THE HEART CENTER

Can we get back to the Transcatheter Fontan?

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Disclosures

- None
- Off label use of FDA approved devices will be discussed

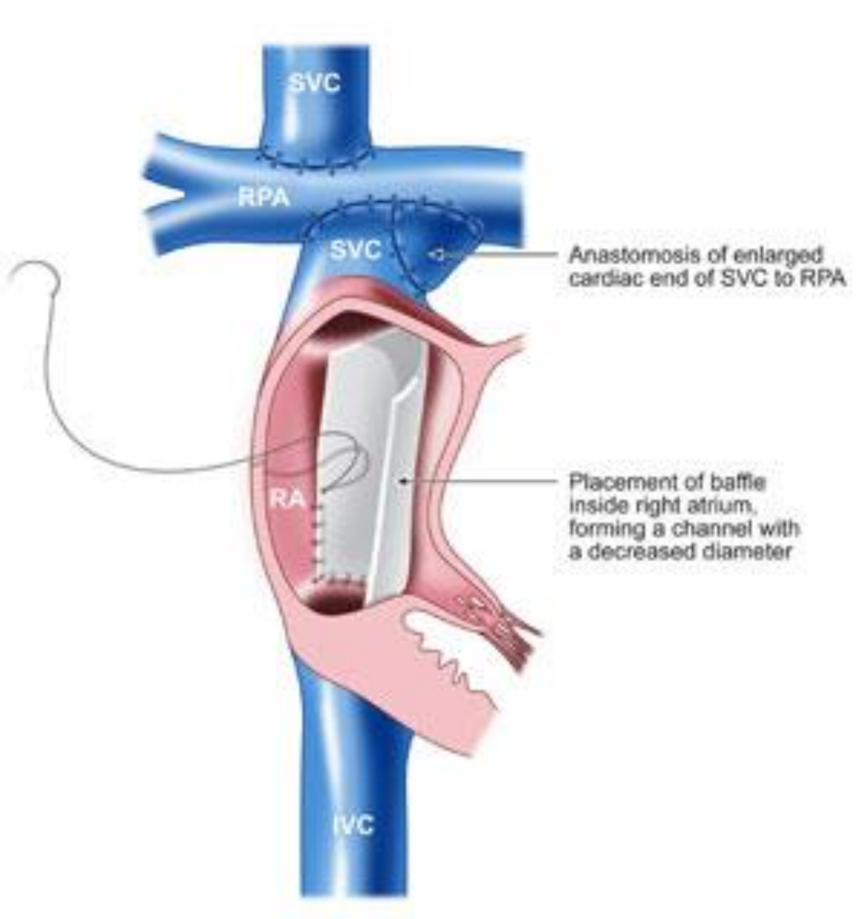
Ideal Fontan Circuit

- unobstructed, laminar flow from IVC+SVC to PAs
- no energy loss through circuit
- ?pulsitility or valved forward motion
- stable flow dynamics over time
- growth potential to match somatic growth
- created with minimal impact
  - does not increase arrhythmia risk
  - does increase injury to ventricle
  - does not increase risk to patient

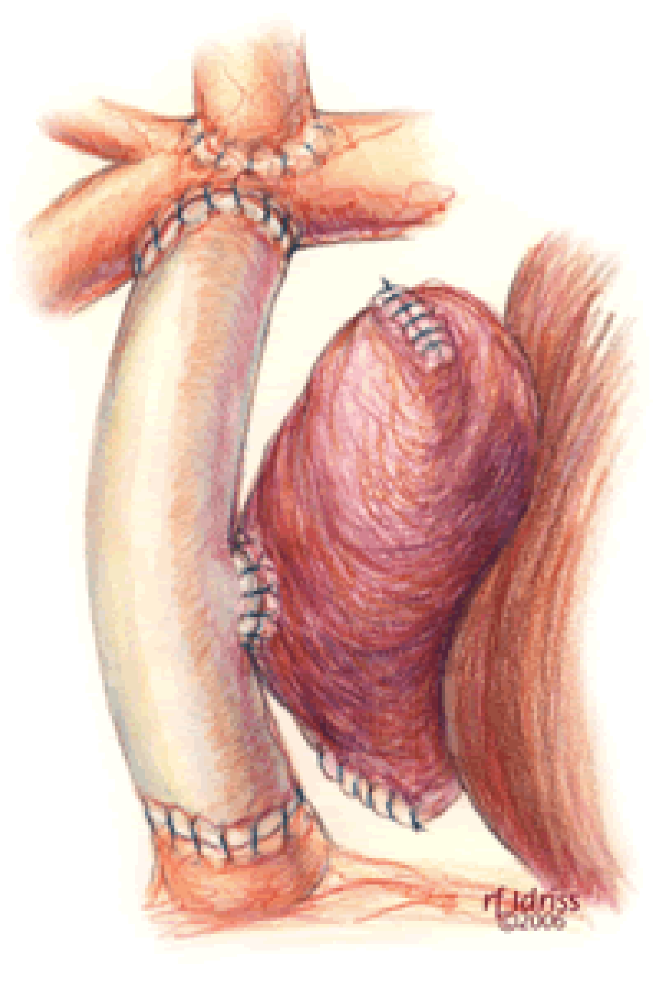
Lateral Tunnel Fontan

- Advantages
  - widespread experience with procedure
  - applicable to most anatomic variations
  - ease of creation
  - growth potential
- Disadvantages
  - potential increased arrhythmias
    - long atrial suture lines & increased atrial pressure
  - loss of laminar flow overtime with dilatation of circuit
  - myocardial ischemia to create circuit

Fontan Technique



B. Lateral tunnel (intra-atrial baffle)



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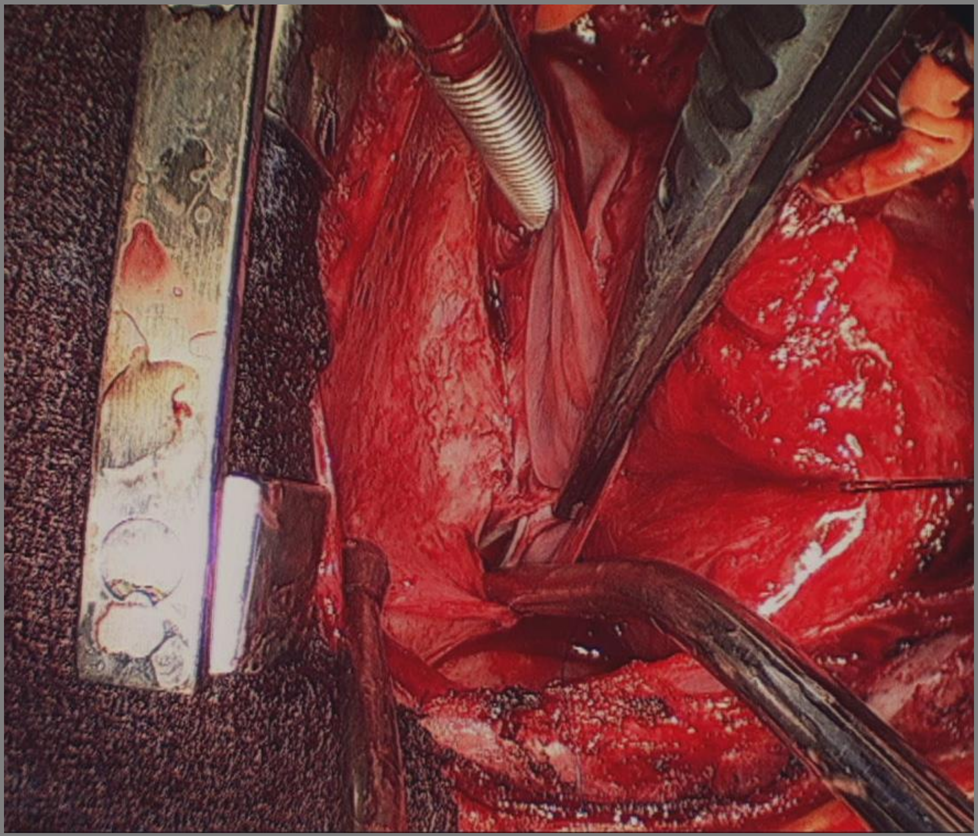
ExtraCardiac Fontan-(tube graft)

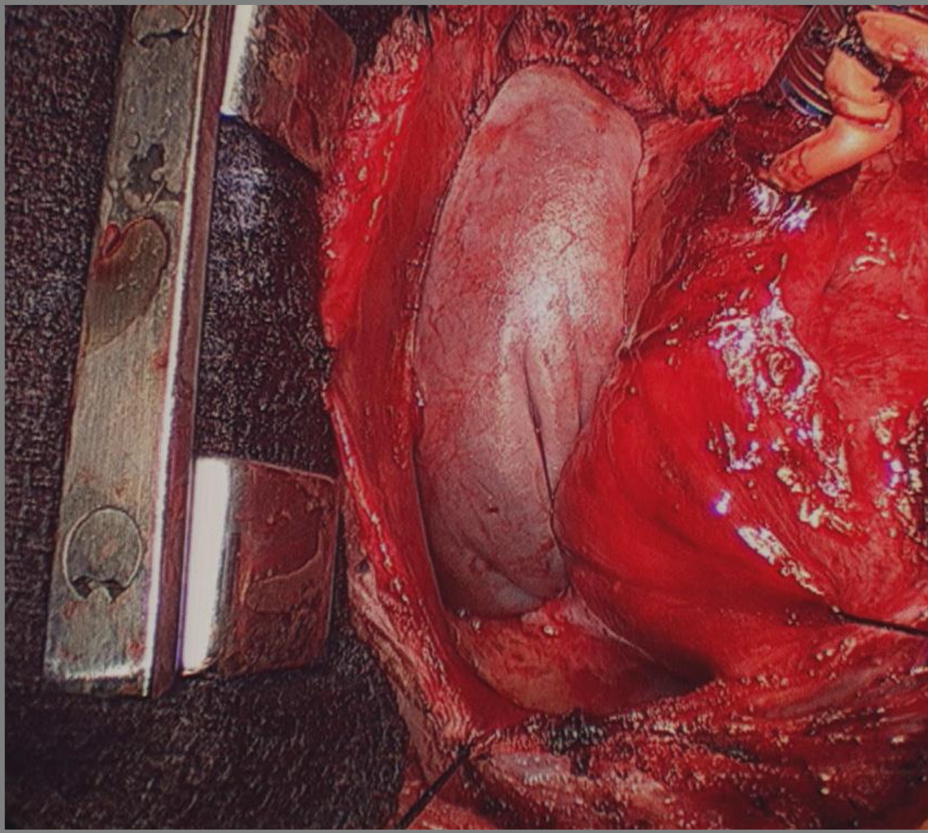
- Advantages
  - stable laminar flow
  - no intra-cardiac suture lines or increased pressure
  - can be created without myocardial ischemia
- Disadvantages
  - no growth potential
  - use of adult sized conduit can create distortion at either entrance from IVC or exit into PAs
  - potential thromboembolism of conduit

NCH Fontan technique

- Modified extra-cardiac pericardial “well”
- On bypass, no x-clamp, no circulatory arrest
- Growth potential, no intra-cardiac suture lines
- Possible respiratory & cardiac “pulsation”

Fontan Technique





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Fontan Technique

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Holy Grail

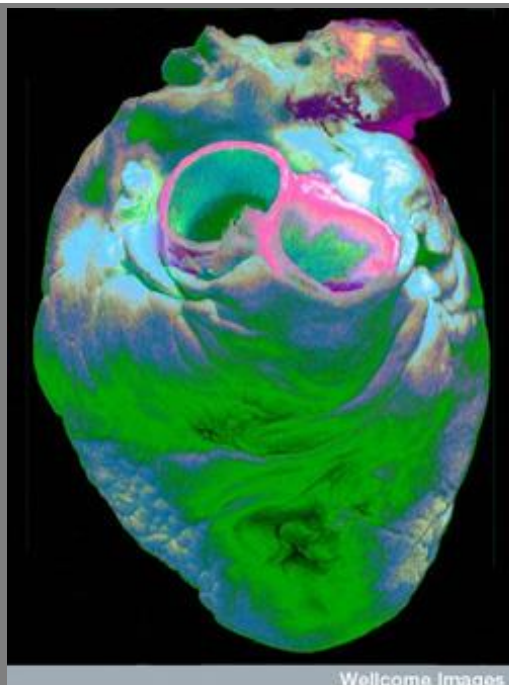
- A growing replacement material
- Versatile in possible applications
  - Sizes
  - Patches vs tubes vs valves
- Easy to handle and suture yet flexible and strong
- Hemostatic
- In-expensive

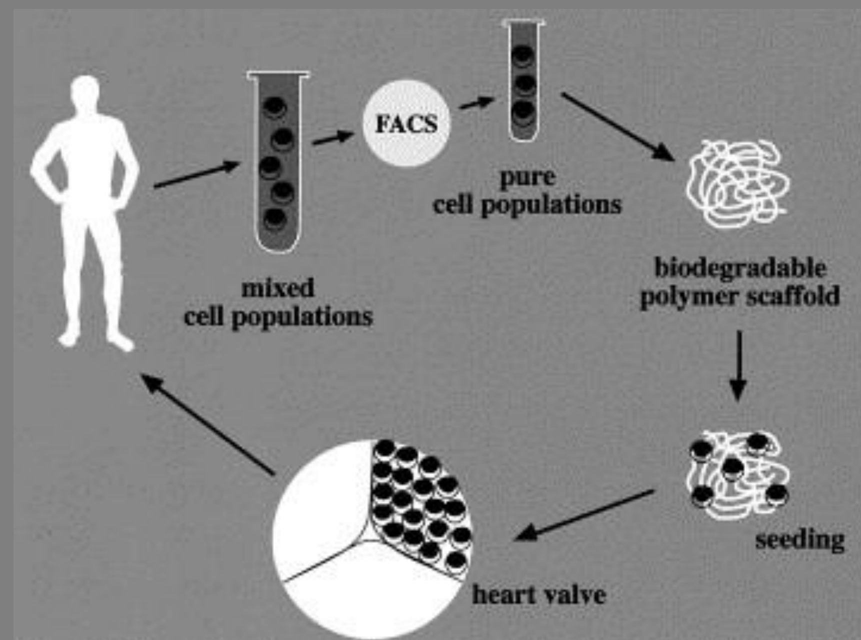
Artificial Organs
26(5):402–406, Blackwell Publishing, Inc.

