Chapter 5

Wearable Dialysis: Current State and Perspectives

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Additional information is available at the end of the chapter

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Abstract

For more than four decades, scientists and engineers are trying to miniaturise dialysis machines to make them wearable. There are many reasons for that—from increased biocompatibility and cost-efficiency to longer life expectancy and higher quality of life. That can be achieved by continuous blood treatment like in natural kidneys, which softly filter blood for 168 h a week when hemodialysis does that quickly—for approximately 20 h a week, which affects the organism in a bad way. Along with that, during hemodialysis, the patient must be near the dialysis machine, in contrary to wearable apparatus that can be carried anywhere. To achieve these advantages, dialysis fluid regeneration system must be developed, and it is a problem to be solved in the next few years. In this chapter, we describe current prototypes of wearable artificial kidneys, their design principles and results of our investigations.

Keywords: wearable health, dialysis, wearable artificial kidney, personalised medicine, dialysate regeneration

1. Introduction

In case of renal failure (RF), products of metabolism remain in blood and cells, and excessive fluid is not removed from the body. There are two types of RF—acute renal failure (ARF), which is often reversible with proper treatment, and chronic kidney disease (CKD), which is usually irreversible. The causes of CKD are diverse, most often diabetes mellitus, high blood pressure, glomerulonephritis, and so on. In **Figure 1**, incidence and accidence of terminal stage of CKD in several countries is shown.

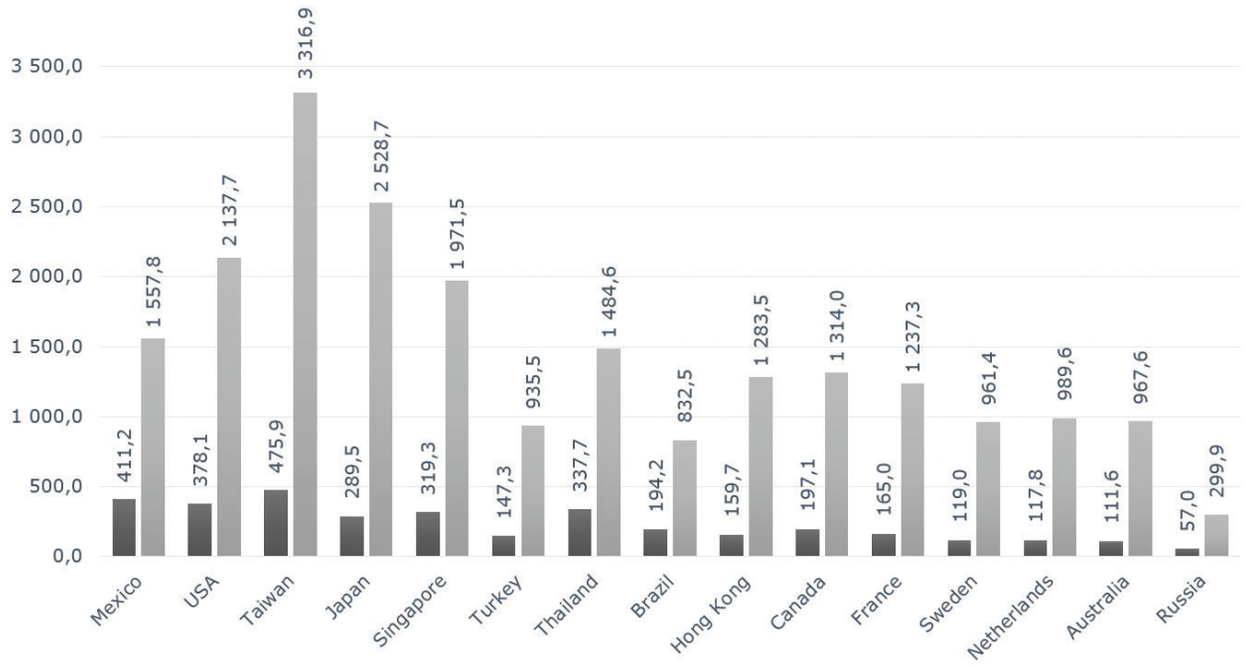

Figure 1. Incidence and prevalence of terminal stage CKD in the world by USRDS Atlas 2013 [1].

The only way of adequate treatment of CKD is kidney transplantation. Renal replacement therapy (RRT) is an artificial blood purification process that is achieved by several methods that do not cure kidney failure but keep living organism of patients for years while there will be a possibility to carry out a kidney transplantation. ARF is also treated via artificial blood purification. Artificial blood purification (or dialysis) is a process of removing metabolites and excess fluid from patient's organism. Dialysis does not replace all kidney functions (e.g., endocrine function), and in some cases, patients require additional therapy (e.g., hormonal). Clinical tasks of renal replacement therapy are to purify the body, remove excess fluid (Ultrafiltration, or UF) and maintain electrolyte balance (concentration of K^+, Na^+, Ca^{2+} ions, etc.).

Methods of dialysis blood purification are divided into two categories: extracorporeal methods (hemodialysis or HD) and intracorporeal methods (peritoneal dialysis or PD). Extracorporeal methods perform blood pumping through a dialyser, in which the metabolic products pass across membranes into dialysate solution due to diffusion and convection. In case of intracorporeal methods, peritoneal (abdominal) cavity represents itself a semipermeable membrane across which the mass transfer is carried out due to diffusion and osmosis. For HD and PD, different dialysis solutions are used. Generally, dialysate consists of highly purified water, sodium, potassium, magnesium, calcium and chlorine ions in concentrations close to their concentrations in the blood. In case of PD, dialysis fluid must also contain an osmotic substance like glucose or icodextrin. There are other differences in pH, buffers, and so on.

