26/442; incidence of 5.88%

	London Experience	US-Trial	German Experience	Italien Registry	Overall incidence
Device dislodgement	2 (1.3 %)	0	0	1 (1.6 %)	3 (0.68 %)
Damage to the tricuspid valve	2 (1.3 %)	0	0	0	2 (0.45 %)
Perforation of the pulmonary artery	1	0	0	0	1 (0.24 %)
Guide-wire perforation of the distal PA	2 (1.3 %)	2 (1.6 %)	0	0	4 (0.90 %)
Obstruction of the pulmonary artery	1 (0.6 %)	0	1 (1.0 %)	0	2 (0.45 %)
Atrioventricular block	0	0	1 (1.0 %)	0	1 (0.24 %)
Femoral vein thrombosis	0	1 (0.8 %)	0	0	1 (0.24 %)
Access complications requiring vascular surgery	0	0	0	3 (4.9%)	3 (0.68 %)
Access complications requiring blood transfusion	0	0	0	1 (1.6 %)	1 (0.24 %)
Homograft rupture with haemodynamic compromise	3 (1.9 %)	2 (1.6 %)	0	0	5 (1.13%)
Coronary compression/dissection	1 (0.6 %)	1 (0.8 %)	1 (1.0 %)	0	3 (0.68 %)

Acute mortality

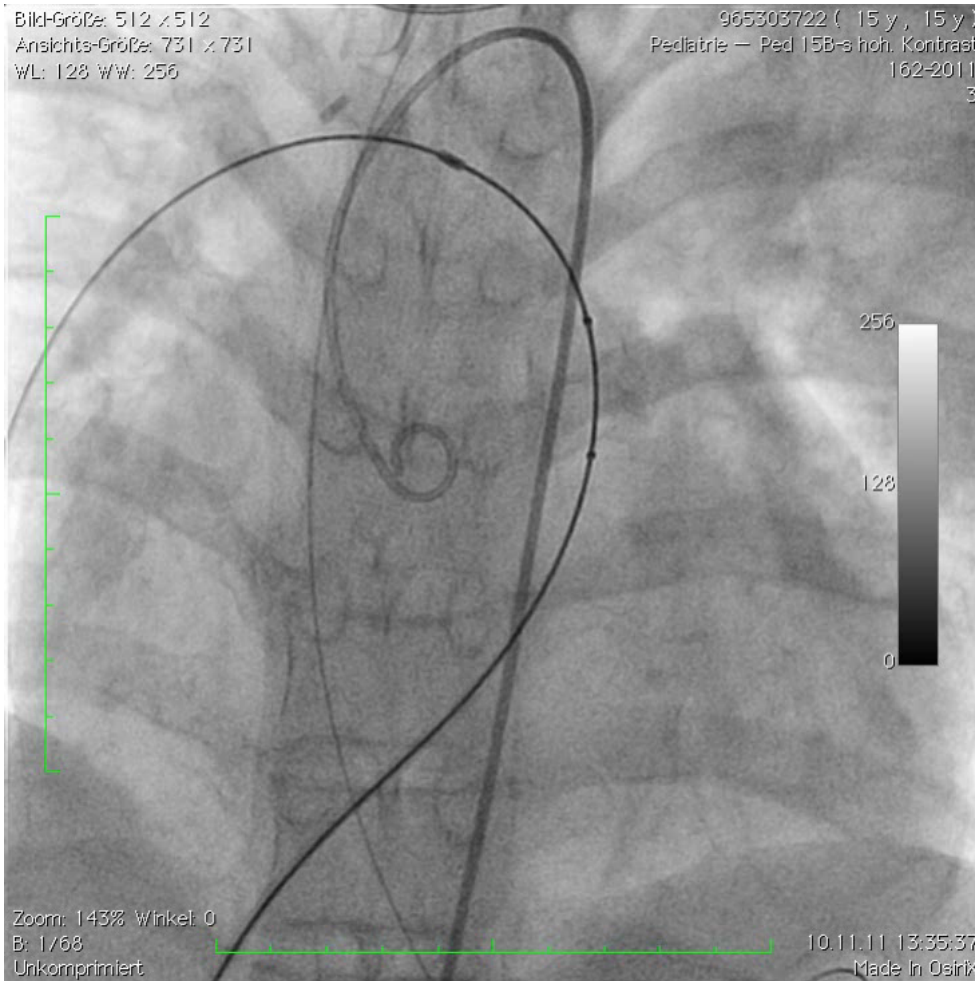
	30-day mortality	Mortality due to procedural complications
London Experience	1/155 (0.6 %)	0
US-Trial	1/124 (0.8 %)	1
German Experience	1/102 (1%)	1
Italien Registry	1/61 (1.6)	0
Overall incidence	4/442 (0.9 %)	2



