21st CardioVascular Summit

TCTAP 2016

April 26-29, 2016
Coex, Seoul, Korea

Percutaneous Pulmonary Valve Replacement: State of the Art

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& The Mater Hospital
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No Disclosures

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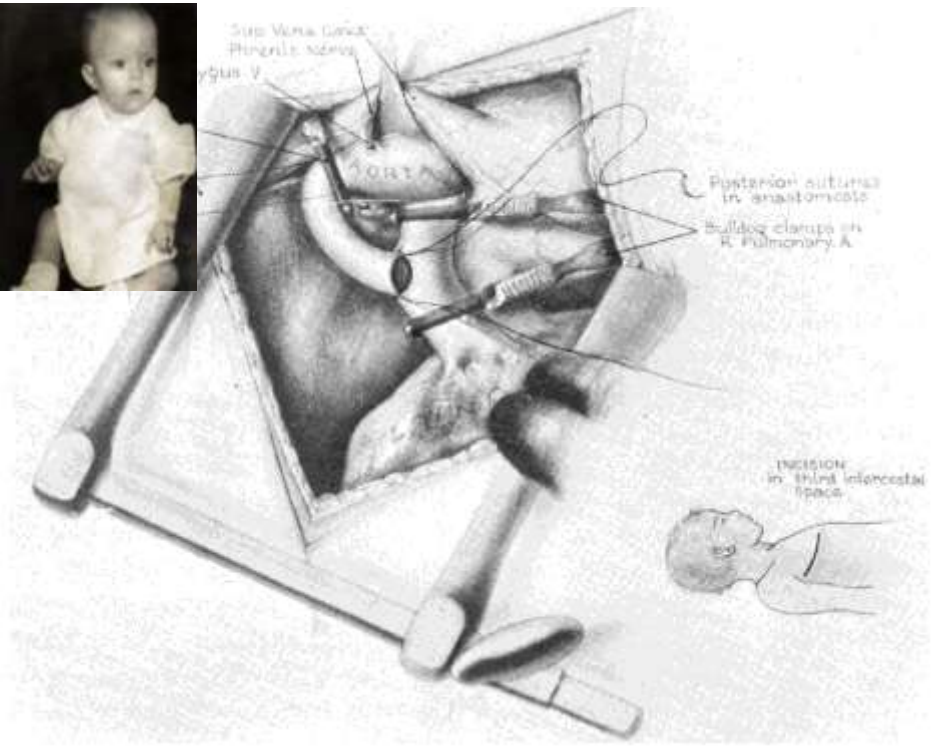
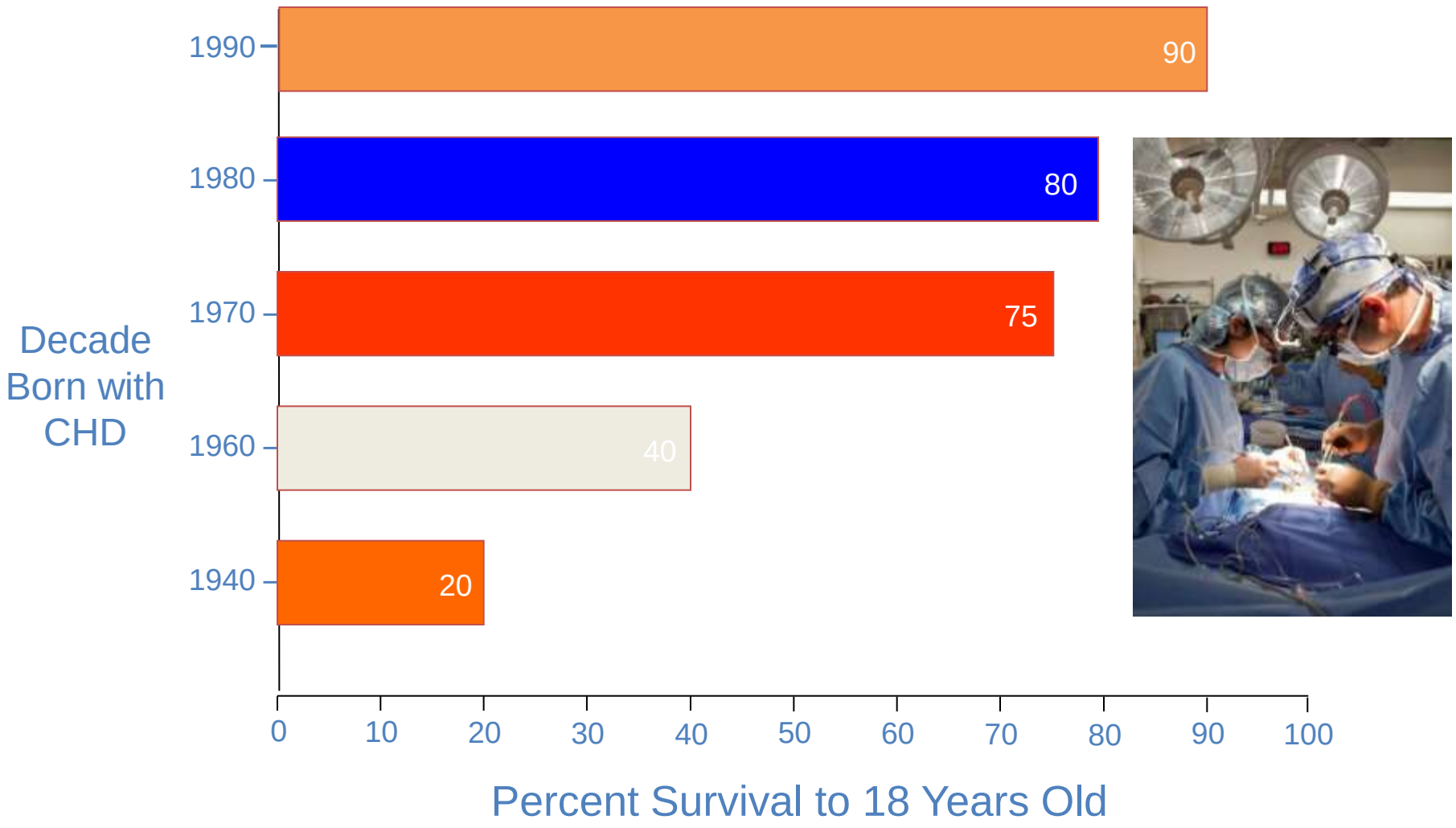
RVOT Disease - Blalock Taussig Shunt

"On November 29, 1944, students and professors crowded into the double-deck observation gallery above the eighth-floor operating room in the Halsted Clinic. Because there was a danger of losing the child Eileen before the operation began, Dr. Merel Harmel decided not to use a strong anaesthetic and put her slowly to sleep with a diluted mixture of ether and oxygen.



Survival to 18 yrs of age with CHD



Warnes CA, et al. *J Am Coll Cardiol*. 2001;37(5):1170-1175.
Moons P et al. *Circulation* 2010.122:2264-2272

~10% : Right Ventricular Outflow Tract Disease

- Congenital
  - Tetralogy of Fallot
  - TGA with VSD and PS
  - Pulmonary Atresia
- “Acquired”
  - Truncus Arteriosus
  - Ross Operation

Right Ventricular Outflow Tract Disease

- Congenital
  - Tetralogy of Fallot
  - TGA with VSD and PS
  - Pulmonary Atresia

RV – PA Conduit

- Acquired
  - Truncus Arteriosus
  - Ross Operation

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What's the Big Deal?

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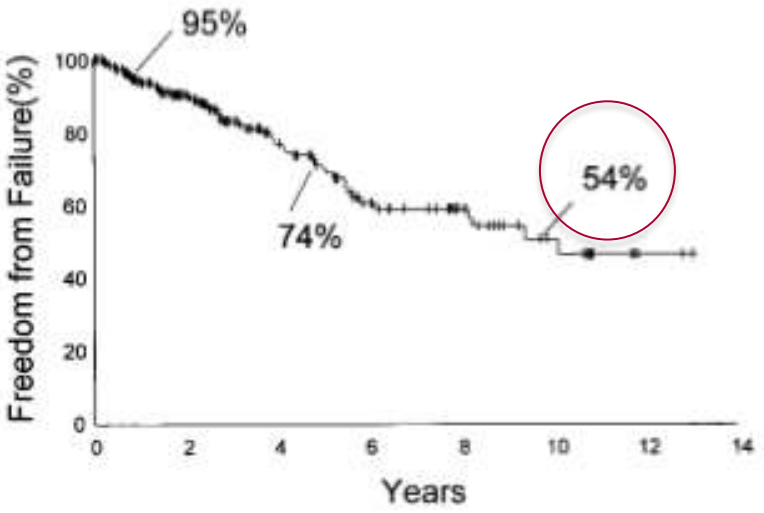
Younger Patients

- 205 Patients (Homograft)
- Median age: 4.4 yrs
- Survival 88% at 10 years
- Freedom from failure was:
  - 74%±4% at 5 years
  - 54%±7% at 10 years



Circulation 2000;102:Iii-130-Iii-135

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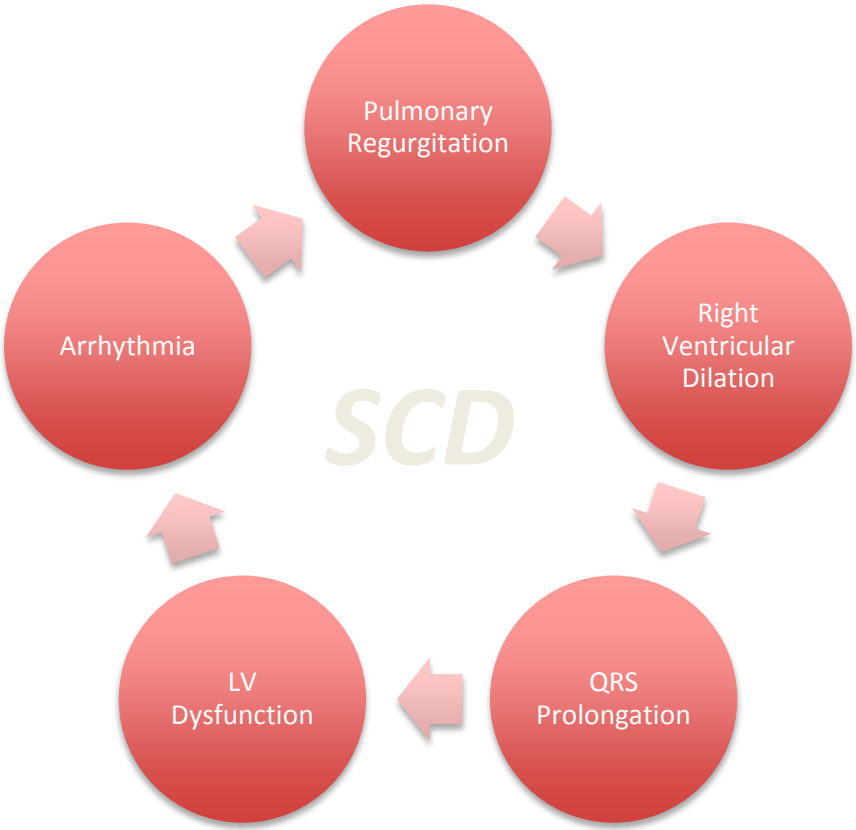
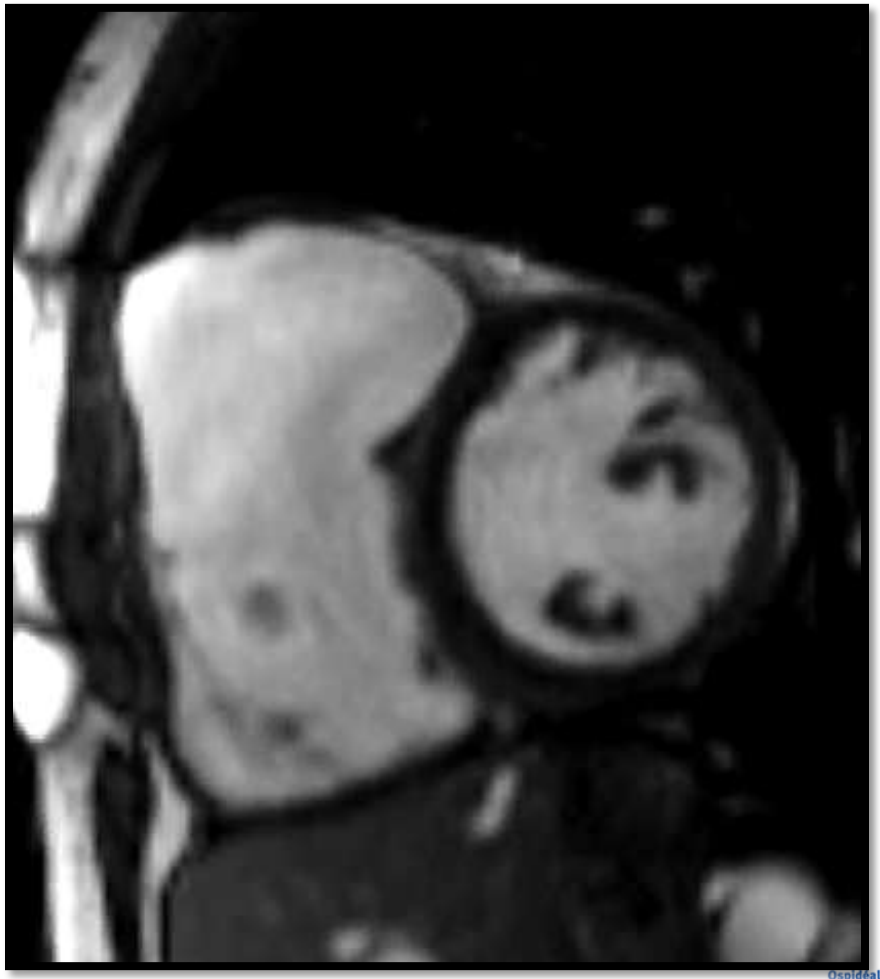
Pulmonary Regurgitation: Not Benign





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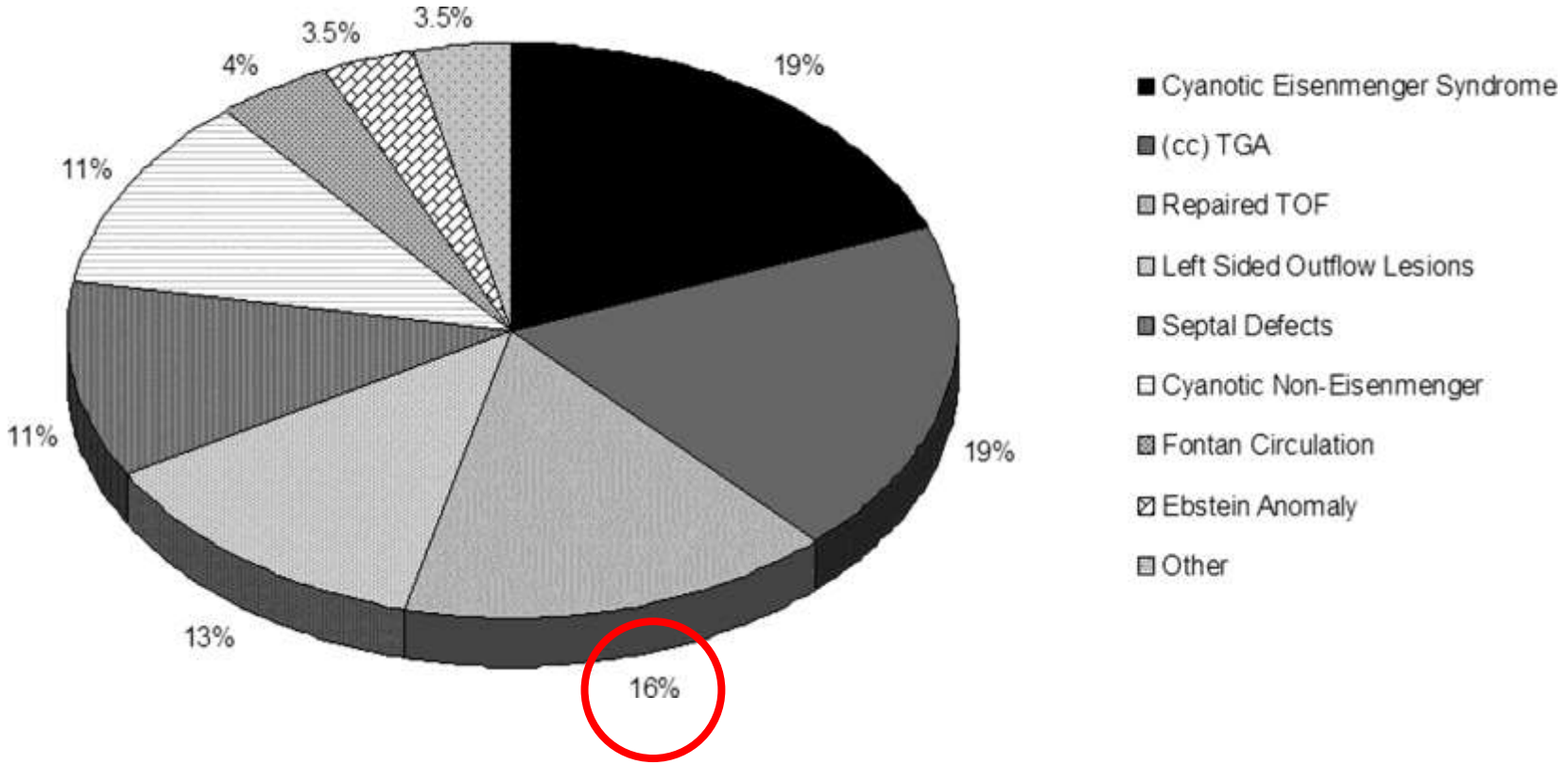
Cardiac Defects in 171 SCD Cases



Zeliha Koyak et al. Circulation. 2012;126:1944-1954

Surgical Pulmonary Valve Replacement: Excellent Results

- 48 studies involving 3,118
- Pooled 30-day mortality was 0.87% (47 studies; 27 of 3,100 patients);
- Pooled 5-year mortality was 2.2% (24 studies; 49 of 2,231 patients);
- Pooled 5-year re-PVR was 4.9% (15 studies; 88 of 1,798 patients).
- Observations:

  1) the RV experiences improvement of its volumes and function;

  2) the left ventricle experiences improvement of its function;

  3) QRS duration decreases;

  4) symptoms improve;

  5) pre-operative RV geometry modulates the effect of PVR;

JACC 2013; 62; 2227-2243

Surgical PVR – Younger Patients

Cohort	*Age*
220 Pts – London	32.0 (25.0–40.0)[1]
148 Pts – Texas	*15.9 (13.6-19.6)[2]*
278 Pts - Rochester	*31 (18-45)[3]*

Younger age independent RF for need for Reintervention

1. *Circulation.* 2014;129:18-27.
2. JTCVS 2014; 148: 1450-3.
3. Am J Cardiol 2014; 114: 901-8.

