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**HIGHLIGHTS:**

A 73-year-old resident of Little Rock, Ca., is the first patient in the Los Angeles area to have an experimental mesh “jacket” implanted to try to slow or reverse the effects of progressive heart failure. This is only the fourth such procedure performed in the state, and is part of a new clinical trial at Cedars-Sinai. Surgeons used the device in an effort to support the patient’s heart, encourage it to return to a more natural shape, improve cardiac function, and ultimately provide a higher quality of life.

**CARDIOTHORACIC SURGEONS AT CEDARS-SINAI MEDICAL CENTER BEGIN IMPLANTING INVESTIGATIONAL MESH “JACKETS” THAT OFFER A NEW EXPERIMENTAL THERAPY FOR HEART FAILURE PATIENTS**

LOS ANGELES, CA (August 5, 2002) – A 73-year-old retired Head Start teacher has become the first patient in the Los Angeles area to be implanted with a first-of-its-kind mesh “jacket” that is positioned around the heart in an effort to slow or reverse damage caused by progressive heart failure. The experimental device was implanted on Monday, July 15, and the patient went home from the hospital a week later.

Physicians at Cedars-Sinai Medical Center report that Evelyn Maiden, a resident of Little Rock, Ca., became the fourth patient in the state to receive the CorCap™ cardiac support device (CSD) developed by Acorn Cardiovascular Inc. Cedars-Sinai is one of 28 centers in the United States and Canada participating in the Acorn study, which has enrolled more than 144 patients nationwide.

“Based on the progress Evelyn is making, we hope that she’ll be able to resume her routine activities over the coming weeks,” said Kathy E. Magliato, M.D., cardiothoracic surgeon and one of two principal investigators at Cedars-Sinai studying the device.

Because Evelyn was in the advanced stages of heart failure and was not a good candidate for a heart transplant, she had very few options remaining, said Dr. Magliato. “For her and many other patients like her, the experimental Acorn device may help extend and improve quality of life.”

Evelyn’s device was implanted by Alfredo Trento, M.D., director of the Division of Cardiothoracic Surgery, and Dr. Magliato, director of the division’s Cardiac Mechanical Assist Device Program. Steven S. Khan, M.D., cardiologist, director of the Heart Failure Program and director of Clinical Trials in the Division of Cardiology at Cedars-Sinai, is the other principal investigator on the study.

Several conditions – including coronary artery disease, long-standing high blood pressure, and leaking heart valves – can lead to congestive heart failure. When the heart’s pumping ability is impaired for any reason, the heart tends to grow larger to compensate for the reduced output. A cycle begins, resulting in numerous structural and functional changes, even down to the cellular level. The heart’s muscle cells, called cardiac myocytes, become stressed and they literally stretch. The heart enlarges further and its shape becomes distorted, causing heart valves to lose their proper fit and the ventricles to pump even less efficiently.

Patients suffering from congestive heart failure are often forced to lead severely limited lives with frequent hospitalizations. Although the underlying disorders and some of the symptoms of heart failure may be treated, the condition is considered progressive and irreversible. Heart transplantation, the only “cure,” is not a viable option for most patients. The need for alternative treatments is made clear by the fact that about half of all those diagnosed with heart failure die within five years.

CorCap is an investigational device that can be implanted in patients, ages 18-80 years of age, who have been diagnosed with dilated cardiomyopathy, Class III or early Class IV heart failure. Patients must meet strict criteria to participate in the current study. In general terms, according to Dr. Khan, patients with Class III heart disease experience symptoms and have difficulty performing basic daily activities such as putting on their clothes or showering. Those with Class IV heart failure experience symptoms even when they are at rest.

Developers hope the device will slow, stop or reverse the progression of heart failure, thereby preventing the need for end-stage alternatives or transplant. They anticipate that by making this alternative available to heart failure patients earlier in the progression of their disease, outcomes will be improved and risks of surgical complications will be reduced.

In animal research and the first, limited human studies, the device prevented heart enlargement, decreased or eliminated mitral valve leakage, preserved or improved heart function, and promoted heart muscle recovery by giving the cells an opportunity to relax. It consists of a patented fiber mesh designed to stretch in the direction that encourages the heart to revert to its natural shape without interfering with normal pumping action.

The manufacturer says the specially engineered polyester fiber – each filament being one-fifth the thickness of a human hair – is highly biocompatible with human tissue and offers very little risk of rejection.

Just over two years ago, Evelyn went to an urgent care center for treatment of a cough and shortness of breath. She was given antibiotics, cough syrup and a diagnosis of bronchitis. But 10 days later – on her 71<sup>st</sup> birthday – extreme breathlessness and weakness forced her to go to a hospital emergency room. Doctors told her she had congestive heart failure.

Over the following months, Evelyn was prescribed a variety of medications to try to control her symptoms. Although some of the medications caused other unpleasant symptoms and Evelyn’s quality of life continued to deteriorate, she was told that her age and illness were both too advanced for more aggressive alternatives such as a heart transplant.

While watching TV in the waiting room of a laboratory one day, she saw a CNN “Access Health” story about the “heart jacket.” She later asked her son to download any information he could find. She called Access Health and Acorn’s corporate offices. She eventually learned that Cedars-Sinai was participating in the study, and she persuaded her daughter to take her there for an evaluation by Dr. Khan, despite the fact that her healthcare contract would not cover the expense.

After Evelyn's examination, Dr. Khan ordered several tests that found that not only was Evelyn's heart enlarged, her mitral valve and tricuspid valve were leaking. He recommended surgical repair, but financial coverage was denied by her insurance plan, and when Evelyn went home to her regular physicians, they said Evelyn was too weak to undergo surgery.

Unwilling to sit quietly, take her pills and give up, Evelyn opted out of her healthcare contract and re-enrolled in Medicare, which would cover the cost of surgery to repair the heart valves. "I've got a lot of living to do yet," she said.

On Tuesday, July 9, Evelyn learned that she met all of the criteria for the CorCap clinical trial. Because this is a randomized trial, however, some patients – randomly selected – would receive the new device while those in a control group would not.

Two days later, Evelyn got the news she hoped for. Dr. Magliato called to say that she would be receiving the implant, and the surgery could be scheduled for July 15. Evelyn's valve defects were also repaired during the operation.

Dr. Magliato said she is delighted that Cedars-Sinai was chosen to participate in this study, especially because Acorn's corporate leaders specifically sought surgeons and medical centers that hope to give extremely ill patients a second chance.

A specialist in the implantation of devices that assist ailing hearts, she said there is a tremendous need for new treatment options. "We hope this device proves to be beneficial to Evelyn and others like her who may not qualify for a transplant but who are too ill to even carry on the activities of daily living."

Cedars-Sinai Medical Center is one of the largest nonprofit academic medical centers in the Western United States. For the fifth straight two-year period, Cedars-Sinai has been named Southern California's gold standard in health care in an independent survey. Cedars-Sinai is internationally renowned for its diagnostic and treatment capabilities and its broad spectrum of programs and services, as well as breakthrough biomedical research and superlative medical education. Named one of the 100 "Most Wired" hospitals in health care in 2001, the Medical Center ranks among the top 10 non-university hospitals in the nation for its research activities.

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