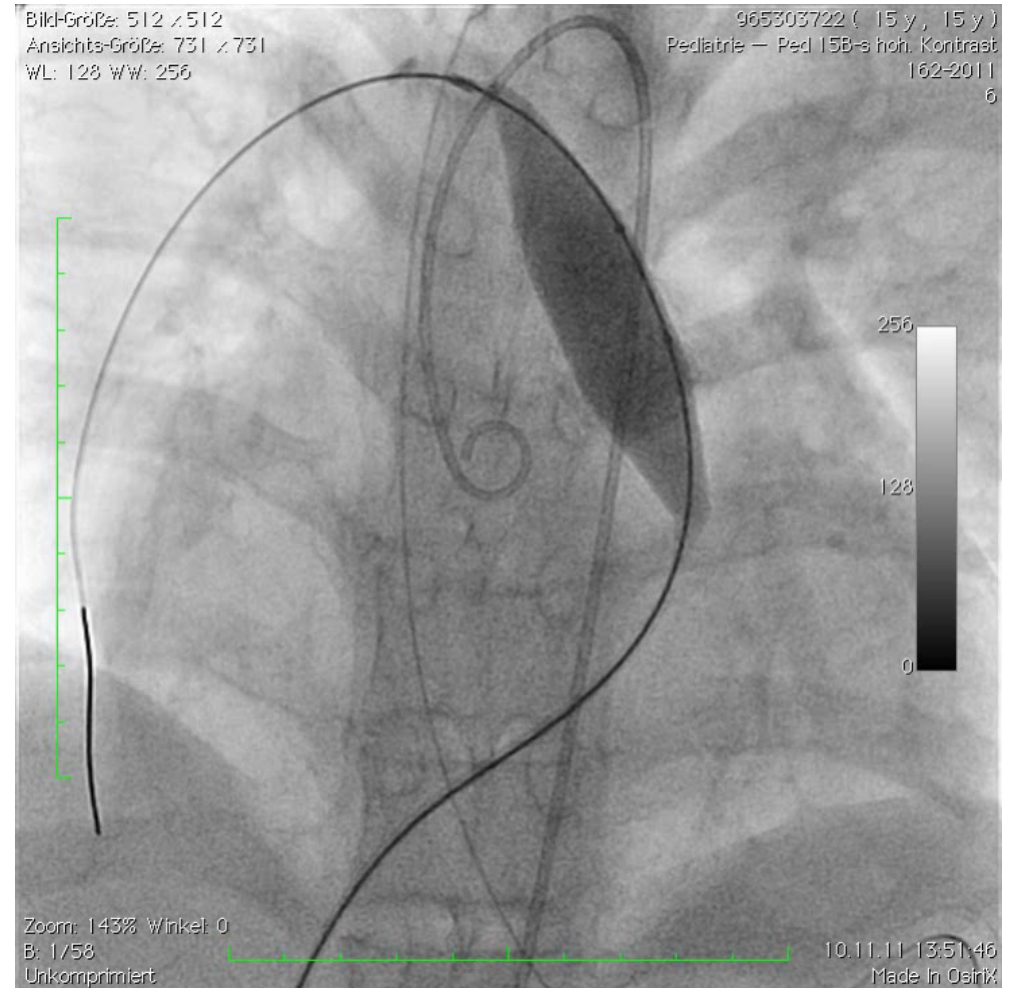


„balloon interrogation“

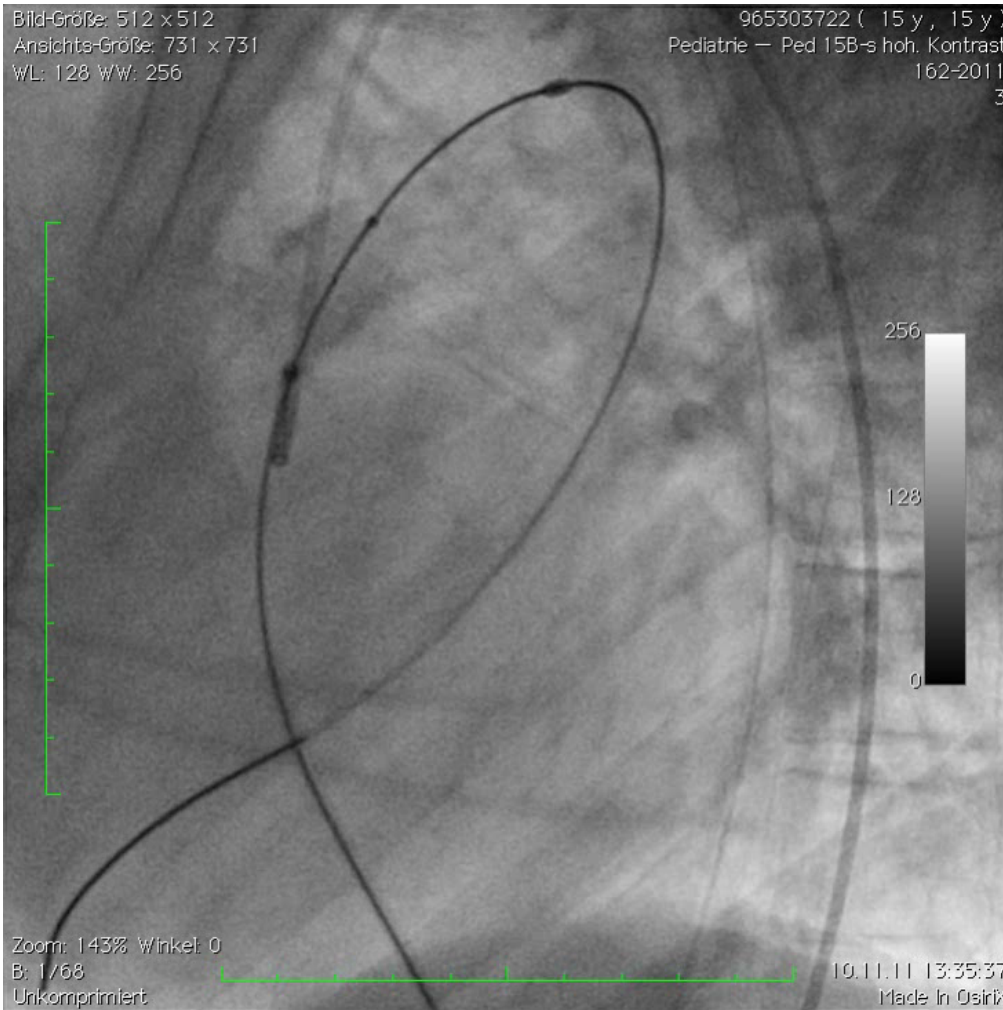
3D imaging



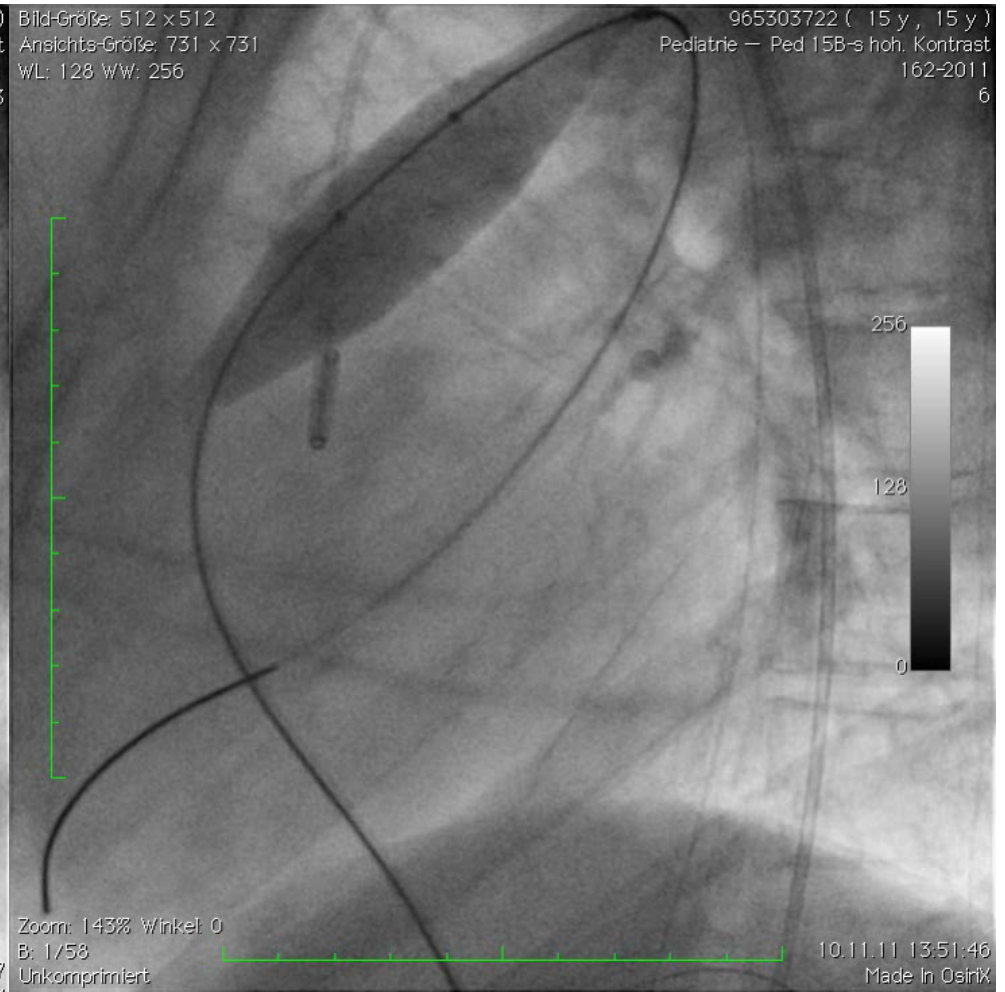
LAD from RCA in PA + VSD



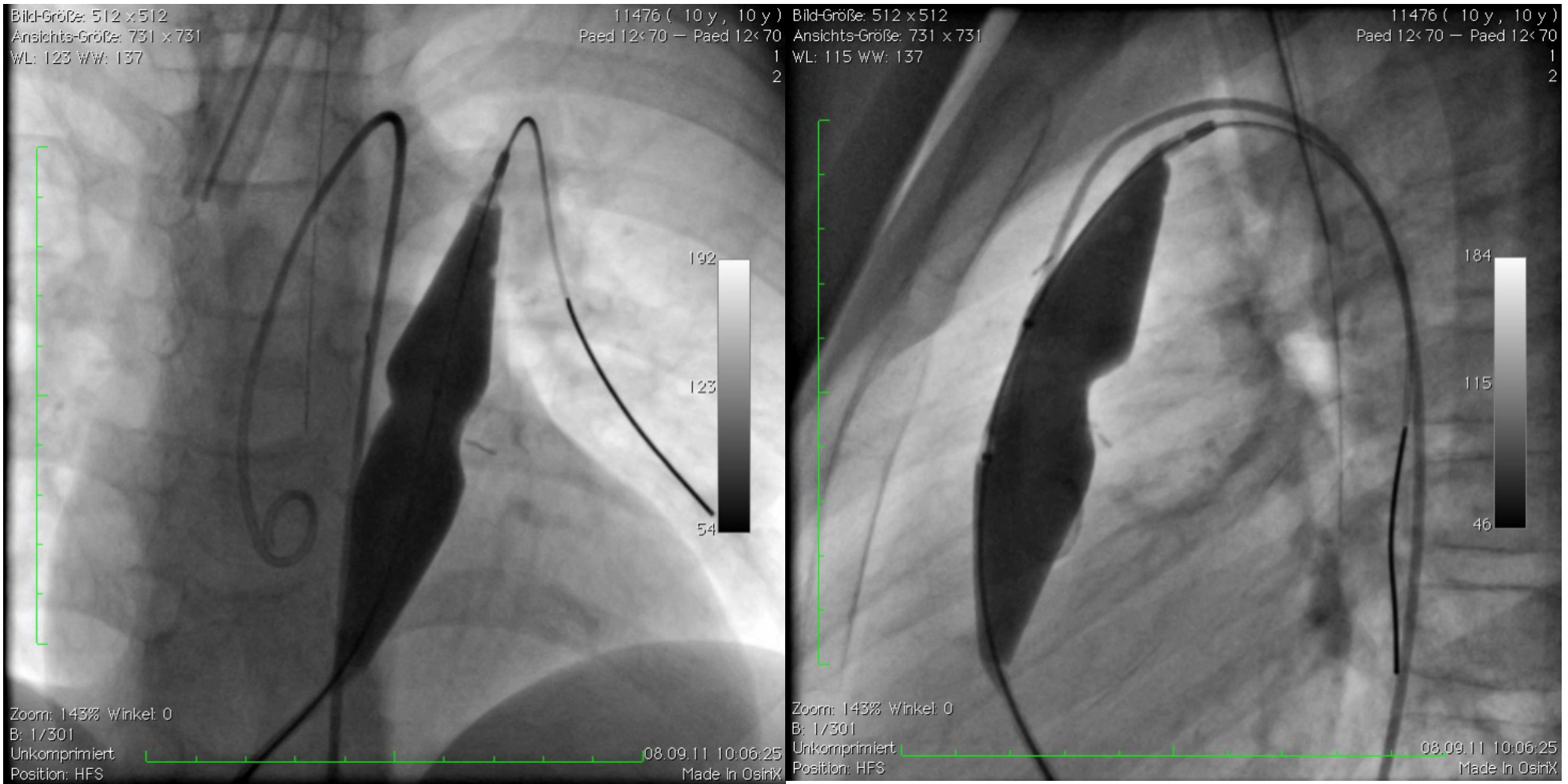
Balloon occludes LAD



