

REVERSED COIL ARTIFICIAL KIDNEY: DEVELOPMENT OF A PROTOTYPE

PETER D. SMITH,* ARTHUR H. GARA,* and WILLEM J. KOLFF, M.D.

Department of Artificial Organs

THE artificial kidneys now in use have one common denominator: the blood is confined in a length of cellophane (tubing or sheets) immersed in dialyzing fluid. The *reversed coil artificial kidney* reverses this concept. The dialyzing fluid is confined within the tubing and the blood is on the outside of the tubing.

The goals of this technic are to reduce the amount of blood needed for priming, to reduce the resistance to blood flow, so that the dialyzer can be used without a blood pump, and to achieve sufficient dialyzance and variable ultrafiltration. The dialyzing unit should be inexpensive and be able to be sterilized after it has been assembled. To have a future in the United States, it must be able to have a long shelf life, be disposable, and be suitable for mass production. Above all other considerations it must be simple and safe to use.

Guarino¹ designed an artificial kidney using the reversed technic. However, the dialyzing fluid was pumped through the cellophane tubes under pressure, thus a leak in the tubing would allow the dialyzing fluid to enter the blood undetected. Our *reversed coil artificial kidney* avoids this hazard by maintaining the dialyzing fluid at a pressure less than the blood pressure. If a leak should occur, blood would enter the dialyzing fluid where it can easily be detected. Collapse of the cellophane tubing is prevented by a supporting plastic screen core within the tubing. The pressure gradient from blood to dialyzing fluid is sufficient to keep the cellophane tubing pressed tightly against the screen. The rate of ultrafiltration can be varied by adjusting the relative pressures of the blood and the dialyzing fluid.

Kolobow, Moskowitz, and Bowman's² report of a sophisticated reversed kidney was published after we had started to work on our model. Earlier Kolobow and Bowman³ had described an oxygenator that operates on the reversed principle.

Construction of the Reversed Coil Artificial Kidney

The reversed coil artificial kidney is 1 ft. in diameter and 2½ in. high (Fig. 1). Basically it is made up of a hard plastic top and bottom, and an inner and an outer cylinder which form the blood chamber between them. The blood flows into and out of the blood chamber through manifold tubes. The entire artificial kidney is suspended in rinsing fluid so that no rinsing fluid manifold is required. The rinsing fluid is aspirated from the inner chamber.

Four cellophane† tubes from 3.2 to 4.0 m. long with a lay-flat width of 4.4 cm., having plastic screens‡ as a core (I) (Fig. 1) are attached to the inner chamber by means of a rubber stopper mechanism.

Supported by a grant from The John A. Hartford Foundation Inc. to The Cleveland Clinic Foundation, for dialysis in the treatment of patients with chronic renal failure.

*Fenn College Cooperative Plan Student, Cleveland, Ohio.

†Dialyzing tubing No. 463, 36 x 1000 ft., Visking Corp., Chicago, Illinois.

‡Chicopee Mfg. Co., Buford, Georgia.

