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"WEARBALE ARTIFICIAL KIDNEY – A NEW HOPE FOR DIALYSIS PATIENTS"

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ABSTRACT
Background: For decades, the implantable artificial kidney (WAK) symbolized the highest standard of kidney failure treatments. The innovations that allowed for the development of both WAK V1.0 and its more advanced variations, V1.1 and 1.2, are explained here.
Modern developments have the potential to change the traditional paradigm for managing renal failure. The US Food and Drug Administration is committed to using accurate research regarding how patients evaluate the advantages and disadvantages of new devices in deciding on them, but there hasn't been much premarket patient preference information (PPI) accepted for renal devices up to this date. They have designed a survey with input from stakeholders with the objective of creating reliable PPI, including how patients balance the potential benefits and drawbacks of in-center hemodialysis and wearable dialysis equipment.

Keywords: Chronic Kidney Disease; Kidney Replacement Therapies; Wearable and Implantable Artificial Kidneys.

OVERVIEW

WEARABLE ARTIFICIAL KIDNEY

Dialysis research continues to grow into novel domains, including as more readily available methods, domestic treatment, and easier blood purification procedures. Advances in artificial renal technology with the use of cutting-edge fields including cutting costs, microfluidics, and nanotechnologies may be able to achieve these goals. Dialysis could encounter novel problems as an outcome of this research, such as those concerning wearability, movement, and possibly the development of implanted dialysis devices. A number of recent investigations demonstrate amazing and beneficial findings regarding the actual use of wearable artificial kidneys (WAK), even if plenty more research needs to be done. Some of them utilize peritoneal dialysis as its curative approach, while others use extracorporeal blood purifying (ViWAK and AWAK).
A few especially interesting instruments for treating overhydration and congestive heart failure is the wearable/portable the ultrafiltration system (WAKMAN). This technique will allow patients get therapy and be released from hospitals with greater tolerance and fewer comorbidities. A complete neonatal hemofiltration device (CARPEDIEM) serves as one of the latest developments on the path towards a wearable artificial kidney. A newborn is actually a typical recipient who might benefit from a smaller dialysis circuit. The assessment looks at the goals of the project and the obstacles that have to be addressed in order to deliver fully portable dialysis therapy. Here are some early findings with these newly released gadgets. Our aim is to encourage interaction in order to create progress in technology that will allow the wearable artificial kidney to become a reality rather than just a pipe dream.

INTRODUCTION

With the growing number of patients suffering from end-stage kidney disease (ESKD), renal replacement therapies are becoming more and more important. Both peritoneal dialysis and hemodialysate are dependable therapy choices that lead to significant and prolonged survival times. Because haemodialysis is still given irregularly, there is a significant degree of physiology because of variations in fluid and electrolyte levels between intra- and interdialytic intervals. Peritoneal dialysis is the only treatment that can properly imitate the kidney. It corrects uremic abnormalities by providing a well-tolerated fluid evacuation and continuous renal replacement therapy. Longer overnight treatments, especially extracorporeal dialysis sessions, have garnered more attention in recent years as they help manage elevated blood pressure, phosphorus derangements, and uremic toxicity. Dialysis is a common procedure in developed nations; however, it still presents challenges for underdeveloped populations and nations. Still, even in dialysis facilities with state-of-the-art equipment, patients' lifestyles are often not optimal, and their daily activities are severely limited. Lastly, in some countries, only after being paid by private insurance or other sources of insurance, dialysis care is provided. As a result, even though we consider dialysis to be a well-established routine therapy, it is expensive and unaffordable, either totally or partially unavailable in some regions of the world, and even when it is performed properly, it still limits the patient's range of motion and everyday activities. In the years to come, what challenges would the creation of a more sophisticated

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form of artificial renal therapy bring? In order to make dialysis feasible without limiting patients' freedom of movement, we suggest making it widely accessible, reasonably priced, and wearable or portable. Mobility includes ambulatory care, home care, and self-care, therefore there may be a connection between this last component and the others.