LAD from RCA in PA + VSD

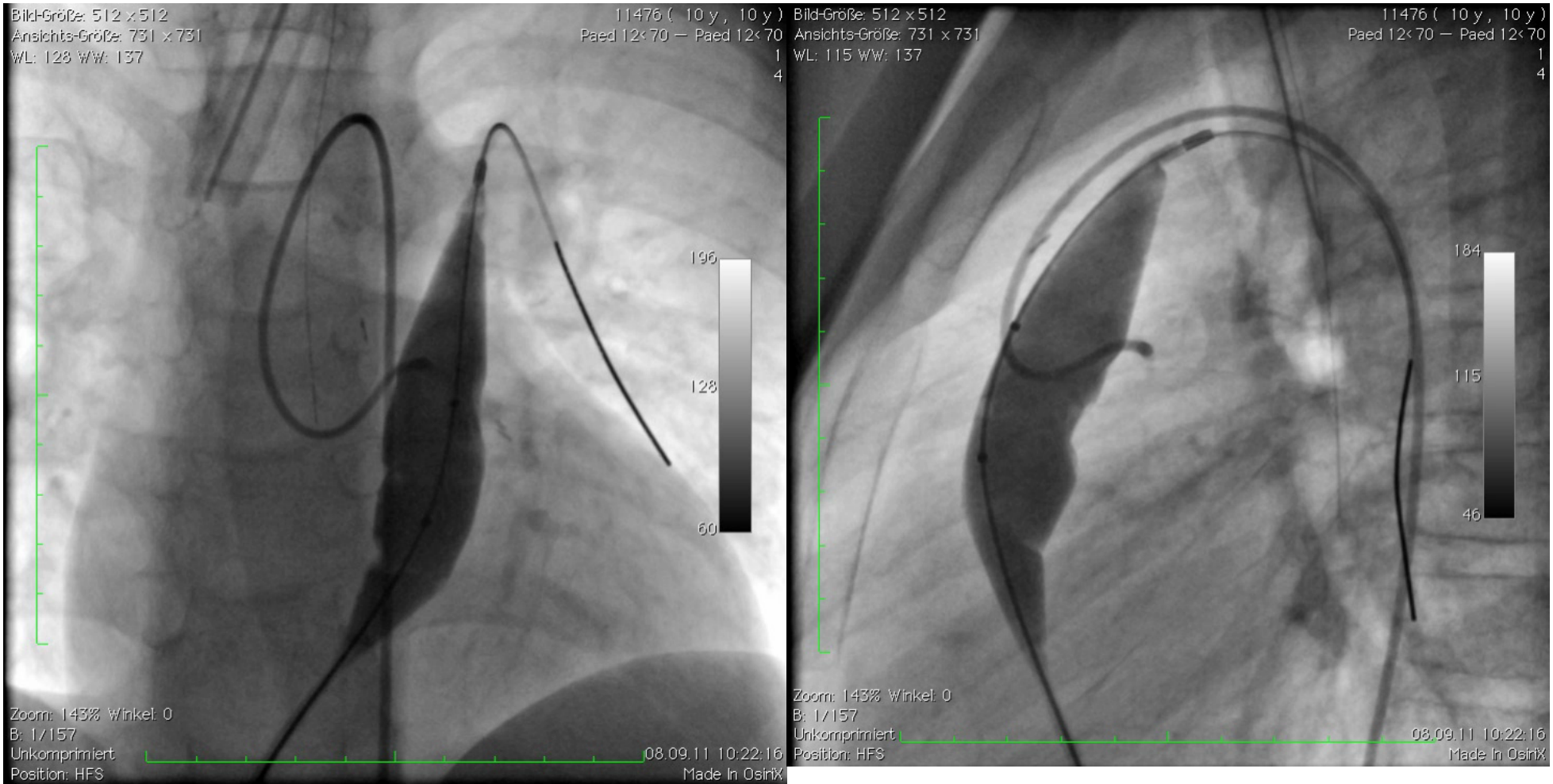


Balloon occludes LAD



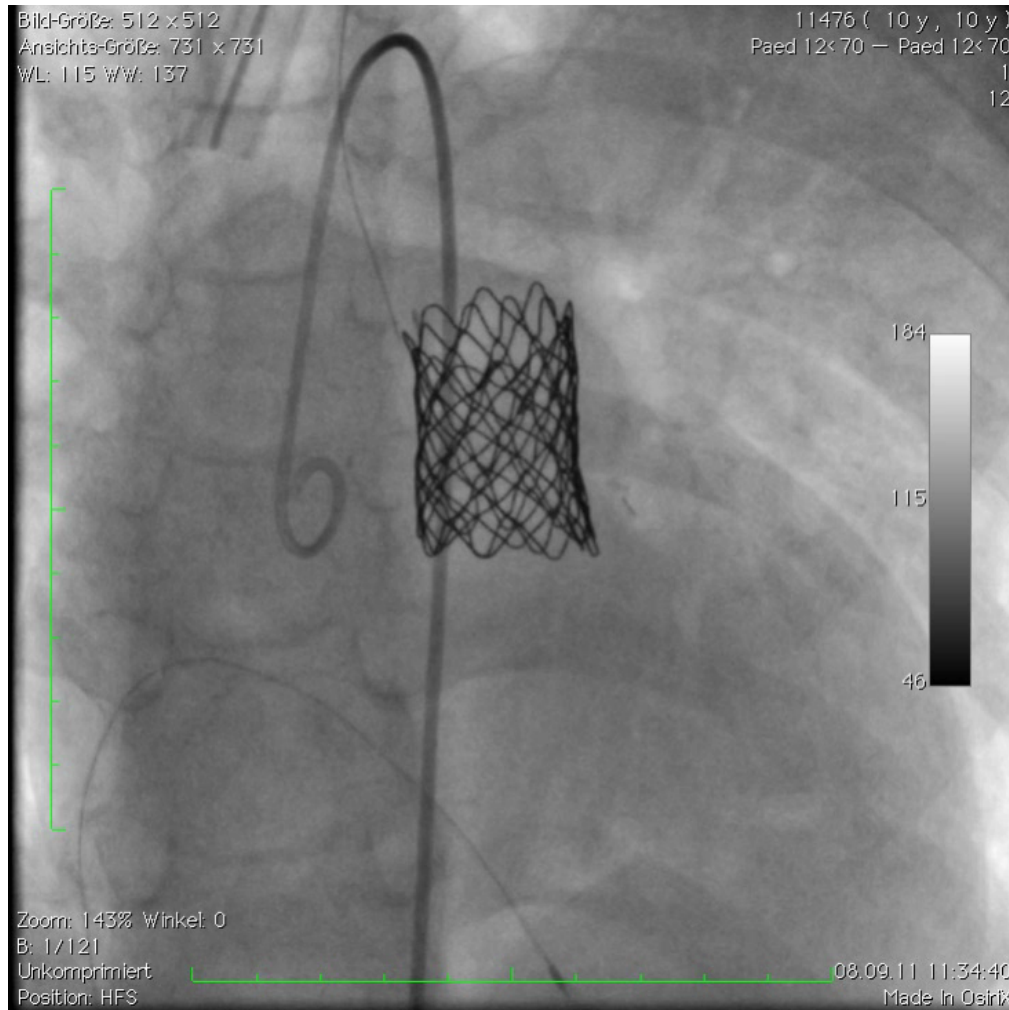
16 mm Atlas balloon pa

16 mm atlas balloon lat

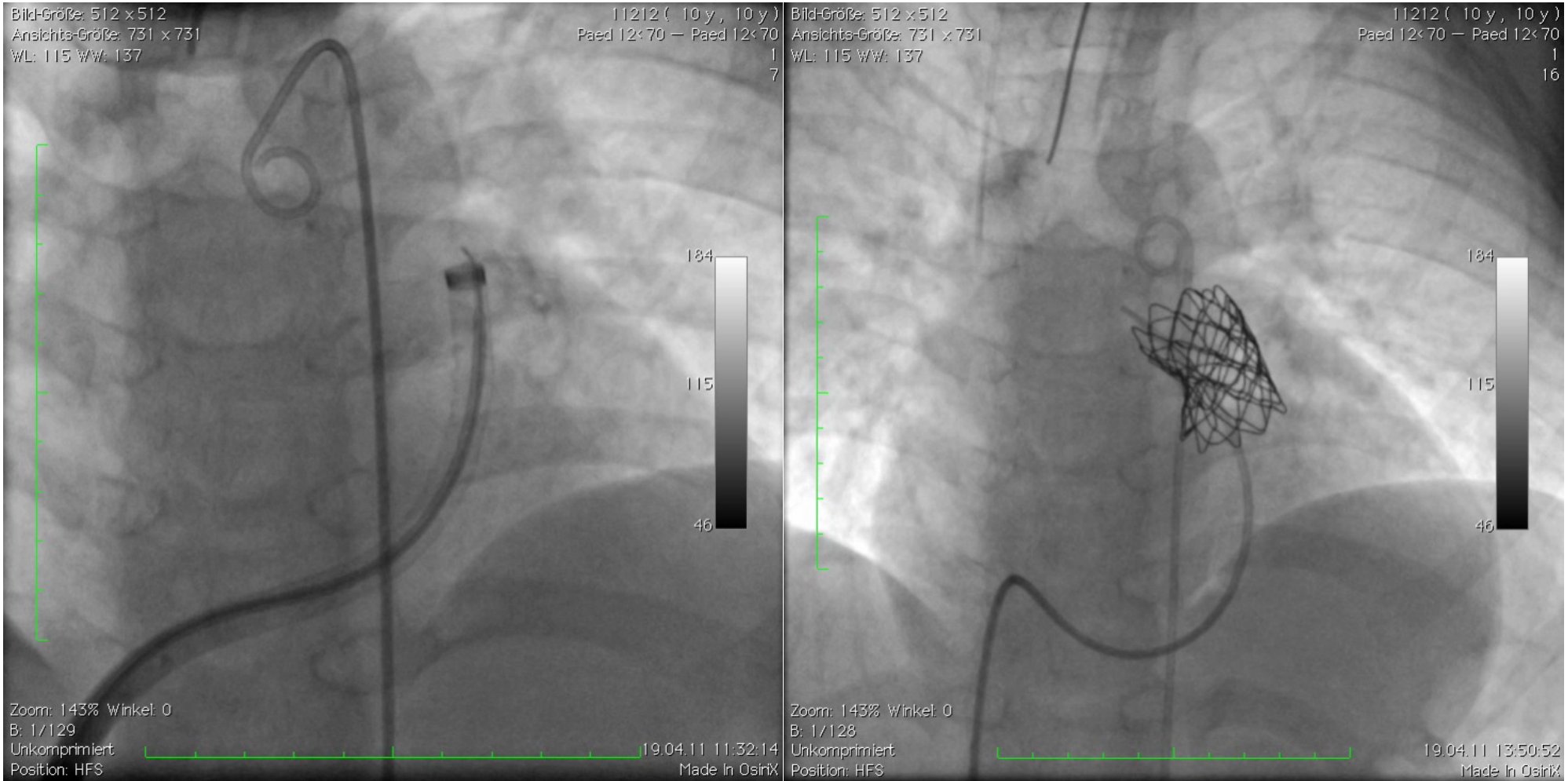


16 mm Atlas balloon pa