Tissue Engineered Heart Valves: Autologous Cell Seeding on Biodegradable Polymer Scaffold

Toshiharu Shinoka

Department of Cardiovascular Surgery, Heart Institute of Japan, Tokyo Women's Medical University, Tokyo, Japan





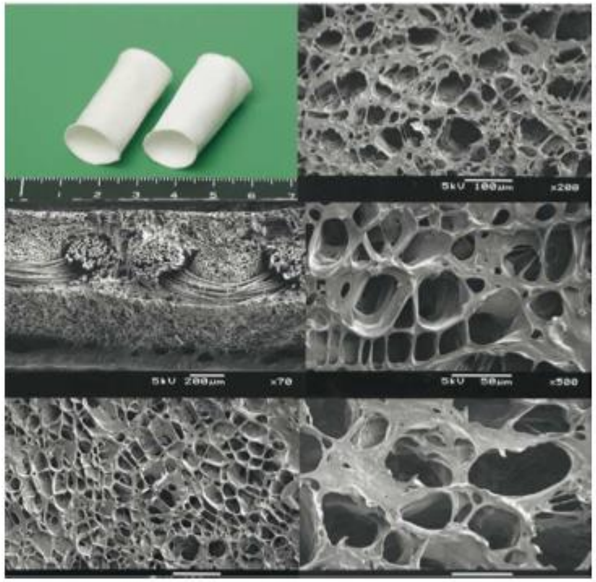


Figure 1. Macroscopic finding of biodegradable scaffolds and scanning electromicroscopic findings of polymer scaffolds. *Upper left,* Macroscopic finding; 18 mm in diameter.Copolymer of L-lactide and ε-caprolactone synthesized by ring-opening polymerization, with weight composition ratio of L-lactide and ε-caprolactone at 50:50. Polymeric woven scaffold composed of polycaprolactum and polylactic acid reinforced with PGA mesh.

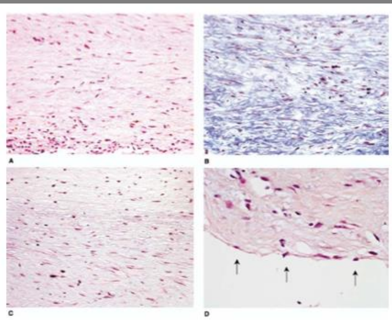


Figure 2. Histopathologic findings on explanted patch in patient with reoperation. *Arrows* indicate endothelium-like cells. A, Hematoxylin-eosin stain, original magnification ×400; B, Masson stain, original magnification ×400; C, Victoria blue, original magnification ×400; D, hematoxylin-eosin stain, original magnification ×800.

Evolving Technology

The tissue-engineered vascular graft using bone marrow without culture

Narutoshi Hibino, MD,[a] Toshiharu Shin'oka, MD, PhD,[a] Goki Matsumura, MD, PhD,[a] Yoshihito Ikada, PhD,[b] and Hiromi Kurosawa, MD, PhD[a]

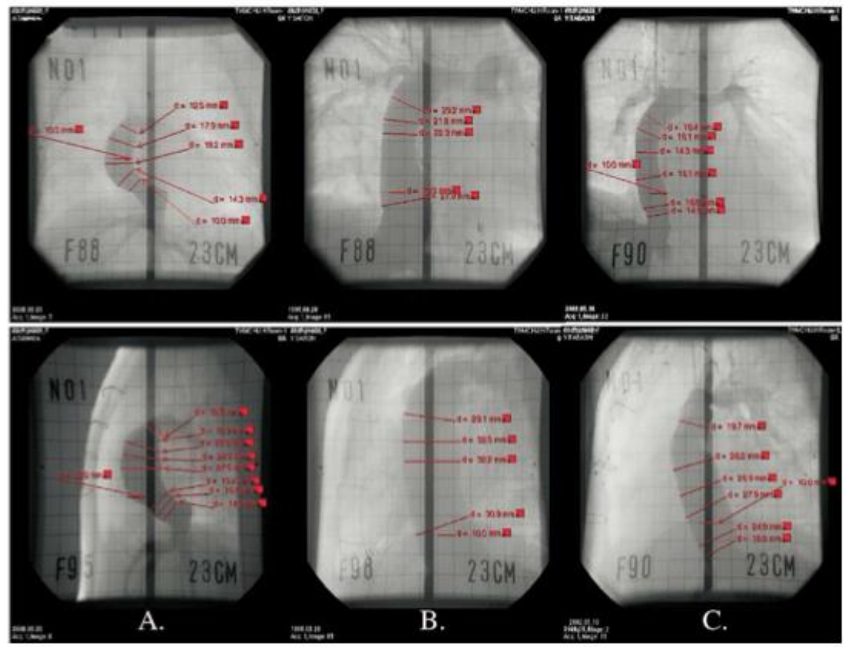


Figure 5. Measurements of major and minor axes of tissue-engineered grafts in patients 2 (A), 4 (B), and 12 (C). *Upper row,* Anteroposterior view; *lower row,* lateral view.

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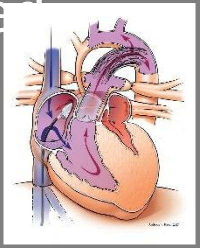
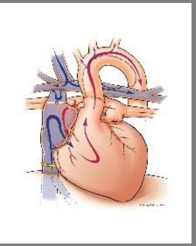
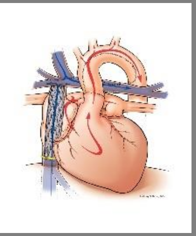
Back to the Future

Our Original Hybrid Concept of HLHS Repair

- One comprehensive open heart procedure (combined stage 1,2 and part of 3), flanked by two less invasive procedures
- Need a way to initially stabilize patient to an age appropriate for the "big operation"
  - Control & protect PBF (LPA/RPA bands)
  - Provide reliable systemic cardiac output (PDA stent)
  - Create unobstructed flow from LA (BAS/stent IAS)
- Develop a way to less invasively complete the Fontan circuit (covered stent)





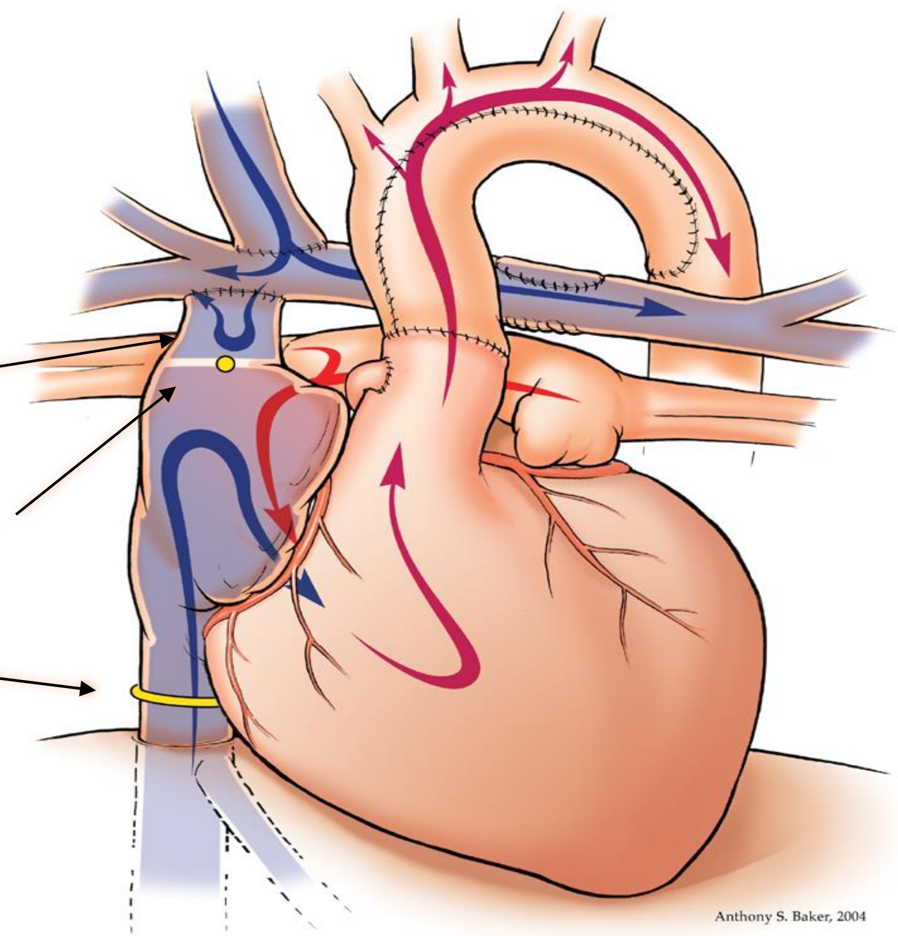


Presented at the Society for Thoracic Surgeons Meeting, January 2003

Amplatzer PA Flow Restrictor

All Transcatheter Stage 1

Comprehensive Stage 2



Blind pouch

Radio-opaque marker

Radio-opaque band

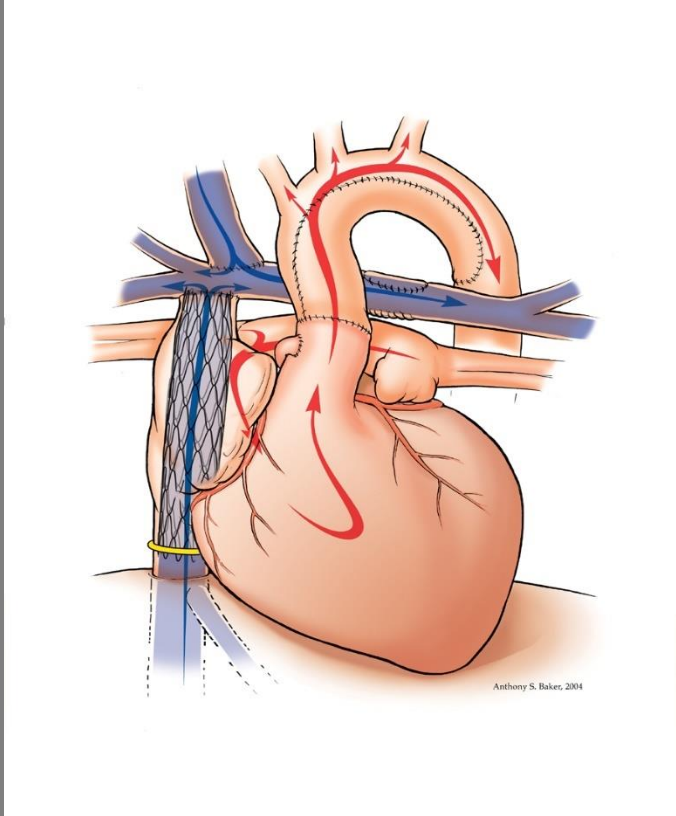
Semin Thorac Cardiovasc Surg Pediatr Card Surg Annu. 2004;7:48-55.

Fontan completion without surgery.

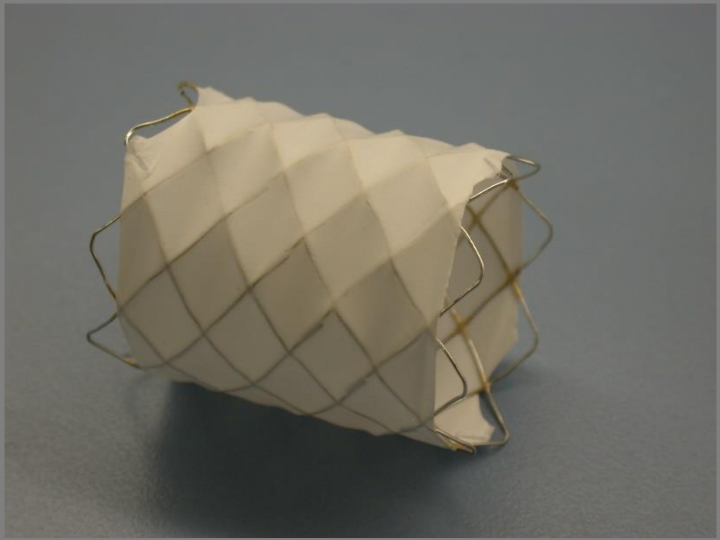
Galantowicz M, Cheatham JP.
Department of Cardiothoracic Surgery, The Heart Center, Columbus Children's Hospital, Columbus, OH 43205, USA.

Abstract
An ideal Fontan procedure would minimize complications while maximizing flow dynamics through the circuit. We report our early experience with a new combined surgical/transcatheter approach which enables a nonoperative, transcatheter Fontan completion. The conceptual rationale of this management strategy, as well as surgical and catheterization techniques, are discussed.

PMID: 15283352 [PubMed - indexed for MEDLINE]



