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History of the Artificial Heart

The improvements in cardiac surgery in a relatively short period of time have been tremendous since the first open heart surgery in 1952. Cardiac surgery, like other modern surgeries, has evolved through three stages as pointed out by Porter (2006). The first the era of extirpation, second the era of restoration, and now a focus on replacement. Cardiac surgery, like many other surgeries, builds on advances from all stages to find ways to promote health in individuals.

Discovery of Anatomy of the Heart

The first known descriptions of the heart come from Galen (130-200). His descriptions were based mainly on the dissections of animals. His descriptions include the valves, and the differences between the arteries and veins, however he did not consider the heart to be the center of the circulatory system. He further proposed that the arteries carried blood rather than air as previously thought. His teachings were followed for 14 centuries (Phillips, 1997).

During the Renaissance a great physician Andreas Vesalius (1514-67), the founder of modern anatomy, noted differences between Galen's view of anatomy and the anatomy revealed from human dissections. He was the first to describe the anatomy of the heart correctly. At the age of 28, he published *De Humani Corporis Fabrica Libri Septem (Seven Books on the Structure of the Human Body)* in 1543. This was the first anatomy book of humans and continues to this day to provide a legitimate and complete view of the human heart (Sherzoi, 1999).

The founder of modern physiology, William Harvey (1578-1657), a prominent English doctor, published in 1628 the *Anatomical Essay on the Motion of the Heart and Blood in Animals*. He described the circulation of blood by the heart. He proposed that there were tiny vessels that connected the arterial circulation to the venous circulation (McMullen, 2002).

Marcello Malpighi (1628-94), the founder of histology, an Italian anatomist using one of the first

microscopes was able to see that the small arteries were connected to small venules by tiny vessels (Phillips, 1997).

Advances in Repairing Hearts

With an understanding of the anatomy of the heart came explorations in the ways to fix a failing or impaired heart. Alexis Carrel (1873-1944) pioneered vascular surgery by replacing parts of arteries that had thinned or ruptured with vascular tissue from other parts of the body. Robert E. Gross performed the first ligation of the ductus arteriosus in 1938. Dwight Harken performed mitral valve operations using a small incision and a finger to blindly widen the valve (Nova Online, 1997). Further operations would have to wait until the development of the heart lung machine (Nova Online, 1997).

John Gibbon worked on such a machine for several years. His machine involved connecting to the great vessels, routing blood through the machine which aerated it, and returned it to the body. The first machine was successful tested in 1953 (Fou, 1997). Dennis Melrose developed a way to stop the heart from beating so surgery on it could take place; this opened the doors to surgery to patch holes in the septums, repair and change valves, and replace blocked coronary arteries (Nova Online, 1997). The invention of Gibbons machine marked the beginning of the modern era of mechanical circulatory support (Frazier, Shah, & Myers, 2003).

Ventricular remodeling was an approach that Dr. Randas Batista a Brazilian physician developed in 1994 to treat enlarged hearts. His method involved cutting a strip out of the enlarged ventricle and then sewing it back together. The reasoning behind this is that the enlarged heart is not able to efficiently pump blood and if it is made smaller it is better able to empty and perform its function (Nova Online, 1997).

Advances in Replacing Hearts

Successful organ transplantations started to take place in 1954 with the first successful kidney transplant, followed in 1963 by the lung and 1967 the liver (New York Organ Donor Network, 2009). In 1967, Dr. Christian Bernard carried out the first heart transplantation; however, the patient only lived for 18 days. In the early years of transplantation many patients did not live longer than 1 year. They either died from infection from receiving too many immunosuppressants or organ rejection from too few immunosuppressants (Nova Online, 1997). Norman Shumway along with his research team developed a way to monitor the process of heart rejection allowing for more controlled use of immunosuppressants. A new immunosuppressant cyclosporine, which did not significantly compromise the immune system, also became available. As much as these new discoveries improved the success of heart transplantation, there are many more people in need of hearts than there are hearts available (Nova Online, 1997).