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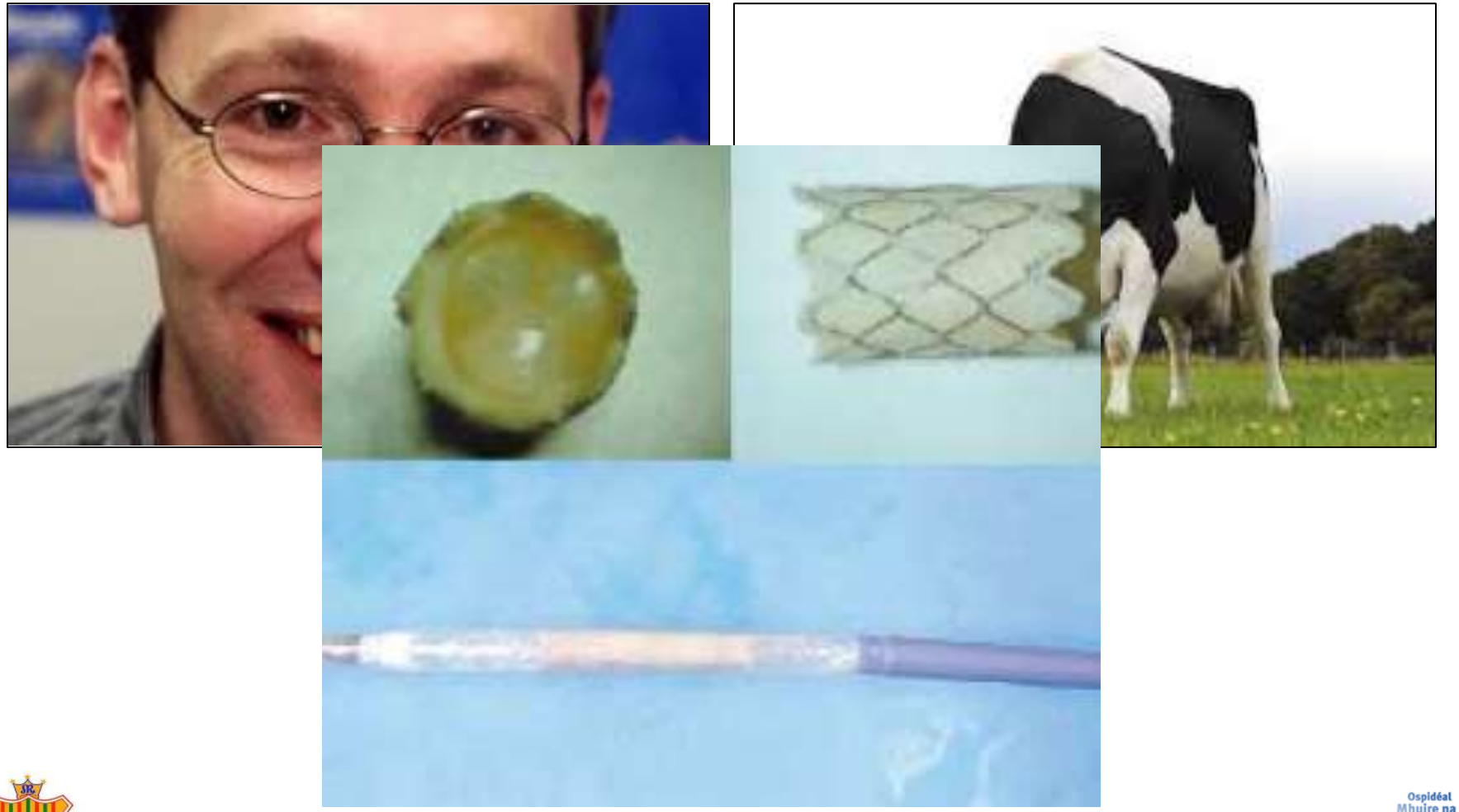
The Birth of Transcatheter PVR



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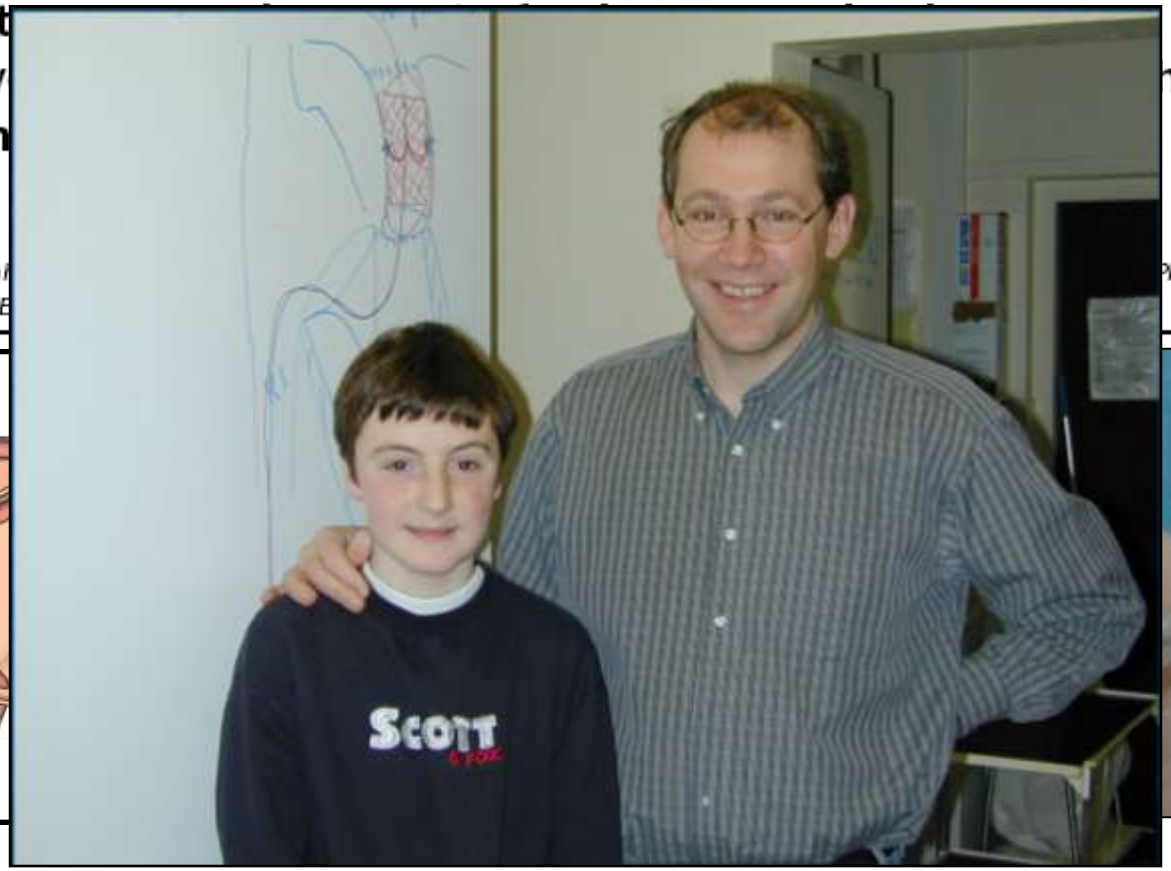
Percutaneous Pulmonary Valve September 12th, 2000…First in Man

Early report

THE LANCET

Percut … right-v … valve dysfun …

Philipp Boni … Philippe Acar, Jérôme Le B …



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Evolution of Transcatheter PVR

1st Implant
Paris, France (2000)

2000
Sept 12

2002

Revised TPV (2003)

Bonhoeffer Cohort
(2003-05)

2004

2005

First tPVR in North America
Dec 2005

CE Mark
(2006)

2006

1st US Implant
(2007)

2008

US
Cohort
(2007-10)

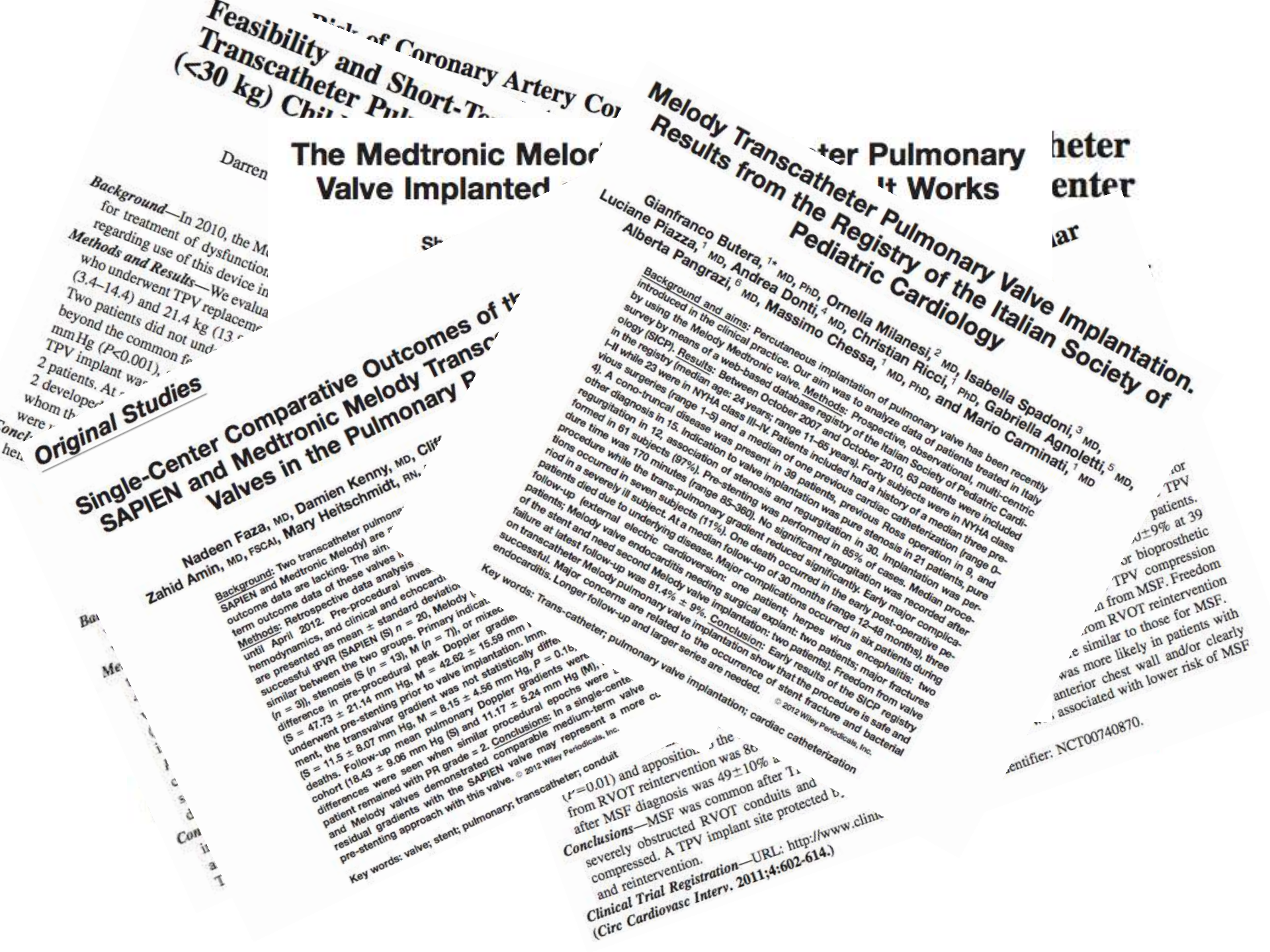
HDE
Approval

2009-10

2016

- > 8,000 Valves Worldwide
- SAPIEN FDA Approval
- SE Systems for Native RVOT

Depicts date of first TAVR



Feasibility and Short-T
Transcatheter Pul
(<30 kg) Chil

Darren

Background—In 2010, the M
for treatment of dysfunctio
regarding use of this device in
Methods and Results—We evalua
who underwent TPV replacem
(3.4–14.4) and 21.4 kg (13
Two patients did not und
beyond the common f
mm Hg ($P<0.001$),
TPV implant wa
2 patients. At
2 develope
whom th
were

Original Studies

The Medtronic Melo
Valve Implanted

Single-Center Comparative Outcomes of th
SAPIEN and Medtronic Melody Transc
Valves in the Pulmonary P

Nadeen Faza, MD, Damien Kenny, MD, Cli
Zahid Amin, MD, FSCAI, Mary Heitschmidt, RN,

Background: Two transcatheter pulmon
SAPIEN and Medtronic Melody) are
outcome data are lacking. The aim
term outcome data of these valves
Methods: Retrospective data analysis
until April 2012. Pre-procedural inves
hemodynamics, and clinical and echocardi
are presented as mean ± standard deviatio
successful tPVR (SAPIEN (S) $n = 20$, Melody
similar between the two groups. Primary indicat
($n = 3$)), stenosis (S ($n = 13$), M ($n = 7$)), or mixed
difference in pre-procedural peak Doppler gradie
(S = 47.73 ± 21.14 mm Hg, M = 42.62 ± 15.59 mm
underwent pre-stenting prior to valve implantation. Imm
ment, the transvalvar gradient was not statistically diffe
(S = 11.5 ± 8.07 mm Hg, M = 8.15 ± 4.56 mm Hg, $P = 0.18$,
deaths. Follow-up mean pulmonary Doppler gradients were
cohort (18.43 ± 9.06 mm Hg (S) and 11.17 ± 5.24 mm Hg (M),
differences were seen when similar procedural epochs were
patient remained with PR grade = 2. Conclusions: In a single-cente
and Melody valves demonstrated comparable medium-term valve
residual gradients with the SAPIEN valve may represent a more c
pre-stenting approach with this valve. © 2012 Wiley Periodicals, Inc.

Key words: valve; stent; pulmonary; transcatheter; conduit

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Melody Transcatheter Pulmonary Valve Implantation.
Results from the Registry of the Italian Society of
Pediatric Cardiology

Gianfranco Butera, 1* MD, PhD, Ornella Milanesi, 2 MD, Isabella Spadoni, 3 MD,
Luciane Piazza, 1 MD, Andrea Donti, 4 MD, Christian Ricci, 1 PhD, Gabriella Agnoletti, 5 MD,
Alberta Pangrazi, 6 MD, Massimo Chessa, 1 MD, PhD, and Mario Carminati, 1 MD

Background and aims: Percutaneous implantation of pulmonary valve has been recently introduced in the clinical practice. Our aim was to analyze data of patients treated in Italy by using the Melody Medtronic valve. Methods: Prospective, observational, multi-centric survey by means of a web-based database registry of the Italian Society of Pediatric Cardiology (SICP). Results: Between October 2007 and October 2010, 63 patients were included in the registry (median age: 24 years; range 11–65 years). Forty subjects were in NYHA class I–II while 23 were in NYHA class III–IV. Patients included had a history of a median three previous surgeries (range 1–5) and a median of one previous cardiac catheterization (range 0–4). A cono-truncal disease was present in 39 patients, previous Ross operation in 9, and other diagnosis in 15. Indication to valve implantation was pure stenosis in 21 patients, pure regurgitation in 12, association of stenosis and regurgitation in 30. Implantation was performed in 61 subjects (97%). Pre-stenting was performed in 85% of cases. Median procedure time was 170 minutes (range 85–360). No significant regurgitation was recorded after procedure while the trans-pulmonary gradient reduced significantly. Early major complications occurred in seven subjects (11%). One death occurred in the early post-operative period in a severely ill subject. At a median follow-up of 30 months (range 12–48 months), three patients died due to underlying disease. Major complications occurred in six patients during follow-up (external electric cardioversion: one patient; herpes virus encephalitis: two patients; Melody valve endocarditis needing surgical explant: two patients; major fractures of the stent and need second Melody valve implantation: two patients). Freedom from valve failure at latest follow-up was 81.4% ± 9%. Conclusion: Early results of the SICP registry on transcatheter Melody pulmonary valve implantation show that the procedure is safe and successful. Major concerns are related to the occurrence of stent fracture and bacterial endocarditis. Longer follow-up and larger series are needed. © 2012 Wiley Periodicals, Inc.

