Artificial kidney offers hope to patients tethered to a dialysis machine

April 29 2013, by Sandy Kleffman

No matter what else is happening in his life, David Anderson knows he cannot go far from the dialysis machine that sustains him.

Jobs, vacations, get-togethers with friends - everything takes a back seat to his thrice-weekly treatments that do the work of his failing kidneys.

But across town, University of California-San Francisco researchers are using Silicon Valley technology to create a device they hope can untether the 63-year-old San Franciscan and 380,000 other Americans who rely on dialysis to cope with kidney disease.

They're developing an implantable, artificial kidney that would shrink the refrigerator-size dialysis machine into a device the size of a coffee cup and perform functions a dialysis machine cannot do.

Anderson, who has been on dialysis more than five years. said he would gladly be the first test case. "I wouldn't hesitate for a second," he said. "It's just amazing. You want to live long enough to see some of this in place."

The device has shown such promise that the U.S. Food and Drug Administration last year selected it as one of three projects for a special fast-track approval process. Researchers hope it will be ready for human trials in 2017.

"We realized we could achieve a dialysis filter that would be one-

twentieth the size of what's commercially available, and would require so little power that we could drive it just off blood pressure alone," said Shuvo Roy, a UCSF associate professor of bioengineering and therapeutic sciences. Researchers are using silicon nanotechnology to design the special filter.

Roy is leading a team of 40 scientists working on the project at nine institutions around the country.

He believes the device has the potential to save the federal Medicare program millions of dollars.

A room-size, external model of the technique was shown to work for very sick patients at the University of Michigan.

More than 600,000 Americans, and nearly 2 million people worldwide, have end-stage renal disease, the complete or nearly complete failure of kidneys.

For decades, little has changed in the treatments available, even though the number of patients is rising by 5 percent a year, mainly because of growing rates of diabetes and high blood pressure.

The best option for those with failing kidneys is a kidney transplant. But not nearly enough organs are available. With more than 95,000 people on a waiting list, and about 18,000 kidney transplants each year, most people are left out.

In 2011, nearly 5,000 people died while awaiting kidney transplants.

That leaves dialysis to help keep people alive until a transplant becomes available. But it is a less-than-ideal solution.

If Anderson misses even one of his 3 {-hour sessions, his body lets him know. His diseased kidneys allow toxins, waste and fluids to accumulate, a risky condition that makes him feel bloated and terrible.

"Your blood pressure goes up; it's a dangerous business," he said.

Many people who undergo dialysis have other health issues, including heart and circulation problems, notes Dr. Lynda Frassetto, a UCSF professor of medicine.

"You're just barely doing OK," Frassetto said. "You have to follow a very strict diet. You have to be careful about the fluid you take in."

In the artificial kidney, blood brought into one side of the device passes through a silicon filter that removes toxins, sugars, salts and water, creating an "ultrafiltrate," Roy explained.

The filtrate would move to the other side of the device, where actual kidney cells would reabsorb the water, sugars and salts back into the bloodstream, mimicking a real kidney's metabolic and water-balancing roles in a way that dialysis cannot. The team obtains the kidney cells from organs rejected for transplantation.

Because the kidney cells in the device would be separated from the immune components of a patient's blood, the researchers believe it would not trigger a rejection, relieving patients from the costly necessity of immune-suppressing drugs.

Roy noted that kidney disease takes a huge bite out of the nation's health care budget. Medicare covers the cost of dialysis for many people, and it is a hefty expense: $82,000 or more annually per patient. A kidney transplant surgery runs $50,000 to $100,000.

All told, end-stage kidney disease costs Medicare $33 billion per year.

Roy hopes an artificial kidney could be manufactured for $30,000 or less. Testing in animals could begin by about 2016, but it would probably be 2020 or later before the device, if proved effective, could become a routine therapy.

Last April, the FDA selected the artificial kidney for its Innovation Pathway, a pilot program to help medical devices reach patients faster, while ensuring their safety.

It will cost about $20 million to develop the artificial kidney and take it through its first clinical trial, Roy estimated. So far, the team has grants and gifts of about $7 million.

Anderson has been watching the developments with excitement. He has been undergoing dialysis since December 2007 - his second stint on the treatment. Before that, he had a transplanted kidney that lasted four years until it failed.

Anderson has toured Roy's lab and is eager to see what changes may come.

"It's really a cutting-edge project," he said. "You realize just what a complicated thing they're putting together. You think: Why can't I get this tomorrow?"

Kidney disease devices

The Food and Drug Administration last year selected three projects for its Innovation Pathway program to streamline approval and get breakthrough treatments to patients faster:

An implantable, artificial kidney being designed at UC San Francisco and eight other institutions.

A wearable artificial kidney in development by Blood Purification Technologies of Beverly Hills.

A special valve designed by CreatiVasc Medical of Greenville, S.C., to make blood vessel access safer during dialysis.

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