

# Partial Heart Transplant Surgical Procedure

## Part 1 of 2

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In April 2022, the world's first partial heart transplant surgical procedure was performed by pediatric surgeons at Duke University Hospital. This groundbreaking surgical procedure prevents the patient from having to undergo multiple cardiac procedures as they grow because the implanted living tissue grows with them. Ever since the procedure was performed, 30 surgeries have been performed worldwide.<sup>1</sup> This article provides a description of the surgical procedure and discussion of related issues.

### ANATOMY OF SEMILUNAR HEART VALVES

The function of semilunar heart valves requires the synchronized activity of several anatomical structures (Figure 1). The leaflets consist of an extracellular matrix organized into three layers – fibrosa, ventricularis, spongiosa. The fibrosa is located on the distal aspect of the valve, consisting of type I and III collagen that is circumferential and provides stiffness to the valve.<sup>2</sup> The ventricularis consists of elastic fibers formed radially that provide for valve leaflet motion. The fibers travel from the valve hinge near the valve annulus to the coapting edge.<sup>2</sup> The spongiosa is the middle layer that consists of proteoglycans.<sup>2</sup> This layer provides integrity to the valve as well as enables tissue flexibility.

### LEARNING OBJECTIVES

- ▲ Describe the anatomy of heart valves
- ▲ Discuss the pathological reason for why the procedure is performed
- ▲ Discuss the surgical options that have been available
- ▲ Explain the process that was completed in developing the PHT procedure

The leaflets attach to the arterial root near the annulus. The annulus consists of fibrous collagen that also provides integrity and stability to the valve. The semilunar heart valves are avascular and gain their nourishment from the blood flowing through the heart, whereas the leaflets of the atrioventricular valves contain capillaries.

The two cells of the valve leaflets are interstitial and endothelial. The interstitial cells are similar to fibroblasts and smooth muscle cells and are located throughout the valve leaflet tissue.<sup>2</sup> They produce the extracellular matrix. The endothelial cells are located on the entire surfaces of the valve and are positioned at a right angle to blood flow.<sup>2</sup> The interstitial and endothelial cells are important towards maintaining the physiology of the valves including growing as a child gets older and extracellular matrix turnover.<sup>2</sup>

Valves grow through annular dilation and leaflet elongation that must occur together. If the growth does not occur at the same time, valvular dysfunctions occur. For example, when annular dilation does not occur, but the leaflets continue to elongate it causes redundant coapting tissue that can either obstruct the outflow tract, causing stenosis, or prolapse, causing insufficiency.<sup>2</sup>

#### TRUNCUS ARTERIOSUS PATHOLOGY

To understand why a partial heart transplant is performed, truncus arteriosus pathology must first be discussed. When the heart of an infant is forming, there is a single blood vessel

leading out of the heart called the truncus arteriosus. During development, the truncus arteriosus splits into two vessels – the aorta and the pulmonary artery. As a review, in a healthy heart, the pulmonary artery carries deoxygenated blood from the right ventricle to the lungs, while the pulmonary vein carries oxygenated blood from the lungs to the left atrium. The oxygenated blood is pumped through the mitral valve into the left ventricle where the blood is then pumped through the aortic valve into the aorta which carries the oxygenated blood to be circulated throughout the body (Figure 2).

Truncus arteriosus is a rare congenital, cyanotic heart defect where the truncus arteriosus vessel did not split into the aorta and pulmonary arteries and therefore, the single blood vessel emerges from the heart (Figure 3). The systemic venous blood travels to the right atrium and flows into the right ventricle. The pulmonary veins carry oxygenated venous blood into the left atrium and the blood flows into the left ventricle. The ventricular septal defect (VSD) allows deoxygenated and oxygenated blood to mix before it exits through the common truncal valve into the truncus arteriosus artery to be transported to the body.<sup>3</sup> The other complication is truncal valve regurgitation allowing blood to regurgitate into the heart.<sup>4</sup>

The mixing of deoxygenated and oxygenated blood and changes in the pulmonary vascular resistance (PVR) and pulmonary blood flow (PBF) cause the pathophysiological symptoms to begin once the infant is born. The PVR



Figure 1. Semilunar Leaflets

is immediately abnormally high, pulmonary hypertension, during the first week of life.<sup>4</sup> The blood with mixed oxygen that enters the systemic circulation causes cyanosis, hence the term “blue baby syndrome” because of the blueish color of the infant’s skin due to low blood oxygen level. Pulmonary over circulation leads to congestive heart failure as the PVR decreases and the PBF increases.<sup>3</sup> If left untreated, irreversible cardiac failure occurs.