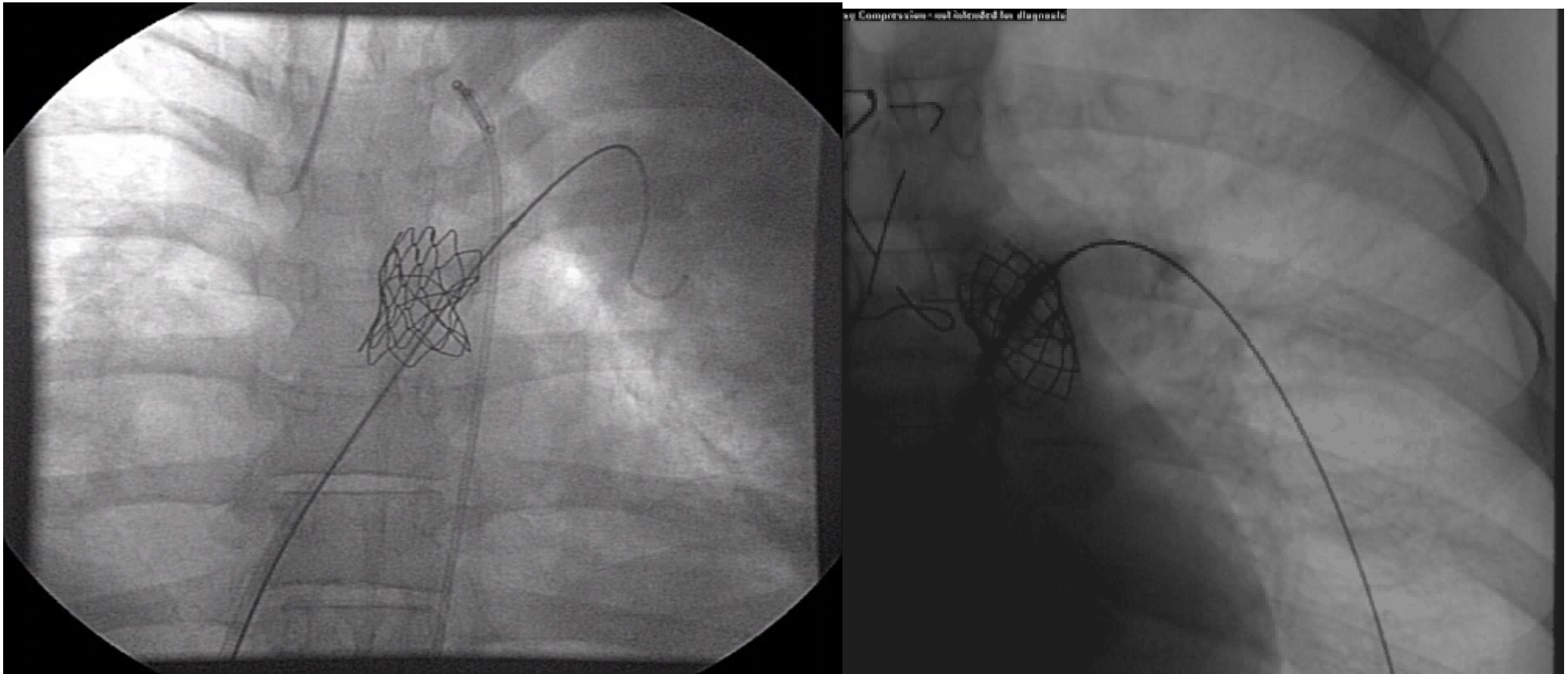
16 mm atlas balloon lat



After Melody with BiB 18 and post dilatation with atlas 18
the LCA was occluded

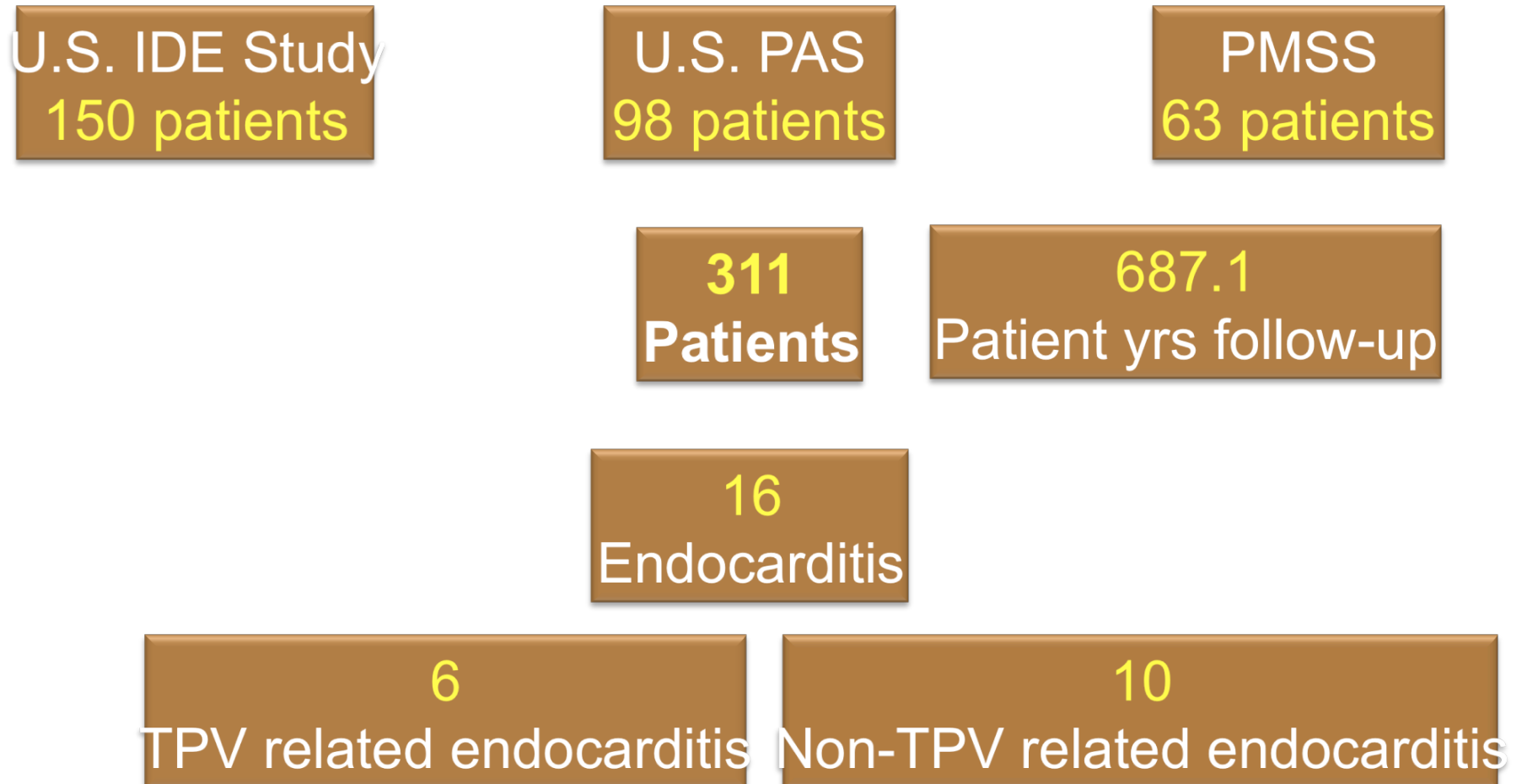


RVOT aneurysm after test balloon dilatation was successfully treated with a covered stent



