A New Concept in the Surgical Treatment of ToF Using An Injectable Pulmonic Valve for Total Primary Repair

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Pulmonary Valve

- Underestimated for a long time since the beginning of Pediatric Cardiac Surgery
  - Procedure of choice = Transannular patch
  - Pulmonary regurgitation = «collateral damage»

- Surgical history, experience and Follow-Ups have shown its fundamental importance
  - Right ventricular pathophysiology and evolution

- Nowadays keynote element in any RVOT surgical procedure
  - Procedure of choice = Valve sparing

Valve Sparing

- **Seldom easy - Sometimes impossible**
  - Too small diameter -> Need for enlargement -> Transannular patch
  - Altered anatomy -> Need for repair -> Consider feasibility and result
- **Which strategy when valve sparing is impossible or not promising?**

Solutions

Forget – Tolerate - Restore

- **Restore «valvular function»**
  - Monocusp, Valved conduit, Valvular prosthesis
- **Limited lifetime**
  - Kind of device and patient characteristics
- **Additional issues in children**
  - Valvular prosthesis -> None available for small babies
  - Growth-related mismatch -> Shorter lifetime -> Reoperations

Injectable Pulmonary Valve

- Biological, self-expanding, injectable
- Developed for secondary valving in adults
- By now 250 implants with very promising results
- May it be useful for primary RVOT surgery?
- May it solve or reduce growth-related mismatch?

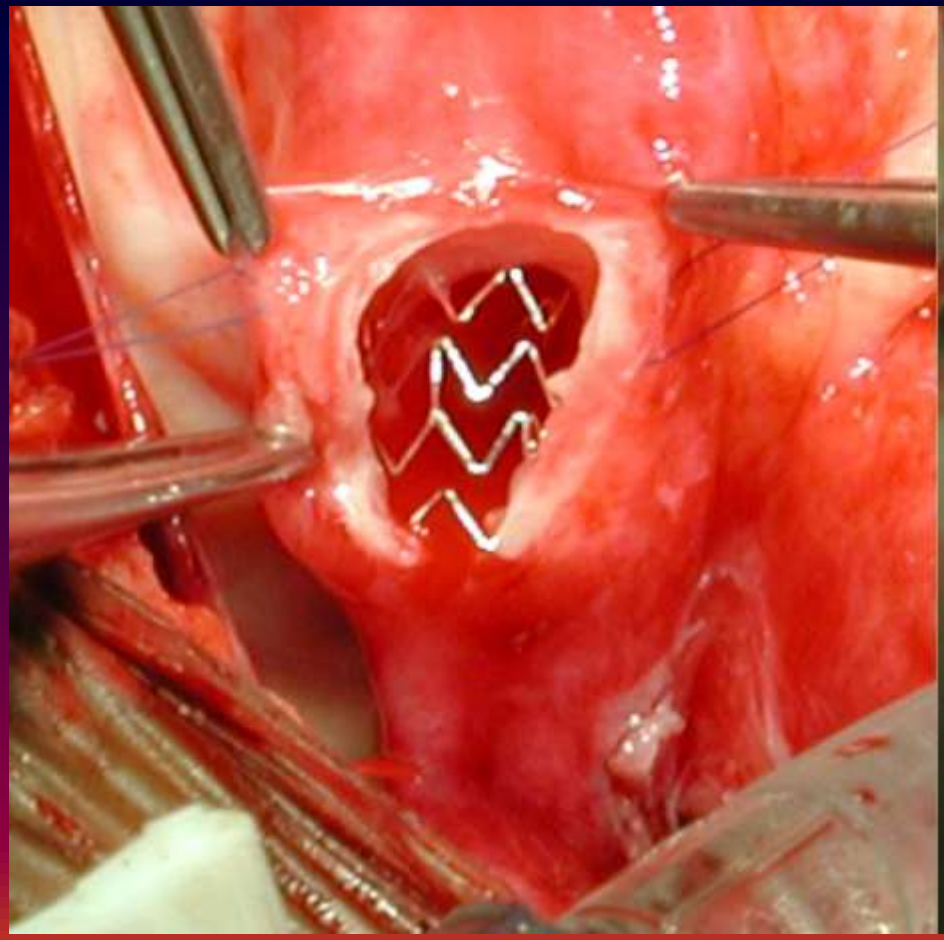
Probably Yes

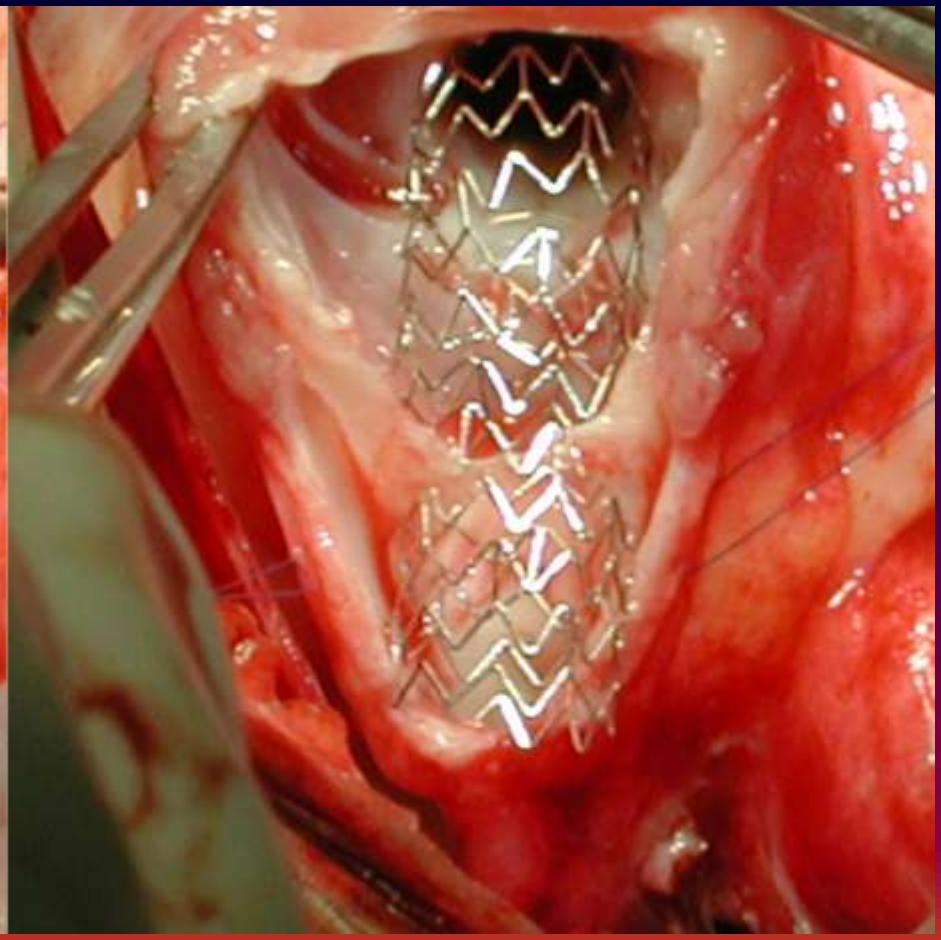
1. Oversize the RVOT
   - According to patient's anatomy

