The Artificial Heart: Not Just a Pump

The goal of building a safe artificial heart has frustrated bioengineers for more than four decades. At last, an end could be in sight.

In the late 1970s American television viewers were captivated by a weekly drama called The Six Million Dollar Man, starring Lee Majors as secret agent Steve Austin. Austin was a cyborg, a flesh-and-blood man brought back from near death and bioengineered to be superhuman in strength, speed and vision. During the series's five-year run, Austin entered the popular idiom as the bionic man.

An era of technological optimism had been gathering momentum since the 1960s, in large part following the stunning successes of the space program. There was a growing confidence that American scientific ingenuity could engineer almost anything—including the human body. Indeed, at the same time that astronauts started flying into space, the government also set its sights on the gold ring of bioengineering: a permanent mechanical replacement for the human heart.

Fast forward to May 1988, when the New York Times dismissed the entire concept of an artificial human heart as the Dracula of Medical Technology, a hubristic 240-million boondoggle. The paper's editorialists opined tersely: The Federal project to create an implantable artificial heart is dead.

What happened? How did the grand hopes of bioengineering a human heart turn to such cynicism in just a decade?

There is a long answer and a short answer to that question. The long answer is complex, encompassing several strands of basic science and technology, from materials to batteries to motors and microprocessors, plus a healthy dose of marketing psychology. The Times may have been premature in writing off the whole enterprise, which many believe is more promising today than ever before. Nevertheless, deconstructing the early setbacks offers a useful lens on recent progress and further challenges.

The short answer is Barney Clark.
Clark was a Seattle dentist who, in 1982, became the first recipient of a permanent mechanical heart. Permanent is something of a grisly misnomer, because Clark lasted only 112 days. More to the point, they were 112 miserable days for the 61-year-old, who never left the hospital and was tethered the entire time to a refrigerator-size compressor powering his noisy new heart. He suffered convulsions, cognitive problems and kidney failure, then died of massive organ failure.

The mechanical heart that kept Clark alive for those months was the so-called Jarvik-7, named after its inventor, Robert Jarvik. The nation followed Clark's progress with rapt attention, fueled by daily press conferences, which turned quickly to sympathy and disappointment as the patient deteriorated. The case was a public-relations disaster for the Jarvik-7. The quality of Clark's life with his new heart was so poor that it turned public opinion sour on the idea for a decade. Four more patients would receive permanent Jarvik-7 hearts over the next few years, and one, William Schroeder, even survived 620 days, but the damage to the dream was done. In 1990 the U.S. Food and Drug Administration withdrew permission to manufacture any more Jarvik-7 hearts.

It's easy, of course, to second-guess quarter-century-old decisions, but many cardiologists today feel that implanting the Jarvik-7 was a mistake--premature given the primitive state of knowledge at the time. Visionaries were seduced by the simplicity of the natural organ's design--which really is just a four-chambered pump--and somewhat naive about its dynamic complexity. Says Alfred Bove, vice president of the American College of Cardiology: The God-given heart is a dynamically balanced, finely tuned organ, with the capacity to generate force, raise and lower pulse. It's not possible to get that in an artificial heart.

But it is possible to approximate it. And if nothing else, the Jarvik-7 experiments demonstrated that the basic concept was not flawed: they proved that people could survive for extended periods with a heartlike thing made of plastic and metal. Back then, that demonstration in itself was a dramatic step forward, and it was very good news for the 50,000-plus Americans with heart failure who die every year, some while awaiting one of the meager 2,200 donated hearts available for transplant. All of the work since the mid-1980s has been figuring out the problems with the Jarvik-7 and fixing them.

Robert Kung was still a young graduate student in physical chemistry when the federal government began its pursuit of an artificial heart. The Framingham (Massachusetts) Heart Study, begun in 1948, was yielding its early results on Americans' high rates of heart disease and mortality, and cardiologists were realizing just how little they understood about either the prevention or treatment of this killer disease. So in a sense, the government's pursuit of a mechanical heart was inspired by the medical inadequacies of the time.