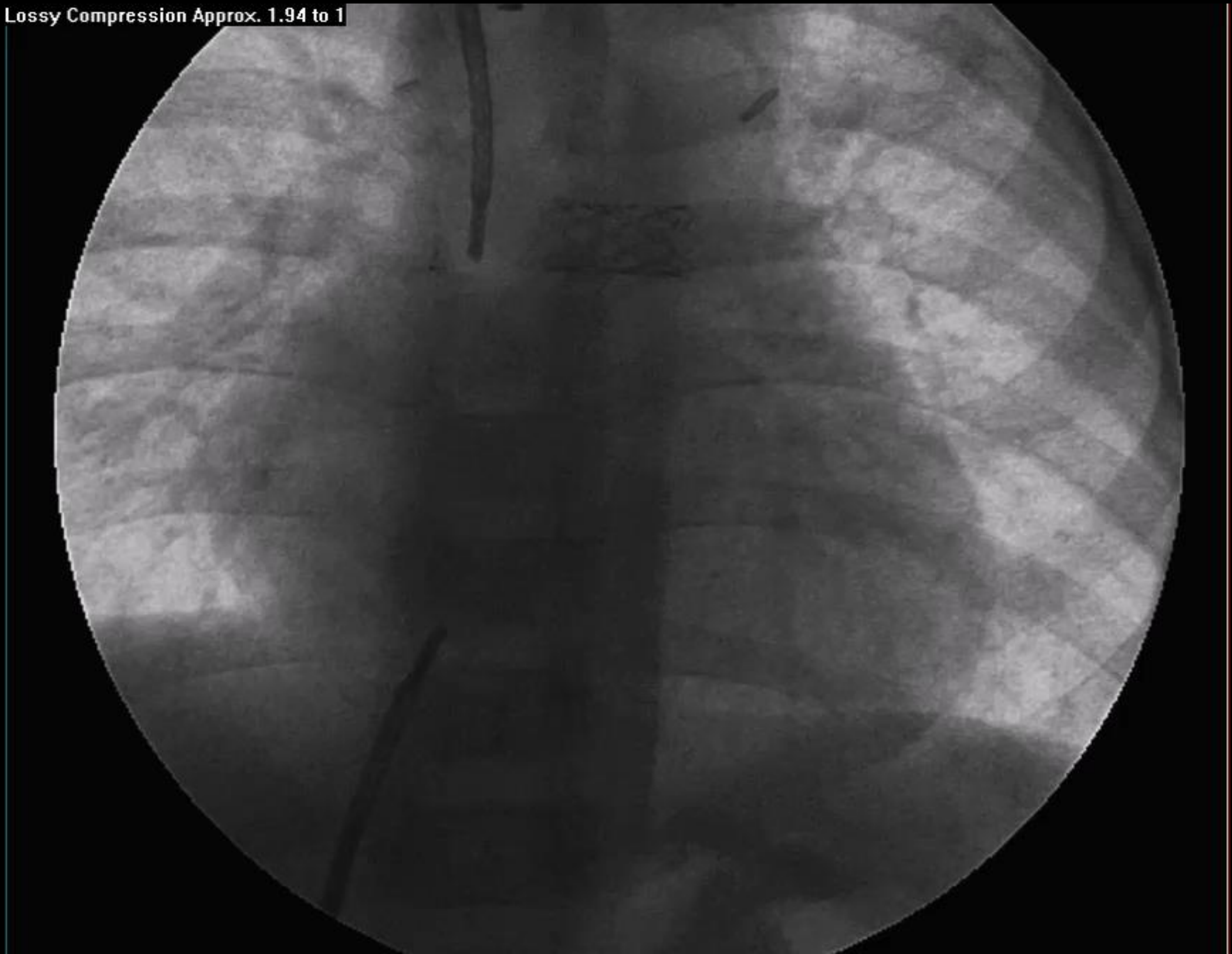
Transcatheter Fontan



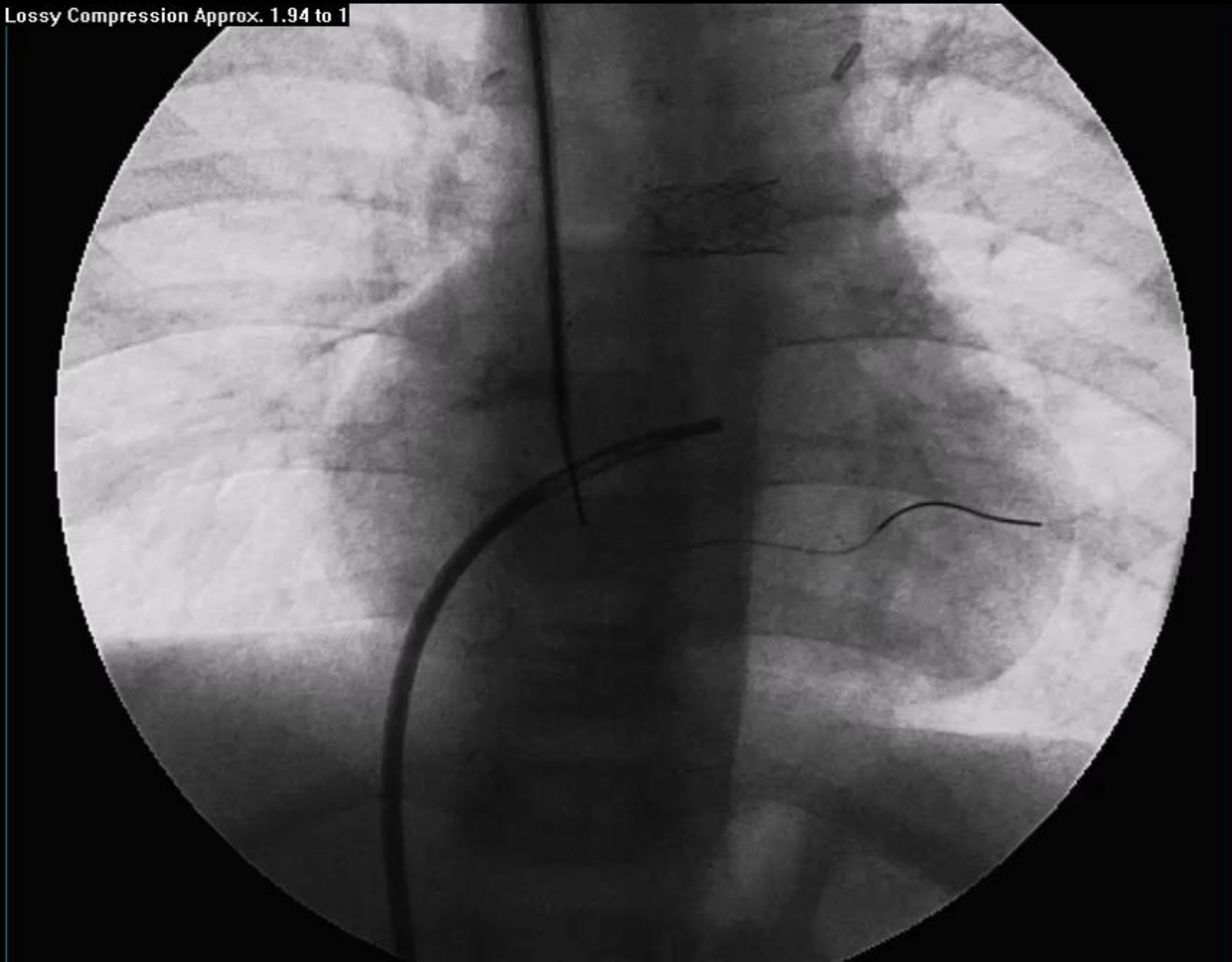
Technique

- Transcatheter Fontan Completion
  - Previous “modified” cavo-pulmonary connection
  - Transseptal needle puncture/RF perforation from jugular vein thru “sweet spot” into RA
  - Snare guidewire to form veno-veno “rail”
  - Custom-made covered stent
    - Delivered from groin through 13 or 14 Fr sheath
  - Goal: No interference with PA or IVC/hepatic vein flow & limit residual R→L shunt
  - Be ready to “bail-out” by converting back to BDG using CREBO (Cheatham Rapid Exchange Bail Out)
    - a 12-16mm x 1cm long balloon on multi-track design delivered from neck

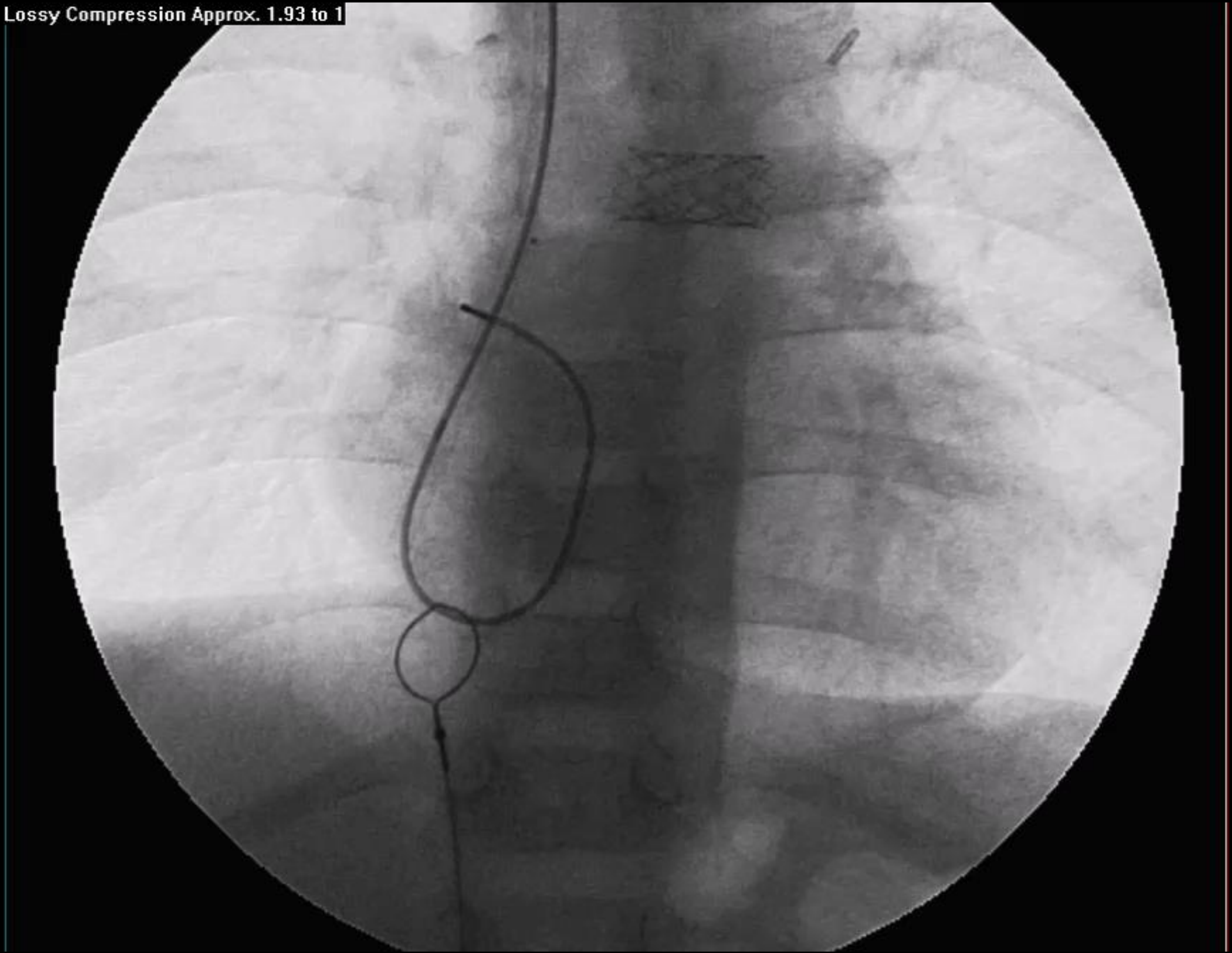
PICS VI, Sept 25th, 2002: 2 y/o HLHS Undergoing Transcatheter Fontan Completion



Transseptal Perforation Along Radio-Opaque Marker (Sweet Spot)