MONETARY ISSUES IN DIALYSIS

One of the main issues facing all public health care services is the cost of chronic illnesses. The increasing need for dialysis treatments among end-stage kidney patients is becoming a serious issue in nations where not everyone can access these medicines. Huge portions of the world could need to reconsider how renal replacement is thought of, perhaps by using simpler and less expensive dialysis treatments. Self-administered care would undoubtedly result in cost savings, with large hospitals serving only as referral hubs for the diagnosis and treatment of issues. These features suggest that peritoneal dialysis might be a viable treatment option, albeit the cost of the fluid supply might skyrocket in places where production is neither feasible nor feasible. Novel water-saving dialytic methods, such as sorbent treatments or recirculation dialysis in small, wearable devices, may be used in place of existing solutions. Even though this technology is still in its early stages of development, research on it could take place in the next years. Thus, an effort should be made to create innovative, reasonably priced, and efficient dialysis equipment that has the potential to be widely used at a fair cost. These kinds of advancements could provide dialysis on a daily or even continuous basis without unduly straining the healthcare system's already with limits financial resources.

DIALYSIS THERAPY FOR COMMOM PEOPLE

Population dynamics are undergoing changes in both developed and developing nations. Older adults in the so-called developed world are frequently left to take care of themselves alone and in every way. The widespread search for better and more fulfilling employment has caused traditional families to disintegrate as young family members have moved away from the once-familiar core. In less developed cultures, families are still small, but the growing need for goods and money has forced the younger family members to go for employment outside the home. Under these conditions, medical professionals are having a great deal of difficulty trying to help elderly and lonely patients who could need expensive and complex therapies. These people could administer their own therapy more easily if dialysis were made simpler. A simple therapy with few technical drawbacks could encourage self-care, which would save costs and increase the use of therapies at home.

SCHEDULES FOR DIALYSIS

Despite ongoing research on nightly and daily haemodialysis, the current renal replacement therapy regimen consists of three sporadic sessions per week. In terms of mortality, morbidity, and quality of life, this pattern still has drawbacks. A rising corpus of research spanning several hundred peer-reviewed articles over the past few years suggests that longer and more frequent dialysis treatments are linked to remarkably better results. The natural kidneys of healthy people filter blood 168 hours a week. Dialysis, as it is commonly given in the US, only filters the blood for 12 hours a week, which is obviously un-physiologic and extremely insufficient, leading to a low quality of life and high rates of morbidity and mortality. When patients switch from the usual three-dialysis treatments per week regimen to daily dialysis, they report not only significant reductions in medication intake, challenges, mental health issues, admissions, and hospitalizations, but also notable improvements in quality of life (such as dietary liberalization and fluid restrictions). The advantages of daily dialysis have been documented; these include improved volume control, elimination of the need for phosphate binding agents, elimination of sodium retention, improved nutrition and desire for food, reduction of elevated blood pressure, elimination of the need for blood pressure drugs, elimination of elevated potassium levels, reduction of predicted death and disability, removal of elevated phosphate levels from bone disease, reduction of severe anaemia, elimination of metabolic acidosis, heart attack, and stroke, and improved serum albumin. There are challenges associated with daily dialysis that make its widespread application all but impossible. The incapacity of the majority of patients to dialyze at home, the lack of nurses and technicians in the dialysis centres to provide more treatments, and the reluctance of government insurers to pay for extra procedures are a few of these. The demand for a workable, round-the-clock solution that would enable ESKD patients to receive noticeably higher dialysis dosages while boosting efficiency and lowering overall costs with reduced labour use is therefore expanding.

THE INVENTION OF SMALL WEARABLE DEVICES FOR DIALYSIS

Significantly higher dosages of treatment are possible with continuous dialysis, although it might not be feasible with the available technology. Machines need a lot of water, are heavy, and are connected to an electrical outlet on the wall. Thus, it becomes evident that there is a significant need for technological advancements to enable continuous or daily dialysis. Apart from portable continuous dialysis through the peritoneum, this has not been thoroughly studied so far. Extracorporeal haemodialysis portable solutions could make regular nighttime therapy dependable and simple. But up until now, this strategy hasn't worked well because its widespread implementation has been hampered by complex technology and unreliable equipment that's hard for the typical patient to operate. There may be fresh opportunities if a new generation of gadgets designed to be worn continuously and managed by an easy-to-use delivery system is developed. These systems, sometimes known as wearable artificial kidneys or WAKs, have been the subject of recent experiments.