Since the peritoneal membrane has a thickness of up to 1000 μm, the efficiency of peritoneal dialysis is significantly lower than the efficiency of hemodialysis because dialyser membranes

are about 200 μm thick. Therefore, renal replacement therapy should be carried out continuously: abdominal cavity must be filled with a dialysis solution for long periods, where it is saturated with metabolites within a few hours, after which solution is replaced with fresh one. Continuity is the main advantage of peritoneal dialysis, as the procedure for purifying the blood proceeds more physiologically, the cardiovascular system experiences less additional stresses, and the residual function of the kidneys remains longer.

Comparison between HD and PD is presented in **Table 1**.

For more than 40 years, scientists and engineers are developing technologies that will enable to create a wearable artificial kidney (**WAK**). WAK has potential to overcome the negative sides of existing methods of RRT. There are some advantages of WAK over HD:

- increasing patient's mobility due to the reduction of its size and weight;
- adjusting blood purification to human physiology (metabolite elimination rate is closer to metabolite production rate);
- reduction of water consumption (2l of dialysate per one procedure vs. 120–150 l for hemodialysis);
- cost reduction (~€ 45,000 annually using WAK [2] vs ~€ 59,600 annually for continuous ambulatory peritoneal dialysis [3]);
- and the following advantages over continuous ambulatory peritoneal dialysis:
- lowering frequency of peritonitis due to rare dialysate exchange (once a day);
- gaining life quality due to the ability to use WAK at work or while travelling;
- reduction of water consumption (2 l of dialysate vs 8 l for 1 day of CAPD).

Dialysis type	Pros	Cons
Peritoneal dialysis	Keep residual kidney function longer	Necessity of peritoneal catheter implantation 2 weeks before the procedures start
	Home dialysis	Existing solutions degrade peritoneal membrane within several years (5+)
	Dialysis for patients with low mass index	Passive source of glucose, it is necessary to monitor the intake of carbohydrates
	Fewer amounts of dialysate are used (cheaper method)	
Hemodialysis	Dialysis takes 3–4 h for 3 days	Rigid schedule of procedures
		Spent time: about 20 h per week
		Necessity to create a vascular access
		Expensive method (up to 85 k€/year/patient)

Table 1. Comparison between HD and PD.

2. WAK design principles

WAK must comply with several requirements, including:

- safety and biocompatibility (WAK must be equipped with temperature, volume, pH, ionic solution sensors, and must have a system for bacterial contamination prevention);
- ease of use (the must be light and ergonomic);
- reliability (the device must function for a long period);
- availability (use of the device should be cheaper than traditional PTA methods);
- continuous power supply (the apparatus must provide continuous operation from the battery for at least 8 h);
- portability or implantability (the device should not significantly reduce patient mobility);
- elimination of substances normally removed by the kidneys (the apparatus should provide an adequate level and speed of removal of uremic toxins). The history of WAK development shows that HD was chosen as the major method. However, PD seems to be a more promising method for a WAK. Comparison between PD- and HD-based WAKs is presented in **Table 2**.

For the last several years, PD is chosen as the main method for WAK development in Europe. Typical schemes of WAKs are presented in **Figure 2**.

Implementation of HD as a base for WAK development is connected to the necessity of anticoagulant infusion to prevent blood clotting in the dialyser. Besides that in case of HD, tubing

Dialysis type/ characteristics	**WAK**	
	PD-based	**HD-based**
Weight and dimensions	2.5…5 kg, waist bag, shoulder bag or backpack	
Usage	Home dialysis, workplace dialysis, nocturnal dialysis, 24/7 dialysis	Short day dialysis, nocturnal home dialysis
Preparative operations	Peritoneal catheter implantation	Arteriovenous fistula formation
Eliminated substances	Small, medium and large molecules removal	Small and medium molecules removal
Infection risk	Peritonitis possible if solution changed frequently	Blood infection possible
Used with	Osmotic agent (glucose/dextrose/icodextrin/amino acids)	Anticoagulant (heparin)
Annual Cost	~€ 45,000 [3]	

Table 2. Comparison between PD- and HD-based WAKs.

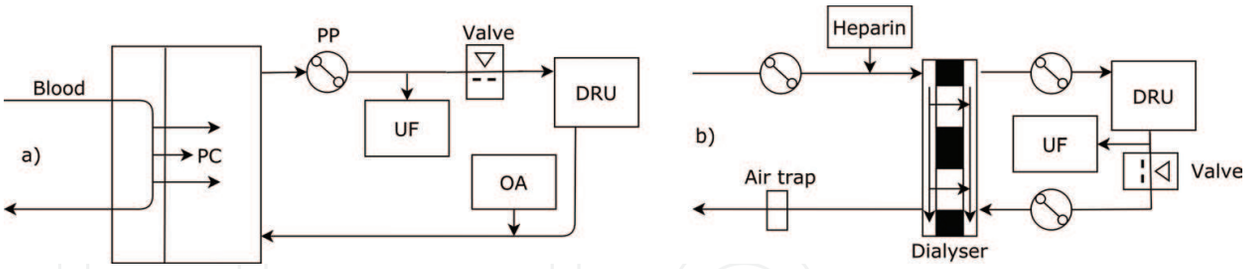

Figure 2. Typical WAK schemes based on a) peritoneal dialysis (AWAK Technologies), b) hemodialysis (nanodialysis); PP—peristaltic pump, DRU—dialysate regeneration unit, PC—peritoneal cavity, UF—ultrafiltrate, OA—osmotic agent.

sets must have a dialyzer and an air trap, while PD-based WAK can avoid using such elements. HD-based WAKs must also have means to fix blood catheters so that they do not disconnect from blood vessels due to physical activity. Therefore, the usage of HD-based WAK is possible only in clinics. Conversely, WAK on PD basis has potential to be used at home or in the office and consequently increase patients' quality of life.

