THE DISPOSABLE ENVELOPE ARTIFICIAL KIDNEY FOR THE KIIL DIALYZER*

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In recent years the Kiil kidney has become very popular for home dialysis because of its low operating cost. However, it takes at least 3.5 hours to assemble, sterilize, flush and prime the kidney before use. This is very time consuming for the home dialysis patient and thereby points out the advantage of having a sterile, disposable membrane package for the Kiil kidney. Most commercially available disposable artificial kidneys are the coil types which are relatively expensive (about $20 per coil). To be practical this membrane package must exhibit the following characteristics: (1) not decrease the efficiency of the dialyzer; (2) simple to use; (3) no adverse reaction to the patient, and (4) inexpensive.

METHODS

Reinforcement of the membrane. Basic in vitro studies (Weber and Nosé, 1968; Weber et al., 1968) have shown that compared to other dialysis membranes the most effective membrane used in the Kiil kidney is cuprophone** of 0.0005 in. thickness. However, because it is extremely fragile some degree of reinforcement is necessary to make it practical for a disposable unit. In previous work two types of reinforcement had been considered: (1) built-in reinforcement and (2) external reinforcement. With a built-in reinforcement the dialysis membrane can be supported with several types of substructures—fibrous, mesh, etc. However, in our studies of available internally reinforced materials none were as efficient as cuprophone. Two types of external reinforcement have been applied to cuprophone: (1) water soluble envelope and (2) simple composite-type envelope.

Water soluble envelope. The two layers of cuprophone are sandwiched in a jacket of water soluble film which dissolves when installed in the dialyzer leaving only cuprophone membrane and blood port connectors in the Kiil board. Polyvinyl alcohol film*** was used for this purpose. The polyvinyl alcohol film sometimes became gluey and partially obstructed the passage of the dialysate, thus decreasing the efficiency of the dialyzer by 20-30%. Even after flushing the dialysate compartment for 2 hours at a dialysate flow rate of 500 ml/min. some of the polyvinyl alcohol film remained inside.

Simple composite-type envelope. Two fine, nylon multifilament screens are laminated outside to two cuprophone sheets with a water soluble bonding agent. The cuprophone sheets are prestretched during the lamination procedure. The principal bonding agent used was methyl cellulose, however, RP starch adhesive and dextran were also used successfully for this purpose. The blood ports are secured in position with the same adhesive. This rugged

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** Cuprophone sheet PT 150 (J. P. Bemberg AG, 56 Wuppertal, Federal Republic of Germany).

*** Polyvinyl alcohol film, 0.0015 in. (Mono Sol Sales, 300 West Adams, Chicago, Ill.)
**Fig. 1.** Installation of the envelope artificial kidney in the Kill board.

**Fig. 2.** Performance diagram of the envelope kidney. The dialysate removes the water soluble bonding agent and the cuprophane and nylon screen are separated in the Kill board. This nylon screen prevents the cuprophane from coming into direct contact with the Kill board, increases the effective surface area of the membrane and prevents membrane deflection which will lead to increased priming volume.
membrane package or envelope can be installed in the ordinary Kiil board without any further modification (Fig. 1). These water soluble bonding agents are not dialysable (molecular weight over 80,000) and do not come inside the membrane. After installation in the Kiil the dialysate flow washes away the bonding agent and the dialysis membrane separates from the supporting substructure (Fig. 2). In this report this type of envelope is described as a possible disposable Kiil unit. The following tests were performed utilizing a single envelope (one-half Kiil): pressure-flow relationship, priming volume change, dissolution rate of bonding agent, effective surface area (Evans blue dye method) (Erben et al., 1967) and metabolite clearances.

EXPERIMENTAL RESULTS

Resistance. The blood flow resistance of the kidney is slightly increased when using the envelope, however, it remains within a practical range similar to that exhibited when using cuprophane alone. Early experimentation indicates that at a blood flow of 150 ml/min the pressure drop through the kidney is approximately 30-40 mm Hg when dialysate flow is 500 ml/min.