Key words: Trans-catheter; pulmonary valve implantation; cardiac catheterization

ter Pulmonary
t Works

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(r=0.01) and apposition
from RVOT reintervention was 80
after MSF diagnosis was 49±10%
Conclusions—MSF was common after T
severely obstructed RVOT conduits and
compressed. A TPV implant site protected b
and reintervention.
Clinical Trial Registration—URL: http://www.clin
(Circ Cardiovasc Interv. 2011;4:602-614.)

heter
enter

patients.
±9% at 39
or bioprosthetic
TPV compression
d from MSF. Freedom
rom RVOT reintervention
e similar to those for MSF.
was more likely in patients with
anterior chest wall and/or clearly
associated with lower risk of MSF

entifier: NCT00740870.

Limitations

Patients With Dysfunctional RVOT

RV-PA Conduit
Bioprosthetic valve

≈ 15%

Ross procedure
Truncus arteriosus
DORV
TGA/VSD
PAVSD
ToF after valve rep

> 30 Kgs

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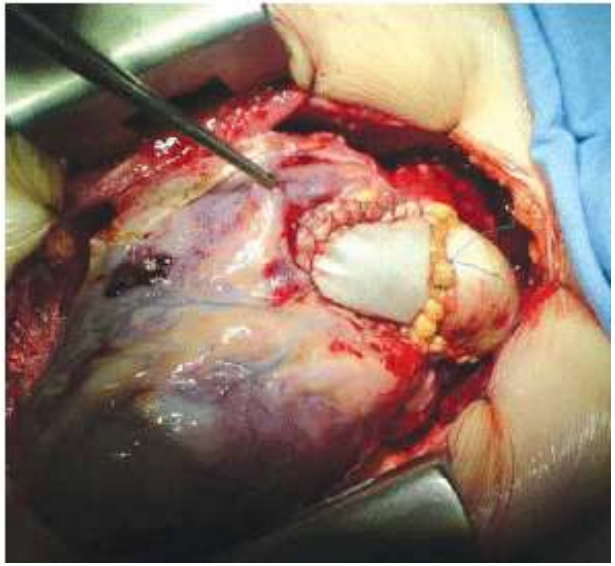
The Native RVOT

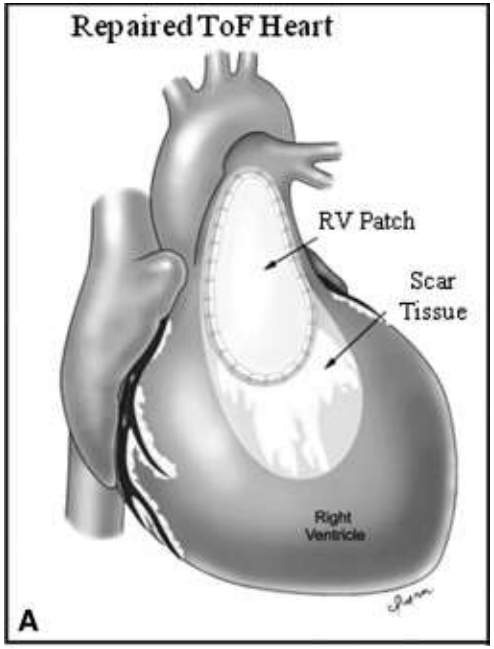
Patients With Dysfunctional RVOT

ToF Transannular Patch



≈ 85%

Majority >> 24mm



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Evolving Solutions

- Patient Size
  - Hybrid Approach
- RVOT Size
  - Hybrid Approach
  - Self-Expanding Systems

Evolving Solutions

- Patient Size
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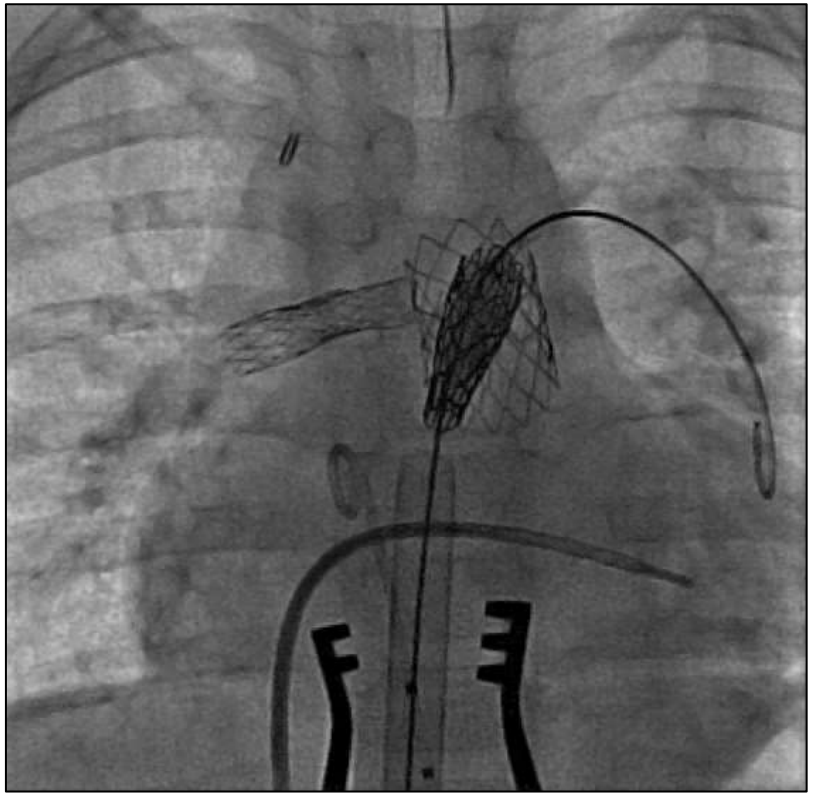
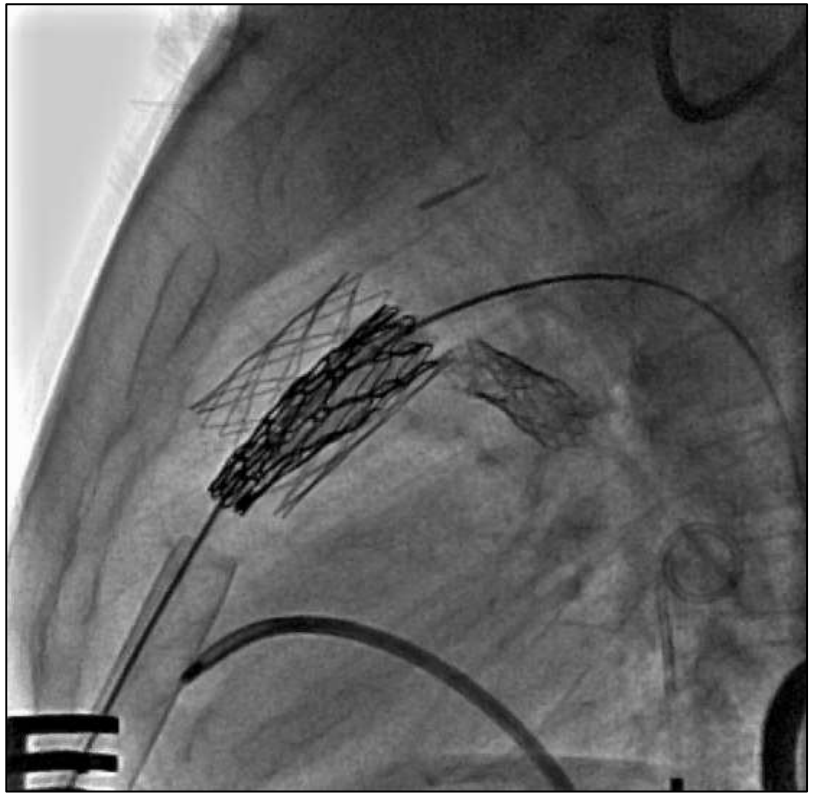
Perventricular Hybrid PVR – Melody Implantation





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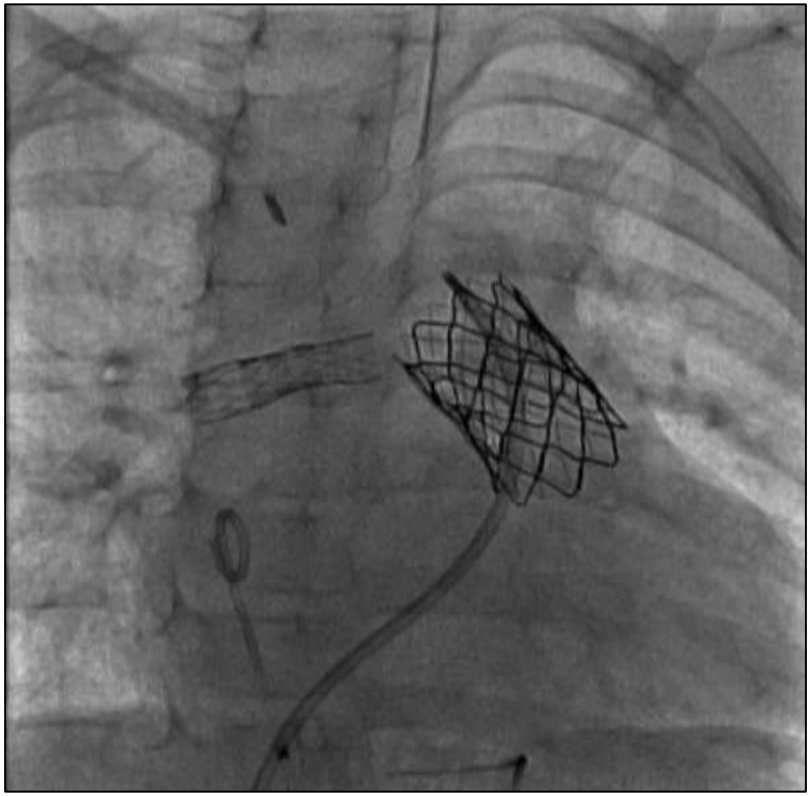
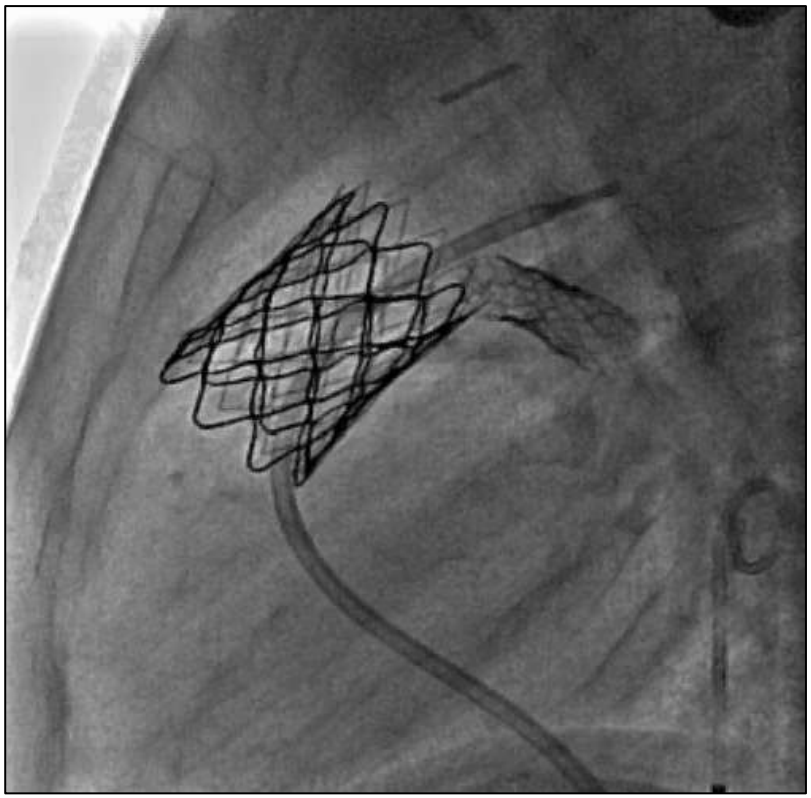
Perventricular Hybrid PVR – Final Angiogram





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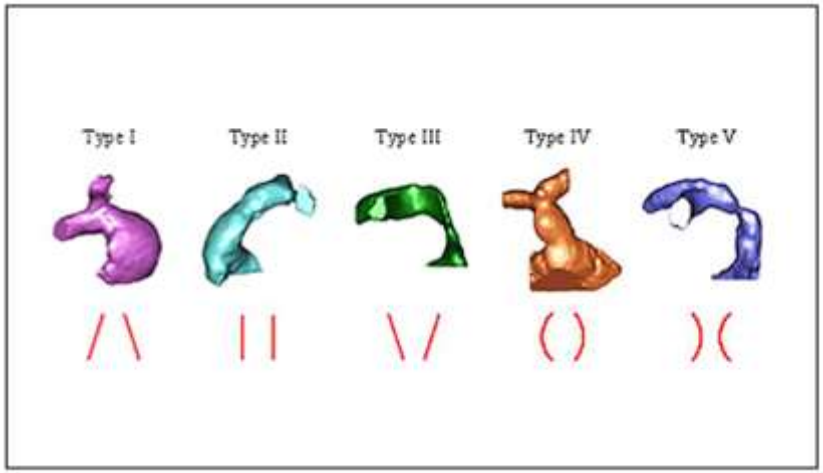
Hybrid Pulmonary Valve Replacement

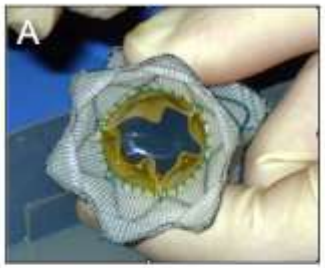
Evolving Solutions

- Patient Size
  - Hybrid Approach
- RVOT Size
  - Hybrid Approach
  - Self-Expanding Systems

RVOT Size – The Native RVOT

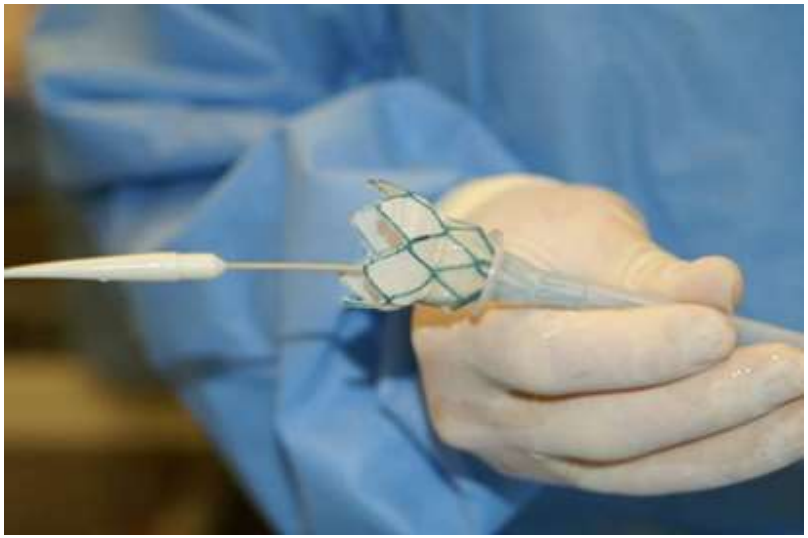
- 85% Pts with Severe PR
- Too large for balloon-expandable valves
- Morphological heterogeneity
- Self-expanding systems