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We believe that more study on this class of devices could make dialysis therapy more accessible, affordable, and beneficial for patients because it would allow for therapy continuity, mobility, and a better likelihood of patient recovery.

CHALLENGES FOR DEVELOPING WEARABLE KIDNEY

In-depth understanding of the typical clinical and technological issues faced by ESKD patients is necessary for the development of wearable dialysis devices (WDDs), as is an attempt to think creatively and unconventionally in order to explore novel avenues.

Creating a suitable vascular access that enables blood flows of up to 100 ml/min is the first difficulty. While this blood flow range is not the same as what is needed for chronic dialysis, it is adequate for continuous therapy. The use of double channel catheters presents opportunities for innovative design, biological materials, and cutaneous exit site technologies. In the search for appropriate vascular access, clotting and infection control must be prioritized.
The circuit should be built with the least amount of priming volume, potentially antithrombogenic chemicals, and unquestionably a simple priming and blood-returning process. The circuit should include enough safety features, such as air detection, pressure sensors, and visual and audio alerts.

A remote control should be used to operate the circuit so that the patient can precisely program and administer the prescribed therapy. Through a personalized, user-friendly software interface, the specification of operating rules and the presentation of delivery information should be simple to access.
It is likely possible to shrink the dialyzer to a tenth of its typical size. With ultrafiltration speeds not exceeding 5 ml/min, it ought to provide a clearance of about 20 millilitres each minute. Once more, the best membrane to reduce the chance of clotting would be non-thrombogenic. The entire gadget needs to be wearable and not reliant on an electrical outlet. A device that operates around the clock may use a lot of energy, so sufficient sources of energy must be accessible. However, light-weight, inexpensive, fuel cells and batteries that use less energy are now available; this ought to be used in this equipment which can be worn to ensure continuous functioning.
There must be very little dialysate used. This means that a tiny amount of dialysate that is constantly regenerable and reusable is required. It is necessary to modify and adapt a commercially accessible absorbing agents technology that has been utilised in dialysis for many years in order to serve as the cleansing medium and enable the use of sterile and pure dialysate in quantities smaller than 500 cc.

Wearing the device and walking should not interfere with the patient's ability to carry out daily tasks. Thus, there was a need for an ergonomic, lightweight design that would fit the contours of the body without being noticeable. It might also lower the expense of treating ESKD patients and the need for nursing personnel. Ongoing kidney replacement treatment is intended to be administered with the WAK., seven days a week, twenty-four hours a day. It ought to be able to provide sufficient dialysis dosages. If the device is worn continually, its effectiveness could be such that the blood chemistry and volume status in uremic patients are nearly returned to normal.

Regardless of the amount of fluid the patient may consume, the treating physician can keep them euvolemic with this device because it can gradually filter fluid from the blood vessels in a amount comparable to what is normally filtered by healthy kidneys. Moreover, reducing the amount of extra fluid may help better control hypertension. Furthermore, the ultrafiltrate's salt content is the same as the plasma's. Therefore, 13.5 to 18 grams of salt will be eliminated for every 1.5 to 2 Liters of fluid removed each day19–25. This alone would lead to ESRD patients' salt consumption being liberalized in addition to improving hypertension control. Better nutrition and a higher quality of life are undoubtedly the new treatment's anticipated direct effects.

The elimination of oral phosphate binders and limitations on oral intake of potassium and phosphorus may be the outcome of the amounts of these elements removed. Even if this technology may have substantial long-term effects on patients' health, well-designed, targeted clinical study will be needed to support the theory. While creating a WAK prototype for clinical testing, these goals ought to be met. A particular study project, a thorough investigation into related topics, or other areas of development may provide multiple innovations. Reassessing previous initiatives and thoroughly analysing the field's history may prove significant and beneficial in certain instances.