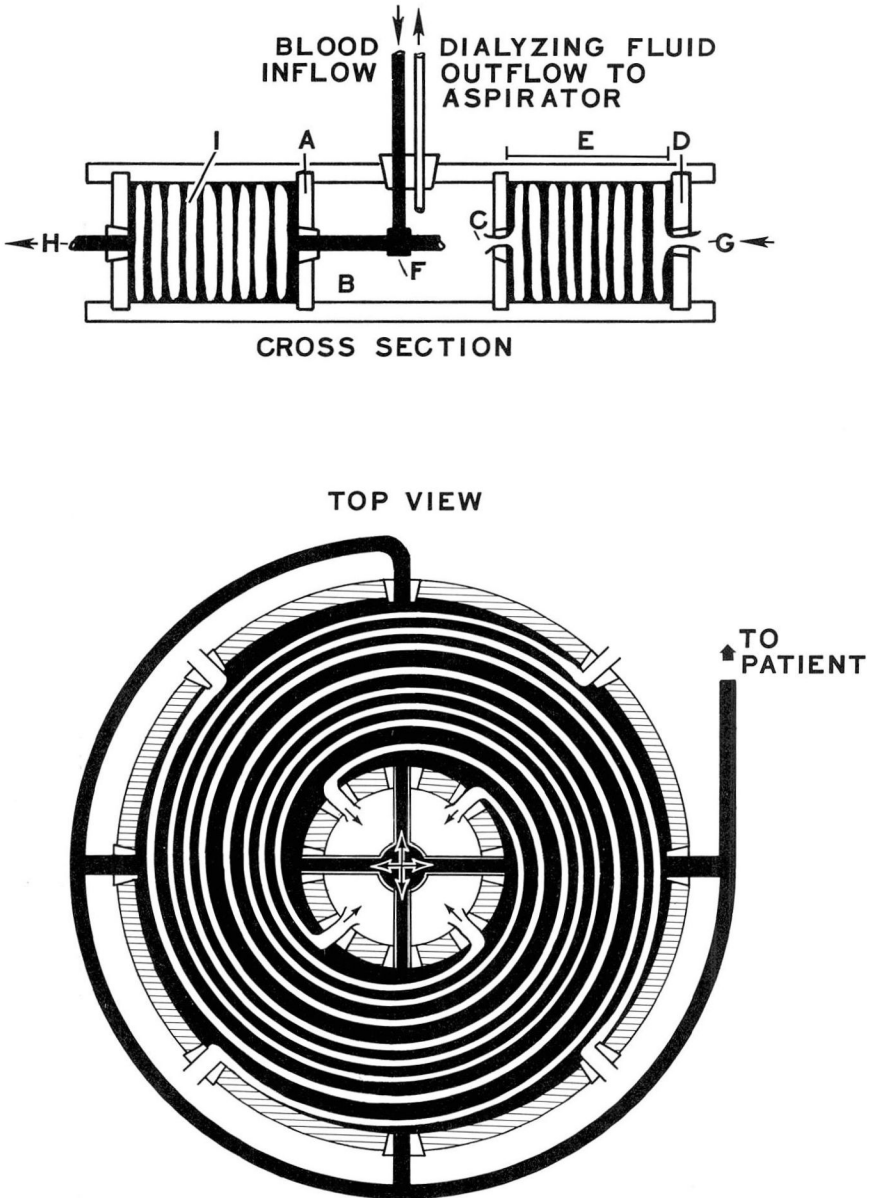


Fig. 1. Schematic diagram of the reversed coil artificial kidney. The small inner cylinder (A) forms the inner chamber (B), that serves as a collecting chamber from which dialyzing fluid is withdrawn. There are eight holes in the inner cylinder; four alternate holes are dialyzing fluid outlets (C) and the other four are for the blood inflow manifold (F). The outer cylinder (D), which encloses the blood and dialyzing fluid tube compartment (E), also has eight holes in it. Four alternate holes are for the dialyzing fluid inflow (G) and the other four are for the blood outflow manifold (H).

The cellophane is sealed in a special way to prevent leaks from blood and rinsing fluid. A short metal tube is inserted within a rubber stopper. The screen core is pulled through the metal tube and the cellophane tubing is pulled over the rubber stopper; the rubber stopper is then pushed into its hole in the inner cylinder. The four cellophane dialyzing tubes are wrapped spirally around the small inner cylinder, and each tube is fixed to the appropriate hole in the outer cylinder by the same type of rubber stopper mechanism.

The blood inflow manifold, placed entirely within the inner chamber, divides the blood into four streams, each of which enters the dialyzing chamber and flows *between* the dialyzing fluid coils. The blood and dialyzing fluid flow in opposite directions. The dialyzing unit is placed in a tank of dialyzing fluid. Any of the currently used artificial kidney tanks can be used for this purpose.

An aspirator maintains a negative pressure in the inner chamber. A pump circulates the dialyzing fluid through the aspirator at a rate of 15 l. per minute. The aspirator 'sucks' the dialyzing fluid from the bath, through the coils, and into the inner chamber. From the inner chamber the dialyzing fluid flows through the aspirator and back into the bath. An additional advantage of the aspirator is that it eliminates air from the system without embarrassing the pump.

The screen core inside the cellophane tube is a clear, lead-free, plastic-coated (polyvinyl chloride), 10 by 10 mesh, fiber glass screen. Threading of the plastic screen through the cellophane tubing without harming the cellophane required a special technic. Strips of screen 6 in. wide were folded together so that their lay-flat widths were $1\frac{3}{8}$ in. with no protruding end fibers exposed. The screens were then threaded into a thin-walled polyethylene tube.* A length of cellophane tubing was soaked in water, and while under water was pulled over the polyethylene tube. The polyethylene tube was then pulled out, leaving the screen inside the cellophane.

It was decided to use a unit of four rinsing fluid tubes. If more than four tubes were used, there would be problems in construction. If fewer but longer tubes were used, the resistance to the rinsing fluid flow would be so high that a blood pump would be required.

