Long-term fate and function of stents implanted in CHD

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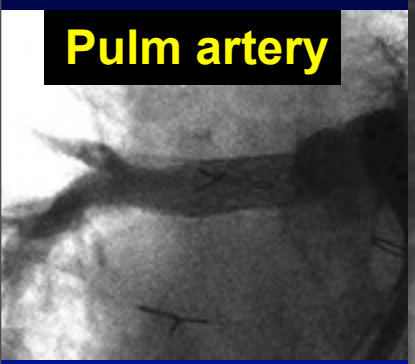
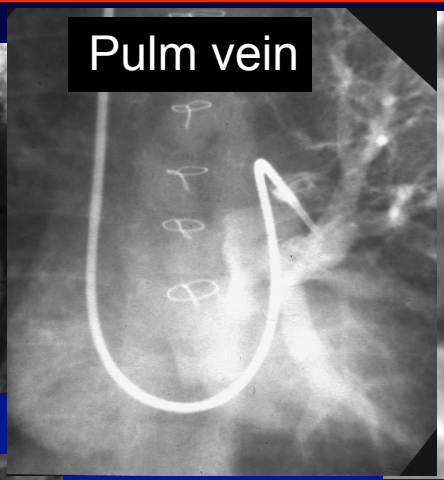
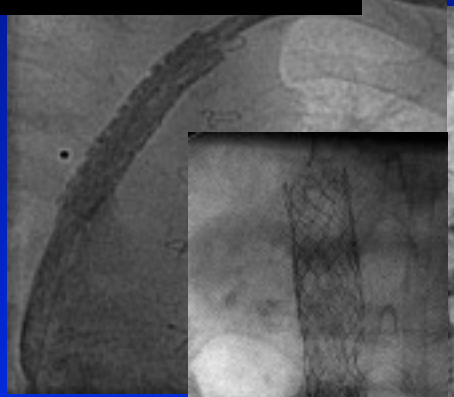
Background

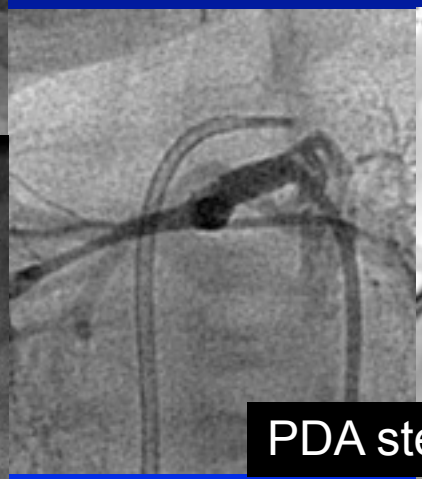
- Mullins et al. Circ 1988;77:188-99. Implantation of balloon-expandable intravascular grafts by catheterization in pulmonary arteries and systemic veins.
- O'Laughlin et al. Circ 1991;83:1923-39. Use of endovascular stents in congenital heart disease.
- Many publications confirm the safety and efficacy of stents in CHD
- Paucity of published long-term follow up data

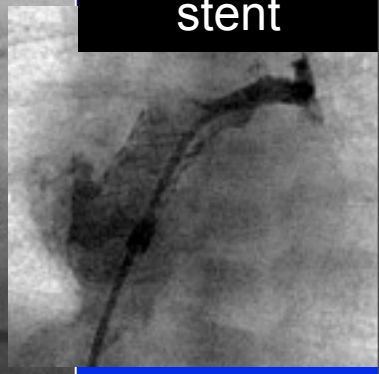
Stent use in CHD











Important questions to ask on long-term FU

- Type of vessel & pathophysiology of stenosis?
- Can stents hold up in the long term:
  - Restenosis? Fracture? Erosion? Growth of distal vessels?
- Can stents be further dilated in growing children?
  - Safety of further dilation? Vessel remodeling?
- What happens to jailed side branches?
- Impact of stents on future surgery? MRI?
- Long term clinical outcomes: quality of life of CHD patients with stents?

JPICS stent survey: medium and long-term outcomes

- Palmaz or Palmaz Genesis stents
- Branch PA, COA, SVC, IVC
- 5/95-2/09 (14 yrs); 14 hospitals
- 255 pts (312 lesions)
- Median age: 10 yrs; FU range 6-144 mo
- PA (199 pt) (253 lesions)
  - 4.7 ± 2.1 to 8.8 ± 2.7mm
- COA (35 pt) (38 lesions)
  - 6.6 ± 2.2 to 12.0 ± 3.8mm
- SVC/IVC (21 pt) (21 lesions)
  - 4.4 ± 2.2 to 9.2 ± 2.9 mm

Doubled in diameter

Tomita et al. Stenting in CHD. Circ J 2010;74:1676-83.

JPICS stent survey: medium and long-term outcomes

- Freedom from redilation PA (84% at 72mo); COA (95% at 54 mo); SIVC (81% at 50 mo)
- Redilation: 187
  - PA (6.1 ± 2.5 to 8.3 ± 2.7mm)
  - COA (7.9 ± 2.9 to 9.8 ± 3.5 mm)
  - SIVC (5.3 ± 2.4 to 7.3 ± 1.9 mm)
- No deaths; Adverse events 80 (most at stent implant)(3% required surgery)
- Conclusion: Little morbidity during medium and long term FU; some redilation required

Tomita et al. Stenting in CHD. Circ J 2010;74:1676-83.

Data in the literature- PA stenting

- 1988-2009: 58 series (exclude case reports and small series) describing 1856 pts

Systolic gradient		Diameter		RV/FA ratio	
pre	post	pre	post	pre	post
42.1 →	14.3	4.36 →	9.21	66.9 →	44.9

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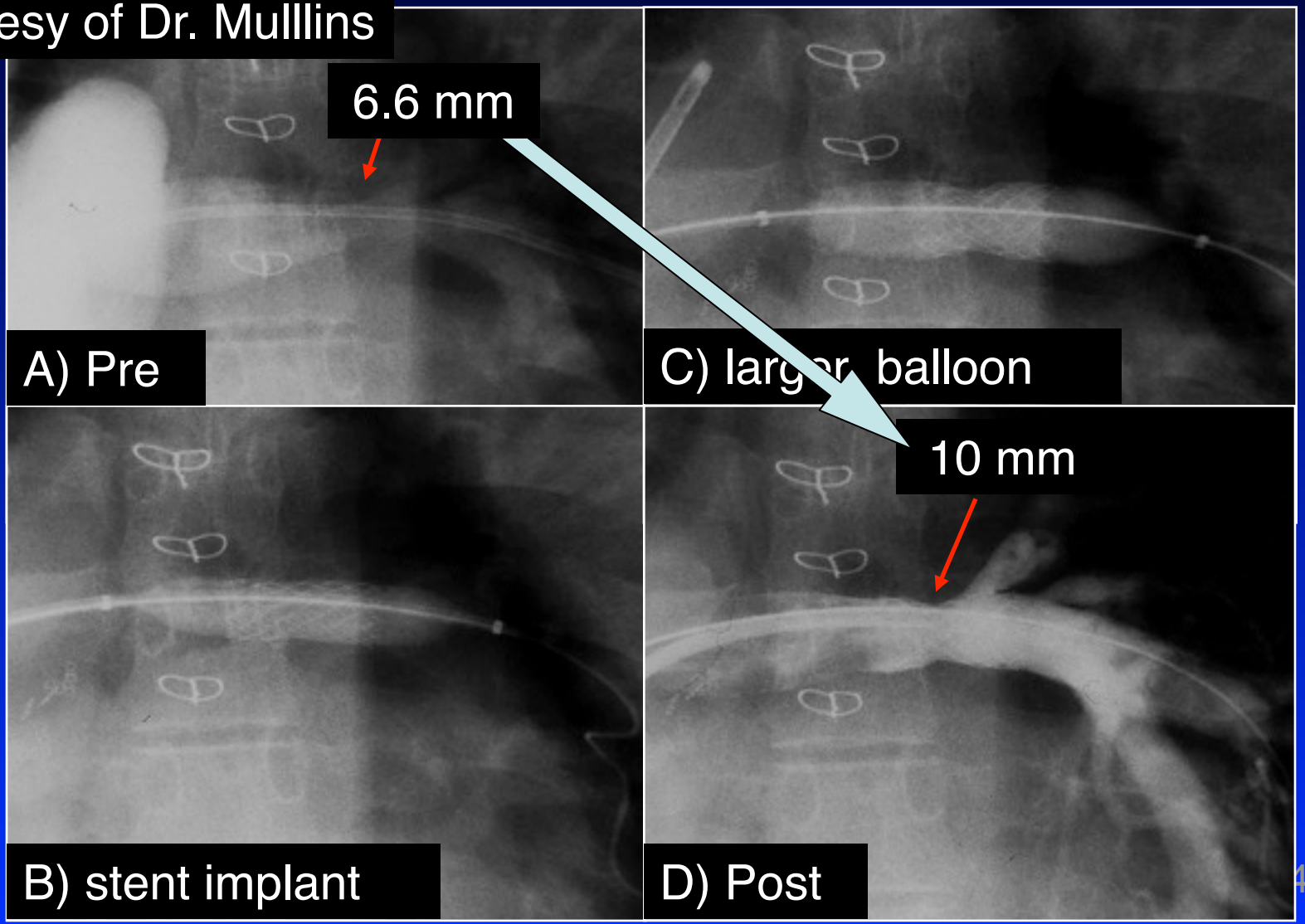
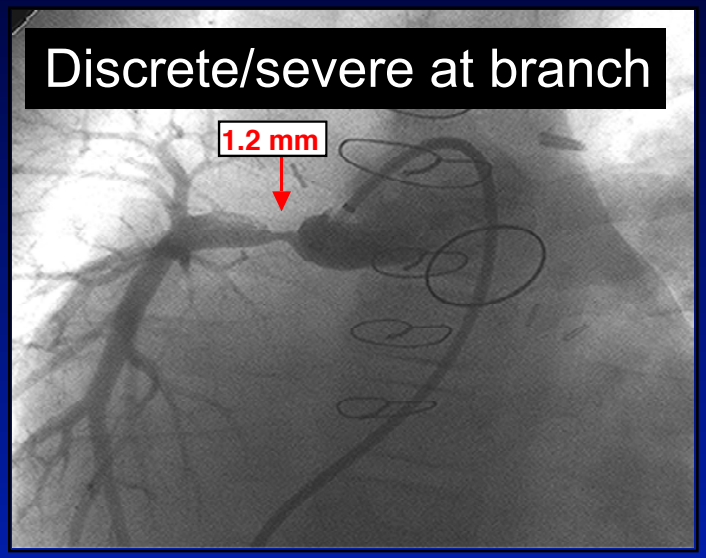
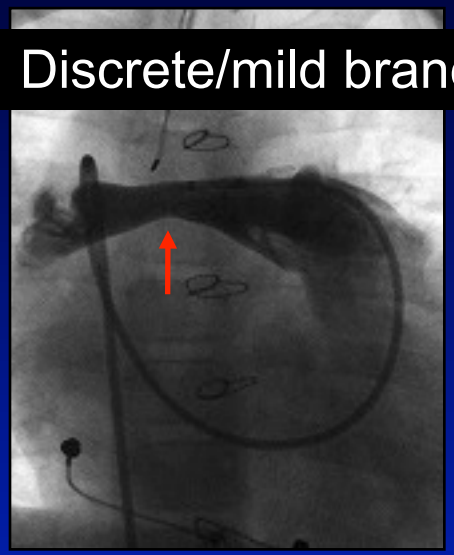
Ist stent implant (at TCH) Sept. 1, 1989

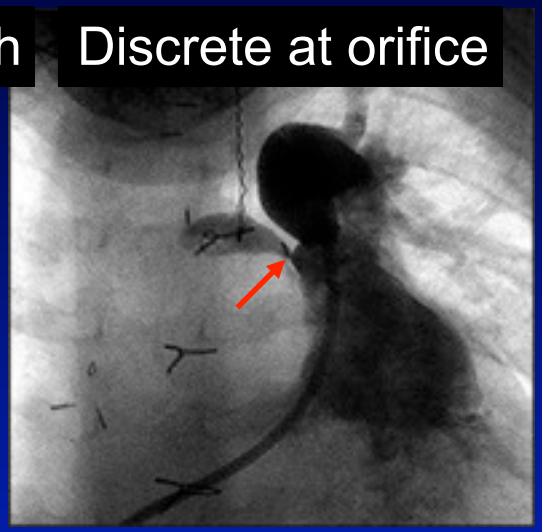
Courtesy of Dr. Mulllins

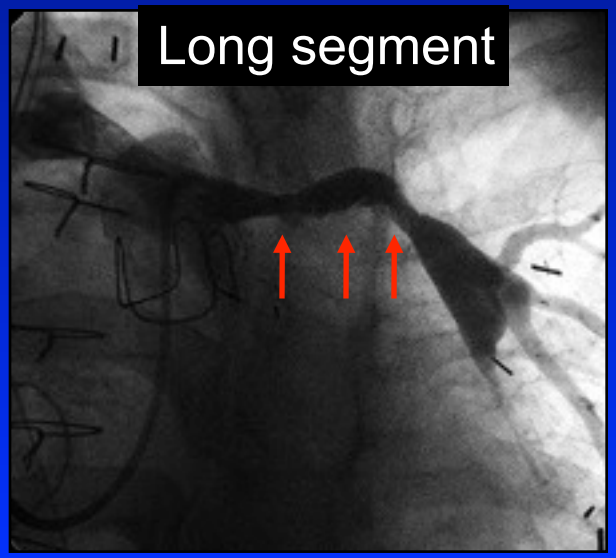


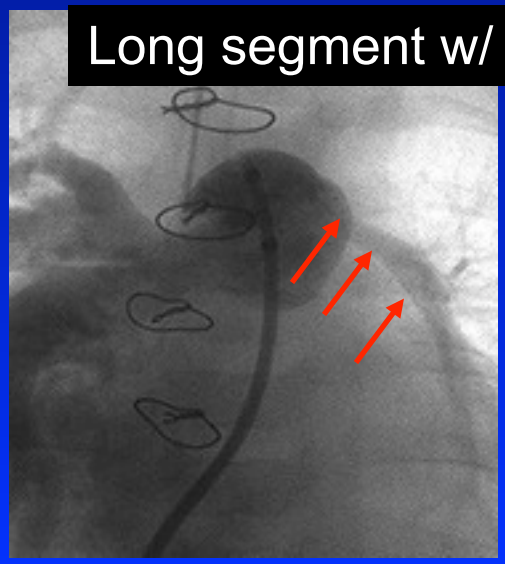
F/U data is a moving target: Not all PA stenosis are equal!

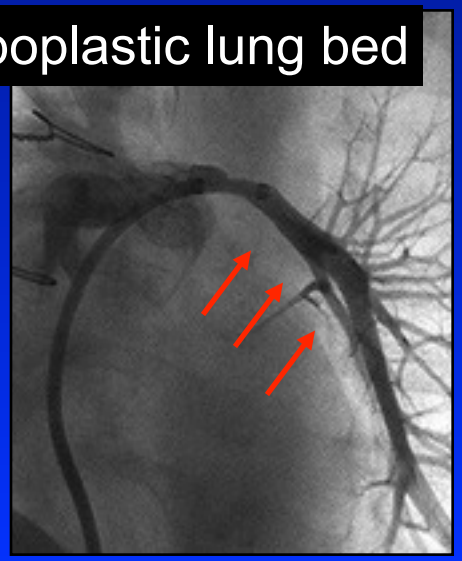




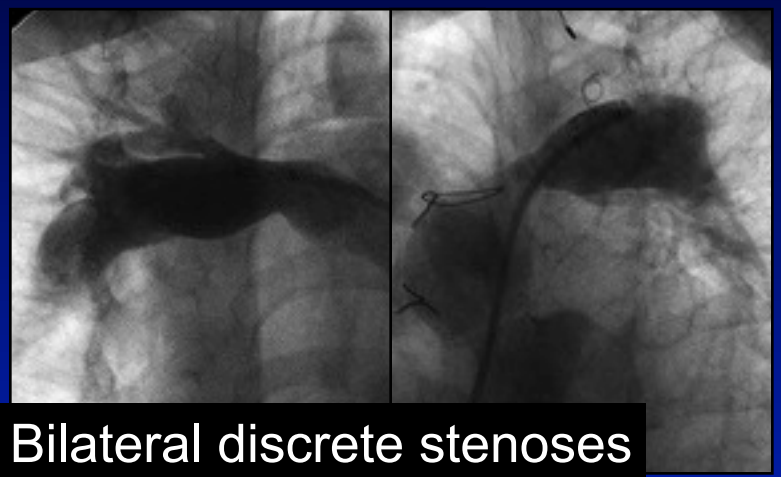




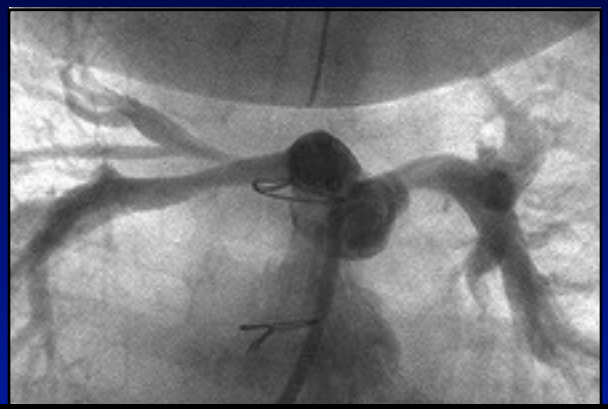




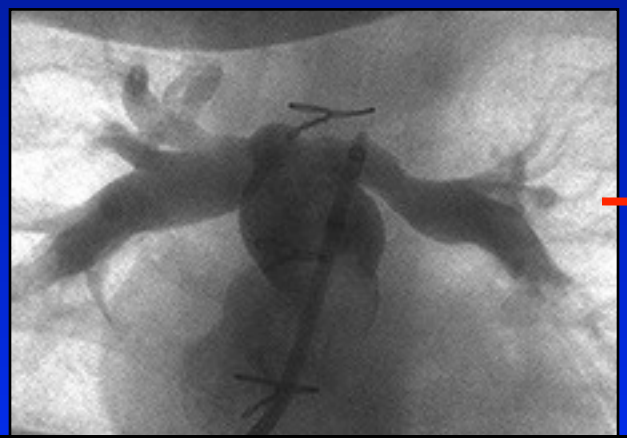
F/U data is a moving target: Bilateral branch stenoses



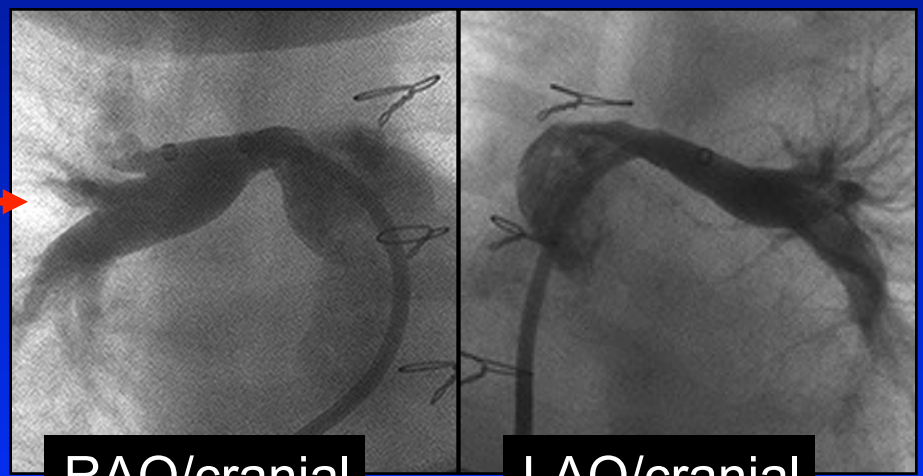
Bilateral discrete stenoses



Bilateral long segment stenoses



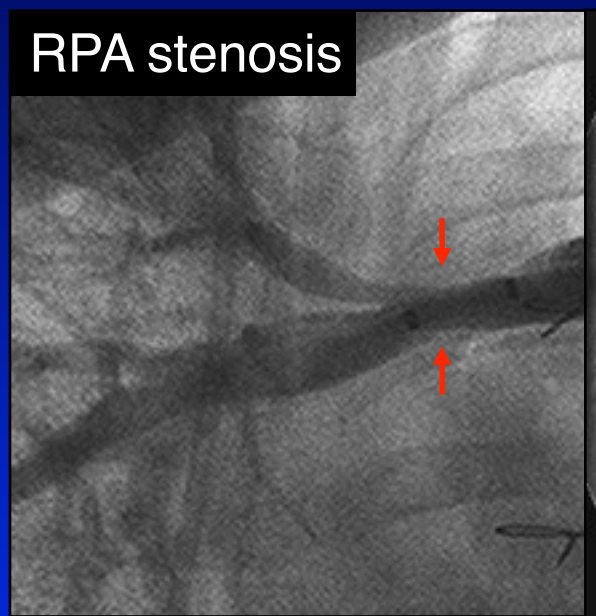
Bilateral (orifice & long segment)

