Study: Heart pump with behind-the-ear power connector

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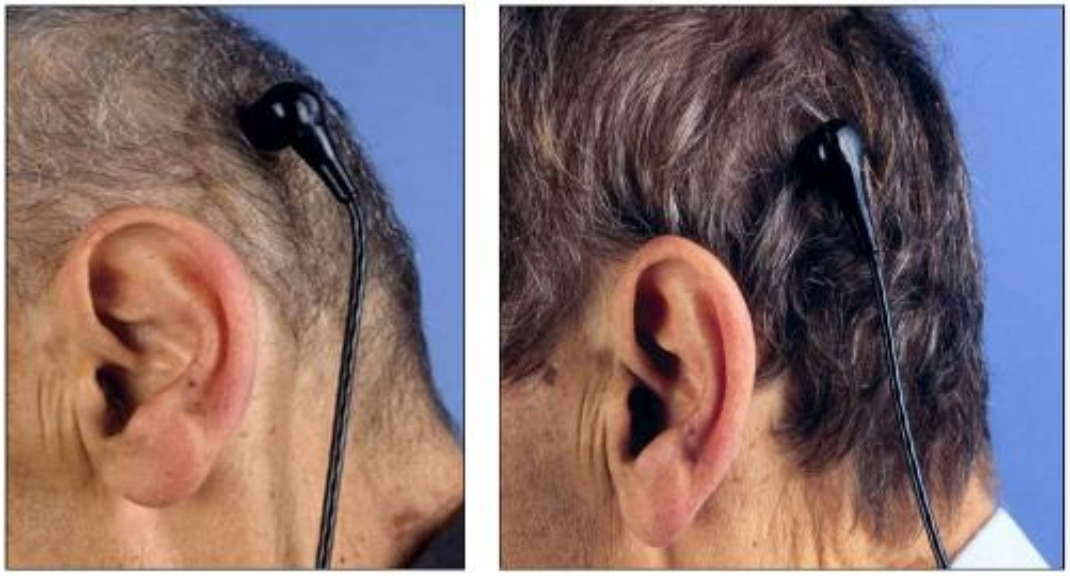

Cardiac surgeons and cardiologists at the University of Maryland Heart Center are part of a multicenter clinical trial evaluating the efficacy of powering heart pumps through a skull-based connector behind the ear. Typically, these devices for patients with severe heart failure are energized through an electrical cord connected at an abdominal site, where potentially deadly infections can develop. The connection under evaluation to power the Jarvik 2000 heart is shown one month after surgery (left) and six months post-surgery. Credit: Jarvik Heart Inc.

Cardiac surgeons and cardiologists at the University of Maryland Heart Center are part of a multi-center clinical trial evaluating the efficacy of powering heart pumps through a skull-based connector behind the ear. Typically, these devices for patients with severe heart failure are

energized through an electrical cord connected at an abdominal site, where potentially deadly infections can develop.

"Over time, nearly one-third of our patients surviving with the assistance of an implanted blood pump develop an infection at the site where the power cord exits the skin. This complication may be lethal but, if not, it is always a difficult problem," says the University of Maryland's principal investigator, Bartley P. Griffith, M.D., the Thomas E. and Alice Marie Hales Distinguished Professor of Surgery at the University of Maryland School of Medicine, and a senior cardiac surgeon at the University of Maryland Medical Center.

The infection-prone abdominal connection also limits some activities such as swimming and bathing, since water may also contribute to infection.

The pumps, called left ventricular assist devices (LVADs), support the heart's main pumping chamber, the left ventricle. LVADs are implanted in the chest and powered with external batteries.

The study, named RELIVE (Randomized Evaluation of Long-term Intraventricular VAD Effectiveness), compares two similar continuous flow heart pumps designed for "destination therapy." The devices provide long-term support to patients with end-stage heart failure who, for a variety of reasons at the time of implant, are ineligible for a heart transplant. The major difference is in the way electrical power from the battery pack gets to each pump implanted in the chest. In one case, the internal power cord is routed through a traditional opening, or pump pocket, in the abdominal wall. In the other, the internal power cable is tunneled through the neck to the head. The internal cable is connected to a socket or pedestal placed behind the ear in the skull, in the same area used to pass cochlear implant electrode wires into the body. On the outside of the skull, a waterproof cable running from the battery pack is

plugged into the socket.