Jailing RPA – distal PA perforation

McElhinney et al.2013 Circ.cardvasc.interv.6(3);292-300

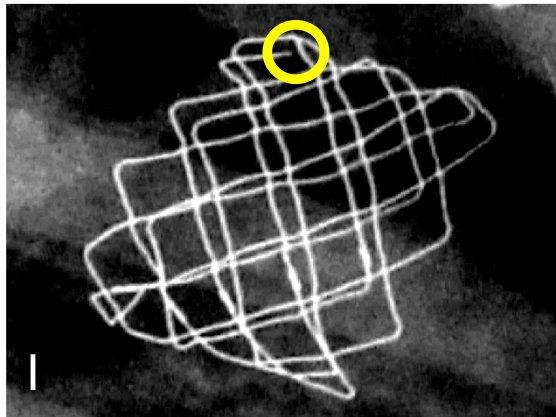


Incidence of Stent fractures

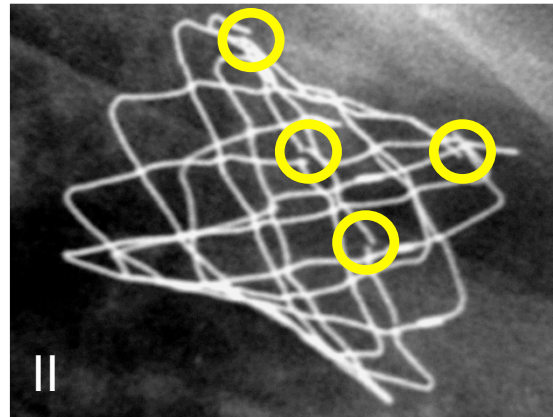
- London experience: 26 / 123 (21%)
Lurz et al. Circ 2008
- The Melody U.S. trial: 25 / 124 (20%)
McElhinney et al. Circ 2010
- The German experience: 5 / 102 (5%)
Eicken et al. EHJ 2011
- The Italien Registry: 10 / 61 (16,4%)
Butera et al. Catheter Cardiovasc Interv 2012