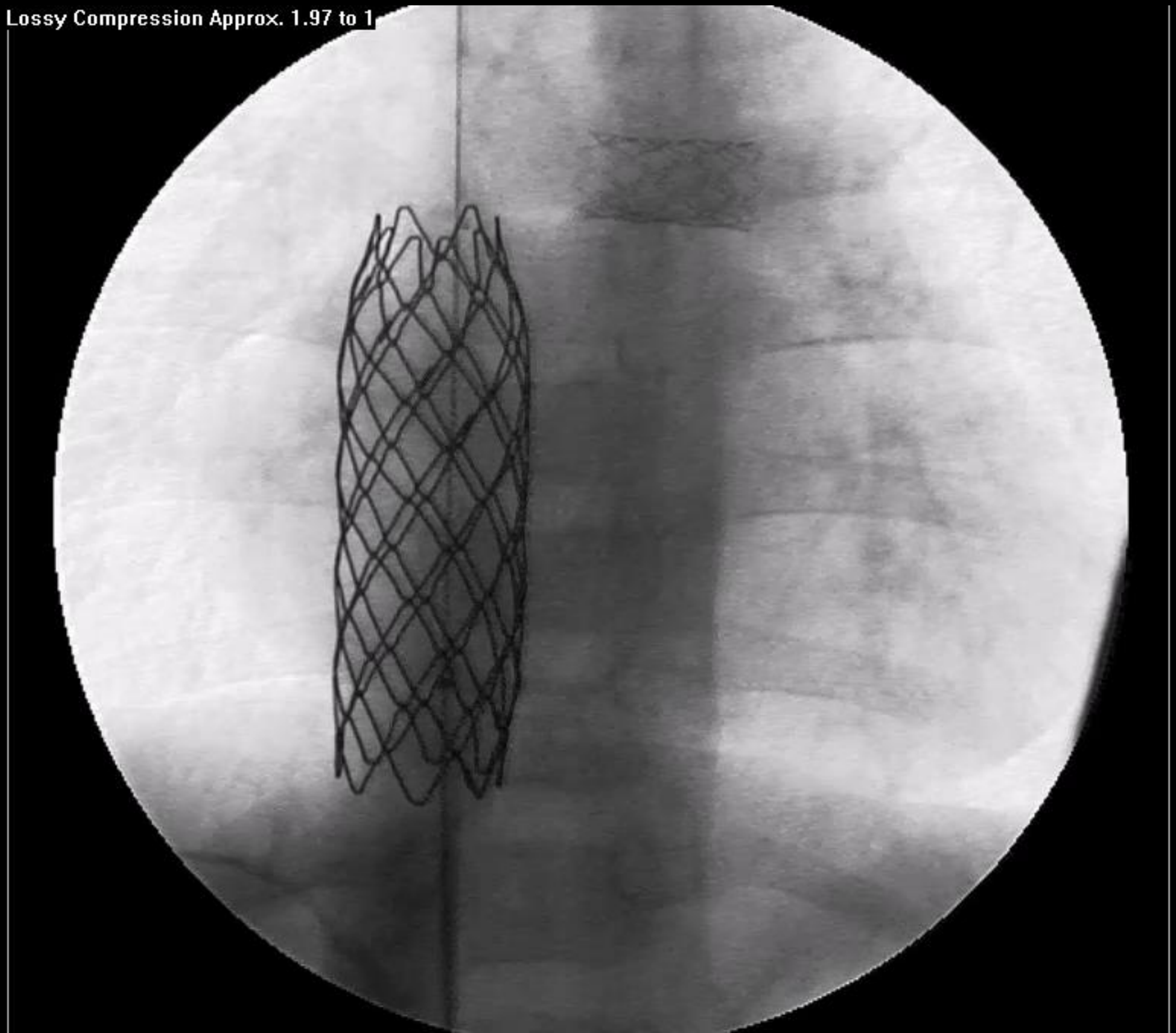


Snare Of Guidewire To Allow CCPS Delivery

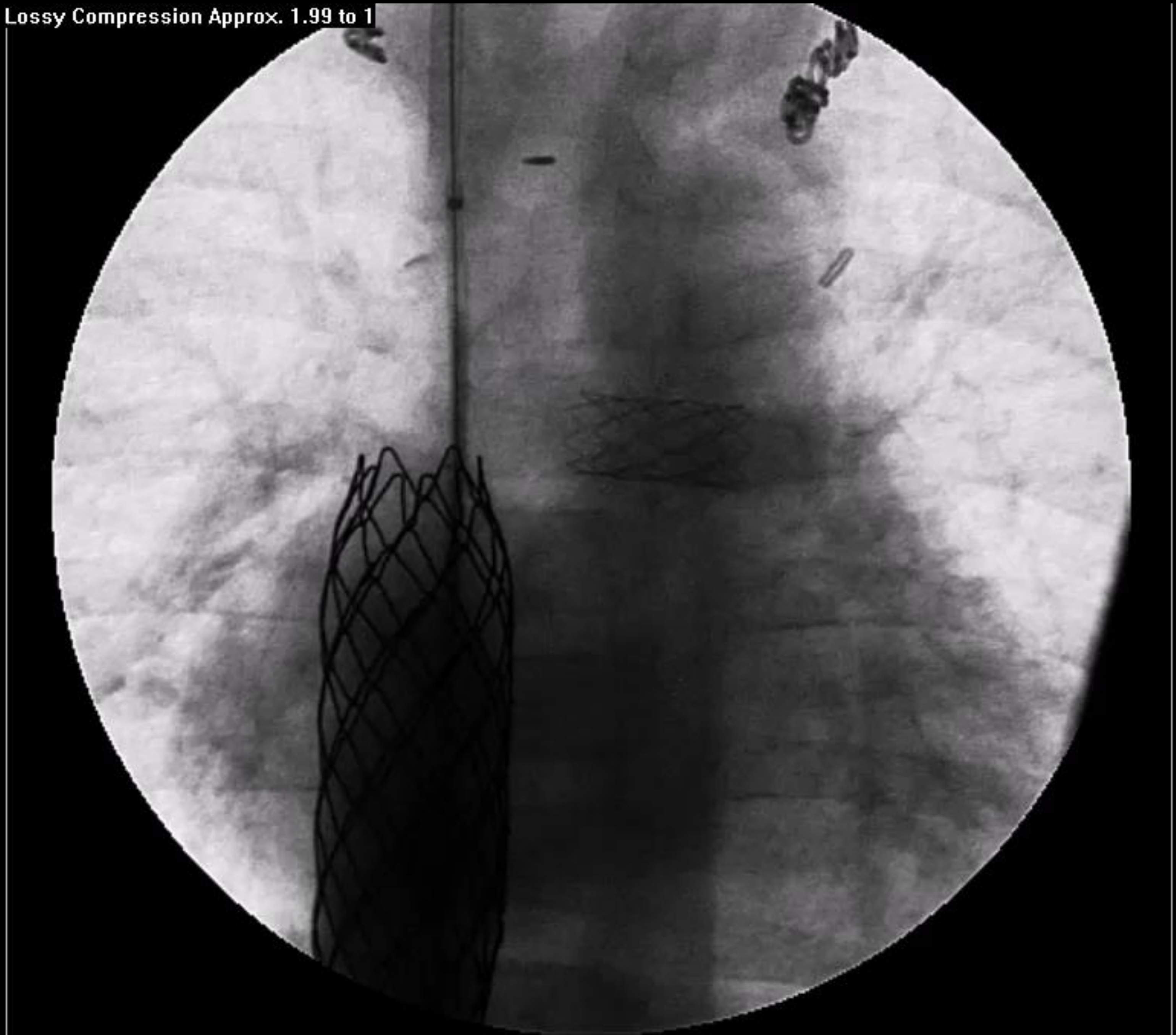


8Zig-60mm CCPS With 1 Row Uncovered @ Each End On 16mm BIB Catheter

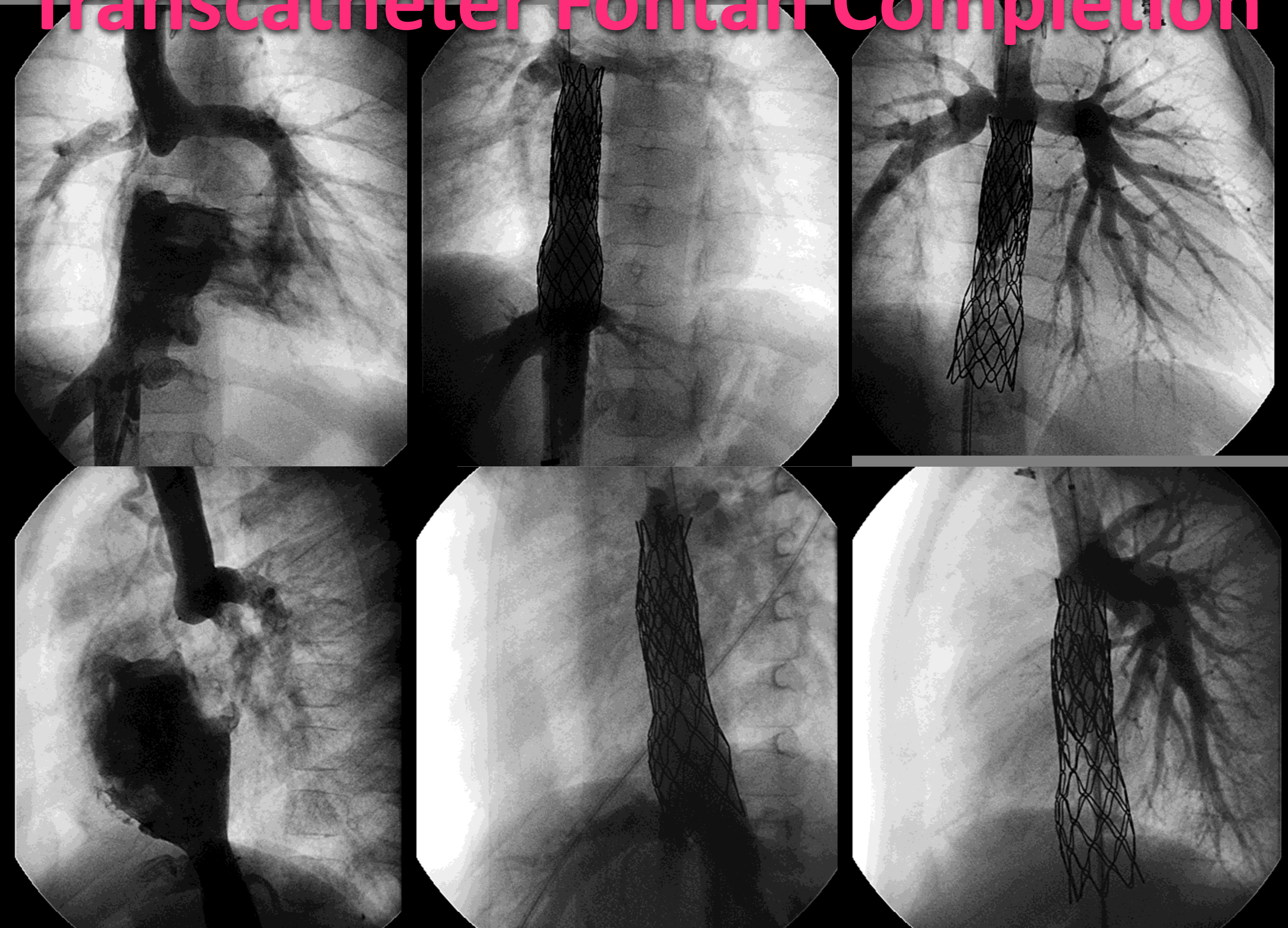
Post Implant: IVC Angiogram… ↑ O2 Sats 95%



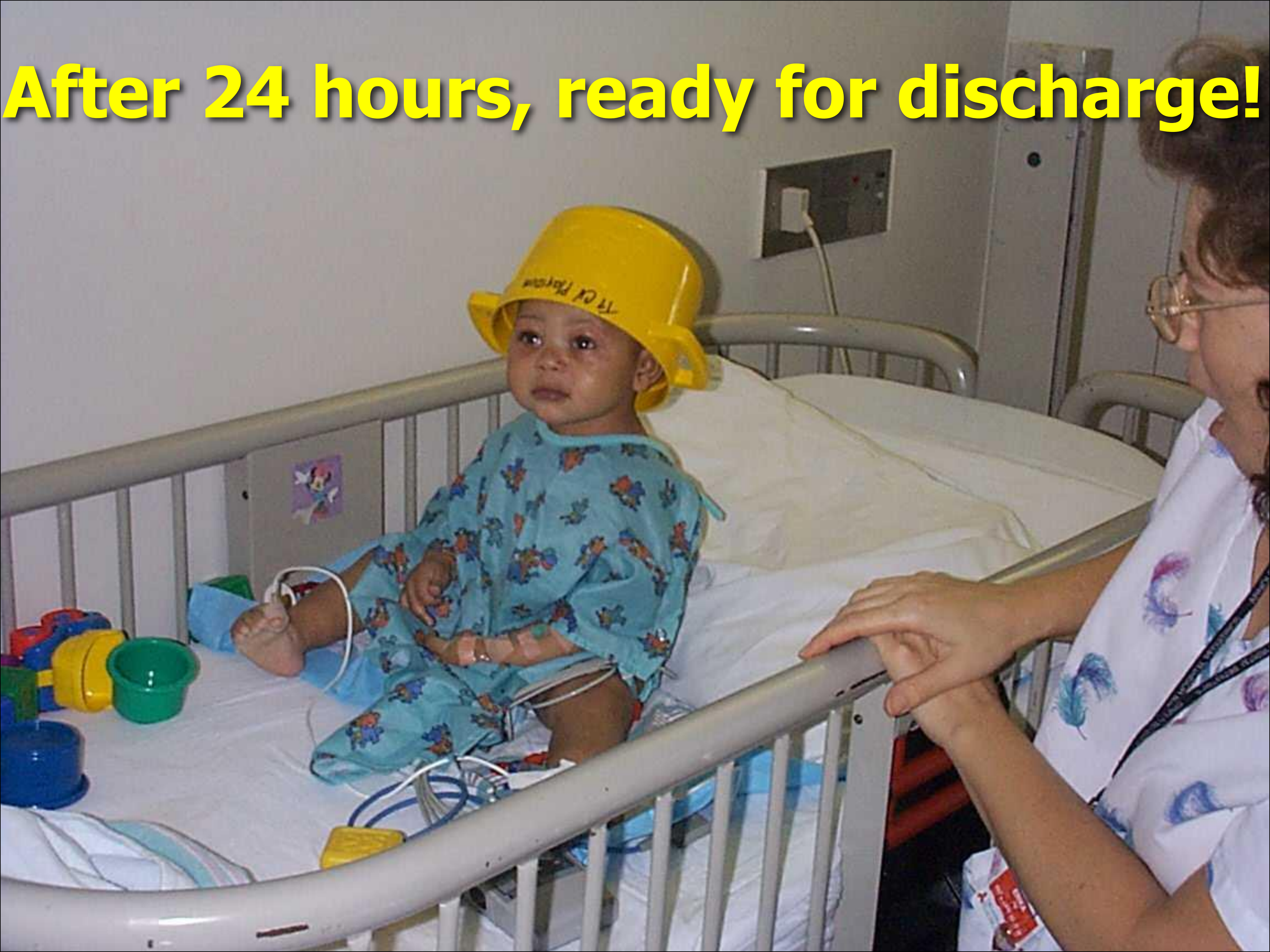
Post Implant: SVC Angiogram… ↑ O2 Sats 95%



Transcatheter Fontan Completion



After 24 hours, ready for discharge!



Results

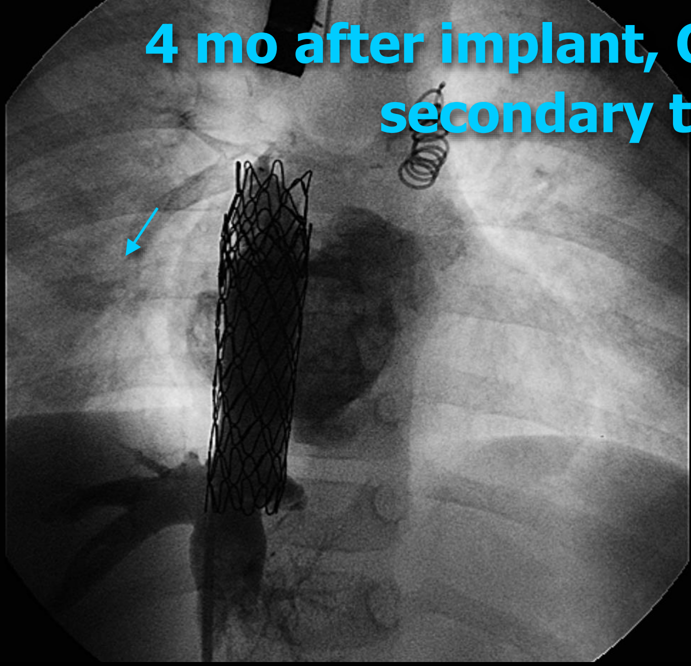
- 5 patients (22-24 months old, 10-12.4 Kg)
- All successful transcatheter Fontan circuit
  - ↑ Sats 95%
  - PAp increased 1 mmHg
  - Unobstructed flow from IVC & hepatic veins into PA
- No deaths, effusions, or blood transfusions
- All discharged home within 24 hours

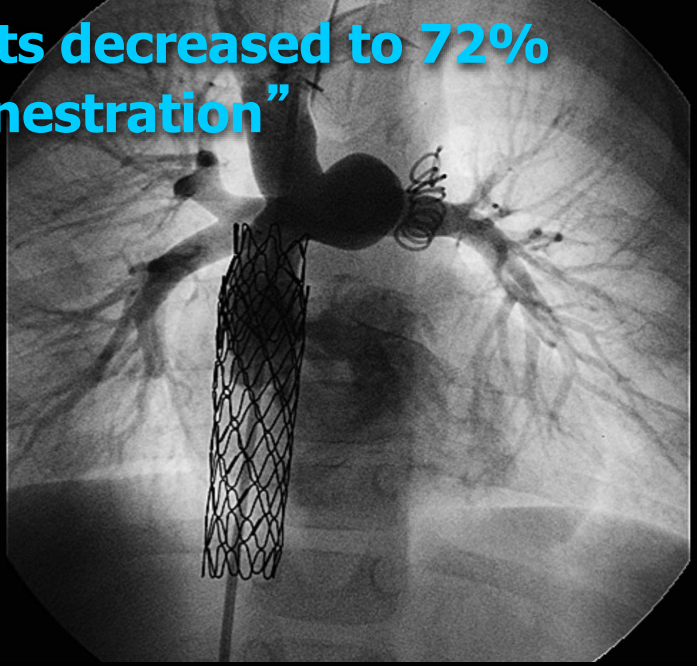
Presented to The American Association of Thoracic Surgeons International Symposium, May 2003

Results - late

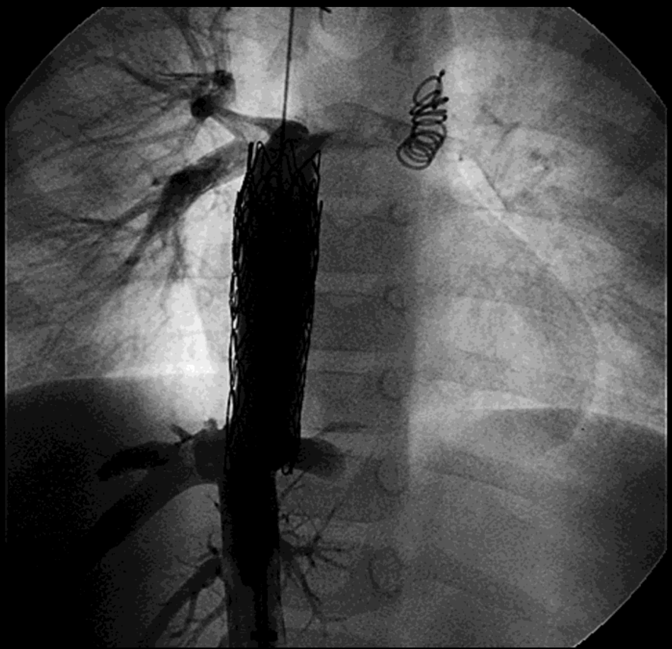
- 4 pts developed R>L shunts with decreased O2 sats
  - 1 btwn interlocking stents
  - 3 at the IVC-RA junction
- All successfully treated with additional transcatheter covered stent

