Artificial Hearts

Introduction:

Before 1900, very few people died of heart disease. Since then, heart disease has become the number one killer in the United States. The age of technology has made life easier and made people more prone to heart disease. Before the Industrial Revolution, most people made their living through some sort of manual labor. Walking was the major means of transportation. Laundry was scrubbed and wrung by hand. Stairs were climbed, carpets were beat, and butter was churned.

As the length of the human life increases, there is an overwhelming need to prolong the inevitable. As technology advances, there are many ways to prevent or cure illnesses that may be fatal. The human body is essentially an advanced machine that is composed of many parts. Like any typical machine, the parts can become fatigued and fail, or quit functioning due to overuse or misuse. When the parts of the human body become dysfunctional, they need to either be repaired or replaced. The same is true with the human heart.

A Total Artificial Heart (TAH) is exactly what the name states, an artificial heart. It is placed in the body and imitates the functioning of a real human heart. It is designed to provide the same circulation, flow rates, and overall functions as the heart it

replaces. Out of approximately 700,000 people who die each year from heart disease, only 2,000 receive heart transplants. A majority of the remaining individuals would greatly benefit from a replacement or transplant heart. The problem is that there are simply not enough transplants available to match the number required. Thus enters the area of research into total artificial hearts. These mechanical replacements can make up for the lack of available transplants. They would provide patients with a viable alternative to a diseased heart where no former option existed. The research into total artificial hearts has been progressing for a number of years and formally began in 1964 as a government funded program. Much progress has been made since the early days of TAH research, but much research must still be done before an acceptable and desirable solution is ready.

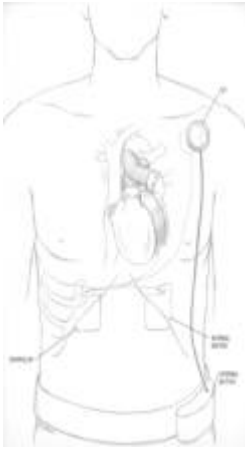
The Customer Needs:

The initial design of the total artificial heart focused on mimicking the natural heart. More recently, the total artificial heart (TAH) has been used for temporary support until a natural heart can be transplanted. One limitation of the total artificial heart is that the native heart must be removed. This shortcoming prompted the development of the ventricular assist devices.

In many cases, heart disease may be so advanced that there is no chance for a patient to survive the

wait for a donor heart. Medical scientists have developed the artificial heart models that can keep patients alive until a suitable donor heart can be found.

Heart disease causes more than 700,000 deaths each year in the United States. Ongoing research has led to drugs, medical devices, and procedures that have provided effective treatment for many types of heart disease. There are still many individuals who suffer from end-stage heart disease who have few treatment options. Current breakthroughs in valve replacement and mechanical assist devices are buying patients additional time. Long-term total artificial hearts are now under development and scheduled for trials early in the next century.



The design of the artificial organ poses many problems. For example, the device must be compatible in size to that of a natural organ. The size becomes a constraint because the device must be able to perform very advanced functions when typically an advanced machine is large due to the many parts required to perform the function desired. For a successful product, the design must be a complex but compact one in order to be able to achieve the desired output in the limited space available.

The purpose of the artificial heart is to advance the art and science of mechanical circulation in patients with end-stage heart failure, with the ultimate goal being to identify appropriate indications for use of left and right ventricular assist devices and the total artificial heart in patient populations most likely to benefit from them.

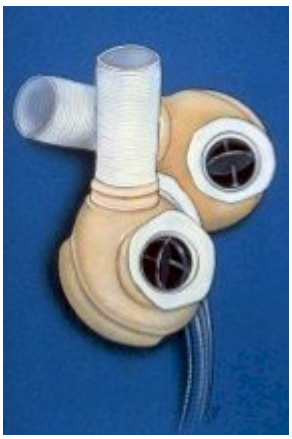
"No matter how you look at it, it's a multibillion dollar opportunity"
"We're finally seeing his (Robert K. Jarvik) many, many years of efforts beginning to bear fruits"

Philips Nalbone, health care analyst in San Francisco.

