A significant technical advance

First self-contained mechanical heart implanted in the US

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6 August 2001

Doctors in Louisville, Kentucky successfully transplanted the world's first self-contained mechanical heart, known as AbioCor, into a diabetic middle-aged man on July 3. In a major achievement for medical science, a battery pack and computerised control unit run the compact-sized artificial heart—all from within the body. These two units control pumping and, for the first time, can adjust the heart rate according to a patient's level of activity.

The patient, who was operated on at the Jewish Hospital in Louisville, had been expected to live only 30 days, but doctors now believe the new heart will at least double his life expectancy. Now in his fifth week, the man's condition is described as stable—blood is being properly pumped around to his organs, rejuvenating their condition and improving his overall health. So far the patient has been on and off ventilators, and according to doctors, has even completed some minor exercise.

The only major complication was a 30-minute surgical procedure eight days after transplant to drain bloody fluid that had accumulated around the artificial heart. The bleeding was due to anti-coagulant drugs administered to the patient in order to prevent the formation of blood clots inside the heart—a known danger that has occurred with other artificial heart devices.

Weighing just one kilogram, the grapefruit-sized AbioCor was implanted into the man's chest cavity in a seven-hour operation. The battery pack and control unit were firstly implanted into the man's abdomen. Doctors then cut out the man's heart ventricles, the section involved in pumping blood to the body and left the two atria—the heart's entry chambers. These were used as a base into which surgeons attached the artificial heart's two cups. The AbioCor unit was then connected to the patient's blood vessels using special vessel grafts.

The operation is the first in a clinical trial involving a total of five people. If successful the device may provide thousands of prospective heart transplant recipients with a temporary bridge until a human heart becomes available. The availability of donor hearts is less and less able to meet the growing need. Every year in the US alone, some 105,000 cardiac patients require a heart transplant, and only about 3,000 become available.

The self-contained heart is the product of advances in the field of computer technology, and particularly in electronic microprocessors and miniaturisation. Scientists have been able to use new available techniques to engineer a mechanical heart, which is smaller and can control pumping from within the body—without external wires.

The AbioCor heart has two major domes within which sits a sealed electric motor. The motor drives a fan blade that sits immersed in a hydraulic fluid. A rotary valve shoots the blood coming into and leaving the heart alternately to the left and right. The blade mimics the human heart's valve system which allows oxygenated or deoxygenated blood to be pumped either to the body or to the lungs. The blood then passes through the artificial heart's valves and into the body's arteries—just like the human heart, except the blood is pumped through two chambers, not four.

The heart is powered by external batteries inserted into the patient's abdomen, alongside the "brain" of the heart—a computerised control unit that regulates pumping. The battery consists of a lithium-ion cell and can only provide the power for about an hour. It is continually recharged by an external battery pack.

In a major technological accomplishment, the energy needed to recharge the internal battery is transmitted via radio waves—all without the need for wires. A pair of spiral coiled transmitters—one outside and one inside the body—send and receive the radio waves across the skin on an hourly basis. The method ensures patients are not exposed to the danger of infection from external wiring, and is also a more efficient system.

The AbioCor is the first artificial device to so closely mimic the human heart. It has an electronically regulated system which adapts to the increase or decrease in activity of the person—that is, microprocessors can adjust blood flow to meet the body's needs. Physicians are also able to receive wireless transmissions from the device to provide performance feedback and set-off alarms in the event of irregularities.

Designers have also developed a smoother internal arrangement—blood flows through the hearts' ventricles via a swirling vortex without forming any slow-moving or stagnant pools that increase the risk of blood clots. The device is also coated with a special polyurethane material to prevent blood cells from clinging to the surface and clotting.

Under development for more than a decade, the newly designed heart is the product of the company Abiomed. Due to technological constraints, previous mechanical attempts needed major external machinery including an outside power source just

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to pump the heart. Various complications resulted, as tubing connecting the outside machinery with the body became a source of infection.