2. Oversize the prosthesis
   - Prosthesis shrinked in the RVOT

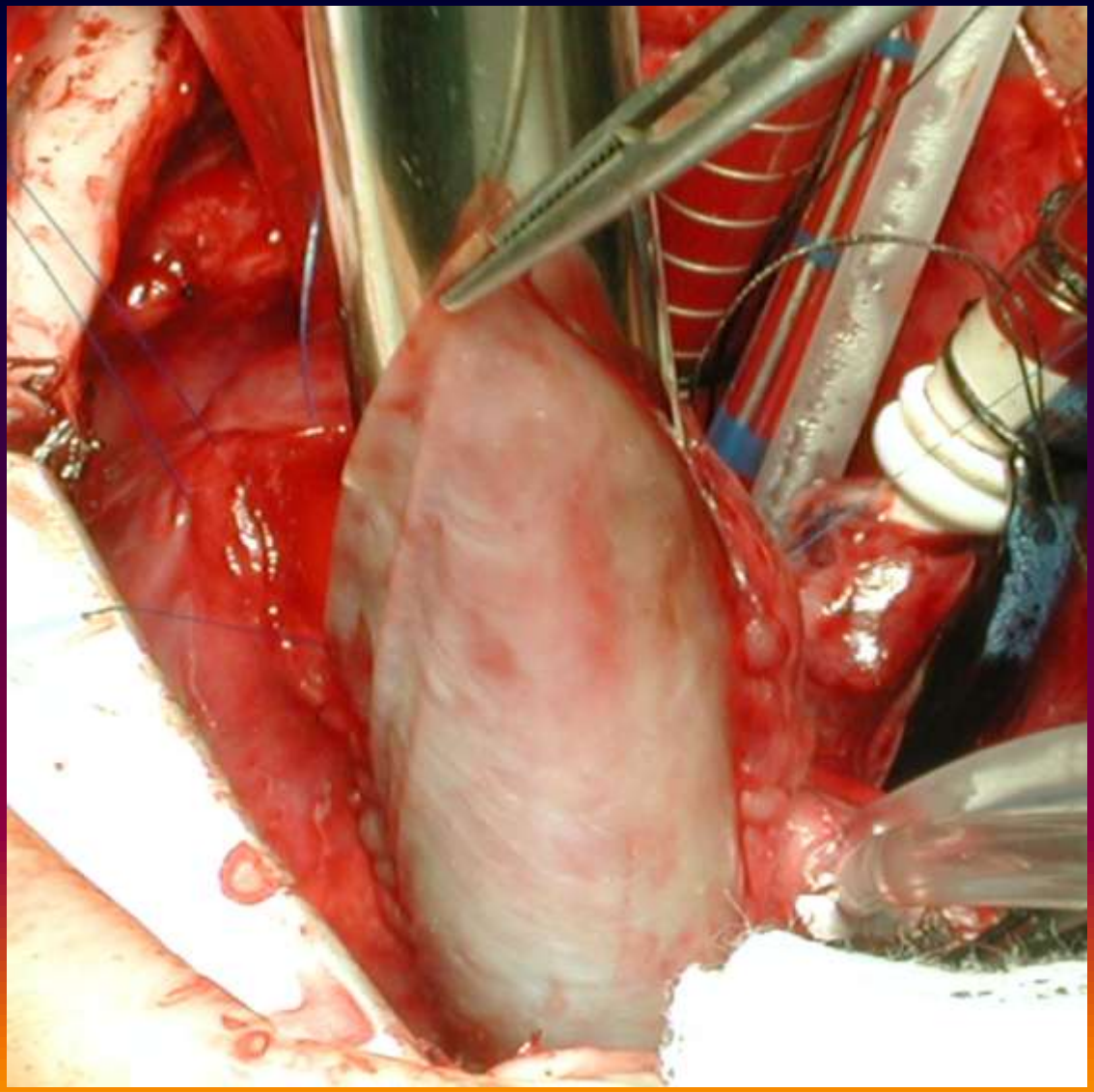
- RVOT dimension anticipates patient growth
- Oversized prosthesis is initially not completely expanded
- RVOT grows -> Prosthesis completes its expansion process
- Prosthesis follows RVOT growth

