Bioengineered blood vessel appears safe for dialysis patients

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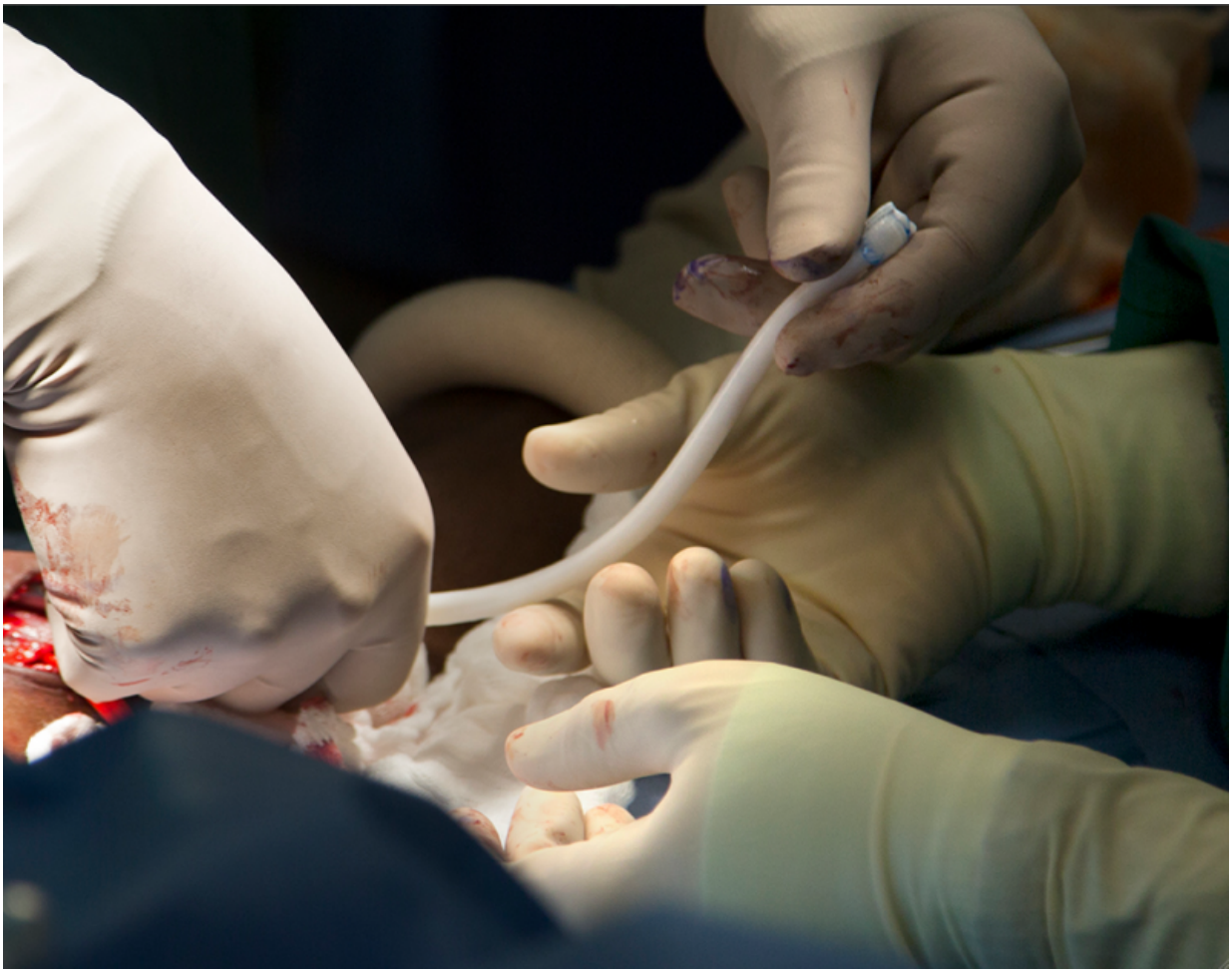

Man-made blood vessels developed by researchers at Duke University, Yale University and the tissue engineering company Humacyte appear to be both safe and more durable than commonly used synthetic versions in patients undergoing kidney dialysis, the researchers report.

The findings, published May 12 in *The Lancet*, resulted from a phase 2 study among 60 patients with kidney failure who required dialysis, which often requires a synthetic graft when the patient's own blood vessel degrades from frequent needle sticks.

Such grafts, however, are prone to infection, clotting, and other complications. And alternative bioengineered grafts derived from the patient, a donor, or animal tissue have been shown to perform no better than synthetics.

The Duke and Yale research team—along with surgeons in Poland and the United States and scientists at Humacyte, which is developing the bioengineered vessel—tested a human acellular vessel, or HAV, that is manufactured to be available to patients on demand, rather than made-to-order using an individual's own cells.

"The bioengineered blood vessel represents a critical step in tissue engineering," said Jeffrey Lawson, M.D., Ph.D., professor of surgery and pathology at Duke and chief medical officer of Humacyte. "Because these vessels contain no living cells, patients have access to off-the-shelf engineered grafts that can be used without any waiting period associated with tailor-made products."

Lawson and co-author Laura Niklason, M.D., Ph.D., professor of anesthesiology and biomedical engineering at Yale, are principals of Humacyte, Inc., which supported the clinical trial.

To create the vessels, the researchers first isolated vascular cells from

human donors and grew them in tissue culture. They then placed the cells on a degradable scaffold shaped like a blood vessel. As the tissue grew, it was bathed in nutrients and stretched to acquire the physical properties of real blood vessels.

"After that process, which takes eight weeks, the scaffold degrades and what we have left is engineered tissue that we have grown from scratch," Niklason said.

The final step was to wash away the cells with a special solution. The remaining "de-cellularized" tissue retains the structure of the vessel but none of the components that would cause tissue rejection.

One year after implantation, the bioengineered vessels appeared to be both safe and functional, maintaining their mechanical integrity, the researchers report. The patients also showed no sign of rejection.

While there were cases of adverse events such as clotting, the rates of those events were comparable to other dialysis grafts. Notably, the durability of the bioengineered vessels at one year was 89 percent, compared to the approximately 60-percent rate of synthetic grafts reported in previous studies.

Additionally, the researchers noted that after implantation, the bioengineered vessels had been repopulated with the patient's own cells, so nonliving tissue became living over time.

"The fact that an implanted acellular tube becomes a living human tissue has implications for regenerative medicine in a very profound way," Lawson said.

More information: Jeffrey H Lawson et al. Bioengineered human acellular vessels for dialysis access in patients with end-stage renal

disease: two phase 2 single-arm trials, *The Lancet* (2016). DOI: 10.1016/S0140-6736(16)00557-2