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Wearable Artificial Kidney Renart-PD

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A pre-production model of the first domestic wearable artificial kidney Renart-PD and the results of its trials are presented. The trials involved regeneration of model solutions and biological fluids (spent solution for peritoneal dialysis). It was shown that the regeneration procedure could continue up to 24 h with a mean mass rate of metabolite removal comparable to that provided by healthy kidneys.

Introduction

Development of autonomous wearable equipment for artificial blood cleansing is one of the most important trends in biomedical engineering of artificial organs. In early 2019, The Food and Drug Administration (FDA) agency of the United States Department of Health and Human Services approved a breakthrough devices program, in which technologies for mobile dialysis are considered as priority areas of biomedical engineering [1]. Currently, there are three foreign prototypes of an autonomous wearable device for artificial blood cleansing: AWAK [2] (USA, Singapore), WAK (USA), and WEAKID (Netherlands) [3]. The first two are now undergoing clinical trials, while the third has passed the preclinical studies.

The goal of this work was to present the results of trials of Renart-PD, a domestic prototype of the autonomous wearable artificial kidney.

Autonomous Wearable Artificial Kidney Renart-PD

The principle of operation of the Renart-PD device is illustrated in Fig. 1. The device provides continuous peritoneal dialysis with recirculation of the dialysis solution in the extracorporeal circuit, in which dialysate is regenerated (i.e., the initial chemical composition of the solution is restored). Dialysate regeneration is carried out by the electrochemical method with sorption purification [4, 5]. Commercially available activated carbon Kausorb-212 is used as sorbent. It provides removal of such low-molecular-weight substances as creosols, creatinin, uric acid, etc. [6, 7]. Electrolysis is used to remove urea [4, 8].

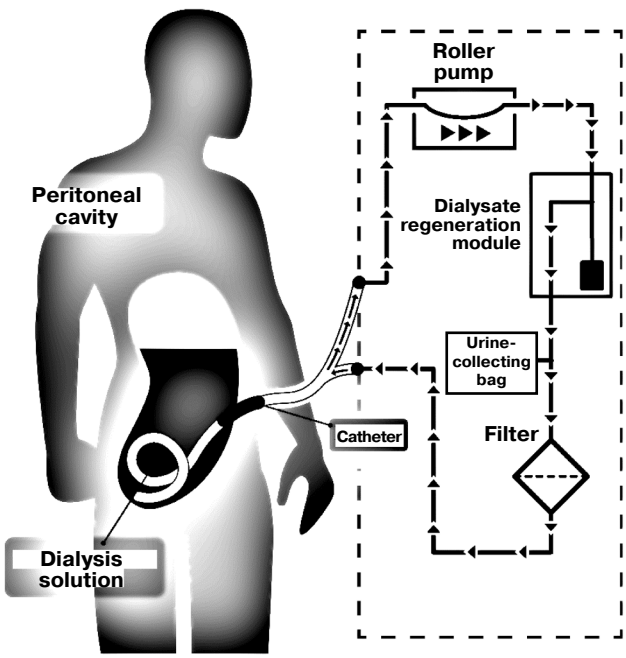

Fig. 1. Functional diagram of artificial blood cleansing by the autonomous wearable artificial kidney Renart-PD.