Special technical aspects of PD-based WAK are connected to the necessity of keeping the initial concentration of osmotic agent in dialysis fluid during artificial blood purification.

Another aspect of WAKs is the method of ultrafiltration. Particularly, ultrafiltration in dialysis regeneration units on HD basis requires two peristaltic pumps to create transmembrane pressure between blood and dialysate compartments of the dialyser. In case of PD-based WAK, drainage of excess fluid occurs when spent dialysate exits patients' body and technically only one peristaltic pump is needed (**Figure 2**).

3. Dialysis regeneration methods

Regeneration of spent dialysate in WAK occurs in dialysis regeneration unit; its structure can be different, as it can be seen in **Figure 3**. Ideal WAK must eliminate all metabolites from spent dialysis solution, but this is difficult to implement and validate. It means that dialysis fluid that comes out of dialysis regeneration unit must be chemically equal to fresh dialysis fluid. However, at the current stage of WAK evolution, this cannot be achieved. In these conditions, we can outline substances that are crucial to being eliminated from the dialysis fluid. They are urea, creatinine, uric acid, phosphates, p-cresol, and potassium. An important aspect of dialysis regeneration is maintaining an ionic compound of dialysis fluid, including concentrations of Ca^{2+}, Mg^{+}, K^{+}, Cl^{-}.

Sorption is the most widespread method for eliminating a wide range of metabolites. This method is easy to implement, but its urea and other small molecules elimination capability is poor, and therefore it must be combined with effective urea removal method. Research and development of new sorbents can increase dialysis efficiency and possibly make WAK usage cheaper. There are several well-known methods for urea elimination.

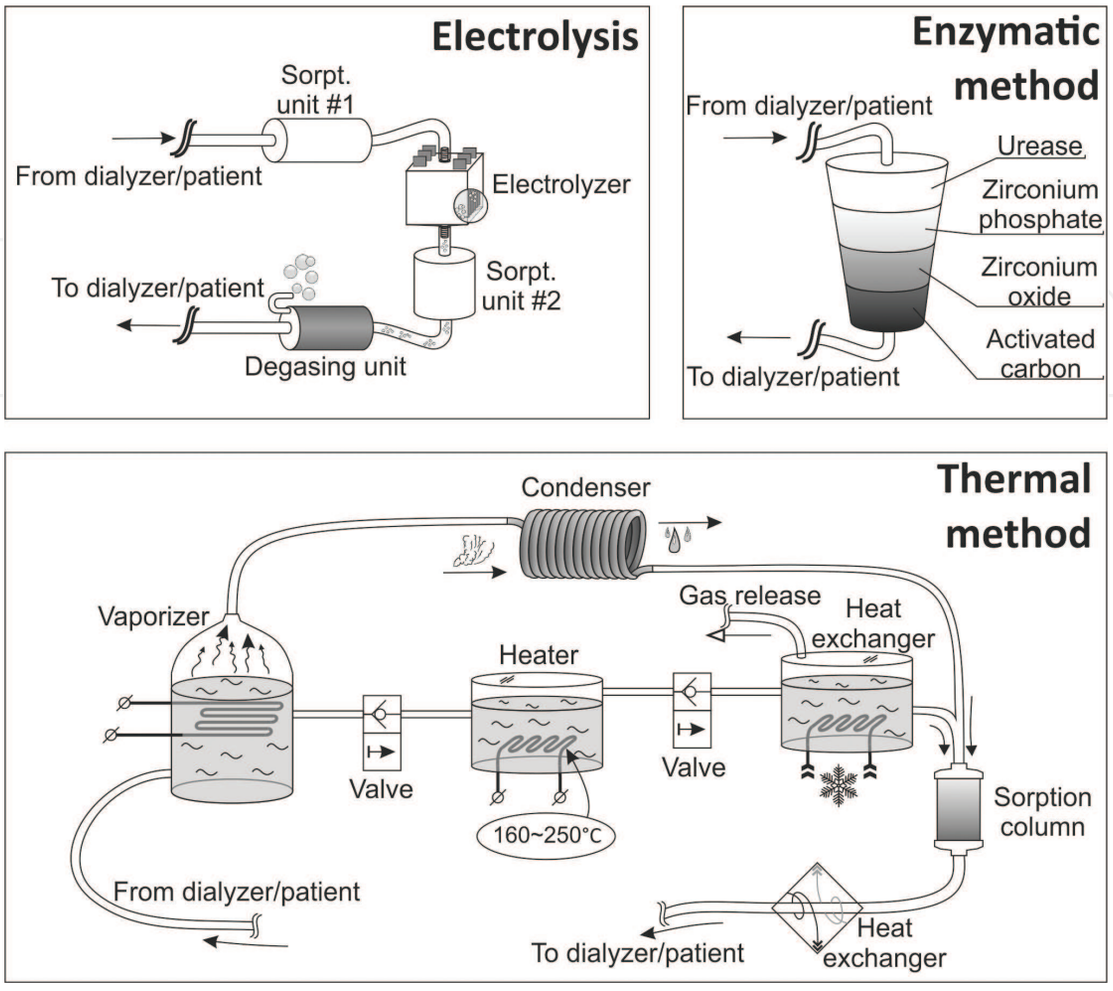

Figure 3. Types of dialysis regeneration units.

