CLINICAL EXPERIENCE WITH A NEW CUPROPHANE NO PRIME DISPOSABLE CARTRIDGE DIALYZER

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With the advantages of Bemberg's 150 PT cuprophane having been demonstrated as being clearly superior (Leonard and Bluemle, 1962) to commercially available cellophane as a haemodialysis membrane, it followed that cuprophane tubing should be evaluated for use in a coil type dialyzer. In 1960, Bemberg was persuaded to produce limited quantities of tubing from cuprophane similar to their 150 PT, and tubing has been available in various diameters since then. Initial attempts at winding coil type dialyzers from this material, however, were disappointing, largely because of frequent coil rupture. During the past year, however, with improvement in manufacturing techniques and an increase in dry thickness from 12 to 15 microns, cuprophane tubing has been available with sufficient strength for use in coil type artificial kidneys.

In 1961, one of us (Bluemle, 1960) suggested that a non-woven plastic mesh material then being introduced by DuPont be used as a membrane support material. Since then similar types of plastic netting (Khastagir et al., 1967) have been used in this fashion. Using cuprophane tubing and netting of this type the authors developed a small, disposable, low-prime coil type dialyzer (Miller et al., 1968) called the EX-01 dialyzer cartridge (Fig. 1).

Fig. 1. Diagram showing a schematic cross-section of the EX-01 dialyzer cartridge.
Presently in clinical use, the EX-01 dialyzer cartridge consists of a spiral of flattened 15 micron cuprophane tubing 10 cm wide and 3.5 m long, supported by a concentric spiral of non-woven polypropylene netting approximately 17 cm wide. A dialyzing surface area of approximately 7,000 cm² is available. The netting has a strand diameter of approximately 0.5 mm. One set of strands is arranged longitudinally and thus runs parallel to the direction of blood flow throughout the length of the membrane tubing, bearing on one side of it. A set of short diagonal strands, disposed at an angle of 60° to the longitudinal strands, bears on the other side, the netting and the membrane being wound in concentric spirals. Thus a series of small continuous channels is provided for the blood path, throughout the length of the membrane tubing. With netting of this configuration and strand diameter, and with the strands in both directions spaced on 4 mm centres, the pressure required to perfuse the coil with blood is held to a practical level, while still permitting average blood film thicknesses below 200 microns.

Passage of dialysate across the membrane surface occurs as follows: The cartridge is pressed into the bottom of a transparent cylindrical plastic holder equal in inside diameter to the outside diameter of the cartridge. A seal is made between the bottom of the cartridge and the cartridge holder by a rubber ‘O’ ring which bears on the lower surface of the bottom cap. Dialysate enters the bottom of the cartridge holder, passes through a hole in the bottom cap and is deflected to the outside of the cartridge by a polyethylene plug in the bottom of the core. Clearance for dialysate flow between the cap and core is provided by having the roll of netting longer than the core, extending approximately 10 mm beyond it at either end. The dialysate can thus pass around the end of the core and into the netting, following the diagonal strands of the netting up across and between the layers of cuprophane tubing and out again through a hole in the top cap spilling over the top of the cartridge holder and back into the recirculating bath. The resistance to dialysate flow with this configuration is of the order of 50 mm Hg at dialysate flow rates of approximately 20 l/min.

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<th>Physical characteristics of the EX-01 dialyzer cartridge</th>
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The physical characteristics of the EX-01 (Table I) include the following: an effective dialyzing surface area of approximately 7,000 cm², a membrane tube length of 3.5 m, a flat width of 100 mm, a priming volume exclusive of tubing sets of 160 ml, a wet bursting pressure of greater than 1,000 mm Hg, and average blood film thickness of 190 microns.

With in vitro studies using a recirculating single pass system (Fig. 2) chloride dialysance was determined at a constant Q_B of 305 ml/min. using increasing dialysate addition rates. Representative in vivo data for the dialysance of urea, creatinine and uric acid is shown at a Q_B of 305 ml/min. at a dialysate addition rate of 350 ml/min. These data represent arithmetic means of dialysance values calculated from 7 sets of samples. Calculations of dialysance were made using the formula of Wolf et al. (1951): \( D_B = Q_B \left[ \frac{C_I - C_O}{C_I - D_T} \right] \).

During the course of 107 consecutive maintenance dialyses of patients with chronic renal failure using the EX-01 cartridge, studies were conducted to determine the dialysance of urea, creatinine, and uric acid at various blood flow rates. The results of a portion of these studies
Fig. 2. *In vitro* dialysance of chloride using a recirculating single pass system. 'Blood' flow was held constant (305 ml/min.) with varying dialysate addition rates. A representative set of points showing *in vivo* dialysance of urea, creatinine and uric acid at $Q_B = 305$ ml/min. and a dialysate addition of approximately 350 ml/min.

using a 100 litre recirculating bath are shown in Figure 3. These studies were all done with a dialysate flow rate of 15–20 l/min.

Ultrafiltration rates *in vitro* were determined using water as both a blood substitute at 200 ml/min. and as the dialysate at a $Q_D$ of approximately 20 l/min. average ‘blood’ pressure $\frac{P_I + P_o}{2}$ ranged from 100 to 400 mm Hg. Ultrafiltration rates averaged 150 ml/m per

Fig. 3. *In vivo* dialysance of EX-01 cartridge with 100 l recirculating system. $Q_D = 15–20$ l/min.
100 mm Hg average pressure. These results were comparable to in vivo studies in which up to 5 kg of water have been removed in a 6 hour dialysis by increasing the outlet blood pressure from the cartridge.

In the course of 107 clinical dialyses conducted, including home dialysis, the EX-01 cartridge has demonstrated its value as a disposable dialyzer for use in currently available recirculating single pass and 100 liters recirculating bath type artificial kidney machines. The use of a new, wide cuprophan tubing with an effective surface area of approximately 7,000 cm² permits clearances comparable to existing coil type devices with a sufficiently small blood hold-up volume so that priming with blood is unnecessary. In none of the dialyses conducted was blood used to prime the cartridge. Furthermore, the construction of the device assures bursting pressures of roughly twice the perfusion pressures normally encountered in clinical use.

In the course of the clinical work with the EX-01 cartridge, a minimal number of problems were encountered. The most serious of these was leakage from the cuprophan-to-blood tubing connector, especially during ultrafiltration at high outlet pressure. This was solved by modification of the assembly procedure of the cartridge.

In summary, acceptance by the nurses and technicians involved was excellent. The advantage in the use of the EX-01 cartridge most often commented upon was the low priming volume and the elimination of blood storage, handling and procurement problems. The high bursting strength contributed to a minimal number of leaks. The EX-01 cartridge demonstrated its efficiency in terms of high dialysance and high ultrafiltration capability. The compact size and simplicity of tubing sets and connectors were also noted, lending it particularly to home dialysis. The single spiral of cuprophan tubing also eliminated the unequal blood flow pattern often observed in twin coil dialyzers. Finally, in the course of clinical use no adverse patient reactions were noted.

REFERENCES