Infundibular Opening - ToF

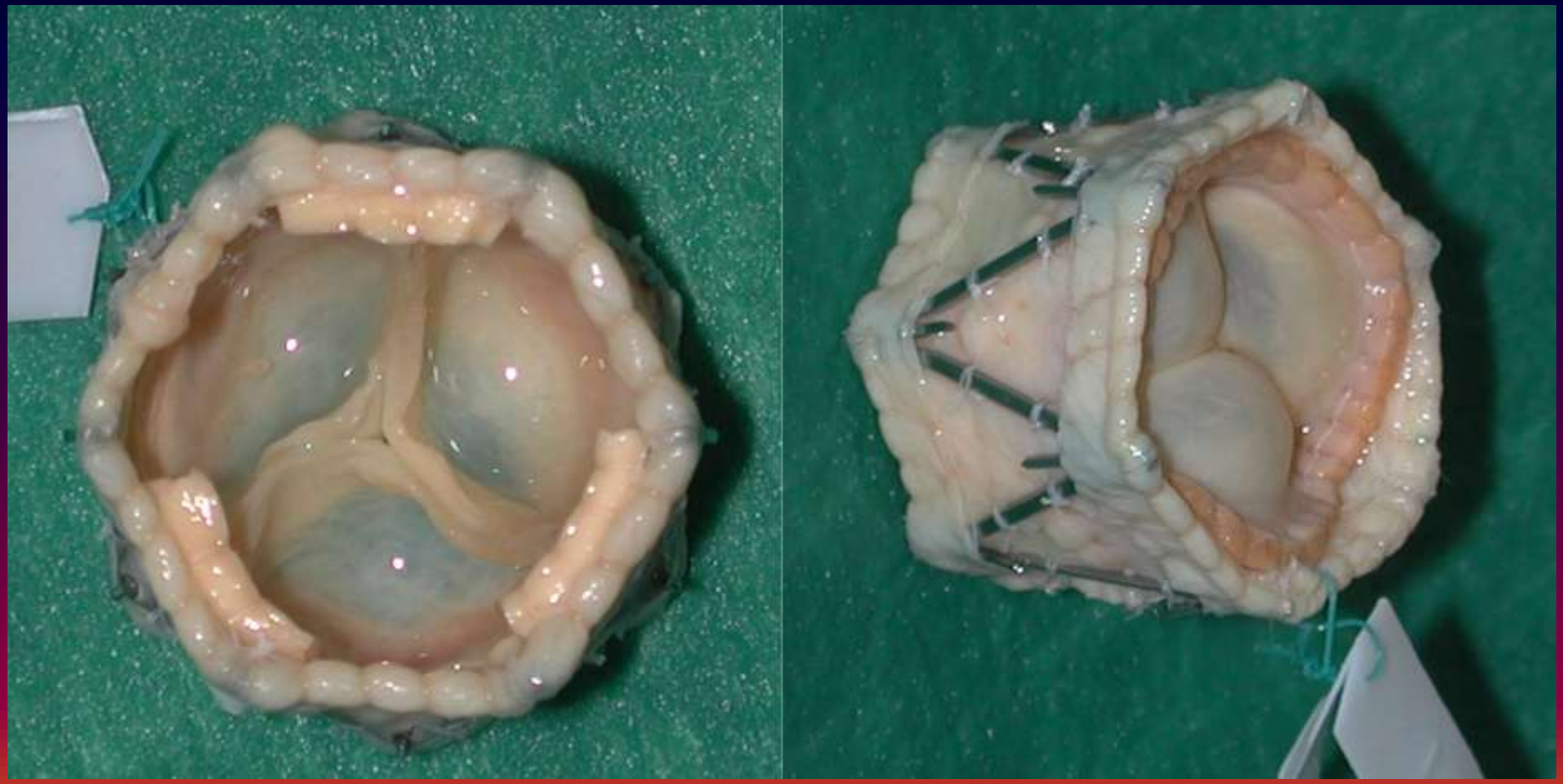




Wide Enlargement Patch

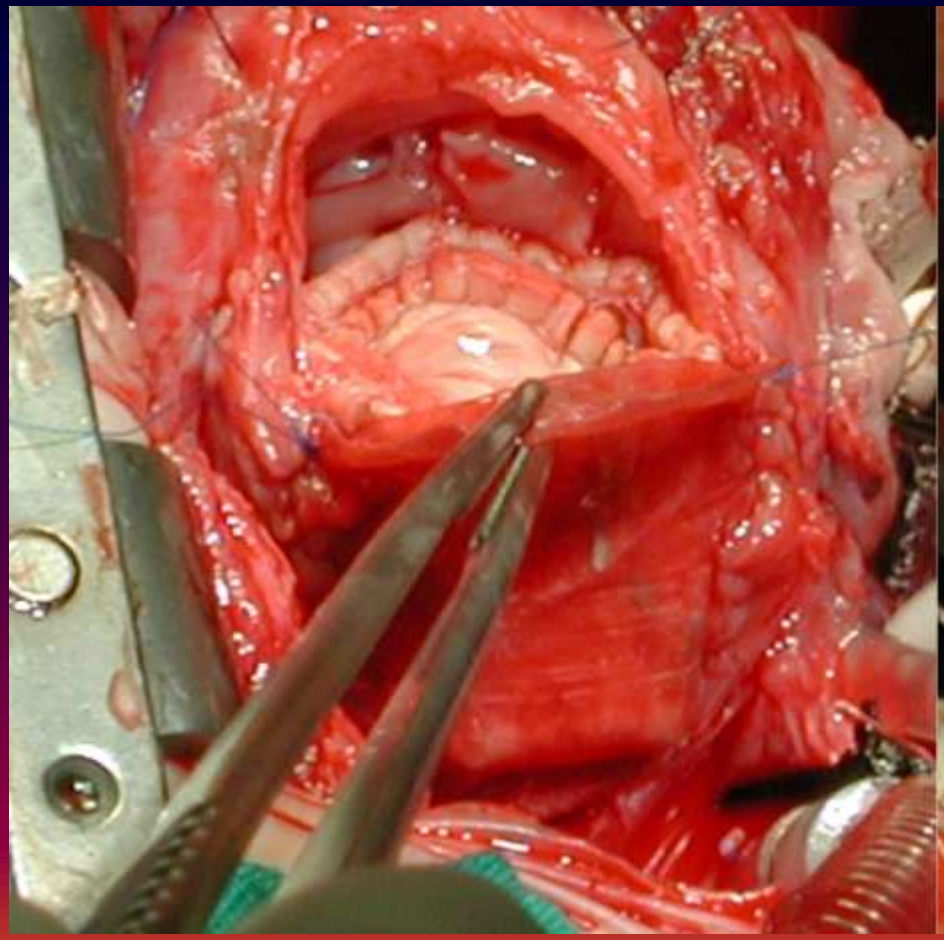


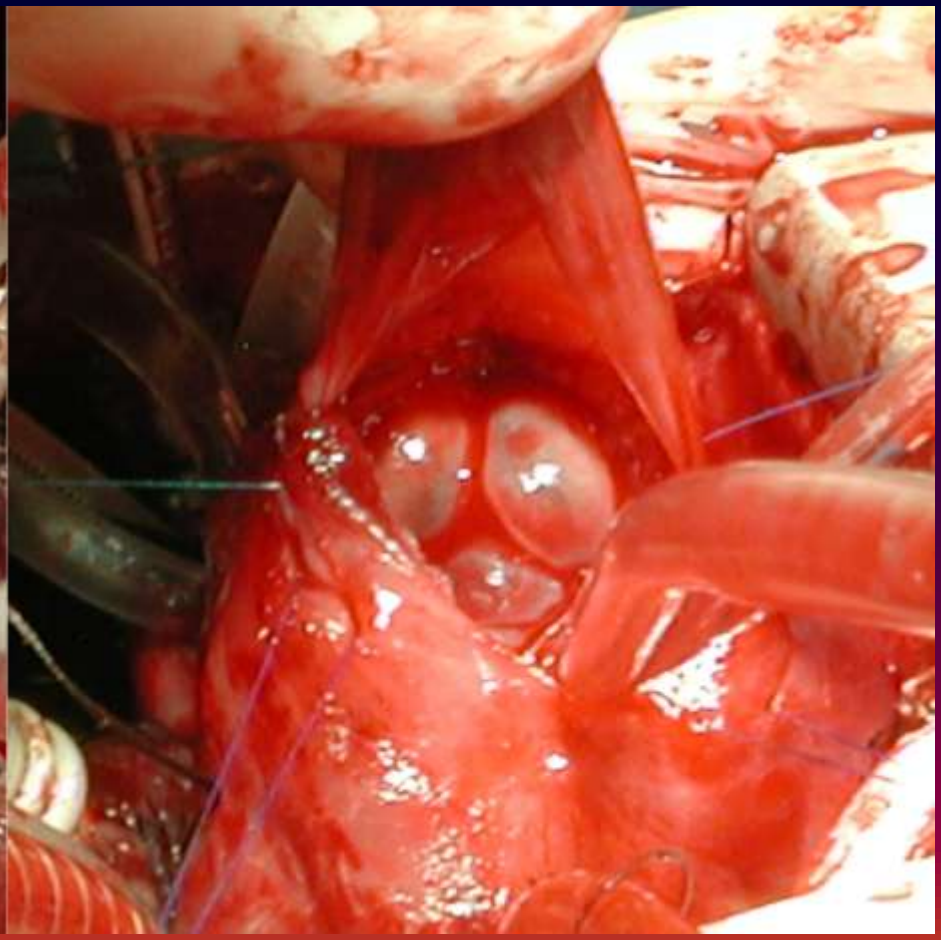
Injectable Self-Expanding



Introducer

In Site





Patients

Since September 2010

- 9 Patients
  - 7 RVOT primary valving procedures
  - 2 RVOT revalving procedures
- 4 males – 5 females
- Mean age 26.4 ± 22.1 months (2 months – 5 years)

Diagnosis

- 6 ToF
  - 3 at first operation (5 months, 4 years, 5 years)
  - 1 previous palliation with infundibular stenting (2 months before)
  - 1 previous palliation with BT shunt (7 months before)
  - 1 previous palliation with transannular patch and 1 month later correction + monocusp (22 months before) – Severe PR with aggressive pulmonary bifurcation stenosis
- 1 PA with intact ventricular septum
  - Previous palliation with balloon valvuloplasty and a few days after with BT shunt (9 months before)
- 1 PA with VSD
  - Previous palliation with transannular patch (3 months before)
- 1 Truncus
  - Previous correction with biological conduit (4 years before) – Moderate/Severe PR with pulmonary hypertension