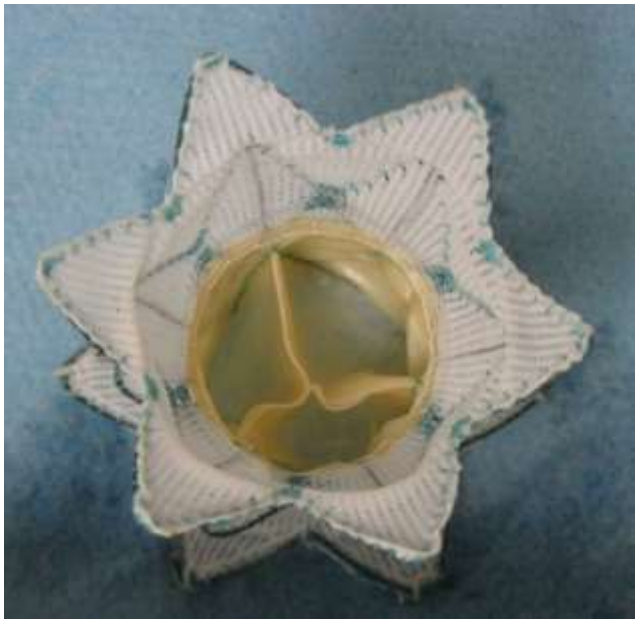




Medtronic Native Outflow Tract Harmony Pulmonary Valve (TPV) Research Clinical Study

"Early Feasibility Trial"





Courtesy of John Cheatham, MD. Columbus

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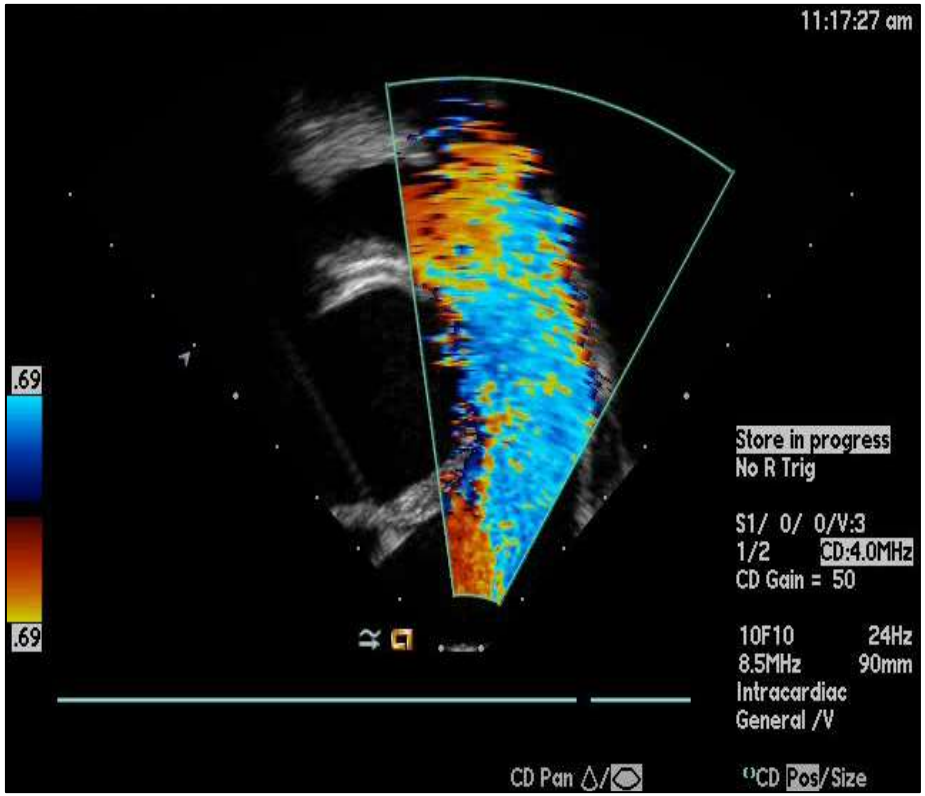
May 30th, 2013 FIM Implant: ICE

PRE



POST

Courtesy of John Cheatham, MD. Columbus

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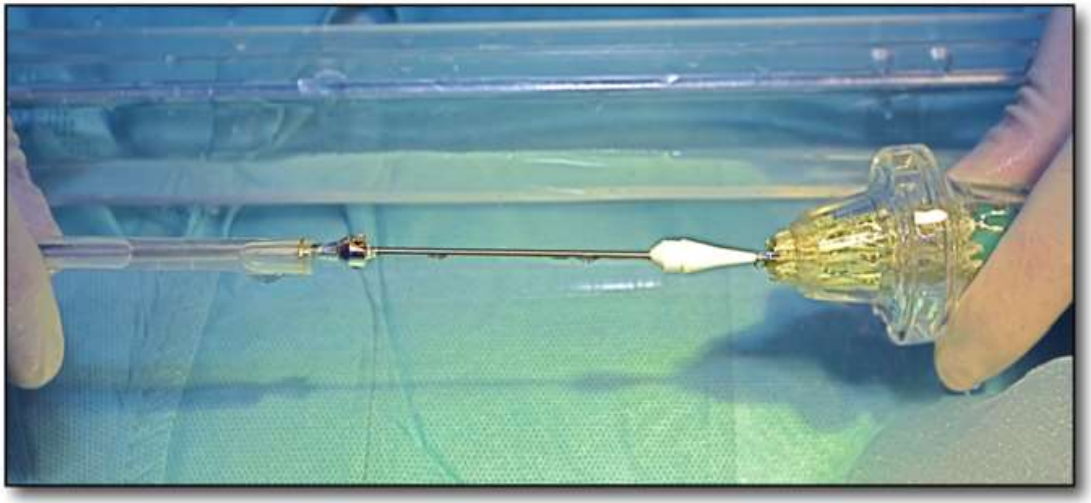
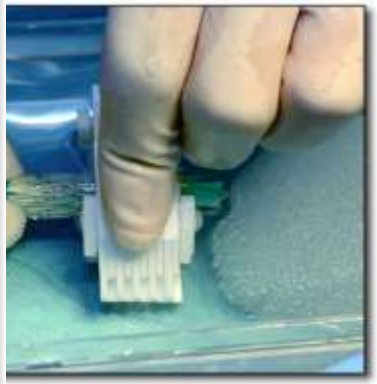
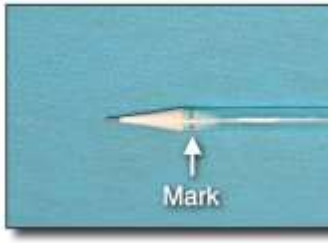
Screened > 110 pts – Implanted 20

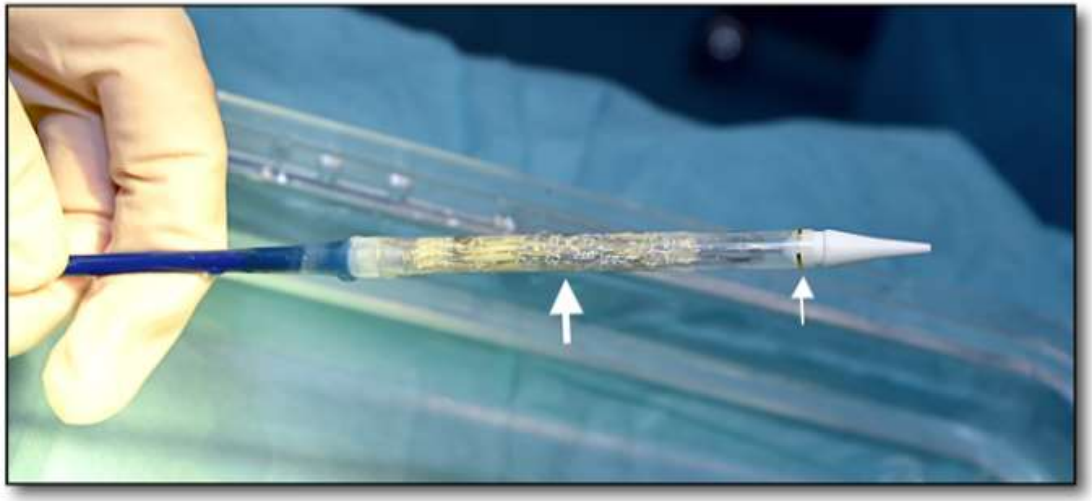
Technology is 5-10 years from Market

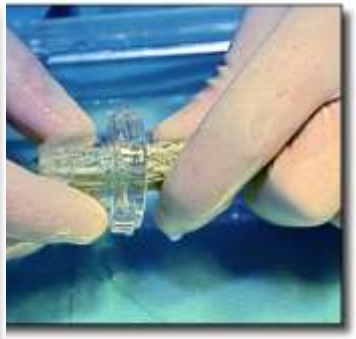
Newer Self-Expanding Systems

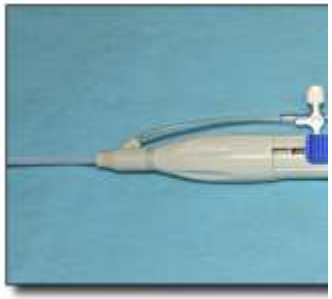












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Limitations Still Exist to Self-Expanding Systems

Size of RVOT and Patient Anatomy/Morphology of RVOT

Our Technique

- MPA is measured angiographically prior to plication
- Plication performed with a longitudinal running or mattress suture to “reduce” the size of RVOT
- RVOT pre-stented to create landing zone
- Transcatheter valve deployed

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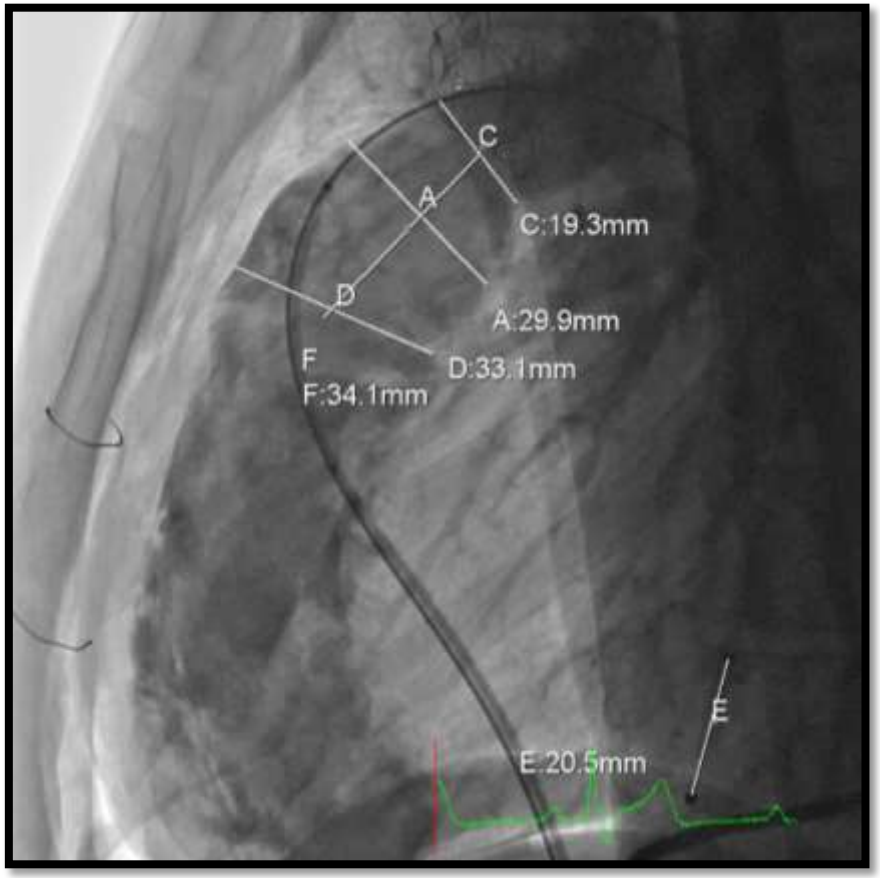
Hybrid Approach in Native RVOT



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MPA Plication

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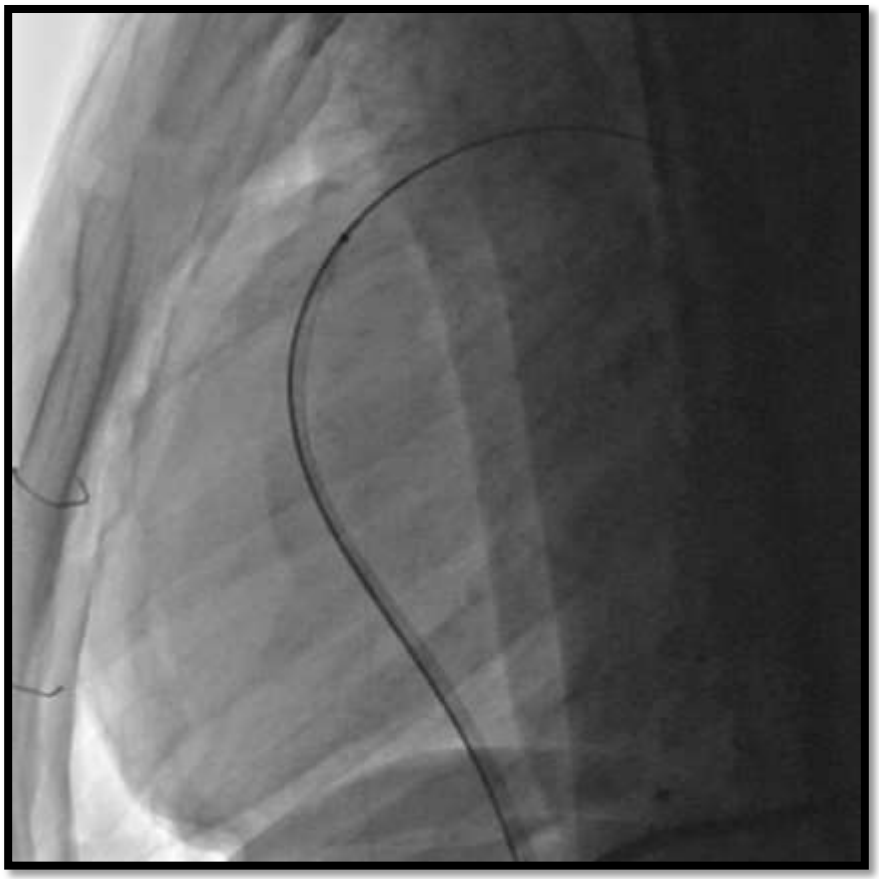
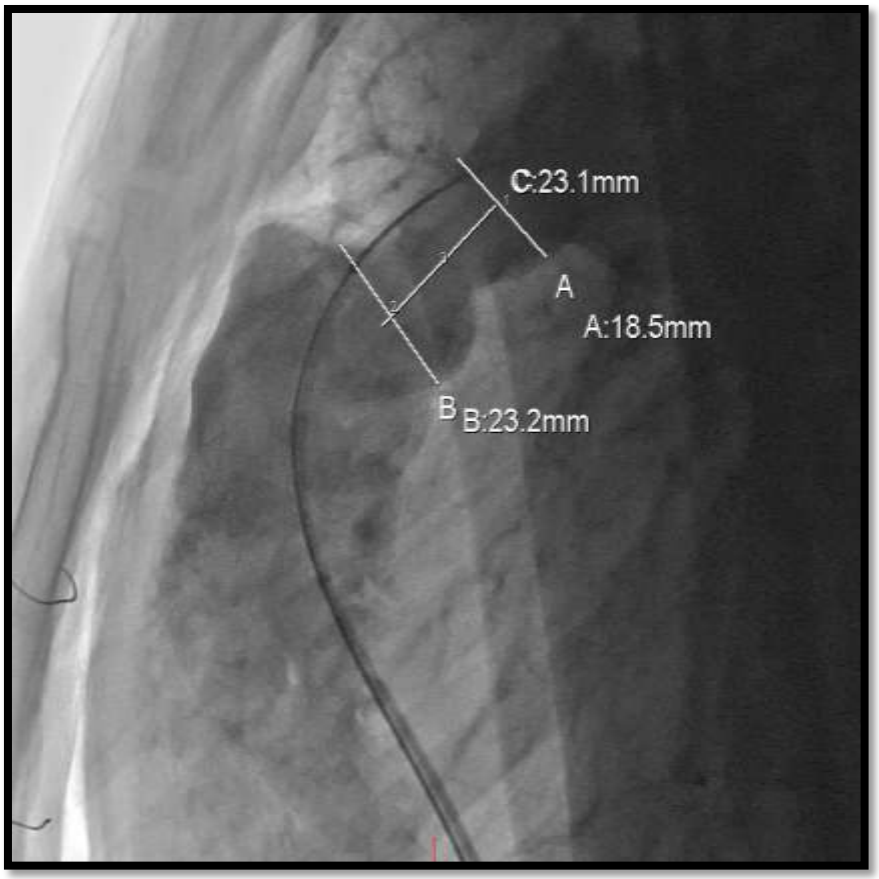
RVOT Post Plication