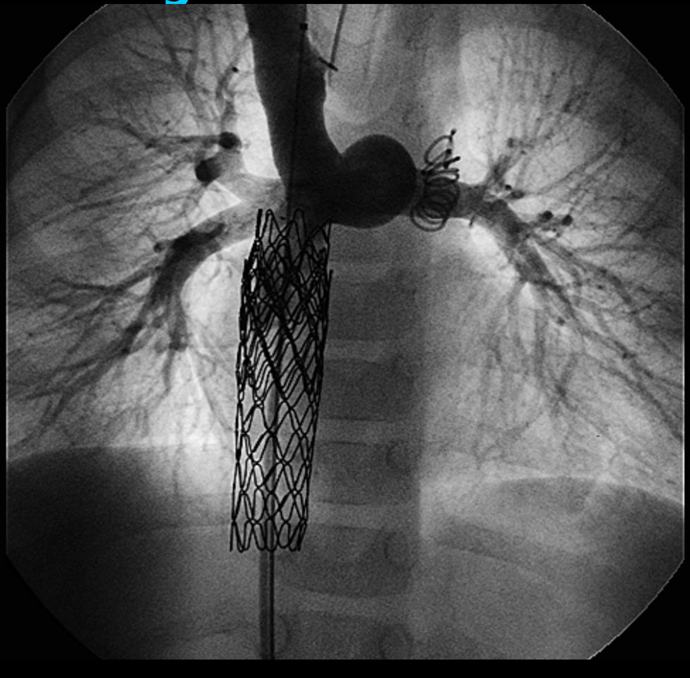
4 mo after implant, O2 sats decreased to 72% secondary to “fenestration”





O2 sats increased to 96% after covering “fenestration”






CHEVROLET

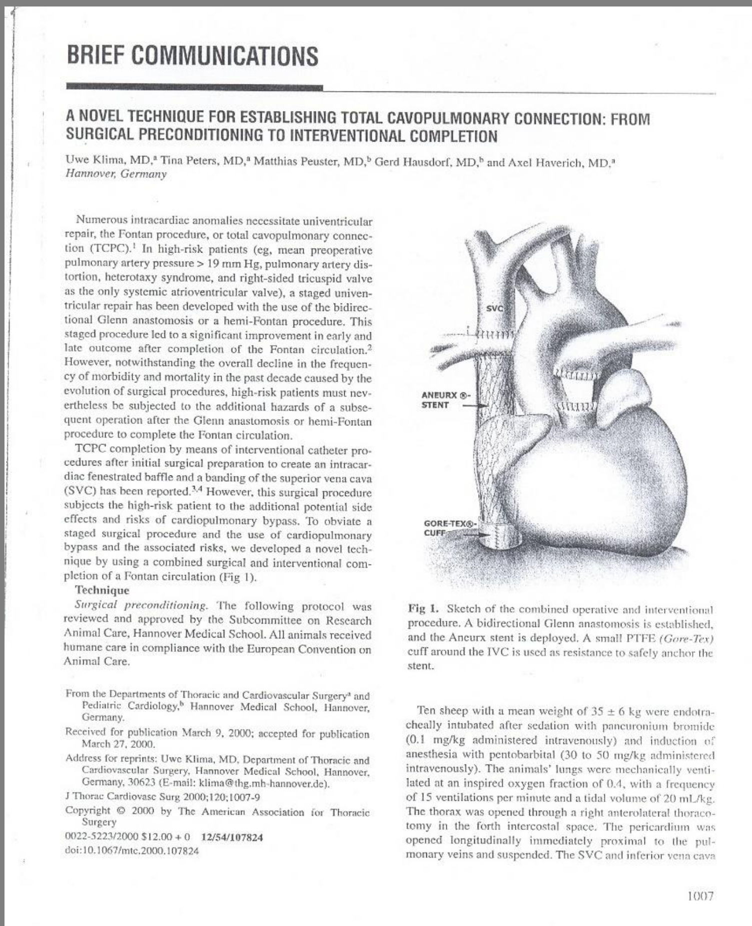
Other Past Attempts

- *"Hausdorf G; Schneider M; Konertz W. Surgical preconditioning and completion of total cavopulmonary connection by interventional cardiac catheterisation: a new concept. Heart. 1996; 75(4): 403-9"*

  - First Stage: modified Hemi Fontan
    - » Subtotal banding of SVC-RA post Glenn
    - » Multiperforated baffle 5-7 (5 mm each) in RA
  - Second Stage: Percutaneous completion
    - – Technique-1: Non-covered stent at surgically banded SVC-RA + Septal Occlusion devices at each fenestration
    - – Technique-2: Angioplasty of surgically banded SVC-RA + Covered stent from IVC to dilated SVC-RA

8 patients with no mortality

The “Set Up” For Transcatheter Completion Of Fontan



BRIEF COMMUNICATIONS

A NOVEL TECHNIQUE FOR ESTABLISHING TOTAL CAVOPULMONARY CONNECTION: FROM SURGICAL PRECONDITIONING TO INTERVENTIONAL COMPLETION

Uwe Klima, MD,[a] Tina Peters, MD,[a] Matthias Peuster, MD,[b] Gerd Hausdorf, MD,[b] and Axel Haverich, MD,[a]
Hannover, Germany

Numerous intracardiac anomalies necessitate univentricular repair, the Fontan procedure, or total cavopulmonary connection (TCPC).[1] In high-risk patients (eg, mean preoperative pulmonary artery pressure > 19 mm Hg, pulmonary artery distortion, heterotaxy syndrome, and right-sided tricuspid valve as the only systemic atrioventricular valve), a staged univentricular repair has been developed with the use of the bidirectional Glenn anastomosis or a hemi-Fontan procedure. This staged procedure led to a significant improvement in early and late outcome after completion of the Fontan circulation.[2] However, notwithstanding the overall decline in the frequency of morbidity and mortality in the past decade caused by the evolution of surgical procedures, high-risk patients must nevertheless be subjected to the additional hazards of a subsequent operation after the Glenn anastomosis or hemi-Fontan procedure to complete the Fontan circulation.

TCPC completion by means of interventional catheter procedures after initial surgical preparation to create an intracardiac fenestrated baffle and a banding of the superior vena cava (SVC) has been reported.[3,4] However, this surgical procedure subjects the high-risk patient to the additional potential side effects and risks of cardiopulmonary bypass. To obviate a staged surgical procedure and the use of cardiopulmonary bypass and the associated risks, we developed a novel technique by using a combined surgical and interventional completion of a Fontan circulation (Fig 1).

Technique

Surgical preconditioning. The following protocol was reviewed and approved by the Subcommittee on Research Animal Care, Hannover Medical School. All animals received humane care in compliance with the European Convention on Animal Care.

SVC
ANEURX ®-STENT
GORE-TEX® CUFF

Fig 1. Sketch of the combined operative and interventional procedure. A bidirectional Glenn anastomosis is established, and the Aneurx stent is deployed. A small PTFE *(Gore-Tex)* cuff around the IVC is used as resistance to safely anchor the stent.

Ten sheep with a mean weight of 35 ± 6 kg were endotracheally intubated after sedation with pancuronium bromide (0.1 mg/kg administered intravenously) and induction of anesthesia with pentobarbital (30 to 50 mg/kg administered intravenously). The animals' lungs were mechanically ventilated at an inspired oxygen fraction of 0.4, with a frequency of 15 ventilations per minute and a tidal volume of 20 mL/kg. The thorax was opened through a right anterolateral thoracotomy in the forth intercostal space. The pericardium was opened longitudinally immediately proximal to the pulmonary veins and suspended. The SVC and inferior vena cava

From the Departments of Thoracic and Cardiovascular Surgery[a] and Pediatric Cardiology,[b] Hannover Medical School, Hannover, Germany.

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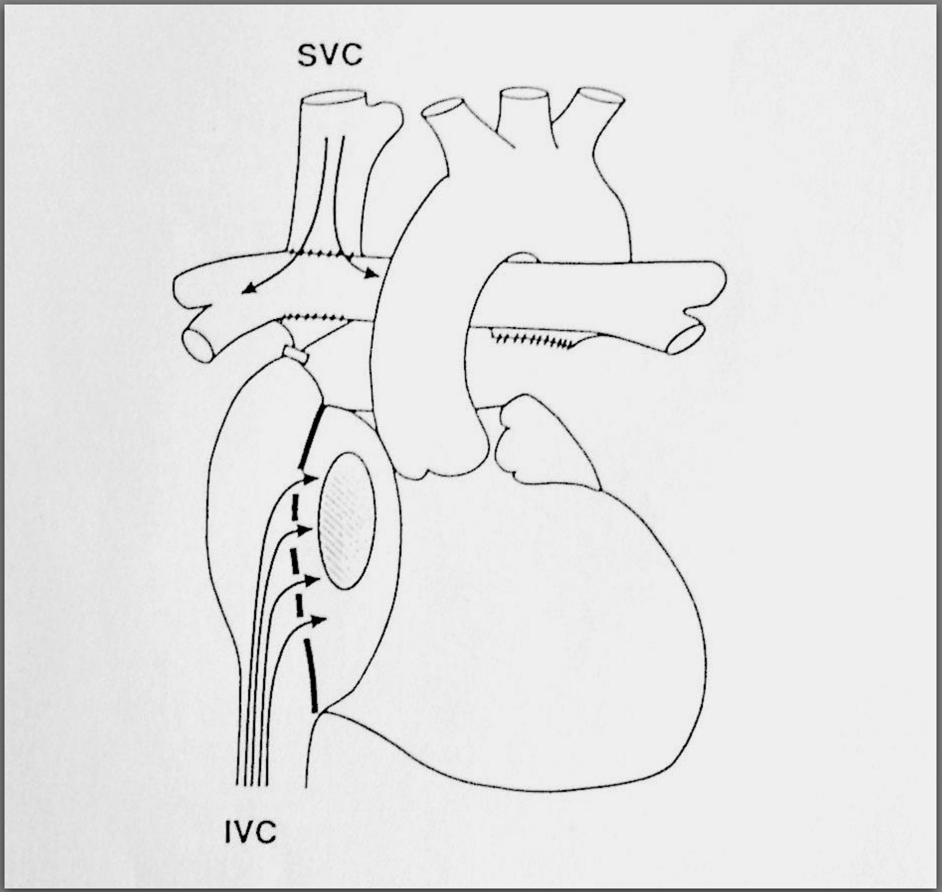
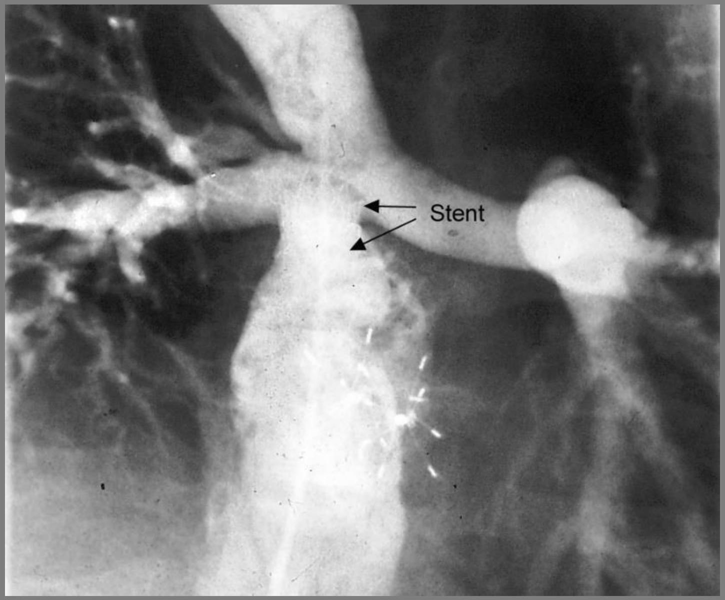
J Thorac Cardiovasc Surg 2000;120;1007-9

