

A NEW DISPOSABLE ARTIFICIAL KIDNEY: EXPERIMENTAL AND CLINICAL EXPERIENCE

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The aims of our design work on a new disposable artificial kidney were a low blood volume (no priming), a fairly high clearance and sufficient ultrafiltration (treatment time usually 6 hours), for the following reasons:

1. In Sweden we are planning to dialyse all patients with acute and chronic renal failure in need of treatment—about 25 cases of acute renal failure, 10 cases of acute intoxication and 60 cases of chronic renal failure per million inhabitants per year. The transplantation cases, an estimated 15 per million per year, are excluded from this discussion. Each subsequent year is calculated to add about the same number of chronic cases, *i.e.* 60 new patients and 6,000 additional dialyses per million per year.

2. We have estimated that 25 dialysis beds per million will cover the need during the first 5-year period if the activity is progressively extended from 1 to 3 shifts a day. This is possible only if dialysis in chronic patients can be carried out in 6 hours twice a week. That allows, in each 8-hour shift, one hour for preparation and one hour for finishing the work.

3. The dialyser must be disposable to economise on staff time and reduce the risks of infections, particularly hepatitis. The main limitation of our programme will be shortage of personnel.

Our disposable kidney, now in commercial production, is of parallel flow type with 8 'sandwiches', totalling a dialysis membrane area of 1 m^2 . The chloride clearances at 200 and 300 ml/min. blood flow are about 120 and 140 ml/min., respectively, with a single pass dialysate flow of 1 l/min. and they rise to 150 and 185 ml/min., respectively, when dialysate flow

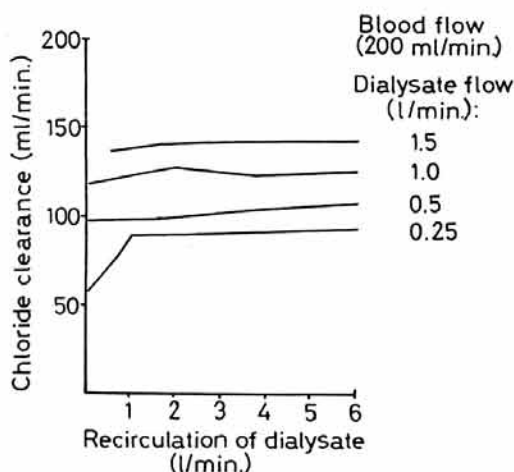


Fig. 1. *In vitro* tests.

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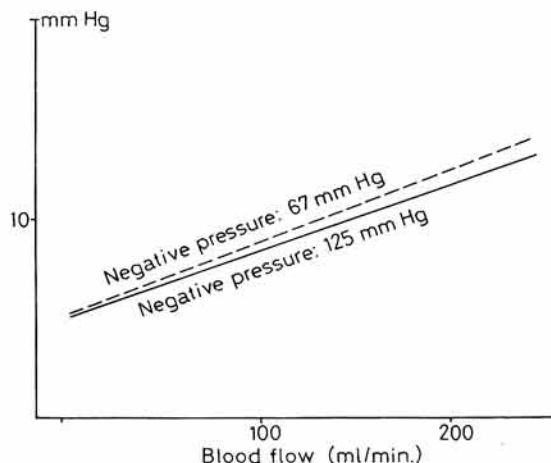


Fig. 2. Fall in 'blood' pressure at different flow rates; negative pressures 67 and 125 mm Hg, respectively.

is increased to 4 l/min. The corresponding figures are 155 and 195 ml/min. with a dialysate flow of 8 l/min.

We next studied the effect of recirculation. Figure 1 shows the effect of recirculating at a flowrate of 1 to 6 l/min. with a dialysis fluid addition rate of 500 to 1,500 ml/min. and a 'blood' flow rate of 200 ml/min. There was little advantage to be gained by recirculation. The results were similar at 'blood' flow rates of 100 and 300 ml/min. We have therefore decided against recirculation which involves technical complications and the problem of bacterial growth. A single pass dialysate flow of 1,500 ml/min. yields a chloride clearance of 140 ml/min. at a 'blood' flow rate of 200 ml/min. These flowrates can be obtained in practice and the resultant clearance should make a 6-hour treatment sufficient in chronic cases. If further experience shows that a higher clearance is desirable we can increase surface area by adding further 'sandwiches'. So far we have only tested 11 layers in place of the usual 8.

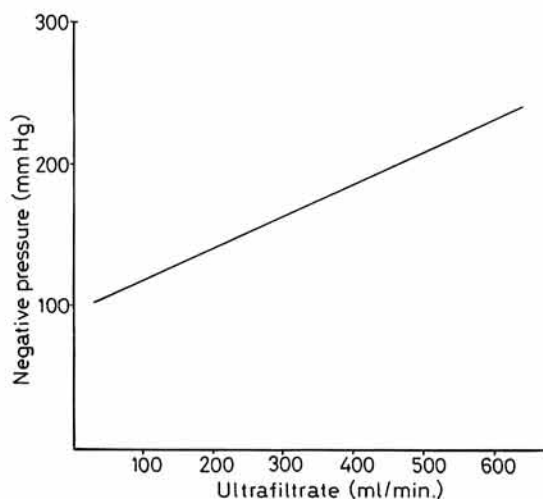


Fig. 3. *In vitro* tests.

The fall of 'blood' pressure during one passage through the dialyser using water at different flow rates is illustrated in Figure 2. The pressure drop is only about 10 mm Hg at a 'blood' flow of 200 ml/min. This low resistance eliminates the need for routine use of a blood pump.

Figure 3 shows the ultrafiltration rate per minute at different negative pressures using thick Cuprophane as membrane.

To date 1,000 kidneys of this type, presterilised with ethylene oxide, have been used in patient treatment in our department. The standard of production has been satisfactory; there have been no leaks and no infections; clearance, blood volume, low resistance and low residual blood volume have remained constant. A blood pump has sometimes been used with the Cimino-Brescia fistula or when the flow from a Scribner shunt was inadequate. In 100 consecutive dialyses the mean priming volume was 199 ml (range 100-280 ml); 82 dialysers had priming volumes of 200 ml or less, and only one exceeded 250 ml. No blood priming was necessary. The limits of priming volume are naturally influenced by the applied negative pressure. The volumes found in our clinical studies corresponded with those we had found in *in vitro* tests. Ultrafiltration was adequate.

So far we have had no practical experience of re-using the same dialyser. The economies of this practice have to be weighed against the staff time and the loss of security.