Stent Fracture Classification

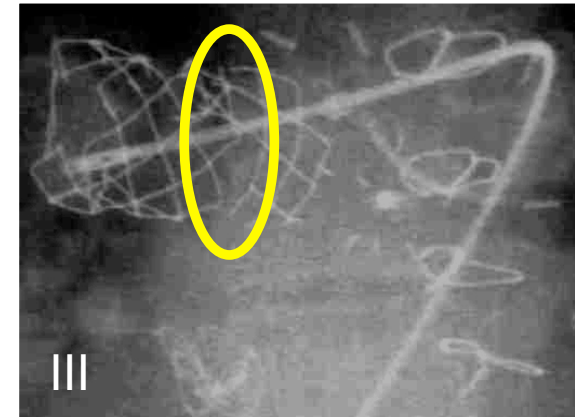
26/123 (21%) had stent fractures; I = 17, II = 8, III = 1



Stent fracture of ≥ 1 strut no loss of stent integrity



Stent fracture of ≥ 1 strut loss of stent integrity



Embolization of the stent and / or separation of segments

Nordmeyer J, et al. *Circulation* 2007; 115: 1392-97

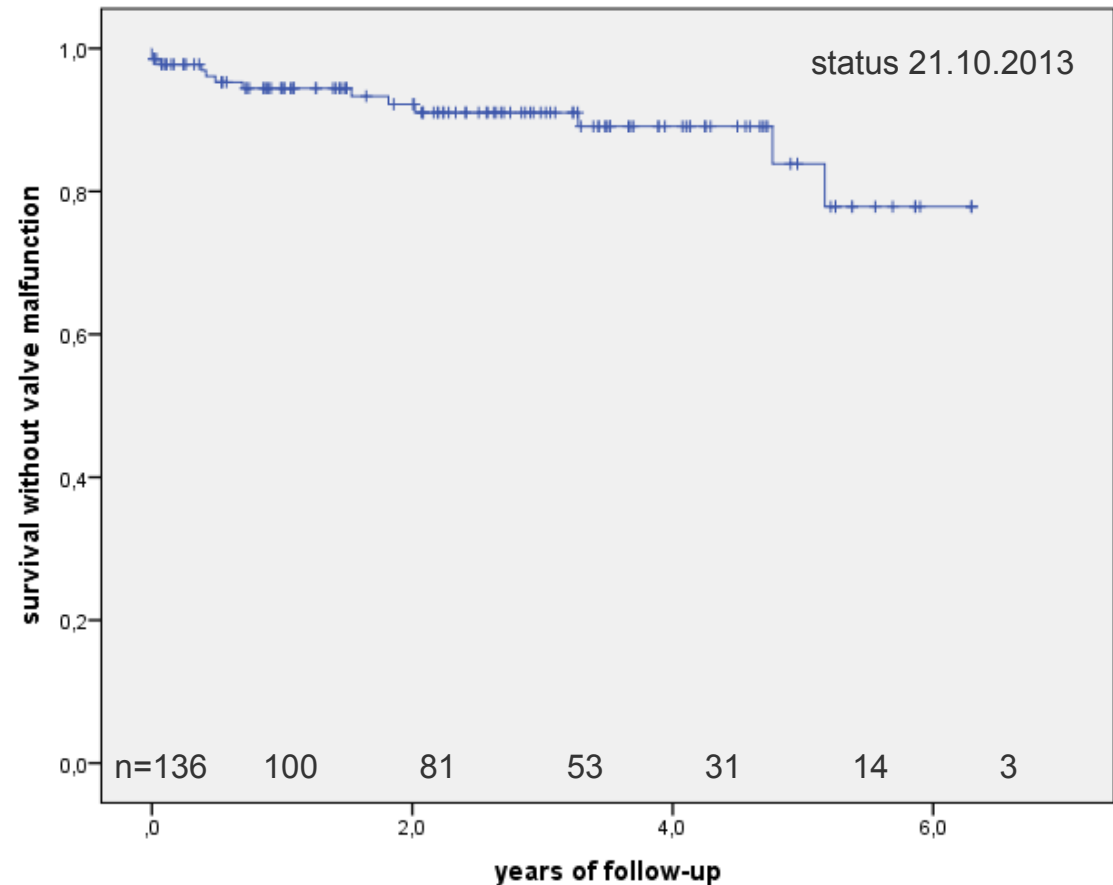
survival without valve dysfunction DHM

- 136 valves
- mean FU 2.5 y
- **341.0 patient × years**

13 events

- 3 Melody in Melody
- 6 surg. valve replacem.
- 4 deaths

1 events in 26 patient years

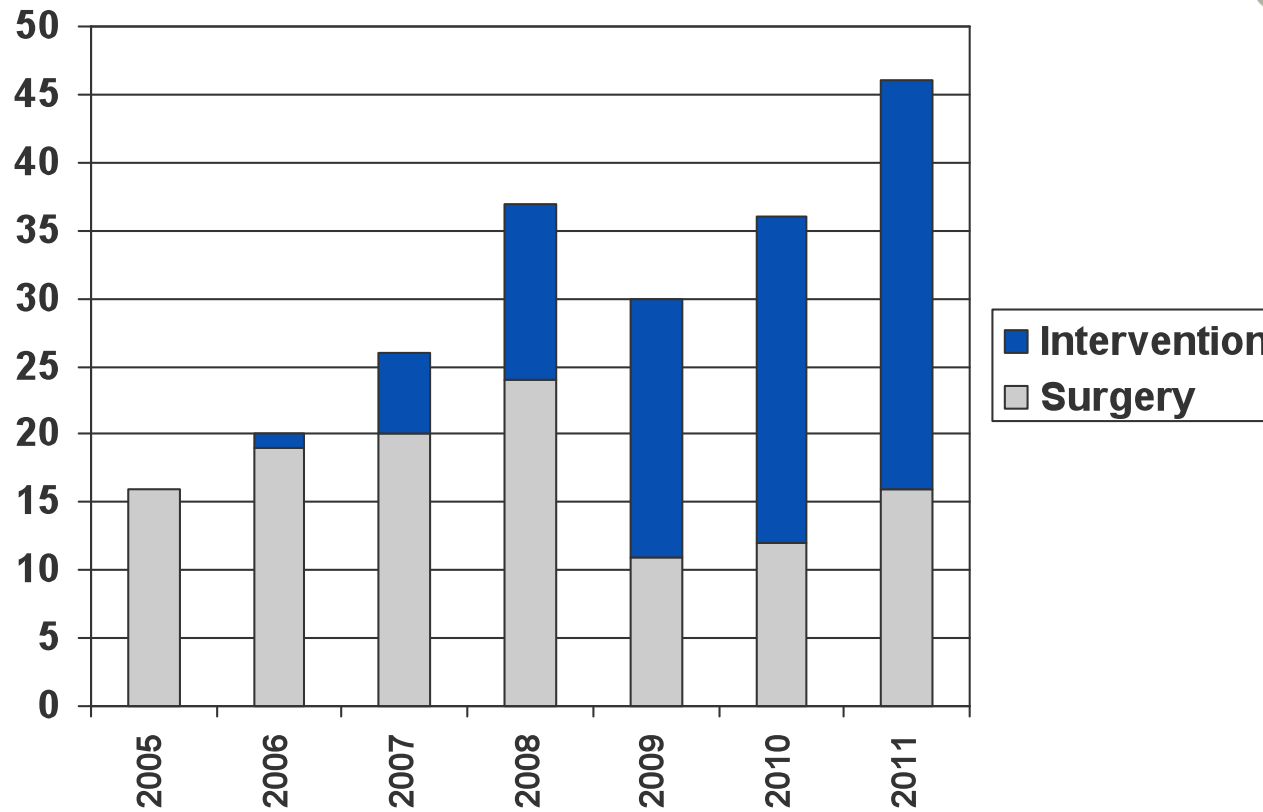


patients n = 109



No.	56
age (y) median	22.8
Prev. OP's median	2
Diagnoses	TOF/PA 42; TAC 2, TGA 1; AoS 1, other 10

No.	53
age (y) median	22.8
Prev. OP's median	3
Diagnoses	TOF/PA 29; TAC 11, TGA 4; AoS 4, other 5



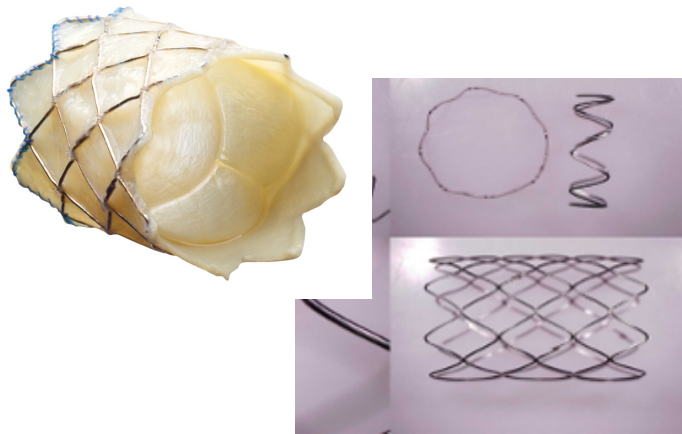
Courtesy C.Schreiber

- PPVI is one of the most significant innovations in the treatment of patients with congenital heart disease
- After careful patient selection the intervention is very effective in sustained reduction of the RVOT gradient and in sustained abolishment of pulmonary regurgitation, however there is a significant periprocedural risk
- Coronary compression and conduit rupture are the major hazard and should be excluded by „balloon interrogation“ to the final diam. of the RVOT if coronary is at risk

- Meticulous preparation of the RVOT prevents stent fractures