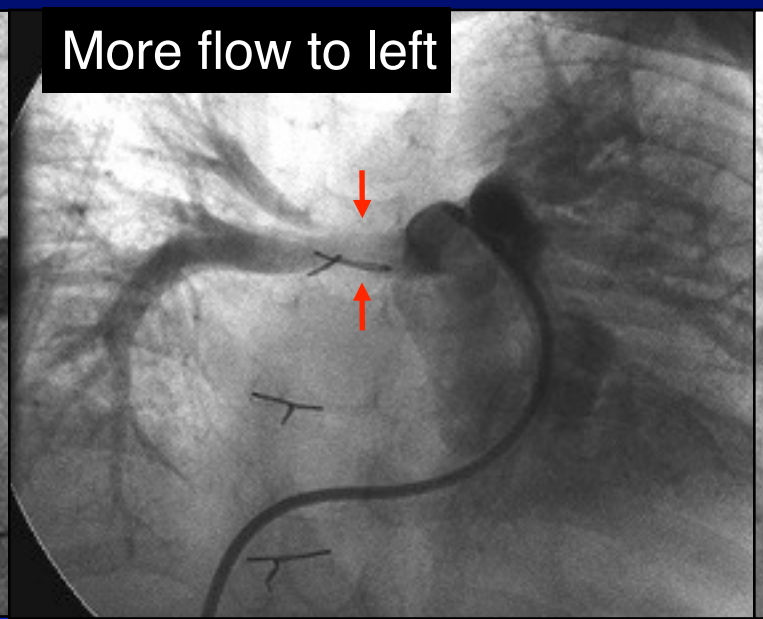


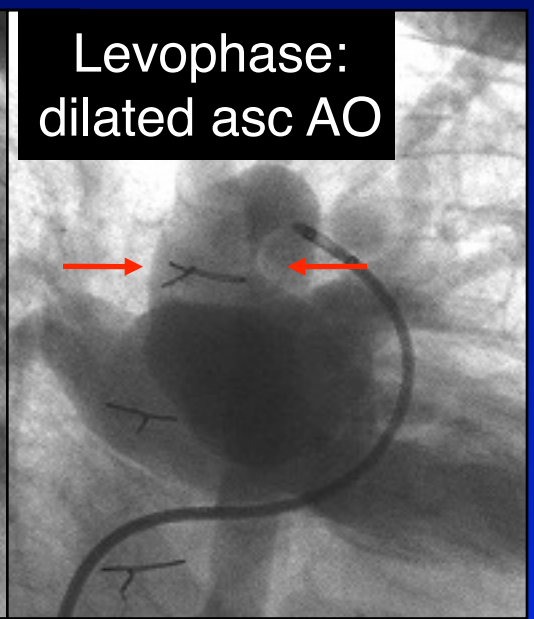
RAO/cranial

LAO/cranial

Branch PS due to external compression







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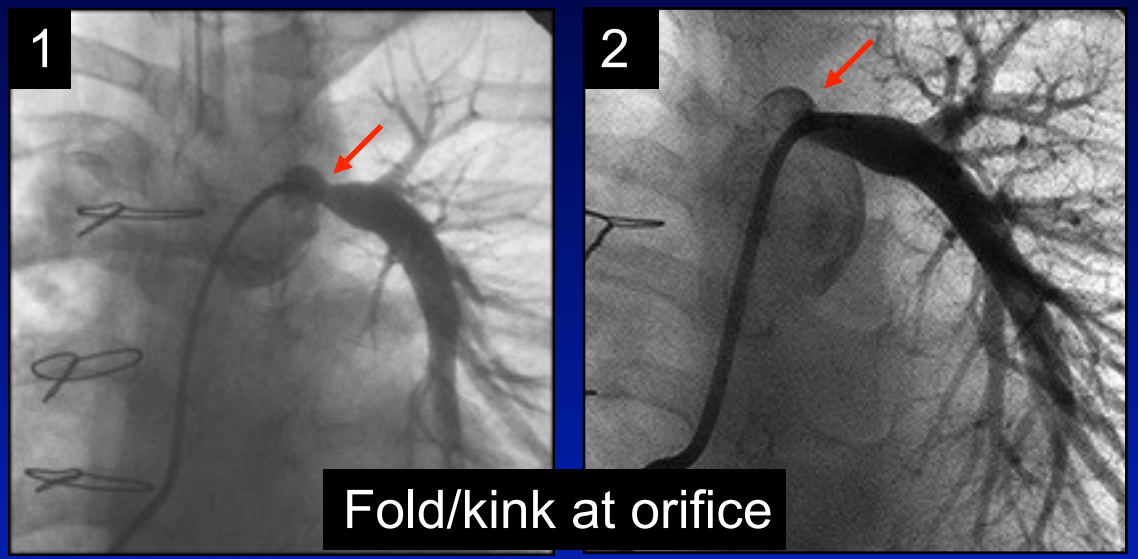
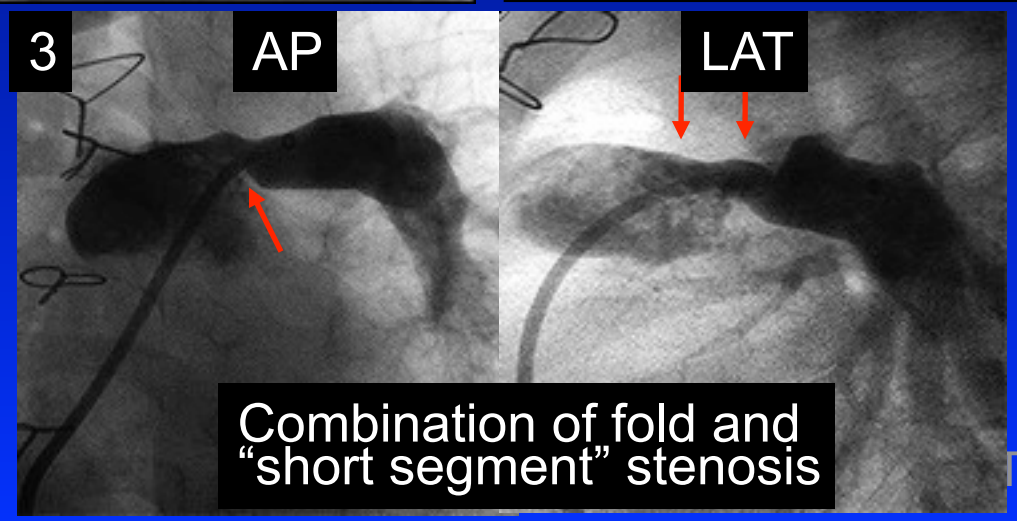
Branch PS due to Folds/kinks

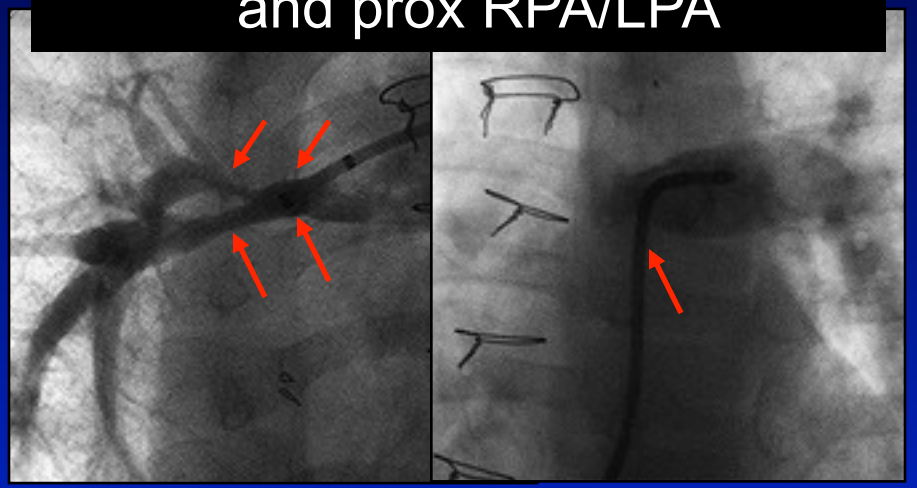




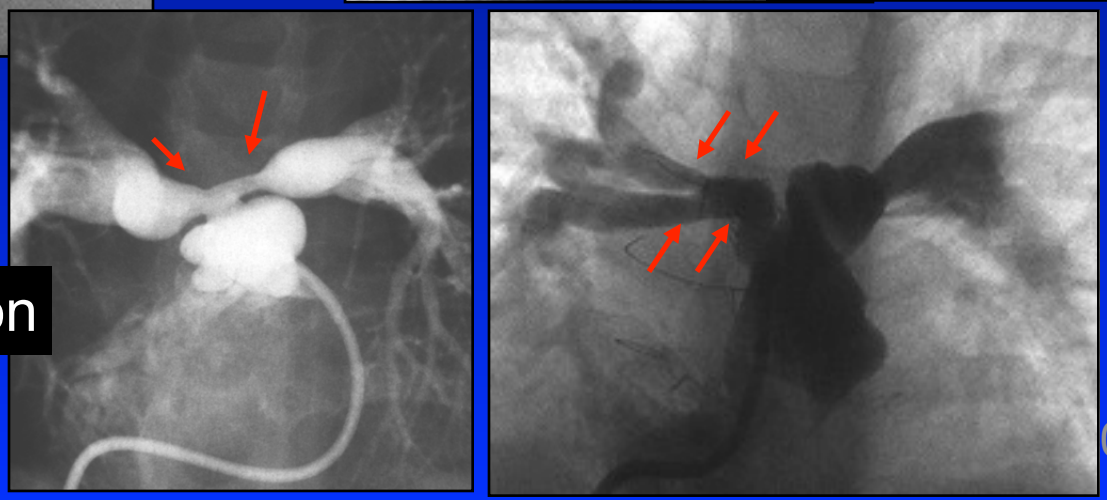
Complex branch stenoses

Complex-RUL/RLL

Complex stenoses of RUL/RLL/ and prox RPA/LPA

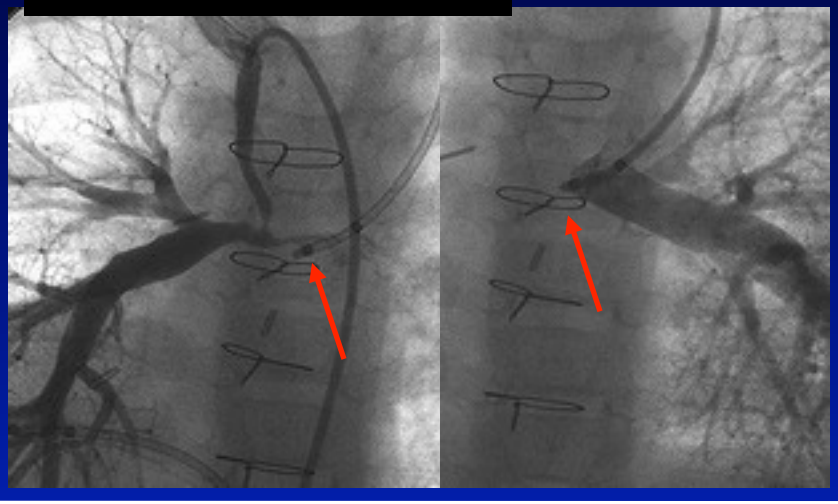


Complex-bifurcation

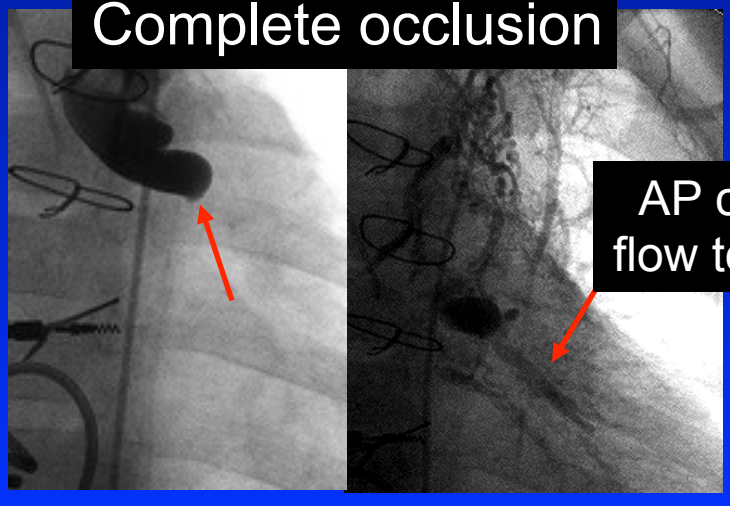


Near/complete occlusions

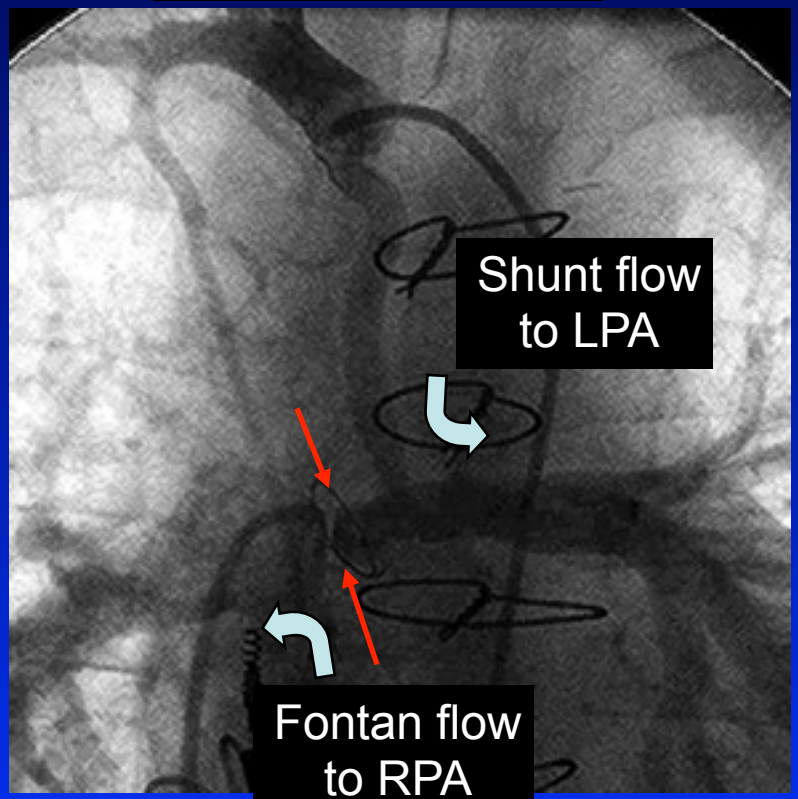
Virtual occlusions



Complete occlusion



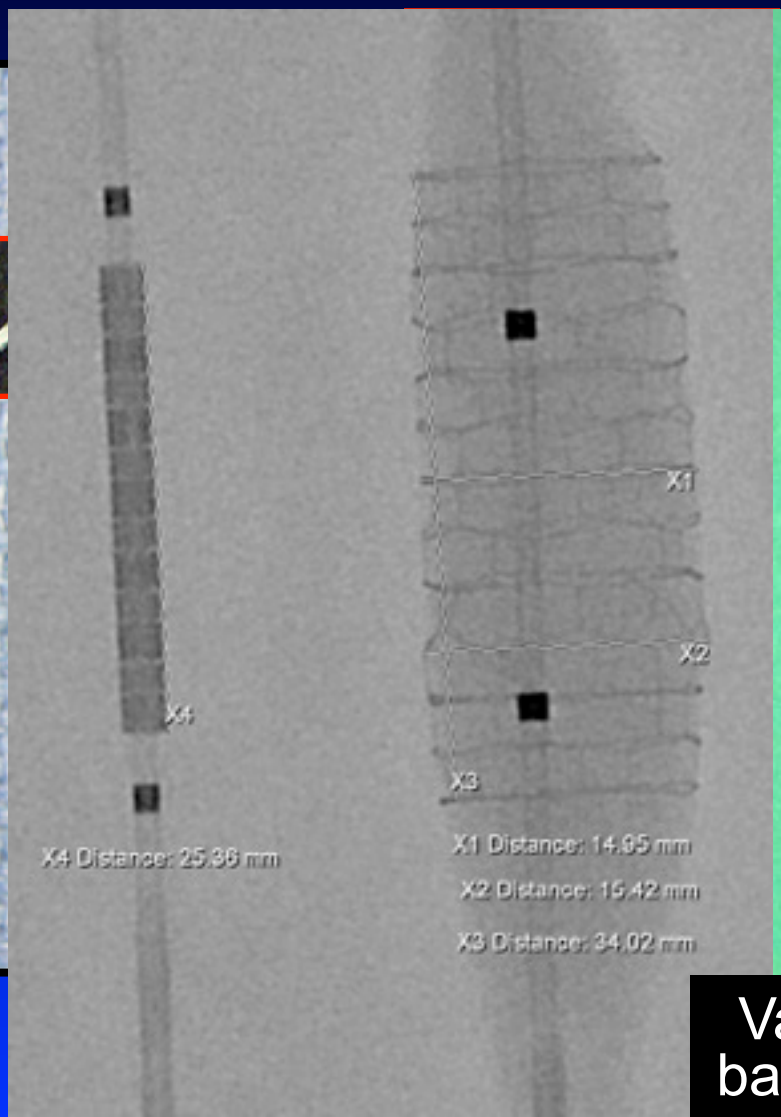
Branch isolation

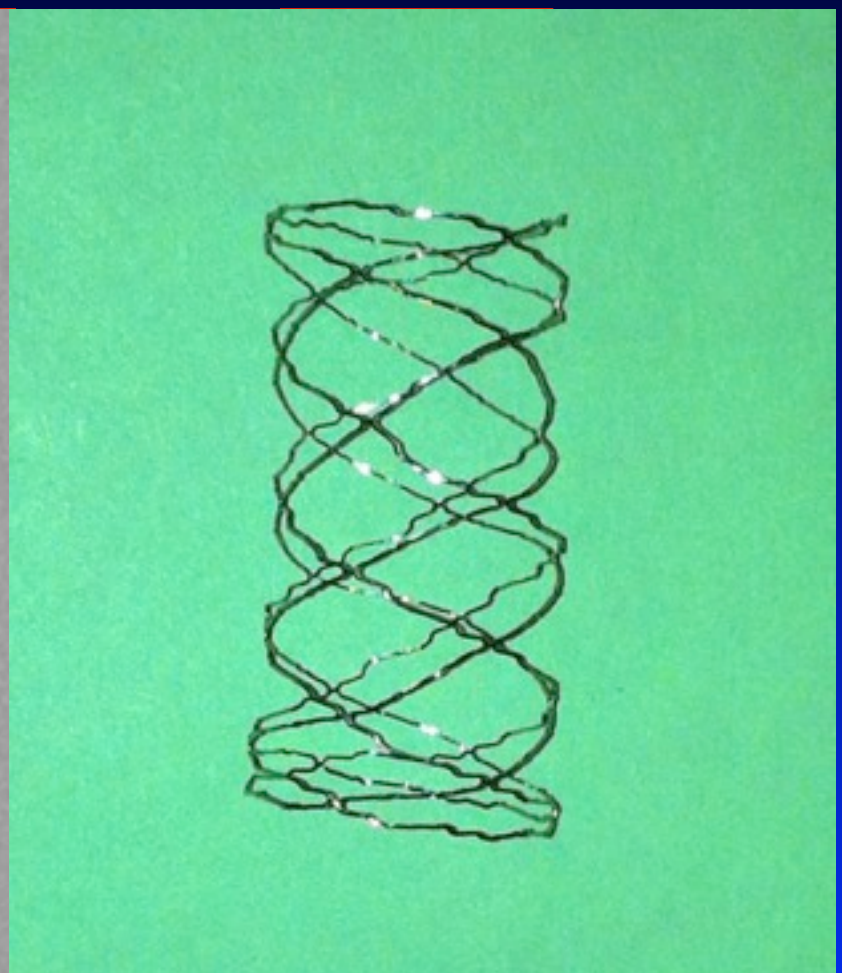


F/U data is a moving target

- **Technology (Stents) improved over time**
  - Original stent-Palmaz (J&J) (1989)
    - large (-8 series)
  - Double strut (Covidien) (2000)
    - large, open-cell design
  - Palmaz XD (J&J) (2000)-x-large size
  - Genesis (J&J)(2001)-large, flexible “s-hinge” design
  - MaxLD, Mega LD (EV3)(2003)
    reinforced large & x-large size
  - Covered stent (Numed)-investigational in USA