RECENT APPROACHES AND CLINICAL RESULTS

New WAK devices have been created using current technology and historical research findings. Our experiences with a wearable artificial kidney (wearable kidney 23) and wearable ultrafiltration device (wearable kidney 22) have been recently described. Patients in both studies had the freedom to walk and move about while receiving treatment. During their treatment among one of the experiments, clients strolled out of the hospital and to a nearby park. As a result, these pilot studies demonstrated the concept's viability and indicated that this could be a viable future route. During a recent symposium on wearable and tiny technologies that took place in Vicenza in October 2010, several experiences—including our own method—were shared.

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THE WAK

A study on a fully wearable hemodialyzer has only lately been published. Eight chronic haemodialysis patients who received treatment for four to eight hours each day wore the device in this pilot study. The gadget, which weighed around 5 kg, was fastened around the waist with a belt. Standard batteries were used to power the blood and other pumps. An ultrafiltration pump precisely controlled the evacuation of fluid, and similar to a traditional hemodialyzer, it included safety mechanisms to stop the flow of blood in the event of intrusion of air or disconnecting. The device was connected by the patient's usual vascular access, which for some people meant utilizing fistula needles and for others involved using a central venous access catheter, with an instance, the arterial needle got detached. Within in no time the sensor sensed the arterial connection, and the blood pump stopped, but with a traditional hemodialyzer, the blood pump would have kept pumping. This made it possible to re-implant the dialysis needle nearly instantly, with little blood loss, and the procedure started right away. In two instances, clotting happened as the heparin infusion was lowered before the scheduled end of treatment. Therefore, this device requires appropriate anticoagulation, much like regular intermittent hemodialysate. In order to replace the finishing dialysate continuously three sorbent bottles containing urease, activated charcoal, and both hydroxyl and zirconium oxide were used. To make sure the bottles had not gotten saturated, the dialysate solution was routinely checked for ammonia. The dialysate was also examined to guarantee sterility.

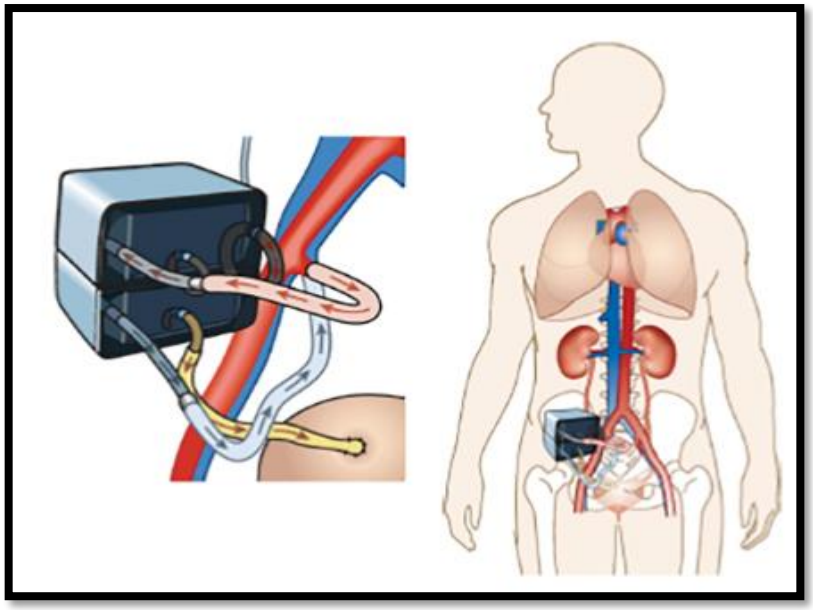
Compared to conventional thrice weekly intermittent hemodialysate, the blood and dialysate fluid flows at 59 and 47 ml/min, much a slower rate respectively. Slowly, small solute particles get clearances were, as predicted, likewise much lesser than those of intermittent hemodialysate, with an average of 21 ml/min for creatinine and 23 ml/min for whole blood urea. The device was born with the intension for extended periods of time, despite the fact that every minute clearances are low and comparable to those obtained in intensive care setting by arterio-venous dialysis. Wearing this wearable hemodialyser on a daily basis might potentially yield an estimate of urea clearance (Kt/V) of around 6.0, which is significantly higher than the thrice weekly intermittent hemodialyser used in the standard method.

