The Flatpack Disposable Dialyser

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The dialyser prototype consists of two liquid-tight envelopes, used with Kiil A-V blood sets, which are held in a dry non-disposable clamping frame. Each envelope or 'flatpack'* consists of two vacuum-formed plastic sheets enclosing two sheets of 'long-grain' Cuprophane PT 150 membrane, giving a total dialyser membrane area of 0.58 m^2. Blood and dialysis fluid enter

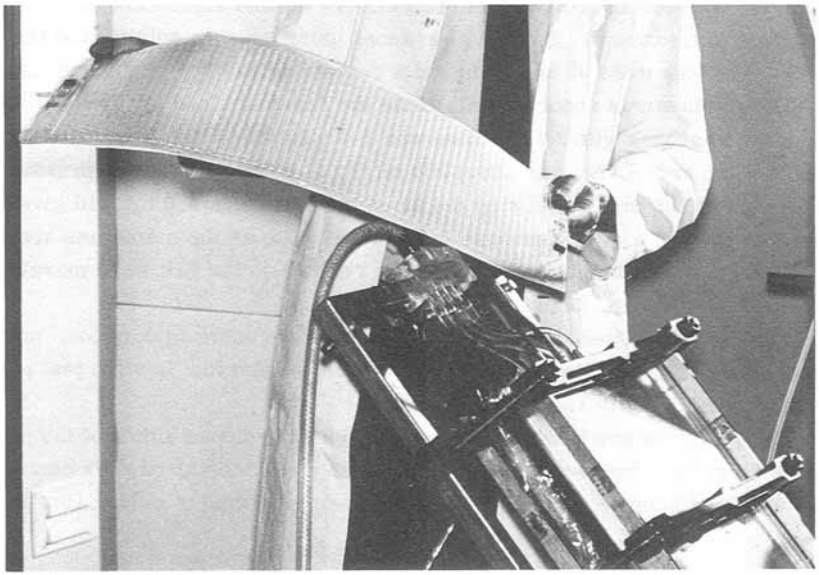

Figure 1. The disposable dialyser and its clamping frame

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the envelope via elastomer ports held within the envelope and do not contact the non-disposable boards of the clamping frame (Figure 1).

The envelopes are assembled from a kit of dry parts in less than five minutes per pair. They can then be stored in a clean, non-sterile state for several weeks, if necessary. When required, the envelopes are placed in the clamping frame and filled with formalin. The formalin is removed before use by dialysis followed by displacement with sterile saline (Parsons & Barker, 1970). Membrane faults are detected before use by a dry pressure test or by the drip test described by Nosé et al (1969). The operational procedures during dialysis are identical to those used with the Kiil. After washback at the end of treatment, the dialyser and attached A-V sets are drained of liquid and then removed from the clamping frame in a dry fashion. The soiled envelopes and blood sets are placed in a stout plastic bag prior to incineration. All 'wet' procedures associated with assembling or dismantling the Kiil are eliminated. The clamping frame can be used for different patients since it does not come into contact with either blood or dialysis fluid thereby reducing or eliminating cross-infection.

During tests, the pressure drop across the dialyser on the blood side was very low, about 10 mm Hg at 200 ml/min using citrated blood. Urea and creatinine clearances at 150 ml/min blood flow rate and 500 ml/min dialysis fluid rate were 80 and 60 ml/min respectively with no significant change over ten hours of treatment. In vitro clearances using aqueous solutions at the same conditions were 95 and 70 ml/min respectively. The priming volume of each envelope was about 120 ml, while the residual blood left in the dialyser after washback with 1 l of saline was 2-3 ml. The ultrafiltration rate both in vitro and in vivo was about 200 ml/hr at a transmembrane pressure difference of 100 mm Hg. Using the same membrane, a 1.0 m^2 Kiil gives over 300 ml/hr, i.e. an increase in the same ratio as the membrane areas. Otherwise, discrepancies in performance relative to the Kiil were marginal (Cestero & Freeman, 1969).

During 42 dialyses lasting from ten to fourteen hours in duration, no pyrogen or other reactions or blood leaks were observed. In vitro test performance was equally reliable.

Currently we are building improved 0.5 m^2 envelopes either of the prototype form as a 'build-it-yourself' kit, or as a self-contained pack containing two blood layers requiring a smaller clamping frame of only 0.15m^2 plan area.

REFERENCES

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