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## Continuous convective renal replacement (CCRR) system: A new modality of wearable artificial kidney

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### Abstract

Wearable artificial kidney (WAK) has undergone clinical trials with results comparable to those of standard hemodialysis. Although they could have been excellent programs to rehabilitate End Stage Renal Disease (ESRD) patients and show them that despite their kidney problems, they could still enjoy the life. Unfortunately they were inconvenient due to different reasons, one of which includes the huge amount of hemofiltration and consequently the amount of replacement fluids. In this article will present our design of the WAK that theoretically intended to overcome previous problems.

**Key words:** hemodialysis, End Stage Renal Disease, wearable artificial kidney

### Introduction

Dialysis as a practical treatment for kidney failure has evolved over centuries. Many have played a role in developing this medical technology, starting with Thomas Graham of Glasgow, who first presented the principles of solute transport across a semi permeable membrane in 1854 (1). And since then continuous efforts were made to develop the ideal dialysis machine for patients with End Stage Renal Disease (ESRD) and while medical technology has made tremendous strides in treating kidney disease, quality of life issues and high mortality rates underscore the limitations of long-term dialysis.

Intermittent Hemodialysis (HD) the most popular treatment for ESRD consumes about 12 to 15 hours weekly of the patient's life during the dialysis sessions. Continuous Ambulatory Peritoneal Dialysis (CAPD) is a more convenient method but it needs special kind of intellectual and well-educated patients in order to reduce the frequency of peritonitis episodes. Haemofiltration has been developing during the last three decades as a possible alternative to the haemodialysis treatment.

Recent clinical data comparing effective dose delivery by three acute dialysis therapies: continuous venovenous hemofiltration (CVVH), daily HD, and sustained low-efficiency dialysis (SLED), found that effective small solute clearance in CVVH is 8% and 60% higher than in SLED and daily HD, respectively. Differences were more pronounced for middle and large solute categories, the superior middle and large solute removal for CVVH is due to the powerful combination of convection and continuous operation (3, 4). Although it would seem an excellent program for ESRD

patients, the feasibility of using continuous hemofiltration in the regular design, as long-term dialysis program is very difficult. But the concept of continuous renal replacement therapy encouraged scientist to develop the wearable model of artificial kidney.

Although "Wearable artificial kidneys" were intended to be excellent programs to rehabilitate renal patients and show them that despite their kidney problems, they could still enjoy the life. Unfortunately, they were inconvenient due to different reasons, such as the huge amount of hemofiltration and consequently the amount of replacement fluids, the volume of the design, the weight, the vascular access, and anticoagulation that made the realization of such a design not feasible.

### *Diffusive versus Convective transport systems*

Before going over our design we will give a brief description on the differences between diffusive transport and convective transport systems to help understand our design of the Wearable artificial kidney (5-8).

### *Diffusive transport*

Diffusion is the physical phenomenon upon which the process of hemodialysis depends. It is driven by the concentration differences between blood and dialysate compartments and the solutes pass through the semipermeable membrane and it is most efficient for the non-protein bound, low-molecular weight solutes.

### *Convective transport*

In contrast, in the convective therapies, the solvents are eliminated by solvent drag, secondary to the removal of plasma water from the blood stream.

Convective transport is more efficient for transport of middle and high molecular weight non-protein bound molecules, which can pass through the greater pores in the applied membranes.

Of course, also the elimination of potentially toxic middle and high molecular weight molecules could be improved. At least this has been shown for  $\beta_2$  micro globulin which might be involved in arthralgia, carpal tunnel syndrome, neuropathy and bone disease. Also other molecules, like for instance the advanced glycation end products (AGEs) (9,10), which recently have been shown to be associated with cardiovascular disease, might be eliminated in a more

efficient way, as well as inflammatory molecules like interleukins and endotoxins

**Continuous Convective Renal Replacement Therapy as a Wearable Artificial Kidney**

Haemofiltration, being superior to haemodialysis in its efficacy (5,10), could not be applied as an alternative for chronic renal failure treatment, due to the huge amounts of highly purified fluid and electrolytes replacement needed to be infused intravascularly. We present here our suggested innovation, which could overcome all the inconveniences of both haemodialysis and haemofiltration.