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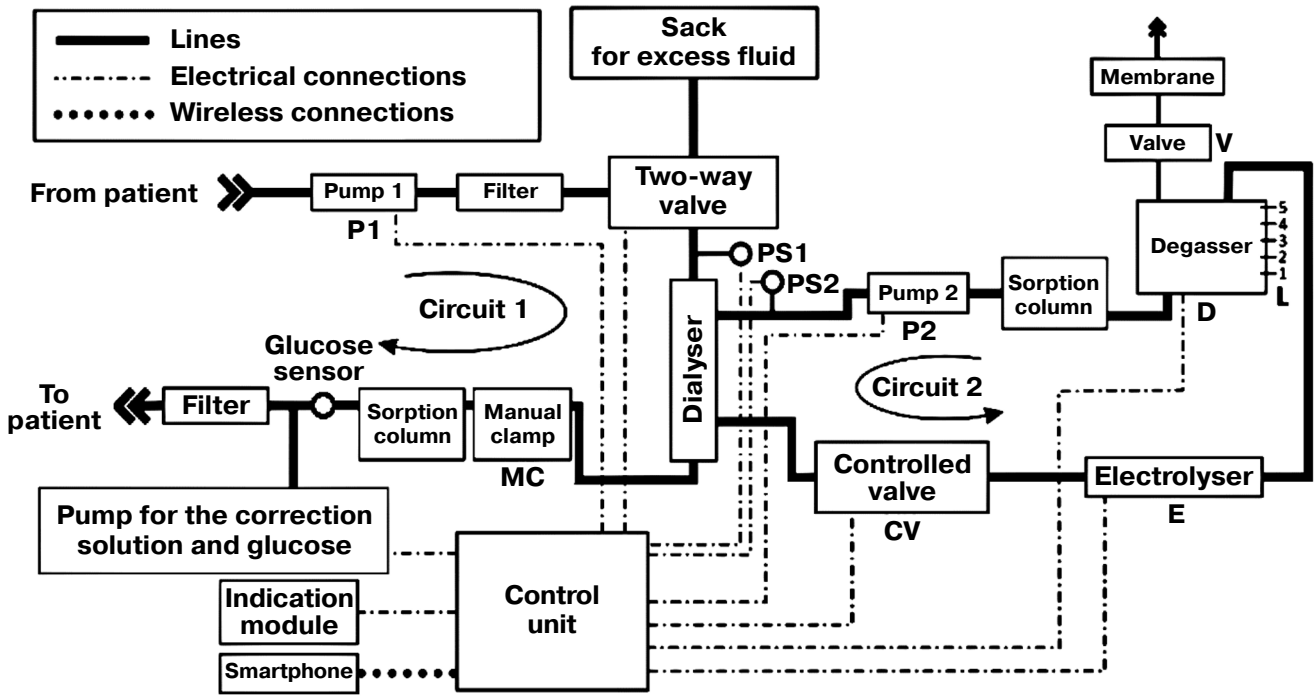

Fig. 2. Functional diagram of the autonomous wearable artificial kidney.

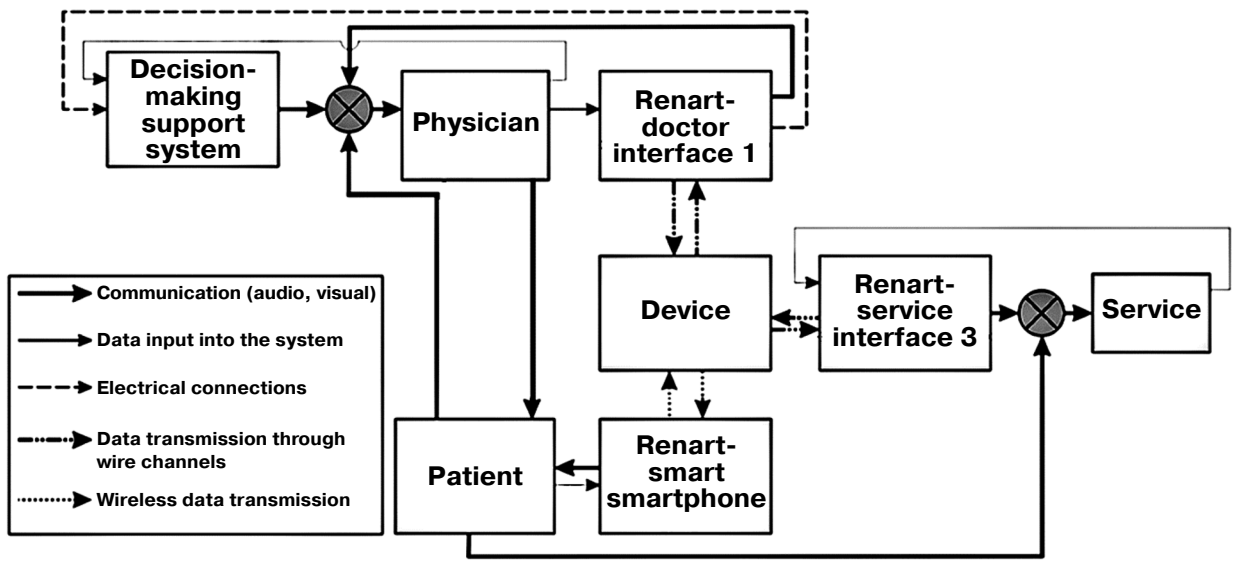

Fig. 3. Control system of the autonomous wearable artificial kidney Renart-PD.

To increase the efficiency of electrolysis, only low-molecular-weight fractions of spent dialysate (separated by the dialyzer in the extracorporeal circuit) are fed to the flow-through cell (Fig. 2).