1. Enzymatic method is using animal- or plant-derived urease ferment to hydrolyse urease and reduce it to carbon dioxide and ammonia; its combination with sorption is used in many WAK prototypes. In our work, we extracted a plant-derived enzyme from jack beans. For the experimental verification, a sorption column was constructed (**Figure 4** top left). The column was tested on a model solution, which consisted of peritoneal dialysis solution (1 l), urea (~36 mmol), creatinine (~820 mmol/l), uric acid (~700 mmol/l). Model solution circulated through the column with use of a peristaltic pump with a flow speed of 100 ml/min. Metabolites' and ions concentrations were measured each hour for 8 hours. Experimental results are presented in **Figures 4** and **5**. After 8 h, this unit eliminated 7.15 g of urea, 2.08 g of creatinine and 0.4 g of uric acid.

The advantage of this method is its ease of use. Expendable materials, in this case, consist of a tubing set with sorption element that can be easily replaced by the patient. Drawbacks of the method are: complexity of storage and preparation of immobilised urease (up to 1 month at 4°C), high cost of the method (expensiveness of zirconium phosphate), presence of aluminium in the dialysis solution, the short lifetime of the sorption element (4–6 h) as well as an increase of pH, that leads to necessity of buffers infusion.

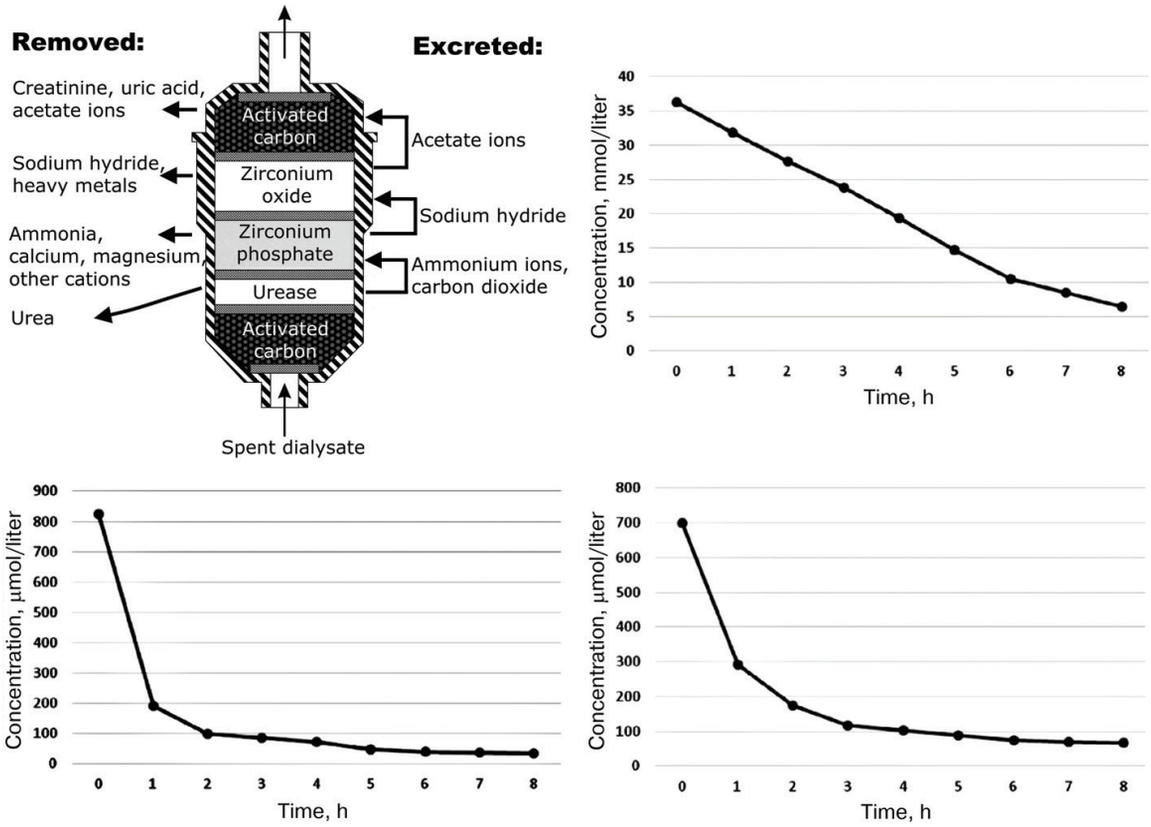

Figure 4. Top left—Sorption column structure: Top right—Urea concentration dynamics; bottom left—Creatinine concentration dynamics; top right—Uric acid concentration dynamics.

The electrochemical method uses electrolysers with special electrodes to electrolyse urea and other metabolites but produces by-products, which can be removed by activated carbons

Urea can be oxidised either directly on the anode (Eq. (1)) [4, 5] or in solution by interacting with the hypochlorite ion released at the anode (Eqs. (2)–(4)). However, toxic chlorine-containing compounds and free chlorine can accumulate in solution during electrolysis. Free chlorine is formed because of the interaction of the chlorine ion with water.

$$(NH_2)_2\,CO + H_2O \rightarrow N_2\uparrow + CO_2\uparrow + 6\,H^+ + 6\,e^- \quad (1)$$

$$2\,Cl^- \rightarrow Cl_2\uparrow + 2\,e^- \quad (2)$$

$$Cl_2 + H_2O \rightarrow HOCl + HCl \quad (3)$$

$$(NH_2)_2\,CO + 3\,OCl^- \rightarrow N_2\uparrow + 3\,CO_2\uparrow + 3\,Cl^- + 2\,H_2O \quad (4)$$

The main requirement for the electrolysis of urea is the choice of an effective and safe electrocatalyst. Studies of various electrode materials have shown that urea can be electrochemically