- Creation of an adequate landing zone enables PPVI-treatment of patients with a „native“ RVOT
- The incidence of endocarditis post PPVI should be assessed within a registry
- In comparison to surgical treatment pts after PPVI have a signif. shorter hospital stay and less periprocedural complications
- PPVI is possible in high risk pts who are no candidates for surgery

What is new?

Expanding possibilities for Patients with Congenital Heart Disease



Melody[®] Brio TPV

More Robust Frame Design

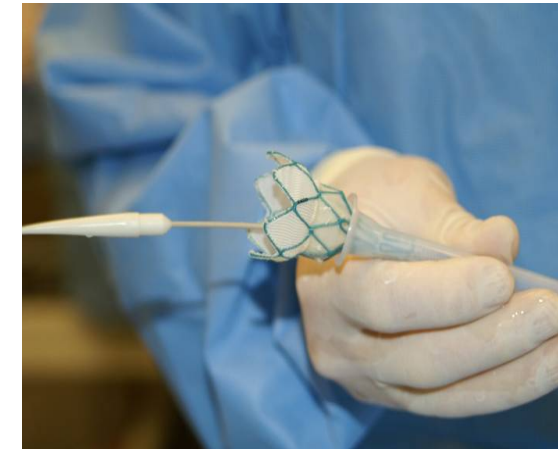
Early 2012



Ensemble[®] FLX

Enhancements to the current

Delivery System



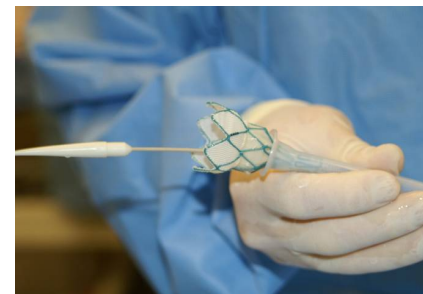
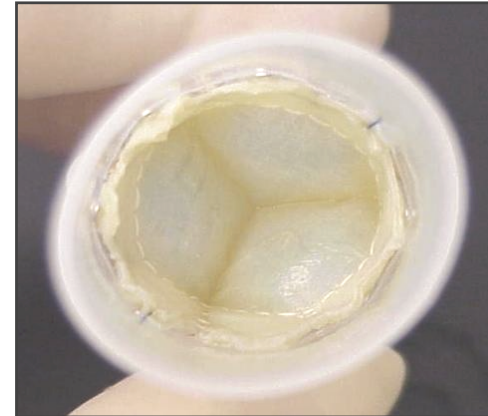
Transcatheter Pulmonary Valve for Native Right Ventricular Outflow Tract (RVOT)

Plan for a small Research Clinical Study are underway

Medtronic TPV for the Native / Patch-Repaired Outflow Tract

Design Goals:

- A device that will accommodate the repaired RVOT in adult and pediatric congenital heart patients
- Self expanding, porcine pericardial valve
- Self-anchoring / self-attaching device
- Repositionable prior to final deployment
- Sheathed delivery system



John Hess	Director DHM
Peter Ewert	Head of cath lab DHZB
Sohrab Fratz	MRI DHM
Titus Kühne	MRI DHZB
Alfred Hager	Head of exercise-testing DHM
Felix Berger	Director DHZB
Rita Langendorf	head technician cath lab DHM
Karin Hermes	leading nurse cath lab DHM



Thank you !