Symptoms include rapid breathing, shortness of breath, sweating, pale skin that is cool to the touch, and rapid heart rate.<sup>3</sup> These are indications of the heart having to work harder to compensate for the mixed blood and the lack of oxygen reaching the vital organs. Echocardiography is used to diagnose truncus arteriosus, though cardiac catheterization and other advanced imaging techniques may be performed to provide additional diagnostic details.<sup>3</sup>

The cause of truncus arteriosus is unknown. However, genetics may play a role in its formation. Truncus arteriosus is associated with 22q11.2 microdeletion, referred to as DiGeorge syndrome, in 12% to 35% of patients.<sup>3</sup> Additionally, abnormalities in the cardiac neural crest cells are strongly associated with truncus arteriosus.<sup>3</sup> Truncus arteriosus occurs in approximately 7 per 100,000 live births or about 230 cases per year.<sup>3,5</sup> While the condition occurs in less than 1% of all congenital heart defects, it accounts for approximately 4% of all critical congenital heart defects.<sup>3</sup>

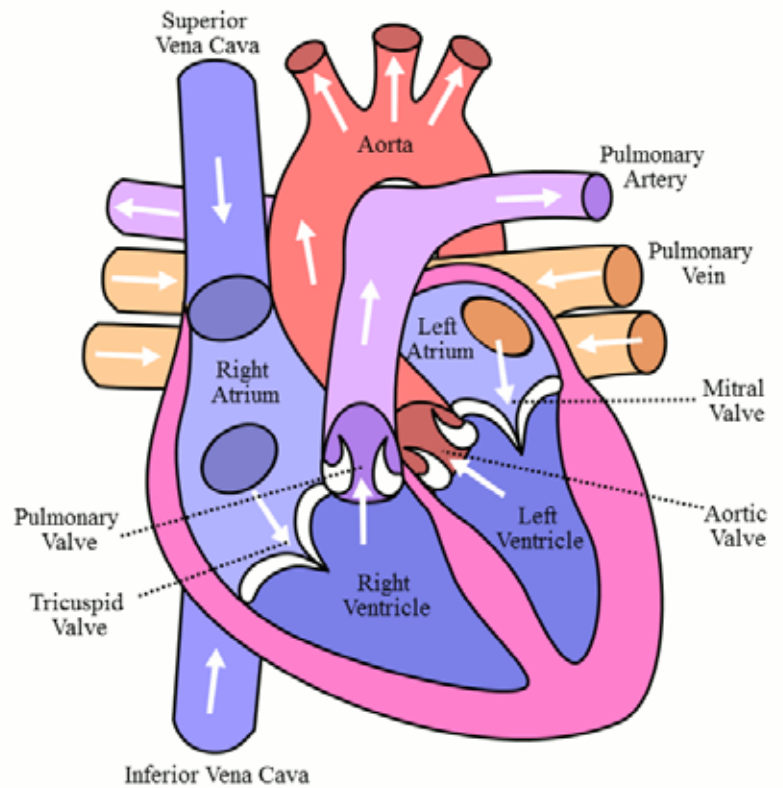


Figure 2. Cardiac Blood Circulation

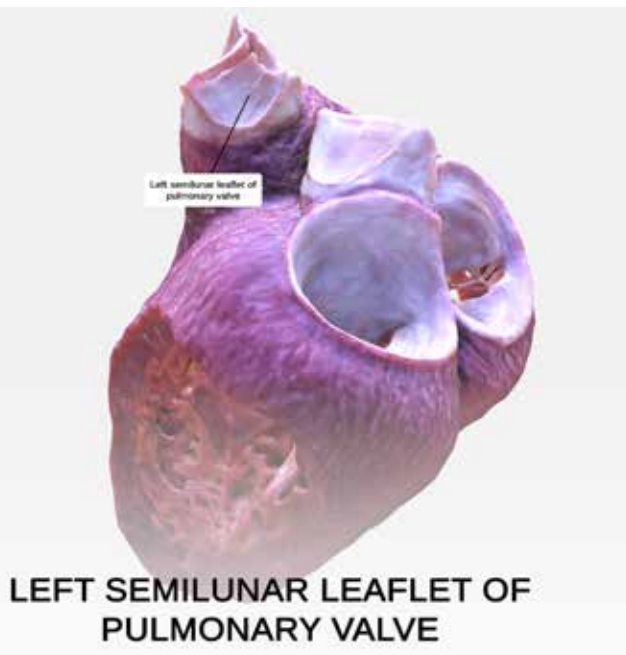


Figure 1 cont.: Semilunar Leaflets

Truncus arteriosus is a rare congenital, cyanotic heart defect where the truncus arteriosus vessel did not split into the aorta and pulmonary arteries and therefore, the single blood vessel emerges from the heart (Figure 3).