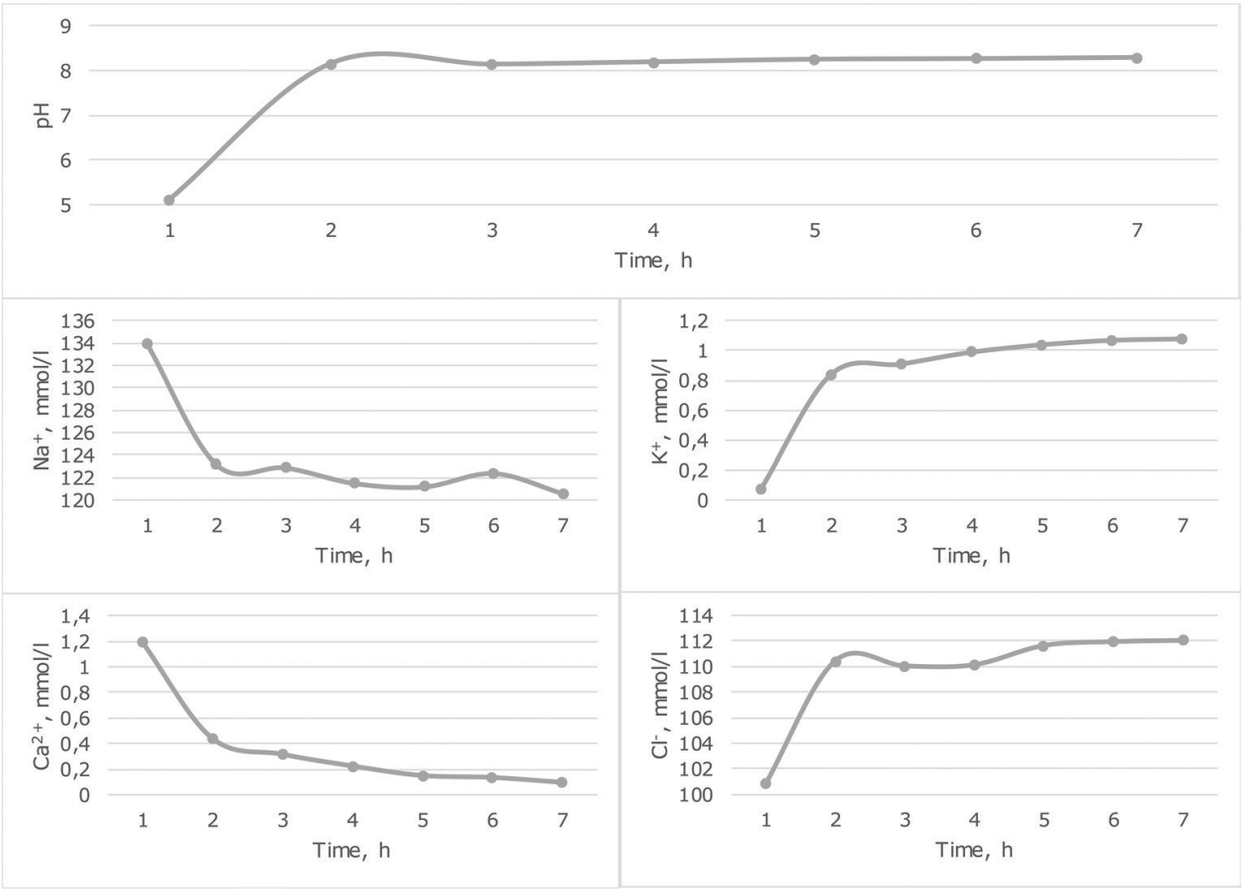

Figure 5. pH and ions' concentration dynamics during dialysate regeneration by urease.

oxidised in a neutral medium using catalysts made of noble metals such as Ru-TiO_2, Ti-Pt, Ti- (Pt-Ir) etc. However, the high cost of such materials is a significant obstacle to their wide practical application.

The possibility of electrochemical urea oxidation on electrodes made of platinum group metals was investigated. To determine the rate of urea removal, depending on the type of electrode, a series of experiments were performed with the following parameters: current density 5 mA/cm^2; initial urea concentration 30 ± 2 mmol/l; perfusion rate 100 ml/min; the distance between electrodes is 1 mm. As an object of study, next electrode types were chosen: graphite; platinum, electrochemically deposited on titanium (Ti-$Pt_{(ec)}$) or by explosion-rolling (Ti-$Pt_{(er)}$); rhodium, electrochemically deposited on titanium (Ti-$Rh_{(ec)}$); ruthenium, electrochemically deposited on titanium (Ti-$Ru_{(ec)}$), as well as electrodes from foamed coal ($C_{(foam)}$); silicon-carbon films deposited on titanium substrates by vacuum spraying, doped with molybdenum (Ti-$SiC_{(Mo)}$); silicon-diamond films deposited on titanium substrates (Ti-$SiC_{(diam)}$); platinum sprayed on titanium substrates (Ti-$Pt_{(spray)}$). The results of the experiment are shown in **Table 3**. Zero removal rate of urea is indicated for electrodes, the coating of which has dissolved before the end of the experiment.

Material	Urea elimination rate, mg/g	Anode surface area, cm^2	Specific urea elimination rate, $mg/cm^2 \cdot h$
Graphite	274	150	1.83
$Ti\text{-}Pt_{(ec)}$	73	150	0.49
$Ti\text{-}Pt_{(er)}$	70	150	0.47
$Ti\text{-}SiC_{(diam)}$	32	100	0.32
$Ti\text{-}Rh_{(ec)}$	30	100	0.30
$C_{(foam)}$	20	100	0.20
$Ti\text{-}Ru_{(ec)}$	0	100	0
$Ti\text{-}SiC_{(Mo)}$	0	50	0
$Ti\text{-}Pt_{(spray)}$	0	18	0

Table 3. Urea elimination rates by electrode material type.

