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Science Fiction Made Real

*AbioCor Replacement Heart Advancing Science,
Extending Lives*

Kathleen E. Jones, RN

The scene is like something out of a science-fiction movie. A surgeon opens a man's chest cavity and removes a diseased heart. In its place, the surgeon inserts a titanium and polyurethane artificial heart. An internal rechargeable battery pack and an internal miniaturized electronics package are also placed into the patient's abdomen.

The new replacement heart begins to pump using a system of motor-driven hydraulic pumps and two manufactured ventricles. The blood then circulates to the lungs for oxygenation while the miniaturized electronic package monitors and controls the system performance of the replacement heart. This includes responding to the needs of the body like a normal heart would, speeding up the heart rate as the physiologic needs of the patient demand. The patient wears an external battery pack that uses a system of wireless energy transference to keep the heart pumping.

It's a fascinating description of advanced technology, but it's not science fiction. It's ABIOMED's AbioCor Implantable Replacement Heart.

Picking the Pioneers

The AbioCor Replacement Heart is currently being tested in an initial clinical trial at six different sites in the US. ABIOMED received FDA approval in January 2001 to test this technology in the first human clinical trials. The testing sites are Brigham and Women's Hospital and Massachusetts General Hospital, both in Boston; Tenet — Hahnemann University Hospital, Philadelphia; Jewish Hospital Heart and Lung Institute, Louisville, KY; Texas Heart Institute and St. Luke's Episcopal Hospital, Houston; UCLA Medical Center, Los Angeles; and University Medical Center, Tucson, AZ.

These hospitals were chosen because of their experience in human heart donor transplantation and because of their significant experience working with other advanced medical devices that support the heart's function. At this time, the plan is to include a total of 15 patients in the initial human clinical trial.

To be included in the clinical trial, a patient must meet six specific criteria that ABIOMED has outlined. The patient must be at least 18 years old, have biventricular heart failure, have fewer than 30 days of life expectancy, be unresponsive to the maximum current available therapies, be ineligible for a human heart transplant, and have a chest cavity large enough to accommodate the current model of the AbioCor. ABIOMED has a model in development that will fit smaller thoracic spaces, but the current trial uses a replacement heart that will fit 50% of men and 18% of women, according to ABIOMED corporate communications specialist Sara Goldstein.

Goldstein says ABIOMED does not decide who receives the replacement heart. A committee that consists of a group of medical specialists, including physicians and ethicists (independent of ABIOMED and independent of the testing site), decides at each site who is a candidate for the clinical trial. The decision is made with the best interest of the patient in mind, but ultimately, the patient must decide if the risks outweigh the possible benefits of participating in the clinical trial.

To date, the AbioCor heart has been implanted into six people. Robert Tools was the first recipient to receive the AbioCor replacement heart. His surgery was performed at Jewish Hospital on July 2, 2001, and he survived until November 30, 2001.

The AbioCor heart was able to double the life expectancy of four of its recipients to 60 days or more. Two men who received the transplanted artificial heart have far surpassed those 60 days. James Quinn, 51, whose transplant was done at Hahnemann, has survived more than four months. Tom Christerson, 70, who received his artificial replacement heart at Jewish Hospital, has survived more than six months.

Family Matters

The AbioCor Replacement Heart has the potential to extend life and improve the quality of life for many. ABIOMED estimates that more than 100,000 people each year need heart replacement while the number of available heart donors every year remains at approximately 2,000. The technology takes on a very real significance when the need for a replacement heart becomes a family matter.

For Kelly Binkley, RN, BSN, the AbioCor is about more than just new technology. It became very personal this past year when physicians determined that her grandfather, Tom Christerson, had fewer than 30 days to live because of end-stage heart failure. Christerson was not a candidate for a human heart transplant, and according to Binkley, when faced with dying as his only prospect, he chose to participate in the clinical trial instead.

He met the criteria for inclusion and underwent the surgery to replace his failing heart with the AbioCor on September

13, 2001. On March 13, 2002, he celebrated six months of life after surgery, and then celebrated his 70th birthday a few days later. Binkley, who is a nurse at Jewish Hospital where her grandfather's surgery took place, says being a nurse is difficult in this situation because you always wonder what can happen. She says a strong family and a wonderful attitude are what keep her grandfather going. Binkley notes he is a young guy at heart and that his goal has always been to go home.