The Total Artificial Hearts

Jarvik-7

The Jarvik-7 total artificial heart was probably the best known of the artificial heart devices during 1980's. Named for its designer, Dr. Robert Jarvik, the Jarvik-7 is designed to function like the natural heart.



The Jarvik-7 has two pumps, much like the heart's ventricles. Each sphere-shaped polyurethane "ventricle" has a disk-shaped mechanism that pushes the blood from the inlet valve to the outlet valve. The ventricles are pneumatically (air) powered. Air is pulsed through the ventricular air chambers at rates of 40 to 120 beats per minute. The artificial heart is attached to the heart's natural atria by cuffs made of Dacron felt. The drivelines out of the ventricular air chambers are made of reinforced polyurethane tubing. The lines are covered where they exit the skin with velour-covered Silastic to ensure stability and encourage tissue growth even with movement by the patient.

Clinical evaluations of a total artificial heart for permanent use in patients began in 1982, when surgeons at the University of Utah implanted the device in a patient named Barney Clark. He survived with the Jarvik-7 for 112 days. Five more implantations of the Jarvik-7 were performed through 1985. The longest survivor was William Schroeder, who was supported by the Jarvik-7 for 620 days. By the late 1980s, surgeons at 16 centers (including Texas Heart Institute) had used the Jarvik-7 as a bridge to transplantation in more than 70 patients.

Akutsu III

In July 1981, Dr. Denton A. Cooley again implanted a total artificial heart, the second such procedure in the world. Developed by Dr. Tetsuzo Akutsu at the Texas Heart Institute, the Akutsu III total artificial heart was implanted in a 36-year-old man. The Akutsu III kept the man alive for 55 hours, until a donor heart was found for transplantation.

The Akutsu III total artificial heart contained two air-powered, double-chambered pumps. The pumping chambers were made of a smooth material called Avcothane, which could be molded in one piece. The inflow and outflow ports contained Bjork-Shiley disc valves. The prosthetic ventricles were attached to the remnants of the natural heart's atria and to the great vessels by flexible inflow and outflow conduits with detachable quick-connectors. The pumps were connected with Dacron velour-covered tubing to an external control console.
The control console was composed of three basic systems: a pneumatic (air-driven) drive system, an electrical monitoring/control system, and an electrical power system:

& The pneumatic drive system provided both pressure and vacuum to each ventricle. Under normal use, the console was connected to wall pressure and vacuum sources. During patient transport, or in the event of in-house power failure, the system automatically switched to on-board compressed air tanks.

& Monitoring of heart rate and systolic duration were the primary functions of the electrical monitoring/control system. The monitoring/control system provided a digital readout of driveline pressure and vacuum supplied, as well as the status of standard and emergency power supplies.

& The electrical power system had two independent sources of power: standard AC/DC power and a back-up battery in case of power failure.

Liotta

On April 4, 1969, Dr. Denton A. Cooley performed the first total artificial heart implant in the world.

The device, developed by Dr. Domingo Liotta, was implanted in a 47-year-old patient with severe heart failure. The Liotta heart supported the patient for nearly three days, at which time a donor heart was found for transplantation. This experience showed doctors that patients could be "bridged" to transplantation, meaning that mechanical circulatory support systems could be used to keep a patient alive until a donor heart is found.

The Liotta total artificial heart was an air-driven (pneumatic), double-ventricle pump. Wada-Cutter hinge less valves controlled the flow of blood through the inflow and outflow areas of the pump. The two pump chambers (the "ventricles"), the cuff-shaped inflow tracts (the "atria"), and the outflow tracts were lined with a special fabric that promoted the formation of a smooth cellular surface. The flexible inflow and outflow tracts were made of Dacron fabric, and the pump chambers were made of Dacron fabric and Silastic plastic. The pumps were connectere connected to the external power unit with Silastic tubing covered by Dacron fabric. The console, also a major engineering accomplishment at the time, was about the size of a large household washing machine.

Two pneumatic power units generated the pumping and

vacuum actions needed to move blood through the artificial heart. The complex control panel included numerous switches and knobs used to adjust pumping rate and pumping pressure.