As can be seen, the highest specific rate of urea elimination occurs on the graphite, $Ti\text{-}Pt_{(ed)}$ and $Ti\text{-}Pt_{(er)}$ electrodes. The operating time of the platinum-coated electrodes is limited due to the active transition of the coating to the solution: electrodeposited platinum has dissolved within 40 h; explosion-rolling platinum remained on the substrate for more than 200 h. Lifetime of graphite electrodes could not be determined. In connection with this, further investigations were carried out on graphite electrodes, since their coating proved to be the most stable.

For these electrodes, a number of additional experiments were carried out, the purpose of which was to study the effect of electrolysis on the ionic composition and the acid-base state of the solution. Results are presented in **Figure 6**. Electrolysis on graphite electrodes alkalises the solution and affects the ionic composition of the solution. The pH of the solution in 7 h of electrolysis is increased from 5.2 to 5.9, and an increase in the concentration of chloride ions and chlorine compounds (including sodium hypochlorite) is observed. In the course of the experiment, there was also a slight decrease in the calcium concentration, which is probably due to the formation of calcium hydroxide on the cathode surface. From the results obtained, it follows that the main advantage of the electrochemical method is the elimination of urea, but at the same time, electrolysis affects the acid-base state of the solution and its ionic composition. To eliminate this disadvantage, it is necessary to apply a post-treatment solution, namely sorption columns with activated carbon.

However, research and development of other perspective electrode materials (i.e. graphite and other carbon materials) is in progress.

2. Thermolysis is heating spent dialysate to the temperature of urea decomposition (around 150°C). This method cannot be used in WAK because of high-energy usage, and difficult to use even in the stationary setting because of many thermolysis by-products and caramelisation of glucose contained in the dialysate. In case of WAK usage, it is only usable in HD conditions.

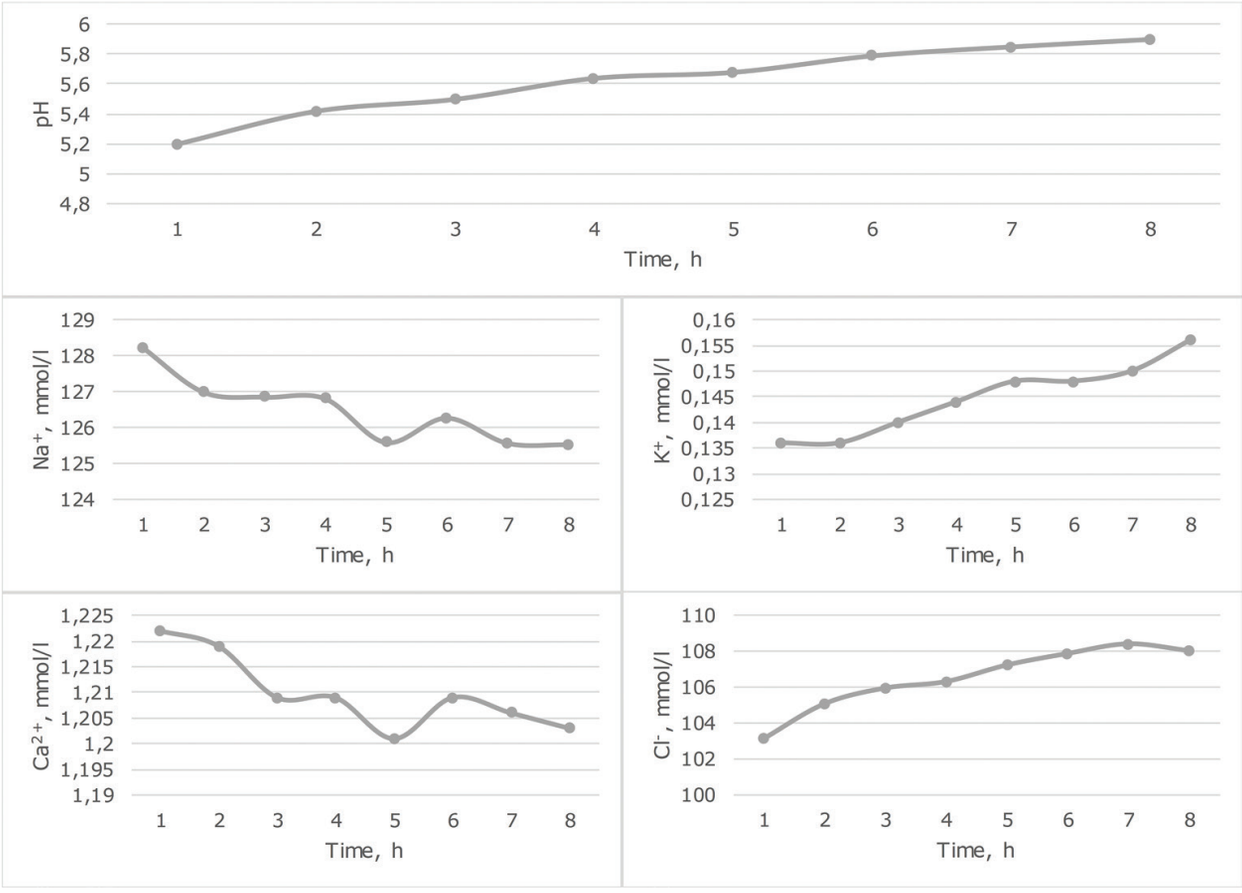

Figure 6. pH and ions' concentration dynamics during dialysate regeneration by electrolysis.

When the spent dialysate is heated to 100°C in a closed loop, organic dialysis products decompose to a gaseous state. For example, thermolysis of urea proceeds according to the following Eq. (5):

$$(NH_2)_2CO + H_2O \xrightarrow{\theta > 373°K} (NH_3)_2CO_2 \xrightarrow{Carbonate} 2NH_3\uparrow + CO_2\uparrow \quad (5)$$

where Θ is the thermolysis temperature, °K.