Follow-Up

- Mean duration: 11.4 ± 5 months (6 - 19)

- Echocardiogram
- CT scan (6 pts)
- Catheterization (6 pts)

Results

	Early Postoperative	Follow-Up
Right ventricular function	Normal	Normal
Prosthetic malfunction	None	None
Prosthetic Regurgitation	None	None
Periprosthetic Leak	2 (1 mild – 1 moderate)	1 (mild)
Prosthetic Stenosis	None	1 (neointima) *
RVOT mean Gradient (mmHg)	18.3 ± 8.5 (10 – 40**)	19.2 ± 10.3 (12 – 40)***
RV/LV Pressure Ratio	0.53 ± 0.1 (0.35 – 0.54)	

* At 15 months - 40 mmHg gradient - ToF with poor pulmonary artery anatomy

** Subvalvular gradient

*** Only 8 pts without stenosis: Mean gradient: 15.2 ± 1.7 mmHg (12 – 16)

3 prostheses returned to its nominal diameter

Mean Oversizing

- Age: 26.4 months
- Weight: 9.8 Kg – Height: 79.8 cm = BSA 0.45 mq
- Expected RVOT: 10.5 mm (W) or 11.16 mm (BSA)

- Obtained RVOT: 14.9 mm
- Obtained-Expected RVOT: +3.7 mm
- Prosthesis: 17.3 mm
- Prosthesis-Obtained RVOT: +2.4 mm
- Total oversizing: 6.1 mm

- 17.3 mm -> BSA 1.5 mq = Height 160 cm – Weight 50 = Adult!