Patients in the study are randomly assigned to one of two groups. The treatment group receives a Jarvik 2000 LVAD equipped with an investigational "post-auricular" connector from Jarvik Heart, Inc., the funder of the study. Control group patients are given a heart pump that employs an abdominal connector, Thoratec Corporation's HeartMate II Left Ventricular Assist System, which is the most widely used FDA-approved LVAD for destination therapy.

Part of the problem with the abdominal approach is related to the softness and flexibility of the abdomen. According to Dr. Griffith, tiny, micro-movements of the power cable at the abdominal entrance are all it takes to set the stage for infection. The investigators theorize that the stability of the bone-mounted terminal coupled with the vast blood supply in the scalp will reduce the chance of infection. "The bone in the skull is a better substrate to locate a foreign body on, because there's good blood flow, and there's no motion," says Dr. Griffith. At the same time, the investigators posit that the location of the connector in the head should provide quality of life benefits for patients who would otherwise not be able to take a shower or swim.

The cardiac team at the University of Maryland Heart Center has years of experience with both the HeartMate II and another version of the Jarvik 2000 with an abdominal pump pocket. Two other cardiac surgeons at the University of Maryland Medical Center are participating in the study: Keshava Rajagopal, M.D., Ph.D., assistant professor of surgery at the University of Maryland School of Medicine, and Si M. Pham, M.D., professor and director of the Heart, Lung Transplant and Thoracic Mechanical Assist Devices Program at the University of Maryland School of Medicine. A cardiologist on the team, Erika D. Feller, M.D., assistant professor at the University of Maryland School of Medicine and medical director of heart transplantation and ventricular

assist devices at the University of Maryland Medical Center, provides continuing cardiac care and monitoring of patients in the study.

Since the Jarvik implantation involves the head and neck, the cardiac team has formed an unusual collaboration with another surgical department at the School of Medicine. Ronna P. Hertzano, M.D., Ph.D., assistant professor of Otorhinolaryngology-Head and Neck Surgery at the University of Maryland School of Medicine, extends the internal Jarvik power cord through the neck and places the socket in the skull. Dr. Hertzano, whose specialty includes hearing restoration and diseases of the ear and lateral skull base, works alongside the cardiac surgical team at the time of the procedure to correctly place the wire and skull connector.

"Cardiovascular disease kills one in three Americans. Particularly desperate is the plight of severely ill heart failure patients who have few options. The shortage of donor hearts for transplant has increased the need for functional and safe heart pump technology that not only keeps patients alive, but also extends the quality of their lives," says E. Albert Reece, M.D., Ph.D., M.B.A., vice president for medical affairs at the University of Maryland and the John Z. and Akiko K. Bowers Distinguished Professor and Dean of the University of Maryland School of Medicine. "It is gratifying to see that School of Medicine faculty surgeons and cardiologists are at the forefront of research efforts that may accomplish both goals. This research is part of our overall strategy to extend the best of care to our cardiac patients while also exploring more effective ways to prevent heart disease in the first place."

Infection was less of an issue in the early days of heart pump technology due to the limited durability of the devices, according to Dr. Rajagopal. "Device failure and many other problems associated with the early pumps, such as bleeding and clotting, limited patient survival. Infection was comparatively low on the list of concerns, but with more durable

ventricular assist device therapies, infection is much more important than it was previously."

Early LVADs tried to mimic the normal heartbeat and its pulsating blood flow, circulating blood with a series of mechanical valves. They produced a pulse, but were prone to wear out quickly, and were used as a "bridge to transplant," a short-term life-saver until a donor heart could be found. Today, improved pump designs that produce continuous, minimally pulsatile blood flow make it possible for LVADs to run for years. Extended pump life, in turn, has been responsible for durable destination therapy, in which the device supports the patient for the remainder of his or her life.

The Jarvik skull model has already been approved for use in Europe. The clinical comparison in the United States opened for patients this year. The University of Maryland enrolled the second patient in the U.S. to receive the Jarvik pump with the skull-based connector. The study will follow 350 patients for up to three years.

Provided by University of Maryland