The first heart transplant in the U.S. was performed three days after the first one by Dr. Bernard. Dr. Adrian Kantrowitz transplanted a donor heart into an infant who died three days later. Kantrowitz went on to invent a left ventricular assist device and developed a company called L-VAD Technology Incorporated. He died in November of 2008 at the age of 90 from complications of heart failure (Sullivan, 2008).

The incidence of heart failure increased in the United States 145% from 1979 to 1999. Each year almost 40,000 people die from heart failure. Currently, heart failure is treated by medical, surgical, and replacement therapy. Medicines help improve some symptoms and provide for a better quality of life; surgery helps repair valves, bypass blocked arteries, and uses lasers to promote revascularization. When these modalities have failed, the only alternative is to get a heart transplant or a mechanical circulating device (MCD). An MCD can be either a

ventricular assist device or a total artificial heart. The ventricular assist device has been used frequently to bridge the time until a transplant becomes possible (Frazier, Shah, & Myers, 2003).

There are only about 2,500 heart transplants done each year with over 4,000 people on the list, and another potentially 40,000 candidates. In 2001 there were 458 people that died on the transplant list. The life expectancy of a heart recipient is about 10-20 years, and is therefore not always the best solution for those younger than 40. This is one reason why further research is continuing on devices and procedures that will assist the heart to perform its function while someone waits on the list or prior to getting on the list (Frazier, Shah, & Myers, 2003).

Advances in Cardiac Assist Devices

A ventricular assist device was an option that was developed along side the development of the artificial heart. This device was intended to provide a bridge to transplantation. It is a device that is attached to the ventricle, either the left, right, or both, and then also attaches to the aorta. It aids the heart by pumping some of the blood that flows through the heart (Stephenson, 2008). In 1963, Domingo Liotta and his colleagues implanted the first ventricular assist device into a 42 year old man with severe aortic stenosis. He died 4 days later. Three years later, the same surgeons implanted 2 other ventricular assist devices. One patient died, however the other, a woman, actually recovered enough to have her device removed and went home (Stephenson, 2008).

In the early 1970's, Dr. Peer Portner, a nuclear physicist, worked with doctors at the Stanford University School of Medicine on the development of an implanted left ventricular assist device. In 1984 the device was implanted into a patient and assisted in keeping the patient alive for 8 days when a transplant was performed. This patient went on to become one of the longest living transplant recipients dying in 2004 in his early 70's. Portner went on to found

Novacor Medical Corporation, a company that continued research and development of the ventricular assist device. Today, owned by World Heart Corporation the device has been implanted in more than 1,800 patients. Dr. Porter died on February 9, 2009 from cancer. He was highly respected by physicians and researchers in his field worldwide (White, 2009).

A Novacor assist device was implanted in Robert Kenyon of Connecticut in 1998. He lived longer than any U.S. citizen with a ventricular assist device. He actually received a heart transplant in 2002 (Yale-New Haven Hospital, 2002).

Types of Artificial Hearts

There have been two main types of devices developed to offer people temporary or permanent mechanical circulatory support. These are the ventricular assist devices and the total artificial hearts. Popular VADs include Novacor, Pierce-Donachy, Jarvik 2000, and Heartmate.

The first artificial heart to be implanted in a living being was done by Akutsu and Kolff in 1957. They implanted a total artificial heart into the body of a dog and it worked for 90 minutes. These physicians did not pursue this technology. In 1963 Dr. Michael DeBakey implanted a left ventricular assist device for the first time into a 42-year old patient. This device is used to assist the left ventricle in pumping blood to the body. This gentleman only lived for 4 days, he died from pulmonary complications. The National Heart Institute in 1964 established the Artificial Heart Program to advance the development of the total artificial heart and other cardiac assist devices (Frazier, Shah, & Myers, 2003).