Priming volume. By changing the pressure in the blood compartment it was found that this envelope has a lower priming volume change than simple cuprophane membrane. As blood pressure is increased from 0 to 200 mm Hg the priming volume of the envelope increases from its initial 50 ml to a final value of 150 ml. In contrast, with ordinary cuprophane sheet the priming volume is initially 120 ml and increases to 240 ml as the blood pressure reaches the 200 mm Hg level.

Dissolution rate of bonding agent. After 25-30 minutes of flushing at the rate of 500 ml/min., the concentration of methyl cellulose in the dialysate was below 1 mg%. There was no trace of methyl cellulose inside the blood compartment. Figure 3 illustrates the rate of dissolution.

![Graph](image)

Fig. 3. Dissolution rate of bonding agent. After 30 minutes most of the bonding agent has been washed from the dialysate compartment. There is no trace of bonding agent inside the blood compartment.

Effective surface area. Ordinary cuprophane when used in the Kiil has approximately 20% ineffective, unstained surface area where the membrane contacts the supports in the Kiil board. With the envelope the effective surface area is increased as shown by the fact that the surface of the cuprophane within the envelope is equally stained.
Fig. 4. Urea clearance. Urea clearance of the envelope is compared to the cuprophone alone as a control. A single-layer Kiil is used and dialysate flow is maintained at 500 ml/min.

Clearance. The urea clearance of the simple composite-type envelope is about 15% better than with ordinary cuprophone membrane (Fig. 4) when the dialysate flow is 500 ml/min. When this flow is increased to 2 l/min, there is an increased efficiency of 50% as compared to ordinary cuprophone membrane. Creatinine clearance and uric acid clearance are also higher with enveloped cuprophone than with the ordinary membrane.

DISCUSSION

The principle of a two-layer support configuration is clearly demonstrated in the coil kidney (Kon et al., 1968). The addition of a finer screen in the quad-coil exposes more surface area of the membrane to dialysate and keeps the priming volume constant, thus increasing the efficiency of the kidney. The simple composite-type envelope is based upon the same principle. The supporting substructure over the cuprophone membrane is like the second layer of the double-layer support in the coil kidney. The Kiil board is like the coarse screen of the coil kidney. Utilizing cuprophone sheet as the primary membrane several substructures have been successfully bonded to the membrane. The most promising composition is cuprophone with a nylon substructure.

The bonding agents used were water soluble and since they are placed only on the dialysate side, they are washed away during initial flushing of the dialysate compartment. Methyl cellulose is not used inside the dialysis membrane and since its molecular weight is over 80,000 it is not dialyzable. A few types of disposable Kiil kidneys have been developed and reported (Bier, 1968). However, most of these require an additional gasket or modification of the Kiil board. The envelope kidney described can be installed in the ordinary Kiil kidney without any modification to the Kiil. The envelope remained leak-free even after 7-8 hours of repeated dialysis. The envelope can easily be gas sterilized.

Adhesive is sufficient to keep the blood ports in place, however, to insure finer positioning of the blood ports mechanical fasteners are used. Cost estimates indicate envelopes can be manufactured for about one-tenth the cost of currently available commercial coils. Because the efficiency of a single envelope is increased if a high dialysate flow is used, one envelope can be just as effective as a two-layer Kiil or two envelopes in the pediatric Kiil can be as efficient as the full-size Kiil.
Summary and conclusion

The disposable envelope for the Kiil kidney is described. Cuprophane membrane is laminated to a nylon substructure with a water soluble bonding agent. After the envelope is installed in the Kiil kidney the water soluble material is washed away by dialysate and the envelope becomes four layers. The blood compartment is located between the cuprophane membranes. The water soluble adhesive is not permeable and never comes in contact with the blood. The nylon substructure gives additional turbulence to the dialysate, reinforces the cuprophane membrane, increases the effective surface area, and keeps the priming volume constant. These factors contribute to the increased efficiency of the kidney. This envelope can be made significantly lower in cost than current prepackaged coil units.

ADDENDUM

After completion of a series of in vitro studies with a two-layer Kiil and in vivo studies (24 haemodialyses) on uraemic dogs, the disposable envelope kidney as described in the text was used clinically. At a dialysate flow rate of 450-500 ml/min., blood flow rate was 225-270 ml/min. without a blood pump and urea clearance was 110-120 ml/min. No pyrogenic reaction or other undesirable effects were observed.

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REFERENCES