Wearable Artificial Kidney

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SECTION 2
Currently, more than 650,000 patients/year in the U.S. and an estimated 2 million patients worldwide are affected by end stage renal disease.

Increasing rates of ~5% each year.

Patients require dialysis treatments when they develop ESRD (usually by the time they lose 85-90% of kidney function).

Typically the next best option to organ replacement.

Dialysis is required to do the work of a healthy kidney by filtering the blood of toxins.

Dialysis is usually required 3 times/week with each session lasting 3-4 hours.

Tethers patients to a machine and lessen a patient’s quality of life.

Not a permanent solution or cure and has a high mortality rate.
1943: Dr. Willem Kolff, a Dutch physician, constructed the first drum dialyzer (artificial kidney)
- Remained the standard treatment for the next decade
- By the 50’s it was the solution to acute renal failure but not end stage renal failure

1950’s: the idea of connecting patients to a dialyzer using plastic tubes emerges as a treatment option for ESRD

1962: first outpatient dialysis facility started by Dr. Belding Scribner

Later on, Dr. Scribner developed a smaller more portable dialysis machine that could be used in a patients own home which freed up more machines in dialysis centers
Current Technology

- Dialysis machine is used to treat renal disease to filter the blood of harmful wastes, salt, and excess fluid.
- Hemodialysis is a treatment that uses this machine to filter the blood.
- Needle is inserted into the arm and a pump draws the blood through one of the needles into a tube, a few ounces at a time.
- Blood travels into filter (dialyzer) via the tube. Inside the dialyzer the blood flows through thin fibers to filter it.
- Once blood is filtered it is brought back into the body through a second needle.
- Medicare pays for much of the cost and supplemental insurance or Medicaid programs pays for the rest.
- Problem:
  - Hemodialysis can replace part of the kidney function but is not a cure.
  - Fixed time slots at dialysis centers. The closest centers may be far from the home resulting in a long commute for treatment.
  - Home hemodialysis is an option but still restrictive.
  - Requires abundant amount of fresh water – about 40 gallons/treatment restricting the patient to a single room where a pipeline can supply the machine with the water.
Wearable Artificial Kidney (WAK)

- Created by Dr. Victor Gura, a physician who specializes in internal medicine and kidney disease.
- Prototype was completed in a lab at Cedars-Sinai hospital in Los Angeles.
- Works continuously and slowly to remove fluids from the body mimicking the *same pace as a healthy kidney*.
  - Allows for more effective treatment since blood is continuously being filtered.
  - Battery powered (9 volt battery), does not require an electrical outlet or attachment to a large water pipeline. This eliminates the restriction to a single room when receiving treatment.
  - Takes about a pint of water each day.
- It is expected that patients will not feel the discomfort of rapid fluid removal as they often would with the typical dialysis methods.
- Miniaturizes a 300-pound dialysis machine to about 11 pounds, which is light enough to allow patients the freedom to move.
- Operates with sterile water which reduces the transfer of bacterial particles, viruses, and toxins.
- Patients are able to maintain normal water, salt, and mineral balance to relieve them of certain diet restrictions which are necessary to maintain electrolyte levels.
How It Works

- Uses a 3-Watt Faulhaber DC motor
  - Faulhaber motors are designed to achieve maximum performance in minimum dimension and weight
- Mechanism with two metal arms that alternatively compress two elastic chambers
- Valves open and close at the entry and exit of these chambers. Allows for alternating pulsatile flow of the blood and dialysate (fluid used to filter the blood) into the dialyzer
- While one chamber propels fluid out of one pump the other is filling fluid into the other pump
- Contains disposable cartridges to purify the water so that it can be recirculated.
- Current prototype weigh about 10 pounds and is worn like a construction worker’s tool belt
- This version is still an experimental prototype, improvements for design involve making the machine smaller, lighter, more streamlined, and easier to use
Human trial of the WAK was completed, the purpose of the trial was to determine the efficacy of the WAK in achieving solute, electrolyte, and volume homeostasis in up to 10 subjects diagnosed with ESRD over the course of 10 hours.

In pending studies researchers plan to test the safety and clinical performance of the current prototype during longer sessions than the previous attempts.
For all subjects of the human trial, serum electrolytes and hemoglobin remained stable for the course of the treatment period and all were hemodynamically stable.

- Average blood flow was 42±24 ml/min.
- Average dialysate flow was 43±20 ml/min.

- Mean weight average concentrations of blood, urea, and nitrogen were recorded 48 hours before treatment and during the 24 hour treatment period. Concentrations were significantly lower during treatment (17 ± 5 mg/dl versus 39 ± 18 mg/dl, \( P = 0.002 \)).

- Mean \( \beta_2 \)-microglobulin concentrations were significantly lower during WAK treatment (17 ± 8 mg/l versus 22 ± 11 mg/l, \( P = 0.04 \)).

- Average urea, creatinine, and phosphorus clearances were 17±10, 16±8, and 15±9ml/min.
- Average \( \beta_2 \)-microglobulin clearance was 5±4 ml/min.

Overall was well tolerated and resulted in effective uremic solute clearance and maintenance of electrolyte and fluid homeostasis.
Limitations

- Device related issues (excessive carbon dioxide bubbles in dialysate circuit and carriable blood and dialysate flows) forced the trial to stop short after the 7th subject
  - This increased resistance in the dialysate circuit, which may have impacted both blood and dialysate flow
- Finding a way to incorporate other chemicals, among them sorbents and enzymes, used in current dialysis machines
- In the trial there were reports of the tubing kinking which disrupted blood and fluid flow
- In the trial there were also issues with the battery dying in the middle of treatment
- Risks of the upcoming trial are similar to those of regular dialysis such as infection in the access sites of the catheter
Future

- Making the machine itself lighter and smaller
- More durable batteries and better plastics
- A new type of pump that manages the flow of blood and water inside the device and has different flow pattern from current dialysis machines
- The redesign will include more effective degassing in the dialysis circuit through the use of larger venting mechanisms
- Less flexible tubing will be included to prevent kinking
- Not a definite time frame for availability; still needs to pass several clinical trials and undergo these design improvements
- Additional funding required to make improvements (current funding is from gifts and donations)
- Pending Seattle trial: WAK is kept working on each patient volunteer for 24 hours. Patients will be encouraged to eat, drink, and move around while the WAK is running. Blood samples will be drawn periodically to determine that no excess water, salt, and toxins accumulate during treatment
- Ultimate goal is for treatment with the WAK to be self-administered independently by patients and caregivers in the home environment.