## DEFINITIONS

**Cardiac neural crest cells:** Neural crest cells are a specialized type of cell in embryos that originate from the neural tube during the early stages of development. The cells migrate and differentiate into a variety of specific cell types, thereby serving an important role in the development of various tissues and organs. Cardiac neural crest cells (cNCCs) are one type of neural crest cells that contribute to the formation of the heart and its structures. Abnormal development of cNCCs can cause congenital heart defects.

**Coapting edge (of valve leaflets):** Refers to the area where the valve leaflets contact each other and overlap during valve closure.

**DiGeorge syndrome:** Genetic condition caused by a deletion of genetic material on chromosome 22 that can affect the development of multiple body systems in the fetus, including causing congenital heart defects.

**Lymphoproliferative disorders:** Group of conditions characterized by the excessive production of lymphocytes. The disorders can be benign or cancerous affecting various organs such as the liver and spleen. The disorders can be caused by genetic factors, immunodeficiency disorders, and complications related to organ transplantation.

**Orthotopic:** Located in the normal, anatomical position. In relation to transplant surgery, the donor organ or tissue is placed in the same anatomical location where the original organ or tissue was located.

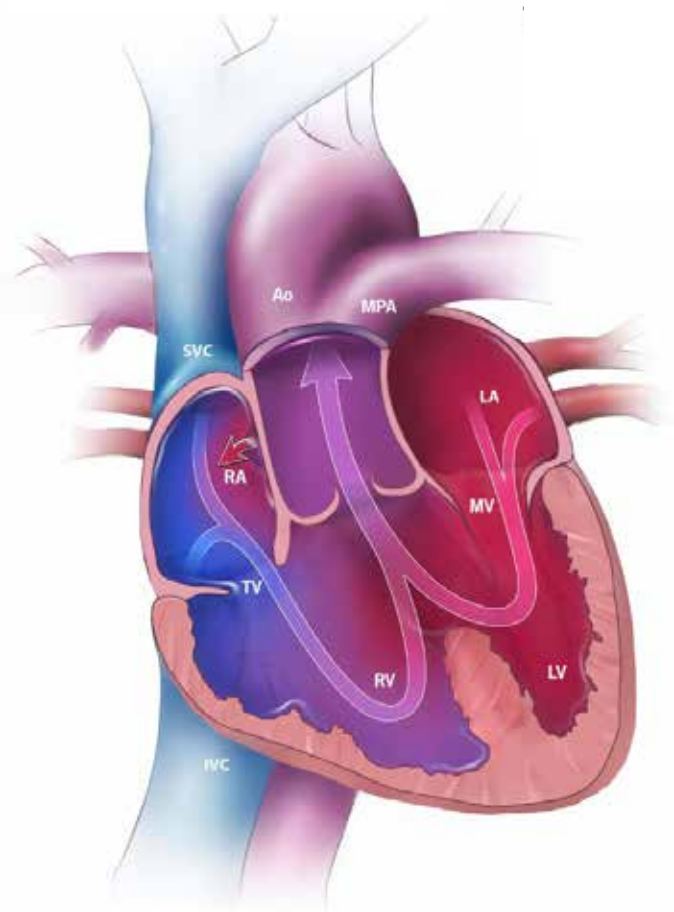
**Proteoglycans:** A class of complex molecules called glycoproteins that are particularly found in the extracellular matrix of connective tissues.

## SURGICAL OPTIONS

Up to this point, the only option in treating irreparable heart valves in neonates has been with cadaveric heart valve homografts obtained from other newborns. Cryopreserved homografts keep the valve extracellular matrix that preserves the ability of the leaflets to ensure unidirectional blood flow.<sup>6</sup> However, the viability of the majority of the valve cells is not preserved, which prevents them from growing or self-repairing.<sup>6</sup> Therefore, the homograft valves eventually stenose as the child grows, placing the child in the position of having to undergo multiple surgical procedures with exposure to all the risks each time to replace the valve until an adult-sized valve can be implanted.