Smallest Diameter (15 mm)

- PA with VSD (previous transannular patch)
  - Female - 2 months, 3.2 Kg, 50 cm, BSA 0.20 mq
  - Expected RVOT: 6 mm (W) or 8 mm (BSA)

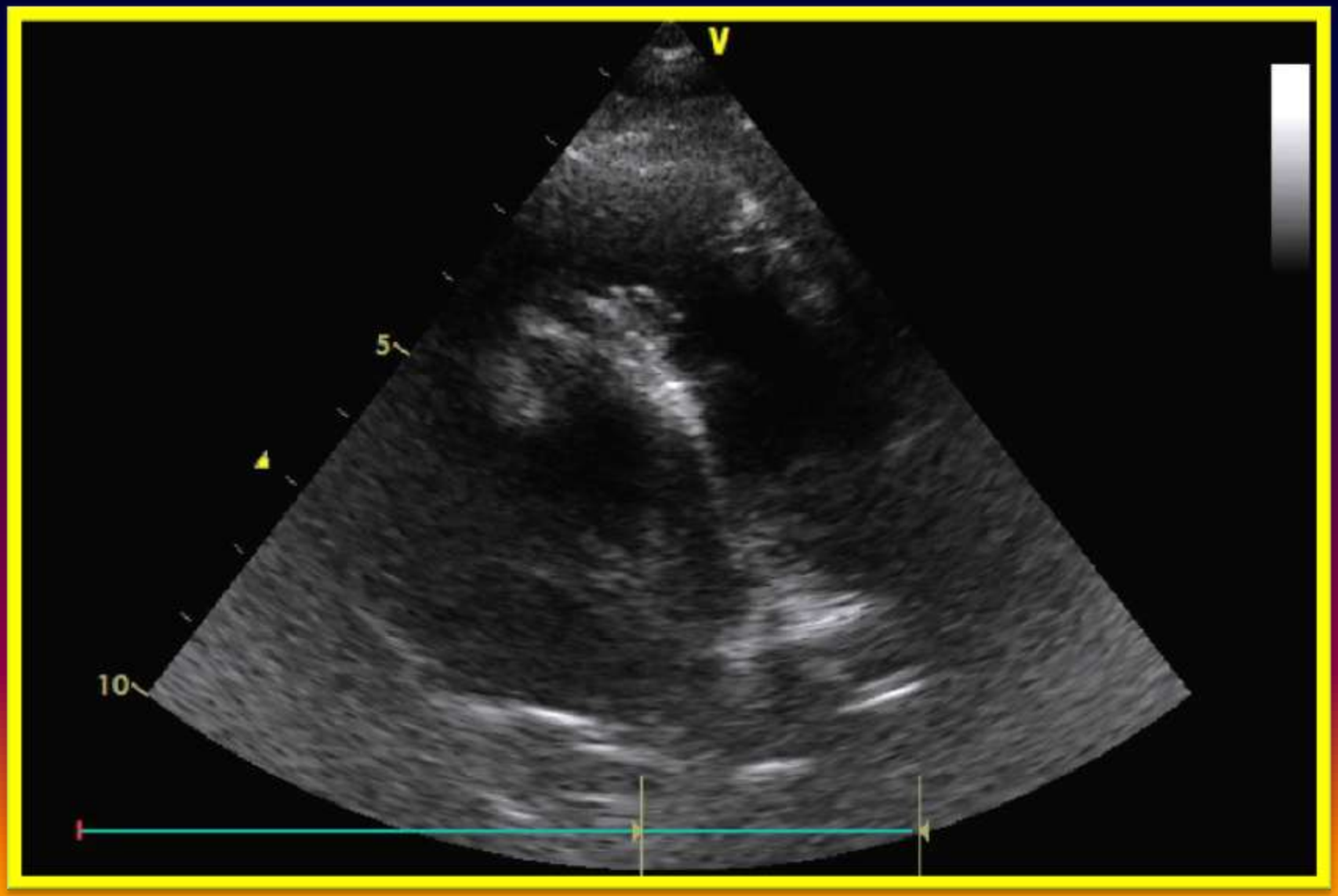
  - Obtained RVOT: 12 mm
  - Prosthesis: 15 mm
  - Total oversizing: 7 mm

- 15 mm -> BSA 1.3 mq = Height 150 cm – Weight 40 = 12 - 13 years!