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Pre-stenting

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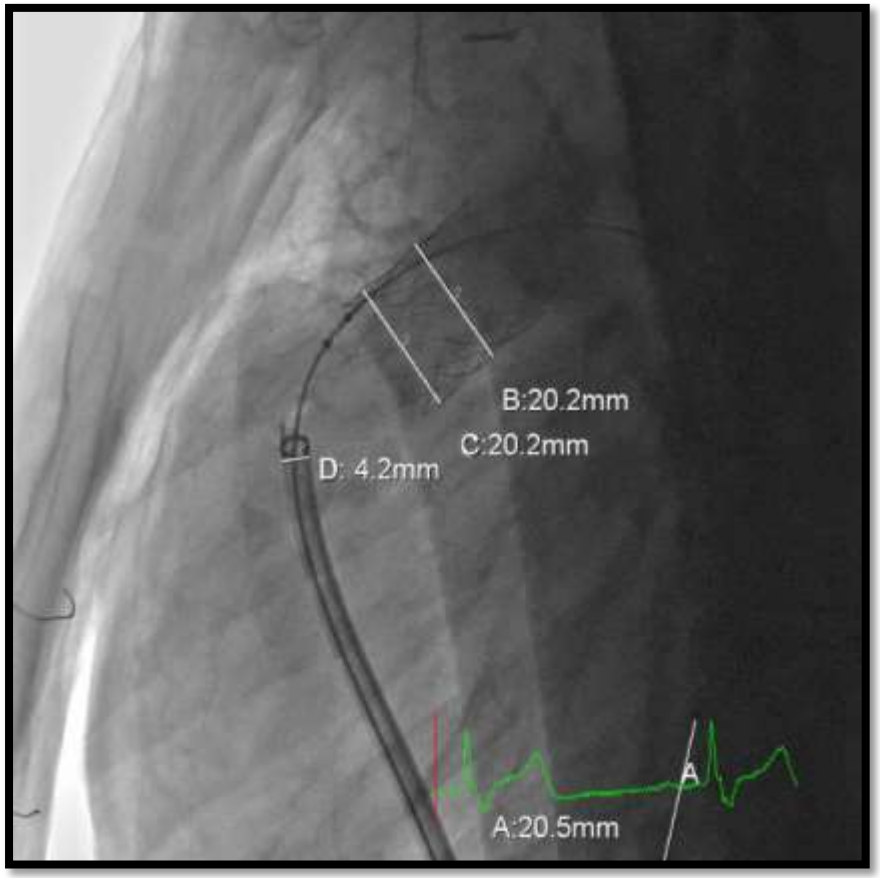
RVOT Reassessment - Post Stenting



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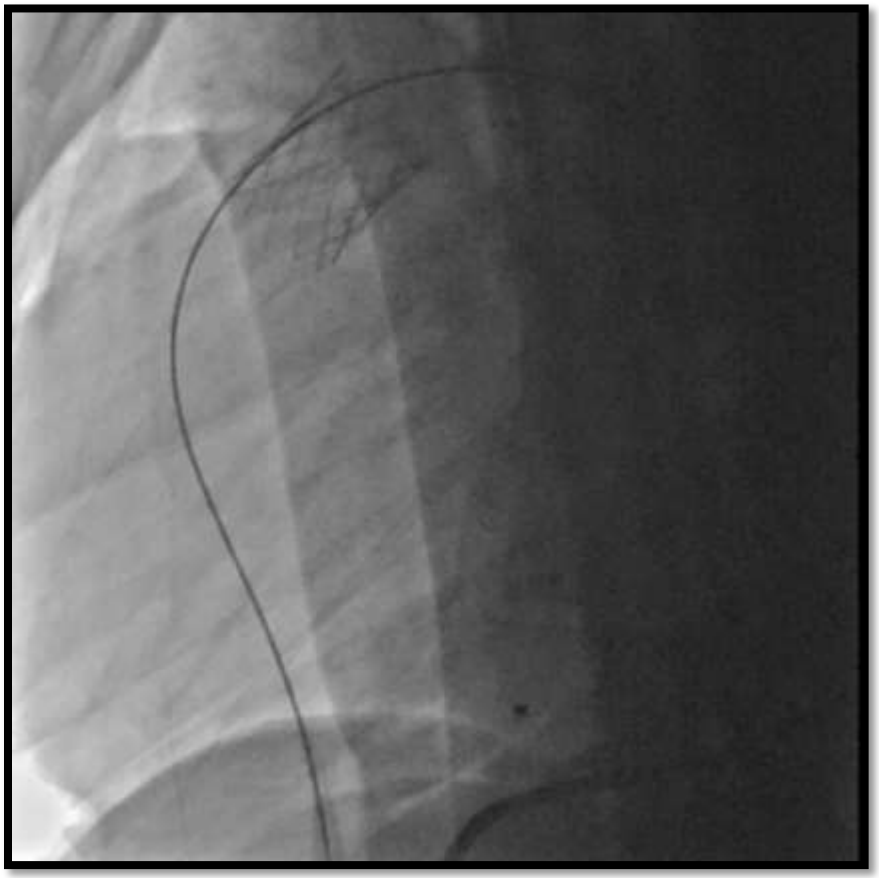
Melody Valve Delivery and Final Result



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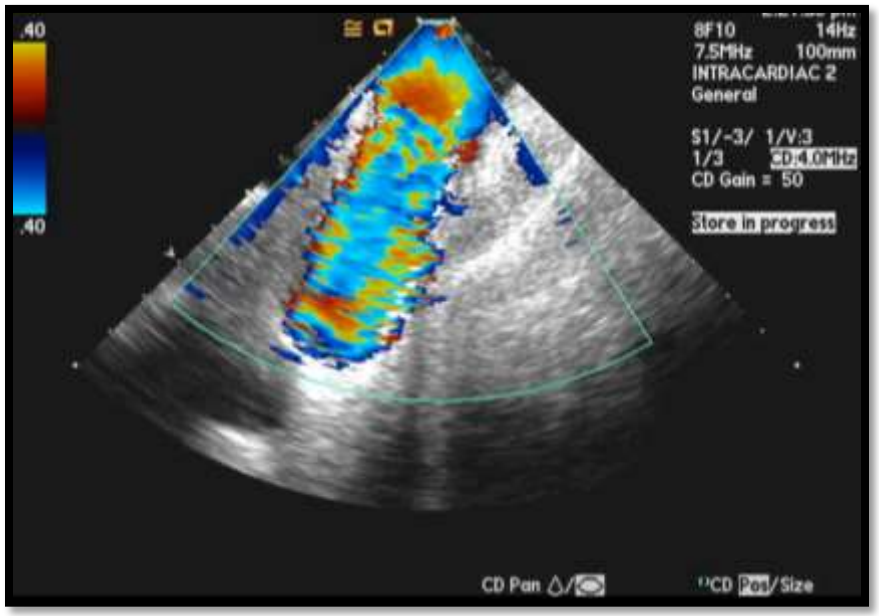
ICE Imaging



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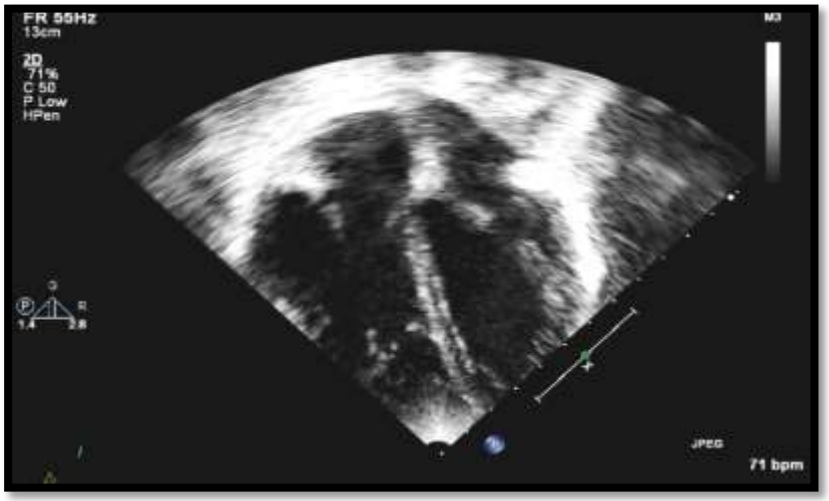
RV Remodeling



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Comparison with Surgical PVR Outcomes

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Outcome Measured	Hybrid PVR n=8 Mean (SD)	Open PVR n=13 Mean (SD)	P-value	Cohen's d
Length of Stay (Days)	4.75 (1.04)	6.46 (3.60)	0.029*	0.739
Blood Products Transfused (Units)	0.125 (0.35)	2.38 (2.4)	0.029*	1.64
# of Days Drains In	2.00 (0.93)	3.08 (1.75)	0.345	0.806
Post-Op Hgb	11.83 (1.56)	10.74 (1.56)	0.807	-0.699

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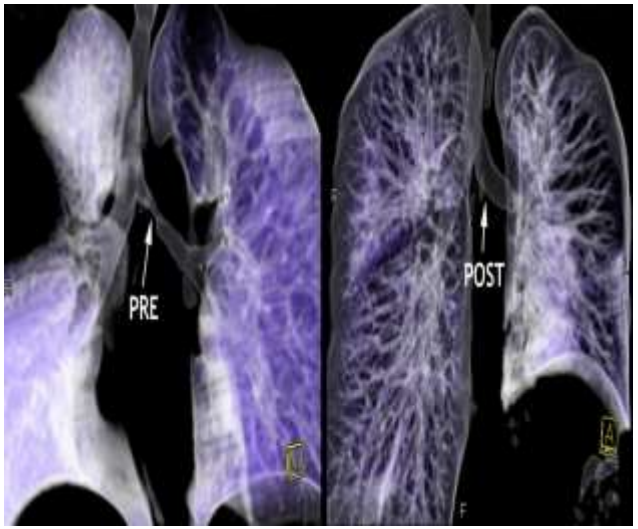
The Future….

The ‘ideal’ replacement vascular graft should have the potential to grow and remodel in vivo

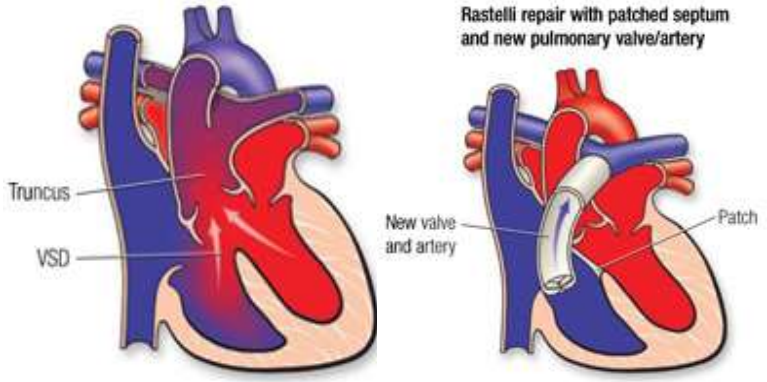
It does not exist yet...



Hypothesis

- Tissue-engineered valves, conduits and vascular patches made of *living* tissue could function like a native structure with the potential to grow/repair/remodel

- Fewer reoperations, better survival and quality of life



The Matrix

Homografts

CorMatrix

Pericardial Patches

Courtesy of Massimo Caputo, MD. Chicago

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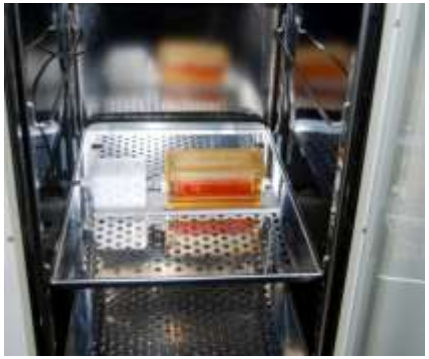
Tissue Engineering of Grafts








Courtesy of Massimo Caputo, MD. Chicago

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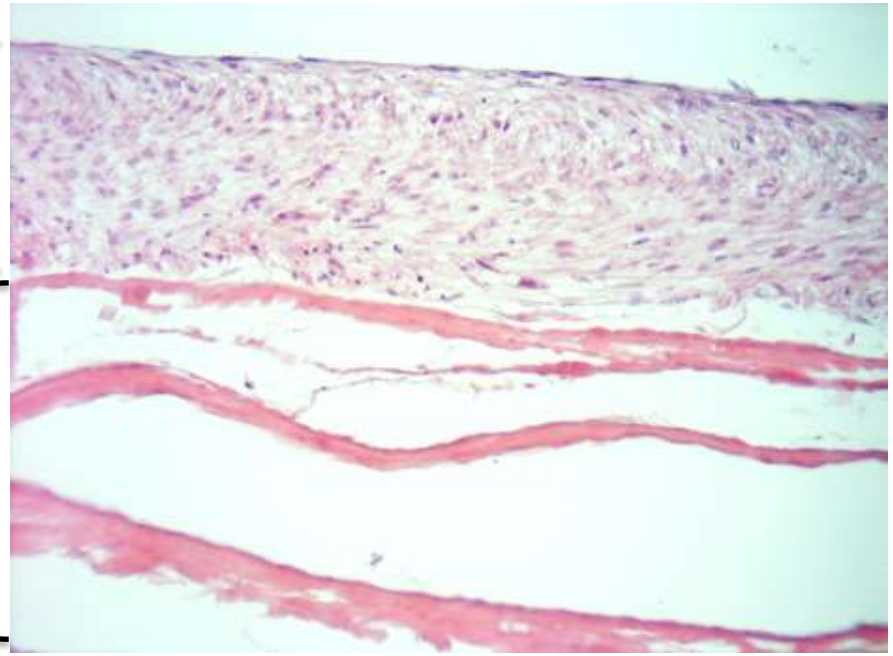
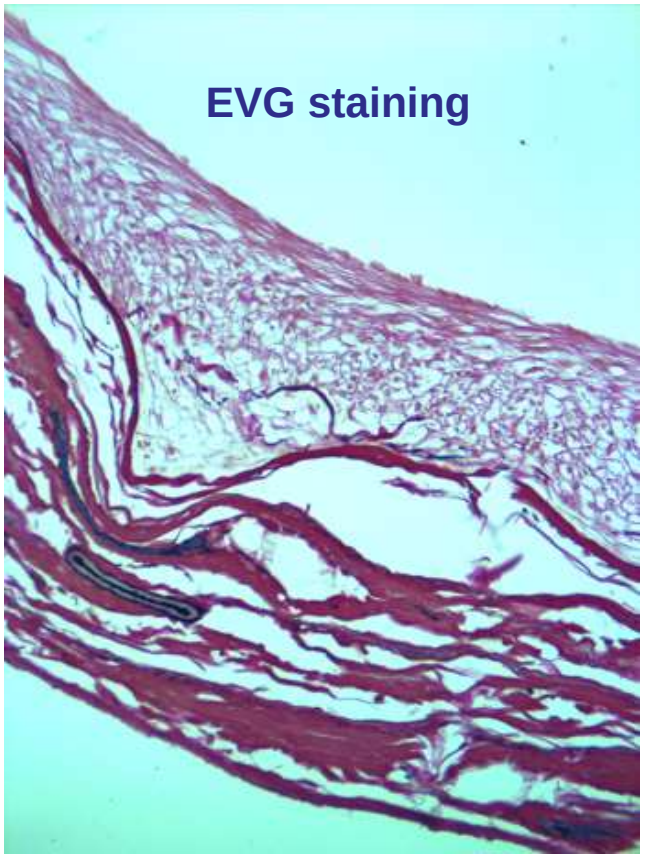
Histology

