A Change of Heart

NIH has ended nearly two decades of support for the artificial heart, and is putting its money on a heart pump that runs on batteries that transfer energy through the skin

THE National Institutes of Health (NIH) decided last week to stop funding research on a new generation of electrically driven artificial hearts, opting instead for a more simple, completely implantable pump that would assist an ailing heart without replacing the entire organ.

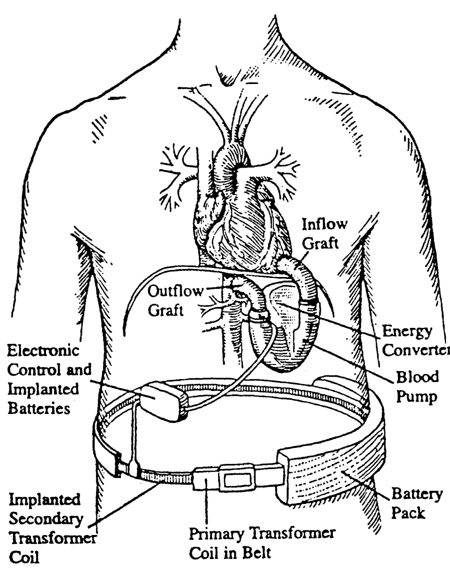
The decision by NIH to cancel contracts worth about $3 million a year has caused disappointment and confusion among researchers, while ending two decades of government support for work on the artificial heart. "This doesn't totally end research on the artificial heart, but it does delay the development of these devices," says Gerson Rosenberg of Pennsylvania State University in Hershey, one of four institutes affected. The others are the Texas Heart Institute in Houston, the Cleveland Clinic in Cleveland, and the University of Utah in Salt Lake City. Rosenberg believes the groups will probably search for private funding. "It doesn't make sense to stop now," says Rosenberg.

Officials at NIH do not agree. "Before sinking a lot more money into artificial hearts, it seemed scientifically more sensible to pursue the assist devices first," says Eugene Passamani of the National Heart, Lung, and Blood Institute, which has spent $239 million on the development of circulatory support systems, including artificial hearts.

Unlike an entire artificial heart, the assist devices simply help the natural heart pump blood more efficiently. Passamani says that the lessons learned during the development and implantation of the less complex pumps will eventually bolster research on completely artificial hearts. "What we're after is really a sense of the interface between man and machine," says Passamani, who believes there is still a great deal to learn about how the human body interacts with alien devices and how best to power the machinery that would run the body's most crucial pump.

A basic flaw of all traditional artificial heart devices is that they must be tethered to the outside world. This is true not only for artificial hearts such as the Jarvik-7, but for assist devices as well, many of which are implanted for only a short period of time, keeping a patient alive long enough to get a heart transplant. This tethering encourages infection and brings into question the quality of life for long-term recipients of such devices. Many people will remember the plucky dentist from Seattle, Barney Clark, the first permanent recipient of an artificial heart who lived with two 6-foot-long tubes protruding from his abdomen. The tubes were plugged into a bulky console that included an air compressor and the control unit which regulated his pneumatic heart. Clark died after 112 days, succumbing to renal failure, infections, and colitis. The four other recipients of permanently implanted artificial hearts have also died.

A Totally Implanted Left Ventricular Assist System.



Batteries included. *Schematic drawing showing scale and location of assist device.*

In the last few years, biomechanical engineers and cardiologists have been struggling to design completely implantable devices, ones that take advantage of the growing technology of miniaturization by utilizing smaller pumps powered by longer lasting batteries and regulated by microprocessors. The decision by NIH to forge ahead with the less complex assist devices is based on the emergence of at least one prototype which appears to have the mechanical gusto necessary to warrant experimentation in humans. The device would assist a failing heart by taking blood from the heart's left ventricle and pumping it directly into the descending aorta. The whole system would reside inside the body. Four biomechanical companies are currently testing the various models. Passamani reports that one system has been sitting on a lab bench, immersed in "a biological milieu," doggedly pumping fluid around in mock loops for the past year. The same device appears to work well in sheep.

In the next few months, the heart institute will begin soliciting contracts to build a large number of these ventricular assist devices, as well as arranging for clinical centers to design protocols for their use. Approval would then be sought from the Food and Drug Administration. Passamani hopes that the first implant will be done by 1990.

The ventricular assist devices consist of a blood pump and an electrically driven control unit. The pump, which is about the size of a large grapefruit, would reside in the abdomen, operating in conjunction with the heart, boosting a surge of pooled blood. The control unit, which is the size of a pack of cigarettes, does its job by sensing the R-wave, the part of the electrocardiogram that defines the onset of ventricular systole. This activates the pump.

The whole system is powered by batteries, which are included. One small battery will be implanted inside the body and will be charged from without by a coil that transfers energy across the barrier consisting of a few centimeters of subcutaneous fat. The patient will wear a belt with a larger battery pack weighing about 10 pounds.

The ventricular assist devices will probably be made available to patients who need help only on the left side of the heart. Others might be offered the assist if they are too old to qualify for a complete heart transplant, but would still benefit from the increased blood pressure.

Patients with end-stage heart disease would continue to pursue heart transplants, of which 1400 were done last year, with 8 out of 10 patients alive after 1 year. The problem with heart transplants, however, is that there are not enough good hearts to go around.

The system that would be required for a completely implantable, electrically driven artificial heart is far more complex, says Rosenberg, who estimates that electrically driven hearts are about 5 or 6 years behind the assist devices. Rosenberg adds that when used as bridges to transplants, artifical hearts appear to work as well as partial assist devices. Of 124 implants done by December 1987, artificial hearts were given to 50 of the patients. About half lived long enough to get transplants and be discharged from the hospital. ■

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