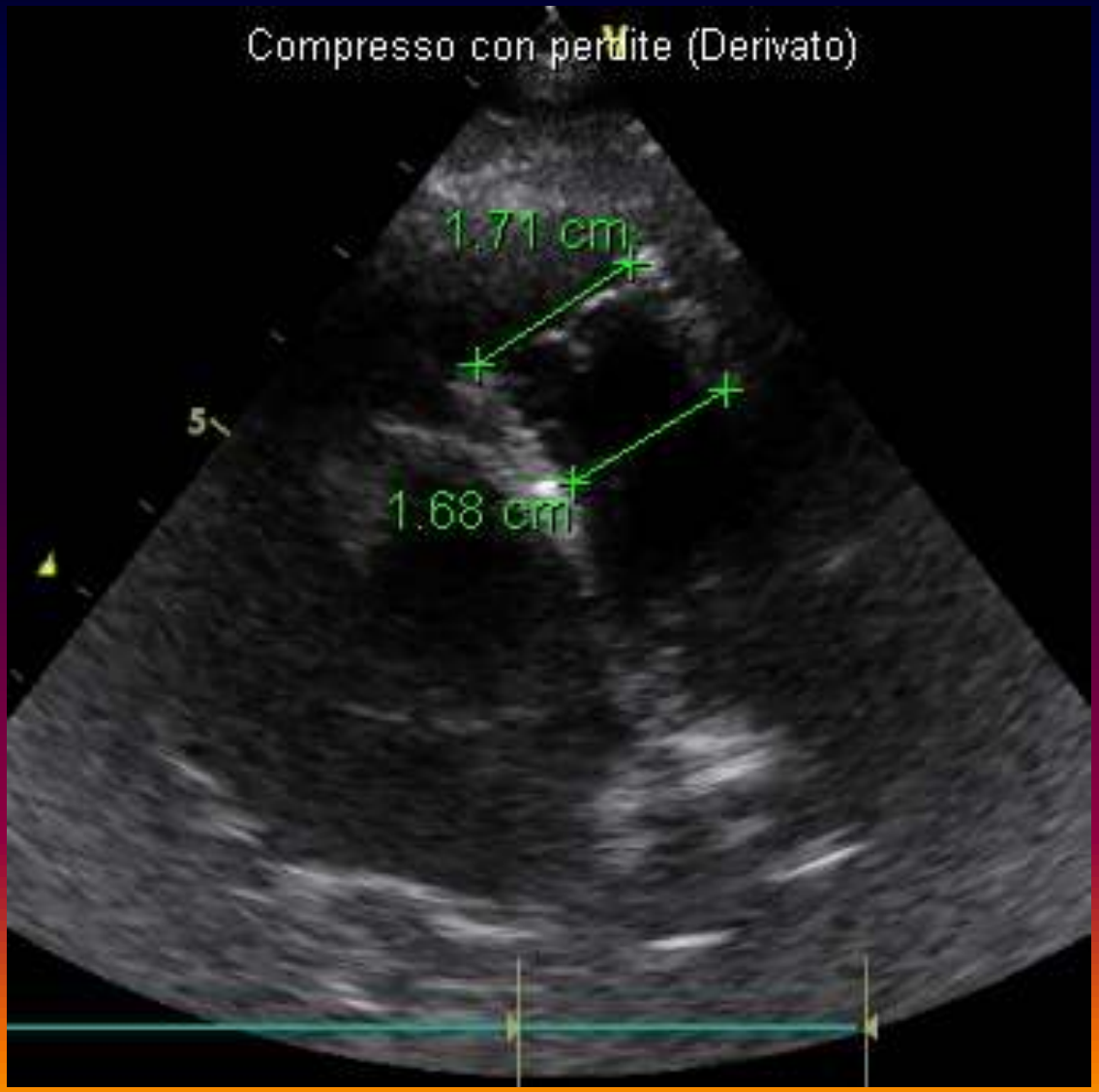
Largest Diameter (19 mm)

- Truncus (corrected with biological conduit)
  - Female - 4 years, 14 Kg, 99cm, BSA 0.62 mq
  - Expected RVOT: 13 (W) or 12.8 mm (BSA)
  - Obtained RVOT: 16 mm
  - Prosthesis: 19 mm
  - Total oversizing: 6.5 mm
- ToF
  - Male - 4 years, 16 Kg, 101 cm, BSA 0.66 mq
  - Expected RVOT: 13.5 (W) and 13.5 mm (BSA)
  - Obtained RVOT: 17 mm
  - Prosthesis: 19 mm
  - Total oversizing: 5.5 mm
- 19 mm -> BSA 2 mq = Height 185 cm – Weight 76 = Adult!