An analysis of the Society of Thoracic Surgeons Congenital

Figure 3. Truncus Arteriosus Pathology



RA: Right Atrium  
RV: Right Ventricle  
LA: Left Atrium  
LV: Left Ventricle  
SVC: Superior Vena Cava

IVC: Inferior Vena Cava  
MPA: Main Pulmonary Artery  
Ao: Aorta  
TV: Tricuspid Valve  
MV: Mitral Valve

Heart Surgery Database showed a 40% early mortality in neonates and infants that received an aortic valve homograft.<sup>6</sup> Additionally, Dr. Rajab completed a meta-analysis that showed truncal valve replacement has an early mortality of 49% and 15% late mortality annually.<sup>6</sup>

One popular method in young adults is the use of mechanical valves. However, the smallest commercially available valve is 16 mm making it impossible to use in infants or small children because it is too large.<sup>7</sup>

As discussed in the July and August editions of *The Surgical Technologist*, the Ross procedure involves replacing a diseased aortic valve with the patient's own healthy pulmonary valve (PV). The native PV is replaced with a homograft PV. The Ross procedure has the following shortcomings.

- Because the pulmonary valve is placed under systemic pressure, it can eventually result in autograft dilation and regurgitation in some patients.<sup>6</sup>
- The procedure can only be performed if the native pulmonary valve is functioning normally. Children with truncus arteriosus or aortic and pulmonary valve disease are excluded.
- The pulmonary valve is replaced with a homograft. As previously indicated, the homograft does not grow with the child's heart subjecting the patient to multiple surgeries until receiving an adult-sized valve.

## CONTINUING SHORTAGE OF PEDIATRIC DONOR HEARTS

Orthotopic heart transplant (OHT) is an option for treating congenital heart diseases. Approximately 600 pediatric OHTs are performed across the world, with the majority occurring in the U.S.<sup>7</sup> The low number of OHTs performed as compared to the number of pediatric patients on the waitlist is due to the shortage of pediatric and infant heart donors. In 2021, 1,087 pediatric patients were on the waitlist in the U.S. with 30% less than one year of age.<sup>7</sup>

The development of and successful use of immunosuppression has been critical towards the success of transplant surgery, including OHT. However, immunosuppression is associated with significant morbidity and mortality in pediatric OHT patients because of its connection to causing postoperative lymphoproliferative disorders and malignant lymphoma.<sup>6,7</sup>

Lastly, a high discard rate of pediatric hearts for transplant has contributed to the continuing shortage of donor hearts. A 2020 consensus statement published by the International Society for Heart and Lung Transplantation showed results from a survey sent to organ procure-

ment organizations that reported a discard rate of pediatric donor hearts to be 57%.<sup>7</sup> However, there have been efforts towards addressing the shortage. In 2018, the United Network for Organ Sharing implemented a new allocation policy to improve the use of high-risk donor grafts and organ access for critically ill patients.<sup>7</sup> Additionally, comprehensive research studies showing the use of certain types of high-risk donor hearts is feasible. For example, donor hearts from influenza A-positive donors incompletely treated with oseltamivir (brand name Tamiflu®) have been transplanted into pediatric patients with favorable outcomes when the recipient has undergone postoperative influenza treatment.<sup>7</sup>

## DEVELOPMENT OF THE PHT CONCEPT

T. Konrad Rajab, MD, pediatric cardiac surgeon at Medical University of South Carolina (MUSC) Shawn Jenkins Children's Hospital and Assistant Professor, Department of Surgery, MUSC, was determined to find a way to improve the surgical treatment of infants and children with valve defects. He developed the hypothesis based on clinical evidence that if an OHT grows with the patient as well as the pulmonary valve grows after a Ross procedure, this could be applied to transplanting only the part of the heart containing the valves, while preserving the native ventricles, thus preserving the viability of the donor cells like in OHT.<sup>6,8</sup> Dr. Rajab named the concept "partial heart transplant" (PHT).<sup>6</sup>

Reactions to the hypothesis were not initially positive. Dr. Rajab proceeded with establishing experimental evidence to support the hypothesis before being able to get approval for clinical trials. He obtained the funding and put together a team of experts in echocardiography and pediatric clinical trial design, as well as animal experts and an academic perfusion team to perform experimental open-heart surgery replacing the pulmonary valve with PHT in piglets.<sup>6,8</sup> Over a 60-day period, echocardiograms showed that the heart valve in three piglets grew as the animals doubled in size.<sup>8</sup> The results were therefore definitive in proving growth of the valve in immunosuppressed piglets. This cleared the way for obtaining institutional review board approval to move forward with the first human clinical trial.

