

Researchers study new heart valve that doesn't require open-heart surgery

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Northwestern's Bluhm Cardiovascular Institute has enrolled its first participant in SALUS, a clinical trial studying the effectiveness of a prosthetic aortic heart valve that can be placed without open-heart surgery. The heart valve under study, the Direct Flow Medical Transcatheter Aortic Valve System manufactured by Direct Flow Medical, Inc., is a non-metallic, investigational device specifically designed to be placed inside the heart using a catheter that is inserted through a blood vessel in the groin and then navigated into the aorta to the heart. The study valve is also designed to have the unique ability to be repositioned or even replaced with a different size after the valve's initial placement to achieve a better fit if one is needed.

SALUS is the first U.S. clinical trial of the Direct Flow Medical Transcatheter Aortic Valve System, and will seek to evaluate how well the test valve can be delivered and its effectiveness once it is in use. Northwestern's enrollment is the first in Illinois and the fourth institute in the country to enroll subjects.

"Aortic stenosis is a condition that commonly affects older individuals. The leaflets of the aortic valve become thick and calcified and ultimately can limit the ability of blood from being pumped out of the heart," said James D. Flaherty, MD, Northwestern Medicine cardiologist and Northwestern's principal investigator for SALUS. "When the narrowing becomes severe, patients develop symptoms such as shortness of breath, fatigue, lightheadedness and chest pain. If uncorrected, their life expectancy is also significantly shortened."

Open-heart surgery has been the gold standard treatment for aortic stenosis since the 1960's. However, many patients are considered high-risk or inoperable for traditional heart surgery. Transcatheter Aortic Valve Replacement (TAVR) is a technique to insert a new [aortic valve](#) through catheters instead of open [heart surgery](#). The only transcatheter heart valve that is commercially available in the United States requires larger catheters than the study valve, sits within a metal ring, and cannot be repositioned or replaced once it is released from the catheter.

"Aortic valve replacement is a life saving procedure for patients with severe symptomatic [aortic stenosis](#). TAVR, which is done without the need of a cardiopulmonary bypass machine, may also prove to be life saving in patients who are not eligible for cardiac surgery," said Flaherty, who is also an Associate Professor of Medicine in Interventional Cardiology at the Feinberg School of Medicine of Northwestern University. "This study valve is inserted through smaller catheters and its unique design allows it to be repositioned or replaced until the Heart Team is satisfied that it is in the optimal position. It is also expected that this design will prove to cut down or even eliminate any leaking, called aortic regurgitation, around the implanted valve."

Instead of using a metal stent frame, the Direct Flow Medical Transcatheter Aortic Valve System's polymer support structure uses an inflatable, conformable cuff that has the ability to provide a better seal and prevent leaking. The study valve is composed of two inflatable rings at each end that are connected by multiple inflatable bars, all of which are covered with a polyester fabric sleeve and surround the heart valve itself. During a procedure, the study valve's inflatable rings and connecting bars are filled with a liquid plastic polymer that hardens to a solid after it has been fitted to further help prevent leakage around the valve.

Provided by Northwestern Memorial Hospital

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