**Definition**

It is a continuous, portable, wearable and disposable renal replacement therapy system, depending on convective elimination of water and nitrogenous waste products, which

can be used as a long-term treatment of end-stage renal failure.

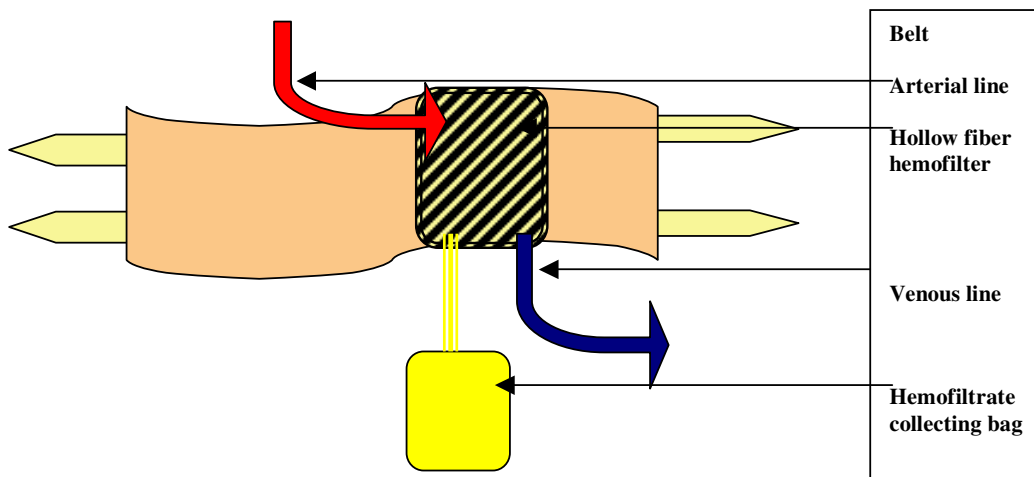
**Description**

*1. Vascular Access:*

Is a prerequisite for initiation of the therapy? The most convenient vascular access modality is Titanium subcutaneous catheters product of PakuMed® Medical products gmbh. Two ports are surgically inserted: one in the central venous system through the right internal jugular vein or the right subclavian vein, the other is installed in the arterial system through the right internal jugular or the right subclavian (innominate artery) Figure 1. (1)

A third Titan Port catheter could optionally be implanted surgically opposite the suprapubic area, subcutaneously extending to inside of the urinary bladder.

**Fig 1.** Graphic design illustrating the Continuous Convective Renal Replacement system



The Continuous Convective Renal Replacement system (Figure 1) is designed in the form of a tight jacket or belt to be worn by the patient. The material of the jacket can be any solid, light, leathery non-allergic substance or tissue water resistant. The jacket extends from the shoulders superiorly down to the hypogastrium inferiorly. The outside surface of the jacket is grooved for embedded bloodlines. Two sets of bloodlines are embedded. Another groove is prepared for the site of a small haemofilter. On the inside surface, there is two protruding needles gage 14 to 16, situated opposite the sites of the Titan Port. These needles are protected with plastic covers, to be removed at the time of wearing the jacket, and the needles will puncture the skin opposite the Titan Ports.

In the blood line grooves, are embedded two sets of lines: a red coded set extending from the arterial needle to the arterial port of the haemofilter, while the blue coded set extends from the venous port of the haemofilter to the venous needle. A third wide bored needle (gage 14) protrudes from the lower end of the jacket opposite the vesicle Teten Port. This needle is connected to the ultrafiltration orifice of the haemofilter through a drainage line.

The whole system of bloodlines, hemofilter and the needles are primed with heparinized sterile normal saline.