H&E staining

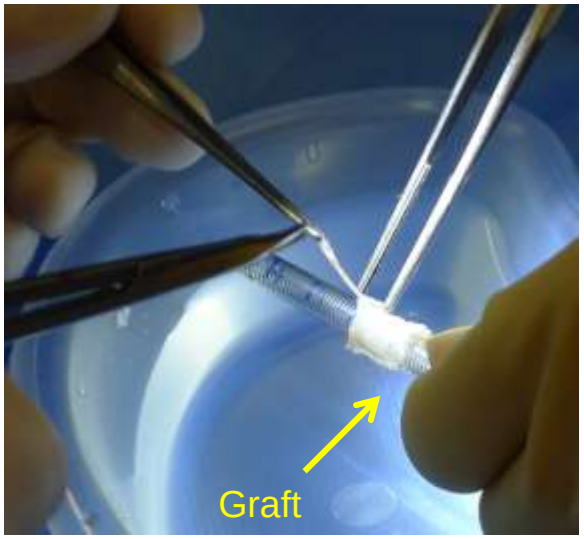


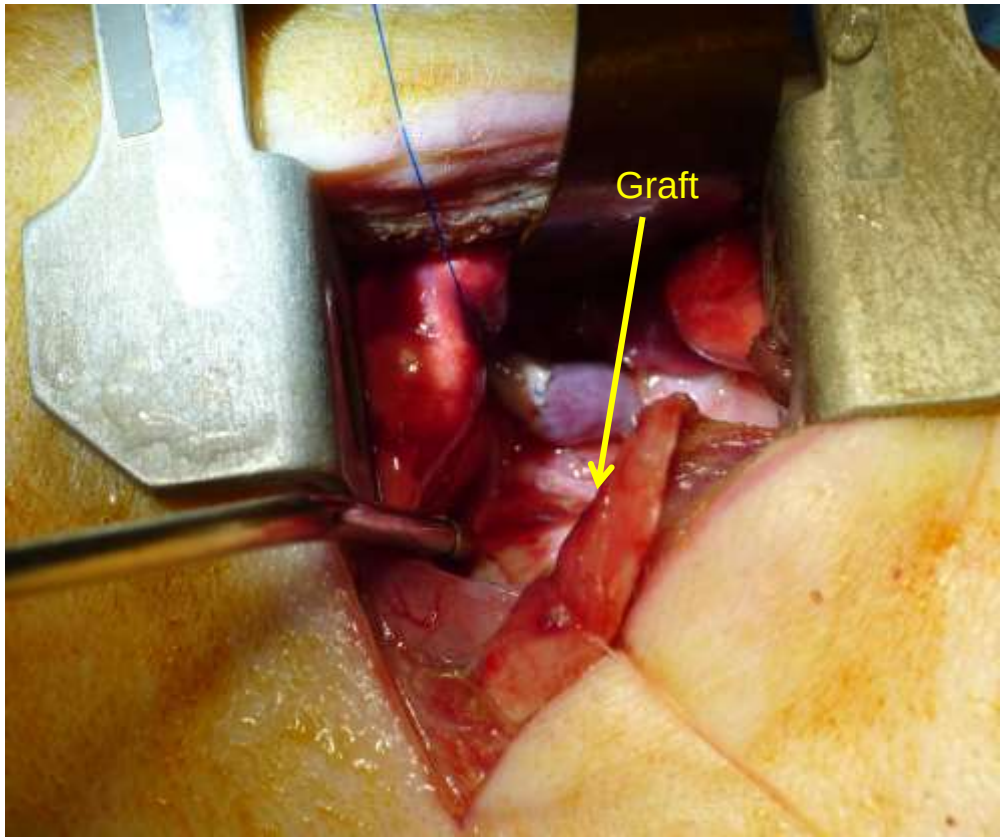


Cells seeded on CorMatrix and grown in bioreactor

Courtesy of Massimo Caputo, MD. Chicago

Piglet Model

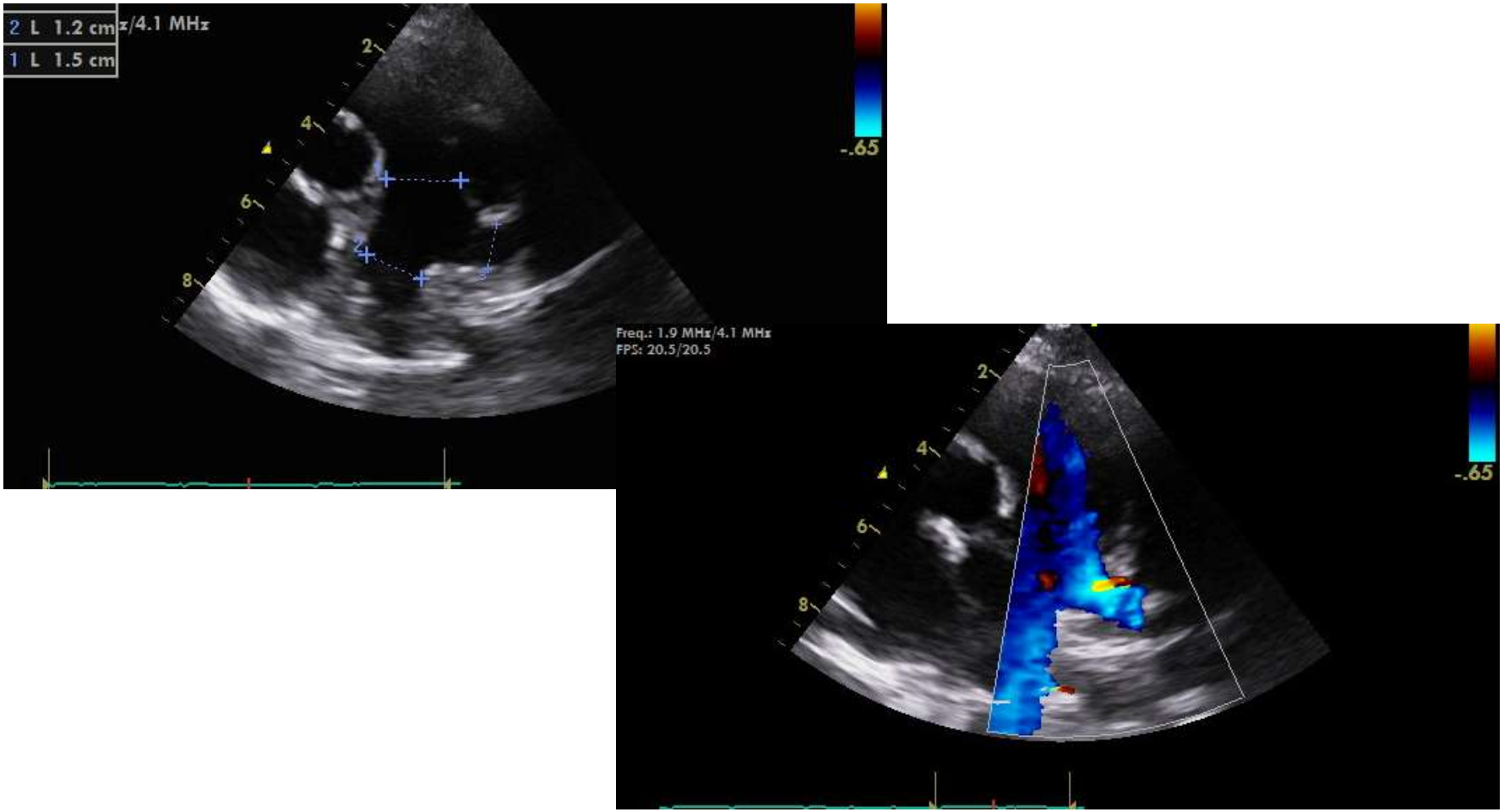




Test engineered grafts performance in vivo

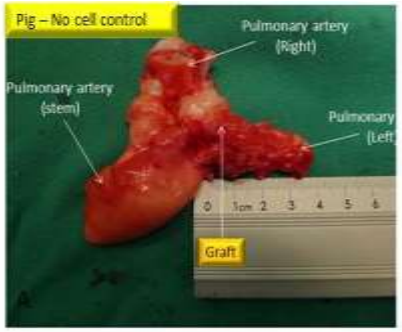
Courtesy of Massimo Caputo, MD. Chicago

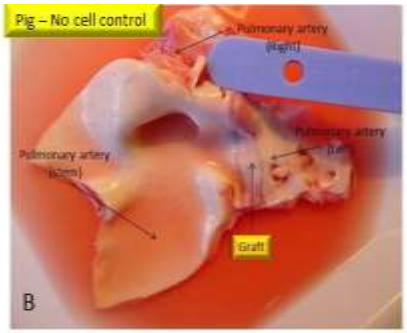
Echo Showing Graft Patency – 6 Months In Vivo