AbioCor

The AbioCor implantable replacement heart is the first completely self-contained total artificial heart. It is the product of 30 years of research, development, and testing conducted by ABIOMED, Inc. and its collaborators, with the support of the National Heart, Lung and Blood Institute. The AbioCor is designed to sustain the body's circulatory system and to extend the lives of patients who would otherwise die of heart failure. Its unique design allows it to be totally implanted within the body. Unlike the artificial hearts of the past, patients are not tethered to a large, air-pumping console nor do they have wires or tubes piercing their skin.
The AbioCor is intended for use in end-stage heart failure patients whose hearts have irreversible left and right ventricular failure and for whom surgery or

medical therapy is inadequate. Currently, heart transplantation is the only proven method of cardiac replacement for extending the lives of such patients; however, there remains a consistent shortage of available donor hearts for transplantation. The Food and Drug Administration has given approval for the initial implantations of the AbioCor, after which it will review the results to determine if the study should be expanded to include more patients, including patients at other medical centers. In the meantime, the FDA and AbioCor officials have determined that the initial patients to receive the AbioCor must meet the following criteria:

· Have end-stage heart failure.
· Have a life-expectancy of less than 30 days.
· Not eligible for a natural heart transplant.
· Have no other viable treatment options.

On July 2, 2001, surgeons at Jewish Hospital in Louisville, Kentucky, performed the first implant of the AbioCor in a human patient-a 59-year-old named Robert Tools. Since that time, additional implants have been performed at other hospitals throughout the country, including the Texas Heart Institute.

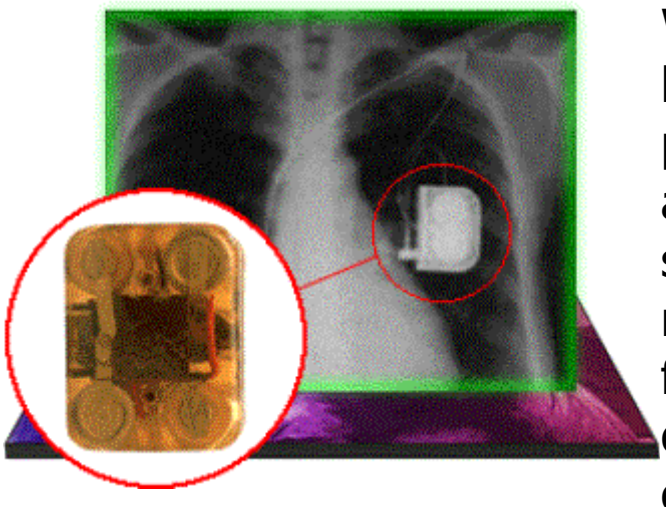
The Beginning

In 1967 William J. Kolff made the first Artificial Kidney, which gave the scientists the hope of making a device to prevent heart failure, and the idea of making an Artificial Heart.

Artificial heart devices have been experimented with since the 1960s, and the Jarvik heart was tried in the early 1980s. The Jarvik heart replaced both the right and left sides of the heart. But one of the most important points is that, in the vast majority of patients, it is probably not necessary to replace both sides of the heart. As we discussed, disease processes usually affect only the left side of the heart, which needs to be very powerful. On the other hand, the right side only pumps to the lungs and doesn't have to be very strong.

Patients given the Jarvik heart did not do so well mainly because of blood clots that were formed in the device, leading to strokes. Since then, the NIH has re-directed its focus into replacing only the left side of the heart. Now there are two companies that

have developed left-side-only artificial hearts. They are the Novacor and Heartmate devices, and both are FDA approved after undergoing about 18 years of clinical trials. Our medical group here at Yale has been involved with the Novacor since its inception.

