'Dialyzer design is the engineers' graveyard' said George Schreiner over the bar at Stockholm. He described the succession of keen young engineers, physicists, scientific doctors and manufacturers who have attended the ASAIO meetings, looked with scorn on our present dialyzers, retired to their drawing boards and returned a year or two later sadder, wiser and humbler men. In the interim, however, they have often published enthusiastic reports on their promising new dialyzers. Sixty-seven designs or modifications are listed by Dittrich and colleagues (1969) most of which were forgotten long ago. Dr. Dukker and his team report on page 105 that about 80% of our patients on RDT are treated with dialyzers directly descended from those of Kiil (1960) or Kolff and Watschinger (1956).

Both the Kiil and the twin coil originated from hospital laboratories and the only fundamental improvement in either — a new membrane support for the coil — was also a piece of inspired medical empiricism (Hoetzenbein, 1966). There is plenty of room for improvement in both — the resistance to solute transfer in the Kiil is about four times as high as in a perfect dialyzer (Babb et al, 1967) and in the latest coils it is still about twice as high as the theoretical minimum (Frost, 1969). The higher efficiency of the coils is bought at the price of a high resistance pathway. As Muth shows on page 112 this causes rapid ultrafiltration which is predictable but rather inflexible. These defects will continue to stimulate the adventurous to attempt better solutions, and all power to their elbow!

Much of the mathematical spadework has already been done and some more ground has been turned by Sohm and colleagues on page 43. The task now is to find materials which can be moulded with the necessary precision and which do not distort with clamping, storage, etc. If the aim is a low resistance dialyzer the margin for error is narrow; blood pathway height is critical (Grimsrud & Babb, 1964) unless the blood compartment is very short.
and wide. In practice this demands multiple parallel pathways as in the Alwall Gambro (pages 3 & 363) and Rhône-Poulenc (page 10) designs. The pathway height now has less effect on efficiency but any differences between the parallel layers prevent a clean wash-out at the end of dialysis; more data are needed on the wash-out characteristics of these new dialyzers.

All designs are uneasy compromises between several conflicting demands. In the past we have received far too little information on the all-round performance of dialyzers before they were marketed. Since the EDTA provides an important publication outlet for this information I have set out in Tables I and II my own view of the minimum information that should be provided about any new artificial kidney; much of it is still lacking for the established ones.

**TABLE I.** Suggested information on a dialyzer that should be provided before clinical trial

**MATERIALS**

- Toxicity
- Durability
- Expense

**IN VITRO TESTING**

- Blood volume — Static
  - Change with pressure
- Dialysance of urea and creatinine
  - (a) at varying 'blood' flow rate (0-400 ml/min), and fixed dialysate flow rate (500 ml/min)
  - (b) at fixed 'blood' flow rate (e.g. 200 ml/min) and varying dialysate flow
- Pressure drop across blood pathway with varying 'blood' flow rate
- Pressure drop across dialysate pathway with varying dialysate flow rate
- Ultrafiltration rate (water against water) at varying trans-membrane pressure
- Effect of high trans-membrane pressure on dialysance at fixed 'blood' and 'dialysate' flow
- Residual blood volume after increasing volumes of wash-in solution (using bank blood).

The information on materials should indicate that no solution of toxic materials (e.g. lead from fibreglass) is likely to occur and that the dialyzer can be economically viable (the most promising design ever published failed to reach commercial production because of the fragility and expense of the membrane support).

In vitro testing is sadly neglected. The precautions necessary for accuracy were set out by Fritz (1964); they include accurate control of temperature.
(37°C) in 'blood' and 'dialysate' pathways and osmotic balance between the solutions. Dialysance studies with a blood pump give a reasonable prediction of in vivo (page 354) results if allowance is made for haematocrit (Grossman et al, 1967). Simulation of unpumped dialysis is harder but some information can be obtained by measuring the pressure drop across the 'blood' pathway at different flow rates. The dialysance at different heads of pressure can then be calculated. This does not give a good prediction of in vivo performance, but it does allow comparison with other dialyzers similarly studied.

Information on the effect of varying dialysate flow is useful, but there is so much capital equipment already in use with dialysate delivery at about 500 ml/minute that it would be permissible to provide information only at this flow rate for a new single pass dialyzer.

Ultrafiltration is much more easily studied in vitro than in vivo where many other factors contribute to weight gain and loss (Miller et al, 1967). The pressure changes during ultrafiltration may alter dialysance; although the effect is usually small (Adjei et al, 1964) this should be confirmed for each new design.

From the washout characteristics a wash-in volume of saline or dextrose should be chosen to give a residual blood volume well below 20 ml; if this cannot be achieved with an acceptable volume of fluid the dialyzer is unsuitable for clinical trial.

The information in Table II should be available before the dialyzer is used on patients. If the manufacturer cannot make the observations he should farm out prototypes to centres equipped for in vitro studies. Clinical trial is only justified if at this stage the new dialyzer has some substantial advantages over the Kill including, in my view, better dialysance of creatinine at comparable blood flow. Kilns of different manufacture vary considerably in their performance (pages 21 & 363); the best Kilns in current production should be the yardstick.

**TABLE II.** Suggested information to be obtained during clinical trial

Blood volume — confirmation of in vitro results on a larger sample

Dialysance of urea and creatinine

<table>
<thead>
<tr>
<th>Blood flow:</th>
<th>pumped 100-300 ml/min</th>
<th>unpumped — spontaneous rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dialysate flow:</td>
<td>500 ml/min or rate selected from in vitro studies</td>
<td></td>
</tr>
</tbody>
</table>

Residual blood volume after standard wash-in

Leakage rate: during building (if assembled in hospital)

during use

Dialysance studies are performed in the first few hours of dialysis when high plasma levels make accurate measurement of A-V difference possible.
The study of Kulatile and colleagues (page 3) suggests that we should routinely check whether dialysance falls off during dialysis.

A high leakage rate is as fatal to a no-transfusion policy as a high residual blood volume, and it is ruinous to patient morale. Tsaltas (1965) - himself a patient - exhorted us to stop making the patient feel like an astronaut and design a dialyzer that does not leak. Preliminary results on the Alwall-Gambro (pages 3 & 363) are encouraging.

How should the results be expressed? The only essential is to publish the original data in tables and graphs that can easily be read back. Engineers are obsessed by the need to express dialyzer efficiency in formulae which relate it to the area of the membrane, but this is of little interest to the clinician. He is much more concerned with the dialysance per 100 ml priming volume which he can calculate himself without any knowledge of differential calculus. If you eschew mathematical hieroglyphics and stick to plain English and French, with legible illustrations, you will not only command a wider audience but also earn the undying gratitude of the next Editor.

David N. S. Kerr

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PART VII

DEMONSTRATIONS