The first total artificial heart to be transplanted into a human was the Liotta total artificial heart (TAH). This device was developed by Dr. Domingo Liotta, it was a double chambered air driven pump with Dacron-lined right and left inflow cuffs and outflow grafts. It had Wada-Cutter hingeless valves controlling the direction of blood flow through the pump. It was connected to a

large external power unit, which unfortunately severely restricted patient mobility. The operation was performed in April 1969 by Dr. Denton Cooley. The patient a 47-year old man could not be weaned from the cardiac bypass machine following a repair of an aneurysm of his left ventricle. The device was used for 64 hours until a donor heart could be transplanted. The patient received a donor heart; however, he died 32 hours later from pseudomonas pneumonia. Even though the Liotta heart performed as planned it was never used clinically again. This heart did prove that a total artificial heart was a device that could be successful and safely used to bridge the gap between a failing heart and a suitable transplant (Frazier, Shah, & Myers, 2003; Texas Heart Institute, 2006c).

The second total artificial heart to be implanted was also done by Cooley in July 1981. This device was the Akutsu-III developed by Dr. Tetsuzo Akutsu at the Texas Heart Institute. It had two pneumatically powered, double-chambered pumps with reciprocating hemispherical diaphragms. It was attached to the remnants of the patient's atria. The patient was a 26-year old male who had developed severe heart failure after coronary artery bypass surgery. He too was unable to be weaned from the bypass machine and the artificial heart was inserted to by time until a donor heart could be found. The patient received a donor heart after 55 hours in stable condition with the artificial heart implanted. The patient unfortunately died 10 days later from infection and multi-organ failure (Frazier, Shah, & Myers, 2003, Texas Heart Institute, 2006b).

Dr. Willem Kolff and a team from the University of Utah developed an artificial heart they named the Jarvik-7 Total Artificial Heart in the early 1970's. This device was a pneumatically powered, biventricular pulsatile device. The pumps were connected to the patient's atria with synthetic cuffs and connectors. Within the pumps was a polyurethane diaphragm that separated an air compartment from the blood compartment. Tubes went outside

the body from the air compartment to an external device. The blood was pumped by alternating pumping air into the chambers. The external device could be adjusted to control the rate, pressure, and duration of systole (Frazier, Shah, & Myers, 2003). Dr. Kolff, known as the “father of artificial organs”, who also built the first kidney dialysis machine died on February 14, 2009, at the age of 97. (Maugh II, 2009).

Dr. William DeVries was the first to permanently implant a total artificial heart (TAH) in a patient. In 1982, he implanted the Jarvik-7 into a dying patient. The Jarvik-7 was implanted into 5 different patients whose survival rate ranged from 10 days to 620 days. A couple of patients were actually able to leave the hospital for short visits; however this heart had a large external console that made activity difficult. This device was not without complications. All patients eventually suffered complications including thromboembolism, stroke, infection, and multiorgan failure (Frazier, Shah, & Myers, 2003).

In 1985 the Jarvik-7 was renamed the Symbion and was put in clinical trials to evaluate it as a bridge to transplantation. Over the next 6 years the device was used in 170 patients as a bridge to a donor heart. Of these, 66 percent went on to receive donor hearts, the rest succumbed to sepsis and multiorgan failure as previous seen with this device. In early 1991 the Food and Drug Administration (FDA) revoked the investigational device exemption for clinical use due to inadequate compliance with FDA regulations (Frazier, Shah, & Myers, 2003).

In 1993 a new device, not much different than the Jarvik-7, called the CardioWest TAH was given approval by the FDA for investigational use in humans. This device has been widely used and in the United States, 93% of those implanted with the CardioWest eventually have received a donor heart and of these 96% have gone home (Frazier, Shah, & Myers, 2003).

