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## Richmond doctor creates new, non-invasive procedure for dialysis patients

By BRIDGET BALCH Richmond Times-Dispatch  
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Dr. **Jeffrey Hull**'s procedure reduces the time before a patient can start dialysis.

Richmond Vascular Center

Robert Faulcon had already lived through several surgeries, including a gastric bypass surgery to manage his weight, when he got the bad news from his doctor.

In 2015, after 15 years of seeing his kidney specialist, Faulcon's kidneys had stopped functioning and he would need to start dialysis, a procedure that filters the blood of toxins. He was one of the 37 million people who suffer from chronic kidney disease and one of more than 500,000 people, as of 2016, to receive dialysis in the U.S., according to the National Kidney Foundation.

The standard procedure for dialysis patients is to have a surgery to create a fistula in the arm, connecting the artery to the vein, but Faulcon didn't want to have another surgery. He was worried about the risks of infection.

So his doctor told him about a new procedure — the first major change to the way fistulas are created for dialysis in more than 50 years.

Nearly a decade earlier, Dr. Jeffrey Hull, a Richmond radiologist, had been speaking with a colleague who had just made a medical breakthrough when he formed the idea for his own breakthrough. Hull had worked with dialysis patients and believed that the procedure to create the fistula that would allow them to receive the life-saving treatment could be vastly improved by making it minimally invasive.

He decided that using an ultrasound to direct the physician could prevent the need to create an incision and open up the arm and believed he could use tissue fusion — the use of pressure and heat to weld the artery and vein together — to prevent the need for stitches or clips. The new procedure would need only local anesthetic and could take less than 30 minutes.

“Our idea was to make it faster, better and less expensive,” Hull said.

Instead of a hospital stay and stitches, patients could walk out of the procedure with a Band-Aid.

But the process to make his idea a reality would take almost another decade.

He had to engineer a prototype for the device, patent it, perform testing on tissue and then do animal testing before ultimately starting human trials in Colombia and Mexico.

When the device, named the Ellipsys Vascular Access System, proved safe in a few dozen people abroad, Hull could then apply to the Federal Drug Administration to begin clinical trials in the U.S., Hull said.

In early 2015, Hull launched a multi-city trial, which included patients in Richmond.

Faulcon agreed to be one of the first U.S. patients to try the procedure. He said the first attempt did not progress the way Hull had hoped, so the doctor tried it a second time.

But when Faulcon went home, the toxins in his blood spiked and he had to go to the hospital. There, the medical team inserted a catheter into his neck to administer emergency dialysis while the fistula created by the Ellipsys healed. Within a couple of months, the fistula had healed and Faulcon hasn't had a problem with it in the four years since, he said.

One of the benefits of the Ellipsys method, Hull said, is that it cuts down on the healing time before a patient can begin dialysis.

On average, in the U.S., it takes 136 days for a fistula to be ready to begin dialysis, but Hull's Ellipsys patients in Richmond average 70 days. The Ellipsys fistulas also tend to last longer than the surgical ones, according to a two-year study published in the Journal of Vascular Access. Ninety-one percent of the non-invasively created fistulas were still functional after two years, compared with 51% of the surgically created fistulas.

Ellipsys was approved by the FDA in 2018.

Terry Litchfield, a national advocate for dialysis patients who co-authored the Ellipsys study, said medical advancement is a good thing for those with kidney disease.

Litchfield's husband, Bill Litchfield, spent decades on dialysis battling kidney disease before he died. His testimony before the U.S. Congress prompted the federal government to make all people with end-stage renal failure eligible for Medicare.

Litchfield said her husband had 37 surgeries to create and re-create fistulas during his lifetime. The process was often exhausting, disappointing and expensive, she said.

She was happy to see some innovation and attention on kidney disease again recently, not only with the invention of the Ellipsys procedure, but also with President Donald Trump's announcement earlier this year that kidney health would be a priority for his administration. The initiative is aimed at reducing the number of people developing end-stage renal disease, increasing the number of kidney patients receiving dialysis at home — as opposed to at a dialysis center — and increasing the number of kidneys available for transplant.

“We hear about cancer. We hear about Alzheimer's,” Litchfield said. “To finally have the disease that affects so many millions of Americans [get more attention] ... it gives hope.”

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