0022-5223/2000 $12.00 + 0 **12/54/107824**
doi:10.1067/mtc.2000.107824

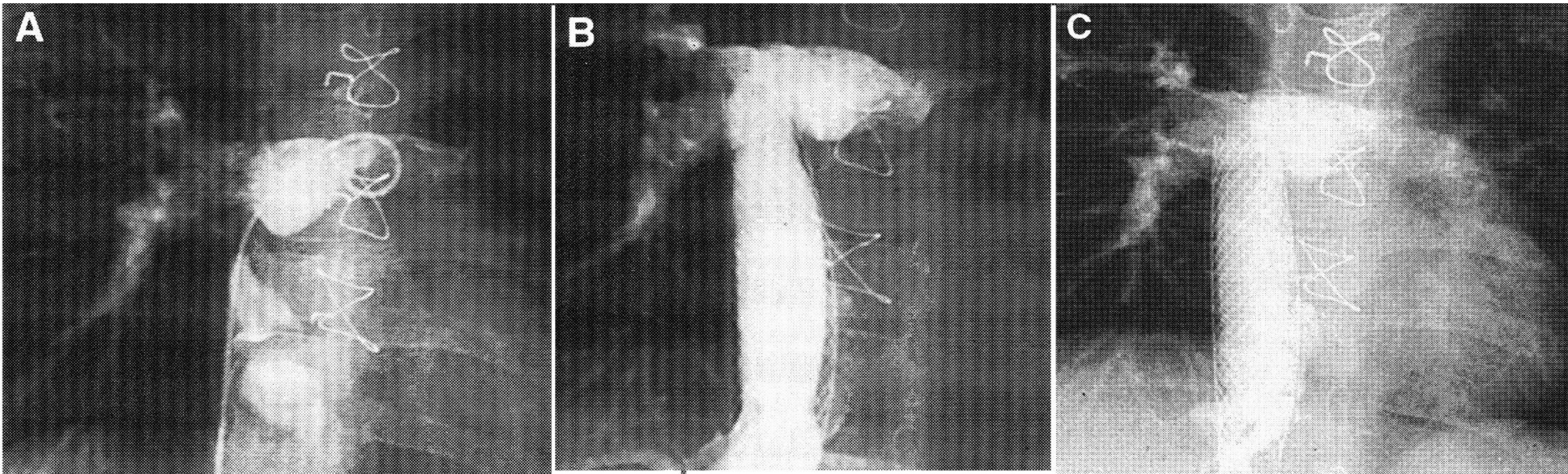


Gerd Hausdorf



Interventional completion of Fontan
Technique 1

Interventional completion of Fontan
Technique 2



International Symposium on the Hybrid Approach to Congenital Heart Disease

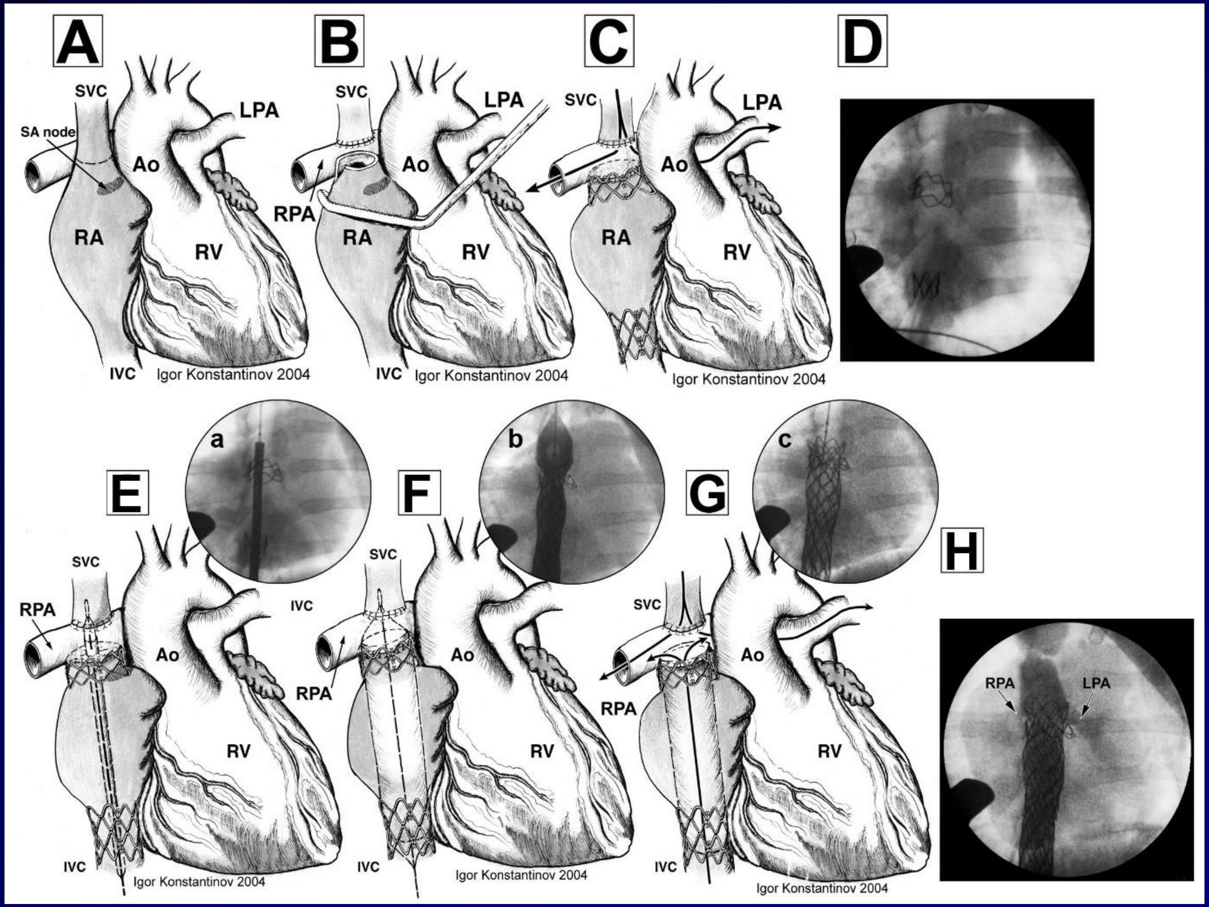
Fontan Completion in the Cath Lab
Lessons Learned
for Surgeons & Interventionalists

Lee Benson & Christopher Caldarone
The Hospital for Sick Children
Toronto, Ontario

Toronto

A Simple Surgical Technique For Interventional Transcatheter Completion Of The Total Cavopulmonary Connection

Igor E. Konstantinov, MD, Lee N. Benson, MD, FRCPC, Christopher Caldarone, MD, Jia Li, MD, PhD, Mikiko Shimizu, MD, John G. Coles, MD, FRCSC, Glen S. Van Arsdell, MD, FRCSC and William G. Williams, MD, FRCSC



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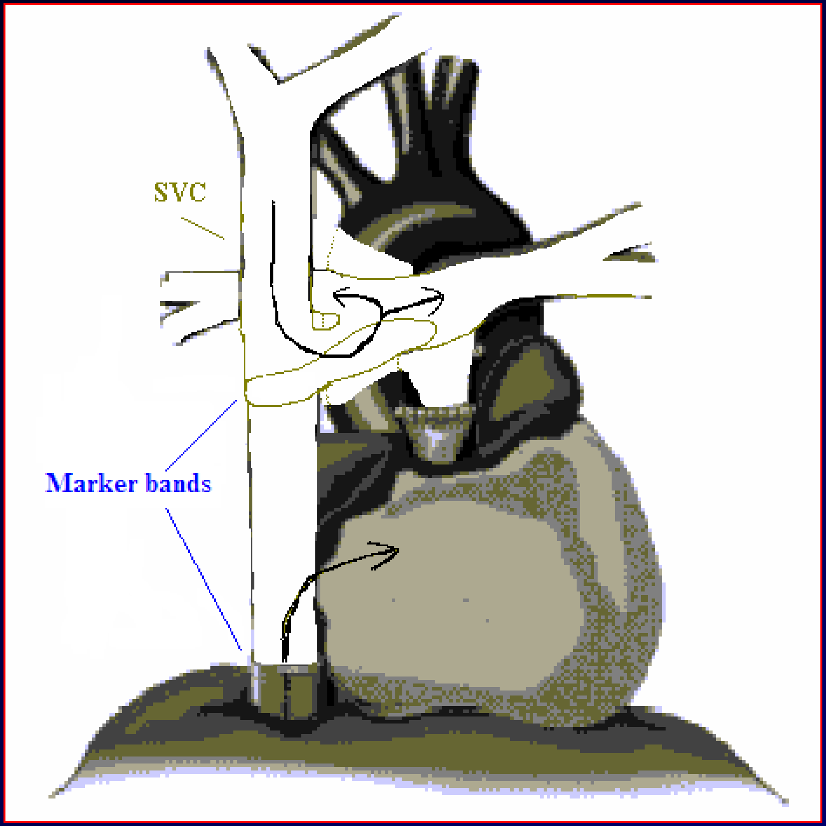
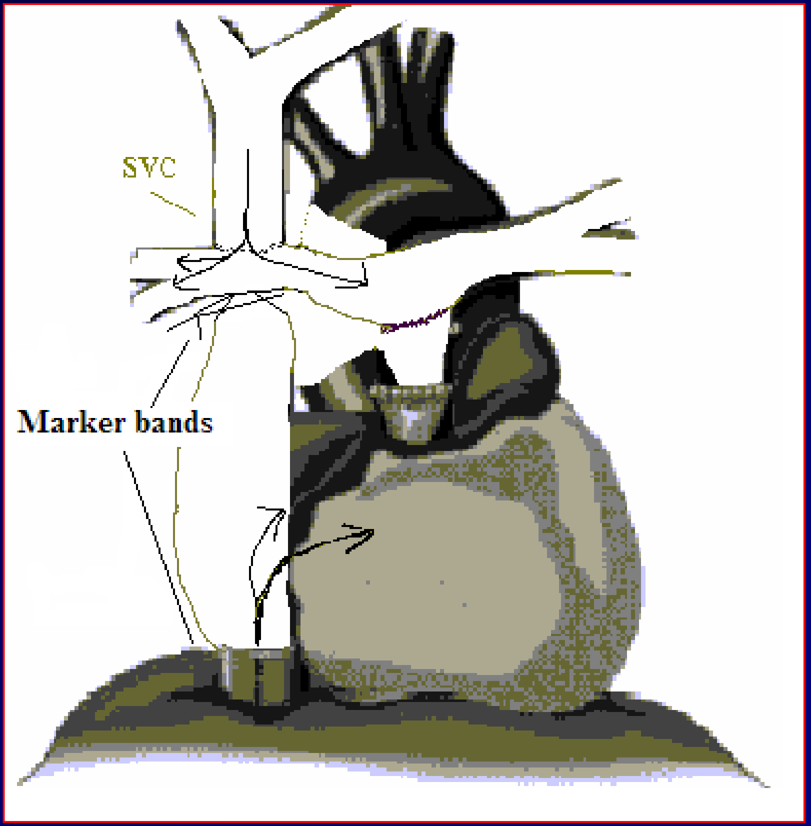
♥ Performed transcatheter Fontan completion successfully in 4 Yorkshire pigs

Surgical Setup at BCPS



Hemi-Fontan



BCPC

Toronto

Outcomes

Procedure performed in 7 children.

Sat's: 77±3% before intervention
96±4% @ case completion
90±8% @ hospital DC (n=4)
95±3% 2 weeks after DC' (n=4)

3/4 children had PAVM's detected @ cath.

A pleural effusion occurred in 6 children, 1 requiring pleurocentesis.

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Outcomes

Morbidity & mortality: due to stent migration.

IVC dislodgement was noted at cath and a 2nd stent placed uneventfully, the child DC' home.

SVC dislodgement in 1, IVC dislodgement in 2 resulting in the need for ECMO support, & ultimately stent removal & surgical Fontan's.

One of these children suffered a neurological injury & was withdrawn from ventilatory support, despite an intact CCF circuit.

Toronto

What have we learned

The concept of a CCF has been supported.

Stent stability in the superior (SVC) & inferior (IVS) ends, is not completely solved.

The IVC-RA junction undergoes dynamic changes in it's topology during respiration and retching

The fixed SVC end exacerbates the problem.

Toronto

Eur J Cardiothorac Surg. 2007 Aug;32(2):195-200; discussion 201. Epub 2007 Apr 27.

Fontan completion without surgery.

Sallehuddin A, Mesned A, Barakati M, Fayyadh MA, Fadley F, Al-Halees Z.

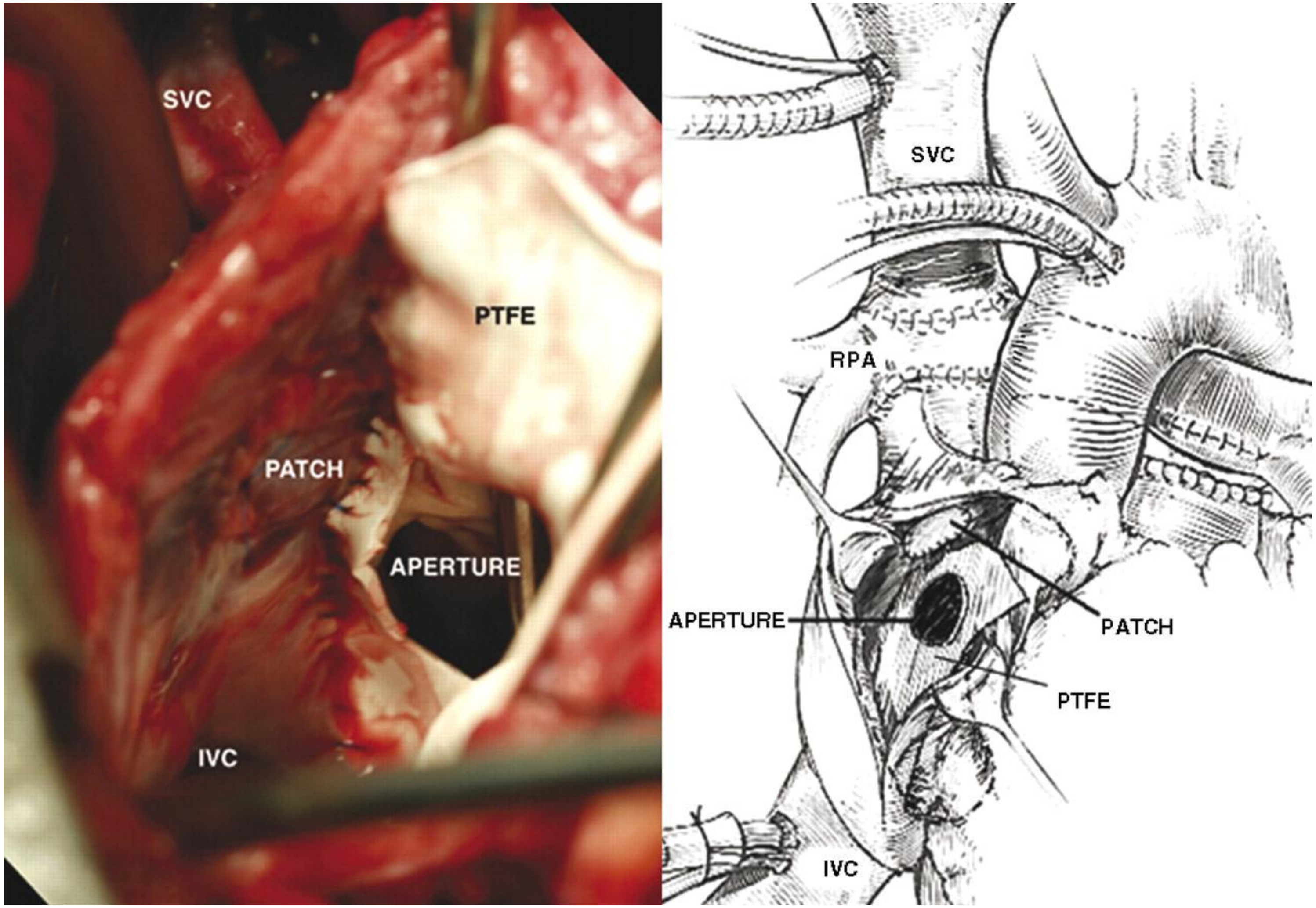
King Faisal Specialist Hospital and Research Centre, Riyadh, Saudi Arabia. asallehuddin@kfshrc.edu.sa

Abstract

OBJECTIVE: There are several modifications introduced in the preparation for a subsequent non-surgical transcatheter completion of the Fontan procedure. We report our experience with one type of the modification and the short-term results following its implementation.