The last major effort to implant an artificial heart was in 1982, when a University of Utah surgical team replaced the diseased heart of 61-year-old dentist Barney Clark with a device called the Jarvik-7. Air cables running from a washing-machine-sized battery and ventilator source powered the heart. The pneumatic pump operated the mechanical heart and sustained Clark for 112 days. The second patient to receive the Jarvik-7, William Schroeder, lived for 620 days.

The Jarvik-7 transplants were associated with a great deal of media hype, but both patients were completely hospital bound and suffered major complications. In Schroeder's case, by the 21st day the device caused a blood infection. He suffered a fever for 420 days and was fed through a tube for 366 days. Four times Schroeder suffered strokes as hardened clots of blood that had built up in the heart broke off into his bloodstream. The hype rapidly turned into a negative campaign summed up in a *New York Times* editorial, which termed the device "The Dracula of Medical Technology".

Scientists have been attempting to copy the heart's design and function for more than 35 years, ever since heart surgeon Dr Michael DeBakey established the US Artificial Heart Program Office in 1964. Many in the field were optimistic that a fully functional artificial heart could be achieved within a decade. After all, this was the decade that saw the Apollo mission to the moon, so pushing blood through a mechanical pump seemed eminently possible.

But technological constraints and negative publicity held back the work. It became clearer that reproducing an organ with unique muscle tissue able to be revived despite a heart attack as well as beat more than 100,000 times a day would be much more difficult than originally thought. The task involves not just mimicking the mechanics of the heart but its interaction with the brain. The heart also has the unique ability of expanding or contracting depending on the amount of blood needed to be pumped.

Alongside the long-term project of designing a fully functional artificial heart, devices have been developed to assist the human heart. Some of these, such as Dr. DeBakey's Left Ventricular Assist Device (LVAD), which aids a weak heart rather than completely replacing it, have been more successful than originally foreseen. Other prototypes are also in the pipeline such as the Jarvik-2000 that also fits into the left ventricle to assist the pumping action of a damaged heart.

The AbioCor's development was assisted by legislation passed in 1988, requiring the US National Heart, Lung and Blood Institute (NHLBI) to award $US22.6 million to four contractors (including Abiomed) to build an artificial heart. So far, the contracts, which was reduced to two—Abiomed and Pennsylvania State University, each received $13 million from the NHLBI. Then Abiomed began to pour private money into the project, with $10 million injected in 1998.

These private companies are seeking to protect their investment. A deal struck between the Jewish Hospital and Abiomed prevents any independent public or scientific scrutiny of the patient's progress. All press statements have been made through Abiomed, not the hospital or the surgeons involved in the operation. According to one of the surgeons involved, Dr Gray, "Abiomed instructed me not to talk to reporters."

The secrecy is directly connected to financial rather than scientific concerns. The company was concerned to manage press coverage to ensure maximum possible boost for their share prices. On the day the operation took place Abiomed stocks surged about 13 percent or $3.18 to $26.66 on the Nasdaq. Last December they rose almost 30 per cent, when the company announced it was ready to launch clinical trials.

Dr Arthur Caplan, head of the Centre for Bioethics at the University of Pennsylvania, pointed out that Abiomed wanted to avoid the type of bad publicity that surrounded Jarvik-7. "The company has decided that by managing the news it can fend off bad news, keep its attractiveness out front for investors. It's a better business strategy," he said.

George J. Annas from Boston University was more critical of the decision. He noted that although medical research is often done without public scrutiny until journal articles appear, Abiomed's research received public money. He said that it was "unheard of to turn over responsibility for information about a patient's condition to a manufacturer, which has the responsibility for keeping the device in running order but no responsibility for clinical care."

Robert Jarvik, inventor of the Jarvik-7 artificial heart, pointed out that public discussion and debate is essential to the further scientific development. "There's a very healthy discussion that usually goes on about cases that are proceeding, and that discussion has been stifled by Abiomed's approach," he said.

Potentially lucrative fields of science such as biotechnology and medicine are, however, big business. The apologists for the capitalism always like to insist that profit and the operation of the market are a spur to scientific progress and achievement. The case of AbioCor illustrates one of the many ways in which the priorities of big business act to impede scientific development. The implantation of the artificial heart is certainly a testimony to human ingenuity—despite, not because of, the operation of the market.

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