The early target date for a fully functional artificial heart was 1972--an overly optimistic expectation, says Kung, who has spent his entire career developing a new, improved mechanical heart. He is chief scientific officer at Abiomed, a Danvers, Mass.-based company created specifically to solve the many problems that were glaringly apparent in the Jarvik-7 experiments. Even though flying rockets to the moon seems so much grander a feat, he says, it is actually much simpler because velocities and trajectories can be accurately predicted with the laws of math and physics. The interface between a mechanical heart and human tissue and blood is much more complex and squishy, involving the delicate interplay of blood-flow patterns, clotting agents, and a small army of immunological sentries and soldiers warding off infection. The heart beats, but it's not like clockwork.

This dynamism was poorly understood a generation ago, resulting in insurmountable problems. The two most daunting threats to the survival of Jarvik-7 recipients were stroke and infection. Kung, in designing a successor to the Jarvik-7 called the AbioCor, has focused on these two problems for most of three decades. The designers of the CardioWest, an iteration of the Jarvik-7 used only as a bridge to transplant, have also been working on these problems in different ways. Here is a look at the lessons learned.

**Blood Wants to Move**

William Schroeder, the longest-lived Jarvik-7 recipient, died of a stroke. It was one of the most common risks associated with the early total-heart replacements: fragments of blood cells would stick to the mechanical device, then break off, causing potentially life-threatening clots.

Part of the problem at the time was that medical scientists simply did not understand very well the physics of blood flow and the behavior of circulating platelets. As Kung says, Blood wants to move. It wants to be in motion all the time. And when it moves too sluggishly, it will clot. On the other hand, if it moves too fast, cells can be sheared off and broken, producing debris that can glom up arteries and cause blockages.
The Jarvik-7 had a couple of fatal clotting problems that subsequent research appears to have solved. First, the materials used to build the Jarvik-7 were too coarse; they had nicks and gullies that allowed blood cells to cling and later to split off and cause problems. The AbioCor is made from titanium and a polyurethane blend called Angioflex, which is produced by a secret process that Abiomed claims makes it very pure and slick--much less susceptible to clotting.

What's more, the Jarvik-7 was powered by a large and clumsy pneumatic pump, which actually jolted the heart recipients' bodies as it forced blood through the mechanical chambers. Barney Clark's 112 days must have been extremely unpleasant, with his body constantly jostled by a clattery machine. That harsh pump has been replaced by a tiny motor-driven hydraulic one, which much more closely approximates the continuous blood flow of the natural heart and circulatory system. The rotary motor pushes hydraulic fluid from one of the AbioCor's ventricles to the other, back and forth, 100,000 times a day, pumping blood slowly but steadily to the lungs and body. A miniature electronic controller adjusts the flow level according to need, keeping the blood flow smooth whether a patient is sleeping or seated or strolling.

The AbioCor was in clinical trials from 2001 to 2004, during which time 14 severely ill patients received the device. All died, but it is important to know that these people were the sickest of the sick, with just weeks to live if they had had no intervention at all. A few did die of stroke, but the average survival time was more than four months, more than quadruple their life expectancy before the trial. One, Kentucky tire dealer Tom Christerson, survived 17 months and actually lived the last nine months at home with his family. Kung says that most of the clotting problems had to do with the cuffs that connect the mechanical heart to the body's circulatory system. The cuffs have since been redesigned to eliminate the clotting.

The CardioWest still has problems with infection, because like its ancestor it is powered externally through large pneumatic tubes. The risk of infection has been reduced, however, by covering the tubes in a polyester fiber. The recipient's tissue intertwines itself with the fibrous surface, creating a tight fit that can keep at least some germs out. Even so, more than 70 percent of patients in a large clinical trial of the CardioWest heart did acquire infections.