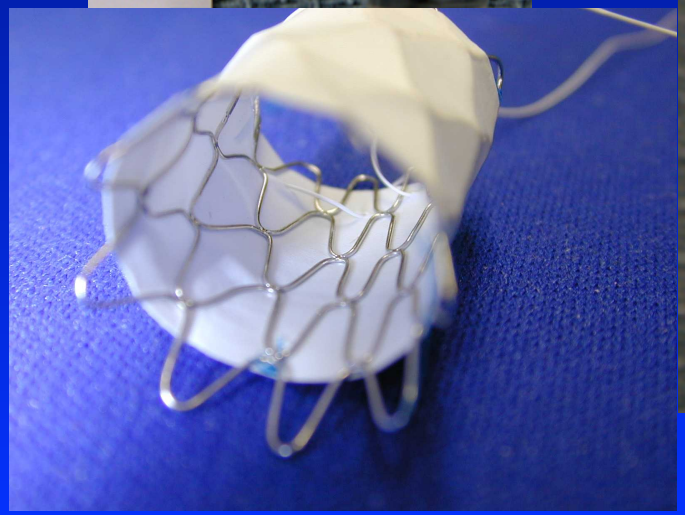
Comparison of large stents

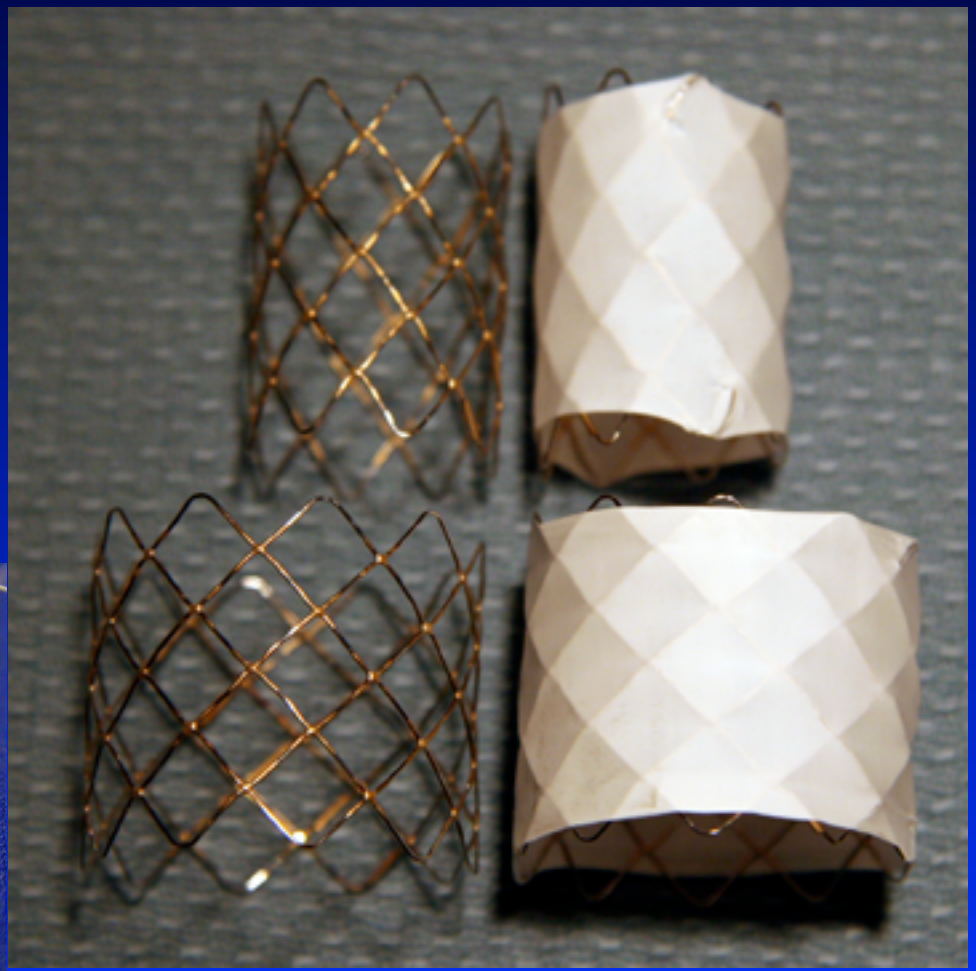




Valeo stent premounted on 9-10mm balloons can dilate to 20mm diameter

Covered CP stents





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F/U data is a moving target

- **Delivery systems downsized & improved**
  - Originally 11 Fr delivery system
  - Now as small as 7 Fr system
- **Patient selection widened over time**
  - Originally ≥ 25 kg
  - Now 4-5 kg
- **Operator experience improve over time** (learning curve)
- **Stent delivery techniques improved over time**
  - Intraoperative implant
  - Front loading

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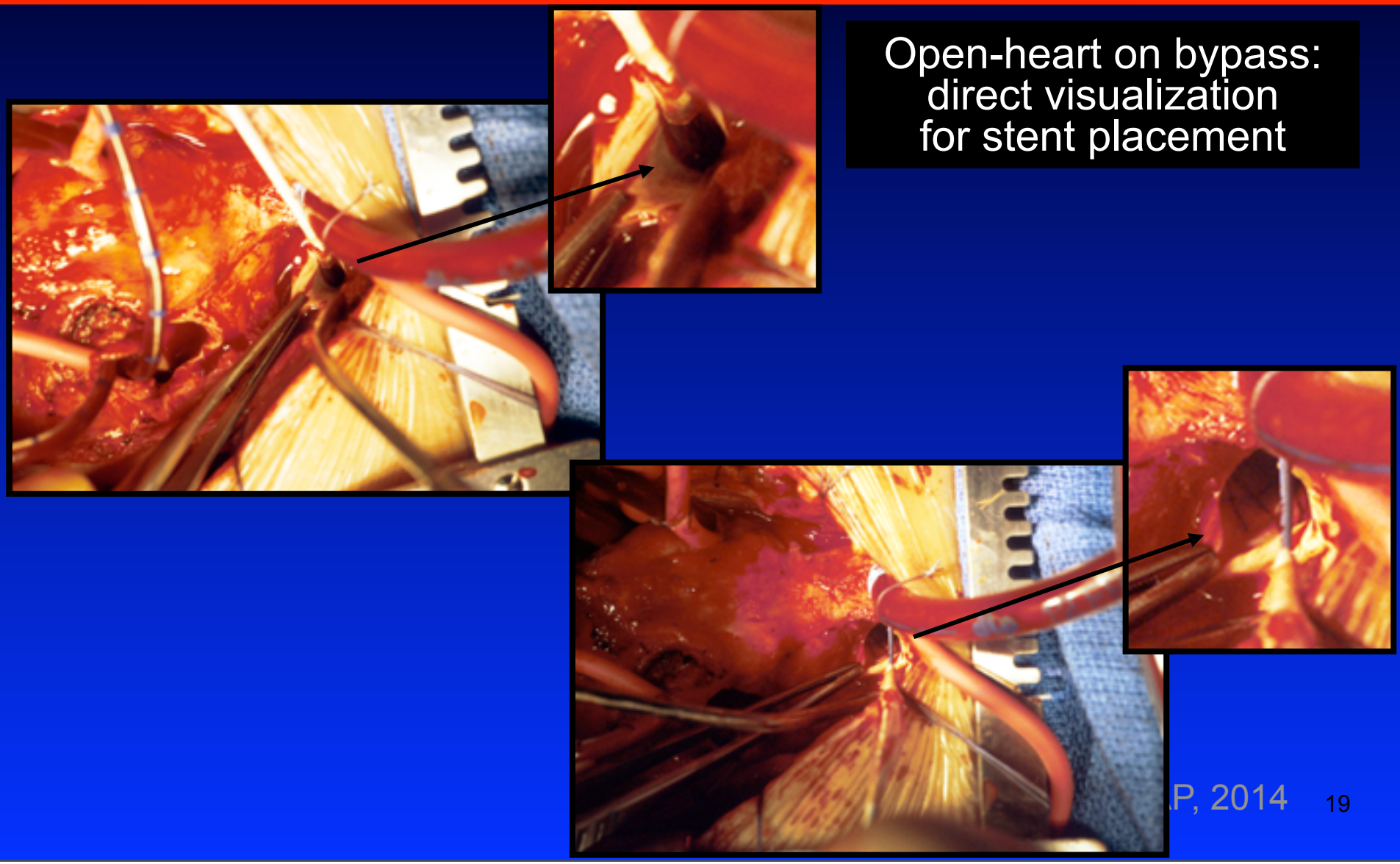
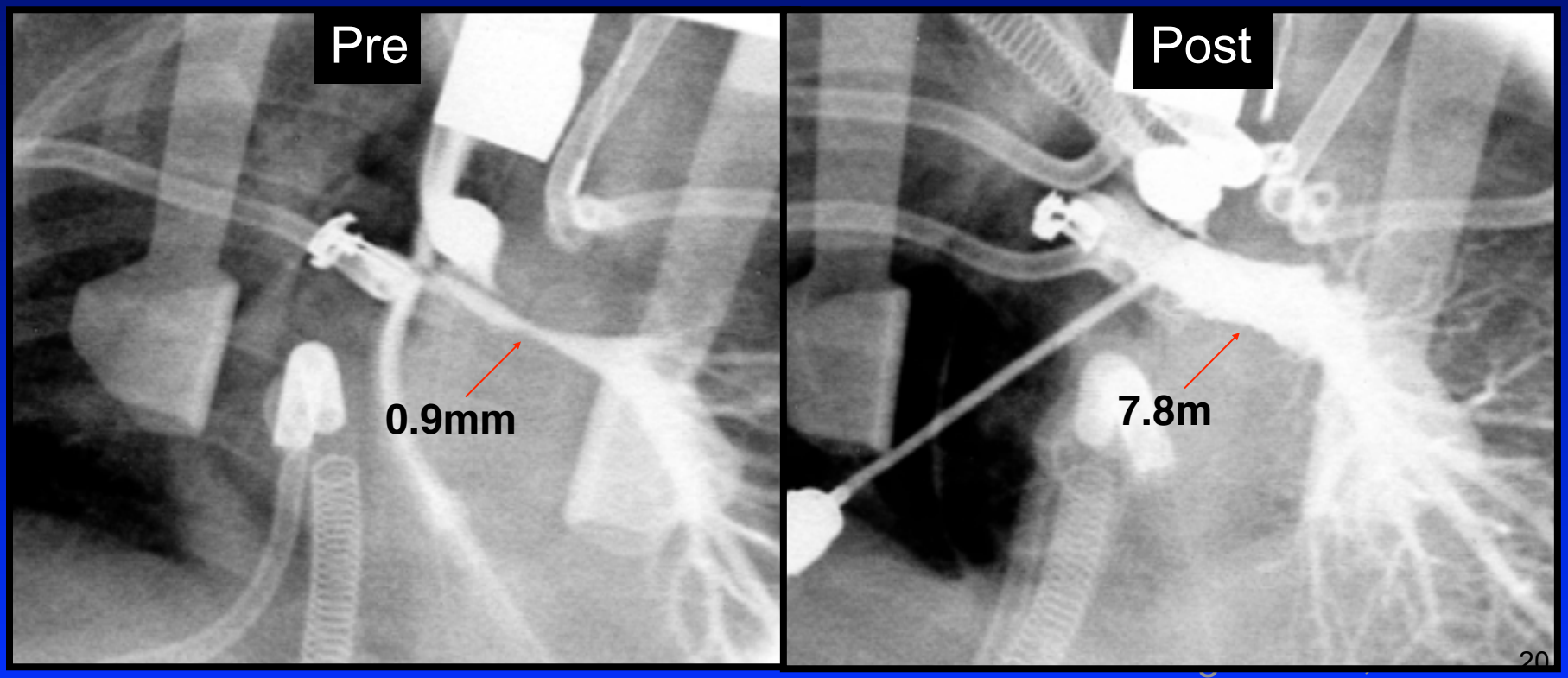
Intraoperative stent implantation on bypass

Open-heart on bypass: direct visualization for stent placement



Intraoperative stent implantation off bypass

Open-chest on beating heart (no bypass): Indirect vascular access for angiogram and stent placement



Background

- Variable vascular anatomy and constant improvements in stent and delivery system designs and new techniques render long term follow up data difficult to interpret for future use
- Same principles apply for all other vascular stenoses

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TCH long-term F/U data for branch PS

- 1989-92: 68 pts received stents
  - 18 pts lost to follow-up (<5 yrs)-excluded
  - 50 pts (71 stents)-included for study
    - 1 procedural death; 5 deaths during follow up
- Long-term data available for 43 pts:
  - Cath, echo, clinic records
- Age at initial stent: 12.6 ± 7.1 yrs
- F/U duration 13.3 ± 2.3 yrs
- Only Palmaz 308 and 188 stents used
- Early moderate/severe procedural complications: 11 (1 death)

Law M et al. Pulmonary Artery Stents: Long term follow up. Catheterization and Cardiovascular Interventions 2010;75(5):757-64.

TCH long-term F/U data

- Late F/U:
  - 4 deaths due to underlying CHD
  - 1 death due to stent rupture (RPA to aorta) during redilation (6 yr post initial stent implant)
  - 4 late complications:
    - Minor: stent fractures 3 (5-6.5 yrs)
    - Major: significant aneurysm 1-LPA (coil occluded)

Cath F/U data

- N=36 pts (55 stents)
  - Mean last F/U interval: 7.2 ± 4.3 yrs
  - Mean: 1.2 ± 0.9 redilation / stent
  - Pre stent min diam: 4.7 ± 1.8 mm
  - Final min diam: 13.4 ± 2.4 mm
  - Pre stent % stenosis: 62 ± 13%
  - Final % stenosis: 12 ± 11%
  - Mean final balloon diameter 16 mm ± 2 mm
  - Higher initial gradient and % stenosis associated with final stent diam of < 14 mm
  - Younger age at initial stent implant was not a factor

Tripled diameter

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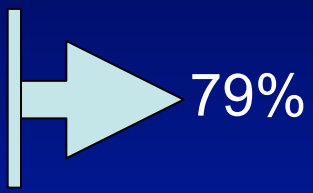
Echo f/u data

- N=38 pts (12.9 ± 2.6 yr)
  - RV function:
    - Normal 25 (66%)
    - Mild decreased 5 (13%)
    - Moderate decreased 2 (5%)
    - Severe 1 (3%)
    - Unknown 5 (13%)



  - RV size:
    - Normal 5
    - Dilated 33 (mild-18, moderate-13, severe-2)

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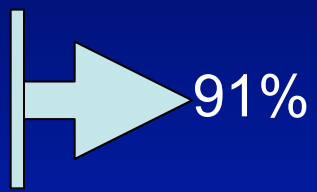
Clinical f/u data

- N=43 pts (13.2 ± 2.4 yrs)
  - NYHA:
    - I 24 (56%)
    - II 15 (35%)
    - III 4 (9%)



  - Additional surgery 7
    - RV-PA conduit 4 (none for PA stenosis alone)
    - Fontan revision 2
    - Attempted repair of PA-aorta erosion 1 (died)

Long term stent fracture data

- Stent fractures:
  - 3/55 stents (5.5%)
  - no fragment embolizations or vessel obstructions

Deaths

- N=6 (1 at initial implant)
  - 5 at F/U period
    - 1 TOF-progressive RV dysfunction 2.2 yrs s/p LPA stent
    - 1 TOF (history of chronic atrial & ventricular arrhythmias) 8.7 yrs s/p LPA stent
    - 1 L-TGA progressive RV dysfunction 14 yr s/p bilateral stents
    - 1 progressive Fontan failure (post revision) 16 yrs s/p stent implant
    - 1 [illegible] rta p[illegible]

Now we have covered stents

Procedural complications

- N=5
  - Major:
    - 1 severe (LPA stent erosion into aorta at further dilation-6.6 yrs)
    - 1 dissection at further dilation of RPA stent(hemothorax-thoracentesis and CT); aneurysm found 3 yrs later at second f/u cath-coil occluded
  - Minor:
    - 1 small RPA aneurysm adjacent to stent at 6.4 yr s/p stent implant-no further intervention
    - 1 Balloon rupture and retrieval of balloon fragment
    - 1 Atrial arrhythmia during repeat dilation-cardioverted

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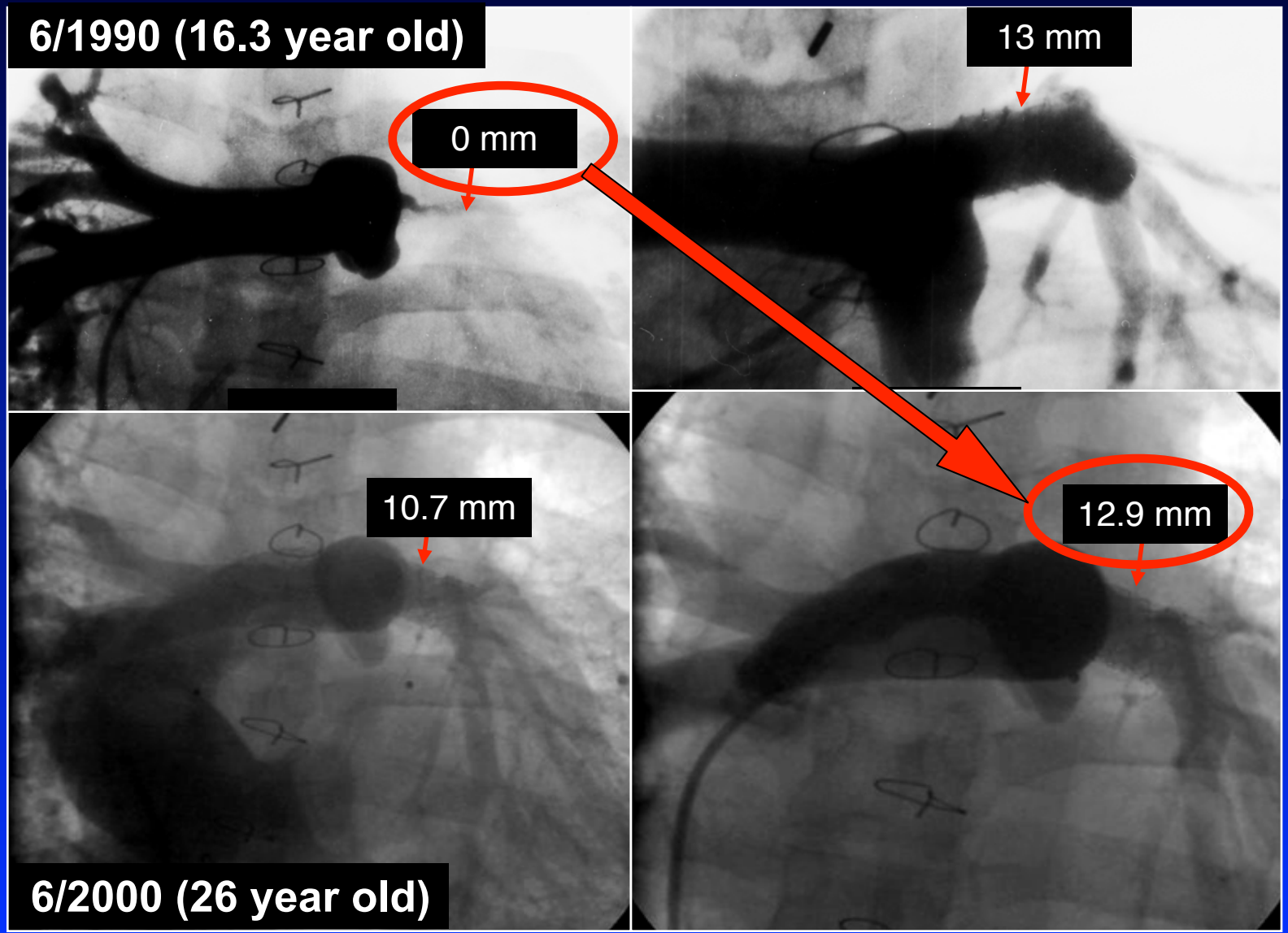
Jailed side branches

- 27/55 stents (49%)
  - Preserved flow 9 (33%)
  - Diminished flow 13 (48%)
  - No flow 5 (19%)
- 18 patients with dim
had persistently improved RV pressure
  - 86 ±14mmHg decreased to 60 ±18mmHg (f/u 6.5 ± 3.9 yrs)

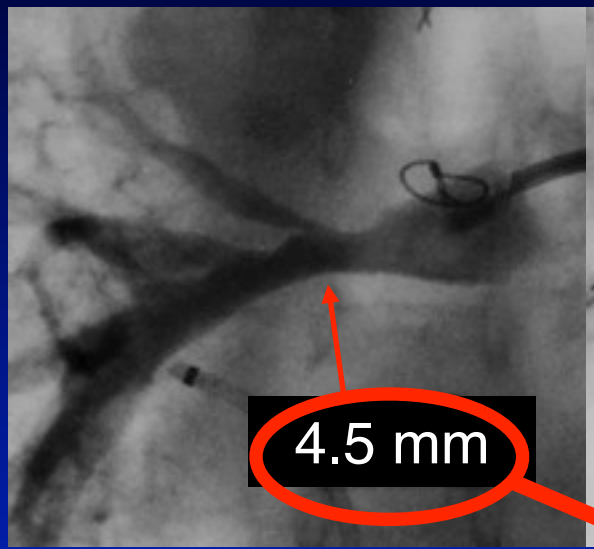
Now we have "open-cell" stents

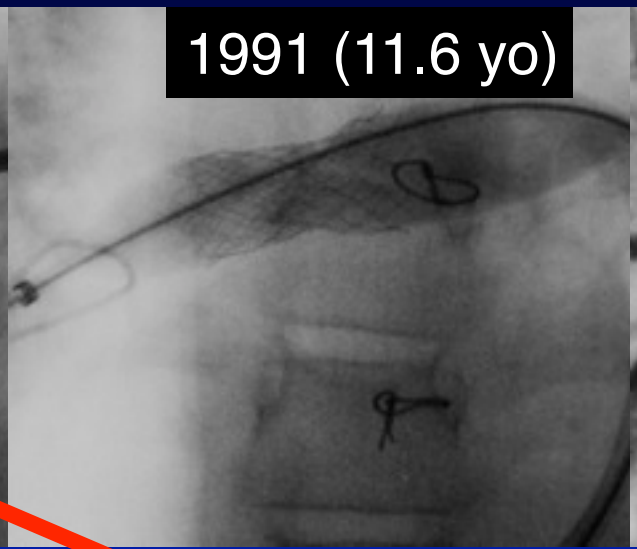
Law M et al. Pulmonary Artery Stents: Long term follow up. Catheterization and Cardiovascular Interventions 2010;75(5):757-64.