The dialyzer divides the extracorporeal circuit into the recirculation (circuit 1) and regeneration (circuit 2) circuits. Roller pumps P1 and P2 provide collection, circulation, and return of dialysate. Only low-molecular-

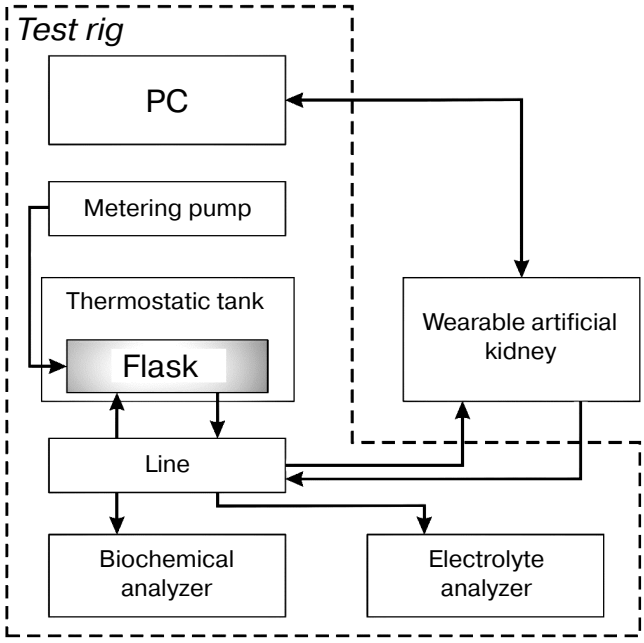

Fig. 4. Functional diagram of the test rig used to test the device performance.

weight compounds are fed into the regeneration circuit. To separate them, a control system providing zero transmembrane pressure is built into the dialyzer [9]. The system includes pressure sensors (PS1 and PS2), an electrode system in the degasser (L = 1-5), and a controlled valve providing the required pressure at the dialyzer output by clamping the line. The pump for the correction solution and glucose is implemented as a linear pusher for moving the syringe plunger. Excess fluid is removed using a two-way valve. The control unit monitors and controls the operation of executive elements. An interface system is provided for the doctor and service engineer (Fig. 3).

The Renart-PD can be operated using the controls on the device, a smartphone application, or special software for PC (Renart-Service software for controlling functioning of the device modules). In the first and second cases, the algorithm provides switching between the operating modes of the device, changing the parameters of the procedure, and information support. The Renart-Service software supports manual dialysis and allows checking the operability of each element of the device individually [10].

Results of Trials

The functional diagram of the test rig used to test the device performance is shown in Fig. 4.

The rig is implemented as a patient simulator (flask with model solution at a constant temperature) with a set of measuring and auxiliary equipment. The model solution temperature is maintained constant using a thermostatic tank. The flask has three orifices: for collecting and returning the dialysate, for the temperature sensor, and for adding the metabolite concentrate (simulating thereby generation of metabolic products in patient's body). Measuring equipment includes a biochemical analyzer and an electrolyte analyzer; auxiliary equipment: a line with connectors for sampling, a metering pump (regulating the rate of supply of metabolites to the tank), a stopwatch, an analytical balance, a set of measuring cylinders and flasks, a personal computer, a power source, and a set of tripods and syringes.

The metering pump was used to simulate the generation of metabolites. 2 mL of a solution containing 0.8 g urea, 0.1 g creatinin, and 0.05 g uric acid was added hourly.

The results of the dialysate regeneration test without adding the metabolite concentrate are given in Table 1.

During dialysate regeneration with the addition of the metabolite concentrate for 24 h, the mean metabolite removal rates were: urea – 0.8 g/h; creatinin – 0.3 g/h; uric acid – 0.3 g/h; phosphates – 62.5 mg/h; protein – 0.01 g/h.

Tests were also conducted on spent solutions for peritoneal dialysis (biological materials) (Fig. 5; Table 2). During the tests, uric acid and creatinin concentrations decreased from 290.7 to 10.7 μM and from 616.1 to 19.6 μM, respectively. Urea concentration dropped from 13.9 to 0.7 mM. Total phosphorus decreased from 320.0

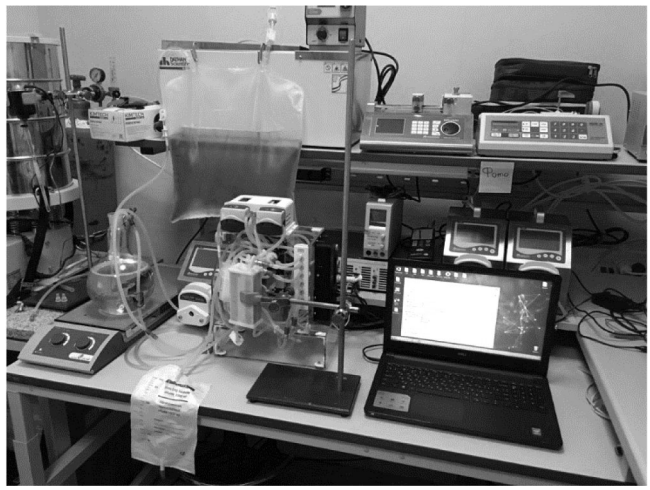

Fig. 5. Tests on biological materials (spent dialysate).

