University of Louisville surgeons perform first prosthetic bypass graft with patient's stem cells at point-of-care

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The first three patients to undergo an investigational surgical procedure for peripheral vascular disease that involves the patient's own stem cells continue to do well, reports the University of Louisville surgeon who is the principal investigator.

The "TGI-PVG IDE" clinical trial initiated at UofL involves using a patient's own stem cells to line man-made bypass grafts to better the chances at saving the limbs of patients with peripheral artery disease. Charles B. Ross, M.D., chief of the Division of Vascular Surgery and Endovascular Therapeutics, is principal investigator and is joined by Marvin E. Morris, M.D., Amit J. Dwivedi, M.D. and Stuart Williams, Ph.D.

The procedure is in Phase I clinical trials and uses a new fully automated system that involves isolating the patient's own stem cells and then coating the inside of the synthetic vein graft to reduce chances of failure caused by clotting. In the new procedure, fatty tissue is harvested from each patient through liposuction. The fatty tissue is processed to concentrate vascular stem cells, which are then attached onto standard prosthetic grafts in the operating room directly at what is known as "point-of-care."

Ross said the idea of lining man-made grafts with stem cells to enhance long-term results is not new. What is revolutionary, however, is taking

the process out of the lab and into the operating room, where it can be safely and efficiently accomplished in a single procedure. "This ultimately could make the technology available in any hospital where vascular bypasses are performed," he said.

The procedure for isolating stem cells from fat and using these cells to coat medical devices was developed by Williams, executive and scientific director of the Cardiovascular Innovation Institute, a collaboration of UofL and Jewish Hospital & St. Mary's HealthCare. "I am so pleased to see our efforts in the laboratory, to perfect and automate this stem cell process, are now being translated to treat patients in Louisville who desperately need new technology to avoid amputations," Williams said.

"We have many more procedures to perform before this technique can be approved by the FDA, but our initial results are excellent and show great promise in helping to alleviate the pain and suffering thousands of patients experience from PVD," Ross said.

About peripheral vascular disease

Peripheral vascular disease or PVD develops when arteries become clogged with plaque—fatty deposits that limit blood flow to the legs. Clogged arteries in the legs greatly increase the risk for heart attack or stroke. The condition causes weakness or pain in the legs, and in severe cases can lead to amputation.

In the most severe cases of PVD, revascularization procedures are required. These are procedures that provide a new, additional, or augmented blood supply to a body part or organ to relieve pain and to prevent amputation. Many revascularization procedures are performed by minimally invasive techniques such as balloon angioplasty and stenting. For more severe cases, bypasses are required. "The best-case

scenario is to be able to bypass long blockages using a patient's own vein," Ross said. "Our challenge with prosthetic grafts is coming up with a way to make them more closely resemble the patient's own blood vessels and increase the long-term survival of the graft."

However, many patients already have had their veins used for other bypasses or have veins that are too small. In such cases, prosthetic or man-made bypass grafts are used, but these grafts do not stay open as long as grafts created from a patient's own veins. "It is our hope that, through lining prosthetic grafts with a patient's own stem cells, we can bring the long term results up to a level closer to that which is achieved with vein grafts," Ross said.

Patients report relief from symptoms almost immediately

More than 125,000 amputations are performed in the United States each year due to PVD, and Harry Carr of Louisville lost one leg to PVD before enrolling in the trial hoping to save his remaining leg.

Carr lives in Louisville, has diabetes and experienced some strokes as well as PVD. "I've been dealing with these blockages for at least 10 years," he said, and required amputation of his right leg after bypasses ultimately failed in 2009.

He was first to receive the stem cell-coated synthetic graft procedure in March. He felt its effects almost immediately. "Complete feeling in my leg and toes returned," he said. "I've had circulatory problems for some time, so (experiencing) my leg feeling normal again was wonderful."

Frank McCauley, 73, of Louisville was diagnosed with PVD "years ago," he said. He is widowed with three grown sons, Kevin, Keith and Kurtis.

McCauley had five previous synthetic grafts successively implanted in

his left leg, only to see each fail. He underwent the new procedure on his right leg in April.

"Before the surgery, I had intense pain when walking. It was like someone was walking behind me and kicking me hard in the calf with every step," McCauley said.

After the procedure, he was walking before he left the hospital. "I can go up and down steps now without hurting," the retired carpenter said.

Billy Buckman, 54, of Louisville had two previous bypasses before undergoing the new procedure. He and wife Kathy have three daughters: Amy, 24, Lindsay, 20 and Carly, 17.

"I was having problems with numbness and lack of circulation to my (left) leg and foot, so I expected another bypass was in my future," said Buckman, who is a production manager at Cylicron in Jeffersonville, Ind.

Instead, he received his new graft in April and was "back on my feet within days. Once the surgery was done, it was like turning a light switch – I could feel the blood flow. The pain and numbness were totally gone."

The procedures were performed at University Hospital, and all three patients said they feel fortunate to have access to the clinical trial. Carr and McCauley each said they were glad to be "guinea pigs."

"I believe I was meant to be a part of this," Carr said. "Dr. Ross is an outstanding surgeon and I left it in his hands."

"The procedure was fully explained to me. Any surgery is serious, but I had faith in the doctors, and I know this can help a whole lot of people eventually," McCauley said.

"Everyone at University Hospital could not have been better. From the moment I registered until I was discharged, the care was phenomenal," Buckman said. "If anyone is suffering the way I was, I recommend getting into the trial. They make you feel like you are being personally watched over."

More information: Enrollment in the trial continues. For information on enrolling in the clinical trial, go to ClinicalTrials.gov and reference TGI: NCT01305863 or call University Surgical Associates at (502) 583-8303.

Provided by University of Louisville