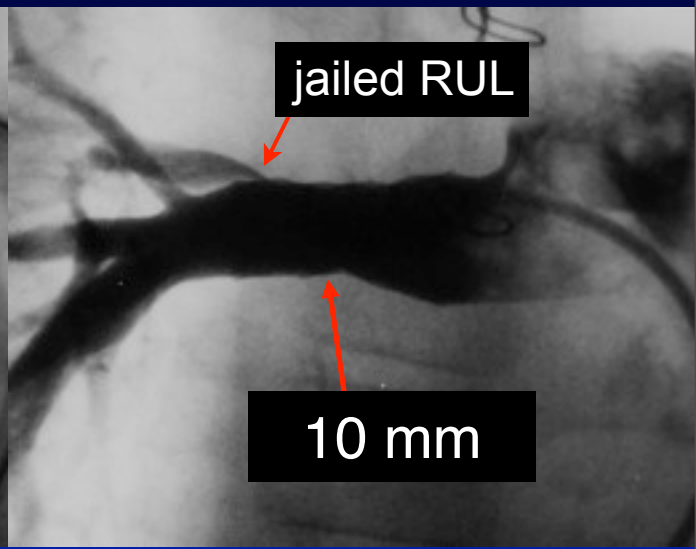
Hypoplastic LPA in Fontan, s/p stent implantation & 10 yr F/U

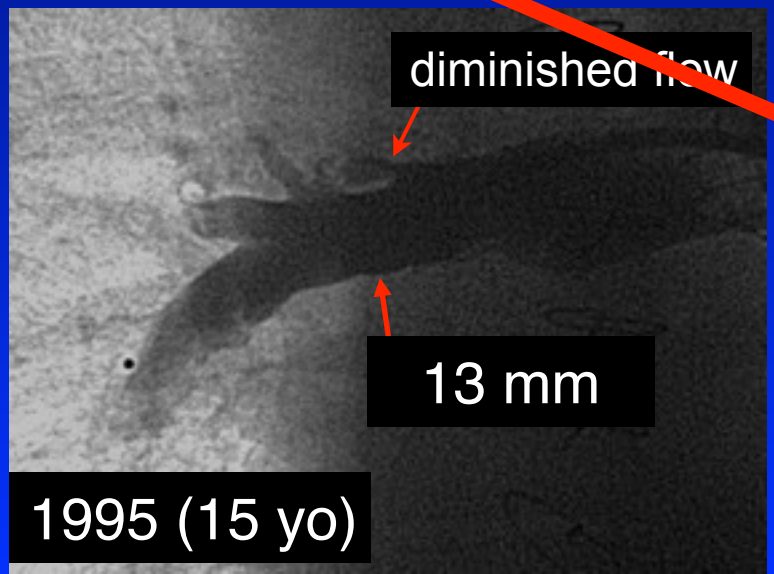


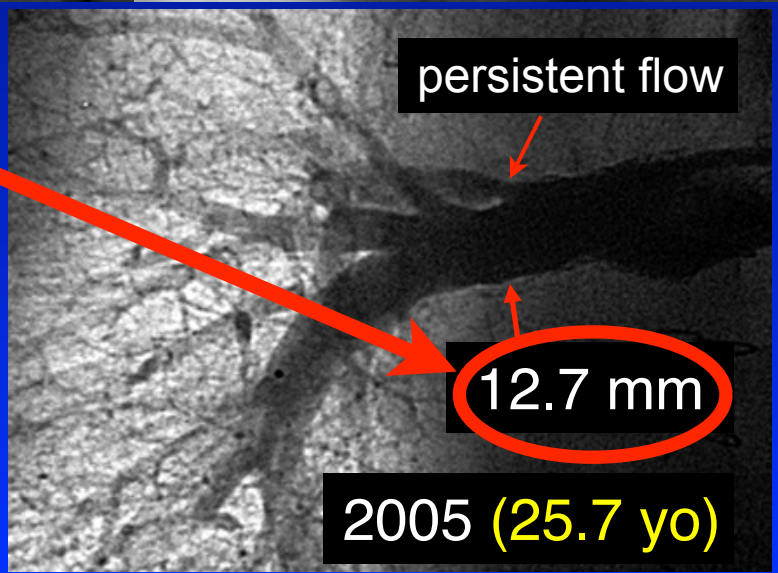
14 year F/U cath
June 1991-2005



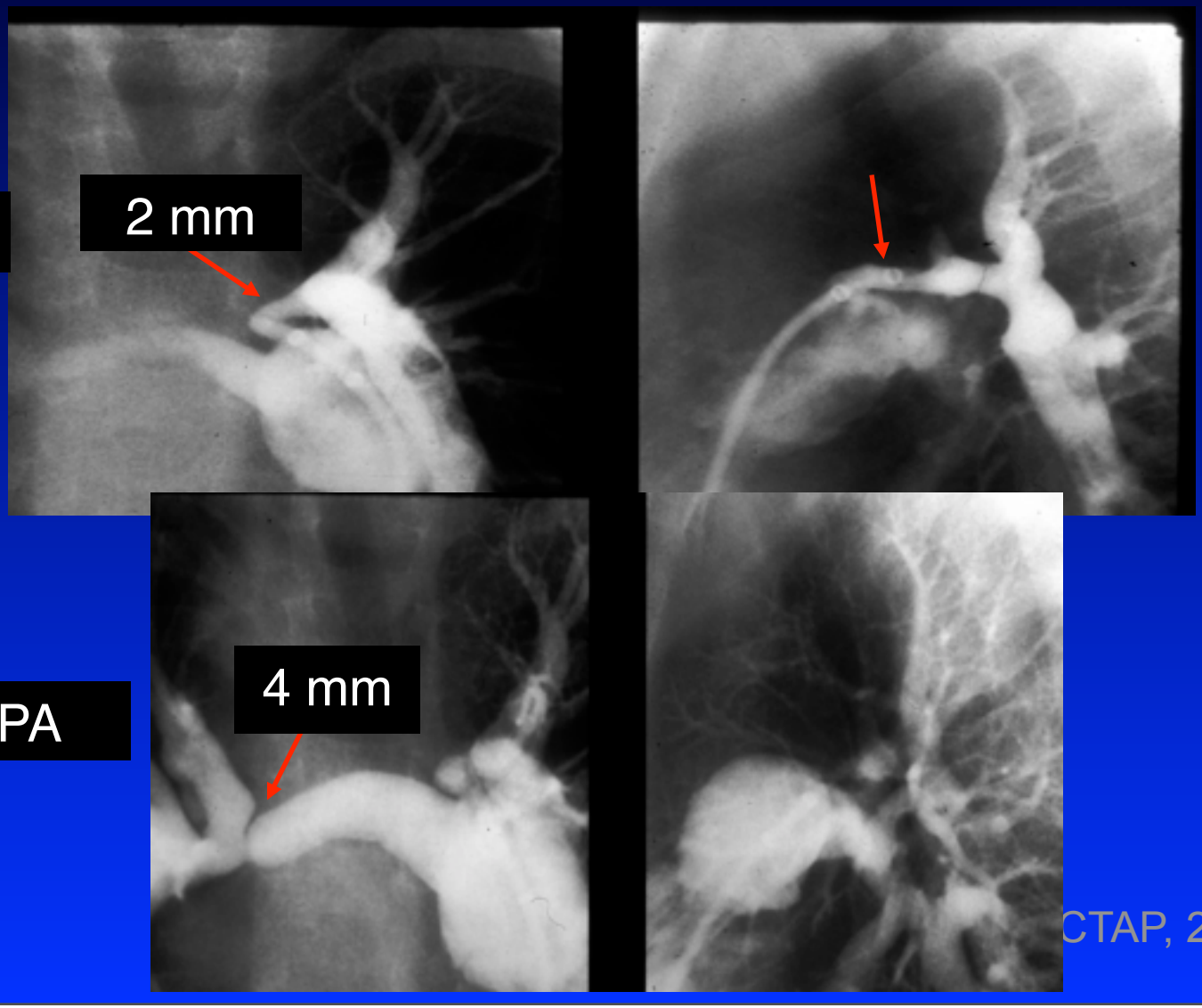




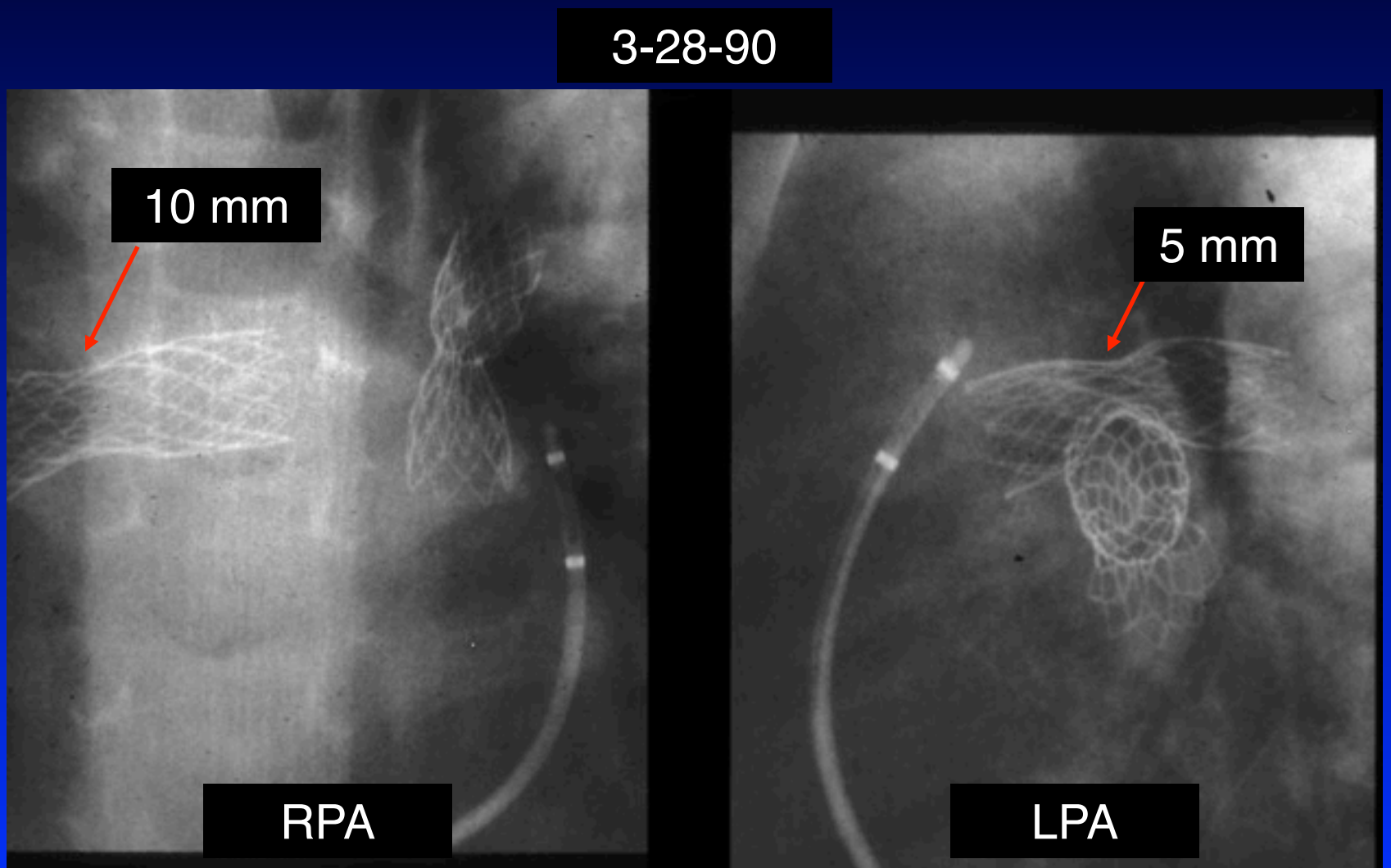




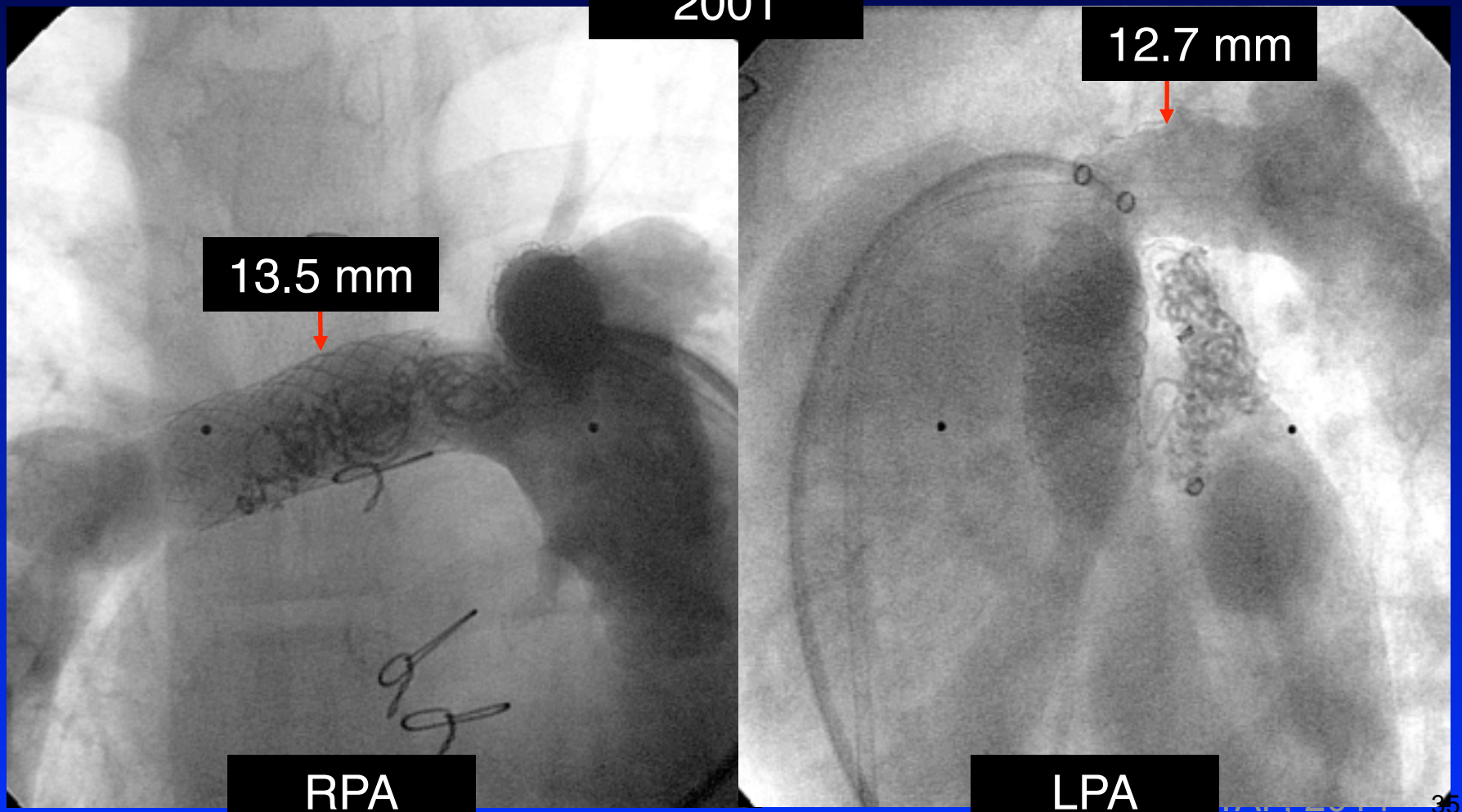
4.9 yr old w/ PA/collateral s/p unifocalization



Bilateral stents



11.4 yr F/U cath, s/p 4 redilations (16.3 yr old)



Stent fractures-RVOT

	Toronto Sugiyama, 2004	Boston Peng, 2006	Detroit Aggarwal, 2007
Stent malposition	4	10	1
Conduit dissection/ aneurysm		6	1
Balloon rupture	6	74 (30%)	4
Stent fracture	2	**54/126 (43%)**	2

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RVOT-Published data-F/U

	Toronto Sugiyama, 2004	Boston Peng, 2006	Detroit Aggarwal, 2007
F/U cath patients	24	126	13
Stent redilation	17	83	8
Additional stent	7	41	5
Freedom from surgery (median yr)	**2.1**	**2.7** **(3.9 in >5 yr age)**	**3.5**

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Stent fractures-Branch PA

	F/U	% stent fracture
McElhinney et al. Cardil. Young, 2008	> 3 yrs FU	21%
Breinholt et al, CCI, 2008	4.2 ± 3.3 yr	2.75

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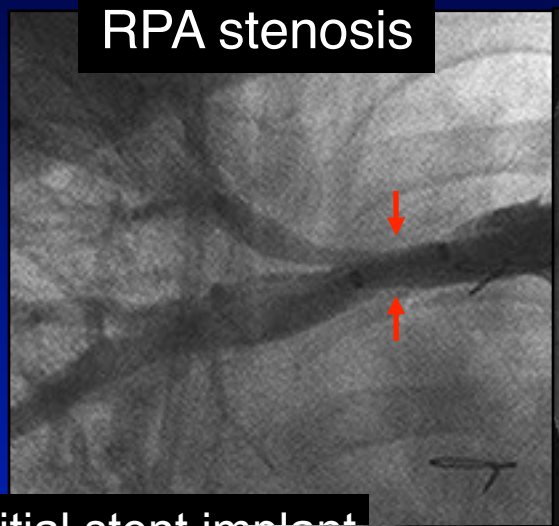
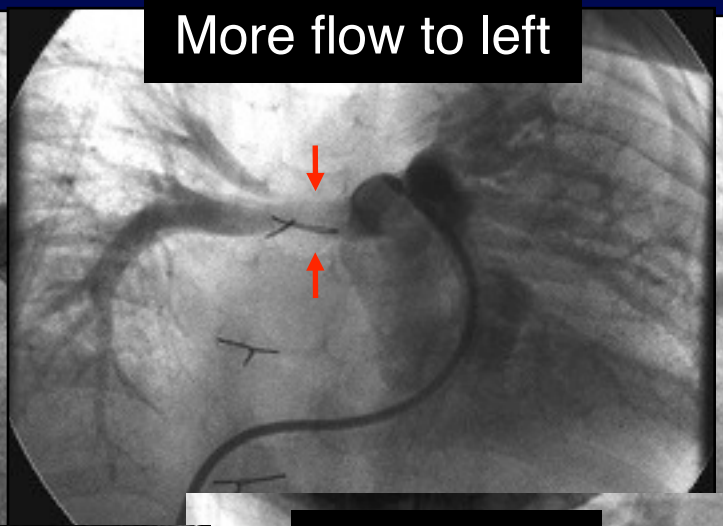
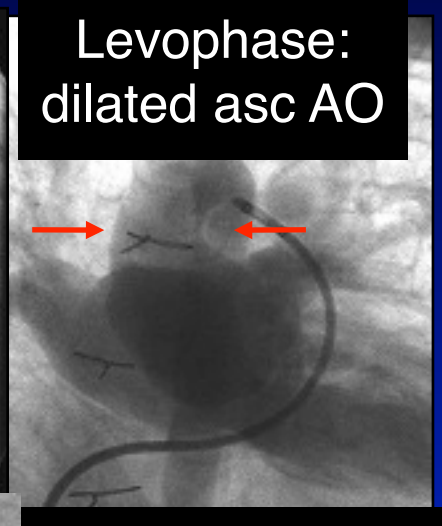
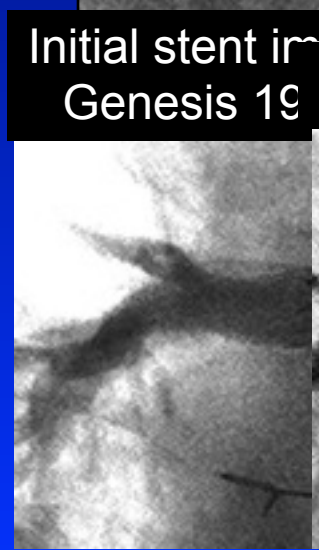
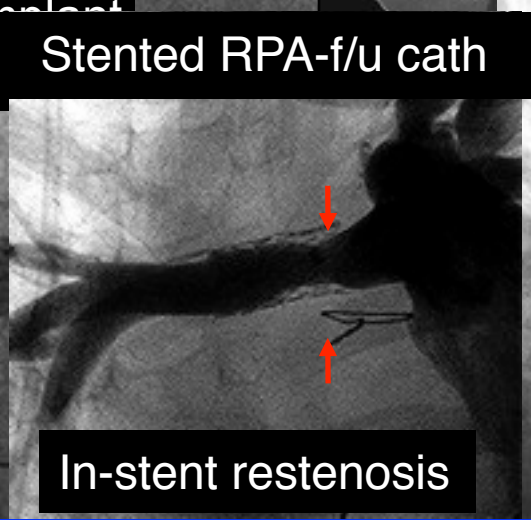
Branch PS due to external compression