**Fighting Infection**

The AbioCor has solved the infection problem even more ingeniously. Instead of a pneumatic pump, the AbioCor uses electrical power, from either a standard outlet, an external battery or a tiny internal battery. But instead of piercing the skin, the heart's so-called transcutaneous energy transfer system, or TET, sends the energy across the skin in electromagnetic waves, from an external coil to an electromagnetically coupled internal coil, which in turn powers the heart and charges an internal battery. Eliminating the need for skin-piercing tubes has dramatically reduced complications caused by infection. Indeed, none of the 14 patients in the clinical trial died of device-related infections, according to Kung.

The TET power system has an added benefit: improved quality of life. Patients are able to power the heart's external battery while sleeping or sitting and are free to move about with a small fanny pack for a couple of hours at a time between charges. What's more, the internal battery can power the heart for about one hour, allowing patients to take showers and so forth without any external attachments. These may sound like small things, but they are a dramatic improvement over the severely restricted lives of Clark and other Jarvik-7 recipients.

The TET power system would not be possible without certain technologies that simply were not available in the early 1980s. For example, the system requires high-capacity lithium ion batteries, which are now ubiquitous in portable electronics but were not commercially available until the 1990s. The TET system also uses a very small microprocessor to regulate the energy flow. The miniaturization of electronics in general has now made this crucial design element possible.

Despite these advances in miniaturization, the AbioCor is far from small. At two pounds, the grapefruit-size device is more than twice
the size of the typical human heart. That means it is too big for all children, most women, and even some grown men. Abiomed scientists are currently working on a design called the AbioCor II, which will be 30 percent smaller--small enough even for some children.

Questions remain about how much wear and tear the AbioCor and similar devices can take. No mechanical device lasts forever, and it is fair to expect some parts of this one to wear down. Cardiologist Robert Dowling, writing in the *Journal of Thoracic and Cardiovascular Surgery* during the clinical trials, estimated the life span of the hydraulic membrane--the part that expands into the ventricles to make them pump--at a year or more. The actual pump and switching valve--the only real moving parts in the heart--could last three to five years, according to Dowling. But the fact is that nobody knows for sure. All that is known is that one AbioCor heart beat inside Christerson's chest for 17 months without breakdown.

The biggest question, not only about the AbioCor but also about the larger enterprise, is how much need there is for a permanent mechanical heart. According to Timothy Baldwin of the National Heart, Blood and Lung Institute--the major funder of mechanical-heart development over the decades--government scientists gradually revised their view of heart technologies over time. While funding research on artificial replacements for full hearts, the institute was double-tracking research on various ventricular-assist devices, or VADs--devices that support left ventricle function only. The left ventricle is the strongest muscle in the heart, responsible for pumping blood throughout the body. (The right ventricle merely pumps blood to the lungs for reoxygenation.) But it is also more prone to problems. Many people suffer only left ventricular failure; their right ventricles remain healthy. With the clinical successes of the simpler devices in the 1990s, it became apparent that many people with heart failure could get by with VADs alone. But the jury is still out on this: a fair number of patients with VADs later require right ventricular support as well. Some believe that a total heart replacement, because it is better at controlling overall circulation, will lead to less kidney and liver failure.

The incidence of heart failure is on the rise, in part the result of the aging of the baby boomer generation. The national supply of human hearts for transplants appears to be stuck at about 2,200--not even 5 percent of what the population with heart failure needs. The bottom line is that for some patients, a permanent mechanical heart literally means life or death. Last fall, after the clinical trial of AbioCor, the FDA approved the mechanical heart for marketing under a special humanitarian ruling. This category of approval is reserved for devices and drugs that have proved beneficial, albeit for a very small number of patients--no more than 4,000 a year. Tom Christerson would have qualified. For him, the 17-month reprieve meant witnessing the birth of his great-granddaughter, Ellen.

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