Christerson remained in the hospital until March 20, when he was released to a hotel nearby so he could still be closely monitored. Binkley states with conviction that her family is blessed every day because "He is still here." With a successful visit to his home recently, plans are being made to send Christerson home if his remarkable progress continues. The local community healthcare team is being educated as to potential problems and needs, should he make it home.

Life Lessons

The AbioCor Replacement Heart has been in development for many years, but before the clinical trial could begin in humans, the device was tested in animals. At Jewish Hospital, two years before the human clinical trial began, an empty room was converted into a surgical suite for animal trials. Cynthia Reeve, RN, BSN, CCRN, began working alongside Robert Dowling, MD, transplanting the replacement heart into cows. Calves were used because their docile behavior allowed the implanted device to function undisturbed, where other animals would not leave the implanted device alone.

Reeve says she acquired many new skills, but she especially appreciates what she learned about the differences in animals that make their physiologic response unique. Her experience with the new technology led her to become one of the educators responsible for teaching staff what they might encounter with the AbioCor recipients.

Reeve says patients who receive AbioCor hearts do have pulses and have to wear battery equipment to maintain the heart's pumping function. An internal battery provides 30 minutes of power without the external battery pack, which allows patients time for a short activity such as a shower. Recipients must be either directly tethered to a computer or connected via a wireless technology system in order to provide constant and immediate feedback about the mechanical heart. However, recipients do not take cyclosporine antirejection drugs as do transplant recipients of human donor hearts.

When Reeve began working on the AbioCor project, the device was not fully implantable. "I got to see the artificial heart in progress and evolution from a cord coming out to a totally implantable device," she says. Reeve says she feels the clinical trials should continue as the device is tested and

refined, despite the potential for loss of life as a result of the experimental surgery.

Because of her involvement from the ground up with the AbioCor heart replacement testing, Reeve has had the unique experience of discussing the ethical and moral issues that are faced in an experimental procedure such as this before the AbioCor was ever implanted in a person. She says there may be a choice for heart failure patients, where before there were no other options for their survival. "A lot of young people died. Maybe this will make a difference."

The Sound of Life

Elizabeth Blank, RN, BSN, began her nursing career in July 2001, in Louisville, KY, the same month the human clinical testing of the AbioCor began at Jewish Hospital. She says working with the artificial replacement heart patients in her step-down unit has changed her entire nursing career, and that she has developed more confidence in her nursing skills as a result.

Blank describes both Christerson and Tools as vivacious and full of life, although she worked more closely with Christerson. Because of Christerson's long and extended stay, Blank was able to develop a relationship with him and his family. She says the AbioCor artificial heart has benefited Christerson by extending his life, something that was not possible by any other means. "He and his wife enjoy life more than anyone I know," Blank says.

Blank was scared when she first began to work with this program because there were so few people that the AbioCor heart had been tested in, leaving everyone with a very narrow frame of reference. When Christerson was first transferred to her area, he was very sick,

but after she returned from a week off, he was able to call her by name and it "made a big difference to see the progress."

When asked what the AbioCor replacement heart sounded like in a patient, Blank described the sound as a soft "choo, choo, choo" type noise. With Christerson's permission, Blank then proceeded to place the phone to his chest. It sounded very much like a soft choo, choo, choo, but more importantly, it also sounded like life.

Kathleen E. Jones, RN, Westerville, OH, has 20 years of nursing experience in med/surg, oncology, pediatrics, and in an outpatient setting. She is currently working on a collection of stories about the many memorable patients for whom she has cared.

Editor's Note: Tom Christerson was released from the hospital to his own home April 16. We would like to wish him and the other patients discussed in this story all the best.

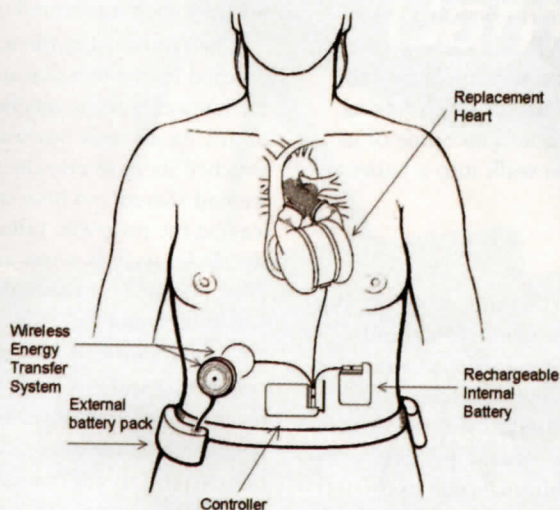


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