Apart from the clearances of urea and creatinine, the clearance of beta-2 microglobulin was also measured. The clearance of beta-2 microglobulin was roughly 50% of that of urea and 55% of that of creatinine. According to a recent reassessment of the HEMO research, beta-2 microglobulin clearance is crucial for predicting patient survival. Due to the fact that tiny solute clearance alone does not determine if hemodialysate therapy is adequate. According to the observed beta-2 microglobulin clearances, the relative clearances for so-called "middle molecules" are likely higher than those for traditional intermittent hemodialysate. This is most likely the result of some internal hemodialyzer haemodiafiltration brought on by the blood pump's pressures.

The design of blood pumping machine was different from a typical hemodialysate machine blood pump in that it had dual chambers—one for blood and the other for dialysate solution —instead a pump which rolls to block the dialysate tubing in such a way that the dialysate chamber gets empty and the blood chamber gets filled, respectively. When compared to traditional dialysis, this led to a distinct pattern of flow through the dialyzer where pulse and pressure was generated in terms of blood and dialysate flows through the dialyzer, which increased the internal hemodialfiltration.

Although this machine is still in its early phases of development, clearings might be enhanced by boosting flows or, in a similar vein, modifying the blood pump to pump more blood.

FIGURE 1- Scheme of implantable artificial kidney (IAK). The iliac vessels are used as intake of arterial blood and outlet for the venous blood, while the removed waste is shunted to the bladder.



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The ViWAK

The Venezia wearable artificial kidney (ViWAK), a novel wearable device for ongoing peritoneal dialysis for patients with chronic kidney disease, was recently published. The study detailed the system's architecture and functional features. The components of the ViWAK system include cartridges of polystyrene resin and activated carbon connected in parallel inside a waterproof container; a filter for microbiological safety and deaeration; a dialysis fluid inflow line; a small rotary pump; a circuit for dialysate regeneration; and a palm computer that functions as a remote control. A dual lumen peritoneal catheter is also supplied. Twelve liters of used PD solution were cycled through the experimental adsorption unit at a rate of twenty milliliters per minute to evaluate the system. Measurements of creatinine, beta-2 microglobulin, and angiogenin were made at baseline, four, and ten hours after using the adsorption unit.

The fluid batch was fully cleansed of beta-2 microglobulin and angiogenin by the polystirenic resin-containing cartridges. Urea and creatinine were totally eliminated from those who used the ion exchange resin. In the end, 11.2 liters of net solute removal were obtained. The following is how the system is intended to be used: Two liters of brand-new PD solution are poured into the peritoneal cavity first thing in the morning. After two hours, recirculation is started at a rate of 20 milliliters per minute for ten hours, or when dialysate/plasma equilibration has reached roughly 50%. Following this time, recirculation ceases, and if necessary, glucose can be optionally injected into the peritoneal cavity to accomplish ultrafiltration. In order to accomplish additional ultrafiltration, the fluid is emptied after two hours and a two-liter icodextrin exchange is carried out overnight. The overnight exchange and the 2-liter exchange add to the clearance that the minicycler already offers. Because of this, the system runs around the clock and can remove 15–16 liters of creatinine and beta-2 microglobulin per day, or 100–110 liters per week.

In comparison to CAPD, the patient uses less fluid and requires fewer exchanges than in APD. Furthermore, the pilot study provides information on cartridge saturation, flow, and pressure conditions, which makes it easier to prescribe and evaluate therapy. It also allows for remote wireless control of operations.

The current configuration still has a few problems that need to be fixed. These involve decreasing the quantity of fibrin supplied to the absorbent, incorporating an infusion system for glucose and bicarbonate as required, and, in the end, employing a more sophisticated combination of sorbents to guarantee that all minute molecules, including urea, are eliminated totally.