The results of the studies [8] demonstrate that nitrogen-containing components (urea, uric acid, and creatinine) elimination rate exponentially depends on the temperature.

Thermal dialysate regenerator functioning can be represented by a sequence of steps. The first stage involves the filling of the thermal regenerator with dialysate and its subsequent heating up to a given thermolysis temperature Θ. The second stage is the regeneration of dialysate. The third stage is cooling the dialysate down and its removal from the thermal regenerator.

The results of the experimental testing of the thermal regenerator presented in [6] confirmed the possibility of using the proposed method for dialysate regeneration; urea elimination rate

was 2.5–10.0 g/h in temperature range of 160–250°C, but this method was not further developed due to the significant energy consumption and the need for the thermal reactor to function at high excess pressures.

Considering all the above, it could be said that combinations of sorption + enzymatic method and sorption+ electrolysis are most perspectives to use in WAKs. Some of the current prototypes are presented below.

4. Prototypes of WAK

4.1. ViWAK PD (Vicenza University, Italy)

The device is implemented in accordance with the scheme a) of **Figure 2**. The device [7] is placed in a vest and is controlled wirelessly by a mobile device. The apparatus includes a system for spent dialysate regeneration based on the urease enzyme. The regeneration unit REDY (REcirculating DialYsis) includes urease, zirconium phosphate, zirconium oxide and activated carbon for the removal of urea, heavy metals, creatinine, uric acid and by-products of chemical reactions. The regeneration unit is designed to purify 12l of spent dialysate (about a day of continuous operation). ViWAK PD uses a double hollow catheter for intraperitoneal infusion of dialysate, which is then purified in an extracorporeal circuit. The device operates from an external battery for 10 h, while the mass of the device is about 200 g. The device is also equipped with a sterilising filter, a degasser, a pressure sensor and a rotary pump.

The apparatus does not perform ultrafiltration (removal of excess fluid from the body), which reduces the applicability of the device in patients with zero residual renal function.

4.2. WAK (University of California, Los Angeles, USA)

Portable hemodialysis apparatus [8] implements HD according to scheme b) of **Figure 2**. The device consists of two sections:

1. A blood transport section in which the patient's blood moves to the dialyzer along the arterial line and then returns to the patient's cardiovascular system;
2. The dialysate transport section, where the dialysis solution enters the mass transfer device and then moves through the regeneration system, at the same time it is cleared of accumulated toxins and saturated with sodium bicarbonate. The apparatus also has pumps for controlling the flow of anticoagulant and for performing ultrafiltration.

The device is made in the form of a belt and weighs 5 kg. The device consists of four pumps, powered by external batteries (provide continuous operation for 8 h), and regulate the removal and addition of fluids in the circuits through the blood and dialysate. The dialysate is continuously regenerated by passing through three containers with sorbents containing urease, activated carbon, zirconium oxide and zirconium phosphate (REDY system).

Initial testing of the device was performed on eight patients, and an average urea removal rate of 1.6 mmol/h, creatinine 1.2 mmol/h was obtained.

4.3. SORB (Fresenius Medical Care, Waltham, USA)

The device [9] realises the PD method according to scheme a) of **Figure 2**. The device is a belt with a mass of 2 kg, in which the dialysate moves through a series of sorption containers, along hollow fibres, on the outside of which there is a sorbent absorbing phosphate, organic substances and ammonium from the volume of dialysate, and urea decomposition by enzymatic method (using urease) with subsequent removal of the reaction products.

Among the shortcomings of this device can be identified the lack of ultrafiltration, as well as the absorption of calcium and magnesium from the dialysate, which requires the use of an infusion pump to return them to the dialysate.

4.4. WABPU (ZITC, Moscow, Russia)

The device [10] implements the PD method according to scheme c) of **Figure 2**. The device is a 3.5 kg backpack containing a hydraulic circuit that realises recirculation and dialysate regeneration and an electrical circuit that realises the control of the procedure, the system as a whole, and communication with the smartphone displaying user interface. The functional diagram of the device is shown in **Figure 7**.