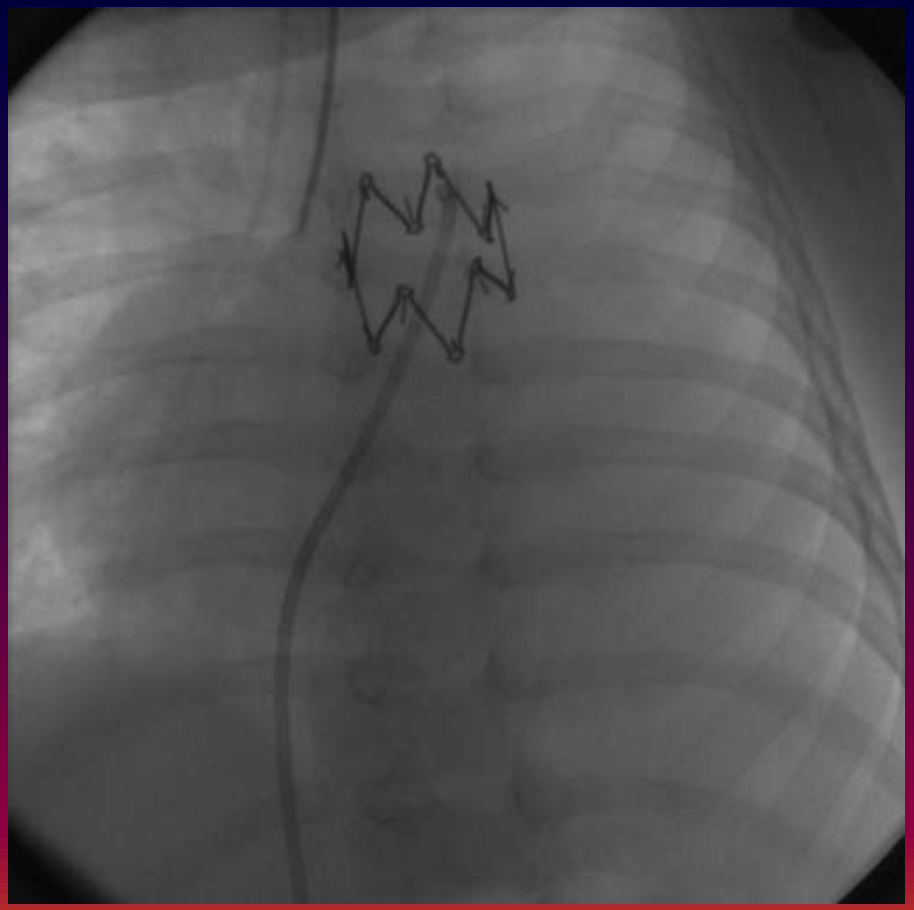
Echo (at 6.3 months) - 17 mm

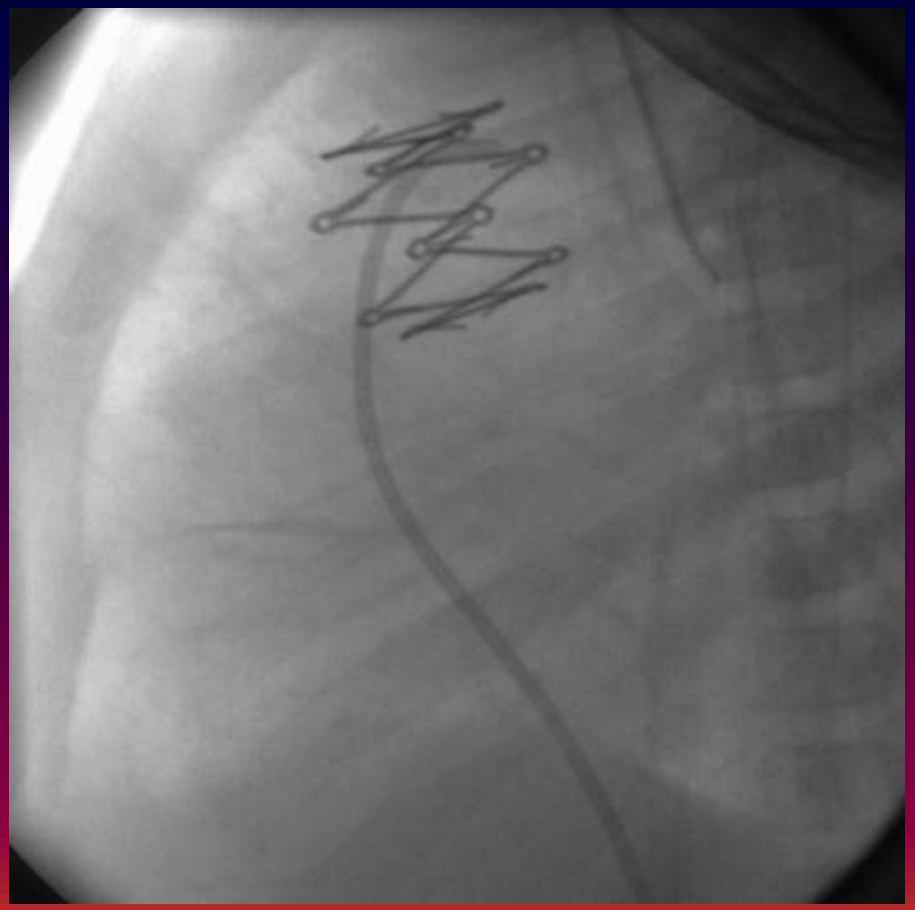


Echo (at 6.3 months) - 17 mm

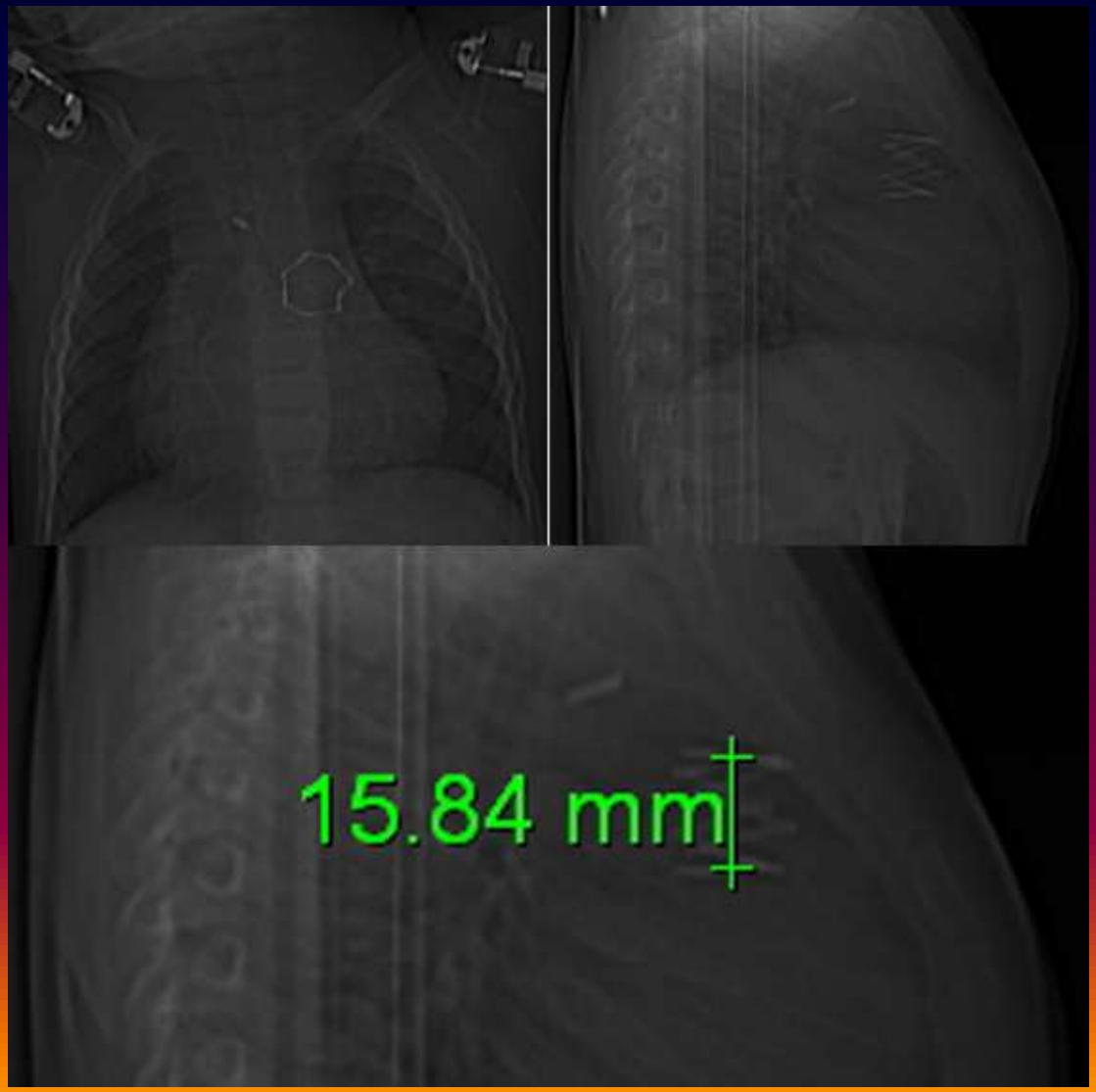


Cath (at 5 months) - 15 mm

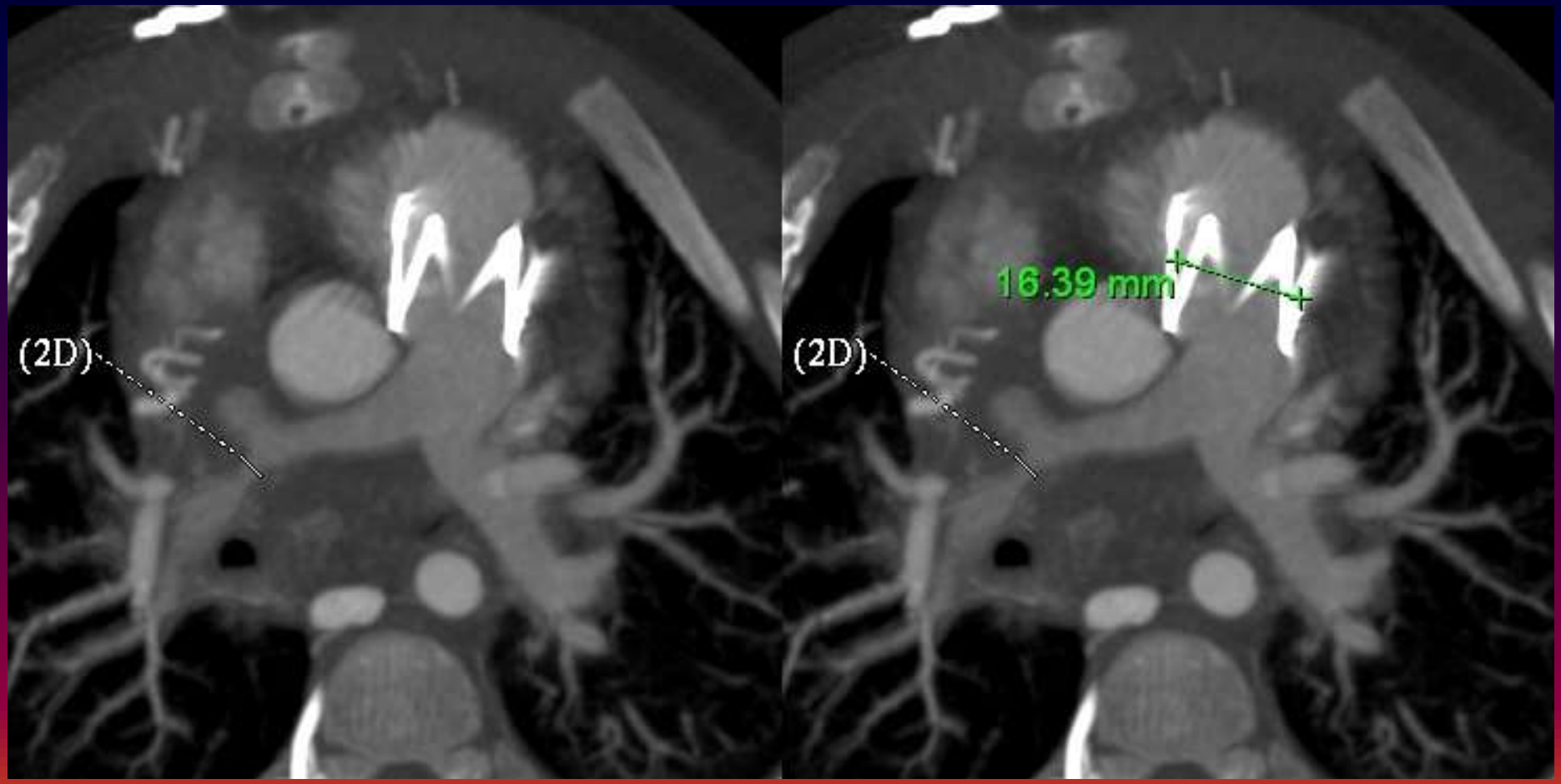




CT, Scout (18 months) - 16 mm



CT (18 months) - 16 mm



CT, 3D (17 months) - 16 mm

Conclusion

- Easy implant technique
- Quite oversizable and well performing even when shrinked

- Probably capable of following growth process
- Wider than anatomically possible

- Avoids or reduces growth-related mismatch
- No or less need for repeated reinterventions

Oversize right from the beginning