Ten months later (range 5–16 months), nine patients underwent transcatheter Fontan completion (mean age 20 months, mean weight 10.6 kg). Demographics of these patients are shown in Table 2 . The mean diameter of the aperture had decreased from 11.8 mm to 7.4 mm; $p \ll 0.001$ (Fig. 2). The mean fluoroscopy time was 41 min (range 27–81 min). The stents across the RF perforated pericardial patch were dilated to 14.4 mm average diameter (range 12–16 mm). Except in one patient, all apertures were closed with Amplatzer devices (sizes 6–8 mm). Average oxygen saturations increased from 85 to 94% ($p = 0.001$) but the pulmonary artery pressures were not significantly altered (16 vs. 19 mmHg, $p = 0.12$). These findings were similar to those reported by Galantowicz and Cheatham [6]. During the catheterization procedure, no patient had hemodynamic compromise and none required inotropic support. There were no early or late deaths. No patient required blood transfusions. No patient required mechanical ventilation and none developed significant pleural effusions or arrhythmias. This is in contrast to an incidence of 15–16% pleural effusions and 7–8% of dysrhythmias in patients following the modified Fontan operation previously reported from our institution [9]. All were discharged from hospital within 6 days of the non-surgical Fontan completion. On average, our surgical patients remain for 14–15 days in hospital after the modified Fontan operation

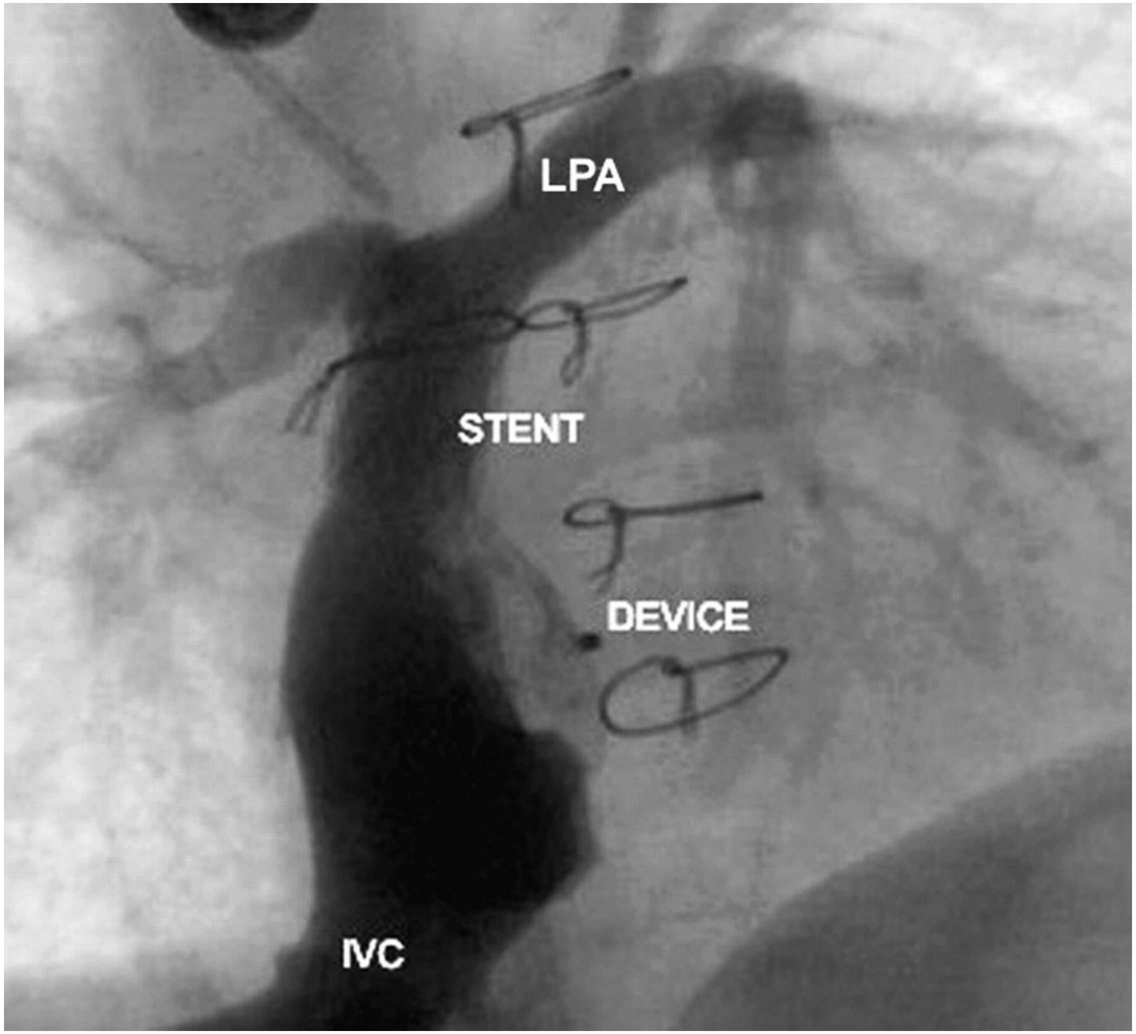
Aperture creation in the PTFE medial wall of the lateral tunnel.



Sallehuddin A et al. Eur J Cardiothorac Surg 2007;32:195-201

EUROPEAN JOURNAL OF CARDIO-THORACIC SURGERY

Angiogram following stent and ASD device placements within the lateral atrial tunnel.

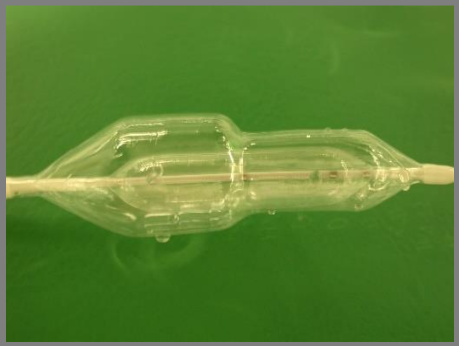


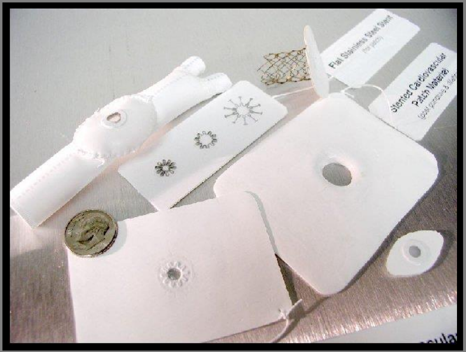
Sallehuddin A et al. Eur J Cardiothorac Surg 2007;32:195-201

EUROPEAN JOURNAL OF CARDIO-THORACIC SURGERY

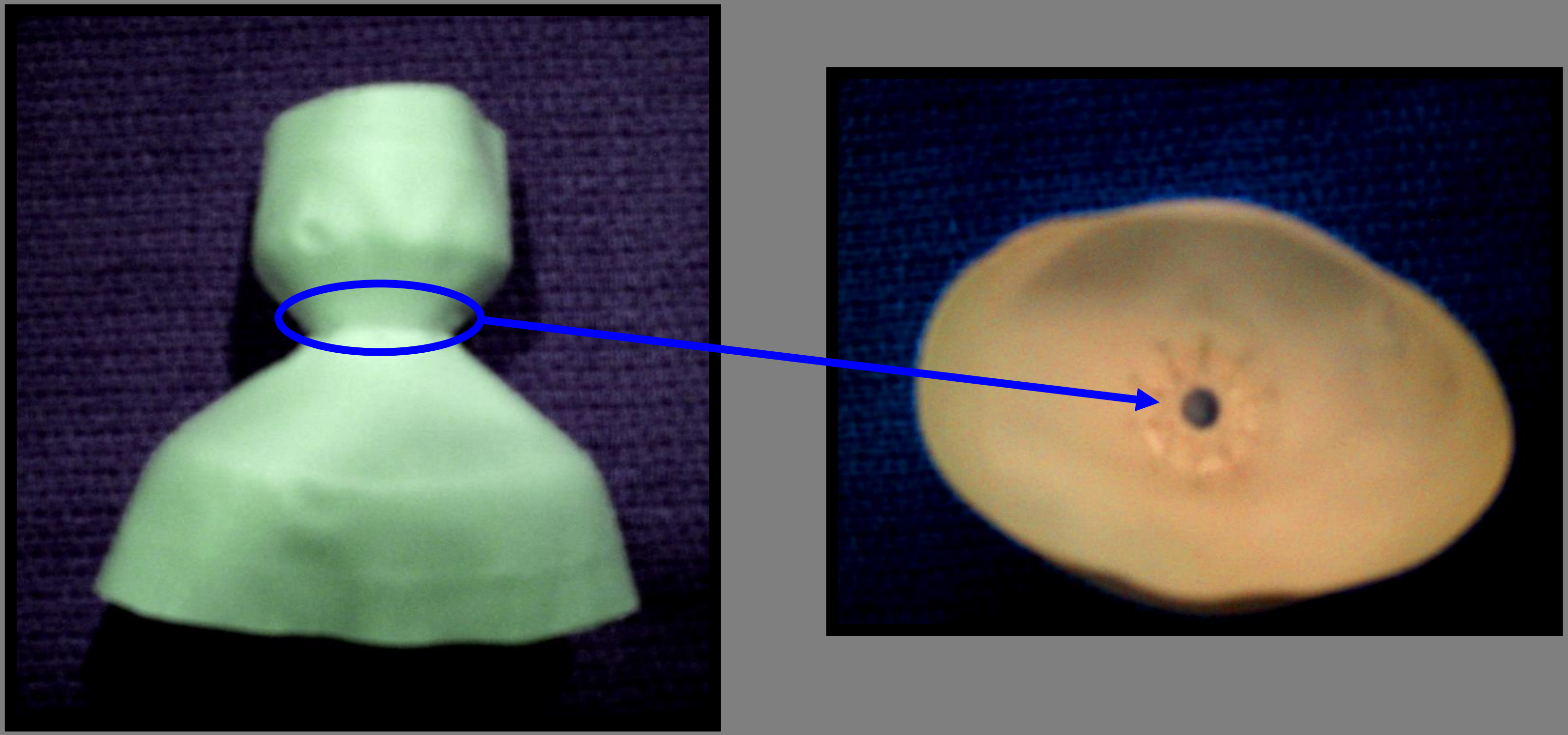
Ideas in the Works

- Novel surgical set-ups
- “Docking stations”
- Different covered stents
  - Self-expanding vs balloon
- Tapered balloons
- Novel membrane materials
- Cavo-pulmonary Assist Device



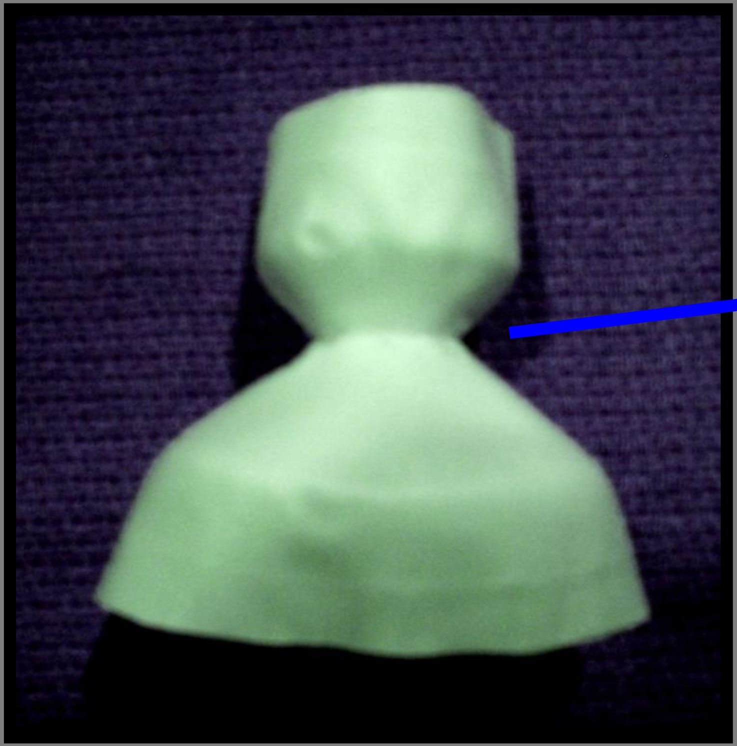


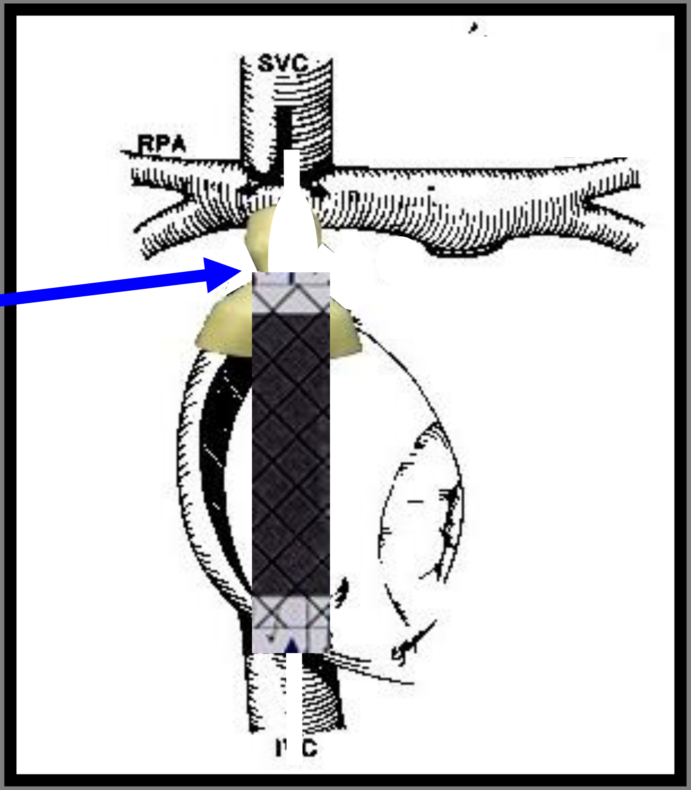
Lateral Tunnel Docking Port



Courtesy of Evan Zahn, M.D.
Miami Children's Hospital

Creating the Docking Port





Courtesy of Evan Zahn, M.D.
Miami Children's Hospital

The Future

Total cavopulmonary connection

The experimental model

PATENT OF INVENTION

For a term of 20 years for an invention for a title

FENESTRATION WITH INTRINSIC MEANS OF SELECTIVECLOSURE INCORPORATED TO A TUBULAR BODY AND USED IN INTERVENTIONAL CARDIOVASCULAR PROCEDURES