## FIRST PHT

After sharing the data obtained from the experiments on piglets with several colleagues, Joseph Turek, MD, PhD, Chief of Pediatric Cardiac Surgery at Duke University Hospital identified an 18-day old, five-pound infant diagnosed with persistent truncus arteriosus and severe truncal valve dysfunction who was not a candidate for OHT because of an anticipated poor prognosis.<sup>6</sup>

During pregnancy, Nick and Taylor Monroe learned Owen had truncus arteriosus during an ultrasound examination at his 20<sup>th</sup> week of development. Typically, the surgery to treat truncus arteriosus involves needing to replace only the pulmonary valve and the single valve the infant has serves as the aortic valve. However, shortly after birth the truncal valve dysfunction was discovered.<sup>9</sup>

Dr. Turek told the parents that their son had only a 50% chance of survival if frozen heart valves harvested from a cadaver were used. Additionally, Owen was already in heart failure and ECMO could not be used because the damaged heart would not have been able to function. Dr. Turek offered the parents the option of Owen being the first patient in the world to undergo PHT.

Obviously, not ever having performed the procedure on a human infant, the two surgical teams used 3D-printed heart models and piglet heart specimens, both without valve defects and with the specific defects of Owen's heart, to practice various approaches to the procedure.<sup>6,8</sup>

On the morning of April 22, 2022, the news was given to the parents that a matching heart had been located and the blood vessels and heart valves were appropriate for transplant. The donor was a neonate with hypoxic ischemic brain injury, but a normal heart. Dr. Rajab's team procured the heart that was transported to Duke Children's Hospital.<sup>6,8</sup> The surgery began at 3:00 p.m., lasting eight hours. His recovery went well, being able to leave with his parents seven weeks postoperatively.<sup>9</sup> During checkups, it showed that he attained all the normal infant developmental targets as well as his heart functioning normally and growing with him with no heart valves leaking.<sup>9</sup> As a result, Owen avoided the necessity of multiple cardiovascular surgeries and less immunosuppressive drug therapy as compared to an OHT patient.

**Part 2 will be published in the November issue of *The Surgical Technologist*.**

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# Partial Heart Transplant Surgical Procedure, Part 1

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1. Which of the following is the middle layer of the semilunar heart valves?
  - a. Ventricularis
  - b. Interstitial
  - c. Spongiosa
  - d. Fibrosa
2. How do the leaflets of atrioventricular valves obtain their blood supply?
  - a. Arterioles
  - b. Capillaries
  - c. Coronary arteries
  - d. Cardiac blood flow
3. Which of the following permits deoxygenated and oxygenated blood to mix?
  - a. Atrial septal defect
  - b. Valve stenosis
  - c. Pulmonary blood flow
  - d. Ventricular septal defect
4. What is the most common imaging technique used to diagnose truncus arteriosus?
  - a. Echocardiography
  - b. Angiography
  - c. Plethysmography
  - d. Computed axial tomography
5. Which of the following syndromes is associated with the formation of truncus arteriosus?
  - a. Marfan
  - b. Down
  - c. Turner
  - d. DiGeorge
6. What is the smallest commercially available mechanical valve in millimeters?
  - a. 14
  - b. 16
  - c. 18
  - d. 20
7. During normal development the truncus arteriosus divides into the:
  - a. aorta and pulmonary arteries.
  - b. right and left coronary arteries.
  - c. right and left ventricles.
  - d. aortic and pulmonic valves.
8. What is the estimated discard rate of pediatric donor hearts?
  - a. 51%
  - b. 54%
  - c. 57%
  - d. 60%
9. Which of the following is immunosuppression associated with causing?
  - a. Cancer
  - b. Thrombocytosis
  - c. Chronic constipation
  - d. Erythrocytosis
10. What percentage chance did Owen have for survival if cryopreserved heart valves were implanted?
  - a. 45%
  - b. 50%
  - c. 55%
  - d. 60%

## PARTIAL HEART TRANSPLANT SURGICAL PROCEDURE, PART 1

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