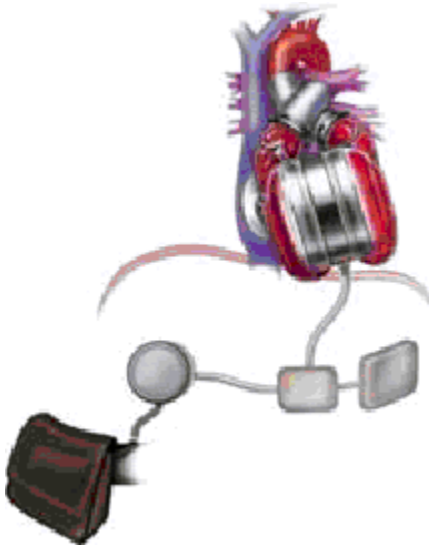


With these devices, the human heart remains in place and the devices are attached onto the left side of the heart to mechanically replace its function. These patients do great and perhaps only 5% will ever need a complete right and left side heart replacement. Three years ago, the Novacor was completely released for clinical use as a temporary solution for heart failure patients until they could obtain a heart transplant.

Truth Behind The History
The Artificial

Truth Behind The History

The Artificial Heart is one of four broad approaches to heart replacement developed by DeBakey and his colleagues, who were among the first generation of revolutionary heart physicians. The other approaches are transplantation of donor heart; assist devices that replace just part of the natural heart, and replacement hearts grown in genetically altered animals or in the laboratory.

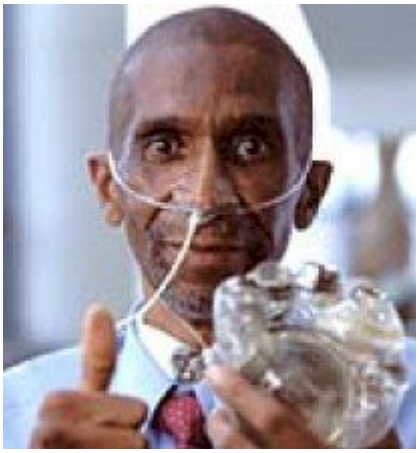


Various forms of artificial hearts pumps have provided temporary "bridges", keeping patients alive while awaiting transplant. Assist pumps, also known as left ventricular assist device, can serve the needs of 80 percent of patients with serious heart failure--patient who once would have been considered candidates for the total artificial heart. But the rest of these patients need some kind of total artificial heart replacement, because neither side of their hearts pumps sufficient blood.

"Some patients have traumatic injuries to the heart, babies are born with hypoplastic hearts (a congenital condition)," said Dr. John Watson, chief of the devices and technology branch at the National Heart, Lung and Blood Institute. "They need total replacement."

Artificial Heats were used as temporary machines until 1982 where the first permanent Artificial Heart (Jarvik-7) was implanted into a patient called Barney Clark by a team led by William DeVries. And He survived for 112 days. Since then, the development of an improved artificial heart has continued.

In July 2, 2001 a man so weak he couldn't lift his head to talk before an artificial heart (AbioCor) was put into his chest now can stand up and walk a short distance without help. Dr. Robert Dowling said his patient, who has not been identified, has gained so much strength in the past five to seven days that he can now spend long stretches of each day sitting in a chair near the nurses' station in the intensive care unit at Jewish Hospital, where he is recovering. Since then, AbioCor has become the number one heart replacement device in the world of artificial hearts.



Evaluation of Designs/Selection of Optimal Design

Alternative designs under development

Two out of the three alternative designs are still under development or improvement. A grown replacement heart, either in a laboratory or in a genetically altered animal is still under development, and a ventricle assist device, which has already been developed, is still under improvement.

Tissue engineering and xenotransplantation are the only two ways to grow a replacement heart. Tissue engineering is the process of growing organs out of cells in a laboratory. Xenotransplantation is the process of humans being able to use a genetically altered animal's heart. Many people think that cloning a heart apart from a human body is an option for growing a replacement heart. According to Ruth SoRelles' research, who is a Houston Chronicle Medical Writer, it is not possible to clone a heart apart from a body. "It will require more scientific research into the basis of life itself - how the cells of an organism that starts as the union between egg and sperm differentiate into all the tissues of a body," said Ruth.

Tissue engineering seems to be progressing faster than xenotransplantation, because it has fewer obstacles in its way. Funding is the only obstacle observed in tissue engineering, while

xenotransplantation has two major obstacles, human immune system rejection, and the release of animal viruses in humans.