Results of Testing With Simulated Blood Flow

Clearance† tests were made with sodium chloride solutions simulating blood and water as the dialyzing fluid. The clearance obtained was a function of both the dialyzing fluid and the blood flow, other factors remaining constant. Since blood flow is usually limited to a range of 100 to 300 ml. per minute, and since we do not want to use a pump, the only variable is the dialyzing fluid flow, and the optimum can be selected.

With a dialyzing fluid flow of 400 ml. per minute, a clearance of between 5 and 9 ml. per minute per meter of dialyzing tube was obtained (*Fig. 2*). The length of the cellophane tube was 10.8 m. (0.94 sq. m.). Clearance in milliliters per minute per meter of dialyzing tube is multiplied by the total length of the membrane, 10.8 m. This gives a conventional clearance range of 50 to 90 ml. per minute. This is twice that for a dialyzing fluid flow rate of 150 ml. per minute.

The amount of blood necessary for priming was from 250 to 300 ml. for 10.8 m. of dialyzing tube, and was determined by the amount of blood contained in the blood chamber and the inflow and outflow lines.

The pressure necessary to propel blood substitute (sodium chloride solution) through the blood chamber was from 20 to 50 mm. of Hg. This pressure is well

*Visking Corp., Chicago, Illinois.

† $\text{Clearance} = (F) \frac{(I-O)}{I}$; $F = \text{NaCl flow, ml./min.}$; $I = \text{NaCl concentration inflow, mg./100 ml.}$; $O = \text{NaCl concentration outflow, mg./100 ml.}$

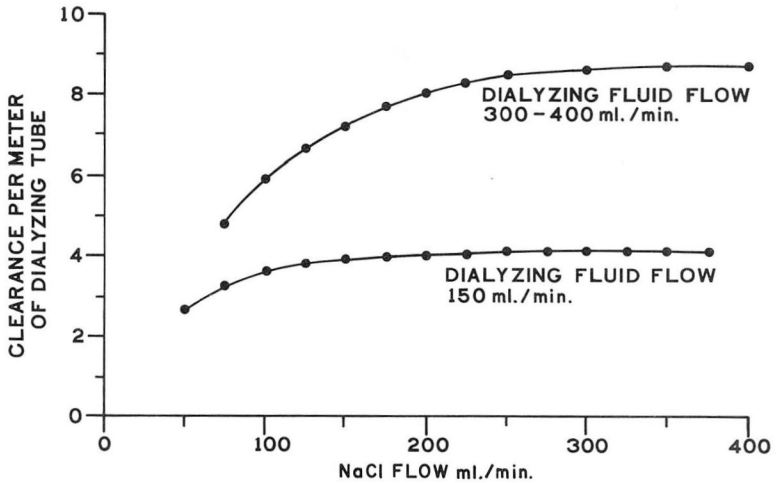


Fig. 2. Clearance is given in milliliters per minute. Graph showing relationship between sodium chloride clearance versus sodium chloride solution flow at a dialyzing fluid flow of 150 ml. per minute (lower curve), and at a dialyzing fluid flow of 300 to 400 ml. per minute (upper curve).

within the range of differences between the arterial pressure and the pressure needed to overcome the resistance in the venous cannula and the patient's vein.

Comment

When the prototype of a reversed coil artificial kidney was tested, it fulfilled the goals set for it. First, blood hold up was of the order of 250 to 300 ml. Tests indicate that the apparatus can achieve a clearance rate of from 70 to 80 ml. per minute for a blood flow of 200 ml. per minute and a dialyzing solution flow of 400 ml. per minute. The pressures necessary to propel the blood through the artificial kidney were well within the range of normal arteriovenous pressure differences. The next steps will include (1) testing the prototype apparatus in a clinical environment, and (2) changing to materials and products or methods that will allow mass production to make the reversed coil artificial kidney disposable.

References

1. Guarino, J. R.: Simplified artificial kidney: performance and capacity. *Trans. Am. Soc. Artif. Int. Organs* **1**: 25-30, 1955.
2. Kolobow, T.; Moskowitz, G. W., and Bowman, R. L.: New dynamic disposable artificial kidney. *Trans. Am. Soc. Artif. Int. Organs* **10**: 116-120, 1964.
3. Kolobow, T., and Bowman, R. L.: Construction and evaluation of alveolar membrane artificial heart-lung. *Trans. Am. Soc. Artif. Int. Organs* **9**: 238-243, 1963.