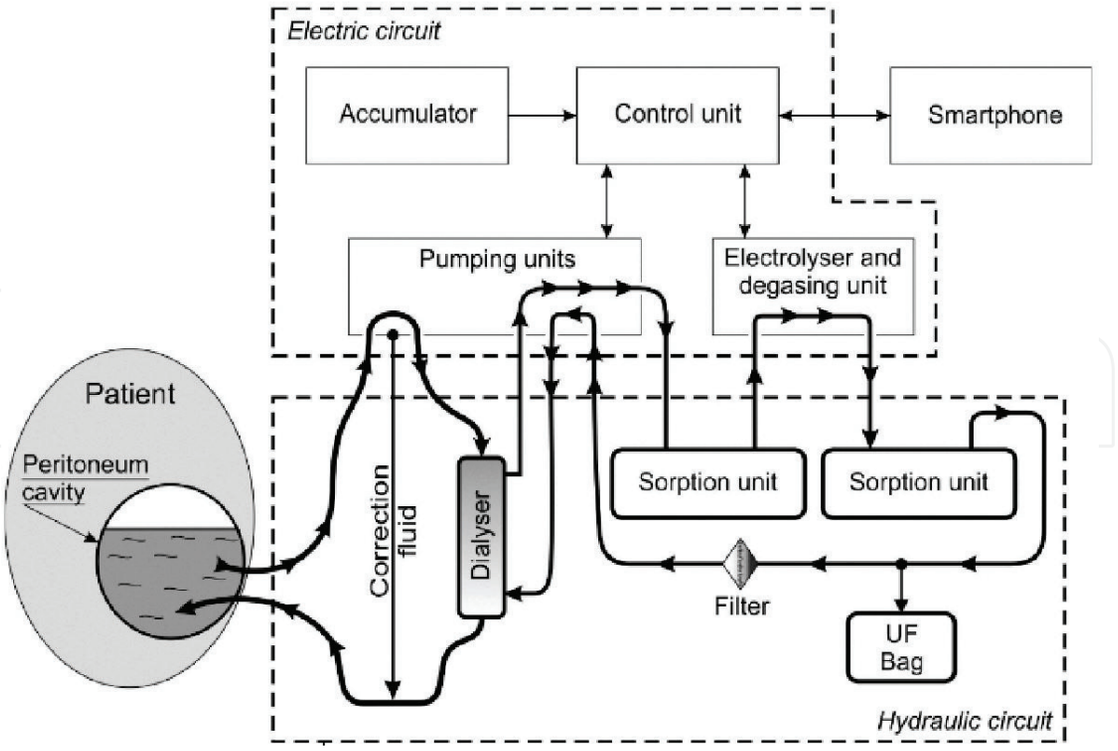

Figure 7. Functional diagram of WABPU: UV—ultrafiltrate [12].

Regeneration of the dialysate solution is carried out by sorption of metabolites by activated charcoal and electro-oxidation of urea in an electrolytic cell. The combination of the material of electrodes and sorbents allows maintaining the pH of the dialysate at a constant level (7.1 … 7.3), but slightly changes the ion composition, which is solved by the selection of specialised sorbents and ion exchange resins. The device includes a control unit, a battery (provides continuous operation for 8 h), pump modules, a dialysate regeneration unit, a trunk and a smartphone. The regeneration unit includes an electrolyzer, a degasser and two sorption columns with activated carbon. The device was successfully tested on an animal model. Now the device is in preparation for clinical trials.

4.5. WAKD (nephron + project, Netherlands)

The apparatus [11] uses a combination of sorption and electrolysis of the spent dialysate [12]. The concept of the device was initially based on the method of hemodialysis, but in the last 2 years, it was changed in favour of peritoneal dialysis. The device is made in the form of a block, located on the belt. Management is carried out using a smartphone. The device assumes the presence of a special pump for introducing a glucose solution to maintain the concentration of the osmotic agent in the dialysate during dialysis to maintain the patient's fluid balance. The hemodialysis-based apparatus underwent preclinical tests on animals. WAKD weighs 3.2 kg, but the developers claim about its possible miniaturisation to 2.5 kg.

A comparison of the existing WAK prototypes devices is presented in **Table 4**.

Name	Type	Regeneration method	Characteristics	Current status
ViWAK [7]	PD	Sorption + urease	0.2 kg, 17 × 8 × 3 cm, 10 h of battery life	The prototype was not further developed
The WAK [8]	HD	Sorption + urease	5 kg, on-waist wearable, 8 h of battery life, urea removal rate 1.6 mmol/h, creatinine 1.2 mmol/h	Pre-clinical trials are under way
EO NAIP [10]	PD	Sorption + electrolysis	3.5 kg, backpack, urea removal rate 1.2 g/h, creatinine 0.3 g/h	Preclinical tests passed
SORB [9]	PD	Sorption + urease	2 kg, on-waist wearable	The prototype was not further developed
AWAK [12]	PD	Sorption + urease	1 kg, shoulder bag or vest, 16 h of battery life, expendables exchange every 7 or 12 h	Pre-clinical trials are under way
WAK-MAN [13]	HD	Sorption	Vest, 24 h of battery life,	The prototype was not further developed
WAKD [11]	HD and PD	Sorption + electrolysis	3.2 kg, on-waist wearable, up to 30 ml of urea clearance	Pre-clinical trials are under way

Table 4. Current WAK prototypes.

Table 4 shows that the current state of development of equipment for artificial blood purification allows you to count on their clinical use in the next 2–5 years.

Wearable equipment for artificial blood purification will overcome the shortcomings of existing apparatus and methods of dialysis and is one of the most promising areas in the field of biomedical engineering of artificial organs.

5. General problems of WAK development

Osmotic agents are added to the peritoneal dialysis solution to remove excess fluid from the body. They make the solution hyperosmolar in comparison with extracellular fluid, which leads to the removal of the liquid through ultrafiltration. The ideal osmotic agent must be cheap, biocompatible, with a sufficiently small molecular mass for changing the viscosity of the RPD, but with a sufficiently large molecular mass to not be absorbed into the bloodstream. The list of potential osmotic agents examined includes glucose, glycerol, xylitol, sorbitol, fructose, mannitol, gelatine, glucose polymers, polypeptides and dextrans. Most of them turned out to be unsuitable due to side effects. Relative success was seen with the use of glycerine, amino acids and glucose polymers, but only glucose, glucose polymers and amino acids are used in everyday clinical practice.

The main disadvantage of low molecular weight osmotic agents is their rapid absorption, resulting in a loss of ultrafiltration speed and metabolic disturbances. Large, loosely absorbed osmotic agents theoretically allow the ultrafiltration to last longer. The driving force, in this case—the colloid osmotic pressure, is determined to a greater extent by the number of osmotically active macromolecules than by the osmotic gradient. This means that osmosis can be maintained even with the use of peritoneal dialysis solution with osmolarity close in value to the osmolarity of extracellular fluid.

6. Conclusion

Development of WAK is held all over the world. The state of the art is that some of them went through animal trials and undergo clinical trials. Most probably first commercial WAKs will penetrate the market in 2–3 years. However, there is still very much work to be done because the tendency is in achieving the performance of native kidney. In the first stage, WAKs must be cheaper than HD and PD that will be the major factor to spread them and that will be a very good option to raise the number of patients with CKD who receive RRT.

Conflict of Interest

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