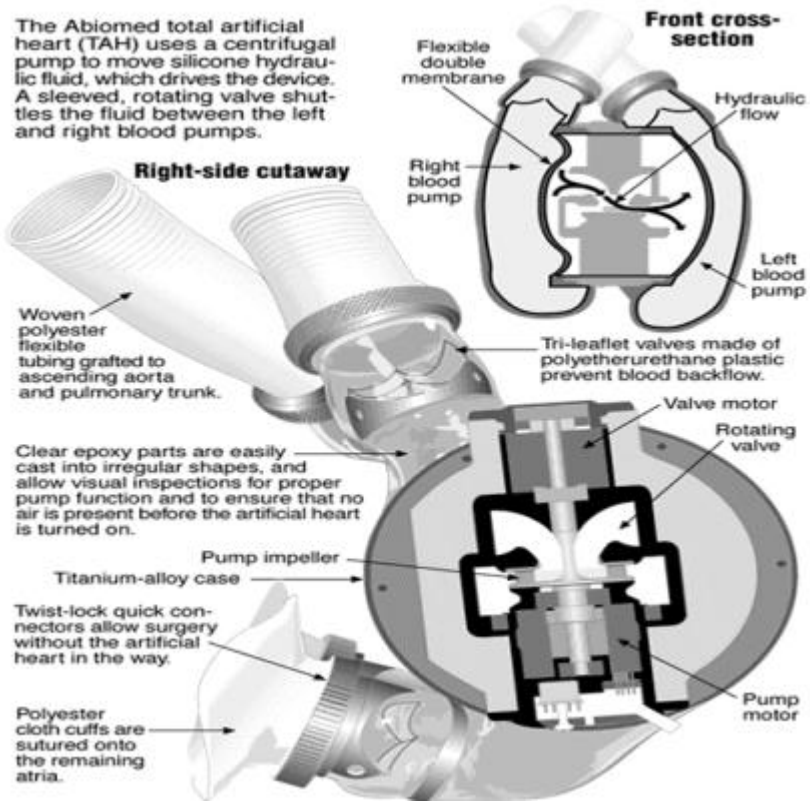
Ventricle assist devices (VADs) assist the human heart with pumping the blood through out the body. There is a wide variety of VADs designed for the many different types of heart failure. VADs are continuously progressing toward a goal to become smaller, more efficient, and to require less power.

Recent modifications and improvements

The AbioCor implements the most recent modifications and improvements over previous designs for the total artificial heart. The previous designs of the Liotta, Akutsu III, and the Jarvik-7 all use air driven pumps that connect to a console about the size of a household refrigerator through tubes that pierce the skin. Doctors monitor these previous designs manually by knobs and controls on the external console. The Akutsu III and the Jarvik-7 both have back up generators or batteries in case of power failure.

Unlike previous designs, an electrical powered motor inside the heart drives the AbioCor. An internal rechargeable battery powers the motor, which is also an emergency battery that the external power source continually charges. The internal battery can provide up to twenty minutes of operation while disconnected from the main battery pack. The transcutaneous energy transmission (TET) system

connects the power from the external battery to the internal components using coils that transmit power across the skin. This decreases the chance of infections, since there is no open wound. A small electronic computer implanted in the abdominal area monitors and controls the pumping speed of the artificial heart.



Evaluation of designs and selection of optimal design

At one point or another, engineers have to evaluate a product to ensure that the design is efficient and that it meets customer need before distributing it. As you are well aware of by now only four artificial hearts have been tested to totally replace the human heart. Doctors since the 1930's have used the Liotta, Akutsu III, Jarvik-7, and the AbioCor to implant into those patients that have heart failure.