A new type of artificial heart called the AbioCor TAH is actually in a new category. It is a totally implantable self-contained replacement heart. It does not have external parts outside of the body. This heart, the product of 30 years of research, was developed and tested by ABIOMED, Inc in Danvers, MA and the Texas Heart Institute. This device uses a transcutaneous energy transfer system and a radiofrequency communication system to transmit signals outside the body to a device that can be used to adjust the settings of the AbioCor. This device has an air chamber that alternates between the left and right therefore removing the need to have air tubes going into the body for the pumping action. (Frazier, Shah, & Myers, 2003; Texas Heart Institute, 2006a).

This device received FDA approval in July 2001 with the following criteria: the patient must have a life expectancy of less than 30 days, end-stage heart failure, not eligible for a natural heart transplant, and have no other viable treatment options. It was first successfully implanted in a 59-year old man with end-stage congestive heart failure. As of 2003 this device had been placed in humans 7 times, with one remaining alive as of 474 days. Four of those 7 lived longer than 60 days. Four of the seven were able to walk and leave the hospital for short periods (Frazier, Shah, & Myers, 2003; Texas Heart Institute, 2006a).

Recipients of Artificial Heart Devices

The first recipient of the first implanted artificial heart the Jarvik 7 was Dr. Barney Clark. Mr. Clark was a dentist from Utah suffering from heart failure and too sick to receive a transplant. His surgery was performed in 1982, and was covered extensively by the media. The large washing machine size air compressor that provided the pumping function for his heart kept him from being mobile. Clark lived for 112 days, succumbing to blood clots, a major complication associated with this artificial. The longest survival with a Jarvik-7 was 620 days by William

Schroeder. He died from a stroke caused also by the formation of blood clots. (Herbert, 2007; Artificial Heart, 2008).

The first recipient of the AbioCor was Robert Tools, suffering from severe heart failure. He was given a month to live when he sought out the experimental treatment after he was turned down for a transplant because his condition was too grave. His operation took place at Kentucky's Jewish Hospital. He reported the heart felt heavier than his original and that it made a whirring noise instead of a beat. Mr. Tools lived for 151 days with his artificial heart, dying from severe abdominal bleeding unrelated to his AbioCor heart (Altman, 2001).

Peter Houghton was the longest living recipient of a ventricular assist device, 7 years. He lived in Birmingham, England. He received a Jarvik 2000 heart in June 2000 at the age of 60. He had been given only a month to live and was considered too old to be given a transplant. After the transplant he was able to walk very well, helped raise money for heart research, and wrote two books. Failing health caused him to spend his last few months in a nursing home. He died in December of 2007 (Maugh II, 2007).

Future of the Artificial Heart

In 2004, the CardioWest temporary Total Artificial Heart, manufactured by SynCardia, became the first implantable artificial heart to get FDA, Health Canada, and CE approval. It boasts the highest bridge to transplant success rate (79%) of any approved device. This device is the descendent of the Jarvik-7. It occupies the space of the removed diseased ventricles. This device has a large external pneumatic driver which provides air for the pump. A smaller portable driver was given approval for use in Europe in 2006, however it has not received approval in the U.S (SynCardia Systems Inc., 2007).

In 2008, the Texas Heart Institute at St. Luke's Episcopal Hospital received a \$2.8 million grant to fund the research and development of a "pulse-less" artificial heart. This new design will allow for smaller versions of the heart. It will have the ability to respond to the bodies needs (Watson, 2008).

Dr. Alain Carpentier, a leading cardiac surgeon in France, has been working with a team over the last twenty years to develop an artificial heart. This heart uses advanced technology. It has a beat that is controlled by electronic sensors. These sensors can cause the heart rate and blood flow to change as needed by the body. The lining of the heart has been specially designed to prevent the formation of clots, which has been a major complication of previous devices. The choice of the most suitable power source is still a significant obstacle facing the team. The device has been tested successfully in calves. Current plans have human clinical trials beginning in 2111 and if all goes well wide spread use by 2113 (The Times, 2008).

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