*2. The haemofilter:*

Is a hollow fiber, or parallel plate dialyser composed of a high flux, biocompatible membrane. The total surface area, the porosity, the membrane thickness and the length of the dialyser are to be calculated to give a rate of hemofiltration is about 250 ml/hour. Blood inlet and outlet are situated at both ends of the haemofilter, and a hemofiltrate drainage outlet is situated on the side of the haemofilter at the arterial end. It's connected to either a urine bag or to the vesicle TITAN PORT.

The whole system is completely sterile and packed in a sterile elegant package labeled with sufficient information and instructions about the system usage. A user manual is included inside the pack.

The driving force of the extracorporeal circulation depends on the arterio-venous pressure gradient without the use of any sort of pump or any source of power.

*3. Replacement fluid:*

In this modality, the replacement fluid is to be given orally to the patient. Sachets containing salts, replacement materials,

vitamins and sugar are to be prepared. Different formulae of these sachets are to be prepared according to the nature of the most common clinical presentations: e.g. those patients who are salt losing or salt retaining, those who are usually acidotic should be given high alkali (sodium bicarbonate) content and so on.

The patient is to be instructed to dissolve the contents of one or two sachets in an amount of water to be calculated by his physician according to the degree of water retention, the degree of dehydration or over hydration, and the degree of residual renal function etc...

#### 4. Anticoagulation:

Could be achieved either by an oral anticoagulant (Coumadine) with adjustment of PT and INR; or low molecular weight heparin (Clexan) in a prophylactic 12 hourly dose.

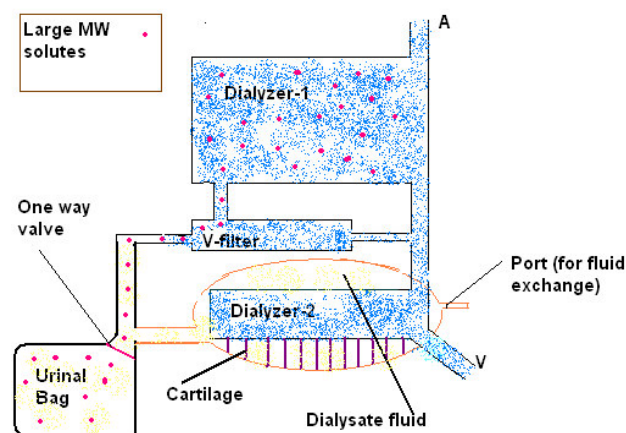
#### Modified design

This model is designed for patient who can't tolerate large volume of replacement fluid. It has the same idea of a continuous, portable, disposable renal replacement therapy system, it depends on hemofiltration properties (convection) but, in addition, it has hemodialysis properties (diffusion) and better control of ultrafiltrate volume and consequently fluid replacement. This design is technically sophisticated.

#### Description:

The modified design (Figure 2) is divided into three filters; the first one is a high flux filter will refer to as dialyzer-1, second one is very low flux filter will refer to as V-filter and a third one is a low flux-high efficiency filter with dialysate compartment will refer to as dialyzer-2.

Fig 2.



Dialyzer-1 intended for the medium and large molecular weight solutes clearance and the V-Filter is used to ultrafiltrate the drainage from dialyzer-1 to decrease volume loss (fluid loss), and by doing so the filtrate blood from dialyzer-1 and the ultrafiltrate from the V-Filter will pass to dialyzer-2 which has a high surface area and small to medium size pores. Dialyzer-2 has fluid, which act as dialysate fluid contains removable adsorbent cartilages around its casing bag to keep the fluid at continuous lower concentration of diffusible solutes.

The filtrate drainage from the V-Filter, which contains a concentrated large molecular weight waist solutes with low volume, will be drained with the drained filtered of the Dilayzer-2 into a one-way valve urinal bag attached to the patient's leg.

In addition, the dialyzer-2 dialysate fluid casing will have a sensor for the most important diffusible solutes that will alarm or change in colour to notify the patients to change the adsorbent cartilage and/or exchange dialysate fluid. Our intention is to be once daily.

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