TABLE 1. Results of Model Solution Regeneration at the First Stage of the Test

Time, h	Urea, mM	Uric acid, μM	Creatinin, μM	K^+, mM	Na^+, mM	Cl^-, mM	Ca^{2+}, mM	pH
0	26.0 ± 1.0	211.0 ± 23.0	1140.0 ± 60.0	0.12 ± 0.01	127.0 ± 1.0	99.8 ± 0.4	1.19 ± 0.01	6.0 ± 0.1
1	14.5 ± 0.6	47.0 ± 4.0	400.0 ± 40.0	0.13 ± 0.01	126.0 ± 1.0	100.1 ± 0.9	1.08 ± 0.01	7.0 ± 0.1
2	12.5 ± 0.6	21.0 ± 7.0	170.0 ± 10.0	0.12 ± 0.01	125.1 ± 0.6	99.9 ± 0.3	1.05 ± 0.01	7.2 ± 0.1
3	12.1 ± 0.5	7.0 ± 2.0	114.0 ± 3.0	0.12 ± 0.01	125.5 ± 0.6	99.9 ± 0.6	1.03 ± 0.01	7.3 ± 0.1
4	11.5 ± 0.6	2.0 ± 1.0	86.0 ± 5.0	0.12 ± 0.01	125.9 ± 0.8	100.4 ± 0.9	1.03 ± 0.01	7.3 ± 0.2
5	10.7 ± 0.6	3.0 ± 2.0	69.0 ± 7.0	0.12 ± 0.01	125.2 ± 0.4	99.8 ± 0.5	1.02 ± 0.01	7.4 ± 0.1
6	10.1 ± 0.4	3.0 ± 1.0	58.0 ± 9.0	0.13 ± 0.01	125.3 ± 0.4	100.0 ± 0.4	1.02 ± 0.01	7.2 ± 0.1

TABLE 2. Results of Spent Dialysate Regeneration by Renart-PD

Time, h	Urea, mM	Creatinin, μM	Uric acid, μM	Albumin, g/L	Phosphorus, mg/dL	pH
0	13.9 ± 0.3	616.1 ± 70.0	290.7 ± 20.0	0.70 ± 0.04	320.0 ± 10.0	8.7 ± 0.1
1	8.5 ± 0.2	346.1 ± 20.0	178.3 ± 5.0	0.70 ± 0.04	270.0 ± 20.0	8.3 ± 0.1
2	6.2 ± 0.3	137.8 ± 10.0	100.4 ± 2.0	0.64 ± 0.06	240.0 ± 20.0	7.9 ± 0.1
3	4.7 ± 0.2	54.6 ± 8.0	57.4 ± 10.0	0.62 ± 0.07	220.0 ± 20.0	7.5 ± 0.1
4	3.0 ± 0.3	26.5 ± 8.0	32.9 ± 7.0	0.60 ± 0.07	200.0 ± 20.0	7.5 ± 0.1
5	1.5 ± 0.2	22.5 ± 7.0	18.0 ± 3.0	0.59 ± 0.08	190.0 ± 20.0	7.4 ± 0.1
6	0.7 ± 0.2	19.6 ± 8.0	10.7 ± 0.9	0.59 ± 0.08	180.0 ± 20.0	7.4 ± 0.1

to 180.0 mg/dl, which shows the effectiveness of the sorbent for this marker.

The tests also showed a decrease in pH from 8.7 to 7.4, i.e., pH of the dialysis solution became normal.

The device eliminated 0.11 g of albumin from the solution, thereby reducing its concentration from 0.7 to 0.6 g/L.

Conclusions

An autonomous wearable artificial kidney Renart-PD was developed. The device provides peritoneal dialysis with constant recirculation and regeneration of spent dialysis solution. This allows the same volume of dialysis solution (2-3 L) to be used for dialysis for 24 h. The results of trials of the Renart-PD device showed the mass rates of metabolite removal to be comparable to those provided by healthy kidneys. Thus, the prospects of autonomous wearable equipment for artificial blood cleansing as an alternative to the hemodialysis equipment currently used in clinical practice are quite high.

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