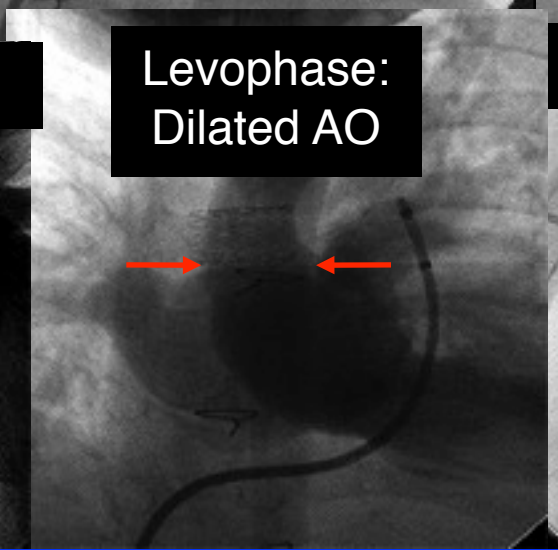


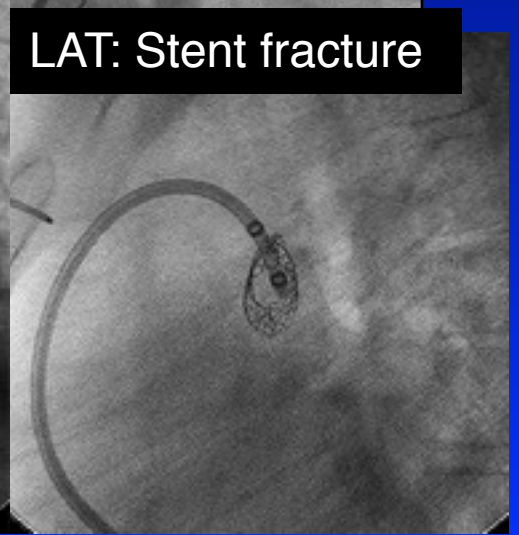




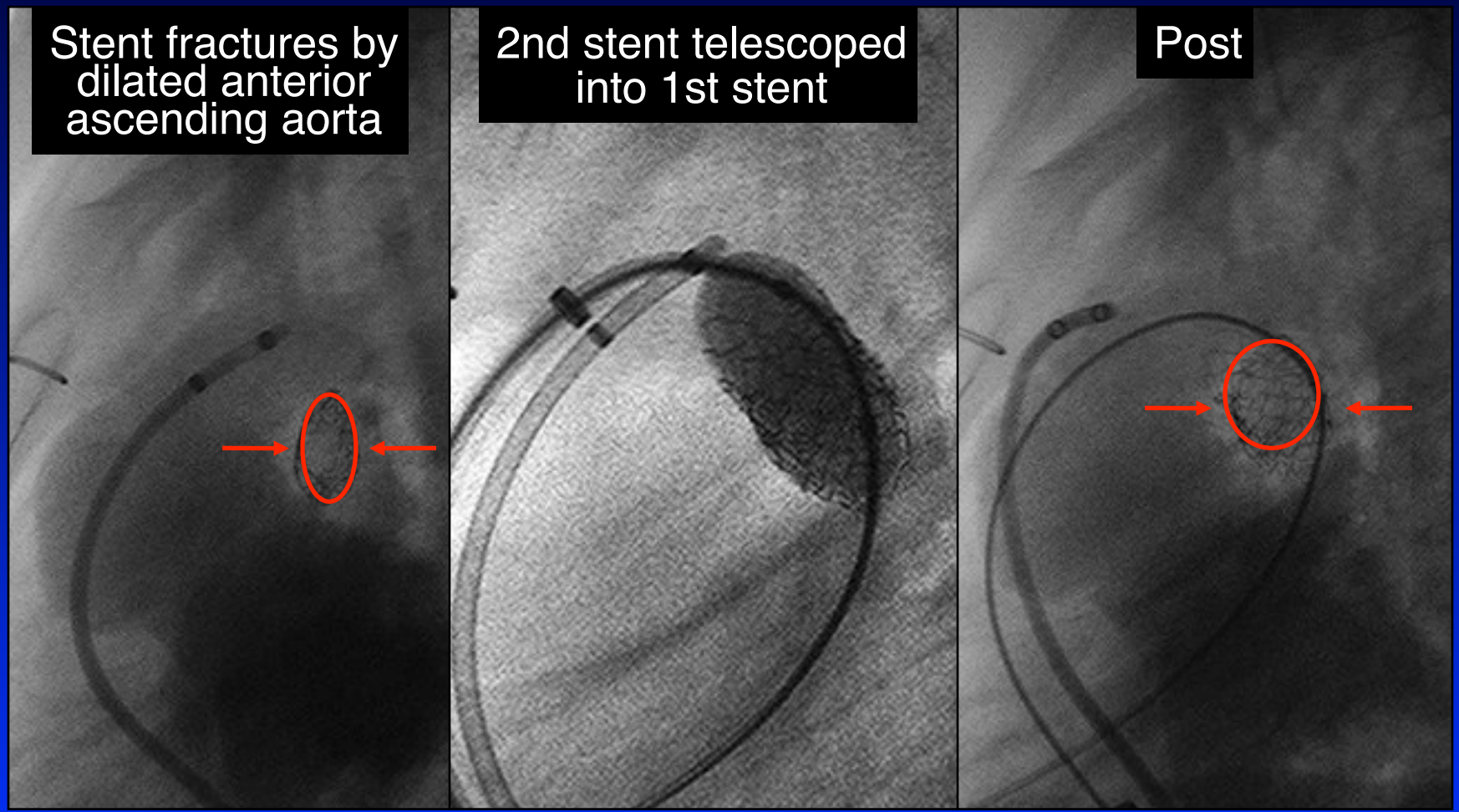








Second stent added to provide additional support



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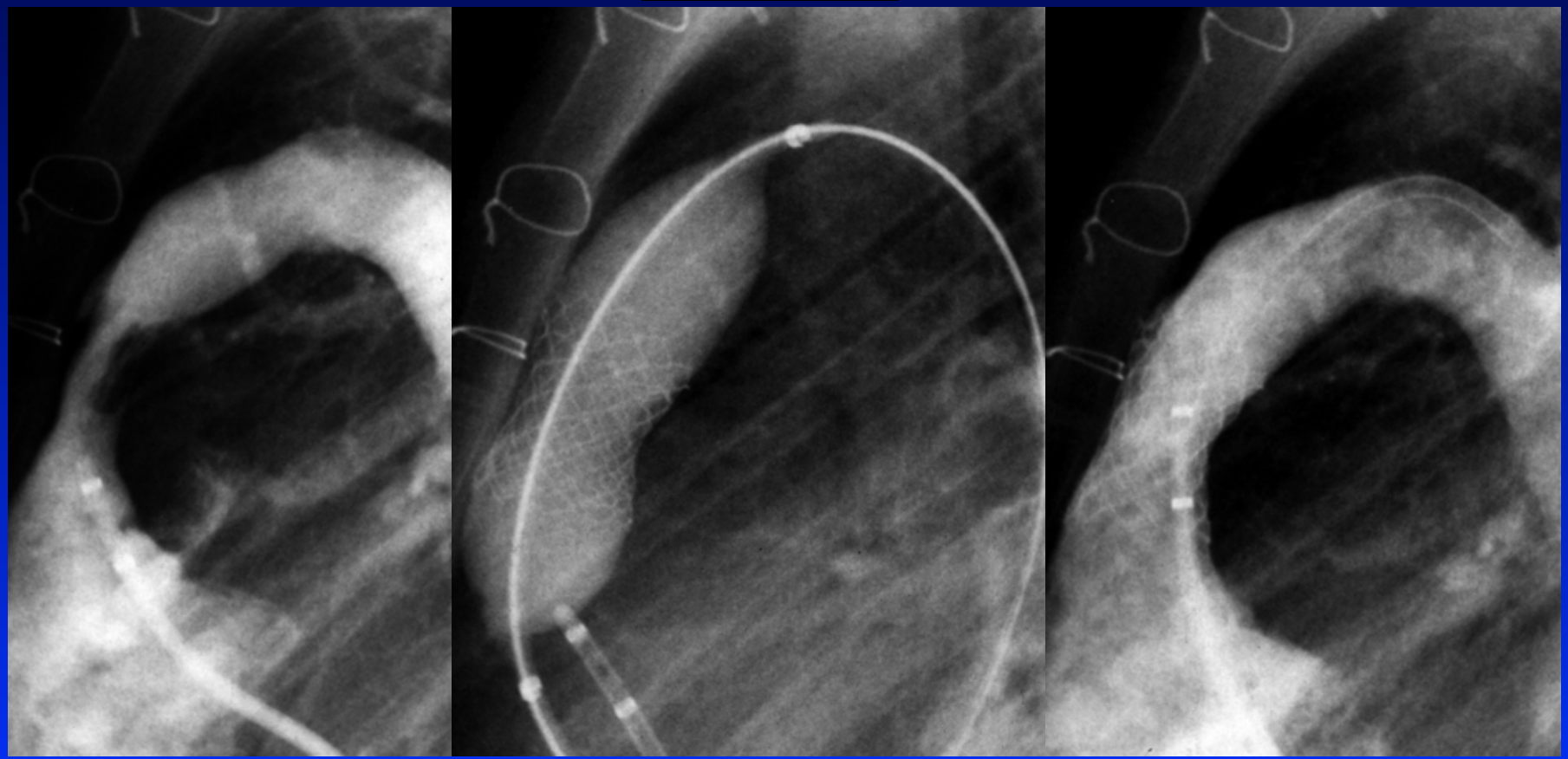
Lateral view of Palmaz stent in RV-PA conduit

Feb. 1998



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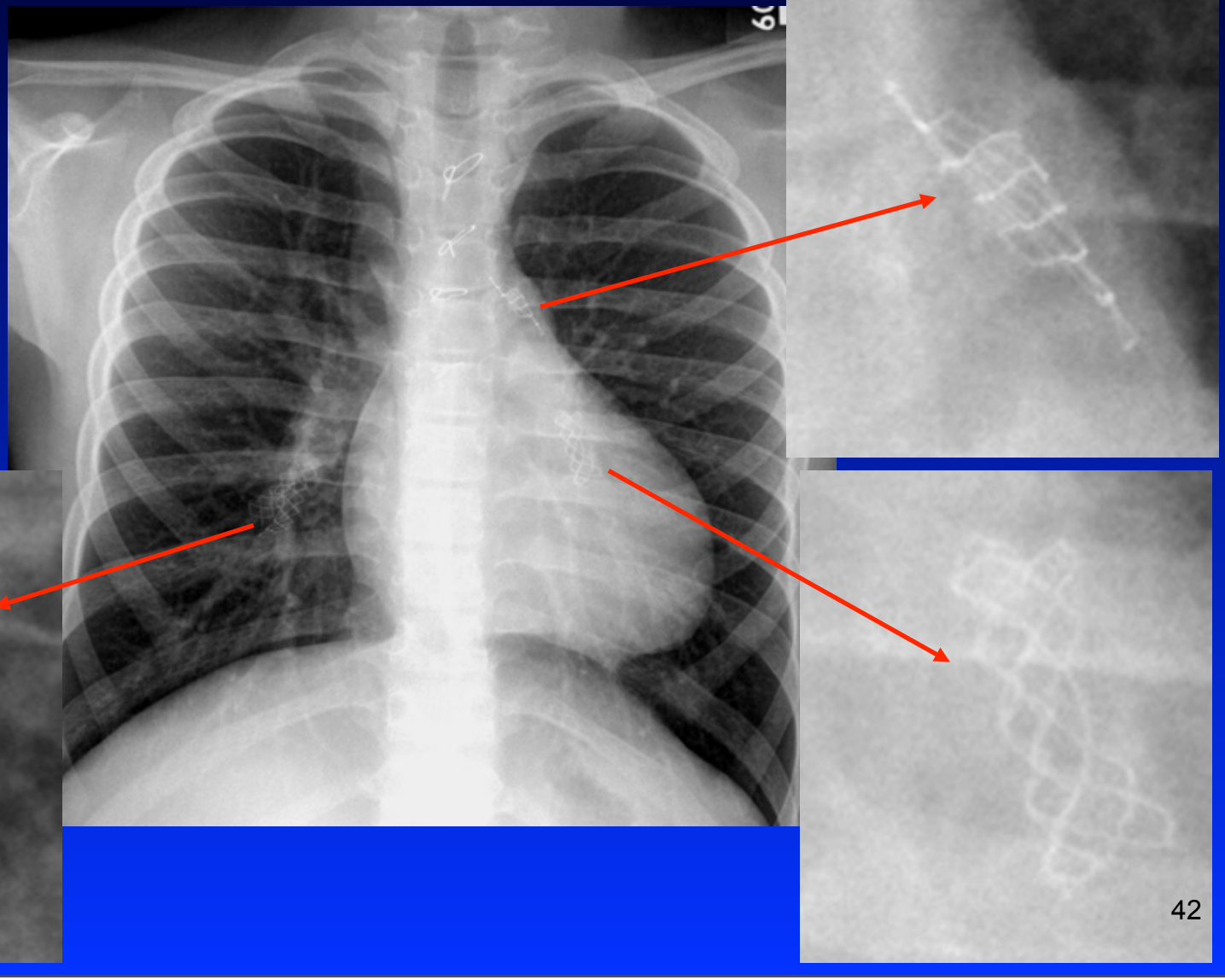
2 month F/u CXR