In conclusion, wearable peritoneal dialysis systems have the potential to replace APD or CAPD by cutting down on the amount of time needed for exchanges, increasing the effectiveness of peritoneal dialysis, and enhancing patient rehabilitation.

TABLE 1- Wearable devices for peritoneal and haemodialysis

Device	Features	Status of development
ViWAK	• double-lumen PD catheter • polystyrenic resin and activated carbon • standard glucose-based dialysate	• In vitro studies • No clinical trials • no recent advances have been published
AWAK	• single-lumen PD catheter • modified REDY sorbent system • standard glucose-based dialysate	• clinical trials
WEAKID[a]	• single-lumen PD catheter • ion exchangers and activated carbon	• in vivo studies (uremic pig model)
CLS	• two singe-lumen PD catheter • ion exchangers and activated carbon	• clinical trials
Wearable HD device	• double-lumen catheter • Gambro Polyflux 6H, Baxter dialyzer (0.6 m^2) • urease, ion exchangers, and activated charcoal	• clinical trials

Abbreviations: AWAK, automated wearable artificial kidney; HD, haemodialysis; CLS, carry life system; PD, peritoneal dialysis; REDY, Recirculating Dialysis; ViWAK, Vicenza wearable artificial kidney; WEAKID, wearable artificial kidney.

THE CARDIO RENAL PAEDIATRIC DIALYSIS EMERGENCY MACHINE PROJECT

Cardio Renal Paediatric Dialysis Emergency Machine, or CARPEDIEM for brief, is a newly designed hemofiltration/dialysis machine which is adequately reduced so that it is completely suitable for specific and safe

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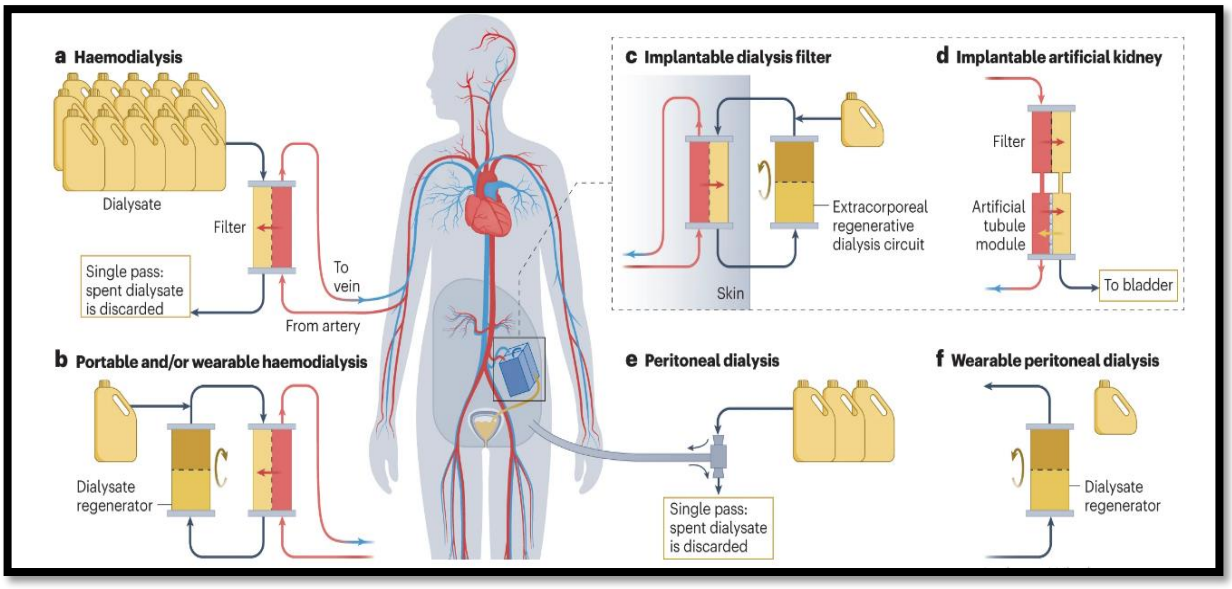
replacement kidney treatment in infants and young children weighing between 2 and 10 kg. The device's hemofiltration circuit requires a fairly small priming quantity (15 ml for the entire circuit, including the haemofilters). The balance of fluid is maintained via a precision of 0.1 ml/min for reduced blood circulates (20 to 80 ml/min) and very low ultrafiltration rates (UFR = 1-8 ml/min); special technology has been developed for these purposes.