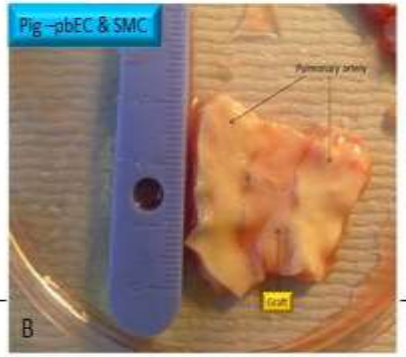


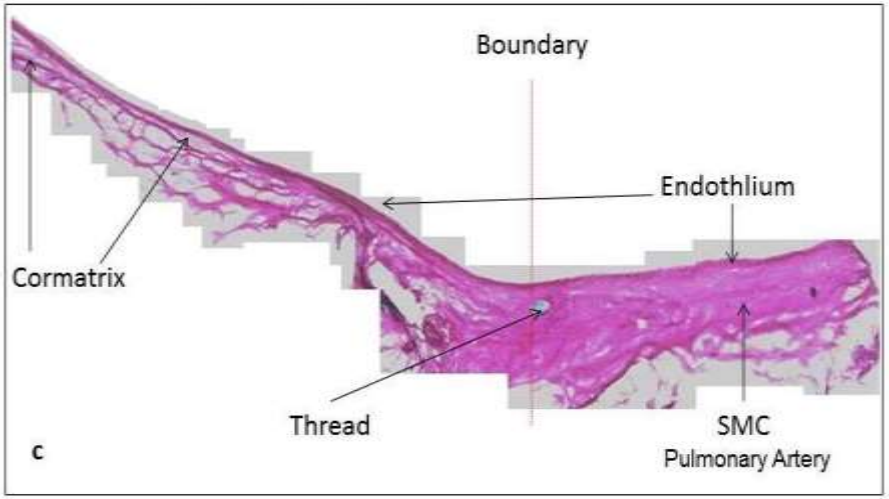
Courtesy of Massimo Caputo, MD. Chicago

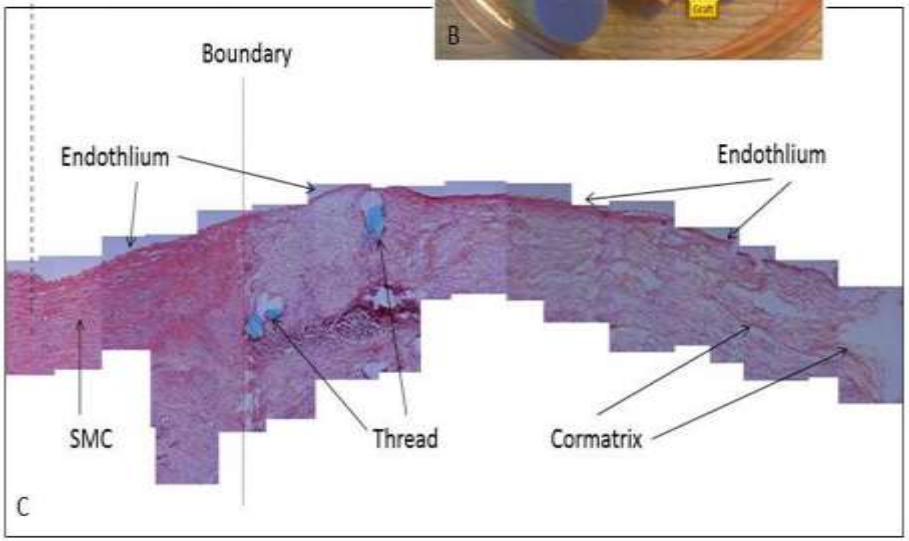
Necropsy





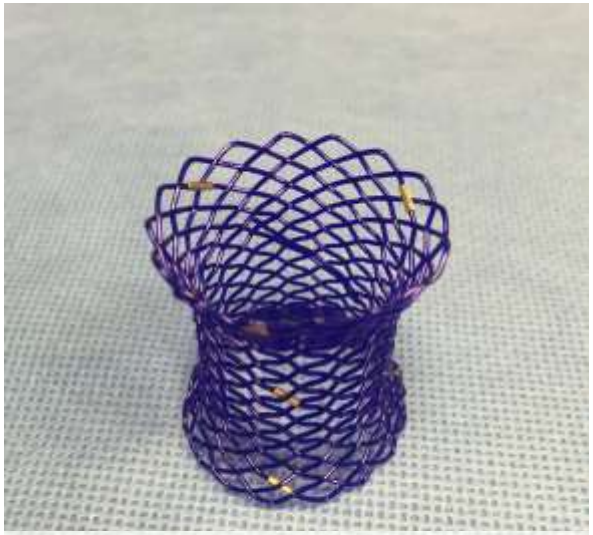


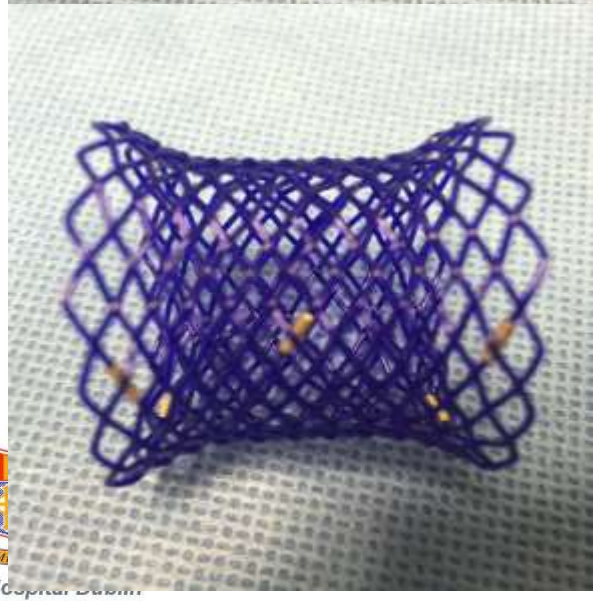


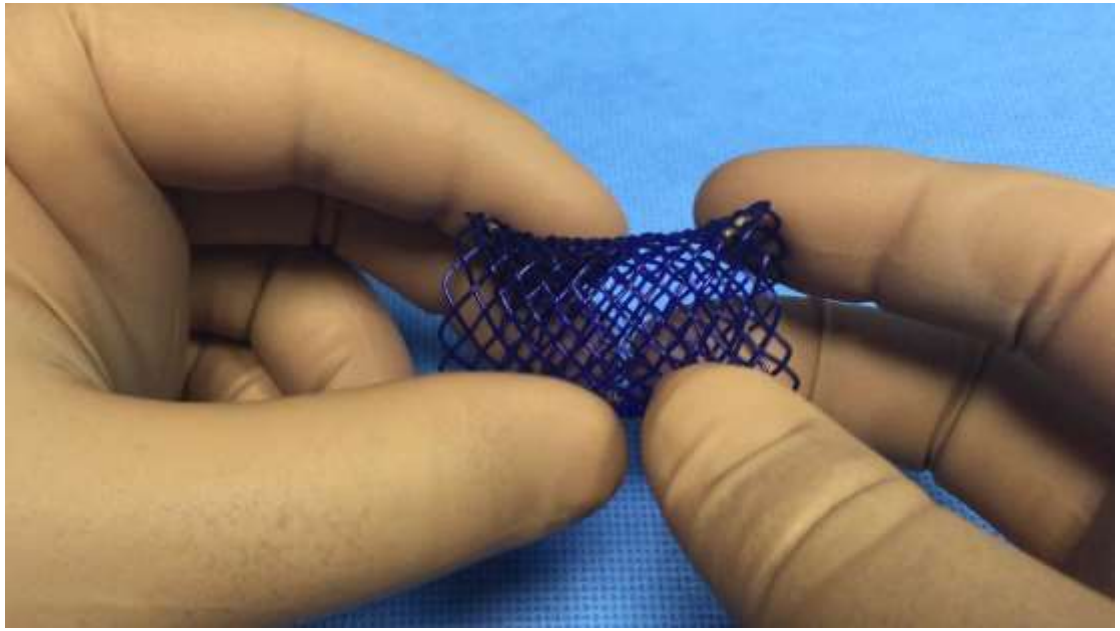


Courtesy of Massimo Caputo, MD. Chicago

Self-Expanding Bioresorbable Scaffold

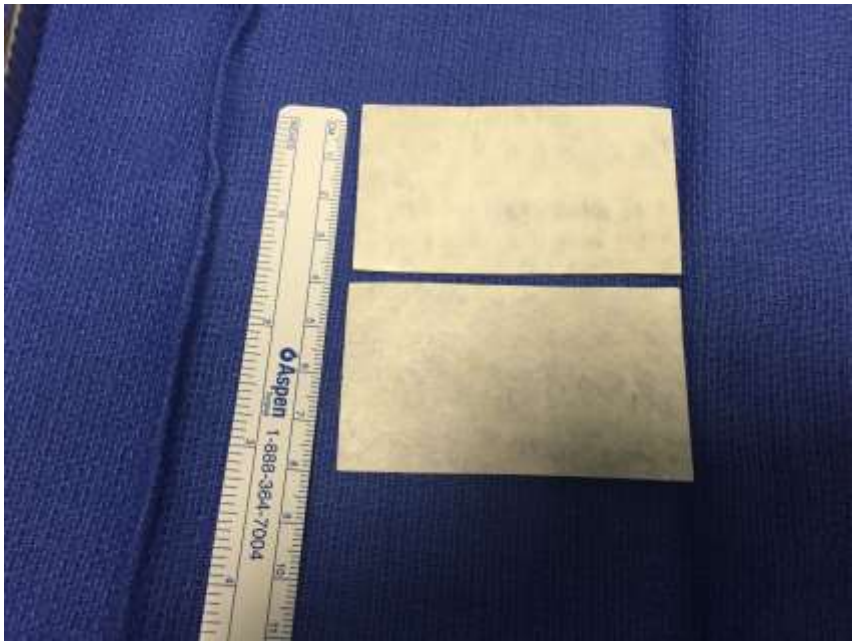


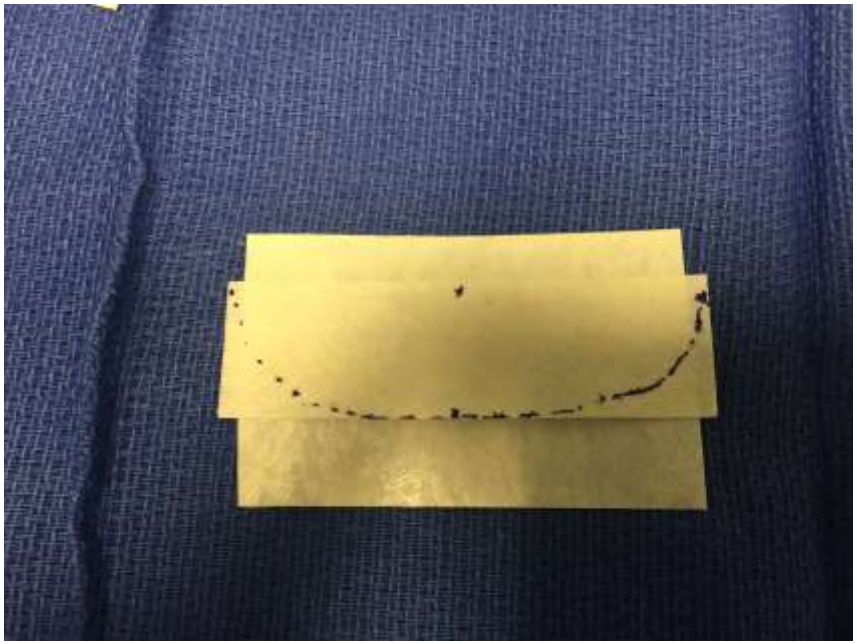




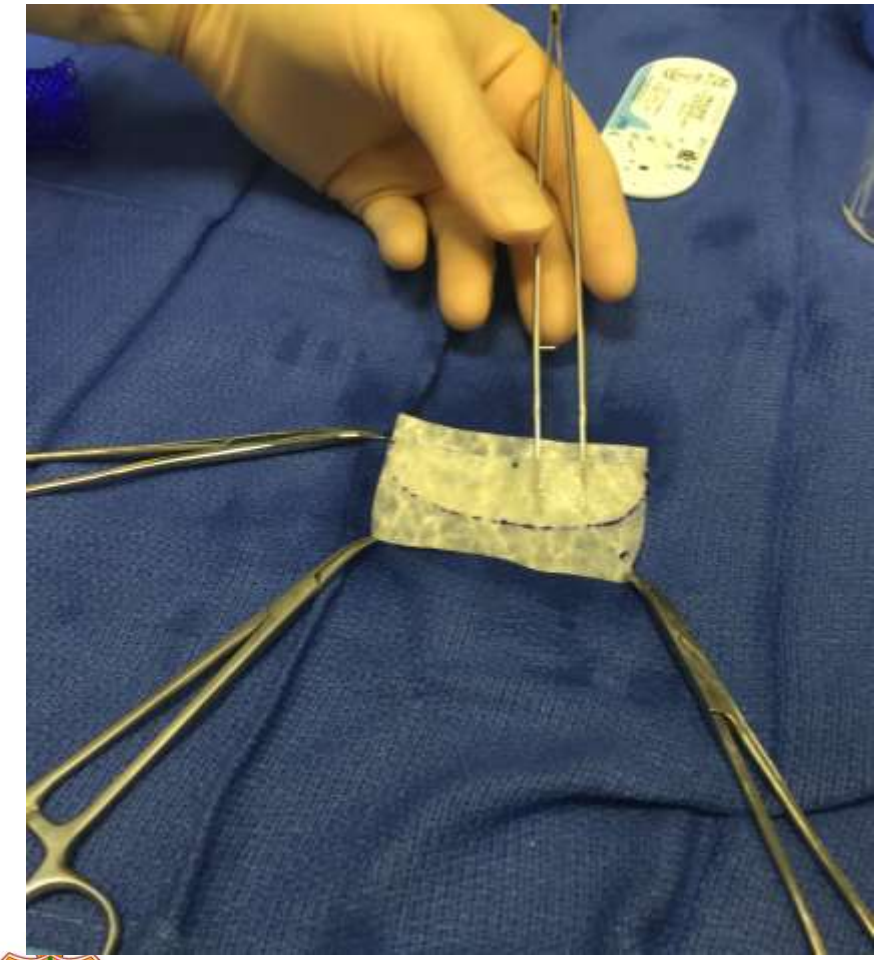
- ***Polydioxanone Stent – Oesophageal Stricture***
- ***Number of Sizes – 31/25/31 x 30mm***
- ***28Fr Delivery System***
- ***Degradation dependent on pH of fluid***

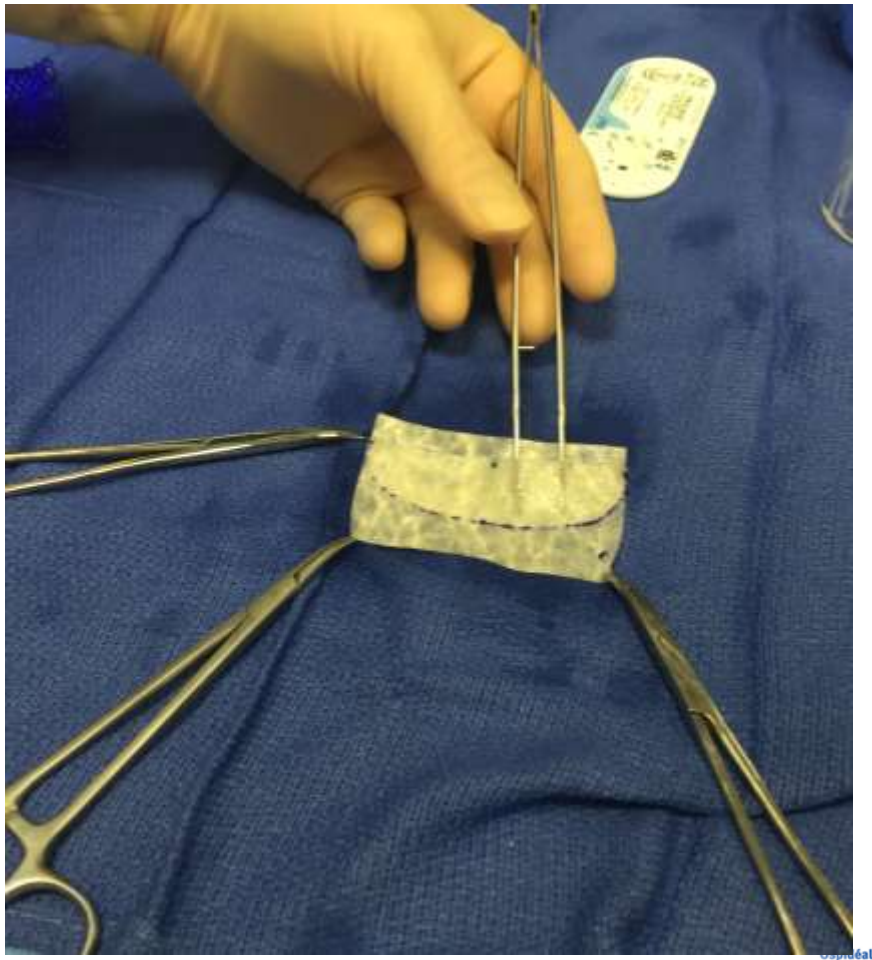
Valve Leaflet Fabrication with Cor-Matrix





Valve Leaflet Fabrication





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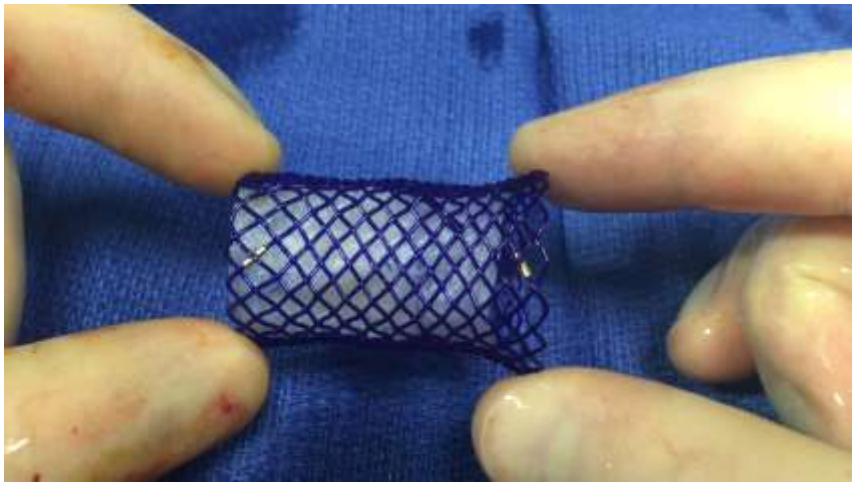
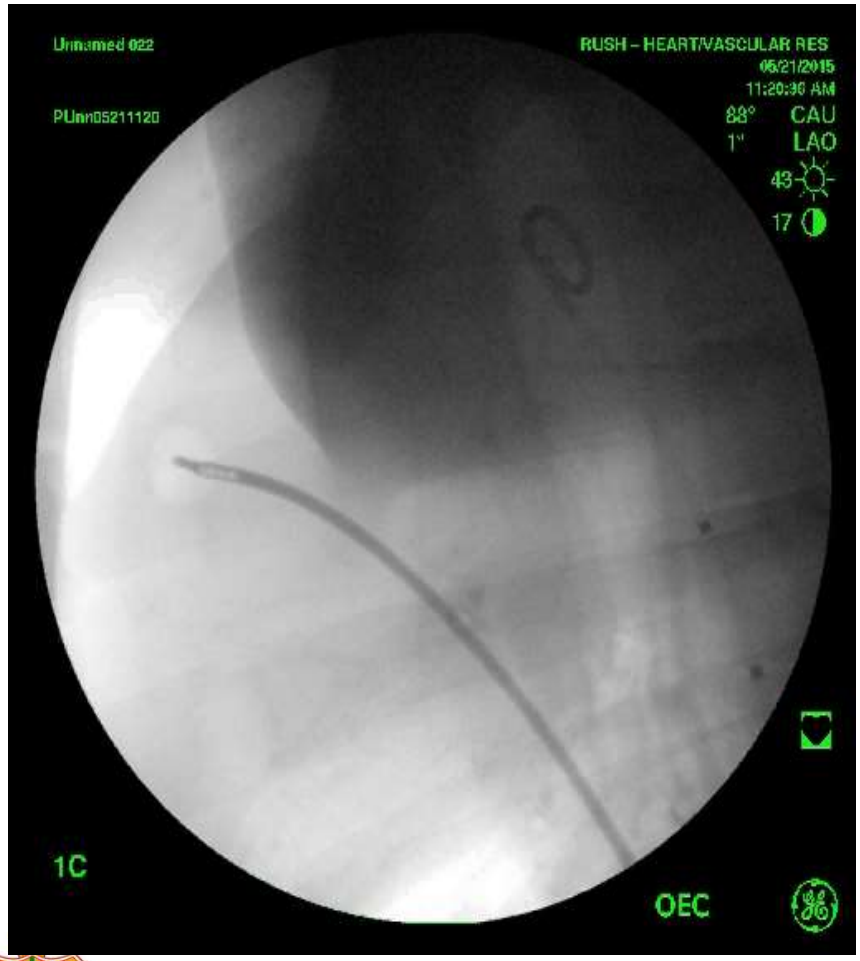
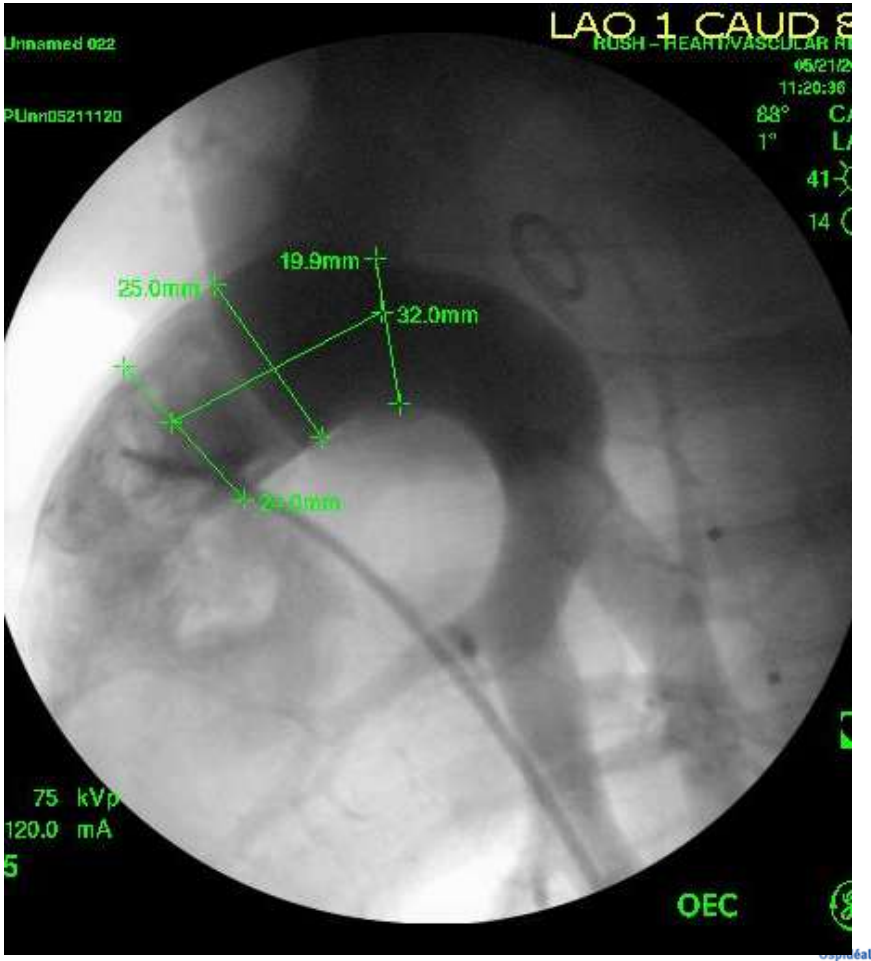
Attaching the Valve to the Scaffold