Applied by **RICARDO GAMBOA MD**

Argentinian

Address: Calle 8 Nº 823

Postal code: 1900

Tolosa, La Plata

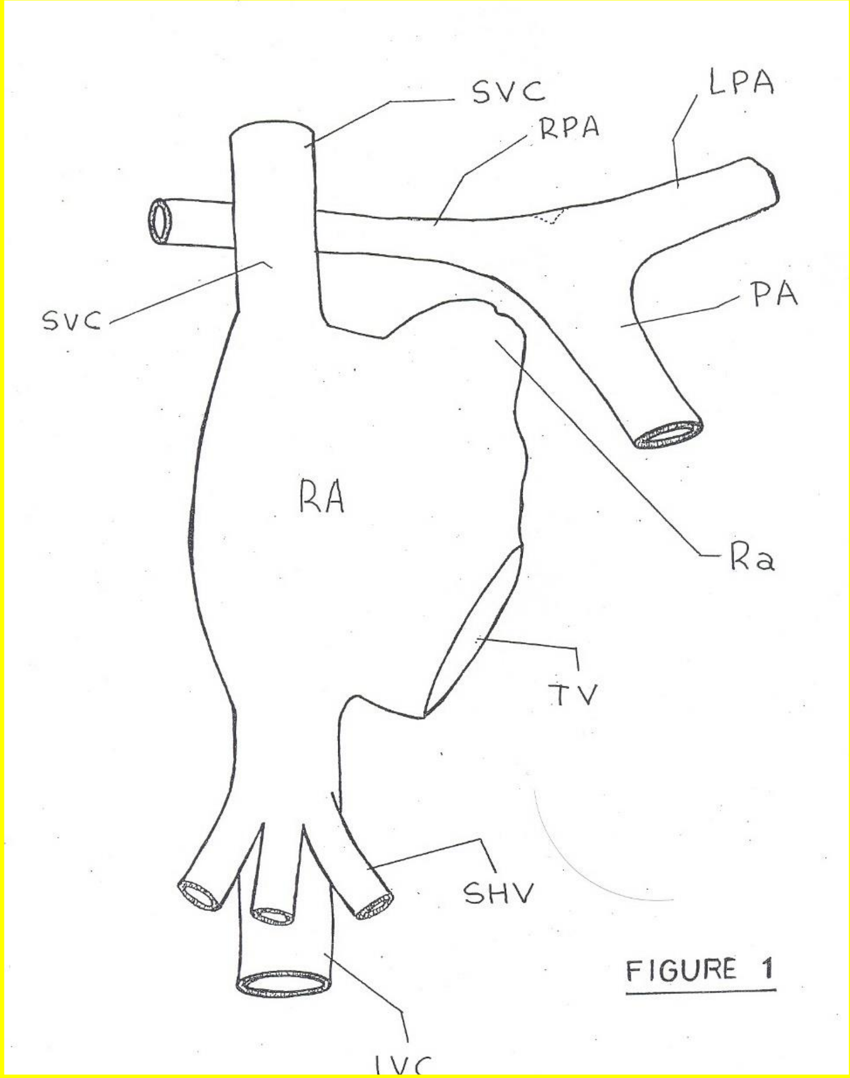
Buenos Aires Province

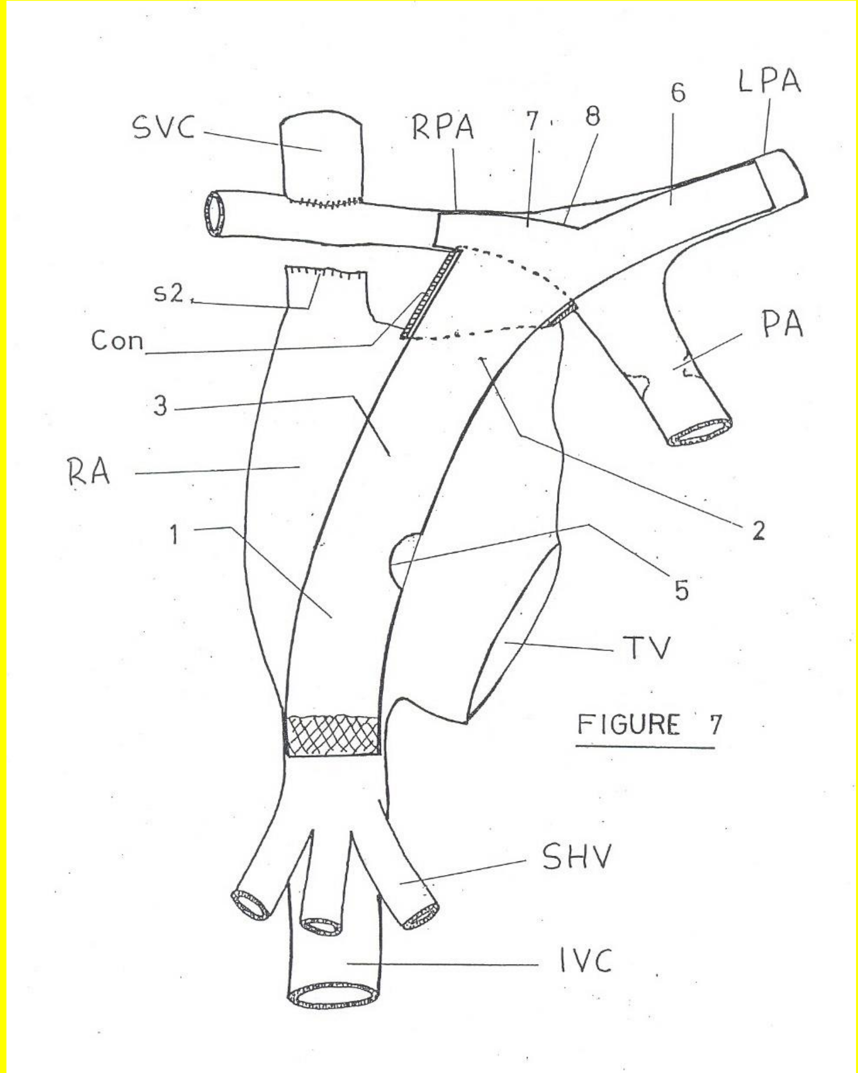
Argentina

Inventor: **Ricardo Gamboa MD**

Total cavopulmonary connection

The experimental model





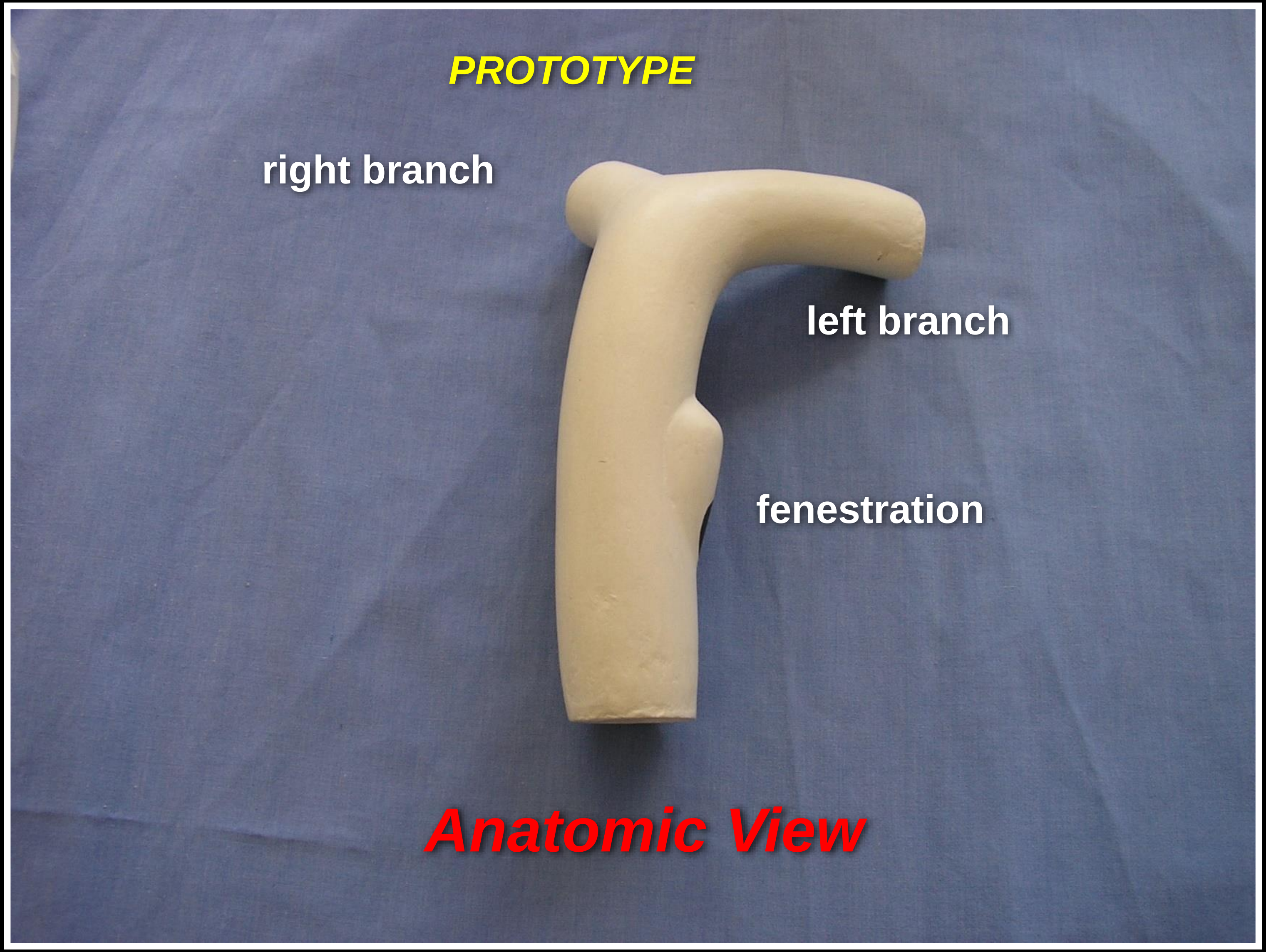
FENESTRATION

Closed

Open

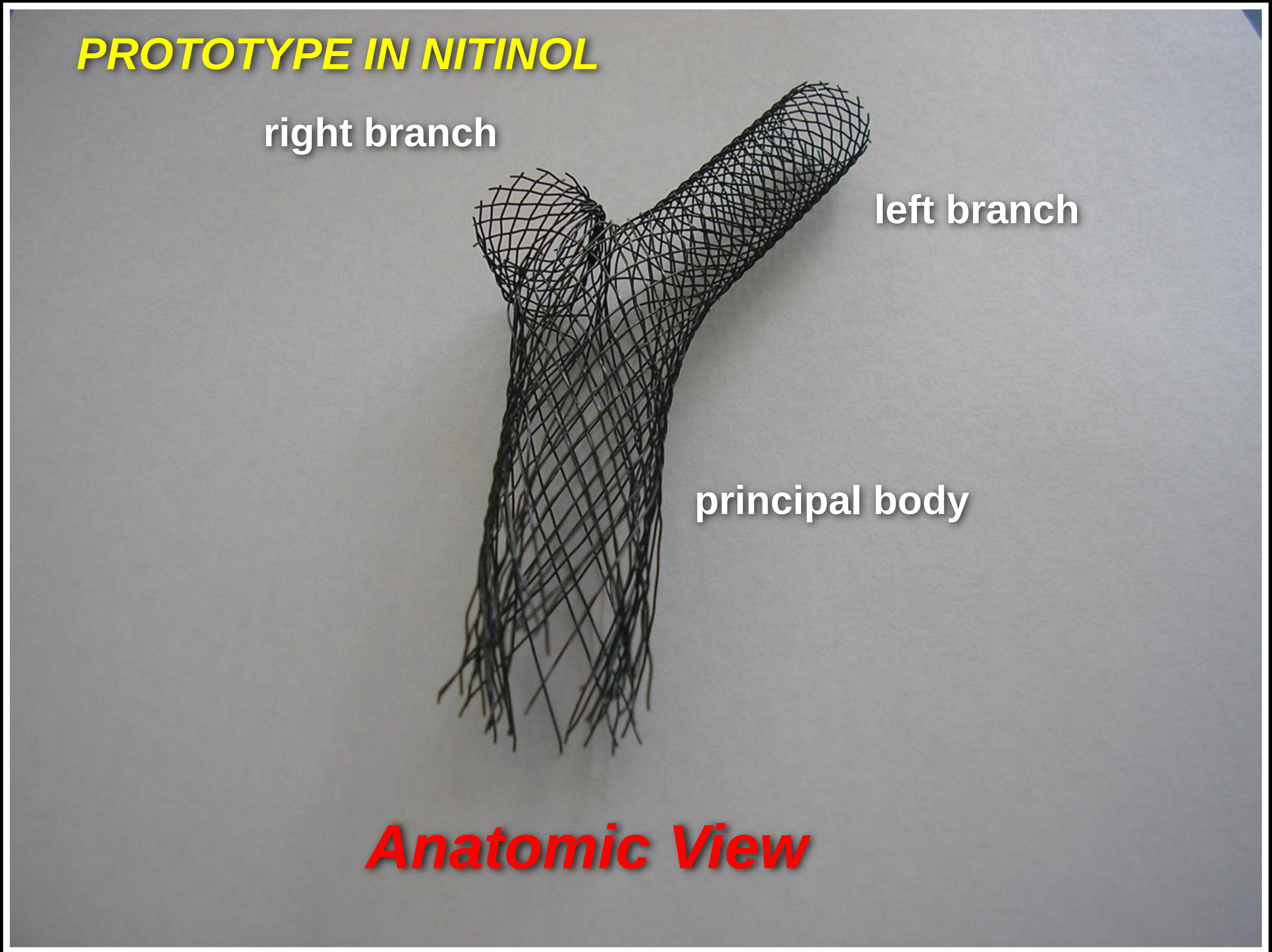
Total cavopulmonary connection

The experimental model



Total cavopulmonary connection

The experimental model



Semin Thorac Cardiovasc Surg Pediatr Card Surg Annu. 2011;14(1):45-54.

Cavopulmonary assist: (em)powering the univentricular fontan circulation.

Rodefeld MD, Frankel SH, Giridharan GA.

Section of Cardiothoracic Surgery, Indiana University School of Medicine, James Whitcomb Riley Hospital for Children, Indianapolis, IN, USA. rodefeld@iupui.edu

- Fontan rescue
- Neonatal Fontan!

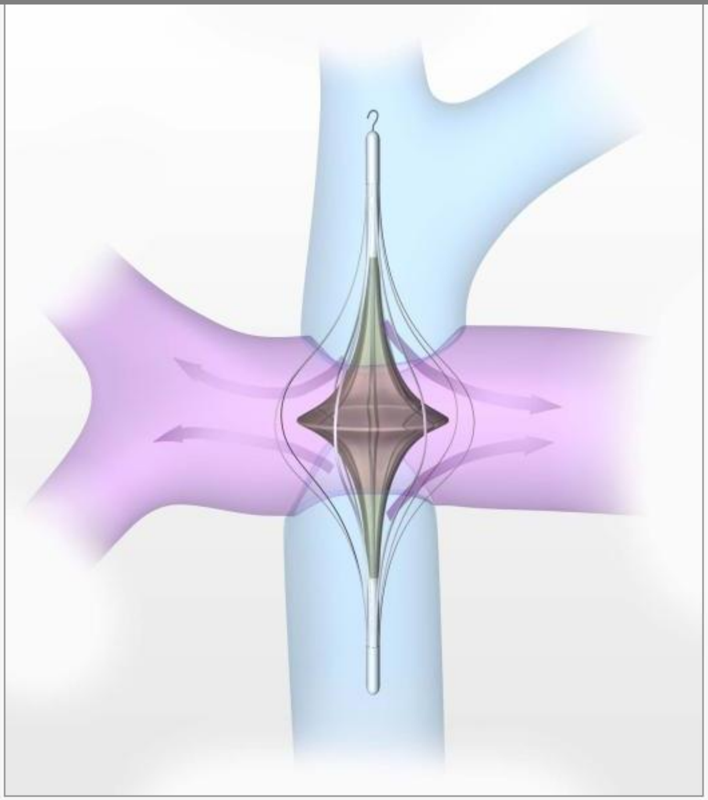


Figure 3

Viscous impeller pump in the 4-way TCPC junction. As a rotary pump, a catheter-based biconical impeller, with a cage to center the impeller and protect the vessel wall, will augment TCPC inflow and outflow in all 4 limbs at ideal pressure. As a static implant it will reduce turbulent kinetic energy loss.

Conclusions

- Yes, there has been and will be again a transcatheter Fontan option
- Merging forces of influence
  - Surgical efforts to limit exposure to cross-clamping and development of techniques for off-bypass Fontan completion
  - Hybrid collaboration yielding new combined surgical-cath procedures
  - Rapidly emerging transcatheter technologies

THANK YOU