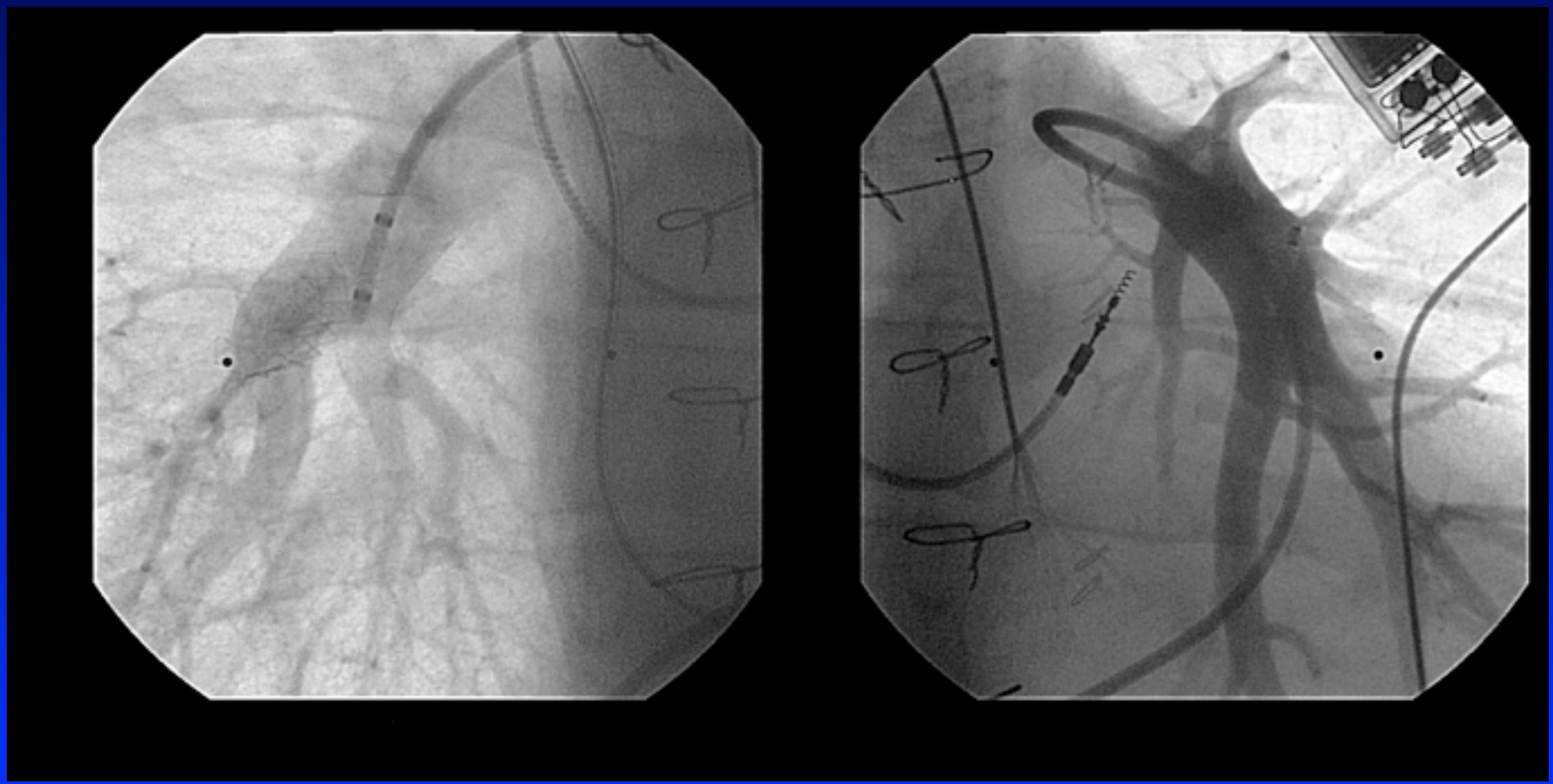


10 yr F/U cath still no flow obstruction

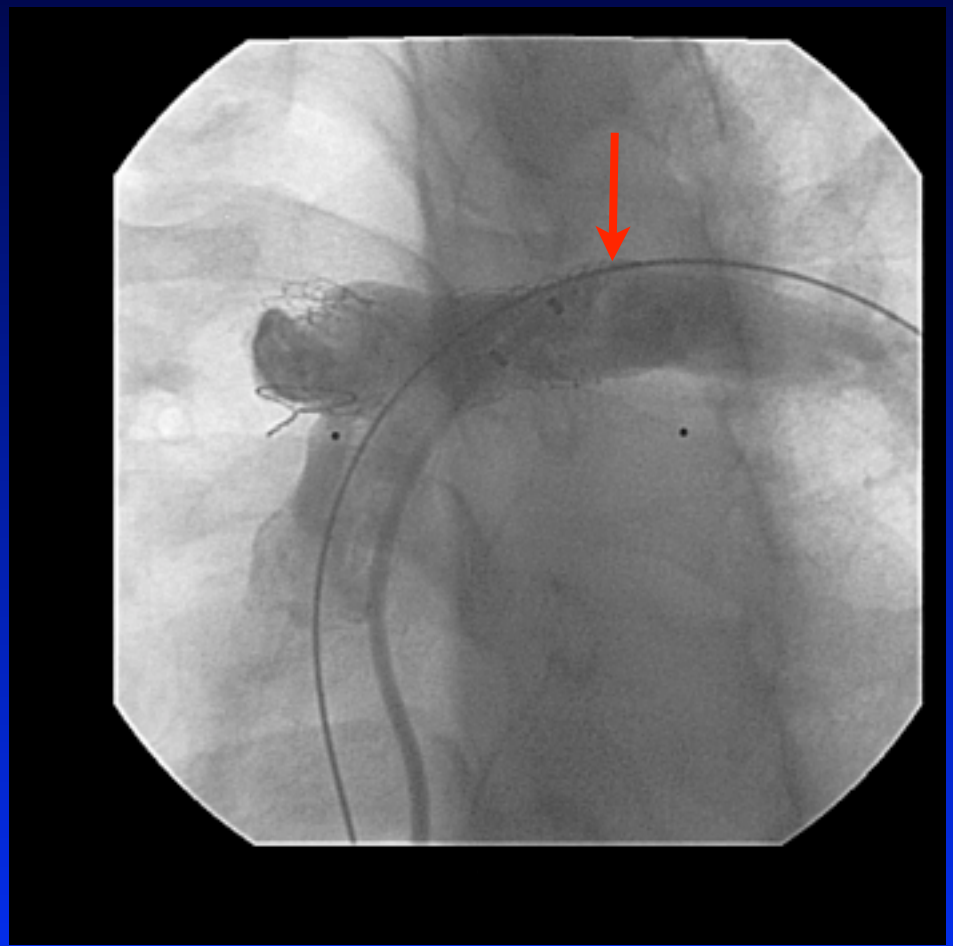
June. 2008

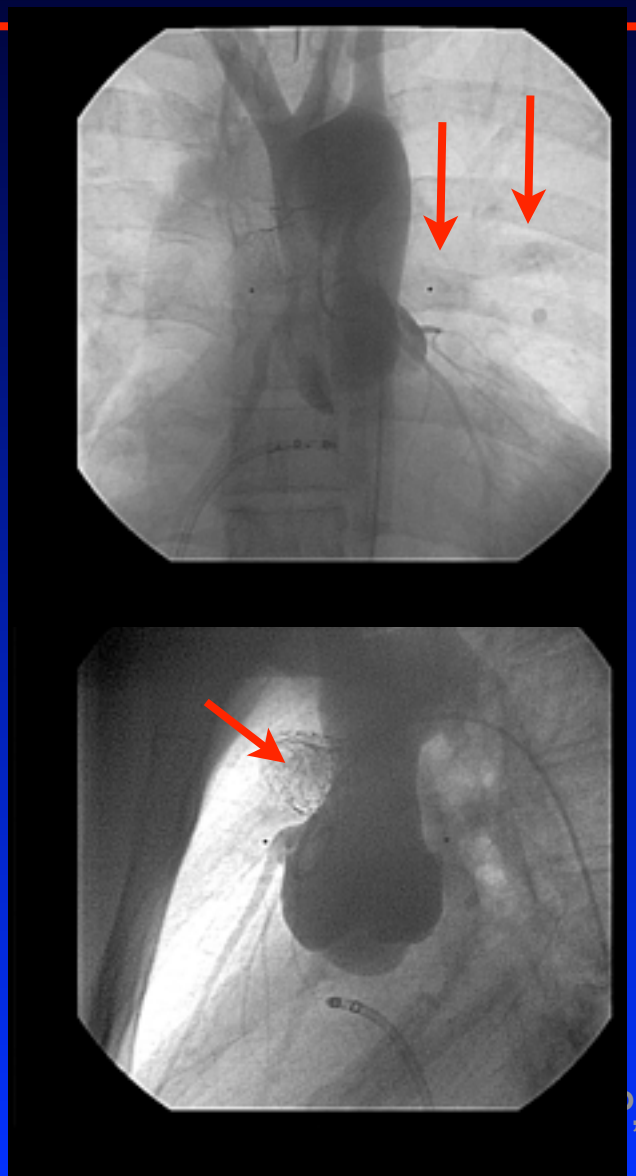
RPA

LPA

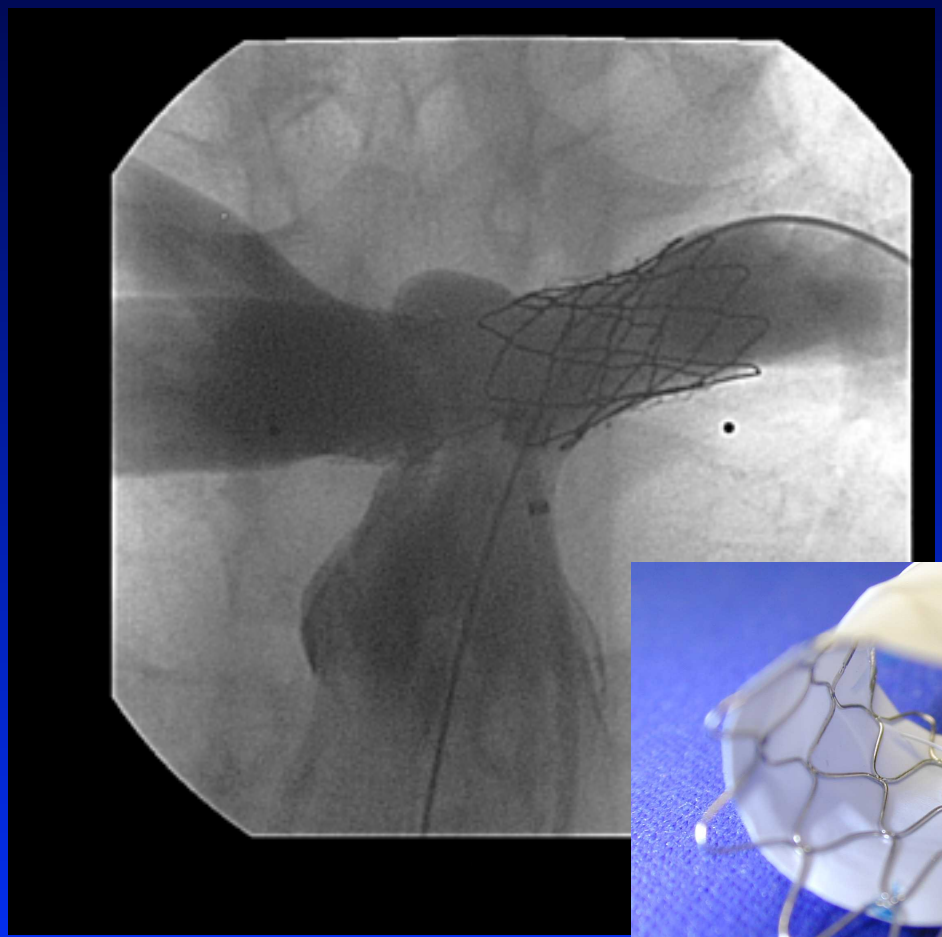


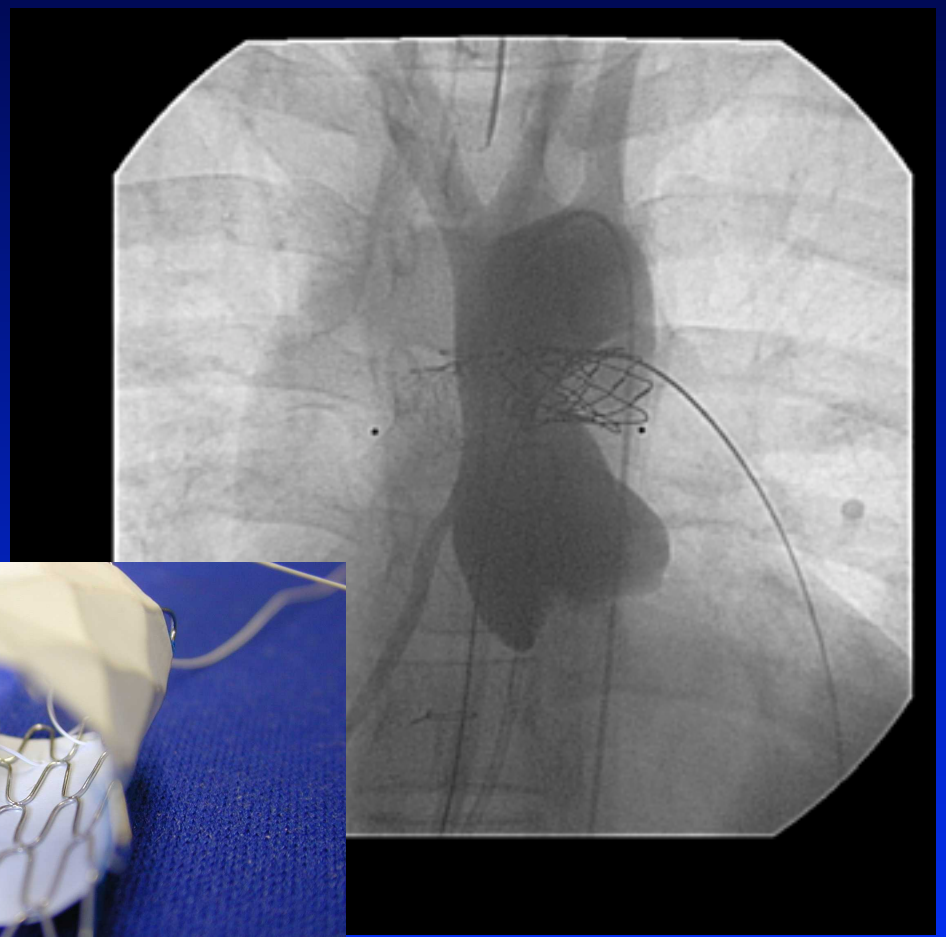
LPA dissection into asc aorta post redilation

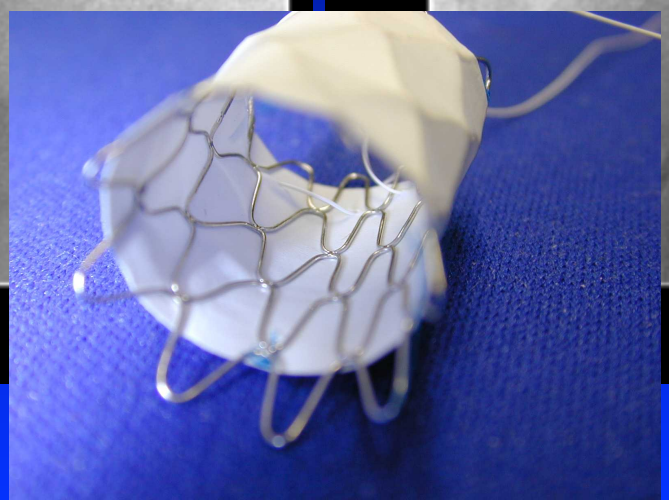




S/P covered stent







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Infant stent studies

Frazer J, Ing FF. Pulmonary artery stents in infants and small children ≤12 kg: short and mid-term results (World Congress 2009)

	≤ 12 kg	≤ 8 kg
• Patients (1998-2008)	64	31
• Vessels	83	38
• Median age (years)	1.1 (0.1-3.2)	0.6 (0.1-1.6)
• Median weight (kg)	8.2 (3.3-12.0)	5.9 (3.3-8.0)
• Prior CHD surgery	100%	100%
– Surgical PA patch plasty	28 (34%)	18 (47%)
– Balloon PA angioplasty	10 (12%)	5 (11%)
– No prior PA treatment	50 (60%)*	17 (45%)*
Total vessels	83(100%)	38(100%)

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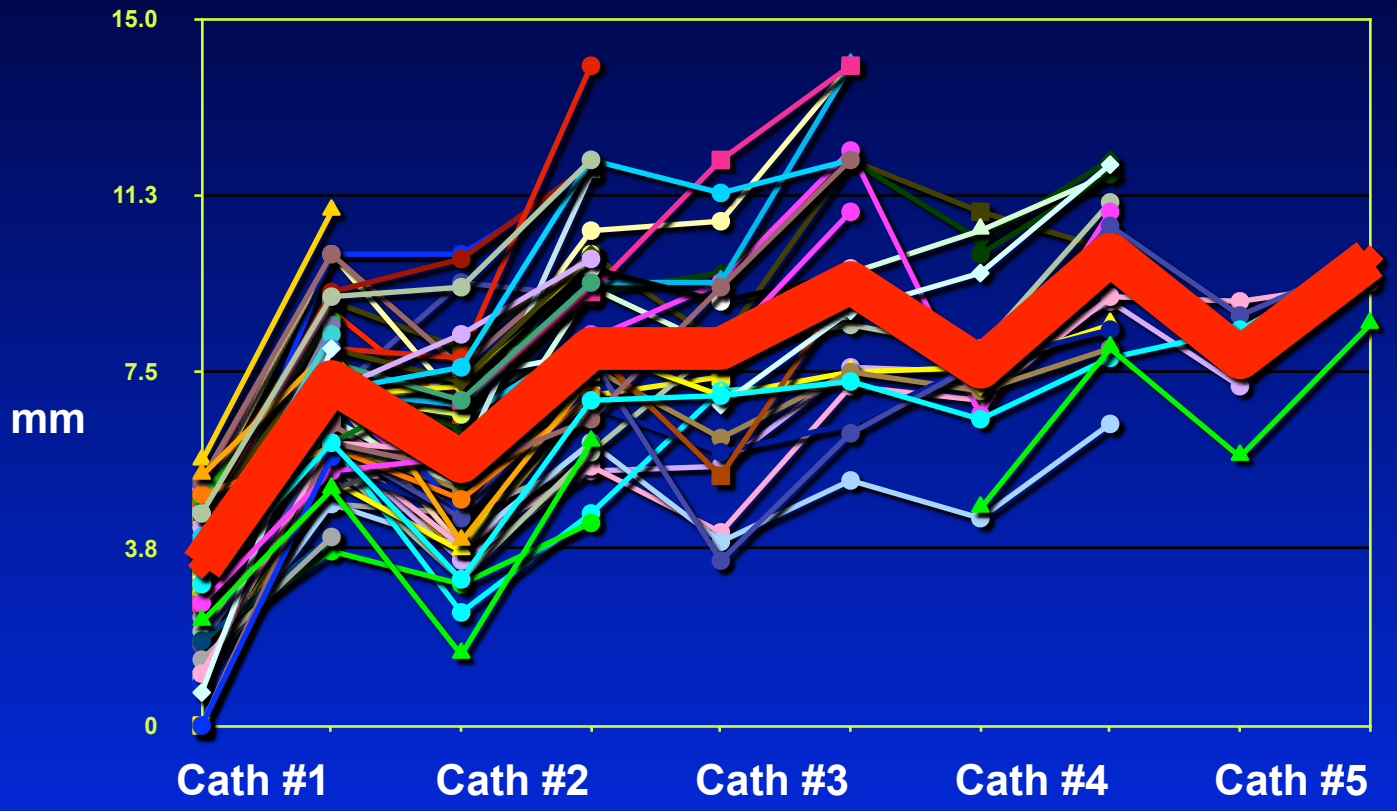
All patients-PA diameters



Pre-3.4 mm → **Post-10.0 mm**

6+ years

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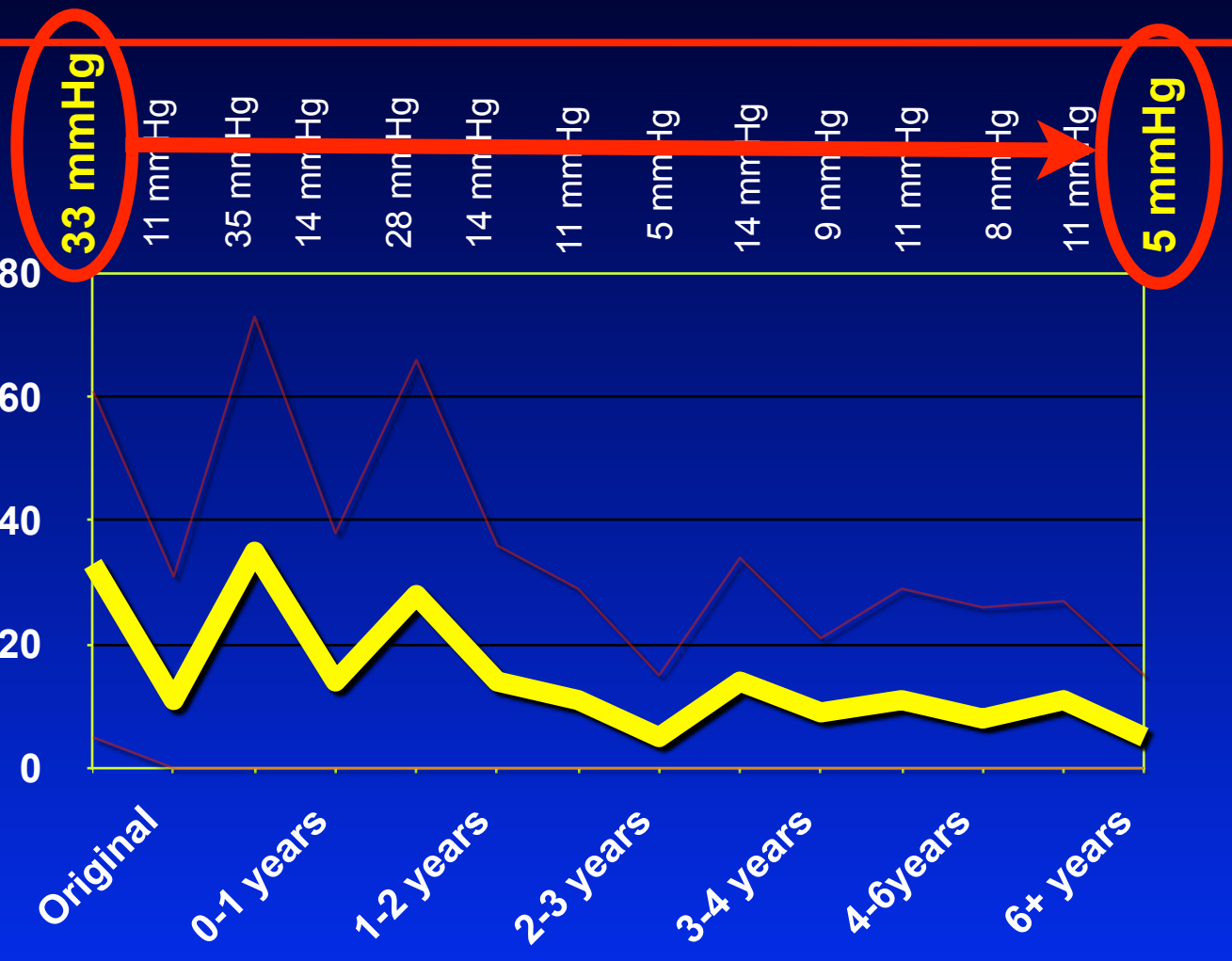
Gradient



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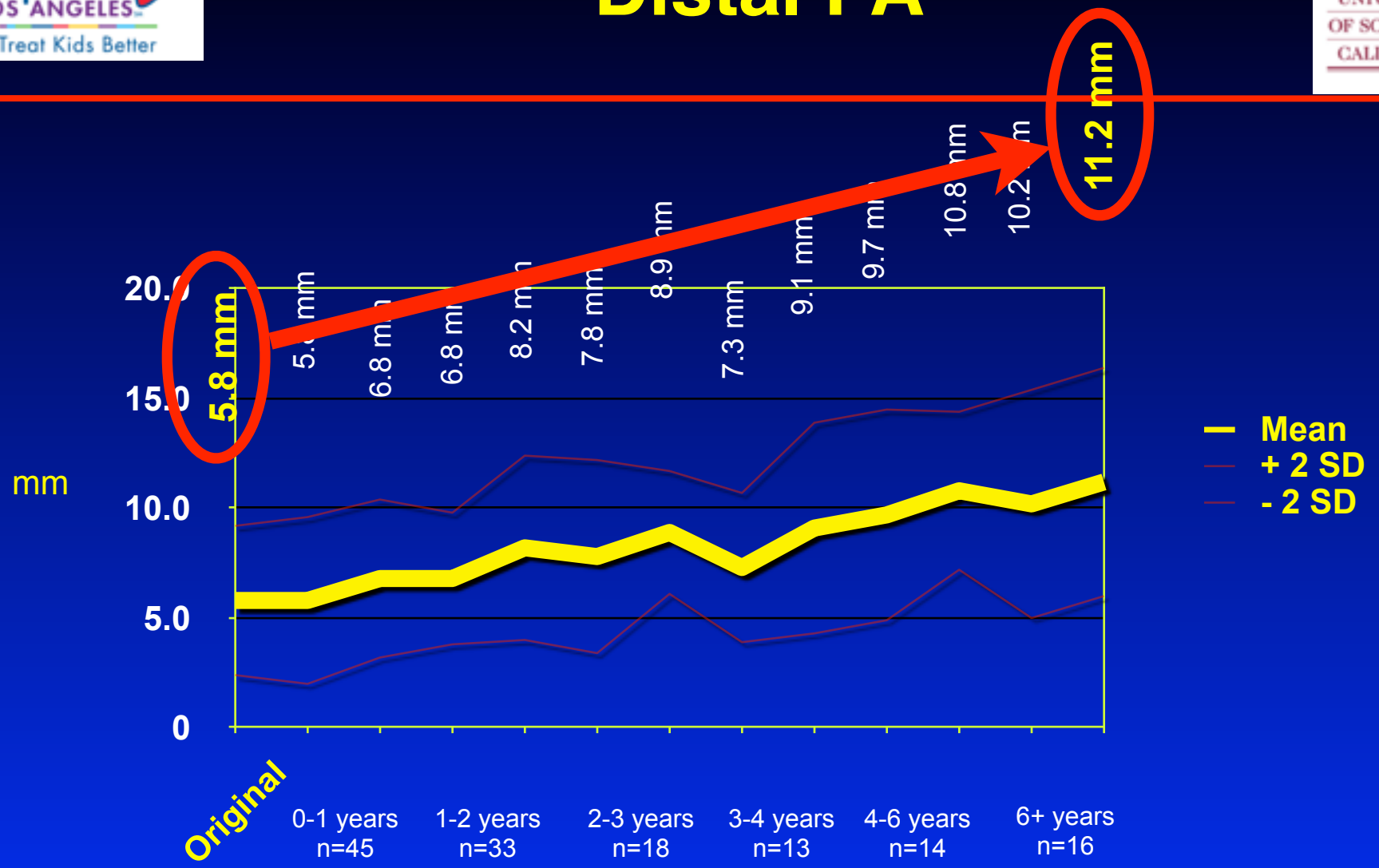
Distal PA



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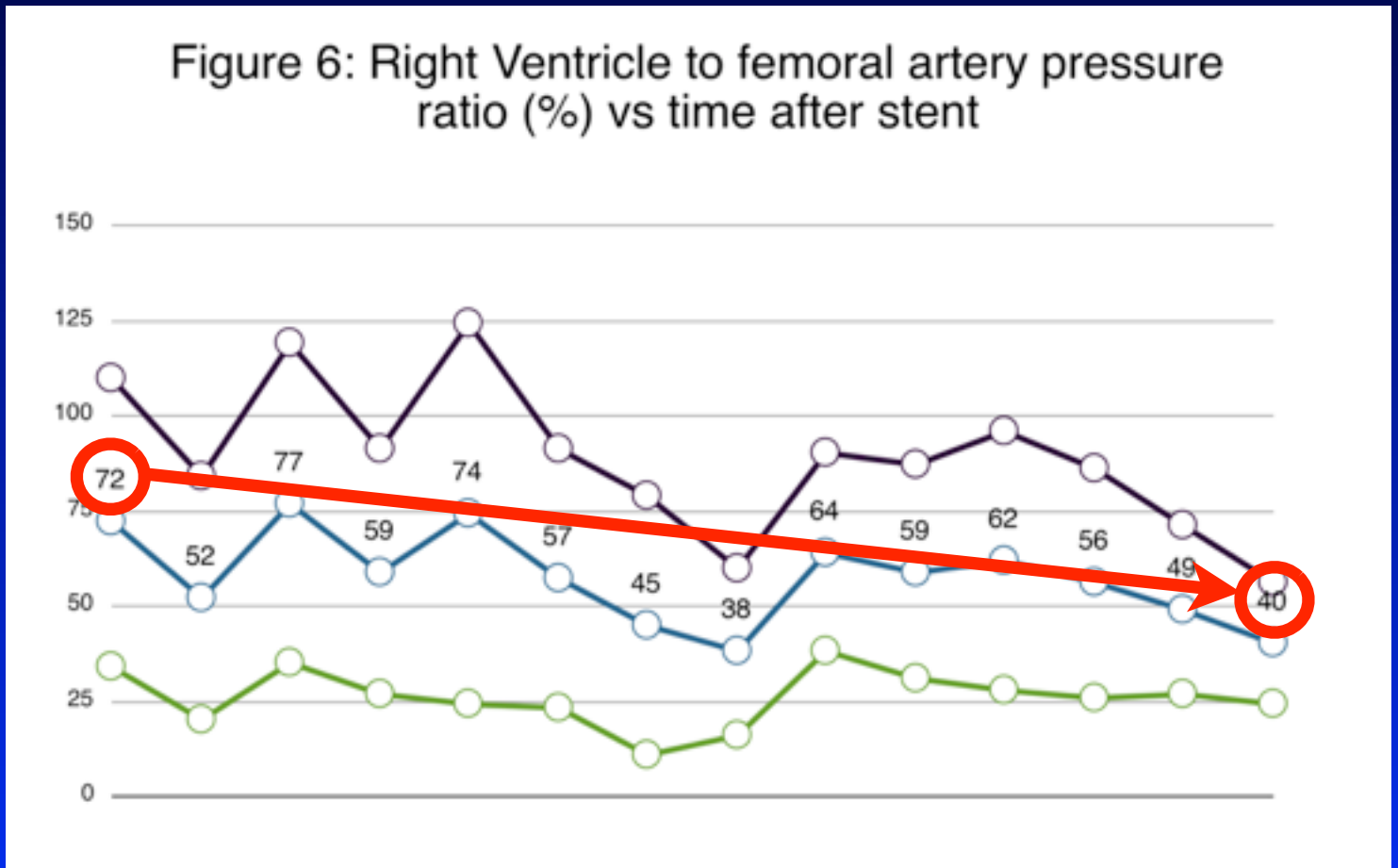
RV/FA ratio