The Stent-Valve

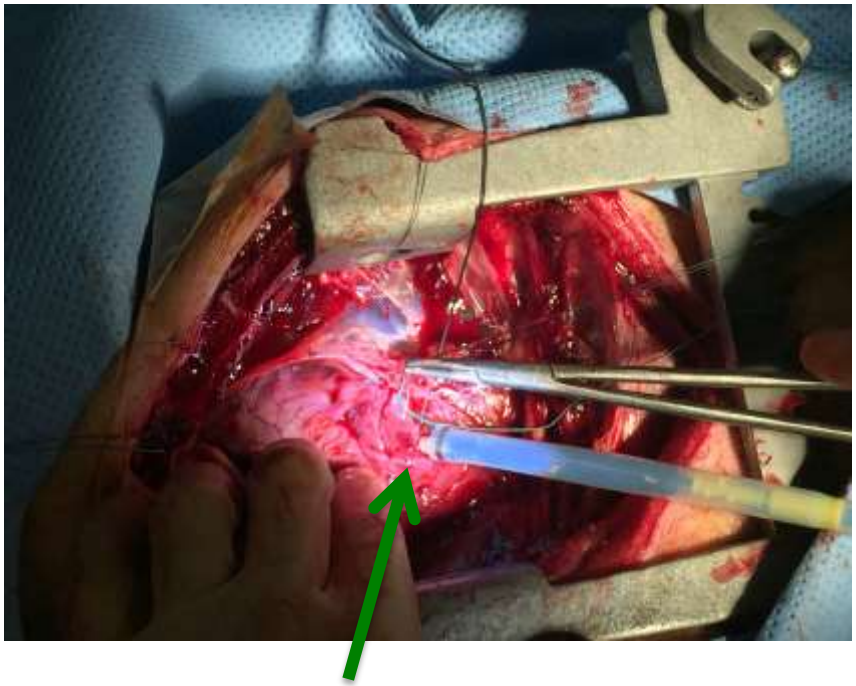


Initial Angiography and Measurements





Perventricular Valve Delivery



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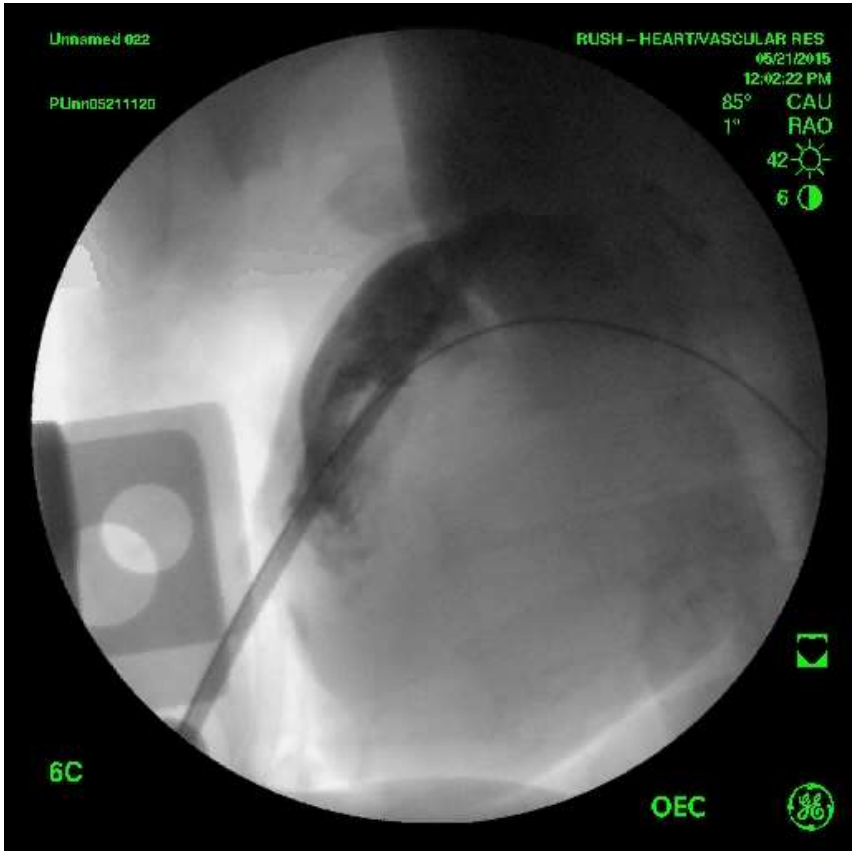
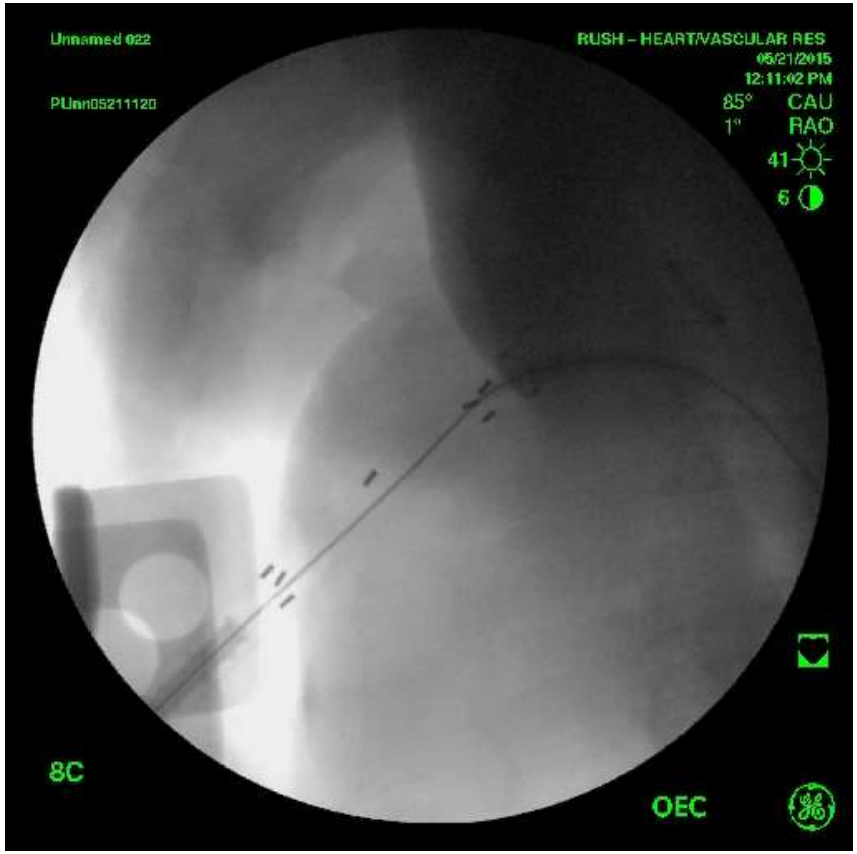
Sheath Placement and Valve Advancement





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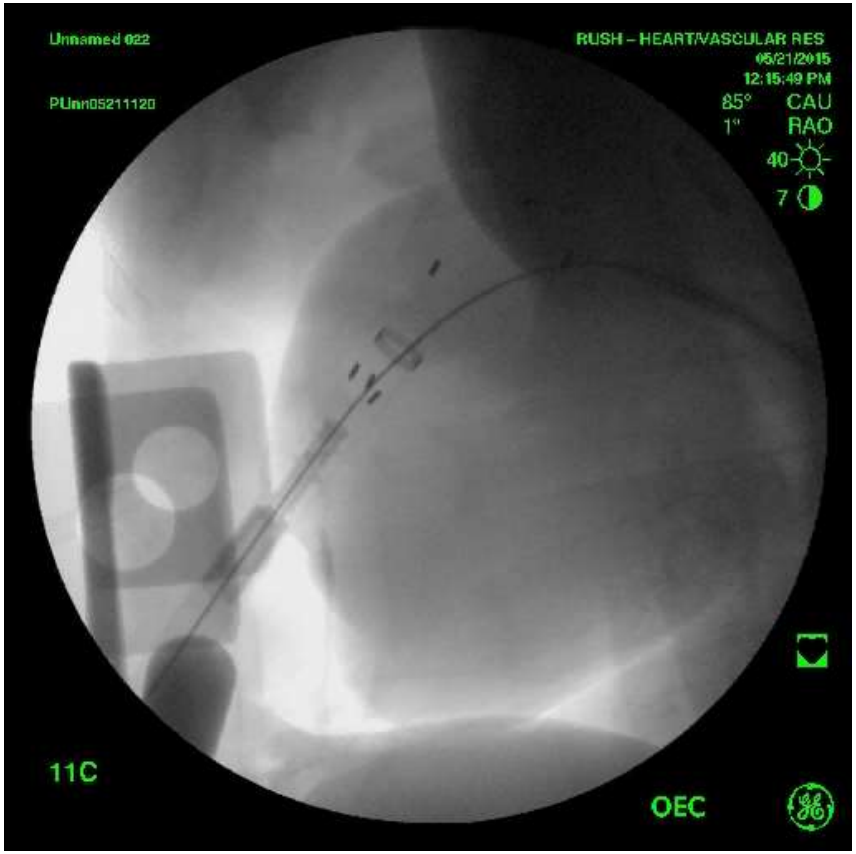
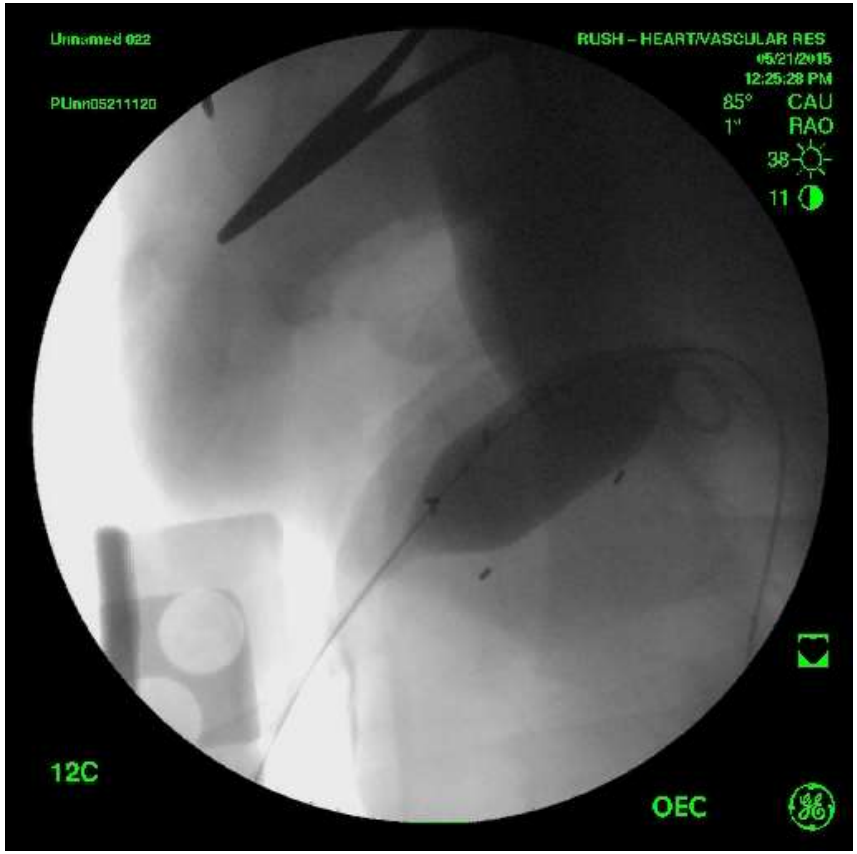
Valve Deployment and Ballooning





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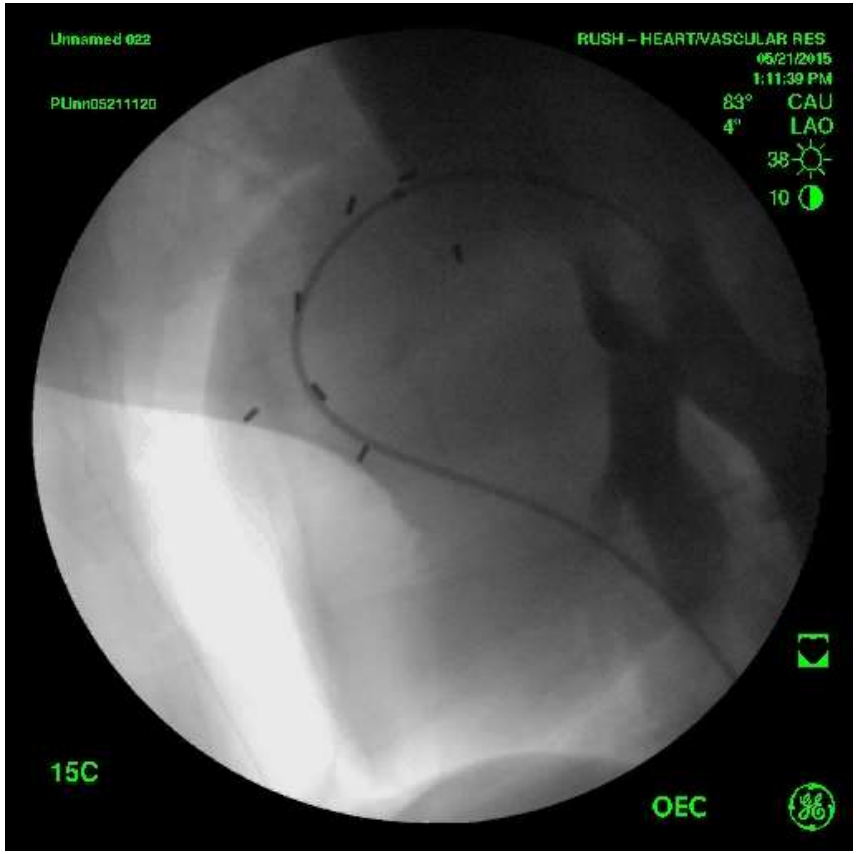
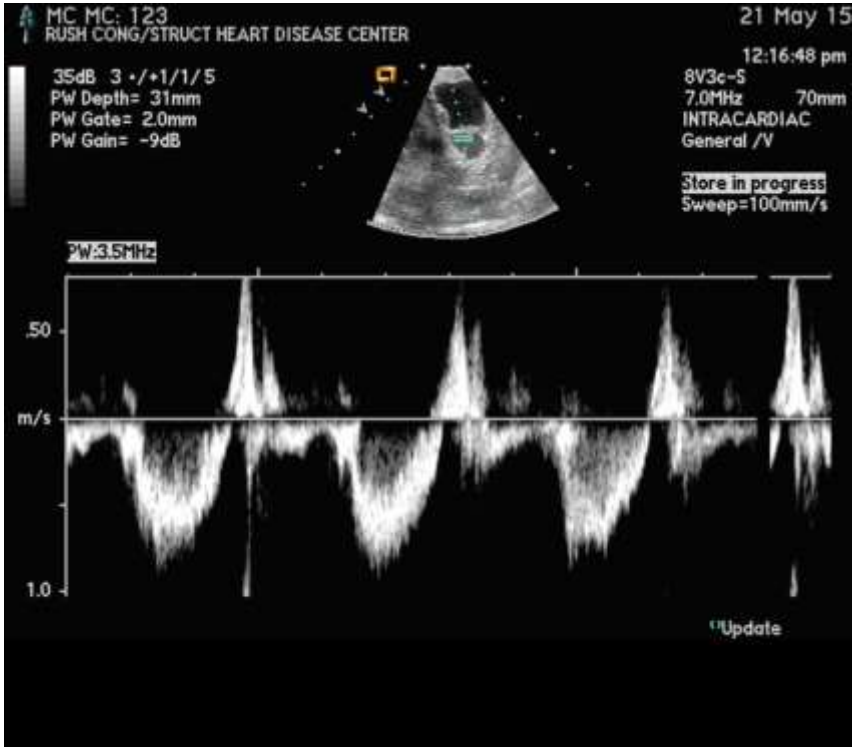
RV and PA Angiography



Epicardial Echocardiography

Doppler Assessment



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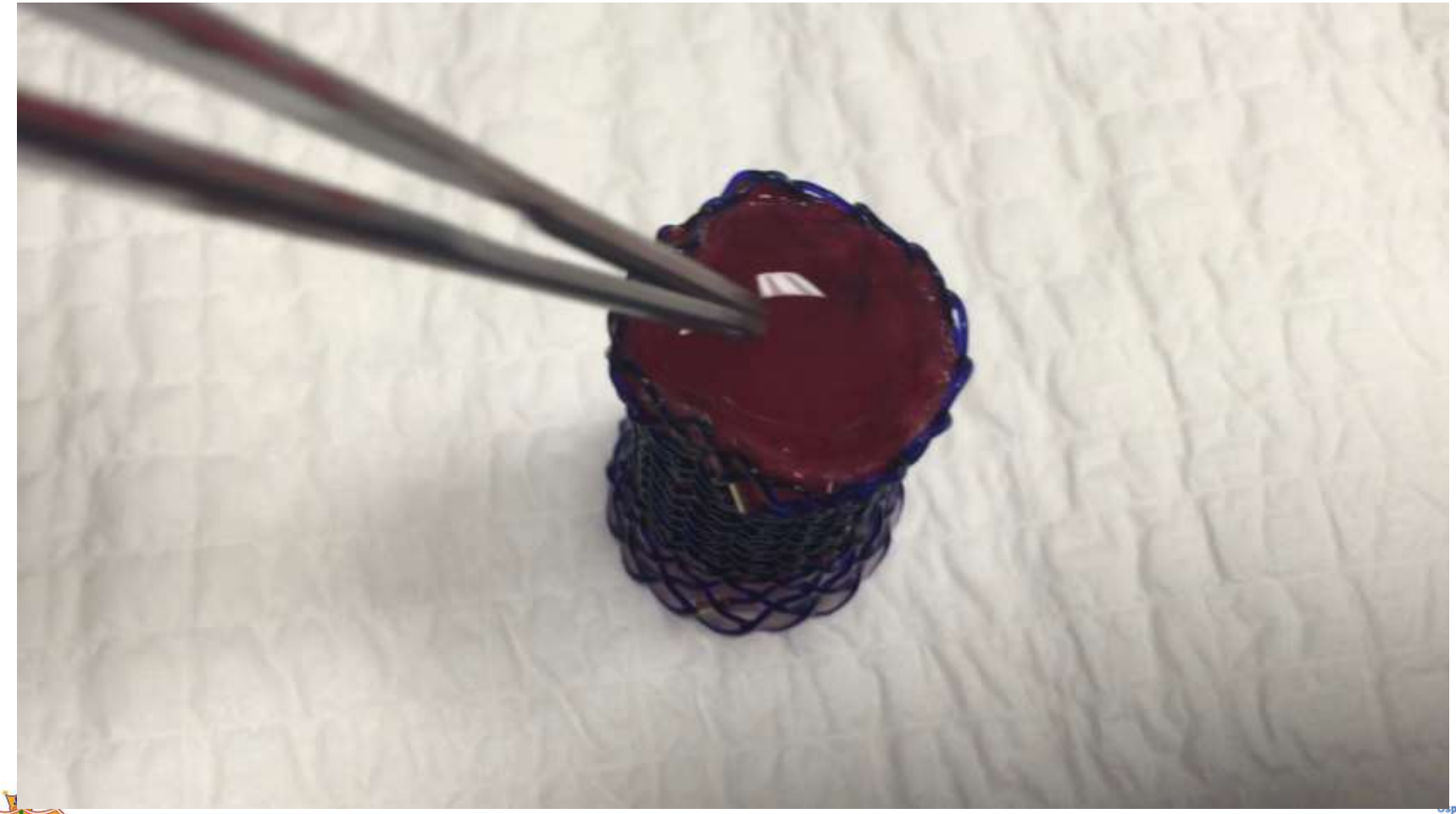
Stent Valve Following Removal



The Future

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