A FURTHER STEP IN SIMPLIFYING HOSPITAL AND HOME HAEMODIALYSIS
(THE CONCEPT OF KIDNEY REGENERATION SERVICE)

M. STRAUCH, G. E. v. HENNING, W. HUBER and W. D. BRITTINGER

Division of Nephrology, Klinikum Mannheim, University of Heidelberg,
Mannheim, Federal Republic of Germany

Unlike the available disposable parts of tube dialyzers, there is to date no commercially
distributed disposable unit for plate dialysis systems at reasonable cost.

The regeneration procedure of any plate dialyzer (cleaning, assembly, testing and sterilizing)
is time consuming and an unwelcome burden to dialysis centres.

As an intermediary procedure, awaiting the development of truly disposable plate dialyzing
systems, a small, uncomplicated, clinically accepted dialyzer has been introduced to a
regeneration service. This dialyzer satisfies the requirements for such a service in that it is
small, solidly constructed and easily mailed (Strauch et al.).

A service process has undergone favourable clinical testing with several European dialysis
centres and home dialysis situations leading to the establishment of a kidney regeneration
centre on a more permanent basis*.

REGENERATION PROCEDURE

There are enough artificial kidneys in each centre so that every patient on the hospital
treatment programme has one unit. Home dialysis patients have two dialyzers. Each patient
uses only his own artificial kidney parts.

Spare units are always in readiness should there be damage to the dialyzer in shipment or
should a ‘pin-hole’ leak be observed at the final check-out as the patient is connected to
the dialyzer for treatment. Pin-hole leaks occur in 1/150 dialysis treatments in our experience.

To date there have been no postal delays or reports of damage to the artificial kidney as
a result of shipping. The hospital and home dialysis system is constructed of uncomplicated
optimally integrated components which allow for complete ease in manipulation of the
artificial kidney in such a situation.

SHIPMENT AND CLEANING

The artificial kidney (Standard Dialung)** is removed from the patient’s area after use
and filled with any light disinfesting solution (peroxide or sodium hypochlorite) before
shipment to the regeneration centre, where immediately upon arrival the cleaning process
begins. The dialyzer is shipped in a water proof bag placed in a reinforced cardboard
packing box lined with cellulose filler material. Shipment is via railway express or by a delivery
van in areas of extensive use. Shipment costs are included in the total regeneration cost.

Soiled membranes are removed from the grid plates of the dialyzer, and these plates together

* Dr. E. Fresenius KG, Bad Homburg, Federal Republic of Germany.
** Cardiovascular Electrodyamics Corporation, Baltimore, Md., U.S.A.
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with the Lexan clamping plates are brushed clean in HemosolR* and placed in a container under concentrated sodium hydroxide where residual proteins are removed. Each artificial kidney is handled separately and there is no mixing of parts. This soaking period (2 hours) is followed by a thorough rinsing in three changes of de-calcified water which is shaken off before a final drying period under UV light.

2. ASSEMBLY AND TESTING

The dialyzer plates are then taken from the drying racks and built together with membranes (Bemberg PT-150R** or others on demand) into the requested surface area by a team under rigid conditions assuring a minimum of contamination during the assembly of the cleaned pieces. Particular effort is taken to prevent contamination of the plates and membranes of the dialyzer with pyrogenic substances. The assembly team members work in an exceptionally clean area and use gloves when handling artificial kidney parts.

A final clamping pressure of 10,000 pounds/inch² seals the dialyzer. Before sterilization the unit is tested under 300 mm Hg for leaks in the seal or membranes. (A second test is made for leaks just after the unit has been connected to the patient by passing sterile physiological solution through the bath compartment of the artificial kidney while blood circulates through the other side for a period of time before the unsterile bath is connected to the system.) The testing and sterilization of the readily prepared dialyzer is supervised by highly trained personnel.

3. STERILIZATION

After assembly, sterilization of the dialyzer is accomplished by filling both compartments of the artificial kidney with a cold sterilization solution of activated dialdehyde (AlhydexR). After a three hour period which is sufficient to sterilize the unit, the Alhydex is drained off with an inflow air filter check and then rinsed with 4% acetic acid prepared with Millipore filtered de-calcified water. This rinse (2 l) and the sterile solution prime (2 l) of the dialyzer prior to its connection to the patient is sufficient to reduce the concentration of Alhydex to a safe level. The dialyzer is packed and shipped to the patient at home or the dialysis centre where it will be used and returned for another regeneration cycle.

DISCUSSION

That the Dialung takes time and practice to clean, build, sterilize and test has been the chief complaint of persons using the dialyzer. Small dialysis centres usually have no time or trained personnel to set up a regeneration team properly. Those centres who have used the experimental regeneration system are satisfied with the convenience it provides. It makes this dialyzer the nearest thing to a completely disposable plate artificial kidney.

COSTS

Cost evaluation for the regeneration process is variable depending on the country where the system is used. The European regeneration is cheaper than the American one. The cost of a regenerated Dialung artificial kidney in the Federal Republic of Germany is 60 DM.

EFFICIENCY

Predictable dialyses have been performed with the standard Dialung (Fig. 1) assembled in the regeneration centre (Esmond et al., 1967). Groups starting regeneration centres who have not yet mastered the several fine points of the Dialung assembly have reported

* Merz, Berne, Switzerland.
** J. P. Bemberg Co., Wuppertal, Federal Republic of Germany.
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difficulty obtaining predictable results. This has been our experience until assembly methods
were developed which assure that striae of membranes were properly placed to allow for
the maximum in available surface area. During the manufacture of the PT-150, most of the
wet elongation under stress is removed by mechanical stretching of the membrane in
the longitudinal direction, while the wet elongation perpendicularly is preserved. Assembly is
controlled to assure membranes in the dialyzer are oriented so that the visible striae, which
indicate the direction of the original stretching, remain in the direction of channels in the
bath fluid plates.

![Graph showing time required to reduce BUN to specific fraction of starting BUN.]

Fig. 1. 1 m² Dialung performance.

One out of 150 dialyzers that have undergone regeneration in this study has demonstrated
a pin-hole leak. There have been no leaks during a dialysis procedure after the suggested two
membrane check-outs have been performed.

Some cracking of the Lexan plates and the grid plates have been observed due to wear and
handling. Better packing and a heavier sealing pressure have all but eliminated this problem.
All defective components are immediately replaced by new components during the regenera-
tion procedure.

Early regenerations, using only 4% acetic acid as an agent for sterilization, demonstrated
pyrogenic reactions. Since the advent of the Alhydrox and the start of this study, there have
been no reactions reported due to the dialyzer component of the varied haemodialysis systems.
In our unit pyrogenic reactions are no longer a problem.

The Dialung may be connected to any commercially available monitoring system. The cost
and reliability of many systems, and the desire of patients to monitor personally their own
dialysis, give rise to the development of more simple monitoring components. A Doppler
flowmeter and a thermo flowmeter are ready to be presented by this group in the near future as
inexpensive reliable indicator instruments for haemodialysis monitoring.
CONCLUSION

The tailor-making of this dialyzer and the ease with which it is used (with or without monitors), in our experience and the experience of others, suggests that such a regeneration service will lighten the working load on dialysis centres. This form of regeneration service is set forth as an intermediary before a truly commercially optimal disposable plate dialyzer is available.

REFERENCES