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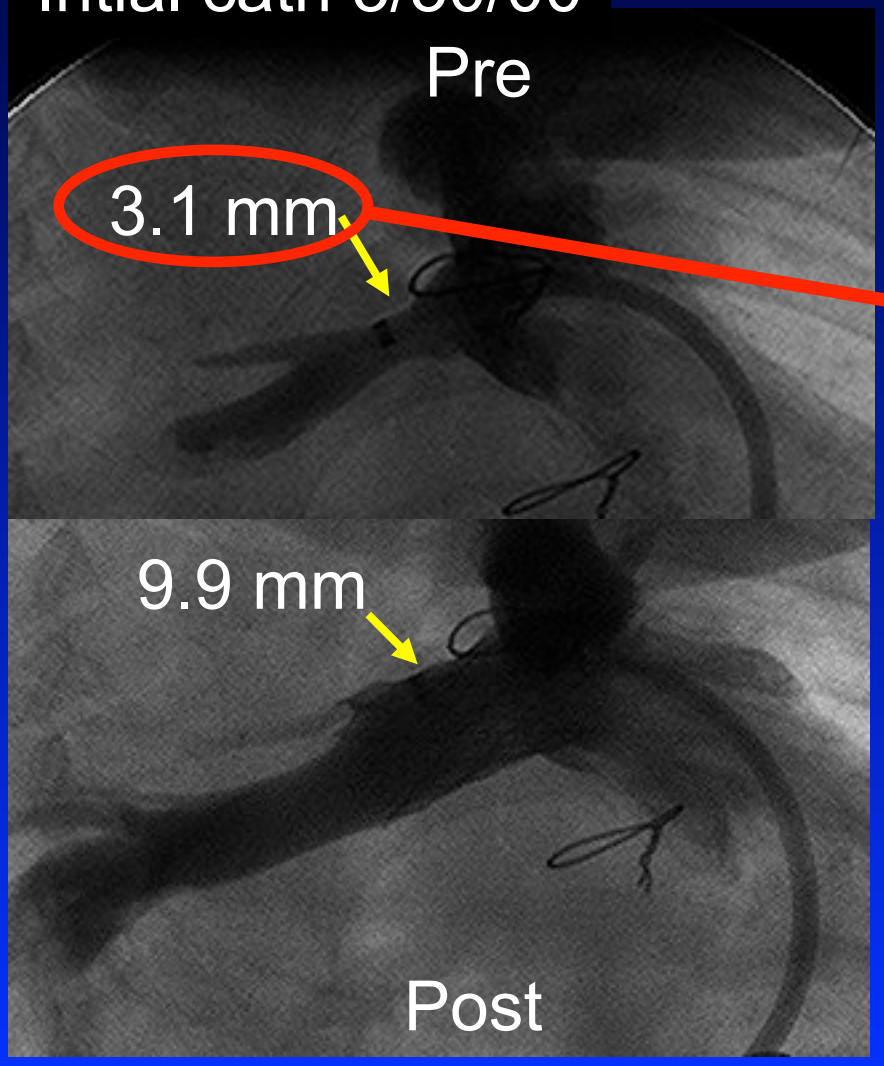
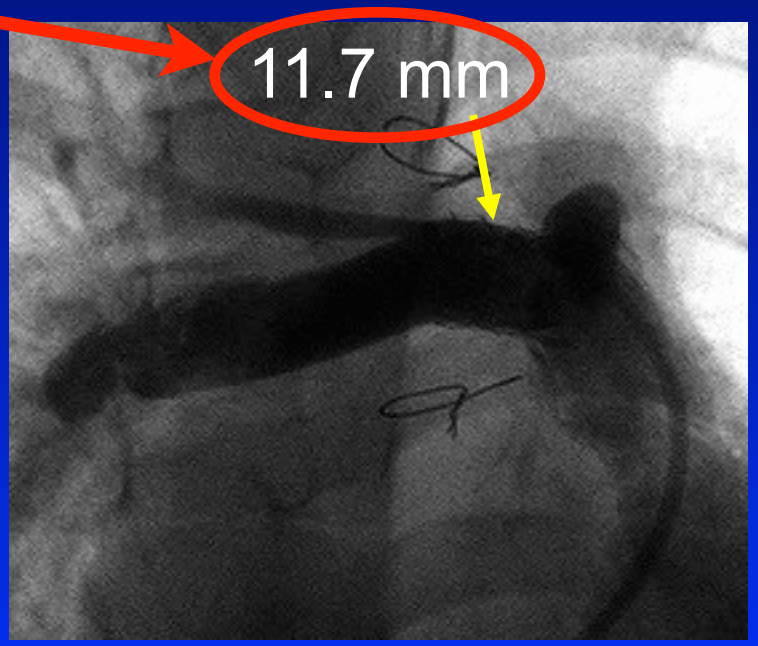
13 m (5.4 kg) old truncus, s/p repair, w/ stented RPA

Intial cath 3/30/00



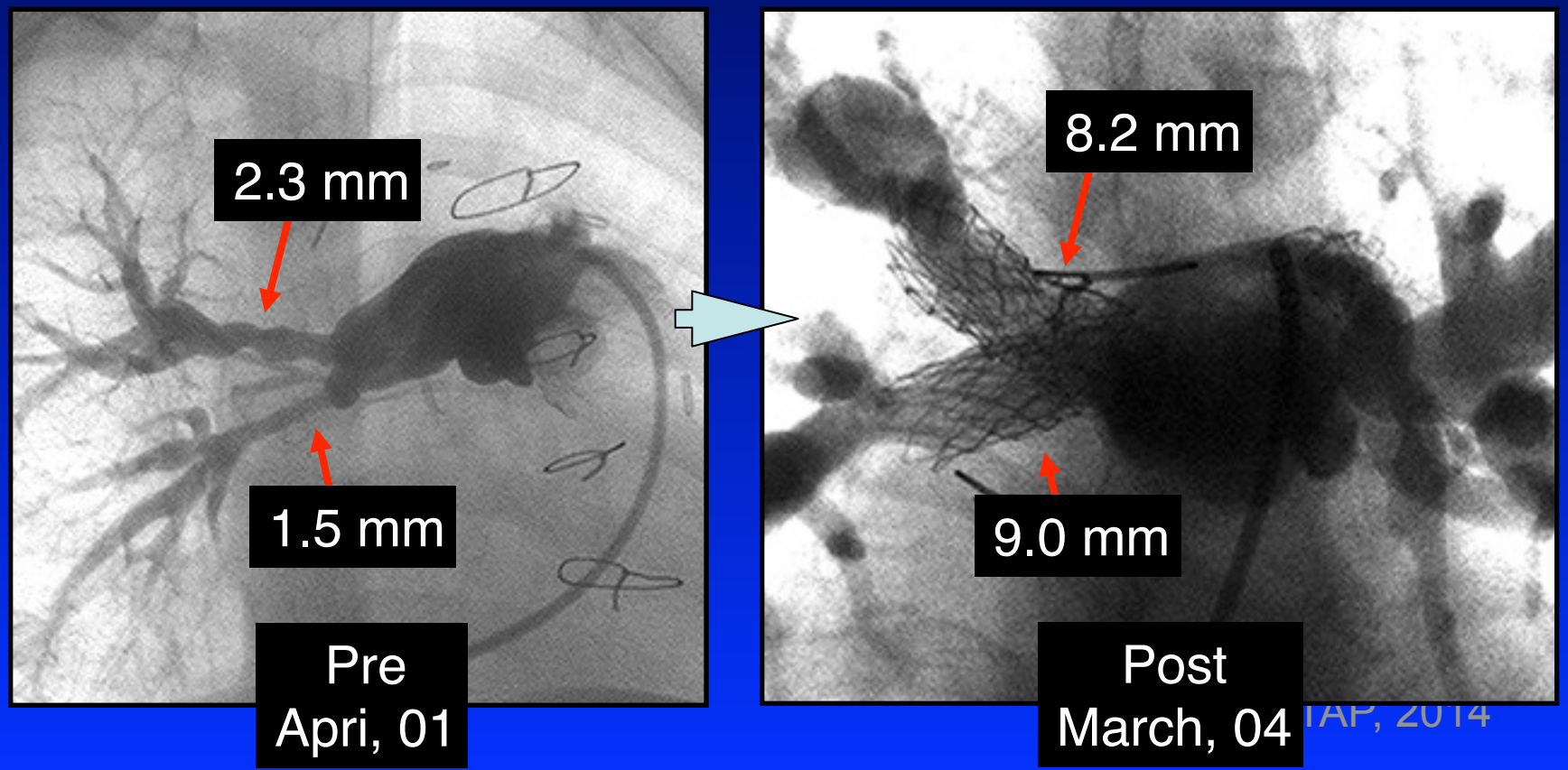
F/U cath 7/8/04
Further dilation
4 1/2 years



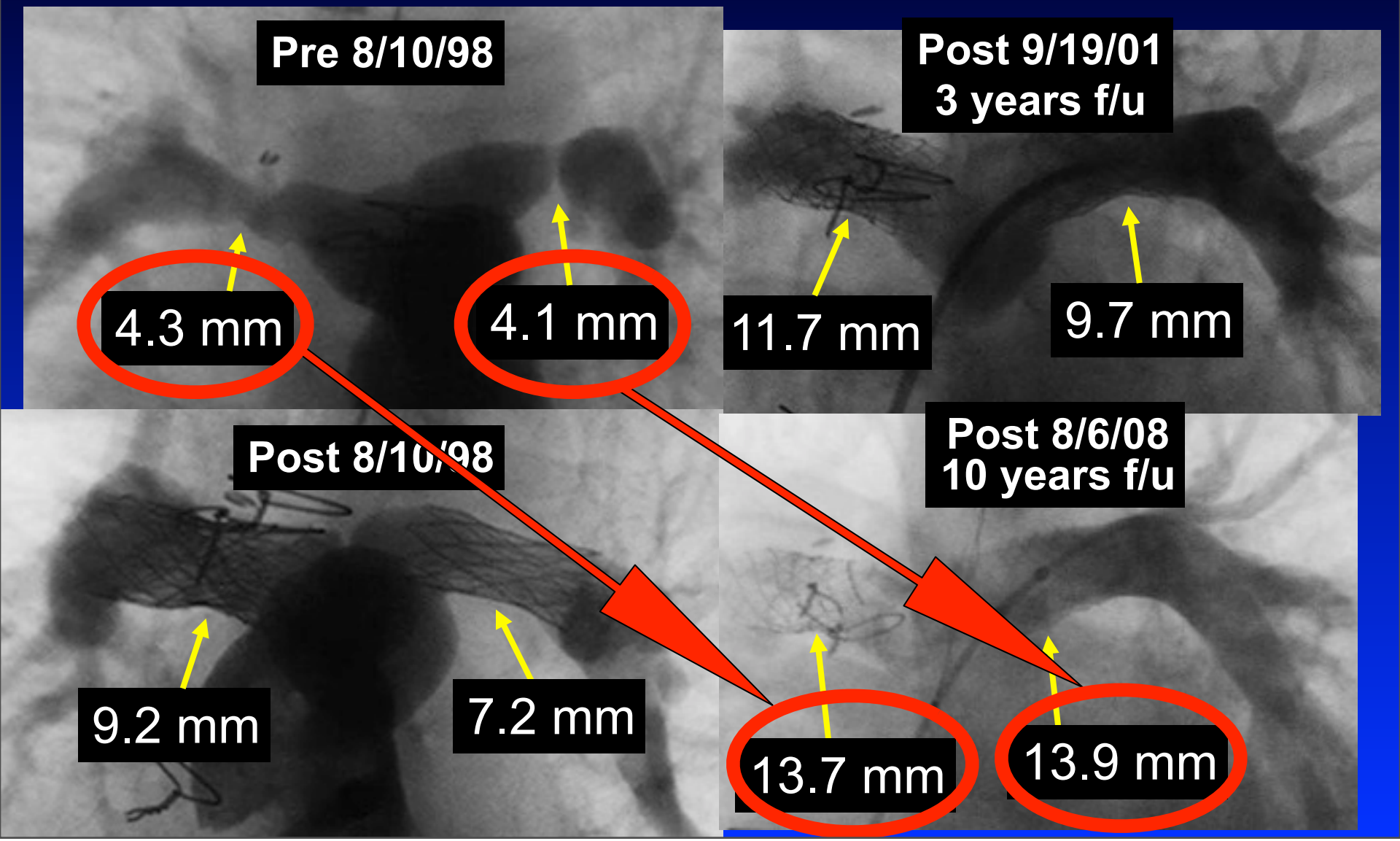
Ing-TCTAP, 2014

Comparison of branch PAs 35 month and 4 caths later

1.6 yr old (wt 8.2 kg) PA/VSD/AP collaterals s/p unifocalization & RV-PA conduit with bilateral severe branch PS



Growth of stented PA after 10 years

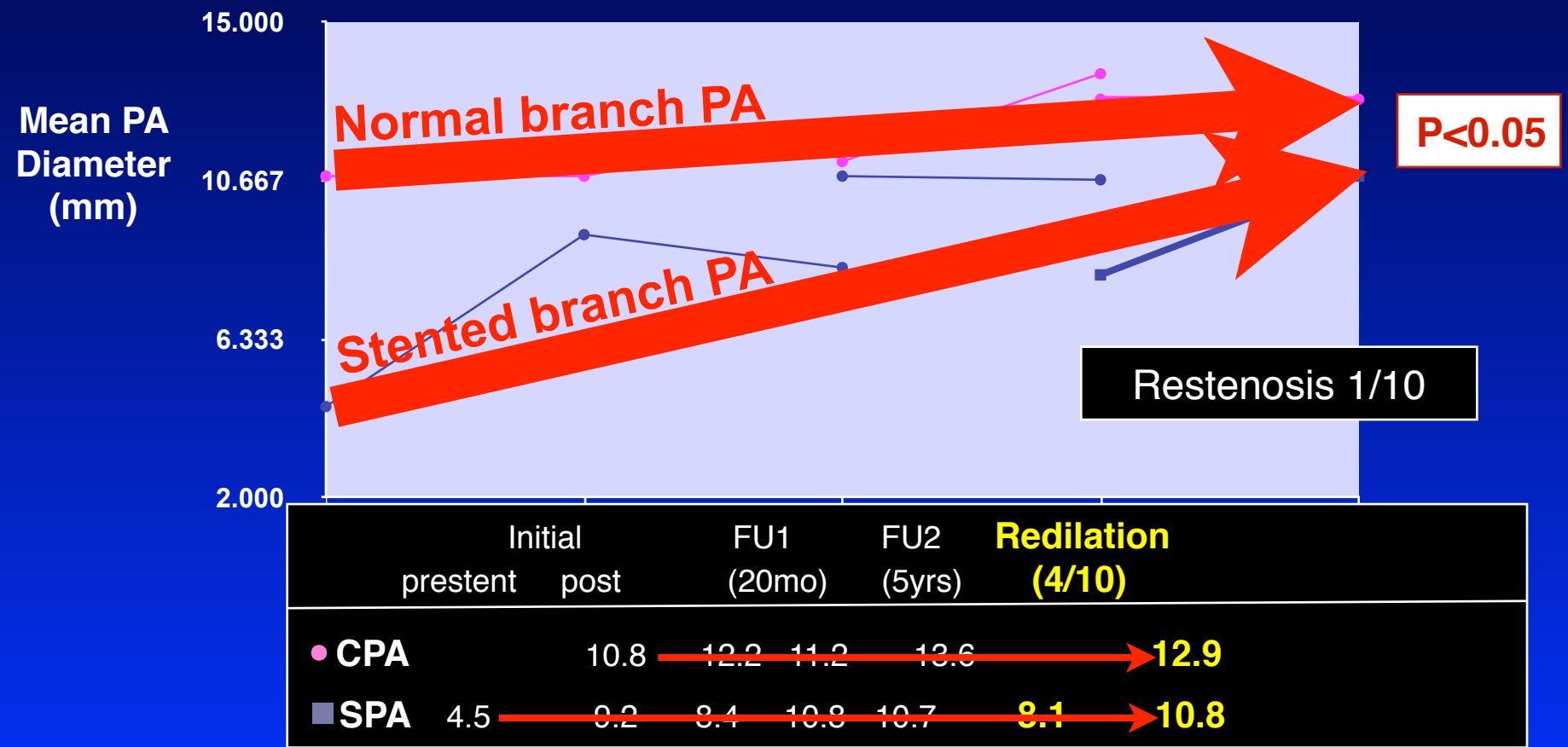


Distal pulmonary artery growth?

- 1998-2009: Compared growth of stented PA to contralateral unstented PA (N=39)
- Single ventricle: N=18
  - Mean age 3.5yrs (range 4.6mo-32yrs)
  - Mean wt 13.8kg (range 4-86kg)
- Two-ventricle: N=21
  - Mean age 4.8yrs (4.5mo-17yrs)
  - Mean wt 16.4kg (5.4-56kg)

Takao CM, Hamzeh RK, Connolly D, **Ing FF**. Impact of Stent Implantation on Pulmonary Artery Growth- *Catheterization and Cardiovascular Interventions* – 2012 Oct 16. doi: 10.1002/ccd.24710.

Two Ventricle
Main Branch PA F/U 2



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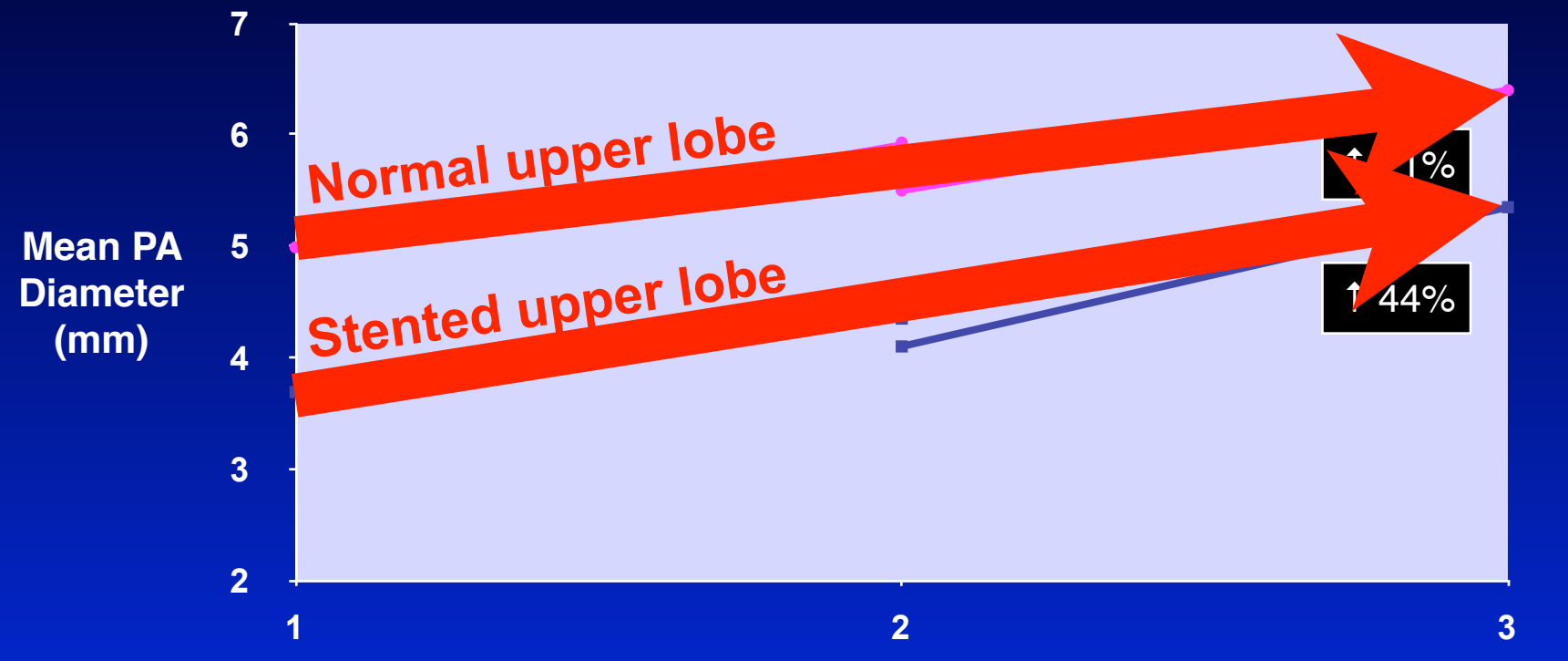
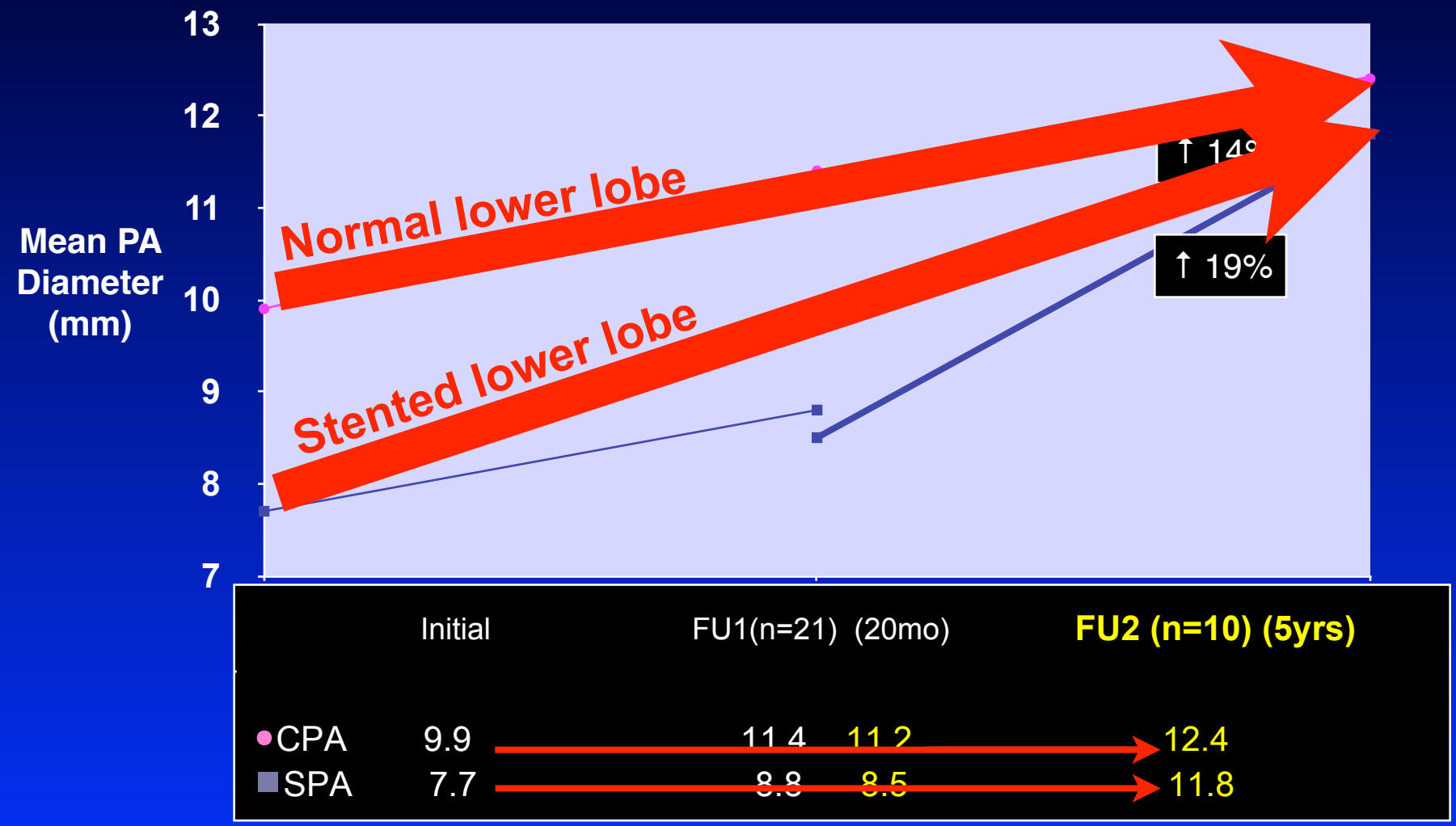
Two Ventricle Upper Lobe PA F/U 2