This is a common example of an unintended outcome of research on wearable technology and miniaturization. The scientific disciplines of the future should incorporate nanotechnologies micromechanics, and microfluidics to help support the continued development of this field.

Methodology: The battery-operated Wearable Artificial pump has two channels with pulsatile counter-phase flow. The importance of dialysate movement and pulse-like circulation, more surface area on the high-flux membrane, and dialysate solution pH correction are explained in this paper. The flows and clearances for traditional pumps and gravity steady flow were compared with the WAK pump.

Figure 2 -



a. The most common kidney replacement therapy technique, single-pass hemodialysate, exhibits restricted portability because of its substantial dialysate volume demands.
b. The dialysis fluid generation devices that utilize biochemical absorbents, urease, electro-oxidation, photo-oxidation, or combinations of these approaches are used in portable and/or wearable hemodialysate devices.
c. An exterior regenerated the dialysate circuit paired with an implanted dialysis filter (typically Si-wafer based) can also be utilized for hemodialysate administration.
d. Additionally, completely implanted artificial kidneys are currently in development. These systems integrate a synthetic tubular component (which in turn might be a bioreactor or an entirely technological solution) with a urine escape to the bladder, functioning as an artificial glomerulus composed of silicon wafer filters.
e. A great deal of dialysate is additionally required for single-pass peritoneal dialysis (the image represents conventional tidal peritoneal dialysis).
f. Dialysate regeneration systems can also be used to miniaturize peritoneal dialysis. This approach works well for peritoneal dialysis without continuous flow.

Results: Ammonia adsorption was enhanced by the dialysate's pH rising to 7.4. Higher clearances were achieved with pulsed flow in comparison to constant flow. The little WAK pump, which is basically wearable, generated precisely similar clearances as larger, more potent, non-battery-operated pumps. Human blood was used to extract beta (2) microglobulin (beta (2)M) in vitro. Charcoal was mainly responsible for trapping the beta (2)M in the dialysate. The WAK V1.1 reliably cleared creatinine from uremic pigs at a rate of 27.0 +/- 4.0 ml/min, but the WAK V1.0 was able to clear 18% +/- 3.2 ml/min.

Conclusions: Convective transport was enhanced by push-pull flow, alternate transmembrane pressures (TMP), larger amplitude pulsations, and half-cycle variations between dialysate and blood. As a result, hemodiafiltration of a sort not yet defined is produced. Higher dialysate pH and a high-surface-area high-flux dialyzer produced even better results.

According to the results, the WAK may be a useful tool for optimizing the treatment of end-stage renal disease (ESRD) and for daily dialysis.

Specific requirements must be met by new blood purification systems: they must be inexpensive enough to enable widespread use even in low-income environments; they must be straightforward to enable quick and efficient self-care; and they must be wearable or portable to enable patient mobility and rehabilitation. When a system possesses these qualities, the benefits of an ongoing treatment plan become apparent in terms of effectiveness and tolerance. Innovation and research should be used to solve technical problems. This method will aid in the creation of fresh approaches in other fields as well, like paediatric dialysis and the care of seriously ill patients. The two most significant technological developments that will likely be needed in the near future are miniaturization and non-thrombogenic surfaces. We are fully aware of the numerous issues facing this subject, but technological advancements are likely to address each one of them one at a time. Even a thousand-mile journey begins with one step.

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Conflict of interest: The authors declare that they have no competing interests.

Participants consent and ethical approval: Considering no health-related data will be obtained, no ethical analysis is needed. The author provided significant thought to moral quandaries related to data manipulation and fraud, confidentiality and safety concerns, wrongdoing, dual publication, capitulation, and replication whereas conducting this study.
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