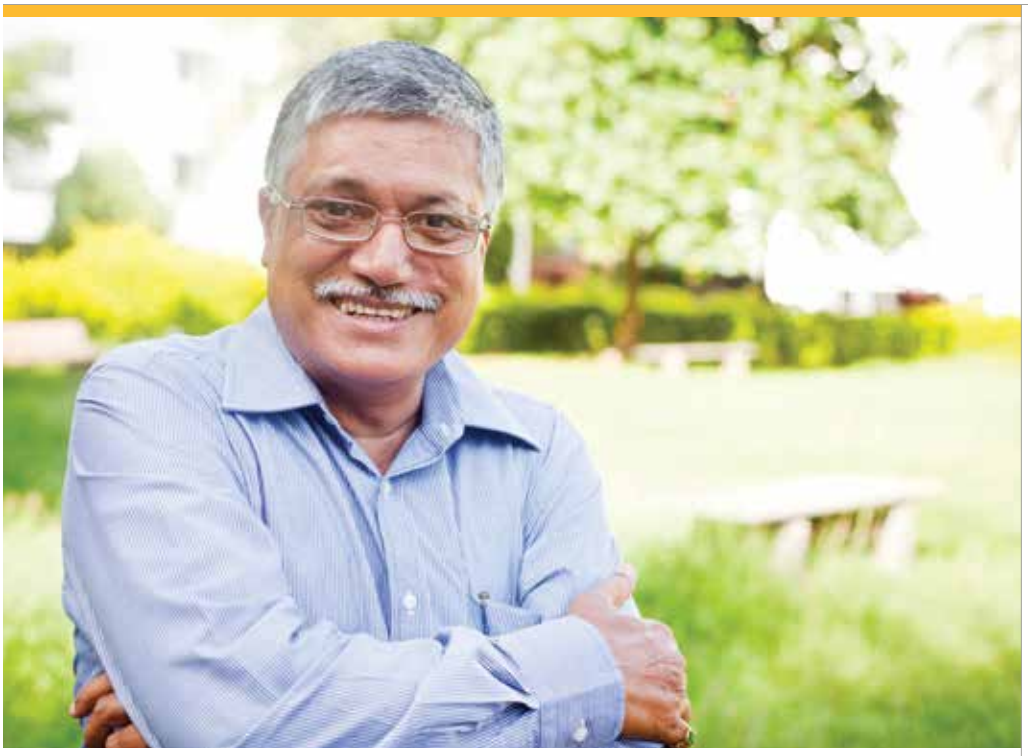
UCLA Health

Investigational rapid-deployment aortic-valve system aims at "sutureless" surgery



A new, rapid-deployment system for aortic-valve replacement (AVR) — now being tested in a nationwide clinical trial — is among the latest minimally invasive surgical innovations for damaged heart valves being advanced by the UCLA Division of Cardiothoracic Surgery.

UCLA is one of 35 sites in the United States evaluating the safety and effectiveness of the INTUITY Elite valve system, which enables virtually sutureless valve replacement. The hybrid INTUITY system combines a bioprosthetic heart valve — composed of bovine heart tissue and a metal mesh stent — with a novel delivery method.

The U.S. Food and Drug Administration (FDA) approved the TRANSFORM clinical trial in 2012 to evaluate the INTUITY valve system in up to 950 patients diagnosed with aortic stenosis or calcification and narrowing of the aortic valve. The system has received CE mark commercial approval from the European equivalent of the FDA.

Aortic stenosis, a progressive valvular heart disease, can cause diminished quality of life and a shortened life span (see sidebar). Historically, standard treatment for severe aortic stenosis has been open-heart surgery. However, up to one-third of all patients are not candidates for open surgery because other health conditions put them at higher risk for complications.

Aortic stenosis underdiagnosed due to largely silent symptoms

Aortic stenosis is the most common form of valvular heart disease in America and Europe. It occurs as calcium builds up, causing the cusps of the aortic valve to stiffen and narrow. The calcified valve is unable to open fully, and the heart must work harder to pump blood.

The clinical signs, if detectable, can be easily ascribed to other conditions. These include shortness of breath, fainting, angina and dizziness. Many people don't notice any symptoms until the condition is severe. As a result, it is underdiagnosed and undertreated.

"It's important to do the valve replacement at the right time in the course of a patient's disease," says Richard Shemin, MD, professor and chair, Division of Cardiac Surgery, and the Robert and Kelly Day Chair in Cardiothoracic Surgery. "We have the experience to time the most appropriate intervention." Dr. Shemin emphasizes that an experienced heart-valve team can assess and recommend an individualized heart therapy for each patient.

Novel expandable-frame design

Courtesy of Edwards Lifesciences

With the INTUITY system, the surgeon works through a tiny incision in the chest to insert the valve, which is then held in place by the outward radial force of the system's circular, balloon-expandable frame. As a result, the valve does not require complex suturing to remain in position. Instead, up to three guiding sutures help ensure placement; these are removed once the valve is properly positioned. In comparison, standard AVR requires approximately 12 to 20 sutures.

With its sutureless approach, the rapid-deployment valve may offer patients shorter surgeries with less time spent on heart-lung bypass machines than even other minimally invasive methods. Early evidence shows that the rapid-deployment valve has lower rates of blood leakage around the valve than is experienced with transcatheter aortic valve replacement (TAVR). In addition, the expandable frame enables the surgeon to remove the diseased valve and calcium deposits — not possible with TAVR — before determining the correct replacement valve size and quickly positioning and deploying the expandable frame.

Life expectancy for patients with aortic stenosis is typically two to five years following diagnosis. So far, the valve has restored life expectancy to nearly normal for someone of similar age and gender without aortic stenosis.

Leadership in heart-valve care

The UCLA Division of Cardiothoracic Surgery is a long-time leader in heart-valve care, with an international reputation for excellence. Working in close collaboration, cardiologists, interventional cardiologists and heart surgeons offer a range of treatment options to patients, including the newest medications, traditional surgical solutions and minimally invasive valve repair and replacement techniques. In addition to TAVR, the latter includes robotic-assisted minimally invasive surgery for mitral-valve replacement.

The INTUITY device has been submitted for FDA approval. TRANSFORM trial patients will continue to be followed for up to five years. In addition to effectiveness and safety, investigators are evaluating durability, potential side effects, and any need for additional surgery, along with determining which patients may benefit the most from rapid-deployment valves.

In the meanwhile, a sutureless valve called Perceval has been approved by the FDA and will be the first such device available in the U.S. Perceval is indicated for the replacement of diseased, damaged or malfunctioning aortic valves. UCLA Cardiac Surgery will continue to offer all available valve technologies, individualizing treatment to match each patient with the most appropriate device.

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