	Initial	FU1(n=18) (20mo)	FU2 (n=7) (5yrs)
CPA	5.0	5.9 5.5	6.4
SPA	3.7	4.5 4.1	5.4

Two Ventricle Lower Lobe PA F/U 2



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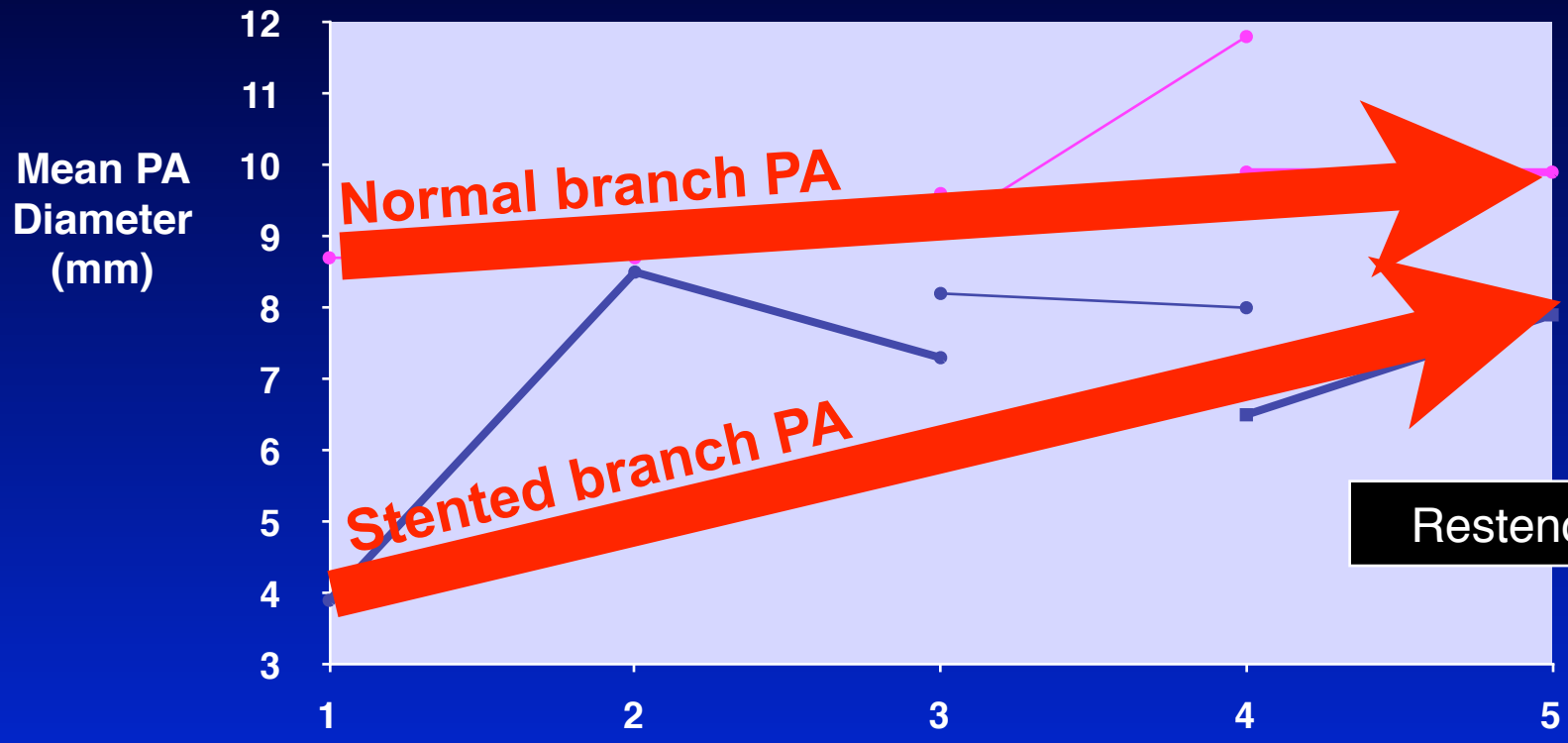
Single Ventricle
Main Branch PA F/U 2



	Initial prestent	Initial post	FU1 (14mo)	FU2 (3.9yrs)	Redilation (4/11)
CPA		8.7	9.6	9.1	11.8 → 9.9
SPA	3.9	8.5	7.3	8.2	8.0 → 6.5 → 7.9

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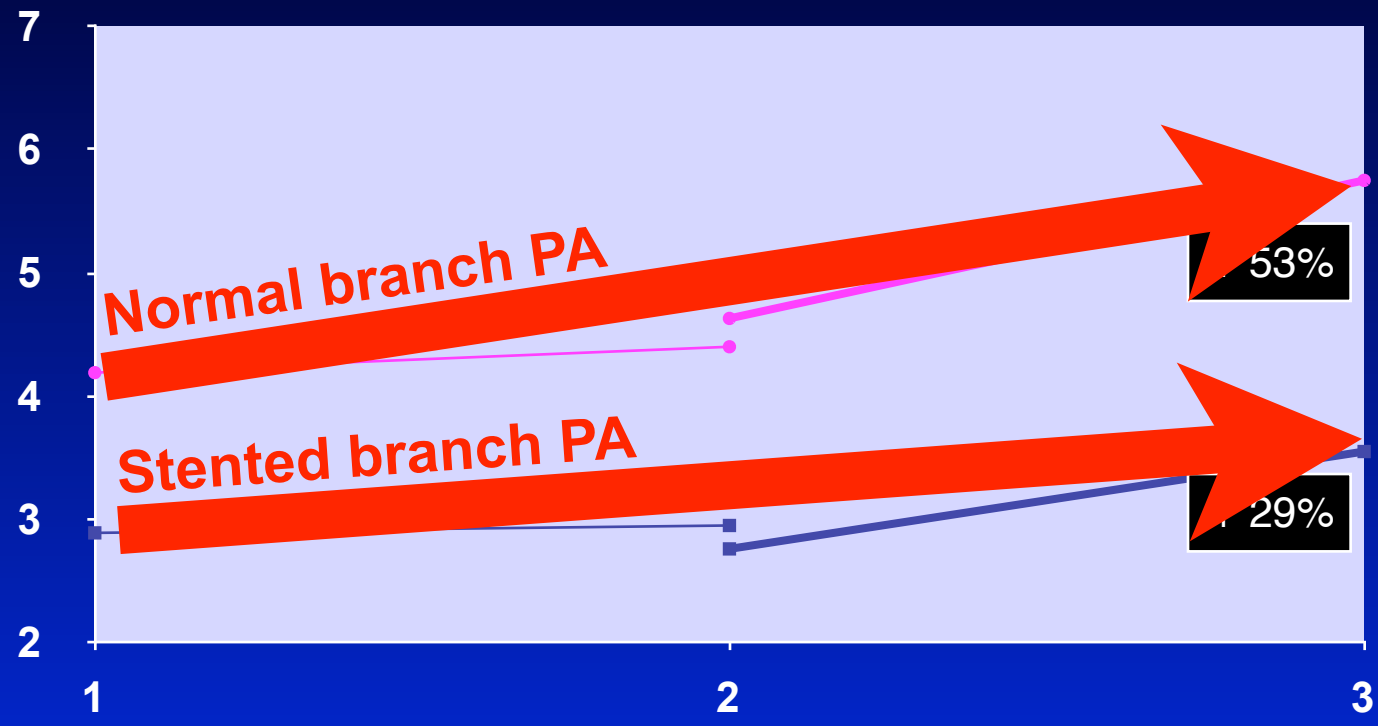
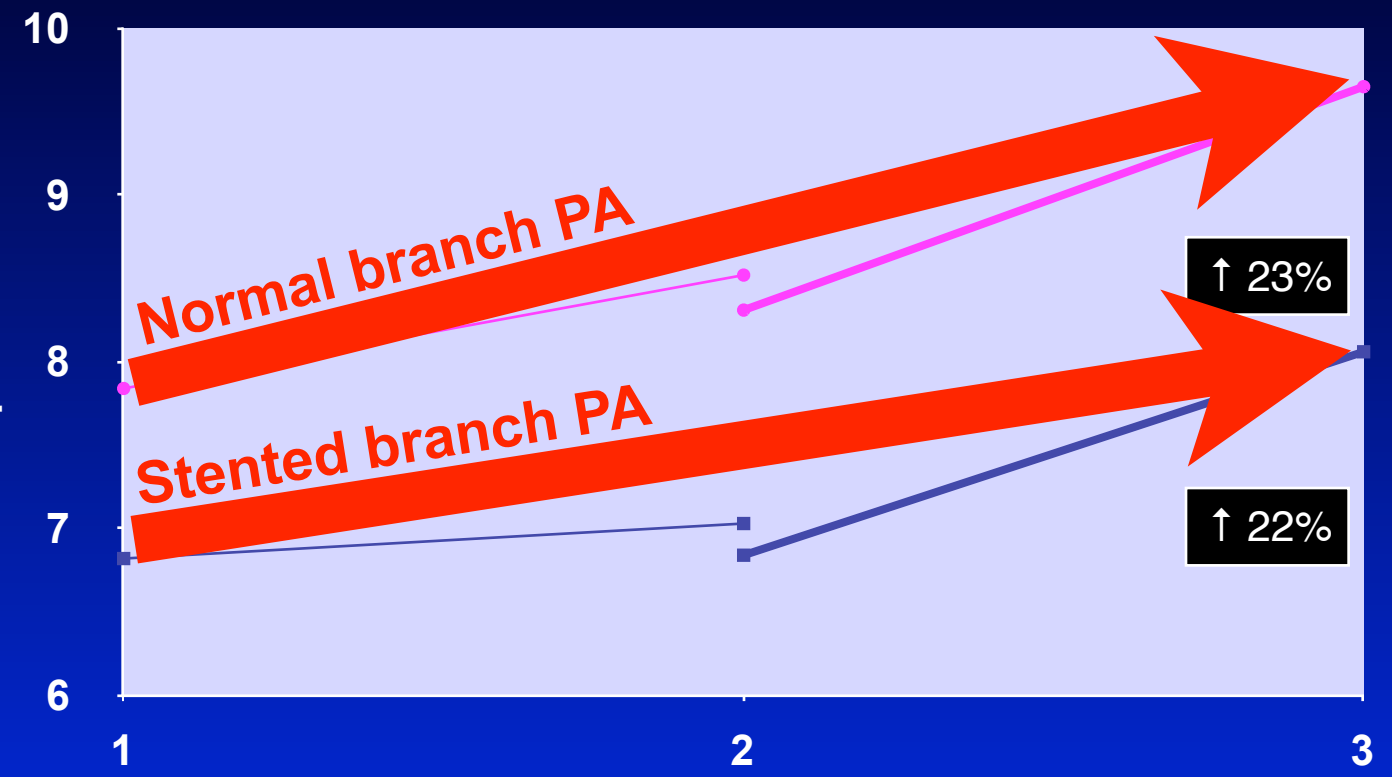
Single Ventricle
Upper Lobe PA F/U 2



	Initial	FU1(n=15) (14mo)	FU2 (n=11) 3.9yrs
CPA	4.2	4.4 4.6	5.8
SPA SPA	2.9	3.0 2.8	3.6

Single Ventricle Lower Lobe PA F/U 2



	Initial	FU1(n=18) (14mo)	FU2 (n=11) 3.9yrs
•CPA	7.8	8.5 8.3	9.7
■SPA	6.8	7.0 6.8	8.1

- Correlation analysis showed lower weight at time of stent implantation was associated with better growth of the stented lower lobar branch (p=0.05).
- Younger age and lower body surface area at time of stent implantation trended towards better growth of the stented lower branch at near significant levels with p=0.06 and p=0.07 respectively.

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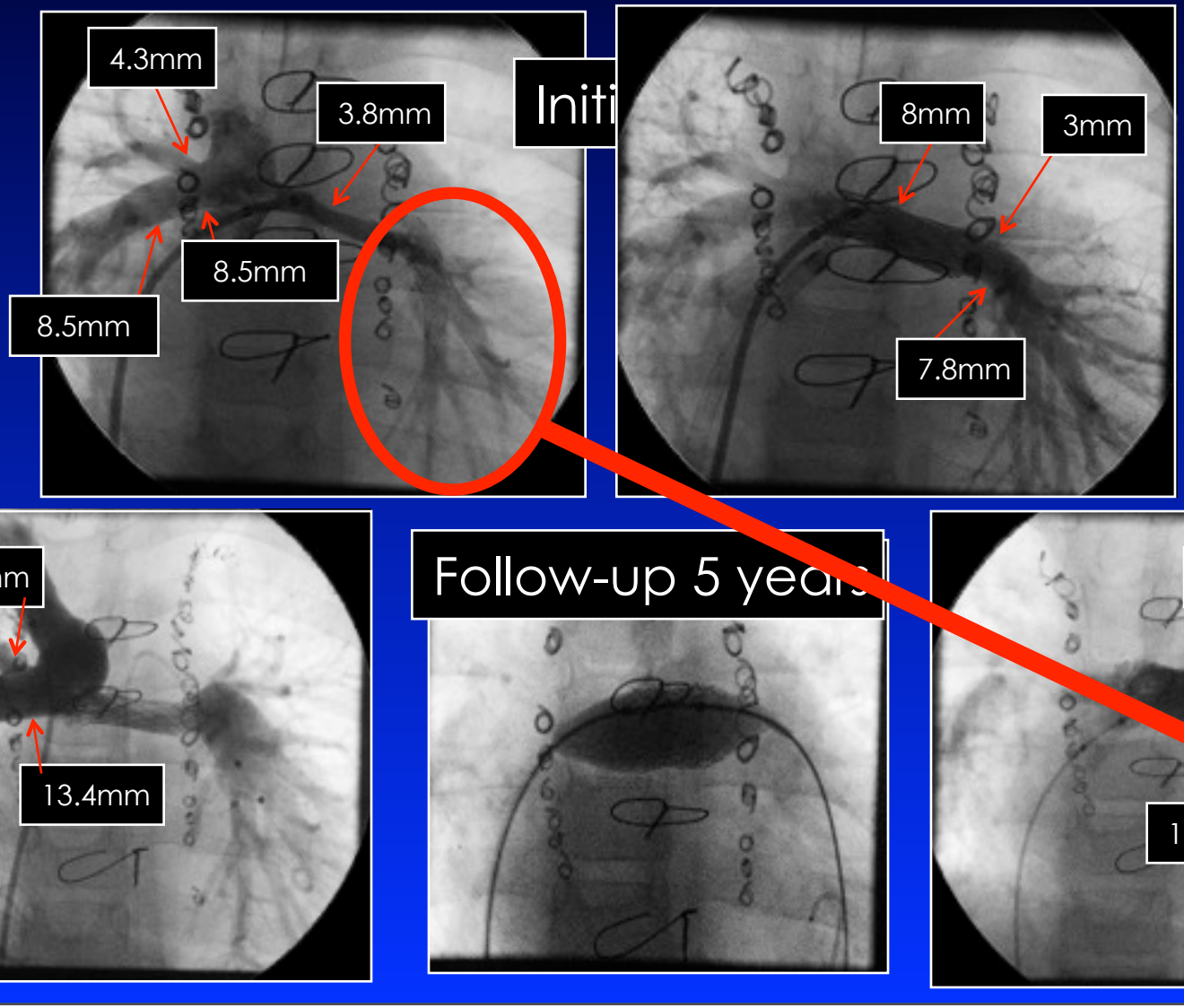
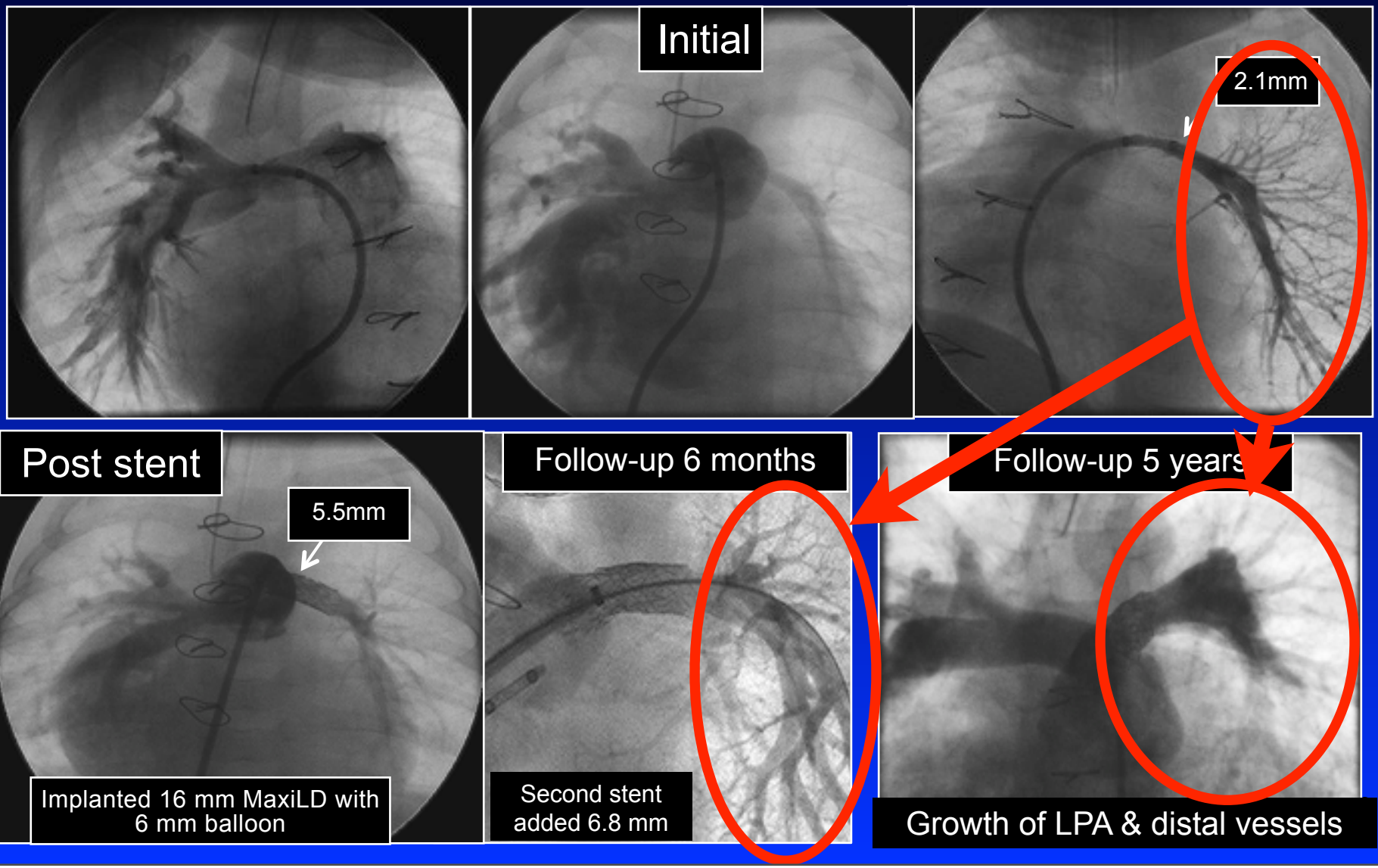
20 mo old HLHS s/p Fontan with LPA stenosis-stented



4.8 mo old (6.2 kg) pt, 3.5 months S/P TOF repair w/ LPA hypoplasia-stented



Long-term F/U: Summary

- Stent implantation is an effective technique to treat various vascular stenoses in CHD
- In general, long-term data to date (15 years) indicates there is long-lasting relief of stenoses by implanted stents, especially in branch PAs and COA
- In adults, relief of PA stenoses by stents preserves RV function, improves quality of life and avoids further surgery due to BPS alone even if there was initial jailing and compromised flow to a side branch
- For COA, there is long term morbidities

Long-term F/U: Summary

- Restenosis occur at very low rates (intimal proliferation, stent fracture or at adjacent unstented segments)
- Stents can be redilated or additional stents added without additional surgery
- In growing children, further dilation to adult size is possible to date, but rare complications can occur (dissection with aneurysm formation or rupture)