The Liotta and the Akutsu III design bridged patients until a donor heart became available. These two artificial hearts paved the way for the Jarvik-7 and the AbioCor, in which had the intent to support a patient permanently. The Jarvik-7 supported many patients for different periods of time. The patient that survived the longest lived 620 days after the implant. The Jarvik-7, after being banned by the FDA, is presently called the CardioWest and is only used to bridge a patient until a donor heart is found. The implied goal for a total artificial heart is to be able to live a normal life after transplantation without being subject to blood clots, constant internal pains, continuous monitoring, or the inconvenience of constantly carrying around external luggage. So based on that goal the evaluation of each design is described below:

Liotta	The Liotta is the farthest away from accomplishing the goal of the total artificial heart, but is considered to be the gateway for improvement for the design of other artificial hearts.
Akutsu III	Although the Akutsu III is still far from reaching the goal of the total artificial heart, it is a step up from the Liotta for its more advanced monitoring/control system

	and back-up battery.
Jarvik-7	The Jarvik-7 is considered much better than the Akutsu III, because it is more maneuverable. The Jarvik-7 is still far from the goal of the total artificial heart, because it still has most, if not all, of the problems that the goal does not have.
AbioCor	The AbioCor is the most technologically advanced total artificial heart that has been tested on humans today. At this time the AbioCor is the optimal design for total artificial hearts. The only problem with the AbioCor is blood clots. All surfaces that contact blood in the AbioCor are smooth except for the cuffs that are sewn to the remnants of the atria. The rough-to-smooth interface there promotes growth of a cell lining that keeps the area blood-tight.

Current status of topic

The total artificial heart is still under development and requires more testing and evaluation. Even the most optimal design of the artificial heart is many decades away from developing the ideal artificial heart. Some say that if the technology used for the AbioCor results in a failure, there is no future for the development of a total artificial heart.

What Is In The Future

In theory, the electric heart will offer advantages over a transplanted heart. There will be no chance for rejection, so people will not need anti-rejection drugs that cause side effects for people with heart transplants. People who have electric hearts will need anti-coagulation medication, but this is generally not problematic and has few side effects. Many people die while waiting for donor hearts. The electric heart could be on the shelf and ready for implantation as soon as the patient needs it.

At this time it is almost impossible to assess the true need for these devices and what the future

population might be. Controlled studies are deperately needed before one can correctly determine this potential. The first step is to critically examine the results of cardiac transplantation. Sub groups of patients do exist where 5 year actuarial survival is limited below 30 to 40%. The future of mechanical support will be for patients who are deemed less than optimal transplant candidates but are still not suffering from end-organ damage.

One such group may be those who suffer from malignancy, where the treatment is recent and disease free survival has yet to be determined clearly. Many of these patients may die within 12 months from CHF but may have a 5-year survival from their malignancy of greater than 50%. A second group may be those with elevated panel reactive antibody levels and are thus sensitized to many potential donors.

The newest heart replacements

Compressed air powered the early artificial hearts. They had to be connected by a tube to an air compressor outside the body. The opening through the skin was prone to infection, and the patient had to stay tethered to the huge machines that powered the device in their chests.
Portable electric motors run the newest artificial hearts, which are scheduled for human trials in the year 2000. With models like this one, no wire passes through the skin. Instead, an electrical coil gets

implanted just under the skin. A second coil, held against the surface of skin, transmits power to the implanted coil. A backup battery also gets implanted in case the recipient wants to temporarily remove the external coil in order to shower or swim.

What does the future hold?

So far, artificial hearts-and transplants as well-have had a very small impact on cardiovascular disease. Only about 150 artificial hearts have been implanted in humans, all for rather short amounts of time. And even though transplants are more common, about 2,500 Americans receive transplants each year. Compare that with the more than 1 million who get treated with heart catheterization.

Heart replacements are meant for patients who risk death because their irreparably damaged hearts can no longer adequately pump blood. Until now, the most that could be expected was that an artificial

heart would allow a patient to survive until a transplant became available.

Perhaps this will change. New models-with promising new designs-will soon be tested on human patients. Maybe soon you'll hear the clicking of an artificial heart in the chest of one of your neighbors.

In Conclusion

The heart is the main part in the human body, and its failure causes death. The future of the total artificial hearts will be a design that allows worldwide mobility and will be similar to the AbioCor, only redesigned so there is no blood clot, or durability problems.

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